

Disclosure FOI Request Log Range from 01/01/2012 Report

Total Records: 34479

Control #	Recd Date / Due Date	Action Office	Signature/ Requester	Subject
2012-1	01/03/2012 02/01/2012	FDA/OC/OES/DFOI/	MERCK & CO., INC.	FOI DAILY LOG 12/19-23/11
2012-2	01/03/2012 02/01/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	DREW BARNHOLTZ INVACARE CORP	PHILIPS HEALTHCARE - EIRS, 483S, TITLED & UNTITLED LTRS, ETC 1/00 TO PRESENT
2012-3	01/03/2012 02/01/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	DREW BARNHOLTZ INVACARE CORP	RESPIRONICS INC - EIRS, 483S, TITLED & UNTITLED LTRS, ETC 1/00 TO PRESENT
2012-4	01/03/2012 02/01/2012	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	DREW BARNHOLTZ INVACARE CORP	SUNRISE MEDICAL - EIRS. 483S, TITLED & UNTITLED LTRS, ETC 1/00 TO PRESENT

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		FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/		
2012-5	01/03/2012 02/01/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	DREW BARNHOLTZ INVACARE CORP	PRIDE MOBILITY PRODUCTS CORP - EIRS, 483S, TITLED & UNTITLED LTRS, ETC 1/00 TO PRESENT
2012-6	01/03/2012 02/01/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	DREW BARNHOLTZ INVACARE CORP	MEDICAL DEPOT INC (DRIVE MEDICAL) - EIRS, 483S, TITLED & UNTITLED LTRS, ETC 1/00 TO PRESENT
2012-7	01/03/2012 02/01/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	DREW BARNHOLTZ INVACARE CORP	DEVILBISS HEALTHCARE LLC - EIRS, 483S, TITLED & UNTITLED LTRS, ETC 1/00 TO PRESENT
2012-8	01/03/2012 02/27/2012	FDA/OMPT/CDRH/OCER/DFOI/	MARK E LOSTROM MERCHANT-TAYLOR INTERNATIONAL	DIMENSIONAL DOSING SYSTEMS, WEXFORD, PA - MY INSULIN DOSER K082512
2012-9	01/03/2012 02/01/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Doe J	OLYMPUS/GRYUS ACMI - RESECTOSCOPE MDRS
2012-10	01/03/2012 02/01/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID G PERKINS ABBOTT LABORATORIES, INC.	CPGM 7356.021 -DRUG QUALITY REPORTING SYS
2012-11	01/03/2012 02/01/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANDREW KELLY ODOM & DES ROCHES LLP	HOFFMAN LAROCHE INC (ROCHE NUTLEY) - XELODA TABS ANDA 90-943, MYLAN - ANDA 91-648, TEVA - ANDA 20-483, ETC APRVL LTRS, ADMINISTRATIVE RECS, CORR, ETC
2012-12	01/03/2012 02/01/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KLARA ROMBAUTS SCIENTIST RELIABLE CANCER THERAPIES	BESPOKE BIOSCIENCE - ALOE VERA RECS

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		FDA/OMPT/CDER/GRP/DIDP/		
2012-13	01/03/2012 02/01/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANDREW J CAMPANELLI CAMPANELLI & ASSOCIATES PC	PFIZER INC - PHYLLIS SCHNEPS LTRS, FAXES, COMM, ETC 1/09 TO PRESENT
2012-14	01/03/2012 02/01/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOEL F GRAHAM MERCHANT & GOULD	INJECTAPAP NDA 17-785 - CHEMISTRY RVWS, ADMINISTRATIVE RECS, CORR
2012-15	01/03/2012 02/01/2012	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	BEATRICE A BRICKELL THARRETTS PALEY CARTER ETAL	GREEN IMPORTS INC - FRESH GINGER LAB RPT 12/7/11
2012-16	01/03/2012 02/10/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	MARK D LURIE LURIE LAW FIRM LLC	MAQUET INC, MAQUET CARDIOVASCULAR INC - EIRS, 483S, RESP TO 483S, ETC 1/08 TO PRESENT
2012-17	01/03/2012 02/01/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OCC/ OC/ORA/OCI/ OC/ORA/OCI/	ELLYN STERNFIELD MINTZ LEVIN ET AL	P&B DISTRIBUTORS, OLSON INSTITUTIONAL PHARMACY - PRESS RELEASE, COURT RECS 1999
2012-18	01/03/2012 02/01/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	SIEGEL, JONATHAN B	STICHTING SANQUIN BLOEDVOORZICNING (SANQUIN BLOOD SUPPLY FOUNDATION), AMSTERDAM - EIRS, 483S, PRE APRVL INSP RECS 1/10 TO PRESENT
2012-19	01/03/2012 02/01/2012	FDA/OMPT/CTP/OD/	GREGORY N CONNOLLY HARVARD SCHOOL OF PUBLIC HEALTH	FAMILY SMOKING PREVENTION & TOBACCO CONTROL ACT - APPL, M FR 1/0 TO PRESENT
2012-20	01/03/2012 02/01/2012	FDA/OFVM/CFSAN/OCD/EOS/	ANGVELA SMYTH IOVATE HEALTH SCIENCES RESEARCH INC	CAERS 14608 - RECS RECEIVED AFTER CMLPNT DATE 11/11/10
2012-21	01/03/2012 02/01/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	DREW BARNHOLTZ INVACARE CORP	PERMOBILL INC - EIRS, 483S, TITLED & UNTITLED LTRS, ETC 1/00 TO PRESENT
2012-22	01/04/2012	FDA/OC/OES/DFOI/	CECELIA FRENCH	FOI DAILY LOG 12/5-9/11

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	02/02/2012		CanReg, Inc.	
2012-23	01/04/2012 02/02/2012	FDA/OC/OES/DFOI/	CECELIA FRENCH CanReg, Inc.	FOI DAILY LOG 12/12-16/11
2012-24	01/04/2012 02/02/2012	FDA/OC/OES/DFOI/	CECELIA FRENCH CanReg, Inc.	FOI DAILY LOG 12/19-23/11
2012-25	01/04/2012 02/02/2012	FDA/OC/OES/DFOI/	FRAN KOCH INFORMATION ACCESS	FOI DAILY LOG 12/5-9/11
2012-26	01/04/2012 02/02/2012	FDA/OC/OES/DFOI/	FRAN KOCH INFORMATION ACCESS	FOI DAILY LOG 12/12-16/11
2012-27	01/04/2012 02/02/2012	FDA/OC/OES/DFOI/	FRAN KOCH INFORMATION ACCESS	FOI DAILY LOG 12/19-23/11
2012-28	01/04/2012 02/02/2012	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 12/5-9/11
2012-29	01/04/2012 02/02/2012	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 12/12-16/11
2012-30	01/04/2012 02/02/2012	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 12/19-23/11
2012-31	01/04/2012 02/02/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 12/5-9/11
2012-32	01/04/2012 02/02/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 12/12-16/11
2012-33	01/04/2012 02/02/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 12/19-23/11
2012-34	01/04/2012 02/02/2012	FDA/OC/OES/DFOI/	GLADYS B TONKIN WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 12/5-9/11
2012-35	01/04/2012 02/02/2012	FDA/OC/OES/DFOI/	GLADYS B TONKIN WASHINGTON INFORMATION SOURCE	FOI DAILY LOGH 12/12-16/11
2012-36	01/04/2012	FDA/OC/OES/DFOI/	GLADYS B TONKIN	FOI DAILY LOG 12/19-23/11

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	02/02/2012		WASHINGTON INFORMATION SOURCE	
2012-37	01/04/2012 02/02/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 12/5-9/11
2012-38	01/04/2012 02/02/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 12/12-16/11
2012-39	01/04/2012 02/02/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 12/19-23/11
2012-40	01/04/2012 02/02/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 12/5-19/11
2012-41	01/04/2012 02/02/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 12/12-16/11
2012-42	01/04/2012 02/02/2012	FDA/OC/OES/DFOI/	KENDLE INTERNATIONAL INC	FOI DAILY LOG 12-5-9/11
2012-43	01/04/2012 02/02/2012	FDA/OC/OES/DFOI/	KENDLE INTERNATIONAL INC	FOI DAILY LOG 12/12-16/11
2012-44	01/04/2012 02/02/2012	FDA/OC/OES/DFOI/	KENDLE INTERNATIONAL INC	FOI DAILY LOG 12/19-23/11
2012-45	01/04/2012 02/02/2012	OC/ORO/ OC/ORO/	STEVEN RENAUT A&A LTD	SEA BORN PRODUCTS INC - 038-0627257-5
2012-46	01/04/2012 02/02/2012	FDA/OGROP/ORO/CE-FO/MIN-DO/MIN-CB/	JOHN DIEDRICH MILWAUKEE JOURNAL SENTINEL	H&P INDUSTRIES; RECALL, RECS
2012-47	01/04/2012 02/02/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORO/CE-FO/CIN-DO/CIN-CB/	WILLIAM R. COLE TECHNICAL INC	SPLS 702016, 702017, 702016 - ANALYTICAL RECS
2012-48	01/04/2012 02/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARY B. SZALKOWSKI PRISMA CORP	INDAPAMIDE; PERINDOPRIL - AER 9/14/11 TO PRESENT
2012-49	01/04/2012	FDA/OMPT/CDER/ORP/DIDP/	MOHAMMED SIDDIQUI	TAXOL - NDA

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	02/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	INTERNATIONAL TRADING PHARMACEUTICALS LABORATORIES INC	
2012-50	01/04/2012 03/22/2012	FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/	SCOTT C. BYRD BYRD LAW FIRM	GREEN VALLEY FOOD CORP - RECS 2006 TO 2011
2012-51	01/04/2012 02/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARCUS PETOYAN GIANNI PETOYAN ATTY	ZOLOFT (SERTRALINE) - PREGNANCY EXPOSURE REGISTRY
2012-52	01/04/2012 02/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GREG HARMAN SAN ANTONIO CURRENT	DR CHANDRA TIWARY - AER SUBMITTED TO FDA, CORR 1996
2012-53	01/04/2012 02/02/2012	FDA/OGROP/ORACE-FO/PHI- DO/PHI-CB/	GREGORY KAUFFMAN PENNSYLVANIA DEMOCRATIC PARTY	MITOS TECHNOLOGIES INC, PHOENIXVILLE, PA - 483 1/1/00 TO 1/2/12
2012-54	01/04/2012 02/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORACE-FO/BLT- DO/BLT-CB/ FDA/OGROP/ORAPA-FO/SAN- DO/SAN-CB/ FDA/OGROP/ORAPA-FO/SEA- DO/SEA-CB/ FDA/OGROP/ORASE-FO/FLA- DO/FLA-CB/ FDA/OGROP/ORASW-FO/DEN- DO/DEN-CB/	SHAWN P. FOX TRACEY LAW FIRM	WYETH PHARMACEUTICALS INC - EFFEXOR (VENLAFAXINE) INTEGRATED SAFETY & EFFICACY SUMMARIES, 15 DAY ALERTS , CORR, ETC
2012-55	01/04/2012 02/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SHAWN P. FOX TRACEY LAW FIRM	PFIZER - ZOLOFT (SERTRALINE) - SAFETY, EFFICACY, CORR BETWEEN FDA & PFIZER, 15 DAY ALERTS
2012-56	01/04/2012	FDA/OMPT/CDER/ORP/DIDP/	SHAWN P. FOX	FOREST LABS - LEXAPRO (ESCITALOPRAM) INTEGRATED

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	02/02/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/ FDA/OC/OES/DFOI/	TRACEY LAW FIRM	SUMMARIES OF SAFETY & EFFICACY, CORR ,15 DAY ALERTS, ETC
2012-57	01/04/2012 02/02/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHAWN P. FOX TRACEY LAW FIRM	FOREST LABS - CELEXA (CITALOPRAM) - SAFETY, EFFICACY, CORR BETWEEN FDA & 5 DAY ALERTS
2012-58	01/04/2012 02/02/2012	FDA/OMPT/CDRH/OCER/DFOI/	CHARMAINE SIDES RODEY DICKASON SLOAN ET AL	GORE TEX VASCULAR GRAFTS/SHUNTS - MDRS, WARNING LTRS, INVESTIGATIONS
2012-59	01/04/2012 02/02/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	RAVI TIRLANGI BELCHER PHARMACEUTICALS INC	BELCHER PHARMS LLC - DESLORATADINE NDA 78-355; SCHERING PLOUGH - CLARINEX NDA 21-165/S-014 APPL
2012-60	01/04/2012 02/02/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BARBARA A. BINZAK BUCHANAN INGERSOLL & ROONEY PC	PREVACID NAPRAPAC 250, 375, 500 (LANSOPRAZOLE & NAPROXEN TABS) NDA 21-507; PREVACID IV (LANSOPRAZOLE INJ) NDA 21-566 - SAFETY & EFFICACY RECS
2012-61	01/04/2012 02/02/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/ORA/	Doe J	INDIVIDUAL RECS

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		OC/OR/ FDA/OGROP/OR/SE-FO/NOL-DO/NOL-CB/ FDA/OGROP/OR/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/OR/SE-FO/SJN-DO/SJN-CB/		
2012-62	01/04/2012 02/02/2012	FDA/OGROP/OR/SW-FO/DAL-DO/DAL-CB/	Eva Gonsalves FOI Services, Inc.	Copy of the disclosable portions of the EIR and 483 for the 08/03/2010 inspection of Proportional Technologies, Inc., located in Houston, Texas.;
2012-63	01/04/2012 02/02/2012	FDA/OGROP/OR/CE-FO/CHI-DO/CHI-CB/ FDA/OGROP/OR/SW-FO/KAN-DO/KAN-CB/	Eva Gonsalves FOI Services, Inc.	Copies of the disclosable portions of the EIRs and 483s for both the 01/19/2010 AND the 01/18/2011 inspections of PETNET Solutions, Inc., located in Omaha, Nebraska; AND the 11/23/2010 inspection of PETNET Solutions, Inc., located in Des Plaines, Illinois; AND the 12/08/2010 inspection of PETNET Solutions, Inc., located in Aurora, Colorado; AND the 01/18/2011 inspection of PETNET Solutions, Inc., located in Overland Park, Kansas.
2012-64	01/04/2012 02/02/2012	FDA/OGROP/OR/CE-FO/PHI-DO/PHI-CB/ FDA/OGROP/OR/SE-FO/FLA-DO/FLA-CB/ FDA/OGROP/OR/SE-FO/NOL-DO/NOL-CB/	Eva Gonsalves FOI Services, Inc.	Copies of the disclosable portions of the EIRs and 483s for the 06/30/2010 inspection of Cardinal Health 414, located in Birmingham, Alabama; AND the 03/10/2011 inspection of Cardinal Health 414, located in Ft. Lauderdale, Florida; AND the 04/11/2011 inspection of Cardinal Health 414, located in Sharon Hill, Pennsylvania.
2012-65	01/04/2012 02/02/2012	FDA/OGROP/OR/CE-FO/BLT-DO/BLT-CB/ FDA/OGROP/OR/CE-FO/NWJ-DO/NWJ-CB/	EGG FOI Services, Inc.	Copy of the disclosable portions of the EIR and 483 for the 08/11/2010 inspection of IBA Molecular, located in Sterling, Virginia; and the EIR for the 09/14/2010 inspection of IBA Molecular, located in Somerset, New Jersey.
2012-66	01/04/2012 02/02/2012	FDA/OGROP/OR/CE-FO/CIN-DO/CIN-CB/	Eva Gonsalves FOI Services, Inc.	Copy of the disclosable portions of the EIR and 483 for the 10/01/2010 inspection of Cardinal Health 420, located in West Chester, Ohio.
2012-67	01/05/2012 02/03/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OGROP/OR/CE-FO/PHI-DO/PHI-CB/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	VIROPHARMA, SANGUIN, CAF-DCF - DENDREON, CINRYZE UNTITLED LTRS, 483S 1/07 TO PRESENT
2012-68	01/05/2012 02/03/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OGROP/OR/CE-FO/PHI-DO/PHI-CB/	BRIAN SKORNEY BREAN MURRAY CARRET & CO	VIROPHARMA INC - 483S 7/09 TO 9/09, 9/10, 5/11
2012-69	01/05/2012 02/03/2012	FDA/OGROP/OR/SW-FO/KAN-DO/KAN-CB/	JIM LEONG CIVCO MEDICAL INSTRUMENTS	CIVCO MEDICAL SOLUTIONS INC, KALONA, IA - EIR 2/8-11/11

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2012-70	01/05/2012 02/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	NARSI RANGACHARI INCARDA THERAPEUTICS INC	GLAXOSMITHKLINE LLC - RYTHMOL TABS NDA 19-151 SBA
2012-71	01/05/2012 02/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DENIS C MITCHELL ESQ STEIN MITCHELL & MUSE LLP	PRADAXA (DABIGATRAN ETEXILATE) - AERS
2012-72	01/05/2012 02/03/2012	FDA/OMPT/CDRH/OCER/DFOI/	PASTORE, MIKE	HERNIA PATCHES - RECS
2012-73	01/05/2012 02/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORACE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORACE-FO/DAL-DO/DAL-CB/	ROBERT L KAVANAUGH AMERICAN HEALTH PACKAGING	PHARMEDIUM - EIRS, 483S, WARNING LTRS, ETC LAST FIVE YRS
2012-74	01/05/2012 02/03/2012	FDA/OGROP/ORACE-FO/NWE-DO/NWE-CB/	ROBERT L KAVANAUGH AMERICAN HEALTH PACKAGING	AMERIDOSE - EIRS, 483S, WARNING LTRS, ETC LAST FIVE YRS
2012-75	01/05/2012 02/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHRISTOPHER BOTH CETERO RESEARCH	TEMOVATE CREAM NDA 19-322 - SBA
2012-76	01/05/2012 02/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHRISTOPHER BOTH CETERO RESEARCH	TEMOVATE OINTMENT NDA 19-323 - SBA
2012-77	01/05/2012	FDA/OFVM/CFSAN/OCD/EOS/	BOBBY SCHOCHET	NEXIRA - FAP 1A4784

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	02/03/2012		OLSSON FRANK WEEDA TERMAN MATZ PC	
2012-78	01/05/2012 02/03/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/CVM/OCD/ OC/ORO/ OC/ORO/	TONY CORBO Food & Water Watch	CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, CENTER FOR VETERINARY MEDICINE, OFFICE OF REGULATORY AFFAIRS - EMPLOYEE AWARD CEREMONY COSTS FY 2009 TO FY 2011
2012-79	01/05/2012 02/03/2012	FDA/OGROP/ORO/CE-FO/PHI- DO/PHI-CB/	Gumpert, David	RAINBOW ACRES FARMS, KINZERS, PA - SPL 570826, 570827 SUMMARY RPTS
2012-80	01/05/2012 02/03/2012	FDA/OGROP/ORO/CE-FO/MIN- DO/MIN-CB/	JONEL ALECCIA MSNBC.COM	TRIAD GROUP, H&P INDUSTRIES, HARTLAND, WI - RECONDITIONING PROPOSALS
2012-81	01/05/2012 02/03/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OGROP/ORO/PA-FO/SAN- DO/SAN-CB/ FDA/OGROP/ORO/SE-FO/ATL- DO/ATL-CB/ FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/	KATE B WILSON CENTER FOR PUBLIC INTEGRITY	CRYOLIFE - RECALL RECS 2002; DONOR REFERRAL SERVICES - RECALL RECS 2006
2012-82	01/05/2012 02/03/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	BRIAN SMITH LEXISNEXIS COURTLINK INC	JOINT MTG OF THE A/C FOR REPRODUCTIVE HEALTH DRUGS AND THE DRUG SAFETY & RISK MANAGEMENT A/C - BRIEFING RECS & ADDENDUM 12/8/11
2012-83	01/05/2012 02/03/2012	OC/CVM/OCD/ OC/OCOS/OES/ OC/OCOS/OES/ OC/OA/OM/OMP/DDM/	JENNIFER SORENSON NATURAL RESOURCES DEFENSE COUNCIL	PENICILLIN AND ANTIBIOTICS USED IN ANIMAL FEED - SAFETY RVWS, ANALYSIS
2012-84	01/05/2012 02/03/2012	FDA/OC/OES/DFOI/	CanReg, Inc.	CLOSED FOI REQUESTS 12/5-9/11
2012-85	01/05/2012 02/03/2012	FDA/OC/OES/DFOI/	CanReg, Inc.	CLOSED FOI REQUESTS 12/26-30/11
2012-86	01/05/2012 02/03/2012	FDA/OC/OES/DFOI/	CECELIA FRENCH CanReg, Inc.	CLOSED FOI REQUESTS 12/19-23/11
2012-87	01/05/2012 02/03/2012	FDA/OC/OES/DFOI/	WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 12/19-23/11
2012-88	01/05/2012 02/03/2012	FDA/OC/OES/DFOI/	WOLTERS KLUWER LAW &	CLOSED FOI REQUESTS 12/26-30/11

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			BUSINESS	
2012-89	01/05/2012 02/03/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 12/19-23/11
2012-90	01/05/2012 02/03/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 12/26-30/11
2012-91	01/06/2012 02/06/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	ETHICON ENDO-SURGERY LLC - ECHELON 60 ENDOSCOPIC LINEAR CUTTER RELOAD BLACK MODEL ECR60T, ECHELEN 45 ENDOSCOPIC LINE K112056
2012-92	01/06/2012 02/06/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	NORPLANT TROCAR - K903490: LIFE PULSE HIGH FREQUENCY JET VENTILATOR - P850064; PURITAN BENNETT 72O00 VENTILATOR - K902506, K9023809, K92002, ETC
2012-93	01/06/2012 02/06/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARY ANDERSON SHIRE INC	WELLBUTRIN NDA 21-515/S10 - SBA
2012-94	01/06/2012 02/06/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARY ANDERSON SHIRE INC	SYMBYAX NDA 21-520/S12 - SBA
2012-95	01/06/2012 02/06/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARY ANDERSON SHIRE INC	NDA 20-151/S000 - SBA
2012-96	01/06/2012 02/06/2012	FDA/OMPT/CDRH/OCER/DFOI/	JOHN G ROONEY ROONEY & ROONEY PA	VAX-D MEDICAL TECHNOLOGIES LLC - K951622, K053503, K071347, ETC (CERTIFIED)
2012-97	01/06/2012 02/06/2012	FDA/OMPT/CDRH/OCER/DFOI/	DARI DARABBEIGI PERSYST DEVELOPMENT CORP	NATUS - NEUROWORKS K090019
2012-98	01/06/2012 02/06/2012	FDA/OMPT/CDRH/OCER/DFOI/	AMNON TALMOR INVIBIO BIOMATERIAL SOLUTIONS	K102026
2012-99	01/06/2012 02/06/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEITH D BODOH ROBERTSON BODOH NASRALLAH	QUALITEST PHARMACUTICALS -CYCLAFEM 1/35, GILDESS FE 1.5/30, PREVIFEN, ETC RECALL RECS 9/15/11

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		FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/		
2012-100	01/06/2012 02/06/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SWOPE, CARL T	ZOCOR, SIMVASTATIN - AERS
2012-101	01/06/2012 02/06/2012	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	MIKE RUSSELL DELAVAL MANUFACTURING	GRAHAM DAIRY SUPPLY INC, GREENSBURG, PA - 6328 - EIRS, 483S 9/4/09
2012-102	01/06/2012 02/06/2012	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	BRENDA M GARTZ ELI LILLY & CO	AVID RADIOPHARMACEUTICALS, PHILADELPHIA, PA - EIRS 1/4/11
2012-103	01/06/2012 02/06/2012	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	PAULL W TRIPP LINCARE INC	FAMILY RESPIRATORY & MEDICAL SUPPLY INC, MD - EIRS, 483S, WARNING LTRS, ETC 1/05 TO PRESENT
2012-104	01/06/2012 02/06/2012	FDA/OC/OES/DFOI/	WAYNE SADOWSKI NOVARTIS PHARMACEUTICAL CORP	DR MARVIN ZELKOWITZ, FLOSSMOOR, IL 6/26/08 DR ROBERT LADA, AKRON, OH 5/9/08; DR STEVEN FREEDMAN, RALEIGH, NC 6/29/09, ETC - EIRS, 483S, 482S, ETC
2012-105	01/06/2012 02/06/2012	FDA/OFVM/CFSAN/OCD/EOS/	FARABAUGH, MATTHEW	PROPYLENE GLYCOL AS GENERALLY REGARDED AS SAFE (GRAS) - RECS
2012-106	01/06/2012 02/06/2012	OC/CVM/OCD/ OC/OCOS/OES/ OC/OCOS/OES/ FDA/OC/OCC/	JEFF RUCH PUBLIC EMPLOYEES FOR ENVIRONMENTAL RESPONSIBILITY	WITHDRAWAL OF NOTICES OF OPPORTUNITY FOR HEARING: PENICILLIN & TETRACYCLINE USED IN ANIMAL FEED - RPTS, COMM 1/10 TO PRESENT
2012-107	01/06/2012 02/06/2012	FDA/OFVM/CFSAN/OCD/EOS/	ANN M OXFORD ALBEMARLE CORP	HYPOBROMOUS ACID - FCN 1098
2012-108	01/06/2012 02/06/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/OA/OM/OMP/DDM/	JEANNE LENZER BMJ	DANIEL SHAMES - DROSPIRENONE APRVL, WARNINGS, MTGS, ETC 12/8/11
2012-109	01/06/2012 02/06/2012	OC/ORACE-FO/PHI-DO/PHI-CB/ OC/ORACE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORAPPA-FO/SEA-DO/SEA-CB/	JEFFERS, TEENA	IDAHO SPUD CANDY BARS SPL 653395 - TEST RESULTS

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2012-110	01/06/2012 02/06/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/OCOS/OES/ OC/OCOS/OES/	GRACE SHEEDY UNITED FOOD AND COMMERICAL WORKERS INTERNATIONAL UNION - SAFE FOOD COALITION	WALMART STORES INC - VISITOR LOGS, CALENDARS, MTG NOTES, ETC 1/09 TO PRESENT
2012-111	01/06/2012 02/06/2012	FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/ FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/ FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/	MEHRABAN, OMID	CMPLNT 123545
2012-112	01/06/2012 02/06/2012	FDA/OGROP/ORASW-FO/KAN- DO/KAN-CB/ FDA/OGROP/ORACE-FO/DET- DO/DET-CB/ FDA/OGROP/ORACE-FO/DET- DO/DET-CB/	MARY FRANCES BROUGHMAN BROWN & CROUPPEN PC	INDIVIDUAL RECS
2012-113	01/06/2012 02/06/2012	FDA/OGROP/ORACE-FO/CIN- DO/CIN-CB/	WILLIAM R. COLE TECHNICAL INC	IOM REPORTS
2012-114	01/06/2012 02/06/2012	FDA/OGROP/ORACE-FO/MIN- DO/MIN-CB/	JOHN DIEDRICH MILWAUKEE JOURNAL SENTINEL	TRIAD/H&P INDUSTRIES - CONSENT DECREE CORR
2012-115	01/09/2012 02/07/2012	FDA/OGROP/ORACE-FO/MIN- DO/MIN-CB/ FDA/OGROP/ORAPA-FO/SAN- DO/SAN-CB/ FDA/OGROP/ORASW-FO/KAN- DO/KAN-CB/ FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/	JULIA MOUSER CANNON & NELMS	WEGIS RANCH, BUTTONWILLOW, CA - ICEBERG LETTUCE ESCHERICHIA COLI OUTBREAK INVESTIGATION RECS 2006-2008
2012-116	01/09/2012 02/07/2012	FDA/OGROP/ORASE-FO/FLA- DO/FLA-CB/	ELIZABETH WOECKNER CITIZENS FOR RESPONSIBLE CARE & RESEARCH	RAJIV CHANDRA MD, MELBOURNE, FL - EIR, 483 4/12/10
2012-117	01/09/2012 02/07/2012	FDA/OGROP/ORASW-FO/KAN- DO/KAN-CB/	QUYNH C SPERRAZZA FAEGRE & BENSON LLP	QUALITY EGG LLC, GALT,IA; CLARION, IA; ALDEN, IA , ETC - PFGE & MLVA TEST RESULTS, ANALYSES 8/10 TO PRESENT
2012-118	01/09/2012 02/07/2012	FDA/OC/OES/DFOI/	MERCK & CO., INC.	FOI DAILY LOG 12/26/30/11
2012-119	01/09/2012	FDA/OC/OES/DFOI/		FOI DAILY LOG 1/2-6/12

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	02/07/2012		MERCK & CO., INC.	
2012-120	01/09/2012 02/07/2012	FDA/OC/OES/DFOI/	MERCK & CO., INC.	2011-9471 REQUEST LETTER
2012-121	01/09/2012 02/07/2012	FDA/OC/OES/DFOI/	MERCK & CO., INC.	2011-9195 REQUEST LETTER
2012-122	01/09/2012 02/07/2012	FDA/OC/OES/DFOI/	MERCK & CO., INC.	CLOSED FOIA REQUESTS 12/1-31/11
2012-123	01/09/2012 02/07/2012	FDA/OC/OES/DFOI/	CROWELL & MORING	FOIA REQUESTS FOR CENTER FOR VETERINARY MEDICINE 12/1-21/11
2012-124	01/09/2012 02/07/2012	FDA/OC/OES/DFOI/	BRIAN SMITH LEXIS NEXIS COURTLINK INC	2009-7825
2012-125	01/09/2012 02/07/2012	FDA/OC/OES/DFOI/	BRIAN SMITH LEXIS NEXIS COURTLINK INC	2009-6581
2012-126	01/09/2012 02/07/2012	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	CLAYON HUNTLEY MORRISON CLAYTON H MORRISON LLC	FRESENIUS MEDICAL CARE HOLDINGS INC, WALTHAM, MA - EIR 6/15/10-8/6/10, 483 6/14/10 TO 1/1/11
2012-127	01/09/2012 02/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	FRISBIE, JEFFREY	VASCULAR OCCLUSION SYS - K983483; TRUFILL DCS ORBIT DETACHABLE COIL & TRUFILL DCS SYRINGE (TRUFILL DCS ORBIT DETACHABLE COIL SYS) - K032553
2012-128	01/09/2012 02/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	FRISBIE, JEFFREY	MICRUS STRETCH-RESISTANT MICROCOIL SYS MSR01 - K022420; MICRUS MICROCOIL SYS - K032872; MICRUS MICROCOIL SYS CASHMERE MODEL SRC - K063653
2012-129	01/09/2012 02/07/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	MERCK SHARP & DOHME - JUVISYNC (SIMVASTATIN, SITALIPTIN PHOSPHATE) AERS 12/1-31/11
2012-130	01/09/2012 02/07/2012	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/ FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	MARY FRANCES BROUGHMAN BROWN & CROUPPEN PC	INDIVIDUAL RECS
2012-131	01/09/2012	FDA/OMPT/CDER/ORP/DIDP/	JOAN STITT (UG2CD-16)	SCHERING - DULERA (FORMOTEROL FUMARATE,

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	02/07/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MERCK & CO., INC.	MOMESTASON FUROATE) AERS 12/1-31/11
2012-132	01/09/2012 02/07/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	SCHERING - VICTRELIS (BOCEPREVIR) AERS 12/1-31/11
2012-133	01/09/2012 02/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	SUE CORBETT RESEARCH INVESTMENT INC	ETHICON INC - COATED VICRYL (POLYGLACTIN) SUTURE LBLG 1994
2012-134	01/09/2012 02/07/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARCUS PETOYAN GIANNI PETOYAN ATTY	PROZAC, FLUOXETINE - PREGNANCY EXPOSURE REGISTRY RECS
2012-135	01/09/2012 02/07/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ROBERT V PRONGAY GLANCY BINKOW & GOLDBERG LLP	INSMED INC - ARIKACE (LIPOSOMAL AMIKACIN FOR INHALATION) CLNCL TRIAL, IND, CORR, ETC
2012-136	01/09/2012 02/07/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ROSIERE, SHAUN	WHAT DRUG OR DRUG PROD APPL ARE AVAILABLE - NDA, PIONEER NDA; APRVLS ARE POSTED ON WHAT WEB ADDRESS - PENDING APRVLS, ENACTMENT DATES LAST 5 YRS; DECISION DATES - WEBSITE ADDRESS, ETC
2012-137	01/09/2012 02/07/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KEITH CHASIN KEITH CHASIN LAW OFC	ZICAM OXYMETAZOLINE HCL SINUS RELIEF NASAL SPRAY OR GEL - AERS 1/1/00 TO 11/1/06
2012-138	01/09/2012 02/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	RONALD L BATE NATIONAL BIOLOGICAL CORP	AVEX INDUSTRIES LTD - PHOTOTHERAPEUTIX K935525, K933952, K933953, ETC
2012-139	01/09/2012 02/07/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ROBERT E SHAPIRO UNIV OF VERMONT COLLEGE OF MEDICNE	ONABOTULINUMTOXIN A - APRVL 10/15/10
2012-140	01/09/2012 02/07/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	RONALD L BATE NATIONAL BIOLOGICAL CORP	AVEX INDUSTRIES LTD, HUDSON FALLS, NY - EIRS 1990 TO 2011

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2012-141	01/09/2012 02/07/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DON J MIZERK HUSCH BLACKWELL LLP	SUN PHARMA GLOBAL - RYZOLT NDA 91-607 APRVL LTR 12/30/11
2012-142	01/09/2012 02/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	RONALD L BATE NATIONAL BIOLOGICAL CORP	AVEX INDUSTRIES LTD - K935525, K933952, K933953, ETC
2012-143	01/09/2012 02/07/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DUSTIN BLOCK IPD ANALYTICS LLC	TRAMADOL HCL ANDA 91-607 - APRVL LTR 12/30/11
2012-144	01/09/2012 02/07/2012	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	RONALD L BATE NATIONAL BIOLOGICAL CORP	AVEX INDUSTRIES LTD, GLENS FALLS, NY - EIRS 1990 TO 2011
2012-145	01/09/2012 02/07/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WILLIAM A GARVIN BUCHANAN INGERSOLL & ROONEY PC	COMPAZINE SPANSULE NDA 21-019 - APRVL RECS
2012-146	01/09/2012 02/07/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	ISR 4660267-1
2012-147	01/09/2012 02/07/2012	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OMPT/CDRH/OCER/DFOI/	RONALD L BATE NATIONAL BIOLOGICAL CORP	MEDTEK LIGHTING, HUDSON FALLS, NY - EIRS 1990 TO 2011; K051330
2012-148	01/09/2012 02/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	MICHAEL C THEODORAKIS FDA/CDER NTEU CHAPTER 282	CDRH NTEU COOPERATION COUNCIL - MINS, AGENDAS 2009-2012, SIGNED COUNCIL CHARTER, ETC
2012-149	01/09/2012 02/07/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOE PETTIGREW SCOTT & SCOTT LLP	PAIN THERAPEUTICS INC, KING PHARMACEUTICALS INC - REMOXY (EXTENDED-RELEASE OXYCODONE) COMPLETE RESP LTR 6/11; CORR, PRTS 12/08 TO PRESENT
2012-150	01/09/2012 02/07/2012	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	KRISTINA FRYE FRYE ELECTRONICS	FRYE ELECTRONICS, TIGARD, OR - EIR 7/14-21/09
2012-151	01/09/2012 02/07/2012	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	MINA KIMES FORTUNE MAGAZINE	SYNTHESE, WEST CHESTER, PA - EIRS 1/00 TO 1/06

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2012-152	01/09/2012 02/07/2012	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	TRAVIS SCHAFTENAAR UBS GLOBAL ASSET MANAGEMENT	INTEGRA LIFESCIENCES - 483 7/11
2012-153	01/09/2012 02/07/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	JOEL FUREY NOBLE BIOMATERIALS INC	MASTER FILE MAF 1260 - NON- REDACTED CORR, NOTES
2012-154	01/09/2012 02/07/2012	FDA/OFVM/CFSAN/OCD/EOS/	ELILOT HARRISON LEWIS & HARRISON	POLYLACIDE POLYMERS CAS 9051-89-2 - FCN 178
2012-155	01/09/2012 02/07/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	BRIAN SKORNEY BREAN MURRAY CARRET & CO	VIROPHARMA/LEV, SANQUIN, CAF - CINRYZE EIRS, 483S, CORR
2012-156	01/09/2012 02/07/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Doe J	FLU MIST - RECS
2012-157	01/09/2012 02/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	JULIE SCHOELL STRYKER INCUBATION OF MEDICAL TECHNOLOGY	CENTERPULSE ORTHOPEDICS INC - NATURAL KNEE II UNCOMPARTMENTAL KNEE SYS K033810
2012-158	01/09/2012 02/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	BAXTER HEALTHCARE CORP - CONTROL-A-FLO REGULATOR K940867
2012-159	01/09/2012 02/07/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	MERCK & CO INC - ROTATEQ (ROTAVIRUS VACCINE) VAERS 12/1-31/11
2012-160	01/09/2012 02/07/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	MERCK & CO INC - GARDASIL (HPV VACCINE) VAERS 12/1-31/11
2012-161	01/10/2012 02/08/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BANKS DZ-5843, RONALD	SELECTIVE SEROTONIN REUPTAKE INHIBITORS - AER
2012-162	01/10/2012 02/16/2012	FDA/OFVM/CFSAN/OCD/EOS/	REGINA HARPER MILLIKEN & COMPANY	FCN 310, 377, 544
2012-163	01/10/2012 10/25/2012	FDA/OFVM/CFSAN/OCD/EOS/	REGINA HARPER MILLIKEN & COMPANY	FCN 5,7 (1,1 -DIMETHYLETHYL)-3-HYDROXY-2(3H)-BENZOFURANONE, REACTION PRODUCTS WITH O-XYLENE
2012-164	01/10/2012 02/08/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	AMERICAN CELLULAR LABS - TREN XTREME AER

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2012-165	01/10/2012 02/08/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SANJAY NAYAK, MD, PhD. MEDITREC LLC	REGENERON PHARMS INC - EYLEA APRVL, CMC RVW, CLNCL RVW
2012-166	01/10/2012 02/08/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	FOI Services, Inc.	2011-9281
2012-167	01/10/2012 02/08/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HELGESON, STEVE	ISRS 6905005, 6986289
2012-168	01/10/2012 02/08/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CAROLE D. MITNICK HARVARD MEDICAL SCHOOL - DEPT OF GLOBAL HEALTH & SOCIAL MEDICINE	SANOFI AVENTIS - RIFADIN NDA SUMMARIES
2012-169	01/10/2012 02/08/2012	OC/ORR/ORM/ OC/ORR/ORM/	DENISE HAMMANG BIOPHARMA COMPLIANCE SERVICES LLC	HUMAN CELL & TISSUE ESTABLISHMENTS 7/1/11 TO 12/31/11
2012-170	01/10/2012 02/08/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OFVM/CFSAN/OCD/EOS/	ELIOT HARRISON LEWIS & HARRISON	FCN 178
2012-171	01/10/2012 02/08/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/ OC/ORR/ OC/ORR/ OC/OA/OM/OMP/DDM/ FDA/OGROP/ORR/CE-FO/BLT- DO/BLT-CB/ FDA/OGROP/ORR/CE-FO/CHI- DO/CHI-CB/ FDA/OGROP/ORR/CE-FO/CIN-	ANGELA ERICKSON INSTITUTE FOR JUSTICE	CORR TO & FROM STATE DENTAL BAORDS 2008 TO PRESENT

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		DO/CIN-CB/ FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/ FDA/OGROP/ORASW-FO/SWID/SWID-CB/		
2012-172	01/10/2012 02/08/2012	FDA/OMPT/CDRH/OCER/DFOI/	EVAN BALLAN STEIN MITCHELL & MEZINES LLP	SORIN GROUP USA INC - CARBOMEDICS PROSTHETIC HEART VALVE - APRVL, LBLG
2012-173	01/10/2012	FDA/OMPT/CDER/ORP/DIDP/	DAVID B. HOFFMAN	MALLINCKRODT INC - OXYMORPHONE PRODUCTS PROCESS OF PRODUCTION

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	02/08/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WOODCOCK WASHBURN LLP	
2012-174	01/10/2012 02/08/2012	FDA/OC/OES/DFOI/	ELENA HOWELL HOGAN LOVELLS LLP	2011-8648
2012-175	01/10/2012 02/08/2012	FDA/OMPT/CDRH/OCER/DFOI/	DIANE R. WHITWORTH DRW RESEARCH & INFORMATION SERVICES LLC	MEDICAL ENTERPIRSES LTD - SYNERGO P010045
2012-176	01/10/2012 02/08/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/OA/OM/OMP/DDM/	CHRIS LETTER ODOM & DES ROCHES LLP	DKT 2005P-0315, RANBAXY - ANDA 76-477 CORR, APRVL RECS
2012-177	01/10/2012 02/08/2012	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	MATTHEW W. COOK MCDONALD CODY ET AL	SUN HONG KAI HOLDING INC - INSP 9/22/10 TO 10/1/10
2012-178	01/10/2012 02/08/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHLOE BIRD PCCA	LIST OF FOREIGN IMPORTED DRUGS PRODS, NDC NUMBERS ISSUED TO US DRUG MFRS
2012-179	01/10/2012 02/08/2012	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	BARBARA FRAZIER LEHL THE LAW OFFICES OF DENNIS BONNER & ASSOCIATES LLC	INDIVIDUAL RECS
2012-180	01/10/2012 02/08/2012	FDA/OMPT/CDRH/OCER/DFOI/OC/OCOS/OES/ OC/OCOS/OES/	RACHEL LEVEN THE HILL	CORR BETWEEN HHS & THE WHITE HOUSE CHIEF OF STAFF SINCE 1/1/11 TO PRESENT
2012-181	01/11/2012 02/09/2012	FDA/OC/OES/DFOI/	KEVIN BOOT Embria Health Sciences LLC	DKT 1995S-0039 - DRAFT 7590 RPT 689
2012-182	01/11/2012 02/09/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	BOEHRINGER INGLEHEIM - 483 MOST RECENT

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		FDA/OMPT/CDER/GRP/DIDP/		
2012-183	01/11/2012 02/09/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	BOEHRINGER INGLEHEIM - EIRS MOST RECENT
2012-184	01/11/2012 02/09/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	WPATRICK NOONAN W PATRICK NOONAN	K-Y BRAND INTRIGUE INTENSE WARMING SENSATION K072360
2012-185	01/11/2012 02/09/2012	FDA/OMPT/CDRH/OCER/DFOI/	MONIKA MCDOLE-RUSSELL SYNTHES SPINE	SYNTHES USA - LIGHT GUIDE K993314
2012-186	01/11/2012 02/09/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FOX, KAREN	ACCUTANE - AERS
2012-187	01/11/2012 02/09/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	COLEMAN, MIRA A	QT PROLONGATION, TORSADES DE POINTES & SUDDEN CARDIAC DEATH - AERS
2012-188	01/11/2012 02/09/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LEE, SHARON L	DARVACET - AERS
2012-189	01/11/2012 02/09/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KENNETH O JOBSON KENNETH O JOBSON MD	30 DRUG COMBINATIONS WITH PHARMACOGENOMICS IN THER LBLG - LIST OF MEDICATIONS APRVD
2012-190	01/11/2012 02/09/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELEN HOWELL HOGAN LOVELLS LLP	NATIONAL ACADEMY OF SCIENCES NATIONAL RESEARCH COUNCIL - CALCIUM LEUCOVORIN INJ - RPT
2012-191	01/11/2012 02/09/2012	FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/	ROBERT LL KAVANAUGH AMERICAN HEALTH PACKAGING	RESOURCE OPTIMIZATION & INNOVTION LLC - EIRS, 483S, WARNING LTRS LAST 4 YRS
2012-192	01/11/2012	FDA/OGROP/ORA/SW-FO/KAN-	AUSTIN NELSON	HOPSIRA INC - 483 1/4/12

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	02/09/2012	DO/KAN-CB/	RBC CAPITAL MARKETS	
2012-193	01/11/2012 02/09/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	JAMES PELUSO AVID RADIOPHARMACEUTICALS	BIOMED IRB, SAN DIEGO, CA - EIRS
2012-194	01/11/2012 02/09/2012	OC/CVM/OCD/	MOLE, BETH	ANTIMICROBIAL DRUG SPONSOR RPTS BY THE CENTER FOR VETINARY MEDICINE 2009, 2010
2012-195	01/11/2012 02/09/2012	FDA/OFVM/CFSAN/OCD/EOS/	HENRY DAO HSP USA LLC	FCN 692
2012-196	01/11/2012 02/09/2012	FDA/OMPT/CDRH/OCER/DFOI/ OC/OCOS/OES/ OC/OCOS/OES/ FDA/OC/OCC/ OC/OER/OPA/ OC/OA/OM/OMP/DDM/	CHARLES G BROWN CONSUMERS FOR DENTAL CHOICE	JEFF SHUREN, ANTHONY WATSON, DR MARY SUSAN RUNNER, ETC - DENTAL AMALGAM RECS 10/10 TO PRESENT
2012-197	01/11/2012 02/09/2012	FDA/OMPT/CDRH/OCER/DFOI/	RALPH AGUILA	CAREFUSION CORP - CLIO2 AUTOMATIC OXYGEN CONTROL IDE, PMA
2012-198	01/12/2012 02/10/2012	FDA/OMPT/CDRH/OCER/DFOI/	GEORGE R KINGSLEY KINGSLEY & KINGSLEY PC	PRODISC L DVC SURGERY - APRVL RECS
2012-199	01/12/2012 02/10/2012	FDA/OMPT/CDRH/OCER/DFOI/	LISA HOSSABI SYBRON DENTAL SPECIALTIES	METREX RESEARCH LLC - ALLRAP/SLIP-N-GRIP K960352
2012-200	01/12/2012 02/10/2012	FDA/OMPT/CDRH/OCER/DFOI/	DAWN TINDALL COVIDIEN	ASCENT HEALTHCARE SOLUTIONS - REPROCESSED HAND ACTIVATE SEALER/DIVIDER K111600
2012-201	01/12/2012 02/10/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	EMILY K STRUNK AKIN GUMP STRAUSS HAUER & FELD, LLP	MIDMARK CORP, VERSAILLES, OH - EIR 8/23/11-9/12/11
2012-202	01/12/2012 02/10/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORA/ OC/ORA/	COMBS, ANDREW	NOVARTIS - AFINITOR NDA 22-334; AMTURNIDE NDA 20-045; CATAFLAM NDA 20-142, ETC RECS
2012-203	01/12/2012 02/10/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	COMBS, ANDREW	UNITED THERAPEUTICS - REMODULIN NDA 21-272, TYVASO NDA 22-387 RECS

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2012-204	01/12/2012 02/10/2012	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	VICTORIA SCOTT HEMISPHERX BIOPHARMA	HEMISPHERX BIOPHARMA INC, NEW BRUNSWICK, NJ - MEMO 9/15/11
2012-205	01/12/2012 02/10/2012	FDA/OFVM/CFSAN/OCD/EOS/OC/CVM/OCD/	GERALDINE E EDENS MCKENNA LONG & ALDRIDGE LLP	EMERALD CAROLINA CHEMICALS LLC - POLYOXYETHYLENE SORBITAN MONOSTEARATE USE IN DRIED & WET DISTILLERS GRAINS GRAS
2012-206	01/12/2012 02/10/2012	FDA/OMPT/CDRH/OCER/DFOI/	STEVEN L BRAMER PHD FIRST-STOP CONSULTING	CHIRON INTRAOPTICS - OPTISOL-GS CORNEAL STORAGE MEDIA K924165
2012-207	01/12/2012 02/10/2012	FDA/OMPT/CDRH/OCER/DFOI/	KAY A SETZER Abbott Vascular	TERUMO MEDICAL CORP - RUNTHROUGH GUIDE WIRE K063695
2012-208	01/12/2012 02/10/2012	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	BARBARA RICH STERIS CORP	STERIS CORP, MONTGOMERY, AL - EIR 10/25-27/11
2012-209	01/12/2012 02/10/2012	FDA/OMPT/CDRH/OCER/DFOI/	ANDRENE HERON ROCHE DIAGNOSTICS CORP	AGAMATRIX - IPHONE GLUCOSE METER K103544
2012-210	01/12/2012 02/10/2012	FDA/OMPT/CDRH/OCER/DFOI/	CYNTHIA FRANCIS COLDSTAR INTERNATIONAL INC	COLDSTAR INTERNATIONAL INC - REGISTRATION & LISTING RECS
2012-211	01/12/2012 02/10/2012	FDA/OMPT/CDRH/OCER/DFOI/	CINDY ZWART SYNTHES SPINE	SOTEIRA INC - SHIELD KYPHOPLASTY SYS K093477
2012-212	01/12/2012 02/10/2012	FDA/OMPT/CDRH/OCER/DFOI/	RICHARD KELLER BRUNO INDEPENDENT LIVING AIDS INC	CMPLNT CPT1100211 - CORR, RECS 12/14/11 TO PRESENT
2012-213	01/12/2012 02/10/2012	FDA/OMPT/CTP/OD/ OC/ORA/ OC/ORA/ OC/ORA/ORM/ OC/ORA/ORM/	SUZANNE D JENSEN Kleinfeld, Kaplan and Becker, LLP	TOBACCO MFRS INSPS - RECS
2012-214	01/12/2012	OC/ORA/	DAVID WAGERS	CMPLNT 123913

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	02/10/2012	OC/OR/ FDA/OGROP/OR/PA-FO/SEA-DO/SEA-CB/	IDAHO CANDY CO	
2012-215	01/12/2012 02/10/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOI REQUESTS 1/2-6/12
2012-216	01/12/2012 02/10/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 1/2-6/12
2012-217	01/12/2012 02/10/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 1/2-6/12
2012-218	01/13/2012 02/13/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	2011-8901 - REQUEST LTR
2012-219	01/13/2012 02/13/2012	FDA/OC/OES/DFOI/	MARILYN WIHTNEY COVINGTON & BURLING LLP	DKT FDA-2010-P-0491
2012-220	01/13/2012 02/13/2012	FDA/OC/OES/DFOI/	FISHER, CASSANDRA	COOPER VISION - NAME OF INVESTIGATOR OR PREFORMED AUDIT 10/14-24/11
2012-221	01/13/2012 02/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	ADRIENNE HAMMOND VUCOMP INC	MATAKINA TECHNOLOGY LTD - VOLPARA IMAGING SOFTWARE K102556
2012-222	01/13/2012 02/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	MERCK - JANUVIA (SITAGLIPTIN PHOSPHATE) ISR 7830521-0, 7809243-8, 7812490-2, ETC
2012-223	01/13/2012 02/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MICHAEL R COHEN INSTITUTE FOR SAFE MEDICATION PRACTICES	MEDWATCH RPTS CODED AS MEDICATION ERRORS 12/1/11 TO 1/1/12
2012-224	01/13/2012 02/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARK BRUNSWICK PROTOX THEAPEUTICS	CIALIS (TADALAFIL) NDA 21-368/S020 - STATISTICAL & MEDICAL RVWS 10/6/11
2012-225	01/13/2012 02/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN M ENGEL ENGEL & NOVITT, LLP	LEVETIRACETAM TABS - ANDAS 76-919, 76-920, 77-319, ETC APRVL PKG

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2012-226	01/13/2012 02/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	RANDALL L TACKETT Tackett, Randall L	DKT 2005--0072/CPI - IBUPROFEN RVWS, POSTMARKETING AERS
2012-227	01/13/2012 02/13/2012	FDA/OC/OES/DFOI/	ELAINE S WALLER SEATTLE GENETICS INC	ADCETRIS (BTRENTUXIMAB VEDOTIN) - IRS 7728607-4, 7819592-5, 7906053-8, ETC
2012-228	01/13/2012 02/13/2012	FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	JOHN WALSH JAMES ALEXANDER CORP	SHELL CHEMICAL LP, HOUSTON, TX - EIRS, 483S, RECALL 1/09 TO PRESENT
2012-229	01/13/2012 02/13/2012	FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/ FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/	ADRIENNE L BUCKMAN SMITH BAKKE ATTY	CENTRAL FARMERS COOPERATIVE, MARION, SD - FEED SPL 6/09, 7/09
2012-230	01/13/2012 02/13/2012	FDA/OFVM/CFSAN/OCD/EOS/	ELIOT HARRISON LEWIS & HARRISON	FCN 643 - TOXICOLOGY RVW, CHEMISTRY RVW
2012-231	01/13/2012 02/13/2012	FDA/OC/OES/DFOI/	BRENDA M. GATRZ ELI LILLY & CO	FXM RESEARCH CORP, MIAMI, FL - 483 5/13/09, 2/7/05
2012-232	01/13/2012 02/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BENTLE, JANE	BONIVA - AERS
2012-233	01/13/2012 02/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	MICHAEL CONRAD LUCERO MEDICAL LLC	ENDURAMESH K093207
2012-234	01/13/2012 02/13/2012	FDA/OFVM/CFSAN/OCD/EOS/	BOBBY SCHOCHET OFW LAW	INFANT FORMULA NOTIFICATIONS (IFN) 7/11 to 12/11
2012-235	01/13/2012 02/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN M. ENGEL ENGEL & NOVITT, LLP	LEVETIRACETAM SOLUTION - ETC, APRVL RECS
2012-236	01/13/2012 02/13/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	ADRIENNE HAMMOND VUCOMP INC	HOLOGIC INC - QUANTRA K082483
2012-237	01/13/2012 02/13/2012	FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/ FDA/OMPT/CDRH/OCER/DFOI/	ELIZABETH DUDLEY, Esq. DUDLEY FIRM LLC	MEDRAD INC - AVANTA FLUID MANAGEMENT INJECTION SYS K050456
2012-238	01/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	PAMELA HOPKINS	DOCTORS RESEARCH GROUP INC - KRYPTONITE BONE

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	02/13/2012		MEDTRONIC SOFAMOR DANEK	CEMENT K091382
2012-239	01/17/2012 02/14/2012	FDA/OC/OES/DFOI/	BRIAN SMITH LEXIS NEXIS COURTLINK INC	2011-9228
2012-240	01/17/2012 02/14/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	WELCH, JOSEPH	BODY COMPOSITION ANALYZER CLASS II DVC - RECALLS, POST-MARKETING SERVEILLANCE, CORR, ETC
2012-241	01/17/2012 02/14/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	WELCH, JOSEPH	EVOFEM INC - SOFTCUP CLASS 11 DVC; AMPHORA - CONDOM CLASS 11 DVC; AMPHORA - LUBRICANT CLASS 1 DVC, ETC - RECALLS, POST-MARKET SRVEILLANCE, CORR, ETC
2012-242	01/17/2012 02/14/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	WELCH, JOSEPH	SPECTRASCIENCE INC, DIEGO, CA - SBIOPSY FORCEPTS CLASS 1 DVC; REUSABLE FORCEPTS CLASS 1 DVC;WAVSTAT OPTICAL BIOPSYS SYS CLASS III DVC, ETC
2012-243	01/17/2012 02/14/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	WELCH, JOSEPH	CYTORI THERAPEUTICS INC, SAN DIEGO, CA - CELUTION CONCENTRATION DVC CLASS II DVC; STEMSOURCE REAGENT A & B CLASS I DVC; CELBRUSH - IRRIGATION NON DENTAL SYRINGE CLASS I DVC, ETC
2012-244	01/17/2012 02/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	CHRISTOSPHER M SLOAN QUINTILES CONSULTING	ACCLARENT INC - RELIEVA SPIN SINUS DILATION SYS K111875 CORR, MINS
2012-245	01/17/2012 02/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANNE E HANOCK MCINTOSH LAW FIRM PC	SANOFI-SYNTHELABO INC - AMBIEN NDA 19-908 PI, MEDICATION GUIDES (CERTIFIED)
2012-246	01/17/2012 02/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANE E HANCOCK MCINTOSH LAW FIRM PC	ZOLPIDEM- PI, MEDICATION GUIDES 2007, 2008 (CERTIFIED)
2012-247	01/17/2012 02/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANNA NORTH GAWKER MEDIA	LORCASERIN - RVWS
2012-248	01/17/2012 02/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANNA NORTH GAWKER MEDIA	QNEXA - RVWS

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		FDA/OMPT/CDER/GRP/DIDP/		
2012-249	01/17/2012 02/14/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	NANCY YUEN GlaxoSmithKline	METHADONE - ISRS 3847412-2, 5006449-0, 5090927-2, ETC
2012-250	01/17/2012 02/14/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ZWIRN, MARY	LIPITOR, CRESTOR - AERS
2012-251	01/17/2012 02/14/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	HALL #332268, TARRENCE	SYNTHETIC CANNABANOIDS MARIJUANA, FAKE MARIJUANA;SPICE K2, HERBAL INCENSE, POTPORRI - RECS
2012-252	01/17/2012 02/14/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOANN DAWSON ELI LILLY & CO	NPIATE (ROMIPLOSTIM; BLA 125268/S077 - REMS MODIFCATION LTR 11/30/10
2012-253	01/17/2012 02/14/2012	FDA/OFVM/CFSAN/OCD/EOS/	SZABO, DAVID	BROMINATED VEGETABLE OIL - SAFETY ASSESSMENT LATE 1970S, EARLY 1980S
2012-254	01/17/2012 02/14/2012	FDA/OFVM/CFSAN/OCD/EOS/	CS WATERS	FOOD ADDITIVES THAT ARE SAFE - GRAS LIST 1958 TO PRESENT
2012-255	01/17/2012 02/14/2012	OC/OM/OSS/OEEODM/ OC/OA/OM/OMP/DDM/	SUSAN L MOFFITT BROWN UNIV - DEPT OF POLITICAL SCIENCE	CARDIO-RENAL DRUGS A/C - PEPCID NDA 19-462 1/16/86; ENDOCRINOLOGIC & MEDTOBOLIC DRUGS A/C - UCEPHAN NDA 19-530 912/86; CARDIO-RENAL DRUGS A/C - SBREVBLOC NDA 19-386 9/30/86, ETC
2012-256	01/17/2012 02/14/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOANN DAWSON ELI LILLY & CO	GLAXOSMITHKLINE, DIVISION OF HEMATOLOGY PRODS - TELECONFERENCE 2/11/11, PROMACTA (ELTROMBOPAG) NDA 22-291/S006 REMS MODIFICATION LTR 11/12/10
2012-257	01/17/2012 02/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	CHRISTOPHER SLOAN QUINTILES CONSULTING	ACCLARENT INC - CYCLOPS MULTI-ANGLE ENDOSCOPE K100577
2012-258	01/17/2012 02/14/2012	OC/ORO/OCI/ OC/ORO/OCI/	HERRERA, MICHELLE	ROBERT GERTIE B & B PHARMACEUTICALS - MEMOS OF INTERVIEW
2012-259	01/17/2012	FDA/OMPT/CDRH/OCER/DFOI/		KNEE IMPLANT - RECALL 1/08 TO PRESENT

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	02/27/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/DET-DO/DET-CB/ FDA/OGROP/ORO/CE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORO/SE-FO/NOL-DO/NOL-CB/	BERNARDI, GENE C	
2012-260	01/17/2012 02/14/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	Doe J	CMLPNT 123465
2012-261	01/17/2012 02/14/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	SANDRA F SELVAGGI ABBOTT MEDICAL OPTICS INC	ABBOTT MEDICAL OPTICS INC - EASY RUB MULTIPURPOSE CONTACT LENS SOL SPL 629813 ANALYTICAL RESULTS
2012-262	01/17/2012 02/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	CAHNDRA RAMCHARAN FUJI MEDICAL SYSTEMS USA INC	LIST OF CERTIFIED MAMMOGRAPHY SITES 12/31/11
2012-263	01/17/2012 02/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANNE E HANCOCK MCINTOSH LAW FIRM PC	FOREST LABS - CELEXA NDA 02-0822 PI, MEDICATION GUIDELINES
2012-264	01/17/2012 02/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANNA NORTH GAWKER MEDIA	NUVARING - RVW PROCESS
2012-265	01/17/2012 02/14/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SE-FO/NOL-DO/NOL-CB/	Doe J	INDIVIDUAL RECS
2012-266	01/17/2012 02/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GULLAH, CHASE	COCAINE, LSD, HEROIN, ETC - CHEMICAL MAKEUP, AERS

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		FDA/OMPT/CDER/GRP/DIDP/		
2012-267	01/17/2012 02/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	RICHARD KELLER BRUNO INDEPENDENT LIVING AIDS INC	ACORN STAIRLIFTS - CMLPNT, CORR
2012-268	01/17/2012 02/14/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID ARMSTRONG BLOOMBERG NEWS	BRISTOL-MYERS SQUIBB - KENALOG LBLG CHANGE RECS
2012-269	01/17/2012 02/14/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	WELCH, JOSEPH	MEDCO HEALTH SOLUTIONS, FRANKLIN LAKES, NJ - MEDCO PHARMACY MOBILE APP RECALL RECS, POST-MARKETING SURVEILLANCE, CORR, ETC
2012-270	01/17/2012 02/14/2012	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	WELCH, JOSEPH	PICIS INC (OPTIMUMINSIGHT), WAKEFIELD, MA - CARESUITE RECALL RECS, POST-MARKETING SURVEILLANCE, CORR, ETC
2012-271	01/17/2012 02/14/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	WELCH, JOSEPH	CLEVELAND HEARTLAB LLC, CLEVELAND, OH - CARDIOMPO RECALL RECS, POST-MARKETING SURVEILLANCE, CORR, ETC
2012-272	01/17/2012 02/14/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	WELCH, JOSEPH	AGA MEDICAL CORP, MINNEAPOLIS, MN - AMPLATZER TORQVUE DX CATHETER, GUIDEWIRES, NOODLEWIRE, ETC RECALL RECS, POST-MARKETING SURVEILLANCE, CORR, ETC
2012-273	01/17/2012 02/14/2012	OC/CVM/OCD/	LAURIE PHARIS NOVARTIS ANIMAL HEALTH	EASOTIC (HYDROCORTISONE ACEPONATE, MICONAZOLE NITRATE, GENTAMICIN SULFATE) OTIC SUSPENSION NADA 141-330 RECS
2012-274	01/17/2012 02/14/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CLOREY TOOMBS RECKITT & COLMAN PHARMACEUTICALS	VYVANSE (LISDEXAMFETAMINE) - SCHEDULE II CORR
2012-275	01/17/2012 02/14/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DANIELLE SPICER AMWAY CORP	MERCK KGAA, DARMSTADT, GERMANY - EIR, 483
2012-276	01/17/2012 02/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	SHOSHANA FRIEDMAN PUSH-MED LTD	EASYGLIDE LTD - CLEARPATH DVC K091305
2012-277	01/17/2012 02/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	CHRISTINE L MACAULEY KIMBERLY-CLARK CORP	BRAHMS PCT SENSITIVE KRYPTOR TEST SYS K070310

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2012-278	01/17/2012 02/14/2012	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	RAFE LEWIS NORTH RUN CAPITAL LP	INVACARE CORP, ELYRIA, OH - 483S 12/19/08, 12/17/10, 8/8/11, ETC
2012-279	01/17/2012 02/14/2012	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	GREGORY HERTZ CITIGROUP	HOSPIRA, MCPHERSON, KS - 483 1/12
2012-280	01/17/2012 02/14/2012	FDA/OFVM/CFSAN/OCD/EOS/	WILLIAM A OLSON PHD WASHINGTON INFORMATION SOURCE	CIBA SPECIALTY CHEMICALS CORP - FCN 554
2012-281	01/17/2012 02/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	IN SAM SONG INFOPIA CO LTD	BIOSITE INC - INRATIO, INRATIO2 TEST STRIPS K092987; ROCHE DIAGNOSTICS - COAGUCHEK XS SYS K060978
2012-282	01/17/2012 02/14/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANNA NORTH GAWKER MEDIA	CONTRACE (BUPROPRION,NALTREXONE) - RVW PROCESS
2012-283	01/17/2012 02/14/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANNA NORTH GAWKER MEDIA	ALLI (OLRISTAT) - NDA
2012-284	01/17/2012 02/14/2012	FDA/OC/OES/DFOI/	MIKE DRUCKMAN HOGAN LOVELLS LLP	ODAC MTG - MINS 7/1/91
2012-285	01/18/2012 02/15/2012	FDA/OMPT/CDRH/OCER/DFOI/	RAYMOND LEE TRIA BEAUTY INC	PHAROS LIFE CORP - TANDA SKINCARE SYS K080591
2012-286	01/18/2012 02/15/2012	FDA/OMPT/CDRH/OCER/DFOI/	SHEILA LITTON TRIA BEAUTY INC	PHOTO THERAPEUTICS INC - OMNILUX CLEAR-U K081307
2012-287	01/18/2012 02/15/2012	FDA/OMPT/CDRH/OCER/DFOI/	THOMAS J QUINN Medical Resources Alliance	XORAN - MINICAB CT SCANNER K032243
2012-288	01/18/2012 02/15/2012	FDA/OMPT/CDRH/OCER/DFOI/	TANIA LUPU CASE MEDICAL INC	AESLAP INC - STERILCONTAINER WITH PRIMELINE LIDS K073168
2012-289	01/18/2012 02/15/2012	FDA/OMPT/CDRH/OCER/DFOI/	GORLACH, IGOR	ANESTESIOLOGY & RESPIRATORY THERAPE DVC PANEL; CLINICAL CHEMISTRY & CLINICAL TOXICOLOGY DVC PANEL; CIRCLATORY SYS DVS PANEL - 12/18/98, 7/16/01, 5/13/05; 3/20/97, 3/21/97, 9/25/197, ETC; 12/4/97, ETC 1/1/97 TO 12/31/05
2012-290	01/18/2012 02/15/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	LYNN KELLER NATIONAL BIOLOGICAL CORP	HOUVA 3 PHOTOTHERAPY SYS - K041212; PANOSOL II TRU-BLU MODEL UBL-417 - K070934; PHOTOTHERAPY TIMER - K924969, ETC

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2012-291	01/18/2012 02/15/2012	FDA/OMPT/CDRH/OCER/DFOI/	ELIZABETWH DOWNEY JOHNSON & JOHNSON VISION CARE INC	MILLIPORE, MOLSHEIM, FRANCE - EIR 11/89
2012-292	01/18/2012 02/15/2012	FDA/OMPT/CDRH/OCER/DFOI/	MELISSA R GAYNOR CHEMENCE MEDICAL INC	SURGISEAL TOPICAL SKIN ADHESIVE - K082993; LIQUIDBAND FLOW CONTROL - K110184
2012-293	01/18/2012 02/15/2012	FDA/OMPT/CDRH/OCER/DFOI/	W PATRICK NOONAN W PATRICK NOONAN	UNITED CONSORTIUM INC, BEVERLY HILLS, CA - SYSTEM JO PERSONAL LUBRICANT CLITORAL STIMULATION GELS 510K
2012-294	01/18/2012 02/15/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	PAM LARSON MEDIGENE, INC	BSL BIOSERVICE SCIENTIFIC LABORATORIES GMBH, GERMANY - QUALITY ASURANCE PROFILE (QAPS) 7/06, 7/11, 8/11
2012-295	01/18/2012 02/15/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LECHER, SHIRLEY	MEFLOQUINE - AERS
2012-296	01/18/2012 02/15/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GORLACH, IGOR	ANTI INFECTIVE DRUGS A/C; ANETHETIC & ANALGESIC DRUG PRODS A/C- 11/19-20/97, 2/19-98, 7/29/98, ETC 1/30/02; ALSDAC 1/31/02, 5/16/02, 9/9/03, ETC CONFLICT OF INTEREST WAIVERS 1/1/97 TO 12/31/05
2012-297	01/18/2012 02/15/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN J MASTRANTONIO AARONSON RAPPAPORT ET AL	NEXIUM - AERS
2012-298	01/18/2012 02/15/2012	FDA/OMPT/CDRH/OCER/DFOI/	TIFFANY JENKINS ACUMED	ACUMED - DRILL BIT MDR
2012-299	01/18/2012 02/15/2012	FDA/OGROP/ORR/SE-FO/FLA- DO/FLA-CB/	LAUREN CUTLER GILEAD SCIENCES INC	MARQUEZ FARID, PALM SPRINGS RESEARCH INSTITUTE, HIALEAH, FL - EIR, 483 6/6/11
2012-300	01/18/2012 02/15/2012	FDA/OGROP/ORR/SW-FO/DEN- DO/DEN-CB/	KEVIN HORKY IPAX INC	IPAX INC, ENGLEWOOD, CO - EIR 8/2/07
2012-301	01/18/2012 02/15/2012	FDA/OGROP/ORR/CE-FO/MIN- DO/MIN-CB/	JEFF JORGENSON SMITH BAKKE ATTY	CENTRAL FARMERS COOPERATIVE - FEED SPLS 6/09, 7/09
2012-302	01/18/2012	FDA/OMPT/CDER/ORP/DIDP/	ANGELIA D SLAYTON	CPPI CV - SUTENT NDA 21-938/S013 APRVL LTR, LBLG,

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	02/15/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KENDLE INTERNATIONAL INC	RVWS, ETC
2012-303	01/18/2012 02/15/2012	FDA/OFVM/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 146840
2012-304	01/18/2012 02/15/2012	FDA/OGROP/ORACE-FO/CHI- DO/CHI-CB/ FDA/OGROP/ORAPA-FO/SEA- DO/SEA-CB/	SCHARBERG, DAVID L	FACILITY PERFORMING GLP NON-CLNCL OR BIOANALYTICAL TESTING - USA 7/11, 10/1/11-12/31/11
2012-305	01/18/2012 02/15/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	KIMBERLY A GRABBE MAGLIO CHRISTOPHER & TOALE LAW FIRM	VAERS RPTS - INDIVIDUAL RECS
2012-306	01/18/2012 02/15/2012	OC/CVM/OCD/	KELLY A MAGURANY NALCO CHEMICAL CO	POLYSORBATE 80, ETHOXYLATED SORBITAN MONOOLEATE - ENFORCEMENT DISCRETION LTR 5/21/08
2012-307	01/18/2012 02/15/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OGROP/ORANE-FO/NYK- DO/NYK-DCB/	THOMAS MAIER NEWSDAY MEDIA GROUP	SUNRISE MEDICAL LABORATORIES INC, HICKSVILLE, NY - ORDER TO CEASE MANUFACTURING OF HCT/P, RVWS, CORR, ETC
2012-308	01/18/2012 02/15/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORA/ OC/ORA/	ATWOOD, KIMBALL C	DESIGN OF THE TRIAL TO ASSESS CHELATION THERAPY - MINS, CORR, RVWS,, ETC
2012-309	01/18/2012 02/15/2012	OC/ORA/ OC/ORA/ FDA/OGROP/ORACE-FO/BLT- DO/BLT-CB/	Abell, Joseph W	OXYGEN TANK SUPPLIER, TESTING LAB, VALVE ASSEMBLY, ETC - FACTS #460653
2012-310	01/18/2012 02/15/2012	FDA/OFVM/CFSAN/OCD/EOS/	ELIOT HARRISON LEWIS & HARRISON	SILOXANES & SILICONES DIMETHYI - FCN 643
2012-311	01/18/2012 03/20/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	GORLACH, IGOR	ALLERGENIC PRODS A/C; BIOLOGICAL RESP MODIFIERS A/C; BLOOD PRODS A/C 4/7/05, 9/17/97, 10/17/97 7/24/ 3/13/97, ETC CONFLICT OF INTEREZT WAIVERS 1/1/97 TO 12/31/05
2012-312	01/18/2012 02/15/2012	FDA/OC/OES/DFOI/	DIANNE L CHAMBERS HOGAN LOVELLS US LLP	SECTION 912 OF THE FDA AMENDMENTS ACT 2007 - CORR, MEMOS, NOTES OF MEETINGS 2/18/10 TO PRESENT

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2012-313	01/18/2012 02/15/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OSHC/OPD/	MARY MORAN POLICY CURES	LIST OF GRANTS OR PROJECTS FUNDED BY CBER - INTRAMURAL & EXTERAMURAL 2000, 2004, 2007, 2008, ETC
2012-314	01/18/2012 02/15/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	ALEXANDER D DEBLIECK CONWAY HOMER & CHIN- CAPLAN PC	INDIVIDUAL RECS
2012-315	01/18/2012 02/15/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORAPA-FO/SEA- DO/SEA-CB/	JAMES B RATON MICHAEL BEST & FREIDRICH	ALEXIA FOODS - USE OF THE TERM NATURAL OR ALL NATURAL WARNING LTRS, CORR, RESP, ETC
2012-316	01/18/2012 02/15/2012	OC/OCOS/OL/ FDA/OC/OCC/ OC/ORA/ OC/ORA/ FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/	MITCHELL S FUERST FUERST ITTLEMAN PL	SUPREME MANUFACTURING COMPANY INC - CONGRESSIONAL CORR, REGULATORY ACTIONS, TESTING, ETC
2012-317	01/18/2012 03/16/2012	FDA/OMPT/CDRH/OCER/DFOI/	RONALD L BATE NATIONAL BIOLOGICAL CORP	DAAVLIN DISTRIBUTING CO, BRYAN, OH - K110912, K111172, K103708
2012-318	01/18/2012 02/15/2012	FDA/OMPT/CDRH/OCER/DFOI/	RONALD L BATE NATIONAL BIOLOGICAL CORP	DAAVLIN DISTRIBUTING CO, BRYAN, OH - ML24000 UVA-1 PHOTOTHERAPY CABINET K082731, DERMAPAL WITH DIGITAL TIMER K073587, 2 SERIES PHOTOTHERAPY CABINET K063621, ETC
2012-319	01/18/2012 02/15/2012	FDA/OMPT/CDRH/OCER/DFOI/	RONALD L BATE NATIONAL BIOLOGICAL CORP	DAAVLIN DISTRIBUTING CO, BRYAN, OH - 1 SERIES T2, SERIES, X2, 1 SERIES, T4, ETC ANNUAL & SUPPLEMENTAL RPTS
2012-320	01/18/2012 02/15/2012	OC/ORA/ OC/ORA/	CAMIE COX TOWN DOCK INC	ENTRY #ED5-0045410-0 - ANALYTICAL W/S
2012-321	01/18/2012 02/15/2012	OC/ORA/ OC/ORA/	CAMIE COX TOWN DOCK INC	ENTRY #ED5-0045411-8 - ANALYTICAL W/S
2012-322	01/18/2012 02/15/2012	OC/ORA/ OC/ORA/	CAMIE COX TOWN DOCK INC	ENTRY #ED5-0045412-6 - ANALYTICAL W/S
2012-323	01/18/2012 02/15/2012	FDA/OMPT/CDRH/OCER/DFOI/	DONNA LUNAK ST JUDE MEDICAL	K102588

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2012-324	01/18/2012 02/15/2012	FDA/OMPT/CDRH/OCER/DFOI/	ROY HARMAN RIGHT TIME BUSINESS	WHIP MIX CORP - CHANGE FROM REGISTERED MEDICAL DVC MFR OF DENTAL ABUTMENT TO REPACKAGER/RELABELER
2012-325	01/18/2012 02/15/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOSEPH REISMAN PHD ESQ KNOBBE MARTENS OLSON & BEAR	RANBAXY - ORTHO TRICYCLEN LO NDA 21-241, SEASONALE NDA 21-544, SEASONIQUE NDA 21-840 NAME, ADDRESS OF APPL HOLDERS
2012-326	01/18/2012 02/15/2012	FDA/OC/OES/DFOI/	ERIC KEISMAN JR CAPITAL GROUP COMPANIES INC	NOVARTIS AG - FOI REQUESTS FOR 483S 9/1/11 TO 1/13/12
2012-327	01/18/2012 02/15/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FRANK FAUNCE ABBOTT LABORATORIES, INC.	IND 010835 - RECS
2012-328	01/18/2012 02/15/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	REEVES, MICHAEL	DOCTOR'S HOSPITAL, DALLAS, TX - AED DEIFBRILLATOR DVCS RECALLS 2002-2003; SEROQUEL, RESPERDAL - AERS, RECALLS, ETC
2012-329	01/18/2012 02/15/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	MINA KIMES FORTUNE MAGAZINE	SYNTHES - JOHN J WALSH LTR 7/2/04
2012-330	01/18/2012 02/15/2012	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	MINA KIMES FORTUNE MAGAZINE	SYNTHES, WEST CHESTER, PA - 483 2002
2012-331	01/18/2012 02/15/2012	FDA/OC/OES/DFOI/	CHRIS CELESTE EAS Consulting Group, LLC	EMC 140, DKT 7610-052N
2012-332	01/19/2012 02/16/2012	OC/OM/OMP/DDM/	ETAN YESHUA ENVIRONMENTAL WORKING GROUP	DKT 1977P-0315
2012-333	01/19/2012 02/16/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TEDESCHI, BARBARA	NOVARTIS - EXCEDRIN RECALL

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2012-334	01/19/2012 02/16/2012	FDA/OC/OES/DFOI/	JOE NEEL NPR	FOI REQUESTS 2011 TO PRESENT
2012-335	01/19/2012 02/16/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KOLOWSKI, LEONARD	TYLOX - AERS
2012-336	01/19/2012 02/16/2012	FDA/OMPT/CDRH/OCER/DFOI/	ANTTI RITVANEN FINNMEDI OY	ORTHOFIX INC - ISKD (intramedullary skeletal kinetic distractor)K010322
2012-337	01/19/2012 02/16/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/SEA-DO/SEA-CB/	RYAN BULLIS BERKLEY NORTH PACIFIC	INDIVIDUAL RECS
2012-338	01/19/2012 02/16/2012	FDA/OMPT/CDRH/OCER/DFOI/	CRAIG DAVIS NEOGENIX LLC	TRANSCU 02 K090681
2012-339	01/19/2012 02/16/2012	FDA/OMPT/CDRH/OCER/DFOI/	MICHAEL THOMPSON AMNISURE INTERNATIONAL LLC	ROM PLUS FETAL MEMBRANES RUPTURE TEST K110605
2012-340	01/19/2012 02/16/2012	FDA/OMPT/CDRH/OCER/DFOI/	RAYMOND LEE TRIABEAUTY	PHOTO THERAPEUTICS INC - OMNILUX CLEAR U K081307
2012-341	01/19/2012 02/16/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	PHILIP COELHO SYNGEN INC	THERMOGENESIS - AXP AUTO EXPRESS PLATFORM BK070006
2012-342	01/19/2012 02/16/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/ OC/ORO/ FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/	AARON D LINDSTROM WARNER NORCROSS & JUDD LLP	SANCON COSTA LIGURE SNC, BRUNO SCHEIDT - OLIVES, OLIVE OIL, OLIVE PASTE SHIPMENT INVESTIGATION 2010
2012-343	01/19/2012 05/08/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	PHILIP COELHO SYNGEN INC	BIOSAFE SEPAX - CELL SEPARATION SYS BK060036
2012-344	01/19/2012 02/16/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/	MELISSA ALLISON SEATTLE TIMES	IMPORT REFUSAL RPT 10/01 TO PRESENT
2012-345	01/19/2012 02/16/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SHAUNAK DEEPAK JEFFERIES & CO	ADCETRIS (BRENTUXIMAB VEDOTIN) - AERS

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2012-346	01/19/2012 02/16/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SHAUNAK DEEPAK JEFFERIES & CO	ADCETRIS - ISR #7808761-6. 7919663-9, 7954114-X
2012-347	01/19/2012 02/16/2012	FDA/OMPT/CDRH/OCER/DFOI/	PETER B. NESBITT QUASAR BIO TECH	LED INTELLECTUAL PROPERTIES - LIGHSTIM ANTI WRINKLE OTC MODEL AAL OTC K101190
2012-348	01/19/2012 02/16/2012	FDA/OMPT/CDRH/OCER/DFOI/	RONALD L BATE NATIONAL BIOLOGICAL CORP	K051330
2012-349	01/19/2012 02/16/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	GILENYA (FINGOLIMOD) - SAFETY RVW
2012-350	01/19/2012 02/16/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	BECKY COOSEMAN BROWN & CROUPPEN PC	INDIVIDUAL RECS
2012-351	01/19/2012 02/16/2012	FDA/OMPT/CDRH/OCER/DFOI/	HARRIS, HELEN	MONARCH VAGINAL BLADDER MESH - MDRS
2012-352	01/19/2012 02/16/2012	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	CLAUDIA HORNBACK ROANOKE TRADE SERVICES INC	ABOUBACAR DIALLO - ENTRY #DL8000429144, FDA REFUSAL & REDELIVERY NOTICES, CF28 &29 REFERENCE CLAIMS
2012-353	01/19/2012 02/16/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	WELCH, JOSEPH	NOVARTIS, SAN CARLOS, CA - PDDS CLNCL LPT 100 NEBULIZER; T326 DRY POWDER INHALER RECALLS, CLNCL TRIALS, CORR
2012-354	01/19/2012 02/16/2012	FDA/OMPT/CDRH/OCER/DFOI/	RAYMOND LEE TRIABEAUTY	K080591
2012-355	01/19/2012 02/16/2012	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	PAUL W TRIPP LINCARE INC	ALLSTAR OXYGEN SERVICES INC, CA - EIRS, 483S, WARNING LTRS ETC 1/1/04 TO PRESENT
2012-356	01/19/2012	FDA/OMPT/CDRH/OCER/DFOI/		ALISO VIEJO, CA - MEDICAL DEVICE DATA SYS RECALL,

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	02/16/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	WELCH, JOSEPH	CORR, CLNCL TRIALS
2012-357	01/19/2012 02/16/2012	FDA/OC/OES/DFOI/ FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	DENISE SMITH Morton Salt	MORTON SALT INC, RITTMAN, OH - EIR, 483 MOST RECTNT
2012-358	01/19/2012 02/16/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	WELCH, JOSEPH	OPTIMUM INSIGHT, ROSEMONT, IL - CARE SUITE RECALL, CORR, CLNCL TRIAL
2012-359	01/19/2012 02/16/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	G MICHAEL WALL O-RAY PHARMA INC	ESTRING NDA 20-472 - RVWS, RISK ASSESSMENT RISK MITIGATION
2012-360	01/19/2012 02/16/2012	OC/OCOS/OES/ OC/OCOS/OES/	JOURNAL OF CLINICAL RESEARCH BEST PRACTICES	ANSWERS TO QUESTIONS FROM GCPQUESTIONS@OC.FDA.GOV
2012-361	01/19/2012 02/16/2012	OC/OM/OMP/DDM/	DAVID MCEACHERN RALLY LABS	DKT 1982N-0166, 1993N-0164
2012-362	01/19/2012 02/16/2012	FDA/OMPT/CDRH/OCER/DFOI/	JOE KLESNEY Oracle Corporation	ELECTRONIC MDR SUBMISSION STATISTICS 2006 TO PRESENT
2012-363	01/19/2012 02/16/2012	FDA/OGROP/ORASE-FO/FLADO/FLA-CB/	JERILYN J SPENCER HORIZON PHARMACEUTICALS INC	HORIZON PHARMACEUTICALS INC, RIVIERA BEACH, FL - EIR, 9/19-26/11
2012-364	01/19/2012 02/16/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	ERIC KEISMAN JR CAPITAL GROUP COMPANIES INC	NOVARTIS AG - 483 2009 TO PRESENT
2012-365	01/19/2012 02/16/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	WELLBUTRIN (BUPROPIOM) - AERS
2012-366	01/19/2012 02/16/2012	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	JULIA A. MOUSER CANNON & NELMS	SAMPLE 290134, 290135, 290136
2012-367	01/19/2012	OC/OM/OMP/DDM/	CHRIS CELESTE	FDA-1995-S-0039 DKT LOG

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	02/16/2012		EAS Consulting Group, LLC	
2012-368	01/19/2012 02/16/2012	OC/OM/OMP/DDM/	AINAT MARGALIT Center for Science in the Public Interest	DKT FDA-2006-D-0298
2012-369	01/19/2012 02/16/2012	OC/OM/OMP/DDM/	CHRIS CELESTE EAS Consulting Group, LLC	DKT 1976N-0052N
2012-370	01/19/2012 02/16/2012	OC/OM/OMP/DDM/	KEVIN BOOT Embria Health Sciences LLC	DKT FDA-1995-S-0039
2012-371	01/19/2012 02/16/2012	FDA/OFVM/CFSAN/OCD/EOS/	DAN DAHLMAN ECOLAB INC	FCN 1035 - CORR
2012-372	01/19/2012 02/16/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	LEX J. PEARCE ICU MEDICAL INC	EDWARDS LIFESCIENCES LLC, IRVINE, CA - VIGILANCE CCO K040287; VIGILANCE II K043103
2012-373	01/19/2012 02/16/2012	FDA/OFVM/CFSAN/OCD/EOS/	MITCHELL A. CHEESEMAN STEPTOE & JOHNSON	SANITIZING SOLUTIONS CHEMISTRY GUIDELINES FOR FOOD ADDITIVE PETITION
2012-374	01/19/2012 02/16/2012	FDA/OMPT/CDRH/OCER/DFOI/	VESA VUORINEN AALTO UNIVERSITY SCHOOL OF TECHNOLOGY	ELLIPSE TECHNOLOGIES INC - INTRAMEDULLARY LIMB LENGTHENING SYS K101997
2012-375	01/19/2012 02/16/2012	OC/OM/OMP/DDM/	BOBBY SCHOCHET OLSSON FRANK WEEDA TERMAN MATZ PC	DKT 1982N-0293
2012-376	01/19/2012 02/16/2012	OC/OM/OMP/DDM/	BOBBY SCHOCHET OLSSON FRANK WEEDA TERMAN MATZ PC	DKT 1982N-0293
2012-377	01/20/2012 02/17/2012	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	SANDRA F SELVAGGI ABBOTT MEDICAL OPTICS INC	AMO - COMPLETE EASY RUB MULTIPURPOSE CONTACT LENS SOL SPL 629813 RECS
2012-378	01/20/2012 02/17/2012	OC/ORA/ORM/ OC/ORA/ORM/	MARGARET R GROEL LACHMAN CONSULTANT SERVICES INC	FOREIGN & DOMESTIC DRUG COMPANIES, MEDICAL DVC MFRS, BIORESEARCH MONITORING (BIMO), ETC - INSPS 11/1-30/11
2012-379	01/20/2012 02/17/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JONES, TRACI	RISPERDAL CONSTA - AERS
2012-380	01/20/2012	FDA/OGROP/ORA/CE-FO/CIN-	MATTHEW MONTGOMERY	INVACARE CORP, ELYRIA, OH - 483S 2010-2011

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	02/17/2012	DO/CIN-CB/	SCOTT & SCOTT LLP	
2012-381	01/20/2012 02/17/2012	OC/OA/OM/OMP/DDM/	YAHIRO, MARTIN	ORTHOPEDIC AND REHABILITATION DVCS FDA ADVISORY PANEL MTG - CLASSIFICATION AND RECLASSIFICATION OF PEDICLE SCREW SPINAL SYSTEMS TRANS 8/20/93, 7/22/94
2012-382	01/20/2012 02/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	CHRISTINE L MACAULEY KIMBERLY CLARK CORP	AMT G-J TUBE K110804
2012-383	01/20/2012 02/17/2012	FDA/OFVM/CFSAN/OCD/EOS/	CHRIS CELESTE EAS Consulting Group, LLC	PHARMAVITE, OTSUKA - S-EQUOL CORR, NEW DIETARY INGREDIENT (NDI), GRAS NOTIFICATIONS, ETC 1/02 TO PRESENT
2012-384	01/20/2012 02/17/2012	OC/ORR/ORM/ OC/ORR/ORM/	KAMAS, KRISTEN	CANTALOUPE - SPL ANALYSIS RESULTS FY 2007 TO FY 2011
2012-385	01/20/2012 02/17/2012	FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/	DR WILMA PRETORIUS I & W RESEARCH INC	FANTASY COOKIE CO, SYLMAR, CA - EIR 11/8-10/11
2012-386	01/20/2012 02/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORR/CE-FO/DET-DO/DET-CB/ FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORR/SE-FO/SJN-DO/SJN-CB/	LOREN LARKIN SAC CAPITAL MANAGEMENT LLC	ELI LILLY, INDIANAPOLIS, IN; GREENWOOD, SC; SLIGO, IRELAND, ETC - 483S LAST THREE YRS
2012-387	01/20/2012 02/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORR/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORR/SE-FO/SJN-DO/SJN-CB/	LOREN LARKIN SAC CAPITAL MANAGEMENT LLC	WARNER CHILCOTT, MANATI, PR; LARNE, NORTHERN IRELAND; ROCKAWAY, NJ, ETC - 483S LAST THREE YRS
2012-388	01/20/2012 02/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	DR BRIGITTE DRENO, NANTES LOIRE ATLANTIQUE, FRANCE - 483 4/2/98

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2012-389	01/20/2012 02/17/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FOI Services, Inc.	DR SRIKANTA, JHANA SANJEEVINI MEDICAL CENTER, BANAGLORE, INDIA - PROTOCOL BI1218.46 483 8/26-30/11
2012-390	01/20/2012 02/17/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	2011-8914
2012-391	01/20/2012 02/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	TAEWOONG MEDICAL - NITI-S BILIARY STENT K073667
2012-392	01/20/2012 02/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	ENDOCHOICE - BONASTENT BILIARY K093003
2012-393	01/20/2012 02/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	WRIGHT MEDICAL TECHNOLOGY - PRO-DENSE BONE VOID FILLER K070437
2012-394	01/20/2012 02/17/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	FOI Services, Inc.	TARGET THERAPEUTICS - TRACKER-25 INFUSION CATHETER K874751
2012-395	01/20/2012 02/17/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 12/19-23/11
2012-396	01/23/2012 02/21/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BARBARA A BINZAK BUCHANAN INGERSOLL & ROONEY PC	DR REDDY'S LABS LTD - LANSOPRAZOLE DELAYED RELEASE CAPS ANDA 91-269; MATRIX LABS LTD - LANSOPRAZOLE DELAYED RELEASE CAPS AND 90-763; SANDOZ - LANSOPRAZOLE DELAYED RELEASE CAPS ANDA 90-331, ETC SBA
2012-397	01/23/2012 02/21/2012	FDA/OC/OES/DFOI/	AMANDA ORLANDA AVALON RISK MANAGEMENT INC	ENTRY #FN501191491 - ENTRY SUMMARY, INVOICE & PACKING LIST, ETC
2012-398	01/23/2012 02/21/2012	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	ELENA HOWELL HOGAN LOVELLS US LLP	WENDY WEIHE STORLIE INC, SPRING PARK, MN - EIR, 483, CORR 2/23/11, 3/11/11
2012-399	01/23/2012 02/21/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	LATESHA R BAKER HINSHAW & CULBERTSON LLP	AVASTIN - STREPTOCOCCAL ENDOPHTHALMITIS OUTBREAK RECS

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		FDA/OGROP/ORR/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORR/SE-FO/NOL-DO/NOL-CB/ FDA/OC/OES/DFOI/		
2012-400	01/23/2012 02/21/2012	FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/	BARTHOLOMEW, DEBBIE	GREAT PLAINS EYE BACK, LIFE GIDT, COVENANT MEDICAL CENTER - EIRS, MEMOS, INVESTIGATION, ETC
2012-401	01/23/2012 02/21/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/	Doe J	INDIVIDUAL RECS
2012-402	01/23/2012 02/21/2012	FDA/OMPT/CDRH/OCER/DFOI/	RAYMOND K KELLY IV ATRIUM MEDICAL CORP	ATRIUM - FLIXENE GRAFTS K051332, K060124, K071923, ETC
2012-403	01/23/2012 02/21/2012	FDA/OMPT/CDRH/OCER/DFOI/	RAYMOND J KELLY IV ATRIUM MEDICAL CORP	ATRIUM - ADVANTA GRAFTS K992441, K992443, K992958, ETC
2012-404	01/23/2012 02/21/2012	FDA/OMPT/CDRH/OCER/DFOI/	RAYMOND J KELLY IV ATRIUM MEDICAL CORP	ATRIUM - CLEARWAY OTW K093431
2012-405	01/23/2012 02/21/2012	FDA/OMPT/CDRH/OCER/DFOI/	RAYMOND J KELLY IV ATRIUM MEDICAL CORP	ATRIUM - CLEARWAY RX K061680
2012-406	01/23/2012 02/21/2012	FDA/OMPT/CDRH/OCER/DFOI/	RAYMOND J KELLY IV ATRIUM MEDICAL CORP	ATRIUM - IVENA PATCH K060396
2012-407	01/23/2012 02/21/2012	FDA/OMPT/CDRH/OCER/DFOI/	RAYMOND J KELLY IV ATRIUM MEDICAL CORP	ATRIUM - ULTRAMAX GRAFTS K991813
2012-408	01/23/2012 02/21/2012	FDA/OMPT/CTP/OD/ OC/OCOS/OL/ FDA/OC/OES/DFOI/	SUZANNE D JENSEN Kleinfeld, Kaplan and Becker, LLP	STAR SCIENTIFIC - ARIVA-BDL, STONEWALL-BDL MODIFIED RISJ TOBACCO PRODS APPL; DISSOLVABLE TOBACCO QUALIFIES AS SMOKELESS TOBACCO RECS, ETC
2012-409	01/23/2012 02/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DANIELLE SPICER AMWAY CORP	SUNLIT FLUO CHEMICAL, TAOYUAN COUNTY, TAIWAN - EIR, 483 MOST RECENT
2012-410	01/23/2012 02/21/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LEON B KAPLAN PHD PRINCETON RESEARCH & CONSULTING CENTER INC	MERCK & CO INC -REBETOL (RIBAVIRIN) HEPATITIS C VACCINE RISK EVALUATION & MITIGATION STRATEGY (REMS) ASSESSMENT MEDICATION GUIDE COMPREHENSION RPT

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2012-411	01/23/2012 02/21/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	MINA KIMES FORTUNE MAGAZINE	SYNTHES - NORIAN XR 510K
2012-412	01/23/2012 02/21/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/	MINA KIMES FORTUNE MAGAZINE	SYNTHES - CONFERENCE CALL MINS 5/8/02
2012-413	01/23/2012 02/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/ FDA/OGROP/ORA/SE-FO/SJN- DO/SJN-CB/	LOREN LARKIN SAC CAPITAL MANAGEMENT LLC	BRISTOL-MYERS SQUIBB, LATINA, ITALY; MANATI,PR; DEVENS, MA, ETC 483S LAST THREE YRS
2012-414	01/23/2012 02/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/ FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/ FDA/OGROP/ORA/SE-FO/SJN- DO/SJN-CB/	LOREN LARKIN SAC CAPITAL MANAGEMENT LLC	AMGEN, THOUSAND OAKS, CA; FREMONT,CA, BOULDER, CO, ETC - 483S LAST THREE YRS
2012-415	01/24/2012 02/22/2012	OC/ORA/ORM/ OC/ORA/ORM/	JONATHAN RICKMAN FDANEWS	PHARMACEUTICAL, BIOLOGICS, MEDICAL DVC MFRS, CLNCL TRIAL FACILITIES IN & OUTSIDE THE US - 483S 11/1-30/11
2012-416	01/24/2012 02/22/2012	FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/ FDA/OC/OES/DFOI/ FDA/OGROP/ORA/CE-FO/CHI- DO/CHI-CB/	TERESA MARSHALL PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS	GW EXOTICS - KMR FORMULA CMLPLNTS, CORR, LAB TESTS, ETC
2012-417	01/24/2012	FDA/OMPT/CDER/ORP/DIDP/	ALEXANDER MIRONOV	JANSSEN PHARMS - ELMIRON (PENTOSAN POLYSULFATE SODIUM) NDA 20-193/S002 SBA

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	02/22/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TIGRIS PHARMACEUTICALS INC	
2012-418	01/24/2012 02/22/2012	OC/ORR/ORM/ OC/ORR/ORM/	JOHN J HAY SALANS ATTY	FOREIGN AND US MFG FACILITIES OF US-BASED AND NON-US BASED PHARMACEUTICAL COMPANIES - INSPS 9/1/08 TO 7/1/11
2012-419	01/24/2012 02/22/2012	OC/ORR/ORM/ OC/ORR/ORM/	JONATHAN RICKMAN FDANEWS	PHARMACEUTICAL, BIOLOGICS, MEDICAL DEVICE MFG, CLINICAL TRIAL FACILITIES IN AND OUTSIDE THE US - 483S 12/1-31/11
2012-420	01/24/2012 02/22/2012	FDA/OFV/CFSAN/OCD/EOS/ KING & SPALDING	CARLA R SCARMAZZI KING & SPALDING	CITREM, MAGNESIUM L-ASPARTATE IN INFANT FORMULA - GRAS 1980 TO PRESENT
2012-421	01/24/2012 02/22/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN J HAY SALANS ATTY	TEVA PHARMACEUTICAL INDUSTRIES LTD, JERUSALEM, ISRAEL - 483 9/12-16/10
2012-422	01/24/2012 02/22/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MICHAEL P MANAPOL BRIAN D WITZER INC	MEDICIS PHARMACEUTICAL CORP - SOLODYN ER TABS NDA 50-808 APRVL RECS
2012-423	01/24/2012 02/22/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MICHAEL P MANAPOL BRIAN D WITZER INC	MEDICIS PHARMACEUTICAL CORP - SOLODYN ER TABS 50-808 LBLG CHANGE 3/18/11
2012-424	01/24/2012 02/28/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	RIVA, CATHERINE	GARDASIL - EFFICACY STUDIES STATISTICAL DATA ANALYSIS PLAN
2012-425	01/24/2012 02/22/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	PHINNY, C WENDY	SUCAMPO PHARMACEUTICALS INC - AMITZA (LUBIPROSTONE); R-TECH UENO LTD, CIBA VISION - RESCULA (UNOPROSTONE ISOPROPYL) STAFF GUIDANCE, CORR, ATTACHMENTS, ETC
2012-426	01/24/2012 02/22/2012	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORA/SW-FO/DEN- DO/DEN-CB/	TREVI PIES NUTRITIONAL LABORATORIES INTL	HAIN NORTH AMERICA, BOULDER, CO 3/31/10-4/14/10; SOMA LABS, MIDDLESEX, NJ 6/28/10-7/8/10 - EIRS
2012-427	01/24/2012	FDA/OFV/CFSAN/OCD/EOS/	ANN M OXFORD	FCN 880 - CHEMISTRY, TOXICOLOGY AND

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	02/22/2012		ALBEMARLE CORP	ENVIRONMENTAL ASSESSMENT RVWS, ETC
2012-428	01/24/2012 02/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	LEX PEARCE ICU MEDICAL INC	EDWARDS LIFESCIENCES LLC - VIGILANCE CCO/SVO2/CEDV MONITOR K040287; VIGILANCE II CCO/SVO2/CEDV MONITOR K043103
2012-429	01/24/2012 02/22/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JAMES FARES NURO PHARMA LLC	NURO PHARMA LLC - MYSOLINE (PRIMIDONE) ORAL SUSPENSION NDA 10-401 FORMULATION, DRUG PROD TEST METHODS, CONTAINER CLOSURE SYS, ETC
2012-430	01/24/2012 02/22/2012	OC/CVM/OCD/ OC/OCOS/OES/ OC/OCOS/OES/ OC/OCOS/OL/ FDA/OC/OCC/	JAYDEE HANSON CENTER FOR FOOD SAFETY	AQUABOUTY TECHNOLOGIES INC, FISHERIES & OCENAS CANADA - GENETICALLY ENGINEERED SALMON, ATLANTIC SALMON, FARM-RAISED SALMON INFECTIOUS SALMON ANAEMIA (ISA) RECS
2012-431	01/24/2012 02/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	MAOLIN WANG ALCOHOL COUNTERMEASURE SYSTEMS CORP	K063443
2012-432	01/24/2012 02/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	THOMAS F. THATCHER THATCHER PHARMACEUTICAL	NATIONAL THERAPY PRODUCTS - WAVELENGTH ULTRASOUND LOTION K013212
2012-433	01/24/2012 02/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	THOMAS F. THATCHER THATCHER PHARMACEUTICAL	VIVOSONIC - MICROTEK MEDICAL K020956
2012-434	01/24/2012 02/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	THOMAS F. THATCHER THATCHER PHARMACEUTICAL	DYNAREX CORP - ULTRASOUND GEL K102637
2012-435	01/24/2012 02/22/2012	FDA/OGROP/ORR/CE-FO/CHI-DO/CHI-CB/ FDA/OGROP/ORR/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORR/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORR/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORR/SE-FO/NOL-DO/NOL-CB/	FREEDBERG, SYDNEY	HEALTH SCIENCES PRODUCTS INC, AL; GRESKO PRODUCTS INC, TX; CMP INDUSTRIES LLC, NY, ETC - EIRS 2006 TO PRESENT

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		FDA/OGROP/ORAS/SE-FO/SJN-DO/SJN-CB/ FDA/OGROP/ORAS/SW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CDRH/OCER/DFOI/		
2012-436	01/24/2012 02/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	DIDI BOWLES PARSONS BEHLE & LATIMER	SORENSEN MEDICAL INC - PALM PUMP K002434
2012-437	01/24/2012 02/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	DIDI BOWLES PARSONS BEHLE & LATIMER	BAXTER HEALTHCARE CORP - MULTI THERAPY PUMP MODEL 2M9832; EPIDURAL PUMP MODEL 2L9351 K002679
2012-438	01/24/2012 02/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	DIDI BOWLES PARSONS BEHLE & LATIMER	SORENSEN MEDICAL INC - 30 PUMP CONTINUOUS LOW FLOW K991363
2012-439	01/24/2012 02/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	DIDI BOWLES PARSONS BEHLE & LATIMER	SORENSEN MEDICAL INC - AMBIT CONTINUOUS AMBULATORY INFUSION PUMP K033325
2012-440	01/24/2012 02/22/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	DIDI BOWLES PARSONS BEHLE & LATIMER	STRYKER CORP - PAINPUMP1 K042405
2012-441	01/24/2012 02/22/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	DIDI BOWLES PARSONS BEHLE & LATIMER	STRYKER INSTRUMENTS - MODIFICATION TO STRYKER PAINPUMP2 K030885
2012-442	01/24/2012 02/22/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	DIDI BOWLES PARSONS BEHLE & LATIMER	STRYKER INSTRUMENTS - STRYKER PAINPUMP2 K030661
2012-443	01/24/2012 02/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	DIDI BOWLES PARSONS BEHLE & LATIMER	STRYKER INSTRUMENTS - PAINPUMP PCA K003543
2012-444	01/24/2012 02/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	DIDI BOWLES PARSONS BEHLE & LATIMER	SABERATEK CORP - 6060 HOMERUN VOLUMETRIC INFUSION PUMP K941984
2012-445	01/24/2012 02/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	DIDI BOWLES PARSONS BEHLE & LATIMER	MICROJECT INC - MODEL PCA-1 K965222
2012-446	01/24/2012 02/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	DIDI BOWLES PARSONS BEHLE & LATIMER	NELLCOR PURITAN BENNETT - SUZANNE PORTABLE POLYSOMNOGRAPH SYS K030611
2012-447	01/24/2012 02/22/2012	OC/OM/OMP/DDM/	MIKE DRUCKMAN HOGAN LOVELLS US LLP	ODAC TRANS & MINS 7/1/1991
2012-448	01/24/2012 02/22/2012	OC/OM/OMP/DDM/	THOMAS FITZGERALD FSI RESEARCH & SERVICES, INC.	DKT 1991N-0384
2012-449	01/24/2012 02/22/2012	OC/OM/OMP/DDM/	AMY JOHNSON SIDLEY AUSTIN LLP	DKT FDA-2008-A-0619, 2010-A-0154, ETC.

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2012-450	01/25/2012 02/23/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/OCOS/OES/ OC/OCOS/OES/ OC/OCOS/OL/	DIANNE L CHAMBERS HOGAN LOVELLS LLP	SECTION 912 OF THE FDA AMENDMENTS ACTS OF 2007 - CORR, MINS, NOTES, ETC 2/18/11 TO PRESENT
2012-451	01/25/2012 02/23/2012	OC/OA/OM/OMP/DDM/	CHARLES AVERY FISHER FISHER WALLACE LABORATORIES LLC	NEUROLOGICAL DVCS PANEL - RECOMMENDATION OF CES TO BE CLASSIFIED AS CLASS 2 TO TREAT SITUATIONAL ANXIETY, INDENTITY OF PANEL MEMBERS, ETC 7/22-23/77
2012-452	01/25/2012 02/23/2012	FDA/OFVM/CFSAN/OCD/EOS/	KELLY A MAGURANY Nalco Company	EPI-DMA COPOLYMER - GRAS EVALUATION RECS
2012-453	01/25/2012 02/23/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORACE-FO/MIN- DO/MIN-CB/	ANNA DEMKOVIC ABBOTT LABORATORIES, INC.	GENERAL MILLS - SCIENTIFIC BASIS FOR CHEERIOS CHOLESTEROL CLAIMS CORR, MINS
2012-454	01/25/2012 02/23/2012	FDA/OFVM/CFSAN/OCD/EOS/	BOBBY S SCHOCHET OLSSON FRANK WEEDA TERMAN MATZ PC	TOTAL DIET STUDY (TDS) FOR DIOXIN - ANALYTICAL PROCEDURES, QUALITY CONTROL DATA, LAB RESULTS, ETC
2012-455	01/25/2012 02/23/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ OC/ORAOE/ OC/ORAOE/ FDA/OGROP/ORAPA-FO/SEA- DO/SEA-CB/ FDA/OGROP/ORACE-FO/PHI- DO/PHI-CB/	DAMON J BRINSON BOWMAN AND BROOKE LLP	MERCK & CO INC - PEDVAXHIB, COMVAX (HAEMOPHLIUS B CONJUGATE VACCINE), HEPATITIS B (RECOMBINANT VACCINE) RECALL, TESTING, MFG, ETC LAST TEN YRS
2012-456	01/25/2012 02/23/2012	FDA/OGROP/ORASE-FO/FLA- DO/FLA-CB/	DENISE HAMMANG BIOPHARMA COMPLIANCE SERVICES LLC	RTI BIOLOGICS INC, ALACHUA, FL - 483, 10/25/11
2012-457	01/25/2012 03/12/2012	OC/ORAOE/ OC/ORAOE/	ERIC KEISMAN JR CAPITAL WORLD INVESTORS	NOVARTIS AG - EIRS 1/1/09 TO 1/20/12
2012-458	01/25/2012 02/23/2012	FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/	DENISE HAMMANG BIOPHARMA COMPLIANCE SERVICES LLC	LONE STAR LIONS EYE BANK, MANOR, TX - 483, 7/25/11
2012-459	01/25/2012 02/23/2012	FDA/OGROP/ORASE-FO/ATL- DO/ATL-CB/	DENISE HAMMANG BIOPHARMA COMPLIANCE SERVICES LLC	CAROLINA BONE & TISSUE INC, GREENVILLE, SC - 483, 8/01/11
2012-460	01/25/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	CHRISTINA CIAMPOLILLO ESQ	MERCK & CO INC - GARDASIL (HUMAN PAPILOMAVIRUS QUADRIVALENT VACCINE) BLA 125126 RECS

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	04/20/2012		CONWAY HOMER & CHIN-CAPLAN PC	
2012-461	01/25/2012 02/23/2012	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	DENISE HAMMANG BIOPHARMA COMPLIANCE SERVICES LLC	ALABAMA ORGAN CTR, BIRMINGHAM, AL - 483, 7/22/11; DCI DONOR SERVICES TISSUE SERVICES DIV, NASHVIOLLE, TN - 483, 12/19/11; NATIONAL EMBRYO DONATION CTR, KNOXVLLLE, TN - 483, 11/10/11
2012-462	01/25/2012 02/23/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/ OC/ORO/ OC/ORO/ FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	ROBIN WINCHESTER KESSLERTOPAZ MELTZERCHECK LLP	ABBOTT - DEPAKOTE LBLG CHANGES, WARNING LTRS, AERS, ETC
2012-463	01/25/2012 02/23/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELLIOT FAVUS MD FAVUS INSTITUTIONAL RESEARCH LLC	QUESTCOR PHARMACURICALS - ACTHAR GEL AERS, 1/1/08 TO PRESENT
2012-464	01/25/2012 02/23/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELLIOT FAVUS FAVUS INSTITUTIONAL RESEARCH LLC	LESINURAD - AERS 1/1/09 TO PRESENT
2012-465	01/25/2012 02/23/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELLIOT FAVUS FAVUS INSTITUTIONAL RESEARCH LLC	PONATINIB - AERS 1/1/11 TO PRESENT
2012-466	01/25/2012 02/23/2012	OC/OA/OM/OMP/DDM/	BRIAN SMITH LEXISNEXIS COURTLINK INC	COMBINED HORMONAL CONTRACEPTIVE (CHC) AND THE RISK OF CARDIOVASCULAR DISEASE ENDPOINTS RVW 11/2/11
2012-467	01/25/2012 02/23/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELLIOT FAVUS FAVUS INSTITUTIONAL RESEARCH LLC	NUDEXTA (DEXTROMETHORPHAN HYDROBROMIDE & QUINIDINE SULFATE) - AERS 1/1/11 TO PRESENT
2012-468	01/25/2012	FDA/OC/OES/DFOI/	ELSPETH CALLAHAN	DRAFT GUIDANCE FOR INDUSTRY IN DESIGNING CLINICAL PROGRAMS FOR DEVELOPING HUMAN DRUGS, MEDICAL

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	02/23/2012	OC/OA/OM/OMP/DDM/	INDEPENDENCE LEGAL SUPPORT	DEVICES, OR BIOLOGICAL PRODUCTS INTENDED FOR THE TREATMENT OF RHEUMATOID ARTHRITIS - WORKSHOP 3/27/96, ETC
2012-469	01/25/2012 02/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	ELLIOT FAVUS FAVUS INSTITUTIONAL RESEARCH LLC	ABIOMED - IMPELLA MDRS 1/1/08 TO PRESENT
2012-470	01/25/2012 02/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OCC/	SHERI O COVINGTON K & L GATES	DR RICARDO RODRIGUEZ, COSMETIC SURGERY FACILITY LLC, MANUFACTURERS ASSISTANCE & TRAINING BRANCH, TISSUE REFERENCE FROUP - PURIFIED STEM CELLS CORR, MINS, RVWS, ETC
2012-471	01/25/2012 02/23/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OC/OCC/	SHERI O COVINGTON K & L GATES	TISSUE REFERNCE GROUP - ADIPOSE TISSUE PROD REGULATION CORR, MINS, RVWS, ETC
2012-472	01/25/2012 02/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELLIOT FAVUS MD FAVUS INSTITUTIONAL RESEARCH LLC	IDX184 - AERS 1/1/09 TO PRESENT
2012-473	01/25/2012 02/23/2012	FDA/OFVM/CFSAN/OCD/EOS/	RENATA NORONHA IOVATE HEALTH SCIENCES RESEARCH INC	CAERS 144708
2012-474	01/25/2012 02/23/2012	FDA/OFVM/CFSAN/OCD/EOS/	JAVIER BAYONA BODEGAS LARCHAGO SA	FDA 173 432 487 68 - RECS
2012-475	01/25/2012 02/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELLIOT FAVUS MD FAVUS INSTITUTIONAL RESEARCH LLC	DIFICID (FIDAXOMICIN) - AERS 1/1/90 TO PRESENT
2012-476	01/25/2012 02/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	ELLIOT FAVUS MD FAVUS INSTITUTIONAL	EDWARDS LIFESCIENCES - SAPIEN, MDRS 1/1/11 TO PRESENT

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			RESEARCH LLC	
2012-477	01/25/2012 02/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	ELLIOT FAVUS MD FAVUS INSTITUTIONAL RESEARCH LLC	HEARTWARE - HVAD PUMP (VENTRICULAR ASSIST DEVICE) MDRS 1/1/09 TO PRESENT
2012-478	01/25/2012 02/23/2012	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	BRUCE E. STEVENS CATALENT	CATALENT PHARMA SOLUTIONS, MORRISVILLE, NC - EIR
2012-479	01/25/2012 02/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	ELLIOT FAVUS MD FAVUS INSTITUTIONAL RESEARCH LLC	MAKO RIO; RESTORIS MCK; MAKOPLASTY KNEE PROCEDURES - MDRS 1/1/07 TO PRESENT
2012-480	01/25/2012 02/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	ELLIOT FAVUS MD FAVUS INSTITUTIONAL RESEARCH LLC	ABIOMED - IMPELLA MDRS 1/1/08 TO PRESENT----- ----DUPE OF 2012-469
2012-481	01/25/2012 02/23/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	KEITH A. BARRITT FISH & RICHARDSON PC	POSITIVE ID CORP - IGLUCOSE SYS K111932
2012-482	01/25/2012 02/23/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	MEYERS, MICHAEL E	SANQUIN BLOOD SUPPLY FOUNDATION - CINRYZE 483, WARNING LTRS 9/28/11
2012-483	01/25/2012 02/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TAMI UJIE TEIKOKU PHARMA USA INC	APOTEX INC - DOCETAXEL NDA 22-312 DRUG APRVL PKG, RVW RECS. CORR
2012-484	01/25/2012 02/23/2012	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	JOHN WALSH JAMES ALEXANDER CORP	ANACHEMIA CHEMICALS INC - ROUSES POINT, NY EIR, 483, RECALL 1/10 TO PRESENT
2012-485	01/25/2012 02/23/2012	FDA/OFVM/CFSAN/OCD/EOS/	ALISON BROWN CENTER FOR SCIENCE IN THE PUBLIC INTEREST	SENOMYX INC - FLAVOR-ENHANCING COMPOUNDS GRAS NOTIFICATION, CORR, RESP, ETC
2012-486	01/25/2012 02/23/2012	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	CLAUDIA HORNBACK ROANOKE TRADE SERVICES INC	AMERICAL CORP - ENTRY #WCJ02738679 NOTICE OF REFUSAL, NOTICE REDELIVERY, CF28 AND/OR CF29
2012-487	01/25/2012 02/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TAMI UJIE TEIKOKU PHARMA USA INC	ACCORD HEALTHCARE - DOCETAXEL NDA 20-1195 DRUG APRVL PKG, RVW RECS, CORR

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2012-488	01/25/2012 02/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TAMI UJIIE TEIKOKU PHARMA USA INC	SANDOZ - DOCETAXEL NDA 20-1525 DRUG APRVL PKG, RVW RECS. CORR
2012-489	01/25/2012 02/23/2012	OC/ORO/OCI/ OC/ORO/OCI/	Doe J	INDIVIDUAL RECS
2012-490	01/25/2012 02/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TAMI UJIIE TEIKOKU PHARMA USA INC	SUN PHARMA GLOBAL - DOCEFREZ NDA 22-534 DRUG APRVL PKG , RVW RECS, CORR
2012-491	01/25/2012 02/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	KEITH S. ERBSTEIN YOUNG RICCHIUTI ET AL	CATHETER - AER
2012-492	01/25/2012 02/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FRANCISCO X ROSAS CONVENTUS BIOMEDICAL SOLUTIONS INC	COSMO TECHNOLOGIES, LAINATE, MILAN, ITALY - EIRS, RECS 11/7-11/11
2012-493	01/25/2012 02/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	DENNIS R. GUMBERT, PhD INDIANA UNIVERSITY	IMAGE WISELY BROCHURES
2012-494	01/25/2012 02/23/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	CARL BEAURLINE CMB REGULATORY SPECIALTIES	VPRO STERILIZATION TRAY K070769; CONMED LINVATEC INSTRUMENT STERIZATION TRAY K052992; OLYMPUS STERILIZATION TRAYS K033222; APTIMAX INSTRUMENT TRAY K013003
2012-495	01/25/2012 02/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	C. CALVIN WARRINER, III SEARCY DENNEY ET AL	SULZER NATURAL KNEE I & II - SUMMARY & EFFECTIVENESS
2012-496	01/25/2012 02/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JENN NORRIS BENSON AREA MEDICAL CENTER	PRADAXA (DABIGATRAN) - AERS
2012-497	01/25/2012 02/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	TATSUHIRO SAIDO SAYA WAVETECH INC	FACEMASTER FACIAL TONING SYS, IRVINE, CA - K040871
2012-498	01/25/2012 02/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RICHARDSON #271264, ALFONZO	VISTARIL, 50 MG; LACTULOSE 10GM/15MG; DOCUSATE 50MG W/SENNAPLUS 8;6MG - MEDICATION RECS, GUIDE, LBLG ETC

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2012-499	01/25/2012 02/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	TATSUHIRO SAIDO SAYA WAVETECH INC	TRANSCUTANEOUS ELECTRICAL NERVE STIMULATOR K103472
2012-500	01/25/2012 02/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRENDAN FAULKNER DAMICO GRIFFIN ET AL	UNIVERSAL LOCKING PLATE SYS K961421
2012-501	01/25/2012 02/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRENDAN FAULKNER DAMICO GRIFFIN ET AL	SYNTHES MATRIX MANDIBLE PLATE & SCREW SYS K063790
2012-502	01/25/2012 02/23/2012	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	VIVKI E. HART JAMES DARK & BRILL ATTY AT LAW	PHILLIP MUCCLO, BIOFLEX INC - WARNING LTR 8/18/03
2012-503	01/25/2012 02/23/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	KATHY L. KOTTOS KATTEN MUCHIN ROSENMAN LLP	ARTHRO CARE CORP - D SPINEWARD 510K
2012-504	01/25/2012 02/23/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELENA HOWELL HOGAN LOVELLS US LLP	VORAXAZE (GLUCARPIDASE) INJ BLA 125327 - SBA, RECS
2012-505	01/25/2012 02/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRANDY SCHNAUTZ MANN JACKSON WALKER LLP	K063744
2012-506	01/25/2012 02/23/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	STEFANIE DECKER ENDO PHARMACEUTICALS INC	ZANAFLEX CAPS - NDA 21-447 SBA
2012-507	01/25/2012 02/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	ANNA DEMKOVIC ABBOTT LABORATORIES, INC.	CORPAK MEDSYS - FARRELL VALVE WITH CORFLO ANTI IV CONNECTORS K100365
2012-508	01/25/2012 02/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	DAVID BRUCE ERIE TIMES NEWS	CORR BETWEEN FDA & JOHN KANZIUS; BETWEEN FDA & STEVEN A CURLEY MD
2012-509	01/25/2012 02/23/2012	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	BOBBY SCHOCHET OFW LAW	CORR BETWEEN FDA & NEUROSCIENCE INC RE WARNING LTR OF 11/19/11
2012-510	01/26/2012 02/24/2012	OC/CVM/OCD/ FDA/OC/OCC/	GENNA REED Food & Water Watch	OXITEC - A AEGYPTI CORR, MTG NOTES, CALENDARS, ETC
2012-511	01/26/2012 02/24/2012	FDA/OMPT/CTP/OD/	MARILYNN WHITNEY COVINGTON & BURLING LLP	CENTER FOR TOBACCO PRODUCTS - STANDARD OPERATING PROCEDURE (SOP), POLICY, METRICS, ETC
2012-512	01/26/2012 02/24/2012	FDA/OFVM/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES	CAERS 142534

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			RESEARCH INC	
2012-513	01/26/2012 02/24/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	ROBERT LOWES MEDSCAPE	ROBERT SILVERMAN, JULIAN OMIDI, MICHAEL OMIDI, 1-800-GET-THIN LLC - CORR, RECS 12/1/11 TO PRESENT
2012-514	01/26/2012 02/24/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WAYNE SADOWSKI NOVARTIS PHARMACEUTICALS CORP	STEVEN R DROSMAN MD, SAN DIEGO, CA 5/19/05, THOMAS W ROSSITER MD, SPRINGFIELD, MO 2/23/06, HARVEY RESNICK MD, LAKE JACKSON, TX 2/21/06, ETC - EIRS, 483S, CORR, ETC
2012-515	01/26/2012 02/24/2012	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	DON WERFELMANN SARA LEE	SARA LEE, SIOUX CITY, IA - EIR
2012-516	01/26/2012 02/24/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	WAYNE SADOWSKI NOVARTIS PHARMACEUTICALS CORP	STEVEN FREEDMAN MD, RALIEGH, NC 6/29/09, HARTLEY COHEN MD, LOS ANGELES, CA - EIRS, 483S, CORR, ETC
2012-517	01/26/2012 02/24/2012	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	WAYNE SADOWSKI NOVARTIS PHARMACEUTICALS CORP	JAMES MELI DO, HENDERSON, NV 1/27/11, STEVEN WEINSTEIN MF, HUNTINGTON BEACH, CA 1/10/11, JAMES PEARLE MF, FULLERTON, CA - EIRS, 483S, CORR, ETC
2012-518	01/26/2012 02/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	WAYNE SADOWSKI NOVARTIS PHARMACEUTICALS CORP	CURTIS BROWN MD, OKLAHOMA CITY, OK 2/9/10, KARL BAUM MD, HENNIGSDORF, GERMANY 5/3/10, IAN FLINN, BALTIMORE, MD 5/10/10, ETC - EIRS, 483S, CORR, ETC
2012-519	01/26/2012 02/24/2012	OC/OA/OM/OMP/DDM/	RUTH LYDDY GRADIENT CORP	SAFETY OF AMINO ACIDS USED AS DIETARY SUPPLEMENTS - DKT 1990N-0379

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2012-520	01/26/2012 02/24/2012	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/ FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	DON WERFELMANN SARA LEE	SARA LEE, TWIN FALLS, ID - EIR
2012-521	01/26/2012 02/24/2012	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	ELISABETH S. GRAY MIDDLETON & REUTLINGER	UST, NASHVILLE, TN - EIR
2012-522	01/26/2012 02/24/2012	FDA/OO/OFBA/OAGS/	JEFF STACHEWICZ FOIA GROUP INC	CONTRACT #HHSF223200850024I
2012-523	01/26/2012 02/24/2012	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	ELISABETH S. GRAY MIDDLETON & REUTLINGER	ALTERNATIVE BRANDS INC, MOCKSVILLE, NC - EIR, 483, CO RESP MOST RECENT
2012-524	01/26/2012 02/24/2012	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	ELISABETH S. GRAY MIDDLETON & REUTLINGER	TAYLOR BROTHERS, WINSTON-SALEM, NC - EIR MOST RECENT
2012-525	01/26/2012 02/24/2012	OC/OCOS/OL/	DEMOCRATIC CONGRESSIONAL CAMPAIGN COMMITTEE	CONGRESSIONAL CORR 1/1/08 TO PRESENT
2012-526	01/26/2012 02/24/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	KEVIN STRANGE WELLS FARGO SECURITIES	THORATEC CORP - WARNING LTR
2012-527	01/26/2012 02/24/2012	FDA/OC/OES/DFOI/	STEVEN WAGNER CITIZENS COMMISSION ON HUMAN RIGHTS INTERNATIONAL	DR MARGARET HAMBURG, DR LAWRENCE PARK, JEFF SHUREN, ETC - DISCLOSURE OF CONFLICTS OF INTEREST RECS
2012-528	01/26/2012 02/24/2012	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	NICK LAGRANGE WFIE 14 NEWS	FARM BOY, EVANSVILLE, IN - EIR, 483 LAST 30 DAYS
2012-529	01/26/2012 02/24/2012	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	TYLER KENYON NORTHCOAST RESEARCH	DEPUY ORTHOPEDICS, WARSAW, IN - 483, CO RESP MOST RECENT
2012-530	01/26/2012 02/24/2012	FDA/OMPT/CDRH/OCER/DFOI/	TOM ALLEN CARDIAC OUTPUT TECHNOLOGIES INC	RHYTHM TECHNOLOGIES INC - RHYTHM CATHETER PMA, CORR 2001 TO 2010
2012-531	01/26/2012 02/24/2012	OC/ORAS/ OC/ORAS/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORASW-FO/SWID/SWID-CB/	MICHELLE RYBAK ROANOKE TRADE SERVICES INC	ENTRY #U72 0516358-8 - NOTICES OF REFUSAL, FDA ACTION, NOTICE OF MARK/REDELIVER
2012-532	01/26/2012 02/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ROBERT BENINCASA NATIONAL PUBLIC RADIO	ISRS 4960867, 4968103, 5214211

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2012-533	01/26/2012 02/24/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/NE-FO/NYK- DO/NYK-DCB/	CLAUDIA HORNBACK ROANOKE TRADE SERVICES INC	ENTRY #AGT00052952 - NOTICES OF REFUSAL, NOTICE OF REDELIVERY, CF28 AND/OR CF29
2012-534	01/26/2012 02/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DELILLO, MIRIAM	CIPRO - AER
2012-535	01/26/2012 02/24/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 1/16-20/12
2012-536	01/26/2012 02/24/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 1/9-13/12
2012-537	01/26/2012 02/24/2012	FDA/OC/OES/DFOI/	MEGAN B PICKEL BEVERIDGE & DIAMOND PC	CFSAN FOIA REQUESTS 12/19/11 TO 1/20/12
2012-538	01/26/2012 03/19/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	LOREN LARKIN SAC CAPITAL MANAGEMENT LLC	ICON PLC, LEOPARDSTOWN, DUBLIN, REPUBLIC OF IRELAND - 483S LAST 3 YRS
2012-539	01/26/2012 02/24/2012	FDA/OC/OES/DFOI/	HOOTNICK, ALEXANDRA	ARSENIC - RECS 1/1/06 TO 1/1/12
2012-540	01/26/2012 02/24/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/OCOS/OES/ OC/OCOS/OES/ OC/OCOS/OL/	HOOTNICK, ALEXANDRA	ARSENIC IN FOOD AND WATER - STANDARDS, TOXICITY, INTERAGENCY COMMENTS, ETC
2012-541	01/26/2012 02/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARC JACOBS MD	GABAPENTIN - AER
2012-542	01/26/2012 02/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS Consulting Group, LLC	TOPICORT OINTMENT NDA 18-594 - MED RVW, CHEMISTRY RVW, STATISTICAL RVW
2012-543	01/26/2012	FDA/OMPT/CDER/ORP/DIDP/	DORON FRIEDMAN	EXPAREL (LIPOSOMAL BUPIVACINE HCI) SBA

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	02/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HEBREW UNIVERSITY HADASSAH MEDICAL SCHOOL	
2012-544	01/26/2012 02/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PRICE CLARK COOK MOTLEY RICE LLC	NOVARTIS - TEKTRUNA APRVL, MEDICAL RVWS, CLNCL STUDIES
2012-545	01/26/2012 02/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	CAITRIONA CONNEELY PROXY BIOMEDICAL	PROXY BIOMEDICAL LTD, GALWAY IRELAND - EIR 7/20-23/09
2012-546	01/26/2012 02/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA SOUZA ONO PHARMA USA INC	SINEMET - SBA
2012-547	01/26/2012 02/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	WOCKHARDT - FLUTICASONE PROPIONATE ANDA 78-492 SBA
2012-548	01/26/2012 02/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WINFIELD JF8770, MICHAEL	LEUOTHYROXINE - AERS
2012-549	01/26/2012 02/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WAYNE SADOWSKI NOVARTIS	DR RAIMUND JAKESZ, DEPT OF GENERAL SURGERY, VIENNA, AUSTRIA - EIR, 483
2012-550	01/26/2012 02/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FILA, JOHN	WATSON PHARMS - SILODOSIN (RAPAFLO) NDA 22-206
2012-551	01/26/2012	FDA/OMPT/CDER/ORP/DIDP/		KAYEXALATE - AER

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	02/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HAREL, ZIV	
2012-552	01/26/2012 02/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	BIOGEN IDEC - NATALIZUMAB IND 006895 MTG MINS 9/8/10 (CERTIFIED)
2012-553	01/26/2012 02/24/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	BIOGEN IDEC - ANTI-JCV ANIBODY ASSAY MTG RECS 11/18/10 (CERTIFIED)
2012-554	01/27/2012 02/27/2012	FDA/OC/OES/DFOI/	JASON, JANINE	CRONOBACTER SAKAZAKII - INVESTIGATIONS, TESTING, CORR, ETC 1/08 TO PRESENT
2012-555	01/27/2012 02/27/2012	FDA/OC/OES/DFOI/	AMANDA ORLANDO AVALON RISK MANAGEMENT INC	ENTRY #22010540056 - NOTICE OF FDA ACTION #1
2012-556	01/27/2012 02/27/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/CVM/OCD/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/ OC/OCS/NCTR/OD/ FDA/OC/OSHC/OPD/	DR JAVIER GUZMAN LONDON INTERNATIONAL DEVELOPMENT CENTER	NEGLECTED DISEASE R&D FUNDING GIVEN BY FDA
2012-557	01/27/2012 02/27/2012	OC/ORA/ OC/ORA/	FREDERIC C FONDREN FREDERIC C FONDREN LAW OFCS	JENSEN TUNA INC - ENTRY #AMG-0083700-9 REQUEST FOR REDELIVERY
2012-558	01/27/2012 02/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEISHAN J DAVIS ESQ TOWNES DAVID & ASSOCIATES LLC	PRECAUTIONS NECESSARY WITH CENTRAL VENOUS CATHETERS, FDA TASK FORCE - FDA DRUG BULLETIN 7/89
2012-559	01/27/2012 02/27/2012	FDA/OMPT/CDRH/OCER/DFOI/	GERALYN MURRAY VITAL SIGNS INC	K082217

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2012-560	01/27/2012 02/27/2012	FDA/OMPT/CDRH/OCER/DFOI/	GARY HANLEY ASEPT PAK INC	NAGEL CO - NALGENE EMERGENCY EYE WASH K760820
2012-561	01/27/2012 02/27/2012	OC/ORO/ OC/ORO/	SONIA KHANA ALL-WAYS FORWARDING OF NY INC	MATERNA MEHADRIN FORMULA - LAB ANALYSIS
2012-562	01/27/2012 02/27/2012	FDA/OGROP/ORO/NE-FO/NWE-DO/NWE-CB/	STEPHEN BEEKMAN ALCON LABORATORIES INC	PRO-PAKS LLC, MIDDLETOWN, CT - 483 5/11
2012-563	01/27/2012 02/27/2012	FDA/OC/OES/DFOI/	DIANA L GESEKING SEDGWICK LLP	MEAD JOHNSON & COMPANY LLC - CRONOBACTER SSP CORR 1/05 TO PRESENT
2012-564	01/27/2012 02/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ADAM ARANYOS SWEDISH TRADE COUNCIL	USE OF NITROUS OXIDE AS A PAINKILLER - US STATISTICS
2012-565	01/27/2012 02/27/2012	FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORO/SW-FO/SWID/SWID-CB/	LISA KELLY KEYE TV	TX FIRMS THAT CREATE, PROCESS, SELL, OR DISTRIBUTE FOOD PRODS THAT HAVE REQUESTED PERMISSION TO RECONDITION ANY PROD 1/10 TO PRESENT
2012-566	01/27/2012 02/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	SANDOZ (NOVARTIS INTERNATIONAL AG), QUEBEC, CANADA - EIR, 483, CO RESP 7/26/11-8/4/11
2012-567	01/27/2012 02/27/2012	FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/	WALTER E CHALKLEY THOMSON REUTERS	BECKMAN COULTER INC, MIAMI, FL - EIR, 483, CO RESP 2/28/11-6/2/11
2012-568	01/27/2012 02/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	AKZO NOBEL CHEMICAL, LOS REYES LA PAZ, EDO, MEXICO - EIR, 483, CO RESP 6/11
2012-569	01/27/2012 02/27/2012	FDA/OGROP/ORO/SE-FO/NOL-DO/NOL-CB/	WALTER E CHALKLEY THOMSON REUTERS	DELTA PHARMA, RIPLEY, MS - EIR, 483, CO RESP 9/14-17/10

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2012-570	01/27/2012 02/27/2012	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	CORELINK, ST LOUIS, MO - EIR, 483, CO RESP 11/9-12/10
2012-571	01/27/2012 02/27/2012	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	BRUCE BERWALD MD, CREVE COEUR, MO - EIR, 483, CO RESP 3/23/10-4/6/10
2012-572	01/27/2012 02/27/2012	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	WALTER E CHALKLEY THOMSON REUTERS	BELL-MORE LABORATORIES,HAMPSTEAD, MD - EIR, 483,CO RESP 3/29/10-4/9/10
2012-573	01/27/2012 02/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	AVECIA, BILLINGHAM, UK - EIR, 483, CO RESP 1/09
2012-574	01/27/2012 02/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	ANTIBIOTICOAS SA, LEON, SPAIN - EIR, 483, CO RESP 7/21-24/11
2012-575	01/27/2012 02/27/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	WALTER E CHALKLEY THOMSON REUTERS	ALPHATEC SPINES, CARLSBAD, CA - EIR, 483, CO RESP 1/1/10-2/11/10
2012-576	01/27/2012 02/27/2012	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	WALTER E CHALKLEY THOMSON REUTERS	A L & S, DEKALB, MS - EIR, 483, CO RESP 7/12-26/10
2012-577	01/27/2012 02/27/2012	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	NOVARTIS CONSUMER HEALTH, LINCOLN, NE - EIR, 483,CO RESP 4/5-16/10
2012-578	01/27/2012 02/27/2012	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	WALTER E CHALKLEY THOMSON REUTERS	HOSPIRA, CALYTON, NC - EIR, 483, CO RESP 6/9-13/08
2012-579	01/27/2012 02/27/2012	FDA/OMPT/CDRH/OCER/DFOI/	WALTER E CHALKLEY THOMSON REUTERS	POLY IMPLANTS PROTHESES SA, LA SEYNE SUR MER, FRANCE - EIR, 483,CO RESP 5/11-17/00
2012-580	01/27/2012 02/27/2012	FDA/OC/OES/DFOI/	KENDLE INTERNATIONAL INC	FOI DAILY LOG 12/26-30/11
2012-581	01/27/2012 02/27/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 12/26-30/11
2012-582	01/27/2012 02/27/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 12/26-30/11
2012-583	01/27/2012 02/27/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOI REQUESTS 1/9-13/12

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2012-584	01/27/2012 02/27/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 1/9-13/12
2012-585	01/27/2012 02/27/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 1/9-13/12
2012-586	01/27/2012 02/27/2012	FDA/OGROP/ORR/SE-FO/SJN-DO/SJN-CB/	WALTER CHALKLEY THOMSON REUTERS	PATHEON PUERTO RICO, CAGUAS, PR - EIR, 483, CO RESP 5/10
2012-587	01/27/2012 02/27/2012	FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/	WALTER CHALKLEY THOMSON REUTERS	HOSPIRA PHARMA, AUSTIN, TX - EIR, 483, CO RESP 4/11
2012-588	01/27/2012 02/27/2012	FDA/OGROP/ORR/NE-FO/NWE-DO/NWE-CB/	WALTER CHALKLEY THOMSON REUTERS	COVANCE LABS, PORTSMOUTH, NH - EIR, 483, CO RESP 4/12-16/10
2012-589	01/27/2012 02/27/2012	FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/	WALTER CHALKLEY THOMSON REUTERS	NATIONAL GENETICS INSTITUTE, LOS ANGELES, CA - EIR, 483, CO RESP 1/11-21/11
2012-590	01/27/2012 02/27/2012	FDA/OMPT/CDRH/OCER/DFOI/	WALTER CHALKLEY THOMSON REUTERS	STORZ MEDICAL, TAGERWILEN, SWITZERLAND - EIR, 483, CO RESP 3/15-19/10
2012-591	01/27/2012 02/27/2012	FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/	WALTER CHALKLEY THOMSON REUTERS	APOTHECA INC, WOODBINE, IA - EIR, 483, CO RESP 3/11
2012-592	01/27/2012 02/27/2012	FDA/OGROP/ORR/CE-FO/CHI-DO/CHI-CB/	WALTER CHALKLEY THOMSON REUTERS	MEDEFIL INC, GLENDALE HEIGHTS, IL - EIR, 483, CO RESP 1/11
2012-593	01/27/2012 02/27/2012	FDA/OGROP/ORR/CE-FO/BLT-DO/BLT-CB/	WALTER CHALKLEY THOMSON REUTERS	AMERICAN RED CROSS, GREATER ALLEGHENIES REGION, HUNTINGTON, WV - EIR, 483, CO RESP 3/11
2012-594	01/27/2012 02/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER CHALKLEY THOMSON REUTERS	ZHEJIANG HISUN PHARMS, TAIZHOU CITY, CHINA - EIR, 483, CO RESP 7/20-23/09
2012-595	01/27/2012 02/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER CHALKLEY THOMSON REUTERS	RANBAXY LABS, MADHYA PRADESH, DEWAS, INDIA - EIR, 483, CO RESP 1/28/08-2/12/08
2012-596	01/27/2012 02/27/2012	FDA/OGROP/ORR/CE-FO/NWJ-DO/NWJ-CB/	WALTER CHALKLEY THOMSON REUTERS	RANBAXY, PRINCETON, NJ - EIR, 483, CO RESP 12/3-19/07
2012-597	01/27/2012 02/27/2012	FDA/OGROP/ORR/CE-FO/MIN-DO/MIN-CB/	WALTER CHALKLEY THOMSON REUTERS	MEDTRONIC NEUROMODULATION, MINNEAPOLIS, MN - EIR, 483, CO RESP 11/17/10 - 1/21/11

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2012-598	01/27/2012 02/27/2012	FDA/OGROP/ORА/SE-FO/SJN-DO/SJN-CB/	WALTER CHALKLEY THOMSON REUTERS	MEDTRONIC PUERTO RICO OPERATIONS, VILLALBA, PA - EIR, 483, CO RESP 4/26/10 TO 5/14/10
2012-599	01/27/2012 02/27/2012	FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/	WALTER CHALKLEY THOMSON REUTERS	HOSPIRA, MULGRAVE, AUSTRALIA - EIR, 483, CO RESP 2011
2012-600	01/27/2012 02/27/2012	FDA/OGROP/ORА/CE-FO/NWJ-DO/NWJ-CB/	WALTER CHALKLEY THOMSON REUTERS	G&W LABS, SOUTH PLAINFIELD, NJ - EIR, 483, CO RESP 4/20/10 TO 5/17/10
2012-601	01/27/2012 02/27/2012	FDA/OGROP/ORА/NE-FO/NWE-DO/NWE-CB/	WALTER CHALKLEY THOMSON REUTERS	FORMATECH, ANDOVER, MA - EIR, 483, CO RESP 8/25/10 TO 10/10/10
2012-602	01/27/2012 02/27/2012	FDA/OMPT/CDRH/OCER/DFOI/	JOHN J. MALLOY MALLOY & ASSOCIATES INC	ROCHE MOLECULAR SYS INC - COBAS 4800 BRAF V600 MUTATION TEST PMA P110020
2012-603	01/27/2012 02/27/2012	FDA/OMPT/CDRH/OCER/DFOI/	MATT CLAUSEN MEDLINE INDUSTRIES INC	MEDLINE - PREVENTION SURGICAL GOWNS K043017
2012-604	01/27/2012 02/27/2012	FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/	ERIC KEISMAN, JR. CAPITAL WORLD INVESTORS	GILENYA (FINGOLIMOD) AER 8/11 TO PRESENT
2012-605	01/27/2012 02/27/2012	FDA/OGROP/ORА/NE-FO/NYK-DO/NYK-DCB/	DOUGLAS N. BLUE ZETETIC	ABBOTT IRELAND, SLIGO IRELAND - FREESTYLE LITE BLOOD GLUCOSE TEST STRIPS ENTRY NO ARE4127536-811
2012-606	01/27/2012 02/27/2012	FDA/OGROP/ORА/NE-FO/NYK-DO/NYK-DCB/	DOUGLAS N. BLUE ZETETIC	ABBOTT IRELAND, SLIGO, IRELAND - FREESTYLE LITE BLOOD GLUCOSE TEST STRIPS ENTRY NO ARE4125206-031
2012-607	01/27/2012 02/27/2012	FDA/OMPT/CDRH/OCER/DFOI/	STEPHEN BEEKMAN ALCON LABORATORIES INC	EXCELVISION SAS, ANNONAY, FRANCE - EIR, 483 MOST RECENT
2012-608	01/27/2012 02/27/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORА/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORА/SE-FO/ATL-DO/ATL-CB/	KEN RAY UNDERWOOD	ANGIODYNAMICS INC - THERMOPAD MDRS 2007 TO 2009
2012-609	01/27/2012 03/15/2012	FDA/OFVM/CFСSАN/OCД/EOS/ FDA/OGROP/ORА/SW-FO/DAL-DO/DAL-CB/ OC/OCM/EMOPS/	SUSAN B. MILLS WEINBERG WHEELER ET AL	MULTISTATE OUTBREAK OF SALMONELLA ENTERITIDIS INFECTIONS - RECS

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2012-610	01/30/2012 02/28/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/OCOS/OES/ OC/OCOS/OES/	ANDREW C BRISCOE III SUGAR ASSOCIATION INC	CORN REFINERS ASSN - HIGH FRUCTOSE CORN SYRUP CORR, MTGS, RPTS, ETC 1/11 TO PRESENT
2012-611	01/30/2012 02/28/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	KATHERINE NEEDLEMAN EMAIL WITH ATTACHMENTS 4/3/06 (CERTIFIED)
2012-612	01/30/2012 02/28/2012	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	SUSAN TODD WEST-WARD PHARMACEUTICAL CORP	KV PAHRMACEUTICAL CO - 483 2/7/00-3/3/00
2012-613	01/30/2012 02/28/2012	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	MARQUARDT, STEVE	UWAJIMAYA (KUSTOM FOODS), SEATTLE, WA - 483S 1/26/00, 7/11/00, 11/28/00, ETC
2012-614	01/30/2012 02/28/2012	OC/ORAOCI/ OC/ORAOCI/	JASON A CHERKIS HUFFINGTON POST	LEGITSCRIPT - CONTRACT #HHSF223201000071C CORR 1/21/09
2012-615	01/30/2012 02/28/2012	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Doe J	CMPLNT #12284
2012-616	01/30/2012 02/28/2012	OC/CVM/OCD/	TIM SCHWAB Food and Water Watch	AQUABOUNTY TECHNOLOGIES - MONEY SPENT BY FDA CONSULTING AND REVIEWING GENETICALLY ENGINEERED SALMON 1/93 TO PRESENT
2012-617	01/30/2012 02/28/2012	OC/ORAO/ OC/ORAO/ FDA/OGROP/ORAOORO/DIOP/ FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	BENJAMIN L ENGLAND ESQ BENJAMIN L ENGLAND & ASSOCIATES LLC	WENZHOUSHI OPTICS INDUSTRY CO LTD - IMPORT ALERT 86-07, CORR, LAB RESULTS, ETC
2012-618	01/30/2012 02/28/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	ANTARES PHARMA - ANTUROL (OXYBUTYNIN) NDA 20-2513 APRVL RECS 12/7/11

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2012-619	01/30/2012 02/28/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	SANDOZ - OMNITROPE (SOMATROPIN RECOMBINANT) NDA 21-426/S07,08 APRVL RECS 4/23/10
2012-620	01/30/2012 02/28/2012	FDA/OMPT/CDRH/OCER/DFOI/	DIDI BOWLES PARSONS BEHLE & LATIMER	SORENSEN MEDICAL INC, WEST JORDON, UT - AMBIT INTERMITTENT AMBULATORY INFUSION PUMP K033425
2012-621	01/30/2012 02/28/2012	FDA/OMPT/CDRH/OCER/DFOI/	DIDI BOWLES PARSONS BEHLE & LATIMER	QRS DIAGNOSTIC LLC, PLYMOUTH, MN - SENSARE DIAGNOSTIC SPIROMETER K001278
2012-622	01/30/2012 02/28/2012	FDA/OFVM/CFSAN/OCD/EOS/	HELLEN A OKETCH USP PHARMACOPEIA	CREATINE - CAERS 1/05 TO 2/12
2012-623	01/30/2012 02/28/2012	FDA/OFVM/CFSAN/OCD/EOS/	HELLEN A OKETCH USP PHARMACOPEIA	ROSMARINUS OFFICINALS - CAERS 1/05 TO 2/12
2012-624	01/30/2012 02/28/2012	FDA/OFVM/CFSAN/OCD/EOS/	HELLEN A OKETCH USP PHARMACOPEIA	BETA CLUCANS - CAERS 1/05 TO 2/12
2012-625	01/30/2012 02/28/2012	FDA/OFVM/CFSAN/OCD/EOS/	HELEN A OKETCH USP PHARMACOPEIA	TOCOTRIENOLS - CAERS 1/05 TO 2/12
2012-626	01/30/2012 02/28/2012	FDA/OFVM/CFSAN/OCD/EOS/	HELLEN A OKETCH USP PHARMACOPEIA	GANODERMA LUCIDUM - CAERS 1/05 TO 2/12
2012-627	01/30/2012 02/28/2012	FDA/OMPT/CDRH/OCER/DFOI/	KATHLEEN PERSON CONSUMER REPORTS	PROSTHESIS HIP FEMORAL COMPONET CEMENTED META; PROSTHESIS HIP SEMI-CONSTRAINED (METAL CEMENTED ACETABULAR COMPONET); PROSTHESIS HIP, SEMI-CONSTRAINED (METAL UNCEMENTED ACETABAULAR COMPONET, ETC MDRS LAST 15 YRS
2012-628	01/30/2012 02/28/2012	OC/ORA/ OC/ORA/	FREDERIC C FONDREN FREDERIC C FONDREN LAW OFCS	JENSEN TUNA INC - ENTRY #AMG-0083700-9 REQUEST FOR REDELIVERY
2012-629	01/30/2012 02/28/2012	FDA/OC/OES/DFOI/	JONATHAN A KNOLL ESQ COHEN & MALAD LLP	BREG INC - EIRS, MEMOS, WARNINGS, ETC 1/08 TO 4/08, 7/25/03-8/6/03 (CERTIFIED)
2012-630	01/30/2012 02/28/2012	FDA/OMPT/CDRH/OCER/DFOI/	KATHLEEN PERSON CONSUMER REPORTS	TOP LIST OF 50 MEDICAL DVC - MDRS LAST 15 YRS
2012-631	01/30/2012 02/28/2012	FDA/OC/OES/DFOI/	JOHNATHAN A KNOLL ESQ COHEN & MALAD LLP	SGARLATO - K990101, K043204 (CERTIFIED)
2012-632	01/30/2012 02/28/2012	FDA/OMPT/CDRH/OCER/DFOI/	KATHLEEN PERSON CONSUMER REPORTS	LIST OF MFR & DVC THAT ARE EXEMPT - MDRS LAST 15 YRS
2012-633	01/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	JOHNATHAN A KNOLL ESQ	MCKINLEY MEDICAL - BEELINE K042228, ACCUFUSER

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	02/28/2012		COHEN & MALAD LLP	K023098, K033039, ETC (CERTIFIED)
2012-634	01/30/2012 02/28/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	DIDI BOWLES PARSONS BEHLE & LATIMER	SORENSEN MEDICAL INC, WEST JORDAN, UT - AMBIT PUSH & PLAY AMBULATORY INFUSION PUMP K052221
2012-635	01/30/2012 02/28/2012	FDA/OMPT/CDRH/OCER/DFOI/	LOVELL, KATHLEEN P	SONDREX P A L SYS - K010388
2012-636	01/30/2012 02/28/2012	FDA/OC/OES/DFOI/ FDA/OGROP/ORASW-FO/KAN- DO/KAN-CB/	MICHAEL CANTOR AMERICAN BRIDGE	VI-JON CORP, VI-JOHN LABS, VI-JON INC, ST LOUIS, MO - CMLPNTS, VIOLATIONS, INVESTIGATIONS, FOI REQUESTS, ETC 2010 TO PRESENT
2012-637	01/30/2012 02/28/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SPIVY, ART .	LILLY - BETAZOLE HCL N003944 APRVL, PI, SUMMARY, ETC
2012-638	01/30/2012 02/28/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ALEXANDER MIRONOV TIGRIS PHARMACEUTICALS INC	GLAXOSMITHKLINE - WELLBUTRIN (BUPROPION HCL) NDA 20-358 SBA
2012-639	01/30/2012 02/28/2012	FDA/OMPT/CDRH/OCER/DFOI/ OC/OA/OM/OMP/DDM/	REININGER, PETER	CYTYC (HOLOGIC) - THINPREP LIQUID BASED PAP TEST CITIZENS PETITION, ACCEPTANCE & DENIAL LTRS; QIAGEN (DIGENE) - DIGENE HYBRID CAPTURE II HPV TEST ACCEPTANCE & DENIAL LTRS, ETC
2012-640	01/30/2012 02/28/2012	FDA/OMPT/CDRH/OCER/DFOI/	ANGELA DUNFORD PENLON	BEAR MEDICAL SYSTEMS INC - PENLON TRANSPORT VENTILATOR SERIES 350 K842362, SERIES 300 K842363
2012-641	01/30/2012 02/28/2012	FDA/OMPT/CDRH/OCER/DFOI/	ANGELA DUNFORD PENLON	PENLON INC - NUFFIELD ANASTHESIA VENTILATOR SERIES 400 K803052
2012-642	01/30/2012 02/28/2012	FDA/OMPT/CTP/OD/	FOI Services, Inc.	TOBACCO MFR INSPS - ASSIGNMENT LTRS 12/1/11 TO 1/23/12
2012-643	01/30/2012 02/28/2012	FDA/OFVM/CFSAN/OCD/EOS/	FOI Services, Inc.	FCN 852
2012-644	01/30/2012 02/28/2012	FDA/OMPT/CTP/OD/	FOI Services, Inc.	TOBACCO PROD LISTINGS 12/11 TO PRESENT
2012-645	01/30/2012 02/28/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 1/16-20/12
2012-646	01/30/2012 02/28/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LAURIE MCCLAIN JANET, JENNER & SUGGS, LLC	CELESTONE (BETAMETHASONE SODIUM PHOSHETE & BETAMETHASONE ACETATE INJ SUSPENSION) - AERS

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2012-647	01/30/2012 02/28/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Laurie McClain Janet, Jenner & Suggs, LLC	EPIDURAL INJ - AERS
2012-648	01/30/2012 02/28/2012	FDA/OMPT/CDRH/OCER/DFOI/	Stanley J Rogaski Contact Lens Institute	CLAO Symposium & Congress, Las Vegas, NV - Silicone Hydrogel Lens Groupings and Testing Strategies, FDA Steps to Improve Safety for Contact Lens Users, etc
2012-649	01/30/2012 02/28/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORA/ OC/ORA/ FDA/OGROP/ORA/ORO/DIOP/	Doe J	123 Biossence - Blocking Recs
2012-650	01/30/2012 02/28/2012	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Carl C Klein Friedenthal Heffernan & K Klein LLP	Fine Mexican Foods, Ontario, CA. Sunshine Exports, Peru - Frozen Avacado Pulp Ltrs, Corr, Testing Recs
2012-651	01/30/2012 02/28/2012	OC/OM/OMP/DDM/	Merle Zimmermann American Herbal Products Association	DKT FDA-1995-S-0039
2012-652	01/30/2012 02/28/2012	OC/OM/OMP/DDM/	Amy Johnson Sidley Austin LLP	DKT 1994N-0308, 1998P-0035, 1992N-0072
2012-653	01/30/2012 02/28/2012	OC/OM/OMP/DDM/	Marilynn Whitney Covington & Burling LLP	DKT FDA-2010-P-0491
2012-654	01/30/2012 02/28/2012	FDA/OC/OES/DFOI/	Joan Stitt Merck & Co., Inc.	2012-59 (requester letter)
2012-655	01/30/2012 02/28/2012	FDA/OC/OES/DFOI/	Joan Stitt Merck & Co., Inc.	2011-9649 (request letter)
2012-656	01/31/2012 02/29/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jody L Green Rocky Mountain Poison	Cough & Cold Preparations - ISRS 7389114-4, 7395402-8, 7403265-7, etc AERS 2011

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DRUG CTR	
2012-657	01/31/2012 02/29/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JODY L GREEN ROCKY MOUNTAIN POISON DRUG CTR	COUGH & COLD PREPARTIONS - ISRS 7482033-4, 7482036-X, 74866118-8 AERS 2011
2012-658	01/31/2012 02/29/2012	OC/ORA/ OC/ORA/ OC/OCM/EMOPS/ FDA/OFVM/CFSAN/OCD/EOS/	JAMES ANDREWS FOOD SAFETY NEWS	SALMONELLA ENTERITIDIS OUTBREAK IN TX, OK, KS, ETC - NAME & LOCATION OF THE RESTAURANT CHAIN 10/31/11
2012-659	01/31/2012 02/29/2012	FDA/OMPT/CDRH/OCER/DFOI/	MINA KIMES FORTUNE MAGAZINE	NORIAN (SYNTHESES) - PHONE CALL MINS 7/8/99
2012-660	01/31/2012 02/29/2012	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	NICK BUDNICK OREGONIAN	BIOTRONIK, PORTLAND, OR - EIRS 1/07 TO PRESENT
2012-661	01/31/2012 02/29/2012	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	MITCHELL S FUERST FUERST ITTLEMAN PL	LLORENS PHARMACEUTICAL INTL, MIAMI, FL - EIRS 8/6/10-9/30/10
2012-662	01/31/2012 02/29/2012	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	JASON R ANDERS AJUBITA LEFTWICH & SALZER	BASIC FOOD FLAVORS INC, NORTH LAS VEGAS, NV - HYDROLZED VEGETABLE PROTEIN RECALL CORR ANALYTICAL RESULTS, FINAL AGENCY RESP (CERTIFIED)
2012-663	01/31/2012 02/29/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 1/23-27/12
2012-664	01/31/2012 02/29/2012	FDA/OFVM/CFSAN/OCD/EOS/	FORNETTI, VERENA	CARBENDAZIM RESIDUES IN ORANGE JUICE - MTG RECS 1/26/12
2012-665	01/31/2012 02/29/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	2011-6843
2012-666	01/31/2012 02/29/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	2011-7004
2012-667	01/31/2012 02/29/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELIZABETH BARBEHENN PUBLIC CITIZEN	BYDUREON (EXENDATIDE) NDA 22-200 - APRVL PKG, RVWS, ADMINISTRATIVE RECS, ETC 1/27/12
2012-668	01/31/2012 02/29/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	2011-7464
2012-669	01/31/2012	FDA/OMPT/CDER/ORP/DIDP/		ACTAVIS - METHYLPHENIDATE HCL CAPS ER 20MG, 30MG,

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	02/29/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BOUREY, ALISON	40MG ANDA 78458 LBLG
2012-670	01/31/2012 02/29/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	2011-7585
2012-671	01/31/2012 02/29/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ERIC L KEISMAN JR CAPITAL WORLD INVESTORS	NOVARTIS AG - MTG MINS, ATTENDEES NAMES 1/17/12
2012-672	01/31/2012 02/29/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	STEVE WALTER UMBRIA PHARMACEUTICALS LLC	EISAI INC - LUSEDRA (FOSPROPOFOL DISODIUM) NDA 22-244 SBA
2012-673	01/31/2012 02/29/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	NATALIA DIAZ FRIEDIN DOBRINKSY	LEVAQUIN - AERS
2012-674	01/31/2012 02/29/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	2011-7679
2012-675	01/31/2012 02/29/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SUSANN REILLY RAINBURST LLC	HYDRIODIC ACID SYRUP - AERS
2012-676	01/31/2012 02/29/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	2011-8062
2012-677	01/31/2012 02/29/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	2011-8847
2012-678	01/31/2012 02/29/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	2011-9322
2012-679	01/31/2012 02/29/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SW-FO/DAL- DO/DAL-CB/	CLAUDIA HORNBACK ROANOKE TRADE SERVICES INC	ANGEL MEDINA (3 BROTHERS) - ENTRY #BYX00293963 NOTICES OF FDA REFUSAL, NOTICE OF REDELIVERY, CF28 AND/OR CF29

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		FDA/OGROP/ORASW-FO/SWID/SWID-CB/		
2012-680	01/31/2012 02/29/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 1/16-20/12
2012-681	01/31/2012 02/29/2012	OC/OM/OMP/DDM/	CARLA SCARMAZZI KING & SPALDING	DKT 1994N-0418
2012-682	01/31/2012 02/29/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOI REQUESTS 1/16-20/12
2012-683	02/01/2012 03/01/2012	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	JAMES E SWAUGER RJReynolds	AMERICAN SNUFF COMPANY LLC, CLARKSVILLE, TN - EIR 1/10-11/12
2012-684	02/01/2012 03/06/2012	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	JAMES E SWAUGER RJReynolds	AMERICAN SNUFF COMPANY LLC, WINSTON-SALEM, NC - EIR10/3-6/11
2012-685	02/01/2012 03/01/2012	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	JAMES E SWAUGER RJReynolds	AMERICAN SNUFF COMPANY LLC, CLARKSVILLE, TN 1/12-13/12
2012-686	02/01/2012 03/01/2012	FDA/OMPT/CDRH/OCER/DFOI/	KATHLEEN PERSON CONSUMER REPORTS	LIST OF PATIENT EVENT CODES - MDRFOI RECS LAST 15 YRS
2012-687	02/01/2012 03/01/2012	FDA/OMPT/CDRH/OCER/DFOI/	TORU FUJINAMI USHIO AMERICA INC	STRAUMANN - K033984, K053088
2012-688	02/01/2012 03/01/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OMPT/CDRH/OCER/DFOI/	ANNE K WALSH Hyman Phelps and McNamara PC	ANGIODYNAMICS INC - NANOKNIFE SYS K102329
2012-689	02/01/2012 03/01/2012	FDA/OMPT/CDRH/OCER/DFOI/	SUSAN CLARK MEDICAL PREDICTIVE SCIENCE CORP	MEDICAL PREDICTIVE SCIENCE CORP - K103543
2012-690	02/01/2012 03/01/2012	FDA/OMPT/CDRH/OCER/DFOI/	DERBY, COLLEEN	DEPUY SPINE INC - CHARITE DISC RECS 10/04
2012-691	02/01/2012 03/01/2012	FDA/OMPT/CDRH/OCER/DFOI/	DAVID R SHOOP SHOOP	COCHLEAR AMERICAS - NUCLEUS 24 COCHLEAR IMPLANT SYS MEDICAL DVC SUPPL, DVC ALTERATIONS, PREMARKET NOTIFICATION, ETC
2012-692	02/01/2012 03/01/2012	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	HARRY SHULMAN SHULMAN LAW	MAYER LABORATORIES INC - WARNING LTR CMS #167292 INVESTIGATION, FOLLOW UP INVESTIGATION, CO RESP, ETC
2012-693	02/01/2012	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/		BATTERY RECYCLING CORP - CONTAMINATION OF COWS MILK WITH LEAD RECS

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	03/01/2012		TED LAWTON	
2012-694	02/01/2012 03/01/2012	FDA/OGROP/ORR/SE-FO/SJN-DO/SJN-CB/	JOSE M BAGGI JUNQUERA BIAGGI & BIAGGI PSC ATTY AT LAW	TYLENOL EXTRA STRENGTH - TEST RESULTS
2012-695	02/01/2012 03/01/2012	FDA/OGROP/ORR/CE-FO/DET-DO/DET-CB/	LORI MANSUR GROUP DEKKO	GROUP DEKKO MEDICAL DVC, AVILLA, IN; GROUP DEKKO, GARRETT, IN - AUDITS
2012-696	02/01/2012 03/01/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ OC/ORR/ OC/ORR/ OC/OM/OFM/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	KATE WILLSON CENTER FOR PUBLIC INTEGRITY	BUDGET ALLOTTED FOR INSP & OVERSIGHT OF FDA-REGISTERED HUMAN CELL & TISSUE ESTABLISHMENTS - RECS
2012-697	02/01/2012 03/01/2012	OC/ORR/ OC/ORR/ FDA/OFVM/CFSAN/OCD/EOS/	ERIK BAUER	STERLING PACIFIC - FLEXIBLE PACKAGING PRODS LTRS OF GUARANTEE
2012-698	02/01/2012 03/01/2012	FDA/OFVM/CFSAN/OCD/EOS/	KEVIN RAMBKE KMR ENTERPRISES	POWDERED BABY FORMULA MFRS IN THE USA REGISTERED WITH FDA - NAMES, ADDRESSES, CONTACT RECS
2012-699	02/01/2012 03/15/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ OC/OA/OM/OMP/DDM/ OC/OA/OM/OMP/DDM/	JOHN B CLASSEN CLASSEN IMMUNOTHERAPIES, INC.	VACCINES & RELATED BIOLOGICAL PRODS A/C - TRANS, BRIEFING RECS 7/11/96
2012-700	02/01/2012 03/01/2012	OC/OA/OM/OMP/DDM/	DIANE HORWITZ MANDELL HORWITZ CONSULTANTS LLC	97P-0048/CCP, 1986P-D426
2012-701	02/01/2012 03/01/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	YUAN, ADAM	NOVARTIS - TRIAMINIC THIN STRIPS DAY TIME COLD & COUGH; THIN STRIPS COUGH & RUNNY NOSE; THIN STRIPS ALLERGY APRVL, RVWS, CLNCL TRIAL
2012-702	02/01/2012 03/01/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CARLOS MEDINA EXPONENT	LIORESAL (BACLOFEN) NDA 17-851 - SBA
2012-703	02/01/2012	FDA/OC/OES/DFOI/	KAI FALKENBERG	AMBIEN - AER 3/14/07 TO PRESENT

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	03/01/2012		FORBES	
2012-704	02/01/2012 03/01/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHARLES CELESTE EAS Consulting Group, LLC	FOSAPREPITANT NDA 22-023/S004 - LBLG, APRVL LTR, MOR, ETC
2012-705	02/01/2012 03/01/2012	OC/OM/OMP/DDM/	CARLA SCARMAZZI KING & SPALDING	DKT FDA-1994-N-0036
2012-706	02/01/2012 03/01/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CAROLINE GILMORE SACRED HEART SCHOOL	CLINDAMYCIN - LINE LISTING
2012-707	02/01/2012 03/01/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WEBBER, WALTER	PHENTERAMINE - APRVL LTRS, RVWS, RESEARCH, ETC
2012-708	02/01/2012 03/01/2012	OC/OM/OMP/DDM/	SRIVIDYA SRINIVASAN HERBAL HEALTH INSTITUTE	OTC VOLS. 210334, 210335, ETC.
2012-709	02/01/2012 03/01/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	NANCY ZHANG, Ph.D. QUANTITATIVE SOLUTIONS INC	LASIX (FUROSEMIDE) NDA 16-273 - MEDICAL & STATISTICAL RVWS
2012-710	02/01/2012 03/01/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ROBERT F. MURDOCK MURDOCK AND ASSOCIATES CHTD	SUICIDE WITH ZOLPIDEM, ZALEPON, AND ESZOPICLONE - OSE RVW 8/31/06
2012-711	02/01/2012 03/01/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	NANCY ZHANG, Ph.D. QUANTITATIVE SOLUTIONS INC	BUMEX (BUMETANIDE) NDA 18-226, NDA 18-225 - STATISTICAL & MEDICAL RVWS
2012-712	02/01/2012 03/01/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	POCHODYLO, JOHN	AXIRON - AER

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2012-713	02/01/2012 03/01/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SARA E. ROSENBAUM, Ph.D. UNIVERSITY OF RHODE ISLAND, COLLEGE OF PHARMACY	METHOTREXATE - AER
2012-714	02/01/2012 03/01/2012	FDA/OC/OES/DFOI/	KARYN M. SCHMIDT AMERICAN CHEMISTRY COUNCIL	NATURAL RESOURCES DEFENSE COUNCIL (NRDC) - FOI REQUEST REGARDING BISPHENOL A (BPA) IN FOOD PACKAGING 10/14/11
2012-715	02/01/2012 03/01/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KATHRYN A. PRYOR, Esq. SIMON GREENSTONE ET AL	IBUPROFEN (MOTRIN, ADVIL) - AERS
2012-716	02/01/2012 03/01/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MATTHEW D. BIRD DRINKER BIDDLE REATH LLP	RISPERDAL NDA 20-272/S036, NDA 20-588/S024, NDA 21- 444/S008 - APRVL RECS
2012-717	02/01/2012 03/01/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	JAMI S. OLIVER OLIVER LAW OFFICES INC	DAVOL INC/C R BARD INC - BARD PERFIX PLUG AERS, WARNING LTRS, CMLPNTS, ETC
2012-718	02/01/2012 03/01/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JI, JUNZHI	AVASTIN (BEVACIZUMAB) - AERS
2012-719	02/02/2012 03/02/2012	FDA/OMPT/CDRH/OCER/DFOI/	KARIM, IMRAN	PHAROS LIFE CORP - TANDA MAX OTC SYS K110735
2012-720	02/02/2012 03/02/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORR/SE-FO/ATL- DO/ATL-CB/	CAROLINE W HERRINGTON ADAMS & JORDAN	PERRY HOSPITAL RADIOLOGY DEPT, PERRY, GA - MAMMOGRAPHY QUALITY STANDARDS ACT VIOLATIONS, RPTS, CMLPNTS, ETC 2008 TO 2011
2012-721	02/02/2012 03/02/2012	FDA/OC/OES/DFOI/ FDA/OGROP/ORR/CE-FO/DET- DO/DET-CB/ FDA/OC/OES/DFOI/	DIANA GESEKING SEDGWICK LLP	MEAD JOHNSON, ZEELAND, MI - EIR 8/26/04
2012-722	02/02/2012	OC/ORR/		INDIVIDUAL RECS

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	03/02/2012	OC/ORO/ FDA/OGROP/ORO/CE-FO/NWJ- DO/NWJ-CB/	Doe J	
2012-723	02/02/2012 03/02/2012	FDA/OGROP/ORO/CE-FO/DET- DO/DET-CB/	EMILY E HUGHES ESQ MILLER LAW FIRM	LIQUID MANUFACTURING LLC, BRIGHTON, MI - EIR 1/9- 14,19.21/10, WARNING LTR 3/26/10, CO RESP
2012-724	02/02/2012 03/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TORMA #07B1783, STEPHEN J	PHARMACIA & UPJOHN INC - MEDROXYPROGESTERONE ACETATE AERS
2012-725	02/02/2012 03/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORO/SE-FO/ATL- DO/ATL-CB/	MATT MAXWELL ATLANTA INSTITUTE FOR MEDICAL RESEARCH INC	BAYER, JOHNSON & JOHNSON - INSP 1/31/11-2/7/11
2012-726	02/02/2012 03/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LEIFFER, LYDIA	MDS PHARMA SERVICES, ST LAURENT, QUEBEC, CANADA - EIR, 483 2006-2007, IRB NAME, ETC
2012-727	02/02/2012 03/02/2012	FDA/OFVM/CFSAN/OCD/EOS/	RACHEL A BOND Keller and Heckman LLP	FCN 1040
2012-728	02/02/2012 03/02/2012	FDA/OGROP/ORO/PA-FO/SAN- DO/SAN-CB/	DOUGLAS N BLUE ZETETIC	JOHNSON & JOHNSON VISION CARE INC - ACCUVUE OASYS CONTACT LENS ENTRY #BDD-0712296-9/7/1 RECS
2012-729	02/02/2012 03/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JACQUELINE CHAN K&L GATES	ACCUCAPS INDUSTRIES LTD, WINDSOR, ONTARIO, CANADA - EIRS, 483S, WARNING LTRS, ETC 1/06 TO 1/12
2012-730	02/02/2012 03/02/2012	FDA/OGROP/ORO/SE-FO/ATL- DO/ATL-CB/	SHERI O COVINGTON K & L GATES	BANNER PHARMACAPS INC, HIGH POINT, NC - EIRS, 483S, WARNING LTRS, ETC 1/06 TO 1/12
2012-731	02/02/2012 03/02/2012	FDA/OGROP/ORO/SE-FO/FLA- DO/FLA-CB/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	SHERI O COVINGTON K & L GATES	CATALENT PHARMA SOLUTIONS, ST PETERSBURG, FL - EIRS, 483S, WARNING LTRS, ETC 1/06 TO /12
2012-732	02/02/2012	FDA/OMPT/CDRH/OCER/DFOI/		BEAM LIMITING DVC, TABLES - MFR, MODEL NUMBER,

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	03/02/2012		DONOVAN, JAMES	DATE MANUFACTURED, ETC
2012-733	02/02/2012 03/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SCOTT A HANNA ZUCKERMAN SPAEDER LLP	CIPLA LTD - 483 2/17/11-9/22/11
2012-734	02/02/2012 03/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELAINE S WALLER PHARM D MBA SEATTLE GENETICS INC	SEATTLE GENETICS - ADCETRIS (BRENTUXIMAB VEDOTIN) ISRS 7728607-4, 7819592-5, 7906053-8, ETC AERS
2012-735	02/02/2012 04/18/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ OC/OA/OM/OMP/DDM/	RUCHIKA RAVAL GLOBAL BIOPHARMACEUTICAL REGULATIONS INC	SANOFI - H5N1 INFLUENZA SBA, CLNCL SUMMARY, VACCINE A/C MTG MINS, ETC
2012-736	02/02/2012 03/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS Consulting Group, LLC	NAPROXEN SODIUM ER TABS ANDA 75-416 - APRVL TR, LBLG, MOR, ETC
2012-737	02/02/2012 03/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WILLIAMS, PEGGY L	FORTEO - AERS 2008 TO PRESENT
2012-738	02/02/2012 03/02/2012	FDA/OMPT/CDRH/OCER/DFOI/	KARIM, IMRAN	LED TECHNOLOGIES LLC - DPL NUVE K101382
2012-739	02/02/2012 03/02/2012	FDA/OMPT/CDRH/OCER/DFOI/	KARIM, IMRAN	PHAROS LIDE CORP - TANDA MAX K103415
2012-740	02/02/2012 03/02/2012	FDA/OGROP/ORANE-FO/NYK- DO/NYK-DCB/	LESLIE PAUL PERRIGO CO	PERRIGO NEW YORK, BRONX, NY - EIR 10/09
2012-741	02/02/2012 03/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HOLLY KORTEWAY PERRIGO PLANT 5	GLAXOSMITHKLINE PANAMA SA; GLAXOSMITHKLINE COSTA RICA SA - EIRS, 483S MOST RECENT
2012-742	02/02/2012 03/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MIKE CLOTHIER PERRIGO CO	DPT LABORATORIES LTD, SAN ANTONIO, TX; DPT BROOKS, SAN ANTONIO, TX - EIR, 48S MOST RECENT; G PRODUCTION INC, QUEBEC, CANADA - 2 MOST RECENT

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/		
2012-743	02/02/2012 03/02/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FOI Services, Inc.	FEINSTEIN - AMMONIA N-13 NDA 22-119/S001 APRVL RECS
2012-744	02/02/2012 03/02/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	CIRCADIANCE LLC - SLEEPWEAVER NASAL CPAP MASK K092362
2012-745	02/02/2012 03/02/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	RESMED LTD - SWIFT FX K090244
2012-746	02/02/2012 03/02/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	RESMED LTD - PIXI PEDIATRIC MASK K102224
2012-747	02/02/2012 03/02/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	REDMED LTD - MIRAGE MICRO K110444
2012-748	02/02/2012 03/02/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SAJJAN ARYAL ACCUCAPS INDUSTRIES LTD	MATRIX LABORATORIES LTD, ANDHRA, PRADESH, INDIA - LORATADINE EIR 3/30/09-4/3/09
2012-749	02/03/2012 03/05/2012	OC/OM/OMP/DDM/	ANICE N. JAMISON MCDERMOTT WILL & EMERY	DKT 1998N-0583
2012-750	02/03/2012 03/05/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	SUZANNE D JENSEN KLEINFELD KAPLAN & BECKER	K933327, K971392
2012-751	02/03/2012 03/05/2012	FDA/OMPT/CDRH/OCER/DFOI/	RANDALL RICH RANDALL RICH LAW OFC	WRIGHT MEDICAL TECHNOLOGY - CONSERVE TOTAL FEMORAL HEAD K051348
2012-752	02/03/2012 03/05/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JENNIFER NEWBERGER Hyman Phelps and McNamara PC	NICTRIC OXIDE - BIOEQV GUIDANCE RECS
2012-753	02/03/2012 03/05/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	REDLUND, PAUL G	ORLEANS MED CENTER, ORLEANS, MA - AVANDARYL SPL RECS

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2012-754	02/03/2012 03/05/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARIE-PIERRE EKOKA MSC JUBILANT DRAXIMAGE INC	GE HEALTHCARE - CERETEC (TECHNETIUM TC-99M EXAMETAZIME KIT) NDA 19-829/S04, S05, S06 SBA
2012-755	02/03/2012 03/05/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	LIST OF APRVD FACILITIES OF PHARMACEUTICAL MFRS IN INDIA
2012-756	02/03/2012 03/05/2012	FDA/OC/OES/DFOI/	SCOTT C LABARRE LABARRE OFC	SECTION 508 OF THE REHABILITATION ACT - TESTS, EVALUATIONS RPTS, ETC 1/03 TO PRESENT
2012-757	02/06/2012 03/06/2012	FDA/OC/OES/DFOI/	JARED MACCLEARY CROWELL MORING	CENTER FOR VETERINARY MEDICINE - FOI REQUESTS 1/12
2012-758	02/06/2012 03/06/2012	FDA/OMPT/CDRH/OCER/DFOI/	RALPH AGUILA	FISHER & PAYKEL HEALTHCARE LTD, AUCKLAND, NEW ZEALAND - EIRS, 483S, INTERNAL DIALOUGE, ETC 11/16-19/09
2012-759	02/06/2012 03/06/2012	FDA/OMPT/CDRH/OCER/DFOI/	RALPH AGULIA RALPH AGUILA	FISHER & PAYKEL - MR850 HUMIDIFIERS K033710
2012-760	02/06/2012 03/06/2012	FDA/OMPT/CDRH/OCER/DFOI/	RALPH AGUILA RALPH AGUILA	FISHER & PAYKEL - M4730 HIMIDIFIERS K913368
2012-761	02/06/2012 03/06/2012	FDA/OMPT/CDRH/OCER/DFOI/	RALPH AUGILIA RALPH AGUILA	DRAEGER MEDICAL AG - OXYLOG 3000 PLUS K103625
2012-762	02/06/2012 03/06/2012	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	RALPH AGUILIA RALPH AGUILA	FISHER & PAYKEL HEALTHCARE INC, IRVINE, CA - EIR, 483, CORR TO WARNING LTR, ETC 10/25/06-12/6/06, 2/2/07
2012-763	02/06/2012 03/06/2012	FDA/OMPT/CDRH/OCER/DFOI/	J ELOY CRUZ UNOMEDICAL INC	UNOMEDICAL S A DE C V, REYNOSA TAMAULIPAS, MEXICO - EIR 6/11-14/07
2012-764	02/06/2012 03/06/2012	FDA/OMPT/CDRH/OCER/DFOI/	JANET COOPER WESTMED INC.	SIMPLEX MEDICAL CORP, RIVERSIDE, CA - UNIVERSAL HEATED TUBING SLSEEVE K881451
2012-765	02/06/2012 03/06/2012	FDA/OMPT/CDRH/OCER/DFOI/	GONZALES, TODD	MISBRANDING ACUPUNCTURE NEEDLES - RECS
2012-766	02/06/2012 03/06/2012	FDA/OMPT/CDRH/OCER/DFOI/	AYA AMEMIYA SEIKO EPSON CORP	ERBE USA INC - ERBEJET 2 SYS K072404
2012-767	02/06/2012 03/06/2012	FDA/OGROP/ORAP/SE-FO/NOL-DO/NOL-CB/	DOUGLAS N BLUE ZETETIC	DEPUY MITEK INC (JOHNSON & JOHNSON CO), RAYNHAM, MA - CLEARFIX RASP ENTRY 112-2967990-2/1/11 PHOTOGRAPHS

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2012-768	02/06/2012 03/06/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	DENISE M POWERS FULBRIGHT & JAWORSKI LLP	SONAR PRODUCTS INC, CARLSTADT, NJ - EIRS, 483S, 482S, ETC 1/09 TO PRESENT
2012-769	02/06/2012 03/06/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	SATIJA, ALBERT	MAQUET CARDIOVASCULAR, WAYNE, NJ - 483S 4/1/11
2012-770	02/06/2012 03/06/2012	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OC/OES/DFOI/	LINDA LEHMKUHL MEDVET	MEDVET MEDICAL CENTER FOR PETS (MEDVET MEDICAL & CANCER CENTERS), WORTHINGTON, OH - EIR 2006
2012-771	02/06/2012 03/06/2012	FDA/OFVM/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 144083 10/25/11
2012-772	02/06/2012 03/06/2012	OC/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	FRANK YIANNAS Walmart	MEAD JOHNSON - ENFAMIL PREMIUM INFANT FORMULA SPLS 487854, 487855 RESULTS 1/9/12
2012-773	02/06/2012 03/06/2012	FDA/OFVM/CFSAN/OCD/EOS/OC/CVM/OCD/	JENKINS, KRIS	BIODIESEL DERIVED GLYCERIN DERRIVED FROM REFINED VEGTABLE OIL BACKGROUND RECS
2012-774	02/06/2012 03/06/2012	FDA/OC/OES/DFOI/	GLADYS B TONKIN WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 12/26-30/11
2012-775	02/06/2012 03/06/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	2012-61
2012-776	02/06/2012 03/06/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	2012-100
2012-777	02/06/2012 03/06/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	2012-146
2012-778	02/06/2012 03/06/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	2012-167 - REQUEST LTR
2012-779	02/06/2012 03/06/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	2012-255 - REQUEST LTR
2012-780	02/06/2012 03/06/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	2012-264 - REQUEST LTR
2012-781	02/06/2012 03/06/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	2012-305 - REQUEST LTR

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2012-782	02/06/2012 03/06/2012	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	KATHIE BARDWELL STERIS CORP	STERIS CORP, MONTGOMERY, AL - EIR 10/09 TO 10/27
2012-783	02/06/2012 03/06/2012	OC/ORAE/ OC/ORAE/	STEVE L. MARKS MAIN STREET GOURMET	CMPLNT 122701
2012-784	02/06/2012 03/06/2012	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	ANNA YUKHANANOV THOMSON REUTERS	SILIMED INC, TX - 483 2003, 2007
2012-785	02/06/2012 03/06/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	2012-314 - REQUEST LTR
2012-786	02/06/2012 03/06/2012	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	SETH GORDON NEWBERG GRAPHIC	GEORGE PACKING CO INC, NEWBERG, OR - EIR, CO RESP, WARNING LTR
2012-787	02/06/2012 03/06/2012	OC/OM/OMP/DDM/	MARILYN WHITNEY COVINGTON & BURLING LLP	DKT FDA-2010-P-0491
2012-788	02/06/2012 03/06/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	PATHEON ITALIA SPA, FERENTINO, ITALY - EIR, 6/09 & 11/11
2012-789	02/06/2012 03/06/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	BRENDA M GARTZ ELI LILLY & CO	PATHEON ITALIA SPA, FERENTINO, ITALY - EIR 5/11
2012-790	02/06/2012 03/06/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	BRENDA M GARTZ ELI LILLY & CO	MERCK KGAA, DARMSTADT, GERMANY - EIRS, 2009 TO PRESENT
2012-791	02/06/2012 03/06/2012	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	BRENDA M GARTZ ELI LILLY & CO	HECTOR WILTZ, MD; FMX RESEARCH CORP, MIAMI, FL - 483S 5/13/09 & 2/7/05
2012-792	02/06/2012 03/06/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	BASF ORGAMOL PHARMA SOLUTIONS SA IN - EVIONNAZ, SWITZERLAND - EIR, 11/08 TO PRESENT

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2012-793	02/06/2012 03/06/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	CARBOGEN AMCIS, SWITZERLAND (AARAU, NEULAND & BUBENDORF) - EIR 2008 TO PRESENT
2012-794	02/06/2012 03/06/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	BRENDA M GARTZ ELI LILLY & CO	IRVINE PHARMACEUTICAL SERVICES, IRVINE, CA - EIR, 11/09 TO PRESENT
2012-795	02/06/2012 03/06/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	DSM FINE CHEMICALS, LINZ, AUSTRIA - EIR 5/09 TO PRESENT
2012-796	02/06/2012 03/06/2012	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	BRENDA M GARTZ ELI LILLY & CO	SGS LIVE SCIENCE SERVICES, LINCOLNSHIRE, IL - EIR, 8/09 TO PRESENT
2012-797	02/06/2012 03/06/2012	OC/ORA/ OC/ORA/ FDA/OMPT/CDRH/OCER/DFOI/	ANNA YUKHANANOV THOMSON REUTERS	POLY IMPLANT PROTHESE, LA SEYNE SUR MER, FRANCE - 2001 TO 2005
2012-798	02/06/2012 03/06/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SQUAILIA, WILLIAM	SINQUAN DOXEPIN - AER
2012-799	02/06/2012 03/06/2012	FDA/OGROP/ORASE-FO/NOLDO/NOL-CB/	DOUGLAS N. BLUE ZETETIC INC	ENTRY NO 112-2967990-2/1/10 CLEARFIX CALIBRATION TOOL
2012-800	02/06/2012 03/06/2012	OC/ORA/ OC/ORA/ OC/CVM/OCD/ OC/OCM/EMOPS/ FDA/OGROP/ORA/ORO/DIOP/ OC/ORA/ORO/ OC/ORA/ORO/ OC/ORA/ OC/ORA/ FDA/OFVM/CFSAN/OCD/EOS/	SCOTT PHILLIPS INSIDE EDITION	CHICKEN JERKY PRODUCTS 1/11

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2012-801	02/06/2012 03/06/2012	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/OA/OM/OMP/DDM/ FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/	KYRIAKIDIS, JOANNA	DOCKET 2005N-0403
2012-802	02/06/2012 03/06/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HARTWELL P. MORSE, III HUSCH BLACKWELL LLP	TEVA PHARMS - RISEDRONATE SODIUM NDA 79-215
2012-803	02/06/2012 03/06/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RHONDA P. CHAMBERS TAYLOR & TAYLOR ATTORNEYS AT LAW	EVAMIST - CLNCL TRIALS, SAFETY, LBLG, PKG
2012-804	02/06/2012 03/06/2012	FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/ FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	JASON D'SOUZA Professional Disposables International, Inc.	ROCKLINE INDUSTRIES - 483, EIR, WARNING LTR, CO RESP
2012-805	02/06/2012 03/06/2012	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DENISE M. POWERS FULBRIGHT & JAWORSKI LLP	STRATUS PHARMS INC, MIAMI, FL - EIR, 483, WARNING LTR 1/09 TO PRESENT
2012-806	02/06/2012 03/06/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	HUBER, MARIE	PROVENGE - CMC RVW
2012-807	02/06/2012 03/06/2012	FDA/OFVM/CFSAN/OCD/EOS/	THOMPSON, CLARENCE LD	CFSAN EMPLOYEES SUBJECT TO INVESTIGATION 1/10 TO PRESENT
2012-808	02/06/2012 03/06/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/	DAVID M DEUTSCH CO LPA	MEDTRONIC LEGACY RODS - RECALL, AER
2012-809	02/06/2012 03/06/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/	DAVID M. DEUTSCH DAVID M DEUTSCH CO LPA	MEDTRONIC ATLANTIS CERVICAL PLATE - CORR

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2012-810	02/07/2012 03/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	ANGELIA D SLAYTON INC REGULATORY CONSULTING & SUBMISSIONS	LEXINGTON INTERNATIONAL - HAIRMAX K081668 NSE LTR 12/19/08; KAREEN S BURNEY TO CASPER ULDRIKS LTR 1/3/11; RESP TO K103368, ETC
2012-811	02/07/2012 03/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	ANGELIA D SLAYTON INC RESEARCH CONSULTING & SUBMISSIONS	K112524
2012-812	02/07/2012 03/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	ANGELIA D SLAYTON INC RESEARCH CONSULTING & SUBMISSIONS	K111714
2012-813	02/07/2012 03/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	ANGELIA D SLAYTON INC RESEARCH CONSULTING & SUBMISSIONS	K110233
2012-814	02/07/2012 03/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	ANGELIA D SLAYTON INC RESEARCH CONSULTING & SUBMISSIONS	K103368
2012-815	02/07/2012 03/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	ANGELIA D SLAYTON INC RESEARCH CONSULTING & SUBMISSIONS	K110301
2012-816	02/07/2012 03/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	ANGELLIA D SLAYTON INC RESEARCH CONSULTING & SUBMISSIONS	K102494
2012-817	02/07/2012 03/07/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	ANGELIA D SLAYTON INC REGULATORY CONSULTING & SUBMISSIONS	K072459
2012-818	02/07/2012 03/07/2012	FDA/OC/OES/DFOI/	PATRICIA L REGENYE Celgene Corporation	DANIEL LORCH, BRANDON, FL - 483S 2/09 TO PRESENT
2012-819	02/07/2012 03/07/2012	FDA/OC/OES/DFOI/	PATRICIA L REGENYE Celgene Corporation	JAMES STOCKS (UNIV OF TEXAS HEALTH CENTER TYLER), TYLER, TX - 483S 9/09 TO PRESENT
2012-820	02/07/2012 03/07/2012	FDA/OC/OES/DFOI/	PATRICIA L REGENYE Celgene Corporation	ROBERT SCHILZ (CLEVELAND CLINIC FOUNDATION), CLEVELAND, OH - 483S 9/05 TO PRESENT
2012-821	02/07/2012 03/07/2012	FDA/OC/OES/DFOI/	PATRICIA L REGENYE Celgene Corporation	FERNANDO MARTINEZ (UNIV MICHIGAN MEDICAL CENTER), ANN ARBOR, MI - 483S 1/10 TO PRESENT
2012-822	02/07/2012 03/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	AMBER R JOHNSON BOSTON SCIENTIFIC	NAVILYST MEDICAL INC - MULTIPURPOSE DRAINAGE CATHETER K111315
2012-823	02/07/2012 03/07/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SUSAN SULLIVAN OMEROS CORP	NEVANAC (NEPAFANAC) NDA 21-862 - PROTOCOL C-02-53, PROTOCOL C-03-32, PROTOCOL C-95-93 SS&E,

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		SAFETY UPDATE
2012-824	02/07/2012 03/07/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/OA/OM/OMP/DDM/	DEBRA HATHAWAY THINC	ODAC A/C - AGENDA, MINS, TRANS, ETC 1/31/92; ODAC - AGENDA, MINS, TRANS, ETC 6/9/95; NDA 20-221/S000 APRVL LTR, RVWS, CORR, ETC 12/8/95
2012-825	02/07/2012 03/07/2012	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	BENAVENTE, MARIA	LLORENS PHARMACEUTICAL INTERNATIONAL, MIAMI, FL - EIR 8/10 TO 9/10
2012-826	02/07/2012 03/07/2012	OC/CVM/OCD/	JUDITH HILL INTERTEK CANTOX	SELENIUM ENRICHED YEAST - SAFETY & UTILITY RECS 6/4/87, 6/4/87, 4/19/89, ETC
2012-827	02/07/2012 03/07/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/CVM/OCD/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	RANDALL C WHATTOFF GOODSILL ANDERSON QUINN & STIFEL	KONA BLUE WATER FARMS INC, KEAHOLE POINT FISH LLC - NOTES, MEMOS, EMAILS, ETC
2012-828	02/07/2012 03/07/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN A HELLMAN LATHAM & WATKINS LLP	INJECTAPAP (ACETAMINOPHEN INJ) NDA 17-785 - RECS, APPLICANTS SUBMISSIONS, CORR, ETC
2012-829	02/07/2012 03/07/2012	FDA/OO/OFBA/OAGS/	MICHAEL R PRANZATELLI MD SOUTHERN ILLINOIS UNIV SCHOOL OF MEDICINE	ADVANCING REGULATORY SCIENCE THROUGH NOVEL BIOMARKER RESEARCH AND SCIENCE-BASED TECHNOLOGIES - RECIPIENT GRANT #1U01 FD004197-01
2012-830	02/07/2012 03/07/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	MARK C AUBUCHON AUBUCHON RANIERE & PANZERI	MYOGENIX INC - MYOGENIX SPAWN CORR, STUDIES, PUBLIC HEALTH ADVISORY WARNING 7/28/09, ETC
2012-831	02/07/2012 03/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	CHARLES H KYPER KYPER & ASSOCIATES	ETEX CORP - EQUIVABONE OSTEOINDUCTIVE BONE GRAFT SUBSTANCES K090855
2012-832	02/07/2012 03/07/2012	FDA/OO/OFBA/OAGS/	IKRAM KORESHI NETHOST INC	BOOZ ALLEN & HAMILTON - CONTRACT #HHSF22301004T

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2012-833	02/07/2012 03/07/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARILYN A APFEL PHD XFDA INC	LILLY - NDA 00-734 TOXICOLOGY RECS
2012-834	02/07/2012 03/07/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SUZANNE D JENSEN Kleinfeld, Kaplan and Becker, LLP	BIOGEN INC - AVONEX UNTITLED LTR 12/5/00; ICN PHARMACEUTICALS INC - VIRAZOLE REGULATORY LTR 3/24/86; PFIZER INC - FELDENE REGULATORY LTR 7/13/82, ETC
2012-835	02/07/2012 03/07/2012	FDA/OGROP/ORR/NE-FO/NWE-DO/NWE-CB/	LORI ROOF PERRIGO CO	BIO-CONCEPT, SALEM, NH - LAST 2 483S
2012-836	02/07/2012 03/07/2012	FDA/OGROP/ORR/CE-FO/NWJ-DO/NWJ-CB/	BRENDA M GARTZ ELI LILLY & CO	WELCH, HOLME & CLARK CO INC, NEWARK, NJ - 483 10/10
2012-837	02/07/2012 03/07/2012	OC/ORR/ OC/ORR/ FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/ FDA/OC/OES/DFOI/ FDA/OGROP/ORR/NE-FO/NYK-DO/NYK-DCB/	Doe J	S A EVIAN CO - CMLPNT 7/26/11
2012-838	02/07/2012 03/07/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MELANIE COTE MEDISCA INC	ATTIX PHARMS, ONTARIO, CANADA - ERS
2012-839	02/07/2012 03/07/2012	FDA/OGROP/ORR/NE-FO/NYK-DO/NYK-DCB/	MELANIE COTE MEDISCA INC	MEDISCA INC, PLATTSBURGH, NY - EIR 9/14-15/10
2012-840	02/07/2012 03/07/2012	FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/	MELANIE COTE MEDISCA INC	ATTIX PAHRMS, WEATHERFORD, TX - EIRS
2012-841	02/07/2012 03/07/2012	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD WASHINGTON INFORMATION SOURCE	2011-3504
2012-842	02/07/2012 03/07/2012	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD WASHINGTON INFORMATION SOURCE	2011-6905
2012-843	02/07/2012	FDA/OFVM/CFSAN/OCD/EOS/	WILLIAM A OLSON PHD	FCN 1090

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	03/09/2012		WASHINGTON INFORMATION SOURCE	
2012-844	02/07/2012 03/07/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WILLIAM C VINCEK PHD PHARMA CMC INC	DIETHYLSTILBESTROL DELAYED RELEASE TABS NDA 04-039 APRVL RECS
2012-845	02/07/2012 03/07/2012	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WILLIAM C VINCEK PHD PHARMA CMC INC	DIETHYLSTILBESTROL VAGINAL SUPPOSITORY NDA 04-040 - APRVL RECS
2012-846	02/07/2012 03/07/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WILLIAM C VINCEK PHD PHARMA CMC INC	DIETHYLSTILBESTROL ORAL TABS NDA 04-041 - APRVL RECS
2012-847	02/07/2012 03/13/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/ FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORACE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORACE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORACE-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORACE-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORACE-FO/SEA-DO/SEA-CB/	MERLE ZIMMERMANN AMERICAN HERBAL PRODUCTS ASSOCIATION	HI TECH PHARMS, NORCROSS, GA 4/13/09-12/8/09; BALCHEM CORP, CHANNAHON, IL 5/20/09-6/10/09; LIVING ESSENTIALS LLC, FARMINGTON, MI 11/22/10-12/3/10, ETC - EIRS, 483S

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2012-848	02/08/2012 03/08/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	XAVIER BONHOMME ALGORITHMHE PHARMA INC	ALGORITHMHE PHARMA INC, MONTREAL, QUEBEC, CANADA - EIRS 2/6-10/06, 4/3-5/07, 4/9-12/07, ETC
2012-849	02/08/2012 03/08/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SHIN KANG PHD WACHOVIA BANK NA	REVLIMID (LENALIDOMIDE) - SAFETY RVW RECS
2012-850	02/08/2012 03/08/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	NICHOLAS J PELLICCIONE PHD AETERNA ZENTARIS	BERNA BIOTECH LTD - VIVOTIF TYPHOID VACCINE PHARMACOKINETICS, SAFETY, TOXICOLOGY RECS, ETC
2012-851	02/08/2012 03/08/2012	OC/ORR/ OC/ORR/ FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORR/SW-FO/SWID/SWID-CB/ FDA/OGROP/ORR/SW-FO/SWID/SWID-CB/	MICHELLE RYBAK ROANOKE TRADE SERVICES INC	ENTRY #U720516383-6 - NOTICES OF REFUSAL, FDA ACTION, NOTICE OF MARK/REDELIVER
2012-852	02/08/2012	FDA/OMPT/CDER/ORP/DIDP/	KAREN HABUCKY PHD	NDA 22-068/S005,S008 - CLNCL & MEDICAL RVWS, CORR

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	03/08/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	NOVARTIS PHARMACEUTICALS CORP	
2012-853	02/08/2012 03/08/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/CVM/OCD/ OC/OCOS/OES/ OC/OCOS/OES/ FDA/OC/OES/DFOI/	DAVID WALLINGA MD MPA INSTITUTE FOR AGRICULTURE AND TRADE POLICY	ETHANOL PRODUCERS & COMPANIES USE OF ANTIMICROBIALS CORR; SUBMISSIONS FROM SUPPLIERS OF ANTIBIOTIC ADDITIVES FOR USE IN ETHANOL PRODUCTION; POLICY GUIDELINES, ETC
2012-854	02/08/2012 03/08/2012	OC/CVM/OCD/ FDA/OC/OES/DFOI/	DAVID WALLINGA MD MPA INSTITUTE FOR AGRICULTURE AND TRADE POLICY	NATIONWIDE SURVEY OF DISTILLERS GRAINS FOR ANTIBIOTIC RESIDUES FY 2010 - SPL DESCRIPTIONS OF ANTIBIOTICS USED IN ETHANOL PRODUCTION, TEST RESULTS, ETC
2012-855	02/08/2012 03/08/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SACHIN AHUJA VERSEON CORP	BOEHRINGER-INGLEHEIM GMBH - PRADAXA (DABIGATRAN) NDA 22-512 IND APPL
2012-856	02/08/2012 03/08/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DORON FRIEDMAN HEBREW UNIVERSITY HADASSAH MEDICAL SCHOOL	EXPAREL (LIPOSOMAL BUPIVACAINE HCI) - SBA
2012-857	02/08/2012 03/08/2012	FDA/OC/OSHC/OPD/	G MICHAEL WALL PHD O-RAY PHARMA INC	FAIRFIELD CLINICAL TRIALS LLC - TRACONAZOLE SUSPENSION ORPHAN DRUG DESIGNATION
2012-858	02/08/2012 03/08/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SANJAY H SHARMA PHD HETERO USA INC	SILODOSIN CAPS - CHEMISTRY & BIOEQV RVWS, CORR
2012-859	02/08/2012 03/08/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SANJAY H SHARMA PHD HETERO USA INC	XENAZINE (TETRABENAZINE TABS) - CHEMISTRY & BIOEQV RVWS, CORR
2012-860	02/08/2012 03/08/2012	FDA/OC/OES/DFOI/	PATRICIA L. REGENYE Celgene Corporation	RODOLFO POSADAS VALAY, MONTERREY NL, MEXICO - 483 7/09 TO 11/11
2012-861	02/08/2012 03/08/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHRISTINE M BURNS DISCOVERY LABORATORIES INC	CORDEN PHARMA SWITZERLAND LLC, LIESTAL, SWITZERLAND - EIR, 483S 12/19-22/11

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2012-862	02/08/2012 03/08/2012	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	CHRISTINE M BURNS DISCOVERY LABORATORIES INC	UNIV OF CALIFORNIA SAN DIEGO, CLNCL TEACHING FACILITY, SAN DIEGO, CA - EIR, 482 12/12-16/11
2012-863	02/08/2012 03/08/2012	FDA/OC/OES/DFOI/	PATRICIA L. REGENYE Celgene Corporation	WAN LONG CHUANG, KAOHSUUNG, TAIWAN - 483 5/10 TO 11/11
2012-864	02/08/2012 03/08/2012	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	CHRISTINE M BURNS DISCOVERY LABORATORIES INC	DISCOVERY LABORATORIES INC, WARRINGTON, PA 12/19-21/11; TOTOWA, NJ 1/24-31/12 - EIRS
2012-865	02/08/2012 03/08/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	TORMA, STEPHEN J	PHARMACIA & UPJOHN INC - MEDROXYPROGESTERONE ACETATE AER, WARNINGS
2012-866	02/08/2012 03/08/2012	FDA/OO/OFBA/OAGS/	PROJECT ON GOVERNMENT OVERSIGHT	MCKINSEY & CO PRESENTATION - CONTRACT GS10F0118S
2012-867	02/08/2012 03/08/2012	FDA/OO/OFBA/OAGS/	ANDREW WYNER PROJECT ON GOVERNMENT OVERSIGHT	DELOITTE & TOUCHE SLIDE PRESENTATION - CONTRACT GS23F9796H
2012-868	02/08/2012 03/08/2012	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	DOUGLAS N. BLUE ZETETIC	ENTRY NO 112-2967990-127
2012-869	02/08/2012 03/08/2012	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	DOUGLAS N. BLUE ZETETIC	ENTRY NO 112-2967990-219
2012-870	02/08/2012 03/08/2012	FDA/OMPT/CDRH/OCER/DFOI/	RIPPER, ERIC B	POLYACRYLAMIDE HYDROGEL
2012-871	02/08/2012 03/08/2012	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	DAVID H. DANOWIT MITCHELL CLAIMS SERVICE INC	INDIVIDUAL RECS
2012-872	02/08/2012 03/08/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ALEXANDER MIRONOV TIGRIS PHARMACEUTICALS INC	NOVARTIS - TRANSDERM SCOPE NDA 17-874 SBA

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2012-873	02/08/2012 03/08/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORA/ OC/ORA/ FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	SHELDON T. BRADSHAW HUNTON & WILLIAMS LLP	FDA WORK PLAN SENT TO SEATTLE DISTRICT
2012-874	02/09/2012 03/09/2012	FDA/OMPT/CDRH/OCER/DFOI/	A ROBERT DEPALMA SAMSUNG MEDISON AMERICA INC	SAMSUNG MEDISON CO LTD, SEOUL , KOREA - EIR 7/3/08
2012-875	02/09/2012 03/09/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RUBY HOLDER STRAUS PARTNERS	VERTEX PHARMS - INCIVEK NDA 20-1917 AERS
2012-876	02/09/2012 03/09/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RUBY HOLDER STRAUS PARTNERS	REGENERON PHARMS - EYLEA BLA 12-5387 AERS
2012-877	02/09/2012 03/09/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANGELIA D SLAYTON INC REGULATORY CONSULTING & SUBMISSIONS	ARCHMEDES - LAZANDA (FENTANYL CITRATE) NDA 22-569 APRVL LTR, LBLG, RVWS 6/30/11
2012-878	02/09/2012 03/09/2012	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	JUNG JAE-YOON JTBC	NONGSHIM HOOROOROOKKUKSOO LA - 8/24/10; NONGSHIM POTATO NOODLE SOUP LA - 4/7/09; LOTT SAMKANG CHOCOLATE FLAVORED ICE BAR (PAPICO) LA 3/16/09, ETC SPL
2012-879	02/09/2012 03/09/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/CVM/OCD/	ANEET PANESAR BURDOCK GROUP	LACTIC ACID CAS 50-21 - FAP
2012-880	02/09/2012 03/09/2012	FDA/OFVM/CFSAN/OCD/EOS/	MIKE VANDERHEIJDEN YALE LAW SCHOOL	ORDINANCE & CODE REGULATING EATING & DRINKING ESTABLISHMENTS - RECS 3/38
2012-881	02/09/2012 03/09/2012	FDA/OC/OES/DFOI/	WILLISTON C WHITE WILLISTON C WHITE & ASSOC PC	MATRIX INITIATIVES INC - ZICAM COLD REMEDY INTRANSAL PRODS CORR, DIRECTIVE ISSUED, ADMINISTRATIVE ORDER
2012-882	02/09/2012	FDA/OMPT/CDER/ORP/DIDP/	ANGELIA D SLAYTON	QUINTILES IRELAND LTD, DUBLIN 3, IRELAND - 483, CO

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2012-883	02/09/2012 03/09/2012	FDA/OC/OSHC/OPD/ FDA/OC/OES/DFOI/	MARILYNN WHITNEY COVINGTON & BURLING LLP	ORPHAN DRUG DESIGNATION - EXEMESTANCE, EPIRUBICIN NON-CONFIDENTIAL PORTIONS, CORR, WRITTEN DECISIONS
2012-884	02/09/2012 03/09/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Cutler, Charles	FREEZING TUMORS PHASE I TRIALS - ADDRESS TO DOCTORS IN FL
2012-885	02/09/2012 03/09/2012	FDA/OMPT/CDRH/OCER/DFOI/	ROBIN L. ROWE STRYKER INCUBATION OF MEDICAL TECHNOLOGY	ORTHOMET INC - AXIOM TOTAL KNEE SYS K926334
2012-886	02/09/2012 03/09/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	MARTHA GUZMAN AMSINO INTERNATIONAL INC	AMSINO - DISPOSABLE VAGINAL SPECULUM K951528
2012-887	02/09/2012 03/09/2012	OC/ORO/ORM/ OC/ORO/ORM/	GAIL LESSICK LACHMAN CONSULTANT SERVICES INC	DOMESTIC & FOREIGN INSP 12/11
2012-888	02/09/2012 03/09/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JUSTIN P. STALPES, Esq. BECK & AMSDEN PLLC	ABILIFY- AERS
2012-889	02/09/2012 03/09/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LESLIE B. ROSE PHARMAVISION CONSULTING LTD	ANTINEOPLASTON - EFFICACY
2012-890	02/09/2012 03/09/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	OWEN GARRICK, MD MBA BRIDGE CLINICAL RESEARCH	CLNCL INVESTIGATORS WHO PERFORM PHASE 3 STUDIES IN THE US 1/06 TO 12/31/11
2012-891	02/09/2012 03/09/2012	FDA/OMPT/CDRH/OCER/DFOI/	NICK DEMCZUK IENJOY TECHNOLOGIES	ADVANTAGEOUS MEDICAL DEVICES - AMD 6605 PRODUCT K092990
2012-892	02/09/2012 03/09/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/LOS-	ROBERT F. CLARKE, Esq. CLARKE LAW OFFICES	BRAIN STATE TECHNOLOGIES CMLPLNTS

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2012-893	02/10/2012 03/12/2012	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	SARAH M JOHNSON GIEGER LABORDE & LAPEROUSE LLC	CHISESI BROTHERS MEAT PACKING COMPANY INC - EIRS, CMLNLS, WARNING LTRS, ETC
2012-894	02/10/2012 03/12/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	NATHAN A BEAVER FOLEY & LARDNER LLP	JANSSEN PHARMS - ELMIRON (PENTOSAN POLYSULFATE SODIUM) NDA 20-193 SBA
2012-895	02/10/2012 03/12/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	SMITH, VIRGIL L	INDIVIDUAL RECS
2012-896	02/10/2012 03/12/2012	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	ELLEN GABLER MILWAUKEE JOURNAL SENTINEL	AMERICAN RED CROSS, OSHKOSH, WI, BLOOD CENTER OF WISCONSIN INC, INTERSTATE BLOOD BANK OF WISCONSIN INC, ETC - EIRS 1/09 TO PRESENT
2012-897	02/10/2012 03/12/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	VAL SAWYER ZYMOGENETICS INC	ISR 7563149
2012-898	02/10/2012 03/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	KATHERINE STRONG CARNER SIDLEY AUSTIN LLP	MEDICAL DVC PROD CODE DXT, IZQ, FPK 0R NEP - UNTITLED LTRS
2012-899	02/10/2012 03/12/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/OCM/EMOPS/ OC/OR/ OC/OR/ FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORASE-FO/FLA-	PATTI WALLER MARLER CLARK ATTYS	WEGMANS FOOD MARKETS, SUNRISE COMMODITIES, BADIA SPICES, ETC - TURKISH PINE NUTS SALMONELLA ENTERIDITIS OUTBREAK LAB RESULTS, CORR, RECALL RECS, ETC 8/11 TO 10/11

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		DO/FLA-CB/		
2012-900	02/10/2012 03/12/2012	OC/OA/OM/OMP/DDM/	TINA WOLFSON AHDoot & Wolfson PC	GUIDANCE FOR INDUSTRY: JUICE HACCP HAZARDS & CONTROLS GUIDANCE FIRST EDITION; FINAL GUIDANCE 3/3/04 - MINS, TOXICOLOGICAL RECS, CORR ETC
2012-901	02/10/2012 03/12/2012	FDA/OMPT/CDRH/OCER/DFOI/ OC/OCOS/OES/ OC/OCOS/OES/ OC/OA/OM/OMP/DDM/	LAURA KNOLL KNOLL LAW FIRM LLC	ATT&T WIRELESS SERVICES INC, SOUTHWESTERN BELL MOBILE SYSTEMS LLC, SBC WIRELESS INC, ETC - BIOLOGICAL AND/OR PSYCHOLOGICAL EFFECTS OF CELL PHONE USE CORR, TEST DATA, MTG MINS, ETC
2012-902	02/10/2012 03/12/2012	OC/OA/OM/OMP/DDM/	DEBRA HATHAWAY THINC	ONCOLOGIC DRUGS A/C - TRANS, MINS, AGENDA, ETC 12/12/94
2012-903	02/10/2012 03/12/2012	FDA/OFVM/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	iOVATE, HYDROXYCUT, SMARTBURN ETC - PRODUCTION & CAERS RECS, 11/14/11 TO PRESENT
2012-904	02/10/2012 03/12/2012	OC/ORa/ OC/ORa/ FDA/OGROP/ORa/SE-FO/FLA-DO/FLA-CB/	JERRY BALDINO JR NORTHEAST PRODUCE INC	CMPLNT #123942
2012-905	02/10/2012 03/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	WILLIAM J GORMAN GORMAN CONSULTING INC	CIRCA SCIENTIFIC - K112376
2012-906	02/10/2012 03/12/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARY B SZALKOWSKI PRISMA CORP	ZOLOFT (SERTRALINE) - AERS
2012-907	02/10/2012 03/12/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DANIEL GETTS TOLERA THERAPEUTICS INC	CENTOCOR ORTHO BIOTECH PRODUCTS LP - ORTHOCLONE OKT3 (MUROMAB-CD3) BLA 103463/0 RECS
2012-908	02/10/2012 03/12/2012	FDA/OC/OES/DFOI/	ANTOINETTE JACKSON AVALON RISK MANAGEMENT INC	ENTRY #S 2009-5201-20018301/NS100040022 - NOTICE TO MARK &/OR REDELIVER; FDA NOTICE OF ACTION 1 RECS
2012-909	02/10/2012 03/12/2012	FDA/OC/OES/DFOI/	ANTOINETTE JACKSON AVALON RISK MANAGEMENT INC	2009-5201-20013301/ASA10135097 - NOTICE TO MARK &/OR REDELIVE; FDA NOTICE OF ACTION #1
2012-910	02/10/2012 03/12/2012	FDA/OC/OES/DFOI/	ANTOINETTE JACKSON AVALON RISK MANAGEMENT	2009-5201-20029801/U16514028' 2009-5201-20031401/U1652147046 - NOTICE TO MARK &/OR RECELIVER, fda NOTICE OF ACTION #1

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2012-911	02/10/2012 03/12/2012	FDA/OC/OES/DFOI/	ANTOINETTE JACKSON AVALON RISK MANAGEMENT INC	2010-5201-20026901/U1652158258 - NOTICE OF MARK &/OR REDEKUYER, FDA NOTICE OF ACTION #1
2012-912	02/10/2012 03/12/2012	FDA/OC/OES/DFOI/	ANTOINETTE JACKSON AVALON RISK MANAGEMENT INC	2010-5201-20015201/DM402619835 - NOTICE TO MARK &/OR REDELIVER' FDA NOTICE OF ACTION #1
2012-913	02/10/2012 03/12/2012	FDA/OC/OES/DFOI/	ANTOINETTE JACKSON AVALON RISK MANAGEMENT INC	ENTRY #S 2010-5201-20039001/AFP10001468 - NOTICE TO MARK &/OR REDELIVER, FDA NOTICE OF ACTION #1
2012-914	02/10/2012 03/12/2012	FDA/OC/OES/DFOI/	ANTOINETTE JACKSON AVALON RISK MANAGEMENT INC	ENTRY NO EPS09846203M CASE #2010-2809-20026401 - BOND (CF301) SUBGKE, NOTICE OF FDA ACTION #1
2012-915	02/10/2012 03/12/2012	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	MEGAN JURGENS Celgene Corporation	APP PHARMACEUTICALS LLC, MELROSE PARK, IL - EIRS,1/15/10, 1/20/10, 1/29/10, ETC 2010-2011
2012-916	02/10/2012 03/12/2012	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	MEGAN JURGENS Celgene Corporation	APP PHARMACEUTICALS LLC, GRAND ISLAND, NY - EIRS 9/9-11/09, 9/14-17/09, ETC 9/09-8/29/11
2012-917	02/10/2012 03/12/2012	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	W PATRICK NOONAN W PATRICK NOONAN	21ST CENTURY HEALTHCARE INC, TEMPE, AZ - EIRS, 483S, CORR ETC, 8/3/11 TO PRESENT
2012-918	02/10/2012 03/12/2012	OC/ORA/ OC/ORA/	MARIA F MUNOZ SEADCO USA CORP	ENTRY # E4P-0018031-5 - FROZEN PASTEURIZED EXTRA JUMBO U-130 SAMPLES LAB RESULTS
2012-919	02/10/2012 03/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	JULIA YEH SHL PHARMA	OWEN MUMFORD USA INC, MARIETTA, GA - K013362
2012-920	02/10/2012 03/12/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	OSBORNE, KAREN	VENOM IMMUNOTHERAPY - VAERS
2012-921	02/10/2012 03/12/2012	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	AMY TRENTAM-DIETZ PHD UNIV OF WISCONSIN SCHOOL OF MEDICINE AND PUBLIC HEALTH	WISCONSIN MAMMOGRAPHY FACILITIES - EIRS 2002 TO PRESENT
2012-922	02/10/2012 03/12/2012	OC/ORA/OCI/ OC/ORA/OCI/	NOAH PRANSKY WTSP-TV	PYURWATER, AKIN ASHEKUN - INVESTIGATION RECS
2012-923	02/10/2012 03/12/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MICHAEL R COHEN RPH MS SCD INSTITUTE FOR SAFE MEDICATION PRACTICES	MEDWATCH RPTS CODED AS MEDICATION ERRORS 1/1/12-2/1/12

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2012-924	02/10/2012 03/14/2012	FDA/OC/OES/DFOI/	DEVANE, HEATHER	LIST OF FDA FOI REQUESTS 12/1-31/99
2012-925	02/10/2012 03/12/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HENRY F BAYARD COOLE SCOTT KISSANE PA	AVASTIN - ISRS 7624779, 7624881, 7625926, ETC
2012-926	02/10/2012 03/12/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/ FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	HENRY F BAYARD COOLE SCOTT KISSANE PA	AVASTIN (BEVACIZUMAB) - AERS
2012-927	02/10/2012 03/12/2012	OC/OA/OM/OMP/DDM/ FDA/OC/OES/DFOI/ OC/ORR/ OC/ORR/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KORENVAES, MAX	NOVARTIS - SYNACTHEN DEPOT A/C TRNAS
2012-928	02/10/2012 03/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	LINDA KO TAIDOC TECHNOLOGY CORP	OMRON HEALTHCARE INC - MICRO-AIR VIBRATING MESH NEBULIZER, K062263; HEALTH & LIFE CO LTD - ULTRASONIC NEBULIZER SYS, K081738
2012-929	02/10/2012 03/12/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SIEGEL, JONATHAN B	NISSHIN PHARMA INC, NAGANO, JAPAN - EIRS, 483S, PRE-APRVL INSP RECS
2012-930	02/10/2012 03/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	THOMAS J HUNTER BIORESOURCE TECHNOLOGY INC	BIORESOURCE TECHNOLOGY INC - NOVA-ONE LIPID CONTROL K040352
2012-931	02/10/2012 03/12/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SYLVESTER & MALEY, INC	THYMOGLOBULIN (ANTI-THYMOCYTE GLOBULIN) - AERS, 2007

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		FDA/OMPT/CDER/GRP/DIDP/		
2012-932	02/10/2012 03/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	THOMAS J HUNTER PHD BIORESOURCE TECHNOLOGY INC	BIORESOURCE TECHNOLOGY INC - LIQUITROL LIQUID HUMAN GLYCOSYLATED HEMOGLOBIN (A1C) CONTROL K023032
2012-933	02/10/2012 03/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	THOMAS J HUNTER PHD BIORESOURCE TECHNOLOGY INC	BIORESOURCE TECHNOLOGY INC - NOD CHEMISTRY CONTROL K060850
2012-934	02/10/2012 03/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	THOMAS J HUNTER PHD BIORESOURCE TECHNOLOGY INC	BIORESOURCE TECHNOLOGY INC - LIQUID HUMAN PROTEIN ELECTROPHORESIS CONTROL K944728
2012-935	02/10/2012 03/12/2012	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	STUART PFEIFER LOS ANGELES TIMES	1-800-GET-THIN LAP-BAND SURGERIES MISLEADING ADS - CORR, CO RESPS
2012-936	02/10/2012 03/12/2012	OC/OA/OM/OMP/DDM/ OC/ORA/ OC/ORA/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KORENVAES, MAX	FARMACIA CERATI - SYNACTHEN DEPOT A/C TRANS
2012-937	02/10/2012 03/12/2012	OC/ORA/ OC/ORA/ OC/ORA/ORM/ OC/ORA/ORM/	THOMPSON, RAY	GMP, GLP & GCP INSPECTIONS - SITES OF INSPS, 6/11-12/11 & F/U RECS
2012-938	02/10/2012 03/12/2012	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	TRAVIS SCHAFTENAAR UBS GLOBAL ASSET MANAGEMENT	INTEGRA LIFESCIENCES, AKRON, OH - 483S, 1/10 TO PRESENT
2012-939	02/10/2012 03/12/2012	OC/CVM/OCD/	MARC J PAULSON SCOULAR CO	LISTING OF APRVD MEDICATED FEED MILL LICENSES
2012-940	02/10/2012 03/12/2012	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	RICHARD KELLER BRUNO INDEPENDENT LIVING AIDS INC	ACORN STAIRLIFTS INC - NON-WORKLOAD OBLIGATION ESTABLISHMENT
2012-941	02/13/2012 03/13/2012	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	CRIAG ROUSH ROCKLINE INDUSTRIES	US NONWOVENS CORP, BRENTWOOD, NY - CORR 11/3010-2/9/12

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2012-942	02/13/2012 03/13/2012	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	PAUL W TRIPP LINCARE INC	MIDWEST SOLUTIONS FOR SLEEP INC, IL - EIRS, 483S, WARNING LTRS 1/05 TO PRESENT
2012-943	02/13/2012 03/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CANACCORD GENUITY	AVANIR - NUEDEXTA (DEXTROMETHORPHAN HYDROBROMIDE, QUINIDINE SULFATE) - AERS 1/11 TO PRESENT
2012-944	02/13/2012 03/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DR PAUL HUTTON GREATER MANCHESTER WEST	LUNDBECK - QUETIAPINE IR CLNCL TRIAL RECS
2012-945	02/13/2012 03/13/2012	OC/ORACE/ORM/ OC/ORACE/ORM/	FDA NEWS	PHARMACEUTICAL, BIOLOGICS, MEDICAL DVC MFG, CLNCL TRIAL FACILITIES IN AND OUTSIDE THE US - 483S 1-/31/12
2012-946	02/13/2012 03/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORACE-FO/NOL-DO/NOL-CB/	ROBERT H TOURTELOT ROBERT H TOURTELOT PLC	MELANOCORP INC, HENDERSONVILLE, TN - MELANOTAN II CMLPNTS
2012-947	02/13/2012 03/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	RICHARD KELLER BRUNO INDEPENDENT LIVING AIDS INC	TRADE CMLPNT 7/20/05
2012-948	02/13/2012 03/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SWOPE, CARL T	ZOCOR, SIMVASTATIN - WARNINGS
2012-949	02/13/2012 03/13/2012	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Doe J	INDIVIDUAL RECS
2012-950	02/13/2012 03/13/2012	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	BOGUE, JIM	GALLIPOT (FAGRON) - ACTIVE PHARMACEUTICAL INGREDIENT (API) QUALITY CONTROL CMLPNTS
2012-951	02/13/2012	FDA/OGROP/ORACE-FO/PHI-	TED JOACHIMOWSKI	GLOBAL PHARMACEUTICAL SUPPLY GROUP LLC,

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	03/13/2012	DO/PHI-CB/	GLOBAL PHARMACEUTICAL SUPPLY GROUP LLC	MALVERN,PA - EIR 5/20/11
2012-952	02/13/2012 03/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	CRAIG ETHEN SPENCER TECHNOLOGIES	CARDIOYNAMICS - BIOZ RX MODEL 7101-SYS K090602; BIOZDX HEMODYNAMIC MONITOR K041294; IMPEDIMED - EXTRACELLULAR FLUID ANAYZER MODEL L-DEX U400 K100811, ETC
2012-953	02/13/2012 03/13/2012	FDA/OGROP/ORO/PA-FO/SEA-DO/SEA-CB/ FDA/OGROP/ORO/SW-FO/DEN-DO/DEN-CB/	TREVI PIES NUTRITIONAL LABORATORIES INTL	NOVACARE LLC, SALT LAKE CITY, UT - EIR 3/8-22/10; AMERICAN PHARMACEUTICAL & NATURAL FOODS CORP, BILLINGS, MT - EIRS 8/5-6/10
2012-954	02/13/2012 03/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	LISA ANDERSON CONMED CORP	IMAGYN TECHNOLOGIES - REFLEX ESC 5MM SCISSORS K924200/A
2012-955	02/13/2012 03/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVIS #149193, RICHARD	PAXIL (PAROXETINE) - AERS
2012-956	02/13/2012 03/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOANNE S HAWANA ARENT FOX LLP	SEPTOCAINE INJ, AREICAINE HCL - ISR 747802, 7701835, 7600666, ETC
2012-957	02/13/2012 03/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	AMY L GOERSS HODGSON RUSS LLP	3M ESPE DENTAL PRODUCTS - LAVA ULTIMATE IMPLANT CROWN RESTORATIVE K110131
2012-958	02/13/2012 03/13/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	TOMAS JOHANSSON PHD ASTRA TECH AB	COLOPLAST A/S - PERISTEEN ANAL IRRIGATION SYS K083770
2012-959	02/13/2012 03/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	TOMAS JOHANSSON PHD ASTRA TECH AB	COLOPLAST A/S - PERISTEEN ANAL IRRIGATION SYS K103254
2012-960	02/13/2012 03/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	TOMAS JOHANSSON PHD ASTRA TECH AB	ROSTAM LTD - SCENTED AND UNSCENTED BIODEGRADABLE PLASTIC APPLICATOR TAMPONS K102445
2012-961	02/13/2012 03/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FAUST 01B2507, BRIAN	SCHIYOPHRENIA
2012-962	02/13/2012 03/13/2012	OC/OCOS/OL/	JIM BRUNNER SEATTLE TIMES	CORR BETWEEN FDA & US REP JAY INSLEE 1/06 TO 2/9/12
2012-963	02/13/2012	FDA/OMPT/CDER/ORP/DIDP/		LIST OF LABS THAT MAKE GENERIC KEPRA

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	03/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	
2012-964	02/14/2012 03/14/2012	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	BECKMAN COULTER, MIAMI, FL - EIR, 483 2/11-6/11
2012-965	02/14/2012 03/14/2012	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	KEN REID WASHINGTON INFORMATION SOURCE	KBS, CRESCENT SPRINGS, KY - EIR, 483 7/11
2012-966	02/14/2012 03/14/2012	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	KEN REID WASHINGTON INFORMATION SOURCE	INTERNATIONAL ISOTOPES INC, IDAHO FALLS, ID - EIR, 483 7/11
2012-967	02/14/2012 03/14/2012	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	KEN REID WASHINGTON INFORMATION SOURCE	CRESCENDO THERAPEUTICS, VISTA, CA - EIR, 483 4/11
2012-968	02/14/2012 03/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEN REID WASHINGTON INFORMATION SOURCE	NOVARTIS INTERNATIONAL, BASEL, SWITZERLAND - EIR, 483 8/11
2012-969	02/14/2012 03/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEN REID WASHINGTON INFORMATION SOURCE	AKZNO NOBEL CHEMICALS, LOS REYES LA PAZ, MEXICO - EIR, 483 6/11
2012-970	02/14/2012 03/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	MEDICAL COMPRESSION SYSTEM, OR-AKIVA, ISRAEL - EIR, 483 6/11
2012-971	02/14/2012 03/14/2012	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	KEN REID WASHINGTON INFORMATION SOURCE	PN MEDICAL, ORLANDO, FL - EIR, 483 2011
2012-972	02/14/2012 03/14/2012	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	PACE TECH, CLEARWATER, FL - EIR, 483 7/11
2012-973	02/14/2012 03/14/2012	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	KEN REID WASHINGTON INFORMATION SOURCE	DENTAL TENCHOLOGIES INC, LINCOLNWOOD, IL - EIR, 483 3/11-4/11
2012-974	02/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	ROBBI PERRY	SEMLER TECHNOLOGIES INC - COMPRESSAR FEMORAL

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	03/14/2012		NORTH AMERICAN RESCUE LLC	ACCESS COMPRESSION DVC K002767
2012-975	02/14/2012 03/14/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/NE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/	Doe J	INDIVIDUAL RECS
2012-976	02/14/2012 03/14/2012	FDA/OFVM/CFSAN/OCD/EOS/	NATHAN A BEAVER FOLEY & LARDNER LLP	GCJ CHEILJEDANG - D-PSICOSE GRAS 400
2012-977	02/14/2012 03/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Doe J	FENTANYL 72 HR PATCHES - AERS
2012-978	02/14/2012 03/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DANIEL R EVANS MERCHANT & GOULD	CASPOFUNGIN ACETATE INJ ANDA 91-598 - WITHDRAWAL RECS
2012-979	02/14/2012 03/14/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/	CLAUDIA HORNBACK ROANOKE TRADE SERVICES INC	ASIAN EXOTIC GROWERS - ENTRY #FE700049490, FE700050597, FE700049854, ETC NOTICES OF REFUSAL, NOTICE OF REDELIVERY, CF28 & CF29
2012-980	02/14/2012 03/14/2012	FDA/OFVM/CFSAN/OCD/EOS/	RODRIGUEZ, JUAN	COCA LEF EXTRACT (ERYTHROXYN COCA) - ANALYSES, TEST RESULTS, GRAS RECS
2012-981	02/14/2012 03/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FLOYD SKEREN & KELLY LLP	DIFLUCAN (FLUCONAZOLE) TABS - AERS
2012-982	02/14/2012 03/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FREDERICK A STEARNS Keller and Heckman LLP	FLUORIDE DRUG PRODS - APPL, SUPPL, CERTIFICATES 1/09 TO PRESENT
2012-983	02/14/2012 03/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOSHUA SILVERMAN WILLIAMSON PETTY LC	RECOMP PERFORMANCE NUTRITION - HAVOC AERS, MEDWATCH FORMS, COMM, ETC

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/		
2012-984	02/14/2012 03/14/2012	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	BENAVENTE, MARIA	ADVANCE GENERIC CORP, MIAMI, FL - EIRS, 483S 8/10
2012-985	02/14/2012 03/14/2012	OC/CVM/OCD/	KRISTI O. SMEDLEY, Ph.D. WASHINGTON INFORMATION SOURCE	CORR BETWEEN FDA & DSM NUTRITIONAL PRODUCTS
2012-986	02/14/2012 03/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KENNETH REID WASHINGTON INFORMATION SOURCE	SMITHKLINE BEECHAM, WORTHING, UK - 483, EIR, CO RESP 3/11
2012-987	02/14/2012 03/14/2012	FDA/OGROP/ORR/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KENNETH REID WASHINGTON INFORMATION SOURCE	JAZZ PHARMS, PALO ALTO, CA - 483, EIR, CO RESP 4/11 TO 5/11
2012-988	02/14/2012 03/14/2012	FDA/OGROP/ORR/CE-FO/BLT-DO/BLT-CB/ FDA/OC/OES/DFOI/ FDA/OGROP/ORR/CE-FO/CIN-DO/CIN-CB/	KENNETH REID WASHINGTON INFORMATION SOURCE	MEASUREMENT SPECIALTIES INC, HAMPTON, VA - EIR, 483, CO RESP 5/11 TO 7/11
2012-989	02/14/2012 03/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	ROCKET MEDICAL, TYNE & WEAR, UK - 483, EIR, CO RESP 7/11
2012-990	02/14/2012 03/14/2012	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	KENNETH REID WASHINGTON INFORMATION SOURCE	LESLIE E DIAZ MD, NORTH PALM BEACH - 483, EIR, CO RESP 1/11 TO 3/11
2012-991	02/14/2012 03/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PAMELA SCHANEEN SHIONOGI INC	ESTRACE - VAGINAL CREAM ANDA 86-069 SBA
2012-992	02/14/2012 03/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PAMELA SCHANEEN SHIONOGI INC	ESTRING - VAGINAL RING SBA

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2012-993	02/14/2012 03/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	BARRY MEIER NEW YORK TIMES	LTR SENT FROM FDA TO DEPUY ORTHOPAEDICS 8/13/09
2012-994	02/14/2012 03/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PAMELA SCHANEEN SHIONOGI INC	VAGIFEM - APRVL
2012-995	02/14/2012 03/14/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SE-FO/ATL- DO/ATL-CB/	GISENDANNER, ROBIN	CMPLNT 120110
2012-996	02/14/2012 03/14/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OGROP/ORO/ORO/DIOP/ FDA/OC/OES/DFOI/	BRAD RACINO INVESTIGATIVE NEWSOURCE	IMPORTED & EXPORTED WHOLE HUMAN BLOOD PRODUCTS 3002905110
2012-997	02/14/2012 03/14/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OC/OES/DFOI/	BRAD RACINO INVESTIGATIVE NEWSOURCE	EMAILS SENT TO CBER STAFF REGARDING BLOOD PRODUCTS FROM MEXICO
2012-998	02/14/2012 03/14/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	DIETMAR WITTMANN, MD, PhD, FACS APERTA LLC	K093166
2012-999	02/14/2012 03/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LAUREN TORNETTA ENDO PHARMACEUTICALS	NUCYNTA ER (TAPENTADOL HYDROCHLORIDE) NDA 00-533 APRL
2012-1000	02/14/2012 03/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	MIKE NIKITAS NEW ENGLAND CABLE NEWS	NUCLEA BIOTECHNOLOGIES , WILMINGTON, DE - PRESS RELEASE
2012-1001	02/15/2012 03/15/2012	FDA/OGROP/ORO/CE-FO/NWJ- DO/NWJ-CB/	WILLIAM R. PINIZIO WOLFF SAMSON PC	RAM MEDICAL, WAYNE, NJ - EIR 9/18-25/07
2012-1002	02/15/2012 03/15/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/ FDA/OC/OES/DFOI/	ANNA DEMKOVIC ABBOTT LABORATORIES, INC.	CMPLNT 123977

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		FDA/OGROP/ORPA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/		
2012-1003	02/15/2012 03/15/2012	OC/ORPA/ OC/ORPA/ FDA/OGROP/ORASORO/DIOP/	ANUJ DESAI ARNALL GOLDEN & GREGORY, LLP	JITC LLC, ROBERT JANITZEK, I-GRAIN LLC, ETC - CHIA SEEDS (SALVIA HISPANICA) SHIPMENT PERMITS, LICENCES, PACKING LISTS, ETC
2012-1004	02/15/2012 03/15/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ARETA L KUPCHYK NIXON PEABODY LLP	WARTSON - INFED (LOW-MOLECULAR WEIGHT IRON DEXTRAN); AMAG - FERAHEME (FERUMOXYTOL) AERS 10/09 TO 6/10
2012-1005	02/15/2012 03/15/2012	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	2011-2016, 2011-5188, 2011-5375, ETC
2012-1006	02/15/2012 03/15/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ARETA KUPCHYK NIXON PEABODY LLP	AMERICAN REGENT - VENOFER (IRON SUCROSE), DEXFERRUM (HIGH MOLECULAR WEIGHT IRON DEXTRAN); SANOFI-AVENTIS - FERRLECIT (SODIUM FERRIC GLUCONATE) AERS 10/09 TO 6/10
2012-1007	02/15/2012 03/15/2012	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	2011-2934, 2011-2951, 2011-3200, ETC
2012-1008	02/15/2012 03/15/2012	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	2011-9081, 9082, 9083, ETC
2012-1009	02/15/2012 03/15/2012	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	2011-9339, 2011-9342, 2011-9345, ETC
2012-1010	02/15/2012 03/15/2012	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	2011-3869, 2011-3871, 2011-3872, ETC
2012-1011	02/15/2012 03/15/2012	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	2011-4142, 2011-4269, 2011-4296, ETC
2012-1012	02/15/2012 03/15/2012	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	2011-4963, 2011-5033, 2011-5034, ETC

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2012-1013	02/15/2012 03/15/2012	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	2011-5328, 2011-5331, 2011-5342, ETC
2012-1014	02/15/2012 03/15/2012	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	2011-5831, 2011-5832, 2011-5837, ETC
2012-1015	02/15/2012 03/15/2012	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	2011-6349, 2011-6364, 2011-6365, ETC
2012-1016	02/15/2012 03/15/2012	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	2011-6402, 2011-6403, 2011-6404, ETC
2012-1017	02/15/2012 03/15/2012	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	2011-6509, 2011-6510, 2011-6511, ETC
2012-1018	02/15/2012 03/15/2012	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	2011-6843, 2011-6996, 2011-7036, ETC
2012-1019	02/15/2012 03/15/2012	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	2011-8315, 2011-8347, 2011-8613, ETC
2012-1020	02/15/2012 03/15/2012	FDA/OMPT/CDRH/OCER/DFOI/	CARRELL, SCOTT H	OTC TENS - K063660
2012-1021	02/15/2012 03/15/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORPA/FO/LOS-DO/LOS-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SUSAN H WEINKLE MD American Society for Dermatologic Surgery Association	DERMATEND - INVESTIGATION CORR 9/11
2012-1022	02/15/2012 04/25/2012	FDA/OMPT/CDRH/OCER/DFOI/	KALVARIA, HYLTON	NATURE'S CRADLE - K9702334, K951024, K901763, ETC
2012-1023	02/15/2012 03/15/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID PATTON PATTON LAW PRACTICE	LIDOCAINE INJ - AERS 2004 TO 2012

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2012-1024	02/15/2012 03/15/2012	FDA/OMPT/CDRH/OCER/DFOI/	CHARLES LIU DONGGUAN NTC CO LTD	DONGGUAN GOLDYIP ELECTRONIC SCIENCE & TECH CO LTD - PORTABLE STEREO CD/MP3 PLAYER WITH AM/FM RADIO LASER PROD RPT
2012-1025	02/15/2012 03/15/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/	NANCY HIGLEY PHD PEPSICO	PEPSICO, BRADENTON, FORT PIERCE - SPLS 687768, 687769, 68770, ETC SUMMARY RPTS
2012-1026	02/15/2012 03/15/2012	OC/OM/OMP/DDM/	ANICE N. JAMISON MCDERMOTT WILL & EMERY	DKT LOG 1990N-0165
2012-1027	02/15/2012 03/15/2012	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	SUZIE KESCHAMRUS AVANIR PHARMS	AVANIR PHARMS - NUEDEXTA AERS, SAFETY RPTS
2012-1028	02/15/2012 03/15/2012	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	SHIPMAN, KIM	ISRS 3011056, 3022350, 3030326, ETC
2012-1029	02/15/2012 03/15/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	CARRELL, SCOTT H	OTC TENS - K052785
2012-1030	02/15/2012 03/15/2012	OC/CVM/OCD/	RUTH LAMLEY BAYER HEALTHCARE ANIMAL HEALTH DIVISION	NOVARTIS ANIMAL HJEALTH US INC - SENTINEL SPECTRUM (MILBEMYCIN OXIME, LUFENURON, PRAZQUANTEL) NADA 141-333 FOI SUMMARY
2012-1031	02/15/2012 03/15/2012	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	CHARLES CELESTE EAS Consulting Group, LLC	ISOSORBIDE MONOITRATE ER TABS ANDA 75-155 - APRVL LTR, LBLG, MOR, ETC
2012-1032	02/16/2012 03/16/2012	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	JOHN J HAY SALANS ATTY	WYETH MEDICA, IRELAND - 483 4/24/09

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2012-1033	02/16/2012 03/16/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN J HAY SALANS ATTY	WATSON PHARMA PRIVATE LTD, VERNA, GOA, INDIA - 483 2/2/11
2012-1034	02/16/2012 03/16/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN J HAY SALANS ATTY	PFIZER GMBH, MOOSWALDALLE, GERMANY - 6/30/11; PFIZER HEALTH AB, STRANGNAS, SWEDEN - 1/27/11; PFIZER, IRELAND PHARMA, ETC - 483S 6/17/11
2012-1035	02/16/2012 03/16/2012	FDA/OMPT/CDRH/OCER/DFOI/	M RHEA LEE DUFFY & PARTNERS	I-FLOW CORP - K97217, K980558, K982946, ETC
2012-1036	02/16/2012 03/16/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HARTWELL P MORSE III HUSCH BLACKWELL LLP	MYLAN PHARMA - IBANDRONATE SODIUM TABS ORAL NDA 78-995 APRVL LTR 12/28/09
2012-1037	02/16/2012 03/16/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HUANG, ED	ACCORD - TAROLIMUS ANDA 91-195; ACCORD - MYCOPHENOLATE MOFETIL ANDA 90-253; ABBOTT - CYCLOSPORINE ANDA 65-003, ETC BIOEQV
2012-1038	02/16/2012 03/16/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FREDERICK A STEARNS Keller and Heckman LLP	FLUORIDE DRUG PRODS NOT APRVD FOR MARKETING IN USA & NOT COVERED BY AN OTC DRUG MONOGRAPH - APPL, SUPPL. CORR, ETC
2012-1039	02/16/2012 03/16/2012	FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	HENRY F BAYARD CSK Labs	CHRONISCRIPIT INC, WALGREENS, MIAMI, FL - INCIDENT RPTS, INVESTIGATION RPTS, CALLS, ETC
2012-1040	02/16/2012 03/16/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	JOHN F FINNERTY JR FINNERTY LAW OFC	DEPUY ORTHOPAEDICS INC - ASR XL ACETUBULAR SYS ARTIFICIAL HIP IMPLANTS, PINNACLE SECTOR II ACETABULAR CUP SYS ARTIFICIAL HIP IMPLANTS - NAMES, ADDRESSES, INDIVIDUALS WHO HAVE SUBMITTED CMLPNTS
2012-1041	02/16/2012 03/16/2012	FDA/OFVM/CFSAN/OCD/EOS/	MCKEEVER, STEVE	A- AMERICAN SELF STORAGE, CHERRY VALLEY, IL - CERTIFICATION OR REGISTRATION NUMBER
2012-1042	02/16/2012 03/16/2012	FDA/OFVM/CFSAN/OCD/EOS/	ANNA DEMKOVIC ABBOTT LABORATORIES, INC.	NESTLE - GOOD START SOOTHE PROD ATTACHMENTS, EXHIBITS, MINS, ETC
2012-1043	02/16/2012	FDA/OMPT/CDER/ORP/DIDP/	JOHN J HAY	BRISTOL-MYERS SQUIBB, ANAGNI, ITALY - 483 3/15/11

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	03/16/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SALANS ATTY	
2012-1044	02/16/2012 03/16/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/	Doe J	INDIVIDUAL RECS
2012-1045	02/16/2012 03/16/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN J HAY SALANS ATTY	HOSPIRA AUSTRALIA PTY, MULGRAVE, AUSTRALIA 3/21/11; HOSPIRA HEALTHCARE INDIA PVT LTD, SRIPERUMBUDUR, INDIA 3/30/11; ZYDUS HOSPIRA ONCOLOGY PVT LTD, AHMEDABAD, INDIA 11/10/09 - 483S
2012-1046	02/16/2012 03/16/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PETER GALLAGHER ZIFF BROTHERS INVESTMENTS	HEALTH CARE PROFESSIONAL CMLPNT LTRS - DRUG, DATE OF CMLPNT, MARKETING VIOLATION 2008 TO PRESENT
2012-1047	02/16/2012 03/16/2012	FDA/OMPT/CTP/OD/	MICHAEL GIVEL UNIV OF OKLAHOMA POLITICAL SCIENCE DEPT	TOBACCO PROD SCIENTIFIC A/C RPT, 7/21/11 - POLICY/PLANNING RECS, RPTS, COMM ETC
2012-1048	02/16/2012 03/16/2012	FDA/OFVM/CFSAN/OCD/EOS/	GRREG THOMPSON GENERAL MILLS	MARS INC - DKT # FDA-2011-C-0878
2012-1049	02/16/2012 03/16/2012	FDA/OC/OES/DFOI/	FRANCES WONG CANACCORD GENUITY	AVANIR - NUJEXETA (DEXTROMETHORPHAN HYDROBROMIDE & QUINIDINE SULFATE), FOIA REQUESTS 1/1/11 TO PRESENT
2012-1050	02/16/2012 03/16/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN J HAY SALANS ATTY	MERCK SERONO SPA, MODUGNO, ITALY 7/16/10; MERCK SHARP & DOHME (SINGAPORE) LTD, SINGAPORE 7/3/09; LABORATORIES MERCK SHARP & DOHME-CHIBRET, SAINT GERMAIN LAPRADE, FRANCE 5/27/11, ETC - 483S
2012-1051	02/16/2012 03/16/2012	FDA/OC/OES/DFOI/	JOHN J HAY SALANS LLP	2011-6955
2012-1052	02/16/2012 03/16/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	ADDERALL - AERS
2012-1053	02/16/2012	OC/ORO/	ALLEN WELCH	MARS PETCARE US, FORT SMITH, AR - SPL 677735 SUMMARY

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	03/16/2012	OC/ORA/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	MARS PETCARE US	
2012-1054	02/16/2012 03/16/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	M WADE SPARKS JENSEN & ASSOCIATES PLLC	IBUPROFEN - AERS
2012-1055	02/16/2012 03/16/2012	FDA/OMPT/CDRH/OCER/DFOI/	RICHARD BALL QIIMAGING LLC	GEN1100056 - INVESTIGATION RESULTS
2012-1056	02/16/2012 03/16/2012	FDA/OGROP/ORASW-FO/DET-DO/DET-CB/ FDA/OC/OES/DFOI/	JOHN GILLINGS COLLINS STEWART LLC	ZIMMER INC - 483S, (FEI:1000220733), CORR
2012-1057	02/16/2012 03/16/2012	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	AMANDA NERONE HEARTLAND LIONS EYE BANKS	VRL LABS, CENTENNIAL, CO - EIRS, 483S 2001
2012-1058	02/16/2012 03/16/2012	FDA/OFVM/CFSAN/OCDEOS/	JOHN DOHERTY IOVATE HEALTH SCIENCES INTERNATIONAL INC	JACKED, HEMO RAGE, HEMORUSH, ETC - CAERS 11/11/11 TO PRESENT
2012-1059	02/16/2012 03/16/2012	FDA/OFVM/CFSAN/OCDEOS/	JOHN DOHERTY IOVATE HEALTH SCIENCES INTERNATIONAL INC	HERB ROBERT, RED ROBIN, CRANESBILL, ETC - CAERS 11/11/11 TO PRESENT
2012-1060	02/16/2012 03/16/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SCOTT #JY1512/L-27, SEAN	SEROQUEL, AMBIEN, ATIVAN, DEPAKOTE - AERS
2012-1061	02/16/2012 03/16/2012	FDA/OC/OES/DFOI/	DR PETER D FOSTER HUHTAMAKI INC	2008-3976, 2008-3977
2012-1062	02/16/2012 03/16/2012	OC/ORA/ OC/ORA/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	ALLEN WELCH MARS PETCARE US	MARS PETCARE US, FORT SMITH, AR - SPL 728890 SUMMARY
2012-1063	02/16/2012 03/16/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	ALAN KATZ BLOOMBERG NEWS	TCA CELLULAR THERAPY - WARNING LTR RESP, CO RESP 4/19/11, TRANS, EMAILS, ETC
2012-1064	02/16/2012 03/16/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GREG POWELL GlaxoSmithKline	BELIMUMAB - ISRS 7635482, 7729932, 7730830, ETC

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		FDA/OMPT/CDER/ORP/DIDP/		
2012-1065	02/16/2012 03/16/2012	FDA/OFVM/CFSAN/OCD/EOS/	HALEY CURTIS STEVENS PHD CALORIE CONTROL COUNCIL	CALORIE CONTROL COUNCIL MTG - MINS 2/7/12
2012-1066	02/16/2012 03/16/2012	OC/ORAO/OCI/ OC/ORAO/OCI/	SHAUN ASSAEL ESPN THE MAGAZINE	LANCE ARMSTRONG INVESTIGATION CLOSURE RECS; JEFF NOVITZKY EXPENSE RECS, 2011 TO PRESENT
2012-1067	02/16/2012 03/16/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ OC/ORAO/ OC/ORAO/ FDA/OGROP/ORAO/CE-FO/BLT- DO/BLT-CB/ OC/ORAO/ OC/ORAO/	DIANE HEMINWAY UNITED STEELWORKERS	AMERICAN RED CROSS - CORR 1/14/12 TO PRESENT
2012-1068	02/16/2012 03/16/2012	FDA/OMPT/CDRH/OCER/DFOI/	ANDREW PROCHAZKA REHABTRONICS INC	NESS H200 WIRELESS HAND REHAB SYS USER KIT & CLINICAN KIT - K111767
2012-1069	02/16/2012 03/16/2012	OC/ORAO/ OC/ORAO/ OC/OCM/EMOPS/ FDA/OC/OES/DFOI/	SALES, BEN	PISTACHIO PRODUCT OUTBREAK 6/09 - SAFETY AUDIT
2012-1070	02/16/2012 03/16/2012	OC/ORAO/ OC/ORAO/ FDA/OGROP/ORAO/PA-FO/LOS- DO/LOS-CB/	SALES, BEN	TACO BELL CORP, E. COLI OUTBREAK 11/06 - SAFETY AUDIT
2012-1071	02/16/2012 03/16/2012	OC/ORAO/ OC/ORAO/ FDA/OGROP/ORAO/CE-FO/BLT- DO/BLT-CB/	SALES, BEN	NESTLE SA, E COLI OUTBREAK 6/09 - SAFETY AUDIT
2012-1072	02/16/2012 03/16/2012	OC/ORAO/ OC/ORAO/ FDA/OFVM/CFSAN/OCD/EOS/	SALES, BEN	CONTAMINATION OF RAW ALFALFA SPROUTS 4/09 - FOOD SAFETY AUDIT
2012-1073	02/16/2012 03/16/2012	OC/ORAO/ OC/ORAO/ FDA/OGROP/ORAO/SE-FO/ATL- DO/ATL-CB/	SALES, BEN	CASTLEBERRY FOOD PRODUCT 7/07 - FOOD SAFETY AUDIT
2012-1074	02/16/2012	OC/ORAO/	JoNel Aleccia	Date Range: 06/01/2011 - 02/10/2012; FDA Office of Regulatory

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	03/16/2012	OC/ORO/ OC/CVM/OCD/ OC/OCM/EMOPS/ FDA/OGROP/ORO/ORO/DIOP/ FDA/OFVM/CFSAN/OCD/EOS/	MSNBC.COM	Affairs assignment for sampling and testing chicken jerky treats imported from China. Msnbc.com seeks any and all documents related to the ORA assignment to sample and test chicken jerky pet treats imported from China.
2012-1075	02/16/2012 03/16/2012	FDA/OC/OES/DFOI/	Joan Stitt, UG2CD-16 MERCK & CO., INC.	"A list of all FOIA requests closed 1/1-31/2012" on CD
2012-1076	02/16/2012 03/16/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/	SALES, BEN	DOLE FOOD COMPANY, E COLI IN SPINICH 9/06 - FOOD SAFETY AUDIT
2012-1077	02/16/2012 03/16/2012	FDA/OC/OES/DFOI/	Joan Stitt, UG2CD-16 MERCK & CO., INC.	FOI DAILY LOG 2/6-10/2012;
2012-1078	02/16/2012 03/16/2012	FDA/OC/OES/DFOI/	Joan Stitt, UG2CD-16 MERCK & CO., INC.	FOI DAILY LOG 1/30/2012- 2/3/2012
2012-1079	02/16/2012 03/16/2012	OC/OM/OMP/DDM/	ANICE JAMISON MCDERMOTT WILL & EMERY	DKT FDA-1990-N-0033
2012-1080	02/16/2012 03/16/2012	OC/ORO/ OC/ORO/ FDA/OFVM/CFSAN/OCD/EOS/	SALES, BEN	SALMONELLA SAINTPAUL 6/08 - FOOD SAFETY AUDIT
2012-1081	02/16/2012 03/16/2012	OC/ORO/OCI/ OC/ORO/OCI/	SALES, BEN	SHELL EGG UPDATE 8/10 - AUDIT REPORT
2012-1082	02/16/2012 03/16/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/	MICHELLE RYBAK ROANOKE TRADE SERVICES INC	PANAMERICAN FOOD CORP - ENTRY NO J3700068268 NOTICES OF REFUSAL, FDA ACTION, NOTICE OF MARK/REDELIVER
2012-1083	02/16/2012 03/16/2012	FDA/OFVM/CFSAN/OCD/EOS/	TAMI L. WAHL Traditional Medicinals, Inc.	CAERS # 146931
2012-1084	02/16/2012 03/16/2012	OC/OCS/OCP/ FDA/OMPT/OSMP/OCP/	DAN GOTTLIEB EPSTEIN BECKER & GREEN PC	REQUEST FOR DISIGNATION (RFD) REDACTED JURISDICTIONAL DECISION LTS 2007
2012-1085	02/16/2012 03/16/2012	OC/OCS/OCP/ FDA/OMPT/OSMP/OCP/	DAN GOTTLIEB EPSTEIN BECKER & GREEN PC	REQUEST FOR DESIGNATION (RFD) REDACTED JURISDICTIONAL DECISION LTRS FOR 2008
2012-1086	02/16/2012 03/16/2012	OC/OCS/OCP/ FDA/OMPT/OSMP/OCP/	LEAH R. KENDALL EPSTEIN BECKER & GREEN PC	REQUEST FOR DESIGNATION (FRD) REDACTED JURISDICTIONAL DECISION LTRS 2009

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2012-1087	02/16/2012 03/16/2012	OC/OCS/OCF/ FDA/OMPT/OSMP/OCF/	DAN GOTTLIEB EPSTEIN BECKER & GREEN PC	REQUEST FOR DESIGNATION (RFD) REDACTED JURISDICTIONAL DECISION LTRS 2010
2012-1088	02/16/2012 03/16/2012	OC/OCS/OCF/ FDA/OMPT/OSMP/OCF/	DAN GOTTLIEB EPSTEIN BECKER & GREEN PC	REQUEST FOR DESIGNATION (RFD) REDACTED JURISDICTIONAL DECISION LTRS 2011
2012-1089	02/16/2012 03/16/2012	FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/	J. ROBERT YEOMAN B & R COMPLIANCE ASSOCIATES LLC	GENERAL CHEMICAL LLC, MIDLOTHIAN, TX; BERKELEY HEIGHTS, NJ -EIRS 6/03 TO 1/12
2012-1090	02/16/2012 03/16/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORASE-FO/FLA- DO/FLA-CB/ FDA/OC/OES/DFOI/	PATRICK J. HIGGINS POWERS & SANTOLA	INVACARE, SANFORD, FL - CORR 8/10 TO PRESENT
2012-1091	02/16/2012 03/16/2012	FDA/OMPT/CDRH/OCER/DFOI/	AYA AMEMIYA SEIKO EPSON CORP	ERBE USA INC - ERBEJET 2 SYS K072404
2012-1092	02/16/2012 03/16/2012	FDA/OMPT/CDRH/OCER/DFOI/	GEORGE REED MEDICA HEALTH SERVICES LLC	RC CORNET MODEL 44F50 K983308
2012-1093	02/16/2012 03/16/2012	FDA/OMPT/CDRH/OCER/DFOI/	CYNTHIA C. LLAMAS HICKS AND LLAMAS	HAKOMED - ELECT PROELECTDT K980892
2012-1094	02/16/2012 03/16/2012	OC/ORAC/ OC/ORAC/ FDA/OGROP/ORAPA-FO/SEA- DO/SEA-CB/	MICHAEL B. KIVORT BREWER LAW GROUP PLLC	CMPLNT 124462
2012-1095	02/16/2012 03/21/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORASW-FO/KAN- DO/KAN-CB/ FDA/OGROP/ORACE-FO/DET- DO/DET-CB/	BECKY COOSEMAN BROWN & CROUPPEN PC	INDIVIDUAL RECS
2012-1096	02/16/2012 03/20/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	BAYER, RICHARD D	BLOOD PRODUCT A/C - EMAILS 7/08 TO 9/08; 6/10 TO 7/10
2012-1097	02/17/2012 03/19/2012	FDA/OC/OES/DFOI/	R IAN KLUGE Hyman, Phelps & McNamara, P.C.	2008-6691, 2008-4833, 2007-6715, ETC
2012-1098	02/17/2012 03/19/2012	FDA/OGROP/ORASW-FO/DEN- DO/DEN-CB/	JONATHAN RICKMAN FDA NEWS	XLEAR INC, OREM,UT; ORALABS INC, PARKER, CO; BIOMERIDIAN INTL INC, SALT LAKE CITY, UT - 483S 11/1- 30/11
2012-1099	02/17/2012 03/19/2012	FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/	JONATHAN RICKMAN FDANEWS	CUSTOM INTERVENTIONAL PAIN MANAGEMENT LLC, SAN ANTONIO, TX - 483S 11/1-30/11

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2012-1100	02/17/2012 03/19/2012	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	JONATHAN RICKMAN FDA NEWS	ALKERMES INC, WILMINGTON, OH; OSTEOSYMBIONICS LLC, CLEVELAND, OH; TRANSMOTION MEDICAL INC, SHARON CENTER, OH, ETC - 483S 11/1-30/11
2012-1101	02/17/2012 03/19/2012	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	JONATHAN RICKMAN FDA NEWS	SAGE PRODUCTS, CARY, ILL; ORGAN RECOVERY SYSTEMS INC, ITASCA, IL; THYSSENKRUPP ACCESS MFG LLC, ROANOKE,IL, ETC - 483S 11/1-30/11
2012-1102	02/17/2012 03/19/2012	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	JONATHAN ROCKMAN FDANEWS	AMERICAN RED CROSS DIAGNOSTIC MFG DIV, GAITHERSBURG,MD; CHEMPACIFIC CORP, BALTIMORE, MD; C-CARE LLC, LINTHICUM HEIGHTS, MD, ETC - 483S 11/1-30/11
2012-1103	02/17/2012 03/19/2012	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	JONATHAN RICKMAN FDA NEWS	ANDERSEN STERILIZERS INC, HAW RIVER, NC; SMISSON-CARTLEDGE BIOMEDICAL LLC,MACON,GA; SHERTECH LABORATORIES LLC, DUNCAN, SC, ETC - 483S 11/1-30/11
2012-1104	02/17/2012 03/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	SORIN GROUP DEUTSCHLAND GMBH, MUNCHEN, GERMANY - EIR, 483, WARNING LTR, ETC 4/11-13/11
2012-1105	02/17/2012 03/19/2012	OC/OA/OM/OMP/DDM/	FOI Services, Inc.	JOINT MTG OF THE GASTROINTESTINAL DRUGS A/C & THE DRUG SAFETY & RISK MANAGEMENT A/C - TYSABRI (NATALIZUMAB) FOR CROHN'S DISEASE 7/31/07
2012-1106	02/17/2012 03/19/2012	OC/OA/OM/OMP/DDM/	FOI Services, Inc.	PERIPHERAL AND CENTRAL NERVOUS SYSTEMS DRUGS A/C - TRANS 3/7-8/06
2012-1107	02/17/2012 03/19/2012	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	FOI Services, Inc.	DR EDWARD KAPLAN MD, RUSH-PRESBYTERIAN ST LUKES MEDICAL CENTER, CHICAGO, IL - EIR, 483, WARNING LTR, ETC 2/6/91 TO 10/27/05
2012-1108	02/17/2012 03/19/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FOI Services, Inc.	JANSSEN PHARMS - NUCYNTA ER (TAPENTADOL HCL) NDA 200-533 APRVL RECS
2012-1109	02/17/2012 03/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	INNOVAMED USA INC - DETRUSAN 500 K994109
2012-1110	02/17/2012 03/19/2012	FDA/OGROP/ORACE-FO/PHIDO/PHI-CB/	FOI Services, Inc.	DR SHELLY KAFKA MD, ALTOONA ARTHRITIS AND OSTEOPOROSIS CENTER ALTOONA CENTER FOR CLINICAL RSEARCH, DUNCANVILLE, PA - 483S 2/00 TO 8/05
2012-1111	02/17/2012 03/19/2012	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	JOHNATHAN RICKMAN FDA NEWS	PAINEXX CORP, DETROIT, MI; CORIUM INTL INC, GRAND RAPIDS, MI; MICH CLONE ASSOC INC, MADISON HEIGHTS, MI - 483 11/11
2012-1112	02/17/2012 03/19/2012	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	JOHNATHAN RICKMAN FDA NEWS	DEEPAK PRODUCTS INC, MIAMI, FL; VIRTUAL IMAGING INC, DEERFIELD BEACH, FL; AVOTEC INC, STUART, FL - 483 11/11

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2012-1113	02/17/2012 03/19/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	JOHNATHAN RICKMAN FDA NEWS	MEKOS LABS APS, HILLEROD, DENMARK; MEDMIRA LABS INC, HALIFAX, CANADA; ALK ABELLO AS, HORSHOLM, DENMARK - 483 11/11
2012-1114	02/17/2012 03/19/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHNATHAN RICKMAN FDA NEWS	MITSUBISHI TANABE PHARMA FACTORY LTD, SANYO ONODA, JAPAN; MERCK SHARP & DOHME, SINGAPORE; JURON PTY LTD, RUTHERFORD, AUSTRALIA - 483 11/11
2012-1115	02/17/2012 03/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	JOHNATHAN RICKMAN FDA NEWS	ANSAMED LTD, BOYLE, IRELAND; FUKUDA DENSHI CO LTD, TOKYO, JAPAN; SUHOU SEN SEN MEDICAL SUPPLIES LTD, SUZHOU, JIANGSU, CHINA - 483 11/11
2012-1116	02/17/2012 03/19/2012	FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/	JOHNATHAN RICKMAN FDA NEWS	GLAXO SMITH KLINE CONSUMER HEALTHCARE, ST. LOUIS, MO; C&S ELECTRONICS INC, COLUMBUS, NE; MASTERCARE PATIENT EQUIP INC, COLUMBUS, NE - 483 11/11
2012-1117	02/17/2012 03/19/2012	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	JOHNATHAN RICKMAN FDA NEWS	MERIT CABLES INC, SANTA ANA, CA; CRANIAL TECHNOLOGIES INC, TEMPE, AZ; KERR CORP, ORANGE, CA - 483 11/11
2012-1118	02/17/2012 03/19/2012	FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/	JOHNATHAN RICKMAN FDA NEWS	TUFECO TECHNOLOGIES INC, GREEN BAY, WI; BIRCHWOOD LABS INC, EDEN PRAIRIE, MI; CHEM RITE COPAC INC, LANNON, WI - 483 11/11
2012-1119	02/17/2012 03/19/2012	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	JOHNATHAN RICKMAN FDA NEWS	AGFA HEALTHCARE CORP, WESTERLY, RI; FRESENIUS MEDICAL CARE HOLDINGS INC, WALTHAM, MA; ZOLL MEDICAL CORP, CHELMSFORD, MA - 483 11/11
2012-1120	02/17/2012 03/19/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 2/6-10/12
2012-1121	02/17/2012 03/19/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI CLOSED REQUESTS 1/30/12-2/3/12
2012-1122	02/17/2012 03/19/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI CLOSED REQUESTS 1/23-27/12
2012-1123	02/17/2012 03/19/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI CLOSED REQUESTS 1/30/12-2/3/12
2012-1124	02/17/2012 03/19/2012	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	JOHNATHAN RICKMAN FDA NEWS	ROCHE MOLECULAR SYS INC, BRANCHBURG, NJ; ELECTRIC MOBILITY CORP, SEWELL, NJ; AUROLIFE PHARMA LLC, DAYTON, NJ - 483 11/11
2012-1125	02/17/2012 03/19/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI CLOSED REQUESTS 1/23-27/12

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2012-1126	02/17/2012 03/19/2012	FDA/OGROP/ORА/SE-FO/NOL-DO/NOL-CB/	JOHNATHAN RICKMAN FDA NEWS	CROWN LABS INC, JOHNSON CITY, TN; HEALZ PLUS INC, SULPHUR, LA; ORALDNA LABS, BRENTWOOD, TN - 483 11/11
2012-1127	02/17/2012 03/19/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOI REQUESTS 1/23-27/12
2012-1128	02/17/2012 03/19/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOI REQUESTS 1/30/12-2/3/12
2012-1129	02/17/2012 03/19/2012	FDA/OGROP/ORА/NE-FO/NYK-DO/NYK-DCB/	JOHNATHAN RICKMAN FDA NEWS	INFIMED INC, LIVERPOOL, NY; IVOCLAR VIVADENT INC, BUFFALO, NY; REICHART INC, DEPEW, NY - 483 11/11
2012-1130	02/17/2012 03/19/2012	FDA/OGROP/ORА/CE-FO/PHI-DO/PHI-CB/	JOHNATHAN RICHMAN FDA NEWS	BOEHRINGER LABS INC, PHOENIXVILLE, PA - 483 11/11
2012-1131	02/17/2012 03/19/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOI REQUESTS 2/6-10/12
2012-1132	02/17/2012 03/19/2012	FDA/OGROP/ORА/PA-FO/SAN-DO/SAN-CB/	JOHNATHAN RICKMAN FDA NEWS	BIO MARIN PHARMS INC, NOVATO, CA; BIOZONE LABS INC, PITTSBURG, CA; XEMAX SURGICAL PRODUCTS INC, NAPA, CA - 483 11/11
2012-1133	02/17/2012 03/19/2012	FDA/OGROP/ORА/PA-FO/SEA-DO/SEA-CB/	JOHNATHAN RICKMAN FDA NEWS	NEUROCYBERNETICS INC, BELLVUE, WA; CASCADIA MANUFACTURING INC, BELLVUE, WA; MELALUECA INC, IDAHO FALLS, ID - 483 11/11
2012-1134	02/17/2012 03/19/2012	FDA/OGROP/ORА/SE-FO/SJN-DO/SJN-CB/	JOHNATHAN RICKMAN FDA NEWS	BAXTER HEALTHCARE CORP, JAYUYA, PR; CLINICAL MEDICAL SERVICES INC, CAROLINA, PR; ETHICON LLC, SAN LORENZO, PR - 483 11/11
2012-1135	02/21/2012 03/20/2012	OC/OA/OM/OMP/DDM/	FOI Services, Inc.	PERIPHERAL & CENTRAL NERVOUS SYSTEM DRUGS A/C - MINS 3/7-8/06 (CERTIFIED)
2012-1136	02/21/2012 03/20/2012	FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/	FOI Services, Inc.	EXTAVIA (INTERFERON BETA-1B) - AERS (CERTIFIED)
2012-1137	02/21/2012 03/20/2012	FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/	FOI Services, Inc.	REBI (NTERFERON BETA-1A)- AERS (CERTIFIED)
2012-1138	02/21/2012 03/20/2012	FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/	FOI Services, Inc.	GILENYA (FINGOLIMOD) - AERS (CERTIFIED)

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2012-1139	02/21/2012 03/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	COPAXONE (GLATRAME ACETATE) - AERS (CERTIFIED)
2012-1140	02/21/2012 03/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	AVONEX (INTERFERON BETA 1-A) - AERS (CERTIFIED)
2012-1141	02/21/2012 03/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	BETASERON (INTERFERON BETA-1B) - AERS (CERTIFIED)
2012-1142	02/21/2012 03/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	ADCETRIS (BRENWTUXIMAB VEDOTIN) - AERS (CERTIFIED)
2012-1143	02/21/2012 03/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	WOCKHARDT - BROMFED-DM (BROMPHENIRAMINE MALEATE; DEXTROMETHORPHAN HYDROBROMIDE; PSEUDOEPHEDRINE HCL) ANDA 88-811 APRVL PKG 6/7/85
2012-1144	02/21/2012 03/20/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	FDA DRUG SAFETY PODCAST FOR HEALTHCARE PROFESSIONAL; SAFETY UPDATES ON PROGRSSIVE MULTIFOCAL LEUKONENCEPHALOPAHTY (PAL) ASOCIATED WISTH TYSABRI (NATAIZUMAB) 4/26/11 (CERTIFIED)
2012-1145	02/21/2012 03/20/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	FDA DRUG SAFETY PODCAST FOR HEALTHCARE PROFESSIONAL; SAFETY UPDATES ON PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY (PAL) ASSOCIATED WITH TYSABRI (NATAZUMAB) 4/26/11 (CERTIFIED)
2012-1146	02/21/2012 03/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HARTWELL P MORSE III HUSCH BLACKWELL LLP	COBALT LABS INC - IBANDRONATE SODIUM TABS ORAL NDA 79-002 APRVL LTR 3/15/11
2012-1147	02/21/2012 03/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HARTWELL P MORSE III HUSCH BLACKWELL LLP	COBALT LABS INC - IBANDRONATE SODIUM TABS ORAL NDA 79-003 APRVL LTR 3/15/11

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2012-1148	02/21/2012 03/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HARTWELL P MORSE III HUSCH BLACKWELL LLP	ORCHID HEALTHCARE - IBANDRONATE SODIUM TABS ORAL NDA 78-998 APRVL LTR 12/29/09
2012-1149	02/21/2012 03/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HARTWELL P MORSE III HUSCH BLACKWELL LLP	COBALT LABS INC - IBANDRONATE SODIUM TABS ORAL NDA 79-003 APRVL LTR 1/4/10
2012-1150	02/21/2012 03/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HARTWELLL P MORSE III HUSCH BLACKWELL LLP	MUTUAL PHARM CO INC - IBANDRONATE SODIUM TABS ORAL NDA 78-996 APRVL LTR 12/13/11
2012-1151	02/21/2012 03/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HARTWELL P MORSE III HUSCH BLACKWELL LLP	SUN PHARM INC LTD - IBANDRONATE SODUME INJ NDA 90-853 APRVL LTR 12/29/10
2012-1152	02/21/2012 03/20/2012	OC/ORO/ORM/ OC/ORO/ORM/	KATE WILSON THE CENTER FOR PUBLIC INTEGRITY	LIST OF HUMAN CELL & TISSUE ESTABLISHMENT REGISTRATIONS - EIRS 1/00 TO PRESENT
2012-1153	02/21/2012 03/20/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	ANGELIA D SLAYTON INC REGULATORY CONSULTING & SUBMISSIONS	K090820
2012-1154	02/21/2012 03/20/2012	FDA/OC/OES/DFOI/	KRISTOPHER P DIULIO GIBSON DUNN & CRUTCHER LLP	AVANIR PHARMACEUTICALS INC, NUDEXTRA; FAVUS INSTITUTIONAL RESEARCH LLC, ELLIOT FAVUS - REQUESTS, RESPS
2012-1155	02/21/2012 03/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	ARZERRA (OFATUMUMAB) - AERS (CERTIFIED)
2012-1156	02/21/2012 03/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	CAMPATH (ALEMTUZUMAB) - AERS (CERTIFIED)

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2012-1157	02/21/2012 03/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	CELLCEPT (MYCOPHENOLATE MOFETIL) - AERS (CERTIFIED)
2012-1158	02/21/2012 03/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	RAPTIVA (EFALIZUMAB) - AERS (CERTIFIED)
2012-1159	02/21/2012 03/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	RITUXAN (RITUXIMAB) - AERS (CERTIFIED)
2012-1160	02/21/2012 03/20/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/	Doe J	INDIVIDUAL RECS
2012-1161	02/21/2012 03/20/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/NE-FO/NWE-DO/NWE-CB/	Doe J	INDIVIDUAL RECS
2012-1162	02/21/2012 03/20/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/NE-FO/NWE-DO/NWE-CB/	Doe J	INDIVIDUAL RECS
2012-1163	02/21/2012 03/20/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16)	2012-401 - REQUEST LTR
			MERCK & CO., INC.	
2012-1164	02/21/2012 03/20/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16)	2012-410 - REQUEST LTR
			MERCK & CO., INC.	
2012-1165	02/21/2012 03/20/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	JOAN STITT (UG-CD-16)	2012-424 - REQUEST LTR
			MERCK & CO., INC.	
2012-1166	02/21/2012 03/20/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16)	2012-455 - REQUEST LTR
			MERCK & CO., INC.	
2012-1167	02/21/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16)	2012-460 - REQUEST LTR

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	03/20/2012		MERCK & CO., INC.	
2012-1168	02/21/2012 03/20/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	2012-489 - REQUEST LTR
2012-1169	02/21/2012 03/20/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	2012-532 REQUEST LTR
2012-1170	02/21/2012 03/20/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/OA/OM/OMP/DDM/	FOI Services, Inc.	MEMO TO LANDS FROM FP LUDENA COMPARATIVE STUDY; MEMO TO BLACKMOLRE FROM NA; HULME, ORAL NEO-SYNEPHINE CINTEST STUDY 2
2012-1171	02/21/2012 03/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	MOLNLYCKE HEALTH CARE INC - MEPILEX K983184
2012-1172	02/21/2012 03/20/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	FDA NEWS RELEASE: FDA PERMITS MARKETING OF FIRST TEST FOR RISK OF RARE BRAIN INJECTIONS 1/20/12(CERTIFIED)
2012-1173	02/21/2012 03/20/2012	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	2010-7611, 2010-7085, 2010-8719 ETC - EIRS, 483S, & CO RESPS
2012-1174	02/21/2012 03/20/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	TYSABRI RISK MINIMIZATION ACTION PLAN SUMMARY OF TOUCH - RECS (CERTIFIED)
2012-1175	02/21/2012 03/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	VASSILIOS CHRISTODOULOPOULOA SANDOZ CANADA INC.	NDA 20-2514 - RECS
2012-1176	02/21/2012 03/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	MYFORTIC (MYCOPHENOLIC ACID) - AERS (CERTIFIED)
2012-1177	02/21/2012 03/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	NULOJIX (BELATACEPT) - AERS (CERTIFIED)
2012-1178	02/21/2012	FDA/OMPT/CDER/ORP/DIDP/		PROGRAF (TACROLIMUS) - AERS (CERTIFIED)

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	03/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	
2012-1179	02/21/2012 03/20/2012	FDA/OGROP/ORR/SE-FO/NOL-DO/NOL-CB/	SALLEE, YARBI	TN HEALTH DEPARTMENT - HEPARIN POISONING RESULTS, CMLPNTS; SALLY HARDY - INVESTIGATION #23242 RECS, NOTES, ETC; METHODIST MEDICAL CENTER - MMCOR CMLPNTS, CORRECTION OF DEFICIENCY RPT, ETC
2012-1180	02/21/2012 03/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	RAPAMUNE (SIROLIMUS) - AERS (CERTIFIED)
2012-1181	02/21/2012 03/20/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	LILLY ELIZABETH DWARKA EQUIPMENTS PVT LTD	SPECTRA GLASS LOR SYRINGES - K082671; TOP HYPODERMIC SYRING PISTON - K843414; TOP HYPODERMIC SYRING LUER LOCK - K843415, ETC
2012-1182	02/21/2012 03/20/2012	FDA/OGROP/ORR/NE-FO/NYK-DO/NYK-DCB/	JOHN M BISHAI JP MORGAN	REGENERON, RENSSELEAR, NY - REGENERON'S EYLEA (AFIBERCEPT INJ) BLA 125387 483S 5/20/11, 3/31/10, 9/21/07
2012-1183	02/21/2012 03/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GABRIEL ZIMMERMAN TEL-AVIV UNIV	1,2-DIMYRISTOYL-SN-GLYCERO-3(PYOSPHO-S-(1-GLYCEROL); 1,2-DIMYRISTOYL-SN-GLYCERO-3-PHOSPHOCHOLINE; 1,2-DIMYRISTOYL-SN-GLYERO-3-PHOSPHOCHOLINE ETC - DRUGS USING THESE INACTIVE INGREDIENTS
2012-1184	02/21/2012 03/23/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ OC/OCOS/OES/ OC/OCOS/OES/ OC/OCOS/OL/ FDA/OGROP/ORR/CE-FO/PHI-DO/PHI-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	ZACHARY D CAPLAN BERGER & MONTAGUE PC	SANOFI-AVENTIS, SANOFI PASTEUR - HAEMOPHILUS INFLUENZAE TYPE B (HIB) VACCINE SHORTAGE EXIBITS 1 & 2 COMM 2007; MERCK & CO INC - PEDVAX HIB, COMVAX COMM, REDUCE OR HALT PRODUCTION 2007 TO 2010; ETC
2012-1185	02/21/2012 03/20/2012	OC/CVM/OCD/ FDA/OC/OES/DFOI/	JILLIAN NASH ALLTECH INC	YUCCA SCHIDIGERA - NO OBJECTION LTRS LAST4 15 YRS
2012-1186	02/21/2012 03/20/2012	FDA/OFVM/CFSAN/OCD/EOS/	GARY J BURIN TECHNOLOGY SCIENCES GROUP INC	FCN #556
2012-1187	02/21/2012	OC/ORR/	MARIA F MUNOZ	ENTRY #E4P-0018031-5 - EXTRA JUMBO U-130 LAB

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	03/20/2012	OC/ORO/	SEADCO USA CORP	RESULTS
2012-1188	02/21/2012 03/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PETER DOSHI JOHNS HOPKINS UNIV SCHOOL OF MED	GLAXOSMITH KLINE & F HOFFMAN-LA ROCHE - ZANAMIVIR, NDA 021036 & OSELTAMIVIR, NDAS 021087 & 021246 INDEX
2012-1189	02/21/2012 03/20/2012	OC/CVM/OCD/	BIRGIT PUSCHNER UNIV OF CALIFORNIA	XYLITOL ACTIVE INGREDIENT IN MEDS, (PRESCRIPTION & OTC) - RECS
2012-1190	02/21/2012 03/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SHIPMAN, KIM	ISR #3229074
2012-1191	02/21/2012 03/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JULIE FRANK REXAHN PHARMACEUTICALS INC	TAXOMERE - NDA 20-449 APRVL LTR RVWS, SBA
2012-1192	02/21/2012 03/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	NED FEDER PROJECT ON GOVERNMENT OVERSIGHT	PROJECT ON GOVERNMENT OVERSIGHT (POGO) CONCERNS ABOUT DRUG INTERACTIONS BTWN SEROQUEL AND METHADONE - CDER EVALUATION & RVWS
2012-1193	02/21/2012 03/20/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORO/NE-FO/NWE- DO/NWE-CB/	KENNETH WILTENBERG COMMERCIAL LEGAL OPERATIONS	CELLAY INC - PROMOTIONAL ACTIVITIES DOCUMENT NUMBER GEN1100561 & GEN110528, WARNING LTRS, UNTITLED LTRS, ETC
2012-1194	02/21/2012 03/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORO/CE-FO/BLT- DO/BLT-CB/	RONALD A MARCHESANI ONYX PHARMACEUTICALS	SIGMA-TAU PHARMACEUTICALS - ONCASPER (PEGASPARGASE) WARNING LTRS, RECALLS, CORR ETC
2012-1195	02/21/2012 04/09/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORO/CE-FO/NWJ- DO/NWJ-CB/	RONALD A MARCHESANI ONYX PHARMACEUTICALS	ENZON INC - ONCASPER (PEGASPARGASE) WARNING LTRS, RECALLS, CORR ETC

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		FDA/OGROP/ORACE-FO/DET-DO/DET-CB/		
2012-1196	02/21/2012 03/20/2012	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	ANTHONY H ANIKEEFF WILLIAM MULLEN	DIDION MILLING INC, CAMBRIA, WI - EIRS, 483S, COMM ETC 9/09 - 7/1/10
2012-1197	02/22/2012 03/21/2012	FDA/OMPT/CDRH/OCER/DFOI/	MARK W TADER PICCIONE KEELEY & ASSOCIATES LTD	FDA PUBLIC HEALTH ADVISORY: NEED FOR CAUTION WHEN USING VACUUM ASSISTED DELIVERY DEVICES (CERTIFIED)
2012-1198	02/22/2012 03/21/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SCOTT, BEVERLY A	NOVARTIS - EXCEDRIN, NODOZ, BUFFERIN, ETC RECALL RECS, CMLPNTS, AERS, ETC
2012-1199	02/22/2012 03/21/2012	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	MICHAEL P CROOKS PETERSON JOHNSON & MURRAY SC	WISCONSIN CHEESE GROUP LLC, MONROE, WI - EIRS, 483S, WARNINGS, ETC 1/11 TO PRESENT
2012-1200	02/22/2012 04/20/2012	OC/ORACE/ OC/ORACE/ FDA/OGROP/ORACE/ORO/DIOP/ OC/ORACE/ OC/ORACE/	LUCY I KOLO PHD Patton Boggs LLP	BETA ALANINE - IMPORT RECS, BILLS OF LADING 1/10 TO 12/11
2012-1201	02/22/2012 03/21/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MATTHRE W LAMB WARNER CHILCOTT	MDS PHARMA SERVICES, MONTREAL, QUEBEC, CANADA - EIR, 483S 2003 TO PRESENT
2012-1202	02/22/2012 03/21/2012	FDA/OFVM/CFSAN/OCD/EOS/	ELENA HOWELL HOGAN LOVELLS LLP	OVOLIFE - GRAS 411
2012-1203	02/22/2012 03/21/2012	FDA/OGROP/ORACE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORACE-FO/SEA-DO/SEA-CB/	JONATHAN RICKMAN FDA NEWS	S&S PRIMELINE CHEMICAL SYSTEMS LLC, GRAPEVIEW, WA; TEC LABORATORIES INC, ALBANY, NY; ACUTE INNOVATIONS LLC, HILLSBORO, OR, ETC - 483S 10/1-31/11
2012-1204	02/22/2012 03/21/2012	FDA/OGROP/ORACE-FO/SAN-DO/SAN-CB/	JONATHAN RICKMAN FDA NEWS	INTRAOP MEDICAL CORP, SUNNYVILLE, CA; AFFYMETRIX INC, SANTA CLARA, CA; FRESENIUS USA INC, WALNUT CREEK, CA - 483S 10/1-31/11
2012-1205	02/22/2012 03/21/2012	FDA/OGROP/ORACE-FO/NYK-DO/NYK-DCB/	JONATHAN RICKMAN FDA NEWS	SURGICAL DESIGN CORP, ARMONK, NY; PROFESSIONAL DISPOSABLES INTERNATIONAL INC, ORANGEBURG, NY; HI-TECH PHARMACAL CO INC, AMITYVILLE, NY, ETC - 483S 10/1-31/11

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2012-1206	02/22/2012 03/21/2012	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	JONATHAN RICKMAN FDA NEWS	WISCONSIN PHARMACAL COMPANY LLC, JACKSON, WI; STERLING CRITICAL PRODUCTS LLC, MINNEAPOLIS, MN; BEMIS MANUFACTURING CO, SHEBOYGAN FALLS, WI, ETC - 483S 10/1-31/11
2012-1207	02/22/2012 03/21/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	JONATHAN RICKMAN FDA NEWS	SUNRISE PHARMACEUTICAL INC, RAHWAY, NJ; ALLCARE MEDICAL, SAYREVILLE, NJ - 483S 10/1-31/11
2012-1208	02/22/2012 03/21/2012	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	JONATHAN RICKMAN FDA NEWS	KNOLL MEDICAL LLC, ANNAPOLIS, MD; HUMAN BIOSCIENCES INC, GAITHERSBURG, MD - 483S 10/1-31/11
2012-1209	02/22/2012 03/21/2012	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	JONATHAN RICKMAN FDANEWS	INNOVATECH MEDICAL RESOURCES LP, MIDLOTHIAN, TX; VUCAMP INC, PLANO, TX; HEALTHTRONICS INC, AUSTIN, TX, ETC - 483S 10/1-31/11
2012-1210	02/22/2012 03/21/2012	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	JONATHAN RICKMAN FDA NEWS	ALLEN MEDICAL INC, MINTICELLO, IN; BRISTOL-MYERS SQUIBB CO INC, MOUNT VERNON, IN; HILL-ROM INC, BATESVILLE, IN, ETC - 483S 10/1-31/11
2012-1211	02/22/2012 03/21/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	JONATHAN RICKMAN FDA NEWS	BIIORELIANCE LTD, GLASGOW, SCOTLAND, UK; WYETH FARMA SA, SAN SEBASTIAN DE LOS REYES, SPAIN - 483S 10/1-31/11
2012-1212	02/22/2012 03/21/2012	FDA/OMPT/CDRH/OCER/DFOI/	JONATHAN RICKMAN FDA NEWS	GOLDEN HORSE MEDICAL EQUIPMENT (WUXI) CO LTD, WUXI, CHINA; OMRON (DALIAN) CO LTD (PLANT 1), DALIAN, CHINA; HEMOCUE AB, ANGELHOLM, SWEDEN, ETC - 483S 10/1-31/11
2012-1213	02/22/2012 04/09/2012	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	JONATHAN RICKMAN FDA NEWS	BIO-CONCEPT LABORATORIES INC, SALEM, NH; IWALK INC, BEDFORD, MA; CANDELA CORP, WAYLAND, MA, ETC - 483S 10/1-31/11
2012-1214	02/22/2012 03/21/2012	FDA/OFVM/CFSAN/OCD/EOS/	KRISTEN GREEN ALLTECH INC	MARTEK BIOSCIENCES CORP - ALGAL OIL GRAS 137; SOLAZYME INC - ALGAL OIL GRAS 384; NUTRASOURCE - CHLORELLA VULGARIS GRAS 396
2012-1215	02/22/2012 03/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SUZIE KESCHAMRUS MD MBA AVANIR PHARMS	AVANIR PHARMACEUTICALS INC - NUEDEXTA (DXTROMETHORPHAN HYDROBROMIDE, QUIDINE SULFATE) NDA 21-879 AERS
2012-1216	02/22/2012 03/21/2012	FDA/OMPT/CDRH/OCER/DFOI/	SUZANNE D JENSEN Kleinfeld, Kaplan and Becker, LLP	CRYOSURGERY INC - VERNUCA-FREEZE CRYOSURGICAL DELIVERY SYS K955083
2012-1217	02/22/2012 03/21/2012	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	JILLIAM NASH ALLTECH INC	LAKELAND NUTRITION GROUP LLC, EATON PARK, FL - 483S LAST 10 YRS
2012-1218	02/22/2012 03/21/2012	FDA/OC/OES/DFOI/	HOHLOWSKI, RICHARD	JUDGE MICHAEL MALIHI - BIOGRAPHY
2012-1219	02/22/2012	FDA/OC/OES/DFOI/	Joan Stitt UG2CD-16	FOI DAILY LOG 2/13-17/12

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	03/21/2012		MERCK & CO., INC.	
2012-1220	02/22/2012 03/21/2012	FDA/OC/OES/DFOI/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	JOHNSON, JILL	DESERET LABORATORIES INTL, SAINT GEORGE, UT - 483S LAST 18 MONTHS
2012-1221	02/22/2012 03/21/2012	FDA/OMPT/CDRH/OCER/DFOI/	JOHN DARNALL DAILY MEDICAL PRODUCTS INC	K896393, K896971, K896972, ETC
2012-1222	02/22/2012 03/21/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	ESTHER C S DEZUBE LAW OFC	MEDEX INFUSION PUMP - MDRS, CORRECTION LTRS, INCIDENT RPTS, ETC 1/09 TO 10/09
2012-1223	02/22/2012 03/21/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDRH/OCER/DFOI/	ESTER C S DEZUBE ESTHER C S DEZUBE LAW OFC	ALARIS SYS PUMP - RECALL RECS, MDRS, CORRECTION LTRS, ETC 10/09
2012-1224	02/22/2012 03/21/2012	FDA/OC/OES/DFOI/	ARETA KUPCHYK NIXON PEABODY LLP	FRESENIUS MEDICAL CATE - FOI REQUESTS & RESP 7/10 TO 12.11
2012-1225	02/22/2012 03/21/2012	FDA/OC/OES/DFOI/	ARETA KUPCHYK NIXON PEABODY LLP	VIFOR PHARMA LTD - FOI REQUESTS & RESP 7/10 TO 12/11
2012-1226	02/22/2012 03/21/2012	FDA/OC/OES/DFOI/	FRAN KOCH INFORMATION ACCESS	FOI DAILY LOG 1/9-13/12
2012-1227	02/22/2012 03/21/2012	FDA/OC/OES/DFOI/ FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	SQUIRE, PERCY	LTR FROM EVELYN BONNIN TO J CHRIS HROUDA 1/13/12 & 6/17/10
2012-1228	02/22/2012 03/21/2012	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	JILLIAN NASH ALLTECH INC	LAKELAND ANIMAL NUTRITION INC, LAKELAND, FL - 483 2002 TO 2012
2012-1229	02/22/2012 03/21/2012	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	MATTHEW W. LAMB WARNER CHILCOTT	PROCTER & GAMBLE PHARMS INC, MASON, OH - EIR, 483
2012-1230	02/22/2012 03/21/2012	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	DIANE R. WHITWORTH DRW RESEARCH & INFORMATION SERVICES LLC	ALLENDALE INSTITUTIONAL RVW BOARD, OLD LYME, CT - 483 2/23/11
2012-1231	02/22/2012 03/21/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	BARRY MEIER NEW YORK TIMES	WITHDRAWN NON APRVL LTR PMA APPLICATIONS 1/1/05 TO PRESENT
2012-1232	02/22/2012 03/21/2012	FDA/OMPT/CTP/OD/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHRISTOPHER HENDEL CONSUMER REPORTS	E-CIGARETTE - AER

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CTP/OD/		
2012-1233	02/22/2012 03/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RAHUL GUPTA PIRAMAL LIFE SCIENCES	PHARMACIA - MEDROXYPROGESTERONE ACETATE INJECTION NDA 20-246 BIOEQUIV STUDY, DISSOLUTION STUDY
2012-1234	02/22/2012 03/21/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	ESTHER C.S. DEZUBE ESTHER C S DEZUBE LAW OFC	OVERINFUSION OF BUSULFAX - AER 2009
2012-1235	02/22/2012 03/21/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	ESTHER C.S. DEZUBE ESTHER C S DEZUBE LAW OFC	BAXTER INFUSION PUMP - AER
2012-1236	02/22/2012 03/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OFVM/CFSAN/OCD/EOS/OC/CVM/OCD/	KATHLEEN M. SANZO MORGAN LEWIS & BOCKIUS LLP	GENENCOR - AFFCO DEFINITION RVW
2012-1237	02/22/2012 03/21/2012	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	JOHNSON, JILL	VMI NUTRITION INC, SALT LAKE CITY, UT - 483 2010
2012-1238	02/22/2012 03/21/2012	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	JOHNSON, JILL	CORNERSTONE RESEARCH & DEVELOPMENT, OGDEN, UT - 483 2010
2012-1239	02/22/2012 03/21/2012	FDA/OC/OES/DFOI/	INFORMATION ACCESS	DAILY LOG 1/2-6/12
2012-1240	02/22/2012 03/21/2012	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	JOHNATHAN RICKMAN FDA NEWS	STRAIGHT ARROW PRODUCTS INC, BETHLEHEM, PA; CATALENT PHARMA SOLUTIONS LLC, PHILADELPHIA, PA - 483 10/11
2012-1241	02/22/2012 03/21/2012	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	JOHNATHAN RICKMAN FDA NEWS	CHATTEM CHEMICALS INC, CHATTANOOGA, TN; KENTRON HEALTH CARE INC, SPRINGFIELD, TN; INNOVISION INC, MEMPHIS, TN - 483 10/11
2012-1242	02/22/2012 03/21/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	JOHNATHAN RICKMAN FDA NEWS	IRISYS INC, SAN DIEGO, CA; SKY SYS CO INC, ONTARIO, CA; DIAMOND WIPES INTL INC, CHINO, CA - 483 10/11

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2012-1243	02/22/2012 03/21/2012	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	JOHNATHAN FDA NEWS	CHEM TECH LTD, PLEASANTVILLE, IA; DERMATOLOGIC LAB & SUPPLY INC, COUNCIL BLUFFS, IA; RAINING ROSE INC, CEDAR RAPIDS, IA - 483 10/11
2012-1244	02/22/2012 03/21/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHNATHAN RICKMAN FDA NEWS	EUROGENTEC, SERAING, BELGIUM; KOWA COMPANY LTD, NAGOYA SHI, JAPAN; KYOWA HAKKO BIO CO LTD, HOFU CITY, JAPAN - 483 10/11
2012-1245	02/22/2012 03/21/2012	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	JOHNATHAN RICKMAN FDA NEWS	LAR MANUFACTURING LLC, PORT RICHEY, FL; COMMAND MEDICAL PRODUCTS INC, ORMOND BEACH, FL; ARBANA GROUP LLC, OVIEDO, FL - 483 10/11
2012-1246	02/22/2012 03/21/2012	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	JOHNATHAN RICKMAN FDA NEWS	MOOG MEDICAL DEVICES GROUP, SALT LAKE CITY, UT; CARIDIAN BCT INC, LAKEWOOD, CO; FMC CORP, GREEN RIVER, WY - 483 10/11
2012-1247	02/22/2012 03/21/2012	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	JOHNATHAN RICKMAN FDA NEWS	NORMAN NOBLE INC, HIGHLAND HEIGHTS, OH; THEKEN SPINE LLC, MEDINA OH; GYRUS ACMI INC, NORWALK, OH - 483 10/11
2012-1248	02/22/2012 03/21/2012	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	JOHNATHAN RICKMAN FDA NEWS	KIK CUSTOM PRODUCTS INC, GAINESVILLE, GA - 483 10/11
2012-1249	02/22/2012 03/21/2012	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	JOHNATHAN RICKMAN FDA NEWS	MCNEIL HEALTHCARE LLC, LAS PIEDRAS, PR - 483 10/11
2012-1250	02/23/2012 03/22/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTES 2/6-10/12
2012-1251	02/23/2012 03/22/2012	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	SUE CARLSON CARGILL ANIMAL NUTRITION	CARGILL INC, CALIFORNIA, MO - FORM 2481, ENDORSEMENT PAGE, INSPECTOR'S NARRATIVE RPT 10/12/11
2012-1252	02/23/2012 03/22/2012	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	SUE CARLSON CARGILL ANIMAL NUTRITION	CARGILL ANIMAL NUTRITION, ANKENY, IA - FORM 2481, ENDORSEMENT PAGE, INSPECTOR'S NARRATIVE RPT 9/28/11
2012-1253	02/23/2012 03/22/2012	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	SUE CARLSON CARGILL ANIMAL NUTRITION	CARGILL ANIMAL NUTRITION, KANSAS CITY, KS - FORM 2481, ENDORSEMENT PAGE, INSPECTOR'S NARRATIVE RPT 9/22/11
2012-1254	02/23/2012 03/22/2012	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	SUE CARLSON CARGILL ANIMAL NUTRITION	CARGILL ANIMAL NUTRITION, WEST BRANCH, IA - FORM 2481, ENDORSEMENT PAGE, INSPECTOR'S NARRATIVE RPT 9/19/11
2012-1255	02/23/2012 03/22/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	SUE CARLSON CARGILL ANIMAL NUTRITION	CARGILL ANIMAL NUTRITION, ALBANY , NY - FORM 2481, ENDORSEMENT PAGE, INSPECTOR'S NARRATIVE RPT 7/27/11
2012-1256	02/23/2012 03/22/2012	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	SUE CARLSON CARGILL ANIMAL NUTRITION	CARGILL INC, LONDON, AR - FORM 2481, ENDORSEMENT PAGE, INSPECTOR'S NARRATIVE RPT 7/26/11

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2012-1257	02/23/2012 03/22/2012	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	SUE CARLSON CARGILL ANIMAL NUTRITION	CARGILL ANIMAL NUTRITION, GUYMON, OK - FORM 2481, ENDORSEMENT PAGE, INSPECTORS NARRATIVE RPT 7/19/11
2012-1258	02/23/2012 03/22/2012	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	SUE CARLSON CARGILL ANIMAL NUTRITION	CARGILL INC, TEMPLE, TX - FORM 2481, ENDORSEMENT PAGE, INSPECTORS NARRATIVE RPT 8/9/11
2012-1259	02/23/2012 03/22/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	ALAN EVANS ESTRIDGE LABORATORIES INC	WESTRIDGE INC - ONE PERSONAL LUBRICANT K110691, MAYER LABORATORIES INC - AQUA LUBE (TX 407) K110325
2012-1260	02/23/2012 03/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	DORI NAZEM ESTRIDGE LABORATORIES INC	WESTRIDGE INC - ONE PERSONAL LUBRICANT (WATER BASED) K110691
2012-1261	02/23/2012 03/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	DORI NAZEM ESTRIDGE LABORATORIES INC	MAYER LABORATORIES INC - AQUA LUBE (TX 407) K110325
2012-1262	02/23/2012 03/22/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	ESTHER CS DEZUBE ESTHER C S DEZUBE LAW OFC	CHILDREN'S HOSPITAL, BOSTON, MA - INFUSION PUMP RECALL; MDRS 6/09 TO 10/09
2012-1263	02/23/2012 03/22/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	S ALBERT EDWARDS S ALBERT EDWARDS, PHARM D	MORTON GROVE PHARMACEUTICALS INC - CARBINOXAMINE, PSEUDOEPHEDRINE, DEXTROMETHORPHAN ORAL LIQUID AERS
2012-1264	02/23/2012 03/22/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	RAHUL GUPTA PIRAMAL HEALTHCARE LTD	MEDROXPROGESTERONE ACETATE INJ ANDA 20-246 BIOEQV STUDIES, IN-VITRO DISSOLUTION STUDIES, ANALYTICAL METHODS
2012-1265	02/23/2012 03/22/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TIMOTHY P WALBERT HORIZON PHARMA INC	DUEXIS (FAMOTIDINE 26.6MG, IBUPROFEN 800 MG) NDA 22-519 APRVL PKG 4/23/11
2012-1266	02/23/2012 03/22/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	THOMAS C MCENTEE EI DU PONT DE NEMOURS & CO	EKA CHEMICALS INC - CHLORINE DIOXIDE (SLIMICIDE) FAP 0A-4716 RECS
2012-1267	02/23/2012 03/22/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JEANNE JARZABEK ASTELLAS PHARMA US INC	MYCAMINE NDA 21-506, 21-506/S008- MEDICAL RVWS, CHEMISTRY RVWS, PHARMACOLOGY RVWS, ETC 3/16/05, 1/22/08

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		FDA/OMPT/CDER/GRP/DIDP/		
2012-1268	02/23/2012 03/22/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WILLIAMS G GAINER TOLIVER & GAINER	MCNEIL-PPC INC - EXTRA STRENGTH TYLENOL NDA 17-053 (ANTIPYRETIC ANTIRHEUMATIC) TENATIVE OR FINAL APRVL LTRS
2012-1269	02/23/2012 03/22/2012	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	JOHN BISHAL JOHN BISHAL PHD	REGENERON PHARMACEUTICAL INC, RENSSELAER, NY - EYLEA (AFLBERCEPT) BLA 12-5387 483S 5/20/11, 3/31/10, 9/21/07, ETC
2012-1270	02/23/2012 03/22/2012	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	GEOFFREY T MISCOE MIR-COM PRODUCTS LLC	ARMEDICA MANUFACTURING & METTLER TRACTION HEAD - KDT 650 KENNEDY TABLE CMLPNT
2012-1271	02/23/2012 03/22/2012	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	SWANN, JACOB	AMERICAN PROTEINS INC - EIRS 12/5/10 TO 12/16/12
2012-1272	02/23/2012 03/22/2012	FDA/OC/OES/DFOI/	ARETA KUPCHYK NIXON PEABODY LLP	IRON SURCOSE, SODIUM FERRIC GLUCONATE, HIGH INOLECULAR WEIGHT IRON DEXTRAN, ETC - FOI REQUESTS 6/10 TO 12/11
2012-1273	02/23/2012 03/28/2012	OC/ORA/ OC/ORA/ OC/OCM/EMOPS/ FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/ FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	PATTI WALLER MARLER CLARK ATTYS	ROMAINE LETTUCE E COLI OUTBREAK - COMM, LAB TEST RESULTS, INVOICES, ETC

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		FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OFVM/CFSAN/OCD/EOS/		
2012-1274	02/23/2012 03/22/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	MICHAEL A CAROME PUBLIC CITIZEN'S HEALTH RESEARCH GROUP	EVALUATION OF AUTOMATIC CLASS III DESIGNATION (DE NOVO)_ DECISION SUMMARIES - GUIDANCE RECS RE REDACTIONS & PERSONS W/AUTHORITY TO REDACT
2012-1275	02/23/2012 03/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	MICHAEL A CAROME PUBLIC CITIZEN'S HEALTH RESEARCH GROUP	AUTOMATIC CLASS III DESIGNATION (DE NOVO) DECISIONS, TEARSCIENCE INC - LIPIFLOW THERMAL PULSATION SYS SUMMARY RVW MEMO 6/23/11....ETC..., 6/23/11; HEM-AVERT PERIANAL STABILIZER (PLEXUS BIOMEDICAL), 1/7/11; DERMAL COOLING DEVICE (ZELTIQ AETHETICS INC) 6/1/10
2012-1276	02/23/2012 03/22/2012	OC/OROA/ OC/OROA/	WILLIAM ALLRED BARRICKMAN ALLRED & YOUNG LLC	NURTURE INC, BROOKLYN, NY - HAPPY-TOT STAGE 4 & HAPPY-BABY STAGE 1 & 2 RECALL 11/10 & 1/11
2012-1277	02/23/2012 03/22/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	BOBBY SCHOCHET OLSSON FRANK & WEEDA	CANDY TREASURE LLC, LEBANON, NJ - CHOCO TREASURE RECS, RPTS, COMM ETC
2012-1278	02/23/2012 04/10/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/ FDA/OMPT/CDRH/OCER/DFOI/	RICHARD J PEARL MORGAN LEWIS & BOCKIUS LLP	INHALATION PLASTICS INC (AKA IPI), CHICAGO,IL - EIRS, RECS, CORR ETC
2012-1279	02/23/2012 03/22/2012	FDA/OMPT/CTP/OD/	CARLA R SCARMAZZI King & Spalding LLP	FDA, OFFICE OF INTERNATIONAL PROGRARMS & WHO TOBACCO FREE INITIATIVE, LEESBURG, VA - INTERNATIONAL TOBACCO REGULATORS' CONF RECS, CORR, PRESENTATIONS ETC 11/14-16/11
2012-1280	02/23/2012 03/22/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	IGAL GIGI ARCH MEDICAL INNOVATIVE MEDICAL DEVICES	BOSTON SCIENTIFIC CORP - EXCELON TRANSBRONCHIAL ASPIRATION NEEDLE K040018; BOSTON SCIENTIFIC CORP - TBAN K963252; MILL ROSE LABORATORY TRANSBRONCHIAL ASPIRATION NEEDLE K014181
2012-1281	02/23/2012 03/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	MATTHEW KHO CUTE BABY INC	K053052 - RECS IN MATERIAL USED & MATERIAL SAFETY & TESTING
2012-1282	02/23/2012	FDA/OMPT/CDRH/OCER/DFOI/		REMESENSE K082594

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	03/22/2012		SPECTOR, GILBERT	
2012-1283	02/23/2012 03/22/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRIAN SMITH LEXIS NEXIS COURTLINK INC	OFFICE OF SURVELLIANCE & EPIDEMIOLOGY STUDIES RVW - OSE RCM 2011-1328, EPIDEMIOLOGIST STUDY COMPARISON RVW 6/6/11, LIDEGAAARD O ET AL HORMONAL CONTRACEPTION & RISK OF VENOUS THROMBOEMBOLISM & VAN HYLCKAMA VLIEG A, ET AL, RESULTS OF MEGA CASE STUDY, 4 COPIES (CERTIFIED)
2012-1284	02/23/2012 03/22/2012	FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/	GERHARDT, NATHAN	UNIVERSAL SUPPLEMENT INC, VISTA, CA - 483 7/14-29/11
2012-1285	02/23/2012 03/22/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CTP/OD/ OC/OCS/NCTR/OD/ OC/OCOS/OES/ OC/OCOS/OES/ OC/OCOS/OL/ OC/OPPL/OP/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CTP/OD/	MARK GREENBLATT ABC NEWS, INC.	DHA IN TANNING BOOTHS - AERS, CORR, RECS ETC
2012-1286	02/23/2012 03/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	BERRYMAN, THOMAS J	MINIGUARD FEMALE CONTINENCE DVC K954215
2012-1287	02/23/2012 03/22/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/CIN- DO/CIN-CB/	PETER D LOFTUS DOWJONES & CO	jOHNSON & JOHNSON & PFIZER - USE OF BEN VENUE LABS, BEDFORD, OH, EIRS, 483S, CO RESP ETC 1/1/10 TO PRESENT
2012-1288	02/23/2012 03/22/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	PRADAXA - AER RESULTS (7/11)
2012-1289	02/23/2012 03/22/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANDRAS BRATINCSAK UNIV OF CALIFORNIA SAN DIEGO SCHOOL OF MED, DEPT OF PEDIATRICS	DOXYCYCLINE - MEDICAL RPTS, SAFETY RECS, SIDE EFFECTS ETC

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		FDA/OMPT/CDER/GRP/DIDP/		
2012-1290	02/23/2012 03/22/2012	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	JENNIFER CONNER INVESTIGATION SOLUTIONS INC	NOVITAS MEDICAL LLC, BREA, CA - 483 5/6/11
2012-1291	02/23/2012 03/22/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	BAYER, RANGE (RICHARD) D	BLOOD PRODUCTS ADVISORY COMM (BPAC) - MTG TRANSCRIPT, 4/29/11
2012-1292	02/23/2012 03/22/2012	OC/ORA/ OC/ORA/	STEPHEN A GARBARINI MARCOR DEVELOPMENT CORP	eNTRY #609-0322008-9 - PANCREATIN 10X (LOT 110813) - LAB TEST RESULTS
2012-1293	02/23/2012 03/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	CHRISTINE L MACAULEY KIMBERLY CLARK CORP	PMA SUBMISSION - NEXT GENERATION INFUSED (R) OR TOWEL (HEMED), NEXT GENERATION INFUSED (R) OR TOWEL (W/BINDING) MODEL HUCKCR17AX27MH,H, K094016
2012-1294	02/23/2012 03/22/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DANIEL ALBAHARI BIOLINE INNOVATIONS JERUSALEM	SANOPI PHARMS INC -PLAQUENIL NDA 09-768 APRVL RECS
2012-1295	02/23/2012 03/22/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WARD, JEANIE	POLYETHYLENE GLYCOL - AER
2012-1296	02/23/2012 03/22/2012	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	SUE CARLSON CARGILL ANIMAL NUTRITION	CARGILL ANIMAL NUTRITION, BIG LAKE, MI - MEDICATED FEED MILL INSPECTION/BSE INSPECTION EIR, 483, FORM 2481 10/29/11
2012-1297	02/23/2012 03/22/2012	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	SUE CARLSON CARGILL ANIMAL NUTRITION	CARGILL INC, SPRINGDALE, M AR - MEDICATED FEED MILL INSPECTION/BSE INSPECTION EIR, 483, FORM 2481 10/11/11
2012-1298	02/23/2012 03/22/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	NELSON, MARGOT	RECLAST - AERS, RPTS ETC
2012-1299	02/23/2012 03/22/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOY PARRIS HUMAN GENOME SCIENCES INC.	ISRS - ABATACEPT, 6491498; NATALUZUMAB, 6426037, 7654659, & 5213865, TOCILIZUMAB, 7270424 ETC
2012-1300	02/23/2012 03/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	SYLVESTER WILLIAMS III WUXIAPPTTEC INC	VALLEY MEDICAL INC, SAN DIEGO, CA - WARNING LTRS, CLOSE OUT LTR 3/24/11
2012-1301	02/23/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/		BURZYNSKI CLINIC, BURZYNSKI RESEARCH INSTITUTE - PHASE II ANTINEOPLASTON CLNCL TRIAL RECS

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	03/22/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SIEGLER, SARA	
2012-1302	02/23/2012 03/22/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA SOUZA ONO PHARMA USA INC	LODOSYN (CARBIDOPA) SBA
2012-1303	02/23/2012 03/22/2012	OC/ORO/OCI/ OC/ORO/OCI/	CHAD MAZUREK JM2 CONSULTING LLC	MIDWEST RESEARCH SWINE, GIBBON, MN - RECS 1/10 TO 7/11
2012-1304	02/23/2012 03/22/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	TIFFANY MILLER ORA SURE TECHNOLOGIES INC	HIV OTC BPAC CLOSED SESSION - TRANS11/17/09
2012-1305	02/23/2012 03/22/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BARBARA WILSON LUNG LLC	UNITED THERAPEUTICS - REMODULIN NDA 21-272/S-005 APRVL, CHEMISTRY RVW, STATISTICAL RVW, MEDICAL RVW
2012-1306	02/23/2012 03/22/2012	FDA/OC/OES/DFOI/	AMANDA ORLANDO AVALON RISK MANAGEMENT INC	ENTRY NO W939061994
2012-1307	02/23/2012 04/12/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	JEROME A. KONKEL SAMSTER KONKEL ET AL	INDIVIDUAL RECS
2012-1308	02/23/2012 03/22/2012	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	GERHARDT, NATHAN	PURE ENCAPSULATIONS INC, SUDBURY, MA - 483 8/4-24/11
2012-1309	02/23/2012 03/22/2012	FDA/OFVM/CFSAN/OCD/EOS/	ANNA T. FLOOD Keller and Heckman LLP	CIBA SPECIALTY CHEMICALS CORP - FCN 330
2012-1310	02/23/2012 03/22/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/	ELIZABETH DUDLEY, Esq. DUDLEY FIRM LLC	MEDRAD INC - AVANTA FLUID MGMT INJECTION SYS K050456 WARNING LTR, RECALL 2005 TO PRESENT
2012-1311	02/23/2012 03/22/2012	OC/OA/OM/OMP/DDM/	WILLIAM J. SKINNER MUSCATATUCK PUBLISHERS INC	75 DAY PREMARKETING NOTICES FILED BY DISTRIBUTORS OF DIETARY SUPPLEMENTS 1/08 TO PRESENT
2012-1312	02/24/2012 03/23/2012	FDA/OC/OES/DFOI/	MEGAN B PICKEL BEVERIDGE & DIAMOND PC	ALL FOIA REQUEST FOR CENTER FOR FOOD SAFETY & APPLIED NUTRITION 1/20/12 TO 2/22/12
2012-1313	02/24/2012	FDA/OC/OES/DFOI/		FOI DAILY LOG 1/2-6/12

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	03/23/2012		FOI Services, Inc.	
2012-1314	02/24/2012 03/23/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 1/9-13/12
2012-1315	02/24/2012 03/23/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 1/9-13/12
2012-1316	02/24/2012 03/23/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 1/2-6/12
2012-1317	02/24/2012 03/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	MICHAEL WARRENER SIRTOLOGY PTY LTD	SIR-SPHERESR - P990065
2012-1318	02/24/2012 03/23/2012	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 1/9-13/12
2012-1319	02/24/2012 03/23/2012	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 1/2-6/12
2012-1320	02/24/2012 03/23/2012	FDA/OC/OES/DFOI/	GLADYS B TONKIN WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 1/2-6/12
2012-1321	02/24/2012 03/23/2012	FDA/OC/OES/DFOI/	GLADYS B TONKIN WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 1/9-13/12
2012-1322	02/24/2012 03/23/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 1/9-13/12
2012-1323	02/24/2012 03/23/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 1/2-6/12
2012-1324	02/24/2012 03/23/2012	FDA/OMPT/CDRH/OCER/DFOI/ OC/ORO/ OC/ORO/ OC/ORO/OCI/ OC/ORO/OCI/ FDA/OGROP/ORO/CE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDRH/OCER/DFOI/	KIM M RUDER CARLOCK COPELAND & STAIR LLP	RAM MEDICAL INC - COUNTERFEIT POLYPROPYLENE SURIGCAL MESH INVESTIGATION RECS

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		OC/ORO/OCI/ OC/ORO/OCI/ FDA/OGROP/ORO/CE-FO/CHI-DO/CHI-CB/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/		
2012-1325	02/24/2012 03/23/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	INC REGULATORY CONSULTING & SUBMISSIONS	FOI DAILY LOG 1/9/13/12
2012-1326	02/24/2012 03/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SAMUEL GEISLER AYLSTOCK WITKIN KREIS & OVERHOLTZ PLLC	SHIRE US INC, VALIDUS PHARMACEUTICALS INC - EQUETRO LBLG CHANGES, WARNING LTRS, EIRS, ETC
2012-1327	02/24/2012 03/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	CARLA A TAYLOR LOPEZ LOPEZ & FANTEL	MEDTRONIC - MODEL 8540 CATHETER ACCESS PORT KIT LBLG CHANGES
2012-1328	02/24/2012 03/23/2012	FDA/OC/OES/DFOI/	INC REGULATORY CONSULTING & SUBMISSIONS	FOI DAILY LOG 1/2-6/12
2012-1329	02/24/2012 03/23/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 1/2-6/12
2012-1330	02/24/2012 03/23/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 1/9-13/12
2012-1331	02/24/2012 03/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	KAREN L LTHOMISON AMUSA	IVERA MEDICAL CORP - CUROS PORT PROTECTOR K110826
2012-1332	02/24/2012 03/23/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	KAREN L THOMISON AMUSA	IVERAL MEDICAL CORP - CUROS PORT PROTECTOR K080466
2012-1333	02/24/2012 03/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SCHONHOFT, BRAD	REGENERON, TARRYTOWN, NY - EYLEA (AFIBERCEPT) AERS 12/1/11 TO 2/22/12
2012-1334	02/24/2012 03/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KRISTOPHER P DIULIO GIBSON DUNN & CRUTCHER LLP	NUDEXTRA - MEDWATCH RPTS 10/29/10 TO PRESENT; AVANIR PHARMACEUTICALS INC - NUDEXTRA FOI REQUESTS 2/5/12 TO PRESENT

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		FDA/OC/OES/DFOI/		
2012-1335	02/24/2012 03/23/2012	FDA/OMPT/CDRH/OCER/DFOI/ OC/OA/OM/OMP/DDM/	JEFFREY N GIBBS Hyman Phelps and McNamara PC	WIRELESS AIR-CONDUCTION HEARING AID - CLASSIFICATION AS CLASS II DVCS RECS
2012-1336	02/24/2012 03/23/2012	FDA/OC/OCC/ OC/ORA/ OC/ORA/ FDA/OGROP/ORPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORPA-FO/LOS-DO/LOS-CB/	PETER S HERRICK PETER S HERRICK PA	MILKY WAY INTERNATIONAL TRADING CORP - HONEY ENTRY #GV8-0150233-9 RECS
2012-1337	02/24/2012 03/23/2012	FDA/OC/OES/DFOI/	AMANDA ORLANDO AVALON RISK MANAGEMENT INC	EG PIAZZA INTERNATIONAL - ENTRY #80501222261 NOTICE OF FDA ACTION #1
2012-1338	02/24/2012 03/23/2012	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	LAWRENCE J BUCKFIRE BUCKFIRE & BUCKFIRE PC	INDIVIDUAL RECS
2012-1339	02/24/2012 03/23/2012	FDA/OFVM/CFSAN/OCD/EOS/	RAJKUMAR VINNAKOTA SKIERMONT PUCKETT LLP	AZTECA MILLING LP, GRUPO INDUSTRIAL MASECA SA DE CV, GRUMA CORP, ETC - FOOD ADDITIVE PETITIONS FOR ENZYME PREPARATIONS
2012-1340	02/24/2012 03/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	STACEY ELLUL NEUROPACE INC	AD-TECH MEDICAL INSTRUMENT CORP - SUBDURAL ELECTRODE K970587
2012-1341	02/24/2012 03/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	STACEY ELLUL NEUROPACE INC	AD-TECH MEDICAL INSTRUMENT CORP - CORTICAL MAPPING UNIT MODEL CMU K992194
2012-1342	02/24/2012 03/23/2012	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	ROBERT E ARMSTRONG ROBERT E ARMSTRONG LAW OFCS	AMERICAN BIOTECH LABS LLC - EIRS, 483S 2010, 2011, 2012
2012-1343	02/24/2012 03/23/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	KAREN L THOMISON AMUSA	APLICARE INC - ALCOHOL PREP PAD K833182
2012-1344	02/24/2012 04/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	KAREN L THOMISON AMUSA	EXCELSIOR MEDICAL CORP - SWABCAP K083508
2012-1345	02/24/2012 03/23/2012	FDA/OFVM/CFSAN/OCD/EOS/	BOBBY SCHOCHET OFW LAW	MARS INC - CAP 2C0293

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2012-1346	02/24/2012 03/23/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OES/DFOI/ FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/ FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	DIANA L. GESEKING SEDWICK LLP	LTRS BETWEEN FDA & ELISA ELLIOTT, BENSON SILVERMAN, DO ZINK REGARDING CRONOBACTER SPP
2012-1347	02/24/2012 03/23/2012	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	MICHAEL P. CROOKS PETERSON JOHNSON & MURRAY SC	NUESTRO QUESO LLC, ELK GROVE VILLAGE, IL; HACKENSACK, NK; SACRAMENTO, CA - 483, EIR, WARNING LTRS
2012-1348	02/24/2012 03/23/2012	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	CRAIG ROUSH ROCKLINE INDUSTRIES	PROFESSIONAL DISPOSABLES INTL, ORANGEBURG, NY; NICE PAK PRODUCTS INC, MOORESVILLE, IN - 483, EIR
2012-1349	02/24/2012 03/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORA/ OC/ORA/	SAMUEL GEISLER ALYSTOCK WITKIN ET AL	SHIRE US INC - EQUETRO LBLG, WARNING LTRS, CORR, AER, 483, EIR
2012-1350	02/24/2012 03/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	ALTHEA BURTON PATH	FEMALE HEALTH COMPANY - FEMALE CONDOM SAFETY & EFFECTIVENESS DATA
2012-1351	02/27/2012 03/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TAYLOR J BASSETT MORROW MORROW RYAN & BASSETT	SANOPI-AVENTIS US LLC, SANOPI-AVENTIS US INC, AVENTIS PHARMACEUTICALS INC, AVENTIS INC, BRISTOL-MYERS SQUIBB - PLAVIX RECS 1997 TO PRESENT
2012-1352	02/27/2012 04/17/2012	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	DOUGLAS N BLUE ZETETIC	LIFESCAN SCOTLAND LTD - ONETOUCH ULTRA STRIPS RECS

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2012-1353	02/27/2012 03/26/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	TYSABRI (NATALIZUMAB) - SAFETY RECS 9/17/09 (CERTIFIED)
2012-1354	02/27/2012 03/26/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	SAFETY COMMUNICATION: SAFETY UPDATE ON PROGRSSIVE MULTIFOCAL LEUKOENCEPHALOPATHY (PML) ASSOCIATED WITH TYSABRI (NATALIZUMAB) 4/22/11 (CERTIFIED)
2012-1355	02/27/2012 03/26/2012	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	ETHICON INC - PDS BARBED SUTURES K113004
2012-1356	02/27/2012 03/26/2012	FDA/OC/OES/DFOI/	ELIZABETH DUDLEY ESQ DUDLEY FIRM LLC	2012-237 - DELETED RECS
2012-1357	02/27/2012 03/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	BIOTEQUE - DOUBLE PIGTAIL URTERAL STENT SET K033210
2012-1358	02/27/2012 03/26/2012	FDA/OFVM/CFSAN/OCD/EOS/	FATIMA ASLAM Keller and Heckman LLP	SHELL OIL CO - POLYALKYL ACRYLATE POLYMER FAP 2A3653
2012-1359	02/27/2012 03/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	SPD DEVELOPEMNT COMPANY LTD - CLEARBLUE EASY PREGNANCY TEST K110433
2012-1360	02/27/2012 03/26/2012	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	WALTER E CHALKLEY THOMSON REUTERS	THOMAS MENDOLIA, DO (NORTHWEST PIEDMONT CLINICAL RESEARCH), LOUISVILLE, NC - EIRS, 483S, CO RESPS 10/18/10- 11/1/10
2012-1361	02/27/2012 03/26/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	FOI Services, Inc.	UNIPATH LTD - CLEARBLUE EASY EARLIEST RESULTS PREGNANCY TEST K040341
2012-1362	02/27/2012 03/26/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	FOI Services, Inc.	UNIPATH LTD - CLEARBLUE EASY EASY READ PREGNANCY TEST K041404
2012-1363	02/27/2012 03/26/2012	FDA/OFVM/CFSAN/OCD/EOS/	FATIMA ASLAM Keller and Heckman LLP	SHELL OIL CO - POLYALKYL ACRYLATE POLYMER FAP 2A3653 CHEMISTRY AND TOXICOLOGY MEMO
2012-1364	02/27/2012 03/26/2012	FDA/OGROP/ORR/CE-FO/CHI-DO/CHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	ANCHOR PRODUCTS CO, ADDISON, IL - EIRS, 483S, CO RESPS, 5/26/10-6/4/10
2012-1365	02/27/2012 03/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	STRYKER ENCOSCOPY - CASSETTE PUMP K042454
2012-1366	02/27/2012 03/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	TYSABRI (NATALIXUMAB) - BLA 12-5104 LTR , LABEL 1/14/08 (CERTIFIED)

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2012-1367	02/27/2012 05/14/2012	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	WALTER E CHALKLEY THOMSON REUTERS	DELTEX PHARMACEUTICALS, ROSENBERG, TX - EIRS, 483S, CO RESPS, 3/22/10-4/16/10
2012-1368	02/27/2012 03/26/2012	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	WALTER E CHALKLEY THOMSON REUTERS	PHARMACEUTICAL ASSOCIATES INC, GREENVILLE, SC - EIRS, 483S, CO RESP 4/11
2012-1369	02/27/2012 03/28/2012	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	PROMEGA BIOSYSTEMS SUNNYVALE INC, SUNNYVALE, CA - EIRS, 483S, CO RESP 10/10
2012-1370	02/27/2012 03/26/2012	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	WALTER E CHALKLEY THOMSON REUTERS	DEPUY ORTHOPAEDICS, WARSAW, IN - EIRS, 483S, CO RESPS - 5/10/11-6/7/11
2012-1371	02/27/2012 03/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TIMOTHY B MCALLISTER KIRKLAND & ELLIS LLP	ALLAN PHARM, WATSON LABS, EXCELLIUM PHARM, ETC - QUININE SULFATE LABELS 1/94 TO 12/04
2012-1372	02/27/2012 03/26/2012	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	WALTER E CHALKLEY THOMSON REUTERS	BAXTER PHARMACEUTICALS SOLUTIONS, BLOOMINGTON, IN - EIRS, 483S, CO RESPS 3/11
2012-1373	02/27/2012 03/26/2012	FDA/OC/OES/DFOI/	ELENA HOWELL HOGAN LOVELLS US LLP	2012-315
2012-1374	02/27/2012 03/26/2012	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	WALTER E CHALKLEY THOMSON REUTERS	XORAN TECHNOLOGIES, ANN ARBOR, MI - EIRS, 483S, CO RESPS 3/11-4/11
2012-1375	02/27/2012 03/26/2012	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	WALTER E CHALKLEY THOMSON REUTERS	NORDIMEX, LLC, SAN DIEGO, CA - EIRS, 483S, CO RESPS 5/11
2012-1376	02/27/2012 03/26/2012	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	WALTER E CHALKLEY THOMSON REUTERS	ROBERT CYWES, MD, JACKSONVILLE, FL - EIRS, 483S, CO RESPS, 3/11
2012-1377	02/27/2012 03/26/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	ROCHE MOLECULAR SYSTEMS INC, SOMMERSVILLE, NJ - EIRS, 483S, CO RESPS 1/11
2012-1378	02/27/2012 03/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	TYSABRI (NATALIZUMAB) BLA 125104 - APRVL HISTORY, LBLG, LTR (CERTIFIED)
2012-1379	02/27/2012 03/26/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	TYSABRI (NATALIZUMAB) INJ - RECS (CERTIFIED)
2012-1380	02/27/2012 03/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	TYSABRI (NATALIZUMAB) BLA 125104 - LTR & LBL DOCS, 6/5/06 (CERTIFIED)

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2012-1381	02/27/2012 03/26/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	FDA DRUG SAFETY COMMUNICATION: NEW RISK FACTOR FOR PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY (PML) ASSOCIATED WITH TYSABRI (NATALIZUMAB) 1/20/12 (CERTIFIED)
2012-1382	02/27/2012 03/26/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	TYSABRI (NATALIZUMAB) - SAFETY ALERT 8/25/08 (CERTIFIED)
2012-1383	02/27/2012 03/26/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	FDA DRUG SAFETY COMMUNICATION: RISK OF PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY (PML) WITH THE USE OF TYSABRI (NATALIZUMAB) 2/5/10 (CERTIFIED)
2012-1384	02/27/2012 03/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	THEROKOS INC, JOHNSON & JOHNSON - UVAR PHOTOPHERESIS SYS P860003
2012-1385	02/27/2012 03/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	ENSEAL G2 SUPER JAW TISSUE SEALER - K112033
2012-1386	02/27/2012 03/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	UNIPATH LTD - CLEARBLUE EASY DIGITAL PREGNACY TEST K060128
2012-1387	02/27/2012 03/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	JOSEPH KICEINA ABBOTT POINT OF CARE INC	INTERNATIONAL TECHIDYNE CORP (ITC) - HEMOCHRON CITRATE APTT K972831, HEMOCHRON JR CITRATE APTT CUVETTE K014008
2012-1388	02/27/2012 03/27/2012	FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/	WALTER E. CHALKLEY THOMSON REUTERS	AMPAC FINE CHEMICALS LLC, RANCHO CORDOVA, CA - EIR, 483 CO RESP 3/11
2012-1389	02/27/2012 03/26/2012	FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/	WALTER E. CHALKLEY THOMSON REUTERS	NYCOMED US INC, MELVILLE, NY - EIR, 483, CO RESP 2/11
2012-1390	02/27/2012 03/26/2012	FDA/OGROP/ORO/SW-FO/KAN-DO/KAN-CB/	WALTER E. CHALKLEY THOMSON REUTERS	NOVARTIS CONSUMER HEALTH, LINCOLN, NE - EIR, CO RESP 1/14/11 TO 1/20/12
2012-1391	02/27/2012 03/26/2012	FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/	WALTER E. CHALKLEY THOMSON REUTERS	HOSPIRA, AUSTIN, TX - EIR, CO RESP 4/24-27/11
2012-1392	02/27/2012 03/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	WALTER E. CHALKLEY THOMSON REUTERS	SORIN GROUP DEUTSCHLAND GMBH, MUCHEN, GERMANY - EIR, 483, CO RESP 4/11-13/11
2012-1393	02/27/2012 03/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	LABOR L+S AG, GROSSENBRACH, GERMANY - EIR, 483, CO RESP 7/18-21/11
2012-1394	02/27/2012	FDA/OMPT/CDER/ORP/DIDP/	WALTER E. CHALKLEY	MERCK SERONO SA, CORSIER SUR VEVEY, FENIL SUR

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	03/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	THOMSON REUTERS (SCIENTIFIC) SAS	CORSIER, SWITZERLAND; MERCK SERONO SA, AUBONNE, SWITZERLAND; MERCK SERONO, ROME, ITALY - EIR, 483, CO RESP 6/11
2012-1395	02/27/2012 03/26/2012	FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/	WALTER E. CHALKLEY THOMSON REUTERS	WEST WARD PHARMS CORP, WEST EATONVILLE, NJ - EIR, 483, CO RESP 6/13-30/11
2012-1396	02/27/2012 03/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	JONATHAN M. PETTY WILLIAMSON PETTY LC	DEPUY ASR - ACETABULAR CUP; TOTAL HIP SYS; TAPER SLEEVE ADAPTER MANUFACTURE, DATE
2012-1397	02/27/2012 03/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	TYSABRI (NATALIZUMAB) BLA 125104 - LTR, LBG CERTIFIED
2012-1398	02/27/2012 03/26/2012	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MATTHEW P. MORIARTY TUCKER ELLIS & WEST LLP	ACTAVIS - DIGITEK (AMIDE) 484 CERTIFIED
2012-1399	02/27/2012 03/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN A. CLARK, MD RISKBENEFITS LLC	MEDWATCH 5247186-7, 5290514-7, 5354972-1
2012-1400	02/27/2012 03/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	SUZAN ANN MOSER RN, BSN, MBA	DAKO CYTOMATION - PMA 030044
2012-1401	02/28/2012 03/27/2012	OC/ORACE/ OC/ORACE/	DANIEL M DELANGE JUICE SOURCE LLC	ENTRY #032-0419322-5 - TEST RESULTS
2012-1402	02/28/2012 03/27/2012	FDA/OMPT/CTP/OD/	KLEIN, LISA	LIST OF ADDITIVES ALLOWED FOR TOBACCO PRODS
2012-1403	02/28/2012 03/27/2012	FDA/OMPT/CDRH/OCER/DFOI/	JOHN BOVIS BODDINGTONS	OLYMPUS ENDOTHERAPY - ENDOSCOPE 510K
2012-1404	02/28/2012 03/27/2012	FDA/OMPT/CDRH/OCER/DFOI/	GLEN FEYE ACCURATE CONSULTANTS INC	XPEREX CORP - HEALTH CHECK KIOSK K063008
2012-1405	02/28/2012 03/27/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORACE/SW-FO/DEN- DO/DEN-CB/	PETER J CREEDON CREEDON & GILL PC	COCHLEAR NUCLEUS C1512 SERIES OF COCHLEAR IMPLANTS - PMA, APRVL LTR, NOTES, ETC

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2012-1406	02/28/2012 03/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OCC/	KATE PURCELL DOCUTRIEVAL INFORMATION SERVICES	RANBAXY, PAONTA, SAHIB, BATAMANDI, DEWAS, INDIA - CONSENT DECREE; RANBAXY OHM LABS, GLOVERSVILLE, NY - VIOLATIONS, CONSENT DECREE
2012-1407	02/28/2012 03/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOSEPH L GODFREY MD CATAWBA PSYCHIATRIC SERVICES PLLC	CELEXA - AERS
2012-1408	02/28/2012 03/27/2012	OC/ORO/ OC/ORO/	LUIS E VERA BONAMAR CORP	PASTEURIZED CRABMEAT ENTRY #D97-0621287-2 - ANALYTICAL RESULTS
2012-1409	02/28/2012 03/27/2012	OC/OA/OM/OMP/DDM/ FDA/OMPT/CDRH/OCER/DFOI/	MORROW, LEN W	DKT 1995S-0158
2012-1410	02/28/2012 03/27/2012	FDA/OO/OFBA/OAGS/	BRANDEN DEROCHE RIGHTBRAIN NETWORKS LLC	AUROTECH INC - CONTRACT #HHSF22320120013A
2012-1411	02/28/2012 04/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	JOCELYN RAPOSO CODMAN & SHURTLEFF INC	MEDTRONIC - ARES ANTIBIOTIC-IMPREGNATED CATHETER K110560
2012-1412	02/28/2012 03/27/2012	FDA/OMPT/CDRH/OCER/DFOI/	LISA ANDERSON CONMED CORP	MODULAP RESUABLE UNIPOLAR ELECTROSURGICAL PROBES AND INSERTS - K983623; MODULAP ASPIRATION/IRRIGATION CANNULA - K982445
2012-1413	02/28/2012 03/27/2012	OC/OM/OMP/DDM/	ANICE N. JAMISON MCDERMOTT WILL & EMERY	DKT 1990N-0165
2012-1414	02/28/2012 03/27/2012	OC/OM/OMP/DDM/	MARILYNN WHITNEY COVINGTON & BURLING LLP	DKT FDA-2010-P-0491
2012-1415	02/28/2012 03/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LAUREN PRIMIANO PONO PHARMA	BORTEZOMIB (VELCADE) NDA
2012-1416	02/28/2012 03/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HOFER, STEVE	ATENOLOL, KLOR-CON, NIACIN, ETC - AERS
2012-1417	02/28/2012 03/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PRIME AID PHARMACY	PEGASYS (PEG-INTERFERON ALFA-2A) - AERS

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2012-1418	02/28/2012 03/27/2012	FDA/OC/OES/DFOI/	DUFF WILSON REUTERS	INTERAGENCY WORKING GROUP ON FOOD MARKETED TO CHILDREN - CONGRESSIONAL CORR, MTGS, RECS 1/09 TO PRESENT
2012-1419	02/28/2012 03/27/2012	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	MURIS DEMIROVIC MANNING & NAPIER ADVISORS INC	FRESENIUS MEDICAL CARE, LIVINGSTON,CA 2/12/10; FRESENIUS MEDICAL CARE HOLDINGS INC,WALTHAM, MA 8/6/10; FRESENIUS MEDICAL CARE NORTH AMERICA, OGDEN, UT 2/4/11 - 483S, WARNING LTRS
2012-1420	02/28/2012 03/27/2012	FDA/OMPT/CDRH/OCER/DFOI/	PRINCE, APRIL	SYNERONS - EMAX MACHINE 510K
2012-1421	02/28/2012 03/27/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	MURIS DEMIROVIC MANNING & NAPIER ADVISORS INC	FRESENIUS KABI ONCOLOGY LTD, NADIA, IN 11/6/09; FRESENIUS KABI NORGE AS BERG, OSTFOLD, NO 11/17/09; FRESENIUS KABI, VILLADOSE, ROVIGO, IT,E TC - 483S, WARNING LTRS
2012-1422	02/28/2012 03/27/2012	FDA/OC/OES/DFOI/	INC REGULATORY CONSULTING & SUBMISSIONS	FOI DAILY LOG 1/16-20/12
2012-1423	02/28/2012 03/27/2012	FDA/OC/OES/DFOI/	INC REGULATORY CONSULTING & SUBMISSIONS	FOI DAILY LOG 1/23-27/12
2012-1424	02/28/2012 03/27/2012	FDA/OC/OES/DFOI/	INC REGULATORY CONSULTING & SUBMISSIONS	FOI DAILY LOG 1/30/12-2/3/12
2012-1425	02/28/2012 03/27/2012	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 1/30/12-2/3/12
2012-1426	02/28/2012 03/27/2012	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	GUILLERM ENRIQUE GONZALEZ LABORATORIOS PISA MEXICO	CERTIFIED RECS
2012-1427	02/28/2012 03/27/2012	FDA/OC/OES/DFOI/	FRAN KOCH INFORMATION ACCESS	FOI DAILY LOG 1/20/12-2/3/12
2012-1428	02/28/2012 03/27/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 1/30/12-2/3/12

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2012-1429	02/28/2012 03/27/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 1/23-27/12
2012-1430	02/28/2012 03/27/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 1/30/12-2/3/12
2012-1431	02/28/2012 03/27/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 1/23-27/12
2012-1432	02/28/2012 03/27/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 1/30/12-2/3/12
2012-1433	02/28/2012 03/27/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 1/23-27/12
2012-1434	02/28/2012 03/27/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 1/16-20/12
2012-1435	02/28/2012 03/27/2012	FDA/OMPT/CDRH/OCER/DFOI/ OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/CHI- DO/CHI-CB/	JUSTIN PIERSON STATE FARM INSURANCE CO	VISIONCARE LABCOLORED CONTACT LENSES - CLAIM 13- B429-560
2012-1436	02/28/2012 03/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MASSEY, ERIN	RITALIN - CLNCL TRIALS
2012-1437	02/28/2012 03/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JULIE FRANK, PhD. REXAHN PHARMACEUTICALS INC	PRAMIPEXOLE NDA 22-421 - APRVL, MEDICAL RVW, CLNCL RVW
2012-1438	02/28/2012 03/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN P. MALEY SYLVESTER & MALEY, INC	THYMOGLOBULIN (THYMOCYTE GLOBULIN) ISR 5573023
2012-1439	02/28/2012 03/27/2012	FDA/OC/OES/DFOI/	SCHNEPS, PHYLLIS	2012-13
2012-1440	02/28/2012 03/27/2012	FDA/OGROP/ORO/CE-FO/CIN- DO/CIN-CB/ FDA/OGROP/ORO/SW-FO/KAN-	Doe J	INDIVIDUAL RECS

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		DO/KAN-CB/		
2012-1441	02/28/2012 03/27/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	MURIS DEMIROVIC MANNING & NAPIER ADVISORS INC	APP PHARMS, GRAND ISLAND, NY; RALEIGH, NC - 483, WARNING LTR 6/30/11 TO PRESENT
2012-1442	02/29/2012 03/28/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	ANGELIA D SLAYTON INC REGULATORY CONSULTING & SUBMISSIONS	AEROCAN FRANCE SAS (ALCAN CEBAL AEROSOLS), BELLEGRADE, FRANCE - EIRS, 483S, CO RESP 8/1/11 TO 1/31/12
2012-1443	02/29/2012 03/28/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	ANGELIA D SLAYTON INC REGULATORY CONSULTING & SUBMISSIONS	PATHEON, MISSISSAUGA, ONTARIO, CANADA - EIRS, 483S CO RESP 8/1/11 TO 1/31/12
2012-1444	02/29/2012 04/10/2012	FDA/OMPT/CDRH/OCER/DFOI/	R IAN KLUGE Hyman Phelps and McNamara PC	W L GORE & ASSOCIATES INC, FLAGSTAFF, AZ - GORE EMBOLIC FILTER K103500
2012-1445	02/29/2012 03/28/2012	FDA/OMPT/CDRH/OCER/DFOI/	MIKE MEDINA LANX	PIONEER SURGICAL TECHNOLOGY - SPINOUS PROCESS FUSION PLATE K101525
2012-1446	02/29/2012 03/28/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	MIKE MEDINA LANX	X-SPINE SYSTEMS INC - AXLE INTERSPINOUS FUSION SYS K101471
2012-1447	02/29/2012 03/28/2012	FDA/OMPT/CDRH/OCER/DFOI/	MIKE MEDINA LANX	MEDTRONIC SOFAMOR DANEK USA INC - CD HORIZON SPINAL SYS K092325
2012-1448	02/29/2012 03/28/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	MIKE MEDINA LANX	PARAGIGM SPINE LLC - INTERSPINOUS FUSION PLATE K093438
2012-1449	02/29/2012 03/28/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	MIKE MEDINA LANX	OSTEOMED SPINE INC - PRIMAL OK SP INTERSPINOUS FUSION SYS K100354
2012-1450	02/29/2012 03/28/2012	FDA/OMPT/CDRH/OCER/DFOI/	MIKE MEDINA LANX	LIFE SPINE INC - INTERSPINOUS FIXATION SYS K100407
2012-1451	02/29/2012 03/28/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	MIKE MEDINA LANX	SPINE FRONTIER INC - VEGA SPAN SPINOUS PROCESS PLATE SYS K100220
2012-1452	02/29/2012 03/28/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	MIKE MEDINA LANX	GLOBUS MEDICAL INC - SP-FIX SPINOUS PROCESS FIXATION PLATE K102195
2012-1453	02/29/2012	FDA/OMPT/CDRH/OCER/DFOI/	MIKE MEDINA	ALPHATEC SPINE INC BRIDGEPOINT SPINOUS PROCESS

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	03/28/2012		LANX	CLAP--POSTERIOR FIXATION SYS K103205
2012-1454	02/29/2012 03/28/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OC/OES/DFOI/	CHAD MESSER PIPER JAFFRAY & CO	SANQUIN BLOOD SUPPLY, BRUSELS - 483 5/11; SANQUIN BLOOD SUPPLY, AMSTERDAM - 483S 9/11
2012-1455	02/29/2012 03/28/2012	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	TONJA NICHOLS PAYNE MITCHELL LAW GROUP	NEW ENGLAND CRYOGENIC CENTER - REGISTRATION #3002733251, #3005374514 8/11 TO PRESENT
2012-1456	02/29/2012 03/28/2012	FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/ FDA/OFVM/CFSAN/OCD/EOS/	ALICE MEIKLE Vital Pharmaceuticals, Inc.	CYTO SPORT INC - MUSCLE MILK IRESP TO WARNING LTR, INVESTIGATION RVWS 8/11 TO PRESENT
2012-1457	02/29/2012 03/28/2012	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/ FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	JOSHUA A MAYES SUTHERLAND ASBILL & BRENNAN	PHARMACAL CORP, HAUPPAGE, NY - EIRS, 483S, WARNING LTRS, ETC 1/10 TO PRESENT
2012-1458	02/29/2012 04/11/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	MICHAEL W CZACK CARAVONA & CZACK LLC	INDIVIDUAL RECS
2012-1459	02/29/2012 03/28/2012	FDA/OC/OES/DFOI/ OC/ORA/OE/ OC/ORA/OE/	LAUREN SILVIS SIDLEY AUSTIN LLP	INFORMATION DISCLOSURE MANUAL (IDM) - CURRENT
2012-1460	02/29/2012 05/17/2012	FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/ OC/OCM/EMOPS/	SHAWN E SEILER GISLASON MARTIN VARNPNESS ET AL	AGRRCOLA ZARAGOZA INC, MCALLEN TX - SALMONELLASAINTPAUL OUTBREAK INVOICES, RECS, COMM, ETC 7/08
2012-1461	02/29/2012 03/28/2012	OC/CVM/OCD/	ANEET PANESAR BURDOCK GROUP	CAS #107-92-6 (BUTURIC ACID) - USES, SAFETY, COMM ETC
2012-1462	02/29/2012 03/28/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DONALD J FARER DONALD J FARBER ATTY	"WORSENING DEPRESSION & SUICIDALITY IN PATIENTS BEING TREATED W/ANTIDEPRESSANT MEDICATIONS" - FDA PUBLIC HEALTH ADVISORY3/22/04
2012-1463	02/29/2012 03/28/2012	FDA/OFVM/CFSAN/OCD/EOS/	HOLLY J BAYNE BAYNE & ASSOCIATES	CORN REFINERS ASSOC/FDA MTG - LBLG USING "NATURAL", 4/16/08; "NATURAL" USE IN LBLG PRE-4/16/08 MET; GERALDINE JUNE LTR (EVALUATION & LBLG TEAM, & DIETARY SUPPLEMENTS TO CORN REFINERS ASSOC, 7/3/08, ETC
2012-1464	02/29/2012 03/28/2012	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	GETZ, STEPHEN M	CELLAR AT JASPER HILL (JASPER HILL CREAMERY), GREENSBORO, VT - EIRS, 2010 & 2011

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2012-1465	02/29/2012 03/28/2012	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	INC REGULATORY CONSULTING & SUBMISSIONS	3M PHARMACEUTICALS, 3M DRUG DELIVERY SYS DIV, NORTHRIDGE, CA - EIRS, 483S, CO CORR 8/1/11 TO PRESENT
2012-1466	02/29/2012 03/28/2012	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	ANGELIA D SLAYTON INC REGULATORY CONSULTING & SUBMISSIONS	CATALENT PHARMA SOLUTIONS (FORMERLY CARDINAL HEALTH PKGING SERVICES, STERILE TECHNOLOGIES), WOODSTOCK, IL - EIRS, 483S, CO CORR 8/1/11 TO PRESENT
2012-1467	02/29/2012 03/28/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANGELIA D SLAYTON INC REGULATORY CONSULTING & SUBMISSIONS	DAINIPPON SUMITOMO PHARMA, SUZUKA, MIE, JAPAN - EIRS, 483S, cCOCORR 8/1/11 TO PRESENT
2012-1468	02/29/2012 03/28/2012	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	ANGELIA D SLALYTON INC REGULATORY CONSULTING & SUBMISSIONS	ABC LABORATORIES, COLUMBIA, MO - EIRS, 483S, CO RESP 8/1/11 TO PRESENT
2012-1469	02/29/2012 03/28/2012	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	ANGELIA D SLAYTON INC REGULATORY CONSULTING & SUBMISSIONS	DOW CHEMICAL CO, MIDLAND, MI - EIRS, 483S, CO RESP 8/1/11 TO PRESENT
2012-1470	02/29/2012 03/28/2012	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	ANGELIA D SLAYTON INC REGULATORY CONSULTING & SUBMISSIONS	HOLOPACK, COLUMBIA, SC - EIRS, 483S, CO RESP 8/1/11 TO PRESENT
2012-1471	02/29/2012 03/28/2012	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	ANGELIA D SLAYTON INC REGULATORY CONSULTING & SUBMISSIONS	PATHEON, CINCINNATI, OH - EIRS, 483S, CO RESP 8/1/11 TO PRESENT
2012-1472	02/29/2012 03/28/2012	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	ANGELIA D SLAYTON INC REGULATORY CONSULTING & SUBMISSIONS	PPD LABORATORIES, MIDDLETON, WI - EIRS, 483, CO RESP 8/1/11 TO PRESENT
2012-1473	02/29/2012 03/28/2012	FDA/OMPT/CDRH/OCER/DFOI/	CARL BEAURLING CMB REGULATORY SPECIALTIES	KIMBERLY-CLARK CORP - KIMGUARD ONE STEP STERILIZATION WRAP K092167
2012-1474	02/29/2012 03/28/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	ETHICON INC - PDS BARBED SUTURES K113004
2012-1475	02/29/2012 03/28/2012	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	GRANT RASALEY ASEPTICO INC	ASI MEDICAL INC, ENGLEWOOD, CO - EIR, 483 MOST RECENT
2012-1476	02/29/2012 03/28/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRENT M ARDAUGH NORTHWESTERN UNIV FEINBERG SCHOOL OF	K022236, K031328, K944353 ETC

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			MEDICINE	
2012-1477	02/29/2012 03/28/2012	OC/CVM/OCD/	KRISTI O SMEDLEY WASHINGTON INFORMATION SOURCE	MASCOMA SUBMISSION - BIOENGINEERED YEAST
2012-1478	02/29/2012 03/28/2012	FDA/OFVM/CFSAN/OCD/EOS/	GRONER, STEFANIE	PHUSION PROJECTS LLC - TEST RESULTS, APRVL, COMM ETC, LAST 5 YRS
2012-1479	02/29/2012 03/28/2012	OC/ORO/ OC/ORO/ OC/OCM/EMOPS/ FDA/OFVM/CFSAN/OCD/EOS/	PATTI WALLER MARLER CLARK ATTYS	TACO BELL CORP - MULTI-STATE SALMONELLA ENTERIDITIS INVESTIGATION RECS, CORR, TEST RESULTS, ETC 10/11 TO 1/12
2012-1480	03/01/2012 03/29/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	HARPER, JENNA	INACTIVE INGREDIENT GUIDE - OLOPATADINE, SODIUM CHLORIDE (NACL), EDENTATE DISODIUM, ETC
2012-1481	03/01/2012 03/29/2012	FDA/OFVM/CFSAN/OCD/EOS/	LI ZHANG PHD BASF CORP	ASHLAND INC - FCN 979 3/10 TO 8/10
2012-1482	03/01/2012 03/29/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/	STACI M TROLIAN BIOMET, INC.	DOUGLAS P SINN DDS - WARNING LTR 1/23/03, CORR
2012-1483	03/01/2012 03/29/2012	FDA/OMPT/CDRH/OCER/DFOI/	JOSEPH CICCONE CHURCH & DWIGHT CO INC	DVC MASTER FILE (DMF) MAF-382
2012-1484	03/01/2012 03/29/2012	FDA/OMPT/CDRH/OCER/DFOI/	JOHNNY NGUYEN PERPPERMINT DENTAL	ARIBEX NOMAD - PORTABLE X-RAY SYS FORM FDA 2579
2012-1485	03/01/2012 03/29/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	NATHAN P CHANEY CHANEY LAW FIRM PA	MARCAINE SPINAL NDA 18-692 - FDA-APPROVED LBLG (FOR PHYSICIANS) (CERTIFIED)
2012-1486	03/01/2012 03/29/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JEANNE JARZABEK ASTELLAS PHARMA US INC	NDA 21-754 - RVWS
2012-1487	03/01/2012 03/29/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	HAILEY M BENTON FLOYD SKEREN & KELLY LLP	NDA 19-949 - APRVL RECS

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		FDA/OMPT/CDER/GRP/DIDP/		
2012-1488	03/01/2012 03/29/2012	OC/ORP/ OC/ORP/ FDA/OGROP/ORP/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORP/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORP/SW-FO/DEN-DO/DEN-CB/	ABRAHAM PAYTON AMERICAN BRIDGE	ICON HEALTH & FITNESS (1994-2006), LEINER HEALTH PRODUCTS (1992-2004), MEDICAL SPECIALTIES GROUP (1995-2003), ETC - CMLNPTS, INVESTIGATION FILES, FINES, ETC
2012-1489	03/01/2012 03/29/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN. J. HAY SALANS LLP	TEVA PHARMS INDUSTRIES LTD, KFAR SAVA, ISRAEL - 483 8/26/10
2012-1490	03/01/2012 03/29/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN J. HAY SALANS LLP	TEVA CANADA LTD, TORONTO, CANADA - 483 2/27/09
2012-1491	03/01/2012 03/29/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN J. HAY SALANS ATTY	TEVA PHARMS FINE CHEMICALS, BULCIAGO, COMO, ITALY - 483 2/3/11
2012-1492	03/01/2012 03/29/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN J. HAY SALANS LLP	TEVA CANADA LTD, MARKHAM, CANADA - 483 7/29/10
2012-1493	03/01/2012 03/29/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN J. HAY SALANS LLP	TEVA PHARMS, WATERFORD, IRELAND - 483 3/6/09
2012-1494	03/01/2012 03/29/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN J. HAY SALANS LLP	TEVA PHARMS, WATERFORD, IRELAND - 483 3/13/09
2012-1495	03/01/2012	FDA/OMPT/CDER/GRP/DIDP/	JOHN J. HAY	TEVA PHARMS, WATERFORD, IRELAND - 483 9/2/10

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	03/29/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SALANS LLP	
2012-1496	03/01/2012 03/29/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN J. HAY SALANS LLP	ASSIA CHEMICAL INDUSTRIES, BEER SHEVA, ISRAEL - 483 9/18/08
2012-1497	03/01/2012 03/29/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN J. HAY SALANS LLP	TEVA RUNCORN, CHESHIRE, UK - 483 4/22/09
2012-1498	03/01/2012 03/29/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN J. HAY SALANS LLP	TEVA RUNCORN, CHESHIRE, UK - 483 11/19/10
2012-1499	03/01/2012 03/29/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN J. HAY SALANS LLP	TEVA PHARMS, JERUSALEM, ISRAEL - 483 9/25/08
2012-1500	03/01/2012 03/29/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN J. HAY SALANS LLP	TEVA PHARMS INDUSTRIES LTD, KFAR, ISRAEL - 483 6/11/09
2012-1501	03/01/2012 03/29/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LAVONNE M PATTON PHD BECKLOFF ASSOCIATES INC	DOXORUBICIN HCL NDA 50-718 - APPROVABLE LTR, LBLG, MOR, ETC
2012-1502	03/01/2012 03/29/2012	FDA/OC/OES/DFOI/	WASHINGTON INFORMATION SOURCE	DAILY LOG 1/16-20-12
2012-1503	03/01/2012 03/29/2012	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 1/23-27/12
2012-1504	03/01/2012	FDA/OC/OES/DFOI/	KENNETH REID	DAILY LOG 1/30/12-2/3/12

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	03/29/2012		WASHINGTON INFORMATION SOURCE	
2012-1505	03/01/2012 03/29/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	USA FAR OCEAN GROUP INC - FEMALE ONE TYPE I & TYPE II RECALL, VAGIFRESH BALL & VAGIFRESH GEL AERS RPT
2012-1506	03/01/2012 03/29/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Doe J	FERRING PHARMS - EUFLEXXA RECS
2012-1507	03/01/2012 03/29/2012	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	CHRISTINE LITTLE RHO INC	DR LYDIE HAZAN, AXIS CLINICAL TRIALS, IMPACT CLINICAL TRIALS, LOS ANGELES, CA - EIRS, 483S, CO RESP 2007 TO PRESENT
2012-1508	03/01/2012 03/29/2012	FDA/OC/OES/DFOI/	WASHINGTON INFORMATION SOURCE	DAILY LOG 1/16-20/12
2012-1509	03/01/2012 03/29/2012	FDA/OC/OES/DFOI/	WASHINGTON INFORMATION SOURCE	DAILY LOG 1/23-27/12
2012-1510	03/01/2012 03/29/2012	FDA/OC/OES/DFOI/	INFORMATION ACCESS	DAILY LOG 1/16-20-12
2012-1511	03/01/2012 03/29/2012	FDA/OC/OES/DFOI/	INFORMATION ACCESS	DAILY LOG 1/23-27/12
2012-1512	03/01/2012 03/29/2012	FDA/OC/OES/DFOI/	LISA TARRISON SCHRAMP CanReg, Inc.	DAILY LOG 1/16-20/12
2012-1513	03/01/2012 03/29/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 1/16-20/12
2012-1514	03/01/2012 03/29/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CTP/OD/	SUZANNE D JENSEN Kleinfeld, Kaplan and Becker, LLP	SWEDISH MATCH AB - NEW TOBACCO PRODS SUBSTANTIAL EQUIVALENCE RPTS AND EXEMPTIONS; FDA DETERMINATIONS ON RPTS SUBMITTED UNDER THE SUBSTANTIAL EQUIVALENCE RPTS
2012-1515	03/01/2012 03/29/2012	FDA/OMPT/CDRH/OCER/DFOI/	STACEY ELLUL NEUROPACE INC	NEOS SURGERY SL - CRANIAL LOOP CRANIAL BONE FIXATION SYS K101235
2012-1516	03/01/2012	FDA/OMPT/CDRH/OCER/DFOI/	DAWN HAAKE	SANDVIK MEDICAL SOLUTIONS, SHEFFIELD, UK - EIR

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	03/29/2012		NUVASIVE INC	1/24/11
2012-1517	03/01/2012 03/29/2012	FDA/OMPT/CDRH/OCER/DFOI/	DAWN HAAKE NUVASIVE INC	GAMMA SERVICE GMBH, RADEBERG, GERMANY - EIR 2/7/11
2012-1518	03/01/2012 03/29/2012	FDA/OMPT/CDRH/OCER/DFOI/	GABRIELA ANCHONDO MEDTRONIC NEUROSURGERY	CODMAN - CERTAS PROGRAMMABLE VALVE SYS K113526
2012-1519	03/01/2012 03/29/2012	FDA/OMPT/CDRH/OCER/DFOI/	GABRIELA ANCHONDO MEDTRONIC NEUROSURGERY	CODMAN - CERTAS PROGRAMMABLE VALVE SYS, CERTAS THERAPY MANAGEMENT SYS K112156
2012-1520	03/01/2012 03/29/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	CHRISTOPHER ORAND BIONUCLEONICS INC	NORDION - CARDIOGEN-82 AND/OR RUBIDIUM-82 GENERATORS AND COLUMNS WITH STRONTIUM-82 483 2008 TO 2012
2012-1521	03/01/2012 03/29/2012	FDA/OGROP/ORR/SE-FO/NOL- DO/NOL-CB/	CHRISTOPHER ORNAD BIONUCLEONICS INC	RBM CO, KNOXVILLE, TN - CARDIOGEN-82, RUBIDIUM-82 INFUSION AND GENERATORS 483S 2008 TO 2012
2012-1522	03/01/2012 03/29/2012	OC/ORR/OCI/ OC/ORR/OCI/	JAKE PEARSON NBC NEWS	INVESTIGATION OF GOOGLE REGARDING THE PURCHASING OF ADVERTISING FOR THE ILLEGAL SALE OF PERScription DURGS WITHOUT PERScriptions 2009 TO 2011
2012-1523	03/02/2012 03/30/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANGELIA D SLAYTON INC RESEARCH CONSULTING & SUBMISSIONS	BESPAK EUROPE LTD, NORFOLK, ENGLAND - EIRS, 483S, CO RESPS 8/1/11 TO PRESENT
2012-1524	03/02/2012 03/30/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANGELIA D SLAYTON INC REGULATORY CONSULTING & SUBMISSIONS	3M HEALTH CARE LT, LEICESTERSHIRE, UK - EIRS, 483S, CO RESPS 8/1/11 TO PRESENT
2012-1525	03/02/2012 03/30/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANGELIA D SLAYTON INC REGULATORY CONSULTING & SUBMISSIONS	SHASUN PHARMA SOLUTIONS (RHODIA PHARMA SOLUTIONS), NORTHUMBERLAND, ENGLAND - EIRS, 483S CO RESP 8/1/11 TO 1/31/12
2012-1526	03/02/2012 03/30/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANGELIA D SLAYTON INC REGULATORY CONSULTING & SUBMISSIONS	NYCOMED GMBH, SINGEN, GERMANY - EIRS, 483S, CO RESPS 8/1/11 TO PRESENT

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2012-1527	03/02/2012 03/30/2012	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	ANGELIA D SLAYTON INC REGULATORY CONSULTING & SUBMISSIONS	PATHEON (MOVA PHARMACEUTICAL CORP), MANATI, PR - EIRS, 483S CO RESP 8/1/11 TO 1/31/12
2012-1528	03/02/2012 03/30/2012	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	ANGELIA D SLAYTON INC REGULATORY CONSULTING & SUBMISSIONS	ALMAC CLINICAL SERVICES, AUDUBON, PA - EIRS, 483S, CO RESP 8/1/11 TO 1/31/12
2012-1529	03/02/2012 03/30/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANGELIA D SLAYTON INC REGULATORY CONSULTING & SUBMISSIONS	DYNAMIT NOBEL GMBH, LEVERKUSEN, GERMANY - EIRS, 483S, CO RESPS 8/1/11 TO PRESENT
2012-1530	03/02/2012 03/30/2012	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	ANGELIA D SLAYTON INC REGULATORY CONSULTING & SUBMISSIONS	CELSIS LABORATORY GROUP, ST LOUIS, MO - EIRS, 483S, CO RESP 8/1/11 TO 1/31/12
2012-1531	03/02/2012 03/30/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	ANGELIA D SLAYTON INC REGULATORY CONSULTING & SUBMISSIONS	KNIPPER & COMPANY INC, LAKEWOOD, NJ -EIRS, 483S, CO RESP 8/1/11 TO 1/31/12
2012-1532	03/02/2012 03/30/2012	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	ANGELIA D SLAYTON INC REGULATORY CONSULTING & SUBMISSIONS	LANCASTER LABS, LANCASTER, PA - EIRS, 483S, CO RESP 8/1/11 TO 1/31/12
2012-1533	03/02/2012 03/30/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANGELIA D SLAYTON INC RESEARCH CONSULTING & SUBMISSIONS	LABOR L & S AG, BAD BOCKLET-GROSSENBRANCH, GERMANY - EIRS, 483S, CO RESPS 8/1/11 TO PRESENT
2012-1534	03/02/2012 03/30/2012	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	ANGELIA D SLAYTON INC REGULATORY CONSULTING & SUBMISSIONS	MEDCOMM SOLUTIONS, EMERYVILLE, CA - EIRS, 483S, CO RESPS 8/1/11 TO PRESENT
2012-1535	03/02/2012 03/30/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID B REDWINE DAVID B REDWINE MD	TAP (ABBOTT) - LUPRON DEPOT (LELUPROLIDE ACETATE) STUDY M84-042, M86-031, M86039, ETC
2012-1536	03/02/2012 03/30/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANGELIA D SLAYTON INC REGULATORY CONSULTING & SUBMISSIONS	MICRONISIERUNGS-KONTOR OBERROT GMBH (MCKO), OBERROT, GERMANY - EIRS, 483S, CO RESPS 8/1/11 TO PRESENT
2012-1537	03/02/2012	FDA/OGROP/ORACE-FO/BLT-	ANGELIA D SLAYTON	NEXT BREATH LLC, BALTIMORE, MD - EIRS, 483S, CO

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	03/30/2012	DO/BLT-CB/	INC REGULATORY CONSULTING & SUBMISSIONS	RESPS, 8/1/11 TO PRESENT
2012-1538	03/02/2012 03/30/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	ANGELIA D SLAYTON INC REGULATORY CONSULTING & SUBMISSIONS	NORWICH PHARMACEUTICALS INC, NORWICH, NY - EIRS, 483S, CO RESPS 8/1/11 TO PRESENT
2012-1539	03/02/2012 03/30/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANGELIA D SLAYTON INC REGULATORY CONSULTING & SUBMISSIONS	PATHEON INC, CEDEX, FRANCE - EIRS, 483S, CO RESPS 8/1/11 TO PRESENT
2012-1540	03/02/2012 03/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	MATTHEW ERJAVEE MATHEW ERJAVEC PA	STRYKER CORP - STRYKER ORTHOPEDICS CERAMIC ON CERAMIC HIP WITH TRIDENT ACETABULAR SHELL & STANDARD ALUMINA-CERAMIC LINER MDRS
2012-1541	03/02/2012 03/30/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANGELIA D SLAYTON INC REGULATORY CONSULTING & SUBMISSIONS	PATHEON INC, ONTARIO, CANADA - EIRS, 483S, CO RESPS 8/1/11 TO PRESENT
2012-1542	03/02/2012 03/30/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANGELIA D SLAYTON INC REGULATORY CONSULTING & SUBMISSIONS	PATHEON INC, WHITBY, ONTARIO, CANADA - EIRS, 483S, CO RESPS 8/1/11 TO PRESENT
2012-1543	03/02/2012 03/30/2012	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	ANGELIA D SLAYTON INC REGULATORY CONSULTING & SUBMISSIONS	PACE ANALYTICAL LIFE SCIENCES LLC, OAKDALE, MN - EIRS, 483S, CO RESPS 8/1/11 TO PRESENT
2012-1544	03/02/2012 04/10/2012	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	ANGELIA D SLAYTON INC REGULATORY CONSULTING & SUBMISSIONS	PFIZER INC, KALAMAZOO, MI - EIRS, 483S, CO RESPS 8/1/11 TO PRESENT
2012-1545	03/02/2012 03/30/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	MARINA GLAZMAN BAINBRIDGE INC	ORMCO - FS ALIGNER 510K 1/09 TO 1/1/12
2012-1546	03/02/2012 03/30/2012	OC/CVM/OCD/ OC/OA/OM/OMP/DDM/	KRISTI O SMEDLEY WASHINGTON INFORMATION SOURCE	NADAS - FOI SUMMARIES, LBLG, ENVIRONMENTAL ASSESSMENTS 1990, 1995
2012-1547	03/02/2012 03/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	DAWN HAAKE NUVASIVE INC	DOT - CHARLES-DARWIN-RING , EIR 1/31/11
2012-1548	03/02/2012 03/30/2012	FDA/OC/OES/DFOI/	JOANNE HOGAN FOI Services, Inc.	2007-2771, 2007-6972, 2007-10869, ETC

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2012-1549	03/02/2012 03/30/2012	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	DOUGLAS N BLUE ZETETIC	MARCS INC - ENTRY AV300242573, AV300242581
2012-1550	03/02/2012 03/30/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOI REQUESTS 2/13-17/12
2012-1551	03/02/2012 03/30/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOI REQUESTS 2/20-24/12
2012-1552	03/02/2012 03/30/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI CLOSED REQUESTS 2/20-24/12
2012-1553	03/02/2012 03/30/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI CLOSED REQUESTS 2/13-17/12
2012-1554	03/02/2012 03/30/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	WOLTERS KLUWER LAW & BUSINESS	FOI CLOSED REQUESTS 2/13-17/12
2012-1555	03/02/2012 03/30/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	BRIAN HARTIMAN ABC NEWS	AAP PHARMACUTICALS LLP, GRAND ISLAND, NY - EIRS, PHOTOGRAPHS, VIDEO, ETC
2012-1556	03/02/2012 03/30/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI CLOSED REQUESTS 2/20-24/12
2012-1557	03/02/2012 03/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	MATT CLAUSEN MEDLINE INDUSTRIES INC	STRYKER - STERI-SHIELD FLYTE TOGAS K073017
2012-1558	03/02/2012 03/30/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	KATE WILLSON ICIJ	TISSUE BANK REGISTRY LIST
2012-1559	03/02/2012 03/30/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	SMITH, VIRGIL L	INDIVIDUAL RECS
2012-1560	03/05/2012 04/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	FOI Services, Inc.	TYSABRI (NATALIZUMAB) - UPDATE OF HEALTHCARE PROFESSIONAL RECS 4/22/11 (CERTIFIED)
2012-1561	03/05/2012 04/02/2012	FDA/OMPT/CDRH/OCER/DFOI/	KALANGE, JOHN T	K060126
2012-1562	03/05/2012 04/02/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	JOHN J HAY SALANS LLP	IVAX PHARMACEUTICALS INC (AKA TEVA), CONGERS, NY - 483, 11/3/08

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2012-1563	03/05/2012 04/02/2012	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	JOHN J HAY SALANS LLP	BARR LABORATORIES INC, FOREST, VA - 483, 4/8/10
2012-1564	03/05/2012 04/02/2012	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	JOHN J HAY SALANS ATTY	TEVA PHARMACEUTICALS USA INC, SELLERSVILLE, PA - 483S, 10/20/08 & 4/28/10
2012-1565	03/05/2012 04/02/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	JOHN J HAY SALANS LLP	TEVA PARENTAL MEDICINES INC, IRVINE, CA - 483S, 9/4/08, 7/24/09, & 5/14/10
2012-1566	03/05/2012 04/02/2012	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	JOHN J HAY SALANS LLP	TEVA WOMENS HEALTH INC, CINCINNATI, OH - 483S, 7/1/09 & 11/8/10
2012-1567	03/05/2012 04/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARYLYNN GRAHAM SNELL & WILMER LAW OFCS	ISRS 3236328-0, 3880852-4, 5778643-2 ETC
2012-1568	03/05/2012 04/02/2012	FDA/OO/OFBA/OAGS/	MARILYN W ANDRULIS MARALINA CORP	FOOD & DRUG ADMIN (FDA), CENTER FOR DISEASE CONTROL (CDC) & PROGRAM SUPPORT CENTER (PSC) - PURCHASE CARD HOLDERS LISTS
2012-1569	03/06/2012 04/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	TYSABRI (NATALIZUMAB) BLA 12-5104 - SUPPLEMENT APRVL LTR 10/7/11 (CERTIFIED)
2012-1570	03/06/2012 04/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	TYSABRI (NATALIZUMAB) BLA 12-5104 - LTR, LBLG 10/3/08 (CERTIFIED)
2012-1571	03/06/2012 04/03/2012	FDA/OMPT/CDRH/OCER/DFOI/	ANDREW LA PIETRA QMETRICS TECHNOLOGIES	K924810, K060845, K961144, ETC
2012-1572	03/06/2012 04/03/2012	FDA/OC/OES/DFOI/	CHANDRAN TIRVATTAR DR REDDY'S LABORATORIES INC	GLENMARK - CICLOPIROX ANDA 09-1595 - SBA
2012-1573	03/06/2012 04/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JESSICA SMYTH MARTIN DIAZ LAW FIRM	AMERICAN PHARMACEUTICAL PARTNERS INC (APP PHARMACEUTICALS LLC) - OXYTOCIN PI 4/25/07
2012-1574	03/06/2012 04/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CRYSTAL LSPINKS GLENMARK PHARMACEUTICAL	HERCEPTIN - SBA

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	INC	
2012-1575	03/06/2012 04/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FARAH MORGAN FARAH MORGAN MD	KORLYM - APRVL PKG
2012-1576	03/06/2012 04/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DANIEL NEWMAN NEWMAN	LEVOTHYROXINE SODIUM - STUDY
2012-1577	03/06/2012 04/03/2012	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	LAURENCE D MASS LAWRENCE D MASS ATTY AT LAW	PARTICLE DYNAMICS INTERNATIONAL, ST LOUIS, MO - EIR 2/27/10
2012-1578	03/06/2012 04/03/2012	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	FOI Services, Inc.	CAMPUS PUB, LEXINGTON, KY - EIRS, 483S, CO RESP, ETC 2/15-16/12
2012-1579	03/06/2012 04/03/2012	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	LIANE LAROCHELLE DEKA RESEARCH & DEVELOPMENT CORP	ORTHOTICS & PROSTHETICS ONE INC, WATERLOO, IA - EIR 11/29/11-12/1/11
2012-1580	03/06/2012 04/03/2012	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	RICARDO RONQUILLO NEUROGESX	HK PLASTICS ENGINEERING INC, OCEANSIDE, CA - EIRS, 483S, WARNING LTRS, ETC 1/07 TO PRESENT
2012-1581	03/06/2012 04/03/2012	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	WENDY BARNHART PERKINELMER INC	NEW JERSEY STATE DEPARTMENT OF HEALTH & SENIOR SERVICES, EWING, NJ - 482, 483, RPTS 1/26/12
2012-1582	03/06/2012 04/03/2012	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	RICHARDO RONQUILLO NEUROGESX	PINTA FOAMTEC, MINNEAPOLIS, MN - EIRS, 483S, WARNING LTRS 1/07 TO PRESENT
2012-1583	03/06/2012 04/03/2012	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	SHAWN H HUBER PROFESSIONAL HOSPITAL SUPPLY INC	AMERICAN CONTRACT SYSTEMS, TIFFIN, OH - EIR, CLOSE OUT LTR 1/5/12, 1/5-14/11
2012-1584	03/06/2012 04/03/2012	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Doe J	INDIVIDUAL RECS
2012-1585	03/06/2012 04/03/2012	OC/OCOS/OES/ OC/OCOS/OES/	STEVEN B TOENISKOETTER FAEGRE BAKER DANIELS	GEONOME ANNOUNCEMENT EXHIBIT A - ANALYSIS RECS, COMPARATIVE ANALYSIS
2012-1586	03/06/2012	FDA/OFVM/CFSAN/OCD/EOS/	JOSEPHINE TORRENTE	OMEGA-3-ACID ETHYL ESTERS - SUBMISSSIONS ESTABLISHING BIOEQV, RESP, GUIDANCE TO ESTABLISH

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	04/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Hyman, Phelps & McNamara P.C.	BIOEQV
2012-1587	03/06/2012 04/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	CHRISTY MENG INNOPHARMA INC	JANSEN PHARMS - ELMIRON (PENTOSAN POLYSULFATE SODIUM CAPS) NDA 20-193 SBA
2012-1588	03/06/2012 04/03/2012	OC/OA/OM/OMP/DDM/ FDA/OMPT/CDRH/OCER/DFOI/	SANDRA S MATSUMOTO ADVANCED BIOHEALING	GENERAL & PLASTIC SURGERY DVC PANEL A/C - BRIEFING BOOK 1/29/98
2012-1589	03/06/2012 04/03/2012	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	CHARLOTTE HUFFMAN NBC-17	DUKE UNIV HEALTH SYSTEM IRB - DEAN'S LTR REFERENCED IN EIR 1/31/11
2012-1590	03/06/2012 04/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORA/ OC/ORA/	BRAD SCHONHOFT	BULK HYDROXPROGESTERONE CAPROATE ACTIVE PHARMACEUTICAL INGREDIENT (APIS) & COMPOUNDED HYDROXPROGESTERONE CAPROATE PRODS - RESULTS
2012-1591	03/06/2012 04/03/2012	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	KRISTEN CHANDLER UT HEALTH SCIENCE CENTER AT SAN ANTONIO	ALLO-ADVANTAGE, BOERNE, TX - EIR, 483 MOST RECENT
2012-1592	03/06/2012 04/23/2012	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	KRISTINE A CROSSWHITE CROSSWHITE LIMBRICK & SINCLAIR LLP	SK FOOD GROUP INC, RENO, NV - INSPS, ANALYSES, FOOD REGISTRY RPTS, ETC 1/08 TO PRESENT
2012-1593	03/06/2012 04/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MICHAEL P MANAPOL ESQ BRIAN D WITZER INC	SOLODYN ER TABS NDA 50-808 - SAFETY RVW 6/3/10
2012-1594	03/06/2012 04/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHANDRAN TIRUVATTAR DR REDDY'S LABORATORIES INC	GLENMARK GENERICS - MARLISSA (ETHINYL ESTRADIOL, LEVONORGESTREL) ANDA 91-452 SBA
2012-1595	03/06/2012	FDA/OFVM/CFSAN/OCD/EOS/	CHRISTOPHER T LEE	CFSAN HEALTH HAZARD EVALUATION (HHE #8065) - RECS

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	04/03/2012	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/ FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	DICKIE MCCAMEY & CHILCOTE	
2012-1596	03/06/2012 04/03/2012	FDA/OFVM/CFSAN/OCD/EOS/	WILLIAM A OLSON PHD WASHINGTON INFORMATION SOURCE	PAPER PAK INDUSTRIES - FCN 1125
2012-1597	03/06/2012 04/03/2012	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	Doe J	SNUGZ USA, SALT LAKE CITY, UT - AUDITS
2012-1598	03/06/2012 04/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	TYBABRI (NATALIZUMAB) BLA 125104 LBLG, CERTIFIED
2012-1599	03/06/2012 04/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	TYSABRI (NATALIZUMAB) BLA 125014 LBG 4/1/11
2012-1600	03/06/2012 04/03/2012	FDA/OMPT/CDRH/OCER/DFOI/	HUDA YUSUF BOSTON SCIENTIFIC CORP	CR BARD INC - BARD DUAL LUMEN URETERAL CATHETER K032521

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2012-1601	03/06/2012 04/03/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	2012-610
2012-1602	03/06/2012 04/27/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	TRANSETERIX INC - SPIDER STANDARD & ADVANCED K102839
2012-1603	03/06/2012 04/03/2012	FDA/OMPT/CDRH/OCER/DFOI/	HUDA YUSUF BOSTON SCIENTIFIC CORP	ACMI CORP - DUAL LUMEN URETERAL CATHETER K043581
2012-1604	03/06/2012 04/03/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	FOI Services, Inc.	TOBACCO MANUFACTURERS - EIRS, WARNING LTRS, 483S, CO RESP 10/1/11 TO 2/29/12
2012-1605	03/06/2012 04/03/2012	FDA/OMPT/CDRH/OCER/DFOI/	HUDA YUSUF BOSTON SCIENTIFIC CORP	COOK UROLOGICAL INC - URETERAL CATHETER K923729
2012-1606	03/06/2012 04/03/2012	FDA/OMPT/CDRH/OCER/DFOI/	HUDA YUSUF BOSTON SCIENTIFIC CORP	APPLIED MEDICAL RESOURCES CORP - URETERAL CATHETER K020577
2012-1607	03/06/2012 04/03/2012	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	ANGELIA D SLAYTON INC REGULATORY CONSULTING & SUBMISSIONS	PHARMACEUTICS INTERNATIONAL INC, HUNT VALLEY, MD - EIRS, 483S, CO RESP 8/11 TO 1/12
2012-1608	03/06/2012 04/03/2012	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	ANGELIA D SLAYTON INC REGULATORY CONSULTING & SUBMISSIONS	UPS SUPPLY CHAIN SOLUTIONS, RENO, NV - EIRS, 483S CO RESP 8/11 TO 1/12
2012-1609	03/06/2012 04/03/2012	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	ANGELIA D SLAYTON INC REGULATORY CONSULTING & SUBMISSIONS	UPS SUPPLY CHAIN SOLUTIONS, LOUISVILLE, KY - EIRS, 483S, CO RESP 8/11 TO 1/12
2012-1610	03/06/2012 04/03/2012	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	MICHAEL P. MANAPOL, Esq. BRIAN D WITZER INC	SOLODYN EXTENDED RELEASE TABS NDA 50-808
2012-1611	03/06/2012 04/03/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	ANGELIA D SLAYTON INC REGULATORY CONSULTING & SUBMISSIONS	PHARMAGISTICS LLC, SOMERSET, NJ - EIRS, 483S, CO RESP 8/11 TO 1/12
2012-1612	03/06/2012 04/03/2012	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	ANGELIA D SLAYTON INC REGULATORY CONSULTING & SUBMISSIONS	UNIV OF IOWA, PHARMACEUTICAL SERVICES DIVISION, COLLEGE OF PHARMACY, IOWA CITY, IA - EIRS, 483S, CO RESP 8/11 TO 1/12
2012-1613	03/06/2012 04/03/2012	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	ANGELIA D SLAYTON INC REGULATORY CONSULTING & SUBMISSIONS	UNIV OF IOWA, PHARMACEUTICAL SERVICES DIVISION, COLLEGE OF PHARMACY, IOWA CITY, IA - EIRS, 483S, CO RESP 8/11 TO 1/12
2012-1614	03/06/2012	FDA/OMPT/CDER/ERP/DIDP/	ANGELIA D SLAYTON	MYLAN - BUDESONIDE ANDA 90-410 APRVL LTR, LBLG,

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2012-1615	03/06/2012 04/03/2012	FDA/OGROP/ORACE-FO/CIN- DO/CIN-CB/	ANGELIA D SLAYTON INC REGULATORY CONSULTING & SUBMISSIONS	WEST ANALYTICAL SERVICES LLC, MAUMEE, OH - EIRS, 483S, CO RESP 8/11 TO 1/12
2012-1616	03/06/2012 04/03/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	TRANSENERIX INC - SPIDER SURGICAL INSTRUMENTS K091697
2012-1617	03/06/2012 04/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	TEVA PHARMS - TESTOSTERONE NDA 20-2763 APRVL RECS
2012-1618	03/06/2012 04/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELLIOT FAVUS, M.D. FAVUS INSTITUTIONAL RESEARCH LLC	ADCETRIS (BRENTUXIMAB VEDOTIN) AER 10/11 TO PRESENT
2012-1619	03/06/2012 04/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	TYSABRI (NATALIZUMAB) BLA 125104 - LBLG 1/21/10 (CERTIFIED)
2012-1620	03/06/2012 04/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	TYSABRI (NATALIZUMAB) BLA 125104 - LBLG 9/16/11 (CERTIFIED)
2012-1621	03/06/2012 04/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARY ANDERSON SHIRE INC	PROZAC - SBA 18-936/S-065; 20-101/S-027; 20-974/S-001
2012-1622	03/06/2012 04/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	NANCY ZHANG, Ph.D QUANTITATIVE SOLUTIONS INC	LUPRON DEPOT (LEUPROLIDE ACETATE) NDA 20011-S000
2012-1623	03/06/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	STEPHANIE KALBERER	TRANSCRIPT OF HCMV WORKSHOP 1/10/12

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	04/03/2012		REDBIOTEC AG	
2012-1624	03/06/2012 04/03/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	JIM NIENDORFF CASSIDAY SCHADE LLP	INDIVIDUAL RECS
2012-1625	03/06/2012 04/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PAMELA SCHANEEN SHIONOGI INC	VAGIFEM (ESTRADIOL VAGINAL TABS) SBA SAFETY
2012-1626	03/06/2012 04/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PAMELA SCHANEEN SHIONOGI INC	KAPVAY (CLONIDINE) SBA NDA 22-331/S001,002
2012-1627	03/06/2012 04/03/2012	FDA/OMPT/CDRH/OCER/DFOI/	GOYAL, RAJU	MOBILE MIM K112930
2012-1628	03/06/2012 04/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ZIMMERMAN, NOAH	ALL NEW DRUG APPLICATIONS INFO 2010-2011
2012-1629	03/06/2012 04/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TAKAHASHI, HELEN	FORTEO - AER
2012-1630	03/06/2012 04/03/2012	FDA/OC/OES/DFOI/	Joan Stitt, UG2CD-16 MERCK & CO., INC.	A list of all FOIA requests closed 2/1-29/2012"on CD
2012-1631	03/06/2012 04/03/2012	FDA/OC/OES/DFOI/	Joan Stitt, UG2CD-16 MERCK & CO., INC.	FOI DAILY LOG 2/27/2012 to 3/2/2012
2012-1632	03/07/2012 04/04/2012	FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/	JOHNATHAN RICKMAN FDA NEWS	DHAIWAL LABORATORIES LLC, DALLAS, TX, CLAVEL CORP, ABILENE, TX, MEDICALTECHNOLOGY INC, GRAND PRAIRE, TX - 483S 12/-31/11
2012-1633	03/07/2012 04/04/2012	FDA/OGROP/ORR/CE-FO/CIN-DO/CIN-CB/	JOHANTHAN RICKMAN FDA NEWS	BEN VENUE LABS, BEDFORD, OH; PIEZOSURGERY INC, COLUMBUS, OH; MP BIOMEDICALS DIAGNOSTICS DIVISION, SOLON, OH - 483S 12/1-31/11
2012-1634	03/07/2012 04/04/2012	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	JOHANTHAN RICKMAN FDA NEWS	PRIME TECHNOLOGICAL SERVICES, SUWANEE, GA, PIE MEDICAL INTL, BUFORD, GA - 483S 12/1-31/11
2012-1635	03/07/2012	FDA/OGROP/ORR/CE-FO/CHI-DO/CHI-CB/	JOHANTHAN RICKMAN	BLUE SKY BIO, GRAYSLAKE, IL, ACCUMEDIX INC, GRAYSLAKE, IL; ASTRON DENTAL CORP, LAKE ZURICH, IL -

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	04/04/2012		FDA NEWS	483S 12/1-31/11
2012-1636	03/07/2012 04/04/2012	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	JOHANTHAN RICKMAN FDA NEWS	FERNDAL LABORATORIES INC, FERNDAL, MI; CARACO PHARMACEUTICAL LABORATORIES LTD, DETROIT, MI; CAYMAN CHEMICAL CO, ANN ARBOR, MI, ETC - 483S 12/31/11
2012-1637	03/07/2012 04/04/2012	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OC/OES/DFOI/	JOHNATHAN RICKMAN FDA NEWS	HEI INC (ADVANCED MEDICAL DIVISION), BOULDER, CO, PUSLEEP INC, SOUTH JORDAN, UT; PERSONAL PERFORMANCE MEDICAL CORP, SALT LAKE CITY, UT, ETC - 483S 12/1-31/11
2012-1638	03/07/2012 04/04/2012	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	JOHANTHAN RICKMAN FDA NEWS	BELCHER PHARMACEUTICALS LLC, LARGO, FL, STINGRAY SURGICAL PRODUCTS LLC, BOCA RATON, FL, ARJ MEDICAL INC, OLDSMAR, FL, ETC - 483S 12/1-31/11
2012-1639	03/07/2012 04/04/2012	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	JOHANTHAN RICKMAN FDA NEWS	CAMBRIDGE MAJOR LABS, GERMANTOWN, WI, LIFE CORP, MILWAUKEE, WI - 483S 12/1-31/11
2012-1640	03/07/2012 04/13/2012	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	JOHNATHAN FDA NEWS	CITRA LABS LLC, BRAINTREE, MA, CUBIST PHARMACEUTICALS INC, LEXINGTON, MA, MILLENNIUM MILLENNIUM PHARMACEUTICALS INC, MA, ETC - 483S 12/1-31/11
2012-1641	03/07/2012 04/04/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	JOHATHAN RICKMAN FDA NEWS	ALPHA OMEGA SERVICES INC, BELLFLOWER, CA, THERA LIGHT INC, CARLSBAD, CA, DREAM WRX DENTAL LAB, LOS ANGELES, CA, ETC - 483S 12/1-31/11
2012-1642	03/07/2012 04/04/2012	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	JOHANTHAN RICKMAN FDA NEWS	FOREST PHARMACEUTICALS INC, EARTH CITY, MO, FLEMING & CO PHARMS, FENTON, MO, ORTHOTICS & PROSTHETICS ONE INC, WATERLOO, IA, ETC - 483S 12/1-31/11
2012-1643	03/07/2012 04/04/2012	FDA/OMPT/CDRH/OCER/DFOI/	JOHNATHAN RICKMAN FDA NEWS	BIOSPHERE MEDICAL SA, ROISSY EN FRANCE, FRANCE, MECTRON SPA, CARASCO, ITALY, BEIJING TOPLASER TECHNOLOGY CO LTD, BEIJING, CHINA, ETC - 483S 1/1-31/11
2012-1644	03/07/2012 04/04/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/CVM/OCD/	JOHNATHAN RICKMAN FDA NEWS	CIPLA LTD, KURKUMBH VILLAGE, DISTRICT PUNE, MAHARASHTRA, INDIA, ENTERPRISE IMPORTFAB INC, POINTE-CLAIRE, CANADA, ALPHORA RESEARCH INC, OAKVILLE, CANADA, ETC - 483S 12/1-31/11
2012-1645	03/07/2012 04/04/2012	OC/ORACE/ORM/ OC/ORACE/ORM/	JOHNATHAN RICKMAN FDA NEWS	A LIST OF PHARMACEUTICAL, BIOLOGICS & MEDICAL DEVICES MFG & CLINICAL TRIAL FACILITIES IN THE USA & OUTSIDE THE USA - 483S 2/1-29/12
2012-1646	03/07/2012 04/04/2012	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	JOHANTHAN RICKMAN FDA NEWS	EX-LAX, INC, HUMACAO, PR, LILNDE GAS PUERTO RICO INC, CATANO, PR - 483S 12/1-31/11

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2012-1647	03/07/2012 04/04/2012	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	JOHNATHAN RICKMAN FDA NEWS	SOLUM & HERBE, PORT TOWNSEND, WA, MICRO CURRENT TECHNOLOGY INC, SEATTLE, WA, PHILIPS ULTRASOUND INC, BOTHELL, WA - 483S 12/1-31/11
2012-1648	03/07/2012 04/04/2012	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	JOHNATHAN RICKMAN FDA NEWS	CARDICA INC, REDWOOD CITY, CA, AQUEDUCT MEDICAL INC, SAN FRANCISCO, CA, SIEMENS INDUSTRY INC, MILPITAS, CA, ETC - 483S 12/1/31/12
2012-1649	03/07/2012 04/04/2012	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	JOHNATHAN RICKMAN FDA NEWS	SIGMAPHARM LABORATORIES LLC, BENSALEM, PA, INTERLETRIC CORP, WARREN, PA, REX MEDICAL LLP, CONSHOHOCKEN, PA - 483S 12/1-31/11
2012-1650	03/07/2012 04/04/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	JOHNATHAN RICKMAN FDA NEWS	INTELLICELL BIOSCIENCES INC, NEW YORK, NY, ASEPT PAK INC, MALONE, NY, ADVANCE PHARMACEUTICAL INC, RONKONKOMA, NY, ETC - 483S 12/1-31/11
2012-1651	03/07/2012 04/04/2012	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	JOHNATHAN RICKMAN FDA NEWS	HAUSTED PATIENT HANDILNG SYSTEMS LLC, MONTGOMERY, AL, ODYSSEY MEDICAL INC, BARLETT, TN, PETER SCHIFF ENTERPRISES, COOKESVILLE, TN, ETC - 483S 12/1-31/11
2012-1652	03/07/2012 04/04/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	JOHNATHAN RICKMAN FDA NEWS	DENTSPLY PROSTHETICS, BURLINGTON, NJ, LINGRAPHICARE AMERICA INC, PRINCETON, NJ, PROSEC PROTECTION SYSTEMS INC, LAKEWOOD, NJ, ETC - 483S 12/1-31/11
2012-1653	03/07/2012 04/04/2012	FDA/OC/OES/DFOI/	(JOAN STITT (UG2CD-16) MERCK & CO., INC.	2010-7537
2012-1654	03/07/2012 04/04/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	(JOAN STITT (UG2CD-16) MERCK & CO., INC.	2011-5850
2012-1655	03/07/2012 04/04/2012	FDA/OC/OES/DFOI/	JOA N STITT (UG2CD-16) MERCK & CO., INC.	2011-6996
2012-1656	03/07/2012 04/04/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	2011-7588
2012-1657	03/07/2012 04/04/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	20118984
2012-1658	03/07/2012 04/04/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	2011-9166
2012-1659	03/07/2012 04/04/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	2011-9188
2012-1660	03/07/2012 04/04/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	2011-9216
2012-1661	03/07/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16)	2012-378

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	04/04/2012		MERCK & CO., INC.	
2012-1662	03/07/2012 04/04/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	2011-9319
2012-1663	03/07/2012 04/04/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	2011-9340
2012-1664	03/07/2012 04/04/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	2011-9342
2012-1665	03/07/2012 04/04/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	2011-9349
2012-1666	03/07/2012 04/04/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 2/20-24/12
2012-1667	03/07/2012 04/04/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	2012-419
2012-1668	03/07/2012 04/04/2012	FDA/OMPT/CDRH/OCER/DFOI/	GABRIELA ANCHONDO MEDTRONIC NEUROSURGERY	CODMAN ISOCOOL BIPOLAR FORCEPS - K023566
2012-1669	03/07/2012 04/04/2012	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHANDRAN TIRUVATTAR DR REDDY'S LABORATORIES INC	TEVA PHARMS - TESTOSTERONE NDA 20-2763 SBA, CHEM, MFG & CONTROLS RECS, PKG RECS, ETC
2012-1670	03/07/2012 04/04/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JONATHAN KIMMELMAN MCGILL UNIVERSITY BIOMEDICAL ETHICS UNIT	ROTIGOTINE - EFFICACY
2012-1671	03/07/2012 04/04/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JONATHAN KIMMELMAN MCGILL UNIVERSITY BIOMEDICAL ETHICS UNIT	BORTEZOMIB - EFFICACY
2012-1672	03/07/2012 04/04/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JONATHAN KIMMELMAN MCGILL UNIVERSITY BIOMEDICAL ETHICS UNIT	SUNITINIB - EFFICACY
2012-1673	03/07/2012	FDA/OMPT/CDER/ORP/DIDP/	JONATHAN KIMMELMAN	GEFETINAB - EFFICACY

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	04/04/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MCGILL UNIVERSITY BIOMEDICAL ETHICS UNIT	
2012-1674	03/07/2012 04/04/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JONATHAN KIMMELMAN MCGILL UNIVERSITY BIOMEDICAL ETHICS UNIT	ZICONOTIDE - EFFICACY
2012-1675	03/07/2012 04/04/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ALI MOSTAGHIMI DYNAVAX TECHNOLOGIES	ERWIN RENTSCHLER, LAUPHEIM, GERMANY - EIR, 483, WARNING LTR 2001 TO PRESENT
2012-1676	03/07/2012 04/04/2012	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	JAYE McGINN HOSPIRA INC	APP PHARMACEUTICALS LLC - WARNING LTR, 483 2/22/12
2012-1677	03/07/2012 04/04/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANIL SACHDEVA STRIDES INC	APOTHECON - KENALOG 40 (TRIAMCINOLONE ACETONIDE) NDA 14-901 SBA
2012-1678	03/07/2012 04/04/2012	FDA/OMPT/CTP/OD/ FDA/OO/OFBA/OAGS/	CAROLINE WINTER BLOOMBERG BUSINESS NEWS	CIGARETTE LABEL - DESIGN
2012-1679	03/07/2012 04/04/2012	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/ FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KRISTEN L. FLAHERTY MORRISON MAHONEY LLP	INDIVIDUAL RECS
2012-1680	03/07/2012 04/04/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	PREVOR, CHERYL	HUMAN CLNCL TRIALS FOR T CELL USE
2012-1681	03/07/2012	FDA/OMPT/CDER/GRP/DIDP/		TEVA CANADA LTD, STOUVILLE, CANADA - 483 2/27/09

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	04/04/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	
2012-1682	03/07/2012 04/04/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN J. HAY SALANS ATTY	TEVA CZECH INDUSTRIES, OPAVA, CZECH REPUBLIC - A483 9/18/08
2012-1683	03/07/2012 04/04/2012	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	COLLIN J. PENG-SUE HOGAN LOVELLS US LLP	DLITES ENTERPRISES, GAINESVILLE, FL - DLITES CMLPTS, COMM
2012-1684	03/07/2012 04/04/2012	FDA/OFVM/CFSAN/OCD/EOS/	GARANACE BURKE ASSOCIATED PRESS	ALL FIELDS OF INFO COLLECTED IN THE DATABASE 2004 TO PRESENT
2012-1685	03/07/2012 04/04/2012	FDA/OGROP/ORR/CE-FO/CIN-DO/CIN-CB/	DAVID W. PRYOR GALLAGHER GAMS ET AL	SHANES GOURMET; CATERING BY SCOTT; PERFECT CATERING - RECS
2012-1686	03/07/2012 04/04/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORR/ OC/ORR/	DAVID E. McCRAW NEW YORK TIMES	ZHEJIANG CASING ANIMAL BY PRODUCTS CO LTD, HANGZOU, CHINA - IMPORT ALERT
2012-1687	03/08/2012 04/05/2012	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	DOUGLAS N BLUE ZETETIC INC	MARS - CONFECTIONERY ENTRY #AV300241294, #AV300241302
2012-1688	03/08/2012 04/05/2012	FDA/OGROP/ORR/CE-FO/CIN-DO/CIN-CB/	CHRIS HOGAN AIR LIQUIDE USA LLC	WESTERN ENTERPRISES, AVON, OH - EIR, COVERSHEET ENDORSEMENT MOST RECENT
2012-1689	03/08/2012 04/05/2012	FDA/OMPT/CDRH/OCER/DFOI/	BEN MA GLOBAL TREASURE INDUSTRIES LTD	GLOBAL TREASURE FLUID FILLED TEETHER - K043033
2012-1690	03/08/2012 04/05/2012	FDA/OMPT/CDRH/OCER/DFOI/	BEN MA GLOBAL TREASURE INDUSTRIES LTD	RAPID DIGITAL THERMOMETER - K062010
2012-1691	03/08/2012 04/05/2012	FDA/OMPT/CDRH/OCER/DFOI/	BEN MA GLOBAL TREASURE INDUSTRIES LTD	FLEXIBLE TIP THERMOMETER - K030673
2012-1692	03/08/2012 04/05/2012	FDA/OC/OES/DFOI/ OC/ORR/	Doe J	GARY NULL'S ULTIMATE POWER MEAL, TRIARCO INDUSTRIES, ARCON VITAMINS, ETC - RECS 2010-2011

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		OC/ORO/ FDA/OGROP/ORO/CE-FO/NWJ- DO/NWJ-CB/ OC/ORO/OCI/ OC/ORO/OCI/		
2012-1693	03/08/2012 04/05/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	BEN MA GLOBAL TREASURE INDUSTRIES LTD	STANDARD THERMOMETER - K030658
2012-1694	03/08/2012 04/05/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HAILEY M BENTON FLOYD SKEREN & KELLY LLP	ISRS 3004334-7, 3070602-6, 3138085-5, ETC
2012-1695	03/08/2012 04/05/2012	FDA/OMPT/CDRH/OCER/DFOI/	BEN MA GLOBAL TREASURE INDUSTRIES LTD	ELECTRONIC THERMOMETER - K021052
2012-1696	03/08/2012 04/05/2012	FDA/OMPT/CDRH/OCER/DFOI/	BEN MA GLOBAL TREASURE INDUSTRIES LTD	DIGITAL THERMOMETER - K001297
2012-1697	03/08/2012 04/05/2012	FDA/OMPT/CDRH/OCER/DFOI/	BEN MA GLOBAL TREASURE INDUSTRIES LTD	ELETRONIC THERMOMETER - K021028
2012-1698	03/08/2012 04/05/2012	FDA/OMPT/CDRH/OCER/DFOI/	KOEPCKE, EDWARD	REVITALITE - K033765
2012-1699	03/08/2012 04/05/2012	FDA/OMPT/CDRH/OCER/DFOI/	STEVEN B SEAL WILLIAMS LOVE O'LEARY & POWERS PC	CARTICEPT MEDICAL INC - NAVIGATOR DELIVERY SYS K101194
2012-1700	03/08/2012 04/05/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	PFIZER - XANAX AERS
2012-1701	03/08/2012 04/05/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MICHAEL R COHEN INSTITUTE FOR SAFE MEDICATION PRACTICES	MEDWATCH RPTS CODED AS MEDICATION ERRORS 2/1/12- 3/1/12
2012-1702	03/08/2012	FDA/OC/OES/DFOI/		2004-10600

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	04/05/2012		TRONIC, ELAINE H	
2012-1703	03/08/2012 04/05/2012	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	ANNA KEIBURTZ Hyman Phelps and McNamara PC	NAS LLC, MEMPHIS, TN - EIR 1/12
2012-1704	03/08/2012 04/05/2012	FDA/OMPT/CTP/OD/	NATHAN PAUL MEHRENS AMERICANS FORLIMITED GOVERNMENT	EXISTING MODIFIED OR NEW TOBACCO PRODS - SUBSTANTIAL EQUIVALENCE RPTS, NUMBER OF RPTS, BACKLOG 1/11 TO PRESENT
2012-1705	03/08/2012 04/05/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	MARK PIFKO BARON & BUDD PC	PROCTOR & GAMBLE - CREST PRO-HEALTH CLINICAL RINSES RECS, INVESTIGATIONS
2012-1706	03/08/2012 04/05/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN J HAY SALANS ATTY	PFIZER GMBH, MOOSWALDALLE, FREIBURG, GERMANY 6/30/11; PFIZER IRELAND PAHRM, LITTLE ISLAND, COUNTY CORK, IRELAND 6/17/11; PFIZER IRELAND PHARMACEUTICALS INC, RINGASKIDDY, COUNTY CORK, IRELAND 6/24/11, ETC - 483S
2012-1707	03/08/2012 04/05/2012	FDA/OFVM/CFSAN/OCD/EOS/	STEPHEN H MEYER NICK STEIN LAW OFC	ENTEROBACTER SAKAZAKII, CRONOBACTER SAKAZAKII IN INDIANA - MEMOS, RPTS, EMAILS, ETC 2010
2012-1708	03/08/2012 04/05/2012	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	CHRIS HOGAN AIR LIQUIDE USA LLC	WESTERN ENTERPRISES, WESTLAKE, OH - EIR MOST RECENT
2012-1709	03/08/2012 04/05/2012	FDA/OMPT/CTP/OD/ FDA/OO/OFBA/OAGS/	WILLIAM WILSON AMERICANS FORLIMITED GOVERNMENT	ANTI-SMOKING CAMPAIGNS - REQUESTS FOR PROPOSAL (RFP) ON OR AFTER 11/1/11
2012-1710	03/08/2012 04/05/2012	FDA/OFVM/CFSAN/OCD/EOS/	MYODA, T TIMOTHY	GRAS NOTICE GRN000094 - THIRD PARTY INQUIRIES, FDA RESP, PUBLIC KNOWLEDGE
2012-1711	03/08/2012 04/05/2012	FDA/OC/OES/DFOI/	KRISTI O SMEDLEY PHD WASHINGTON INFORMATION SOURCE	2011-9295
2012-1712	03/08/2012 04/05/2012	FDA/OFVM/CFSAN/OCD/EOS/	CARPENTER, MURRAY	GREEN MOUNTAIN , KEURIG, ETC COFFEE ADDED TO COFEE IN K-CUPTS RECS 1/09 TO 12/21/11
2012-1713	03/08/2012 04/05/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	THOMAS KROENKE SPEED TO MARKET INC	KAVO DENTAL - HEALZONE 510K, PMA REQUIREMENTS, DVC CLASSIFICATION, ETC

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		FDA/OMPT/CDRH/OCER/DFOI/		
2012-1714	03/08/2012 04/05/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WHITE #1028750, MATTHEW	LEXAPRO (ESCITALOPRAM) - AERS
2012-1715	03/08/2012 04/05/2012	FDA/OMPT/CDRH/OCER/DFOI/	G MICHAEL WALL PHD O-RAY PHARMA INC	MED-EL CORP - COMBI 40+ COCHLEAR IMPLANT SYS LBLG, SS&E, APRVL ORDER
2012-1716	03/08/2012 04/05/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SEAN BRYNJELSEN AKORN INC	HOSPIRA - PROPOFOL ANDA 77-908 RECS
2012-1717	03/08/2012 04/05/2012	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	MENTOR - SALINE-FILLED MAMMARY PROSTHESIS RPTS
2012-1718	03/08/2012 04/05/2012	FDA/OGROP/ORAP/PA-FO/SEA-DO/SEA-CB/	RICH BLY ENVIRONMENTAL HEALTH SERVICES	QUINAULT PRIDE SEAFOOD, TAHOLAH, WA - RECALLED PROD PHOTOGRAPHS 2/28-29/12
2012-1719	03/08/2012 04/05/2012	OC/OCOS/OL/	LINDSAY YOUNG SUNLIGHT FOUNDATION	P & D DAIRY - REP KEN CALVERT CORR, DAIRY FEED SUBSIDIES, SULFADIMETHOXINE OR PENICILLIN G PROCAINE CORR 2/9/10
2012-1720	03/08/2012 04/05/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	G SRINIVAS ZYDUS PHARMACEUTICALS USA INC	GD SEARLE LLC - NORPACE CR (DISOPYRAMIDE ER CAPS) NDA 18-655 SBA
2012-1721	03/08/2012 04/05/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	G SRIVINAS ZYDUS PHARMACEUTICALS USA INC	TEVA PHARMS - TRIAMCINOLONE ACETONIDE NASAL SPRAY ANDA 78-104 SBA
2012-1722	03/08/2012 04/05/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS Consulting Group, LLC	NORPACE CR NDA 18-655 - APRVL LTR, LBLG, RVWS, ETC
2012-1723	03/08/2012 04/05/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS Consulting Group, LLC	ROSUVASTATIN ZINC NDA 20-2172 - APRVL LTR, LBLG, RVWS, ETC

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		FDA/OMPT/CDER/GRP/DIDP/		
2012-1724	03/08/2012 04/05/2012	FDA/OMPT/CDRH/OCER/DFOI/	G MICHAEL WALL PHD O-RAY PHARMA INC	HOUSE/3M - COCHLEAR IMPLANT LBLG, SS&E, APRVL ORDER
2012-1725	03/08/2012 04/05/2012	FDA/OMPT/CDRH/OCER/DFOI/	G MICHAEL WALL PHD O-RAY PHARMA INC	COCHLEAR AMERICAS - COCHLEAR NUCLEUS FREEDOM 24 COCHLEAR IMPLANT SYS LBLG, SS&E, APRVL ORDER
2012-1726	03/08/2012 04/05/2012	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	L WALSH WPTV-TV	DIRTY MEDICAL INSTRUMENTS IN FL - INVESTIGATIONS, CMLPNTS 2005 TO PRESENT
2012-1727	03/09/2012 04/06/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	EMILY C JOHNSON AKIN GUMP ET AL	MOMENTA PHARMACEUTICALS INC, SANDOZ INC - ENOXAPARIN SODIUM USP 207 TEST DEVELOPMENT, APRVL RECS, CORR, ETC
2012-1728	03/09/2012 04/06/2012	OC/ORR/ OC/ORR/	NICOLE CELLA ALL-WAYS FORWARDING INTERNATIONAL	SIMILAC ISOMIL ENTRY #DP4-0553996-7 LAB RESULTS
2012-1729	03/09/2012 04/06/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KYLE D SMITH JEFFERIES & COMPANY INC	K-V PHARMS - BULK HYDROXYPROGESTERONE CAPROATE COVER LTR, ANALYSES, PHOTOGRAPHS, ETC
2012-1730	03/09/2012 04/06/2012	FDA/OGROP/ORR/CE-FO/DET-DO/DET-CB/	COLLEEN BOSWELL SYBRON DENTAL SPECIALTIES	KERR CORP, ROMULUS, MI - EIR 2010
2012-1731	03/09/2012 04/06/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	WILBUR JOHNSON JR COSMETIC INGREDIENT REVIEW	CHLORPHENSIN - AERS, CAERS
2012-1732	03/09/2012 04/06/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MICHAEL A CAROME MD PUBLIC CITIZEN	INSTITUTIONAL REVIEW BOARD (IRB) REQUIREMENTS FOR SPECIFIC RESEARCH ACTIVITIED INITIATED UNVER AN INVESTIGATIONAL NEW DRUG APPL (IND) - DECISION LTRS, MEMOS, EMAILS, ETC
2012-1733	03/09/2012 04/06/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	HAINES, DAVID S	MEFLOQUINE - APRVL RECS, TEST DATA

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		FDA/OMPT/CDER/GRP/DIDP/ OC/OA/OM/OMP/DDM/		
2012-1734	03/09/2012 04/06/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELENA HOWELL HOGAN LOVELLS US LLP	TEVA PHARMS - TESTOSTERONE NDA 20-2763 APRVL RECS
2012-1735	03/09/2012 04/06/2012	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	DOUGLAS N BLUE ZETETIC	LIFESCAN SCOTLAND LTD - ONE TOUCH ULTRA 50S BLOOD GLUCOSE TEST STRIPS ENTRY #ARE-4122974-6/1/1
2012-1736	03/09/2012 04/06/2012	FDA/OFVM/CFSAN/OCD/EOS/	ERIN E SEDER VENABLE LLP	ALIGN, FLORASTER, CENTRUM PRONUTRIENTS PROBIOTIC, ETC - CAERS
2012-1737	03/09/2012 04/06/2012	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/	Doe J	INDIVIDUAL RECS
2012-1738	03/09/2012 04/06/2012	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	ELISABETH S GRAY MIDDLETON & REUTLINGER	TAYLOR BROTHERS (AMERICAN SNUFF COMPANY LLC, RJ REYNOLDS TOBACCO CO), WINSTON-SALEM, NC - EIRS MOST RECENT
2012-1739	03/09/2012 04/06/2012	FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/	WILLIAM MESTRANDREA PFIZER INC	SCIENTIFIC PROTEIN LABORATORIES LLC, WAUNAKEE,WI - EIRS 1/00 TO PRESENT
2012-1740	03/09/2012 04/06/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/OA/OM/OMP/DDM/ FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	ED SILVERMAN PHARMALOT	MARY HOLLOWAY - DECISION NOT TO DEBAR
2012-1741	03/09/2012 04/06/2012	FDA/OGROP/ORA/CE-FO/BLT- DO/BLT-CB/	WEBB, JACQUELINE	INOVA ALEXANDRIA HOSPITAL, ALEXANDRIA, VA - X-RAY EQUIPMENT INSPS 2008 TO PRESENT
2012-1742	03/09/2012 04/06/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/OA/OM/OMP/DDM/	FOI Services, Inc.	ELIZABETH BIOCHEMICAL - NASAL DECONGESTANT STUDY MEMO TO SUTER FROM N A HULME
2012-1743	03/09/2012	FDA/OMPT/CDER/GRP/DIDP/		ELIZABETH BIOCHEMICAL - NASAL DECONGESTANT STUDY MEMO TO WESSINGER FROM N A HULME

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	04/06/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/OA/OM/OMP/DDM/	FOI Services, Inc.	
2012-1744	03/09/2012 04/06/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/OA/OM/OMP/DDM/	FOI Services, Inc.	OBJECTIVE AND SUBJECTIVE EVALUATION OF PHENYLEPHRINE HCI VS PLACEBO TABS - MEMO
2012-1745	03/09/2012 04/06/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/OA/OM/OMP/DDM/	FOI Services, Inc.	WHOLE WHEAT FLOUR MFG PROCESS - CORR; PUBLIC HEARING TRANS RELATED TO DKT FDC-21 8/1/40
2012-1746	03/09/2012 04/06/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	2011-9281
2012-1747	03/09/2012 04/06/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	CORTECHS LABS INC - NEUROQUANT K061855
2012-1748	03/09/2012 04/06/2012	FDA/OFVM/CFSAN/OCD/EOS/	WILBUR JOHNSON JR COSMETIC INGREDIENT REVIEW	TIN - TOXICITY, PHYSICAL PROPERTIES, DERMAL PENETRATION, ETC
2012-1749	03/12/2012 04/09/2012	FDA/OC/OES/DFOI/	JOAN STIT (UG2CD-16) MERCK & CO., INC.	2012-418
2012-1750	03/12/2012 04/09/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	2011-9585
2012-1751	03/12/2012 04/09/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	2011-9221
2012-1752	03/12/2012 04/09/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	2011-9025
2012-1753	03/12/2012 04/09/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	2010-7685
2012-1754	03/12/2012 04/09/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	2011-4299
2012-1755	03/12/2012 04/09/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	2011-9344
2012-1756	03/12/2012 04/09/2012	FDA/OMPT/CDRH/OCER/DFOI/	PETTHY, JONATHAN M	DEPUY - ASR ACETABULAR CUP, S-ROM TOTAL HIP SYS FEMORAL STEM STANDARD, S-ROM TOTAL HIP SYS ZTT PROXIMAL SLEEVE, ETC - POINT & DATE OF MFG

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2012-1757	03/12/2012 04/09/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KIM SHIPMAN	ISR CO17883740795
2012-1758	03/12/2012 04/09/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	LAUREN SIROIS WEITZ & LUXEMBERG PC	AMGEN INC, AMGEN MANUFACTURING LTD, JANSSEN BIOTECH INC (CENTOCOR ORTHO BIOTECH PRODUCTS LP), ETC - EPOGEN, PROCIT (EPOETIN ALFA) RECALL STUDIES, TEST EVALUATIONS
2012-1759	03/12/2012 04/09/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANDRE PEARSON BIOTECH GENERICS LLC	TYLENOL (ACETANINOPHEN) - NDA & USE: CMC SECTION FOR THE IND & NDA SUBMISSIONS
2012-1760	03/12/2012 04/09/2012	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	BRANDON BROWN MACUGA LIDDLE & DUBIN PC	KROGER CO, MI, NC, TN - PET PRIDE CAT FOOD 3,5 LB, 18 LB PKG 10/24/11; PET PRIDE TASTY BLEND POULTRY & SEAFOOD CAT FOOD 3.5 LB, 18 LB, PET PRIDE KITTEN FORMULA 3.5 LB PKG, ETC 10/10 TO PRESENT
2012-1761	03/12/2012 04/09/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	WEBB, JACQUELINE	INOVA ALEXANDRIA HOSPITAL; - X-RAY EQUIPMENT MFRS & MODEL NUMBERS
2012-1762	03/12/2012 04/09/2012	OC/ORACE-FO/ OC/ORACE-FO/	GAIL LESSICK LACHMAN CONSULTANT SERVICES INC	LIST OF DOMESTIC & FOREIGN INSP - DRUG COMAPNIES, MEDICAL DVC MFR, BIOESEARCH MONTORING, ETC 1/1-31/12
2012-1763	03/12/2012 04/09/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	FRAN KOCH INFORMATION ACCESS	2011-9372
2012-1764	03/12/2012 04/09/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	JENNIFER SORENSON NATURAL RESOURCES DEFENSE COUNCIL	2012-83 - MINOR DELETIONS
2012-1765	03/12/2012 04/09/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	MARIO CADAVID CANFIELD SCIENTIFIC INC	CANFIELD SCIENTIFIC INC - EIR 11/28-30/11, 12/1, 5-6/11
2012-1766	03/12/2012	FDA/OGROP/ORACE-FO/DET-	DIANA L. GESEKING	MEAD JOHNSON, ZEELAND, MI - EIR 8/26/04

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	04/09/2012	DO/DET-CB/	SEDGWICK LLP	
2012-1767	03/12/2012 04/16/2012	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	MELISSA F. CURRY HELPER BROOM LLC	SCHNUCKS SUPERMARKETS - E COLI INVESTIGATION CORR, CERTIFIED 9/11 TO 11/11
2012-1768	03/12/2012 04/09/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	BRIANNE RIDEOUT ASHCRAFT AND GEREL LLP	CORDIS CORP, MIAMI LAKES, FL - 483, CO RESP 9/2-12/03; SAN GERMAN, PR - 483, CO RESP 10/10/03-12/1/03; WARREN, NJ - 483, CO RESP 10/29/03-12/4/03
2012-1769	03/12/2012 04/09/2012	FDA/OC/OES/DFOI/	ASHA LAMBATOS AVALON RISK MANAGEMENT INC	ENTRY #M85-00508733 - NOTICE OF FDA ACTION #1
2012-1770	03/12/2012 04/09/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ OC/OCOS/OES/ OC/OCOS/OES/	JOHN ALTHEN JUDICIAL WATCH	AMERICAN ACADEMY OF PEDIATRICS - POLICY STATEMENT HPV VACCINE RECOMMENDATIONS 3/12
2012-1771	03/12/2012 04/09/2012	OC/OM/OMP/DDM/	MERLE ZIMMERMANN AMERICAN HERBAL PRODUCTS ASSOCIATION	DKT FDA-1995-S-0039
2012-1772	03/13/2012 04/10/2012	OC/OM/OMP/DDM/	MARILYNN WHITNEY COVINGTON & BURLING LLP	DKT 1995N-0371, 1995N-0411
2012-1773	03/13/2012 04/10/2012	OC/OM/OMP/DDM/	GLORIA GASKINS KLEINFELD KAPLAN & BECKER	DKT 1987P-0118, 1995P-0366, 1997P-0079
2012-1774	03/13/2012 04/10/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	KIM C CAPONE PORZIO PHARMACEUTICAL SERVICES LLC	SUN PHARMACEUTICAL INDUSTRIES INC, CRANBURY, NJ - EIRS, 483S
2012-1775	03/13/2012 04/10/2012	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	CHRIS INGALLS KING 5 TV	SNOKIST GROWERS, YAKIMA, WA - FDA FORM 766 RECS 3/09
2012-1776	03/13/2012 04/10/2012	FDA/OMPT/CDRH/OCER/DFOI/	ROLING, DIANNE M	DOCUMENT #CPT 1100163
2012-1777	03/13/2012 04/10/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ALAN BECKMAN MOBIUS THERAPEUTICS LLC	ISRS 8085764, 8100418, 7797470, ETC

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2012-1778	03/13/2012 04/10/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CANDICE DURRENCE OPTIMER PHARMACEUTICALS INC	DIFICID (FIDAXOMICIN) TABS NDA 201-699 - PHARMACOLOGY, TOXICOLOGY & MICROBIOLOGY RVWS
2012-1779	03/13/2012 04/10/2012	FDA/OMPT/CDRH/OCER/DFOI/	HEATHER-GRACE A EBANKS ELEKTA INC	CYBERKNIFE VSI ROBOTIC RADIOSURGERY SYS - K102650
2012-1780	03/13/2012 04/10/2012	FDA/OFVM/CFSAN/OCD/EOS/	LYNN P TORDO THOR SPECIALTIES INC	LANXESS CORP - FCN 1078
2012-1781	03/13/2012 04/10/2012	FDA/OFVM/CFSAN/OCD/EOS/	LYNN P TORDO THOR SPECIALTIES INC	LANXESS - FCN 560
2012-1782	03/13/2012 04/10/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORAP/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORAP/PA-FO/SAN- DO/SAN-CB/	SUZETTE MESKELL KINERK SCHMIDT & SETHI, PLLC	MIZUHO OSI MODULAR TABLE, MODEL #5803 RECALL, INVESTIGATION RPTS, CORR ETC
2012-1783	03/13/2012 04/10/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/OA/OM/OMP/DDM/ FDA/OGROP/ORAP/CE-FO/CHI- DO/CHI-CB/ FDA/OGROP/ORAP/CE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORAP/NE-FO/NWE- DO/NWE-CB/ FDA/OC/OES/DFOI/ FDA/OGROP/ORAP/SE-FO/NOL- DO/NOL-CB/ OC/OA/OM/OMP/DDM/	PATRICIA N SYVERSON BONNETT FAIRBOURN ET AL	CHATTEM INC - ACT TOTAL CARE ANTICAVITY FLUORIDE MOUTHWASH PRDS INVESTIGATION MEMO, RPTS, STUDIES, ETC
2012-1784	03/13/2012 04/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	JAMES R WELSH WELSH & WELSH PC LLO	AGA MEDICAL CORP - AMPLATZER SEPTAL OCCLUDER DISCLOSURES TO FDA
2012-1785	03/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRENT M ARDAUGH	K901235, K870729, K852097

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	04/10/2012		NORTHWESTERN UNIV FEINBERG SCHOOL OF MEDICINE	
2012-1786	03/13/2012 04/10/2012	FDA/OFVM/CFSAN/OCD/EOS/	MICHELE SIMON MUCKROCK NEWS	FACTS UP FRONT LBLG SCHEME LTR 12/11
2012-1787	03/13/2012 04/10/2012	FDA/OMPT/CDRH/OCER/DFOI/	SEAN BUNDY COCHLEAR AMERICAS	ADVANCED BIONICS CORP - AURIA HARMONY HIRESOLUTION BIONIC EAR SYS P960058/S089
2012-1788	03/13/2012 04/10/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SPECTOR, GILBERT	PERRIGO R&D CO - GUAIFENESIN RT TABS ANDA 78-912 RECS
2012-1789	03/13/2012 04/10/2012	FDA/OGROP/ORR/SE-FO/FLA- DO/FLA-CB/ FDA/OGROP/ORR/SE-FO/FLA- DO/FLA-CB/	MARTIN N ZAIAC, MD MOUNT SINAI MEDICAL CENTER GREATER MIAMI SKIN & LASER CTR	DR MARTIN ZAIAC - EIR, 483 (OBSERVATION 2) 4/22/10- 7/14/10
2012-1790	03/13/2012 04/10/2012	OC/ORR/ OC/ORR/	BILL MOBERLY WISCONSIN COUNCIL 40, AFSCME, AFL-CIO	AMERICAN RED CROSS - RESP TO ADVERSE DETERMINATION LTR 1/13/12, CORR, CO RESPS ETC
2012-1791	03/13/2012 04/10/2012	FDA/OMPT/CDRH/OCER/DFOI/	BECKY DITTY STRYKER INCUBATION OF MEDICAL TECHNOLOGY (IMT)	MAKO SURGICAL CORP, FORT LAUDERDALE, FL - RESTORIS PARTIAL KNEE APPLICATION (PKA) RIO STANDARD SYS K112507
2012-1792	03/13/2012 04/10/2012	FDA/OMPT/CDRH/OCER/DFOI/	AGUILA, JOSE	FISHER & PAYKEL HEALTHCARE - MR 880 K100554
2012-1793	03/13/2012 04/10/2012	FDA/OGROP/ORR/CE-FO/MIN- DO/MIN-CB/	DINESH SAXENA B BRAUN MEDICAL INC	SCIENTIFIC PROTEINS LABORATORIES LLC, WAUNAKEE, WI - EIR, WARNING LTR, ETC 1/20/11 TO PRESENT
2012-1794	03/13/2012 04/10/2012	FDA/OMPT/CDRH/OCER/DFOI/	GENARO GARCIA GARCIA DEVELOPMENTS INC	EIDAM DIAGNOSTICS CORP, RICHMOND, CANADA - CRT 2000 THERMOGRAPHIC SYS K971956 EIR, 483, CO RESP
2012-1795	03/13/2012 04/10/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TYRAH L MILES DJA GLOBAL PHARMACEUTICALS INC	EPIPEN, TWINJECT, INTELLIJECT - FINAL RVWS, SBAS
2012-1796	03/13/2012 04/10/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KUMAR, ROGER	AMPYRA (DALFAMPRIDINE) - AERS

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2012-1797	03/13/2012 04/10/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	FRAN KOCH INFORMATION ACCESS	2011-9007
2012-1798	03/13/2012 04/10/2012	FDA/OC/OES/DFOI/	FRAN KOCH INFORMATION ACCESS	2011-9006
2012-1799	03/13/2012 04/10/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FULLER, STEPHEN	TORADOL (KETOROALC); MOTRIN, ADVIL (IBUPROFEN) - AERS 1/89 TO 12/11
2012-1800	03/13/2012 04/10/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	FRAN KOCH INFORMATION ACCESS	2011-9009
2012-1801	03/13/2012 04/10/2012	FDA/OC/OES/DFOI/	FRAN KOCH INFORMATION ACCESS	2011-9015
2012-1802	03/13/2012 04/10/2012	FDA/OMPT/CDRH/OCER/DFOI/	JON C GARITO LifeSciences	ELLMAN INT'L INC - NON-ABLATIVE TECHNIQUE FOR SURGITRON IEC K082834
2012-1803	03/13/2012 04/10/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/SEA-DO/SEA-CB/ FDA/OGROP/ORO/PA-FO/SEA-DO/SEA-CB/ OC/ORO/OCI/ OC/ORO/OCI/	Doe J	CMPLNT 120720
2012-1804	03/13/2012 04/10/2012	FDA/OMPT/CDRH/OCER/DFOI/	JON C GARITO LifeSciences	ELLMAN INT'L INC - NON-ABLATIVE WRINKLE TREATMENT HANDPIECE K102368
2012-1805	03/13/2012 04/10/2012	FDA/OMPT/CDRH/OCER/DFOI/	JON C GARITO LifeSciences	ELLMAN INT'L INC - NON-ABLATIVE WRINKLE TREATMENT HANDPIECE MODEL PELLEVE K101967
2012-1806	03/13/2012 04/10/2012	FDA/OMPT/CDRH/OCER/DFOI/	MATTO TULIKOURA PALODEX GROUP	SOREDEX, TUUSULA, FINLAND - EIRS (UNREDACTED) 9/09
2012-1807	03/13/2012 04/10/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BENDA M GARTZ ELI LILLY & CO	GULF PHARMACEUTICALS INDUSTRIES, RAS AL KHAIMAH, UNITED ARAB EMIRATES - 483 9/25/11-10/3/11
2012-1808	03/13/2012 04/10/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	UNIMARK REMEDIES LTD, VAPI GUJARAT, INDIA - EIR 9/25/09

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2012-1809	03/13/2012 04/10/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/	RUSSELL V RANDLE Patton Boggs LLP	DR LEWIS P STOLMAN - CONSENT AGREEMENT, EIR 1990, FDA RESP, ETC
2012-1810	03/13/2012 04/10/2012	OC/ORACE/ OC/ORACE/ FDA/OGROP/ORACE-ORO/DIOP/ FDA/OFVM/CFSAN/OCD/EOS/	ANTHONY SAMBROTTO NORMAN G. JENSEN	NORMAN G JENSEN INC - AGENT UNDER STATUTES US DEPT OF JUSTICE V TAX ANALYSIS, CASTANEDA V US, AIR FORCE V ROSE, ETC
2012-1811	03/13/2012 04/10/2012	FDA/OGROP/ORACE-SW-FO/KAN- DO/KAN-CB/	JULIE PEAK INTERCON CHEMICAL CO	B&G LABS, ST LOUIS, MO - 483S
2012-1812	03/13/2012 04/10/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KATHLEEN STERGIOPOULOS STONY BROOK UNIVERSITY MEDICAL CTR	SIMAVASTATIN, ATORVASTATIN, CRESTOR, ETC - AERS
2012-1813	03/13/2012 04/10/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	FRAN KOCH INFORMATION ACCESS	2011-9005
2012-1814	03/13/2012 04/10/2012	FDA/OO/OFBA/OAGS/	DANIELLE IVORY BLOOMBERG FINANCIAL MARKETS COMMODITIES NEWS	AMERICAN MEDICAL DEPOT, AMERICAN PURCHASING SERVICES, APS TECHNOLOGIES, ETC - BIDS
2012-1815	03/13/2012 04/10/2012	FDA/OMPT/CDRH/OCER/DFOI/	NYROBIA FREEMAN CONMED LINVATEC CORP	LOOK INC, ADA, OK - POLYVIOLENE SURGICAL SUTURE K943949
2012-1816	03/13/2012 04/10/2012	FDA/OC/OES/DFOI/	MERCK & CO., INC.	2012-709
2012-1817	03/13/2012 04/10/2012	FDA/OC/OES/DFOI/	MERCK & CO., INC.	2012-897
2012-1818	03/13/2012 04/10/2012	FDA/OC/OES/DFOI/	MERCK & CO., INC.	2012-1394
2012-1819	03/13/2012 04/10/2012	FDA/OC/OES/DFOI/	MERCK & CO., INC.	2012-1399
2012-1820	03/13/2012	FDA/OMPT/CDER/ORP/DIDP/		AMPYRA (DALFAMPRIDINE) - AERS

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	04/10/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KUMAR, ROGER	
2012-1821	03/13/2012 04/10/2012	FDA/OC/OES/DFOI/	MERCK & CO., INC.	2012-1416
2012-1822	03/13/2012 04/10/2012	FDA/OC/OES/DFOI/	MERCK & CO., INC.	2012-1440
2012-1823	03/13/2012 04/10/2012	FDA/OC/OES/DFOI/	MERCK & CO., INC.	2012-1458
2012-1824	03/13/2012 04/10/2012	FDA/OC/OES/DFOI/	MERCK & CO., INC.	2012-1559
2012-1825	03/13/2012 04/10/2012	FDA/OC/OES/DFOI/	MERCK & CO., INC.	2012-415
2012-1826	03/13/2012 04/10/2012	FDA/OC/OES/DFOI/	MERCK & CO., INC.	2011-9026
2012-1827	03/13/2012 04/10/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/	Doe J	INDIVIDUAL RECS
2012-1828	03/13/2012 04/10/2012	FDA/OC/OES/DFOI/	MERCK & CO., INC.	2011-9630
2012-1829	03/13/2012 04/10/2012	FDA/OC/OES/DFOI/	MERCK & CO., INC.	2012-294
2012-1830	03/13/2012 04/10/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	MERCK & CO., INC.	2011-9357
2012-1831	03/13/2012 04/10/2012	FDA/OC/OES/DFOI/	MERCK & CO., INC.	2011-9030
2012-1832	03/13/2012 04/10/2012	FDA/OC/OES/DFOI/	MERCK & CO., INC.	2011-8772
2012-1833	03/13/2012 04/10/2012	FDA/OC/OES/DFOI/	MERCK & CO., INC.	2011-8724
2012-1834	03/13/2012 04/10/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LANGE, VERA	CARBATROL - AERS

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		FDA/OMPT/CDER/ORP/DIDP/		
2012-1835	03/13/2012 04/10/2012	FDA/OC/OES/DFOI/	MERCK & CO., INC.	2011-8717
2012-1836	03/13/2012 04/10/2012	FDA/OC/OES/DFOI/	MERCK & CO., INC.	2011-8163
2012-1837	03/13/2012 04/10/2012	FDA/OMPT/CDRH/OCER/DFOI/	HAMILTON, Ph.D., LEROY	TRANSILLUMINATOR FOR BREAST EVALUATION
2012-1838	03/13/2012 04/10/2012	FDA/OMPT/CDRH/OCER/DFOI/	HAMILTON PHD, LEROY L	IONTOPHORESIS DEVICE
2012-1839	03/13/2012 04/10/2012	FDA/OMPT/CDRH/OCER/DFOI/	HAMILTON PHD, LEROY L	STIMULATOR CRANIAL ELECTROTHERAPY
2012-1840	03/13/2012 04/10/2012	FDA/OMPT/CDRH/OCER/DFOI/	HAMILTON PHD, LEROY L	DIATHERMY SHORTWAVE
2012-1841	03/14/2012 04/11/2012	OC/OM/OMP/DDM/	GABRIEL SHERMAN Hyman, Phelps & McNamara, P.C.	DKT FDA-1995-S-0039
2012-1842	03/14/2012 04/11/2012	OC/OM/OMP/DDM/	CHRIS CELESTE EAS Consulting Group, LLC	DKT 1978N-7830
2012-1843	03/14/2012 04/11/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	2012-414
2012-1844	03/14/2012 04/11/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	2012-577
2012-1845	03/14/2012 04/11/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	2012-588
2012-1846	03/14/2012 04/11/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	2011-6866
2012-1847	03/14/2012 04/11/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	2011-9263
2012-1848	03/14/2012 04/11/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	2011-9264
2012-1849	03/14/2012 04/11/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	2011-9446
2012-1850	03/14/2012 04/11/2012	FDA/OC/OES/DFOI/	JOAN STITT (8G2CD-16) MERCK & CO., INC.	2011-9519

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2012-1851	03/14/2012 04/11/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	2012-68
2012-1852	03/14/2012 04/11/2012	FDA/OC/OES/DFOI/	JOAN STITT (8G2CD-16) MERCK & CO., INC.	2012-661
2012-1853	03/14/2012 04/11/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	2012-796
2012-1854	03/14/2012 04/11/2012	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	2012-825
2012-1855	03/14/2012 04/11/2012	FDA/OC/OES/DFOI/	JOAN STIT (UG2CD-16) MERCK & CO., INC.	2012-937
2012-1856	03/14/2012 04/11/2012	FDA/OC/OES/DFOI/	INC REGULATORY CONSULTING & SUBMISSIONS	FOI DAILY LOG 2/20-24/12
2012-1857	03/14/2012 04/11/2012	FDA/OC/OES/DFOI/	INC REGULATORY CONSULTING & SUBMISSIONS	FOI DAILY LOG 2/13-17/12
2012-1858	03/14/2012 04/11/2012	FDA/OC/OES/DFOI/	INC REGULATORY CONSULTING & SUBMISSIONS	FOI DAILY LOG 2/6-10/12
2012-1859	03/14/2012 04/11/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 2/20-24/12
2012-1860	03/14/2012 04/11/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 2/13-17/12
2012-1861	03/14/2012 04/11/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 2/6-10/12
2012-1862	03/14/2012 04/11/2012	FDA/OC/OES/DFOI/	FRAN KOCH INFORMATION ACCESS	FOI DAILY LOG 2/20-24/12
2012-1863	03/14/2012 04/11/2012	FDA/OC/OES/DFOI/	FRAN KOCH INFORMATION ACCESS	FOI DAILY LOG 2/13-17/12
2012-1864	03/14/2012 04/11/2012	FDA/OC/OES/DFOI/	FRAN KOCH INFORMATION ACCESS	FOI DAILY LOG 2/6-10/12
2012-1865	03/14/2012 04/11/2012	FDA/OC/OES/DFOI/	GLADYS B TONKIN WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 2/20-24/12

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2012-1866	03/14/2012 04/11/2012	FDA/OC/OES/DFOI/	GLADYS B TONKIN WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 2/13-17/12
2012-1867	03/14/2012 04/11/2012	FDA/OC/OES/DFOI/	GLADYS B TONKIN WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 2/6-10/12
2012-1868	03/14/2012 04/11/2012	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 2/20-24/12
2012-1869	03/14/2012 04/11/2012	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 2/20-24/12
2012-1870	03/14/2012 04/11/2012	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 2/13-17/12
2012-1871	03/14/2012 04/11/2012	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 2/6-10/12
2012-1872	03/14/2012 04/11/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 2/20-24/12
2012-1873	03/14/2012 04/11/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 2/13-17/12
2012-1874	03/14/2012 04/11/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 2/6/-10/12
2012-1875	03/14/2012 04/11/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 2/20-24/12
2012-1876	03/14/2012 04/11/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 2/13-17/12
2012-1877	03/14/2012 04/11/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 2/6-10/12
2012-1878	03/14/2012 04/11/2012	FDA/OC/OES/DFOI/	DOMINION GROUP INC	FOI DAILY LOG 2/20-24/12
2012-1879	03/14/2012	FDA/OC/OES/DFOI/	BARBARA JONES	FOI DAILY LOG 2/13-17/12

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	04/11/2012		DOMINION GROUP INC	
2012-1880	03/14/2012 04/11/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 2/6-10/12
2012-1881	03/14/2012 04/11/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RAYMOND, WALTON K31994	HEALTHY EYES SUPERVISION SFTGL CAPSULE - AER
2012-1882	03/14/2012 04/11/2012	FDA/OMPT/CDRH/OCER/DFOI/	MARY HOLMES LONDON-IP INC	APERTA LLC - K093166
2012-1883	03/14/2012 04/11/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	CAROL POLLACK-NELSON PHD	INTERNAL NASAL DILATORS - AER LAST 10 YRS
2012-1884	03/14/2012 04/11/2012	FDA/OMPT/CDRH/OCER/DFOI/	MARTIN GABLER RADIOMETER MEDICAL APS	NOVA BIOMEDICAL CORP - CRT ANALYZER K924547
2012-1885	03/15/2012 04/12/2012	OC/ORA/ OC/ORA/	SANTO PEREZ CONCORD FOODS	LEMON JUICE - ENTRY NOS 231-3344531-0; 231-3327627-3
2012-1886	03/15/2012 04/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	THERESA DE PRAT COOK ENDOSCOPY	INVENDO C20 COLONOSCOPY SYS - K100624
2012-1887	03/15/2012 04/12/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANNAMIEKE M TENNIS KANNER & WHITELEY LLC	SHIRE PHARMACEUTICALS INC - VYVANSE (LISDEXAMFETAMINE DIMESYLATE) CAPS NDA 21-977 RESP TO DDMAC LTR 5/6/11, CMLPNTS, ETC
2012-1888	03/15/2012 04/12/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TYRAH L MILES DJA GLOBAL PHARMACEUTICALS INC	EPIPEN, TWINJET, INTELLIJECT - SBA
2012-1889	03/15/2012 04/12/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	THOMAS M MORTON CPMG INC	ARMOUR PHARMS - ACTHAR GEL-SYNTHETIC NDA 17-861 DISCONTINUATION OF MARKETING, CURRENT OWNERSHIP, LABEL ACTIONS, ETC
2012-1890	03/15/2012	FDA/OMPT/CDER/ORP/DIDP/	JOHN A CLARK MD MSPH	ISRS 6233952-8, 6254515-4, 6353969-2, ETC

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	04/12/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	RISKBENEFITS LLC	
2012-1891	03/15/2012 04/12/2012	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	DOUGLAS N BLUE II ZETETIC INC	HEALTH CARE PRODS ENTRY # 82301494447 - RECS
2012-1892	03/15/2012 04/12/2012	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	DOUGLAS N BLUE II ZETETIC INC	JOHNSON & JOHNSON - SHOWER GEL ENTRY #M5001850259 RECS
2012-1893	03/15/2012 04/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	ANDREA P DEMERS MAYNARD O'CONNOR ET AL	ZIMMER - LPS-FLEX GSF PROSTHETIC KNEE MDRS
2012-1894	03/15/2012 04/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	KEITH A BARRITT FISH & RICHARDSON PC	AGAMATRIX INC - IBGSTAR BLOOD GLUCOSE MONITORING SYS K103544
2012-1895	03/15/2012 04/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	DON MIZOTA SANARUS TECHNOLOGIES LLC	ARBEL MEDICAL LTD - ICE-BENSE K072883
2012-1896	03/15/2012 04/12/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHARLES CELESTE EAS Consulting Group, LLC	DIHYDROCODEINE, BPM, PHENYLEPH HCL LIQUID (DIHYDROCODEINE BITARTRATE, BROMPHENIRAMINE MALEATE, PHENYLEPHRINE HCL) - AERS
2012-1897	03/15/2012 04/12/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	THOMAS COTTER BOSTON UNIVERSITY SCHOOL OF/PUBLIC HEALTH	DRUG STABILITIY TESTING & RESLUTS UNDER THE SHELF LIFE EXTENSION PROGRAM (SLEP), DEPLOYMENT LOGISTICS OF SLEP DRUGS, ETC 2002 TO PRESENT
2012-1898	03/15/2012 04/12/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FERA, SHARON	ABBOTT LABS - SYNTHROID AERS
2012-1899	03/15/2012 04/12/2012	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	KRISTI O SMEDLEY PHD WASHINGTON INFORMATION SOURCE	HUVEPHARMA, ST LOUIS, MO - EIRS, 483S 6/08 TO PRESENT
2012-1900	03/15/2012 04/25/2012	FDA/OMPT/CDRH/OCER/DFOI/	JAE H KIM GENORAY AMERICA INC	PORT-X II K063121 - ACCESSION NUMBER
2012-1901	03/15/2012 04/25/2012	FDA/OMPT/CDRH/OCER/DFOI/	JAE H KIM GENORAY AMERICA INC	ZENIS K103181 - ACCESSION NUMBER
2012-1902	03/15/2012	FDA/OMPT/CDRH/OCER/DFOI/	JAE H KIM	ZEN-7000 K103425 - ACCESSION NUMBER

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	04/25/2012		GENORAY AMERICA INC	
2012-1903	03/15/2012 04/25/2012	FDA/OMPT/CDRH/OCER/DFOI/	JAE H KIM GENORAY AMERICA INC	VOLUX K092171 - ACCESSION NUMBER
2012-1904	03/15/2012 04/25/2012	FDA/OMPT/CDRH/OCER/DFOI/	JAE H KIM GENORAY AMERICA INC	TRIANA K103182 - ACCESSION NUMBER
2012-1905	03/15/2012 04/12/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOI REQUESTS 3/5-9/12
2012-1906	03/15/2012 04/12/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOI REQUESTS 2/27/12-3/2/12
2012-1907	03/15/2012 04/12/2012	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/ORASOCI/ OC/ORASOCI/	RHIANNON MEYERS CORPUS CHRISTI CALLER TIMES	MOHAMED AYMAN GHRAWI MD, SOUTH TEXAS COMPREHENSIVE CANCER CENTERS - CORR
2012-1908	03/15/2012 04/12/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 3/5-9/12
2012-1909	03/15/2012 04/12/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 2/27/12-3/2/12
2012-1910	03/15/2012 04/12/2012	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	KIM C. CAPONE PORZIO PHARMACEUTICAL SERVICES LLC	FOREST PHARMS INC, EARTH CITY, MO - EIR, 483 12/21/10
2012-1911	03/15/2012 04/12/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/ORASOCI/ OC/ORASOCI/	RHIANNON MEYERS CORPUS CHRISTI CALLER TIMES	COUNTERFEIT AVASTIN - INVESTIGATION
2012-1912	03/15/2012 04/12/2012	OC/ORAS/ OC/ORAS/ FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Doe J	INDIVIDUAL RECS

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2012-1913	03/15/2012 04/12/2012	OC/CVM/OCD/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KRISTINE BURGESS TUFTS UNIV CUMMINGS SCHOOL OF VETERINARY MEDICINE	GLUCOPHAGE - TOXICOLOGY RVW
2012-1914	03/15/2012 04/12/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 2/27/12-3/2/12
2012-1915	03/15/2012 04/12/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 3/5-9/12
2012-1916	03/15/2012 04/12/2012	FDA/OC/OES/DFOI/	LeAnn Runke MICHAEL FOODS INC	METHODS FOR CONDUCTING RECALL EFFECTIVENESS CHECKS - COPY
2012-1917	03/15/2012 04/12/2012	FDA/OFVM/CFSAN/OCD/EOS/	JEFFREY J. HARRINGTON MICHAEL FOODS INC	USE OF NISIN IN LIQUID EGGS, EGG PRODS, HARD- COOKED EGGS - STUDIES, VIOLATIONS; M G WALDBAUM CO - DKT 1994G-0027 (GRAS PETITION 4G0405), ETC
2012-1918	03/15/2012 04/12/2012	FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	WILLIAM J. HARTIG PRESCRIPT PHARMACEUTICALS INC	PRESCRIPT PHARMACEUTICALS INC - EIR 2000, 2003, 2006, 2009, 2011
2012-1919	03/15/2012 04/12/2012	OC/CVM/OCD/	KRISTI O. SMEDLEY, Ph.D. WASHINGTON INFORMATION SOURCE	HUVEPHARMA, PESHTERA, RAZRAD, BOTEVGRAD, BULGARIA - EIR, 483 1/2010
2012-1920	03/15/2012 04/12/2012	OC/CVM/OCD/	KRISTI O. SMEDLEY, Ph.D. WASHINGTON INFORMATION SOURCE	HUVEPHARMA, SHIP, MACEDONIA - EIR, 483 1/08
2012-1921	03/15/2012 04/12/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/CVM/OCD/ FDA/OC/OES/DFOI/	QUYNH C. SPERRAZZA FAEGRE BAKER DANIELS	SALMONELLA HEIDELBERG PFGE PATTERN XBAL
2012-1922	03/15/2012 04/12/2012	FDA/OC/OES/DFOI/	QUYNH C. SPERRAZZA FAEGRE BAKER DANIELS	GASS WEBER MULLINS LLC; MARLER CLARK LLP - FOI REQUESTS 7/11 TO 12/11
2012-1923	03/15/2012 04/12/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/ FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	ALEX TOMASEVIC NICHOLAS & BUTLER LLP	DREAM PRODUCTS LLC, GOLDEN BEACH, FL - DREAM WATER RECS
2012-1924	03/15/2012	FDA/OGROP/ORA/CE-FO/BLT-	MICHELE JONES	HUMAN GENOME SCIENCES - BENLYSTA EIR, 483 9/7-30/10

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	04/12/2012	DO/BLT-CB/	HUMAN GENOME SCIENCES INC.	
2012-1925	03/15/2012 04/12/2012	OC/CVM/OCD/ FDA/OC/OES/DFOI/	MIKE McGRAW KANSAS CITY STAR	CVM SUBMISSION TRACKING & REPORTING SYS (STARS) DATABASE
2012-1926	03/15/2012 04/12/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHANDRAN TIRUVATTAR PROMIUS PHARMA LLC	TENEX NDA 19- 032 - RECS
2012-1927	03/16/2012 04/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	ABBOT VASCLAR - ABSOLUTE PRO VASCULAR SELF-EXPANDING STENT SYS P110028 APRVL RECS
2012-1928	03/16/2012 04/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	COOK MEDICAL - FORMULA BALLOON-EXPANDABLE RENAL STENT SYS -P100028 APRVL RECS
2012-1929	03/16/2012 06/06/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	BOSTON SCIENTIFIC - EXPRESS SD RENAL MONORAIL PREMOUNTED TENT SYS P060006 APRVL RECS
2012-1930	03/16/2012 06/06/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	BOSTON SCIENTIFIC - EXPRESS LD LILIAC PREMOUNTED STENT SYS P090003 APRVL RECS
2012-1931	03/16/2012 04/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	AMPLIFY RHBMP-2 MATRIX - P050036 NON-APRVL LTR, REJECTED - APRVL LTR
2012-1932	03/16/2012 04/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	MEDTRONICS - ASSURANT COBALT ILIAC BALLOON-EXPENDABLE STENT SYS P110011 APRVL RECS
2012-1933	03/16/2012 04/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	ABBOTT VASCULAR - RX HERCULINK ELITE RENAL STENT SYS P110001 APRVL RECS
2012-1934	03/16/2012 04/13/2012	FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	FOI Services, Inc.	HOSPIRA, CLAYTON, NC - 483 4/6-29/09
2012-1935	03/16/2012 04/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS Consulting Group, LLC	ALDARA NDA 20-723/S001 - APRVL LTR, LBLG MOR ETC
2012-1936	03/16/2012 04/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS Consulting Group, LLC	CENTUSSIN DHC (DIHYDROCEDEINE BITARTATE, BROMPHENIRAMINE MALEATE & PHENYLEPHRINE HCL) LIQUID - AERS 1/07 TO PRESENT

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2012-1937	03/16/2012 04/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHARLES CHRIS EAS Consulting Group, LLC	POLY-TUSSIN EX (DIHYDROCODEINE BITARTARTE, PHENYLEPHRINE HCL & GUAIFENSIN) SYRUP - AERS 1/07 TO PRESENT
2012-1938	03/16/2012 04/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHARLES CHRIS EAS Consulting Group, LLC	POLY HIST DHC (DIHYDROCODEINE BITARATE, PHENYLEPHRINE HCL, PYRILAMINE MALEATE) LIQUID - AERS 1/07 TO PRESENT
2012-1939	03/16/2012 04/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHRLES CELESTE EAS Consulting Group, LLC	ENDACOF DH (DIHYDROCODEINE BITARTARTE, BROMPHENIRAMINE MALEATE & PHENYLEPHRINE HCL) LIQUID - AERS 1/07 TO PRESENT
2012-1940	03/16/2012 04/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHARLES CELESTE EAS Consulting Group, LLC	DONATUSS DC (DIHYDROCODEINE BITARTRATE, PHENYLEPHRINE HCL, GUAIFENSIN) SYRUP - AERS 1/07 TO PRESENT
2012-1941	03/16/2012 04/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LIESELOTTE L BLOSS KYOWA PHARMACEUTICAL INC	NOVARTIS - PARLODEL NDA 17-962 SBA, CLNCL RVWS 7///28/78
2012-1942	03/16/2012 04/13/2012	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	STEPHANIE ELSBERRY BIODEN INC	BIOEDEN INC, AUSTIN, TX - EIR, 483, CO RESP 1/12-18/12
2012-1943	03/16/2012 04/13/2012	FDA/OC/OES/DFOI/	CHERYL L BUNEVICH TUCKER ELLIS LLP	DIGITEK - SPL 157503, 157504, 178890, ETC RECS (CERTIFIED)
2012-1944	03/16/2012 04/13/2012	FDA/OFVM/CFSAN/OCD/EOS/	LI ZHANG PHD BASF CORP	BUCKMAN LABORATORIES INTERNATIONAL INC - FCN 871
2012-1945	03/16/2012 04/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LUK, CHEE PHUN	PROTON PUMP INHIITORS (PPI) - RVWS, AERS
2012-1946	03/16/2012	FDA/OMPT/CDRH/OCER/DFOI/	ANGELIA D SLAYTON	B BRAUN MEDICAL INC - ULTRASITE VALVES PS100006

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	04/13/2012		INC RESEARCH CONSULTING & SUBMISSIONS	
2012-1947	03/16/2012 04/13/2012	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	ANGELIA D SLAYTON INC REGULATORY CONSULTING & SUBMISSIONS	LESLIE DIAZ, INFECTIOUS DISEASE ASSOCIATION OF THE PALM BEACHES, N PALM BEACH, FL - EIR, 483, CO RESP 1/12/11
2012-1948	03/16/2012 04/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	BREANNE WANDERMEER MUELLER LAW OFC	C R BARD INC, DAVOL INC - PERFIX PLUG MDRS, CORR, APRVL RECES, ETC
2012-1949	03/16/2012 04/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS Consulting Group, LLC	ALDARA NDA 20-723/S016 - APRVL LTR, LBLG, RVWS, ETC
2012-1950	03/16/2012 04/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GRUBER, SHEILA G	AC CUTANE (ISOTRETINOIN) - AERS
2012-1951	03/16/2012 04/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JESSICA LAM HOSPITAL FOR SICK CHILDREN	EXPOSURE TO CODEINE VIA BREAST MILK - AERS
2012-1952	03/16/2012 04/13/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	BIOGEN - AVONEX PRODUCT LICENSE APPLICATION (PLA) AND ESTABLISHMENT LICENSE (ELA) APPEAL NUMBER 96-A-084 LTR 8/20/96
2012-1953	03/16/2012 04/13/2012	FDA/OC/OCC/	FOI Services, Inc.	AVONEX PLA - WILLIAM C BRASHARES ESQ, MINTZ, LEVIIN, COHN, FERRIS, GLOVSKY & POPEO PC; KATE C BEARDSLEY ESQ, BUC & BEARDSLEY LTR 9/11/96
2012-1954	03/16/2012 04/13/2012	FDA/OC/OCC/	FOI Services, Inc.	BERLEX - AVEONEX PLA WILLIAM C BRASHARES ESQ, MINTX, LEVIN, COHN, FERRIS, GLOVSKY & POPEO PC LTR 9/18/96
2012-1955	03/19/2012 04/16/2012	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	AMY ERICKSON CRYOGENIC LABORATORIES INC	CRYOGAM COLORADO LLC, LOVELAND, CO - EIR, 483, CO RESP 5/05 TO PRESENT
2012-1956	03/19/2012 04/16/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	AMY ERICKSON CRYOGENIC LABORATORIES INC	FERTILITY CRYOBANK LLC, ENCINCO, CA - EIR, 483, CO RESP 5/05 TO PRESENT
2012-1957	03/19/2012 04/16/2012	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	AMY ERICKSON HAGEN CRYOGENIC LABORATORIES	MIDWEST FERTILITY CENTER, DOWNERS GROVE, IL - EIR, 483, CO RESP 5/05 TO PRESENT

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			INC	
2012-1958	03/19/2012 04/16/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	AMY EKICKSON HAGEN CRYOGENIC LABORATORIES INC	REPORDUCTIVE MEDICINE ASSOCIATES OF NY LLP, NEW YORK, NY - EIR, 483, CO RESP 5/05 TO PRESENT
2012-1959	03/19/2012 04/16/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OES/DFOI/	BRIANNA L. SILVERSTEIN DRINKERBIDDLE & REATH LLP	GRAS NO 94 - RECS PRIOR TO 2004
2012-1960	03/19/2012 04/16/2012	FDA/OMPT/CDRH/OCER/DFOI/	LILY HO NEPHOSITY LLC	CALGARY SCIENTIFIC INC - RESOLUTION MD MOBILE; GENERAL ELECTRIC HEALTHCARE - CENTRICITY RADIOLOGY MOBILE ACCESS 2.0 - 510K
2012-1961	03/19/2012 04/16/2012	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	AMY ERICKSON HAGEN CRYOGENIC LABORATORIES INC	COLORADO CENTER FOR REPRODUCTIVE MEDICINE, LONE TREE, CO - EIR, 483, CO RESP 5/05 TO PRESENT
2012-1962	03/19/2012 04/16/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANETTE KRAUS LEO PHARMA	FRAGMIN NDA 20-287/S035 RVW
2012-1963	03/19/2012 04/16/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/ FDA/OGROP/ORANE-FO/NWEDO/NWE-CB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	PATRICIA SABATINI PITTSBURGH POST-GAZETTE	MYLAN INC - EIRS, 483S, CORR, ETC 2011, 2012
2012-1964	03/19/2012 04/16/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PATRICK MORIARTY Ph.D. HEALTHCOR MANAGEMENT LP	VERTEX - INCIVEK (TELAPREVIR) AERS
2012-1965	03/19/2012 04/16/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PATRICK MORIARTY, Ph.D. HEALTHCOR MANAGEMENT LP	MERCK - VICTRELIS (BOCEPREVIR) AER

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2012-1966	03/19/2012 04/16/2012	FDA/OFVM/CFSSAN/OCD/EOS/ OC/CVM/OCD/	PETER KRASUCKI FERMATRIX LLC	MASCOMA DROP-IN MGT YEAST PROD - GRAS
2012-1967	03/19/2012 04/16/2012	FDA/OGROP/ORA/SE-FO/SJN- DO/SJN-CB/	PATTI SABATINI PITTSBURGH POST-GAZETTE	MYLAN INC - EIRS, 483S, CORR, ETC SINCE 10/13/11
2012-1968	03/19/2012 04/16/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	A. LUKE SMITH FARUQI & FARUQI LLP	RANBAXY - LIPITOR (ATORVASTATIN) ANDA 76-477, SBA
2012-1969	03/19/2012 04/16/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAN HIMMELFARB Mayer Brown LLP	TEVA PHARMS - TESTOSTERONE APRVL, MEDICAL RVW, CHEMISTY RVW, LBLG
2012-1970	03/19/2012 04/16/2012	OC/CVM/OCD/	ARLENE MORALES BURDOCK GROUP	SELENIUM FAP 2238 - REGULATORY STATUS, CONSUMPTION, USES, ETC
2012-1971	03/19/2012 04/16/2012	FDA/OGROP/ORA/CE-FO/BLT- DO/BLT-CB/	AMY ERICKSON HAGEN CRYOGENIC LABORATORIES INC	SHADY GROVE FERTILITY REPRODUCTIVE SCIENCE CTR, ROCKVILLE, MD - EIR, 483, CO RESP 5/05 TO PRESENT
2012-1972	03/19/2012 04/16/2012	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	Doe J	INDIVIDUAL RECS
2012-1973	03/19/2012 04/16/2012	FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/	CHARLES, GAITHER	NESTLE USA INC, LITTLE, CHUTE, WI; MEDFORD, WI - INSP, ENFORCEMENT ACTIONS
2012-1974	03/19/2012 04/16/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TSURUTA ERIKO, MD OSAKA UNIV GRADUATE SCHOOL OF MEDICINE	PROPYLTHIOURACIL - AER
2012-1975	03/20/2012 04/17/2012	FDA/OGROP/ORA/SE-FO/SJN- DO/SJN-CB/	FOI Services, Inc.	PHARMACOVIGILANCE (MCNEIL CONSUMER HEALTHCARE DIVISION) - EIRS, 483S, CO RESP, ETC 2/08 TO PRESENT
2012-1976	03/20/2012 04/17/2012	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/ FDA/OGROP/ORA/SE-FO/SJN- DO/SJN-CB/	FOI Services, Inc.	PHARMACOVIGILANCE (GLAXOSMITHKLINE CONSUMER DIVISION) - EIRS, 483S, CO RESP, ETC 2/08 TO PRESENT
2012-1977	03/20/2012	FDA/OGROP/ORA/CE-FO/NWJ-		PHARMACOVIGILANCE (NOVARTIS CONSUMER

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	05/17/2012	DO/NWJ-CB/ FDA/OGROP/ORAP/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	FOI Services, Inc.	HEALTHCARE DIVISION) - EIRS, 483S, CO RESP 2/08 TO PRESENT
2012-1978	03/20/2012 04/17/2012	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	CORTES, DAVE	MYLAN, CAGUAS, PR - 483S 2/24/11, 3/29/10
2012-1979	03/20/2012 04/17/2012	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	CORTES, DAVE	ABBOTT BIOTECHNOLOGY LTD, BARCELONETA, PR; ABBOTT PHARMACERUTICALS LTD, BARCELONETA, PR; ABBOTT DIAGNOSTICS INTERNATIONAL, BARCELONETA, PR, ETC - 483S 9/20/11, 3/11/14, 6/17/09, ETC
2012-1980	03/20/2012 04/17/2012	FDA/OGROP/ORAP/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	SCHARBERG, DAVID L	IOWA STATE UNIVERSITY COLLEGE VET MED, AMES, IA; VETERINARY RESOURCES INC, AMES, IA; CARDIOVASCULAR RESEARCH FOUNDATION, ORANGEBURG, NY, ETC - 483S 1/1/12-2/29/12
2012-1981	03/20/2012 04/17/2012	FDA/OGROP/ORAP/PA-FO/SEA-DO/SEA-CB/ OC/ORAO/CI/ OC/ORAO/CI/	CHRIS L NIELSEN NIELSEN CITRUS PRODUCTS INC	ACNE FOOD SALES INC, SEATTLE, WA - LEMON JUICE RESULTS
2012-1982	03/20/2012 04/17/2012	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	THOMAS J KARDOS COOK VASCULAR INC	COOK VASCULAR INC, VANDERGRIFT, PA - EIR 3/23-26/10
2012-1983	03/20/2012 04/17/2012	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	CORTES, DAVE	BRISTOL-MYERS SQUIBB HOLDINGS PHARMA LLC, MANATI, PR;/ BRISTOL MYERS SQUIBB MANUFACTURING CO, HUMACAO, PR - 483S 3/28/11, 8/13/10/6/25/10
2012-1984	03/20/2012 05/10/2012	FDA/OGROP/ORAP/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HENRY F BAYARD CSK Labs	INFUPHARMA LLC - EIRS, INCIDENT RPTS, STATEMENTS, ETC 1/11 TO PRESENT
2012-1985	03/20/2012 04/17/2012	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	MARIA HINKLIN Beutlich Pharmaceuticals LP	UNIQUE LABS, CHATSWORTH, GA - EIRS 4/21/11-5/4/11
2012-1986	03/20/2012 04/17/2012	FDA/OGROP/ORAP/PA-FO/SAN-DO/SAN-CB/	MICHALE A CHIBBARO PROMEGA BIOSYSTEMS SUNNYVALE	PROMEGA BIOSYSTEMS, SUNNYVALE, CA - EIRS 10/5-8/10
2012-1987	03/20/2012 04/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FRANK P AGELLO ESQ ROY LEGAL GROUP	VELCADE (BORTEZO) - INVESTIGATION RESULTS

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2012-1988	03/20/2012 04/17/2012	OC/OCOS/OL/	KAREN GULLO BLOOMBERG NEWS	REP JACK KINGSTON, REP JOE BARTON - LANCE ARMSTRONG RACING TEAM CRIMINAL INVESTIGATION CORR 1/10 TO PRESENT
2012-1989	03/20/2012 04/17/2012	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	JOHNSON, JILL	ASEPTIC SOLUTIONS USA, CORONA, CA - 483S LAST 18 MONTHS
2012-1990	03/20/2012 04/17/2012	OC/ORA/OCI/ OC/ORA/OCI/	KAREN GULLO BLOOMBERG FINANCIAL MARKETS COMMODITIES NEWS	JEFF NOVITIZKY - TRAVEL RECS 1/10 TO 2/12
2012-1991	03/20/2012 04/17/2012	OC/ORA/OCI/ OC/ORA/OCI/	KAREN GULLO BLOOMBERG FINANCIAL MARKETS COMMODITIES NEWS	FEDERAL CRIMINAL CONDUCT BY MEMBERS & ASSOCIATES OF A PROCESSIONAL BICYCLE RACING TEAM OWNED IN PART BY LANCE ARMSTRONG -CLOSED INVESTIGATIONS,, MEMOS, DIARIES, ETC 4/10 TO PRESENT
2012-1992	03/20/2012 04/17/2012	OC/ORA/ OC/ORA/ OC/CVM/OCD/	CAROL ZAMOJCIN HARTZ MOUNTAIN CORP	CHICKEN JERKY PRODS FROM CHINA - VENDOR NAMES, FACTORY NAMES, ADDRESSSES
2012-1993	03/20/2012 04/17/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	JAMIE R MOGIL FARUQI & FARUQI LLP	LIFEWAY FOODS INC, MORTON GROVE, IL - LIFEWAY PROBOOST, BIOKEFIR BLACKBERRY, GOO-BERRY PIE, ETC MARKETING VIOLATIONS, PROD MISBRANDING, INVESTIGATION RECS
2012-1994	03/20/2012 04/17/2012	FDA/OC/OES/DFOI/	LA TOYA SUTTON MANATT PHELPS & PHILLIPS LLP	BURT'S BEES NATURAL ACNE SOLUTIONS MAXIMUM STRENGTH SPOT TREATMENT CREAM - RECS, CORR
2012-1995	03/20/2012 04/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SHANNON HOUGH PHARM D UNIV OF MICHIGAN HOSPITALS & HEALTH CENTERS	CABAZITAXEL - AERS
2012-1996	03/20/2012 04/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	REUMOFAN PLUS - AERS
2012-1997	03/20/2012	FDA/OMPT/CDER/ORP/DIDP/	LAUREN BRIESE	ZOLOFT NDA 19-839, PROZAC NDA 18-936, PAXIL NDA 20-031, ETC - LBLG, LTR, RVWS

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	04/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PHYSICIANS COMMITTEE FOR RESPONSIBLE MEDICINE	
2012-1998	03/20/2012 04/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	CORTES, DAVE	LILLY DE CARIBE, CAROLINA, PR 4/28/11, 9/23/10; GUAYAMA, PR 12/3/10, ETC - 483S
2012-1999	03/20/2012 04/17/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	PEGGY McLAUGHLIN MPM ADVISORS	K090061
2012-2000	03/20/2012 04/17/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	PEGGY McLAUGHLIN MPM ADVISORS	K090269
2012-2001	03/20/2012 04/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	PEGGY McLAUGHLIN MPM ADVISORS	K110503
2012-2002	03/20/2012 04/17/2012	OC/OA/OM/OMP/DDM/	THOMAS, JEFFREY G	NEUROLOGICAL DVCS PANEL MTG, ROCKVILLE, MD - TRANS 5/14/09
2012-2003	03/20/2012 04/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	PEGGY McLAUGHLIN MPM ADVISORS	K112235
2012-2004	03/20/2012 04/17/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	PEGGY McLAUGHLIN MPM ADVISORS	K912824
2012-2005	03/20/2012 04/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	ANTHONY E. AUSIELLO AMNISURE INTERNATIONAL LLC	ROM PLUS FETAL MEMBRANES RUPTURE REST; ROM PLUS QUALITY CONTROL KIT K110605
2012-2006	03/20/2012 04/17/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	RAMONA KULIK STRYKER SUSTAINABILTY SOLUTIONS	MEDTRONIC XOMED INC, JACKSONVILLE, FL - XPS 3000 SYS K041413
2012-2007	03/20/2012 04/17/2012	FDA/OFVM/CFSAN/OCD/EOS/	MICHELLE L WELLS METRO CUSTOMS BROKERS INC	LISTING AS AGENT
2012-2008	03/20/2012 04/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	MARC C. SANCHEZ CONTRACT IN HOUSE COUNSEL AND CONSULTANTS LLC	MARIETTA VISION K002647, K052606, K992339
2012-2009	03/20/2012 04/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ALEX JOHN LONDON CARNEGIE MELLON UNIV PHILOSOPHY DEPT	BORTEZOMIB - PRECLNCL EFFICACY STUDIES

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2012-2010	03/20/2012 04/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	DOLLY MISTRY COVIDIEN	HEURISTIC MEDICAL SYS INC, HERRIN, IL - CONTOUR ELECTRODE K844345
2012-2011	03/20/2012 04/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ALEX JOHN LONDON CARNEGIE MELLON UNIV PHILOSOPHY DEPT	ROTIGOTINE - PRECLNCL EFFICACY STUDIES
2012-2012	03/20/2012 04/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	SEAN BUNDY COCHLEAR AMERICAS	COCHLEAR LTD, LANE COVE, NSW AUSTRALIA - EIR 11/8-17/04
2012-2013	03/20/2012 04/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ALEX JOHN LONDON CARNEGIE MELLON UNIV PHILOSOPHY DEPT	GEFETINIB - PRECLNCL EFFICACY STUDIES
2012-2014	03/20/2012 04/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	SEAN BUNDY COCHLEAR AMERICAS	COCHLEAR BONE ANCHORED SOLUTIONS AB. MOLNLYCKE, SWEDEN - EIR 6/9-12/08
2012-2015	03/20/2012 04/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRIAN TODT CAREFUSION CORP	ARARIS SMART PUMP - MEDWATCH RPT
2012-2016	03/20/2012 04/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRIAN TODT CAREFUSION CORP	SMART SITE INFUSIONSET - MEDWATCH RPT
2012-2017	03/20/2012 04/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRIAN TODT CAREFUSION CORP	ALARIS PUMP - MEDWATCH RPT
2012-2018	03/20/2012 04/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	CIPROFLOXACIN - RECS
2012-2019	03/20/2012 04/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRIAN TODT CAREFUSION CORP	10 ML BDLUER LOK TIP SYRINGE MW5021694
2012-2020	03/20/2012 04/17/2012	OC/CVM/ OCD/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KRISTINE BURGESS MS DVM TUFTS UNIV CUMMINGS SCHOOL OF VETERINARY MEDICINE	GLUCOPHAGE - NONCLNCL TOXICOLOGY RECS

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2012-2021	03/20/2012 04/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	HAMILTON, Ph.D., LEROY	MEDICAL DVC CLASSIFICATION QUESTIONNAIRE
2012-2022	03/20/2012 04/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	HAMILTON, LEROY L	CONCERNS ABOUT THE MEDICAL DEVICE AMENDMENTS - CDRH VIDEO SEMINAR 10/3/83
2012-2023	03/20/2012 04/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SARAH HUTCHINS VIRGINIAN-PILOT	BIAXIN (CLARITHROMYCIN) - AERS
2012-2024	03/20/2012 04/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	LIANE LaROCHELLE DEKA RESEARCH & DEVELOPMENT CORP	ABBOTT LABS - FREE STYLE INSULINX BLOOD GLUCOSE MONITORING SYS K111874
2012-2025	03/20/2012 04/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	WILLYARD #503162, DEWAYNE	LIPOIC ACID, ALPHA LIPOIC ACID - AERS
2012-2026	03/20/2012 04/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	KATHERINE STRONG CARNER SIDLEY AUSTIN LLP	DVC USED IN BREAST SURGERY - CDRH UNTITLED LTRS, INQUIRY LTRS, CORR, ETC LAST 5 YRS
2012-2027	03/20/2012 04/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	KATHERINE STRONG CARNER SIDLEY AUSTIN LLP	SURGICAL MESH DVCS - CHRH UNTITLED LTRS, INQUIRY LTRS, CORR, ETC LAST 5 YEARS LAST 5 YRS
2012-2028	03/20/2012 04/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OCC/ OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORO/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORO/CE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/	ELISABETH NEUBERG Bingham McCutchen LLP	QUESTCOR PHARMACEUTICALS INC - CMLPNTS, INVESTIGATIONS, SETTLEMENTS

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2012-2029	03/20/2012 04/17/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARY SHINN PHOENIX BUSINESS JOURNAL	PHARMACEUTICAL SHORTAGE LAST 5 YRS
2012-2030	03/20/2012 04/17/2012	FDA/OFVM/CFSAN/OCD/EOS/	DIANA DOBRIN IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 147168, 147174, 147177
2012-2031	03/20/2012 04/17/2012	FDA/OFVM/CFSAN/OCD/EOS/	DR DAVID SMITH FRESHWATER FARMS OF OHIO INC	PICHIA PASTORIS (DRIED YEAST) - FAP
2012-2032	03/20/2012 04/17/2012	FDA/OFVM/CFSAN/OCD/EOS/	WILLIAM A OLSON PHD WASHINGTON INFORMATION SOURCE	ANTIOXIDANT FOR POLYMER - GRAS
2012-2033	03/20/2012 04/17/2012	FDA/OC/OES/DFOI/	MEGAN B PICKEL BEVERIDGE & DIAMOND PC	CFSAN FOI REQUESTS 2/17/12-3/16/12
2012-2034	03/20/2012 04/17/2012	FDA/OC/OES/DFOI/	BRIAN SMITH LEXISNEXIS COURTLINK INC	FOI DAILY LOG 3/5-9/12
2012-2035	03/21/2012 04/18/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FOI Services, Inc.	EFALIZUMBA - ISR 5960794, 5964686, 6107859, ETC
2012-2036	03/21/2012 04/18/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FOI Services, Inc.	ETANERCEPT - ISR 3718371, 5212086, 5280079, ETC
2012-2037	03/21/2012 04/18/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ALEX JOHN LONDON CARNEGIE MELLON UNIV PHILOSOPHY DEPT	SUNITINIB - PRE-CLNCL STUDIES
2012-2038	03/21/2012 04/18/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ALEX JOHN LONDON CARNEGIE MELLON UNIV	ZICONOTIDE - PRE-CLNCL STUDIES

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2012-2039	03/21/2012 04/18/2012	FDA/OFVM/CFSAN/OCD/EOS/	ANITA RASMUSSEN MCCORMICK & COMPANY INC	PIMURSA, MURCIA, SPAIN - AUDIT 1/23/12
2012-2040	03/21/2012 04/18/2012	FDA/OFVM/CFSAN/OCD/EOS/	ANITA RASMUSEN MCCORMICK & COMPANY INC	RAMON SABATER, MURCIA, SPAIN - AUDIT 1/26-27/12
2012-2041	03/21/2012 04/18/2012	FDA/OMPT/CDRH/OCER/DFOI/	VICTOR J BARANOWSKI SCHMEISER OLSEN & WATTS LLP	DOMAIN SURGICAL, SALT LAKE CITY, UT - K110439
2012-2042	03/21/2012 04/18/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELLIOT FAVUS MD FAVUS INSTITUTIONAL RESEARCH LLC	TEVA, APP, BEDFOR - GENERIC INJECTABLE LEUCOVORIN- COMPANIES PLANNING TO SELL DRUG APPL
2012-2043	03/21/2012 04/18/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHANDRAN TIRVATTAR DR REDDY'S LABORATORIES INC	GLENMARK - CICLOPIROX ANDA 91-595 SBA
2012-2044	03/21/2012 04/18/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	VERONICA-ADELE R CAO WEISS & MOY PC	LATISSE (BIMATOPROST) - SAFTEY RECS, REQUEST TO PERMIT OTC SALE
2012-2045	03/21/2012 04/18/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELIZABETH BARBEHENN PUBLIC CITIZEN	IRS 7399370, 7402390, 7423077, ETC
2012-2046	03/21/2012 04/18/2012	FDA/OGROP/ORR/SW-FO/DAL- DO/DAL-CB/	FISHER, BRIANNA	INVESTIGATOR ID NO 374038 - 483 11/1/94
2012-2047	03/21/2012 04/18/2012	FDA/OC/OES/DFOI/	ASHA LAMBATOS AVALON RISK MANAGEMENT INC	ENTRY M42-12335648 - FAILURE TO DEDELIVER NOTICE OF FDA ACTION #1
2012-2048	03/21/2012 04/18/2012	FDA/OC/OES/DFOI/	WILLILAM II IIRANCHAK NEAL R GROSS & CO	OFFICE OF ACQUISITION & GRANTS, CENTR FOR BIOLOGICS EVALUATION & RESEARCH, CENTER FRO DEVICES & RADIOLOGICAL HEALTH, ETC - LIST OF ALL GOVERNMENT CARD HOLDERS
2012-2049	03/21/2012	FDA/OMPT/CTP/OD/	GREGORY S KEVER	KENTUCKY CUT RAG, LEXINGTON, KY - FORMSS, LISTINGS

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	04/18/2012		KENTUCKY CUT RAG LLC	FOR OWNERS & OPERATORS OF DOMESTIC TOBACCO PROD ESTABLISHMENTS 2011
2012-2050	03/21/2012 04/18/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	INFLIXIMAB ISRS 5530158, 5612356, 6223108
2012-2051	03/21/2012 04/18/2012	FDA/OGROP/ORR/SE-FO/SJN-DO/SJN-CB/	FOI Services, Inc.	PFIZER MANUFACTURING, CAROLINA, PR - EIR, 482, 483, WARNING LTR, CO RESP 3/14/10 TO PRESENT
2012-2052	03/21/2012 04/26/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OGROP/ORR/CE-FO/BLT-DO/BLT-CB/	FOI Services, Inc.	SOLUBLE SYSTEMS LLC, SKIN AND WOUND ALLOGRAFT INSTITUTE (SWAI), LIFENET HEALTH INC (LHI) - THERASKIN HUMAN SKIN ALLOGRAFT
2012-2053	03/21/2012 04/18/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	REMICADE ISR 6121836
2012-2054	03/21/2012 04/18/2012	FDA/OGROP/ORR/CE-FO/NWJ-DO/NWJ-CB/	FOI Services, Inc.	JOHNSON & JOHNSON, RARITAN, NJ - EIR, 483, WARNING LTR, CO RESP 3/18-27/09
2012-2055	03/21/2012 04/18/2012	FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/	FOI Services, Inc.	J MURPHY, SOUTHWESTERN RESEARCH, BEVERLY HILLS, CA - EIR, 483, WARNING LTR, CO RESP 2/20/09
2012-2056	03/21/2012 04/18/2012	OC/OM/OMP/DDM/	MERLE ZIMMERMANN AMERICAN HERBAL PRODUCTS ASSOCIATION	DKT FDA-1995-S-0039
2012-2057	03/21/2012 04/18/2012	FDA/OGROP/ORR/CE-FO/PHI-DO/PHI-CB/	FOI Services, Inc.	CENTOCOR, MALVERN, PA - EIR, 483, WARNING LTR, CO RESP 4/14-18/08, 11/10-13/08
2012-2058	03/21/2012 04/18/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORR/CE-FO/CIN-DO/CIN-CB/	FOI Services, Inc.	PROCTER & GAMBLE PRINGLES POTATO CHIPS FORTIFIED WITH CALCIUM CORR
2012-2059	03/21/2012 04/18/2012	FDA/OMPT/CDRH/OCER/DFOI/	PAIVI MESIRANTA CONMED LINVATEC BIOMATERIALS LTD	STRYKER LEIBINGER RESORBABLE FIXATION SYS K993061
2012-2060	03/21/2012 04/18/2012	FDA/OC/OES/DFOI/	BARBARA FRAZIER LEHL LAW OFFICES OF DENNIS BONNER & ASSOCIATES LLC	2012-179 REDACTED
2012-2061	03/21/2012	FDA/OMPT/CDRH/OCER/DFOI/	DAVID J. FISCHMAN	ACMI - IGLESIAS RESECTOSCOPE WARNING LTR, RPTS, PRODUCT MANUAL

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	04/18/2012		JAROSLAWICZ & JAROS LAW OFCS	
2012-2062	03/21/2012 04/18/2012	FDA/OC/OES/DFOI/	LaTOYA SUTTON MANATT PHELPS & PHILLIPS LLP	BURTS BEES - NATURAL ACNE SOLUTIONS CLARIFYING TONER CORR
2012-2063	03/21/2012 04/18/2012	FDA/OC/OES/DFOI/	LaTOYA SUTTON MANATT PHELPS & PHILLIPS LLP	BURTS BEES - NATURAL ACNE SOLUTIONS PURIFYING GEL CLEANSER CORR
2012-2064	03/21/2012 04/18/2012	FDA/OC/OES/DFOI/	LaTOYA SUTTON MANATT PHELPS & PHILLIPS LLP	BURTS BEES - NATURAL ACNE SOLUTIONS TARGETED SPOT TREATMENT CREAM CORR
2012-2065	03/21/2012 04/18/2012	FDA/OC/OES/DFOI/	LaTOYA SUTTON MANATT PHELPS & PHILLIPS LLP	BURTS BEES - NATURAL ACNE SOLUTIONS DAILY MOISTURIZING LOTION CORR
2012-2066	03/21/2012 04/18/2012	FDA/OC/OES/DFOI/	LaTOYA SUTTON MANATT PHELPS & PHILLIPS LLP	BURTS BEES - NATURAL ACNE SOLUTIONS REGIMEN KIT CORR
2012-2067	03/21/2012 04/18/2012	FDA/OC/OES/DFOI/	LaTOYA SUTTON MANATT PHELPS & PHILLIPS LLP	BURTS BEES - NATURAL ACNE SOLUTIONS PORE REFINING SCRUB CORR
2012-2068	03/21/2012 04/18/2012	OC/ORO/ OC/ORO/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORO/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORO/CE-FO/DET-DO/DET-CB/ FDA/OGROP/ORO/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORO/SE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORO/SW-FO/KAN-DO/KAN-CB/ FDA/OGROP/ORO/CE-FO/CHI-DO/CHI-CB/	PATTI WALLER MARLER CLARK ATTYS	MULTI STATE OUTBREAK OF E COLI 026 LINKED TO RAW CLOVER SPROUTS AT JIMMY JOHNS RESTAURANTS TEST RESULTS, RPTS, ETC 12/11 TO 2/12
2012-2069	03/21/2012 05/07/2012	FDA/OFVM/CFSAN/OCD/EOS/	MOTEN, LAVEETA	RECORD OF OVERTIME PAID TO CFSAN EMPLOYEES 1/10 TO 3/9/12
2012-2070	03/21/2012 04/18/2012	FDA/OFVM/CFSAN/OCD/EOS/	THOMPSON, CLARENCE LD	PMAP RATINGS FOR CFSAN EMPLOYEES BUDGET ANALYSTS, SENIOR BUDGET ANALYST EMPLOYEES 2011
2012-2071	03/21/2012	OC/ORO/OCI/		INDIVIDUAL RECS

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	04/18/2012	OC/ORAO/CI/	HERRERA, MICHELLE .	
2012-2072	03/21/2012 06/12/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	ROBERT D. KING, Jr. LAW OFFICE OF ROBERT D KING JR PC	INDIVIDUAL RECS
2012-2073	03/22/2012 05/11/2012	FDA/OGROP/ORAO/SE-FO/SJN- DO/SJN-CB/ FDA/OGROP/ORAO/PA-FO/SAN- DO/SAN-CB/ FDA/OGROP/ORAO/PA-FO/SAN- DO/SAN-CB/	CINDY RYAN ACTAVIS	LORAZAPAM 2MG,CLONAXAPAM 2M TABS - PHOTOGRAPHS
2012-2074	03/22/2012 04/19/2012	OC/ORAO/ OC/ORAO/ FDA/OGROP/ORAO/CE-FO/DET- DO/DET-CB/	DENNIS BABJACK ADYA INC	SAMPLE #720483 - TEST RESULTS 9/10/12
2012-2075	03/22/2012 04/19/2012	FDA/OGROP/ORAO/SE-FO/FLA- DO/FLA-CB/	MARTIN N ZAIAC MOUNT SINAI MEDICAL CENTER GREATER MIAMI SKIN & LASER CTR	GREATER MIAMI SKIN & LASER CTR, MIAMI BEACH, FL - 483, OBSERVATION #2, MISSING CHART & COPIES OF 0270309 4/22/10-7/14/10
2012-2076	03/22/2012 04/19/2012	FDA/OFVM/CFSAN/OCD/EOS/	MITCHELL A GOLDSTEIN BABENER & ASSOCS	MAX INTERNATIONAL - MAXONE CAERS
2012-2077	03/22/2012 04/19/2012	FDA/OFVM/CFSAN/OCD/EOS/	MITCHELL A GOLDSTEIN BABENER & ASSOCS	MAX INTERNATIONAL - CELLGEVITY CAERS
2012-2078	03/22/2012 04/19/2012	OC/ORAO/ OC/ORAO/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDRH/OCER/DFOI/ OC/CVM/OCD/	KATE B WILLSON CENTER FOR PUBLIC INTEGRITY	CERTIFICATE TO FOREIGN GOVERNMENT REQUESTS - EXPORT CERTIFICATE DATA FROM FORM FDA 3613
2012-2079	03/22/2012 04/19/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RALPH R TURNER PHASE V TECHNOLOGIES INC	LIST OF FDA PERSONNEL WHO ACCESSED DRUG MASTER FILE #22780
2012-2080	03/22/2012 04/19/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DOW, KATELYN	STATIN PRODUCTS - AERS 1/1/00 TO PRESENT

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2012-2081	03/22/2012 04/19/2012	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Doe J	MIKE SELLS POTATO CHIP CO - CMLPLNTS
2012-2082	03/22/2012 04/19/2012	OC/OA/OM/OMP/DDM/	SUE MCGOVERN JUST LABEL IT ORGANIC VOICES ACTION FUND	TOBACCO PETITION FDA-1995-N-0397 - NUMBER OF SIGNATURES
2012-2083	03/22/2012 04/19/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHARLES VAN DER HORST UNIV OF NORTH CAROLINA AT CHAPEL HILL	SYSTEMIC VASCULITIS (RENAL & RETINAL DISEASE & PANCYTOPENIA) - AERS , DES/PLAVIX RELATED?
2012-2084	03/22/2012 04/19/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHRISTINA PEDRO CORNELL UNIV	VESICARE - DRUG DEVELOPMENT/RESEARCH INFO, CONTROLLED TRIAL RECS, ETC
2012-2085	03/22/2012 04/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	PATRICIA SCHNOOR PHILIPS CONSUMER LIFESTYLE	K110349
2012-2086	03/22/2012 04/19/2012	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	MARK BROOKS UTILITY WORKERS UNION OF AMERICA	CITY BREWING CO, LACROSSE, WI, LATROBE PA & MEMPHIS, TN - EIRS, 483S, RECALLS ETC 1/1/10 TO PRESENT
2012-2087	03/22/2012 04/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	JENNIFER RUETHER VASCULAR SOLUTIONS	ZENUSA LTD - GUARDIAN NC K101113
2012-2088	03/22/2012 04/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	JASON KYUNG-SOO HONG MD CAROLINAS PAIN INSTITUTE PA	AMBULATORY MONITORING INC - WRIST ACTIGRAPH K854030B
2012-2089	03/22/2012 04/19/2012	FDA/OFVM/CFSAN/OCD/EOS/	CHARLES CELESTE EAS Consulting Group, LLC	MICHAEL JACOBSON, CENTER FOR SCIENCE IN THE PUBLIC INTEREST (CPI) - WHOLE GRAIN LABLG MTG MINS, CORR 2/8/12
2012-2090	03/22/2012 04/19/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/CVM/OCD/	SPALLA, SHANE	BIOVECGTRA INC, BIOCHEM FACILITY, CHARLOTTETOWN, PE; BIOVECTRA INC, BIOEXTRACTION FACILITY, CHARLOTTETOWN, PE - 483S 2002 TO 2012
2012-2091	03/22/2012 04/19/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WEBSTER, DOROTHY	LISINOPRIL, LIPTOR, ATENOLOL, ETC - AERS

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2012-2092	03/22/2012 04/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	MARK YOUNG PA	HEM-O-LOK SMX POLYMER CLIPS, MODEL 544220 - K993157
2012-2093	03/22/2012 04/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	MARK YOUNG PA	HEM-O-LOK LIGATING CLIPS - K982944
2012-2094	03/22/2012 04/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	MARK YOUNG PA	HEM-O-LOK LIGATING CLIPS - K003337
2012-2095	03/22/2012 04/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	MARK YOUNG PA	HEM-O-LOK LIGATING CLIP - K030311
2012-2096	03/22/2012 04/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	MARK YOUNG PA	HEM-O-LOK LIGATING CLIPS - K062914
2012-2097	03/22/2012 04/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	MARK YOUNG PA	HEM-O-LOK LIGATING CLIPS - K982941
2012-2098	03/22/2012 04/19/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/OA/OM/OMP/DDM/	JOHN R RAPOZA MD RPH JR RAPOZA ASSOCIATES INC	OXYCODONE HCL DMF 16399 - RECS
2012-2099	03/22/2012 04/19/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/CVM/OCD/	CONNER, MARYBETH	BIOVECTRA INC, CHATLOTTETOWN, PE - 483S LAST 10 YRS
2012-2100	03/22/2012 04/19/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/OCM/EMOPS/ OC/ORA/ OC/ORA/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	PATTI WALLER MARLER CLARK ATTYS	FAMILY COW FARM, CHAMBERSBURG, PA - UNPASTURIZED MILK CAMPYLOBACTER JEJUNI OUTBREAK NOTES, TEST RESULTS, COMM ETC 1/12 -2/12
2012-2101	03/22/2012 04/19/2012	FDA/OGROP/ORACE-FO/ATL-DO/ATL-CB/	DEBORAH KLOOS MEDICAL ACTION INDUSTRIES INC	MEDICAL ACTION INDUSTRIES, ARDEN, NC - EIR 3/26-31/09
2012-2102	03/22/2012	FDA/OGROP/ORACE-FO/FLA-	MARTIN N ZAIAC	GREATER MIAMI SKIN & LASER CTR, MIAMI BEACH FL - EIR

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	04/19/2012	DO/FLA-CB/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	MOUNT SINAI MEDICAL CENTER GREATER MIAMI SKIN & LASER CTR	4/22/10 -7/14/10
2012-2103	03/22/2012 04/19/2012	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	CAROLINA M HEAVNER K & L GATES	INNOTEQ INC, STRATFORD, CT - EIR, 483S, CORR ETC 3/06 TO 3/12
2012-2104	03/22/2012 04/19/2012	OC/OA/OM/OMP/DDM/	SUE MCGOVERN JUST LABEL IT ORGANIC VOICES ACTION FUND	DKT 1995N-0259
2012-2105	03/22/2012 04/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	MARTHA GUZMAN AMSINO INTERNATIONAL INC	HYDROPHILIC ANTIBACTERIAL INTERMITTENT CATHETER K033477
2012-2106	03/22/2012 04/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	MARTHA GUZMAN AMSINO INTERNATIONAL INC	BARDEX LUBRI-SIL 3-WAY FOLEY CATHETER K070558
2012-2107	03/22/2012 04/19/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOI REQUESTS 3/12-16/12
2012-2108	03/22/2012 04/19/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 3/12-16/12
2012-2109	03/22/2012 04/19/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 3/12-16/12
2012-2110	03/22/2012 04/19/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	CLOSED FOI REQUESTS 3/12-16/12
2012-2111	03/22/2012 04/19/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC	CLOSED FOI REQUESTS 3/5-9/12
2012-2112	03/23/2012 04/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	AMY L GOERSS HODGSON RUSS LLP	SIRONA DENTAL SYSTEMS GMBH - CAD/CAM SYS k100152
2012-2113	03/23/2012 04/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	AMY L GOERSS HODGSON RUSS LLP	NT-TRADING GMBH & CO KG - TI-BASE ABUTMENT, 1 CONNECT ABUTMENT K111935
2012-2114	03/23/2012 04/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	AMY L GOERSS HODGSON RUSS LLP	3M ESPE AG DENTAL PRODUCTS - LAVA FRAME LAVE FRAME SHADE K072055
2012-2115	03/23/2012 04/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	ROBIN PAYNTER OREGON HEALTH & SCIENCE UNIV	MEDTRONIC - INFUSE BONE GRAFT P050053 ORAL MAXILLOFACIAL PROTOCOL, SUMMARY, CASE HISTORIES
2012-2116	03/23/2012 04/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	ROBIN PAYNTER OREGON HEALTH & SCIENCE UNIV	WYETH - INFUSE BONE GRAFT P000054 ORTHOPEDIC TRAUMA PROTOCOL. SUMMARY, CASE HISTORIES

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2012-2117	03/23/2012 04/20/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	JASON T SCHNEIDER JASON T SCHINEIDER PC	BARD, MURRAY HILL, NJ - G2 FILTER SYS EIRS WARNING LTRS, 510K, 1/00 TO PRESENT
2012-2118	03/23/2012 04/20/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OC/OES/DFOI/	JASON SCHNEIDER JASON T SCHINEIDER PC	BARD PV, TEMPE, AZ - G2 FILTER SYS EIRS, WARNING LTRS, 510K 1/00 TO PRESENT
2012-2119	03/23/2012 04/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	ANDREA P DEMERS MAYNARD O'CONNOR ET AL	PRECISION MEDICAL - EASY PULSE 5 OXYGEN CONSERVING REGULATOR INVESTIGATION, PHOTOGRAPHS, RPTS, ETC
2012-2120	03/23/2012 04/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	KRISTIN R DAVEPORT GOODWIN PROCTER LLP	OTTO BOCK HEALTHCARE LP - SENSOR WALK K052771
2012-2121	03/23/2012 04/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	JEFFERY P FISHER EZ PEDO	TUFF KID CROWNS LLC - ZIRCONIUM-BASED CERAMIC PEDIATRIC PREFORMED CROWNS CMLPLNTS
2012-2122	03/23/2012 04/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	DAVID B JONES BERLINHEART	A-MED SYSTEMS, WEST SACRAMENTO, CA - A-MINIATURE CENTRIFUGAL BLOOD PUMP SYS K992592
2012-2123	03/23/2012 04/20/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	DAVID B JONES BERLINHEART	A-MED SYSTEMS INC - VASCULAR CANNULA - K99154131
2012-2124	03/23/2012 04/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	DAVID JONES BERLINHEART	A-MED SYSTEMS INC - LARGE CENTRIFUGAL BLOOD PUMP K020529
2012-2125	03/23/2012 06/01/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	JESSICA L MONSELI MOTLEY RICE LLC	DR THOMAS LITTLEJOHN III - CLNCL STUDIES, TRIALS, SUBMISSIONS, ETC
2012-2126	03/23/2012 04/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	COLAS, BRIAN	ABBOTT LABS - BAXIN (CLARITHROMYCIN) AERS
2012-2127	03/23/2012	FDA/OMPT/CDER/ORP/DIDP/	ANDREA S FRANKS	VICTOZA (LIRGLUTIDE) AERS

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	04/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	UNIV OF TENNESSEE/COLLEGE OF PHARMACY	
2012-2128	03/23/2012 04/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GARY HAIGHT ETHYPHARM INC	PERCOCET, OXYCODONE TABS - PRE-CLNCL, CLNCL RECS
2012-2129	03/23/2012 04/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/CVM/OCD/	NEWMAN, ARIEL	REGU-MATE (ALLYL TRENBOLORE) - AERS
2012-2130	03/23/2012 04/20/2012	FDA/OMPT/CTP/OD/	SUZANNE D JENSEN KLEINFELD KAPLAN & BECKER	TOBACCO ESTABLISHMENTS REGISTERED WITH FDA - MFGS OR IMPORTERS, SECTION 905 (J) RPTS
2012-2131	03/23/2012 04/20/2012	FDA/OGROP/ORACE-FO/CHI- DO/CHI-CB/	COLLEEN GRACE DONOFRIO PQ CORP	PQ CORP, UTICA, IL - EIR 7/11
2012-2132	03/23/2012 04/20/2012	OC/ORACE/ OC/ORACE/	ADRIANA MCKINNON DENNICK FRUITSOURCE	13 DRUMS - ENTRY #EDA-000-1177-1 ANALYTICAL RESULTS
2012-2133	03/23/2012 04/20/2012	OC/ORACE/OCI/ OC/ORACE/OCI/ FDA/OGROP/ORACE-FO/ATL- DO/ATL-CB/	GEORGIA L MCGOWAN EVERAGE LAW FIRM PLLC	MOUSE FOUND IN MS BUTTERWORTH SYRUP - RECS
2012-2134	03/23/2012 04/20/2012	FDA/OO/OFBA/OAGS/	JEFF STACHEWICZ, Esq. FOIA GROUP INC	HHSF22301002T
2012-2135	03/23/2012 04/20/2012	OC/CVM/OCD/	LAURIE PHARIS NOVARTIS ANIMAL HEALTH	DRONCIT (PRAZQUANTEL) NADA 111-607 INJECTIBLE CESTOCIDE
2012-2136	03/23/2012 04/20/2012	OC/CVM/OCD/	LAURIE PHARIS NOVARTIS ANIMAL HEALTH	DRONCIT (PRAZQUANTEL) NADA 111-798 CESTOCIDE TABS
2012-2137	03/23/2012 04/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	JOSEPH KICEINAY ABBOTT POINT OF CARE INC	DIAGNOSTICA STAGO INC - XA TEST K111822
2012-2138	03/23/2012 04/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	JOSEPH KICEINA ABBOTT POINT OF CARE INC	AMERICAN BIOPRODUCTS CO - STA AUTOMATED COAGULATION ANALYZER K942117
2012-2139	03/23/2012	FDA/OMPT/CDER/ORP/DIDP/		FELODIPINE; HYDRALAZINE; LEVOTHYROXINE - AER

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	04/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FAM, PAULINA	
2012-2140	03/23/2012 04/20/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/CVM/OCD/	R. LEONARD VANCE, Ph.D. VIRGINIA COMMONWEALTH UNIVERSITY	ROXARSONE (3 NITROARSINILIC) RECS
2012-2141	03/23/2012 04/20/2012	FDA/OFVM/CFSAN/OCD/EOS/	MITCHELL A. CHEESEMAN STEPTOE & JOHNSON	FCN 000852 - CHEMISTRY RVW, TOXICOLOGY RVW
2012-2142	03/23/2012 04/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	AMY L. GOERSS HODGSON RUSS LLP	NOBEL BIOCARE AB - PROCERA IPS E MAX CROWN K100512
2012-2143	03/23/2012 04/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	AMY L. GOERSS HODGSON RUSS LLP	WILLIAMS GOLD REFINING CO INC - SRARTAN SOLDER K854738
2012-2144	03/23/2012 04/20/2012	FDA/OFVM/CFSAN/OCD/EOS/	BRIANNA L. SILVERSTEIN DRINKERBIDDLE & REATH LLP	GRAS NO 94 - RECS PRIOR TO 1/1/04
2012-2145	03/23/2012 04/20/2012	FDA/OGROP/ORAPA-FO/SEA- DO/SEA-CB/	ROSS S. LANDERMAN KOWA RESEARCH INSTITUTE INC	XUE QIAO ZHAO MD, LAKE UNION PLACE, SEATTLE, WA - EIR, 483 12/10
2012-2146	03/23/2012 04/20/2012	FDA/OMPT/CDRH/OCER/DFOI/ OC/OA/OM/OMP/DDM/	VASILIKI BEGKOU CERAMTEC	PROTEK - CERAMIC FEMORAL HEADS; RECLASSIFICATION PETITION 10/15/86, MTG MINS
2012-2147	03/23/2012 04/20/2012	FDA/OFVM/CFSAN/OCD/EOS/	TRUUS TIEMERSMA DSM AHEAD BV	TRIMETHYMELLITATE - PETITION
2012-2148	03/23/2012 04/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JAY HENDERSON PLLC	PARKE DAVIS - DILANTIN LBLG, NDA 1/07 TO 3/12
2012-2149	03/23/2012 04/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JAY HENDERSON PLLC	PARKE DAVIS - DILANTIN NDA, LBLG 1/07 TO 3/12
2012-2150	03/23/2012 04/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JAY HENDERSON PLLC	PARKE DAVIS - DILANTIN NDA 84-427, LBLG
2012-2151	03/23/2012	FDA/OMPT/CDER/ORP/DIDP/		PARKE DAVIS - DILANTIN NDA 84-349 LBLG

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	04/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JAY HENDERSON PLLC	
2012-2152	03/23/2012 04/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JAY HENDERSON PLLC	TARO - PHENYTOIN NDA 40-521, LBLG
2012-2153	03/23/2012 04/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JAY HENDERSON PLLC	TARO - PHENYTOIN NDA 40-684, LBLG 1/07 TO 3/12
2012-2154	03/23/2012 04/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JAY HENDERSON PLLC	AMNEAL PHARMS NY - PHENYTOIN NDA 40-765, LBLG 1/07 TO 3/12
2012-2155	03/23/2012 04/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JAY HENDERSON PLLC	MYLAN - PHENYTOIN NDA 40-298, LBLG 1/07 TO 3/12
2012-2156	03/23/2012 04/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JAY HENDERSON PLLC	SUN PHARM INDS - PHENYTOIN NDA 40-731, LBG
2012-2157	03/23/2012 04/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JAY HENDERSON PLLC	SUN PHARMS INDS - PHENYTOIN NDA 40-621, LBLG
2012-2158	03/23/2012 04/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JAY HENDERSON PLLC	WATSON - PHENYTOIN NDA 85-894, LBLG
2012-2159	03/23/2012 04/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JAY HENDERSON PLLC	ACTAVIS MID ATLANTIC LLC - PHENYTOIN NDA 89-892, LBLG

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2012-2160	03/23/2012 04/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	Doe J	DIETARY SUPPLEMENTS - AER 1/1/08 TO 3/1/12
2012-2161	03/23/2012 04/20/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/ FDA/OFVM/CFSAN/OCD/EOS/	ROBERT A. DeCAMP DERINGER LOGISTICS CONSULTING GROUP	AN DERINGER INC - RECS
2012-2162	03/23/2012 04/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	AMY L. GOERSS HODGSON RUSS LLP	IYOVLAR - GOLDEN CERAMIC SOLDERS K905419
2012-2163	03/26/2012 04/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	GREGORY H LEVINE ROPES & GRAY LLP	CLRS TECHNOLOGY CORP (SOLTA MEDICAL) - K09744
2012-2164	03/26/2012 04/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	GREGORY LEVINE ROPES & GRAY LLP	SHASER INC (REMINGTON) - K103560
2012-2165	03/26/2012 04/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	GREGORY LEVINE ROPES & GRAY LLP	HOME SKINOVATIONS LTD - K103184
2012-2166	03/26/2012 04/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	GREGORY LEVINE ROPES & GRAY LLP	LED INTELLECTUAL PROPERTIES LLC - K101190
2012-2167	03/26/2012 04/23/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	GREGORY LEVINE ROPES & GRAY LLP	PHOTO THERAPEUTICS INC - K072459
2012-2168	03/26/2012 04/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	GREGORY LEVINE ROPES & GRAY LLP	PHOTO THERAPEUTICS INC - K081307
2012-2169	03/26/2012 04/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	GREGORY LEVINE ROPES & GRAY LLP	SILVER BAY LLC - K093963
2012-2170	03/26/2012 04/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	GREGORY LEVINE ROPES & GRAY LLP	RADIANCY (ISRAEL) LTD - K102477
2012-2171	03/26/2012 04/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	DORENE MARKWIESE ST JUDE MEDICAL	ADVANCED BONICS CORP - PRECISION SPINAL CORD STIMULATION (SCS) SYS - P030017/S008, S010, S011, S018, S022
2012-2172	03/26/2012 04/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	DORENE MARKWIESE ST JUDE MEDICAL	MEDTRONIC INC - RESTORE PRIME, PRIMEADVANCED RESTORE RECHARGEABLE, RESTORE ADVANCED, ETC

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				P840001/S126
2012-2173	03/26/2012 04/23/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	CHELSIE KING GARZA ABRAHAM WATKINS ET AL	SIEMENS HEALTHCARE DIAGNOSTICS INC, BAYER HEALTHCARE - ADVIA CLNCL CHEMISTRY SYS 1800 APRVL RECS, MDRS, COMM, ETC
2012-2174	03/26/2012 04/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	CHELSIE KING GARZA ABRAHAM WATKINS ET AL	SIEMENS HEALTHCARE, BAYER HEALTHCARE - ADVIA CLNCL CHEMISTRY SYS 1650 APRVL RECS, MDRS, COMM, ETC
2012-2175	03/26/2012 04/23/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	LIEBERMAN, MARC S	ALL CRYOSURGERY INC - VERRUCA FREEZE SYS K982506, K944221, K881349
2012-2176	03/26/2012 04/23/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	EJ SMITH SMITH ASSOCIATES	LIFELINES TRACKIT RECORDED - K010460
2012-2177	03/26/2012 05/02/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/	DONNA R CORCORAN COOLEY MANION MOORE & JONES PC	CADD-LEGACY INFUSION PUMP MODEL 6400 - RPTS, INTERVIEWS, FINDINGS, ETC
2012-2178	03/26/2012 04/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARILYNN WHITNEY COVINGTON BURLING LLP	AESICA QUEENBOROUGH LTD, KENT, UK - EIRS, 483S 3/18/10
2012-2179	03/26/2012 04/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEVIN PYUN CONSONANCC CAPITAL	SEATTLE GENETICS - ADCETRIS (BRENTUXIMAB VEDOTIN) AERS, SAFETY RECS
2012-2180	03/26/2012 04/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN D'ANGELO FERA PHARMACEUTICALS	FERA PHARMACEUTICAL LLC - DAPIPRAZOLE HCL 0.5% OPHTHALMIC SOL IND 27286 RECS
2012-2181	03/26/2012 04/23/2012	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	MATT SCHRADER KOVV-TV	LEVELS OF ANTIBIOTICS, DRUGS FOUND IN RESIDUE TESTS IN DAIRY CATTLE MEAT FROM CALIFORNIA 2007- 2011
2012-2182	03/26/2012	FDA/OGROP/ORA/PA-FO/LOS-	NINOS SAROUKHANNIOFF	WINDSOR QUALITY FOOD CO, HUNTINGTON PARK, CA -

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	04/23/2012	DO/LOS-CB/ FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/OCI/ OC/ORO/OCI/ FDA/OC/OES/DFOI/	MARANGA MORGENSTERN LAW CORP	EIRS, RPTS, PHOTOGRAPHS, ETC 3/20/12
2012-2183	03/26/2012 04/23/2012	FDA/OFVM/CFSAN/OCD/EOS/	PAULINA DO EXPONENT	ABBOTT LABS - DKT 2012F-0138
2012-2184	03/26/2012 04/23/2012	OC/ORO/ OC/ORO/ OC/ORO/ORM/ OC/ORO/ORM/	ELENA HOWELL HOGAN LOVELLS LLP	FOOD INSPECTOR TRAINING MATERIALS FY 2011, FY 2012
2012-2185	03/26/2012 07/20/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ OC/OCOS/OES/ OC/OCOS/OES/ OC/OER/OPA/ FDA/OC/OEXA/OMA/	KATE B WILLSON CENTER FOR PUBLIC INTEGRITY	TISSUE BANK INSP PROTOCOLS, REGULATIONS ON IMPORTING HUMAN TISSUE, DISTRIBUTION & TRANSPLANTATION RECS, ETC
2012-2186	03/26/2012 04/23/2012	FDA/OFVM/CFSAN/OCD/EOS/	A SMYTH IOVATE HEALTH SCIENCES RESEARCH INC	CAERS 148279, 148276, 145980, ETC
2012-2187	03/26/2012 04/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	SUZANNE O'SHEA FAEGRE BAKER DANIELS	HAMAMATSU PHOTONICS KK - PDE K110480
2012-2188	03/26/2012 04/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEVIN PYUN CONSONANCC CAPITAL	AVANIR PHARMS - NUEDEXTA (DEXTROMETHORPHAN HYDROBROMIDE, QUINIDINE SULFATE) AERS
2012-2189	03/26/2012 04/23/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORO/CE-FO/DET- DO/DET-CB/	MARIO C PALERMO WOODRUFF JOHNSON & PALERMO	STRYKER CORP - MX-PRO AMBULANCE COTS MDRS; INDIVIDUAL RECS
2012-2190	03/26/2012 04/23/2012	FDA/OGROP/ORO/SW-FO/DEN- DO/DEN-CB/	ANGELIA D SLAYTON INC REGULATORY CONSULTING & SUBMISSIONS	EDUARDO R PAJON, ROCKY MOUNTAIN CANCER CENTER, DENVER, CO - EIRS, 483S,CO RESP 8/4/04
2012-2191	03/26/2012 04/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANGELIA D SLAYTON INC RESEARCH CONSULTING & SUBMISSIONS	PRONOVA BIOPHARMA, SANDEFJORD, NORWAY - EIRS, 483S, CO RESP 2004 TO 2012

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2012-2192	03/26/2012 04/23/2012	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	ANGELIA D SLAYTON INC REGULATORY CONSULTING & SUBMISSIONS	DAVID H HENRY III, PENNSYLVANIA ONCOLOGY HEMATOLOGY ASSOCIATES, PHILADELPHIA, PA - EIRS, 483S,CO RESP 10/10/96
2012-2193	03/26/2012 04/23/2012	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	ANGELIA D SLAYTON INC REGULATORY CONSULTING & SUBMISSIONS	DAVID H HENRY III, PENNSYLVANIA ONCOLOGY HEMATOLOGY ASSOCIATES, PHILADELPHIA, PA - EIRS, 483S, CO RESP 2/5/02
2012-2194	03/26/2012 04/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	AMY KINCANON LEXISNEXIS COURTLINK INC	K020110 - SUBSTANTIALLY EQUIVALENT APRVL LTR 4/3/02 (CERTIFIED)
2012-2195	03/26/2012 04/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	AMY KINCANON LEXISNEXIS COURTLINK INC	K081275 - SUBSTANTIALLY EQUIVALENT APRVL LTR 8/27/08 (CERTIFIED)
2012-2196	03/26/2012 04/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	AMY KINCANON LEXISNEXIS COURTLINK INC	K081048 - SUBSTANTIALLY EQUIVALENT APRVL LTR 8/22/08 (CERTIFIED)
2012-2197	03/26/2012 04/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	AMY KINCANON LEXISNEXIS COURTLINK INC	K040787 - SUBSTANTIALLY EQUIVALENT APRVL LTR 4/14/04 (CERTIFIED)
2012-2198	03/26/2012 04/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	AMY KINCANON LEXISNEXIS COURTLINK INC	K071957 - SUBSTANTIALLY EQUIVALENT APRVL LTR 1/13/09 (CERTIFIED)
2012-2199	03/26/2012 04/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DR YA PING LEE CURTIN UNIV SCHOOL OF PHARMACY	ORAL PROTON PUMP INHIBITORS (OMEPRAZOLE, ESOMEPRAZOLE, RABEPRAZOLE, ETC) - AERS
2012-2200	03/26/2012 04/23/2012	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	BOWMAN COX GOLD SHEET	AIDAPAK SERVICES LLC, VANCOUVER, WA - 483 1/6/11
2012-2201	03/26/2012 04/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	BREANNE VANDERMEER MUELLER LAW OFC	ETHICON INC, JOHNSON & JOHNSON - GYNECARE PROLIFT CORR, APRVL 2005-2007
2012-2202	03/26/2012 04/23/2012	FDA/OFVM/CFSAN/OCD/EOS/	DIANE C MCENROE SIDLEY AUSTIN LLP	HERBALIFE - CAERS, CMLPNTS
2012-2203	03/26/2012 04/23/2012	FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	CORTES, DAVE	MERCK & CO, ARECIBO, PR 4/14/11; BARCELONETA, PR 3/31/11, 5/21/09, ETC - 483S
2012-2204	03/26/2012 04/23/2012	FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	CORTES, DAVE	TAPI PUERTO RICO INC, GUAYAMA, PR 9/30/11, 5/19/09; HUMACAO, PR 8/6/09 - 483S
2012-2205	03/26/2012 04/23/2012	FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	CORTES, DAVE	WARNER CHILCOTT COMPANY LLC, FAJARDO, PR - 483S 12/29/09, 7/29/11

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2012-2206	03/26/2012 04/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	BRENDA M GARTZ ELI LILLY & CO	PATHEON ITALIA SPA, FERENTINO, ITALY - EIR 5/11
2012-2207	03/26/2012 04/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	PATHEON ITALIA SPA, FERENTINO, ITALY - EIR 6/09
2012-2208	03/27/2012 04/24/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/PHI- DO/PHI-CB/	SUSAN BROWN MCCORMICK & COMPANY INC	SAFFRON ENTRY #UPS-2765756-4 - LAB ANALYSIS
2012-2209	03/27/2012 04/24/2012	FDA/OGROP/ORO/PA-FO/SAN- DO/SAN-CB/	TERESA WEBSTER ARMANINO FOODS OF DISTINCTION INC	ARMANINO FOODS OF DISTINCTION INC, HAYWARD, CA - 482 9/30/11
2012-2210	03/27/2012 04/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	VICKIE SEEGER Reckitt Benckiser Pharmaceuticals	THE BASIS FOR RESCHEDULING OF BUPRENORPHINE AS A SCHEDULE V NARCOTIC UNDER THE CONTROLLED SUBSTANCES ACT
2012-2211	03/27/2012 04/24/2012	FDA/OGROP/ORO/SW-FO/KAN- DO/KAN-CB/	JULIE PEAK INTERCON CHEMICAL CO	B & G LABS, ST LOUIS, MO - ENFORCEMENT ACTIONS
2012-2212	03/27/2012 04/24/2012	OC/ORO/ OC/ORO/	KATHY MCINTOSH PHD SASKATOON COLOSTRUM COMPANY LTD	SASKATOON COLOSTRUM COMPANY LTD - BOVINE DRIED COLOSTRUM ENTRY #112-6413972-1 TESTING RECS
2012-2213	03/27/2012 05/03/2012	FDA/OGROP/ORO/PA-FO/SAN- DO/SAN-CB/	LATESHA R BAKER HINSHAW & CULBERTSON LLP	GENENTECH INC - EIRS, 483S, DEVIATION RPTS, ETC 6/11, 9/2-27/11
2012-2214	03/27/2012 05/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/	CHRISTOPHER MARLBOROUGH FARUQI & FARUQI LLP	HYLAND'S INC - HOMEOPATHIC PRODS AERS, CORR, SAFETY & EFFICACY RECS, ETC
2012-2215	03/27/2012	FDA/OMPT/CDER/ORP/DIDP/		PALADIN LABS - ANTIZOL (FOMEPIZOLE) NDA 20-696

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	04/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DORAIS, JULIE	MEDICAL, STATISTICAL RVWS
2012-2216	03/27/2012 04/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DORAIS, JULIE	ROCHE PALO - CYTOVENE (GANCICLOVIR SODIUM) NDA 19-661 MEDICAL & STATISTICAL RVWS
2012-2217	03/27/2012 04/24/2012	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	HALTER, PAUL	PURE SOURCE INC, MIAMI, FL - 483, CO RESP 9/22/11
2012-2218	03/27/2012 04/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	NOBILUS ENT, KUTNO, POLAND - 483 9/12-15/11
2012-2219	03/27/2012 04/24/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	2012-1074
2012-2220	03/27/2012 04/24/2012	FDA/OMPT/CTP/OD/	FOI Services, Inc.	CENTER FOR TOBACCO PRODUCT SITE TOUR PROGRAM VISITS - RECS, SUMMARIES 7/1/11 TO 3/16/12
2012-2221	03/27/2012 04/24/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	DAVOL INC - DAVOL X-STREAM LAPAROSCOPIC IRRIGATION SYS K003790
2012-2222	03/27/2012 04/24/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	FOI Services, Inc.	DAVOL INC - HYDRO-FLEX LI LAPAROSCOPIC IRRIGATION SYS K961224
2012-2223	03/27/2012 04/24/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	DAVOL INC - HYDRO-SURG LAPAROSCOPIC IRRIGATION SYS K961492
2012-2224	03/27/2012 04/24/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	DAVOL INC - NAZHAT-DORSEY REUSABLE ELECTROSURGICAL ATTACHMENTS K003674
2012-2225	03/27/2012 04/24/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	STRYKER ENDOSCOPY - STRYKERFLOW SUCTION IRRIGATOR K954726
2012-2226	03/27/2012 04/24/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	STRYKER ENDOSCOPY - STRYKER IRRIGATION TUBE SET K000493
2012-2227	03/27/2012 04/24/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	CIRCON CORP - CIRCON SURGIFLEX WAVE TSUNAMI SUCTION IRRIGATION SYS K992126
2012-2228	03/27/2012 04/24/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	GYRUS MEDICAL INC - GYRUS PLASMACION LAPAROSCOPIC SPATULA K041633

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2012-2229	03/27/2012 04/24/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	ETHICON ENDO-SURGERY INC - ENSEAL LCJ TISSUE SEALER K101520
2012-2230	03/27/2012 04/24/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	VALLEYLAB - LIGASURE 5MM BLUNT TIP LAPAROSCOPIC SEALER-DIVIDER K092879
2012-2231	03/27/2012 04/24/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	ETHICON ENDO-SURGERY - ETHICON ENDO-SURGERY GENERATOR G-11 K101990
2012-2232	03/27/2012 04/24/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	OLYMPUS MEDICAL SYSTEMS CORP - SURGICAL TISSUE MANAGEMENT SYS K111202
2012-2233	03/27/2012 04/24/2012	FDA/OGROP/ORAP/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORAP/PA-FO/SAN-DO/SAN-CB/	FOI Services, Inc.	BIOZONE LABS, PITTSBURG, CA - 483, WARNING LTR, CO RESP, ETC 1/11
2012-2234	03/27/2012 04/24/2012	FDA/OGROP/ORAP/SW-FO/DEN-DO/DEN-CB/	FOI Services, Inc.	OSO BIOPHARMACEUTICALS MANUFACTURING LLC, ALBUQUERQUE, NM - EIR, 483, WARNING LTR, ETC 8/11-16/11
2012-2235	03/27/2012 04/24/2012	FDA/OGROP/ORAP/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORAP/PA-FO/SAN-DO/SAN-CB/	FOI Services, Inc.	BIOZONE LABS, PITTSBURG, CA - CO RESP, CORR 4/22-28/09
2012-2236	03/27/2012 04/24/2012	FDA/OC/OES/DFOI/	JULIE PEAK INTERCON CHEMICAL CO	B & G LABS, ST LOUIS, MO - WARNING LTRS
2012-2237	03/27/2012 04/24/2012	FDA/OFVM/CFSAN/OCD/EOS/	WILCOX 0955193, RAS TORREY	VEGAN DIET FOR INMATES
2012-2238	03/27/2012 04/24/2012	OC/OM/OMP/DDM/	ZACH ROTHSTEIN ZACH ROTHSTEIN	DKT 2006P-0068, DKT & DKT LOG OF 1978N-0065
2012-2239	03/28/2012 04/25/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 2/27/12-3/2/12
2012-2240	03/28/2012 04/25/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 3/5-9/12
2012-2241	03/28/2012 04/25/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DEBRA COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 2/27/12-3/2/12
2012-2242	03/28/2012 04/25/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 3/5-9/12
2012-2243	03/28/2012	FDA/OC/OES/DFOI/	KEN REID	FOI DAILY LOG 2/27/12-3/2/12

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	04/25/2012		WASHINGTON INFORMATION SOURCE	
2012-2244	03/28/2012 04/25/2012	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 3/5-9/12
2012-2245	03/28/2012 04/25/2012	FDA/OC/OES/DFOI/	GLADYS B TONKIN WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 3/5-9/12
2012-2246	03/28/2012 04/25/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 3/5-9/12
2012-2247	03/28/2012 04/25/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 2/27/12-3/2/12
2012-2248	03/28/2012 04/25/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 3/27/12-3/2/12
2012-2249	03/28/2012 04/25/2012	FDA/OC/OES/DFOI/	LISA LARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 3/5-9/12
2012-2250	03/28/2012 04/25/2012	FDA/OC/OES/DFOI/	GLADYS B TONKIN WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 2/27/12-3/2/12
2012-2251	03/28/2012 04/25/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORACE-FO/PHI- DO/PHI-CB/	THOMAS E CRENNY THOMAS E CRENNY & ASSOCIATES LLC	BRUNTON DAIRY, BEAVER COUNTY, PA - RECS 1/11 TO PRESENT
2012-2252	03/28/2012 04/25/2012	FDA/OC/OES/DFOI/ FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORASW-FO/KAN- DO/KAN-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	TRINA M MCPHERSON GREEN & GREEN	EXCEDRIN MIGRAINE - AERS, RECALLS, FINDINGS OF INVESTIGATION, ETC 1/11 TO PRESENT
2012-2253	03/28/2012 04/25/2012	FDA/OMPT/CDRH/OCER/DFOI/	ANNA DEMKOVIC ABBOTT LABORATORIES, INC.	BIOPORTO - NGAL TEST CORR, MINS, RECS, ETC
2012-2254	03/28/2012	FDA/OMPT/CDER/ORP/DIDP/	RACHEL DEPOMPA	METHYLPHENIDATE & METHADONE MIX-UPS BY PHARMACIES SINCE 1995 - RECS

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	04/25/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WWBT/NBC12	
2012-2255	03/28/2012 04/25/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ OC/OCOS/OES/ OC/OCOS/OES/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	SEAN DUNAGAN JUDICIAL WATCH	LARIAM, MEFAQUIN (MEFLOQUINE) - VAERS
2012-2256	03/28/2012 04/25/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 3/12-16/12
2012-2257	03/28/2012 04/25/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 3/12-16/12
2012-2258	03/28/2012 04/25/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 3/12-16/12
2012-2259	03/28/2012 04/25/2012	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 3/12-16/12
2012-2260	03/28/2012 04/25/2012	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 3/12-16/12
2012-2261	03/28/2012 04/25/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 3/12-16/12
2012-2262	03/28/2012 04/25/2012	FDA/OC/OES/DFOI/	FRAN KOCH INFORMATION ACCESS	FOI DAILY LOG 3/12-16/12
2012-2263	03/28/2012	FDA/OC/OES/DFOI/	FRAN KOCH	FOI DAILY LOG 3/5-9/12

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	04/25/2012		INFORMATION ACCESS	
2012-2264	03/28/2012 04/25/2012	FDA/OC/OES/DFOI/	FRAN KOCH INFORMATION ACCESS	FOI DAILY LOG 2/27/12-3/2/12
2012-2265	03/28/2012 04/25/2012	FDA/OC/OES/DFOI/	INC REGULATORY CONSULTING & SUBMISSIONS	FOI DAILY LOG 3/12-16/12
2012-2266	03/28/2012 04/25/2012	FDA/OC/OES/DFOI/	INC REGULATORY CONSULTING & SUBMISSIONS	FOI DAILY LOG 3/5-9/12
2012-2267	03/28/2012 04/25/2012	FDA/OC/OES/DFOI/	INC REGULATORY CONSULTING & SUBMISSIONS	FOI DAILY LOG 2/27/12-3/2/12
2012-2268	03/29/2012 04/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	STEPHANIE BEBUSK DEROYAL CORPORATE	PIONEER SURGICAL TECHNOLOGY - INTERVERTEBRAL FUSION DVC SYS K073177; PIONEER SURGICAL TECHNOLOGY INC - CROSSFUSE 11 1BF/VBR SYS K112496
2012-2269	03/29/2012 04/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	STEPHANIE DEBUSK DEROYAL CORPORATE	SPINAL ELEMENTS INC - LUCENT K071724, MODIFICATION TO LUCENT K081968
2012-2270	03/29/2012 04/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	STEPHANIE DEBUSK DEROYAL	STRYKER CORP - AVSALIGN PEEK SPACERS K093864, AVS ANTERIOR LARGE PEEK SPACERS K090166, AVS PL PEEK SPACERS K093704, ETC
2012-2271	03/29/2012 04/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	STEPHANIE DEBUSK DEROYAL CORPORATE	AMEDICA (NOW) US SPINE - PHANTOM PLUS CAGE SYS K082801
2012-2272	03/29/2012 04/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	STEPHANIE DEBUSK DEROYAL	BIOMET (NOW) EBI LP - IBEX SPINAL SYS K091381; BIOMET SPINE - ZYSTON STRAIGHT SPACER SYS K112014; BIOMET SPINE (EBI LLC) - K110650
2012-2273	03/29/2012 04/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	STEPHANIE BEBUSK DEROYAL CORPORATE	CUSTOM SPINE - PATHWAY K111774; CUSTOM SPINE INC - PATHWAY K080281
2012-2274	03/29/2012 04/26/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	STEPHANIE DEBUSK DEROYAL CORPORATE	DEPUY (NOW) JOHNSON & JOHNSON) - CONCORDE BULLET SPINAL SYS K110694, CONCORDE CURVE SYS - K103743, CONCORDE BULLET CAGE SYS - K103488, ETC
2012-2275	03/29/2012 04/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	STEPHANIE DEBUSK DEROYAL CORPORATE	DIFUSION TECHNOLOGIES - XIPOS INTERBODY FUSION SYS K100042
2012-2276	03/29/2012 04/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LISA CASTRO UCB INC	LLAMICTAL XR (LAMOTRIGINE) - SBA, RVWS

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2012-2277	03/29/2012 04/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	STEPHANIE DEBUSK DEROYAL CORPORATE	GLOBAL (GLOBUS) MEDICAL INC - RISE SPACER K113447, PATRIOT SPACERS - K072970
2012-2278	03/29/2012 04/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	STEPHANIE DEBUSK DEROYAL CORPORATE	MEDTRONIC SOFAMOR DANEK - CAPSTONE R SPINAL SYS K103731; MEDTRONIC SOFAMOR DANEK USA INC - CAPSTONE SPINAL SYS K073291, MODIFICATION TO: CAPSTONE SPINAL SYS - K082732
2012-2279	03/29/2012 04/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GREG POWELL GlaxoSmithKline	ISRS 375073, 3781222, 3842799, ETC
2012-2280	03/29/2012 04/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LINDER, DAVID W	STUDY DETERMINED THAT 1,4 BUTANEDIOL CONVERTS TO GHB IN HUMANS
2012-2281	03/29/2012 04/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LAUREN D COHEN DONALD A SHAPIRO LTD	BENLYSTA - AERS
2012-2282	03/29/2012 04/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GERRIE OLIVER DAVA PHARMACEUTICAL INC	LEDERLE LABS, PEARL RIVER, NY - DOXEPIN CAPSULES, 50 MG, 75MG, 100 MG ETC, ANDA 71-673, ANDA 71-674, ANDA 71-675 ETC
2012-2283	03/29/2012 04/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	JASON T SCHNEIDER JASON T SCHNEIDER PC	C R BARD INC - BARD G2 FILTER SYS CORR, 510K, RPTS TO CONSUMERS, ETC
2012-2284	03/29/2012 04/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DEAN A FERGUSSON OTTAWA HOSPITAL RESEARCH INSTITUTE	BORTEZOMIB, GEFETINIB, ROTIGOTINE, ETC - PRE-CLNCL (ANIMAL) EFFICACY STUDIES
2012-2285	03/29/2012 04/26/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/OCOS/OES/ OC/OCOS/OES/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	FERNANDO, VIRGIL	USP LABS - OXYELITE PRO RECS, JACK3D
2012-2286	03/29/2012	FDA/OMPT/CDER/ORP/DIDP/	GERRIE OLIVER	CLONMEL HEALTHCARE LTD, IRELAND - CHORTHALIDONE TABS ANDA 87-450 50 MG TABS, ANDA 87-451 25 MG TABS

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	04/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVA PHARMACEUTICAL INC	
2012-2287	03/29/2012 04/26/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Doe J	INDIVIDUAL RECS
2012-2288	03/29/2012 04/26/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	STEPHANIE DEBUSK DEROYAL CORPORATE	MEDTRONIC SOFAMOR DANEK - CAPSTONE R SPINAL SYS K103731 & K073291; MODIFICATION TO CAPSTONE SPINAL SYS - K082732
2012-2289	03/29/2012 04/26/2012	FDA/OC/OSHC/OPD/	DIANE SCHULMAN DIANE SCHULMAN	QUESTCOR PHARMS - H P ACTHAR GEL (REPOISTORY CORTICOTROPIN OR ADRENOCORITICOTROPIC HORMONE) CORR, RVWS
2012-2290	03/29/2012 04/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	STEPHANIE DEBUSK DEROYAL CORPORATE	MEDICAL CONCEPTS INC - INTERBODY FUSION SYS, K110659
2012-2291	03/29/2012 04/26/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/OCOS/OL/ OC/OA/OM/OMP/DDM/	FERNANDO VIGIL FERNANDO VIGIL	LEGALY OF DMAA (1,3 DIMETHYLAMYLAMINE) AS A SUPPLEMENT - PETITIONS, CMLPTS, CONGRESSIONAL CORR
2012-2292	03/29/2012 04/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	STEPHANIE DEBUSK DEROYAL CORPORATE	K2M INC - ALEUTIAN IBF SYS, K082698 & K101302, ALEUTIAN SPACER SYS, K119843; ALEUTTIAN, K103169 ETC
2012-2293	03/29/2012 04/26/2012	OC/CVM/OCD/	TAMRA BARRICK NEOGEN CORP	PEGASUS LABORTORIES, INC - PHENYLPROPANOLAMINE HCL NADA 141-324 LTRS
2012-2294	03/29/2012 04/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	STEPHANIE DEBUSK DEROYAL CORPORATE	ZIMMER (ABBOTT SPINE INC) - ARDIS SPACER, K073202
2012-2295	03/29/2012 05/23/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	AVITAL VARLEV ALPHA BIO TEC LTD	HANS BIOMED CORP, REPUBLIC OF KOREA - AERS, AUDITS, RECALLS, ETC
2012-2296	03/29/2012 04/26/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	STEPHANIE DEBUSK DEROYAL CORPORATE	SYNTHES SPINE - ORACLE SPACER (OPAL SPACER), K072791; SYNTHES T-PAL SPACER, K100089
2012-2297	03/29/2012 04/26/2012	FDA/OC/OES/DFOI/	NORA COLEMAN HAWORTH COLEMAN GERSTMAN LLC	POWERS & SANTOLA LLP, ALBANY, NY - RECS
2012-2298	03/29/2012	FDA/OMPT/CDRH/OCER/DFOI/	STEPHANIE DEBUSK	ORTHO DEVELOPMENT - VUSION(R) OS, K111965

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	04/26/2012		DEROYAL CORPORATE	
2012-2299	03/29/2012 04/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	STEPHANIE DEBUSK DEROYAL CORPORATE	NUVASIVE INC - COROENT XLR STANDALONE SYS, K100043; NUVASIVE COROENT NO-PROFILE SYS, K112561; NUVASIVE COROENT SYS, K071795
2012-2300	03/29/2012 04/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	STEPHANIE DEBUSK DEROYAL CORPORATE	ADVANCED VERTEBRAL SOLUTIONS LLC - EXPRESS BFD, K100037
2012-2301	03/29/2012 04/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LAWRENCE C FARRAR RESODYNE CORPORATION	IND 14107 - SUBMISSION RECS, SAFETY/EFFECTIVENESS RECS, TRANSFER OF SAID INFO TO RESODYN'S APPL
2012-2302	03/29/2012 04/26/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORA/ OC/ORA/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	LEVIN, R	SHIITAKE-YA GOURMET SHIITAKE SLICES - NAMES OF FARMS, CHEMICAL SPRAYS, US DISTRIBUTORS, ETC
2012-2303	03/29/2012 04/26/2012	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	JOHN WALSH JAMES ALEXANDER CORP	MASON CHEMICAL CO, ARLINGTON HEIGHTS, IL - EIRS, 483S, RECALLS
2012-2304	03/29/2012 04/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANGELIA D SLAYTON INC REGULATORY CONSULTING & SUBMISSIONS	8 FACTOR ANALYSIS DATA REGARDING THE 4/9/99 SCHEDULES OF CONTROLLED SUBSTANCES: PROPOSED PLACEMENT OF KETAMINE INTO SCHEDULE III
2012-2305	03/29/2012 04/26/2012	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	FOI Services, Inc.	INFUPHARMA LLC, HOLLYWOOD, FL - EIR, 483S, CORR 9/27/11
2012-2306	03/29/2012 04/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	MATTHEW ERJAVEC PA	STRYKER ORTHOPEDICS - TIRDENT CERAMIC ACETABULAR SYS; TRIDENT ACETABULAR SYS; TRIDENT PSL ACETABULAR SHELLS, PMA STANDARDS
2012-2307	03/29/2012 05/31/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	NORA COLEMAN HAWORTH COLEMAN GERSTMAN LLC	INVACARE CORP - BED RAILS INVESTIGATION RECS
2012-2308	03/29/2012	OC/ORA/	KRISTEN C GUNTER	TAMPA JUICE SERVICE INC, TAMPA FL - FROZEN

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	04/26/2012	OC/ORO/ FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/	MACFARLANE FERGUSON & MCMULLEN	CONCENTRATED ORANGE JUICE ENTRY #032-0421151-4 ANALYTICAL RESULTS
2012-2309	03/29/2012 04/26/2012	FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/	RICARDO RONQUILLO NEUROGESX INC	CORE RX PHARMA, TAMPA, FL - EIRS, 483S, WARNING LTRS, ETC 1/07 TO PRESENT
2012-2310	03/29/2012 04/26/2012	OC/OA/OM/OMP/DDM/	SUE MCGOVERN JUST LABEL IT ORGANIC VOICES ACTION FUND	DKT 1995N-0259
2012-2311	03/29/2012 04/26/2012	OC/OA/OM/OMP/DDM/	SUE MCGOVERN JUST LABEL IT ORGANIC VOICES ACTION FUND	DKT 1995N-0397
2012-2312	03/29/2012 04/26/2012	OC/OM/OMP/DDM/	MARILYNN WHITNEY COVINGTON & BURLING LLP	DKT FDA-2010-P-0491
2012-2313	03/29/2012 04/26/2012	FDA/OC/OES/DFOI/	SIMI Z BOTIC DINSMORE & SHOHL LLP	INDIVIDUAL RECS
2012-2314	03/29/2012 04/26/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 3/19-23/12
2012-2315	03/29/2012 04/26/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 3/19-23/12
2012-2316	03/29/2012 04/26/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	CLOSED FOI REQUESTS 3/19-23/12
2012-2317	03/29/2012 04/26/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOI REQUESTS 3/19-23/12
2012-2318	03/29/2012 04/26/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	ADRIENNE HOTCHKISS BOSTON SCIENTIFIC CORP	BOSTON SCIENTIFIC CORP - ROTABLATOR ROTATIONAL ANGIOPLASTY SYS K970296
2012-2319	03/29/2012 04/26/2012	FDA/OC/OES/DFOI/	SEWARD #973383, THADDAEUS H	FDA - PROGRAMS AND RECS
2012-2320	03/29/2012 04/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DENNIS W RAISCH UNIV OF MEXICO, COLLEGE OF PHARMACY	THROMBOTIC THROMBOCYTOPENIC PURPURA - AERS
2012-2321	03/30/2012 04/27/2012	OC/OM/OMP/DDM/	MICHAEL WEBER MICHAEL WEBER	DKT FDA-2011-N-0842

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2012-2322	03/30/2012 04/27/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2012-1566
2012-2323	03/30/2012 04/27/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2012-1205
2012-2324	03/30/2012 04/27/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2012-1206
2012-2325	03/30/2012 04/27/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2012-1211
2012-2326	03/30/2012 04/27/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2012-1229
2012-2327	03/30/2012 04/27/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2012-1290
2012-2328	03/30/2012 04/27/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2012-1308
2012-2329	03/30/2012 04/27/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2012-1465
2012-2330	03/30/2012 04/27/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DARRELL MAAG SOUTHWESTERN RESEARCH INC	jOHNSON & JOHNSON - R228060 TRIALS & SAFETY STUDIES
2012-2331	03/30/2012 04/27/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DARREL MAAG SOUTHWESTERN RESEARCH INC	PFIZER - PD-0332334 TRIALS & SAFETY STUDIES
2012-2332	03/30/2012 04/27/2012	FDA/OMPT/CDRH/OCER/DFOI/	RANDOLPH L COOKE WASHINGTON REGULATORY SERVICES	HAKKO SHOJI CO LTD - TUOHY EPIDURAL NEEDLES K961152
2012-2333	03/30/2012 04/27/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARK STOVEKEN WISCONSIN ANALYTICAL & RESEARCH	UPJOHN CO - CALDEROL (CALCIFEDIOL CAPS) NDA 18- 312, APRVL PKG
2012-2334	03/30/2012 04/27/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CINDY HSU CINDY HSU	EXPAREL NDA 22-496 - CLNCL PHARMACOLOGY, BIOPHRMACEUTICS RVWS, CHEMISTRY RVWS, PHARM, TOXICOLOGY RVWS, ETC

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2012-2335	03/30/2012 04/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CINDY HSU CINDY HSU	MARCAINE HCL NDA 16-964 - CLNCL PHARMACOLOGY, BIOPHARMACETICS RVWS, CHEMISTRY RVWS, PHARM, TOXICOLOGY, ETC
2012-2336	03/30/2012 04/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHRISTINE LIVOTI BIOPHARM INSIGHT	MERCK SHARP & DOHME - JANVIA, JANUMET NDA 22-044 POSTMARKETING STUDIES THAT RESULTED IN THE WARNING LTR
2012-2337	03/30/2012 04/27/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	AFIA ASAMOAH COVINGTON BURLING LLP	CYTOCELL LTD/ RAINBOW SCIENTIFIC INC - DIAGNOSTIC TEST LTRS 11/11 TO 3/23/12
2012-2338	03/30/2012 04/27/2012	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	GILBERT WEINER ADVANCED PHARMA CR LLC	SFBC INTERNATIONAL INC - CORR, 483 10/19/05, 11/7/05
2012-2339	03/30/2012 04/27/2012	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	Doe J	INDIVIDUAL RECS
2012-2340	03/30/2012 04/27/2012	OC/ORA/ OC/ORA/ OC/ORA/ORM/ OC/ORA/ORM/	LADENHEIM, BENNETT	EGG PRODUCING FACILITIES IN AL, AR, CA, CT, ETC - INSPS
2012-2341	03/30/2012 04/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JEFFREY A KRAWITZ STARK & STARK	TEVA - SEASONIQUE BLACK BOX WARNINGS, AERS, CMLPTS, ETC
2012-2342	03/30/2012 04/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	SUSAN M SUTTER Elsevier Business Intelligence	ROCHE/GENENTECH - AVASTIN (BEVACIZUMAB) JANET WOODCOCK, DENISE ESPOSITO, JAYNE PETERSON, ETC CORR, MINS, CALENDAR ENTRIES, ETC

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		FDA/OC/OCC/ OC/OER/OPA/ OC/OER/OPA/ FDA/OC/OES/ FDA/OC/OEXA/OMA/		
2012-2343	03/30/2012 04/27/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/OCOS/OES/ OC/OCOS/OES/ FDA/OC/OES/DFOI/ FDA/OC/OES/	SUSAN M SUTTER Elsevier Business Intelligence	ONCOLOGIC DURGS A/C - TRAVEL INVOICES, PER DIEM EXPENSES, LODGING 6/28-29/11
2012-2344	03/30/2012 04/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	METHOTREXATE - LONG TERM DAMAGE
2012-2345	03/30/2012 04/27/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/	MICHELLE RYBAK ROANOKE TRADE SERVICES INC	WAH SUN INTERNATIONAL INC - ENTRY #BRI 0061772-0 NOTICES OF REFUSAL, FDA ACTION, NOTICE OF MARK/REDELIVER
2012-2346	03/30/2012 04/27/2012	FDA/OGROP/ORO/NE-FO/NYK- DO/NYK-DCB/	DIEDRICH, JOHN	PDI, NY - EIRS, 483S, CO RESP, ETC
2012-2347	03/30/2012 04/27/2012	FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	THOMAS MCGRATH AMRI BURLINGTON	ALTHEA TECHNOLOGIES INC, SAN DIEGO, CA - 483 MOST RECENT
2012-2348	03/30/2012 04/27/2012	FDA/OGROP/ORO/NE-FO/NWE- DO/NWE-CB/	JOSEPH P SCHWARTZ LEERINK SWANN & CO	EXEMPLAR PAHRMACEUTICALS LLC - LEVADEX (DIHYDROERGOTAMINE) 483
2012-2349	03/30/2012 04/27/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2012-970
2012-2350	03/30/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND	2012-964

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	04/27/2012		FDA WEBVIEW/FERDIC INC	
2012-2351	03/30/2012 04/27/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2012-805
2012-2352	03/30/2012 04/27/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2011-9579
2012-2353	03/30/2012 04/27/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2012-989
2012-2354	03/30/2012 04/27/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2012-1002
2012-2355	03/30/2012 04/27/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2012-1130
2012-2356	03/30/2012 04/27/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2012-1132
2012-2357	03/30/2012 04/27/2012	OC/ORO/ OC/ORO/	YU YANG RONGCHENG ZHENGHAI AQUATIC FOODS CO	RONGCHENG ZHENCHAI AQUATIC FOODS CO LTD - FROZEN PREPARED MACKEREL ENTRY #481-0167223-S/3/1
2012-2358	04/02/2012 04/30/2012	OC/OM/OMP/DDM/	DOREEN FRANK ENVISAGE CONSULTING LLC	OTC VOLS. 210296, 210297, 210298, ETC.
2012-2359	04/02/2012 04/30/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	VALEANT INTERNATIONAL - ZOVIRAX (ACYCLOVIR) NDA 18-604 APRVL RECS 3/29/82
2012-2360	04/02/2012 04/30/2012	FDA/OGROP/ORO/CE-FO/DET- DO/DET-CB/	FOI Services, Inc.	DR SAMYA Z NASR, ANN ARBOR, MI - EIR, 483, CO RESP, ETC 11/11
2012-2361	04/02/2012 04/30/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	FOI Services, Inc.	DR ANDRE VETRUYEN, CAMPUS SINT- VINCENTIUSZIEKENHUIS, ANTWERP, BELGIUM - 483 4/11
2012-2362	04/02/2012 04/30/2012	FDA/OGROP/ORO/SE-FO/FLA- DO/FLA-CB/ FDA/OC/OES/DFOI/	FOI Services, Inc.	INFUPHARMA LLC, HOLLYWOOD, FL - EIRS, 483S, CO RESP, ETC 9/27/11
2012-2363	04/02/2012	FDA/OMPT/CDRH/OCER/DFOI/		CDRH OMBUDSMAN - POSITION DESCRIPTION

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	04/30/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OO/OHR/	HAMILTON PHD, LEROY L	
2012-2364	04/02/2012 04/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	HAMILTON PHD, LEROY L	COMM BTWN CDRH OMBUDSMAN & OTHER CDRH PERSONNEL - EMAILS, INTERNAL MEMOS, NOTES, ETC 2/14/12-3/30/12
2012-2365	04/02/2012 04/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	TRONIC, ELAINE H	XOMED - EDNO-SCRUB/ENDO-SCRUB 2 K982594
2012-2366	04/02/2012 04/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	TRONIC, ELAINE H	VYKOR MEDICAL - SURGICAL ACCESS SYS K060973
2012-2367	04/02/2012 04/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	TRONIC, ELAINE H	INTUITIVE SURGICAL ENDOSCOPIC INSTRUMENTS - INTUITIVE ENDOSCOPIC INSTRUMENTS CONTROL SYS K990149
2012-2368	04/02/2012 04/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	TRONIC, ELAINE H	KARL STORZ - KSEA CLEARVISION LENS IRRIGATION SYS K013838
2012-2369	04/02/2012 04/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	ANDRENE HERON Roche Diagnostic Corporation	MEDTRONIC - NEW ONE TOUCH ULTRALINK BLOOD GLUCOSE METER K100130; ABBOTT - FREESTYLE NAVIGATOR; MINIMED - PARADIGM REAL TIME REVEL SYS, ETC
2012-2370	04/02/2012 04/30/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JAY H HENDERSON JAY HENDERSON PLLC	PARKE-DAVIS/PFIZER - DILANTIN NDA 84-4227, NDA 84-349, NDA 10-151, ETC; TARO - ANDA 40-521 ANDA 40-684, AMNEAL - ANDA 40-765 AERS 1/06 TO PRESENT
2012-2371	04/02/2012 04/30/2012	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	LIANE LAROCHELLE DEKA RESEARCH & DEVELOPMENT CORP	FRESENIUS MEDICAL CARE, WALTHAM, MA - EIRS 8/1/11 TO 2/29/12
2012-2372	04/02/2012 04/30/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	DOWDA, STEPHAINE	MAP PHARMS - LEVADEX (DIHYDROEROTAMINE) 483, RESP LTR 3/12
2012-2373	04/02/2012 04/30/2012	FDA/OFVM/CFSAN/OCD/EOS/	LYNN P TORDO MS THOR SPECIALTIES INC	ZENCA BIOCIDES - THRESHOLD OF REGULATION EXEMPTION #96-004 NON-CONFIDENTIAL RECS
2012-2374	04/02/2012	FDA/OFVM/CFSAN/OCD/EOS/		ARSENIC IN RISE & RICE PRODS - RFPS STUDY,

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	04/30/2012	FDA/OO/OFBA/OAGS/	ISSLER, MACKENZIE	STAKEHOLDERS RECS AT MEETINGS, SUMMARY OF FINDINGS, ETC 10/11
2012-2375	04/02/2012 04/30/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/OCOS/OES/ OC/OCOS/OES/ OC/OCOS/OL/ OC/OCOS/OES/ OC/OCOS/OES/	ISSLER, MACKENZIE	ARSENIC IN RICE - MEMOS, RPTS, COMMENTS, ETC 1/00 TO PRESENT; ARSENIC STANDARDS & HEALTH EFFECTS FOR ANY FEDERAL & STATE AGENCIES SCHEDULES, NOTES PRESENTATIONS, ETC 2010, 2011
2012-2376	04/02/2012 04/30/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	PROPYLTHLOURACIL (PTU) - APRVD LBLG
2012-2377	04/02/2012 04/30/2012	OC/OA/OM/OMP/DDM/	FOI Services, Inc.	ISTA PHARMS - APPL FOR OPHTHALMIC NON-STEROIDAL ANTI-INFLAMMATORY DRUG PRODS 2 CITIZEN PETITIONS 5/11/11
2012-2378	04/02/2012 04/30/2012	FDA/OFVM/CFSAN/OCD/EOS/	BASF SE	FCN 064
2012-2379	04/02/2012 04/30/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/	Doe J	CMPLNT
2012-2380	04/02/2012 04/30/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/OCOS/OES/ OC/OCOS/OES/ OC/OCOS/OL/ OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/	KEVIN WISNIEWSKI NEWS CHANNEL 5	HRC MEDICAL CLINICS (HORMONE REPLACEMENT CENTER) - AMOR VIE HORMONE REPLACEMENT PELLETS INTERNAL COMM, APPLS, CMPLNTS, ETC 11/15/11 TO PRESENT
2012-2381	04/02/2012	OC/OA/OM/OMP/DDM/	LYNN P TORDO MS	DKT 2006F-0058

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	06/07/2012	FDA/OFVM/CFSAN/OCD/EOS/	THOR SPECIALTIES INC	
2012-2382	04/02/2012 04/30/2012	OC/CVM/OCD/ OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORO/SW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORO/SW-FO/KAN-DO/KAN-CB/	JOSEPH COHEN SCOTT & SCOTT LLP	WAGGIN TRAIN LLC, NESTLE PURINA PETCARE CO - CHICKEN JERK DOG TREATS INVESTIGATION, CMLPLNTS, ETC 1/07 TO PRESENT
2012-2383	04/02/2012 05/14/2012	FDA/OGROP/ORO/CE-FO/CHI-DO/CHI-CB/ FDA/OGROP/ORO/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORO/CE-FO/DET-DO/DET-CB/	DAVID LEVINE R1 TECHNOLOGIES LLC	SMITHS HEALTHCARE MANUFACTURING SA DE CV, CHICAGO, IL; OH; SMITHS MEDICAL ASD INC, GARY, IN - EIRS, 483S 1/05 TO 10/10
2012-2384	04/03/2012 05/01/2012	OC/OM/OMP/DDM/	DOREEN FRANK ENVISAGE CONSULTING LLC	OTC VOLS. 180008,18009, 05AFM
2012-2385	04/03/2012 05/01/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	BECCA CRITSER CGBT LLC	MEDSEP CORP - MEDSEP FREEZING BAG BK980030
2012-2386	04/03/2012 05/01/2012	FDA/OFVM/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 149322
2012-2387	04/03/2012 05/01/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JAY H HENDERSON JAY HENDERSON PLLC	LEVAQUIN (LEVOFLOXACIN) NDA 20-634, NDA 20-635, NDA 21-721 - AERS, LBLG. POST-MARKETING SAFETY RVWS, ETC
2012-2388	04/03/2012	FDA/OFVM/CFSAN/OCD/EOS/	SUSAN KOHN ROSS	ORE-CAL CORP; SUPERIOR SEAFOOD, KENTWOOD, MI - HARVEST OF THE SEA FROZEN SHRIMP INVESTIGATION

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	05/01/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/DET-DO/DET-CB/ FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORO/SW-FO/KAN-DO/KAN-CB/	MITCHELL SILBERBERG & KNUPP LLP	RECS; INDIVIDUAL RECS
2012-2389	04/03/2012 05/01/2012	FDA/OC/OES/DFOI/	TONY CHEN FDAZILLA	LIST OF 483S 2012
2012-2390	04/03/2012 05/01/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DONALD P COX Clinsmart	NAPROXEN SODIUM TABS - AERS 7/11 TO 9/11
2012-2391	04/03/2012 05/01/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	PAX-ALL MANUFACTURING INC, MISSISSAUGA, ONTARIO, CANADA - EIR, 483, CO RESP 9/19-23/11
2012-2392	04/03/2012 05/01/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	DR NANCY OLIVIERI MD, TORONTO, ONTARIO,CANADA - EIR, 483, CO RESP 7/6-10/09
2012-2393	04/03/2012 05/01/2012	FDA/OGROP/ORO/CE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	SUNRISE PHARMS, RAHWAY, NJ - EIR, 483, CO RESP 12/9-20/10
2012-2394	04/03/2012 05/01/2012	FDA/OMPT/CDRH/OCER/DFOI/	WALTER E CHALKLEY THOMSON REUTERS	PROXI BIOMEDICAL, GALWAY, IRELAND - EIR, 483,CO RESP 7/20-23/09
2012-2395	04/03/2012 05/01/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	LABORATORIOS JALOMA, GUADALAJARA, MEXICO - EIR, 483, CO RESP 9/26-29/11
2012-2396	04/03/2012 05/01/2012	FDA/OGROP/ORO/CE-FO/CIN-DO/CIN-CB/	DREW BARLOW VERTEX PHARMACEUTICALS INC	PATHEON PHARMSACEUTICALS INC, CINCINNATI, OH - EIR 2/22-3/24/11
2012-2397	04/03/2012	FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY	NOBILUS ENT, KUTNO, POLAND - EIR, 483, CO RESP 9/12-15/11

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	05/01/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	THOMSON REUTERS	
2012-2398	04/03/2012 05/01/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	WINTAC LTD, BANGALORE, INDIA - EIR, 483, CO RESP 9/12-20/11
2012-2399	04/03/2012 05/01/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	FARMA QUIMIA SA DE CV, CUAMATLA CUAUTITLAN IZCALLI, MEXICO - EIR, 483 CO RESP 9/12-15/11
2012-2400	04/03/2012 05/01/2012	FDA/OGROP/ORAP/PA-FO/SEA-DO/SEA-CB/	R. CHRISTOPHER PRESTON SMITH HARTVIGSEN PLLC	RANGEN INC - 483, CO RESP, WARNING LTR 2/10
2012-2401	04/03/2012 05/14/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	WALTER E CHALKLEY THOMSON REUTERS	CSL BEHRINGER, MARBURG, DEUTSCHLAND - EIR, 483S, CO RESP MOST RECENT
2012-2402	04/03/2012 05/01/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	IBA MOLECULAR, SOMERSET, NJ - EIR, 483, CO RESP 8/4/10-9/14/10
2012-2403	04/03/2012 05/01/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	BIOGENESIS INC, HACKENSACK, NJ - EIR, 483, CO RESP 6/2310-8/5/10
2012-2404	04/03/2012 05/01/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	H & P INDUSTRIES, LAWRENCEVILLE, NJ - EIR, 483, CO RESP 9/20/10-11/10/10
2012-2405	04/03/2012 05/17/2012	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	WALTER E CHALKLEY THOMSON REUTERS	PIONEER SURGICAL TECHNOLOGY, MARQUETTE, MI - EIR, 483, CO RESP 12/7-21/10
2012-2406	04/03/2012 05/01/2012	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	WALTER E CHALKLEY THOMSON REUTERS	RTI BIOLOGICS, ALACHUA, FL - EIR, 483, CO RESP 10/25/11
2012-2407	04/03/2012 05/01/2012	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	WALTER E CHALKLEY THOMSON REUTERS	ROTECH HEALTHCARE INC (CAREMED SOUTHAVEN MS) - EIR, 483, CO RESP 9/10
2012-2408	04/03/2012 05/01/2012	FDA/OGROP/ORAP/PA-FO/SEA-DO/SEA-CB/	WALTER E CHALKLEY THOMSON REUTERS	HOLLISTER STIER LABS, SPOKANE, WA - EIR, 483, CO RESP 1/13/09
2012-2409	04/03/2012 05/01/2012	FDA/OGROP/ORAP/PA-FO/SEA-DO/SEA-CB/	WALTER E. CHALKLEY THOMSON REUTERS	HOLLISTER STIER LABS, SPOKANE, WA - EIR, 483, CO RESP 5/28/10
2012-2410	04/03/2012 05/01/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	WALTER E. CHALKLEY THOMSON REUTERS	NAVILYST MEDICAL INC, GLEN FALLS, NY - EIR, 483, CO RESP 9/8-21/09

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2012-2411	04/03/2012 05/01/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	WALTER E. CHALKLEY THOMSON REUTERS	NAVILYST MEDICAL INC, GLEN FALLS, NY - EIR, 483, CO RESP 5/10
2012-2412	04/03/2012 05/01/2012	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	WALTER E. CHALKLEY THOMSON REUTERS	ELMORE ALEXANDER DO, - EIR, 483, CO RESP 11/13/09-10/20/10
2012-2413	04/03/2012 05/01/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	GULF PHARMACEUTICAL INDUSTRIES, DIGDAGA AREA RAS AL KHAIMAH, UNITED ARAB EMIRATES - EIR, 483, CO RESP 9/25-10/3/11
2012-2414	04/03/2012 05/01/2012	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	WALTER CHALKLEY THOMSON REUTERS	MERCK SHARP & DOHME CORP, NORTH WALES, PA - EIR, 483, CO RESP MOST RECENT
2012-2415	04/03/2012 05/01/2012	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	WALTER E. CHALKLEY THOMSON REUTERS	GABRIEL PEREZ LASALA MD, TCA CELLULAR THERAPY LLC, COVINGTON, LA - EIR, 483, CO RESP 2/22-3/31/11
2012-2416	04/03/2012 05/14/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	WALTER E. CHALKLEY THOMSON REUTERS	SANQUIN PLASMA PRODUCTS, AMSTERDAM, NETHERLANDS - EIR, 483, CO RESP 9/19-28/11
2012-2417	04/03/2012 05/02/2012	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	WALTER E. CHALKLEY THOMSON REUTERS	THORATEC CORP, PLEASANTON, CA - EIR, 483, CO RESP 8/22-9/7/11
2012-2418	04/03/2012 05/01/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E. CHALKLEY THOMSON REUTERS	WARNER CHILCOTT CO LLC, ROCKAWAY, NJ - EIR, 483, CO RESP 6/22-29/11
2012-2419	04/03/2012 05/01/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	WALTER E. CHALKLEY THOMSON REUTERS	INTELLICELL BIOSCIENCES INC, NEW YORK, NY - EIR, 483, CO RESP 11/8-12/12/11
2012-2420	04/03/2012 05/01/2012	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	WALTER E. CHALKLEY THOMSON REUTERS	SPINAL SOLUTIONS LLC, MURRIETA, CA - EIR, 483, CO RESP 7/11-9/15/11
2012-2421	04/03/2012 05/01/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	WALTER E. CHALKLEY THOMSON REUTERS	APP PHARMS, GRAND ISLAND, NY - EIR, CO RESP 6/13-7/8/11
2012-2422	04/03/2012 05/01/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	WALTER E. CHALKLEY THOMSON REUTERS	REGENERON PHARMS, RENSSELAER, NY - EIR, CO RESP 3/23-31/10
2012-2423	04/03/2012	FDA/OMPT/CDER/ORP/DIDP/		CYMBALTA (DULOXETINE HYDROCHLORIDE) - AER, SAFETY RVW, LBLG

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	05/01/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JAY HENDERSON PLLC	
2012-2424	04/03/2012 05/01/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/ FDA/OC/OES/DFOI/	MICHAEL R. HAMRELL, Ph.D. MORIAH CONSULTANTS	MERCY MEDICAL CTR-DES MOINES IRC, DES MOINES, IA - EIR, 483 11/13/08
2012-2425	04/03/2012 05/01/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANGELIA D. SLAYTON INC RESEARCH CONSULTING & SUBMISSIONS	ROBERTS PHARMS- DOXOFYLLINE APRVL, MEDICAL RVW, CHEMISTRY RVW, LBLG 1988 TO 1998
2012-2426	04/03/2012 05/01/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANGELIA D. SLAYTON INC REGULATORY CONSULTING & SUBMISSIONS	APP PHARMS - OXYTOCIN NDA 18-248
2012-2427	04/04/2012 05/02/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2012-1113
2012-2428	04/04/2012 05/02/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2012-1393
2012-2429	04/04/2012 05/02/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2012-1645
2012-2430	04/04/2012 05/02/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2012-1642
2012-2431	04/04/2012 05/02/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2011-7611
2012-2432	04/04/2012 05/02/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2011-8627
2012-2433	04/04/2012 05/02/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2011-9005
2012-2434	04/04/2012 05/02/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2011-9192
2012-2435	04/04/2012 05/02/2012	FDA/OGROP/ORASW-FO/BLT-DO/BLT-CB/	JOHNATHAN RICKMAN FDA NEWS	H&H ASSOCIATES, ORDINARY, VA, CREATIVE TECHNOLOGIES INC, CHESAPEAKE, VA - 483S 1/1-31/12

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2012-2436	04/04/2012 05/02/2012	FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/	JOHNATHAN RICKMAN FDA NEWS	QUADRANT CHEMICAL CORP, GARLAND, TX, NEURO RESOURCE GROUP INC, PLANO, TX, ORTHOFIX INC, LEWISVILLE, TX, ETC - 483S 1/1-31/12
2012-2437	04/04/2012 05/02/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	MARTHA GUZMAN AMSINO INTERNATIONAL INC	MEDLINE - SILVERTOUCH 100% SILICONE FOLEY CATHETER K052168
2012-2438	04/04/2012 05/02/2012	FDA/OMPT/CDRH/OCER/DFOI/	M ELIZABETH BIERMAN MORGAN LEWIS COUNSELORS AT LAW	PALOMAR MEDICAL TECHNOLOGIES INC - K111840
2012-2439	04/04/2012 05/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MEINDA K PLAIKSER WASHINGTON ACTION FOR SAFE WATER	FLUORIDE (SODIUM FLUORIDE OR SILICOFLUORIDES) - QUESTIONS
2012-2440	04/04/2012 05/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SEPHY PHILIP PHARMD SCIENTIFIC EXCHANGE LLC	TEVA PHARMS, PADDOCK LLC - HYDROCORTISONE RECTAL ENEMA 100 MG, 60 ML ANDA 74-17, ANDA 75-172 SBA
2012-2441	04/04/2012 05/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	JEANNE DOUKAS GOLDBERG SIMPSON	RHBMP-2 - AERS 1/02 TO PRESENT
2012-2442	04/04/2012 05/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	BECKUM, LISA	HYDROXCHLOROQUINE RESTASIS (CYCLOSPORINE) - OPTHALMIC EMULISON) - RECS
2012-2443	04/04/2012 05/02/2012	FDA/OGROP/ORR/PA-FO/SEA-DO/SEA-CB/	DIANE B MCGINNESS ALLSTATE INSURANCE CO	RS MEDICAL, VANCOUVER, WA - EIRS 1/06 TO 12/31/11
2012-2444	04/04/2012 05/02/2012	FDA/OC/OES/DFOI/	DAVID McFARLAND FDA WEBVIEW/FERDIC INC	2011-8917
2012-2445	04/04/2012 05/02/2012	FDA/OC/OES/DFOI/	DAVID McFARLAND FDA WEBVIEW/FERDIC INC	2011-9015
2012-2446	04/04/2012 05/02/2012	FDA/OC/OES/DFOI/	DAVID McFARLAND FDA WEBVIEW/FERDIC INC	2011-9521

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2012-2447	04/04/2012 05/02/2012	FDA/OC/OES/DFOI/	DAVID McFARLAND FDA WEBVIEW/FERDIC INC	2011-7886
2012-2448	04/04/2012 05/02/2012	FDA/OC/OES/DFOI/	DAVID McFARLAND FDA WEBVIEW/FERDIC INC	2010-5814
2012-2449	04/04/2012 05/02/2012	FDA/OC/OES/DFOI/	DAVID McFARLAND FDA WEBVIEW/FERDIC INC	2012-1219
2012-2450	04/04/2012 05/02/2012	FDA/OC/OES/DFOI/	DAVID McFARLAND FDA WEBVIEW/FERDIC INC	2012-1475
2012-2451	04/04/2012 05/02/2012	FDA/OC/OES/DFOI/	DAVID McFARLAND FDA WEBVIEW/FERDIC INC	2012-1056
2012-2452	04/04/2012 05/02/2012	FDA/OC/OES/DFOI/	DAVID McFARLAND FDA WEBVIEW/FERDIC INC	2010-6977
2012-2453	04/04/2012 05/02/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DONALD P. COX Clinsmart	ALEVE OTC NDA 20-204
2012-2454	04/04/2012 05/02/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	RACHEL DePOMPA WWBT/NBC12	METHYLPHENIDATE; METHADONE PHARMACY ERRORS SINCE 1995
2012-2455	04/04/2012 05/02/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	LOVKO, RAE	KENDALL - Q-TRACE ECG TABS AERS
2012-2456	04/04/2012 05/02/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARK FRANZEN PRECISION DOSE INC	RISPERIDONE ORAL SOLUTION ANDA 76-797 - SUBMISSION
2012-2457	04/04/2012 05/04/2012	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OGROP/ORA/NE-FO/NYK-	TIM SULOLLI GOODMAN ACKER PC	DR MARLO CORACI, MACOMB, MI - RECALL LTRS, LOT NUMBERS 2/1/10 TO 2/1/12

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		DO/NYK-DCB/		
2012-2458	04/04/2012 05/02/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SW-FO/KAN-DO/KAN-CB/	KUSTKA, DENISE	CMLPNT
2012-2459	04/04/2012 06/08/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/ FDA/OC/OCC/	MITCHELL LS FUERST FUERST ITTLEMAN PL	INTELLCELLL BIOSCIENCES INC - CBER ADMINISTRATIVE ENFORCEMENT ACTION IN WARNING LTRS 12/01, EIRS, 483S, ETC 3/13/12
2012-2460	04/04/2012 05/02/2012	FDA/OFVM/CFSAN/OCD/EOS/	MARSHALL P LEVINE SOROS FUND MANAGEMENT	GNC HOLDINGS - DMAA RECS
2012-2461	04/04/2012 05/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WOOSTER, ANNALEE	MEDICIS - DYSPORT AER
2012-2462	04/04/2012 05/02/2012	OC/ORO/OCI/ OC/ORO/OCI/	ANDERSON, MIKE	PHONE INTERVIEW WITH JEFF NOVITZKY
2012-2463	04/04/2012 05/02/2012	OC/OA/OM/OMP/DDM/ FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/	PROFESSOR LISA HEINZERLING GEORGETOWN UNIVERSITY LAW CENTER	PUBLIC HEARING ON AMMONIUM HYDROXIDE TRANS - FEDERAL REGISTER (FR) 34219 1974
2012-2464	04/04/2012 05/02/2012	FDA/OFVM/CFSAN/OCD/EOS/	WEI WEI TIANJIN GOURMET SELECT FOOD CO LTD	FFR 11997439292, FEI 3006330759
2012-2465	04/04/2012 05/02/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/ FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/	YU YANG RONGCHENG ZHENGHAI AQUATIC FOODS CO	FROZEN PREPARED MACKEREL - IMPORT REFUSAL RPT 1/24/12
2012-2466	04/04/2012 05/02/2012	FDA/OMPT/CTP/OD/ FDA/OC/OES/DFOI/	MARILYNN WHITNEY COVINGTON & BURLING LLP	LIST OF TOBACO PRODS WHICH HAVE BEEN ISSUED A SUBSTANTIAL EQUIVALENCE ORDER FOR APPLICATIONS SUBMITTED TO SECTION 905 OF THE FEDERAL FOOD, DRUG, & COSMETIC ACT - AERS
2012-2467	04/04/2012 05/02/2012	FDA/OGROP/ORO/CE-FO/CIN-DO/CIN-CB/	JOHNATHAN RICKMAN FDA NEWS	FERRO CORP, CLEVELAND, OH; SCOTTCARE CORP, CLEVELAND, OH; CLEVELAND HEARTLAB INC, CLEVELAND, OH - 483 1/12

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2012-2468	04/04/2012 05/02/2012	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	JOHNATHAN RICKMAN FDA NEWS	AMGEN INC, LONGMONT, CO; AMGEN INC, BOULDER, CO; FMC CORP, GREEN RIVER, WY - 483 1/12
2012-2469	04/04/2012 05/02/2012	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	JOHNATHAN RICKMAN FDA NEWS	MONITOR INSTRUMENTS INC, HILLSBOROUGH, NC; UNISPLINT CORP, BUFORD, GA - 483 1/12
2012-2470	04/04/2012 05/02/2012	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	JOHNATHAN RICKMAN FDA NEWS	SAGEMAX BIOCERAMICS INC, AUBURN, WA - 483 1/12
2012-2471	04/04/2012 05/02/2012	OC/ORASORM/ OC/ORASORM/	JOHNATHAN RICKMAN FDA NEWS	INSP FOR DEVICE MANUFACTURING, CLNCL TRIAL FACILITIES IN US 3/12
2012-2472	04/04/2012 05/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GERLAD J. OREHOSTKY ANTARES PHARMA INC	HUZHOU ZHANWANG PHARMACEUTICAL CO LTD - WARNING LTR, EIR, CO RESP
2012-2473	04/04/2012 05/02/2012	OC/OA/OM/OMP/DDM/	ANGELIA D. SLAYTON INC REGULATORY CONSULTING & SUBMISSIONS	DKT FDA-2012-N-171
2012-2474	04/04/2012 05/02/2012	FDA/OC/OES/DFOI/ FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/ FDA/OC/OES/DFOI/	Doe J	2011-7930
2012-2475	04/04/2012 05/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELIZABETH A. KURTZ HEWITT WOLENSKY LLP	LISTERINE ANTISEPTIC - CMLPNTS, AER 1987 TO PRESENT
2012-2476	04/04/2012 05/02/2012	FDA/OMPT/CDRH/OCER/DFOI/	ARDAUGH, BRENT M	K922276, K837347, K837152
2012-2477	04/04/2012 05/02/2012	FDA/OC/OES/DFOI/	LUCY A. DALGLISH REPORTERS COMMITTEE	10 OLDEST PENDING REQUESTS
2012-2478	04/05/2012 05/03/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OFVM/CFSAN/OCD/EOS/ OC/OCOS/OES/ OC/OCOS/OES/	TERESA GREEN NATIONAL CONSUMERS LEAGUE	NU VAL NUTRITION RATING SYS, OVERALL NUTRITIONAL QUALITY INDEX - RECS 2004 TO PRESENT
2012-2479	04/05/2012 05/03/2012	FDA/OC/OES/DFOI/	BOBBY SCHOCHET OLSSON FRANK WEEDA TERMAN MATZ PC	2012-2183 - REQUEST LTR

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2012-2480	04/05/2012 05/03/2012	FDA/OC/OES/DFOI/	JARED MACCLEARY CROWELL & MORING	CVM FOI REQUESTS 3/12
2012-2481	04/05/2012 05/03/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2012-1372
2012-2482	04/05/2012 05/03/2012	OC/CVM/OCD/	PATTY LOVERA Food & Water Watch	SADEX CORP - CORR; FOOD ADDITIVE PETITION (ANIMAL USE) ELECTRON BEAM AND X-RAY SOURCES FOR IRRADIATION OF POULTRY FEED AND POULTRY FEED INGREDIENTS
2012-2483	04/05/2012 05/03/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2012-1104
2012-2484	04/05/2012 05/03/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2012-1124
2012-2485	04/05/2012 05/03/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2012-1129
2012-2486	04/05/2012 05/03/2012	FDA/OMPT/CDRH/OCER/DFOI/	LEX J PEARCE ICU MEDICAL INC	B BRAUN MEDICALINC - PS100006 INITIAL ORDER LTR 7/10, STUDY PROTOCOL, STUDY RPT
2012-2487	04/05/2012 05/03/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2012-1207
2012-2488	04/05/2012 05/03/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2012-1240
2012-2489	04/05/2012 05/03/2012	OC/OA/OM/OMP/DDM/	NANCY MARCHANT LUBRIZOL CORP	DKT 1980N-0042
2012-2490	04/05/2012 05/03/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2012-1210
2012-2491	04/05/2012 05/03/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2012-1633
2012-2492	04/05/2012 05/03/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OO/OFBA/OAGS/ FDA/OMPT/CDRH/OCER/DFOI/	ALEX VEIZIS FDALIVE.COM	CBER A/C WEBCAST - PRODUCTION COSTS, 508 COMPLIANCE, NETWORK RECS, ETC
2012-2493	04/05/2012 05/03/2012	FDA/OGROP/ORASE-FO/NOL- DO/NOL-CB/	JOHNATHAN RICKMAN FDA NEWS	AMCOL HEALTH & BEAUTY SOLUTIONS INC, LAFAYETTE, LA; TITEREK INSTRUMENTS INC, HUNTSVILLE, AL; LEISURE PRODUCTS INC, KINGSPORT, TN, ETC - 483S 1/1-31/12
2012-2494	04/05/2012	FDA/OGROP/ORAPA-FO/SAN-	JOHNATHAN RICKMAN	LIBBY LABORATORIES INC, BERKELEY, CA; CELERA CORP,

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	05/03/2012	DO/SAN-CB/	FDA NEWS	ALAMEDA, CA; CEPHEID, SUNNYVALE, CA, ETC - 483S 1/1-31/12
2012-2495	04/05/2012 05/03/2012	FDA/OC/OES/DFOI/	AMANDA ORLANDO AVALON RISK MANAGEMENT INC	ENTRY #AZO00448054 - NOTICE OF FDA ACTION #1
2012-2496	04/05/2012 05/03/2012	FDA/OGROP/ORR/NE-FO/NYK-DO/NYK-DCB/	JOHNATHAN RICKMAN FDA NEWS	INVAGEN PHARMACEUTICALS INC, HAUPPAUGE, NY; ARCH CHEMICALS, ROCHESTER, NY; CONTRACT PHARMACAL CORP, HAUPPAGE, NY, ETC - 483S 1/1-31/12
2012-2497	04/05/2012 05/03/2012	FDA/OGROP/ORR/CE-FO/PHI-DO/PHI-CB/	JOHNATHAN RICKMAN FDA NEWS	BIO DATA CORP, HORSHAM, PA; ZOLL LIFECOR CORP, PITTSBURGH, PA; CUSTOM ULTRASONICS INC, IVYLAND, PA - 483S 1/1-31/12
2012-2498	04/05/2012 05/03/2012	FDA/OGROP/ORR/NE-FO/NWE-DO/NWE-CB/	JOHNATHAN RICKMAN FDA NEWS	SHIRE HUMAN GENTICS THERAPIES INC, CAMBRIDGE, MA; EXEMPLAR PHARMACEUTICALS LLC, FALL RIVER, MA; IMMUEX RHODE ISLAND CORP, WEST GEENWICH, RI, ETC - 483S 1/1-31/12
2012-2499	04/05/2012 05/03/2012	FDA/OGROP/ORR/CE-FO/MIN-DO/MIN-CB/	JOHNATHAN RICKMAN FDA NEWS	ROCKLINE INDUSTRIES INC, SHEBOYAN, WI; NATIONAL CREATIVE ENTERPRISES INC, BURNSVILLE, MN; AD-TECH MEDICAL INSTRUMENT CORP, RACINE, WI, ETC - 483S 1/1-31/12
2012-2500	04/05/2012 05/03/2012	FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/	JOHNATHAN RICKMAN FDA NEWS	HOSPIRA INC, MCPHERSON, KS; NOVARTIS CONSUMER HEALTH, LINCOLN, NE - 483S 1/1-31/12
2012-2501	04/05/2012 05/03/2012	FDA/OMPT/CDRH/OCER/DFOI/	JOHNATHAN RICKMAN FDA NEWS	MEDIAGNOST GMBH, REULINGEN, GERMANY; ITEM INDUSTRIES LTD, SHENZHEN, GUANGDONG, CHINA; COPAN ITALIA, BRESCIA, ITALY, ETC - 483S 1/1-31/12
2012-2502	04/05/2012 05/03/2012	FDA/OGROP/ORR/CE-FO/DET-DO/DET-CB/	JOHNATHAN RICKMAN FDA NEWS	APPLIED LABORATORIES INC, COLUMUS, IN; ROYAL OAK MEDICAL DEVICES LLC, OXFORD, MI; ACUMEDIA MANUFACTURERS INC, LANSING, MI, ETC - 483S 1/1-31/12
2012-2503	04/05/2012 05/03/2012	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	JOHNATHAN RICKMAN FDA NEWS	MEDOP INC, OLDSMAR, FL; CERAGROUP INDUSTRIES INC, FORT LAUDERDALE, FL; CHAMCO INC, LAUDERDALE, FL, ETC - 483S 1/1-31/12
2012-2504	04/05/2012 05/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RITA F REDBERG MD UNIV OF CALIFORNIA SAN FRANCISCO	LIPITOR (ATORVASTATIN), LESCOL (FLUVASTATIN), CRESTOR (ROSUVASTATIN), ETC - AERS 1/1/12-3/27/12
2012-2505	04/05/2012 05/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHNATHAN RICKMAN FDA NEWS	ESTEVE HUAYI PHARMACEUTICAL CO LTD, SHAOXING, CHINA; SANDOZ PRIVATE LTD, NAVI MUMBAI, INDIA; S A AJINOMOTO OMIKEM NV - LOVAIN LA NEUVE, BELGIUM, ETC - 483S 1/1-31/2
2012-2506	04/05/2012	FDA/OGROP/ORR/PA-FO/LOS-	JOHNATHAN RICKMAN	3M DRUG DELIVERY SYSTEMS, NORTHIDGE, CA; LEE

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	05/03/2012	DO/LOS-CB/	FDA NEWS	PHARMACEUTICALS INC, SOUTH EL MONTE, CA; NUTRI GRANULATIONS, LA MIRADA, CA, ETC - 483S 1/1-31/12
2012-2507	04/05/2012 05/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARTIN S MASAR KATTEN MUCHIN ROSENMAN LLP	LUMIGAN (BIMATOPROST OPHTHALMIC SOL) NDA 21-275 - RECS
2012-2508	04/05/2012 05/03/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	JOHNATHAN RICKMAN FDA NEWS	MYCONE DENTAL SUPPLY CO INC, CHERRY HILL, NJ; CASE MEDICAL, SOUTH HACKENSACK, NJ; GLAXOSMITHKLINE CONSUMER HEALTHCARE LP, CLIFTON, NJ, ETC - 483S 1/1-31/12
2012-2509	04/05/2012 05/03/2012	FDA/OC/OES/DFOI/	GEORGE SADLER PHD PROVE IT LLC	FCN 140 - CHEMISTRY, TOXICOLOGY, ENVIRONMENTAL RVWS
2012-2510	04/05/2012 05/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRADLEY J SHISLER CPMG INC	NOVARTIS - SYNACTHEN, SYNACTHEN DEPOT (SYNACTHEN)- APRVL PKG, APRVL, WITHDRAWL
2012-2511	04/05/2012 05/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LAROCCA, PAT	SUCAMPO PHARMA AMERICAS - AMITIZA NDA 21-908/S008 CLNCL STUDIES, RVWS, NDA FORMS, ETC
2012-2512	04/05/2012 05/03/2012	FDA/OFVM/CFSAN/OCD/EOS/	WILLIAM R COLE TECHNICAL INC	STAPHYLOCOCCUS AUREUS GROWTH AND TOXIN FORMATION PERTINENT TO THE CLEANING, LOINING AND PACKING STEPS IN A FROZEN LOIN/CANNED TUNA PROCESSING FACILITY - RECS
2012-2513	04/05/2012 05/03/2012	FDA/OMPT/CDRH/OCER/DFOI/	FRANCES RICHMOND PHD UNIV OF SOUTHERN CALIFORNIA SCHOOL OF PHARMACY	MICROMAXX HIGH-RESOLUTION ULTRASOUND SYS K053069
2012-2514	04/05/2012 05/03/2012	FDA/OMPT/CDRH/OCER/DFOI/	SHERYL HIGGINS DENTIUM USA	MEGAGEN CO LTD - RESCUE INTERNAL IMPLANT SYS K073058, K063216; RESCUE IMPLANT SYS K053353
2012-2515	04/05/2012 05/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RAJAN EMBRAN JUBILANT CADISTA PHARMACEUTICALS INC	WARNER CHILCOTT - ACTONEL (RISEDRONATE SODIUM) TABS NDA 20-835 SBA
2012-2516	04/05/2012 05/03/2012	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	NORBERT GOTTESMAN AVET CAPITAL MANAGEMENT	EXEMPLAR PHARMS, EXEMPLAR PHARMA LLC, FALL RIVER, MA - EIRS, 483S

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			LLC	
2012-2517	04/05/2012 05/03/2012	FDA/OMPT/CDRH/OCER/DFOI/	MATT MORTENSEN PHD CARDIOCOM LLC	HONEYWELL HOMMED LLC - GENESIS TOUCH SYS K112858
2012-2518	04/05/2012 05/03/2012	FDA/OMPT/CDRH/OCER/DFOI/	NARGES GHAZI CITY COLLEGE OF NEW YORK	NEURONETICS INC - NON-INVASIVE, NON-SYSTEMIC TREATMENT FOR DEPRESSION CLNCL TRIAL RECS
2012-2519	04/05/2012 05/03/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	LOFGREN, DON	3M - FILTERING FACEPIECE RESPIRATOR K062070 GUIDANCE FOR INDUSTRY RECS
2012-2520	04/05/2012 05/03/2012	FDA/OMPT/CDRH/OCER/DFOI/	MATT CLAUSEN MEDLINE INDUSTRIES INC	MERIDIAN MEDICAL SYSTEMS - BREATHING FILTER K025217
2012-2521	04/05/2012 05/03/2012	FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/	JONATHAN C WILK THERMO FISHER SCIENTIFIC	WATERS CORP, MILFORD, MA - EIRS, 483S
2012-2522	04/05/2012 05/03/2012	FDA/OMPT/CDRH/OCER/DFOI/	JONATHAN C WILK THERMO FISHER SCIENTIFIC	AGILENT TECHNOLOGIES, SINGAPORE - EIRS, 483S
2012-2523	04/05/2012 05/03/2012	FDA/OMPT/CDRH/OCER/DFOI/	JONATHAN C WILK THERMO FISHER SCIENTIFIC	WATERS TECHNOLOGIES CORP, WYTHENSHAW, UK - EIRS, 483S
2012-2524	04/05/2012 05/03/2012	FDA/OMPT/CDRH/OCER/DFOI/	JONATHAN C WILK THERMO FISHER SCIENTIFIC	AGILENT TECHNOLOGIES, WALDBRONN, GERMANY - EIRS, 483S
2012-2525	04/05/2012 05/03/2012	FDA/OMPT/CDRH/OCER/DFOI/	JONATHAN C WILK THERMO FISHER SCIENTIFIC	WATERS TECHNOLOGIES IRELAND LTD, DRINAGH, IRELAND - EIRS, 483S
2012-2526	04/06/2012 05/04/2012	FDA/OC/OES/DFOI/	DAIVE MCFARLAND FDA WEBVIEW/FERDIC INC	2012-935
2012-2527	04/06/2012 05/04/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2011-9206
2012-2528	04/06/2012 05/04/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2012-67
2012-2529	04/06/2012 05/04/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2010-4246
2012-2530	04/06/2012 05/04/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	ANGELIA D SLAYTON INC REGULATORY CONSULTING & SUBMISSIONS	K091496
2012-2531	04/06/2012 05/04/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	ANGELIA D SLAYTON INC REGULATORY CONSULTING & SUBMISSIONS	K103560
2012-2532	04/06/2012	FDA/OMPT/CDRH/OCER/DFOI/	BARBARA LIPPERT	K091769

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	05/04/2012		GLYDE USA INC	
2012-2533	04/06/2012 05/04/2012	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	THOMPSON, RAY	ASTRAZENCA PHARMACEUTICAL LP, NEWARK, DE 6/27/11-7/5/11; APTER INDUSTRIES INC, MCKEESPORT, PA 6/30/11-7/5/11; BOEHRINGER LABORATORIES INC, PHOENIXVILLE, PA 10/24/11-11/7/11, ETC - 483S
2012-2534	04/06/2012 05/04/2012	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	THOMPSON, RAY	ACUTE INNOVATIONS LLC, HILLBORO, OR 10/13-21/11; INOVISE MEDICAL INC, BEAVERTON, OR 4/27/11-6/1/11; CASCADIA MANUFACTURING INC (ORAMELTS CORP), BELLEVUE, WA 8/24/11-9/7/11, ETC - 483S
2012-2535	04/06/2012 05/04/2012	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	THOMPSON, RAY	CHEM-TECH LTD, PLEASNTVILLE, LA 10/18-19/11; HERITAGE LABS INTERNATIONAL LLC, OLATHE, KS 6/13-17/11; CHEMISPHERE CORP, SAINT LOUIS, MO 9/7-16/11, ETC - 483S
2012-2536	04/06/2012 05/04/2012	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	THOMPSON, RAY	AUGUSTA MEDICAL SYSTEMS LLC, AUGUSTA, GA 9/19-23/11; OPHTHAL MED LLC, ROSWELL, GA 7/27/11-8/2/11; PRIME TENHNOLOGICAL SERVICES, SUWANEE, GA 12-5-12/11, ETC - 483S
2012-2537	04/06/2012 05/04/2012	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	THOMPSON, RAY	ABBOTT LABS, ABBOTT PARK, IL 7/11-15/11; ACQUAMED TECHNOLOGIES INC, WEST CHICAGO, IL 5/24/11-6/6/11; CORPAK MEDSYSTEMS, WHEELING, IL 5/3/11-7/8/11, ETC - 483S
2012-2538	04/06/2012 05/04/2012	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	THOMPSON, RAY	EV3 INC, PLYMOUTH, MN 8/4-24/11; LIFECORE BIOMEDICAL LLC, CHASKA, MN 7/13-21/11; ALLIANCE PACKAGING GROUP INC, SAUKVILLE, WI 12/15-21/11, ETC - 483S
2012-2539	04/06/2012 05/04/2012	FDA/OMPT/CDRH/OCER/DFOI/	ALAN EVANS WESTRIDGE LABORATORIES INC	ONE INC - ONE PERSONAL LUBRICANT (SILICONE) K110690
2012-2540	04/06/2012 05/04/2012	OC/ORACE-FO/CHI-DO/CHI-CB/	Doe J	INDIVIDUAL RECS
2012-2541	04/06/2012 05/04/2012	FDA/OMPT/CDRH/OCER/DFOI/	NARGES GHAZI CITY COLLEGE OF NEW YORK	NEURONETICS INC - PON SYSTEMIC TREATMENT IDE, PMA APPL
2012-2542	04/06/2012 05/04/2012	FDA/OMPT/CDRH/OCER/DFOI/	KATHERINE STRONG CARNER SIDLEY AUSTIN LLP	CDRH UNTITLED LTRS LAST 5 YRS
2012-2543	04/06/2012 05/04/2012	OC/ORACE-FO/ORO/DIOP/	SANDRA BARTLETT NATIONAL PUBLIC RADIO	IMPORTED TISSUE PRODUCT CODES 57JH01, 57JH02, 57JI03, ETC - COUNTRY OF ORIGIN, VALUE OF GOODS, UNIT OF MEASURE, ETC
2012-2544	04/06/2012	FDA/OMPT/CDRH/OCER/DFOI/		CDRH UNTITLED LTRS, INQUIRY LTRS, CORR LAST 5 YRS

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	05/04/2012		SIDLEY AUSTIN LLP	
2012-2545	04/06/2012 05/04/2012	FDA/OMPT/CDRH/OCER/DFOI/	JEANNA H BASNETT REFLEXION HEALTH INC	PEAK MOTUS MOTION MEASUREMENT - K030714
2012-2546	04/06/2012 05/04/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	EDWARDS, SANDRA	LEVOFLOXACIN, MOXIFLOXACIN - AERS
2012-2547	04/06/2012 05/04/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELI D EHRENPREIS MD	ACCUTANE - ISR 5752495, 6023192, 6023920, ETC
2012-2548	04/06/2012 05/04/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ALICE CHEN UNIV OF CHICAGO BOTH SCHOOL OF BUSINESS	DRUG SHORTAGES - NDC 1/99 TO 12/09
2012-2549	04/06/2012 05/04/2012	FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/ FDA/OGROP/ORANE-FO/NYK- DO/NYK-DCB/	JOHN DIEDRICH MILWAUKEE JOURNAL SENTINEL	PROFESSIONAL DISPOSABLE INC, ORANGEBURG, NY - WIPES TEST RESULTS 9/11 TO 10/11
2012-2550	04/06/2012 05/04/2012	OC/ORAN/ OC/ORAN/ FDA/OGROP/ORAN/ORO/DIOP/ FDA/OGROP/ORAN/SW- FO/SWID/SWID-CB/ FDA/OGROP/ORAN/SW-FO/DAL- DO/DAL-CB/	MICHELLE RYBAK ROANOKE TRADE SERVICES INC	NOTICES OF REFUSAL/MARK/REDELIVER - ENTRY BYX - 0039009-D
2012-2551	04/06/2012 05/31/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	SANDRA BARLETT NATIONAL PUBLIC RADIO	JHO1-FASCIA, JHO2 - CARTRIDGE, JHO - BONE, ETC - DEVIATION RPTS 1/02 TO PRESENT
2012-2552	04/06/2012 05/04/2012	FDA/OMPT/CDRH/OCER/DFOI/	COREY PHELPS PHD HEC PARIS	ESTABLISHMENT REGISTRATION & DVS LISTING, PROD RECALLS, PMA, ETC 1995 TO 2012
2012-2553	04/06/2012 05/04/2012	OC/OA/OM/OMP/DDM/	YATES, RANDAL W	DKT 1995S-0316
2012-2554	04/06/2012 05/04/2012	FDA/OFVM/CFSAN/OCD/EOS/	Doe J	SOY - RECS

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2012-2555	04/06/2012 05/04/2012	FDA/OFVM/CFSAN/OCD/EOS/	BRADLEY C BHROW ZIMMERMAN REED PLLP	STANDARD IDENITY FOR YOGURT - 21 RESP OBJECTIONS FILED
2012-2556	04/06/2012 05/04/2012	FDA/OMPT/CDRH/OCER/DFOI/	JEANNA H BASNETT REFLEXION HEALTH INC	CHARNWOOD DYNAMICS LTD - CODA CX1 MOTION ANALYSIS SYS K033514
2012-2557	04/06/2012 05/04/2012	FDA/OC/OES/DFOI/	JONEL ALECCIA MSNBC	PACIFIC DISPOSABLES INTERNATION INC, ORANGEBURG, NY - 483S 8/11 TO PRESENT
2012-2558	04/06/2012 05/04/2012	OC/OM/OSS/OEEODM/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Doe J	INDIVIDUAL RECS
2012-2559	04/06/2012 05/04/2012	OC/OA/OM/OMP/DDM/ FDA/OGROP/ORACE-FO/PHI- DO/PHI-CB/ FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARIAN S ROSEN MARIAN S ROSEN & ASSOCIATES	LISTERINE MOUTHWASH - CMLPNTS
2012-2560	04/06/2012 05/04/2012	FDA/OGROP/ORASE-FO/SJN- DO/SJN-CB/	THOMPSON, RAY	ETHICON LLC, SAN LORENZO, PR 9/27/11-11/15/11; BAXTER HEALTHCARE COR, JAYUYA, PR 10/24/11-11/3/11; CORDIS LLC, SAN GERMAN, PR 8/9-16/11, ETC - 483S
2012-2561	04/06/2012 05/04/2012	FDA/OGROP/ORACE-FO/BLT- DO/BLT-CB/	THOMPSON, RAY	ACTION PRODUCTS INC, HAGERSTOWN, MD 8/4-9/11; AVANZA LABORATORIES LLC, GAITHERSBURG, MD 7/11-27/11; KNOLL MEDICAL LLC, ANNAPOLIS, MD 10/12-20/11, ETC - 483S
2012-2562	04/06/2012 05/04/2012	FDA/OGROP/ORASW-FO/DEN- DO/DEN-CB/	THOMPSON, RAY	ASI MEDICAL INC, CENTENNIAL, CO 12/19-22/11; SANDHILL SCIENTIFIC INC, LITTLETON, CO 6/27/11-7/6/11; BIOMERIDIAN INTERNATIONAL INC, SALT LAKE CITY, UT 11/10-22/11, ETC - 483S
2012-2563	04/06/2012 05/04/2012	FDA/OGROP/ORACE-FO/DET- DO/DET-CB/	THOMPSON, RAY	BRISTOL-MYERS SQUIBB COMPANY INC, MOUNT VERNON, IN 10/24-28/11; DEPUY ORTHOPAEDICS INC, WARSAW, IN 5/10/11-6/7/11; SIGMA-TAU PHARMASOURCE INC, INDIANAPOLIS, IN 5/7/11-6/7/11, ETC - 483S
2012-2564	04/06/2012 05/04/2012	FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/	THOMPSON, RAY	DEEPWATER CHEMICALS INC, WOODWARD, OK 8/29/11-9/6/11; EAGLE DIAGNOSTICS INC, CEDAR HILL, TX 10/11-14/11; HEALTHTRONICS INC, AUSTIN, TX 10/11-19/11, ETC - 483S
2012-2565	04/06/2012 05/04/2012	FDA/OGROP/ORASE-FO/NOL- DO/NOL-CB/	THOMPSON, RAY	VINTAGE PHARMACEUTICALS LLD (QUALITEST PHARMS), HUNTSVILLE, AL 11/29/11/12/7/11; CAGENIX, MEMPHIS, TN 8/9-16/11; AOSS MEDICAL SUPPLY INC, MONROE, LA 8/4-

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				11/11, ETC - 483S
2012-2566	04/06/2012 05/18/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	ELLEN RELKIN ESQ WEITZ & LUXEMBERG PC	BIOMET INC - M2A MAGNUM HIP IMPLANT, M2A-38 HIP IMPLANT MDRS, PMA, MDA APPL
2012-2567	04/06/2012 05/04/2012	FDA/OMPT/CDRH/OCER/DFOI/	NOEL M RELYEA PHD SINGULEX INC	MITSUBISHI CHEMICAL MEDIENCE - PATHFAST CTNL-II TEST K100130
2012-2568	04/06/2012 05/04/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	HENRY F BAYARD COLE SCOTT AND KISSANE	AVASTIN - INFECTIONS, CONTAMINATIONS IN MINNEAPOLIS, MN 2011 TO PRESENT
2012-2569	04/06/2012 05/04/2012	OC/ORACE/ OC/ORACE/	DR KATHY MCINTOSH SASKATOON COLOSTRUM COMPANY LTD	BOVINE DRIED COLOSTRUM ENTRY #112-6413972-1 - TEST RESULTS
2012-2570	04/06/2012 05/04/2012	FDA/OMPT/CDRH/OCER/DFOI/	DONNA R CORCORAN COOLEY MANION JONES LLP	ALARMS AND MONITORING DVCS - INVESTIGATION RPTS, INTERVIEWS, FINDINGS, ETC 2005 TO 2012
2012-2571	04/06/2012 05/04/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SEPHY PHILIP RPH PHARM D SCIENTIFIC EXCHANGE LLC	ABLE LABORATORIES INC - TRIMETHOPRIM/SULFAMETHOXAZOLE NDA 21-105; WYETH PHARMACEUTICALS INC - PHENOBARBITAL, HYOSCYAMINE SULFATE, ATROPINE SULFATE, SCOPOLAMINE (HBR) ELIXIR ANDA 86-661, ETC SBA
2012-2572	04/06/2012 06/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	ANGELIA D SLAYTON INC RESEARCH CONSULTING & SUBMISSIONS	K113097
2012-2573	04/06/2012 05/04/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2012-1101
2012-2574	04/06/2012 05/04/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2012-836
2012-2575	04/06/2012 05/04/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2011-8001
2012-2576	04/06/2012 05/04/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2012-864
2012-2577	04/06/2012 05/04/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	NARGES GHAZI CITY COLLEGE OF NEW YORK	K061053

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2012-2578	04/09/2012 05/07/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/	KLELLY MCALLISTER ST JOSEPH/BREAST CARE CNETER	ST JOSEPH HOSPITAL (MILFORD CAMPUS), MILFORD, NH - EIR 9/7/11
2012-2579	04/09/2012 05/07/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/	KELLY MCALLISTER ST JOSEPH/BREAST CARE CNETER	ST JOSEPH HOSPITAL, NASHUA, NH - EIR 9/9/11
2012-2580	04/09/2012 05/07/2012	FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/	G RICHARD JAMES LUCERNE FARMS	ANITA COONS (LUERNE FARMS FORAGE FEED) - HI FIBER EIRS 3/11 TO 5/11
2012-2581	04/09/2012 05/07/2012	FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/	G RICHARD JAMES LUCERNE FARMS	DOVER SADDLERY RETAIL INC (LUCERNE FARMS), CONCORD, NH - HI FIBER EIRS 3/11 - 5/11
2012-2582	04/09/2012 05/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	JONN M EBERSOLE BAVER & BOOKWATER CO LPA	DIALYSIS OR HEMODIALYSIS EQUIPMENT - CMLPNTS, RPTS, INVESTIGATIONS, ETC
2012-2583	04/09/2012 05/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	THOMAS O'MALLEY ESQ OSHMAN & MIRSOLA LLP	MERK, COMUMED - OSTERGRAM DVC CORR, APPL FOR APRVL
2012-2584	04/09/2012 05/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	YANG YANG PAC-DENTAL INTERNATIONAL INC	K031588
2012-2585	04/09/2012 05/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	JOVAN IVOSEVIC IVOSEVIC LAW CORP	MAQUET GMBH & CO KG - ALPHSTAR (ALPH STAR) MDRS 556121, 679461, 721784, ETC
2012-2586	04/09/2012 05/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	QUINN, TOM	MR ROMANELL DETERMINATION OF K801407 ASSIGNMENT - PHILIPS CORR, MTGS, PHONE LOG
2012-2587	04/09/2012 05/07/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PATRICIA TANG MD FRCP TOM BAKER CANCER CENTRE	ANAGRELIDE, ANASTROZOLE, AZACITIDINE, ETC - SUBMISSION DATES
2012-2588	04/09/2012 05/07/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	A LUKE SMITH RADICE LAW FIRM	TEVA PHARMACEUTICALS USA INC - ANDA 76-565; IMPAX LABS - ANDA 78-057; MYLAN ANDA 78-789 SBA
2012-2589	04/09/2012 05/07/2012	FDA/OGROP/ORASE-FO/NOL- DO/NOL-CB/	HENRY F BAYARD CSK Labs	VETERNANS AFFAIRS HOSPITAL, NASHVILLE, TN - AVASTIN INCIDENT RPTS, INVESTIGATION RPTS, FINAL RPTS, ETC 1/11 TO PRESENT
2012-2590	04/09/2012 05/07/2012	FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORAPA-FO/SAN-	HENRY F BAYARD CSK Labs	CALIFORNIA DEPARTMENT OF VETERANS AFFAIRS - AVASTIN INCIDENT RPTS, INVESTIGATION RPTS, FINAL RPTS, ETC 1/11 TO PRESENT

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		DO/SAN-CB/		
2012-2591	04/09/2012 05/07/2012	FDA/OFVM/CFSAN/OCD/EOS/	JAMIE A KOUFMAN MD NEW YORK MEDICAL	ACID AS A PRIMARY FOOD PRESERVATIVE - PEER RVW STUDIES
2012-2592	04/09/2012 05/07/2012	FDA/OC/OES/DFOI/	GAILL LESSICK LACHMAN CONSULTANT SERVICES INC	LIST OF ALL DOMESTIC & FOREIGN INSP 2/1-29/12
2012-2593	04/09/2012 05/07/2012	OC/ORO/ OC/ORO/	Doe J	WALGREENS - CMLNT
2012-2594	04/09/2012 05/07/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	YANG YANG PACDENT INTERNATIONAL INC	K050145
2012-2595	04/09/2012 05/07/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID MOSSBURG MOSSBURG MEDIA INC	PROGENICS PHARMACEUTICALS; SALIX PHARMACEUTICALS - RELISTOR (METHYLNALTREXONE) PHASE 3 COMM 11/1/11-12/31/11
2012-2596	04/09/2012 05/07/2012	OC/OM/OMP/DDM/	CHRIS CELESTE EAS Consulting Group, LLC	DKT 2004D-0466
2012-2597	04/09/2012 05/07/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	MARK A NASCHE OPPENHEIMER & CO INC	MAP PHARMACEUTICALS INC - LEVADEX, NDA COMPLETE RESPONSE LTR
2012-2598	04/09/2012 05/07/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	SCOTT HAIRSCH SUREYOR CAPITAL CITCEL LLC	MAP PHARMS, EXEMPLAR PHARMS - 483S, WARNING LTRS, CORR 1/09 TO PRESENT
2012-2599	04/09/2012 05/07/2012	OC/ORO/ OC/ORO/ OC/ORO/OE/ OC/ORO/OE/	EADDY, LASHONDA L	JOHNSON & JOHNSON (ADVANDED SSTERIXATION PRODS, ANIMAS CORP, CORDIS, CORP), ETC - RECALLS 11/109 TO 3/22/12
2012-2600	04/09/2012 05/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRAD BREZDEN ENDURANCE THERAPEUTICS	HI-DOW INTERNATIONAL INC, SAINT LOUIS, MO - K101598

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2012-2601	04/09/2012 05/07/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	DALENA DEGREZIA PROSTRAKAN INC	ESOTERIX - EIR, 482, 483 ETC 11/1-9/07
2012-2602	04/09/2012 05/07/2012	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	LESLIE SHOJI INTEREX INDUSTRIES LTD	DHALIWAL LABS, DALLAS TX - EIR, 483 11/11
2012-2603	04/09/2012 05/07/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	G RICHARD JAMES LUCERNE FARMS	CARGILL ANIMAL NUTRITION, ALBANY, NY - LUCERNE FARMS (FORAGE FEED - LUCERINE HI FIBER) 3/11 TO 5/11
2012-2604	04/09/2012 05/07/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID C BONNIN DLA PIPER US LLP	HORMONE REPLACEMENT THERAPY - AERS
2012-2605	04/09/2012 05/07/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PETER S REICHERTZ SHEPPARD MULLIN RICHTER & HAMPTON, LLP	LUITPOLD PHARMACEUTICALS INC - SPRIX (KETOROLAC TROMETHAMINE NASAL SPRAY) NDA 022-382, AERS 5/1/11 TO PRESENT
2012-2606	04/09/2012 05/07/2012	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	TRAVIS SIVERSON BIRCHWOOD LABORATORIES INC	CARELINE INC, GREENBRIER, TN - EIRS, 483S, 10/22/11-11/2/11
2012-2607	04/09/2012 05/07/2012	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	TRAVIS SIVERSON BIRCHWOOD LABORATORIES INC	TRADEMARK MEDICAL LLC, BALDWIN, MO - EIRS, 483S 10/22/11-11/2/11
2012-2608	04/09/2012 05/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	SHERRY FRIEDT SOMNETICS INTERNATIONAL INC	PHILLIPS REMSTAR AUTO M SERIES W/C-FLEX - K09024
2012-2609	04/09/2012 05/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	SHERRY FRIEDT SOMNETICS INTERNATIONAL INC	PHILLIPS REMSTAR AUTO W/C-FLEX - K041010
2012-2610	04/09/2012 05/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	SHERRY FRIEDT SOMNETICS INTERNATIONAL INC	RESMED S8 ESCAPE II AUTO - K080079
2012-2611	04/09/2012 05/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	SHERRY FRIEDT SOMNETICS INTERNATIONAL INC	PHILLIPS REMSTAR AUTO W/C-FLEX - K031460
2012-2612	04/09/2012 05/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	THOMAS J CONLIN CONLIN LAW FIRM LLC	MEDTRONIC - CONSULTA DEFIBRILATTOR W/CARDIAC RESYNCHRONIZATION THERAPY MODEL D224TRK
2012-2613	04/09/2012	FDA/OMPT/CDER/ORP/DIDP/	KEVIN A ZAK	EXPAREL (LIPOSOME INJECTABLE SUSPENSION) -

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	05/07/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PARTNERS HEALTHCARE INC	SUMMARY, MEDICAL/CLINICAL & STATISTICAL RVWS
2012-2614	04/09/2012 05/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	EDWARDS, MARY	K042523 - SUMMARY & CLEARANCE LTR.
2012-2615	04/09/2012 05/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	CHRISTOPHER M SLOAN QUINTILES CONSULTING	EDWARDS LIFESCIENCES LLC - EDWARDS BOVINE PERICARDIAL PATCH K082139 CORR CORR, MTGS, RVWS ETC 10/23/08
2012-2616	04/09/2012 05/07/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OES/DFOI/	Doe J	GREAT MEADOW CORRECTONAL FACILITY MEALS - INGREDIENTS & NUTRITIONAL FACTS PAMPHLETS, MATERIAL, RECS ETC
2012-2617	04/10/2012 05/08/2012	OC/OA/OM/OMP/DDM/	COLLINS, MELISSA	DKT 2010P-0091
2012-2618	04/10/2012 05/08/2012	FDA/OC/OES/DFOI/	NELSON LOPEZ GRIFOLS BIOLOGICALS INC	RUGER CHEMICAL CO, LINDEN, NJ - EIRS, 483S 1/09 TO 3/12
2012-2619	04/10/2012 05/08/2012	FDA/OMPT/CDRH/OCER/DFOI/	NOOSHIN AZIZI ABBOTT MEDICAL OPTICS INC	K884251, K861642, K861643
2012-2620	04/10/2012 05/08/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	WILLIAM TANNER LAZARD CAPITAL MARKETS	EXEMPLAR PHARMS - LEVADEX 483, RECS
2012-2621	04/10/2012 05/08/2012	OC/ORA/ORM/ OC/ORA/ORM/	DENISE HAMMANG BIOPHARMA COMPLIANCE SERVICES LLC	HUMAN CELL AND TISSUE ESTABLISHMENTS - 483S 1/12 TO 3/12
2012-2622	04/10/2012 05/08/2012	FDA/OMPT/CDRH/OCER/DFOI/	DAWN M COULSON ESQ EPPS YONG & COULSON LLP	METAL TRANSCEND ARTICULATION SYS K004043
2012-2623	04/10/2012 05/08/2012	FDA/OMPT/CDRH/OCER/DFOI/	DAWN M COULSON ESQ EPPS YONG & COULSON LLP	CONSERVE PLUS REVISION SHELL AND CONSERVE PLUS THICK SHELL K041425
2012-2624	04/10/2012 05/08/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	DAWN M COULSON ESQ EPPS YONG & COULSON LLP	CONSERVE TOTAL FEMORAL HEAD K051348
2012-2625	04/10/2012	FDA/OMPT/CDRH/OCER/DFOI/	MELISSAN G ABBOTT	MW5023502

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	05/08/2012		SPECTRANETICS CORP	
2012-2626	04/10/2012 05/08/2012	FDA/OMPT/CDRH/OCER/DFOI/	MELISSA G ABBOTT SPECTRANETICS CORP	MDR RPT #2017865-2012-00088
2012-2627	04/10/2012 05/08/2012	FDA/OMPT/CDRH/OCER/DFOI/	MELISSA G ABBOTT SPECTRANETICS CORP	MDR RPT #2938836-2006-00420
2012-2628	04/10/2012 05/08/2012	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	JOHN R MOORE LIND JENSEN SULLIVAN & PETERSON	WILLMAR POULTRY FARMS INC - EVER CAT VEGETABLE BOTTOMS INVESTIGATION RECS
2012-2629	04/10/2012 05/08/2012	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	JOHN R MOORE LIND JENSEN SULLIVAN & PETERSON	WILLMAR POULTRY FARMS INC - EVER CAT FUELS INVESTIGATION RECS
2012-2630	04/10/2012 05/08/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	CLSOED FOI REQUESTS 3/26-30/12
2012-2631	04/10/2012 05/08/2012	FDA/OMPT/CDRH/OCER/DFOI/	MELISSA G. ABBOTT SPECTRANETICS CORP	MDR RPT # 2017865-2012-00061
2012-2632	04/10/2012 05/08/2012	FDA/OMPT/CDRH/OCER/DFOI/	MELISSA G. ABBOTT SPECTRANETICS CORP	MDR RPT # 2134265-2012-00131
2012-2633	04/10/2012 05/08/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	MICHAEL R. HAMRELL, Ph.D. MORIAH CONSULTANTS	MERCY MEDICAL CTR, DES MOINES, IA - 483, EIR 11/13/08
2012-2634	04/10/2012 05/08/2012	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	MIKE CLOTHIER PERRIGO CO	LEO LABS LTD, DUBLIN, IRELAND - 483, EIR 2 MOST RECENT
2012-2635	04/10/2012 05/08/2012	FDA/OC/OES/DFOI/	MICHELE SINOWAY, Ph.D. LACHMAN CONSULTANT SERVICES INC	ASTRA ZENECA - NEXIUM (ESOMEPRAZOLE MAGNESIUM) NDA 21-153/S-008 RVW, APRL
2012-2636	04/10/2012 05/08/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	TRAVIS SCHAFTENAAR USB GLOBAL ASSET MANGEMENT	ANGIODYNAMIC, QUEENSBURY, NY - 483 1/4-13/11, 1/12
2012-2637	04/10/2012 05/08/2012	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	MARY BETH CONNER FALCON RESEARCH	DMAA (1,3 DIMETHYLAMYLAMINE) - AERS

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/		
2012-2638	04/10/2012 05/08/2012	FDA/OMPT/CDRH/OCER/DFOI/	ANNE SAVAS MAGSTIM COMPANY US LLC	NEXSTIM - K091457
2012-2639	04/10/2012 05/08/2012	FDA/OMPT/CDRH/OCER/DFOI/	ANNE SAVAS MAGSTIM COMPANY US LLC	MAGSTIM - K051864
2012-2640	04/10/2012 05/08/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 3/26-30/12
2012-2641	04/10/2012 05/08/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 3/26-30/12
2012-2642	04/10/2012 05/08/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	DAWN M. COULSON, Esq. EPPS YONG & COULSON LLP	WRIGHT MEDICAL TECHNOLOGY - METAL TRANSCEND ARTICULATION SYS K021349
2012-2643	04/10/2012 05/08/2012	FDA/OMPT/CDRH/OCER/DFOI/	DAWN M. COULSON, Esq. EPPS YONG & COULSON LLP	WRIGHT MEDICAL TECHNOLOGY - CONSERVE PLUS SPIKED SHELL & CONSERVE TOTAL 56MM FEMORAL HEAD K031963
2012-2644	04/10/2012 05/08/2012	FDA/OMPT/CDRH/OCER/DFOI/	DAWN M. COULSON, Esq. EPPS YONG & COULSON LLP	WRIGHT MEDICAL TECHNOLOGY - CONSERVE PLUS HA ACETABULAR SHELL K042530
2012-2645	04/10/2012 05/08/2012	OC/CVM/OCD/	MATTHEW MONEY PELLEGRINO AND ASSOCIATES LLC	NEW ANIMAL DRUG APPLICATIONS (NADA) - TOTAL NUMBER SUBMITTED AND TOTAL NUMBER APRVD 2001 TO 2011
2012-2646	04/10/2012 05/08/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LATESHA R. BAKER HINSHAW & CULBERTSON LLP	AVASTIN INJ STREPTOCOCCAL ENDOPHTHALMITIS OUTBREAK - RECS
2012-2647	04/10/2012 05/08/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	AMY EICHNER, Ph.D. UNITED STATES ANTI-DOPING AGENCY	ELI LILY - FORTHANE (METHYLHEXANAMINE) AERS, CORR, ANNUAL RPTS, ETC
2012-2648	04/10/2012 05/08/2012	OC/OM/OMP/DDM/	TARRA FULLER Hyman Phelps and McNamara PC	DKT FDA-1995-S-0039
2012-2649	04/11/2012 05/09/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	CAITLIN WILCOX IOVATE HEALTH SCIENCES INTERNATIONAL INC	GARDEN STATE NUTRIONAL, VITAQUEST INTERNATIONAL - DIETARY SUPPLEMNT FACILITIES US OR FOREIGN 483S
2012-2650	04/11/2012	OC/ORAI/	TRAVIS HULL	LIVINGSTON INTERNATIONAL, PBB GLOBAL LOGISTICS INC, GREAT LAKES CUSTOMS BROKERAGE INC, ETC - US

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	05/09/2012	OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/ FDA/OFVM/CFSAN/OCD/EOS/	LIVINGSTON INTERNATIONAL INC	AGENTS UNDER VARIOUS ACTS
2012-2651	04/11/2012 05/09/2012	FDA/OMPT/CDRH/OCER/DFOI/	M CASEY MATTOX ALLIANCE DEFENSE FUND	CURRENTLY ACTIVE CERTIFICATES, SUBMISSION TO OPERATE MAMMOGRAPHY FACILITES FROM PLANNED PARENTHOOD OF AMERICA LAST 5 YRS
2012-2652	04/11/2012 05/09/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/ OC/ORO/ OC/ORO/ORO/ OC/ORO/ORO/ OC/ORO/ OC/ORO/ FDA/OC/OPP/OP/	ELENA HOWELL HOGAN LOVELLS US LLP	FOOD FACILITY INSP PILOT PROJECTS 1/11 TO PRESENT
2012-2653	04/11/2012 05/09/2012	FDA/OO/OFBA/OAGS/	GARY GEIMAN KRELLER CONSULTING GROUP	CONTRACT #HHSF223200950158G
2012-2654	04/11/2012 05/09/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/	MARK A J FASSOLD WATTS GUERRA CRAFT LLP	DONJOY INC, CARLSBAD, CA; DJ ORTHOPEDICS LLC, VISTA, CA; DJO LLC, VISTA, CA, ETC - DONJOY ICEMAN, AIRCAST CRYO/CUFF EIRS, WARNING LTRS, CORR, ETC
2012-2655	04/11/2012 05/09/2012	FDA/OMPT/CDRH/OCER/DFOI/ OC/OCOS/OES/ OC/OCOS/OES/ OC/OCOS/OL/ FDA/OGROP/ORO/CE-FO/MIN- DO/MIN-CB/	JENNIFER NEWBERGER Hyman Phelps and McNamara PC	UNITED HEALTH, HEALTINNOVATIONS - ONLINE HEARING TEST CORR
2012-2656	04/11/2012 05/09/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DANIEL KOCH WALKER SMITH CAPITAL LP	SYNACTHEN DEPOT (TETRACOSACTRIN SINCE PHOSPHATE COMPLEX, SYNTHETIC ACTH) - 505(B) FILING, APRVL FILINGS
2012-2657	04/11/2012 05/09/2012	FDA/OMPT/CDRH/OCER/DFOI/	ALISON D KENNAMER COLVIN CHANEY SAENZ & RODRIGUEZ LLP	KCI VACUUM ASSISTED THERAPY FREEDOM SYS - MDRS PRIOR TO 9/5/08
2012-2658	04/11/2012 05/09/2012	FDA/OMPT/CDRH/OCER/DFOI/	ALISON D KENNAMER COLVIN CHANEY SAENZ & RODRIGUEZ LLP	KCI VACUUM ASSISTED THERAPY ATS SYS - MDRS PRIOR TO 9/5/08

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2012-2659	04/11/2012 05/09/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	NELSON LAM INTUITY MEDICAL	ARKRAY INC - K110709
2012-2660	04/11/2012 05/09/2012	FDA/OFVM/CFSAN/OCD/EOS/	SANNI RAJU PHD RPH Natreon, Inc.	EMBLICA OFFICINALIS GRAS 000322, 000295 - MEMOS, CORR
2012-2661	04/11/2012 05/09/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/PHI-DO/PHI-CB/	Doe J	CANYON CREEK RANCH - YAM DOG TREATS CONTAMINATION INVESTIGATION RECS
2012-2662	04/11/2012 05/09/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	BAYER, RANGE (RICHARD) D	HEMOGLOBIN STANDARDS AND MAINTAINING ADEQUATE IRON STORES IN BLOOD DONORS PUBLIC WORKSHOP PRESENTATIONS - REDS II DONOR IRON STUDY 11/8/11; IRON STORES AND IRON DEFICIENCY IN BLOOD DONORS 11/9/11; IRON STORES AND IRON REPLACEMENT IN BLOOD DONORS 11/9/11, ETC
2012-2663	04/11/2012 05/09/2012	FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	RANIL M FERNANDO BIOSCREEN TESTING SERVICES INC	MICRO CONNECTION ENTERPRISES, TORRANCE, CA - EIRS, 483S, WARNING LTRS ETC, LAST FIVE YRS
2012-2664	04/11/2012 05/09/2012	FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	RANIL M FERNANDO BIOSCREEN TESTING SERVICES INC	ACCU-BIO CHEM LABS, GLENDALE, CA - EIRS, 483S, WARNING LTRS ETC, LAST FIVE YRS
2012-2665	04/11/2012 05/25/2012	FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/	RANIL M FERNANDO BIOSCREEN TESTING SERVICES INC	PACIFIC BIOLABS, HERCULES, CA - EIRS, 483S, WARNING LTRS ETC, LAST FIVE YRS
2012-2666	04/11/2012 05/09/2012	FDA/OGROP/ORO/SW-FO/KAN-DO/KAN-CB/	TRAVIS SIVERSON BIRCHWOOD LABORATORIES INC	TRADEMARK MEDICAL LLC, BALDWIN, MO - EIR, 483 10/22/11-11/2/11
2012-2667	04/11/2012 05/09/2012	FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	RANIL M FERNANDO BIOSCREEN TESTING SERVICES INC	IRVINE PHARMACEUTICAL SERVICES, IRVINE, CA - EIRS, 483S, WARNING LTRS ETC, LAST FIVE YRS
2012-2668	04/11/2012 05/09/2012	FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	RANIL M FERNANDO BIOSCREEN TESTING SERVICES INC	SUNCARE RESEARCH LABORATORIES, WINSTON SALEM, NC - EIRS, 483S, WARNING LTRS ETC, LAST FIVE YRS
2012-2669	04/11/2012 05/09/2012	FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/	RANIL M FERNANDO BIOSCREEN TESTING SERVICES INC	AMA LABS, NEW CITY, NEW YORK - EIRS, 483S, WARNING LTRS ETC, LAST FIVE YRS

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2012-2670	04/11/2012 05/09/2012	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	RANIL M FERNANDO BIOSCREEN TESTING SERVICES INC	CELSIS LABS, ST LOUIS, MO - EIRS, 483S, WARNING LTRS ETC, LAST FIVE YRS
2012-2671	04/11/2012 05/09/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	RANIL M FERNANDO BIOSCREEN TESTING SERVICES INC	MICRO QUALITY LABS INC, BURBANK, CA - EIRS, 483S, WARNING LTRS ETC, LAST FIVE YRS
2012-2672	04/11/2012 05/09/2012	FDA/OMPT/CDRH/OCER/DFOI/OC/ORA/ OC/ORA/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	THOMAS M BURTON WALL STREET JOURNAL	ST JUDE MEDICAL INC - RIATA, RIATA ST DEFIBRILLATOR LEAD RPTS, CORR, ANALYSES, ETC
2012-2673	04/11/2012 05/09/2012	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	RANIL M FERNANDO BIOSCREEN TESTING SERVICES INC	NELSON LABS, ELK GROVE VILLAGE, IL - EIRS, 483S, WARNING LTRS ETC, LAST FIVE YRS
2012-2674	04/11/2012 05/09/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	RANIL M FERNANDO BIOSCREEN TESTING SERVICES INC	EXOVA, SANTA FE SPRINGS, CA - EIRS, 483S, WARNING LTRS, ETC, LAST FIVE (5) YRS
2012-2675	04/11/2012 05/09/2012	OC/OA/OM/OMP/DDM/	CHARLES COOPER BERENBERG BANK	PERIPHERAL AND CNS A/C - BETASERON 1993, AVONEX 1995, COPAXONE 1996, ETC RECS
2012-2676	04/11/2012 05/09/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BYOUNGIN JUNG SAMSUNG BIOEPIS CO LTD	CENTOCOR - REMICADE PK STUDY RESULTS
2012-2677	04/11/2012 05/09/2012	FDA/OC/OES/DFOI/	FLETCHER, MARY JANE	ACRYLAMIDE IN MCDONALD'S FOOD - RECS
2012-2678	04/12/2012 05/10/2012	FDA/OMPT/CDRH/OCER/DFOI/	MARSHALL, WAYNE	ZIMMER - CONTOUR PROVISIONAL COPING K113092
2012-2679	04/12/2012 05/10/2012	FDA/OMPT/CDRH/OCER/DFOI/	MARSHALL, WAYNE	ADJUSTABLE PM POSITIONER - K955503
2012-2680	04/12/2012 05/10/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DON J MIZERK HUSCH BLACKWELL LLP	MEGACE OS MDULE 2.7 ORAL SUSPENSION - NDA 20-264, ANDA 77-404, 75-671 BIOEQV PRODS, DEFICIENCIES, AMENDMENTS, ETC

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2012-2681	04/12/2012 05/10/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARY B SZALKOWSKI PRISMA CORP	INDAPAMIDE, PERINDOPRIL - AERS 1/19/12 TO PRESENT
2012-2682	04/12/2012 05/10/2012	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	MICHAEL LEDEBOER AS RESEARCH LLC	ATF SCI-FIT, PITTSBURG, PA - EIR 11/11, 3/12
2012-2683	04/12/2012 05/10/2012	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	TZU-HSUAN YANG PRO PHARMA TAIWAN INC	ASPEN SURGICAL PRODUCTS, CALEDONIA, MI - EIR
2012-2684	04/12/2012 05/10/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	MICHELLE THOMAS OCuSOFT, Inc.	ALTAIRE PHARMACEUTICALS INC, AQUEBOGUE, NY - EIRS 8/10 TO PRESENT
2012-2685	04/12/2012 05/10/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEVIN PYUN CONSONACC CAPITAL	BENLYSTA (BELIMUMAB) - AERS
2012-2686	04/12/2012 05/10/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/OA/OM/OMP/DDM/ OC/ORO/ OC/ORO/	ERIC H WEINBERG EIRC H WEINBERG ESQ ATTY	PRADAXA, DABIGATRAN ETEXILATE MEYSLATE - AERS, INDS, NDAS, ETC
2012-2687	04/12/2012 05/10/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/OA/OM/OMP/DDM/	SYLVIA L BRIDGES CANTOX Health Sciences International	MITSUBISHI CHEMICAL GAS CO INC - PYROLOQUINOLINE QUINONE DISODIUM SALT, DKT NO 6/11/07
2012-2688	04/12/2012 05/10/2012	OC/ORO/ OC/ORO/ OC/CVM/OCD/	MINDY LARCOM FOX 5 NEWS ATLANTA	CHICKEN JERKY DOG TREATS - CMLPNTS
2012-2689	04/12/2012 05/10/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	CAUSE OF ACTION	ACQUISITION OF COMMEMORATIVE COINS, TROPHIES, CERTICATES, ETC - EXPENDITURES FOR FISCAL YR, COMM, CRITERIA

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		FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CTP/OD/ OC/CVM/OCD/ OC/OCOS/OES/ OC/OCOS/OES/ OC/ORO/ OC/ORO/ OC/ORO/ORM/ OC/ORO/ORM/ OC/OIASI/OIP/IAS/ FDA/OMPT/CTP/OD/		
2012-2690	04/12/2012 05/10/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/	STEPHANIE ARMOUR BLOOMBERG NEWS	IMPORT REFUSAL RPTS 2001 TO PRESENT
2012-2691	04/12/2012 05/10/2012	FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	BRENDA MICHAEL DUANE MORRIS LLP	CAGLE'S INC, ROCKMART, GA; PINE MOUNTAIN VALLEY, GA - VIOLATIONS, FINES, PENALTIES
2012-2692	04/12/2012 05/10/2012	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	KRISTEN H STRAIN VENABLE LLP	REGLAN INJ NDA 17-862 - LBLG, PI
2012-2693	04/12/2012 05/10/2012	FDA/OMPT/CDRH/OCER/DFOI/	CLARICE ARRUDA PROCEDURE PRODUCTS INC	PROCEDURE PRODUCTS INC - 10CC SYRINGE CONTROL RING SET K874747
2012-2694	04/12/2012 05/10/2012	FDA/OMPT/CDRH/OCER/DFOI/	KELLY JABBAL ACCESS CLOSURE	BOSTON SCIENTIFIC CORP - OCCLUSION BALLOON CATHETER K062202
2012-2695	04/12/2012 05/10/2012	FDA/OMPT/CDRH/OCER/DFOI/	SCOTT HUNTSMAN BIOCARE MEDICAL	K042884, K103818
2012-2696	04/12/2012 05/10/2012	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	BARRY SUGARMAN DIVERSTECH CO	INO THERAPEUTICS (IKARIA) - INOMAX NDA 20-845 FDA FORM 3542, 3542A

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		FDA/OMPT/CDER/GRP/DIDP/		
2012-2697	04/12/2012	FDA/OMPT/CDER/GRP/DIDP/	LA TOYA SUTTON	BURT'S BEES - NATURAL ACNE SOLUTIONS PURIFYING
	05/10/2012	FDA/OMPT/CDER/GRP/DIDP/	MANATT PHELPS & PHILLIPS	GEL CLEANSER CORR, RECS
		FDA/OMPT/CDER/GRP/DIDP/		
		FDA/OMPT/CDER/GRP/DIDP/		
		FDA/OFVM/CFSAN/OCD/EOS/		
		OC/OCOS/OES/		
		OC/OCOS/OES/		
		OC/OCOS/OL/		
		FDA/OC/OES/DFOI/		
		FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/		
2012-2698	04/12/2012	FDA/OMPT/CDER/GRP/DIDP/	LA TOYA SUTTON	BURT'S BEES - NATURAL ACNE SOLUTIONS TARGETED
	05/10/2012	FDA/OMPT/CDER/GRP/DIDP/	MANATT PHELPS & PHILLIPS	SPOT TREATMENT CREAM CORR, RECS
		FDA/OMPT/CDER/GRP/DIDP/		
		FDA/OMPT/CDER/GRP/DIDP/		
		FDA/OFVM/CFSAN/OCD/EOS/		
		OC/OCOS/OES/		
		OC/OCOS/OES/		
		OC/OCOS/OL/		
		FDA/OC/OES/DFOI/		
		FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/		
2012-2699	04/12/2012	FDA/OMPT/CDER/GRP/DIDP/	LA TOYA SUTTON	BURT'S BEES - NATURAL ACNE SOLUTIONS DAILY
	05/10/2012	FDA/OMPT/CDER/GRP/DIDP/	MANATT PHELPS & PHILLIPS	MOISTURIZING LOTION CORR, RECS
		FDA/OMPT/CDER/GRP/DIDP/		
		FDA/OMPT/CDER/GRP/DIDP/		
		FDA/OFVM/CFSAN/OCD/EOS/		
		OC/OCOS/OES/		
		OC/OCOS/OES/		
		OC/OCOS/OL/		
		FDA/OC/OES/DFOI/		
		FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/		

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2012-2700	04/12/2012 05/10/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/ OC/OCOS/OES/ OC/OCOS/OES/ OC/OCOS/OL/ FDA/OC/OES/DFOI/ FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	LA TOYA SUTTON MANATT PHELPS & PHILLIPS	BURT'S BEES - NATURAL ACNE SOLUTIONS CLARIFYING TONER CORR, RECS
2012-2701	04/12/2012 05/10/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/ OC/OCOS/OES/ OC/OCOS/OES/ OC/OCOS/OL/ FDA/OC/OES/DFOI/ FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	LA TOYA SUTTON MANATT PHELPS & PHILLIPS	BURT'S BEES - NATURAL ACNE SOLUTIONS MAXIMUM STRENGTH SPOT TREATMENT CREAM CORR, RECS
2012-2702	04/12/2012 05/10/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/ OC/OCOS/OES/ OC/OCOS/OES/ OC/OCOS/OL/ FDA/OC/OES/DFOI/ FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	LA TOYA SUTTON MANATT PHELPS & PHILLIPS	BURT'S BEES - NATURAL ACNE SOLUTIONS PORE REFINING SCRUB CORR, RECS
2012-2703	04/12/2012	FDA/OMPT/CDER/GRP/DIDP/	LA TOYA SUTTON	BURT'S BEES - NATURAL ACNE SOLUTIONS REGIMEN KIT

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	05/10/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/ OC/OCOS/OES/ OC/OCOS/OES/ OC/OCOS/OL/ FDA/OC/OES/DFOI/ FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	MANATT PHELPS & PHILLIPS	CORR, RECS
2012-2704	04/12/2012 05/10/2012	FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/	RONALD A MARCHESANI ONYX PHARMACEUTICALS	ENZON INC - ONCASPER (PEGASPARGASE) WARNING LTRS, RECALLS, CORR ETC 2009 TO PRESENT
2012-2705	04/12/2012 05/10/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	EMCURE PHARMS, PUNE, INDIA - 483S 2/19/09, 8/19/09, 11/10/09, 11/22/09
2012-2706	04/12/2012 05/10/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	IPCA, SILVASA, INDIA - 483S 5/28/09
2012-2707	04/12/2012 05/10/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	UNICHEM LABS, ROHA, INDIA 5/22/09; PITHAMPUR, INDIA 5/28/09; GOA, INDIA 5/15/09 - 483S
2012-2708	04/13/2012 05/11/2012	OC/OM/OMP/DDM/	JONATHAN R. LUTINSKI WILSON SOSINI GOODRICH & ROSATI	DKT FDA-2006-P-0346
2012-2709	04/13/2012 05/11/2012	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	SYRON A JACK MASHEL LAW LLC	DPT LAKEWOOD INC, LAKEWOOD, NJ - 483 2/12 TO 3/12
2012-2710	04/13/2012 05/11/2012	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/ FDA/OGROP/ORA/SW-FO/DAL-	BECKY COOSEMAN BROWN & CROUPPEN PC	INDIVIDUAL RECS

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		DO/DAL-CB/		
2012-2711	04/13/2012 05/11/2012	FDA/OFVM/CFSAN/OCD/EOS/	RON SIMON SIMON & LUKE LLP	MULTISTATE OUTBREAK OF HUMAN SALMONELLA ENTERITIDIS ASSOCIATED WITH SHELL EGGS 5/10 TO 12/10; MULTISTATE OUTBREAK OF HUMAN SALMONELLA CHESTER ASSOCIATED WITH MARIE CALLENDER'S CHEESY CHICKEN & RICE 4/4/10-12/31/10. ETC
2012-2712	04/13/2012 05/11/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	TYSABRI (NATALIZUMAB) A/C - MEMO 7/20/07 (CERTIFIED)
2012-2713	04/13/2012 05/11/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	SCREENSHOT OF FDA WEBPAGE REGARDING TYSABRI (CERTIFIED)
2012-2714	04/13/2012 05/11/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	NEUROMED INC - MULTIPROGRAMMABLE INPLANTABLE NEUROLOGICAL STIMULATOR K833813
2012-2715	04/13/2012 05/11/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	FOI Services, Inc.	APP PHARMS, GRAND ISLAND, NY - CO RESP, 483 7/8/11
2012-2716	04/13/2012 05/11/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	2008-678
2012-2717	04/13/2012 05/11/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/OA/OM/OMP/DDM/	FOI Services, Inc.	DKT FDC 21 - WHOLE WHEAT STANDARD REGULATIONS
2012-2718	04/13/2012 05/11/2012	FDA/OMPT/CTP/OD/	FOI Services, Inc.	IDENTITY OF TOBACCO PRODS FOR WHICH FDA ISSUED AN ORDER OF SUBSTANTIAL EQUIVALANCE 3/22/11 TO PRESENT
2012-2719	04/13/2012 05/11/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	2012-1479
2012-2720	04/13/2012 05/11/2012	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	FOI Services, Inc.	J M SMUCKER, RIPON, WI - EIR, 483, WARNING LTR, ETC 1/12
2012-2721	04/13/2012 05/11/2012	OC/CVM/OCD/	FOI Services, Inc.	MASCOMA GRAIN TECHNOLOGY (MGT) - MEMOS, LTRS, TOXICOLOGY RVWS, ETC
2012-2722	04/13/2012 05/11/2012	OC/OA/OM/OMP/DDM/	TERI S KREBS NORWEGIAN UNIV OF SCIENCE AND TECHNOLOGY	JOINT FDA/NIMH PSYCHOTOMIMETIC A/C - MEMBER NAMES, RESERACH PROJECTS, PROGRESS RPTS, ETC 1967 TO 1975
2012-2723	04/13/2012 05/11/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	SIFAVITOR, ITALY - 483 3/27/09
2012-2724	04/13/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	PAMELA LOCATELL	GUTHY RENKER, SANTA MONICA, CA - 483 2011

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	05/11/2012		SAGE QUALITY SERVICE	
2012-2725	04/13/2012 05/11/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	PAMELA LOCATELL SAGE QUALITY SERVICE	COBE CHEMICAL CO INC, PICO RIVERA, CA - 483 8/25/10
2012-2726	04/13/2012 05/11/2012	OC/ORA/ OC/ORA/ OC/ORA/ORM/ OC/ORA/ORM/	JOHN DIEDRICH MILWAUKEE JOURNAL SENTINEL	FACTS DATABASE
2012-2727	04/13/2012 05/11/2012	FDA/OMPT/CDRH/OCER/DFOI/	ROBERTA LEE ACUEITY HEALTHCARE INC	EXCISOR BIOPTOME K032847
2012-2728	04/13/2012 05/11/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENDA M. GARTZ ELI LILLY & CO	CHANGZHOU PHARMACEUTICAL FACTORY, JIANGSU, CHINA - 483
2012-2729	04/13/2012 05/11/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KRISTEN H. STRIN VENABLE LLP	REGLAN NDA 17-862 LBLG 1/02
2012-2730	04/13/2012 05/11/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ERIC VARMA, M.D. ORACLE INVESTMENT MANAGEMENT	MAP PHARMS - LEVADEX (DIDYDROERGOTAMINE) 3/26/12
2012-2731	04/13/2012 05/11/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	PLEASE PROVIDE A VAERS LINE LIST REPORT OF ALL ADVERSE EXPERIENCES RECEIVED BY FDA for GARDASIL, (HPV VACCINE, MERCK & CO., INC.), FROM 1/1/2012 to 3/31/2012 ON CD ;
2012-2732	04/13/2012 05/11/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	REQUEST LETTER ONLY 2012-1307
2012-2733	04/13/2012 05/11/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	REQUEST LETTER 2012-1190
2012-2734	04/13/2012 05/11/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	REQUEST LETTER 2012-1184
2012-2735	04/13/2012 05/11/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	REQUEST LETTER 2012-1114
2012-2736	04/13/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	REQUEST LETTER 2012-1050

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	05/11/2012		MERCK & CO., INC.	
2012-2737	04/13/2012 05/11/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	REQUEST LETTER 2012-1338
2012-2738	04/13/2012 05/11/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	REQUEST LETTER 2012-1175
2012-2739	04/13/2012 05/11/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	REQUEST LETTER 2012-1028
2012-2740	04/13/2012 05/11/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	REQUEST LETTER 2012-949
2012-2741	04/13/2012 05/11/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	REQUEST LETTER 2012-948
2012-2742	04/13/2012 05/11/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 3/5-9/2012
2012-2743	04/13/2012 05/11/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	JoNel Aleccia MSNBC.COM	Date Range: 11/01/2011 - 03/28/2012; Msnbc.com requests copies of FDA Form 483 inspection documents issued to IntelliCell Biosciences Inc., of New York, after FDA inspections conducted in November and December 2011. Msnbc.com also requests copies of any other Form 483s that may have been issued to the firm. Correspondence between FDA and the firm would have gone to: Dr. Steven Victor Chief Executive Officer IntelliCell Biosciences, Inc. 30 East 76th Street New York, NY 10012
2012-2744	04/13/2012 05/11/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	PLEASE PROVIDE A LINE LISTING OF ALL ADVERSE EXPERIENCES REPORTED TO THE FDA for JUVISYNC, (SIMVASTATIN; SITAGLIPTIN PHOSPHATE: MERCK SHARP DOHME), FROM 1/1/2012 to 3/31/2012 ON CD
2012-2745	04/13/2012 05/11/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	PLEASE PROVIDE A VAERS LINE LIST REPORT OF ALL ADVERSE EXPERIENCES OF INTUSSUSCEPTION AND KAWASAKI DISEASE RECEIVED BY FDA for ROTATEQ, (ROTAVIRUS VACCINE, LIVE ORAL PENTAVALENT, MERCK & CO., INC.), FROM 1/1/2012 to 3/31/2012 ON CD
2012-2746	04/13/2012 05/11/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	PLEASE PROVIDE A LINE LISTING OF ALL ADVERSE EXPERIENCES REPORTED TO THE FDA for DULERA, (FORMOTEROL FUMARATE; MOMETASONE FUROATE, SCHERING), FROM 1/1/2012 to 3/31/2012 ON CD
2012-2747	04/13/2012 05/11/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	PLEASE PROVIDE A LINE LISTING OF ALL ADVERSE EXPERIENCES REPORTED TO THE FDA for VICTRELIS,

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		(BOCEPREVIR, SCHERING), FROM 1/1/2012 to 3/31/2012 ON CD
2012-2748	04/13/2012 05/11/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 3/12-16/2012;
2012-2749	04/13/2012 05/11/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 3/19-23/2012;
2012-2750	04/13/2012 05/11/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 3/26-30/2012
2012-2751	04/13/2012 05/11/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/ OC/OCOS/OES/ OC/OCOS/OES/ OC/OCOS/OL/ FDA/OC/OES/DFOI/	BRODY MULLINS WALL STREET JOURNAL	CORR BETWEEN FDA & MICHAEL SULLIVAN 1/09 TO 4/1/12
2012-2752	04/13/2012 05/11/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	"A list of all FOIA requests closed 3/1-31/2012" on CD
2012-2753	04/13/2012 05/11/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	SCHUMAN, AUSTIN L	P890046/S020,S027; K002703, K954124
2012-2754	04/13/2012 05/11/2012	OC/ORA/OCI/ OC/ORA/OCI/	Doe J	2012-1692
2012-2755	04/13/2012 05/11/2012	OC/ORA/OCI/ OC/ORA/OCI/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Doe J	2012-1692
2012-2756	04/13/2012 05/11/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PETER G ANGELOS LAW OFC	SANOFI AVENITS - ELOXATIN AER, RECALL

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/		
2012-2757	04/13/2012 06/04/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	TIFFANY K. HANNUS LOMMEN ABDO COLE KING STAGEBERG PA	INDIVIDUAL RECS, CERTIFIED
2012-2758	04/13/2012 05/11/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	YEOLAN LEE OHIO STATE UNIVERSITY	ORANGE BOOK 1985 TO 1989
2012-2759	04/16/2012 07/05/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	HARVEY M ARBIT ARBIT CONSULTING LLC	THERADOME INC, SUMMERVILLE, NC - LASER HELMENT LH80 PRO K113097
2012-2760	04/16/2012 05/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	NANCH SCHON OXUS	RESPIRONICS - SIMPLY GO PORTABLE OXYGEN CONCENTRATOR K112886
2012-2761	04/16/2012 05/14/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ALBERT C BEATTY JR MD	MIRAPEX (PRAMIPEXOLE) - AERS
2012-2762	04/16/2012 05/14/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ALBERT C BEATTY JR MD	AZILECT - AERS
2012-2763	04/16/2012 05/14/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/CVM/OCD/	NICOLE BEARCE LOWENSTEIN SANDLER ATTY	BRISTOL-MYERS SQUIBB - AMPHO B LOT NDA 60-570; AMPHOTERCIN - B (FUNGIZONE) NDA 50-341, NDA 61-144, NDA 62-259, ETC; CHOLOGRAFIN (MEGLUMINE) NDA 9-321, ETC
2012-2764	04/16/2012 05/14/2012	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	JOHN WALSH JAMES ALEXANDER CORP	PHARMACO-AAPER PRODUCTS INC, BROOKFIELD, CT - EIRS, 483S, RECALLS 4/09 TO PRESENT

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2012-2765	04/16/2012 05/14/2012	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/ FDA/OC/OES/DFOI/	CORI SCHRADER BIOQUALITY	APP PHARMACEUTICALS LLC, GRAND ISLAND, NY 1/13/10; AMGEN INCORP, LONGMONT, CO 9/3/10; AMGEN INC, BOULDER, CO 9/3/10 - 483S, ETC
2012-2766	04/16/2012 05/14/2012	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Doe J	GENENTECH MFG PLANT, SOUTH SAN FRANCISCO, CA - EIRS 1/07 TO PRESENT
2012-2767	04/16/2012 05/14/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 4/2-6/12
2012-2768	04/16/2012 05/14/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOI REQUESTS 4/2-6/12
2012-2769	04/16/2012 05/14/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	CLOSED FOI REQUESTS 4/2-6/12
2012-2770	04/16/2012 05/14/2012	FDA/OFVM/CFSAN/OCD/EOS/	RICHARD F TAYLOR TC Associates Inc.	FUJI HEALTH SCIENCE INC, BURLINGTON, NJ - ASTAXANTHIN 12 MG NEW DIETARY INGREDIENT NOTIFICATION (NDIN), COMM 12/7/11
2012-2771	04/16/2012 05/14/2012	FDA/OFVM/CFSAN/OCD/EOS/OC/OA/OM/OMP/DDM/	RICHARD F TAYLOR TC Associates Inc.	GRAS ASSOCIATES LLC, BEND, OR - ASTAXANTHIN 12 MG NEW DIETARY INGREDIENT NOTIFICATION (NDIN), COMM 12/7/11
2012-2772	04/16/2012 05/14/2012	FDA/OMPT/CTP/OD/	SUZANNE D JENSEN Kleinfeld, Kaplan and Becker, LLP	HBI TECHNOLOGIES,, HBI HERBAL BAR INDUSTRIES, HBI INTERNATIONAL, ETC - REGULATORY SUBMISSIONS LIST, PRODUCTS INVOLVED, EIRS ETC
2012-2773	04/16/2012 05/14/2012	FDA/OC/OES/DFOI/	JASON SMATHERS MUCKROCK NEWS	PINK SLIME - RECS
2012-2774	04/16/2012	FDA/OC/OSHC/OPD/	JAMES A BOIANI	HYPERION THERAPEUTICALS INC - GLYCEREL TRI (4-PHENYLBUTYRADE) LTRS, MINS, DESIGNATION APPL

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	05/14/2012	FDA/OMPT/OSMP/OCP/ FDA/OMPT/OSMP/OOPD/ FDA/OMPT/OSMP/OCP/	EPSTEIN BECKER & GREEN PC	4/27/09
2012-2775	04/16/2012 05/14/2012	FDA/OC/OES/DFOI/	JASON SMATHERS MUCKROCK NEWS	DIVESTITURE OF PROHIBITED HOLDINGS - VINCE TOLINO MEMOS, LAST 60 DAYS
2012-2776	04/16/2012 05/14/2012	FDA/OC/OSHC/OPD/ FDA/OMPT/OSMP/OCP/ FDA/OMPT/OSMP/OOPD/	JAMES A BOIANI EPSTEIN BECKER & GREEN PC	ORPHAN DRUG DESIGNATION - IMPROVEMENTS IN PROD TASTE LTRS, MINS, DECISION RECS, ETC
2012-2777	04/16/2012 05/14/2012	FDA/OC/OSHC/OPD/ FDA/OMPT/OSMP/OCP/ FDA/OMPT/OSMP/OOPD/	JAMES A BOIANI EPSTEIN BECKER & GREEN PC	NAVINTA LLC - SODIUM PHENYLBUTYRATE LTRS, MINS, APPL 1/19/10
2012-2778	04/16/2012 05/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SHIPMAN, KIM	NOVARTIS - AREDOA ISRS 3977064, 3977066, 3977038 ETC
2012-2779	04/16/2012 05/23/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	TONY CHEN FDAZILLA	483S - 9/1/11 TO PRESENT
2012-2780	04/16/2012 05/14/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/ OC/ORO/ OC/OCM/EMOPS/ FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/	STEPHANIE ARMOUR BLOOMBERG NEWS	SAINTPAUL SALMONELLA OUTBREAK 2008; MEXICO PAPAYAS SALMONELLA OUTBREAK 2011 - EIRS, NAMES OF FARMS, PACKING HOUSES, ETC
2012-2781	04/16/2012 05/14/2012	FDA/OC/OES/DFOI/	AMY KINCANON LEXISNEXIS COURTLINK INC	2010-1736
2012-2782	04/16/2012 05/14/2012	FDA/OC/OES/DFOI/	AMY KINCANON LEXISNEXIS COURTLINK INC	2010-1737
2012-2783	04/16/2012 05/14/2012	FDA/OC/OES/DFOI/	AMY KINCANON LEXISNEXIS COURTLINK INC	2010-1738
2012-2784	04/17/2012 05/15/2012	FDA/OMPT/CDRH/OCER/DFOI/	CAROL NAKAGAWA MERGE HEALTHCARE	MIM SOFTWARE INC - MOBILE MIM K112930
2012-2785	04/17/2012 05/15/2012	FDA/OFVM/CFSAN/OCD/EOS/	ROACH, ALICE	MONSANTO CO - MON 87701 LEPIDOPTERAN INSECT-RESISTANT SOYBEAN GRAS, SAFETY & NUTRITIONAL FILINGS, ETC

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2012-2786	04/17/2012 05/15/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	AMY MARTEL CYNTHIA R CHIHAK & ASSOCS	ALLEZ SPINE LLC (PHYGEN LLC), IRVINE, CA - EIRS, 483S, CORR, ETC 2007 TO PRESENT
2012-2787	04/17/2012 05/15/2012	FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/	LENA D GIANGROSSO PROVOSTY & GANKENDORFF LLC	TEXAMERICAN, DALLAS, TX; HOT SPRINGS, AR - VIOLATIONS, CMLPNTS, RPTS, ETC
2012-2788	04/17/2012 05/17/2012	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	BECKY COOSEMAN BROWN & CROUPPEN PC	SPLS 614606, 614607, 614808, ETC - NOTES, RESULTS, W/S, ETC
2012-2789	04/17/2012 05/15/2012	FDA/OMPT/CDRH/OCER/DFOI/	DEBORAH LAVOIE GRAYESKI M SQUARED ASSOCIATES INC	CYNOSURE - CELLULAZE LASER K102541
2012-2790	04/17/2012 05/15/2012	FDA/OO/OFBA/OAGS/	GARY GEIMAN KRELLER CONSULTING GROUP	DUN & BRADSTREET - CONTRACT #HHSF223200950158G INVOICES
2012-2791	04/17/2012 05/15/2012	FDA/OO/OFBA/OAGS/	GARY GEIMAN KRELLER CONSULTING GROUP	DUN & BRADSTREET - CONTRACT #HHSF223200950158G
2012-2792	04/17/2012 05/15/2012	FDA/OMPT/CDRH/OCER/DFOI/	MARTIN HERZOG MED-EL MEDICAL ELECTRONICS	MED-EL ELEKTROMEDIZINISCHE GERAETE, INNSBRUCK AUSTRIA - EIR 11/23/09
2012-2793	04/17/2012 05/15/2012	OC/CVM/OCD/	PAUL MOSTYN WESTWAY FEED PRODUCTS LLC	BIODIESEL-DERIVED GLYCERIN - TENTATIVE DEFINITION RECS
2012-2794	04/17/2012 05/15/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	CREAN, SARAH	NEW YORK SHELLFISH SANITATION PROGRAM - ANNUAL EVALUATION RPT (APER) FY 2011; NEW YORK SHELLFISH GROWING AREA CLASSIFICATION ELEMENT - PROGRAM ELEMENT EVALUATION RPT (PEER) 2009, 2011
2012-2795	04/17/2012 05/15/2012	FDA/OC/OES/DFOI/	PICHE, JESSICA	WARNING LTRS ISSUED TO COMPANIES REGARDING ARSENIC IN JUICE LAST 2 YRS
2012-2796	04/17/2012 06/05/2012	FDA/OMPT/CDRH/OCER/DFOI/	LISA ANDERSON CONMED CORP	IMAGYN TECHNOLOGIES - TISSUE ISOLATION & RETRIEVAL BAG K931886
2012-2797	04/17/2012 05/15/2012	FDA/OMPT/CDRH/OCER/DFOI/	AMBER R JOHNSON BOSTON SCIENTIFIC CORP	NAVILYST MEDICAL INC - MULTIPURPOSE DRAINAGE CATHETER K093392
2012-2798	04/17/2012 05/15/2012	OC/ORAI/ OC/ORAI/	PAULINE MARALIT MEDLINE INDUSTRIES INC	ENTRY #916-2189404-6, #916-2189453-3 - LAB RESULTS
2012-2799	04/17/2012 05/15/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELLIOT FAVUS MD FAVUS INSTITUTIONAL RESEARCH LLC	JAKAFI (RUXOLITINIB) - AERS 7/11 TO PRESENT

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		FDA/OMPT/CDER/ORP/DIDP/		
2012-2800	04/17/2012 05/15/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELLIOT FAVUS MD FAVUS INSTITUTIONAL RESEARCH LLC	ADCETRIS (BRENTUXIMAB VEDOTIN) - AERS 3/15/12 TO PRESENT
2012-2801	04/17/2012 05/15/2012	FDA/OMPT/CDRH/OCER/DFOI/	HAMILTON, LEROY L	DVCS WHICH ARE CONSIDERED TO PRESENT A POTENTIAL UNREASONABLE RISK OF ILLNESS OR INJURY PART3
2012-2802	04/17/2012 05/15/2012	FDA/OMPT/CDRH/OCER/DFOI/	HAMILTON, LEROY L	DVCS WHICH ARE CONSIDERED TO PRESENT A POTENTIAL UNREASONABLE RISK OF ILLNESS OR INJURY PART2
2012-2803	04/17/2012 05/15/2012	FDA/OMPT/CDRH/OCER/DFOI/	HAMILTON, LEROY L	DVCS WHICH ARE CONSIDERED TO PRESENT A POTENTIAL UNREASONABLE RISK OF ILLNESS OR INJURY PART1
2012-2804	04/18/2012 05/16/2012	OC/CVM/OCD/ FDA/OFVM/CFSAN/OCD/EOS/	SIDNEY M WOLFE PUBLIC CITIZEN	CARRAGEENAN EFFECTS ON ANIMALS & HUMANS - RECS, MEMOS
2012-2805	04/18/2012 05/16/2012	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	HOWELL ARNOLD PARALLON BUSINESS SOLUTIONS	PARALLON BUSINESS SOLUTIONS, DENVER, CO - EIRS, 483S
2012-2806	04/18/2012 05/16/2012	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/ FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	CONNER, MARYBETH	GREEN MOUNTAIN COFFEE, CASTROVILLE, CA; KNOXVILLE, TN, WATERBURY, VT ETC - EIRS, 483 LAST 2 YRS
2012-2807	04/18/2012 05/16/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARGARET FILIPIAK PHARMACEUTICAL REGULATORY AFFAIRS	SCINOPHARM TAIWAN LTD - EIRS 10/20-23/08
2012-2808	04/18/2012 05/16/2012	FDA/OMPT/CDRH/OCER/DFOI/	LISA BURNS CHURCH & DWIGHT CO INC	K070054 & K100355

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2012-2809	04/18/2012 05/16/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN LDIEDRICH MILWAUKEE JOURNAL SENTINEL	PDI, ORANGEBURG, NY - MED WATCH CMLPTS #US-193105 & US-FDA-456119
2012-2810	04/18/2012 05/16/2012	FDA/OMPT/CTP/OD/	NATALIE N SANDERS LATHLAM & WATKINS LLP	REQUESTS FOR EXEMPTIONS FOR TOBACCO PRODUCTS, COMM RECS
2012-2811	04/18/2012 05/16/2012	FDA/OFVM/CFSAN/OCD/EOS/	JEFF SPEDDING API-ADDITIVES FOR PAPER INDUSTRY GMBH	ICL-IP AMERICA INC - APIGARD 01 (AMMONIUM BROMIDE 35% AQUEOUS SOL) FCN 959
2012-2812	04/18/2012 05/16/2012	OC/ORA/ OC/ORA/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	MELISSA MANDELL PAUL SANDLER TRAVIS & ROSENBERG PA	ENTRY #BAO-00136668-9 - INVESTIGATIVE RPT
2012-2813	04/18/2012 05/16/2012	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	DANA THOMPSON FULBRIGHT & JAWORSKI LLP	ACELLA PHARMACUTICALS LLC, ALPHARETTA, GA - EIRS, 483S, 482S ETC 11/09 TO PRESENT
2012-2814	04/18/2012 05/16/2012	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	JANET R NAAS ST MARY'S MEDICAL CENTER	ST MARYS MEDICAL CTR, EVANSVILLE, IN - 482 9/12/11
2012-2815	04/18/2012 05/16/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KARIMAH S LYNUM DEPT OF VETERANS AFFAIRS MEDICAL CTR	AMBIEN (ZOLPIDEM)/AMBIEN XR (ZOLPIDEM XR) - SUDDEN DEATH AERS
2012-2816	04/18/2012 05/16/2012	FDA/OMPT/CDRH/OCER/DFOI/	DEBRA F MANNING COEUR INC	COEUR - COEUR 16" LONG CATHETER W/ADAPTOR, 14FR & 12 FR, K885202 (UNREDACTED) FMD
2012-2817	04/18/2012 05/16/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	TERRY ASBERT LEEMON+ROYER PLLC	DEPUY PINNACLE 100 SERIES - 52 MM OUT DIAMETER TITANIUM CUP, PINNACLE IDE METAL INSERT, 36MM ID, 52 MM OD, 10.5 MM SMALL STATUTE AMS FEMORAL STEM ETC, AERS
2012-2818	04/18/2012 05/16/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HARTWELL P MORSE, III HUSCH BLACKWELL LLP	MYLAN PHARMS INC ABBREVIATED NEW DRUG APPL #078995, RLD:IBANDRONATE SODIUM EQ 150MG BASE - TABLET, ORAL - FDA APRVL LTR 3/19/12
2012-2819	04/18/2012 05/16/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HARTWELL P MORSE, III HUSCH BLACKWELL LLP	ORCHID HEALTHCARE, ABBREVIATED NEW DRUG APPL #078998 RLD: IBNDRONATE SODIUM EQ 150MG BASE, TABLET/ORAL - FDA APRVL LTR 3/19/12

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2012-2820	04/18/2012 05/16/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HARTWELL P MORSE, III HUSCH BLACKWELL LLP	WATSON LABS INC, ABBREVIATED NEW DRUG APPL #079003 RLD: IBANDRONATE SODIUM EQ 150MG BASE, TABLET/ORAL - FDA APRVL LTR 3/20/12
2012-2821	04/18/2012 05/29/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ FDA/OFVM/CFSAN/OCD/EOS/	LA TOYA SUTTON MANATT PHELPS & PHILLIPS LLP	BURT'S BEES NATUAAL ACNE SOLUTIONS MAXIMUM STRENGTH SPOT TREATMENT CREAM, PURIFYING GEL CLEANSER, DAILY MOISTURIZING LOTION ETC - RECS, CORR
2012-2822	04/18/2012 05/16/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	STEPHEN E. BRANDT, R.Ph. Garden State Phamacy Owners, Inc.	NUMBER OF APRVD SPECIALTY DRUGS THAT CAN BE DISPENSED BY LICENSED COMMUNITY PHARMACIES
2012-2823	04/18/2012 05/16/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/OCS/NCTR/OD/ OC/ORA/ OC/ORA/ FDA/OGROP/ORA/ORO/DIOP/	PICHE, JESSICA	ARSENIC IN JUICE COMPLIANCE/INFRACTION NOTICES - MFR, COUNTRY OF ORIGIN, BRAND NAMES, ETC LAST 2 YRS
2012-2824	04/18/2012 05/16/2012	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/ORO/DIOP/	PICHE, JESSICA	ARSENIC IN JUICE BLOCKED SHIPMENTS - MFR, COUNTRY OF ORIGIN, BRAND NAMES, ETC LAST 2 YRS
2012-2825	04/19/2012 05/17/2012	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	SHIRLEY ROSS ROANOKE TRADE SERVICES INC	NAVIGATORS INSURANCE - ENTRY #AR820069334
2012-2826	04/19/2012 05/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	DR. PAUL KOSTERS FINAPRES MEDICAL SYSTEMS BV	FINAPRES MEDICAL SYS BV - FINOMETER NONINVASIVE HEMODYNAMIC MONITOR MODEL 1 K023723
2012-2827	04/19/2012 05/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	DR. PAUL KOSTERS FINAPRES MEDICAL SYSTEMS BV	FINAPRES MEDICAL SYS BV - FINOMETER MODEL 2 W/ACCESORIESK063111
2012-2828	04/19/2012	FDA/OMPT/CDER/ORP/DIDP/		LSD CLNCL THERAPEUTIC RESEARCH 1950-1975

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	05/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/OA/OM/OMP/DDM/	ORAM, MATTHEW	
2012-2829	04/19/2012 05/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RIVERA AS-2743, ROBERTO	PROZAC, PAXIL, TRAZADONE, REMERON - AER
2012-2830	04/19/2012 05/17/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SE-FO/NOL- DO/NOL-CB/	PARIS, CASSANDRA .	CMLPNT 123465
2012-2831	04/19/2012 05/17/2012	FDA/OFVM/CFSAN/OCD/EOS/	MADHU SONI SONI & ASSOCIATES INC	GREEN TEA - AER 1/05 TO 3/12
2012-2832	04/19/2012 05/17/2012	FDA/OGROP/ORO/CE-FO/MIN- DO/MIN-CB/ FDA/OGROP/ORO/SE-FO/NOL- DO/NOL-CB/	PETER DiGASBARRO TRADEMARK MEDICAL	BIRCHWOOD LABS, EDIN PRAIRIE, MN - MOTHWASH INVESTIGATION 10/25/11-11/4/11
2012-2833	04/19/2012 05/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RICHARDSON MD, KARL	STATIN - AER
2012-2834	04/19/2012 05/17/2012	FDA/OGROP/ORO/NE-FO/NYK- DO/NYK-DCB/	JANET DIXON, RN, JD CHILDRENS HOSPITAL OF WISCONSIN	KENDALL HEALTHCARE - EIR 2011, 2012
2012-2835	04/19/2012 05/17/2012	OC/ORO/ OC/ORO/	MATT SCHRADER KOVY-TV	CHICKEN JERKY TREAT CMLPNTS 2011 TO PRESENT
2012-2836	04/19/2012 05/17/2012	FDA/OC/OES/DFOI/	TAYLOR X51082, MILMUS	BENEFITS AVAILABLE TO PRISONERS
2012-2837	04/19/2012 05/17/2012	FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/	DANA THOMPSON FULBRIGHT & JAWORSKI LLP	ULTIMATE FORMULATIONS INC, CITY OF INDUSTRY, CA - 482, 483 2/10 TO PRESENT
2012-2838	04/19/2012 05/17/2012	FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/	DANA THOMPSON FULBRIGHT & JAWORSKI LLP	CAPTEK SOFTGEL INTL INC, CERRITOS, CA - 482, 483 2/10 TO PRESENT
2012-2839	04/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	CAROL NAKAGAWA	CARESTREAM HEALTH INC - LIGHTWEIGHT VIEWER K110919

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	05/17/2012		MERGE HEALTHCARE	
2012-2840	04/19/2012 05/17/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	CAROL NAKAGAWA MERGE HEALTHCARE	MIM SOFTWARE INC - MOBILE MIM K103785
2012-2841	04/19/2012 05/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GREGORY J. WOOD O'LEARY WOOD ET AL LLP	ARTCAINE - AER, APRVL
2012-2842	04/20/2012 05/18/2012	OC/OM/OMP/DDM/	KRISTI SMEDLEY WASHINGTON INFORMATION SOURCE	DKT 1995G-0039
2012-2843	04/20/2012 05/18/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 3/26-30/12
2012-2844	04/20/2012 05/18/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 3/19-23/12
2012-2845	04/20/2012 05/18/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 3/26-30/12
2012-2846	04/20/2012 05/18/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 3/19-23/12
2012-2847	04/20/2012 05/18/2012	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 3;/26/30/12
2012-2848	04/20/2012 05/18/2012	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 3/19-23/12
2012-2849	04/20/2012 05/18/2012	FDA/OC/OES/DFOI/	GLADYS B TONKIN WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 3/26-30/12
2012-2850	04/20/2012 05/18/2012	FDA/OC/OES/DFOI/	GLADYS B TONKIN WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 3/19-23/12
2012-2851	04/20/2012 05/18/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 3/26-30/12
2012-2852	04/20/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP	FOI DAILY LOG 3/19-23/12

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	05/18/2012		CanReg, Inc.	
2012-2853	04/20/2012 05/18/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 3/26-30/12
2012-2854	04/20/2012 05/18/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 3/19-23/12
2012-2855	04/20/2012 05/18/2012	FDA/OC/OES/DFOI/	INC REGULATORY CONSULTING & SUBMISSIONS	FOI DAILY LOG 3/19-23/12
2012-2856	04/20/2012 05/18/2012	FDA/OC/OES/DFOI/	INC REGULATORY CONSULTING & SUBMISSIONS	FOI DAILY LOG 3/26-30/12
2012-2857	04/20/2012 05/18/2012	FDA/OC/OES/DFOI/	FRAN KOCH INFORMATION ACCESS	FOI DAILY LOG 3/26-30/12
2012-2858	04/20/2012 05/18/2012	FDA/OC/OES/DFOI/	FRAN KOCH INFORMATION ACCESS	FOI DAILY LOG 3/19-23/12
2012-2859	04/20/2012 05/18/2012	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	ROGER DONALDSON ALLSTATE INSURANCE CO	PRESCRIPTION PARTNERS - EIRS, AUDITS, POLICES, ETC
2012-2860	04/20/2012 05/18/2012	FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/	ROGER DONALDSON ALLSTATE INSURANCE CO	INDUSTRIAL PHARMACY MANAGEMENT - EIRS, AUDITS POLICES, ETC
2012-2861	04/20/2012 05/18/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARK FRANZEN PRECISION DOSE INC	RISPERIDONE ORAL SOL 1 MG/ML ANDA 76-797 - ELECTONIC SEQUENCES SN000 TO SN0015
2012-2862	04/20/2012 05/18/2012	FDA/OFVM/CFSAN/OCD/EOS/	FATIMA ASLAM Keller and Heckman LLP	MARS INC - CAP 2C0293 SPIRYCINA BLUE
2012-2863	04/20/2012 05/18/2012	FDA/OGROP/ORR/PA-FO/SAN-DO/SAN-CB/ FDA/OFVM/CFSAN/OCD/EOS/	BOBBY SCHOCHET OLSSON FRANK WEEDA TERMAN MATZ PC	CYTOSPORT INC - CORR, MINS REGARDING WARNING LTR 6/29/11
2012-2864	04/20/2012 06/25/2012	FDA/OFVM/CFSAN/OCD/EOS/	PAULINA DO EXPONENT	AMERICAN BOTTLED WATER ASSN - GRAS 4G0043
2012-2865	04/20/2012 05/18/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OCC/	JOY J LIU ROPES GRAY LLP	FRENCH BRONZE TABLETS, NEW YORK, NY - DKT 88CB1936 VERIFIED CMLPNT 6/20/88, AMENDED & SUPPL VERIFIED CMLPNT 9/30/88 , NOTICE OF MOTION FOR SUMMARY JUDGMENT 12/19/88, ETC
2012-2866	04/20/2012	FDA/OMPT/CDER/ORP/DIDP/	DUSTIN BLOCK	DOXYCYCLINE HYCLATE ANDA 91-052 - APRVL LTR 2/8/12

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	05/18/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	IPD ANALYTICS LLC	
2012-2867	04/20/2012 05/18/2012	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	DANA THOMPSON FULBRIGHT & JAWORSKI LLP	ARIZONA NUTRITIONAL SUPPLEMENTS INC, CHANDLER, AZ - EIRS, 483S, WARNING LTRS, ETC 1/10 TO PRESENT
2012-2868	04/20/2012 05/18/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	R IAN KLUGE Hyman, Phelps & McNamara P.C.	AZTREONAM ANDA 65-439, ANDA 65-286 - APRVL RECS
2012-2869	04/20/2012 05/18/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BARBARA MORRISON BIOMARIN PHARMACEUTICAL INC	ALDURAZYME BLA 125058 - STATISTICAL RVWS, CORR
2012-2870	04/20/2012 05/18/2012	FDA/OGROP/ORAP/SE-FO/FLA-DO/FLA-CB/	ANDREW M PARISH ESQ ANDREW M PARISH PA	ENTRY #86201240565 - RECS
2012-2871	04/20/2012 05/18/2012	FDA/OFVM/CFSAN/OCD/EOS/	CHRISTOPHER HANDEL CONSUMER REPORTS	DIETARY SUPPLEMENTS - CAERS 2008 TO PRESENT
2012-2872	04/20/2012 05/18/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KATHLEEN G ENGER HOSPIRA INC	AMIDATE (ETOMIDATE INJ) NDA 18-227 - MEDICAL RVW
2012-2873	04/20/2012 05/18/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	STEVE ROOSE MD Columbia Univ. College of Physicians and Surgeons	CELEXA (CITALOPRAM HYDROBROMIDE) - POST MARKETING RPTS, QT STUDY RECS, BLACK BOX WARNING, ETC
2012-2874	04/20/2012 05/18/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	KRETZ, MICHAEL	AMERIGEL OINTMENT K970133 - INDICATIONS, LIMITATIONS
2012-2875	04/20/2012 05/18/2012	FDA/OMPT/CDRH/OCER/DFOI/	GILI FALBISH NAVOTEK MEDICAL LTD	INTUITIVE SURGICAL INC - DA VINCI SURGICAL SYS K101581
2012-2876	04/20/2012 05/18/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/CVM/OCD/	JoNel Aleccia MSNBC.COM	Date Range: 01/01/2012 - 04/13/2012; Any and all FDA Inspection records of plants in China that produce chicken jerky pet treats.
2012-2877	04/20/2012 05/18/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ATUL KHARE PHD AKORN INC	ALCON LABORATORIES INC - TOBRADEX (TOBRAMYCIN & DEXAMETHASONE OPHTHALMIC OINTMENT) NDA 50-616

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2012-2878	04/20/2012 05/18/2012	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	MSNBC.COM	Date Range: 08/27/2003 - 10/24/2011; FDA Form 483 inspection records for Diamond Wipes International Inc. of Chino, Calif. Specific dates from August 2003 through October 2011.
2012-2879	04/20/2012 05/18/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ORIGINAL REQUEST LETTER 2012-2279
2012-2880	04/20/2012 05/18/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ORIGINAL REQUEST LETTER 2012-2333
2012-2881	04/20/2012 05/18/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ATUL KHARE PHD AKORN INC	BAXTER HEALTHCARE CORP - NEXTERONE (AMIODARONE HCL) NDA 22-325
2012-2882	04/20/2012 05/18/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ORIGINAL REQUEST LETTER 2012-2336
2012-2883	04/20/2012 05/18/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ORIGINAL REQUEST LETTER 2012-1812
2012-2884	04/20/2012 05/18/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ORIGINAL REQUEST LETTER 2012-1777
2012-2885	04/20/2012 05/18/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-731
2012-2886	04/20/2012 05/18/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-2199
2012-2887	04/20/2012 05/18/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ORIGINAL REQUEST LETTER 2012-2203
2012-2888	04/20/2012 05/18/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-2050
2012-2889	04/20/2012 05/18/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-794
2012-2890	04/20/2012 05/18/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-2053
2012-2891	04/20/2012 05/18/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-2045
2012-2892	04/20/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	ORIGINAL REQUEST LETTER 2012-2072

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	05/18/2012		MERCK & CO., INC.	
2012-2893	04/20/2012 05/18/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ORIGINAL REQUEST LETTER 2012-1965
2012-2894	04/20/2012 05/18/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ORIGINAL REQUEST LETTER 2012-2080
2012-2895	04/20/2012 05/18/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ORIGINAL REQUEST LETTER 2012-1890
2012-2896	04/20/2012 05/18/2012	FDA/OMPT/CDRH/OCER/DFOI/	DAVID SZYDLOSKI KEITH L DAVIDSON LAW OFC	MEDTRONIC - CAPSURE PACING LEAD MODEL 4695 P950024S001-S041
2012-2897	04/20/2012 05/18/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-805
2012-2898	04/20/2012 05/18/2012	FDA/OMPT/CDRH/OCER/DFOI/	DAVID SZYDLOSKI KEITH L DAVIDSON LAW OFC	MEDTRONIC - CAPSURE PACING LEAD MODEL 4695 P950024
2012-2899	04/20/2012 05/18/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ORIGINAL REQUEST 2012-2091
2012-2900	04/20/2012 05/18/2012	FDA/OMPT/CDRH/OCER/DFOI/	DAVID SZYDLOSKI KEITH L DAVIDSON LAW OFC	MEDTRONIC - KAPPA 700/600 SERIES PULSE GENERATORS & MODEL 9953 SOFTWARE P980035
2012-2901	04/20/2012 05/18/2012	FDA/OMPT/CDRH/OCER/DFOI/	DONALD GRIGGS CONVAID	K082314
2012-2902	04/20/2012 05/18/2012	FDA/OMPT/CDRH/OCER/DFOI/	DONALD GRIGGS CONVAID	K111045
2012-2903	04/20/2012 05/18/2012	FDA/OMPT/CDRH/OCER/DFOI/	DONALD GRIGGS CONVAID	K111739
2012-2904	04/20/2012 05/18/2012	FDA/OC/OES/DFOI/	DEAN GRESHAM PAYNE MITCHELL LAW GROUP	WARNING LETTERS SINCE 2009 REGARDING ALL NATURAL LABELS
2012-2905	04/20/2012 05/18/2012	FDA/OMPT/CDRH/OCER/DFOI/	ELLOIT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	ABIOMED - MTG RECS 2/24/12
2012-2906	04/20/2012 05/18/2012	FDA/OMPT/CDRH/OCER/DFOI/	DAVID SZYDLOSKI KEITH L DAVIDSON LAW OFC	MEDTRONIC - KAPPA 70/600 SERIES PULSE GENERATORS & MODEL 9953 SOFTWARE P980035/S001-S265
2012-2907	04/20/2012 05/18/2012	FDA/OC/OES/DFOI/	LUKE, DANIEL	PHARMACEUTICAL COMPANIES CONSUMER REWARDS PROGRAMS - REGULATIONS
2012-2908	04/20/2012	FDA/OMPT/CDER/ORP/DIDP/		MERCK PHARMS - PROPECIA MALE FERTILITY CMLPNTS, SYMPTOMS AFTER STOPING THE DRUG, AGE OF

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	05/18/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BLOOM, DIANE L	PATIENTS, ETC
2012-2909	04/20/2012 05/18/2012	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	JAMIE L. WILHITE STURGILL TURNER ET AL	CYNOSURE INC, WESTFORD, MA - SMART LIPO 483, EIR 2006 TO 4/16/12
2012-2910	04/20/2012 05/18/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ORIGINAL REQUEST LETTER 2012-1694
2012-2911	04/20/2012 05/18/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	COMPLETE RESPONSE 2012-589
2012-2912	04/20/2012 05/18/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	COMPLETE RESPONSE 2012-600
2012-2913	04/20/2012 05/18/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ORIGINAL REQUEST LETTER 2012-1567
2012-2914	04/20/2012 05/18/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-864
2012-2915	04/20/2012 05/18/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-916
2012-2916	04/20/2012 05/18/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-915
2012-2917	04/20/2012 05/18/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-304
2012-2918	04/20/2012 05/18/2012	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/ORO/DIOP/	PAM ZEKMAN CBS 2 NEWS CHICAGO	SUPERMAX HEALTHCARE, SUPERMAX INC - IMPORT REFUSAL RPTS SINCE 2008
2012-2919	04/20/2012 05/18/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-730
2012-2920	04/20/2012 05/18/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MICHELE SINOWAY, PhD. LACHMAN CONSULTANT SERVICES INC	ASTRA ZENECA - NEXIUM (ESOMEPRAZOLE MAGNESIUM) NDA 21-153/S008 RVW, APRVL
2012-2921	04/20/2012 05/18/2012	OC/ORA/ORM/ OC/ORA/ORM/	GAIL LESSICK LACHMAN CONSULTANT SERVICES INC	DOMESTIC & FOREIGN INSP FOR DRUG COMPANIES, MEDICAL DEVICE MANUFACTURERS, BIORESEARCH MONITORING 2/1-29/12

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2012-2922	04/20/2012 05/18/2012	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	PAM ZEKMAN CBS 2 NEWS CHICAGO	SUPERMAX HEALTHCARE, AURORA, IL - EIRS LAST 5 YRS
2012-2923	04/20/2012 05/18/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	COLAS, BRIAN .	ABBOTT LABS - BIAXIN AND CLARITHROMYCIN AER
2012-2924	04/20/2012 05/18/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KATHERINE STETSON GLAXO SMITH KLINE	TEVA PHARMS - PROAIR HFA INHALATION AEROSOL (ALBUTEROL SULFATE) FIELD ALERT RPTS 2011 TO PRESENT
2012-2925	04/20/2012 05/18/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	SYDNEY A. HALPERN, Ph.D. UNIVERSITY OF ILLINOIS AT CHICAGO COLLEGE OF LIBERAL ARTS AND SCIENCES	MTG OF 12/6/50 COMMITTEE ON STERILIZATION OF THE BLOOD & BLOOD DERIVATIVES OF THE HEMATOLOGY STUDY; MTG OF 3/28/51 LAB OF BIOLOGICS CONTROL & ARMED FORCES EPIDEMIOLOGY BOARD ETC
2012-2926	04/20/2012 05/18/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	YASINOW, STEPHEN	TEVA - OLANZAPINE AER
2012-2927	04/20/2012 05/18/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ABDUR RASHID, Ph.D. BIOQ IRB INC	ZOVIRAX (ACYCLOVIR) - CMC INFO
2012-2928	04/20/2012 05/18/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BAMBANG S. ADIWIJAYA, Ph.D. MERRIMACK PHARMACEUTICALS INC	TARCEVA (ERLOTINIB HYDROCHLORIDE) - SBA
2012-2929	04/20/2012 05/18/2012	FDA/OC/OES/DFOI/	LAUREN S. BARR INC RESEARCH CONSULTING & SUBMISSIONS	DAILY LOG 3/9-13/12
2012-2930	04/20/2012 05/18/2012	FDA/OC/OES/DFOI/	LARUREN S. BARR INC RESEARCH CONSULTING & SUBMISSIONS	DAILY LOG 3/9-13/12
2012-2931	04/20/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP	DAILY LOG 4/9-13/12

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	05/18/2012		CanReg, Inc.	
2012-2932	04/20/2012 05/18/2012	FDA/OC/OES/DFOI/	DAVID McFARLAND FDA WEBVIEW/FERDIC INC	DAILY LOG 4/9-13/12
2012-2933	04/20/2012 05/18/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 4/9-13/12
2012-2934	04/20/2012 05/18/2012	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	DAVID SELL PHILADELPHIA INQUIRER	MTG BETWEEN HANSJORG WYSS, NORIAN, INC, WEST CHESTER, PA & FDA - RPTS, CORR
2012-2935	04/20/2012 05/18/2012	FDA/OMPT/CDRH/OCER/DFOI/	JEFFREY G THOMAS ATTY	DURASEAL EXACT SPINE SEALANT SYS P80013/S007, DURASEAL DURAL SEALANT SYS P40034/S019, ETC - TEXT OF SUPPLS, CORR, REVISIONS, ETC
2012-2936	04/20/2012 05/18/2012	FDA/OFVM/CFSAN/OCD/EOS/	KEVIN S. FRIES COSMETIC INGREDIENT REVIEW	VCRP DATA
2012-2937	04/20/2012 05/18/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	HOFFSTADTER, LYNN	VBEC PATCHES - RECS
2012-2938	04/23/2012 05/21/2012	FDA/OFVM/CFSAN/OCD/EOS/	RICHARD LARDNER ASSOCIATED PRESS	NU SKIN, PROVO, UT; PHARMANEX, PROVO, UT; HERBALIFE, LOS ANGELES, CA, ETC - DIETARY SUPPLEMENTS CAERS 1/1/08 TO 4/15/12
2012-2939	04/23/2012 05/21/2012	FDA/OMPT/CDRH/OCER/DFOI/	LAURA LUSTER-SANTANGELO HERZFELD RUBIN	ALLERGAN - LAP BAND SYS STUDIES, REGISTRATION, MDRS, ETC
2012-2940	04/23/2012 05/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	MERIT MEDICAL, GALWAY, IRELAND - EIRS, 483S CO RESP, ETC 9/11 TO 12/11
2012-2941	04/23/2012 05/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	FOI Services, Inc.	CSL BEHRING - BERINERT (C1 ESTERASE INHIBITOR HUMAN) BLA 12-587 AERS NON-CLNCL SAFETY RECS
2012-2942	04/23/2012 05/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JAY H HENDERSON JAY HENDERSON PLLC	BAXTER HEALTHCARE - VANCOCIN, VANCOCIN HCL (VANCOMYCIN HCL) NDA 50-871 RECS

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2012-2943	04/23/2012 05/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	SANOFI AVENTIS - DANOCRINE (DANAZOL) NDA 17-557 AERS, NON-CLNCL SAFETY RECS
2012-2944	04/23/2012 05/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	FOI Services, Inc.	LUNDBECK - WINSTROL (STANOZOLOL) NDA 12-885 AERS, NON-CLNCL SAFETY RECS
2012-2945	04/23/2012 05/23/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	ANGELA D COBLE KENNEDY BERKLEY YARNEVICH & WILLIAMSON CHTD	INDIVIDUAL RECS - VAERS
2012-2946	04/23/2012 05/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	FOI Services, Inc.	LEV PHARMS - CINRYZE (C1 ESTERASE INHIBITOR HUMAN) BLA 12-567 AERS, NON-CLNCL SAFETY RECS
2012-2947	04/23/2012 05/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	SHIRE ORPHAN THERAP - FIRAZYR (ICATIBANT INJ) NDA 22-150 AERS, NON-CLNCL SAFETY RECS
2012-2948	04/23/2012 05/21/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/CVM/OCD/	FOI Services, Inc.	YANTAI CHINA PET FOODS, SHANDONG PROVINCE, CHINA - EIRS, 483S, CO RESP, ETC 2012
2012-2949	04/23/2012 05/21/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/CVM/OCD/ OC/ORA/ OC/ORA/	THOMAS E SOULE EDELMAN COMBS LATTURNER ET AL	IMPORTED CHICKEN JERKY USED AS PET FOOD - TESTING, RESEARCH, INVESTIGATION, ETC
2012-2950	04/23/2012 05/21/2012	FDA/OGROP/ORO/SE-FO/NOL- DO/NOL-CB/	MAX H BURNELL KIKO FOODS INC	KIKO FOODS INC, KENNER, LA - CERTIFICATE OF FREE TRADE
2012-2951	04/23/2012 05/21/2012	FDA/OFVM/CFSAN/OCD/EOS/	DAVID SHELTON DAVID SHELTON ATTY	ALEXIA FOODS INC, CONAGRA FOODS INC - RESP TO WARNING LTR 11/16/11; CONAGRA FOOD INC - MISBRANDING OF FOOD PRODS RECS
2012-2952	04/23/2012	FDA/OFVM/CFSAN/OCD/EOS/	DAVID SHELTON	NESTLE USA INC, NESTLE HOLDINGS INC, GERBER

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	05/21/2012		DAVID SHELTON ATTY	PRODUCTS CO - RESP TO WARING LTR 2/22/10, MISBRANDING OF FOOD PRODS RECS
2012-2953	04/23/2012 05/21/2012	FDA/OMPT/CDRH/OCER/DFOI/	TONY BARTISH PARK WEST ASSET MANAGEMENT LLC	MEETING 2/24/12 - RECS
2012-2954	04/23/2012 05/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANGELIA D SLAYTON INC REGULATORY CONSULTING & SUBMISSIONS	APP PHARMS - OXYTOCIN NDA 18-248 NON-CLNCL SAFETY RECS
2012-2955	04/23/2012 05/21/2012	FDA/OMPT/CDRH/OCER/DFOI/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	ABIOMED, MIKE MINOGUE, DAVID WEBER, KARIM BENALI, ETC - MINS, AGENDA, TRANS, ETC 2/24/12
2012-2956	04/23/2012 05/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GOURAB DE	ELI LILLY & CO - STRATTERA (ATOMOXETINE HCL ATX) ADHD-RS-IV SCORES
2012-2957	04/23/2012 05/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ALEX GURIEV CPMG INC	HP ACTHAR GEL (REPOSITORY CORTICOTROPIN INJ) - AERS
2012-2958	04/23/2012 05/21/2012	FDA/OO/OFBA/OAGS/	PHILIP SONSON WALTERS KLUWER PHARMA SOLUTIONS	THOMSON REUTERS - DERWANT WORLD DRUG INDEX HHSF22301110176C-178C
2012-2959	04/23/2012 05/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DUFFEY, ALEX	LARIAM - AERS
2012-2960	04/23/2012 05/21/2012	FDA/OC/OCC/	LANCE ROBINSON LONDON AND MEAD	NATIONAL WHISTLEBLOWER CENTER ET AL V DEPT OF HEALTH AND HUMAN SERVICES ET AL - RECS
2012-2961	04/23/2012 05/21/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRETT, MURDOCK	HUGE DENTAL MATERIAL CO LTD - SYNTHERIC POLYMER TEETH K101029
2012-2962	04/23/2012 05/21/2012	FDA/OFVM/CFSAN/OCD/EOS/	BEN F PIERCE GORE BEN F PIERCE GORE ATTY	UNILEVER AMERICAS, UNILEVER INC - RESP TO WARNING LTR, MISBRANDING OF FOOD PRODS 8/23/10
2012-2963	04/23/2012 05/21/2012	FDA/OO/OFBA/OAGS/	MIRANDA HOOKER WILMER HALE	DELTA HEALTH ALLIANCE - DELTA HEALTH INITIATIVE COOPERATIVE AGREEMENT AWARD NUMBER U1FRH07411

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2012-2964	04/23/2012 05/21/2012	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	EDWARD R BLUMBERG DEUTSCH & BLUMBERG PA	INFUPHARMA LLC - INVESTIGATION RECS, MEMOS, STATEMENTS, ETC
2012-2965	04/23/2012 05/21/2012	FDA/OC/OES/DFOI/	HONG SAJONZ Bayer HealthCare Pharmaceuticals	BAYER - MARGARET HECKLER HOLDING ASPRIN BOTTLE PHOTO 10/85
2012-2966	04/23/2012 05/21/2012	FDA/OMPT/CDRH/OCER/DFOI/	MICHAEL TREAS HOLLYWOG, llc	BIO PROTECH INC, GANWON-DO, REPUBLIC OF KOREA - EIR MOST RECENT
2012-2967	04/23/2012 05/21/2012	FDA/OMPT/CDRH/OCER/DFOI/	MICHAEL TREAS HOLLYWOG, llc	APEX MEDICAL CORP, TUCHENG, TAWAIN, CHINA - EIR MOST RECENT
2012-2968	04/23/2012 05/21/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	TEI BIOSCIENCES INC - PROMATRIX DERMAL REPAIR SCAFFOLD K083440
2012-2969	04/23/2012 05/21/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	TEI BIOSCIENCES INC - PROMATRIX DERMAL REPAIR SCAFFOLD K061407
2012-2970	04/23/2012 05/21/2012	FDA/OC/OES/DFOI/	TAMMARA, RANDOLPH	PHARMACEUTICAL FACILITIES AND SUPPLIERS IN CHINA & INDIA - INSPS, ACTIVE INDREDIENT RECS
2012-2971	04/23/2012 05/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/OA/OM/OMP/DDM/	GARY L VERON SIDLEY AUSTIN LLP	GENERIC IRON SUCROSE INJ PRODS - SCIENTIFIC TESTS AND STANDARDS, DRAFT GUIDANCE FOR INDUSTRY ON BIOEQV RECOMMENDATION
2012-2972	04/23/2012 05/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GARY L VERON SIDLEY AUSTIN LLP	GENERIC SODIUM FERRIC GLUCONATE COMPLEX PROD ANDA 78-215 - APRVL RECS 3/31/11
2012-2973	04/23/2012 05/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KATHRYN D MATHEWS INTERMOUNTAIN MEDICAKL CTR	BIVALIRUDIN - AERS
2012-2974	04/23/2012 05/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GERALD J OREHOSTKY ANTARES PHARMA INC	SANDOZ, INC, EBewe PHARMA GESMBH MFG KG, ATTERSEE, AUSTRIA - EIRS, 483S, RPTS ETC
2012-2975	04/23/2012	FDA/OMPT/CDER/ORP/DIDP/	R. IAN KLUGE	RUIBANG (ZHEJIANG RUIBANG LABS), ZLHEJIANG PROVIDENCE, CHINA - EIRS, 483S, CO RESPS ETC

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	05/21/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/CVM/OCD/	Hyman Phelps and McNamara PC	
2012-2976	04/23/2012 05/21/2012	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	BECKY COOSEMAN BROWN & CROUPPEN PC	MEAD JOHNSON - ENVIRONMENTAL SPLS, RESULTS, OBSERVATIONS, ETC
2012-2977	04/23/2012 05/21/2012	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	GERHARDT, NATHAN	HEALTH ONE PHARMACEUTICALS INC, EL MONTE, CA - 483S 9/14/11 - 10/5//11
2012-2978	04/23/2012 05/21/2012	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	GERHARDT, NATHAN	PROTICA INC, WHITEHALL, PA - 483S, 9/29/11 - 10/6/11
2012-2979	04/23/2012 05/21/2012	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	ROBERT STEELE STRYKER MEDICAL	HILL-ROM INC, BATESVILLE IN - 483, 9/20/11-10/11/11
2012-2980	04/23/2012 05/21/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	DIANA-LYNNE HSU SADAKA ASSOCIATES LLC	GARDASIL - VAERS
2012-2981	04/23/2012 05/21/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PRICE CLARK COOK MOTLEY RICE LLC	VALEANT PHARMS/GLAXOSMITHKLINE - WELLBLUTRIN, SNDA 344, NDA 18-644
2012-2982	04/23/2012 05/21/2012	OC/OM/OMP/DDM/	KIRSTEIN LUSTILA KIRSTEIN LUSTILA	DKT 1978N-0023
2012-2983	04/23/2012 05/21/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	AUXILIUM PHARMACEUTICALS INC, MALVERN, PA - XIAFLEX AERS, RPTS 2/2/10 TO PRESENT
2012-2984	04/23/2012 05/21/2012	OC/ORA/OCI/ OC/ORA/OCI/	JULIA HARUMI MASS AMERICAN CIVIL LIBERTIES UNION OF NORTHERN CALIFORNIA	INVESTIGATION AND SURVEILLANCE OF MUSLIM COMMUNITIES IN NORTHERN CALIFORNIA - FBI RECS 12/17/09 TO PRESENT
2012-2985	04/24/2012 05/22/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CRAWFORD, WANDA	ONGLYZA - MEDWATCH RPT

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2012-2986	04/24/2012 05/22/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	BRENDA M. GARTZ ELI LILLY & CO	CATALENT PHARMA SOLUTIONS, BRUSSELS, BELGIUM - 483 7/09
2012-2987	04/24/2012 05/22/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORA/ OC/ORA/ FDA/OGROP/ORANE-FO/NYK- DO/NYK-DCB/	SYMONE J. REDWINE KELLEY WITHERSPOON LLP	LOREAL COSMETICS - GARNIER FRUCTIS SLEEK & SHINE CMLNTS
2012-2988	04/24/2012 05/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	RUBLEIN, TOM	UNSAFE AND INEFFECTIVE DEVCS IN THE EU THAT WERE NOT APRVD IN THE US - CPRT
2012-2989	04/24/2012 05/22/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RAJAN S. EMBRAN JUBILANT CADISTA PHARMACEUTICALS INC	ACTONEL NDA 20-835 - LBLG, APRVL
2012-2990	04/24/2012 05/22/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS Consulting Group, LLC	ALDARA CREAM NDA 20-723 - APRVL, LBLG, CHEMISTRY RVW 2/27/97
2012-2991	04/24/2012 05/22/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 4/2-20/2012;
2012-2992	04/24/2012 05/22/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	BRENT M. ARDAUGH NORTHWESTERN UNIV FEINBERG SCHOOL OF MEDICINE	K022236, K031328
2012-2993	04/24/2012 05/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	FERNAND TERRADAS, Ph.D. MEDTRONIC INTERNATIONAL TRADING SARL	SI-LOK SACROILIAC JOINT FIXATION SYS K112028
2012-2994	04/24/2012 05/22/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	FERNAND TERRADAS, Ph.D. MEDTRONIC INTERNATIONAL TRADING SARL	SIMMERTRY SACROILIAC JOINT FUSION SYS K102907
2012-2995	04/24/2012 05/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	FERNAND TERRADAS, Ph.D. MEDTRONIC INTERNATIONAL	SIJF CANNULATED SCREW SYS K051296

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			TRADING SARL	
2012-2996	04/24/2012 05/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	FERNAND TERRADAS, Ph.D. MEDTRONIC INTERNATIONAL TRADING SARL	SYNTHES 6.5MM CANNULATED SCREW K021932
2012-2997	04/24/2012 05/22/2012	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	STEVEN SCHUSTER McLAUGHLIN & STERN LLP	SHISHI HUABAO MINGXIANG FOODSTUFF CO LTD - ENTRY NO 224-3078522-4/5/1, IMPORT REFUSAL RECS
2012-2998	04/24/2012 05/22/2012	FDA/OC/OES/DFOI/	GAYLORD, BRAIN	INDIVIDUAL RECS 1965 TO PRESENT
2012-2999	04/24/2012 05/22/2012	FDA/OFVM/CFSAN/OCD/EOS/	JEFF SPEDDING Additives for Paper Industry GmbH	APIGARD 01 - FCN 959
2012-3000	04/24/2012 05/22/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	MARK PIKKO BARON & BUDD PC	CYTOSPORT INC - MEMOS, TRANS, LTRS, ETC 9/11 TO PRESENT
2012-3001	04/24/2012 05/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	RENAE N. FEO INTEGRA LIMIT UNCERTAINTY	INSTRUMED FORCEPS OBSTETRICAL K092840
2012-3002	04/24/2012 05/22/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	G. SRINIVAS ZYDUS PHARMACEUTICALS USA INC	INTELGENX CORP - FORFIVO XL (BUPROPION HYDROCHLORIDE) NDA 22-497 SBA
2012-3003	04/24/2012 05/22/2012	FDA/OGROP/ORA/ORO/DIOP/	BRIAN HARTMAN ABC NEWS	SEAFOOD IMPORT REFUSALS 2011
2012-3004	04/24/2012 05/22/2012	FDA/OC/OES/DFOI/	BRIAN F. TODT CARE FUSION CORP	4 FOI REQUESTS - DELETED RECS
2012-3005	04/25/2012 05/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	SERA LAM FILIGENT (HK) LTD	BIOFRIEND, BIOMASK SURGICAL FACEMASK - K101128
2012-3006	04/25/2012 05/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	HAMILTON, LEROY L	INSTRUCTIONS PROVIDED TO OFFICIAL CORRESPONDENTS OF MEDICAL DVC COMPANIES CONCERNING THEIR DUTIES TO PROVIDE INFO FOR CDRH ONLINE REGISTRATION & LISTING DATABASE
2012-3007	04/25/2012 05/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HELTON, SHARLA	ALLERGAN - BOTOX & BOTOX COSMETIC AERS
2012-3008	04/25/2012 05/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	GOLDSTEIN, KEITH	DOCUMENT NUMBER GEN 1001245

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2012-3009	04/25/2012 05/23/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KEELEY ZECCA SUPERIOR RESEARCH & SUBMISSIONS	LIST OF ALL WITHDRAWN, ADANDONED OR INACTIVE NDA'S
2012-3010	04/25/2012 05/23/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	CRAIG KRUMAN VPCI INC	SODIUM FERRIC GLUCONATE - LIST OF COMPANIES WHO HAVE FIELD DRUG APPLS
2012-3011	04/25/2012 05/23/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	MAXALT - AERS
2012-3012	04/25/2012 05/23/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	MARK PIFKO BARON & BUDD PC	CYTOSPORT INC - VANILLA CREME MUSCLE MILK LIGHT NUTRITIONAL SHAKES, CHOCOLATE MUSCLE MILK PREOTEIN NUTRITION SHAKE, ETC MEMOS, TRANS, INVESTIGATION, ETC
2012-3013	04/25/2012 05/23/2012	FDA/OO/OFBA/OAGS/	TITUS, DAVID M	SHIPLEY GROUP, FARMINGTON, UT - REQUESTS FOR PROPOSALS, CURRENT AND PAST CONTRACTS, SUBMITTED BIDS, ETC
2012-3014	04/25/2012 05/23/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	EMIL M DEGOMA MD PENN MEDICINE	LOVASTATIN, SIMVASTATIN, PRAVASTATIN, ETC - AERS
2012-3015	04/25/2012 05/23/2012	FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/	REMA C BHAMRE SELF & BHAMRE ATTY	ADYA INC - ADYA CLARITY TEST RECS
2012-3016	04/25/2012 05/23/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHERI BUTLER SHEPPARD MULLIN RICHTER & HAMPTON, LLP	LUITPOLD PHARMACEUTICALS INC - VENOFER (IRON SUCROSE INJ) NDA 21-135 AERS
2012-3017	04/25/2012 05/23/2012	FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	VY TRAN VARIAN MEDICAL SYSTEMS INC	VARIAN MEDICAL SYSTEMS INC, PALO ALTO, CA - EIRS 10/5-18/10
2012-3018	04/25/2012 05/23/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHRISTOPHER MARLBOROUGH FARUQI & FARUQI LLP	GSC PRODUCTS LLC, CLIFTON PARK, NY, SICAP INDUSTRIES LLC, ALBANY, NY - SINUS BUSTER, COLD BUSTER, ALLERGY BUSTER, ETC EIRS, MISBRANDING, AERS, ETC

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2012-3019	04/25/2012 05/23/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	JOHN F COSTELLO JR TROUTMAN SANDERS LLP	NEW CHAPTER INC - Cmplnts, Corr, Investigation, ETC
2012-3020	04/25/2012 05/23/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/OA/OM/OMP/DDM/	MORGAN LAMARE BECK & AMSDEN PLLC	BRISTOL-MYERS SQUIBB CO - ABILIFY CORR
2012-3021	04/25/2012 05/23/2012	FDA/OFVM/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 150444 - ADDITIONAL RECS
2012-3022	04/25/2012 05/23/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHERI BUTLER SHEPPARD MULLIN RICHTER & HAMPTON, LLP	LUITPOLD PAHRMACEUTICALS INC - DEXFERRUM (IRON DEXTRAN INJ) NDA 40-024 AERS 4/1/11 TO PRESENT
2012-3023	04/25/2012 05/23/2012	FDA/OFVM/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CARES 135811 - ADDITIONAL RECS
2012-3024	04/25/2012 05/23/2012	FDA/OFVM/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 141371 - ADDITIONAL RECS
2012-3025	04/25/2012 05/23/2012	FDA/OFVM/CFSAN/OCD/EOS/	MITCHELL A GOLDSTEIN BABENER & ASSOCS	MAX INTERNATIONAL - MAXGXL CAERS
2012-3026	04/25/2012 05/23/2012	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	ARUN K CHOPRA TISHCON CORP	GARDEN STATE NUTRITIONALS, WEST CALDWELL, NJ - EIR, 483 MOST RECENT
2012-3027	04/25/2012 05/23/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SEPHY PHILIP RPH PHARM D SCIENTIFIC EXCHANGE LLC	BOCA PHARMA - HYDROCORTISONE ACETATE, PRAMOXINE HCL ANDA 89-440 SBA
2012-3028	04/25/2012	FDA/OGROP/ORA/SE-FO/FLA-	ROGER DONALDSON	UNIT DOSE SERVICE LLC - INSPS, POLICIES, PROGRAMS,

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	05/23/2012	DO/FLA-CB/	ALLSTATE INSURANCE CO	ETC
2012-3029	04/25/2012 05/23/2012	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	MICHAEL E ATWATER ESQ ATWATER AND DAVIS LLC	PICTSWEET CO - FROZEN PEAS RECALL, NOTES, RPTS, DATA COMPILATIONS, ETC 2010
2012-3030	04/25/2012 05/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	ALEX GURIEV CPMG INC	ABIOMED MANAGEMENT TEAM MTG - RECS 2/24/12
2012-3031	04/25/2012 05/23/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	O'LEARY, KEVIN	INVIVO - DYNACAD 1.0 K041286
2012-3032	04/25/2012 05/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	O'LEARY, KEVIN	SENTINELLE MEDICAL INC - AEGIS NAVIGATION K093672
2012-3033	04/25/2012 05/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	O'LEARY, KEVIN	CONFIRMA - CADSTREAM 5 K081556
2012-3034	04/26/2012 05/24/2012	OC/OM/OMP/DDM/	H. CARL JENKINS WOOD BURDITT GROUP	DKT 1981N-0033P
2012-3035	04/26/2012 05/24/2012	OC/OM/OMP/DDM/	MARILYNN WHITNEY COVINGTON & BURLING LLP	DKT FDA-2010-P-0491
2012-3036	04/26/2012 05/24/2012	FDA/OC/OES/DFOI/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	AMY ERICKSON HAGEN CRYOGENIC LABORATORIES INC	CRYOBANK, PITTSBURGH, PA - EIR, WARNING LTR, CO RESP 5/05 TO PRESENT
2012-3037	04/26/2012 05/24/2012	FDA/OC/OES/DFOI/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	AMY ERIKSON HAGEN CRYOGENIC LABORATORIES INC	CRYOBIOLOGY INC, LA CROSSE, WI - EIR, WARNING LTR, CO RESP 5/05 TO PRESENT
2012-3038	04/26/2012 05/24/2012	FDA/OC/OES/DFOI/ FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	AMY ERICKSON HAGEN CRYOGENIC LABORATORIES INC	CRYOBIOLOGY INC, COLUMBUS, OH - EIR, WARNING LTR, CO RESP 5/05 TO PRESENT
2012-3039	04/26/2012 05/24/2012	FDA/OC/OES/DFOI/ FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	AMY ERICKSON HAGEN CRYOGENIC LABORATORIES INC	REPRODUCTIVE DIAGNOSTICS INC, COLUMBUS, OH - EIR, WARNING LTR, CO RESP 5/05 TO PRESENT
2012-3040	04/26/2012 05/24/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SPEARS 297965, PHILLIP LEE	GEODONE, TRAZADONE, DIPHENHYDRAMINE, REMAZON, BENZTROPINE, NEPROXEN - AER
2012-3041	04/26/2012 05/24/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	COOPER 328257, JACK	BENADRYL, ULTRAM, KLONOPIN - AER

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		FDA/OMPT/CDER/GRP/DIDP/		
2012-3042	04/26/2012 05/24/2012	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	ALICE MOORE HARVEST SELECT CATFISH	HARVEST SELECT CATFISH, UNIONTOWN, AL - 483 7/25/11
2012-3043	04/26/2012 05/24/2012	FDA/OC/OES/DFOI/	LAUREN S. BARR INC RESEARCH CONSULTING & SUBMISSIONS	2012-2756
2012-3044	04/26/2012 05/24/2012	FDA/OMPT/CDRH/OCER/DFOI/	TANYA RHODES MANUKA MEDICAL	MANUKA TEX K110042, MANUKA HD K102659
2012-3045	04/26/2012 05/24/2012	OC/OCOS/OES/ OC/OCOS/OES/	ANTHONY W. LEE NTEU CHAPTER 282	FDA DIVERSITY COUNCIL - RPT 1/12 - 3/7/12
2012-3046	04/26/2012 05/24/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	SHAMEEN AFIF-RIDER MEDIMMUNE INC	VAERS 362911
2012-3047	04/26/2012 05/24/2012	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ OC/ORA/ OC/ORA/	BRANDON BROWN MACUGA LIDDLE & DUBIN PC	DIAMOND NATURALS LAMB & RICE - CMLPLNTS 1/12 TO PRESENT
2012-3048	04/26/2012 05/24/2012	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	DOUGLAS N. BLUE ZETETIC	GLOBAL MED LTD, ESSEX, UK - GLUCOSE TEST STRIP ENTRY NO F23-9050001- 5/1/1
2012-3049	04/26/2012 05/24/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	NED FEDER, M.D. PROJECT ON GOVERNMENT OVERSIGHT	ADVISORY COMMITTEE MTG 2/22/12 ENDOCRINOLOGIC & METABOLIC DRUGS ADVISORY COMMITTEE
2012-3050	04/26/2012 05/24/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	AARON M. TEJANI, BSc, PHARMD, ACPR FRASER HEALTH AUTHORITY	ANGLOTENSIN RECEPTOR BLOCKERS - AER
2012-3051	04/26/2012	FDA/OMPT/CDER/GRP/DIDP/	DR. NIR SHTAYER	BAXTER - TISSEEL (FIBREN SEALANT) CMC DATA, LBLG

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	06/26/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	OMRIX PHARMACEUTICALS LTD	
2012-3052	04/26/2012 05/24/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/OA/OM/OMP/DDM/	GERBER, LUCIE	PARKE-DAVIS, WARNER-LAMBERT, COGNEX (TACRINE) - CORR, HISTORY, CLNCL TRIALS, ETC
2012-3053	04/26/2012 05/24/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORR/SE-FO/ATL- DO/ATL-CB/ FDA/OGROP/ORR/SW-FO/KAN- DO/KAN-CB/	DANIEL r. LEATHERS LIEFF CABRASER ET AL	SIMPLY TICK GEL; XANTHAN GUM POWDER - INVESTIGATIONS
2012-3054	04/26/2012 05/24/2012	OC/CVM/OCD/	JENNIFER SORENSON NATURAL RESOURCES DEFENSE COUNCIL	QUALITATIVE MICROBIAL FOOD SAFETY RISK ASSESSMENTS OF ANIMAL DRUG PRODS - RESULTS, ANALYSIS, CORR, ETC
2012-3055	04/27/2012 05/25/2012	FDA/OFVM/CFSAN/OCD/EOS/	JACK MEYERSON MEYERSON & O'NEILL ATTY	MELTDOWN - CAERS
2012-3056	04/27/2012 05/25/2012	FDA/OFVM/CFSAN/OCD/EOS/	JACK MEYERSON MEYERSON & O'NEILL ATTY	OXYELITE - CAERS
2012-3057	04/27/2012 05/25/2012	FDA/OMPT/CDRH/OCER/DFOI/	PETE KILPATRICK ORTHOSCAN INC	INSIGHT - FD MINI C-ARM FLUOROSCOPIC IMAGING SYS K120388
2012-3058	04/27/2012 05/25/2012	FDA/OMPT/CDRH/OCER/DFOI/	LINDA KARIYA NIHON KOHDEN AMERICA	K080546, K050833, K022121
2012-3059	04/27/2012 05/25/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WARREN WILLIAMS FOREST RESEARCH INSTITUTE	SERQUEL XR (QUETIAPIINE FUMARATE) ER TABS NDA 22- 047/S011 - APRVL RECS
2012-3060	04/27/2012 05/25/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	YELENA PIMENOV LANDON-IP INC	ARAVA NDA 20-905 - FORM FDA 3242

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2012-3061	04/27/2012 05/25/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	BRAD E COOPER HAMOT MEDICAL CENTER	PRECEDEX (DEXEMEDETOMIDINE) - AERS
2012-3062	04/27/2012 05/25/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	LORRAINE J PUGNI AARONSON RAPPAPORT ET AL	MARC STRAUS MD - CONSENT AGREEMENT 5/18/82 (CERTIFIED)
2012-3063	04/27/2012 05/25/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	SRINIVASA R PARUCHURI CISPHARMA OMC	CISPHARMA INC, CRANBURY, NJ - EIR 12/16/10 TO 1/24/11
2012-3064	04/27/2012 05/25/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRAYDON BURGESS LYPRO BIOSCIENCES INC	ABELCET NDA 50-724/S000 - APRVL PKG PHARMACOLOGY, MICROBIOLOGY RVWS
2012-3065	04/27/2012 05/25/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/OA/OM/OMP/DDM/	SHAWN FOX TRACEY LAW FIRM	LUNDBECK - CELEXA (CIPRAMIL, CITALOPRAM) ANIMAL STUDIES, CORR, MINS, ETC
2012-3066	04/27/2012 05/25/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRAYDON BURGESS LYPRO BIOSCIENCES INC	AMPHOTEC NDA 50-729/000 - APRVL PKG PHARMACOLOGY, MICROBIOLOGY RVWS
2012-3067	04/27/2012 05/25/2012	FDA/OC/OES/DFOI/	WILLIAM KONSTAND TAG HEALTHCARE	THE ARESON GROUP INC, TAG HEALTHCARE, TAG MEDICAL, ETC - EIRS 2001
2012-3068	04/27/2012 05/25/2012	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	DAWN HAAKE NUVASIVE INC	NUVASIVE INC, MEMPHIS, TN - EIR NON-REDACTED 9/09, 11/11
2012-3069	04/27/2012 05/25/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	DAWN HAAKE NUVASIVE INC	NUVASIVE INC, SAN DIEGO, CA - EIRS NON-REDACTED DVC INSP 4/04, TISSUE INSP 8/03
2012-3070	04/27/2012	FDA/OMPT/CDER/ORP/DIDP/		BURZYNSKI RESEARCH INSTITUTE IRB - NOTIFICATION

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	05/25/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	LTR
2012-3071	04/27/2012 05/25/2012	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	RUCHIKA CHANDRAN REGULATORY COMPLIANCE ASSOCIATES INC	MEDRAD INC, INDIANOLA, PA - EIRS 8/11, 1/11, 2/11
2012-3072	04/27/2012 05/25/2012	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	KIM NGUYEN AP PHARMA INC	LIFECORE BIOMEDICAL LLC - EIRS, 483S LAST 3 YRS
2012-3073	04/27/2012 05/25/2012	OC/OCOS/OL/	WADMAN, MEREDITH	REP HENRY WAXMAN - RESP TO CONGRESSIONAL CORR
2012-3074	04/27/2012 06/29/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/OCOS/OES/ OC/OCOS/OES/ FDA/OC/OCC/ OC/ORACE/ OC/ORACE/	BARRETT LAW GROUP PA	DEL MONTE - FOOD PRODS MISBRANDING CORR, RECS
2012-3075	04/27/2012 05/25/2012	FDA/OMPT/CDRH/OCER/DFOI/	PATRICK SCHREXNAILDER AMIPURDUE	CASA FUTURA TECHNOLOGIES - BIOFEEDBACK SYS FOR SPEECH DISORDERS K942651
2012-3076	04/27/2012 05/25/2012	FDA/OMPT/CDRH/OCER/DFOI/	MELISSA EGAN WATERS CORP	THERMO SCIENTIFIC - QMS EVEROLIMUS REAGENTS, QMS CALIBRATORS, QMS CONTROLS K100144
2012-3077	04/27/2012 05/25/2012	FDA/OMPT/CDRH/OCER/DFOI/	AMY FOWLER Ecolab	STRYKER - T6 HOODS AND TOGAS K063005
2012-3078	04/27/2012 05/25/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	AMY FOWLER Ecolab	STRYKER - STRI-SHIELD FLYTE TOGAS K073017
2012-3079	04/27/2012 05/25/2012	FDA/OMPT/CDRH/OCER/DFOI/	KORINA AKHONDZADEH KARA & ASSOCIATES INC	BACTERIN K091321
2012-3080	04/27/2012 05/25/2012	FDA/OMPT/CDRH/OCER/DFOI/	KORINA AKHONDZADEH KARA & ASSOCIATES INC	DYNAGRAFT II K040419
2012-3081	04/27/2012 05/25/2012	FDA/OMPT/CDRH/OCER/DFOI/	KORINA AKHONDZADEH KARA & ASSOCIATES INC	NANOFUSE K120279
2012-3082	04/27/2012 05/25/2012	FDA/OMPT/CDRH/OCER/DFOI/	KORINA AKHONDZADEH KARA & ASSOCIATES INC	OSTEOTECH K043048
2012-3083	04/27/2012	FDA/OMPT/CDRH/OCER/DFOI/		MESYNTHES LTD - ENDOFORM DENTAL TEMPLATE K101546

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	05/25/2012		FOI Services, Inc.	
2012-3084	04/27/2012 05/25/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	MESYNTHES LTD - ENDOFORM DENTAL TEMPLATE K092096
2012-3085	04/27/2012 05/25/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	COOK BIOTECH INC - OASIS WOUND MATRIX K061711
2012-3086	04/30/2012 05/29/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	IVAN KORENDOVYCH SYRACUSE UNIV CENTER FOR SCIENCE AND TECHNOLOGY	BYDUREON NDA 22-200 - APRVL LTR, LBLG, RVWS, ETC
2012-3087	04/30/2012 05/29/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CANDICE DURRENCE OPTIMER PHARMACEUTICALS INC	DIFICID (FIDAXOMICIN TABS) NDA 201-699 AERS 7/18/11 TO 4/26/12
2012-3088	04/30/2012 05/29/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JODY L GREEN PHD ROCKY MOUNTAIN POISON AND DRUG CENTER	COUGH AND COLD PREPARATIONS - ISRS 7591076-1, 7597960-7, 7598122-X, ETC
2012-3089	04/30/2012 05/29/2012	FDA/OMPT/CDRH/OCER/DFOI/	RICHARD O WOOD WOOD BURDITT GROUP	UCSF MEDICAL CENTER, SAN FRANCISCO, CA - MEDWATCH 3500A, FORM FDA 3419
2012-3090	04/30/2012 05/29/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	KATE B WILSON CENTER FOR PUBLIC INTEGRITY	ALLOGRAFT TISSUE DATABASE
2012-3091	04/30/2012 05/29/2012	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	DAVID E LINDEN MD LINDEN & ASSOCIATES	LINDEN RESEARCH CONSULTANTS LLC - 483S, CO RESP 2006, 2007
2012-3092	04/30/2012 05/29/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	BEDFORD LABS - COSMEGEN (DACTINOMYCIN) ANDA 90-304 RECS
2012-3093	04/30/2012 05/29/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JODY L GREEN PHD ROCKY MOUNTAIN POISON AND DRUG CENTER	COUGH AND COLD PREPARATIONS - ISRS 7912526-4, 7919138-4, 7919802-X, ETC
2012-3094	04/30/2012 05/29/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JODY L GREEN PHD ROCKY MOUNTAIN POISON AND	COUGH AND COLD PREPARATIONS - ISRS 7802323-9, 7821102-3, 7823760-6, ETC

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DRUG CENTER	
2012-3095	04/30/2012 05/29/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JODY L GREEN PHD ROCKY MOUNTAIN POISON AND DRUG CENTER	COUGH AND COLD PREPARATIONS - ISRS 7652851-8, 7652852-X, 7655799-8, ETC
2012-3096	04/30/2012 05/29/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SUSANNA GREENBERG ESQ BALLARD SPAHR LLP	WOCKHARDT - ANDA 78-492 APRVL RECS
2012-3097	04/30/2012 05/29/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOSEPH MUSTO METHYLGENE INC	PFIZER - DIFLUCAN (FLUCONAZOLE) NDA 19-949 CMC RVW SECTION
2012-3098	04/30/2012 05/29/2012	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOGS 4/2-6/12
2012-3099	04/30/2012 05/29/2012	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 4/9-13/12
2012-3100	04/30/2012 05/29/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JORGE L CARDENAS UNILEVER DISCOVER	RIMANTADINE, AMANTADINE, ADOPALENE - APRVL RECS
2012-3101	04/30/2012 05/29/2012	FDA/OMPT/CDRH/OCER/DFOI/	Samradni Patil CYBERSONICS INC	MED-SONICS CORP - URETRON MULTI PROBE LITHOTRIPTER K111058
2012-3102	04/30/2012 05/29/2012	FDA/OMPT/CDRH/OCER/DFOI/	SERA LAM FILLIGENT (HK) LTD	BIOFRIEND, BIOMASK SURGICAL FACEMASK K101128
2012-3103	04/30/2012 05/29/2012	FDA/OMPT/CDRH/OCER/DFOI/	ROBERTA LEE ACUEITY HEALTHCARE INC	VIADUCT MINISCOPE AND ACCESSORIES K040949
2012-3104	04/30/2012 05/29/2012	FDA/OC/OES/DFOI/	Doe J	BARD - HERNIA MESH RECALL,CMLPLNTS
2012-3105	04/30/2012 05/29/2012	FDA/OGROP/ORACE-FO/DET- DO/DET-CB/	TRAVIS SCHAFTENAAR UBS GLOBAL ASSET	HILL-ROM, BATESVILLE, IN - 483S 1/10 TO PRESENT

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			MANAGEMENT	
2012-3106	04/30/2012 05/29/2012	FDA/OMPT/CDRH/OCER/DFOI/	MELISSA EGAN WATERS CORP	NEOBASE NON-DERIVATIZED MSMS KIT MODEL 3040-001U K093916
2012-3107	04/30/2012 05/29/2012	FDA/OMPT/CDRH/OCER/DFOI/	MELISSA EGAN WATERS CORP	THERMO SCIENTIFIC - QMS EVEROLIMUS REAGENTS, QMS CALIBRATORS, QMS CONTROLS K100144
2012-3108	04/30/2012 05/29/2012	FDA/OC/OES/DFOI/	MEGAN B PICKEL BEVERIDGE & DIAMOND PC	CFSAN FOIA REQUESTS 3/16/12-4/26/12
2012-3109	04/30/2012 05/29/2012	FDA/OC/OES/DFOI/	GLADYS B TONKIN WASHINGTON INFORMATION SOURCE	FOI DAILY LOGS 4/9-13/12
2012-3110	04/30/2012 05/29/2012	FDA/OC/OES/DFOI/	GLADYS B TONKIN WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 4/2-6/12
2012-3111	04/30/2012 05/29/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 4/2-6/12
2012-3112	04/30/2012 05/29/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 4/9-13/12
2012-3113	04/30/2012 05/29/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 4/2-6/12
2012-3114	04/30/2012 05/29/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 4/9-13/12
2012-3115	04/30/2012 05/29/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 4/2-6/12
2012-3116	04/30/2012 05/29/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 4/9-13/12
2012-3117	04/30/2012 05/29/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 4/2-9/12
2012-3118	04/30/2012 05/29/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 4/9-13/12
2012-3119	04/30/2012 05/29/2012	FDA/OC/OES/DFOI/	INC REGULATORY CONSULTING & SUBMISSIONS	FOI DAILY LOG 4/2-6/12
2012-3120	04/30/2012	FDA/OC/OES/DFOI/		FOI DAILY LOGS 4/9-13/12

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	05/29/2012		INC REGULATORY CONSULTING & SUBMISSIONS	
2012-3121	04/30/2012 05/29/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	AMIODARONE - AERS
2012-3122	04/30/2012 05/29/2012	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	TRAVIS SCHAFTENAAR UBS GLOBAL ASSET MANAGEMENT	INVACARE, ELYRIA, OH - EIRS 2010. 2011
2012-3123	04/30/2012 05/29/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OC/OES/DFOI/	ANGELA MITCHELL VIACORD CORD BLOOD BANKING RESEARCH	STEMCYTE INC, COVINA, CA - EIR, 483, CO RESP ETC 2/3-11/10
2012-3124	04/30/2012 05/29/2012	FDA/OMPT/CDRH/OCER/DFOI/	MELISSA EGAN WATERS CORP	NEOBASE NON-DERIVATIZED MSMS KIT MODEL 3040 - K083130
2012-3125	04/30/2012 06/05/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OGROP/OIP/	KATE WILLSON ICIJ	NIKOLAEV REGIONAL BUREAU OF FORENSIC MEDICAL EXAMINATION (NIK1) - DATE OF FDA INACTIVE CHANGE, COMM, RECS ETC
2012-3126	04/30/2012 05/29/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	KATE KIADDY DSM I-HEALTH INC	ULTRA-SEAL CORP, NEW PALTZ, NY - EIRS, 483S CO RESPS ETC LAST 5 YRS
2012-3127	04/30/2012 05/29/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	KATE CADDY DSM I-HEALTH INC	ULTRA -TAB LABS INC, HIGHLAND, NY - EIRS, 483S CO RESPS ETC LAST 5 YRS
2012-3128	04/30/2012 05/29/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	KATE CADDY DSM I-HEALTH INC	ASPIRE PHARMS, SOMERSET, NJ - EIRS, 483S CO RESPS ETC LAST 5 YRS
2012-3129	04/30/2012 05/29/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	KATE CADDY DSM I-HEALTH INC	US PHARMA LAB INC, NORTH BRUNSWICK, NJ - EIRS, 483S CO RESPS ETC LAST 5 YRS
2012-3130	04/30/2012 05/29/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	KATE CADDY DSM I-HEALTH INC	GARDEN STATE NUTRITIONALS (VITAQUEST), WEST CALDWELL, NJ - EIRS, 483S CO RESPS ETC LAST 5 YRS
2012-3131	04/30/2012 05/29/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	KATE CADDY DSM I-HEALTH INC	AMNEAL PHARMACEUTICALS, LLC, PATERSON, NJ - EIRS, 483S CO RESPS ETC LAST 5 YRS
2012-3132	04/30/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	KATE CADDY	NUTRI-SPORT PHARMACAL, FRANKLIN, NJ - EIRS, 483S CO RESPS ETC LAST 5 YRS

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	05/29/2012		DSM I-HEALTH INC	
2012-3133	04/30/2012 05/29/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	KATE CADDY DSM I-HEALTH INC	MULTI-PAK PACKAGING, FAIRFIELD, NJ - EIRS, 483S, CO RESPS ETC LAST 5 YRS
2012-3134	04/30/2012 05/29/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	KATE CADDY DSM I-HEALTH INC	CONTRACT PHARMACAL CORP, HAUPPAUGE, NY - EIRS, 483S CO RESPS ETC LAST 5 YRS
2012-3135	04/30/2012 05/29/2012	FDA/OC/OES/DFOI/	FRAN KOCH INFORMATION ACCESS	FOI DAILY LOGS 4/2-6/12
2012-3136	04/30/2012 05/29/2012	FDA/OC/OES/DFOI/	FRAN KOCH INFORMATION ACCESS	FOI DAILY LOG 4/9-13/12
2012-3137	05/01/2012 05/30/2012	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	TZU-HSUAN YANG PRO PHARMA TAIWAN INC	ASPEN SURGICAL PRODUCTS, CAREDONIA, MI - CLEARANCE LTR 2/17/10
2012-3138	05/01/2012 05/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JIM FAUCETT NORTHWEST CLINICAL RESEARCH CTR	COREG NDA 20-297 - SBA
2012-3139	05/01/2012 05/30/2012	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	TAMISHA RAQIB FACET TECHNOLOGIES LLC	FACET TECHNOLOGIES LLC, KENNESAW, GA - EIR 2005 TO 2006
2012-3140	05/01/2012 05/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KIMBERLY D. BARONE BADEN MOTLEY RICE LLC	WELLBUTRIN NDA 18-644 - LBLG, CO RESP 9/8/83
2012-3141	05/01/2012 05/30/2012	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	AMY ERICKSON HAGEN CRYOGENIC LABORATORIES INC	MIDWEST SPERM BANK LLC, DOWNERS GROVE, IL - EIR, 483, CO RESP 5/1/05 TO PRESENT
2012-3142	05/01/2012 05/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	PEERY, JAAMES	SILK N FX K110301
2012-3143	05/01/2012 05/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	PEERY, JAAMES	LIGHT FOR WRINKLES K101190
2012-3144	05/01/2012 05/30/2012	FDA/OC/OSHC/OPD/	LOAR, S B	ARSENIC TRIOXIDE (TRISENOX) - APRVL, CO RESP
2012-3145	05/01/2012 05/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARGARET GROEL LACHMAN CONSULTANT SERVICES INC	EFAVIRENZ, LAMIVUDINE, TENOFOVIR DISOPROXIL FUMARATE NDA 22-142 APRVL

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		FDA/OMPT/CDER/GRP/DIDP/		
2012-3146	05/01/2012 05/30/2012	OC/CVM/OCD/	DENA WHITE BOEHRINGER INGELHEIM	EQUIPOISE NDA 34-705 SUMMARY
2012-3147	05/01/2012 05/30/2012	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	NICHOLE ROFFI FRONTIER ADJUSTER	INDIVIDUAL RECS
2012-3148	05/01/2012 05/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DEBORAH L GETZ ATTORNEY AT LAW	ISOTRETINOIN - AER
2012-3149	05/01/2012 05/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/OCOS/OES/ OC/OCOS/OES/	CHRIS HAWLEY ASSOCIATED PRESS	7/28/04 LTR FROM KAREN TANDY OF DEA TO CRISTINA BEATO OF HHS REGARDING PETITION FROM RONALD DOUGHERTY - ALL FOLLOW UP
2012-3150	05/01/2012 05/30/2012	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORA/SW-FO/SWID/SWID-CB/	ANN M. BEGLEY K & L GATES	VINCEEL THROAT SPRAY, NECTADYN COUGH SYRUP - ENTRY NO 328-7206489-7
2012-3151	05/01/2012 05/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	HONHART, TRACY	MAKO SURGICAL CORP - VOYAGER LINUX K050973, VOYAGER LINUX W/TACTILE GUIDANCE SYS K052851, UNICONDYLAR KNEE SYS K060017
2012-3152	05/01/2012 05/30/2012	FDA/OFVM/CFSAN/OCD/EOS/	THOMPSON, CLARENCE LD	CASH AWARDS GIVEN TO CFSAN EMPLOYEES IN 2011
2012-3153	05/01/2012 05/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	STEVE WALDMAN MILLER WEISBROD LLP	MEDTRONIC - SPECIFY 2X8 MODEL 39286 LEAD KIT - APRVL,
2012-3154	05/01/2012 05/30/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	"A list of all FOIA requests closed 4/1-30/2012" on CD;
2012-3155	05/01/2012 05/30/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 4/23-27/2012
2012-3156	05/02/2012 05/31/2012	OC/OM/OMP/DDM/	ROSS RENDELMAN HOGAN LOVELLS LLP	DKT 2000P-1471, 1998P-0821, 200P-1621, ETC.

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2012-3157	05/02/2012 05/31/2012	OC/OM/OMP/DDM/	VIVIAN BROWN WESTLAW COURT EXPRESS	APPROVED DRUG PRODUCT 16TH EDITION 1996
2012-3158	05/02/2012 05/31/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	AMAURY SANCHEZ NOVEN PHARMACEUTICALS INC	NEUPRO (ROTIGOTINE TRANSDERMAL SYS) NDA 21-829/S001/S002 - RVWS
2012-3159	05/02/2012 05/31/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	J. DONALD HENSON, SR Henson, J. Donald	P980022/S010 - SSED'S APRVL PKG
2012-3160	05/02/2012 05/31/2012	FDA/OMPT/CDRH/OCER/DFOI/	J. DONALD HENSON, SR Henson, J. Donald	P980022/S010 - SSED CRITERIA
2012-3161	05/02/2012 05/31/2012	FDA/OFVM/CFSAN/OCD/EOS/	FATIMA ASLAM Keller and Heckman LLP	RECYCLED PLASTICS - FOOD CONTACT SUBSTANCES NO OBJECTION LTRS
2012-3162	05/02/2012 05/31/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OES/DFOI/ OC/ORA/ OC/ORA/	JAMES E WALKER III ESQ TUCKER & ASSOCIATES	MULTISTATE SALMONELLA ENTERIDITIS OUTBREAK - LAB RESULTS, INVOICES, HARVEST RECS, ETC 10/11 TO 1/12
2012-3163	05/02/2012 05/31/2012	FDA/OMPT/CDRH/OCER/DFOI/	JOHN DAVID HART JOHN DAVID HART LAW OFC	BIOMET - M2A MAGNUM HIP IMPLANT SYS 510K, PMA SUBMISSIONS,, MDRS, ETC
2012-3164	05/02/2012 05/31/2012	FDA/OMPT/CDRH/OCER/DFOI/	JOHN DAVID HART JOHN DAVID HART LAW OFC	STELKAST - PROVIDENT HIP IMPLANT SYS 510K, PRE-MARKET APRVL NOTICES , MDRS, ETC
2012-3165	05/02/2012 05/31/2012	FDA/OMPT/CDRH/OCER/DFOI/	DONALD S SOLOMON PHD CATHETER CONNECTIONS	IVERA MEDICAL INC - CUROS PORT PROTECTOR K111992
2012-3166	05/02/2012 05/31/2012	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	BEADLE RETNARAJAN BIND BIOSCIENCES INC	OSO BIOPHARMACEUTICALS MANUFACTURING LLC, ALBUQUERQUE, NM - EIR 8/9-16/11
2012-3167	05/02/2012 05/31/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/CVM/OCD/	KRISTI O SMEDLEY PHD WASHINGTON INFORMATION SOURCE	HYDROPHOBIC SILICA GRAS 2419 - RVW MEMO, CORR
2012-3168	05/02/2012 05/31/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	J. DONALD HENSON, SR Henson, J. Donald	MEDTRONIC INC - INSULIN PUMP P890022 SSED'S APRVL PKG
2012-3169	05/02/2012 05/31/2012	FDA/OMPT/CDRH/OCER/DFOI/	SCOTT E SPELL MICHAEL ALDER PC	ST JUDE MEDICAL - RIATE ENDOCARDIAL DEFIBRILLATION LEAD PRE-MARKET APRVL APPL, APPL FOR MODIFICATIONS, MDRS, ETC
2012-3170	05/02/2012 05/31/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DE WALT-BARNER, DENISE	RISPERDAL (RISPERDONE) - AERS

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2012-3171	05/02/2012 05/31/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	NANCY BAKER MD SMILEYS CLINIC	TAMIFLU (OSELTAMIVIR) - AERS
2012-3172	05/02/2012 05/31/2012	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	JENNIFER WILEY ALDER BIOPHARMACEUTICALS	DR VIJ, WASHINGTON UNIV SCHOOL OF MEDICINE - 483 12/12
2012-3173	05/02/2012 05/31/2012	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	SRINIVASA R PARUCHURI CISPHARMA OMC	CISPHARMA INC, CRANBURY, NJ - EIR 12/1610 TO 1/24/11
2012-3174	05/02/2012 05/31/2012	FDA/OC/OES/DFOI/	JAMES E WALKER III TUCKER & ASSOCIATES	RESTAURANT CHAIN A MULTI-STATE OUTBREAK OF SALMONELLA ENTERIDITIS - FOI REQUESTS THAT HAVE REQUESTED FOI REQUEST
2012-3175	05/02/2012 05/31/2012	FDA/OFVM/CFSAN/OCD/EOS/	NEUHAUS, NICOLE	INSECT-BASED FOOD COLORING IN STARBUCKS STORES - REGULATIONS
2012-3176	05/02/2012 05/31/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CROSS, AMY	TYSABRI - AERS
2012-3177	05/02/2012 05/31/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	LIVALO - AERS
2012-3178	05/02/2012 05/31/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	IRINA RIVKIND CANTOR FITZGERALD	HOVIONE FARMACIENCIA SA - RESP TO 483S 9/25/09, 1/27/11
2012-3179	05/02/2012 05/31/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRODY MULLINS WALL STREET JOURNAL	STEVE WILLIAMS, MARWOOD GROUP - DUREON RECS, CORR 9/15/10-10/30/10
2012-3180	05/02/2012 05/31/2012	FDA/OMPT/CDRH/OCER/DFOI/ OC/ORA/ OC/ORA/	JENNIFER L REDIEHS WIEDNER & MCAULIFFE LTD	PARI NEBULIZERS - RPTS, CLAIMS, INVESTIGATIONS, ETC 1/90 TO PRESENT

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		FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/		
2012-3181	05/02/2012 05/31/2012	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	CRAWFORD, IAN	VITAGANIC - VITAMINS TESTING, VIOLATIONS, CONSUMER RECOMMENATIONS, ETC
2012-3182	05/02/2012 05/31/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JACQUELYN A CANNATA MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C.	TYSABRI (NATALIZUMAB) - MEMO OF MTG MINS 9/8/10 LTR (CERTIFIED)
2012-3183	05/02/2012 05/31/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JACQUELYN A CANNATA MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C.	GASTROINTESTINAL DRUGS A/C AND DRUG SAFETY AND RISK MANAGEMENT A/C JOINT MTG - TYSABRI (NATALIZUMAB) MEMO 7/20/07 (CERTIFIED)
2012-3184	05/02/2012 05/31/2012	FDA/OMPT/CDRH/OCER/DFOI/	JACQUELYN A CANNATA MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C.	TYSABRI (NATALIZUMAB) MTG 11/18/10 - RECS (CERTIFIED)
2012-3185	05/02/2012 05/31/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JACQUELYN A CANNATA MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C.	TYSABRI (NATALIZUMAB) - EMAIL 4/3/06 (CERTIFIED)
2012-3186	05/02/2012 05/31/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JACQUELYN A CANNATA MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C.	TYSABRI (NATALIZUMAB) - LTR 11/18/05 (CERTIFIED)
2012-3187	05/02/2012 05/31/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PETER S REICHERTZ SHEPPARD MULLIN RICHTER & HAMPTON, LLP	GENERAMEDIX - NULECIT (SODIUM FERRIC GLUCONATE) ANDA 78-215 AERS 10/09 TO PRESENT
2012-3188	05/02/2012 05/31/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PETER S REICHERTZ SHEPPARD MULLIN RICHTER & HAMPTON, LLP	SANOFI-AVENTIS - FERRLECIT (SODIUM FERRIC GLUCONATE) NDA 17-44 AERS 10/09 TO PRESENT
2012-3189	05/02/2012 05/31/2012	OC/OM/OMP/DDM/	CECEILE RICHTER CECEILE RICHTER	DKT 1980N-0140
2012-3190	05/02/2012	OC/OA/OM/OSS/OAGS/	EDDIE W LACKEY	JEFFERSON LABORATOIRES COMPLEX - CURRENT

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	05/31/2012		JEFFERSON FACILITIES MAINTENANCE UNION	MAINTENANCE CONTRACT 11/1/11 TO 11/1/12
2012-3191	05/03/2012 06/01/2012	FDA/OC/OES/DFOI/	KRISTI O. SMEDLEY, Ph.D. WASHINGTON INFORMATION SOURCE	2012-854
2012-3192	05/03/2012 06/25/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	SIEGEL, JONATHAN B	BLOEDVOORICNING, AMSTERDAM, NETHERLANDS, BRUSSELS - STICHTING SANQUIN - 483, EIR
2012-3193	05/03/2012 06/01/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KATHLEEN G. ENGER HOSPIRA INC	AMIDATE (ETOMIDATE INJECTION) NDA 18-227 CLNCL RVW
2012-3194	05/03/2012 06/01/2012	OC/ORA/ OC/ORA/ FDA/OFVM/CFSAN/OCD/EOS/	SCOTT BRADLEY FLOUR CONFECTIONS INC.	FLOUR CONFECTIONS INC, ONTARIO - DOCS
2012-3195	05/03/2012 06/01/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARY ANDERSON SHIRE INC	PROZAC S18-936/S-065, 20-101/S-027, 20-974/S-001 - SBA
2012-3196	05/03/2012 06/01/2012	OC/CVM/OCD/	KRISTI O. SMEDLEY, Ph.D. WASHINGTON INFORMATION SOURCE	CALCIUM FORMATE - CORR SINCE 9/1/11
2012-3197	05/03/2012 06/01/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/CVM/OCD/ OC/CVM/OCD/	BRENDA M. GARTZ ELI LILLY & CO	BIOVET JOINT STOCK CO, PESHTERA, BULGARIA - EIR 4/1/10
2012-3198	05/03/2012 06/01/2012	FDA/OMPT/CDRH/OCER/DFOI/	CORRIE GOODING BOSTON SCIENTIFIC	AERO TRACHEOBRONCHIAL STENT SYS K062511
2012-3199	05/03/2012 06/01/2012	FDA/OMPT/CDRH/OCER/DFOI/	CORRIE GOODING BOSTON SCIENTIFIC	AERO DV TRACHEOBRONCHIAL STENT SYS K083625
2012-3200	05/03/2012 06/01/2012	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	NINOS SAROUKHANIOFF MARANGA MORGENSTERN LAW CORP	WINDSOR QUALITY FOOD CO - FEI 2022675 8/25/11, 2022675 9/13/10, 2022675 5/27/09 - EIR, 483, CO RESP, SAMPLE RPT

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2012-3201	05/03/2012 06/01/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	RYAN WILDER SAC CAPITAL ADVISORS LP	IMPAX LABS INC, HAYWARD CA - 483 1/12 TO 5/1/12
2012-3202	05/03/2012 06/01/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	STEPHEN ALLEN ATKINSON WILLIAMSON PETTY LC	BIONICS HIRES 90K COCHLEAR IMPLANTS - AER, 1/08 TO PRESENT
2012-3203	05/03/2012 06/01/2012	FDA/OGROP/ORA/ORO/DIOP/	GRAHAM MARTIN BENJAMIN L ENGLAND & ASSOCIATES LLC	ALERT 53-06
2012-3204	05/03/2012 06/01/2012	FDA/OMPT/CDRH/OCER/DFOI/	RICHARD KELLER BRUNO INDEPENDENT LIVING AIDS INC	CMPLNT CPT1100211
2012-3205	05/03/2012 06/01/2012	FDA/OMPT/CTP/OD/	AZIM CHOWDHURY Keller and Heckman LLP	M RTP SINCE 6/12/09
2012-3206	05/03/2012 06/01/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/ FDA/OMPT/CDRH/OCER/DFOI/	JAY L. BREAKSTONE PARKER & WAICHMAN ATTYS	MEDTRONIC - INFUSE BONE GRAFT RHBMP 2 LT CAGE; INFUSE BONE GRAFT LT CAGE LUMBAR TAPERED FUSION DEVICE - AER, CORR,
2012-3207	05/03/2012 06/01/2012	OC/ORA/ OC/ORA/ FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	CASEY R. MARION BEAVER STEET FISHERIES INC	SEA BEST AHI TUNA TEAK SPL 733497
2012-3208	05/03/2012 06/01/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GAVIN JOHNSON WECT-TV	VYVANSE - AER
2012-3209	05/03/2012 06/01/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	ANGELIA D. SLAYTON INC REGULATORY CONSULTING & SUBMISSIONS	SANT CHAWLA MD, SARCOMA ONCOLOGY CENTER, SANTA MONICA, CA - 483, CO RESP 8/5/09
2012-3210	05/03/2012 06/01/2012	FDA/OMPT/CDRH/OCER/DFOI/	KATHRYN A. LACHOWSKY LAW OFFICE OF DAVID H WILLIAMS PLLC	HOSPIRA INC - INFUSION PUMP CORR CERTIFIED
2012-3211	05/03/2012	OC/ORA/	ERIK P. CREP	AVASTIN - GENENTECH 483, SMPLS, 2011 TO 2012

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	06/01/2012	OC/OR/ FDA/OGROP/OR/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/OR/SE-FO/NOL-DO/NOL-CB/	WICKER SMITH ET AL	
2012-3212	05/03/2012 06/01/2012	FDA/OMPT/CDRH/OCER/DFOI/ OC/OA/OM/OMP/DDM/	CHRISTOPHER SHAKIB TERRELL HOGAN ELLIS YEGELWEL PA	MEDTRONIC - CONCERTO MODEL C154DWK ICD APRVL
2012-3213	05/03/2012 06/01/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	AMAURY SANCHEZ NOVEN PHARMACEUTICALS INC	DURAGESIC (FENTANYL TRANSDERMAN SYS) NDA 19-813/S044,S033 RVW
2012-3214	05/04/2012 06/04/2012	FDA/OGROP/OR/NE-FO/NWE-DO/NWE-CB/	THOMPSON, RAY	AMERICAN DIAGNOSTICA INC, STANFORD, CT 6/20-22/11; CARDIOPULMONARY CORP, MILFORD CT 6/13-16/11; COVIDIEN LP, 6/1-16/11, ETC 483S
2012-3215	05/04/2012 06/04/2012	FDA/OGROP/OR/NE-FO/NWE-DO/NWE-CB/	THOMPSON, RAY	FORMATECH INC, ANDOVER, MA 7/15/11-08/31/11; GENZYME CORP, WALTHAM, MA 10/08-27/11; HAEMONETICS CORP, BRAINTREE, MA 08/24/11-09/19/11, ETC 483S
2012-3216	05/04/2012 06/04/2012	FDA/OGROP/OR/CE-FO/NWJ-DO/NWJ-CB/	THOMPSON, RAY	ACCESS BIO INC, SOMERSET, NJ 6/22/11-08/29/11; AUROLIFE PHARMA LLC, DAYTON, NJ 10/25/11-11/02/11; BUXTON BIOMEDICAL INC, EAST HANOVER, NJ 12/19-22/11, ETC 483S
2012-3217	05/04/2012 06/04/2012	FDA/OGROP/OR/NE-FO/NYK-DO/NYK-DCB/	THOMPSON, RAY	A & Z PHARMACEUTICAL INC, DEER PARK, NY 11/03-05/11; ADVION BIOSCIENCES INC, ITHACA, NY 09/06-14/11; APP PHARMACEUTICALS LLC, GRAND ISLAND, NY 06/13/11-07/08/11, ETC
2012-3218	05/04/2012 06/04/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	THOMPSON, RAY	SANDOZ CANADA INC, BOUCHERVILLE, CANADA 07/26/11-08-04/11; TEVA CZECH INDUSTRIES SPO, OPAVA, CZECH REPUBLIC 09/19-22/11; NOVARTIS PHARMA PRODUKTIONS GMBH, WEHR, GERMANY 09/12-15/11, ETC 483S
2012-3219	05/04/2012 06/04/2012	FDA/OGROP/OR/PA-FO/SAN-DO/SAN-CB/	THOMPSON, RAY	APEX MEDICAL TECHNOLOGIES INC, SAN DIEGO, CA 11/29-30/11; CARDIONET INC, SAN DIEGO, CA 12/14-20/11; GENENTECH INC, SOUTH SAN FRANCISCO, CA 06/14-23/11, ETC 483S
2012-3220	05/04/2012 06/04/2012	FDA/OGROP/OR/CE-FO/CIN-DO/CIN-CB/	THOMPSON, RAY	GOLD STANDARD ORTHOPAEDICS LLC, LOUISVILLE, KY 11/16-18/11; ISOPURE CORP, SIMPSONVILLE, KY 08/23-25/11; ACCUPACK MIDWEST INC, CINCINNATI, OH 07/18/11-09/16/11, ETC 483S
2012-3221	05/04/2012	FDA/OGROP/OR/SE-FO/FLA-		AIG TECHNOLOGIES INC, DEERFIELD BEACH, FL 06-27/11-

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	06/04/2012	DO/FLA-CB/	THOMPSON, RAY	07-01/11; ADVANCED ORTHOGONAL EQUIPMENT INC, SAINT PETERSBURG, FL 08/18/11; AVEVA DRUG DELIVERY SYSTEMS INC, MIRAMAR, FL 08/24/11-09/28/11, ETC 483S
2012-3222	05/04/2012 07/09/2012	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAP/PA-FO/SAN-DO/SAN-CB/	THOMPSON, RAY	ALPHAPROTECH INC, NOGALES, AZ 09/12-14/11; ABCO LABORATORIES INC, FAIRFIELD, CA 08/26/11-09/09/11; ADVANCED MEDICAL INNOVATIONS, CHATSWORTH, CA 09/28/11-10/06/11, ETC 483S
2012-3223	05/04/2012 06/04/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANGELIA D SLAYTON INC REGULATORY CONSULTING & SUBMISSIONS	WYETH PHARMS INC - EFFEXOR XR (VENLAFAXINE HCL) NDA 20-699/S054/S057 APRVL LTR, LBLG, MEDICAL RVWS, ETC
2012-3224	05/04/2012 06/04/2012	FDA/OGROP/ORAP/NE-FO/NYK-DO/NYK-DCB/	ANGELIA D SLAYTON INC REGULATORY CONSULTING & SUBMISSIONS	BARTOR PHARMACAL RYE, NY - EIRS, 483S 01/01/07 TO 12/31/10
2012-3225	05/04/2012 06/04/2012	FDA/OMPT/CDRH/OCER/DFOI/	VIK BAJNATH ARTHREX INC	MW#5024558 - RPT
2012-3226	05/04/2012 06/04/2012	FDA/OMPT/CDRH/OCER/DFOI/	VIK BAJNATH ARTHREX INC	MW#5024874 - RPT
2012-3227	05/04/2012 06/04/2012	FDA/OMPT/CDRH/OCER/DFOI/	VIK BAJNATH ARTHREX INC	2506865 - RPT
2012-3228	05/04/2012 06/04/2012	FDA/OMPT/CDRH/OCER/DFOI/	DAVID MOYNHAM HUNTLEIGH HEALTHCARE LTD	SONICAID - K912639
2012-3229	05/04/2012 06/04/2012	FDA/OMPT/CDRH/OCER/DFOI/	HUNTLEIGH HEALTHCARE LTD	PHILLIPS - AVALON CTS CORDLESS FETAL TRANSDUCER SYS K023931
2012-3230	05/04/2012 06/04/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FIX, MELALNIE	MERCK - SINGULAIR AERS
2012-3231	05/04/2012 06/04/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LAUREN PEARLE ABC, INC.	TAMIFLU - AERS 01/02 TO 12/12
2012-3232	05/04/2012 06/04/2012	FDA/OGROP/ORAP/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORAP/CE-FO/MIN-	MARY ROBERTS BUZZ MONKEYS INC	ROCKLINE INDUSTRIES, SHEBOYGAN, WI - EIRS 2012

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		DO/MIN-CB/ FDA/OGROP/ORASE-FO/NOL- DO/NOL-CB/		
2012-3233	05/04/2012 06/04/2012	FDA/OFVM/CFSAN/OCD/EOS/	MAE WU NATURAL RESOURCES DEFENSE COUNCIL	PESTICIDE RESIDUE MONITORING OF FOOD - RESULTS 1/08 TO PRESENT, RPT1/05 TO PRESENT, TESTING 12/31/05 TO PRESENT, ETC
2012-3234	05/04/2012 06/04/2012	OC/OCOS/OL/	ROBERT A PAARLBERG PAARLBERRG & ASSOCIATES LLC	REP WAXMAN, REP MARKEY, REP DEGETTE RESP TO CONGRESSIONAL LTR 02/14/12 - CLNCL DRUG TRIAL RESULTS
2012-3235	05/04/2012 06/04/2012	OC/ORO/ OC/ORO/ OC/ORO/ORM/ OC/ORO/ORM/	FASS, THOMAS	LIST OF FIRMS THAT COMPRISE OFFICIAL ESTABISHMENT INVENTORY
2012-3236	05/04/2012 06/04/2012	OC/ORO/ORM/ OC/ORO/ORM/	SHUKLA, JAY	LIST OF FACILITIES INSPECTED 01/01/10-05/02/12
2012-3237	05/04/2012 06/04/2012	FDA/OC/OSHC/OPD/	DIANE SCHULMAN THE INDAGO GROUP	QUESTCOR PHARMACEUTICALS INC - HP ACTHAR GEL ORPAH DRUG DESIGNATION
2012-3238	05/04/2012 06/04/2012	OC/CVM/OCD/	KRISTI O SMEDLEY PHD WASHINGTON INFORMATION SOURCE	DEGUSSAL/EVONIK - HYDROPHOBIC SILLCA REQUEST & RESP
2012-3239	05/04/2012 06/04/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELISE C BIGLEY KELLER ROHRBACK LLP	SUAVE - PROFESSIONAL KERATIN INFUSION HAIR TREATMENT CMLPNTS, COMMENTS, ADVERTSING, ETC
2012-3240	05/07/2012 06/05/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HARTWELL P MORSE III HUSCH BLACKWELL LLP	DR REDDY'S LABS LTD - IBANDRONATE SODIUM ANDA 78-997 APRVL LTR 4/30/12
2012-3241	05/07/2012 06/05/2012	FDA/OGROP/ORANE-FO/NYK- DO/NYK-DCB/	JAMES R SCHIFFER ALLEGAERT BERGER & VOGEL LLP	REGIONCARE INC, GREAT NECK, NY - EIRS 2008 TO 2011
2012-3242	05/07/2012 06/05/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHANDRAN TIRUVATTAR DR REDDY'S LABORATORIES INC	PADDOCK LLC - CLOBETASOL PROPIONATE ANDA 90-898 SBA

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		FDA/OMPT/CDER/ORP/DIDP/		
2012-3243	05/07/2012 06/05/2012	FDA/OFVM/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	HYDROXYCUT, SMARTBURN, RAPID SLIM, ETC
2012-3244	05/07/2012 06/05/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MICHAEL P MANAPOL ESQ BRIAN D WITZER INC	MEDICIS PHARMACEUTICAL CORP - SOLODYN ER TABS NDA 50-808 AERS 1/1/06 TO 12/3/09
2012-3245	05/07/2012 06/05/2012	FDA/OGROP/ORAPA-FO/SAN- DO/SAN-CB/	RYAN WILDER SAC CAPITAL ADVISORS LP	IMPAX LABORATORIES INC, HAYWARD, CA - 483S 1/1/12- 5/1/12
2012-3246	05/07/2012 06/05/2012	FDA/OC/OES/DFOI/	AMANDA ORLANDO AVALON RISK MANAGEMENT INC	EG PIAZZA INTERNATIONAL - ENTRY #80501222261 NOTICE OF ACTION #1
2012-3247	05/07/2012 06/05/2012	FDA/OC/OES/DFOI/	AUSTIN NELSON RBC CAPITAL MARKETS	HOSPIRA INC, AUSTIN, TX - UNTITLED LTR 1/1/12 TO PRESENT
2012-3248	05/07/2012 06/05/2012	FDA/OC/OES/DFOI/	AUSTIN NELSON RBC CAPITAL MARKETS	HOSPIRA INC, CLAYTON, NC - 483S 1/1/12 TO PRESENT
2012-3249	05/07/2012 06/05/2012	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Brown, Sanders E	MICROCHIP IMPLANTS - CMLPNTS
2012-3250	05/07/2012 06/05/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PEDRICK, RUSSELL	METOPROLOL - AERS
2012-3251	05/07/2012 06/05/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LAWLER, JOSEPH F	AMIDATE (ETOMIDATE) NDA 18-227 APRVL LTRS, LBLG, RVWS, ETC
2012-3252	05/07/2012 06/05/2012	OC/CVM/OCD/	FOI Services, Inc.	GAMBOL PET PRODUCTS (LIAOCHENG) CO LTD, SHANDONG PROVINCE, CHINA - EIRS, 483S, CO RESP, ETC 2012
2012-3253	05/07/2012 06/05/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OES/DFOI/ OC/CVM/OCD/	FOI Services, Inc.	JINAN WELCOME FOOD CO LTD, SHANDONG PROVINCE, CHINA - EIRS, 483S, CO RESP, ETC 2012
2012-3254	05/07/2012	OC/CVM/OCD/		SHANDONG PETSWELL FOOD CO LTD, SHANDONG PROVINCE, CHINA - EIRS, 483S, CO RESP, ETC 2010

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	06/05/2012		FOI Services, Inc.	
2012-3255	05/07/2012 06/05/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	FOI CLOSED REQUESTS 4/16-20/12
2012-3256	05/07/2012 06/05/2012	OC/CVM/OCD/ OC/ORO/ OC/ORO/ FDA/OGROP/OIP/	FOI Services, Inc.	QUARANTINE SERVICES, CHINA - MTG SUMMARY RPTS 2012
2012-3257	05/07/2012 06/05/2012	FDA/OC/OES/DFOI/	LAUREN S BARR INC RESEARCH CONSULTING & SUBMISSIONS	FOI CLOSED REQUESTS 4/16-20/12
2012-3258	05/07/2012 06/05/2012	FDA/OC/OES/DFOI/	LAUREN S BARR INC RESEARCH CONSULTING & SUBMISSIONS	FOI CLOSED REQUESTS 4/23-27/12
2012-3259	05/07/2012 06/05/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI CLOSED REQUESTS 4/16-20/12
2012-3260	05/07/2012 06/05/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/CVM/OCD/ FDA/OC/OES/DFOI/ OC/CVM/OCD/	FOI Services, Inc.	SHANDONG HONVA FOOD CO LTD, SHANDONG PROVINCE, CHINA - EIRS, 483S, CO RESP, ETC 2012
2012-3261	05/07/2012 06/05/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI CLOSED REQUESTS 4/16-20/12
2012-3262	05/07/2012 06/05/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	BRISTOL MYERS SQUIBB - ORENCIA (ABATACEPT) BLA 125118 APRVL RECS
2012-3263	05/07/2012 06/05/2012	FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/	FOI Services, Inc.	LUITPOLD PHARMS, SHIRLEY, NY - EIRS, 483S, CO RESP, ETC 2/8/12-3/28/12
2012-3264	05/07/2012 06/05/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	MERCK SHARP DOHME - JUVISYNC (SIMVASTATIN, SITAGLIPTIN PHOSPHATE) NDA 202-343 APRVL RECS
2012-3265	05/07/2012 06/05/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	ALLERGAN INC - BOTOX BLA 103000 PROMOTION & MARKETING CMLPNTS, CORR

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		FDA/OMPT/CDER/ORP/DIDP/		
2012-3266	05/07/2012 06/05/2012	FDA/OFVM/CFSAN/OCD/EOS/	FOI Services, Inc.	MARS INC - SPIRULINA (ANTHROSPIRA PLATENSIS) COLOR ADDITIVE PETITION
2012-3267	05/07/2012 06/05/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	CAREFUSION 303 INC - ALARIS PC UNIT MODULE 8000 WITH SOFTWARE CORRECTION K110535
2012-3268	05/07/2012 06/05/2012	FDA/OC/OES/DFOI/	LAUREN S BARR	FOI DAILY LOG 4/16-20/12
		FDA/OC/OES/DFOI/	JH BARR & ASSOCIATES LLC	
2012-3269	05/07/2012 06/05/2012	FDA/OC/OES/DFOI/	AUSTIN NELSON RBC CAPITAL MARKETS	IMPAX LABORATORIES INC, HAYWARD, CA - 483 1/12 TO PRESENT
2012-3270	05/08/2012 06/06/2012	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	TYLER KENYON NORTHCOAST RESEARCH	ZIMMER HOLDINGS INC - CO RESP 12/11 T0 PRESENT; 483, CO RESP ETC 4/12
2012-3271	05/08/2012 06/06/2012	FDA/OMPT/CDRH/OCER/DFOI/	RANDY BYRD	EUROTROL INC, BURLINGTON, MA & EUROTROL BV, EDE, NETHERLANDS - DVCS SOLD W/O 510K CLEARANCE, COMM, RECS ETC
		FDA/OMPT/CDRH/OCER/DFOI/	BIONOSTICS INC	
2012-3272	05/08/2012 06/06/2012	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	LOPER, MATTHEW	IMPAX LABORATORIES - 483S, CO RESPS 2012
2012-3273	05/08/2012 06/06/2012	OC/ORA/	WHITNEY DOCKEN	TARGET CORP - IRS #41-0215170TS, ENTRIES, RECS, NOTES, ETC, 2011
		OC/ORA/	TARGET CUSTONS BROKERS INC	
		FDA/OGROP/ORA/ORO/DIOP/		
2012-3274	05/08/2012 06/06/2012	FDA/OC/OES/DFOI/	KEEL D-12127, KENNETH G	LACTULOSE SOL, MARIJUANA, AMITRIPTLINE ETC - INFORMATION, RECS, ETC
2012-3275	05/08/2012 06/06/2012	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	ELYSSA M FRIED Finkelstein and Partners	NY GOURMET SALADS INC; CRYSTAL SALADS; FARM FRESH GOURMET SALADS LLC ETC - CUSTOMERS, GROCERS, ETC 1/10 - 4/10
2012-3276	05/08/2012 07/06/2012	FDA/OMPT/CDRH/OCER/DFOI/	GARY LEHNUS Lehnus & Associates	BRAHMS DIAGNOSTICA, LLC PCT LIA - ENDOTOXIN ACTIVITY ASSAY, K040887; BIOMERIEUX INC, - VIDAS BRAHMS PCT ASSAY, K071146; BRAHMS AKTIENGESELLSCHAFT - BRAHMS PCT SENSITIVE KRYPTOR TEST SYS, K070310
2012-3277	05/08/2012 06/06/2012	FDA/OMPT/CDRH/OCER/DFOI/	CURTIS RAYMOND ORCHID DESIGN	OLYMPUS XCHF-T160 VIDEOSCOPE K082576
2012-3278	05/08/2012 06/06/2012	FDA/OMPT/CDRH/OCER/DFOI/	CURTIS RAYMOND ORCHID DESIGN	OLYMPUS ENDOSCOPIC CO2 REGULATION UNIT K081173
2012-3279	05/08/2012 06/06/2012	FDA/OFVM/CFSAN/OCD/EOS/	CHRISTOPHER MARLBOROUGH	NATURE'S WAY & SCHWABE NORTH AMERICA INC, GREEB BAY, WI - UMCKA PRODS, PELARGONIUM SIDOIDES, EIRS, CAERS, MISLABELING ETC
		FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	FARUQI & FARUQI LLP	

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2012-3280	05/08/2012 06/06/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M. GARTZ ELI LILLY & CO	RANBAXY, DEWAS, INDIA - 483 1/28-2/12/08
2012-3281	05/08/2012 06/06/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TOM JEFFERSON, MD COCHRANE ACUTE RESPIRATORY INFECTIONS GROUP	HOFFMAN-LA ROCHE - OSELTAMIVIR, CLNCL STUDY RPTS 2000 TO PRESENT
2012-3282	05/08/2012 06/06/2012	OC/OA/OM/OMP/DDM/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAN BURNS INFACARE PHARMACEUTICAL CORP	GASTROINTESTINAL DRUG AC - TRANS 3/13/12
2012-3283	05/08/2012 06/06/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEVIN XIE ACCORDA HEALTHCARE LLC	SEPRACOR (SUNOVION PHARMACEUTICALS INC) - LUNESTA (ESZOPICLONE), SBA, PRODUCT QUALITY STANDARDS
2012-3284	05/08/2012 06/06/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PARAKKAL DEEPAK CTR FOR STUDY OF COMPLEX DISEASES RESEARCH INSTITUTE	AER #'S 3806336, 3888821, 3961282 ETC
2012-3285	05/08/2012 06/06/2012	FDA/OC/OES/DFOI/	CHARLES J. LANDY PILLSBURY WINTHROP ET AL	SANOFI AVENTIS - ACTHAR GEL SYNTHETIC REQUESTS 12/31/07 TO PRESENT
2012-3286	05/08/2012 06/06/2012	FDA/OC/OES/DFOI/	CHARLES J. LANDY PILLSBURY WINTHROP ET AL	AMPHASTAR PHARMS INC - CORTROSYN (COSYNTROPIN) REQUESTS 12/31/07 TO PRESENT
2012-3287	05/08/2012 06/06/2012	FDA/OC/OES/DFOI/	CHARLES J. LANDY PILLSBURY WINTHROP ET AL	QUESTCOR PHARMS INC - ACTHAR GEL (REPOSITORY CORTICOTROPIN INJECTION) 12/31/07 TO PRESENT
2012-3288	05/08/2012 06/06/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SEAN CAHILL MEDICURE	INTEGRILIN RENAL STUDY NDA 20-718/S17 - CLNCL STUDY
2012-3289	05/08/2012	FDA/OFVM/CFSAN/OCD/EOS/	J. PRICE COLEMAN	BIGELOW TEA COMPANY - CORR, COMMENTS, PETITIONS,

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	06/06/2012		COLEMAN LAW FIRM	HEALTH CLAIMS, ETC
2012-3290	05/08/2012 06/06/2012	FDA/OFVM/CFSAN/OCD/EOS/	DEWITT M. LOVELACE LOVELACE LAW FIRM PA	BUMBLE BEE FOODS LLC - FOOD PROD MISBRANDING, COMPLIANCE RECS
2012-3291	05/08/2012 06/06/2012	OC/CVM/OCD/ FDA/OFVM/CFSAN/OCD/EOS/ OC/OCOS/OES/ OC/OCOS/OES/ OC/OCOS/OL/ OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/	MARTINA BERNSTEIN PETA	ANIMAL FEED SAFEGUARDS DESIGNED TO PREVENT BSE - RPTS, ETC
2012-3292	05/08/2012 06/06/2012	FDA/OGROP/ORO/ORO/DIOP/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	JOHN F. JOHNSON III, Esq. BENJAMIN L ENGLAND & ASSOCIATES LLC	LONGHAI GELEN FOODS CO - IMPORT ALERT 16-81, 16-119, 16-127, 99-08
2012-3293	05/09/2012 06/07/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	CURTIS RAYMOND ORCHID DESIGN	OLYMPUS - EVIS 180 SYS K061313
2012-3294	05/09/2012 06/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	CURTIS RAYMOND ORCHID DESIGN	OLYMPUS - SINGLE USE 3-LUMEN EXTRACTION BALLOON V K091495
2012-3295	05/09/2012 06/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	CURTIS RAYMOND ORCHID DESIGN	OLYMPUS - TRACHEAL INTUBATION FIBER VIDEOSCOPE K082720
2012-3296	05/09/2012 06/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	CURTIS RAYMOND ORCHID DESIGN	OLYMPUS - EVIS EXERA 160A SYS K051645
2012-3297	05/09/2012 06/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	CURTIS RAYMOND ORCHID DESIGN	OLYMPUS - SINGLE USE ELECTROSURGICAL KNIFE SERIES K092309
2012-3298	05/09/2012 06/07/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN F THOMPSON ROBINSON & THOMPSON	ESICITALOPRAM, LEXAPRO - AERS
2012-3299	05/09/2012 06/07/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN F THOMPSON ROBINSON & THOMPSON	CYCLOSPORIN A, NEORAL - AERS

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2012-3300	05/09/2012 06/07/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN F THOMPSON ROBINSON & THOMPSON	CITALOPRAM, CELXA - AERS
2012-3301	05/09/2012 06/07/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MICHAEL R COHEN INSTITUTE FOR SAFE MEDICATION PRACTICES	MEDWATCH RPTS CODED AS MEDICATION ERRORS 3/01/12-04/30/12
2012-3302	05/09/2012 06/07/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	FRANCIS J MARTIN DELPOR INC	JANSEN PHARMS - INVEGA SUSTENNA (PALIPERIDONE PALMITE) RX INJ SUSPENSION NDA 22-264 SBA
2012-3303	05/09/2012 06/07/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PAUL J ROSCH MD AMERICAN INSTITUTE OF STRESS	LIPITOR - AERS
2012-3304	05/09/2012 06/07/2012	FDA/OGROP/ORAC/CE-FO/MIN- DO/MIN-CB/	RICARDO RONQUILLO NEUROGESX INC	FONTAROME CHEMICAL INC, ST FRANCIS, WI - EIRS, 483S, WARNING LTRS, ETC 01/07 TO PRESENT
2012-3305	05/09/2012 06/07/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BOB LUND BECKMAN COULTER INC	BECKMAN COULTER INC - DMF 1325 (TENITE POLYALLOMER CIEFINS) RECS 1970 TO 1980
2012-3306	05/09/2012 06/07/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/OA/OM/OMP/DDM/ FDA/OC/OES/DFOI/	J PRICE COLEMAN COLEMAN LAW FIRM	WM WRIGLEY JR CO - DKT 200N-0463 CORR , EMAILS, NOTES, ETC
2012-3307	05/09/2012 06/07/2012	FDA/OGROP/ORAC/CE-FO/CIN- DO/CIN-CB/	DIANA L GESEKING SEDWICK LLP	ABBOTT LABS, COLUMBUS, OH - EIRS, 483S, WARNING LTRS ETC 1/00 TO PRESENT
2012-3308	05/09/2012 06/07/2012	FDA/OGROP/ORAC/SE-FO/FLA- DO/FLA-CB/ FDA/OC/OES/DFOI/	GERHARDT, NATHAN	SEI PHARMACEUTICALS INC, MIAMI, FL - 483 9/19-29/11

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2012-3309	05/09/2012 06/07/2012	FDA/OFVM/CFSAN/OCD/EOS/	PAULINE DO EXPONENT	DANONE TRADING BV, 1118BG SCHIPHOL AIRPORT, THE NETHERLANDS - GRN 425
2012-3310	05/09/2012 06/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	TANI MOK COTRONIC TECHNOLOGY LTD	COTRONIC TECHNOLOGY LTD, CHINA - K103407
2012-3311	05/09/2012 06/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	PAULINE DO COTRONIC TECHNOLOGY LTD	COTRONIC TECHNOLOGY LTD, CHINA - K032434
2012-3312	05/09/2012 06/07/2012	FDA/OMPT/CTP/OD/	JOSEPH ZALESKI CAPSTONE LLC	CTP'S DRAFT RPT SBMTD TO EXTERNAL PEER REVIEW PANEL 7/11
2012-3313	05/09/2012 06/07/2012	FDA/OMPT/CTP/OD/	JOSEPH ZALESKI CAPSTONE LLC	CTP'S DRAFT RPT SBMTD TO EXTERNAL PEER REVIEW PANEL 7/11 - ROSTER OR LIST OF NAMES & AFFILIATIONS
2012-3314	05/09/2012 06/07/2012	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	DIANA L GESEKING SEDWICK LLP	NESTLE USA, ANDERSON, IN - EIRS, 483S, WARNING LTRS 1/00 TO PRESENT
2012-3315	05/09/2012 06/07/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KUMAR, ROGER	VICTOZA (LIRAGLUTIDE) - AERS
2012-3316	05/09/2012 06/07/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KUMAR, ROGER	BYETTA (EXENATIDE) - AERS
2012-3317	05/09/2012 06/07/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KUMAR, ROGER	BYDUREON (EXENATIDE) - AERS
2012-3318	05/09/2012 06/07/2012	OC/OM/OMP/DDM/	VON LINDSEY FAEGRE DB CONSULTING	DKT 1977N-0143
2012-3319	05/10/2012 06/08/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	CHRISTINE R THOMPSON TODD & WELD LLP	UNAPPROVED INTRAUTERINE DVCS (IUD) AND INTRAUTERINE SYSTEMS (IUS) - PURCHASE, USE, DISTRIBUTION BY MEDICAL PROVIDERS IN MA
2012-3320	05/10/2012 06/08/2012	OC/ORAE/ OC/ORAE/ FDA/OGROP/ORASE-FO/ATL-	SUZETTE BINNIE BLUE RIDGE HONEY CO	SPL #461789 - ANALYSIS RESULTS

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		DO/ATL-CB/		
2012-3321	05/10/2012 06/08/2012	OC/OCOS/OES/ OC/OCOS/OES/	HOOTNICK, ALEXANDRA	TOTAL DIET SURVEY AND ARSENIC IN RICE BRIEFING - MINS, CORR, MEMOS, ETC 3/23/12
2012-3322	05/10/2012 06/08/2012	OC/ORO/ OC/ORO/	CYNDY BURINDA PHOENIX REGULATORY ASSOCIATES LTD	L-PHENYLALANINE - CMPLNTS
2012-3323	05/10/2012 06/08/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FELDMAN, DAVID I	ASTRA ZENECA - ZOLADEX (GOSERELIN DEPOT) AERS
2012-3324	05/10/2012 06/08/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARILYNN WHITNEY COVINGTON BURLING LLP	CIMZIA - SUMMARY, MEDICAL, STATISTICAL RVWS, ETC
2012-3325	05/10/2012 06/08/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	PAUL HEYWOOD ALTRAN PRAXIS LTD	VALERITAS LLC - V-GO DISPOSABLE INSULIN DELIVERY DVC K100504
2012-3326	05/10/2012 06/08/2012	FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/	RICARDO RONQUILLO NEUROGESX INC	DPT LABORATORIES LTD, SAN ANTONIO, TX - EIRS, 483S, WARNING LTRS, ETC 1/07 TO PRESENT
2012-3327	05/10/2012 06/08/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	LEIGHANN STAHLI BLUE RIDGE CAPITAL	PARKEDALE - CORTICOTROPIN NDA 08-317; ORGANICS LAGRANGE - CORTICOTROPIN NDA 10-831; WATSON LABS - CORTICOTROPIN NDA 88-772, ETC RECS
2012-3328	05/10/2012 06/08/2012	OC/OCOS/OL/	HAMILTON, LEROY L	COMMISSIONER HAMBURG, REP THORNBERYY, REP BARTON - LTR 3/7/12
2012-3329	05/10/2012 06/08/2012	FDA/OMPT/CDRH/OCER/DFOI/	DAVID C FURR FDC SERVICES LLC	NOMED - TITANIUM CALCANEUS PLATES K022324
2012-3330	05/10/2012 06/08/2012	FDA/OMPT/CDRH/OCER/DFOI/	DAVID C FURR FDC SERVICES LLC	NOMED - MINI-EXTERNAL FIXATORS K022230
2012-3331	05/10/2012 06/08/2012	FDA/OMPT/CDRH/OCER/DFOI/	DAVID C FURR FDC SERVICES LLC	NOMED - TITANIUM RONDO FIX SYS K022323
2012-3332	05/10/2012 06/08/2012	FDA/OMPT/CDRH/OCER/DFOI/	DAVID C FURR FDC SERVICES LLC	NOMED - BONE TRANSPORT SYS K021341

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2012-3333	05/10/2012 06/08/2012	FDA/OMPT/CDRH/OCER/DFOI/	DAVID C FURR FDC SERVICES LLC	NOMED - MANDIBULAR FIXATION SYS K010118
2012-3334	05/10/2012 06/08/2012	OC/CVM/OCD/	ARLENE MORALES BURDOCK GROUP	BUTYRIC ACID IN ANIMAL FEED - REGULATORY STATUS, CONSUMPTION, SAFETY RECS, ETC
2012-3335	05/10/2012 06/08/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	DENISE HAMMANG BIOPHARMA COMPLIANCE SERVICES LLC	UPSTATE NEW YORK TRANSPLANT SERVICES, BUFFALO, NY 2/17/02; GRAMERCY FERTILITY SERVICES, NEW YORK, NY 3/22/12 - 483S
2012-3336	05/10/2012 06/08/2012	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	DENISE HAMMANG BIOPHARMA COMPLIANCE SERVICES LLC	ST JUDE CHILDREN'S RESEARCH HOSPITAL, MEMPHIS, TN 1/11/12; DCI DONOR SERVICES (TENNESSEE DONOR SERVICES), NASHVILLE, TN 1/27/12 - 483S
2012-3337	05/10/2012 06/08/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DORA GAUL MEDISCA INC	FIDP LIST
2012-3338	05/10/2012 06/08/2012	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	DENISE HAMMANG BIOPHARMA COMPLIANCE SERVICES LLC	ADVANCED REPRODUCTIVE LABS, IRVING, TX; SAN ANTONIO EYE BANK, SAN ANTONIO, TX - 483
2012-3339	05/10/2012 06/08/2012	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	DENISE HAMMANG BIOPHARMA COMPLIANCE SERVICES LLC	FROEDTART HOSPITAL REPRODUCTIVE MIDICINE CLINIC, WILWAUKEE, WI; LIFE SOURCE UPPER MIDWEST OPO, SAINT PAUL, MN; REPRODUCTIVE SPECIALTY CTR, MILWAUKEE, WI - 483
2012-3340	05/10/2012 06/08/2012	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	DENISE HAMMANG BIOPHARMA COMPLIANCE SERVICES LLC	TISSUE BANKS INTERNATIONAL-NATIONAL, SAN RAFAEL, CA 2/17/12; TISSUE LINK INC, WALNUT CREEK, CA 3/15/12 - 483S
2012-3341	05/10/2012 06/08/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSD FOI REQUESTS 4/23-27/12
2012-3342	05/10/2012 06/08/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RICARDO RONQUILLO NEUROGESX INC	SCM PHARMA LTD UK, NORTH THUMBERLAND - EIR, 483, WARNING LTR 1/07 TO PRESENT
2012-3343	05/10/2012 06/08/2012	OC/ORO/ OC/ORO/ FDA/OFVM/CFSAN/OCD/EOS/	JAMES GOODWIN JD MPP CENTER FOR PROGRESSIVE REFORM	INFANT FORMULA CURRENT GOOD MANUFACTURING PRACTICES, QUALITY CONTROL PROCEDURES, NOTIFICATION REQUIREMENTS, ETC - BRIEFING DATE, NAMES OF ATTENDEES, TITLES, ETC
2012-3344	05/10/2012 06/08/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	CLOSED FOI REQUESTS 4/23-27/12

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2012-3345	05/10/2012 06/08/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRMAP CanReg, Inc.	CLOSED FOI REQUESTS 4/23-27/12
2012-3346	05/10/2012 06/08/2012	FDA/OMPT/CDRH/OCER/DFOI/	HAMILTON, LEROY	AUDIO RE RADIOLOGICAL DEVICES PANEL MTG 4/12/12
2012-3347	05/10/2012 06/08/2012	FDA/OMPT/CDRH/OCER/DFOI/ OC/OA/OM/OMP/DDM/	HAMILTON, LEROY L	ELECTROMEDICAL PRODUCTSINTL - CRANIAL ELECTROTHERAPY STIMULATOR DEVICE PETITION AUG, SEPT 2011
2012-3348	05/10/2012 06/08/2012	FDA/OMPT/CDRH/OCER/DFOI/	DAVID C. FURR FDC SERVICES LLC	NORMED - BI MULTIDIRECTIONAL DISTRACTION K021342
2012-3349	05/10/2012 06/08/2012	FDA/OMPT/CDRH/OCER/DFOI/	DAVID C. FURR FDC SERVICES LLC	NORMED - TITANIUM OSTEOTOMY SYS K022325
2012-3350	05/10/2012 06/08/2012	FDA/OMPT/CDRH/OCER/DFOI/	DAVID C. FURR FDC SERVICES LLC	NORMED - DISTAL RADIUS SYS K022231
2012-3351	05/10/2012 06/08/2012	FDA/OMPT/CDRH/OCER/DFOI/	DAVID C. FURR FDC SERVICES LLC	NORMED - CBS SYS K032634
2012-3352	05/10/2012 06/08/2012	FDA/OMPT/CDRH/OCER/DFOI/	DAVID C. FURR FDC SERVICES LLC	NORMED - TITANIUM MINIPLATE SYS K931539
2012-3353	05/10/2012 06/08/2012	FDA/OMPT/CDRH/OCER/DFOI/	DAVID C. FURR FDC SERVICES LLC	NORMED - EXTREMITY TITANIUM SYS K011118
2012-3354	05/10/2012 06/08/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/OA/OM/OMP/DDM/	DAN BURNS INFACARE PHARMACEUTICAL CORP	GASTROINTESTINAL DRUG A/C MTG TRANS 3/13/12
2012-3355	05/10/2012 06/08/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ZYMO INFACARE PHARMACEUTICAL CORP	BOVINE THROMBIN - ISR 7930300
2012-3356	05/10/2012 06/08/2012	OC/OM/OMP/DDM/	JEFF GERTH PROPUBLICA	DKT 1977N-0094W
2012-3357	05/10/2012 06/08/2012	OC/OM/OMP/DDM/	PROPUBLICA	DKT 1977N-0094W
2012-3358	05/10/2012 06/08/2012	FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/	REEVES, MICHAEL .	DOCTORS HOSPITAL, DALLAS, TX - WARNING LTRS, CMPLNTS 2008-2009, AER

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2012-3359	05/10/2012 06/08/2012	FDA/OFVM/CFSAN/OCD/EOS/	MARIA JOSE FLORES FAMILY FOODS DISTRIBUTORS INC	INDUSTRIAS LACTEAS TONI SA - MILK-BASED PRODS SID 2011-05-25/001, 2011-06-01/001, 2011-05-31/001 APRVL
2012-3360	05/10/2012 06/08/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/	STEVE ELLENBECKER GLOOR LAW GROUP LLC	RAM MEDICAL INC - COUNTERFEIT POLYPROPYLENE SURGICAL MESH INVESTIGATION RECS, CMLPNTS, LAB ANALYSES, ETC
2012-3361	05/10/2012 06/08/2012	FDA/OC/OES/DFOI/	HOOTNICK, ALEXANDRA.	ARSENIC IN RICE, RICE PRODUCTS, JUICE - FOI REQUESTS
2012-3362	05/10/2012 06/08/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/OIP/ FDA/OO/OFBA/OAGS/	HOOTNICK, ALEXANDRA	FDA ARSENIC IN RICE STUDY - CONTRACT, SUMMARIES, CORR, ETC
2012-3363	05/11/2012 06/11/2012	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	WENDY B ACCARDI WICKER, SMITH, O'HARA, MCCOY, GRAHAM & FORD, PA	GLIPIZIDE 10 MG - AERS 2008, 2009
2012-3364	05/11/2012 06/11/2012	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	WENDY B ACCARDI WICKER, SMITH, O'HARA, MCCOY, GRAHAM & FORD, PA	METOPROLOL TARTRATE 100 MG - AERS 2008, 2009
2012-3365	05/11/2012 06/11/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/	STEPHANIE B JOHNSON REDING & PILNEY	ADVANCED COSMETIC RESEARCH LABS, CHATSWORTH, CA - TCA HAIR COLOR ACCELERATOR CMLPNTS, CAERS
2012-3366	05/11/2012 06/11/2012	FDA/OGROP/ORACE-FO/BLT- DO/BLT-CB/	STEPHANIE B JOHNSON REDING & PILNEY	KPSS INC, LINTHICUM HEIGHTS, MD - TOPCHIC HAIR COLOR 250 ML CMLPNTS, CAERS
2012-3367	05/11/2012 06/11/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORACE-FO/BLT- DO/BLT-CB/	STEPHANIE B JOHNSON REDING & PILNEY	KPSS INC, LINTHICUM HEIGHTS, MD - GOLDWELL TOPCHIC LOTION 6% CMLPNTS, CAERS
2012-3368	05/11/2012 06/11/2012	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	SHAPIRO, STUART	WYETH/PFIZER - ZOSYN (TAZOBACTAM) NDA RVW
2012-3369	05/11/2012 06/11/2012	FDA/OFVM/CFSAN/OCD/EOS/	J PRICE COLEMAN COLEMAN LAW FIRM	BROMLEY TEA CO - HEALTH CLAIMS FOR TEA PRODS, COMM, EMAILS, MEETINGS , ETC

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2012-3370	05/11/2012 06/11/2012	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	SELINGER, MARC	DIAMOND PET FOODS, GASTON, SC - EIRS LAST 6 MONTHS
2012-3371	05/11/2012 06/11/2012	FDA/OFVM/CFSAN/OCD/EOS/	J PRICE COLEMAN COLEMAN LAW FIRM	TATA GLOBAL BEVERAGES LTD, TETLEY USA INC - HEALTH CLAIMS FOR TEA PRODS CORR, EMAILS, MEETINGS, ETC
2012-3372	05/11/2012 06/11/2012	FDA/OFVM/CFSAN/OCD/EOS/	J PRICE COLEMAN COLEMAN LAW FIRM	ASSOCIATED BRITISH FOODS, TWININGS NORTH AMERICA INC - HEALTH CLAIMS FOR TEA PRODS, CORR, EMAILS, MEETINGS, ETC
2012-3373	05/11/2012 06/11/2012	FDA/OFVM/CFSAN/OCD/EOS/	JJ PRICE COLEMAN COLEMAN LAW FIRM	HONEST TEA INC - HEALTH CLAIMS FOR TEA PRODS CORR, EMAILS, MEETINGS, ETC
2012-3374	05/11/2012 06/11/2012	FDA/OMPT/CDRH/OCER/DFOI/	MELANIE USSYK EXCITON TECHNOLOGIES INC	THERABOND ANTIMICROBIAL BARRIER SYS K073213
2012-3375	05/11/2012 06/11/2012	FDA/OFVM/CFSAN/OCD/EOS/	J PRICE COLEMAN COLEMAN LAW FIRM	HAIN CELESTIAL GROUP, CELESTIAL SEASONINGS - HEALTH CLAIMS FOR TEA PRODS CORR, EMAILS, MEETINGS, ETC
2012-3376	05/11/2012 06/11/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	JAE H KIM GENORAY AMERICA INC	ZEN-7000 - K103425 ACCESSION NUMBER
2012-3377	05/11/2012 06/11/2012	FDA/OMPT/CDRH/OCER/DFOI/	DAVID MOYNHAM HUNTLEIGH HEALTHCARE LTD	COVIDIEN - KENDALL - SCD SEQUENTIAL COMPRESSION COMFORT SLEEVE K100306
2012-3378	05/11/2012 06/11/2012	FDA/OMPT/CDRH/OCER/DFOI/	CAROL NAKAGAWA MERGE HEALTHCARE	CALGARY SCIENTIFIC INC - RESOLUTION MD MOBILE K111346
2012-3379	05/11/2012 06/11/2012	FDA/OMPT/CDRH/OCER/DFOI/	STEPHANIE BERGERON IMPLANT DIRECT	NOBEL BIOCARE - MEDICAL DVC PACKAGING ISSUES MDRS
2012-3380	05/11/2012 06/11/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	AUTUMN L BORTON PFIZER	WEST AGRO, HAMILTON, NY - EIRS, 483S 2/27/12 TO PRESENT
2012-3381	05/11/2012 06/11/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SANJAY H SHARMA PHD HETERO USA INC	PROMACTA (ELTROMBOPAG OLAMINE) TABS - CHEMISTRY, BIOEQV RVWS, CORR, ETC
2012-3382	05/11/2012 06/11/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	LAURA TANK CBR SYSTEMS INC	CBR SYSTEMS INC - UMBILICAL CORD BLOOD STEM CELLS EIRS, 483S 2008 TO 2010
2012-3383	05/11/2012 06/11/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	LUCAS, STEVE	DPT LAKEWOOD INC, LAKEWOOD, NJ - EIRS 02/12 TO 03/12
2012-3384	05/11/2012 06/11/2012	FDA/OMPT/CDRH/OCER/DFOI/	MURDOCK, BRETT	K060507

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2012-3385	05/11/2012 06/11/2012	OC/CVM/OCD/	DR LAURENS HAVENGA MULTIMIN USA INC	BOVI-CU NADA 140-904 - LBLG, PI
2012-3386	05/11/2012 06/11/2012	FDA/OFVM/CFSAN/OCD/EOS/	VERONICA KNAPP HOGAN LOVELLS LLP	SAVORY SNACKS - TRANS FAT INTAKE BY US POPULATION BRAND NAME, PRODUCT CODE, PKG SIZE, ETC
2012-3387	05/11/2012 06/11/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	AVINASH HASAMNIS HEMMO PHARMACEUTICALS PRIVATE LTD	HEMMO PHARMACEUTICALS PRIVATE LTD, INDIA - EIR 3/11
2012-3388	05/11/2012 06/11/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OCC/ OC/OCS/OCP/ FDA/OMPT/OSMP/OCP/	ANDREW M GREEN HALSCION	HALSCION INC - HYDROGEL SCAFFOLD REQUEST FOR DESIGNATION LTR RVW MEMOS, EMAILS
2012-3389	05/11/2012 06/11/2012	OC/OA/OM/OMP/DDM/	JENNIFER BROWN INFOTRIEVE INC	ANTIVIRAL DRUGS A/C - MITOCHODRIAL DAMAGE ASSOCIATED WITH NUCLEOSIDE ANALOGUES, ROCKVILLE,MD, 9/20-21/93
2012-3390	05/11/2012 06/11/2012	FDA/OO/OFBA/OAGS/	JOHN DAVIS PROCUREMENT REVIEW COUNCIL	COUNTY OF SAN DIEGO FEDERAL GRANTS - FINANCIAL STATUS RPTS SF 269A/SF 425 2004 TO 2012
2012-3391	05/11/2012 06/11/2012	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	DOUGLAS N BLUE II ZETETIC INC	LIFESCAN - ONE TOUCH ULTRA BLOOD GLUCOSE TEST STRIPS ENTRY #FY620082153 RECS
2012-3392	05/11/2012 06/11/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CATHERINE SAINT LOUIS NEW YORK TIMES	MIRALAX (POLYETHYLENE GLYCOL) - AERS LAST TEN YRS
2012-3393	05/11/2012 06/11/2012	FDA/OMPT/CDRH/OCER/DFOI/	KAROL RODRIGUEZ MEDICAL EQUIPMENT OF FLORIDA	TINGLE X-RAY INC - 13-FBT STATIONARY X-RAY MEDICAL TABLE, 13-BF-7E DLOOR-WALL WALL STAND; SEDECAL - G310R.1LO.APM02 32KW X-RAY HIGH FREQUENCY GENERATOR, ETC FDA APRVD CERTIFICATE LTR
2012-3394	05/11/2012	FDA/OGROP/ORR/SE-FO/FLA-	WILLIAM KONSTAND	THE ARENSON GROUP INC, TAG HEALTHCARE, TAG

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	06/11/2012	DO/FLA-CB/	TAG HEALTHCARE	MEDICAL, ETC - EIRS 2001 TO PRESENT
2012-3395	05/11/2012 06/11/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/OCM/EMOPS/ OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/MIN- DO/MIN-CB/ FDA/OGROP/ORO/NE-FO/NWE- DO/NWE-CB/ FDA/OGROP/ORO/SE-FO/ATL- DO/ATL-CB/ FDA/OGROP/ORO/SW-FO/DEN- DO/DEN-CB/ FDA/OGROP/ORO/SW-FO/KAN- DO/KAN-CB/	MICHAEL BOOTH DENVER POST	MULTISTATE E COLI OUTBREAK IN THE MIDWEST & WEST 9/09 - STAFF RPTS, MEMOS, SUMMARIES, ETC
2012-3396	05/11/2012 06/11/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CLARK G SULLIVAN ARNALL GOLDEN GREGORY LLP	FOLIC ACID DRUG EFFICACY STUDY - DESI 5897, FDC-D- 265 PROCEEDINGS, NATIONAL ACADEMY OF SCIENCES PRTS
2012-3397	05/11/2012 06/11/2012	OC/OM/OMP/DDM/	ANNA WOLONCIEJ SIDLEY AUSTIN LLP	DKT 2003P-0110, 2006P-0533, 2006P-0534, ETC.
2012-3398	05/11/2012 06/11/2012	OC/OM/OMP/DDM/	JEFF GERTH PROPUBLICA	DKT 1977N-0094
2012-3399	05/11/2012 06/11/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	CLOSED DAILY LOG 4/30/12 TO 5/4/12
2012-3400	05/11/2012 06/11/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED LOG REQUESTS 4/30-12 TO 5/4/12
2012-3401	05/11/2012 06/11/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED LOG REQUESTS 4/30/12 TO 5/4/12
2012-3402	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	LAUREN S BARR INC RESEARCH CONSULTING & SUBMISSIONS	FOI REQUESTS 4/23-27/12
2012-3403	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	LAUREN S BARR INC RESEARCH CONSULTING &	FOI REQUESTS 4/30/12 TO 5/4/12

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SUBMISSIONS				
2012-3404	05/14/2012 06/12/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	JENNIFER K REGISTER BLASINGAME BURCH ET AL ATTYS	POST MARKET SURVEILLANCE STUDIES - PS120002, PS120003, PS120004, ETC, RECS
2012-3405	05/14/2012 06/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	JENNIFER STAUNTON INSTRUMED INTERNATIONAL INC	INSTRUMED - RONGEUR K081651
2012-3406	05/14/2012 06/12/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JERRY L. CHAPMAN INTERNATIONAL PHARMACEUTICAL QUALITY	MUSTAFA NEVZAT ILAC SANAYII AS, YENIBOSNA, TURKEY - EIR 4/20/12-5/3/12
2012-3407	05/14/2012 06/12/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID B RHEINGOLD RHEINGOLD, VALET, ET AL	INDIVIDUAL RECS
2012-3408	05/14/2012 06/12/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORA/ OC/ORA/ FDA/OGROP/ORACE-FO/BLT- DO/BLT-CB/ FDA/OGROP/ORACE-FO/CIN- DO/CIN-CB/ FDA/OGROP/ORACE-FO/DET- DO/DET-CB/ FDA/OGROP/ORACE-FO/PHI- DO/PHI-CB/ FDA/OGROP/ORACE-FO/NWE- DO/NWE-CB/ FDA/OGROP/ORACE-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORACE-FO/SAN- DO/SAN-CB/ FDA/OGROP/ORACE-FO/SEA- DO/SEA-CB/ FDA/OGROP/ORACE-FO/ATL- DO/ATL-CB/	CHARLES BARRETT CHARLES F BARRETT ATTORNEY AT LAW	DOLE - MISBRANDING FOOD PRODS CORR

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		FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/		
2012-3409	05/14/2012 06/12/2012	FDA/OFVM/CFSAN/OCD/EOS/	JONATHAN BERMAN JONES DAY	CENTER FOR SCIENCE IN THE PUBLIC INTEREST (CSPI) - RESP TO 3/14/06
2012-3410	05/14/2012 06/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	ROBERTA LEE ACUEITY HEALTHCARE INC	ACUEITY - MEDICAL LIGHT SOURCE K032430; VIADUCT - MICROENDOSCOPE & ACCESSORIES K011189
2012-3411	05/14/2012 06/12/2012	OC/CVM/OCD/	KRISTI O. SMEDLEY WASHINGTON INFORMATION SOURCE	NADA 55-099, 55-101, 139-941 FOI SUMMARIES
2012-3412	05/14/2012 06/12/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/OR/ OC/OR/	SEAN DUNAGAN JUDICIAL WATCH	ASPARTAME - CAERS 1/1/11-5/1/12
2012-3413	05/14/2012 06/12/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	ANNA DEMKOVIC ABBOTT LABORATORIES, INC.	ABBOTT LABS, FAIRFIELD, CA - EIR 6/18-7/6/09, 4/13-15/11
2012-3414	05/14/2012 06/12/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANGELIA D. SLAYTON INC RESEARCH CONSULTING & SUBMISSIONS	A TAKEDA CO, BADEN-WUERTTEMBERG, GERMANY - 483 4/19/11
2012-3415	05/14/2012 06/12/2012	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	GISSENDANNER, ROBIN	CMPLNT 120110 - RPT
2012-3416	05/14/2012 06/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	WYNN STOCKING CAROLINA LIQUID CHEMISTRIES CORP	ALBUMIN REAGENT K021636; CK NAC REAGENT K974833; DIRECT BILIRUBIN REAGENT K011972
2012-3417	05/14/2012 06/12/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	SHLONOGI, OSAKA, JAPAN - 483 7/31/09
2012-3418	05/14/2012	FDA/OGROP/ORACE-FO/NWJ-	BRENDA M GARTZ	BIOCHEM LABS, LYNDHURST, NJ - 483 5/18/11

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	06/12/2012	DO/NWJ-CB/	ELI LILLY & CO	
2012-3419	05/14/2012 06/12/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	JOHN R. McLEOD BROWN & JAMES PC	SYNTRAX INNOVATIONS - LIPOKINETIX RPTS CERTIFIED
2012-3420	05/14/2012 06/12/2012	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	ERIK P. CREP WICKER SMITH ET AL	INFUPHARMA - RPTS
2012-3421	05/14/2012 06/12/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	STRULOVIC, SOLOMAN	CIBA VISION INC - CLEAR CARE SOL, LBLG INFO RECS, DOC CPT1200070
2012-3422	05/14/2012 06/12/2012	OC/CVM/OCD/	KRISTI O SMEDLEY WASHINGTON INFORMATION SOURCE	HYDROLYZED YEAST (AAFCO DEFINITION 96.12) - SUBMISSIONS, CORR, MEMO RECS ETC
2012-3423	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ORIGINAL REQUEST LETTER 2012-2676
2012-3424	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-1100
2012-3425	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ORIGINAL REQUEST LETTER 2012-2757
2012-3426	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ORIGINAL REQUEST LETTER 2012-2829
2012-3427	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ORIGINAL REQUEST LETTER 2012-2833
2012-3428	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ORIGINAL REQUEST LETTER 2012-2908
2012-3429	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ORIGINAL REQUEST LETTER 2012-2945
2012-3430	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ORIGINAL REQUEST LETTER 2012-2980
2012-3431	05/14/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2012-1132

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	06/12/2012		MERCK & CO., INC.	
2012-3432	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ORIGINAL REQUEST LETTER 2012-2546
2012-3433	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ORIGINAL REQUEST LETTER 2012-3011
2012-3434	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ORIGINAL REQUEST LETTER 2012-3046
2012-3435	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 5/7-11/12
2012-3436	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ORIGINAL REQUEST LETTER 2012-2583
2012-3437	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ORIGINAL REQUEST LETTER 2012-3050
2012-3438	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ORIGINAL REQUEST LETTER 2012-2414
2012-3439	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ORIGINAL REQUEST LETTER 2012-3040
2012-3440	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ORIGINAL REQUEST LETTER 2012-3014
2012-3441	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ORIGINAL REQUEST LETTER 2012-2504
2012-3442	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 4/30/2012 - 5/4/2012
2012-3443	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-835
2012-3444	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2010-5894
2012-3445	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-6176
2012-3446	05/14/2012 06/12/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	VAERS DIRECT REPORTS, MEDWATCH REPORTS and ANY SOURCE DOCUMENTS for THE FOLLOWING TWO (2) CASES, VAERS IDs # 433364-1 # 434427-1 for Gardasil (HPV VACCINE, MERCK & CO, INC.)
2012-3447	05/14/2012	FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16)	DIRECT REPORTS, MEDWATCH REPORTS and ANY

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	06/12/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MERCK & CO., INC.	SOURCE DOCUMENTS for THE FOLLOWING FOUR (4) CASES, ISR NUMBERS: 8180426 8190044 8217210 8255342 for JANUVIA, (SITAGLIPTIN PHOSPHATE, MERCK)
2012-3448	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-1530
2012-3449	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	COMPLETE RESPONSE FOR Log Request # 2012-1532 LANCASTER LABS, LANCASTER, PA - EIRS, 483S, CO RESP 8/1/11 TO 1/31/12;
2012-3450	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-1532
2012-3451	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-1372
2012-3452	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-1389
2012-3453	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-945
2012-3454	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-1390
2012-3455	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-1441
2012-3456	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-1468
2012-3457	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-1469
2012-3458	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-1472
2012-3459	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-1526
2012-3460	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-984
2012-3461	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-1537
2012-3462	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-1543

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2012-3463	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-1544
2012-3464	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-1564
2012-3465	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-1565
2012-3466	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-1640
2012-3467	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-1613
2012-3468	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-1615
2012-3469	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-1636
2012-3470	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-1649
2012-3471	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-1650
2012-3472	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-1774
2012-3473	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-1032
2012-3474	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-2054
2012-3475	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-1942
2012-3476	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-2419
2012-3477	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-2422
2012-3478	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-1182
2012-3479	05/14/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2012-1211

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	06/12/2012		MERCK & CO., INC.	
2012-3480	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-1287
2012-3481	05/14/2012 06/12/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-1229
2012-3482	05/15/2012 06/13/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OC/OES/DFOI/	MICHAEL W CZACK CZACK, MICHAEL	INDIVIDUAL RECS
2012-3483	05/15/2012 06/13/2012	OC/CVM/OCD/	CHRISTOPHER HATTON CIRCA HEALTHCARE LLC	ANIKA THERAPEUTICS INC - HYVISC STERILE INJ NADA 122-578 FOI SUMMARY
2012-3484	05/15/2012 06/13/2012	FDA/OC/OCC/ OC/ORA/OCI/ OC/ORA/OCI/	Doe J	SEC CMLPNT TCR 1309184950901
2012-3485	05/15/2012 06/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	ANGELIA D SLAYTON INC REGULATORY CONSULTING & SUBMISSIONS	HOSPIRA, LA AURORA DE HEREDIA, COSTA RICA - 483S 1/11 TO PRESENT
2012-3486	05/15/2012 06/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DANIEL KOCH WALKER SMITH CAPITAL LP	WATSON LABS - CORTICOTROPIN ANDA 88-772 EQUIVALENT GENERIC RECS
2012-3487	05/15/2012 06/13/2012	FDA/OGROP/ORA/ORO/DIOP/	LACY L KOLO PHD Patton Boggs LLP	BETA-ALANINE - BILL OF LADING, WEIGHT, SHIPPER, ETC
2012-3488	05/15/2012 06/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ALAN BECKMAN MOBIUS THERAPEUTICS LLC	MITOMYCIN - ISRS 7556657, 7556658, 7964160, ETC
2012-3489	05/15/2012 06/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DINA ONISHI JAZZ PHARMS	ELESTRIN (ESTRADIOL) NDA 21-813 - ECTD SEQUENCE SUBMISSIONS 0000 TO 0007
2012-3490	05/15/2012	FDA/OMPT/CDER/GRP/DIDP/	DUSTIN BLOCK	CORTICOTROPIN ANDA 88-772 - PI, APRVL LTR

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	06/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	IPD ANALYTICS LLC	
2012-3491	05/15/2012 06/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BEAUDOIN, DERIC J	KENALOG TOPICAL SPRAY - TESTING, SUPPLIERS, RAW MATERIALS, ETC
2012-3492	05/15/2012 06/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SKALIOTIS, ROSS	NDA 17-078/S000,S030,036; ANDA 76-137/S000,S001 - APRVL RECS
2012-3493	05/15/2012 06/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KAREN SCHULTZ DOMINION GROUP INC	GALDERMA LABS - METROGEL (METRONIDAZOLE) 1% PUMP ACTION LTR, NDA 021789/S-004
2012-3494	05/15/2012 06/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KAREN SCHULTZ DOMINION GROUP INC	GALDERMA LABS - METROGEL (METRONIDAZOLE) 1% PUMP SBA, NDA 021789/S-004
2012-3495	05/15/2012 06/13/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 4/16-20/12
2012-3496	05/15/2012 06/13/2012	FDA/OFVM/CFSAN/OCD/EOS/	ANN E CRUM SENSIENT IMAGING TECHNOLOGIES	EDTA USE IN FOODS, DRUGS, COSMETICS - CAP 9C0218
2012-3497	05/15/2012 06/13/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 4/23-27/12
2012-3498	05/15/2012 06/13/2012	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 4/16-20/12
2012-3499	05/15/2012 06/13/2012	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 4/23-27/12
2012-3500	05/15/2012 06/13/2012	FDA/OC/OES/DFOI/	INC REGULATORY CONSULTING	FOI DAILY LOG 4/16-20/12

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			& SUBMISSIONS	
2012-3501	05/15/2012 06/13/2012	FDA/OC/OES/DFOI/	INC REGULATORY CONSULTING & SUBMISSIONS	FOI DAILY LOG 4/23-27/12
2012-3502	05/15/2012 06/13/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	PETER MALONE BRISTOL MYERS SQUIBB CO	BRISTOL MYERS SQUIBB CO INC, EAST SYRACUSE, NY - EIR 8/16- 20/10
2012-3503	05/15/2012 06/13/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 4/16-20/12
2012-3504	05/15/2012 06/13/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 4/23-27/12
2012-3505	05/15/2012 06/13/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	PETER MALONE BRISTOL MYERS SQUIBB CO	BRISTOL MYERS SQUIBB CO INC, SYRACUSE, NY - EIR 4/1-18/08
2012-3506	05/15/2012 06/13/2012	FDA/OC/OES/DFOI/	GLADYS TONKIN WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 4/16-20/12
2012-3507	05/15/2012 06/13/2012	FDA/OC/OES/DFOI/	GLADYS TONKIN WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 4/23-27/12
2012-3508	05/15/2012 06/13/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 4/16-20/12
2012-3509	05/15/2012 06/13/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 4/23-27/12
2012-3510	05/15/2012 06/13/2012	OC/ORAE/ OC/ORAE/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Doe J	CMPLNT
2012-3511	05/15/2012 06/13/2012	OC/ORAE/ORM/ OC/ORAE/ORM/	MERLE ZIMMERMANN AMERICAN HERBAL PRODUCTS ASSOCIATION	LIST OF DOMESTIC & FOREIGN GOOD MANUFACTURING PRACTICES (GMP) INPS 1/10 TO 4/12
2012-3512	05/15/2012 06/13/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 4/16-20/12
2012-3513	05/15/2012 06/13/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 4/23-27/12

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2012-3514	05/15/2012 06/13/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2009-7997
2012-3515	05/15/2012 06/13/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2009-8380
2012-3516	05/15/2012 06/13/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-5613
2012-3517	05/15/2012 06/13/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-7187
2012-3518	05/15/2012 06/13/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-8479
2012-3519	05/15/2012 06/13/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-8719
2012-3520	05/15/2012 06/13/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-8805
2012-3521	05/15/2012 06/13/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-9004
2012-3522	05/15/2012 06/13/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-9241
2012-3523	05/15/2012 06/13/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-9361
2012-3524	05/15/2012 06/13/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-9374
2012-3525	05/15/2012 06/13/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-182
2012-3526	05/15/2012 06/13/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-9534
2012-3527	05/15/2012 06/13/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-9635
2012-3528	05/15/2012 06/13/2012	FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OGROP/ORR/CE-FO/MIN-DO/MIN-CB/	MUSCARELLA, LAWRENCE .	PSUEDOMONAS AERUGINOSA OUTBREAK AT METHODIST HOSPITAL, HOUSTON, TX 2009 RECS

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		FDA/OGROP/ORPA/PA-FO/SAN-DO/SAN-CB/		
2012-3529	05/15/2012 06/13/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-9562
2012-3530	05/15/2012 06/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ERIC WALTER CAMIL SR CAMIL CONSULTING CORP	WATSON LABS - CORTICOTROPIN NDA 88-772; QUESTCOR PHARMA - HP ACTHAR GEL NDA 22-432; ORGANIVS LAGRANGE - CORTICOTROPIN NDA 10-831, ETEC RECS
2012-3531	05/15/2012 06/13/2012	OC/CVM/OCD/ FDA/OGROP/ORPA/SE-FO/ATL-DO/ATL-CB/	JAMES ANDREWS FOOD SAFETY NEWS	DIAMOND PET FOOD, GASTON, SC - 483, CMLPNTS
2012-3532	05/15/2012 06/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MORGAN LAMARE BECK & AMSDEN PLLC	ABILIFY - PROMOTIONAL RECS
2012-3533	05/15/2012 06/13/2012	OC/ORPA/ OC/ORPA/ FDA/OGROP/ORPA/PA-FO/LOS-DO/LOS-CB/	Doe J	CMLPNT
2012-3534	05/15/2012 06/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MORGAN LAMARE BECK & AMSDEN PLLC	ABILIFY - AERS 2002 TO 2007
2012-3535	05/15/2012 06/13/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CTP/OD/	DAVID FISCHER BLUNT WRAP USA	BLUNT WRAP INC - KS SLIM GOLD US NON FOILED, KSS GREEN UNBLEACHED/EXECUTIVE BRANCH UNBLEACHED, KSS SNOOP DOGG - EQUIVALENCE RPT
2012-3536	05/15/2012 06/13/2012	FDA/OGROP/ORPA/SE-FO/ATL-DO/ATL-CB/	MEG KINNARD ASSOCIATED PRESS	DIAMOND PET FOODS, GASTON, SC - SALMONELLA RPTS, INSP, DATE
2012-3537	05/15/2012 06/13/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	APRIL HARRY INTEGRA LIMIT UNCERTAINTY	PHYSICIAN INDUSTRIES - RADIO ABLATION NEEDLE K040565
2012-3538	05/15/2012 06/13/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/OA/OM/OMP/DDM/	ROBIN FELDMAN LSRO SOLUTIONS	DCK 1984F-0050
2012-3539	05/15/2012 06/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	APRIL LEE KODENT INC	CURASAN AG, FRANKFURT, GERMANY - CERASORB DENTAL, CERASORB M DENTAL, CERASORB PERIO K01443
2012-3540	05/15/2012	FDA/OMPT/CDRH/OCER/DFOI/	APRIL LEE	BIOMATLANTE - MBCP K051885

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	06/13/2012		KODENT INC	
2012-3541	05/15/2012 06/13/2012	OC/CVM/OCD/	PAUL MARTIN, Ph.D. PJM SCIENTIFIC PTY LTD	ESTRUMATE (CLOPROSTENOL SODIUM) NADA 113-645 FOI SUMMARY
2012-3542	05/15/2012 06/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/OCOS/OES/ OC/OCOS/OES/ OC/OCOS/OL/ OC/OA/OM/OMP/DDM/ FDA/OC/OES/DFOI/ OC/OA/OM/OMP/DDM/	WILLIAM WILSON AMERICANS FOR LIMITED GOVERNMENT	PUBLIC CITIZEN, ALLIANCE FOR JUSTICE, CENTER FOR PROGRESSIVE REFORM, ETC - FDA CHANGES-BEING-EFFECTED PROCESS MTGS, EMAILS, LTRS, ETC
2012-3543	05/15/2012 06/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	DEANNA R. SWITS NIXON PEABODY LLP	MYOSURE - HYSTEROSCOPIC TISSUE REMOVAL SYS K120593
2012-3544	05/15/2012 06/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	SCHAFFER, DEBORAH	ZETEK - OVACUE CUE FERTILITY MONITOR K850579
2012-3545	05/15/2012 06/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	CHRISTOPHER SHAKIB TERRELL HOGAN ELLIS YEGELWEL PA	MEDTRONIC - CONCERTO MODEL C154DWK ICD RECS
2012-3546	05/15/2012 06/13/2012	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	AUDREY E. VARWIG DICKIE MCCAMEY & CHILCOTE	ISP TECHNOLOGIES INC, TEXAS CITY, TX - RECALL, FINES, CITATIONS
2012-3547	05/15/2012 06/13/2012	OC/ORAS/ OC/ORAS/	PAIGE SAVITZ BEAVER STEET FISHERIES INC	MAOMING XINZHOU SEAFOOD CO LTD - FROZEN TILAPIA FILLETS ENTRY #002-8139311-6 ANALYTICAL RESULTS
2012-3548	05/16/2012 06/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	DEANNA R SWITS NIXON PEABODY LLP	MYOSURE HYSTEROSCOPIC TISSUE REMOVAL SYS K120593
2012-3549	05/16/2012 06/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	SCHAFFER, DEBOARAH	OB/GYN CONCEPTS LTD - OVU-TRAC OVULATION TIMING KIT K870528
2012-3550	05/16/2012 06/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TISCHER LOCKHART HOLLINGSWORTH LLP	IONTOPHERETIC DRUG DELIVERY SYS - SS&E, LBLG, PI, ETC 1991 TO 1995
2012-3551	05/16/2012	FDA/OMPT/CDER/ORP/DIDP/	TISCHER LOCKHART	ANGIOTENSIN-VONVERTING-ENZXYME INIBITORS (ACE INHIBITORS) SS&E, LBLG, PI, ETC 1991 TO 1995

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	06/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HOLLINGSWORTH LLP	
2012-3552	05/16/2012 06/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	MARK K REMUS STEPTOE & JOHNSON	APP PHARMACEUTICALS LLC - NAROPIN (ROPIVACAINE HCL) NDA 20-533 FOI REQUESTS, LTRS, EMAILS, ETC
2012-3553	05/16/2012 06/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	TISCHER LOCKHART HOLLINGSWORTH LLP	SPINAL CATHETERS ASSOCIATED WITH CAUDA EQUINA SYNDROME SS&E, LBLG, PI, ETC 1991 TO 1995
2012-3554	05/16/2012 06/29/2012	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	MARTHA SLOBODA ADHESIVES RESEARCH INC	MONOSOL RX LLC, PORTAGE, IN - EIRS 2006-2012
2012-3555	05/16/2012 06/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TISCHER LOCKHART HOLLINGSWORTH LLP	ALBUNEX - SS&E, LBLG, PI, ETC 1991 TO 1995
2012-3556	05/16/2012 06/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	NORBERT GOTTESMAN AVET CAPITAL MANAGEMENT LLC	AVANIR PHARMS - NUEDEXTA (DEXTROMETHORPHAN HYDROBROMIDE, QUINIDINE SULFATE) AERS, CORR
2012-3557	05/16/2012 06/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MICHELE SINOWAY PHD LACHMAN CONSULTANT SERVICES INC	BOEHRINGER INGELHEIM - VIRAMUNE XR NDA 201-152 APRVL SUMMARY, RVWS
2012-3558	05/16/2012 06/14/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	WASHBURN, KIMBERLEE	STRYKER - HIP MODULE NAVIGATION SYS K022365, CT BASED HIP MODULE NAVIGATION SYS K050615; MAKO SURGICAL CORP - ROBOTIC ARM INTERACTIVE ORTHOPEDIC SYS K093425, ETC
2012-3559	05/16/2012 06/14/2012	OC/CVM/OCD/	KRISTI O SMEDLEY PHD WASHINGTON INFORMATION SOURCE	PFIZER - ORBESEAL (BISMUTH SUBNITRATE) WARNING LTRS, LBLG, RVWS, ETC
2012-3560	05/16/2012 06/14/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	GLOSSOP, NATASHA	TRAXTAL TECHNOLOGIES INC - ABARIS K053610

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2012-3561	05/16/2012 06/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	GLOSSOP, NATASHA	EIGEN LLC - 3-D IMAGING WORKSTATION K081093
2012-3562	05/16/2012 06/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	GLOSSOP, NATASHA	KOELIS - UROSTATION 3D PROSTATE SUITE K100793
2012-3563	05/16/2012 06/14/2012	OC/OSMP/OOPD/	BRIAN WALTER ACORDA THEMAPEUTICS	CLOBAZAM, FELBAMATE, LAMOTRIGINE, ETC - ORPHAN DRUG DESIGNATION
2012-3564	05/16/2012 06/14/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	SUSAN D GOLDSTEIN-FALK MDI CONSULTANTS INC	DENTSPLY INTERNATIONAL - QMIX ENDODONTIC IRRIGATIING SOL K103244
2012-3565	05/16/2012 06/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LYNDSY HASSETT STASON PHARMACEUTICALS INC	ZYRTEC ORAL TABS NDA 19-835 - APRVL RECS
2012-3566	05/16/2012 06/14/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	JESSIE L JANDOVITZ MORELLI RATNER PC	RISPERIDONE (RISPERIDAL) - AERS
2012-3567	05/16/2012 06/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WARREN WILLIAMS FOREST RESEARCH INSTITUTE	ABILIFY (ARIPIPARAZOLE NDA 21-336/S002 - APRVL RECS
2012-3568	05/16/2012 06/14/2012	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	ELIZABERH J MAHONEY BAXTER HEALTHCARE CORP	BAXTER HEALTHCARE CORP, DEERFIELD, IL - EIRS 03/05/08-06/06/08
2012-3569	05/16/2012 06/14/2012	FDA/OGROP/ORACE-FO/ATL-DO/ATL-CB/	MEG KINNARD AP ASSOCIATED PRESS	DIAMOND PET FOOD, GASTON, SC - EIRS, RECALLS 2005 TO PRESENT
2012-3570	05/16/2012 06/14/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	BRENT M ARDAUGH MPH MS NORTHWESTERN UNIV FEINBERG SCHOOL OF MEDICINE	K001122, K984220, K972412, ETC
2012-3571	05/16/2012 06/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRENT M ARDAUGH MPH MS NORTHWESTERN UNIV FEINBERG SCHOOL OF MEDICINE	K050558, K944353, K901659
2012-3572	05/16/2012 06/14/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI CLOSES REQUESTS 5/7-11/12
2012-3573	05/16/2012 06/14/2012	FDA/OC/OES/DFOI/	LAUREN S BARR INC RESEARCH CONSULTING & SUBMISSIONS	FOI CLOSED REQUESTS 4/30 12 TO 5/4/12

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2012-3574	05/16/2012 06/14/2012	FDA/OC/OES/DFOI/	LAUREN S BARR INC RESEARCH CONSULTING & SUBMISSIONS	FOI CLOSED REQUESTS 5/7-11/12
2012-3575	05/16/2012 06/14/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI CLOSED REQUESTS 3/26-30/12
2012-3576	05/16/2012 06/14/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI CLOSED REQUESTS 4/2-6/12
2012-3577	05/16/2012 06/14/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI CLOSED REQUESTS 4/0-13/12
2012-3578	05/16/2012 06/14/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI CLOSED REQUESTS 4/16-2012
2012-3579	05/16/2012 06/14/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI CLOSED REQUESTS 4/23-27/12
2012-3580	05/16/2012 06/14/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI CLOSED REQUESTS 4/30 12 TO 5/4/12
2012-3581	05/16/2012 06/14/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI CLOSED REQUESTS 5/7-11/12
2012-3582	05/16/2012 06/14/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/OCM/EMOPS/ OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SW-FO/DEN- DO/DEN-CB/ FDA/OGROP/ORO/CE-FO/MIN- DO/MIN-CB/ FDA/OGROP/ORO/NE-FO/NWE- DO/NWE-CB/ FDA/OGROP/ORO/SW-FO/KAN- DO/KAN-CB/	NICHOLAS J PAROLISI LITCHFIELD CAVO LLP	10 ALLEGED E COLI ILLNESSES ASSOCIATED WITH CLUSTER NO 0910MLEXH-1 - RPTS, MEMOS, ANALYTICAL STUDIES, ETC
2012-3583	05/16/2012	FDA/OMPT/CBER/OCOD/DDOM/	LEXIA B KROWN	CBER, CDER, CDRH, ETC - ORGANIZATIONAL CHARTS,

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	06/14/2012	ALFB/ FDA/OMPT/CTP/OD/ OC/CVM/OCD/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/ OC/OCS/NCTR/OD/ OC/OCOS/OES/ OC/OCOS/OES/ OC/ORO/ OC/ORO/ OC/ORO/ORM/ OC/ORO/ORM/ OC/ORO/ OC/ORO/	O'DONNELL & WILLIAMS PC	NAMES, TITLES, ETC
2012-3584	05/16/2012 06/14/2012	OC/ORO/ORM/ OC/ORO/ORM/	JORDAN, DAVID P	LIST OF FORIEGN & DOMESTIC DRUG INSPS; 10/11 TO PRESENT
2012-3585	05/16/2012 06/14/2012	FDA/OFVM/CFSAN/OCD/EOS/	ROMAR ROENFELD POINTSTATE CAPITAL LP	EXCLUSIVE SUPPLEMENTS, FAHRENHEIT, GASPARI NUTRITION, ETC - DMAA (DIMETHYLAMYLAMINE) RESP TO WARNING LTRS
2012-3586	05/16/2012 06/14/2012	FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/	IVAN CABEZUELA NOMURA INTERNATIONAL PLC	NYCOMED US, MELLVILLE, NY - 483, WARNING LTRS, EIRS 2007 TO PRESENT
2012-3587	05/17/2012 06/15/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI CLOSED REQUESTS 5/7-12/12
2012-3588	05/17/2012 06/15/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN F. THOMPSON ROBINSON & THOMPSON	CITALOPRAM; CELEXA - AER
2012-3589	05/17/2012 06/15/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN F. THOMPSON ROBINSON & THOMPSON	CYCLOSPORIN A; NEORAL - AER

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		FDA/OMPT/CDER/GRP/DIDP/		
2012-3590	05/17/2012 06/15/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN F. THOMPSON ROBINSON & THOMPSON	ESICITALOPRAM; LEXAPRO - AER
2012-3591	05/17/2012 06/15/2012	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	SCOTT ANTONIA, MD, Ph.D. MOFFITT CANCER CENTER	DR. ANTONIA - 483 8/15/02 BB-IND-7952
2012-3592	05/17/2012 06/15/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	RON JEFFREY CASMED MEDICAL SYSTEMS INC	SOMANETICS CORP K080769
2012-3593	05/17/2012 06/15/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	RON JEFFREY CASMED MEDICAL SYSTEMS INC	SOMANETICS K082327
2012-3594	05/17/2012 06/18/2012	FDA/OFVM/CFSAN/OCD/EOS/	WILLIAM A. OLSON, Ph.D. WASHINGTON INFORMATION SOURCE	FAP 6B4495
2012-3595	05/17/2012 06/15/2012	FDA/OFVM/CFSAN/OCD/EOS/	WILLIAM A. OLSON, Ph.D. WASHINGTON INFORMATION SOURCE	FCN 1091
2012-3596	05/17/2012 06/15/2012	FDA/OMPT/CDRH/OCER/DFOI/	AILEEN M. GARIEPY, MD, MPH YALE UNIVERSITY	ESSURE - RPTS
2012-3597	05/17/2012 06/15/2012	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	KARINA CASTILLO INTERFARMA CORP	INTERFARMA CORP, MIAMI, FL - EIR 1/10
2012-3598	05/17/2012 06/15/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANNE E. HANCOCK MCINTOSH LAW FIRM PC	WATSON PHARMS - PREDNISOLONE NDC 0591-5059 PACKAGE INSERT
2012-3599	05/17/2012 06/15/2012	OC/OM/OMP/DDM/	SETH A. MAILHOT SHEPPARD MULLIN RICHTER & HAMPTON, LLP	DKT 1978N-0021D
2012-3600	05/17/2012 06/15/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANNE E. HANCOCK MCINTOSH LAW FIRM PC	PHARMACIA & UPJOHN CO - SOLU MEDROL PACKAGE INSERT CERTIFIED
2012-3601	05/17/2012	FDA/OMPT/CDER/GRP/DIDP/	ANNE E. HANCOCK	BEDFORD LABS - METHYLPREDNISOLONE SODIUM

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	06/15/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MCINTOSH LAW FIRM PC	SUCCINATE PACKAGE INSERT CERTIFIED
2012-3602	05/17/2012 06/15/2012	OC/OM/OMP/DDM/	SETH MAILHOT SHEPPARD MULLIN RICHTER & HAMPTON, LLP	DKT FDA-2012-P-0317
2012-3603	05/17/2012 06/15/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANNE E. HANCOCK MCINTOSH LAW FIRM PC	GREENSTONE LLC - METHYLPREDNISOLONE NDC 59762-3327 PACKAGE INSERT CERTIFIED
2012-3604	05/17/2012 06/15/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANNE E. HANCOCK MCINTOSH LAW FIRM PC	PHARMACIA & UPJOHN CO - DEPO MEDROL NDC 0009-0306 PACKAGE INSERT CERTIFIED
2012-3605	05/17/2012 06/15/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANNE E. HANCOCK MCINTOSH LAW FIRM PC	WATSON PHARMS - PREDNISONE NDC 0591-5442 PACKAGE INSERT CERTIFIED
2012-3606	05/17/2012 06/15/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANNE E. HANCOCK MCINTOSH LAW FIRM PC	TEVA PARENTAL MEDICINES - METHYLPREDNISOLONE ACETATE PACKAGE INSERT CERTIFIED
2012-3607	05/17/2012 06/15/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANNE E. HANCOCK MCINTOSH LAW FIRM PC	WATSON PHARMS - PREDNISONE NDC 0951-5442 PACKAGE INSERT CERTIFIED
2012-3608	05/17/2012 06/15/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	F. DOUGLAS HARTNETT ELITOK & HARTNETT AT LAW PLLC	INDIVIDUAL RECS
2012-3609	05/17/2012 06/15/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	TRAN, DUONG	RIMED LTD - DIGI LITE TCD DVC K062578
2012-3610	05/17/2012	FDA/OFVM/CFSAN/OCD/EOS/	JOAN SYLVAIN BAUGHAN	WR GRACE & CO - FAP OB4231

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	06/15/2012		Keller and Heckman LLP	
2012-3611	05/17/2012 06/15/2012	FDA/OGROP/ORR/SE-FO/NOL-DO/NOL-CB/	WAFF 48	NANCY E ECKERT, LIFESOUTH COMMUNITY BLOOD CTR - WARNING LTR
2012-3612	05/18/2012 06/18/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-601
2012-3613	05/18/2012 06/18/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-478
2012-3614	05/18/2012 06/18/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-2533
2012-3615	05/18/2012 06/18/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-790
2012-3616	05/18/2012 06/18/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-986
2012-3617	05/18/2012 06/18/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-364
2012-3618	05/18/2012 06/18/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-1201
2012-3619	05/18/2012 06/18/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-2535
2012-3620	05/18/2012 06/18/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-1739
2012-3621	05/18/2012 06/18/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-2402
2012-3622	05/18/2012 06/18/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ISR 8199431-6
2012-3623	05/18/2012 06/18/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORR/ORO/DIOP/	STEPHANIE ARMOUR BLOOMBERG NEWS	LUCKY STAR MARKETING LLC, SAN BERNARDINO, CA - EIRS, ENFORCEMENT ACTIONS 2009 TO PRESENT
2012-3624	05/18/2012 06/18/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/	STEPHANIE ARMOUR BLOOMBERG NEWS	PAUHLER FRESH, NOGALES, AZ, CULIACAN, MEXICO, AGRICOLA, SAN JUAN - EIR, ENFORCEMENT ACTIONS 2009 TO PRESENT

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		FDA/OGROP/ORO/ORO/DIOP/		
2012-3625	05/18/2012 06/18/2012	FDA/OMPT/CDRH/OCER/DFOI/	ANN WATERHOUSE HILL-ROM	K972111, K970636, K964873, ETC
2012-3626	05/18/2012 06/18/2012	FDA/OMPT/CDRH/OCER/DFOI/	PETER A TAKES KYPHA INC	DADE BEHRING MARBUG GMBH (DADE BEHRING INC) - DIMENSION VISTA C3 & C4 COMPLEMENT FLEX K061852
2012-3627	05/18/2012 06/18/2012	FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	VALERIE SCHEIDT PF CHANG'S	HUY FONG FOODS, ROSEMEAD,CA - EIRS, 483S MOST RECENT
2012-3628	05/18/2012 06/18/2012	OC/OSMP/OOPD/ FDA/OMPT/OSMP/OOPD/	NORBERT GOTTESMAN AVET CAPITAL MANAGEMENT LLC	ABBOTT, DEPOMED - GRALISE (GABEPENTIN) 300 MG, 600 MG TABS NDA 22-544 ORPHAN DRUG DESIGNATION
2012-3629	05/18/2012 06/18/2012	FDA/OC/OES/DFOI/	AMY KINCANON LEXIS NEXIS COURTLINK INC	2012-2423
2012-3630	05/18/2012 06/18/2012	OC/ORO/ORM/ OC/ORO/ORM/	GAIL LESSICK LACHMAN CONSULTANT SERVICES INC	FOREIGN & DOMESTIC DRUG COMPANIES, MEDICAL DVC MFRS, BIORESEARCH MONITORING (BIMO), ETC - INSPS 3/1-31/12
2012-3631	05/18/2012 06/18/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SEAN HIGGINS ANDREWS THORNTON	JACK3d, OXYELITE PRO, NUTREX LIPO-6 BLACK ETC (DMAA) - AERS
2012-3632	05/18/2012 06/18/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	KATE WILLSON CENTER FOR PUBLIC INTEGRITY	HUMAN CELL & TISSUE ESTABLISHMENTS OUTSIDE THE US 2001 TO PRESENT
2012-3633	05/18/2012 06/18/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	MERCK - ISRS 5792504, 587293, 6228059, ETC
2012-3634	05/18/2012 06/18/2012	FDA/OMPT/CTP/OD/	FOI Services, Inc.	MARLBORO SELECT - CORR 06/22/09 TO PRESENT
2012-3635	05/18/2012 06/27/2012	FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	MATTHEW ROMAN MACUGA LIDDLE & DUBIN PC	KIRKLAND - SIGNATURE SUPER PREMIUM ADULT DOG LAMB & CHICKEN, RICE & VEGETABLE FORMULA, ETC CMLPNTS
2012-3636	05/18/2012 06/18/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORO/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORO/PA-FO/LOS-	BLAKE A EUDY MORRIS POLICH & PURDY LLP	AIRCAST INC - DJO AIRCAST ACCESSORY KIT K925677

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		DO/LOS-CB/		
2012-3637	05/18/2012 06/18/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OGROP/ORACE-FO/CHI- DO/CHI-CB/ FDA/OGROP/ORACE-FO/CIN- DO/CIN-CB/ FDA/OGROP/ORACE-FO/DET- DO/DET-CB/ FDA/OGROP/ORACE-FO/MIN- DO/MIN-CB/ FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORACE-FO/PHI- DO/PHI-CB/ FDA/OGROP/ORANE-FO/NYK- DO/NYK-DCB/ FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORAPA-FO/SEA- DO/SEA-CB/ FDA/OGROP/ORASE-FO/ATL- DO/ATL-CB/ FDA/OGROP/ORASE-FO/FLA- DO/FLA-CB/ FDA/OGROP/ORASE-FO/NOL- DO/NOL-CB/ FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/ FDA/OC/OES/DFOI/	KATE WILLSON ICIJ	INTERPORT CROSS INTERNATIONAL LLC 04/09/03; MUSCULOSKELETAL TRANSPLANT FOUNDATION 11/25/03, 08/09/06, 07/31/06, NUVASIVE INC 08/14/03, ETC - 483S
2012-3638	05/18/2012 06/18/2012	FDA/OMPT/CDRH/OCER/DFOI/	PETER A TAKES KYPHA INC	IBL GMBH - C3D-CIC EIA TEST K032796
2012-3639	05/18/2012 06/18/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORAI	Doe J	INDIVIDUAL RECS

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		OC/ORO/ OC/ORO/OCI/ OC/ORO/OCI/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/		
2012-3640	05/18/2012 06/18/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/ORO/DIOP/	STEPHANIE ARMOUR BLOOMBERG NEWS	RODRIGUEZ FRUIT, SAN DIEGO, CA; EMPAQUE PARRA, TECOMAN, MEXICO - EIRS, ENFORCEMENT ACTIONS 2009 TO PRESENT
2012-3641	05/18/2012 06/18/2012	FDA/OFVM/CFSAN/OCD/EOS/	FOI Services, Inc.	SAVORY SNACKS - TRANS FAT INTAKE BY US POPULATION BRAND NAME, PRODUCT CODE, PKG SIZE, ETC
2012-3642	05/21/2012 06/19/2012	OC/OM/OMP/DDM/	MARILYNN WHITNEY COVINGTON & BURLING LLP	DKT FDA-2006-P-0007, FDA-2008-D-0626
2012-3643	05/21/2012 06/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	EILEEN BOYLE HOLOGIC INC	GE - LUNAR DXA BONE DENSITOMETER ENCORE 14 SOFTWARE RELEASE K113286
2012-3644	05/21/2012 06/19/2012	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	BOBBY SCHOCHET OLSSON FRANK WEEDA TERMAN MATZ PC	FUNFRESH FOODS INC, SAN CLEMENTE, CA - WORLD BERRIES ORGAN CACAO NIBS RECALL CORR, RPTS, MINS, ETC
2012-3645	05/21/2012 06/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	KIM CHRISTIAN TELEFLEX MEDICAL	TELEFLEX MEDICAL - AQUAPAK PREFILLED HUMIDIFIER K780562
2012-3646	05/21/2012 06/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	FABRICE VINCENT ESQ LIEF CABRASER HELMANN & BERNSTEIN LLP	ST JUDE MEDICAL INC - RIATA, RIATA ST SILICONE ENDOCARDIAL DEFIBRILLATION LEADS MDRS, CMPLNTS, WARRANTY OBLIGATIONS, ETC
2012-3647	05/21/2012 06/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRENT M ARDAUGH MPH MS NORTHWESTERN UNIV FEINBERG SCHOOL OF MEDICINE	K050558, K944353, K901659
2012-3648	05/21/2012 06/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRENT M ARDAUGH MPH MS NORTHWESTERN UNIV FEINBERG SCHOOL OF MEDICINE	K001122, K984220, K972412, ETC
2012-3649	05/21/2012 06/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	KIM CHRISTIAN TELEFLEX MEDICAL	TELEFLEX MEDICAL RESPIRATORY CARE INC - AQUAPAK K811073
2012-3650	05/21/2012	FDA/OMPT/CDRH/OCER/DFOI/	ANGELA BOUSE	AIRLIFE NEBULIZER CAP K072119

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	06/19/2012		TELEFLEX MEDICAL	
2012-3651	05/21/2012 06/19/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	CLOSED FOI REQUESTS 5/7-11/12
2012-3652	05/21/2012 06/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	CHAMNESS, ERIC	GUIDANT CORP - ACS HI-TORQUE CROSS-IT 100XT GUIDE WIRE WITH HYDROCOAT HYDROPHILIC COATING K990639
2012-3653	05/21/2012 06/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	CHAMNESS, ERIC	GUIDANT CORP - HI-TORQUE CROSS-IT GUIDE WIRE WITH HYDROCOAT HYDROPHILIC COATING K981381
2012-3654	05/21/2012 06/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	CHAMNESS, ERIC	GUIDANT CORP - HI-TORQUE BALANCE GUIDE WIRE WITH HYDROCOAT HYDROPHILIC COATING K973494
2012-3655	05/21/2012 06/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	CHAMNESS, ERIC	ASAHI INTECC CO LTD - ASAHI ULTIMATEBROS 3 PTCA GUIDE WIRE K101986
2012-3656	05/21/2012 06/19/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	GETZ, DEBORAH	NUTRISYSTEM - AER
2012-3657	05/21/2012 06/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	CHAMNESS, ERIC	NEOMETRICS INC - NEO WIRE PTA/PTCA GUIDEWIRE K101729
2012-3658	05/21/2012 06/19/2012	OC/CVM/OCD/ FDA/OFVM/CFSAN/OCD/EOS/	BILL THOMSON WALL STREET JOURNAL	BOVINE SPONGIFORM ENCEPHALOPATHY - RESEARCH
2012-3659	05/21/2012 06/19/2012	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	CHARLES CELESTE EAS Consulting Group, LLC	DRUG SAFETY ALLIANCE INC, DURHAM, NC - EIR 8/23-25/11
2012-3660	05/21/2012 06/19/2012	FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/	MARC SELINGER EXAMINER.COM	PURINA VETERINARY DIETS - CMLPNTS LAST 6 MTHS
2012-3661	05/21/2012 06/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	CHAMNESS, ERIC	BRIDGEPOINT MEDICAL - ENTERA PERCUTANEOUS CORONARY AND PERIPHERAL GUIDEWIRE K081187
2012-3662	05/21/2012 06/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	CHAMNESS, ERIC	OVALUM LTD - CITOP 0.014" GUIDEWIRE K070212
2012-3663	05/21/2012 06/19/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	CHAMNESS, ERIC	ASAHI INTECC CO LTD - ASAHI WIRE ASAHI PTCA GUIDE WIRE CONFIANZA PRO K041531
2012-3664	05/21/2012 06/19/2012	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	MARC SELINGER EXAMINER.COM	DIAMOND PET FOODS - CMLPNTS LAST 12 MTHS
2012-3665	05/21/2012	FDA/OMPT/CDRH/OCER/DFOI/		MEDTRONIC INC - GT2 FUSION GUIDE WIRE K001969

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	06/19/2012		CHAMNESS, ERIC	
2012-3666	05/21/2012 06/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	HOLLY IMES MOOG MEDICAL DEVICES GROUP	VILTECHMEDA, VILNIUS, LITHUANIA - EIR 1/19-23/12
2012-3667	05/21/2012 06/19/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	KATHLEEN BIEDERWOLF ALLSTATE INSURANCE CO	ELECTRONIC WAVEFORM LAB INC, HUNTINGTON BEACH, CA - ALL INSPS, POLICIES, PROGRAMS, ETC.
2012-3668	05/21/2012 06/19/2012	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	IRINA RIVKIND CANTOR FITZGERALD	WARNER CHILCOTT, FAJARDO, PUERTO RICO - 483, WARNING LTR 3/12
2012-3669	05/21/2012 06/19/2012	OC/ORA/ OC/ORA/ FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	CHRISTINO, NICOLE	RECALLED TUNA PRODUCTS - RPTS, CMLPNTS 1/11 TO 1/12
2012-3670	05/21/2012 06/19/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	NIKOLAS BURLEW REGULUS PHARMACEUTICAL CONSULTING	REGULUS PHARMS CONSULTING INC, BOULDER, CO - 483, EIR 2/7-8/11, 10/31/11-11/8/11
2012-3671	05/21/2012 06/19/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PAMELA VENTURA APTALIS PHARMA SRL	FEI 1000573478

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2012-3672	05/21/2012 06/19/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DRRICK STOBAUGH CENTER FOR THE STUDY OF COMPLEX DISEASES	ISRS 6570960, 6570960, 6629342
2012-3673	05/21/2012 06/19/2012	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	FOI Services, Inc.	RUNAWAY COUNTRY EVENT, MELBORNE, JAMBOREE - 5/4/12 TOBACCO INSP, CORR, SUMMARIES
2012-3674	05/21/2012 06/19/2012	FDA/OGROP/ORA/ORO/DIOP/	KATE WILSON ICIJ	2011-8978 TISSUE IMPORTED FOR RE-EXPORT RECS
2012-3675	05/21/2012 06/19/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	AMY KINCANON LEXIS NEXIS COURTLINK INC	2012-2981
2012-3676	05/21/2012 06/19/2012	FDA/OC/OES/DFOI/ FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/ FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/ FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	NELSON, AUSTIN	IMPAX LABS INC, HAYWARD, CA; HOSPIRA INC, CLAYTON, NC; HOSPIRA INC, AUSTIN, TX - 483 SINCE 1/12 TO PRESENT
2012-3677	05/21/2012 06/19/2012		Doe J	INDIVIDUAL RECS
2012-3678	05/22/2012 06/20/2012	FDA/OFVM/CFSAN/OCD/EOS/	DAVID J ETTINGER Keller and Heckman LLP	LYONDELL CHEMICAL - FAMF 000341
2012-3679	05/22/2012 06/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	PHILIP BENZ ADVANCED VASCULAR DYNAMICS	VASCULAR SOLUTIONS - K061219; HEMOSTASIS LLC - K072900; HEMCON - K080818 ETC
2012-3680	05/22/2012 06/20/2012	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	Doe J	CMPLNT 125934 - RECS & RESULTS
2012-3681	05/22/2012 06/20/2012	FDA/OC/OES/DFOI/ OC/ORA/ OC/ORA/ FDA/OGROP/ORA/ORO/DIOP/	WENDY FONG GRIFOLS BIOLOGICALS INC	EXPEDITORS INTERNATIONAL OF WASHINGTON INC, NIPPON EXPRESS USA INC - ENTRY NUMBERS, NOTATIONS OF ERRORS, CORRECTIONS, ETC
2012-3682	05/22/2012 06/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MIDOLO, JOE	APOTEX INC, ONTARIO, CANADA - EIRS, 483S, CO RESPS ETC

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		FDA/OMPT/CDER/GRP/DIDP/		
2012-3683	05/22/2012 06/20/2012	FDA/OGROP/ORP/PA-FO/SEA-DO/SEA-CB/	DOUGLAS J LAPOINTE CAMERON HODGE ET AL	ENDOGASTRIC SOLUTIONS INC, REDMOND, WA - CLEARANCE LTRS, INSPS, WARNINGS, ETC
2012-3684	05/22/2012 06/20/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	AMPHETAMINES - AERS (PERIPHERAL NERVE DISEASE OR NERVE CONDUCTION BLOCKS)
2012-3685	05/22/2012 06/20/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	RETALIN - AERS (PERIPHERAL NERVE DISEASE OR NERVE CONDUCTION BLOCKS)
2012-3686	05/22/2012 06/20/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	ADDERALL - AERS (PERIPHERAL NERVE DISEASE OR NERVE CONDUCTION BLOCKS)
2012-3687	05/22/2012 06/28/2012	FDA/OGROP/ORP/CE-FO/NWJ-DO/NWJ-CB/	MICHAEL P HICKEY TESCHON RICCOBENE & SISS PA	MAPLEWOOD BEVERAGES, MAPLEWOOD, NJ - INDIVIDUAL RECS; INSPS, HEALTH VIOLATIONS, TEST RESULTS, ETC 1/08 TO 12/11
2012-3688	05/22/2012 06/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	INDIVIDUAL RECS
2012-3689	05/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	GAIL H JAVITT	LIFECCELL CORP - EIRS, 483S, CO RESPS ETC 11/2/10

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	06/20/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	SIDLEY AUSTIN LLP	
2012-3690	05/22/2012 06/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	ISRS 3786570, 3898207, 3910895 ETC
2012-3691	05/22/2012 06/20/2012	OC/ORACE/ORM/ OC/ORACE/ORM/	JOHN GRAY OHIO STATE UNIV, FISHER COLLEGE OF BUSINESS	HUMAN DRUG MFG FIRMS LIST - NAMES, ADDRESSES, PRODS, ETC
2012-3692	05/22/2012 06/20/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OFVM/CFSAN/OCD/EOS/	ROBERT D PELTZ LEESFIELD & PARTNERS	DIMETHYLAMYLAMINE, DMAA, METHYLHEXANAMINE ETC - CAERS, STUDIES, RECS ETC
2012-3693	05/22/2012 06/20/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORACE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORACE-FO/ATL-DO/ATL-CB/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORACE-FO/ATL-DO/ATL-CB/	SPILLER JR, ROBERT M	MEHERRIN AGRICULTURAL & CHEMICAL CO, SEVERN, N CAROLINA - EIRS, RECS (PICTURES OF SAWS), RECS 12//6/11 TO PRESENT
2012-3694	05/22/2012 06/20/2012	FDA/OGROP/ORACE-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORACE-FO/LOS-DO/LOS-CB/	CHARLES J LANDY PILLSBURY WINTHROP SHAW PTTMAN LLP	TEVA PHARMACEUTICALS, IRVINE, CA - TEVA PARENTAL MEDICINES, IRVINE, CA - COMM, 483S
2012-3695	05/22/2012 06/20/2012	FDA/OGROP/ORACE-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORACE-FO/LOS-DO/LOS-CB/	GARY C COOPER LAW OFC	ANHING CORP - CUSTOMS & BORDER PROTECTION LIQUIDATED DAMAGE CASE 2012-2704-200865-01, DESTRUCTION, INVESTIGATION RPTS, RECS ETC
2012-3696	05/22/2012 06/20/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	AKIO KUBO SRD CO LTD	ORAL ICEBERG SL, SPAIN - CERAROOT IMPLANT SYS K093595; NOBEL BIOCARE USA LLC - ZIRCONIA IMPLANT SYS K061971; Z-SYS AG SWITZERLAND - Z-LOOK3 DENTAL IMPLANT K062542, ETC
2012-3697	05/23/2012 08/02/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OFVM/CFSAN/OCD/EOS/	BOBBY SCHOCHET OLSSON FRANK WEEDA TERMAN MATZ PC	REPORTABLE FOOD REGISTRY - FOREIGN OBJECT SUBMISSIONS RECS
2012-3698	05/23/2012 06/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LOUIS D LETO ESQ PHD WILSON SOSINI GOODRICH & ROSATI	FUJIFILM PHARMACEUTICALS USA INC - FAVIPRAVIR CLNCL TRIALS SUBMISSIONS, PROTOCOLS, RESULTS, ETC
2012-3699	05/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRANT WIGGER	C! SYS K070589

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	06/21/2012		TRANSPHOTON CORP	
2012-3700	05/23/2012 06/21/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRENT M ARDAUGH MPH MS NORTHWESTERN UNIV FEINBERG SCHOOL OF MEDICINE	K823145, K844050, K851421, ETC
2012-3701	05/23/2012 06/21/2012	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	ONA SCANDURRA MS RD COUNTRY LIFE LLC	M & L PHARMS, SAN BERNADINO, CA - EIRS, 483S 6/10 TO PRESENT
2012-3702	05/23/2012 06/21/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DUSTIN BLOCK IPD ANALYTICS LLC	ROPINIROLE HCL ANDA 99-869 - EFFECTIVE APRVL LTR 5/17/12
2012-3703	05/23/2012 06/21/2012	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	MARIA MATTERN GLAXO SMITH KLINE	ISRS M00959230, M00959259, M01345239, ETC
2012-3704	05/23/2012 06/21/2012	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	TYLER KENYON NORTHCOAST RESEARCH	NOVARTIS AG, LINCOLN, NE - 483 7/8/11 CORR
2012-3705	05/23/2012 06/21/2012	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	STEVE ELLMAN UGOPRINT	HOSPIRA INC, ROCKY MOUNT, NJ - 483S 8/21/09, 1/9/10
2012-3706	05/23/2012 06/21/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	HUBER, MARIE	PROVENGE - STATISTICAL ANALYSIS PLAN
2012-3707	05/23/2012 06/21/2012	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	TRINE TSOUDEROS CHICAGO TRIBUNE	KIRKMAN GROUP - 483 4/9/08, 9/1809
2012-3708	05/23/2012 09/26/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	JONATHAN A. KNOLL, Esq. COHEN & MALAD LLP	TIMOTHY A ULATOWSKI - TRANSCRIPTS, SPEECHES, COMM
2012-3709	05/23/2012 06/21/2012	FDA/OMPT/CDRH/OCER/DFOI/	FRISBIE, JEFFREY.	MICRO THERAPEUTICS - SOLITAIRE FR REVASCULARIZATION DEVICE SAFETY
2012-3710	05/23/2012 06/21/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARY K. OLSON TULANE UNIVERSITY DEPT OF ECONOMICS	NEVANAC 21-862; HYDASE 21-716; HYLENEX RECOMBIANT 21-859
2012-3711	05/23/2012	FDA/OMPT/CDER/GRP/DIDP/	BRODY MULLINS	COMM BETWEEN FDA & SHELDON BRADSHAW OF HUNTON

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	06/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	WALL STREET JOURNAL	& WILLIAMS 1/10 TO 1/31/10
2012-3712	05/23/2012 06/21/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	HUBER, MARIA	SIPULEUCEL-T PHASE III TRIAL - STATISTICAL ANALYSIS PLAN (SAP)
2012-3713	05/23/2012 06/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/OCOS/OES/ OC/OCOS/OES/ FDA/OC/OES/DFOI/	BRODY MULLINS WALL STREET JOURNAL	COMM BETWEEN FDA & MICHAEL SULLIVAN OF SAC CAPITOL 1/05 TO 12/31/08
2012-3714	05/23/2012 06/21/2012	FDA/OC/OES/DFOI/	BRODY MULLINS WALL STREET JOURNAL	COMM BETWEEN FDA & STEVE WILLIAMS AT MARWOOD GROUP 1/10 TO 12/31/10
2012-3715	05/23/2012 06/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JEFF GERTH PROPUBLICA	TYLENOL NDA 17-756, NDA 19-872; MUCOMYST NDA 13-601/S029 - APRVL RECS
2012-3716	05/23/2012 06/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MALIK M. ADIL, MD UNIVERSITY OF MINNESOTA DEPT OF NEUROLOGY	ALTEPLASE, RETEPLASE, UROKINASE - AER
2012-3717	05/23/2012 06/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WILSON JIAO SANTEC CHEMICALS CORP	MINSHENG GROUP SHAOXINHG PHARMACEUTICAL CO LTD - PRAZQUANTEL NDC NUMBER
2012-3718	05/23/2012 06/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RAENEL GIBSON MYLAN INSTITUTIONAL	KINEVAC (SINCALIDE) NDA 17-697
2012-3719	05/23/2012 06/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN L. VILLANO, Ph.D. UNIVERSITY OF KENTUCKY	TEMOZOLOMIDE - AER 9/08 TO PRESENT

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CANCER CENTER	
2012-3720	05/23/2012 06/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WILSON JIAO SANTEC CHEMICALS CORP	SICHUAN LONG MARCH PHARMACEUTICAL CO LTD - NEOMYCIN SULFATE NDC NUMBER
2012-3721	05/23/2012 06/21/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 5/7-11/12
2012-3722	05/23/2012 06/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/OCOS/OES/ OC/OCOS/OES/ FDA/OC/OCC/ OC/OA/OM/OMP/DDM/	THOMAS CLUDERAY ENVIRONMENTAL WORKING GROUP	COMM BETWEEN FDA & PERSONAL CARE PRODUCTS COUNCIL SINCE 6/17/11
2012-3723	05/23/2012 06/21/2012	FDA/OMPT/CTP/OD/	GREGORY N. CONNOLLY HARVARD SCHOOL OF PUBLIC HEALTH	LIST OF INGREDIENTS
2012-3724	05/23/2012 06/21/2012	OC/OCOS/OL/ OC/OA/OM/OMP/DDM/ FDA/OFVM/CFSAN/OCD/EOS/	CHRIS KNIGHT Agra Informa Group	CORR TO REP ED MARKEY 3/16/12
2012-3725	05/23/2012 06/21/2012	OC/ORO/ OC/ORO/	EDWYN POON TG MEDICAL (USA) INC	ENTRY NO W69-3236857-5
2012-3726	05/23/2012 07/30/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/ OC/ORO/	ELENA HOWELL HOGAN LOVELLS US LLP	FOOD FACILITY INSP - ALL CORR
2012-3727	05/23/2012 08/31/2012	FDA/OGROP/ORO/SE-FO/ATL- DO/ATL-CB/	CYNTHIA M. INCORVATI NCA TECHNOLOGIES INC	DSM PHARMS, GREENVILLE, NC - EIR, 483
2012-3728	05/23/2012 06/21/2012	OC/ORO/ OC/ORO/	GARY C. COOPER LAW OFFICES OF GARY C COOPER	ENTRY NO W33-0779436-0
2012-3729	05/23/2012 06/21/2012	FDA/OGROP/ORO/SE-FO/ATL- DO/ATL-CB/	SHAWN H. HUBER PROFESSIONAL HOSPITAL	ANDERSEN STERILIZERS INC , HAW RIVER, NC - EIR 11/11/11 TO 5/16/12

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			SUPPLY INC	
2012-3730	05/23/2012 06/21/2012	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	JOAN M. BECHTOLD SWEENEY & BECHTOLD LLC	INDIVIDUAL RECS
2012-3731	05/23/2012 06/21/2012	OC/ORAS/ OC/ORAS/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	LOVELACE, RUTH	RITE AID, FLAX SEED OIL - CMLNT
2012-3732	05/23/2012 06/21/2012	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	WALCKER, CURTIS	ABCO LABS, FAIRFIELD, CA - 483, CO RESP
2012-3733	05/23/2012 06/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LAUREN M. BROCK LANGLEY & LEE LLC	TORODAL (KETOROLAC) - APRVL, PKG, LBLG 1/89 TO PRESENT
2012-3734	05/23/2012 06/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TAMI T. MARTIN SUPERNUS PHARMACEUTICALS INC	BOEHRINGER INGELHEIM - VIRAMUNE XR NDA 01-152 RVW
2012-3735	05/23/2012 06/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	TISCHER LOCKHART HOLLINGSWORTH LLP	PERSONNEL FILES OF FDA STAFF INSTRUCTORS FROM 1991-1995
2012-3736	05/23/2012 06/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BIJAN ESFANDIARI, Esq. BAUM HEDLUND ET AL	DR THOMAS LAUGHREN - LEXAPRO DOCS
2012-3737	05/24/2012 06/22/2012	OC/OM/OMP/DDM/	MARILYNN WHITNEY COVINGTON & BURLING LLP	DKT FDA-2010-P-0491, FDA-2010-P-0196
2012-3738	05/24/2012 06/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	TINA MAYER LUMENIS INC	NIDEK - MULTICOLOR SCAN LASER PHOTOCOAGULATOR MC-500 VIXI K111493
2012-3739	05/24/2012 06/22/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	CAROLYN L WAGNER CARESTREAM HEALTH INC	RIVERAIN MEDICAL GROUP - SOFTVIEW MODEL 2.01 SYS K092363
2012-3740	05/24/2012	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	NANCY DUENSKIE	MIKE GARCIA, CHICKEN BARN/EGG COLLECTION FACILITY, DANVILLE, PA - INSPS

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	06/22/2012		ZURICH AMERICAN INSURANCE CO	
2012-3741	05/24/2012 06/22/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OCC/ OC/ORO/OCI/ OC/ORO/OCI/	KAREN PAULS CBC RADIO-CANADA	COUNTERFEIT AVASTIN & ALTUZAN - HIPAA SUBPEONA, RECS
2012-3742	05/24/2012 06/22/2012	OC/ORO/OCI/ OC/ORO/OCI/	MICHAEL KOSNAR NBC NEWS	FDA INVESTIGATOR JEFF NOVITSKY - TRAVEL EXPENSES, SALARY 1/09 TO 2/12
2012-3743	05/24/2012 06/22/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	PATRICK F LINEHAN STEPTOE & JOHNSON	KV PHARMACEUTICAL CO - MAKENA (HYDROXYPROGESTERONE CAPROATE) EMAILS, MTG MINS, DISCUSSIONS, ETC
2012-3744	05/24/2012 06/22/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRIAN EDWARDS CUSTARD INSURANCE ADJUSTERS INC	WELLSPRING PHARMACEUTICAL CANADA CORP, OAKVILLE, CANADA - COLACE RECALL EIRS, 483S
2012-3745	05/24/2012 06/22/2012	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	JOHNSON, JILL	LABELLE'S, BELLINGHAM, WA - INSPS LAST 18 MONTHS
2012-3746	05/24/2012 06/22/2012	FDA/OC/OES/DFOI/	ROCKNEY S TAVEAU BUTLER SNOW ET AL	TYLENOL - FOIA REQUESTS 1/10 TO PRESENT
2012-3747	05/24/2012 06/22/2012	FDA/OFVM/CFSAN/OCD/EOS/	SPRUTH 08569-097, MICHAEL	CAFFEINE - LBLG REQUIREMENTS, POLICIES, MARKETING, ETC
2012-3748	05/24/2012 06/22/2012	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	JOAN M BECHTOLD SWEENEY & BECHTOLD LLC	CONMED ELECTROSURGERY - 483
2012-3749	05/24/2012 06/22/2012	OC/ORO/OCI/ OC/ORO/OCI/	Doe J	INDIVIDUAL RECS
2012-3750	05/24/2012 06/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	CURTIS RAYMOND ORCHID DESIGN	OLYMPUS - UHI-4 HIGH FLOW INSUFFLATION UNIT K110294
2012-3751	05/24/2012	FDA/OMPT/CDRH/OCER/DFOI/	CURTIS RAYMOND	OLYMPUS - LTF-S190-10, OTV-S190, CLV-S190

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	06/22/2012		ORCHID DESIGN	ENDOSCOPES K111425
2012-3752	05/24/2012 06/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	CURTIS RAYMOND ORCHID DESIGN	OLYMPUS - CF-Y0023-L/I COLONOVIDEOSCOPE K101053
2012-3753	05/24/2012 06/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	CURTIS RAYMOND ORCHID DESIGN	OLYMPUS - EVIS EXERA III VIDEO SYS K112680
2012-3754	05/24/2012 06/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	CURTIS RAYMOND ORCHID DESIGN	OLYMPUS - VI SYS ENDOSCOPIC VIDEO IMAGING SYS K111756
2012-3755	05/24/2012 06/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	TOSHIO MURATA NIDEK INC	TOPCON CORP - OPTICAL COHERENCE TOMOGRAPHY 3D OCT-2000 K092470
2012-3756	05/24/2012 06/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	TOSHIO MURATA NIDEK INC	OPTOVUE - IVUE MODEL 100 K091404
2012-3757	05/24/2012 06/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	TOSHIO MURATA NIDEK INC	CARL ZEISS MEDITEC INC - CIRRUS HD-OCT WITH RETINAL NERVE FIBER LAYER K111157
2012-3758	05/24/2012 06/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	TOSHIO MURATA NIDEK INC	OPTOVUE - RT-VUE XR OCT K120238
2012-3759	05/24/2012 06/22/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MICHAEL S LABSON COVINGTON BURLING LLP	EXHALED NITRIC OXIDE (ENO) DOSE-RESPONSE STUDY - FINAL RPT
2012-3760	05/24/2012 06/22/2012	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	STEPHANIE ELSBERRY BIODEN INC	PROVIA LABORATORIES LLC, LEXINGTON, MA - EIRS 483S, CO RESP 2010 TO PRESENT
2012-3761	05/24/2012 06/22/2012	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	STEPHANIE ELSBERRY BIODEN INC	GENECCELL INTERNATIONAL LLC, KENDALL, FL - EIRS, 483S, CO RESP 2010 TO PRESENT
2012-3762	05/24/2012 06/22/2012	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	STEPHANIE ELSBERRY BIODEN INC	NEW ENGLAND CRYOGENIC CENTER INC, NEWTON, MA - EIRS, 483S, CO RESP 2010 TO PRESENT
2012-3763	05/24/2012 06/22/2012	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	STEPHANIE ELSBERRY BIODEN INC	AMERISTEM INC, HOUSTON, TX - EIRS, 483S, CO RESP 2010 TO PRESENT
2012-3764	05/24/2012 06/22/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	STEPHANIE ELSBERRY BIODEN INC	STEMSAVE INC, NEW YORK, NY - EIRS, 483S, CO RESP 2010 TO PRESENT
2012-3765	05/24/2012 07/30/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	GEISE, RUSSELL	FENWAL INC - BONE MARROW COLLECTION KIT WITH FLEXIBLE PRE-FILTER & INLINE FILTERS, BONE MARROW COLLECTION STAND BK940005
2012-3766	05/24/2012 06/22/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	GEISE, RUSSELL	FENWAL INC - BONE MARROW COLLECTION/TRANSFUSION KIT BK090031

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2012-3767	05/25/2012 06/25/2012	OC/OM/OMP/DDM/	CHRIS CELESTE EAS Consulting Group, LLC	DKT 2003N-0539
2012-3768	05/25/2012 06/25/2012	OC/OM/OMP/DDM/	CHRIS CELESTE EAS Consulting Group, LLC	DKT 1998P-0683
2012-3769	05/25/2012 06/25/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DENNIS W RAISCH PHD MS RPH UNIV OF NEW MEXICO COLLEGE OF PHARMACY	ROMIPLOSTIM - ISRS 6119047, 6134011, 6149668, ETC
2012-3770	05/25/2012 06/25/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SARAH SORSCHER JD MPH PUBLIC CITIZEN	NICARDIPINE HCI NDA 78-405; ALBUTEROL SULFATE, IPUTROPIUM BROMIDE NDA 21-747; BUPROPION HYDROBROMIDE, AZILSARTAN KAMEDOXOMIL NDA 22-497, ETC - ARPVL RECS
2012-3771	05/25/2012 06/25/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	REBECCA MOCK GILEAD SCIENCES INC	HOLOPACK-VERPACKUNGSTECHNIK-GMBH, ABTSGMUND-UNTERGRONINGEN, GERMANY - EIR MOST RECENT
2012-3772	05/25/2012 06/25/2012	FDA/OMPT/CDRH/OCER/DFOI/	HEATHER MUNDAY-MCGINLEY BENNETT BIGELOW & LEEDOM PS	XOMED (MEDTRONIC) - LASER SHIELD II ENDOTRACHEAL TUBE, MDRS 1815162, 1079060, 694643, ETC
2012-3773	05/25/2012 06/25/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PAMELA SHEPPARD TARO PHARMACEUTICALS U.S.A., INC	VALEANT INTL - ZOVIRAX (ACYCLOVIR) NDA 20-478 SBA
2012-3774	05/25/2012 06/25/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PAMELA SHEPPARD TARO PHARMACEUTICALS USA INC	MERZ PHARMS - NAFTIN (NAFTFINE HCL) NDA 19-599 SBA
2012-3775	05/25/2012 06/25/2012	FDA/OMPT/CDRH/OCER/DFOI/	ASSAF LIVNE LAP-SPACE MEDICAL LTD	ADVANCED SURGICAL INC - LAPAROSCOPIC CURVED TRIANGLE RETRACTOR K922435
2012-3776	05/25/2012 06/25/2012	OC/ORO/ OC/ORO/ OC/CVM/OCD/	JILL FRANKS MARS PETCARE US	DOG FOOD JERKY PRODS - CMLPNTS 2007 TO 2011
2012-3777	05/25/2012	FDA/OMPT/CDRH/OCER/DFOI/	HEATHER MUNDAY-MCGINLEY	LASER ENGINEERING INC - CO2 SURGICAL LASERS, 832525, MDRS

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	06/25/2012		BENNETT BIGELOW & LEEDOM PS	
2012-3778	05/25/2012 06/25/2012	FDA/OMPT/CDRH/OCER/DFOI/	LORI J BARR KIMBERLY-CLARK CORP	PERSONAL PRODUCTS CO - UNSCENTED MENSTRUAL TAMPONS APPLICATOR K974629
2012-3779	05/25/2012 06/25/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ROBERT N TAUB MD PHD COLUMBIA UNIV MEDICAL CENTER	IND 056350 - APPL, CORR
2012-3780	05/25/2012 06/25/2012	FDA/OMPT/CDRH/OCER/DFOI/	MICHAEL R HAMRELL MORIAH CONSULTANTS	DR PAUL OVERLIE - NIDPOE LTR 7/31/07, RESP, HEARING, PROCEEDING, ETC
2012-3781	05/25/2012 06/25/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TIMOTHY P WALBERT HORIZON PHARMA INC	DUEXIS (FAMOTIDINE, IBUPROFEN) NDA 22-519 - APRVL RECS
2012-3782	05/25/2012 06/25/2012	FDA/OMPT/CDRH/OCER/DFOI/	PETER A TAKES KYPHA INC	QUIDEL CORP - SOFIA ANALYZER & INFLUENZA A+B FIA K112177
2012-3783	05/25/2012 06/25/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CARLOTA O ANDREWS WEGMANS SCHOOL OF PHARMACY	FIRST APRVD PI TO 1975
2012-3784	05/25/2012 06/25/2012	FDA/OMPT/CDRH/OCER/DFOI/	NEIL R ARMSTRONG MEDDIQUEST LTD	CHROMOGENEX TECHNOLOGIES LTD - I-LIPO SYS, K111501
2012-3785	05/25/2012 06/25/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BLUMHARDT CONSULTING	ATIVAN (LORAZEPAM) NDA 17-794 - TOXICOLOGY, PHARMACOLOGY, STATISTICS, ETC
2012-3786	05/25/2012 06/25/2012	FDA/OFVM/CFSAN/OCD/EOS/	ROBERT S MCQUATE PHD GRAS ASSOCIATES LLC	GRAS 000403 - MEMOS, CORR
2012-3787	05/25/2012 06/25/2012	FDA/OMPT/CTP/OD/	MARILYNN WHITNEY COVINGTON & BURLING LLP	FAMILY SMOKING PREVENTION & TOBACCO CONTROL ACT - NEW TOBACCO PROD RVW SOPS; NEW PROD SUBMISSIONS 2/23/11 TO PRESENT ETC
2012-3788	05/25/2012 06/25/2012	FDA/OMPT/CDRH/OCER/DFOI/	PETER A TAKES KYPHA INC	DADE BEHRING INC - N ATISERA TO HUMAN COMPLEMENT FACTORS (C3C,C4), K050665, RECS
2012-3789	05/25/2012	FDA/OMPT/CDRH/OCER/DFOI/	VIK BAJNATH	MW #5024673

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	06/25/2012		ARTHREX INC	
2012-3790	05/25/2012 06/25/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RAENEL GIBSON MYLAN INSTITUTIONAL	BRACCO DIAGNOSTICS - KINEVAC (SINCALIDE) INJ NDA 17-697/S012-S015 APRVL RECS
2012-3791	05/25/2012 06/25/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DENNIS W RAISCH UNIV OF NEW MEXICO COLLEGE OF PHARMACY	EPOETIN - VENOUS THROMBOEMBOLISM AERS 4041629, 4041639, 4042246 ETC
2012-3792	05/25/2012 06/25/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DENNIS W RAISCH UNIV OF NEW MEXICO COLLEGE OF PHARMACY	THALIDOMIDE - VENOUS THROMBOEMBOLISM ISRS, 4034563, 4039930, 4040990, ETC
2012-3793	05/25/2012 06/25/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DENNIS W RAISCH UNIV OF NEW MEXICO COLLEGE OF PHARMACY	ELTROMBOPAG - VENOUS THROMBOEMBOLISM, ISRS 6207294, 6283119, 6311598 ETC
2012-3794	05/25/2012 06/25/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DENNIS W RAISCH UNIV OF NEW MEXICO COLLEGE OF PHARMACY	DARBEPOETIN - VENOUS THROMBOEMBOLISM ISRS 4041629, 4041639, 4042226 ETC
2012-3795	05/25/2012 06/25/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DENNIS W RAISCH UNIV OF NEW MEXICO COLLEGE OF PHARMACY	LENALIDOMIDE - VENOUS THROMBOEMBOLISM ISRS 4958393, 4991573, 4991588 ETC
2012-3796	05/25/2012 06/25/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/	ALICE MEIKLE VPX/REDLINE	CYTOSPORT INC - INVESTIGATION, PROD RVWS, 8/1/11 TO PRESENT
2012-3797	05/29/2012 06/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BATTS, SHERREEN	PERCOCET - AERS
2012-3798	05/29/2012	OC/CVM/OCD/	KRISTI O SMEDLEY	LALLEMAND - PENICILLIN G POTASSIUM IN DISTILLERS GRAINS GRAS NOTIFICATION 11

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	06/26/2012		WASHINGTON INFORMATION SOURCE	
2012-3799	05/29/2012 06/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	RICK CONFER BLUE BELT TECHNOLOGIES INC	ZIMMER - UNICOMPARTMENTAL KNEE SYS IMPLANT K033363
2012-3800	05/29/2012 06/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	RICK CONFER BLUE BELT TECHNOLOGIES INC	INSTRUMENT MAKAR INC - BONE SCREW K923841
2012-3801	05/29/2012 06/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	RICK CONFER BLUE BELT TECHNOLOGIES INC	MAKO SURGICAL CORP - RESTORIS MCK UNI IMPLANT K090763
2012-3802	05/29/2012 06/26/2012	FDA/OFVM/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 151606 - ADDITIONAL RECS
2012-3803	05/29/2012 06/26/2012	FDA/OFVM/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CARES 151607 - ADDITIONAL RECS
2012-3804	05/29/2012 06/26/2012	FDA/OFVM/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CARERS 151217 - ADDITIONAL RECS
2012-3805	05/29/2012 06/26/2012	FDA/OFVM/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 151881 - ADDITONAL RECS
2012-3806	05/29/2012 06/26/2012	FDA/OFVM/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 151213 - ADDITIONAL RECS
2012-3807	05/29/2012 06/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANIL HITESHI SPECTRUM PHARMACEUTICALS INC	ZEVALIN (IBRITUMOMAB TIUXETAN) IND 4850 - RECS
2012-3808	05/29/2012 06/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MALIK M ADIL MD UNIV OF MINNESOTA - ZEENAT QURESHI STROKE RESEARCH CTR	ALTEPLASE - ISR 5634726, RETEPLASE - ISR 4418122, UROKINASE - ISR 4341451, ETC
2012-3809	05/29/2012 06/26/2012	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOGS 5/7-11/12
2012-3810	05/29/2012	FDA/OC/OES/DFOI/	KENNETH REID	FOI DAILY LOG 4/30/12 TO 5/4/12

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	06/26/2012		WASHINGTON INFORMATION SOURCE	
2012-3811	05/29/2012 06/26/2012	FDA/OC/OES/DFOI/	INC REGULATORY CONSULTING & SUBMISSIONS	FOI DAILY 5/7 - 11/12
2012-3812	05/29/2012 06/26/2012	FDA/OC/OES/DFOI/	INC REGULATORY CONSULTING & SUBMISSIONS	FOI DAILY LOG 4/30/12 TO 5/4/12
2012-3813	05/29/2012 06/26/2012	FDA/OC/OES/DFOI/	GLADYS B TONKIN WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 4/30/12 TO 5/4/12
2012-3814	05/29/2012 06/26/2012	FDA/OC/OES/DFOI/	GLADYS B TONKIN WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 5/7-11/12
2012-3815	05/29/2012 06/26/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 4/30/12 TO 5/4/12
2012-3816	05/29/2012 06/26/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 5/7-11/12
2012-3817	05/29/2012 06/26/2012	FDA/OC/OES/DFOI/	CEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 4/30/12 TO 5/4/12
2012-3818	05/29/2012 06/26/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY 5/7-11/12
2012-3819	05/29/2012 06/26/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 4/30/12 TO 5/4/12
2012-3820	05/29/2012 06/26/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	5/7-11/12
2012-3821	05/29/2012 06/26/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 4/30/12 TO 5/4/12
2012-3822	05/29/2012 06/26/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 5/7-11/12
2012-3823	05/29/2012 06/26/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 5/21-25/2012
2012-3824	05/29/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	FOI DAILY LOG 5/14-18/2012

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	06/26/2012		MERCK & CO., INC.	
2012-3825	05/30/2012 06/27/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORR/SE-FO/SJN-DO/SJN-CB/	JOSHUA KINCANNON ESQ KEEFE BARTELS CLARK ATTY AT LAW	MEDTRONIC - QUICK-SET INFUSION SETS MDRS, COMM, RECALL RECS
2012-3826	05/30/2012 06/27/2012	FDA/OFVM/CFSAN/OCD/EOS/	SEAN HIGGINS ESQ ANDREWS & THORNTON	EXCLUSIVE SUPPLEMENTS INC, FAHRENHEIT NUTRITION, GASPARI NUTRITION INC, ETC - RESP TO DMAA WARNING LTR 4/24/12
2012-3827	05/30/2012 06/27/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRIAN R BOWMAN AMERIOWATER	MAR COR MILLENIUM HX K110578
2012-3828	05/30/2012 06/27/2012	OC/CVM/OCD/	BRIAN COBERTT ARK SCIENCES INC	NADA 141-217 - CMC SECTION, BATCH RECS FOR PRODUCTION
2012-3829	05/30/2012 06/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANDREW P ZAPPIA LECLAIR RYAN	EPIC PHARMA LLC - MECLIZINE HCL ANDA 200-294 APRVL LTR 4/13/12, FILING DATE, RECS
2012-3830	05/30/2012 06/27/2012	OC/CVM/OCD/	GUYLANDO A M MORENO FROST BROWN TODD LLC	MASCOMA CORP - MASCOMA GRAIN TECHNOLOGY YEAST ESTABLISHMENT OF AN INGREDIENT DEFINITION
2012-3831	05/30/2012 06/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PAMELA SHEPPARD TARO PHARMACEUTICALS USA INC	MERZ PHARMS - NAFTIN (NAFTIFINE HCL) NDA 19-599 SBA
2012-3832	05/30/2012 06/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PAMELA SHEPPARD TARO PHARMACEUTICALS USA INC	VALEANT INTL - ZOVIRAX (ACYCLOVIR) NDA 21-478 SBA
2012-3833	05/30/2012 06/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SAVID S BLOCH WINSTON & STRAWN LLP	MALATHION ANDA 78-743, ANDA 91-559 - RECS
2012-3834	05/30/2012 06/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORR/SW-FO/KAN-	LISA HANSEN AM LEGAL SERVICES INC	KV PHARMS - MAKENA (HYDROXYPROGESTERONE CAPROATE) TEST RESULTS, SLIDES, COMM, ETC

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		DO/KAN-CB/		
2012-3835	05/30/2012 06/27/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN L VILLANO MD PHD UNIV OF KENTUCKY MAKRKEY CANCER CENTER	ISRS 3615969, 3625646, 3667776, ETC
2012-3836	05/30/2012 06/27/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	AARON S KESSELHEIM MD JD MPH BRIGHAM & WOMEN'S HOSPITAL	TRUTHFUL PRESCRIPTION DRUG ADVERTISING AND PROMOTION (BAD AD) PROGRAM - RECS 2010 TO PRESENT
2012-3837	05/30/2012 06/27/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	YANNA LAMBRINIDOU PHD Parents for Nontoxic Alternatives	ENVIRONMENTAL HEALTH PESPCTIVES (EHP), DR TEE L GUIDOTTI - EMAILS, LTRS, RPTS
2012-3838	05/30/2012 06/27/2012	FDA/OMPT/CDRH/OCER/DFOI/	STUART, DARLA	CHILDREN'S HOSPITAL COLORADO, AURORA, CO - MEDICAL DVC REPORTING ANNUAL USER FACILITY RPT 2008, 2009
2012-3839	05/30/2012 06/27/2012	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	JOHN LIPPOTH ALEXION PHARMACEUTICALS	ALEXION PHARMS, SMITHFIELD, RI - EIR 1/25,26,28/11,2/4/11, 2/16-18/11
2012-3840	05/30/2012 06/27/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	REMICADE - AERS
2012-3841	05/30/2012 06/27/2012	FDA/OMPT/CDRH/OCER/DFOI/	GAIL RICHARDS WHIZBANG! CREATIVE	VESTICON - EPLEY OMNIIAX K071973
2012-3842	05/30/2012 06/27/2012	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	MEHUL GOVANI PL DEVELOPMENTS	PL DEVELOPMENTS, WESTBURY, NY - EIR 8/9/11
2012-3843	05/30/2012 06/27/2012	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	Doe J	ULTIMATE POWER MEAL - MEDICAL ANALYSIS, RECALL RECS, CORR, ETC
2012-3844	05/30/2012 06/27/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/OA/OM/OMP/DDM/	TERRY G MAHN FISH & RICHARDSON PC	SUN PHARMACEUTICAL INDUSTRIES - XEROSTOMIA ANDA 77-126 INDICATION CARVE-OUT RECS, CORR; DKT 2006P-0410
2012-3845	05/31/2012 06/28/2012	FDA/OC/OES/DFOI/	HELLEN A OKTECH USP PHARMACOPEIA	VINPOCETINE - CAERS 1/05 TO 5/12
2012-3846	05/31/2012	OC/OA/OM/OMP/DDM/	BURT GOODSON	DKT 2012N-0091

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	06/28/2012		APTUS ENDOSYSTEMS INC	
2012-3847	05/31/2012 06/28/2012	FDA/OC/OES/DFOI/	HELLEN A OKETCH USP PHARMACOPEIA	ASTAXANTHIN - CAERS 1/05 TO 5/12
2012-3848	05/31/2012 06/28/2012	FDA/OC/OES/DFOI/	HELLEN A OKETCH USP PHARMACOPEIA	HOLY BASIL (OCIMUN SANCTUM OR OCIMUM OCIMUM TENUIFLORUM) - CAERS 1/05 TO 5/12
2012-3849	05/31/2012 06/28/2012	FDA/OC/OES/DFOI/	HELLEN A IKETCH USP PHARMACOPEIA	GINKGO (GINKGO BILOBA) - CAERS 1/05 TO 5/12
2012-3850	05/31/2012 06/28/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	BRENDA BATTAT HEARING LOSS ASSOC OF AMERICA	DR LISA TSENG, HI HEALTHINNOVATIONS - ONLINE HEARING TEST LTR 3/28/12
2012-3851	05/31/2012 06/28/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	JOSEPH MUENCH ST PETER'S HOSPITAL	CLEVIDIPINE - ISRS 7327914, 7332187, 7352457, ETC
2012-3852	05/31/2012 06/28/2012	FDA/OMPT/CDRH/OCER/DFOI/	ROBERT PINTO SPARTECH POLYCAST CELL CAST ACRYLIC	SPARTECH POLYCAST CELL CAST ACRYLIC - MAF-300 MASTER FILE
2012-3853	05/31/2012 06/28/2012	FDA/OO/OFBA/OAGS/ OC/ORA/OCI/ OC/ORA/OCI/	DUFFIELD, WILL	FIREARMS, DESTRUCTIVE DVCS - ACQUISITION, MAINTENANCE, DEPLOYMENT, ETC
2012-3854	05/31/2012 06/28/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	ROGER KUMAR GOLDMAN SACHS & CO	VIROPHARMA - (SANQUIN) 483S
2012-3855	05/31/2012 06/28/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ARTHUR P BEDROSIAN LANNETT CO INC	SIMVASTATIN TABS ANDA 78-735 - SBA
2012-3856	05/31/2012 06/28/2012	FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/	CAROLINA M HEAVNER K & L GATES	TAPEMARK CO, ST PAUL, MN - EIRS, 483S, WARNING LTRS, ETC 5/07 TO 5/12
2012-3857	05/31/2012 06/28/2012	FDA/OGROP/ORA/CE-FO/CIN- DO/CIN-CB/	PAULA EICHMAN APTALIS PHARMATECH INC	APTALIS PHARMATECH - EIR 11/11
2012-3858	05/31/2012 06/28/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FOI Services, Inc.	NDA 202-107

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		FDA/OMPT/CDER/GRP/DIDP/		
2012-3859	05/31/2012 08/01/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	FOI Services, Inc.	SANQUIN PLASMA PRODUCTS, AMSTERDAM, NETHERLANDS - EIR, 483, CO RESP 9/19-28/11, ETC
2012-3860	05/31/2012 06/28/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FOI Services, Inc.	EXENATIDE SYNTECH NDA 22-220
2012-3861	05/31/2012 06/28/2012	FDA/OFVM/CFSAN/OCD/EOS/	ANGELIA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 151890
2012-3862	05/31/2012 06/28/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FOI Services, Inc.	ANDA 202-727
2012-3863	05/31/2012 06/28/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FOI Services, Inc.	ANDA 202-194
2012-3864	05/31/2012 06/28/2012	FDA/OMPT/CDRH/OCER/DFOI/	INGRAM #AE6335, CURTIS	TASER MODEL X-26 ELECTRIC CONTROL DVC (ECD) - RECS
2012-3865	05/31/2012 06/28/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FOI Services, Inc.	US-MERCK-0612USA01635 - ISR 5245743; US-MERCK- 0701USA01851 - ISR 5245747; US-MERCK-0711USA04183 - ISR 5542962 ETC
2012-3866	05/31/2012 06/28/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LISA HERNANDEZ PHD ZOSANO PHARMA	EPIPEN NDA 19-430 - SBA
2012-3867	05/31/2012 08/07/2012	FDA/OFVM/CFSAN/OCD/EOS/	FOI Services, Inc.	BISPHENOL A RESEARCH FUNDED BY THE NATIONAL INSTITUTE OF ENVIRONMENT HEALTH SCEINCES (NIEHS) - MEMOS, EMAILS, RECS, ETC
2012-3868	05/31/2012 06/28/2012	OC/CVM/OCD/	Doe J	VIOLATIONS OF REGULATIONS PROHIBITING THE USE OF MAMMALIAN PROTEIN IN THE MANUFACTURE OF ANIMAL FEED - FINAL RULE 1997

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2012-3869	05/31/2012 06/28/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MICHAEL GRAY PHARMASHIELD LLC	ELECTRONIC ORANGE BOOK, 2000 TO 20010
2012-3870	05/31/2012 06/28/2012	OC/ORA/ OC/ORA/ FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Doe J	INDIVIDUAL RECS
2012-3871	05/31/2012 06/28/2012	FDA/OMPT/CDRH/OCER/DFOI/	HENRY D ACCIANI O'CONNOR ACCIANI ET AL	MEDTRONIC - STIMULATION SYS MODEL #37711 CMLPNTS, RPTS BY DOCTORS, CO RESP
2012-3872	05/31/2012 06/28/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORA/ OC/ORA/ FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	MARCUS PETOYAN GIANNI PETOYAN ATTY	NEXIUM (ESOMEPRAZOLE) - AERS, EIRS, CORR, ETC
2012-3873	05/31/2012 06/28/2012	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	BRUCE D GOODMAN STEINBERG GOODMAN & KALISH	BLACKSTONE MEDICAL INC - ICON MODULAR SPINAL FIXATION SYS MDRS, EIRS, CORR, ETC
2012-3874	05/31/2012 06/28/2012	FDA/OMPT/CDRH/OCER/DFOI/	DR DEBORAH COHEN BMJ GROUP	ST JUDE MEDICAL - MECHANICAL HEART VALVE SJM MASTERS SERIES WITH SILIZONE COATING P810002/S046
2012-3875	05/31/2012 06/28/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TIM BENNETT SUNSHINE HOSPITAL	PROLIA (DENOSUMAB) - AERS
2012-3876	05/31/2012 08/16/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	PATRICK C MORROW MORROW MORROW RYAN & BASSETT	FAROUK SYSTEMS INC - RECS, 2000 TO PRESENT
2012-3877	05/31/2012 06/28/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	STEPHEN E ABRAHAM LAW OFFICES OF STEPHEN ABRAHAM	NU SCIENCE CORP, LANCASTER, CA - EIRS, 483S, RECS
2012-3878	05/31/2012	FDA/OFVM/CFSAN/OCD/EOS/	STEPHEN E ABRAHAM	DEUTREL INDUSTRIES INC, LANCASTER, CA - EIRS, 483S,

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	06/28/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	LAW OFFICES OF STEPHEN ABRAHAM	RECS
2012-3879	05/31/2012 06/28/2012	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	CRAIG ROUSH ROCKLINE INDUSTRIES	GUY & O'NEILL INC, FREDONIA WI - EIRS, 483S, COMM 3/4/05, 7/13/09 TO PRESENT
2012-3880	06/01/2012 06/29/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MICHELE SINOWAY LACHMAN CONSULTANT SERVICES INC	TEVA PHARMACEUTICALS - ANDA 78-730 APRVL SUMMARY
2012-3881	06/01/2012 08/02/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	CHARLES H KYPER KYPER & ASSOCIATES	REGENLAB SARL - REGEN-BC FAMILY KITS BK110061
2012-3882	06/01/2012 06/29/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CAPOLONGO, DENNIS J	PHARMACIA/UPJOHN-PFIZER - DEPO-DROL/METHYLPREDNISOLONE ACETATE, 40 & 80 MG INJ, AERS, CORR, RECS ETC 2000 TO PRESENT
2012-3883	06/01/2012 06/29/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARY LYONS ALEXION PHARMACEUTICALS	ALEXION PHARMACEUTICALS INC - SOLIRIS (ECULIZUMAB), MEDICAL RVWS
2012-3884	06/01/2012 06/29/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JULIA W MONACK COLLORA LLP	APPENDIX B-PROD NAME SORTED BY APPLICANT; BARBARA GOULDING LTR 4/12/10 - CERTIFIED
2012-3885	06/01/2012 06/29/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ALISON M. AGNEW PILLSBURY	ORGANICS LAGRANGE - CORTICOTROPIN NDA 10-831
2012-3886	06/01/2012 06/29/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ALISON M. AGNEW PILLSBURY	ORGANON USA INC - PURIFIED CORTROPHIN GEL NDA 08-975
2012-3887	06/01/2012 06/29/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG CLOSED 5/14-18/12
2012-3888	06/01/2012	FDA/OC/OES/DFOI/		FOI DAILY REQUESTS CLOSED 5/21-25/12

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	06/29/2012		CanReg, Inc.	
2012-3889	06/01/2012 06/29/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ALISON M. AGNEW PILLSBURY	ORGANON USA INC - CORTROPHIN ZINC NDA 09-854
2012-3890	06/01/2012 06/29/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY REQUESTS CLOSED 5/21-25/12
2012-3891	06/01/2012 06/29/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY REQUESTS CLOSED 5/14-18/12
2012-3892	06/01/2012 06/29/2012	FDA/OC/OES/DFOI/	WOLTERS KLUWER LAW & BUSINESS	FOI DAILY REQUESTS CLOSED 5/21-25/12
2012-3893	06/01/2012 06/29/2012	FDA/OC/OES/DFOI/	WOLTERS KLUWER LAW & BUSINESS	FOI DAILY REQUESTS CLOSED 5/14-18/12
2012-3894	06/01/2012 06/29/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ALISON M. AGNEW PILLSBURY	PARKEDALE PHARMACEUTICALS - CORTICOTROPIN NDA 08-317
2012-3895	06/01/2012 06/29/2012	FDA/OC/OES/DFOI/	FDA WEBVIEW/FERDIC INC	FOI DAILY REQUESTS CLOSED 5/21-25/12
2012-3896	06/01/2012 06/29/2012	FDA/OC/OES/DFOI/	FDA WEBVIEW/FERDIC INC	FOI DAILY REQUESTS CLOSED 5/14-18/12
2012-3897	06/01/2012 06/29/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ALISON M. AGNEW PILLSBURY	SANOFI AVENTIS - ACTHAR NDA 07-504
2012-3898	06/01/2012 06/29/2012	FDA/OFVM/CFSAN/OCD/EOS/	THOMPSON, CLARENCE LD	CALL FOR APPLICATIONS FOR 2012 STUDENT LOAN REPAYMENT PROGRAM - E-MAIL, LINKS, JUSTIFICATION MEMO TEMPLATE, CFSAN-ALLHANDS E-MAIL, 4/17/12 (2:25 PM)
2012-3899	06/01/2012 06/29/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ALISON M. AGNEW PILLSBURY	WATSON LABS - CORTICOTROPIN NDA 88-772

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2012-3900	06/01/2012 06/29/2012	FDA/OFVM/CFSAN/OCD/EOS/	MOTEN, LEVEETA	2012 STUDENT LOAN REPAYMENT PKG - APPLICATION PKG
2012-3901	06/01/2012 06/29/2012	FDA/OC/OES/DFOI/	ALSION M. AGNEW PILLSBURY WINTHROP SHAW PTTMAN LLP	2009-4213, 2009-5482
2012-3902	06/01/2012 06/29/2012	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OC/OES/DFOI/	DAVID J GRYCZ SEDWICK LLP	INDIVIDUAL RECS - 2011-5406 ATTACHMENT & ADDITIONAL LAB RESULTS, RECS ETC
2012-3903	06/01/2012 06/29/2012	FDA/OC/OES/DFOI/	ALISON M. AGNEW PILLSBURY WINTHROP SHAW PTTMAN LLP	2011-326, 2011-327
2012-3904	06/01/2012 06/29/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	ALISON M. AGNEW PILLSBURY WINTHROP SHAW PTTMAN LLP	TEVA PHARMS, IRVINE, CA - 483
2012-3905	06/01/2012 06/29/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PAMELA VENTURA APTALIS PHARMA SRL	APTALIS PHARMA CANADA INC, CANADA - QAP
2012-3906	06/01/2012 06/29/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PAMELA VENURA APTALIS PHARMA SRL	APTALIS PHARMATECH INC, VANDALIA, OH - QAP
2012-3907	06/01/2012 06/29/2012	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OC/OES/DFOI/	BREININGER, JASON	MEAD JOHNSON NUTRITIONALS, EVANSVILLE, IN - 483
2012-3908	06/01/2012 09/13/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/OCOS/OES/ OC/OCOS/OES/	ABIGAIL MOSS BIOPHARM INSIGHT	DENDREON - PROVENGE (SIPULEUCEL-T), IMPACT STUDY SAFETY & EFFICACY RECS

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		OC/OCOS/OL/		
2012-3909	06/01/2012 06/29/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/OCOS/OES/ OC/OCOS/OES/ OC/OCOS/OL/	KIRSTY BARNES BIOPHARM INSIGHT	BRILINTA (TICAGRELOR) - COMM, CLNCL DATA, AERS, ETC
2012-3910	06/01/2012 06/29/2012	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	LOLI, GENE	MIRGEN PHARMS, BIOSE, ID - 483 1/12/12-2/17/12
2012-3911	06/01/2012 06/29/2012	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	TIFFANY E. TIBBETTS GRIMM VRANJES ET AL	INDIVIDUAL RECS
2012-3912	06/01/2012 06/29/2012	OC/OM/OMP/DDM/	ANNA WOLONCIEJ SIDLEY AUSTIN LLP	DKT 1988G-0288
2012-3913	06/01/2012 06/29/2012	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	MUSCARELLA, LAWRENCE.	PSEUDOMONAS AERUGINOSA OUTBREAK - METHODIST HOSP, HOUSTON, TX
2012-3914	06/01/2012 06/29/2012	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	KERI VAN BECELAERE CLINICAL SITE MONITOR	DR RAM PATAK, WEST HILLS, CA - 483
2012-3915	06/01/2012 06/29/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	STAIGER, LUANA	URACIL MUSTARD NDA 12-892 - MED RVW, CHEMISTRY RVW, TOXICOLOGY RVW
2012-3916	06/01/2012 06/29/2012	OC/OM/OMP/DDM/	ANGELIA SLAYTON INC RESEARCH	DKT 1998C-0431
2012-3917	06/01/2012 06/29/2012	OC/OM/OMP/DDM/	CARLA SCARMAZZI KING & SPALDING	DKT 1978N-1241
2012-3918	06/04/2012 07/02/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	EILEEN BOYLE HOLOGIC INC	ORTHOSCAN-HD K051754
2012-3919	06/04/2012 07/02/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/OCOS/OES/	STEVE MILLOY JUNKSCIENCE.COM	SAM KASS (WHITE HOUSE CHEF) - FOOD/NUTRITION RECS, EMAILS, MINS, MEMOS, ETC

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		OC/OCOS/OES/ OC/ORO/ OC/ORO/		
2012-3920	06/04/2012 07/02/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	WILLIAMS, VINCENT M	SUPERVISORY CONSUMER SAFETY OFFICER GS-696-14 - POSTITION DESCRIPTION, DATE OF HIRING, JOB ANNOUNCEMENT, ETC
2012-3921	06/04/2012 07/02/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/	DEWITT M LOVELACE LOVELACE LAW FIRM PA	BLUE DIAMOND GROWERS - PROD MISBRANDING RECS
2012-3922	06/04/2012 07/02/2012	FDA/OC/OES/DFOI/	ALISON M AGNEW PILLSBURY WINTHROP SHAW PTTMAN LLP	ABIOMED INC - FOI REQUESTS 12/05 TO PRESENT
2012-3923	06/04/2012 07/02/2012	FDA/OMPT/CDRH/OCER/DFOI/	MICHAEL A LOCKE IMMUNOSTICS INC	MEDTEK LLC - LIFEGUARD 510K SUBMISSION
2012-3924	06/04/2012 07/02/2012	FDA/OMPT/CDRH/OCER/DFOI/	CHRISTOPHER SHAKIB TERRELL HOGAN ELLIS YEGELWEL PA	SYNTHES (USA) - PLATE FEMORAL LCP PLATE MDRS
2012-3925	06/04/2012 07/02/2012	FDA/OMPT/CDRH/OCER/DFOI/	BETHANY J HILLS TRACHTENBERG HODGSON RUSS LLP	LIFE-TECH INC - ULTRASONIC PULSED DOPPLER IMAGING SYS K120234
2012-3926	06/04/2012 07/02/2012	OC/OCOS/OES/ OC/OCOS/OES/	ALEX WAYNE BLOOMBERG NEWS	TRAVEL RECS FOR THE HEAD OF FDA 10/10 TO 9/11
2012-3927	06/04/2012 07/02/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	BRENT M ARDAUGH NORTHWESTERN UNIV FEINBERG SCHOOL OF MEDICINE	K893626, K894703, K912144, ETC
2012-3928	06/04/2012 07/02/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRENT M ARDAUGH NORTHWESTERN UNIV FEINBERG SCHOOL OF MEDICINE	K852097, K870729, K874096
2012-3929	06/04/2012 07/02/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PETER T MURPHY DC SAFETY CO INC	MEDICAL DRESSING CO, JINTAN CITY, JIANGSU, CHINA - 483 9/19/11

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2012-3930	06/04/2012 07/02/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	A LUKE SMITH RADICE LAW FIRM	TEVA PHARMS - LIPTOR (ATORVASTATIN) NDA 78-773; MYLAN LABS - NDA 91-226; APOTEC INC - NDA 90-548, ETC SBA
2012-3931	06/04/2012 07/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	BOTOX - AERS
2012-3932	06/04/2012 07/02/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/CHI- DO/CHI-CB/	GEORGIA L MCGOWAN EVERAGE LAW FIRM PLLC	INDIVIDUAL RECS
2012-3933	06/04/2012 07/02/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SW-FO/KAN- DO/KAN-CB/	WILLIAM THYMIUS CHRISTOPHER P DI GIULIO PC	CONAGRA FOODS INC - PAM NON-STICK COOKING SPRAY CMLPTS
2012-3934	06/04/2012 07/02/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELIF A ORAL UNIV OF MICHIGAN HEALTH SYSTEM	CHEMX PHARMS - APHTHALSOL NDA 20-511/S000 PI
2012-3935	06/04/2012 07/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORO/OCI/ OC/ORO/OCI/	KAREN PAULS CBC RADIO-CANADA	MEDIPLAN, RXNORTH - COUNTERFEIT LIPITOR, CRESTOR, CELEBREX INVESTIGATION RECS
2012-3936	06/04/2012 07/02/2012	FDA/OMPT/CDRH/OCER/DFOI/	BETHANY J HILLS TRACHTENBERG HODGSON RUSS LLP	LIFE-TECH INC - ULTRASONIC PULSED DOPPLER IMAGING SYS K102813
2012-3937	06/04/2012 07/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANGELLIA D SLAYTON INC REGULATORY CONSULTING	CENTOCOR - REMICADE (INFLIXIMAB) BLA 10-3772/S5012 APRVL LTR, LBLG, MEDICAL RVWS, ETC

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	& SUBMISSIONS	
2012-3938	06/04/2012 07/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARY F MORRISON TEMPLE UNIVERSITY SCHOOL OF MEDICINE	MINOCYCLINE - NDA PHASE I & PHASE II CLNCL TRIAL RECS
2012-3939	06/04/2012 07/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FRATTI, JOHN	LEVAQUIN, CIPRO & AVELOX - AERS
2012-3940	06/04/2012 07/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MORRIS, LARRY	THALLIUM CHLORIDE T201, THALLIUM T201
2012-3941	06/04/2012 07/02/2012	FDA/OMPT/CDRH/OCER/DFOI/	TRISH LANDRY BEAUFORT LLC	CDT SPECULUM - OPERATOR'S MANUAL, CORR REGARDING EXEMPTION
2012-3942	06/04/2012 07/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	NANCY YUEN GlaxoSmithKline	FINASTERIDE - ISRS M00959230, M00959259, MO1345239, ETC
2012-3943	06/04/2012 07/02/2012	FDA/OMPT/CDRH/OCER/DFOI/	TRISH LANDRY BEAUFORT LLC	MEDTRONIC - TYMPANOCENTESIS COLLECTOR OPERATOR'S MANUAL, CORR REGADRING EXEMPTION
2012-3944	06/04/2012 07/05/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	ELIZABETH MASON MEDSEP CORP	CELL PRO - CEPRATE SC STEM CELL CONCENTRATION SYS BP940001
2012-3945	06/04/2012 07/05/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	ELIZABETH MASON MEDSEP CORP	NEXELL THERAPEUTICS INC - ISOLEX 300 MAGNETIC CELL SELECTION SYS BP970001
2012-3946	06/04/2012 07/02/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	ELIZABETH MASON MEDSEP CORP	COBE LABORATORIES INC - COBE 2991 CELL PROCESSOR BK840009
2012-3947	06/04/2012 09/04/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	ELIZABETH MASON MEDSEP CORP	BIOMET BIOLOGICS INC - BIOCUE MINI PLATELET CONCENTRATION KIT BK100027
2012-3948	06/04/2012 07/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	COLEEN KLASMEIER SIDLEY AUSTIN LLP	CLAIRE M DEMATTEIS LTR - CONSUMER DIRECTED RX DRUG PROMOTIONAL LBLG, MINS10/21-22/08

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2012-3949	06/04/2012 07/02/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	ELIZABETH MASON MEDSEP CORP	FENWAL INC - BONE MARROW COLLECTION KIT WITH FLEXIBLE PRE-FILTER & INLINE FILTERS BK0900031
2012-3950	06/04/2012 07/02/2012	FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/	R IAN KLUGE Hyman Phelps and McNamara PC	CMPLNT 32782
2012-3951	06/04/2012 07/02/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	DR MICHAEL DESBOROUGH OXFORD UNIV HOSPITALS DEPT OF HEMATOLOGY	IMMUNOGLOBULIN - NUMBER OF HEMOLYSIS CASES, AERS, BRANDS, ETC
2012-3952	06/04/2012 07/02/2012	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JESSIE L JANDOVITZ MORELLI RATNER PC	RISPERIDAL (RISPERIDONE) - AERS
2012-3953	06/04/2012 07/02/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MANON VRANDERICK DUCHESNAY	MANNITOL - AERS LAST 5 YRS
2012-3954	06/04/2012 07/02/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/	KIM NGUYEN AP PHARMA INC	DOW CHEMICAL CO, PLAQUEMINE, LA; HUBEI HASUN PHARMACEUTICALS CO LTD - EIRS, 483S LAST 3 YRS
2012-3955	06/04/2012 07/02/2012	FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/	R IAN KLUGE Hyman Phelps and McNamara PC	CMPLNT 32782
2012-3956	06/04/2012 07/02/2012	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	ANNA KIEBURTZ Hyman Phelps and McNamara PC	NETWORK INC (VAXA INTERNATIONAL & WESTERN HEALTH PRODS), TAMPA, FL - EIRS, 483S, CO RESP
2012-3957	06/04/2012 07/02/2012	FDA/OGROP/ORA/CE-FO/CHI- DO/CHI-CB/	MELSSIA WILSON	J.R. CARLSON LABS, ARLINGTON HEIGHTS, IL - EIRS, 483S
2012-3958	06/04/2012 07/02/2012	FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/	ROBERT SZWAJKOS CURTIN & HEEFNER LLP	TRUCKERS WORLD ADULT NOVELTY, GARY, TN - NOTICE OF INVESTIGATION NAME & CONTACT RECS
2012-3959	06/05/2012 07/03/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MUN, HEE JIN	LIST OF EXPIRED DRUG PATENTS 1989 TO 1/10

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2012-3960	06/05/2012 07/03/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	STEPHEN J CARR AKERMAN SENTERFITT ATTYS	ELECTROSTIM MEDICAL SUPPLIES INC, TAMPA,FL - WARNING LTRS, 510K APPL, COMM, ETC
2012-3961	06/05/2012 07/03/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	BIJAN ESFANDIARI ESQ BAUM HEDLUND ET AL	POMONA VALLEY HOSPITAL MEDICAL CENTER - IRB PROCEDURES, MEMBERSHIP LISTS 1/1/08 TO 10/1/08
2012-3962	06/05/2012 07/03/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DIANE MARKS TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D INC	ADDERALL TABS NDA 11-522 - SBA
2012-3963	06/05/2012 07/03/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/	ANTHONY J D'AMICO ESQ SAVINIS D'AMICO & KANE LLC	STELKAST PROVEN KNEE MEDICAL DVC - WARNINGS, COMM, QUALITY SYS AUDITS, ETC
2012-3964	06/05/2012 07/03/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PRENDERGAST, JOYCE E	CHANTIX (VERENICLINE) - AERS 5/16/09 TO 5/26/12
2012-3965	06/05/2012 07/03/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MICHELE SINOWAY PHD LACHMAN CONSULTANT SERVICES INC	SNBL LTR 4/13/12
2012-3966	06/05/2012 07/03/2012	FDA/OMPT/CDRH/OCER/DFOI/	ELINOR E BAXTER BRENNAN MANNA & DIAMOND PL	KELLY MILLER, 580 SERVICES LLC - 510K SUBMISSIONS
2012-3967	06/05/2012 07/03/2012	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	KAREEM KHAIRAT EMCCO FOR OILS AND FOOD INDUSTRIES SAE	ENTRY #605-1576021-7 - RECS
2012-3968	06/05/2012 07/03/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PETER WHORISKEY WASHINGTON POST	AMGEN INC - EPO-8903 CLNCL TRIAL RPT
2012-3969	06/05/2012 07/03/2012	FDA/OC/OES/DFOI/	JULIA G YOUNG STRICK LAW FIRM PLLC	LSG SKY CHEFS INC - RECS
2012-3970	06/05/2012	FDA/OGROP/ORA/ORO/DIOP/	PAM ZAKMAN	SUPERMAX HEALTH CARE, SUPERMAX INC - INSPS,

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	07/03/2012		CBS 2 NEWS CHICAGO	INVESTIGATIONS OF GLOVES; IMPORT REFUSALS 2011, 2012
2012-3971	06/05/2012 07/03/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	BRUCE D GOODMAN STEINBERG GOODMAN & KALISH	BLACKSTONE MEDICAL INC, ORTHOFIX INC - PHOENIX MINIMALLY INVASIVE SPINAL FIXATION SYS EIRS, APRVLS, MDRS, ETC 2000 TO PRESENT
2012-3972	06/05/2012 07/03/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	BRUCE D GOODMAN STEINBERG GOODMAN & KALISH	BLACKSTONE MEDICAL INC, ORTHOFIX INC - SFS SPINAL FIXATION SYS EIRS, APRVLS, MDRS, ETC 2000 TO PRESENT
2012-3973	06/05/2012 07/03/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	BRUCE D GOODMAN STEINBERG GOODMAN & KALISH	BLACKSTONE MEDICAL INC, ORTHOFIX INC - FIREBIRD SPINAL FIXATION SYS EIRS, APRVLS, MDRS, ETC 2000 TO PRESENT
2012-3974	06/05/2012 07/03/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	CLOSED FOI REQUESTS 5/28/12-6/1/12
2012-3975	06/05/2012 07/03/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 5/28/12-6/1/12
2012-3976	06/05/2012 07/03/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 5/28/12-6/1/12
2012-3977	06/05/2012 07/03/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOI REQUESTS 5/28/12-6/1/12
2012-3978	06/05/2012 07/03/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	FRANCISCO JOSE dos SANTOS MARTINS DYNATECH	BENZENESULFONIC ACID - TOXICOLGY STUDY
2012-3979	06/05/2012 07/03/2012	FDA/OC/OES/DFOI/	BEVERIDGE & DIAMOND PC	CFSAN REQUESTS 4/26/12-5/23/12
2012-3980	06/06/2012 07/05/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 5/28/2012- 6/1/2012
2012-3981	06/06/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	A list of all FOIA requests closed 5/1-31/2012

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	07/05/2012		MERCK & CO., INC.	
2012-3982	06/06/2012 08/08/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ OC/OCOS/OES/ OC/OCOS/OES/	Doe J	Corr re: Wyeth/Pfizer's Prevnar 13 vaccine (04/22/2012 - 06/06/2012)
2012-3983	06/06/2012 08/06/2012	FDA/OMPT/CDRH/OCER/DFOI/	Kay Taylor PERKINELMER INC	K091283
2012-3984	06/06/2012 07/05/2012	FDA/OFVM/CFSAN/OCD/EOS/	ROBIN FELDMAN LSRO SOLUTIONS	POLYSORBATE 60 (POLYOXYETHYLENE (20) SORBITAN MONOSTERATE) - FAP 4A3775 & FAP 4A3824
2012-3985	06/06/2012 07/05/2012	FDA/OMPT/CDRH/OCER/DFOI/	MICHELLE SCHILTZ-TAING BISCO INC	SEPTODONT - BIODENTINE K092251
2012-3986	06/06/2012 07/05/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/OA/OM/OMP/DDM/ FDA/OC/OES/DFOI/	MEROLA, ERIC	MEMORIAL SLOAN KETTERING CANCER CTR, FDA & NCI MTG, BELTSVILLE, MD - MINS, 7/2/74
2012-3987	06/06/2012 07/05/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	SHIN KANG WELLS FARGO	SANQUIN/VIROPHARMA - CINRYZE, EUROPE (BELGIUM & HOLLAND), EIRS, 483S, CORR
2012-3988	06/06/2012 07/05/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/OCOS/OES/ OC/OCOS/OES/ OC/OCOS/OL/ OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/ OC/CVM/OCD/ FDA/OGROP/OIP/ FDA/OC/OCC/	JACK KASKEY BLOOMBERG NEWS	FOOD IMPORT ACTION PLANS - CORR 1/1/08 TO PRESENT; EUROPEAN UNION RECS
2012-3989	06/06/2012 07/05/2012	OC/ORO/ OC/ORO/	MARTINA BERNSTEIN PETA	FEED MFG ESTABLISHMENTS, CA - EIRS, RECS 1/1/08 TO PRES; FDA VIOLATIONS OF FDA ON PROHIBITED ANIMAL PROTEINS
2012-3990	06/06/2012 07/05/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LYNCH, REAGAN	WARNER CHILCOTT - ASACOL 400 MG, AERS

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2012-3991	06/06/2012 07/05/2012	FDA/OMPT/CDRH/OCER/DFOI/	LEX J PEARCE ICU MEDICAL INC	NEUTRAL LUER ACTIVATED DEVICE & EXTENSION SETS K120443, SUMMARY, SUBSTANTIAL EQUIVALENCE DECISION LTR, INDICATIONS FOR USE STATEMENT
2012-3992	06/06/2012 07/05/2012	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	ANITA FENTY Covance Inc.	PHT CORP, CHARLESTOWN, MA - EIR 9/6-15/11
2012-3993	06/06/2012 07/05/2012	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	MARK B FREDKIN MORGAN, FRANICH, FREDKIN & MARSH	WHITTLESTONE INC, CASTLE ROCK, CO - EIR, 2007
2012-3994	06/06/2012 07/05/2012	OC/CVM/OCD/	ROBERT H SINDT ATTY	GEVO - ANIMAL FOOD GRAS NOTICE 13
2012-3995	06/06/2012 07/05/2012	OC/CVM/OCD/	ROBERT H SINDT ATTY	GEVO - ANIMAL GRAS NOTICE 10
2012-3996	06/07/2012 07/06/2012	OC/OM/OMP/DDM/	JOYCE RIDLEY WOLTER KLOWER	DKT FDA-1995-S-0039, FDA-1997-S-0039
2012-3997	06/07/2012 07/06/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELIZABETH BARBEHENN PHD PUBLIC CITIZEN	TRADJENTA (LINAGLIPTIN) NDA 201-281/S002 - MEDICAL, STATISTICAL RVWS
2012-3998	06/07/2012 07/06/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Gordon, Ian	SHELLFISH, KRILL OIL IN RX DRUGS & SUPPLEMENTS - MFRS, DISTRIBUTORS
2012-3999	06/07/2012 07/06/2012	FDA/OMPT/CDRH/OCER/DFOI/	LEX PEARCE ICU MEDICAL INC	NEUTRAL LUER ACTIVATED DVC AND EXTENSION SETS K120443
2012-4000	06/07/2012 07/06/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Brown, Sanders E	GPS TRACKING IMPLANT - MDRS
2012-4001	06/07/2012 07/06/2012	FDA/OFVM/CFSAN/OCD/EOS/	MEADY AMORY LD AMORY CO INC	FDA EVALUATION OF THE KOREAN SHELLFISH SANITATION PROGRAM 2008, 2012
2012-4002	06/07/2012 07/06/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MICHAEL R COHEN RPH MS SCD INSTITUTE FOR SAFE	MEDWATCH RPTS CODED AS MEDICATION ERRORS 5/1-30/12

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2012-4003	06/07/2012 07/06/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ERIC H WEINBERG ERIC H WEINBERG ESQ	PRADAXA (DABIGATRAN ETEXILATE MESYLATE) - IND SUBMISSIONS, CLNCL TRIAL PROTOCOLS, SAFETY MONITORING, ETC
2012-4004	06/07/2012 07/06/2012	OC/ORO/OCI/ OC/ORO/OCI/	Doe J	INDIVIDUAL RECS
2012-4005	06/07/2012 07/06/2012	OC/CVM/OCD/	GREGORY P BERGT PENNFIELD OIL CO	PUCHENG LIFECOME BIOCHEMISTRY CO LTD - LASALOCID NADA 096-298 FERMENTATION PROCEDURES RECS
2012-4006	06/07/2012 07/06/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ALISON M AGNEW PILLSBURY WINTHROP SHAW PITTMAN LLP	HP ACTHAR NDA 08-372 - ANNUAL RPT
2012-4007	06/07/2012 07/06/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ALISON M AGNEW PILLSBURY WINTHROP SHAW PTTMAN LLP	ORGANICS LAGRANGE - CORTICOTROPIN NDA 10-831; ORGANON USA INC - PURIFIED CORTROPHIN GEL NDA 08-975; SANOFI AVENTIS - ACTHAR (CORTICOTROPIN) NDA 07-504, ETC LBLG
2012-4008	06/07/2012 07/06/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ALISON M AGNEW PILLSBURY WINTHROP SHAW PITTMAN LLP	CORTICOTROPIN NDA 08-317 - ANNUAL RPT
2012-4009	06/07/2012 07/06/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ALISON M AGNEW PILLSBURY WINTHROP SHAW PITTMAN LLP	CORTICOTROPIN NDA 88-772 - ANNUAL RPT
2012-4010	06/07/2012 07/06/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ALISON M AGNEW PILLSBURY WINTHROP SHAW PITTMAN LLP	CORTICOTROPIN NDA 07-504 - ANNUAL RPT
2012-4011	06/07/2012 07/06/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ALISON M AGNEW PILLSBURY WINTHROP SHAW PITTMAN LLP	CORTICOTROPIN NDA 10-831 - ANNUAL RPT

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2012-4012	06/07/2012 07/06/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	MICAEL JOHANSSON ETTEPLAN	SYNOVIS MICRO COMPANIES ALLIANCE INC - MICROVASCULAR ANASTOMOTIC COUPLER K040162; VIOPTIX INC - VESSELINK MICROVASCULAR ANASTOMOTIC COUPLER SYS K090679
2012-4013	06/07/2012 07/06/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ALISON M AGNEW PILLSBURY WINTHROP SHAW PITTMAN LLP	CORTICOTROPIN NDA 08-975 - ANNUAL RPT
2012-4014	06/07/2012 07/06/2012	FDA/OC/OES/DFOI/	William Hu Philips Healthcare Informatics	Philips Healthcare Informatics, Foster City, CA (04/13/2012 - 04/18/2012) - EIR
2012-4015	06/07/2012 07/06/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ALISON M AGNEW PILLSBURY WINTHROP SHAW PITTMAN LLP	CORTICOTROPIN-ZINC HYDROXIDE NDA 09-854 - ANNUAL RPT
2012-4016	06/07/2012 07/06/2012	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	David G. Perkins Abbott Laboratories, Inc	Cook Endoscopy's (FEI 1037905) response to the April 19, 2011 FDA 483 and any response to any Untitled Letter associated with this inspection (04/14/2011 - 06/06/2012)
2012-4017	06/07/2012 07/06/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Peter Gerold Gerold, Peter J	Lexiscan - AERS
2012-4018	06/07/2012 07/06/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ALISON M AGNEW PILLSBURY WINTHROP SHAW PITTMAN LLP	NDA 17-861 - ANNUAL RPT
2012-4019	06/07/2012 07/06/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Deborah Eickhoff LEO Pharma Inc.	NDA 202-833: PICATO (ingenol mebutate) gel - Unredacted Reviewer/Evaluation Reports (03/01/2011 - 02/02/2012)
2012-4020	06/07/2012 07/06/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Allison Olenginski Larson & Anderson LLC	IND 7656 PEGylated Recombinant Methionyl Human Soluble Tumor Necrosis Factor Type I Receptor (PEG sTNF- RI) (03/30/1998 - 06/06/2012)

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2012-4021	06/07/2012 07/06/2012	FDA/OMPT/CDRH/OCER/DFOI/	BARD PERIPHERAL VASCULAR INC	K034021
2012-4022	06/07/2012 07/06/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tracy White White, Tracy M	Ambien - AERS
2012-4023	06/07/2012 07/06/2012	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	TERI G. POON REED SMITH LLP	DAVOL INC, WARWICK, RI - EIR 3/10
2012-4024	06/07/2012 07/06/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tina Babos IPD ANALYTICS LLC	NDA No. 202343 - Summary Review and Medical Review
2012-4025	06/07/2012 07/06/2012	FDA/OFVM/CFSAN/OCD/EOS/	Scott Gould scott gould	Voluntary Cosmetic Registration Program - List of Labelers and contact information
2012-4026	06/07/2012 07/06/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dan Moellentín, PharmD, Associate Professor EASTERN MAINE MEDICAL CENTER	Exanatide associated nephrotic syndrome (04/01/2005 - 03/01/2012)
2012-4027	06/07/2012 07/06/2012	FDA/OMPT/CDRH/OCER/DFOI/	CALLIE G. MOORE ACERTARA ACOUSTIC LABORATORIES	INTRAOPERATIVE DOPPLER SYS - FLOWMETER BLOOD CARDIOVASCULAR VTI K082870
2012-4028	06/07/2012 07/06/2012	FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/	Rodolfo J Ricart Ricart, Rodolfo J	Vortech Pharmaceuticals LTD, Dearborn, MI - EIRs, 483s (01/01/2000 - 06/01/2012)
2012-4029	06/07/2012 07/06/2012	FDA/OMPT/CDRH/OCER/DFOI/	MICHELE LEE BUENAFE MORGAN LEWIS & BOCKIUS LLP	ULTHERA SYS K072505
2012-4030	06/07/2012 07/06/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	IRINA RIVKIND CANTOR FITZGERALD	RIFAXIMIN - 483 6/08 TO 9/09
2012-4031	06/07/2012 07/06/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANNE E. HEROLD JONES WARD PLC	REGLAN - PKG, RVW, LBLG

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2012-4032	06/07/2012 07/06/2012	FDA/OC/OES/DFOI/	Vijay Hingorani Vanguard Healthsciences, Inc.	PRADAXA - clinical review documents
2012-4033	06/07/2012 07/06/2012	FDA/OMPT/CDRH/OCER/DFOI/	HAROLD T. DODGE, Jr. RUSH HANNULA ET AL	SYNTHES INC - NORIAN CRS, SRS, R, XR DOCS
2012-4034	06/07/2012 07/06/2012	FDA/OMPT/CDRH/OCER/DFOI/	J. DONALD HENSON, SR Henson, J. Donald	NAME OF INDIVIDUAL WHO PREPARED PMA 980022/S010
2012-4035	06/07/2012 07/06/2012	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	STATUS OF CMLPNT 1100031
2012-4036	06/07/2012 07/06/2012	OC/CVM/OCD/	Melinda Culver Culver, Melinda	Submission to the FDA Center for Veterinary Medicine by Nestle Purina regarding the use of medium chain triglycerides (MCTs) in animal food or feed and the response(s), if any, by the agency (01/01/2008 - 06/07/2012)
2012-4037	06/07/2012 07/06/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Doe J	Reumofan Plus - Recall Recs
2012-4038	06/07/2012 07/06/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kim Wagner BIOPHARM DEVELOPMENT ASSOCIATES, LLC	Remicade BLA 103772
2012-4039	06/08/2012 07/09/2012	FDA/OMPT/CDRH/OCER/DFOI/	Loretta Szczotka-Flynn OD, PhD CWRU Dept of Ophthalmology	Silicone Hydrogel Contact Lenses; 510K applications which lead to the approval of several silicone hydrogel contact lenses for either daily or extended wear. Representative materials (and companies) are: lotrafilcon A, lotrafilcon B, balafilcon A, comfilcon A, narafilcon B, efrofilcon A, galyfilcon A, silficon A, enfilcon A, senofilcon A. (companies: CibaVision, Bausch&Lomb, CooperVision, Vistakon, Contamac) (01/01/1998 - 06/07/2012)
2012-4040	06/08/2012 07/09/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	EGG FOI Services, Inc.	Complete copy of page 6 of the Clinical Review for BLA 98-0369 for Herceptin, approved on 09/25/1998

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2012-4041	06/08/2012 07/09/2012	FDA/OMPT/CDRH/OCER/DFOI/	Steven Walsh Plasma Surgical, Inc.	Rhytec Portrait PSR 510(k) submission - K071786
2012-4042	06/08/2012 07/09/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kelly Marie Sohn Kelly M. Sohn	FDA Staff Manual Guide 4850.7 The recommended contents of such a submission are described more fully in FDA Staff Manual Guide 4850.7 that is publicly available under FDA's public information regulations in part 20. TITLE 21--FOOD AND DRUGS PART 312 -- INVESTIGATIONAL NEW DRUG APPLICATION Subpart C--Administrative Actions Sec. 312.47 Meetings.
2012-4043	06/08/2012 07/09/2012	FDA/OMPT/CDRH/OCER/DFOI/	Caroline McKenna Law Offices of G. Oliver Koppell & Assoc	Wichita Fusion Nail -- approval, reports, or complaints
2012-4044	06/08/2012 07/09/2012	OC/CVM/OCD/ FDA/OFVM/CFSAN/OCD/EOS/ OC/OCOS/OES/ OC/OCOS/OES/ FDA/OC/OCC/	TIM SCHWAB Food & Water Watch	AQUABOUNTY TECHNOLOGIES - AQUADVANTAGE SALMON SHAREHOLDER DISCLOSURE RECS 8/15/08
2012-4045	06/08/2012 07/17/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	DEWITT M LOVELACE LOVELACE LAW FIRM PA	KELLOGG CO - PROD MISBRANDING RECS
2012-4046	06/08/2012 07/09/2012	FDA/OGROP/ORACE-FO/SAN-DO/SAN-CB/	MARIANNA CARUSO CHARLES RIVER LABS	ISIS SERVICES LLC, SAN CARLOS, CA -EIR 3/22/11-4/7/11
2012-4047	06/08/2012 07/09/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORACE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORACE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORACE-FO/NYK-DO/NYK-DCB/	DEWIT M LOVELACE LOVELACE LAW FIRM PA	PEPISCO INC - PROD MISBRANDING RECS
2012-4048	06/08/2012 07/09/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CTP/OD/ OC/CVM/OCD/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/ORP/DIDP/	ANN L WEISMANN CITIZENS FOR RESPONSIBILITY & ETHICS IN WASHINGTON	REP JIM RENACCI - COMM 1/11 TO PRESENT; SUAREZ CORPORATION INDUSTRIES (SCI) - RECS 1/05 TO PRESENT

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2012-4049	06/08/2012 08/07/2012	FDA/OMPT/CTP/OD/	GREGORY N CONNOLLY DMD MPH HARVARD SCHOOL OF PUBLIC HEALTH	PHILIP MORRIS, ALTRIA GROUP INC - MARLBORO LIGHTS CIGARETTES RECS, RESP TO LTR 6/17/11
2012-4050	06/08/2012 07/09/2012	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Doe J	UNILEVER - SOFT AND BEAUTIFUL CMLPNT
2012-4051	06/08/2012 07/09/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	AMGEN - PROLIA AERS
2012-4052	06/08/2012 07/09/2012	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	DAMARYS DEL CASTILLO GOYA DE PUERTO RICO INC	CMLPNT
2012-4053	06/08/2012 07/09/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DR K C JINDAL FDC LTD	PREDNISONE ACETATE OPHTHALMIC SUSPENSION NDA17-011, TOBRAMYCIN OPHTHALMIC SOL NDA 50-541, TRIFLURIDINE OPHTHALMIC SOL NDA 18-299 - SBA
2012-4054	06/08/2012 07/09/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRYAN SAYLER HOUNDS PARTNERS	DMAA (DIMETHYLAMYLAMINE) - AERS

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		FDA/OFVM/CFSAN/OCD/EOS/		
2012-4055	06/08/2012 07/09/2012	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	RITU BARAL COLLINS STEWART LLC	BANNER PHARMACAPS, HIGH POINT, NC - 483 3/12
2012-4056	06/08/2012 07/09/2012	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	RITU BARAL COLLINS STEWART LLC	BANNER PHARMACAPS, HIGH POINT, NC - 483 4/12
2012-4057	06/08/2012 07/09/2012	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	RITU BARAL COLLINS STEWART LLC	BANNER PHARMACAPS, HIGH POINT, NC - 483 5/12
2012-4058	06/08/2012 07/09/2012	FDA/OGROP/ORR/CE-FO/NWJ-DO/NWJ-CB/	RITU BARAL COLLINS STEWART LLC	CATALENT PHARMA SOLUTIONS, SOMERSET,NJ - 483 3/12
2012-4059	06/08/2012 07/09/2012	FDA/OGROP/ORR/CE-FO/NWJ-DO/NWJ-CB/	RITU BARAL COLLINS STEWART LLC	CATALENT PHARMA SOLUTIONS, SOMERSET, NJ - 483 4/12
2012-4060	06/08/2012 07/09/2012	FDA/OGROP/ORR/CE-FO/NWJ-DO/NWJ-CB/	RITU BARAL COLLINS STEWART LLC	CATALENT PHARMA SOLUTIONS, SOMERSET, NJ - 483 5/12
2012-4061	06/08/2012 07/09/2012	FDA/OMPT/CDRH/OCER/DFOI/	HAMILTON PHD, LEROY L	FORM 3429 & RELATED DOCS SINCE 1/12
2012-4062	06/08/2012 07/09/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JONATHAN B. NACE PAULSON & NACE	HUMIRA - CLNCL TRIAL
2012-4063	06/08/2012 07/09/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	JANE BROWN MD NEEDHAM PEDIATRICS PC	INDIVIDUAL RECS
2012-4064	06/08/2012 07/09/2012	FDA/OGROP/ORR/NE-FO/NYK-DO/NYK-DCB/	JAMES McCREADY LONG ISLAND JEWISH MEDICAL CENTER	CIRCULATORY TECHNOLOGY INC - BIGGER BETTER BLADDER WARNING LTR
2012-4065	06/08/2012 07/09/2012	FDA/OC/OES/DFOI/	REID, JUSTUS	ERADICATION OF THE FOX POPULATION AT THE TOWN OF PALM BEACH
2012-4066	06/08/2012 07/09/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELAINE S. WALLER SEATTLE GENETICS INC	ADCETRIS (BRENTUXIMAB VEDOTIN) AER 9/11 TO 5/31/12
2012-4067	06/08/2012 07/09/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANDREW D. ASHE, Esq. DYAX CORP	KALBITOR (ECALLANTIDE) - APRVL

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2012-4068	06/08/2012 07/09/2012	FDA/OMPT/CDRH/OCER/DFOI/	Nicole Dove SUMMIT MEDICAL LTD	K102148
2012-4069	06/08/2012 07/09/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Francis G. Gleason, Jr. Gleason & Gleason Attorneys at Law	Records regarding 510K application(s) for market approval of a medical device submitted by Medelle Corporation beginning in the first quarter of 2004 through the end of 2008.
2012-4070	06/08/2012 07/09/2012	FDA/OMPT/CDRH/OCER/DFOI/	Francis G. Gleason, Jr. Gleason & Gleason Attorneys at Law	Correspondence between FDA and Invo Bioscience and of any 510K application for market approval on a medical device known as the "Invo cell" which may have been submitted by Invo Bioscience. Invo Bioscience has been and may still be located in Beverly, Massachusetts.
2012-4071	06/08/2012 07/09/2012	OC/OA/OM/OMP/DDM/	ANGELIA D. SLAYTON INC RESEARCH	DCK FDA-2012-N-0171
2012-4072	06/08/2012 07/09/2012	FDA/OMPT/CDRH/OCER/DFOI/	Summit Medical	K112535
2012-4073	06/08/2012 07/09/2012	FDA/OMPT/CDRH/OCER/DFOI/	Semi Condoianis Dentistry360	K02836
2012-4074	06/08/2012 07/09/2012	FDA/OMPT/CDRH/OCER/DFOI/	Mihir Shah UE LifeSciences Inc	K113259
2012-4075	06/08/2012 07/09/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORA/ OC/ORA/	Nancy Burton Nancy Burton	All records of fish caught in Pacific Ocean waters and inspected by the Food and Drug Administration and found to contain radioisotopes released in the Fukushima triple nuclear reactor meltdown since March 11, 2011.
2012-4076	06/08/2012 07/09/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	J. PRICE COLEMAN COLEMAN LAW FIRM	CORR BETWEEN FDA & MCCORMICK & CO
2012-4077	06/08/2012 07/09/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORA/ OC/ORA/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	J. PRICE COLEMAN COLEMAN LAW FIRM	CORR BETWEEN FDA & APPLE & EVE LLC
2012-4078	06/08/2012 07/09/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORA/ OC/ORA/	J. PRICE COLEMAN COLEMAN LAW FIRM	CORR BETWEEN FDA & CHICKEN OF THE SEA

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2012-4079	06/08/2012 07/09/2012	FDA/OC/OES/DFOI/	LONERY 0849065, JOHN	FOOD & NUTRITION MGMT POLICY MANUAL
2012-4080	06/08/2012 07/09/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI CLOSED REQUESTS 5/14-18/12
2012-4081	06/08/2012 07/09/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI CLOSED REQUESTS 5/21-25/12
2012-4082	06/11/2012 07/10/2012	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Mary E. Lynn The Windward Company	North American Science Associates, Inc., Northwood Ohio - EIR (04/10/2005 - 05/10/2005)
2012-4083	06/11/2012 07/10/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Eric Hall Hall, Eric	Teva budesonide inhalation aerosol ANDA approval package
2012-4084	06/11/2012 07/10/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Eric Hall Hall, Eric	Ciclesonide pediatric studies
2012-4085	06/11/2012 07/10/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Raphael Lewis North Run Capital, LP	All correspondence, including but not limited to emails, in relation to Abiomed Inc.'s Impella products.
2012-4086	06/11/2012 07/10/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Maggie Palmisano Hallberg & McClain, P.A.	Investigation of the relationship between Simply Thick and the development of NEC in infants including, including lab results (05/01/2011 - 06/08/2012)
2012-4087	06/11/2012 07/10/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Marian S. Rosen & Association	ISR Number 4755457-3 ISR Number 6436946-2 ISR Number 6259539-9 ISR Number 6436946-2
2012-4088	06/11/2012	FDA/OMPT/CDER/GRP/DIDP/	Eric Hall	The Asmanex full pediatric program

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2012-4089	06/11/2012 07/10/2012	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Eric Hall Hall, Eric	Exemplar Pharmaceuticals, LLC- EIRs, 483s (2011-2012)
2012-4090	06/11/2012 07/10/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Eric Hall Hall, Eric	Flovent HFA S-004 sNDA approval package
2012-4091	06/11/2012 07/10/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Diane Nelms ALCON LABORATORIES	Urokinase - testing requirements for release of FDA approved product (06/02/1997 - 06/08/2012)
2012-4092	06/11/2012 07/12/2012	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	HART, TARA	DIAMOND PET FOODS - DRY PET FOOD RECALL CMLNPTS 05/05/12
2012-4093	06/11/2012 07/12/2012	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	HART, TARA	DIAMOND PET FOODS - PUPPY FORMULA RECALL COMPLNPTS 4/30/12
2012-4094	06/11/2012 07/12/2012	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	HART, TARA	DIAMOND PET FOODS - ONE PRODUCTION RUN DRY DOG FOOD RECALL CMLNPTS 4/26/12
2012-4095	06/11/2012 07/12/2012	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	HART, TARA	DIAMOND PET FOODS - DRY DOG FOOD BAGS CMLNPTS 04/06/12
2012-4096	06/11/2012 07/10/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RITU BARRAL	EQUATEQ LTD, LEIWIS, SCOTLAND - 483S 5/12
2012-4097	06/11/2012 07/10/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RITU BARAL	EQUATEQ LTD, LEWIS, SCOTLAND - 483S 4/12

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2012-4098	06/11/2012 07/10/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RITU BARAL	EQUATEQ LTD, LEWIS, SCOTLAND - 483S 3/12
2012-4099	06/11/2012 07/10/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	RITU BARAL	CHEMPORT LAB, FONH DU-FONH NSJU-DI JROLLANAM-DO, SOUTH KOREA - 483S 3/12
2012-4100	06/11/2012 07/10/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RITU BARAL	CHEMPORT INC, DONGSU-DONG NAJU-SI JEOLLANAM-DO, SOUTH KOREA - 483S 4/12
2012-4101	06/11/2012 07/10/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RITU BARAL	CHEMPORT INC, DONGSU-DONG NAJU-SI JEOLLANAM-DO, SOUTH KOREA - 483S 5/12
2012-4102	06/11/2012 07/10/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CINDY HSU	TRAVERT NDA 16-717- CLNCL PHARMACOLOGY, BIOPHARMACEUTICS, CHEMISTRY REVWS, ETC
2012-4103	06/11/2012 07/10/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELIZABETH BARBEHENN PUBLIC CITIZEN	LIRAGLUTIDE - ISRS 7792076, 7793173, 7798076, ETC
2012-4104	06/11/2012 07/10/2012	FDA/OFVM/CFSAN/OCD/EOS/	NATHAN A BEAVER FOLEY & LARDNER LLP	NUTRASWEET CO - MICROPARTICULATED PROTEIN PROD FAP
2012-4105	06/11/2012 07/10/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	SHAMEEN AFIF-RIDER MEDIMMUNE INC	VAERS 397055, 417991, 422860, ETC
2012-4106	06/11/2012	FDA/OMPT/CDER/ORP/DIDP/	RITU BARAL	NISSHIN PHARMA, JAPAN - 483 5/12

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	07/10/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	COLLINS STEWART LLC	
2012-4107	06/11/2012 07/10/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RITU BARAL COLLINS STEWART LLC	NISSHAN PHARMA, JAPAN - 483 4/12
2012-4108	06/11/2012 07/10/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RITU BARAL COLLINS STEWART LLC	NISSHIN PHARMA, JAPAN - 483 3/12
2012-4109	06/11/2012 07/10/2012	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	TARA HART WOODRUFF SWEITZER	APEX - PET FOOD RECALL 5/4/12
2012-4110	06/11/2012 07/10/2012	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	TARA HART WOODRUFF SWEITZER	CANIDAE - PET FOOD RECALL 5/5/12
2012-4111	06/11/2012 07/10/2012	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	TARA HART WOODRUFF SWEITZER	WELLPET LLC - PET FOOD RECALL 5/7/12
2012-4112	06/11/2012 07/10/2012	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	TARA HART WOODRUFF SWEITZER	SOLID GOLD HEALTH PRODUCTS FOR PETS INC - PET FOOD RECALL 5/8/12
2012-4113	06/11/2012 07/10/2012	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	TARA HART WOODRUFF SWEITZER	NATURAL BALANCE - PET FOOD RECALL 5/4/12
2012-4114	06/11/2012 07/10/2012	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	TARA HART WOODRUFF SWEITZER	DIAMOND - PET FOOD RECALL 5/21/12
2012-4115	06/11/2012 07/10/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	SHAMEEN AFIF-RIDER MEDIMMUNE INC	VAERS 295697, 331721, 362590
2012-4116	06/11/2012 07/10/2012	OC/ORR/ OC/ORR/ FDA/OGROP/ORR/CE-FO/DET-DO/DET-CB/ FDA/OGROP/ORR/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORR/CE-FO/NWJ-DO/NWJ-CB/	Vick, Linda	CHICKEN JERKY - PET TREATS ANALYSIS, RESULTS

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		FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/ OC/ORA/ OC/ORA/		
2012-4117	06/11/2012 07/10/2012	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OMPT/CDRH/OCER/DFOI/	PHIL SHUGART CAROLINA LIQUID CHEMISTRIES CORP	DIERCT BILIRUBIN REAGENT K011972; CK-NAC REAGENT K974833; TOTAL BILIRUBIN REAGENT K003892
2012-4118	06/11/2012 07/10/2012	FDA/OMPT/CDRH/OCER/DFOI/	semi condoianis Dentistry360	K070700
2012-4119	06/11/2012 07/10/2012	OC/OSMP/OOPD/	Yamil Hernandez Yamil Hernandez	Orphan Drug Designation Application Package for the drug H.P. Acthar Gel (Repository Corticotropin Or Adrenocorticotropic Hormone) in the treatment of Infantile Spasms (IS) submitted by Questcor Pharmaceuticals
2012-4120	06/11/2012 07/10/2012	OC/ORA/ OC/ORA/	Sue Longacre SAFETY RESEARCH & STRATEGIES INC	Dried Pasta Products - Complaints (01/01/2002 - 06/10/2012)
2012-4121	06/11/2012 07/10/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	N. KIRKLAND POPE POPE MCGLAMRY ET AL ATTYS	WRIGHT MEDICAL TECHNOLOGY INC - CONSERVE PLUS HIP REPLACEMENT SYS; CONSERVE PLUS TOTAL RESURFACING SYS; CONSERVE TOTAL HIP SYS W/BFH TECH - ADRS, CLNCL STUDIES, 510K
2012-4122	06/11/2012 07/10/2012	FDA/OFVM/CFSAN/OCD/EOS/	ALICIA B. RICHARDS AQUASOL CORP	FCN 1125 PAPERPAK INDUSTRIES
2012-4123	06/11/2012 07/10/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	KATE WILLSON CENTER FOR PUBLIC INTEGRITY	HUMAN CELL & TISSUE ESTABLISHMENT REGISTRATION DATABASE
2012-4124	06/11/2012 07/10/2012	FDA/OMPT/CDRH/OCER/DFOI/	PAUL BARBER BARBER, PAUL	HEARTLAND TAN SYSTEMS - ALPHA SOLAR SYS TANNING BED K943656
2012-4125	06/11/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	LYNN REICHHHELM	INDIVIDUAL RECS

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	07/10/2012		PESSIN KATZ LAW PA	
2012-4126	06/12/2012 07/11/2012	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	AUSTIN NELSON RBC CAPITAL MARKETS	HOSPIRA INC, MCPHERSON, KS - 483 2/1/12
2012-4127	06/12/2012 07/11/2012	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	JOHN A CHIOCCA CHIOCCA & CHIOCCA	ANITA A DONSKY, MAURICE E DONSKY, BLUE WATER CONNECTION SEAFOOD CORP - INVESTIGATION RECS 7/15/11
2012-4128	06/12/2012 07/11/2012	OC/ORAS/ OC/ORAS/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	AILEEN CHOY GREAT GLOVE USA INC	TG MEDICAL SDN BHD - ENTRY #112-7161512-7 FDA NOTICE OF ACT, TESTING RPT, PACKING LIST, ETC
2012-4129	06/12/2012 07/11/2012	OC/ORAS/ OC/ORAS/ FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	Doe J	INDIVIDUAL RECS
2012-4130	06/12/2012 07/11/2012	OC/ORAS/ORM/ OC/ORAS/ORM/	DANNY ROBBINS ASSOCIATED PRESS DALLAS BUREAU	DIETARY SUPPLEMENT COMPANIES - NUMBER OF INSPS, CGMP REGULATIONS 2011
2012-4131	06/12/2012 07/11/2012	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	JOHNATHAN RICKMAN FDA NEWS	CARDINAL HEALTH 414 LLC, BELTSVILLE, MD - 483S 3/1-31/12
2012-4132	06/12/2012 07/11/2012	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	JOHNATHAN RICKMAN FDA NEWS	DENTAL TECHNOLOGIES INC, LINCOLNWOOD, IL; CPC LABORATORIES INC, CHICAGO, IL; BIOSYNERGY INC, ELK GROVE VILLAGE, IL, ETC - 483S 3/1-31/12
2012-4133	06/12/2012 07/11/2012	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	JOHNATHAN RICKMAN FDA NEWS	PFIZER PHARMACEUTICALS LLC, CAROLINA, PR; FENWAL INTL INC, MARICAO, PR - 483S, 2/1-29/12
2012-4134	06/12/2012 07/11/2012	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	JOHNATHAN RICKMAN FDA NEWS	DOW PHARMACEUTICAL SCIENCES, PETALUMA, CA; ANGIODYNAMICS INC, FREMONT, CA; ASPINE USA INC, SAN FRANCISCO, CA - 483S 2/1-29/12
2012-4135	06/12/2012 07/11/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	JOHNATHAN RICKMAN FDA NEWS	FOUGERA PHARMACEUTICALS INC, HICKSVILLE, NY; TOPIDERM INC, NORTH AMITYVILLE, NY; ANGIODYNAMICS INC, QUEENSBURY, NY, ETC - 483S, 2/1-29/12
2012-4136	06/12/2012 07/11/2012	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	JOHNATHAN RICKMAN FDA NEWS	ONYX MEDICAL CORP, MEMPHIS, TN; INTEC INDUSTRIES INC, BIRMINGHAM, AL; PERMOBIL INC, LEBANON, TN ETC - 483S 2/1-29/1/2
2012-4137	06/12/2012 07/11/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	JOHNATHAN RICKMAN FDA NEWS	BIOGENESIS INC, HACKENSACK, NJ; UNETTE CORP, RANDOLPH, NJ; DAVAGEN PHARMACEUTICALS LLC, SOMERSET, NJ ETC - 483S 2/1-29/12
2012-4138	06/12/2012 07/11/2012	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	JOHNATHAN RICKMAN FDA NEWS	QUARTET TECHNOLOGY INC, DRACUT, MA; MICROSPECIALITIES INC, MIDDLETOWN, CT; ADVANCED

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				INSTRUMENTS INC, NORWOOD, MA ETC - 483S, 2/1-29/12
2012-4139	06/12/2012 07/11/2012	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	JOHNATHAN RICKMAN FDA NEWS	SCHWABE NORTH AMERICA INC, GREEN BAY, WI; DIVERSIFIED MANUFACTURING CORP, NEWPORT, MN; BRENNTAG GREAT LAKES LLC, MENOMONEE FALLS, WI ETC - 483S, 2/1-29/12
2012-4140	06/12/2012 07/11/2012	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	JOHNATHAN RICKMAN FDA NEWS	OGENIX CORP, BEACHWOOD, OH; AFASSCO INC, ORRVILLE, OH; GRIMM SCIENTIFIC INDUSTRIES, MARIETTA, OH, ETC - 483S 3/1-31/12
2012-4141	06/12/2012 07/11/2012	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	JOHNATHAN RICKMAN FDANEWS	PROPORTIONAL TECHNOLOGIES INC, HOUSTON, TX; ALOESCIENCE LABS INC, GARLAND, TX; ALCON RESEARCH LTD, FT WORTH, TX, ETC - 483S 3/1-31/12
2012-4142	06/12/2012 07/11/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	JOHNATHAN RICKMAN FDA NEWS	INTRACEUTICALS LLC, LONG BEACH, CA; PACIFIC CONSOLIDATED INDUSTRIES LLC, RIVERSIDE, CA; AMERICAN OPTISURGICAL INC, LAKE FOREST, CA, ETC - 483S, 2/1-29/12
2012-4143	06/12/2012 07/11/2012	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	JOHNATHAN RICKMAN FDA NEWS	B&G LABS INC, ST LOUIS, MO; MERIDIAN MEDICAL TECHNOLOGIES, ST LOUIS, MO & BRENTWOOD, MO - 483S, 2/1-29/12
2012-4144	06/12/2012 07/11/2012	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Riemer, Todd	Inova Blood Donor Services, Sterling, VA - 483s, EIRs (1/23/2012- 2/13/2012) and EIRs (2009-2011)
2012-4145	06/12/2012 07/11/2012	FDA/OMPT/CDRH/OCER/DFOI/	JOHNATHAN RICKMAN FDA NEWS	BAITELLA AG, ZURICH, SWITZERLAND; GE HEALTHCARE FINLAND OY, HELSINKI, FINLAND; BTS SPA, PADOVA, ITALY ETC - 483S, 2/1-29/12
2012-4146	06/12/2012 07/11/2012	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Aaron M. White Stern & Goldberg	Protica, Inc., Whitehall, PA - Corr, 483s (01/01/2011 - 06/11/2012)
2012-4147	06/12/2012 07/11/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHNATHAN RICKMAN FDA NEWS	FROSST IBERICA SA, ALCALA DE HENARES, SPAIN; WATSON PHARMA PRIVATE LTD, VERNA, GOA, INDIA; PETRA HYGIENIC SYS INTL, CONCORD, CANADA ETC - 483S, 2/1-29/12
2012-4148	06/12/2012 07/11/2012	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	JOHNATHAN RICKMAN FDA NEWS	LASERSIGHT TECHNOLOGIES INC, WINTER PARK, FL; GULF FIBEROPTICS INC, OLDSMAR, FL; CLOROX HEALTHCARE HOLDINGS LLC (DBA HEALTHLINK), JACKSONVILLE, FL ETC - 483S, 2/1-29/12
2012-4149	06/12/2012 07/11/2012	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	JOHNATHAN RICKMAN FDA NEWS	BIOPRO INC, PORT HURON, MI; 3T MEDICAL SYStems LLC, LIVONIA, MI; LEBANON CORP, LEBANON, IN - 483S, 2/1-29/12
2012-4150	06/12/2012 07/11/2012	FDA/OMPT/CDRH/OCER/DFOI/	JOHNATHAN RICKMAN FDA NEWS	FLAEM NUOVA SPA, DELLA BATTAGLIA, ITALY; ALBERT BROWNE LTD, LEISTER, UK; HAAG STREIT UK LTD, HARLOW, UK ETC - 483S, 3/1-31/12

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2012-4151	06/12/2012 07/11/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORACE-FO/CHI- DO/CHI-CB/	Sue Longacre SAFETY RESEARCH & STRATEGIES INC	Recall Records dated September 30, 2011 involving Velveeta shells and Cheese and Velveeta Rotini and Cheese manufactured by Kraft Foods Global, Inc.
2012-4152	06/12/2012 07/11/2012	FDA/OGROP/ORACE-FO/PHI- DO/PHI-CB/	JOHNATHAN RICKMAN FDA NEWS	SIEMENS HEALTHCARE DIAGNOSTICS INC, NEWARK, DE - 483S, 2/1-29/12
2012-4153	06/12/2012 07/11/2012	FDA/OMPT/CDRH/OCER/DFOI/	Eli Bental, Eliyahu	K110565
2012-4154	06/12/2012 07/11/2012	FDA/OGROP/ORAPA-FO/SEA- DO/SEA-CB/	JOHNATHAN RICKMAN FDA NEWS	NATUS MEDICAL INC, SEATTLE, WA; GLOBAL PATHOGEN SOLUTIONS INC, CAMAS, WA; PETNET SOLUTIONS INC, KENT, WA - 483S, 2/1-29/12
2012-4155	06/12/2012 07/11/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bhupesh ASTRON RESEARCH LTD	ANDA A078179 - Clinical pharmacology and bio pharmaceuticals review
2012-4156	06/12/2012 07/11/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	r.p.shah memorial trust for children with disabilities r.p.shah memorial trust for children	Steroids - AERs
2012-4157	06/12/2012 07/11/2012	FDA/OGROP/ORASW-FO/DEN- DO/DEN-CB/	JOHNATHAN RICKMAN FDA NEWS	DYNASTHETICS, SALT LAKE CITY, UT; FRESENIUS MEDICAL CARE NORTH AMERICA, OGDEN, UT - 483S 3/1-31/12
2012-4158	06/12/2012 07/11/2012	FDA/OGROP/ORASE-FO/ATL- DO/ATL-CB/	JOHNATHAN RICKMAN FDA NEWS	HOSPIRA INC, CLAYTON, NC; DERMATREATE LLC, MONCKSCORNER, SC; COOK ENDOSCOPY, WINSTON-SALEM, NC ETC - 483S, 3/1-31/12
2012-4159	06/12/2012 07/11/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Francois Ravenelle oncozyme pharma inc.	Pentamidine Isethionate toxicology review
2012-4160	06/12/2012 07/11/2012	FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/	ONA SCANDURRA COUNTRY LIFE LLC	M & L PHARMS, SAN BERNADINO, CA - EIRS, 483S 6/05 TO PRESENT
2012-4161	06/12/2012 07/11/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHNATHAN RICKMAN FDA NEWS	SIGMA-ALDRICH CO LTD, GILLINGHAM, UK; KINGKEY GROUP KINGKEY DAILY CHEMICAL CO LTD, SHANTOU CITY, CHINA; ZHEJIANG XINHUA PHARMACEUTICAL CO LTD, LINHAI, ZHEJIANG, CHINA, ETC - 483S, 3/1-31/12
2012-4162	06/12/2012	FDA/OGROP/ORASE-FO/FLA- DO/FLA-CB/	JOHNATHAN RICKMAN	PRODUCT QUEST MANUFACTURING LLC, HOLLY HILL, FL; BAUSCH & LOMB INC, TAMPA, FL; HILL DERMACEUTICALS

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	07/11/2012		FDA NEWS	INC, SANFORD, FL, ETC - 483S, 3/1-31/12
2012-4163	06/12/2012 07/11/2012	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	RENEERS, PATRICK	FLUORIDE (HYDROFLUOSILICIC ACID) IN WATER - WARNINGS, GOAL BLOOD LEVELS
2012-4164	06/12/2012 07/11/2012	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	JOHNATHAN RICKMAN FDA NEWS	INTEGRATED BIOMEDICAL TECHNOLOGY INC, ELKHART, IN; CARDINAL HEALTH MSU PET SITE, EAST LANSING, MI; TOWER LABORATORIES LTD, MONTAGUE, MI, ETC - 483S, 3/1-31/12
2012-4165	06/12/2012 07/11/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KOBER, MARY JANE	FORTEO - AERS
2012-4166	06/12/2012 07/11/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	DEABOLD, GEORGE	GED-1, GED-4 SKIN SHOCK DVCS - APRVL RECS
2012-4167	06/12/2012 07/11/2012	FDA/OMPT/CDRH/OCER/DFOI/	DEBORAH ARTHUR COCHLEAR AMERICAS	COCHLEAR BONE-ANCHORED SOLUTIONS AB, MOLNLYCKE, SWEDEN - EIR 5/14-17/07
2012-4168	06/12/2012 07/11/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	TORRENT PHARMACEUTICALS LTD, GUJARAT STATE, INDIA - EIR 3/8/11
2012-4169	06/12/2012 07/11/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	STRIDES ARCOLAB LTD, KAMATAKA, INDIA - EIR 3/17/09, 2/3/11
2012-4170	06/12/2012 07/11/2012	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	DANNY ROBBINS ASSOCIATED PRESS DALLAS BUREAU	ADVOCARE INTERNATIONAL - 483S, WARNING LTRS, CO RESP, ETC
2012-4171	06/12/2012 07/11/2012	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	DANNY ROBBINS ASSOCIATED PRESS DALLAS BUREAU	NUTRITION SCIENCE LABORATORIES LLC - 483S, WARNING LTRS, CO RESP, ETC
2012-4172	06/12/2012	FDA/OGROP/ORASW-FO/DAL-	DANNY ROBBINS	CUSTOM NUTRITION LABORATORIES LLC - 483S,

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	07/11/2012	DO/DAL-CB/	ASSOCIATED PRESS DALLAS BUREAU	WARNING LTRS, CO RESP, ETC
2012-4173	06/13/2012 07/12/2012	FDA/OC/OES/DFOI/	JONATHAN BERMAN JONES DAY	FDA TELEPHONE DIRECTORIES - NUMBERS, POSITION, OFFICES
2012-4174	06/13/2012 07/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	JENNIFER K REGISTER BLASINGAME BURCH ET AL ATTYS	ALIGN & ALIGN TO URETHRAL SUPPORT SYS - K093747
2012-4175	06/13/2012 07/12/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	JENNIFER K REGISTER BLASINGAME BURCH ET AL ATTYS	URETEX TO TRANS-OBTURATOR URETHRAL SUPPORT SYS - K041176
2012-4176	06/13/2012 07/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	JENNIFER K REGISTER BLASINGAME BURCH ET AL ATTYS	URETEX SUP PUBOURETHRAL SLING - K012949
2012-4177	06/13/2012 07/12/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	JENNIFER K REGISTER BLASINGAME BURCH ET AL ATTYS	ALIGN URETHRAL SUPPORT SYS - K070073
2012-4178	06/13/2012 07/12/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/OCOS/OES/ OC/OCOS/OES/ FDA/OC/OES/DFOI/	JOHN MORGAN CITIZENS FOR RESPONSIBILITY & ETHICS IN WASHINGTON	JEFFERIES & CO, QVT FINANCIAL, NEW YORK, NY, JAFFRAY OF MINNEAPOLIS, MN, ETC - HEDGE FUNDS, FINANCIAL FIRMS OR TRADERS TRANS, MINS, TELEPHONE CONVERSATIONS, ETC 1/10 TO PRESENT
2012-4179	06/13/2012 07/12/2012	FDA/OC/OES/DFOI/	ANNE L WEISMANN CITIZENS FOR RESPONSIBILITY & ETHICS IN WASHINGTON	FOIA REQUESTS 3/11 TO PRESENT
2012-4180	06/13/2012 07/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	ANNE SAVAS MAGSTIM COMPANY US LLC	NEURONETICS - K061053
2012-4181	06/13/2012 07/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	GREGORY H ARABIAN GREGORY H ARABIAN & ASSOC PC	ENDO GIA STAPLING DVC - RECS
2012-4182	06/13/2012 07/12/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TIM BOYD AIDS HEALTHCARE FOUNDATIONS	GILEAD SCIENCES INC - APPL FEES, PROD FEES, ESTABLISHMENT FEES 1/10 TO PRESENT

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2012-4183	06/13/2012 07/12/2012	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	TINA LIVESAY HEARTLAND LIONS EYE BANKS	HEARTLAND LIONS EYE BANKS, SPRINGFIELD, IL - EIRS 2010
2012-4184	06/13/2012 07/12/2012	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	JOHN WALSH JAMES ALEXANDER CORP	UNIVAR USA INC, STRONGSVILLE, OH - EIRS, 483S, RECALLS 6/09 TO PRESENT
2012-4185	06/13/2012 07/12/2012	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ OC/ORAOI/ OC/ORAOI/	ADRIANNA IWASINSKI KWTN NEWS 9	CHAD KERKSICK,, UNIV OF OKLAHOMA - INVESTIGATION
2012-4186	06/13/2012 07/12/2012	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	THOMAS A LUCAS	GIUSTO'S SPECIALTY FOODS, SOUTH SAN FRANCISCO, CA - SOY BREAD CONTAMINATION WARNING LTR, INSP SCHEDULE & RESULTS 1978
2012-4187	06/13/2012 07/12/2012	FDA/OFVM/CFSAN/OCD/EOS/	LIISA RAPELI-LIKTALO CHEMIGATE OY	WESTERN POLYMER CORP - CATIONIC STARCH FCN 964
2012-4188	06/13/2012 07/12/2012	OC/ORAOI/ OC/ORAOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	INDIVIDUAL RECS
2012-4189	06/13/2012 07/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	JENNIFER STAUNTON INSTRUMED INTERNATIONAL INC	DENTAL MEDICAL INSTRUMENT CASE & CASSETTE K962545
2012-4190	06/13/2012 07/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	JENNIFER STAUNTON INSTRUMED INTERNATIONAL INC	INSTRUMED VESSEL DILATORS K100518
2012-4191	06/13/2012 07/25/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	SAMANTHA GAN CSL RESEARCH AND DEVELOPMENT	H1N1 - RECS
2012-4192	06/13/2012 07/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	JENNIFER STAUNTON INSTRUMED INTERNATIONAL INC	ISTRUMED OBSTETRICAL FORCEPS K100517
2012-4193	06/13/2012 07/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	JENNIFER STAUNTON INSTRUMED INTERNATIONAL INC	INSTRUMED FORCEPS GYNAECOLOGICAL K092840
2012-4194	06/13/2012 07/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	JENNIFER STAUNTON INSTRUMED INTERNATIONAL	INSTRUMED VASCULAR CLAMPS K092544

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			INC	
2012-4195	06/13/2012 07/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	JENNIFER STAUNTON INSTRUMED INTERNATIONAL INC	INSTRUMED RETRACTORS K071771
2012-4196	06/13/2012 07/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	JENNIFER STAUNTON INSTRUMED INTERNATIONAL INC	INSTRUMED LAPAROSCOPES & ACCESSORIES K040855
2012-4197	06/13/2012 07/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	DAMON J WHITAKER BRYAN CAVE LLP	2010-2889 - UNREDACTED RECS
2012-4198	06/13/2012 07/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	BURGESS, CLAY	FRESENIUS USA - K991459, K922005 RECS, LBLG, PKG
2012-4199	06/13/2012 07/12/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SCHOENTHAL, FRANK	PRADAXA - AER
2012-4200	06/13/2012 07/12/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FRANK, RENEE	BARR LABS - JOLESSA AER
2012-4201	06/13/2012 07/12/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	ALELVIA - AER
2012-4202	06/13/2012 07/12/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CTP/OD/ OC/CVM/OCD/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/ OC/OCOS/OES/	WILLIAM BEJAN CAUSE OF ACTION	DOCS REFERRING TO EXPENDITURES OR DIRECT PYMTS MADE TO NON GVT ENTITIES FOR GIFT PURCHASE

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		OC/OCOS/OES/ OC/ORO/ OC/ORO/		
2012-4203	06/13/2012 07/12/2012	FDA/OC/OES/DFOI/ FDA/OGROP/ORO/ORO/DIOP/	ZHANG JI RUI AA USA TRADING INC	CASE 297037
2012-4204	06/13/2012 07/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	RAMONA KULIK STRYKER SUSTAINABILITY SOLUTIONS	VENOUS HEALTH SYS INC, SUNNYVALE, CA - VASCULAIRE COMPRESSION SYS K103113
2012-4205	06/13/2012 07/12/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	MONIKA BHATT HODGSON RUSS LLP	CARDINAL HEALTH INC - NICOLET CORTICAL STIMULATOR K072964; RADIONICS INC - OJEMANN CORTICAL STIMULATOR K924226; DELSYS INC - BAGNOLI 8 EMG SYS K990356
2012-4206	06/13/2012 07/12/2012	OC/CVM/OCD/	ELISABETH HOLMES CENTER FOR FOOD SAFETY	ETHOXYQUIN - AER
2012-4207	06/13/2012 07/12/2012	OC/CVM/OCD/	ELISABETH HOLMES CENTER FOR FOOD SAFETY	RPT 4/12 BY MARLA LUTHER PhD OF FDA REGARDING ANTIMICROBIALS
2012-4208	06/13/2012 07/12/2012	OC/ORO/ OC/ORO/	PAMELA PICIRILLO HOSPIRA INC	ENTRY NO WIG-2062122-1
2012-4209	06/13/2012 07/12/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	THERESA MARCHETTA KMGH-TV	NUMBER OF RX WRITTEN FOR FLUOROQUINOLONES
2012-4210	06/13/2012 07/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	KIM CHRISTIAN KMGH-TV	TELEFLEX MEDICAL RESPIRATORY INC - HUDSON RCI CONCHA COLUMN & CIRCUIT K993355
2012-4211	06/13/2012 07/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	ALLERGAN BREAST IMPLANTS
2012-4212	06/14/2012 07/13/2012	FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/	JOHNATHAN RICKMAN FDA NEWS	SOVEREIGN PHARMACEUTICALS LLC, FORT WORTH, TX; MILLAR INSTRUMENTS INC, HOUSTON, TX; JK PRODUCTS & SERVICES INC, JONESBORO, AR, ETC - 483S 2/1-29/12
2012-4213	06/14/2012 07/13/2012	FDA/OGROP/ORO/CE-FO/CIN-DO/CIN-CB/	JOHNATHAN RICKMAN FDA NEWS	TANGO3 LLC, SIMPSONVILLE, KY - 483 2/1-29/12
2012-4214	06/14/2012 07/13/2012	FDA/OGROP/ORO/CE-FO/CHI-DO/CHI-CB/	JOHNATHAN RICKMAN FDA NEWS	CYPRESS MEDICAL PRODUCTS LLC, ELWOOD, IL; COVIDIEN, CRYSTAL LAKE, IL; SYSMEX AMERICA INC, MUNDELEIN, IL, ETC - 483S 2/1-29/12
2012-4215	06/14/2012 07/13/2012	FDA/OGROP/ORO/CE-FO/BLT-DO/BLT-CB/	JOHNATHAN RICKMAN FDA NEWS	PETNET SOLUTIONS, CHARLOTTESVILLE, VA; MEDICAL SUPPLIES CORP, BALTIMORE, MD - 483S 2/1-29/12

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2012-4216	06/14/2012 07/13/2012	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	JOHNATHAN RICKMAN FDA NEWS	SHIONOGI INC, ALPHARETTA, GA; PETNET SOLUTIONS INC, DURHAM, NC; KALE RESEARCH & TECHNOLOGY, MOUNT PLEASANT, NC, ETC - 483S 2/1-29/12
2012-4217	06/14/2012 07/13/2012	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	JOHNATHAN RICKMAN FDA NEWS	JAMES G COLE INC (ASN/MAXAM NEUTRACEUTICS, HOOD RIVER, OR - 483S 3/1-31/12
2012-4218	06/14/2012 07/13/2012	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	JOHNATHAN RICKMAN FDA NEWS	ABBOTT PHARMACEUTICALS PR LTD, BARCELONETA, PR - 483S 3/1-31/12
2012-4219	06/14/2012 07/13/2012	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	JOHNATHAN RICKMAN FDA NEWS	FORCES OF NATURE INC, SONOMA, CA; IMPAX LABORATORIES INC, HAYWARD, CA; NIDEK INC, FREMONT, CA, ETC - 483S 3/1-31/12
2012-4220	06/14/2012 07/13/2012	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	JOHNATHAN RICKMAN FDA NEWS	DIGESTIVE CARE INC, BETHLEHEM, PA; ABBEY COLOR INC, PHILADELPHIA, PA; MEDISURG RESEARCH & MANAGEMENT CORP, NORRISTOWN, PA, ETC - 483S 3/1-31/12
2012-4221	06/14/2012 07/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARC RENDELL CREIGHTON DIABETES CENTER	GLARGINE, DETEMIR, DEGLUDEC ETC - CANCER RISK RECS
2012-4222	06/14/2012 07/13/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	JOHNATHAN RICKMAN FDA NEWS	INVAGEN PHARMACEUTICALS INC, HAUPPAUGE, NY; ALTAIRE PHARMACUETICALS INC, AQUEBOGUE, NY; ANSEN CORP, OGDENSBURG, NY, ETC - 483S 3/1-31/12
2012-4223	06/14/2012 07/13/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	JOHNATHAN RICKMAN FDA NEWS	GUARDIAN DRUG CO INC, DAYTON, NJ; DPT LAKEWOOD LLC, LAKEWOOD, NJ - 483S 3/1-31/12
2012-4224	06/14/2012 07/13/2012	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	JOHNATHAN RICKMAN FDA NEWS	TORBOT GROUP INC, CRANSTON, RI; CORREX INC, WALTHAM, MA; ATC TECHNOLOGIES INC, WILMINGTON, MA, ETC - 483S 3/1-31/12
2012-4225	06/14/2012 07/13/2012	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	JOHNATHAN RICKMAN FDA NEWS	ALTHEA LABORATORIES INC, MILWAUKEE, WI; FONTAROME CHEMICAL INC, ST FRANCIS, WI; SMT HEALTH SYSTEMS INC, DETROIT LAKES, MN, ETC - 483S 3/1-31/12
2012-4226	06/14/2012 07/13/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	JOHNATHAN RICKMAN FDA NEWS	HEALING WAYS, DESERT HOT SPRINGS, CA; BLUEFIELD ASSOCIATES INC, ONTARIO, CA; GINGI-PAK, CAMARILLO, CA, ETC - 483S 3/1-31/12
2012-4227	06/14/2012 07/13/2012	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	JOHNATHAN RICKMAN FDA NEWS	SIMMLER INC, HIGH RIDGE, MO; PERIO PROTECT LLC, ST LOUIS, MO - 483S 3/1-31/12
2012-4228	06/14/2012 07/13/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	JOHNATHAN RICKMAN FDA NEWS	CSL BEHRING, BERN, SWITZERLAND - 483S 2/1-29/12
2012-4229	06/14/2012 07/13/2012	OC/ORA/ORM/ OC/ORA/ORM/	SHRITEH, HAITHAM	US INFANT FORMULA FACTORIES - LIST OF CONTACTS, VIOLATIONS 2008 TO PRESENT,

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		OC/OM/OEO/ FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/ OC/ORA/ OC/ORA/		
2012-4230	06/14/2012 07/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/OCOS/OES/ OC/OCOS/OES/ FDA/OC/OCC/	DAVID LOHMAN SANESA PARTNERS	ELIZABETH H DICKINSON, ESQ, CHIEF COUNSEL - NEW DRUG APRVL APPLICATION MTG, 5/18/12 MINS, RECS ETC
2012-4231	06/14/2012 07/13/2012	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	JOHNATHAN RICKMAN FDA NEWS	QUADRANT CHEMICAL CORP, GARLAND TX; NEURO RESOURCE GROUP INC, PLANO, TX; ORTHOFIX INC, LEWISVILLE, TX, ETC - 483S, 1/1-31/12
2012-4232	06/14/2012 07/13/2012	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	JOHNATHAN RICKMAN FDA NEWS	FERRO CORP, SCOTTCARE CORP, CLEVELAND HEARTLAB INC CLEVELAND, OH, ETC - 483S, 1/1-31/12
2012-4233	06/14/2012 07/13/2012	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	JOHNATHAN RICKMAN FDA NEWS	H&H ASSOCIATES, ORDINARY, VA; CREATIVE TECHNOLOGIES INC, CHESAPEAKE, VA - 483S, 1/1-31/12
2012-4234	06/14/2012 07/13/2012	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	JOHNATHAN RICKMAN FDA NEWS	MONITOR INSTRUMENTS INC, HILLSBOROUGH, NC; UNISPLINT CORP, BUFORD, GA - 483S, 1/1-31/12
2012-4235	06/14/2012 07/13/2012	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	JOHNATHAN RICKMAN FDA NEWS	MELALEUCA INC, KNOXVILLE, TN; CROWN LABORATORIES INC (DBA DEL-RAY DERMATOLOGICALS), JOHNSON CITY, TN; NIDEK MEDICAL PORDUCTS INC, BIRMINGHAM, AL - 483S, 3/1-31/12
2012-4236	06/14/2012	FDA/OFVM/CFSAN/OCD/EOS/	ANEET PANESAR	CAS NO. 58-08-2, CAFFEINE NOT COMBINED WITH ALCOHOL - CAFFEINE NOT COMBINED WITH ALCOHOL -

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	07/13/2012		BURDOCK GROUP	REGULATORY STATUS, CONSUMPTION, SAFETY, ETC
2012-4237	06/14/2012 08/10/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	CHRISTINA CIAMPOLILLO CONWAY, HOMER ET AL	MERCK & CO INC - GARDASIL (HPV VACCINE) - VAERS
2012-4238	06/14/2012 07/13/2012	FDA/OFVM/CFSAN/OCD/EOS/	LEIANN LAIKS FUSION LAW GROUP	ALLURE COSMETICS, HAYWARD, CA - CAERS, CMLPLNTS, RESPS 1/1/12 TO 4/1/12
2012-4239	06/14/2012 07/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	LEIANN LAIKS FUSION LAW GROUP	DERMAQUEST INC, HAYWARD, CA - AERS, CMLPLNTS, RESPS, 1/1/12 TO 4/1/12
2012-4240	06/14/2012 07/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELIZABETH BARBEHENN PUBLIC CITIZEN	EXENATIDE - ISRS 7793203, 7793223, 782229 ETC
2012-4241	06/14/2012 07/13/2012	OC/CVM/OCD/	KRISTI O SMEDLEY WASHINGTON INFORMATION SOURCE	RICHMOND CHEMICAL CO - BIOENGINEERED YEAST-WITH GLUCOAMYLASE SUBMISSIONS, CORR, RESPS ETC
2012-4242	06/14/2012 07/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OC/OES/DFOI/	JEFFREY S KERR PETA FOUNDATION	PETA & INGRID NEWKIRK - RECS, RPTS, CORR ETC
2012-4243	06/14/2012 07/13/2012	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	PAUL B CALLAHAN CHARLES RIVER LABS	ISIC SERVICES LLC, SAN CARLOS, CA - EIR, 3-22-11 TO 4-7-11
2012-4244	06/15/2012 07/16/2012	OC/OM/OMP/DDM/	MERLE ZIMMERMANN AMERICAN HERBAL PRODUCTS ASSOCIATION	DKT FDA-1995-S-0039
2012-4245	06/15/2012	FDA/OC/OES/DFOI/	TISA TARRISON-SCHRAMP	FOI DAILY LOG 5/21-25/12

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	07/16/2012		CanReg, Inc.	
2012-4246	06/15/2012 07/16/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 5/21-25/12
2012-4247	06/15/2012 07/16/2012	FDA/OC/OES/DFOI/	WILLIAM A OLSON WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 5/21-25/12
2012-4248	06/15/2012 07/16/2012	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 5/21-25/12
2012-4249	06/15/2012 07/16/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 5/21-25/12
2012-4250	06/15/2012 07/16/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 5/21-25/12
2012-4251	06/15/2012 07/16/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 5/14-18/12
2012-4252	06/15/2012 07/16/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 5/14-18/12
2012-4253	06/15/2012 07/16/2012	FDA/OC/OES/DFOI/	WILLIAM A OLSON WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 5/14-18/12
2012-4254	06/15/2012 07/16/2012	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 5/14-18/12
2012-4255	06/15/2012 07/16/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 5/14-18/12
2012-4256	06/15/2012 07/16/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 5/14-5/18/12
2012-4257	06/15/2012 07/16/2012	FDA/OMPT/CDRH/OCER/DFOI/	JOHNATHAN RICKMAN FDA NEWS	MEDIAGNOST GMBH, REUTLINGEN, GERMANY; ITEM INDUSTRIES LTD, SHENZHEN, GUANGDONG, CHINA; COPAN ITALIA, BRESCIA, ITALY, ETC - 483S 1/1-31/12
2012-4258	06/15/2012 07/16/2012	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	JOHNATHAN RICKMAN FDA NEWS	HOSPIRA INC, MEPHERSON, KS; NOVARTIS CONSUMER HEALTH, LINCOLN, NE - 483S 1/1-31/12
2012-4259	06/15/2012 07/16/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	JOHNATHAN RICKMAN FDA NEWS	3M DRUG DELIVERY SYSTEMS, NORTHRIDGE, CA; LEE PHARMACEUTICALS INC, SOUTH EL MONTE, CA; NUTRI

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				GRANULATIONS, LA MIRADA, CA, ETC - 483S 1/1-31/12
2012-4260	06/15/2012 07/16/2012	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	JOHNATHAN RICKMAN FDA NEWS	ROCKLINE INUDSTRIES INC, SHEBOYGAN, WI; NATIONAL CREATIVE ENTERPRISE INC, BURNSVILLE, MN; AD-TECH MEDICAL INSTRUMENT CORP, RACINE, WI, ETC - 483S 1/1-31/12
2012-4261	06/15/2012 07/16/2012	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	JOHNATHAN RICKMAN FDA NEWS	SHIRE HUMAN GENETICS THERAPIES INC, CAMBRIDGE, MA; EXEMPLAR PHARMACEUTICALS LLC, FALL RIVER, MA; IMMUNEX RHODE ISLAND CORP, WEST GREENWICH, RI, ETC - 483S 1/1-31/12
2012-4262	06/15/2012 07/16/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	JOHNATHAN RICKMAN FDA NEWS	MYCONE DENTAL SUPPLY CO INC, CHERRY HILL, NJ; CASE MEDICAL, SOUTH HACKENSACK, NJ; GLAXOSMITHKLLINE CONSUMER HEALTHCARE LP, CLIFTON, NJ, ETC - 483S 1/1-31/112
2012-4263	06/15/2012 07/16/2012	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	JOHNATHAN RICKMAN FDA NEWS	AMCOL HEALTH & BEAUTY SOLUTIONS INC, LAFAYETTE, LA; TITERTEK INSTRUMENTS INC, HUNTSVILLE, AL; LEISURE PRODUCTS INC, KINGSPORT, TN, ETC 1/1-31/12
2012-4264	06/15/2012 07/16/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	JOHNATHAN RICKMAN FDA NEWS	INVAGEN PHARMACEUTICALS INC, HAUPPAUGE, NY; ARCH CHEMICALS, ROCHESTRER, NY; CONTRACT PHARMACAL CORP, HAUPPAGE, NY, ETC - 483S 1/1-31/12
2012-4265	06/15/2012 07/16/2012	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	JOHNATHAN RICKMAN FDA NEWS	BIO DATA CORP, HORSHAM, PA; ZOLL LIFECOR CORP, PITTSBURGH, PA; CUSTOM ULTRASONICS INC, IVYLAND, PA - 483S 1/1-31/12
2012-4266	06/15/2012 07/16/2012	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	JOHNATHAN RICKMAN FDA NEWS	LIBBY LABORATORIES INC, BERKELEY, CA; CELERA CORP, ALAMEDA, CA; CEPHEID, SUNNYVALE, CA, ETC - 483S 1/1-31/12
2012-4267	06/15/2012 07/16/2012	OC/ORACE/ORM/ OC/ORACE/ORM/	TONY CHEN FDAZILLA	483S ISSUED FROM 1/12 TO 6/12/12
2012-4268	06/15/2012 07/16/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PAUL B. CALLAHAN CHARLES RIVER LABS	EUROGENTEC SA, SERAING, BELGIUM - EIR 10/16-28/11
2012-4269	06/15/2012 07/16/2012	OC/ORACE/ORM/ OC/ORACE/ORM/	GAIL LESSICK LACHMAN CONSULTANT SERVICES INC	DOMESTIC & FOREIGN INSP 4/1-30/12
2012-4270	06/15/2012 07/16/2012	FDA/OFVM/CFSAN/OCD/EOS/	IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 150166, 150606
2012-4271	06/15/2012 07/16/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	BARRETT W. STETSON LAW FIRM OF BARRETT W	INDIVIDUAL RECS

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		FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	STETSON	
2012-4272	06/15/2012 08/08/2012	FDA/OMPT/CDRH/OCER/DFOI/	AMIR PELED ALPHA BIO TEC LTD	BIOMATERIALS COMPANIES THAT PRODUCE DENTAL PRODUCTS APRVD BY FDA
2012-4273	06/15/2012 07/16/2012	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	JOHNATHAN RICKMAN FDA NEWS	MEDOP INC, OLDSMAR, FL; CERAGROUP INDUSTRIES INC, FORT LAUDERDALE, FL; CHAMCO INC, COCOA, FL - 483 1/1-31/12
2012-4274	06/15/2012 07/16/2012	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	JOHNATHAN RICKMAN FDA NEWS	APPLIED LABS INC, COLUMBUS, IN; ROYAL OAK MEDICAL DEVICES LLC, OXFORD, MI; ACUMEDIA MANUFACTURERS INC, LANSING, MI - 483 1/1-31/12
2012-4275	06/15/2012 07/16/2012	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	JOHNATHAN RICKMAN FDA NEWS	AMGEN INC, LONGMONT, CO; AMGEN INC, BOULDER, CO; FMC CORP, GREEN RIVER, WY - 483 1/1-31/12
2012-4276	06/15/2012 07/16/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHNATHAN RICKMAN FDA NEWS	ESTEVE HUAYI PHARMACEUTICAL CO LTD, SHAOXING, CHINA; SANDOZ PRIVATE LTD, NAVI MUMBAI, INDIA; SA AJINOMOTO OMNICHEN NV, LOUVAIN LA NEUVE, BELGIUM - 483 1/1-31/12
2012-4277	06/15/2012 07/16/2012	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	JOHNATHAN RICKMAN FDA NEWS	SAGEMAX BIOCERAMICS INC, AUBURN, WA - 483 1/1-31/12
2012-4278	06/15/2012 07/16/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PAMELA SHEPPARD TARO PHARMACEUTICALS USA INC	ALLERGAN - TAZAROTENE (TAZORAC) MEDICAL RVW, CHEMISTRY RVW, LBLG
2012-4279	06/15/2012 07/16/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PAMELA SHEPPARD TARO PHARMACEUTICALS USA INC	ALLERGAN - TAZAROTENE (TAZORAC) MEDICAL RVW, CHEMISTRY RVW, LBLG
2012-4280	06/15/2012 07/16/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PAMELA SHEPPARD TARO PHARMACEUTICALS USA INC	ALLERGAN - TAZAROTENE (TAZORAC) MEDICAL RVW, CHEMISTRY RVW, LBLG
2012-4281	06/18/2012 07/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	Bret Andre EyeReg Consulting Inc.	K050157
2012-4282	06/18/2012 07/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	Noe M. Rivera Covidien- Product Monitorig	MW5024199, MW5024200
2012-4283	06/18/2012	FDA/OO/OFBA/OAGS/	Veronica Jenkins	FDA-SOL-12-1104293

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	07/17/2012		Healthy And Happy America (HAHA) Corpora	
2012-4284	06/18/2012 07/17/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ogden & Sullivan, P.A.	Equetro - AERs; Influenza Vaccines and Stephens Johnson Syndrome - AERs
2012-4285	06/18/2012 07/17/2012	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Leigh Turner Leigh Turner	Celltex Therapeutics - 483 (04/01/2011 - 06/13/2012)
2012-4286	06/18/2012 07/17/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Erich J Weidenbener, MD Erich J. Weidenbener, MD	InVivo Therapeutics - Meeting Minutes, etc.
2012-4287	06/18/2012 07/17/2012	FDA/OFVM/CFSAN/OCD/EOS/	Richard Hudson Baerlocher USA LLC	FCN 204
2012-4288	06/18/2012 07/27/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OGROP/ORASW-FO/CHI-DO/CHI-CB/	MYER Services d/b/a MSI Detective Servis	Dr. Alan Buchman, Chicago, IL - Reports
2012-4289	06/18/2012 07/17/2012	FDA/OFVM/CFSAN/OCD/EOS/	Richard M. Niles MARSHALL UNIVERSITY	FAP4A4754
2012-4290	06/18/2012 07/17/2012	OC/ORASW-FO/CHI-DO/CHI-CB/	Doe J	Investigatory Records
2012-4291	06/18/2012 07/17/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Francis Ginah GILEAD SCIENCES INC	LETAIRIS (ambrisentan) - Approval letter (certified)
2012-4292	06/18/2012 07/17/2012	FDA/OGROP/ORASW-FO/LOS-DO/LOS-CB/	Jonathan Siegel Kingdon Capital Management	McGuff Pharmaceuticals, Inc., Santa Ana, CA - 483s, EIRs, Pre-approval inspections (08/01/2011 - 06/15/2012)
2012-4293	06/18/2012 07/17/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	Remicade (infliximab) - BLA 103772 S 5129
2012-4294	06/18/2012 07/17/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JEFFERIES & CO	Coricotropin (ANDA 088772)- Labeling, etc.

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2012-4295	06/18/2012 07/17/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 6/4-8/2012
2012-4296	06/18/2012 07/17/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 6/11-15/2012
2012-4297	06/18/2012 07/17/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	dinicola, victor j	Cellcept - AERs
2012-4298	06/18/2012 07/17/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dr. Johan Haggblad Pharmalink AB	NDA 20-954 (Busulfex) - Toxicology Study
2012-4299	06/18/2012 07/17/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy or list of all approved products that went through the 505 b2 application process from 2005 to the present.
2012-4300	06/18/2012 07/17/2012	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	Jeanne Hathaway Jeanne Hathaway	Burt's Bees - 483 (2012)
2012-4301	06/18/2012 07/17/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/ FDA/OC/OES/DFOI/ FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	Leslie S. Harris, Paralegal Campiche Blue Arnold PLLC	Trident Hemispherical Acebutular Shell 54 MM E - Corr, Warnings, Recalls, etc.
2012-4302	06/18/2012 07/17/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-987
2012-4303	06/18/2012 07/17/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-2213
2012-4304	06/18/2012 07/17/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-1269
2012-4305	06/18/2012 07/17/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-3263

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2012-4306	06/18/2012 07/17/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-3502
2012-4307	06/18/2012 07/17/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-3063
2012-4308	06/18/2012 07/17/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-9353
2012-4309	06/18/2012 07/17/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-2674
2012-4310	06/18/2012 07/17/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-2670
2012-4311	06/18/2012 07/17/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-3630
2012-4312	06/18/2012 07/17/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-968
2012-4313	06/18/2012 07/17/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-3217
2012-4314	06/18/2012 07/17/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-2813
2012-4315	06/18/2012 07/17/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-733
2012-4316	06/18/2012 07/17/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-2986
2012-4317	06/18/2012 07/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CAPSUGEL	C.I. Farmacapsulas S.A. - Response to WL issued 5/15/12
2012-4318	06/18/2012 08/16/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Joe Landolina Joseph Landolina	K112215, K010933, K072681 etc.
2012-4319	06/18/2012 07/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OCC/	LISA HANSEN AM LEGAL SERVICES INC	KV PHARMS MTG 5/18/12 - RECS

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2012-4320	06/18/2012 07/17/2012	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OFVM/CFSAN/OCD/EOS/	SEAN HIGGINS ESQ ANDREWS & THORNTON	EXCLUSIVE SUPPLEMENTS INC, FAHRENHEIT NUTRITION, MUSCLE WARFARE INC, ETC - RESP TO DMAA WARNING LTR 2/24/12
2012-4321	06/18/2012 07/17/2012	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	DAVID LOHMAN SANESA PARTNERS	EXEMPLAR PHARMS, FALL RIVER, MA - 483S, WARNING LTRS. UNTITLED LTRS, ETC 1/11 TO PRESENT
2012-4322	06/18/2012 07/17/2012	OC/CVM/OCD/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JIM FAUCETT NORTHWEST CLINICAL RESEARCH CTR	KETASET VERTIRNARY FORMULATIONS NADA 043-304, VETALAR NADA 045-290,; KETALAR FOR HUMANS NDA 16-812, ETC - SUMMARY RPTS
2012-4323	06/18/2012 07/17/2012	OC/ORARM/ OC/ORARM/	JOHNATHAN RICKMAN FDA NEWS	PHARMACEUTICAL, BIOLOGICS, MEDICAL DVC MFRS, ETC IN & OUTSIDE THE US - 483S 5/1-31/12
2012-4324	06/18/2012 07/17/2012	OC/ORARM/ OC/ORARM/	JOHNATHAN RICKMAN FDA NEWS	PHARMACEUTICAL, BIOLOGICS, MEDICAL DVC MFRS, ETC IN & OUTSIDE THE US - 483S 4/1-30/12
2012-4325	06/18/2012 07/17/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 5/28/12-6/1/12
2012-4326	06/18/2012 07/17/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	BRENDA M GARTZ ELI LILLY & CO	BACHEM INC, TORRANCE, CA - EIR 6/1411
2012-4327	06/18/2012 07/17/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FRATTI, JOHN	DR KAREN WEISS, JOHNSON & JOHNSON - EMAILS, LTRS, CONFLICT OF INTEREST STATEMENTS, ETC
2012-4328	06/18/2012 07/17/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 6/4-8/12
2012-4329	06/18/2012 07/17/2012	FDA/OFVM/CFSAN/OCD/EOS/	ALVIN J LORMAN ALVIN J LORMAN LAW OFC	2,2-DIMETHYLOLPROPIOIC ACID - FCN 1061
2012-4330	06/18/2012 07/17/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 6/4-8/12

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2012-4331	06/18/2012 07/17/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	CLOSED FOIA REQUESTS 6/4-8/12
2012-4332	06/18/2012 07/17/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 6/4-8/12
2012-4333	06/18/2012 07/17/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 6/4-8/12
2012-4334	06/18/2012 08/08/2012	FDA/OFVM/CFSAN/OCD/EOS/	ALVIN J LORMAN ALVIN J LORMAN LAW OFC	ACRYLIC RESINS - FCN 1130
2012-4335	06/18/2012 07/17/2012	FDA/OFVM/CFSAN/OCD/EOS/	ALVIN J LORMAN ALVIN J LORMAN LAW OFC	ISOPHORONE DISOCYANATE - FCN 1060
2012-4336	06/18/2012 07/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	UCB INC - NEUPRO (ROTIGOTINE) NDA 21-829/S2 APRVL RECS
2012-4337	06/18/2012 09/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	ANDON MEDICAL CO - AG-608N SINGLE & MULTI BLOOD GLUCOSE MONITORING SYS K110017
2012-4338	06/18/2012 07/17/2012	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	Yale New Haven Hospital	Individual Records
2012-4339	06/18/2012 07/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	ACON LABORATORIES INC - ON CALL VIVID BLOOD GLUCOSE MONITORING SYS K112653
2012-4340	06/18/2012 07/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	BIONIME CORP - RIGHTEST BLOOD GLUCOSE MONITORING SYS GM700 K110737
2012-4341	06/18/2012 07/17/2012	FDA/OC/OES/DFOI/	Lisa Erwin OFFICE OF THE ATTORNEY GENERAL	Date Range: 07/01/2011 - 09/30/2011; All records, especially transcripts and notes, from and pertaining to the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee Meeting that took place on September 8-9, 2011. See: https://www.federalregister.gov/articles/2011/07/14/2011-17695/obstetrics-and-gynecology-devices-panel-of-the-medical-devices-advisory-committee-notice-of-meeting ;
2012-4342	06/18/2012 07/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	DAVID CHOTENOVSKY CRH MEDICAL CORP	HEMORROHOID LIGATOR K963166 - CLNCL RECS
2012-4343	06/18/2012	FDA/OMPT/CDRH/OCER/DFOI/	BETH HAMLETT	FREUND MEDICAL PRODUCTS, DAYTON, OH - K863427

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	07/17/2012		ADVANCED VASCULAR DYNAMICS	
2012-4344	06/18/2012 07/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RITU BARAL CANACCORDGENUITY	NISSHIN PHARMA PRODUCTION PLANT, JAPAN - 483S 2/12
2012-4345	06/18/2012 07/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CANCICE DURRENCE OPTIMER PHARMACEUTICALS INC	OPTIMER PHARMACEUTICALS INC - DIFICID (FIDAXOMICIN) TABS NDA 20-1699 ISRS 7985701
2012-4346	06/18/2012 07/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RICHARD O WOOD WOOD BURDITT GROUP	CDER ROUTINE PRIORITY INSP & SPL REQUEST, TOPICAL ANTISEPTIC SKIN PREPERATION PROD MFG
2012-4347	06/18/2012 07/17/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	BRAD SCHONHOFT	GRIFOL, LOS ANGELES, CA, CLAYTON, NC, MELVILLE, NY - EIRS, 483S 1/11 TO PRESENT
2012-4348	06/18/2012 07/17/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	GENEVIEVE P RUPELLL CSK	GENENTECH INC, CA - 483S 3/1/07, 9/21/07, 10/29/07, ETC
2012-4349	06/18/2012 07/17/2012	FDA/OFVM/CFSAN/OCD/EOS/	ROBIN FELDMAN LSRO SOLUTIONS	ATLAS POWDER CO - POLYSORBATE 60 (POLYOXYETHYLENE 20 SORBITAN MONOSTEARATE) FAP OAO029
2012-4350	06/18/2012 07/17/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OCC/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	NORTH RUN CAPITAL LP	Abiomed Inc. Impella - Internal FDA emails
2012-4351	06/18/2012 07/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	TIANJIN EMPECS MEDICAL DEVICE CO - MEDISIGN BLOOD GLUCOSE MONITORING SYS, MEDISIGN MULTI BLOOD GLUCOSE MONITORING SYS K111456
2012-4352	06/18/2012	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	BRENDA M GARTZ	JHP PHARMS, ROCHESTER, MI - EIRS 6/8/11

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	07/17/2012		ELI LILLY & CO	
2012-4353	06/18/2012 07/17/2012	OC/OA/OM/OMP/DDM/	MAHMOUD AYESH Zx Pharma, LLC	DKT 1995S-0039
2012-4354	06/18/2012 07/17/2012	OC/OA/OM/OMP/DDM/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JENNIFER HSIEH	DRUG APRVLS & CLNCL TRIALS MTG - TRANS 5/22/12
2012-4355	06/18/2012 07/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	TAIDEC TECHNOLOGY CORP - FORA DIAMOND PRIMA & MINI BLOOD GLUCOSE MONITORING SYS K111890
2012-4356	06/18/2012 07/17/2012	OC/ORO/ OC/ORO/ OC/ORO/ORM/ OC/ORO/ORM/	JENNIFER HSIEH	483S 5/1/12-6/13/12
2012-4357	06/18/2012 07/17/2012	FDA/OGROP/ORO/NE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	BRAD SCHONHOFT BALYASNY ASSET MANAGEMENT	ALERE INC, WALTHAM, MA; SCARBOROUGH, MA; SAN DIEGO, CA - EIRS, 483S 1/12 TO PRESENT
2012-4358	06/18/2012 07/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORO/CE-FO/PHI-DO/PHI-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	BRAD SCHONHOFT BALYASNY ASSET MANAGEMENT	VIROPHARMA, EXTON, PA; SANQUIN, AMSTERDAM & BRUSSELS/BELGIUM - EIRS 1/1/11 TO 6/11/12
2012-4359	06/18/2012 07/17/2012	FDA/OC/OES/DFOI/	INC RESEARCH CONSULTING & SUBMISSIONS	FOI DAILY LOG 5/21-25/12
2012-4360	06/18/2012 07/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	BESTGEN BIOTECH CORP - BLOOD GLUCOSE MONITORING SYS MAJOR GLUCOSE SOLUTION K103230
2012-4361	06/18/2012 07/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	BAYER HEALTHCARE - CONTOUR NEXT BLOOD GLUCOSE MONITORING SYS K111268
2012-4362	06/18/2012 07/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	FADASIS MEDICAL INC - MEDICAL FM1 NO BLENDER K003665

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2012-4363	06/18/2012 07/17/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 5/21-25/12
2012-4364	06/18/2012 07/17/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 5/14-18/12
2012-4365	06/18/2012 07/17/2012	FDA/OC/OES/DFOI/	INC RESEARCH CONSULTING & SUBMISSIONS	FOI DAILY LOG 5/14-18/12
2012-4366	06/18/2012 07/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	INO THERAPEUTICS - INOBLENDER MODEL 10004 K052663
2012-4367	06/18/2012 07/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	RD SHANUE POLY MEDICURE LTD	B BRAUN, MELSUNGEN, GERMANY - EIRS 2005 TO PRESENT
2012-4368	06/18/2012 07/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	WL GORE - BIO A FISTULA PLUG K083266
2012-4369	06/18/2012 07/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	RD SHANUE POLY MEDICURE LTD	BECTON DICKINSON INFUSION THERAPY AB, HELSINGBORG, SWEDEN - EIRS 2005 TO PRESENT
2012-4370	06/18/2012 07/17/2012	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OC/OES/DFOI/	RD SHANUE POLY MEDICURE LTD	B BRAUN MEDICAL INC, ALLENTOWN, PA - EIRS, 2005 TO PRESENT
2012-4371	06/18/2012 07/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	WL GORE - BIOABSORBABLE MESH K033671
2012-4372	06/18/2012 07/17/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	FOI Services, Inc.	WHITMAN MEDICAL CORP - SAFE T VUE IRREVERSIBLE TEMPERATURE INDICATOR BK910005
2012-4373	06/18/2012 07/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SUZIE KESCHAMRUS AVANIR PHARMACEUTICALS INC	NUJEXETA (DEXTROMETHORPHAN HYDROBROMIDE 20 MG/QUINIDINE SULFATE 10MG) NDA 22-879 - AERS 10/29/10 TO PRESENT
2012-4374	06/18/2012 07/17/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	FOI Services, Inc.	LIQUID CRYSTAL PRODUCTS INC - HEMO TEMP II BLOOD TEMPERATURE INDICATOR BK830006
2012-4375	06/18/2012 07/17/2012	OC/ORA/ OC/ORA/ FDA/OGROP/ORACE-FO/MIN-	STANFIELD, BARBARA	OCEAN SPRAY CO - CMPLNT 126418 RESULTS

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		DO/MIN-CB/		
2012-4376	06/18/2012 07/17/2012	FDA/OMPT/CTP/OD/	FOI Services, Inc.	REYNOLDS AMERICAN INC - ECLIPSE CORR, RECS ETC
2012-4377	06/18/2012 07/19/2012	OC/OCOS/OES/ OC/OCOS/OES/ FDA/OFVM/CFSAN/OCD/EOS/ OC/OCS/NCTR/OD/	FOI Services, Inc.	CORR FROM JESSE GOODMAN REGARDING BISPHENOL A
2012-4378	06/18/2012 07/17/2012	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	FOI Services, Inc.	DR MARTIN H KOLLEF, WASHINGTON UNIV SCHOOL OF MEDICINE, ST LOUIS, MO - EIRS, WARNING LTR, CO RESP ETC 8/7/-15/07
2012-4379	06/18/2012 07/17/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-3835 REQUEST LETTER
2012-4380	06/18/2012 07/17/2012	FDA/OC/OES/DFOI/	Jason Cherkis The Huffington Post	LegitScript - emails, etc. Jan. 2009-present
2012-4381	06/18/2012 07/17/2012	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	BRENDA M. GARTZ ELI LILLY & CO	LYNE LABS, BROCKTON, MA - 483 2/26/09, 3/25/11
2012-4382	06/18/2012 07/17/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-3770 REQUEST LETTER
2012-4383	06/18/2012 07/17/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-3840 REQUEST LETTER
2012-4384	06/18/2012 07/17/2012	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Capasso, Maria Capasso, Maria	FDA 483 issued to Edward J. Kosinski, MD 01/01/1980 - 12/31/1988
2012-4385	06/18/2012 07/17/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OES/DFOI/ OC/ORA/ORM/ OC/ORA/ORM/ OC/ORA/ORM/ OC/ORA/ORM/ OC/ORA/OE/ OC/ORA/OE/	Raisa Bruner ABC NEWS	Food Product Imported From China - Inspections (06/01/2007 - 06/18/2012)
2012-4386	06/18/2012 07/17/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/ OC/ORA/ OC/ORA/	Raisa Bruner ABC NEWS	Chicken Jerky Dog Treats - complaints, test results, etc. (06/01/2011 - 06/18/2012)

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2012-4387	06/18/2012 07/17/2012	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/ FDA/OGROP/ORASE-FO/ATLDO/ATL-CB/	BRAD SCHONHOFT BALYASNY ASSET MANAGEMENT	HOSPIRA INC, ROCKY MOUNT, NC - EIR 7/25-8/4/11
2012-4388	06/18/2012 07/17/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDRH/OCER/DFOI/	Brian Barber Willson International Inc.	Willson International Inc. - List of Companies using as Agent for BT and Devices
2012-4389	06/18/2012 07/17/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jonathan Siegel Kindgon Capital Management	Nisshin Pharma Inc., Nagano Japan - 483s, EIRs (12/31/2011 - 06/12/2012)
2012-4390	06/18/2012 07/17/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	heil, john w heil, john w	Rubella vaccine contents of 1970; corticosteroid (hexadrol)
2012-4391	06/18/2012 07/17/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rocco Bravoco Devon Medical Products	K024117, K033602, K061784, K120373
2012-4392	06/18/2012 07/17/2012	FDA/OGROP/ORASE-FO/ATLDO/ATL-CB/	NORBERT GOTTESMAN AVET CAPITAL MANAGEMENT LLC	SALIX PHARMS LTD, RALEIGH, NC - 483, EIR
2012-4393	06/18/2012 07/17/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORASW-FO/DENDO/DEN-CB/	Carla Tolbert Schremof, Kelly, Napp & Darr, Ltd	Shiley Tracheostomy Tubes - Recall records, MAUDE reports (01/01/2010 - 06/17/2010)
2012-4394	06/18/2012 07/17/2012	FDA/OMPT/CTP/OD/	FOI Services, Inc.	CENTER FOR TOBACCO PRODUCT SITE TOUR PROGRAM - SUMMARIES 7/1/11 TO 3/16/12
2012-4395	06/18/2012 10/10/2012	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/ FDA/OGROP/ORANE-FO/NYKDO/NYK-DCB/ FDA/OGROP/ORAPA-FO/LOSDO/LOS-CB/ FDA/OGROP/ORASE-FO/ATLDO/ATL-CB/ FDA/OGROP/ORASW-FO/DALDO/DAL-CB/	NORBERT GOTTESMAN AVET CAPITAL MANAGEMENT LLC	HOSPIRA, INC - AUSTIN, TX; BUFFALO, NY; BOULDER, CO - 483, EIR

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		FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/		
2012-4396	06/18/2012 07/17/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ben Joseph Rice, Voelker LLC	Acthar Gel - AERS
2012-4397	06/18/2012 07/17/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	bernie murphy BURGESS, BERNIE	CDER, DSI: bioresearch monitoring complaint No. 1639
2012-4398	06/18/2012 07/17/2012	OC/CVM/OCD/ FDA/OFVM/CFSSAN/OCD/EOS/	Richard M Niles MARSHALL UNIVERSITY	CAP7C0283
2012-4399	06/18/2012 07/17/2012	FDA/OC/OES/DFOI/	NATIONAL INSTITUTES OF HEALTH	Date Range: 01/01/2007 - 12/31/2011; Post-Donation Fatality Reports by Donated Product, FY2007 through FY2011 Additional information about the fatality cases: 17 in 2007, 10 in 2008, 6 in 2009, 5 in 2010 and 10 in 2011, as well as the total number of donations by donated product type, each year, namely the denominator data for each product type each year.;
2012-4400	06/18/2012 07/17/2012	FDA/OGROP/ORASW-FO/ATL-DO/ATL-CB/	Marissa Sullivan Olympus Biotech Corporation	Fuji Diosynth Biotechnologies, N.C. - EIR, 06/01/1990 - 06/14/2012
2012-4401	06/18/2012 07/17/2012	FDA/OGROP/ORASW-FO/PHI-DO/PHI-CB/	NORBERT GOTTESMAN AVET CAPITAL MANAGEMENT LLC	VIRO PHARMA INC, EXTON, PA - 483, EIR
2012-4402	06/18/2012 07/17/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	Propofol (Diprivan) - AERs (01/01/2010 - 06/14/2012)
2012-4403	06/18/2012 07/17/2012	OC/OCS/OCP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	List of combination products in 505 b2 application process (01/01/2005 - 06/14/2012)
2012-4404	06/18/2012 07/17/2012	FDA/OGROP/ORASW-FO/LOS-DO/LOS-CB/	NORBERT GOTTESMAN AVET CAPITAL MANAGEMENT	QUESTCOR PHARMS, ANAHEIM, CA - 483, EIR

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			LLC	
2012-4405	06/18/2012 07/17/2012	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Christos Yatrakis Patterson Belknap Webb & Tyler LLP	OneTouch Ultra - Import Records (05/01/2011 - 06/01/2012); H&H Wholesale Services Inc., Troy, MI - 483, WL
2012-4406	06/18/2012 07/17/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	NORBERT GOTTESMAN AVET CAPITAL MANAGEMENT LLC	HI TECH PHARMACAL CO, AMITYVILLE, NY - 483, EIR
2012-4407	06/18/2012 07/17/2012	OC/OA/OM/OMP/DDM/	Yi Zhang	Docket No. 96P-0459/CP1, PSA1, CP2, PSA2
2012-4408	06/18/2012 07/17/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Richard Shea Norgenix LLC	K843699, K981207 K945427, etc.
2012-4409	06/18/2012 08/03/2012	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	NORBERT GOTTESMAN AVET CAPITAL MANAGEMENT LLC	JAZZ PHARMS INC, PALO ALTO, CA; PHILADELPHIA, PA - EIR, 483
2012-4410	06/18/2012 07/17/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-3855 REQUEST LETTER
2012-4411	06/18/2012 07/17/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-3719 REQUEST LETTER
2012-4412	06/18/2012 07/17/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-3703 REQUEST LETTER
2012-4413	06/18/2012 07/17/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-3690 REQUEST LETTER
2012-4414	06/18/2012 07/17/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-3677 REQUEST LETTER
2012-4415	06/18/2012 07/17/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-3672 REQUEST LETTER
2012-4416	06/18/2012 07/17/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-3639 REQUEST LETTER
2012-4417	06/18/2012 07/17/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-3608 REQUEST LETTER
2012-4418	06/18/2012 07/17/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-3482 REQUEST LETTER
2012-4419	06/18/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2012-3886 REQUEST LETTER

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	07/17/2012		MERCK & CO., INC.	
2012-4420	06/18/2012 07/17/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-3889 REQUEST LETTER
2012-4421	06/18/2012 07/17/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-3407 REQUEST LETTER
2012-4422	06/18/2012 07/17/2012	FDA/OMPT/CTP/OD/	FOI Services, Inc.	TOBACCO PRODUCTS MFR SUBSTANTIAL EQUIVALENCE ORDERS - 4/1/12 TO PRESENT; COMM, RECS
2012-4423	06/18/2012 07/17/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-3392 REQUEST LETTER
2012-4424	06/18/2012 07/17/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-3288 REQUEST LETTER
2012-4425	06/18/2012 07/17/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-3284 REQUEST LETTER
2012-4426	06/18/2012 07/17/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-3230 REQUEST LETTER
2012-4427	06/18/2012 08/31/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FOI Services, Inc.	CLARIS LIFESCIENCES, NORTH BRUNSWICK, NJ - EIRS, 483S, CO RESPS ETC 7/1-13/09, 1/22/10-2/2/10
2012-4428	06/18/2012 08/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	BAYER HEALTHCARE - CONTOUR NEXT LINK WIRELESS BLOOD GLUCOSE METER, K110894
2012-4429	06/18/2012 07/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	ROCHE DIAGNOSTICS - ACCU-CHEK AVIVA PLUS ABLOOD GOUCOSE MONITORING SYS, K101299
2012-4430	06/18/2012 07/17/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOSEPY KUDLA PROTEA BIOSCIENCES EUROPE	CHARLES RIVER LABS, ERKATH, GERMANY - EIRS. 483S, CO RESP 9/21-23/11
2012-4431	06/18/2012 07/17/2012	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	JONATHAN AYERS STANDARD INSURANCE CO	COX SEAFOOD TARPON SPRINGS INC, TARPON SPRINGS, FL - EIRS, 483S, CO RESP, 1/1/92 TO PRESENT
2012-4432	06/18/2012 07/17/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/GRP/DIDP/	LESTER GIBBS ACTELION CLINICAL RESEARCH INC	AVASTIN (BEVAQL-UMAB), BL 125085/169 - SUMMARY

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2012-4433	06/18/2012 07/17/2012	OC/CVM/OCD/ FDA/OC/OES/DFOI/	ELISABETH HOLMES CENTER FOR FOOD SAFETY	DISTILLERS GRAINS -SUMMARY RPT 4/12; NATIONWIDE SURVEY OF DISTILLERS PRODS FOR ANTIBIOTIC RESIDUES FY2010
2012-4434	06/18/2012 07/17/2012	FDA/OO/OFBA/OAGS/	JASON CHERKIS HUFFINGTON POST	COMM BETWEEN GLENN WATSON & JONH HORTON
2012-4435	06/18/2012 07/17/2012	OC/OA/OM/OMP/DDM/	JOHNNY ZHANG DECHERT LLP	DKT #96P-0459/CPI, PSAI, CP2, PSA2
2012-4436	06/18/2012 07/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SHERRY L. ROLLO HUSCH BLACKWELL LLP	MYLAN PHARMS INC - OLMESARTAN MEDOXOMIL NDA 78-276 TENTATIVE APRVL LTR 3/8/08
2012-4437	06/18/2012 07/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	Brown, Sanders E	REMOTE NEURAL MONITORING SYS - RECS
2012-4438	06/18/2012 07/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	ACIPHEX - AERS
2012-4439	06/19/2012 07/18/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	BURGESS, BERNIE	2007-3879
2012-4440	06/19/2012 08/16/2012	FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/	TONY JIMENEZ MED-LEGAL LLC	AIR LIQUIDE AMERICA, RICHMOND, CA - RECS 1/10 TO PRESENT
2012-4441	06/19/2012 07/18/2012	FDA/OMPT/CDRH/OCER/DFOI/	ANDREW CAUSON UNIV OF SOUTHAMPTON	COCHLEAR IMPLANTS - NUMBER OF SUCCESSFUL SURGERIES 2000 TO PRESENT
2012-4442	06/19/2012 07/18/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 5/28/12-6/1/12
2012-4443	06/19/2012 07/18/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 6/4-8/12
2012-4444	06/19/2012	FDA/OC/OES/DFOI/		FOI DAILY LOG 6/4-8/12

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	07/18/2012		INC RESEARCH CONSULTING & SUBMISSIONS	
2012-4445	06/19/2012 07/18/2012	FDA/OC/OES/DFOI/	INC RESEARCH CONSULTING & SUBMISSIONS	FOI DAILY LOG 5/28/12-6/1/12
2012-4446	06/19/2012 07/18/2012	FDA/OFVM/CFSAN/OCD/EOS/	JOHN DOHERTY IOVATE HEALTH SCIENCES INTERNATIONAL INC	IOVATE- JACKED OR JACK3D OR JACK 3D; OXY ELITE PRO OR OXYELITE PROOR OXY-ELITE PRO; 1-MR OR 1 MR OR 1.M.R., ETC CAERS
2012-4447	06/19/2012 07/18/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	GENENTECH - RITUXAN (RITUXIMAB) BLA 10-3705/S5344 APRVL RECS
2012-4448	06/19/2012 07/18/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	CLARIS LIFESCIENCES, CHACHARWADI-VASANA, INDIA - EIRS, 483S CO RESP 6/5-16/10
2012-4449	06/19/2012 07/18/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OO/OIM/OPILS/DFOI/ FDA/OO/OIM/OPILS/DFOI/ FDA/OC/OES/DFOI/ FDA/OO/OIM/OPILS/DFOI/ FDA/OO/OIM/OPILS/DFOI/	ALLISON CHEN HARVEST CONSULTING CORP	Z-SYSTEM AG - Z-LOOK3 DENTAL IMPLANT SYS K062542
2012-4450	06/19/2012 07/18/2012	FDA/OMPT/CDRH/OCER/DFOI/	ARTHUR J WARD AJW TECHNOLOGY CONSULTANTS INC	KING DENTAL CORP, NEW STETIC, MEDELLIN, COLOMBIA - K931162
2012-4451	06/19/2012 07/18/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SHIPMAN, KIM	ISRS 3852728, 3977721
2012-4452	06/19/2012 07/18/2012	FDA/OGROP/ORAP/PA-FO/SEA-DO/SEA-CB/	PAUL W TRIPP LINCARE INC	RESPIRATORY CONNECTIONS INC, WA - EIRS, 483S, WARNING LTRS 1/05 TO PRESENT
2012-4453	06/19/2012 07/18/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KELSEY M LARSON O'MELVENY & MYERS LLP	AMYLIN PHARMACEUTICALS INC - BYETTA LBLG, APRVL RECS AERS, ETC

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		FDA/OMPT/CDER/ORP/DIDP/		
2012-4454	06/19/2012 07/19/2012	FDA/OC/OES/DFOI/	BRIAN DILKS DILKS & KNOPIK LLC	LIMITED PAYABILITY CANCELLATION RPTS FOR REFUNDS & CREDITS FOR UNDELIVERABLE CHECKS FOR DHHS 1/1/10 TO 1/1/12
2012-4455	06/19/2012 07/18/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/	DRAGUICH BALARIN PRODUMAR SAC	MAHI MAHI - LAB RESULTS
2012-4456	06/19/2012 07/18/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN F THOMPSON ROBINSON & THOMPSON	DILITAZEM, MYOCARDIAL INFARCTION - AERS
2012-4457	06/19/2012 07/18/2012	FDA/OMPT/CDRH/OCER/DFOI/	LILLIAN LLULL TECHLINK	VETRA 2C, VECTRA 4C - K982317
2012-4458	06/19/2012 07/18/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORO/OCI/ OC/ORO/OCI/	LAWRENCE P EAGEL BRAGAR WEXLER EAGEL & SQUIRE PC	PFIZER INC - IMPROPER PAYMENTS TO PHYSICIANS & FOREIGN OFFICIALS 2004 TO PRESENT
2012-4459	06/19/2012 07/18/2012	FDA/OGROP/ORO/ORO/DIOP/ FDA/OGROP/ORO/SW-FO/SWID/SWID-CB/	SHIRLEY ROSS ROANOKE TRADE SERVICES INC	WASHINGTON INTERNATIONAL INSURANCE CO - ENTRY #BYX00308282, #BYX00344006, #BYX00286884 NOTICES OF FDA ACTIONS, REDLIVERY NOTICES, NOTICES OF REFUSAL
2012-4460	06/19/2012 07/18/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/	JENNETTE BENNETT CENORIN LLC	INDIVIDUAL RECS
2012-4461	06/19/2012 07/18/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/CHI-DO/CHI-CB/	GEORGIA L MCGOWAN EVERAGE LAW FIRM PLLC	INDIVIDUAL RECS
2012-4462	06/19/2012 08/21/2012	FDA/OGROP/ORO/SW-FO/DEN-DO/DEN-CB/	NORBERT GOTTESMAN AVET CAPITAL MANAGEMENT LLC	CORDEN PHARMA COLORADO INC (ROCHE COLORADO CORP), BOULDER, CO - EIRS, 483S
2012-4463	06/19/2012	FDA/OMPT/CDER/ORP/DIDP/		INDO-PHARMA SA - SOLADEK VITAMIN SOL EIRS, 483S, CO

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	07/18/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FOI Services, Inc.	RESP, ETC
2012-4464	06/19/2012 07/18/2012	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	NORBERT GOTTESMAN AVET CAPITAL MANAGEMENT LLC	POLYPEPTIDE LABS - EIRS, 483S
2012-4465	06/19/2012 07/18/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TEASLEY, D L	CELLCEPT (MYSOPHENOLATE MOFETIL) ORAL SUSPENSION - AERS
2012-4466	06/19/2012 07/18/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TEASLEY, D L	PROGRAF (TACROLIMUS CAPS) ORAL SUSPENSION - AERS
2012-4467	06/19/2012 07/18/2012	FDA/OC/OES/DFOI/	oly@zymergi.com Zymergi LLC	TURBO data
2012-4468	06/19/2012 07/18/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FOI Services, Inc.	JANUVIA, RISTABEN, TESAVEL, ETC - AERS
2012-4469	06/19/2012 07/18/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FOI Services, Inc.	COPAXONE (GLATIRAMER ACETATE INJ) - APRVL FOR GENERIC VERSIONS, MEMOS, POLICY STATEMENTS, ETC
2012-4470	06/19/2012 07/18/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FOI Services, Inc.	PRESCRIPTION DRUG WRAP-UP LIST
2012-4471	06/19/2012 07/18/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/OA/OM/OMP/DDM/	FOI Services, Inc.	NEW DIETARY INGREDIENTS DATAABSE 1/01 TO PRESENT
2012-4472	06/19/2012 07/18/2012	FDA/OFVM/CFSAN/OCD/EOS/	WILLIAM A OLSON PHD WASHINGTON INFORMATION SOURCE	EXXONMOBIL CHEMICAL CO - FCN 501
2012-4473	06/19/2012	OC/CVM/OCD/	KRISTI O SMEDLEY PHD	NORBROOK LABS - EIRS, 483S, WARNING LTRS, ETC 1/11

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	07/18/2012		WASHINGTON INFORMATION SOURCE	TO PRESENT
2012-4474	06/19/2012 07/18/2012	OC/CVM/OCD/	KRISTI O SMEDLEY PHD WASHINGTON INFORMATION SOURCE	NORBROOK LABS - ANIMAL DRUG PROD 483S 1/11 TO PRESENT
2012-4475	06/19/2012 07/18/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BURGESS, BERNIE	Memorandum dated February 26, 2007 to Bioresearch Research Monitors Los Angeles District from Dan-My Chu Ph.D Regulatory Review Officer, GCP2 Division of Scientific Investigation (FACTS 808885);
2012-4476	06/19/2012 07/18/2012	FDA/OMPT/CDRH/OCER/DFOI/	Amanda L. Luker MORRIS HAYNES & HORNSBY	P950022
2012-4477	06/19/2012 07/18/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/OCOS/OES/ OC/OCOS/OES/	BURGESS, BERNIE	letter dated February 27,2012 re: EIR/CFN 2082851 from Jesse Goodman, MD Chief Scientist and Deputy Commissioner for Science and Public Health.;
2012-4478	06/19/2012 07/18/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BURGESS, BERNIE	Letter dated March 22, 2011 from Dr. Woodcock, Director CDER re: EIR/CFN 2082851. Copy with Virginia Behr, CDER Ombudsman;
2012-4479	06/19/2012 07/18/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	BURGESS, BERNIE	EIR - Exhibit
2012-4480	06/19/2012 07/18/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BURGESS, BERNIE	Letter dated Nov 2 2010, from Deborah Autor Esq, Director, Office Of Compliance Center for Drug Evaluation and Research regarding EIR/CFN 2082851. Copy of letter can be located in the Division of Scientific Investigation records-Memorandum from Dan-My Chu FACTS (808885).;
2012-4481	06/19/2012 07/18/2012	FDA/OGROP/ORAP/PA-FO/SAN-DO/SAN-CB/	COOLEY MANION JONES LLP	Buffalo Fish - foodborn illness (June 2011)
2012-4482	06/19/2012	FDA/OGROP/ORAP/NE-FO/NYK-	Stephen Latzman	JC World Bell Wholesale Co., Inc., NY, NY - 483s, 482s, EIRs,

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	07/18/2012	DO/NYK-DCB/	Stephen Latzman, Attorney	etc. (01/01/2005 - 12/31/2010)
2012-4483	06/19/2012 07/18/2012	FDA/OFVM/CFSAN/OCD/EOS/	Marisa Rihner Toxicology Regulatory Services (TRS)	FCN 368
2012-4484	06/19/2012 07/18/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Shekhar Natarajan Biocon Limited	NDA 20-622 - RVW RECORDS, SBA
2012-4485	06/19/2012 07/18/2012	FDA/OFVM/CFSAN/OCD/EOS/	Marisa Rihner Toxicology Regulatory Services (TRS)	FCN 424
2012-4486	06/19/2012 07/18/2012	FDA/OC/OES/DFOI/ FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	Craig A. Stewart Stewart, Craig A	Catfish Carl's Realistic Washes, Tuscan, AZ -- Recall, Investigation Records
2012-4487	06/19/2012 07/18/2012	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORAP/OCI/ OC/ORAP/OCI/ FDA/OGROP/ORAP/PA-FO/SAN-DO/SAN-CB/	Debbie A. Andersen Debbie A. Andersen, REHS	Sodium Dichloride Acid - Investigation Recs (California)
2012-4488	06/20/2012 07/19/2012	OC/OM/OMP/DDM/	JEFF BOSH SIDLEY AUSTIN LLP	DKT 1995P-0136
2012-4489	06/20/2012 07/19/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JIM FAUCETT NORTHWEST CLINICAL RESEARCH CTR	EFFEXOR ER NDA 20-699/S047 - APRVL
2012-4490	06/20/2012 07/19/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JIM FAUCETT NORTHWEST CLINICAL RESEARCH CTR	SEROQUEL XR NDA 22-047/S007 - APRVL
2012-4491	06/20/2012	FDA/OMPT/CDER/ORP/DIDP/	JIM FAUCETT	CYMBALTA NDA 21-427/S011 - APRVL

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	07/19/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	NORTHWEST CLINICAL RESEARCH CTR	
2012-4492	06/20/2012 07/19/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ROWENA DODARO ALKERMES GAINESVILLE L LLC	VIVITROL - AER
2012-4493	06/20/2012 07/19/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/	Doe J	INDIVIDUAL RECS
2012-4494	06/20/2012 07/19/2012	FDA/OFVM/CFSAN/OCD/EOS/	DR. CONSUELO FERNANDEZ RIVAS ITENE	FCN 932
2012-4495	06/20/2012 07/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	CHRISTINE A. CAMPBELL WILLIAMS CUKER & BEREZOFSKY	MEDTRONIC - TALENT THORACIC STENT GRAFT SYS PMA PO 70007
2012-4496	06/20/2012 07/19/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OCC/	STERN, CHERYL	USA VS RANBAXY LABS LTD ET AL - FINANCIAL STATEMENT
2012-4497	06/20/2012 07/19/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN L. VILLANO, MD, Ph.D. UNIVERSITY OF KENTUCKY CANCER CENTER	TEMOZOLOMIDE - MEDWATCH
2012-4498	06/20/2012 07/19/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHANDRAN TIRUVATTAR DR REDDY'S LABORATORIES INC	ADAPALENE (TOLMAR) ANDA 200298 SBA
2012-4499	06/20/2012 07/19/2012	FDA/OC/OES/DFOI/	CUTLER 322866, CHARLES	TOP 10 COMPANIES TO GET MEDICAL DEVICE APRVL
2012-4500	06/20/2012 07/19/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joanna Gerry ALLERGAN GLOBAL	Dr. Shiyao Wu, Shanghai, PRC (02/03/2012 - 02/03/2012)

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	REGULATORY AFFAIRIS	
2012-4501	06/20/2012 07/19/2012	OC/ORO/ OC/ORO/ OC/ORO/OE/ OC/ORO/OE/	YU, OLIVER	TURBO - EIR
2012-4502	06/20/2012 07/19/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OGROP/ORA/CE-FO/CHI- DO/CHI-CB/	PAUL D. NELSON BULLIVANT HOUSER BAILEY ET AL	DENTSPLY - CAVITRON ULTRONIC SCALERS CORR
2012-4503	06/20/2012 07/19/2012	FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	WILLIAM TANNER, Ph.D. LAZARD CAPITAL MARKETS	JAZZ PHARMS, PALO ALTO, CA - 483 5/30/12
2012-4504	06/20/2012 07/19/2012	FDA/OGROP/ORA/CE-FO/BLT- DO/BLT-CB/ FDA/OGROP/ORA/CE-FO/CIN- DO/CIN-CB/ FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/ FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/ FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/ FDA/OGROP/ORA/PA-FO/SEA- DO/SEA-CB/ FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/ FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/ FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/ FDA/OGROP/ORA/SW-FO/DEN- DO/DEN-CB/	SCHARBERG, DAVID L	FACILITIES PERFORMING GLP NON CLNCL, BIOANALYTICAL TESTING 3/1-5/31/12
2012-4505	06/20/2012 07/19/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	PATRICIA STOEHR, Ph.D. Novartis Vaccines and Diagnostics, Inc.	INDIVIDUAL RECS
2012-4506	06/20/2012 07/19/2012	OC/CVM/OCD/	ARLENE MORALES BURDOCK GROUP	L-LYSINE - SAFETY

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2012-4507	06/20/2012 07/19/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Doe J	TETANUS - AER
2012-4508	06/21/2012 07/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/OCOS/OES/ OC/OCOS/OES/ OC/OCOS/OL/ FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	LATESHA R BAKER HINSHAW & CULBERTSON LLP	EYE INFECTIONS AT THE VETERANS AFFAIRS GREATER LOS ANGELES HEALTHCARE SYSTEM 2011 - TEST RESULTS
2012-4509	06/21/2012 07/20/2012	FDA/OGROP/ORA/CE-FO/CIN- DO/CIN-CB/ FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/ FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/ FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/ FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/ FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/ FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/ FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/ FDA/OC/OES/DFOI/	CHASTITY RODRIQUEZ INTERNATIONAL SIGHT RESTORATION INC	ARKANSAS LIONS EYE BANK & LAB, LITTLE ROCK, AR; BATON ROUGE REGIONAL EYE BANK, BATON ROUGE, LA; DONOR SERVICES OF INDIANA, FT WAYNE, IN, ETC - 483S, WARNING LTRS
2012-4510	06/21/2012 07/20/2012	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	HARMON, ROBERT	CMPLNT 125934
2012-4511	06/21/2012 07/20/2012	OC/ORA/OCI/ OC/ORA/OCI/	ROBERT G BERNHOFT BERNHOF LAW FIRM SC	INDIVIDUAL RECS
2012-4512	06/21/2012 07/20/2012	OC/CVM/OCD/	VERONICA KNAPP HOGAN LOVELLS LLP	LALLEMAND ETHANOL TECHNOLOGY, MASCOMA CORP - BIOENGINEERED YEAST GRAS STATUS, RECS

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2012-4513	06/21/2012 07/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ALISON M AGNEW PILLSBURY WINTHROP SHAW PITTMAN LLP	CORTICOTROPIN NDA 08-317, ANDA 88-772, NDA 07-504, ETC - ANNUAL RPTS MOST RECENT
2012-4514	06/21/2012 07/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRIGGS Y40816, JAMES	XANODY PHARMS - ROXICODONE NDA 02-101; VINTAG PHARMS - OXYCODONE HCL ANDA 07-771; RHODES PHARMS - OXYCODONE HCL ANDA 09-149 RECS
2012-4515	06/21/2012 07/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kim Wagner BioPharm Development Development Associa	Remicade BLA 103772, Supplement 5113 (09/15/2005)
2012-4516	06/21/2012 07/20/2012	FDA/OC/OES/DFOI/	Raisa Bruner ABC NEWS	Egg Rule Facility Inspections
2012-4517	06/21/2012 07/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Daven Mody Impax Pharmaceuticals	Diastat and Diastat Acudial - Approval Records, letters, reviews, etc.
2012-4518	06/21/2012 07/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Daven Mody Impax Pharmaceuticals	Kerlone, Betoptic, and Betoptic S - All Approval History, Letters, Reviews, and Related Documents
2012-4519	06/21/2012 08/29/2012	FDA/OMPT/CDRH/OCER/DFOI/	Dynacardia, Inc.	K111487
2012-4520	06/21/2012 07/20/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/ OC/ORO/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORO/CE-FO/CIN- DO/CIN-CB/	Christopher Schillios Pharmacy 1	Reumofan Plus - Lab Results (01/01/2012 - 06/19/2012)

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		FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/		
2012-4521	06/21/2012 07/20/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	PAUL W TRIPP LINCARE INC	PARMANN INC (VALLEY RESPIRATORY & MEDICAL), CA - EIRS, 483S, WARNING LTRS, 6/04 TO PRESENT
2012-4522	06/21/2012 07/20/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kandarp Prajapati Advantagene Inc.	Valtrex (NDA # 020487) - Approval Package
2012-4523	06/21/2012 07/20/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sidney P. Cominsky Trial Lawyers, LLC	Duragesic (fentanyl transdermal system) Med Watch Alert (7/2005) with 7/08/2005 Letter by Janssen (CERTIFIED); FDA Statement of 7/2005 entitled "FDA Issues Public Health Advisory on the Fentanyl Patch" (CERTIFIED); Information for Healthcare Professionals dated 7/15/2005 (CERTIFIED); Public Health Advisory 7/2005 "Safety Warnings Regarding Use of Fentanyl Transdermal (Skin Patches)" (CERTIFIED); Public Health Advisory "Fentanyl Transdermal Patch" 12/21/2007(CERTIFIED); Information for Healthcare Professionals: Fentanyl Transdermal System (marketed as Duragesic and generics)12/21/2007 (CERTIFIED)
2012-4524	06/21/2012 07/20/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/OCOS/OES/ OC/OCOS/OES/ FDA/OC/OCC/ OC/ORAOCI/ OC/ORAOCI/	Ryan Zehl Fitts Zehl LLP	GlaxoSmithKline - Records re: November 2011 Settlement (lawsuits, correspondence, settlement agreements)
2012-4525	06/21/2012 07/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	Angelia Slayton INC REGULATORY CONSULTING & SUBMISSIONS	K030876
2012-4526	06/21/2012 07/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	Angelia Slayton INC RESEARCH	K990445
2012-4527	06/21/2012 07/20/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sharif Ahmed Scinergist Pharmaceuticals, LLC	ANDA 090410 - Cover Sheet, Chemistry Review, Bioequivalence Review, Administrative Documents, Correspondence

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2012-4528	06/21/2012 07/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michael Jack Kaczynski Michael Jack Kaczynski	Matrixx Initiatives, Inc. (Zicam) - AERS (01/01/2004 - 01/01/2011)
2012-4529	06/21/2012 07/20/2012	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	PAUL W TRIPP LINCARE INC	MAK MEDICAL LLC, GA - EIRS, 483S, WARNING LTRS 1/05 TO PRESENT
2012-4530	06/21/2012 07/20/2012	OC/OSMP/OOPD/ FDA/OMPT/OSMP/OOPD/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	Diastat rectal gel, approved 7/29/97, made by Valeant (NDA 20648 Orphan Application Number 91-615) - Designation review, Orphan Application Approval Letter, the Office of Orphan Drug's review of the Orphan Application, and the written designation review for the orphan product
2012-4531	06/21/2012 07/20/2012	FDA/OGROP/ORR/CE-FO/NWJ-DO/NWJ-CB/	FUGO, ROBERT J	TABATCHNICK FINE FOODS INC, SOMERSET, NJ - CMLNTS, FOOD SAFETY VIOLATIONS
2012-4532	06/21/2012 07/27/2012	FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/	Fiona Hudson Herald Sun	Australian Foods - EIRs, 483s (01/01/2011 - 06/20/2012)
2012-4533	06/21/2012 07/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sharif Ahmed Scinergist Pharmaceuticals, LLC	ANDA 202121 (Progesterone Capsules) - Cover Sheet, Chemistry Review, Bioequivalence Review, Administrative Documents, Correspondence
2012-4534	06/21/2012 07/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	Zhang, Fa Qi	K113336
2012-4535	06/21/2012 07/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	POOL, SUSAN	K935643, K943835
2012-4536	06/21/2012 07/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	Jay Patel Jay Patel	K102541
2012-4537	06/21/2012 07/20/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	DS LABS INC	POWERED & NON-POWERED BREAST PUMPS - 510K APPLS; WHISPER WEAR BREAST PUMP - K022140
2012-4538	06/21/2012 07/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	Philips Healthcare	K103489, K103424, K120579 - 510K Summary Documents
2012-4539	06/21/2012 07/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	Ellie White Terumo BCT	K111702
2012-4540	06/21/2012	FDA/OMPT/CDER/ORP/DIDP/	SARASWATHY V NOCHUR PHD	PFIZER - TAFAMIDIS MEGLUMINE NDA 202-737 COMPLETE RESP LRT 6/12

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	07/20/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Alnylam Pharmaceuticals	
2012-4541	06/21/2012 07/20/2012	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OC/OES/DFOI/	STEPHEN C RATHKE LOMMEN ABDO COLE KING STAGEBERG PA	MEAD JOHNSON - EIRS 1/17/12-2/16/12, ENTEROBACTER SAKAZAKII INVESTIGATION RECS
2012-4542	06/21/2012 07/20/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JONATHAN B NACE PAULSON & NACE	REMICADE - CLNCL TRIAL RECS, APRVL RECS, AERS, ETC
2012-4543	06/21/2012 07/20/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JONATHAN B NACE PAULSON & NACE	ENBREL - CLNCL TRIAL RECS, APRVL RECS, AERS, ETC
2012-4544	06/21/2012 07/20/2012	FDA/OC/OES/DFOI/	NATHANIEL ENOS CONWAY HOMER & CHIN- CAPLAN PC	INDIVIDUAL RECS
2012-4545	06/22/2012 07/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	KRAUSER, JACK T	EMERGING TECHNOLOGIES GROUP, NORTH PALM BEACH, FL - K961385
2012-4546	06/22/2012 07/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	LILIAN LLULL TECHLINK	DEFLEX - K113608
2012-4547	06/22/2012 07/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	MURIS DEMIROVIC MANNING & NAPIER ADVISORS INC	TERUMO MEDICAL PRODUCTS, HANGZHOU, CHINA - 483S 12/12/11
2012-4548	06/22/2012 07/23/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOANNE S HAWANA ARENT FOX LLP	SEPTOCAINE INJ, ARTICAINE HCL - ISRS 7806512, 7806527, 78222075, ETC
2012-4549	06/22/2012 07/23/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KIMBERLY D BARONE BADEN MOTLEY RICE LLC	WELLBUTRIN - NDA 18-644/S33/S34 PREGNANCY CATEGORY CHANGE
2012-4550	06/22/2012 07/23/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELSPETH CALLAHAN INDEPENDENCE LEGAL	ADENOCARD NDA 19-937, ADENOSCAN NDA 20-059 - APRVL RECS

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2012-4551	06/22/2012 07/23/2012	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	DOROTHY LORIG GOLDEN ORGANICS	ORGANIC PARTNERS INTERNATIONAL - SUNFLOWER KERNELS TEST RESULTS
2012-4552	06/22/2012 07/23/2012	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	JON MCNEELY NEWTON JONES & SPAETH COUNSELORS AT LAW	SANGAR FRESHCUT RPRODUCE INC (NINO'S PRODUCE & PROCESSING CO), SAN ANTONIO, TX - EIRS, RPTS, STATEMENTS, ETC 10/10
2012-4553	06/22/2012 07/23/2012	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	JOAN BECHTOLD SWEENEY & BECHTOLD LLC	CONMED ELECTROSURGERY - EIR 2012
2012-4554	06/22/2012 07/23/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OO/OFBA/OAGS/	JONATHAN LEE THOMPSON REULTERS IP & SCIENCE	PHARMAPENDIUM - COOPERATIVE RESEARCH & DEVELOPMENT AGREEMENT (CRADA) BETWEEN FDA & MDL INFORMATION SYSTEMS
2012-4555	06/22/2012 10/05/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	MELANIE COURTOL UNIV OF BRITISH COLUMBIA	INFLUENZA A (HINI) - VAERS11/22/09 TO 1/31/10, 2/1/10-4/28/10
2012-4556	06/22/2012 07/23/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/OER/OPA/	MARIANO, JOSEPHINE	MEDSCAPE MEDICAL NEWS - GREATER SUICIDE RISK WITH VARENICLINE VS OTHER CESSATION MEDS STATEMENT
2012-4557	06/22/2012 07/23/2012	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/OCOS/OL/ FDA/OC/OES/DFOI/ OC/OCOS/OES/ OC/OCOS/OES/	KAI FALKENBERG FORBES	AMBIEN, AMBIEN CR (ZOLPIDEN TATRATE) - AERS 3/14/07 TO PRESENT
2012-4558	06/25/2012 07/24/2012	FDA/OFVM/CFSAN/OCD/EOS/	Jeffrey Vinnick Haight, Brown & Bonesteel	Jensen Farms, Colorado - PulseNet pattern codes
2012-4559	06/25/2012	OC/OCOS/OL/	MARK L FLATTEN	CONGRESSIONAL CORR SEEKING TO DESIGNATE SPENDING BY HHS BEYOND NORMAL BUDGET &

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	07/24/2012	OC/OCOS/OES/ OC/OCOS/OES/	WASHINGTON EXAMINER	APPROPRIATIONS PROCESS 1/11 TO PRESENT
2012-4560	06/25/2012 08/03/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORASE-FO/ATL- DO/ATL-CB/	JOHN B MERCHANT III MERCHANT LAW FIRM	SUSAN J WHEATLEY MD, CRABAPPLE OBSTETRICS & GYNECOLOGY PC - CLNCL TRIAL CORR, RESP
2012-4561	06/25/2012 07/24/2012	FDA/OGROP/ORACE-FO/MIN- DO/MIN-CB/	VERONICA KNAPP HOGAN LOVELLS US LLP	MIDWEST NORTHERN INC - CORR, RESP TO WARNING LTR 4/27/12
2012-4562	06/25/2012 07/24/2012	OC/ORAO/ORM/ OC/ORAO/ORM/	MICHAEL MORISY MUCKROCK NEWS	SAFETY AND HYGIENE OF AIRLINE CATERERS - INSP RPTS
2012-4563	06/25/2012 07/24/2012	OC/ORAO/ORM/ OC/ORAO/ORM/	MICHAEL MORISY MUCKROCK NEWS	QUALITY, SAFETY, POTABILITY OF WATER SERVED ON AIRLINES - LIST OF INSPS
2012-4564	06/25/2012 07/24/2012	FDA/OMPT/CTP/OD/	MUJAHIDIN, MUHAMMAD	CIGARETTES - EFFECTS OF NICOTINE, ADDITIVES
2012-4565	06/25/2012 07/24/2012	FDA/OMPT/CDRH/OCER/DFOI/	BETH HAMLETT ADVANCED VASCULAR DYNAMICS	PRESSURE PRODUCTS - K863427
2012-4566	06/25/2012 07/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	AMY MITCHELL GLAXO SMITH KLINE	GLAXOSMITHKLINE, BARNARD CASTLE, PARMA, ULVERSTON, ETC - QUALITY ASSURANCE PROFILE (QAP)
2012-4567	06/25/2012 07/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARIA GRAZIA VIMERCATI APTALIS PHARMA SRL	MIPHARM SPA, MILAN, ITALY - QUALITY ASSURANCE PROFILE (QAP)
2012-4568	06/25/2012 07/24/2012	OC/OA/OM/OMP/DDM/	JOHN RIOLO RA/QA CONSULTING SERVICES	DKTS 2011M-0726, 2012M-0056
2012-4569	06/25/2012 07/24/2012	OC/OM/OMP/DDM/	HICHAM SOBHI HUNTON & WILLIAMS LLP	DKT 1985P-0197, 1986P-0129
2012-4570	06/25/2012 07/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lea Humphrey Lea Humphrey, DO at Des Peres Hospital	Propofol - Acute Pancreatitis
2012-4571	06/25/2012 07/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gary M. O'Bannon Balchem Corporation	Balchem Italia, Via del Porto snc, Marano Ticino, Italy - FEI #

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2012-4572	06/25/2012 07/24/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sharif Ahmed Scinergist Pharmaceuticals, LLC	ANDA 090410 (Budesonide) & ANDA 202121 (Progesterone) - Appl Ltr and Bioequiv Rvw
2012-4573	06/25/2012 07/24/2012	FDA/OMPT/CDRH/OCER/DFOI/	Sarah Larson Argon Medical Devices, Inc.	K772354
2012-4574	06/25/2012 07/24/2012	FDA/OMPT/CDRH/OCER/DFOI/	Mike Sinai Michael Sinai, Topcon Medical Systems	K083291
2012-4575	06/25/2012 07/24/2012	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	Sheila Garland High Point Clinical Trials Center	Comprehensive Phase One, Fort Myers Florida - EIRs (03/01/2007 - 06/21/2012)
2012-4576	06/25/2012 07/24/2012	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Todd Ackerman HOUSTON CHRONICLE	Celltex Therapeutics - 483s, Warning Letters, etc. (02/21/2012 - 06/21/2012)
2012-4577	06/25/2012 07/24/2012	FDA/OC/OES/DFOI/	Megan Pickel BEVERIDGE & DIAMOND PC	FOIA Requests Assigned to CFSAN 05/22/2012 - 06/22/2012
2012-4578	06/25/2012 07/24/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Catherine O'Mara-Cherubin MORRISON MAHONEY LLP	Transvaginal Mesh Implant Surgery to treat POP - "Monarc Subfascial Hammock Sling" and "Elevate Anterior and Apical System" manufactured by American Medical Systems.
2012-4579	06/25/2012 07/24/2012	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Laura Robinson PAREXEL	Dr. Victor Tapson, Durham NC - 483 08/29/1994
2012-4580	06/25/2012 07/24/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Julie Nguyen Cedars-Sinai	Bactrim (sulfamethoxazole/trimethoprim) - AERs
2012-4581	06/25/2012 07/24/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CEDARS-SINAI MEDICAL CENTER	Cipro and ruptured tendon - AERs

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		FDA/OMPT/CDER/GRP/DIDP/		
2012-4582	06/25/2012 07/24/2012	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Edward W Skepnek Valnet Inc.	Hart Enterprises, Sparta, MI - EIR (April 2011)
2012-4583	06/25/2012 07/24/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Heather Flynn THERMO FISHER SCIENTIFIC	'Drug Establishments Current Registration Site' - Full Company List
2012-4584	06/25/2012 07/24/2012	FDA/OFVM/CFSAN/OCD/EOS/	Dan O Brien O BRIEN, DANIEL B	FCN No. 707
2012-4585	06/26/2012 07/25/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	PATRICIA L REGENYE Celgene Corporation	NICHOLAS LOWE, SANTA MONICA, CA - 483S 4/22/02-5/1/02
2012-4586	06/26/2012 07/25/2012	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	PATRICIA L REGENYE Celgene Corporation	FERNANDO MARTINEZ (UNIV MICHIGAN MEDICAL CTR), ANN ARBOR, MI - 483S 1/10 TO 6/12
2012-4587	06/26/2012 07/25/2012	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	PATRICIA L REGENYE Celgene Corporation	DANIEL LORCH, BRANDON, FL - 483S 2/09 TO 6/12
2012-4588	06/26/2012 07/25/2012	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	PATRICIA L REGENYE Celgene Corporation	EDWARD ARROWSMITH (CHATTANOOGO ONCOOLOGY & HEMATOLOGY), CHATTANOOGO, TN - EIRS, 483S, CO RESP 6/11 TO 6/12
2012-4589	06/26/2012 07/25/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	PATRICIA L REGENYE Celgene Corporation	MICHAEL WEISMAN (THORNTON HOSPITAL), LA JOLLA, CA - 483S 5/99 TO 6/12
2012-4590	06/26/2012 07/25/2012	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	PATRICIA L REGENYE Celgene Corporation	JOHN MCCARTY (MEDICAL COLLEGE OF VIRGINIA), RICHMOND, VA - 483S 12/01 TO 6/12
2012-4591	06/26/2012 07/25/2012	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	PATRICIA L REGENYE Celgene Corporation	JAMES STOCKS (UNIV OF TEXAS HEALTH CENTER TYLER), TYLER, TX - 483S 9/09 TO 6/12
2012-4592	06/26/2012 07/25/2012	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	PATRICIA L REGENYE Celgene Corporation	ROBERT SCHILZ (CLEVELAND CLINIC FOUNDATION), CLEVELAND, OH - 483S 9/05 TO 6/12
2012-4593	06/26/2012 07/25/2012	FDA/OMPT/CDRH/OCER/DFOI/	MARTHA GUZMAN AMSINO INTERNATIONAL INC	AMSELF CLOSED CATHERIZATION SYS - K082831
2012-4594	06/26/2012 07/25/2012	FDA/OMPT/CDRH/OCER/DFOI/	JACK T KRAUSER	K071638
2012-4595	06/26/2012 07/25/2012	FDA/OMPT/CDRH/OCER/DFOI/	ANDRENE HERON ROCHE DIAGNOSTICS	K022774, K101299, K113137

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2012-4596	06/26/2012 07/25/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	JAMES PEERY	GENTLEWAVES CONSUMER LED PHOTOMODULATION DVC - K062991
2012-4597	06/26/2012 07/25/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	JAMES PEERY	OMNILUX NEW-U DVC - K072459
2012-4598	06/26/2012 07/25/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	ELENA HOWELL HOGAN LOVELLS LLP	LA LINK (HUNTINGTON BEACH) CORP OF CERRITOS, CA - FLUORANTHENE & PYRENE IN SHITAKE-YA BRAND GOUMENT SHITAKE MUSHROOM SLICES LAB RESULTS 5/12
2012-4599	06/26/2012 07/25/2012	FDA/OFVM/CFSAN/OCD/EOS/	CYNTHIA B LIEBERMAN Keller and Heckman LLP	SILICONE PRODUCTS DEPARTMENT, GENERAL ELECTRIC CO - FAP 1088; MORTON SALT CO - FAP 7A2065
2012-4600	06/26/2012 07/25/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/	DEAN GRESHMAN PAYNE MITCHELL LAW GROUP	FOOD BEVERAGE OR SUPPL PROD LABELED AS GLUTEN FREE MISBRANDED OR MISLABELED - WARNING LTRS, RESP LTRS LAST 3 YRS
2012-4601	06/26/2012 07/25/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/OA/OM/OMP/DDM/	TOM MYERS AIDS HEALTHCARE FOUNDATION	ANTIRETROVIRAL DRUGS A/C - EVALUATION OF SEATING, CORR, QUALIFICATIONS OF EACH MEMBER, ETC 1/12 TO PRESENT
2012-4602	06/26/2012 07/25/2012	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	Doe J	INDIVIDUAL RECS
2012-4603	06/26/2012 07/25/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TSURUTA ERIKO MD OSAKA UNIV GRADUATE SCHOOL OF MEDICINE	PROPYLTHIOURACIL - ISRS 3560746-4, 3670958-7, 4257561-5, ETC
2012-4604	06/26/2012 07/25/2012	OC/ORAOCI/ OC/ORAOCI/	DOCKERY, TIM	CORR BTWN JEFF NOVITSKY & US ANTI-DOPING AGENCY 1/05 TO PRESENT; LANCE ARMSTRONG INVESTIGATION RECS
2012-4605	06/26/2012 08/16/2012	OC/ORAO/ OC/ORAO/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	ADONICA-JO R WADA SIMON GLUCK & KANE LLP	NAVIGATORS MANAGEMENT COMPANY INC (ENDURANCE RESINSURANCE CORPORATION OF AMERICA) - ENTRY #DZ1-0423234-0 NOTICE OF FDA ACTION 10/25/11
2012-4606	06/26/2012 07/25/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	SUSANNE N SCOVERN AUDET & PARTNERS, LLP	INTUITIVE SURGICAL - DA VINCI SURGICAL SYS (ENDOSCOPIC INSTRUMENT CONTROL SYS) K965001, K990188 MDRS, CORR, PROMOTIONAL MATERIALS, ETC
2012-4607	06/26/2012 07/25/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PARIETTI, MICHAEL	NUMBER OF NEW DRUGS APRVD, NDAS SUBMITTED, DRUG TRIALS CONDUCTED, ETC

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		FDA/OMPT/CDER/GRP/DIDP/		
2012-4608	06/26/2012 07/25/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	YVONNE M FLAHERTY LOCKRIDGE GRINDAL NAUEN PLLP	ST JUDE MEDICAL - RIATA, RIATA ST LEADS P950022/S001/S002/S003, ETC CMLNPTS, RESULTS, INVESTIGATIONS, ETC
2012-4609	06/26/2012 07/25/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELENA HOWELL HOGAN LOVELLS US LLP	DRAFT GUIDANCE ON BIOEQV FOR ACYCLOVIR 3/10
2012-4610	06/26/2012 07/25/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELENA HOWELL HOGAN LOVELLS US LLP	RESEARCH ON METHODS FOR EVALUATIING BIOAVAIL & BIOEQV FOR TOPICALLY APPLIED LOCALLY ACTING DRUGS 1/07 TO PRESENT
2012-4611	06/26/2012 07/25/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELENA HOWELL HOGAN LOVELLS US LLP	BIOEQV STANDARDS FOR PRODS IN AN OINTMENT DOSAGE FORM & WITH A TOPICAL ROUTE OF ADMINISTRATION 1/07 TO PRESENT
2012-4612	06/26/2012 07/25/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	ELENA HOWELL HOGAN LOVELLS LLP	FUNDING FOR INITIATIVES ON ALTERNATIVE METHODS FOR ASSESSING BIOEQV FOR LOCALLY ACTING TOPICAL DRUGS AS PART OF THE REGULATORY SCIENCE PLAN, ETC
2012-4613	06/26/2012 07/25/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELENA HOWELL HOGAN LOVELLS US LLP	ZOVIRAX (ACYCLOVIR) OINTMENT NDA 18-604 - CORR 1/07 TO PRESENT
2012-4614	06/26/2012 07/25/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	RYAN WILDER SAC CAPITAL ADVISORS LP	NISSHIN PHARMA INC, JAPAN - 483S 1/12 TO 6/12
2012-4615	06/26/2012	FDA/OMPT/CDER/GRP/DIDP/	RYAN WILDER	NISSHIN PHARMA INC, JAPAN - EIRS 1/12 TO 6/12

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	07/25/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SAC CAPITAL ADVISORS LP	
2012-4616	06/26/2012 07/25/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/	Doe J	INDIVIDUAL RECS
2012-4617	06/26/2012 07/25/2012	FDA/OO/OFBA/OAGS/	JEFF STACHEWICZ FOIA GROUP INC	DOVEL'S TECHNICAL PROPOSAL - HHSF22320110027I
2012-4618	06/26/2012 07/25/2012	FDA/OC/OES/DFOI/	TOLBERT #1551278, ZSWALUN	INDIVIDUAL RECS
2012-4619	06/26/2012 07/25/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TERRY J ENFIELD Kleinfeld, Kaplan and Becker, LLP	EUGENE LU - NIDPOE LTR 2010 CONSENT AGREEMENT
2012-4620	06/26/2012 07/25/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TERRY J ENFIELD Kleinfeld, Kaplan and Becker, LLP	DAVID CRAIG LOUCKS - NIDPOE LTR 2010 CONSENT AGREEMENT
2012-4621	06/26/2012 07/25/2012	FDA/OMPT/CDRH/OCER/DFOI/	MARTHA GUZMAN AMSINO INTERNATIONAL INC	AMSURE PVC INTERMITTENT CATHETER - K091306
2012-4622	06/26/2012 07/25/2012	FDA/OMPT/CDRH/OCER/DFOI/	RON JEFFREY CAS MEDICAL SYSTEMS INC	NONIN MEDICAL INC - K113215
2012-4623	06/26/2012 07/25/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	JEROEN VAN GOUDOEVER BMEYE BV QA-RA MANAGER	BMEYE - NEXFIN HD MONITOR K072049
2012-4624	06/26/2012 07/25/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	UBE INDUSTRIES LTDS, YAMAGUCHI, JAPAN - EIR 10/31/11- 11/4/11
2012-4625	06/26/2012 07/25/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHARON E KNUTSON RN VOGEL LAW FIRM	PHENEGAN (PROMETHAZINE) - AERS

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		FDA/OMPT/CDER/GRP/DIDP/		
2012-4626	06/26/2012 07/25/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DUSTIN BLOCK IPD ANALYTICS LLC	OLANZAPINE, FLUOXETINE HCL ANDA 77-528 - EFFECTIVE APRVL LTR
2012-4627	06/26/2012 07/25/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Deana Coons Ronald E. Osman & Associates, Ltd.	Kenalog-10 and Kenalog-40 - Labeling (2000-2005)
2012-4628	06/26/2012 07/25/2012	FDA/OFVM/CFSAN/OCD/EOS/	Robert Deering	Kombucha, Manchurian mushroom tea or Kagarosk tea - Microbiological and chemical analytic (including alcohol) test results and reports (06/06/1994 - 06/25/2012)
2012-4629	06/26/2012 07/25/2012	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	Bridget Kuehn JAMA Medical News	International Cellular Medicine Society's IRB - 483 (05/01/2012 - 06/25/2012)
2012-4630	06/26/2012 07/25/2012	FDA/OC/OES/DFOI/	Edra Harrison John I. Haas, Inc	John I. Haas, Inc. - EIRs
2012-4631	06/26/2012 07/25/2012	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	Michelle A. Nolan Luboja & Thau, LLP	Individual Records
2012-4632	06/26/2012 07/25/2012	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Miriam Maxwell OCEAN SPRAY CRANBERRIES INC	#692159 - Sample Results
2012-4633	06/26/2012 07/25/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Jonathan Siegel Kindgon Capital Management	Viropharma and/or Sanquin Plasma Products (Amsterdam) - EIR (09/2011)
2012-4634	06/26/2012 07/25/2012	FDA/OMPT/CDRH/OCER/DFOI/	J. DONALD HENSON, SR Henson, J. Donald	SSED's Package for P980022/S010
2012-4635	06/26/2012 07/25/2012	FDA/OMPT/CDRH/OCER/DFOI/	Timothy Adkins Alcon Laboratories Inc.	EN VISTA ONE PIECE HYDROPHOBIC ACRYLIC LENS P910056/S010 Approved Labeling Summary of Safety and Effectiveness Approval Order
2012-4636	06/26/2012 07/25/2012	FDA/OMPT/CDRH/OCER/DFOI/	Troy Fleming Brown & Jennings, PLC	Folding Lighthouse Shower Chair Valentine International Ltd. Patterson Medical Homecraft Rolyan Ltd. Report Number: 2128677-2010-00001 Device Event Key: 1974676 MDR Report

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				Key: 1946528 Event Key: 1843524
2012-4637	06/27/2012 07/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Alvogen Group	DMF #5715
2012-4638	06/27/2012 07/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/OA/OM/OMP/DDM/	WESTLAW COURT EXPRESS	Topamax - Medical, scientific and safety reviews, memoranda, corr, etc.
2012-4639	06/27/2012 07/26/2012	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	Max Harriger ÜBER FOODS	LARABAR - EIR for manufacturer
2012-4640	06/27/2012 07/26/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	Aaron M. White Stern & Goldberg	Protica, Inc., Whitehall, PA - Reports, corr, batch records, etc.
2012-4641	06/27/2012 09/05/2012	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Doe J	INDIVIDUAL RECS
2012-4642	06/27/2012 07/26/2012	OC/ORA/ OC/ORA/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/ORO/DIOP/	STEPHANIE ARMOUR BLOOMBERG NEWS	NGOC SINH SEAFOODS, CA MAU, VIETNAM; CAMAU SEAFOOD FACTORY 4, CAMAU CITY, VIETNAM; NGOC TRI SEAFOOD JOINT STOCK CO, BAC LIEU, VIETNAM - INSPS 2009 TO PRESENT
2012-4643	06/27/2012 07/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	NICHOLAS K JUNGLUTH M SQUARED ASSOCIATES INC	EIGEN LLC - MULTI-MODALITY IMAGE FUSION K120187
2012-4644	06/27/2012	FDA/OMPT/CDRH/OCER/DFOI/	MONIKA BHATT	ROBERT BOSCH CORP - IMPULS 3 IT SELECTOR K842805;

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	07/26/2012		HODGSON RUSS LLP	RAMI INTERNATIONAL CORP - GALVANIC UNIT K790949; MED GENERAL - MAXICEPTOR K780632
2012-4645	06/27/2012 07/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORO/OCI/ OC/ORO/OCI/	TASCHNER, DANA	DEPT OF JUSTICE, RI NATIONAL GUARD - INVESTIGATION OF GOOGLE'S ACCEPTANCE OF ADVERTISEMENTS PLACED BY ONLINE PHARMACY ADVERTISERS 2003
2012-4646	06/27/2012 07/26/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	DONALD N BLUE ZETETIC INC	UNILEVER PAKISTAN LTD - SOAP ENTRY #BGK-0387652-2
2012-4647	06/27/2012 07/26/2012	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	DONALD N BLUE ZETETIC INC	UNILEVER UNITED STATES INC - SOTTON SWABS ENTRY #AM1-0177829-9
2012-4648	06/27/2012 07/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRODY MULLINS WALL STREET JOURNAL	MARWOOD GROUP, WAYPOINT, HUNTON & WILLIAMS - CORR, RECS 6/10 TO 10/10
2012-4649	06/27/2012 07/26/2012	OC/OCOS/OES/ OC/OCOS/OES/ FDA/OC/OPP/OP/	BRODY MULLINS WALL STREET JOURNAL	ACTING DEPUTY COMMISSIONER DAVID DORSEY, MARWOOD GROUP, JEFF COUGHLIN, ETC - CORR, RECS 6/10 TO 10/10
2012-4650	06/27/2012 07/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRODY MULLINS WALL STREET JOURNAL	DAVID GRAHAM, MARWOOD GROUP, STEVE WILLIAMS, ETC - CORR, RECS 6/10 TO 10/10
2012-4651	06/27/2012 07/26/2012	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	LOPER, MATTHEW	HI-TECH PHARMACAL - EIR, 483, CO RESP, ETC 2012
2012-4652	06/27/2012 07/26/2012	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	KRISTA WHALEY Vi-Jon, Inc.	CHEMISPHERE CORP, ST LOUIS, MO - EIRS, 483S, WARNING LTRS, ETC 2011,2012
2012-4653	06/27/2012 07/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HAL LIPTON GYMA LABORATORIES OF AMERICA INC	ESTEVE HUAYI PHARMACEUTICAL CO LTD, ZHEJIANG, CHINA - EIR 1/3-6/12
2012-4654	06/27/2012 07/26/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	BRENT M ARDAUGH MPH MS NORTHWESTERN UNIV	K970741, K883341, K883344

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2012-4655	06/27/2012 07/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELLIOT FAVUS MD FAVUS INSTITUTIONAL RESEARCH LLC	ADCETRIS (BRENTUXIMAB) - AERS 4/16/12 TO PRESENT
2012-4656	06/27/2012 07/26/2012	FDA/OGROP/ORAN/NE-FO/NWE- DO/NWE-CB/	LOPER, MATTHEW	EXEMPLAR PHARMACEUTICALS LLC - 483S, WARNING LTRS MOST RECENT
2012-4657	06/27/2012 07/26/2012	FDA/OGROP/ORAN/PA-FO/LOS- DO/LOS-CB/	BURGESS, BERNIE	FEI 2082851 - EIR (4/4/2007-5/9/07)
2012-4658	06/27/2012 07/26/2012	FDA/OC/OES/DFOI/	Doe J	Butterfly Bakery
2012-4659	06/27/2012 07/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PATRICIA L REGENYE Celgene Corporation	RODOLFO POSADAS-VALAY, FACULTAD DE MED HOSP UNIV, MONTERREY NL, MEXICO - 483S 7/09 TO PRESENT
2012-4660	06/27/2012 07/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PATRICIA L REGENYE Celgene Corporation	WAN-LONG CHUANG, KAOHSIUNG MED UNIV HOSPITAL, KAOHSIUNG, TAIWAN - 483S 5/10 TO PRESENT
2012-4661	06/27/2012 07/26/2012	FDA/OC/OES/DFOI/	ELENA HOWELL HOGAN LOVELLS US LLP	2012-4076
2012-4662	06/27/2012 07/26/2012	FDA/OC/OES/DFOI/	ELENA HOWELL HOGAN LOVELLS US LLP	2012-4077
2012-4663	06/27/2012 07/26/2012	OC/OM/OMP/DDM/	CARLOS CELESTINO UNITED STATES PHARMACOPEIA	DKT 1995N-0310B
2012-4664	06/27/2012 07/26/2012	OC/ORAN/OCI/ OC/ORAN/OCI/	SHAUN ASSAEL ESPN THE MAGAZINE	ILLEGAL USE AND DIVERSION OF PRESCRIPTION AND PERFORMANCE ENHANCING DRUGS IN SPORTS - CORR, RECS, GRAND JURY TESTIMONY, ETC
2012-4665	06/27/2012 07/26/2012	OC/OM/OMP/DDM/	WILLIAM CLAY III NATIONAL CORPORATE RESEARCH	DKT 1995P-0366
2012-4666	06/27/2012	OC/OM/OMP/DDM/	VIVIAN BROWN	DKT & DKT LOG OF 1994P-0168

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	07/26/2012		WESTLAW COURT EXPRESS	
2012-4667	06/27/2012 08/10/2012	FDA/OC/OES/DFOI/	Jay Smith Smith, Jay D	Terbutaline Brethine (terbutaline sulfate) - Medical Reports
2012-4668	06/27/2012 07/26/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/	Michael J. Heineman Mingace & Heineman, PC	Algee Type I Fast Setting Alginate Impression Material, White, Non-flavored - device history, complaint history, and approval letters
2012-4669	06/27/2012 07/26/2012	FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/	Michael J. Heineman Mingace & Heineman, PC	Accurate Set, Inc., Newark, NJ - inspection records, warning letters, and discipline history
2012-4670	06/28/2012 07/27/2012	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Jurij Petrin Pharmaceutical Regulatory Services, Inc	AMISULPRIDE - IND Status
2012-4671	06/28/2012 07/27/2012	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Mike Melillo MCDONALD HOPKINS LLC	HUMATROPE (Brand Name Drug) - supplement 000 (03/08/1987) and supplement 013 (08/01/1996), approval letters
2012-4672	06/28/2012 07/27/2012	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/	Robert Logan Logan, Robert	QrxPharma - Corr re: MoxDuo (06/22/2012 - 06/28/2012)
2012-4673	06/28/2012 07/27/2012	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Jessica Saucier University of Wisconsin Hospital	Methotrexate - AERs
2012-4674	06/28/2012 07/27/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORASE-FO/NOL- DO/NOL-CB/	Deb Myerson Intelysis Corp	Sqwincher Corporation, MS - approval records, complaints
2012-4675	06/28/2012 07/27/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 6/4-8/12
2012-4676	06/28/2012 07/27/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 5/28/12-6/1/12
2012-4677	06/28/2012	FDA/OC/OES/DFOI/	DEBI COHEN	FOI DAILY LOG 6/4-8/12

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	07/27/2012		WOLTERS KLUWER LAW & BUSINESS	
2012-4678	06/28/2012 07/27/2012	FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 5/28/12-6/1/12
2012-4679	06/28/2012 07/27/2012	FDA/OC/OES/DFOI/	KEN RIED WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 6/4-8/12
2012-4680	06/28/2012 07/27/2012	FDA/OC/OES/DFOI/	Test FDA	Test
2012-4681	06/28/2012 07/27/2012	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 5/28/12-6/1/12
2012-4682	06/28/2012 07/27/2012	FDA/OC/OES/DFOI/	GLADYS B TONKIN WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 6/4-8/12
2012-4683	06/28/2012 07/27/2012	FDA/OC/OES/DFOI/	GLADYS B TONKIN WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 5/28/12-6/1/12
2012-4684	06/28/2012 07/27/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 6/4-8/12
2012-4685	06/28/2012 07/27/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 5/28/12-6/1/12
2012-4686	06/28/2012 07/27/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 6/4-8/12
2012-4687	06/28/2012 07/27/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 5/28/12-6/1/12
2012-4688	06/28/2012 07/27/2012	FDA/OMPT/CDRH/OCER/DFOI/	KATRINA FIEDLER CONVATEC	C.R. BARD - DIGNISHIELD STOOL MANAGEMENT SYS K102391
2012-4689	06/28/2012 07/27/2012	FDA/OMPT/CDRH/OCER/DFOI/	KATRINA FIEDLER CONVATEC	HOLLISTER - RESTORE WOUND CLEANSER K040779
2012-4690	06/28/2012 07/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID T LIN BIOLOGICS CONSULTING GROUP	TEVA - COPAXONE NDA 20-622 APRVL PKG

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2012-4691	06/28/2012 07/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	THEIS, CYNTHIA	RECLAST ONCE A YR INJ (ZOLENDRONIC ACID) - AERS
2012-4692	06/28/2012 07/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SARAH F KASS CANNON & DUNPHY SC ATTYS	PFIZER - LO/OVRAL 28 BIRTH CONTROL CMLNPTS, TEST RESULTS, WARNINGS, ETC
2012-4693	06/28/2012 08/16/2012	FDA/OGROP/ORR/CE-FO/DET-DO/DET-CB/	STEPHANIE ELSBERRY BIOEDEN INC	COOK GENERAL BIO TECHNOLOGY LLC, INDIANAPOLIS, IN - EIRS, 483S, CO RESP 1/10 TO PRESENT
2012-4694	06/28/2012 07/27/2012	FDA/OGROP/ORR/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORR/PA-FO/SEA-DO/SEA-CB/	CARLA R SCARMAZZI King & Spalding LLP	PHILIPS MEDICAL SYSTEMS, SEATTLE, WA - 3/22-28/12; PHILIPS MEDICAL CENTER CLEVELAND, OH EIRS, 483S, CO RESP, ETC 3/22/11, 3/28/11, 6/6/11
2012-4695	06/28/2012 07/27/2012	OC/CVM/OCD/	ROB GRUBB COOK ANIMAL HEALTH	GENTOCIN PINK EYE SPRAY NADA 130-952- FOI SUMMARY
2012-4696	06/28/2012 07/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CYNTHIA HOLLAND HOLLAND, CYNTHIA J	CIMZIA (certolizumab pegol) - AERs (01/01/2007 - 07/01/2012)
2012-4697	06/28/2012 07/27/2012	FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/	Robin Strickland TECMAC, LLC	Evolution Packaging, Grand Prairie, TX and Coppell, TX - Complaints, etc. (06/01/2010 - 06/27/2012)
2012-4698	06/28/2012 07/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ENGLISH, ELIZABETH	TYSABRI - AER
2012-4699	06/28/2012 07/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TIMOTHY LITZENBURG MILLER FIRM	CORR RECEIVED BY DR JERI EL HAGE RE POIGLITAZONE (ACTOS)
2012-4700	06/28/2012 07/27/2012	FDA/OC/OES/DFOI/ OC/ORR/OE/ OC/ORR/OE/	RAVNITZKY, MICHAEL	INFORMATION DISCLOSURE MANUAL
2012-4701	06/28/2012	FDA/OMPT/CDRH/OCER/DFOI/	JACK N. McCUTCHEON	CMLNPT AGAINST NEEQUIP INC

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	07/27/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	SAM MEDICAL PRODUCTS	
2012-4702	06/28/2012 07/27/2012	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	BRANDON FERGUSON OC WEEKLY	OZELLE PHARMS - ANVIRZEL 483, WARNING LTRS 1/99 TO PRESENT
2012-4703	06/28/2012 07/27/2012	OC/ORAOCI/ OC/ORAOCI/	MARK S. LEVINSTEIN WILLIAMS & CONNOLLY LLP	DOCUMENTS PERTAINING TO LANCE ARMSTRONG
2012-4704	06/28/2012 07/27/2012	OC/CVM/OCD/	ANN MARIE GAITAN SANDLER TRAVIS & ROSENBERG PA	GLUCOAMYLASE PORTEASE - INVESTIGATIONS
2012-4705	06/28/2012 07/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID N. SIMON MARULLI LINDENBAUM ET AL	INDIVIDUAL RECS
2012-4706	06/28/2012 07/27/2012	FDA/OC/OES/DFOI/	MICHELE LEE BUENAFE MORGAN LEWIS	AM2PAT INC, ANGIER, NC - EIR, 483
2012-4707	06/28/2012 07/27/2012	FDA/OC/OES/DFOI/	MICHELE LEE BUENAFE MORGAN LEWIS	AM2PAT INC, ANGIER, NC - EIR, 483 12/18/07-1/08
2012-4708	06/29/2012 07/30/2012	OC/OM/OMP/DDM/	VIVIAN BROWN WESTLAW COURT EXPRESS	DKT 1994P-0168
2012-4709	06/29/2012 07/30/2012	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	JOHNATHAN RICKMAN FDA NEWS	MARLIN COMPANY INC, LENOIR, NC; DSM PHARMACEUTICALS INC, GREENVILLE, NC; METRICS INC, GREENVILLE, NC, ETC - 483S 4/12 TO 5/12
2012-4710	06/29/2012 07/30/2012	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	JOHNATHAN RICKMAN FDA NEWS	BTE TECHNOLOGIES INC, HANOVER, MD; SPECIALTY THERAPY EQUIPMENT INC, TOWSON, MD; BOEHRINGER INGELHEIM CHEMICALS INC, PETERSBURG, VA, ETC - 483S 4/12 TO 5/12
2012-4711	06/29/2012 07/30/2012	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	JOHNATHAN RICKMAN FDA NEWS	THORNTON INDUSTRIES INC, MORRIS, IL; MERICON INDUSTRIES INC, PEORIA, IL; AKORN INC, DECATUR, IL, ETC - 483S 4/12 TO 5/12
2012-4712	06/29/2012 07/30/2012	FDA/OGROP/ORACE-FO/CINDO/CIN-CB/	JOHNATHAN RICKMAN FDA NEWS	APPLIED MEDICAL TECHNOLOGY INC, BRECKSVILLE, OH; SPARTON MEDICAL, STRONGSVILLE, OH; USA INSTRUMENTS INC, AURORA, OH, ETC - 483S 4/12 TO 5/12
2012-4713	06/29/2012 07/30/2012	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	JOHNATHAN RICKMAN FDA NEWS	CELLTEX THERAPEUTICS CORP, SUGAR LAND, TX; GENESYS ORTHOPEDIC SYSTEMS LLC, AUSTIN, TX; SUTURAS MEDICAL LLC, EAGLE PASS, TX, ETC - 483S 4/12 TO 5/12
2012-4714	06/29/2012	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	JOHNATHAN RICKMAN	OSO BIOPHARMACEUTICALS MANUFACTURING LLC, ALBUQUERQUE, NM; HOSPIRA BOULDER INC, BOULDER,

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	07/30/2012		FDA NEWS	CO; CONMED ELECTROSURGERY, CENTENNIAL, CO, ETC - 483S 4/12 TO 5/12
2012-4715	06/29/2012 07/30/2012	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	JOHNATHAN RICKMAN FDA NEWS	L PERRIGO CO, ALLEGAN, MI; DOW CORNING CORP, HEMLOCK, MI; ZIMMER INC, WARSAW, IN, ETC - 483S 4/12 TO 5/12
2012-4716	06/29/2012 07/30/2012	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	JOHNATHAN RICKMAN FDA NEWS	21ST CENTURY ONCOLOGY LLC, PORT CHARLOTTE, FL; AWARENESS TECHNOLOGY INC, PALM CITY, FL; MICROTEK MEDICAL INC, JACKSONVILLE, FL, ETC - 483S 4/12 TO 5/12
2012-4717	06/29/2012 07/30/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	JOHNATHAN RICKMAN FDA NEWS	SANOPI PASTEUR SA, MERCY L ETOILE, FRANCE; SANOPI PASTEUR LTD, TORONTO, CANADA; KEDRION SPA, BOLOGNA, ITALY - 483S 4/12 TO 5/12
2012-4718	06/29/2012 07/30/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHNATHAN RICKMAN FDA NEWS	NORDION CANADA INC, KANATA, CANADA; BIZEN CHEMICAL CO LTD, OKAYAMA, JAPAN; PEPTIDO GMBH, BEXBACH, GERMANY, ETC - 483S 4/12 TO 5/12
2012-4719	06/29/2012 07/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	JOHNATHAN RICKMAN FDA NEWS	BOUKHARI PRINCE MEDICAL, BIZERTE, TUNISIA; GE HEALTHCARE JAPAN CORP, HINO-SHI TOKYO, JAPAN; BL INDUSTRIA OTICA LTD, PORTO ALEGRE, BRAZIL, ETC - 483S 4/12 TO 5/12
2012-4720	06/29/2012 07/30/2012	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	JOHNATHAN RICKMAN FDA NEWS	EMERALD 3 ENTERPRISES INC, CAMDENTON, MO; RELIABLE BIOPHARMACEUTICAL CORP, OVERLAND, MO; QA LABORATORIES INC, KANSAS CITY, MO, ETC - 483S 4/12 TO 5/12
2012-4721	06/29/2012 07/30/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	JOHNATHAN RICKMAN FDA NEWS	AARON INDUSTRIES INC, LYNWOOD, CA; WESTWOOD LABORATORIES, AZUSA, CA; ALLIANCE MEDICAL PRODUCTS INC, IRVINE,, CA, ETC - 483S 4/12 TO 5/12
2012-4722	06/29/2012 07/30/2012	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	JOHNATHAN RICKMAN FDA NEWS	DAKOTA LABORATORIES LLC, MITCHELL, SD; AJD LABORATORIES LLC, PARK RAPIDS, MN; CONVERTING BIOPHILE LABORATORIES INC, FOND DU LAC, WI, ETC - 483S 4/12 TO 5/12
2012-4723	06/29/2012 07/30/2012	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	JOHNATHAN RICKMAN FDA NEWS	PRECISION DERMATOLOGY INC, CUMBERLAND, RI; PHARMALUCENCE INC, BEDFORD, MA; SPECTRA MEDICAL DEVICES INC, WILMINGTON, MA, ETC - 483S 4/12 TO 5/12
2012-4724	06/29/2012 07/30/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	JOHNATHAN RICKMAN FDA NEWS	CONTRACT COATING INC, HACKENSACK, NJ; CISPHARMA INC, CRANBURY, NJ; AKORN INC, SOMERSET, NJ, ETC - 483S 4/12 TO 5/12
2012-4725	06/29/2012 07/30/2012	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	JOHNATHAN RICKMAN FDA NEWS	NIDEK MEDICAL PRODUCTS INC, BIRMINGHAM, AL; AIRERX HEALTHCARE LLC, HENDERSONVILLE, TN; MERGE HEALTHCARE, WINCHESTER, TN, ETC - 483S 4/12 TO 5/12
2012-4726	06/29/2012	FDA/OGROP/ORANE-FO/NYK-	JOHNATHAN RICKMAN	MALLINCKRODT INC, HOBART, NY; CONMED CORP, UTICA,

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	07/30/2012	DO/NYK-DCB/	FDA NEWS	NY; NETECH CORP, FARMINGDALE, NY, ETC - 483S 4/12 TO 5/12
2012-4727	06/29/2012 07/30/2012	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	JOHNATHAN RICKMAN FDA NEWS	ALEX C FERGUSON INC, CHAMBERSBURG, PA; SCANDINAVIAN FORMULAS INC, SELLERSVILLE, PA; GLOBUS MEDICAL INC, AUDOBON, PA, ETC - 483S 4/12 TO 5/12
2012-4728	06/29/2012 07/30/2012	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	JOHNATHAN RICKMAN FDA NEWS	NOVARTIS VACCINE AND DIAGNOSTICS INC, EMERYVILLE, CA; GENERITECH CORP, FRESNO, CA; ALZA CORP, VACAVILLE, CA, ETC - 483S 4/12 TO 5/12
2012-4729	06/29/2012 07/30/2012	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	JOHNATHAN RICKMAN FDA NEWS	OLAY LLC, CAYEY, PR; LILLY DEL CARIBE INC, CAROLINA, PR - 483S 4/12 TO 5/12
2012-4730	06/29/2012 07/30/2012	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	JOHNATHAN RICKMAN FDA NEWS	FORMULA CORP, AUBRUN, WA; MICRO CURRENT TECHNOLOGY INC, SEATTLE, WA; PEDIGO PRODUCTS INC, VANCOUVER, WA, ETC - 483S 4/12 TO 5/12
2012-4731	06/29/2012 07/30/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	CLOSED FOI REQUESTS 6/11-15/12
2012-4732	06/29/2012 07/30/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 6/11-15/12
2012-4733	06/29/2012 07/30/2012	FDA/OC/OES/DFOI/	WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 6/11-15/12
2012-4734	06/29/2012 07/30/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 6/18-22/12
2012-4735	06/29/2012 07/30/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOI REQUESTS 6/11-15/12
2012-4736	06/29/2012 07/30/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOI REQUESTS 6/18-22/12
2012-4737	06/29/2012 07/30/2012	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Liz Wagner NBC Bay Area News (KNTV)	San Francisco Herb & Natural Food Company, Fremont, California - Inspection and Enforcement Records since 2002
2012-4738	06/29/2012 07/30/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Todd Greenberg Steinbrecher & Associates	Carex Model No. A222-00 Roller Walker - Recall, Complaint Recs
2012-4739	06/29/2012 07/30/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Janet McChristion Fresenius Kabi - APP	Approval Letters for 39 products: 065286 -3/23/2011, 076619-6/29/2011, 078339-7/25/2011, etc.

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2012-4740	06/29/2012 07/30/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Cindy McReynolds UNIVERSITY OF CALIFORNIA AT DAVIS	IND 77,262
2012-4741	06/29/2012 07/30/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nikki Cimas Fitts Zehl LLP	NDA 20-031 (Paxil)
2012-4742	06/29/2012 07/30/2012	FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/	Melanie Jackson Fresenius Kabi USA	Allergy Laboratories, Inc., Oklahoma City, Oklahoma - 483 (06/12/2012 - 06/27/2012)
2012-4743	06/29/2012 07/30/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 6/18-22/2012
2012-4744	06/29/2012 07/30/2012	FDA/OGROP/ORO/CE-FO/PHI-DO/PHI-CB/	Stroupe, Kim Stroupe, Kim	Fragrance Manufacturing Inc. D/b/a FMI, Allentown, PA - Inspection Records (08/30/10)
2012-4745	06/29/2012 07/30/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	INC RESEARCH	Hetrazan - approval letter, labeling, medical review, etc.
2012-4746	06/29/2012 07/30/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	NEW YORK MEDICAL COLLEGE	Sample of 510 (k) application for PICC line
2012-4747	06/29/2012 07/30/2012	OC/OA/OM/OMP/DDM/	Smilja Pejanovic CTK; University of Ljubljana	Retrospective review of ecotoxicity data submitted in environmental assessment for public display; Docket No. 96N-0057
2012-4748	06/29/2012 07/30/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 6/25-29/2012
2012-4749	06/29/2012 07/30/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOIA requests closed 6/1-30/2012
2012-4750	06/29/2012 07/30/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 6/18-22/12
2012-4751	06/29/2012 07/30/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 6/18-22/12
2012-4752	06/29/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND	CLOSED FOIA REQUESTS 6/18-22/12

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	07/30/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	FDA WEBVIEW/FERDIC INC	
2012-4753	07/02/2012 07/31/2012	OC/OM/OMP/DDM/	VALERIE RAMSEY CB FLEET COMPANY	DKT 1978N-0021D
2012-4754	07/03/2012 08/01/2012	FDA/OMPT/CDRH/OCER/DFOI/	STOFFREGEN, ROBERT T	LOMA LINDA UNIVERSITY MEDICAL CENTER, LOMA LINDA, CA - PROTON RADIATION THERAPY K872369
2012-4755	07/03/2012 08/01/2012	FDA/OMPT/CDRH/OCER/DFOI/	TERRY THOMAS ARIZONA ONCOLOGY SERVICES	ISORAY - PROXCLEAN CS 131 PRELOADED BRAIDED STRANDS K092136
2012-4756	07/03/2012 08/01/2012	FDA/OMPT/CDRH/OCER/DFOI/	MATT CLAUSEN MEDLINE INDUSTRIES INC	ENDOCHOICE INC - BIOPSY VALVE K111821; BYRNE MEDICAL INC - DEFENDO BIOPSY VALVE FOR OLYMPUS K090851; UNITED STATES ENDOSCOPY GROUP INC - BIOSHIELD-ERCP BIOPSY VALVE K070420, ETC
2012-4757	07/03/2012 08/01/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FRED TROMBERG LAW OFFICES OF FRED TROMBERG	NOVARTIS PHARMS - RECLAST (ZOLEDONATE) AERS
2012-4758	07/03/2012 08/01/2012	FDA/OFVM/CFSAN/OCD/EOS/	FOI Services, Inc.	BIOENGINEERED SUPPLEMENTS & NUTRITION INC - CAERS #97789, 99626, 10256, ETC
2012-4759	07/03/2012 08/01/2012	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	DAVID LOHMAN SANESA PARTNERS	CORDEN PHARMA COLORADO, BOULDER, CO - 483S, WARNING LTRS, UNTITLED LTRS, ETC 7/1/11 TO PRESENT
2012-4760	07/03/2012 08/01/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHANDRAN TIRUVATTAR DR REDDY'S LABORATORIES INC	PERRIGO, ISRAEL - CLINDAMYCIN PHOSPHATE & BENZOYL PEROXIDE ANDA 90-979 SBA
2012-4761	07/03/2012 08/01/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JENNIFER R KELLEY NEOS THERAPEUTICS	HYDROCOCODONE POLISTIREX, CHLORPHENIRAMINE POLISTIREX ER ORAL SUSPENSION ANDA 91-632 AERS
2012-4762	07/03/2012 08/01/2012	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	JENNIFER HSIEH	XEMPLAR PHARMS - 483S 2012
2012-4763	07/03/2012 08/01/2012	FDA/OMPT/CTP/OD/	GREGORY N CONNOLLY HARVARD SCHOOL OF PUBLIC HEALTH	PHILIP MORRIS - MARLBORO LIGHT CIGARETTES LTR 6/17/11
2012-4764	07/03/2012	FDA/OFVM/CFSAN/OCD/EOS/	BRYAN W BLACK	PROLAB NUTRITION INC - CLASS 1 RECALLS EIRS, INCIDENTS RPTS, PHOTOGRAPHS, ETC 9/30/11

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	08/01/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	DERREVERE, HAWAKES, BLACK ET AL	
2012-4765	07/03/2012 08/01/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	MEDTRONIC INC - ACTIVE RC RECHARGEBLEP960009/S051; ACTIVA PC IMPLANTABLE....P960009/S052
2012-4766	07/03/2012 08/01/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	CYBERONICS INC - CYBERONICS VNS THERAPY, P970003/S065
2012-4767	07/03/2012 09/11/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	FOI Services, Inc.	SYSMEX AMERICA INC - SYSMEX XE-2100D; XS-1000i, BK080067
2012-4768	07/03/2012 08/01/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	THALOMID (THALIDOMIDE), NDAS 21-430 & 20-485; REVLIMID (LENALIDOMIDE), NDA 21-880; VELCADE (BORTEZOMIB), NDA 21-602 -RPTS, ANALYSES, RECS
2012-4769	07/03/2012 08/01/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	FOI Services, Inc.	SANQUIN PLASMA PRODUCTS, AMSTERDAM, NETHERLANDS - EIRS, 2012
2012-4770	07/03/2012 08/01/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	PLAXTRON - PLAXTRON SUCTION UNIT MODEL 88AA51/88AA61 SERIES, K120065
2012-4771	07/03/2012 08/01/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	STERIS CORP- AMSCO V-PRO 1 LOW TEMP STERILIZATION SYS; AMSCO V-PRO 1 PLUS LOW TEMP STERILIZATION SYS, K102394
2012-4772	07/03/2012 08/01/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	FOI Services, Inc.	STERIS CORP - AMSCO V-PRO MAX LOW TEMP STERILIZATION SYS, K102330
2012-4773	07/03/2012 08/01/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	AMNEAL PHARMACEUTICALS - NITROFURANTION (NITROFURANTOIN) ANDA 201-679
2012-4774	07/03/2012 08/01/2012	OC/ORPA/ OC/ORPA/ FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	TURNER, ERWIN L TURNER, ERWIN L	CMPLNT #121322
2012-4775	07/03/2012 08/01/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLOTTE HEYMAN NEOS THERAPEUTICS	DEXTROAMPHETAMINE SACCHARATE, AMPHETAMINE ASPARTATE, DEXTROAMPHETAMINE SULFATE ETC ANDA 77-302 - APRVL RECS
2012-4776	07/03/2012	FDA/OMPT/CDRH/OCER/DFOI/		CMPLNT RESULTS (3/20/12) - TEMPO MEDICAL CO-EASE & FISHER-BRAND LATEX-FREE BANDAGES

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	08/01/2012		Doe J	
2012-4777	07/03/2012 08/01/2012	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	CMLPNT RESULTS, (2/8/12) - TEMPO MEDICAL PRODUCTS, FISHER HEALTHCARE, MOORE MEDICAL LLC, COVIDIEN (TYCO HEALTHCARE) ETC
2012-4778	07/03/2012 08/01/2012	FDA/OC/OES/DFOI/	MICHAEL SMITH BLOOMBERG NEWS	2012-2780 - MINOR DELETIONS
2012-4779	07/03/2012 08/01/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/ FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/ FDA/OC/OES/DFOI/	JENNIFER HSIEH HEALTHCARE RESEARCH CONSULTING GROUP	ACTAVIS PHARMA MFG PRIVATE LTD, KANCHIPURAM, INDIA, 5/21/12; APOTEX FERMENTATION INC, WINNIPEG, CANADA, 6/7/12; APP PHARMACEUTICALS LLC, SCHAUMBURG, IL, 5/4/12 ETC - 483S
2012-4780	07/03/2012 08/01/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Andrew Kempton LEO-Pharma	Coumadin (warfarin) - Original Review Package
2012-4781	07/03/2012 08/01/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	LEO-Pharma	Coumadin (warfarin) original review package
2012-4782	07/03/2012 08/01/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kimberly Schlatter	Records re: Unauthorized Promotion of Effient (04/01/2012 - 06/29/2012)

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2012-4783	07/03/2012 08/01/2012	FDA/OC/OES/DFOI/	Rosemarie Donnelly Texas Attorney General	Medicine Chest Institutional in Sulphur Springs, TX and Medical Discount Pharmacy a/k/a Lifecek Pharmacies in Rosenberg, TX.
2012-4784	07/03/2012 08/01/2012	FDA/OC/OES/DFOI/	MATTHEW PERRONE ASSOCIATED PRESS	CELLTEX THERAPEUTICS CORP, SUGAR LAND, TX - 483
2012-4785	07/03/2012 08/01/2012	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	LaToya Fox NOW Foods contact LaToya Fox	Pharmaceuticals, Inc., Indianapolis, IN (09/05/2011 - 11/01/2011) - EIR, 483, etc.
2012-4786	07/03/2012 08/01/2012	FDA/OFVM/CFSAN/OCD/EOS/	Dianne L. Chambers HOGAN LOVELLS LLP	Section 912 of the FDA Amendments Act of 2007 - Corr etc. (02/01/2012 -06/29/2012)
2012-4787	07/03/2012 08/01/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Willene Brondum Insys Therapeutics, Inc.	NDA 20-732 - SBA
2012-4788	07/03/2012 08/01/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Wei-wei Chang NuTec Incorporated	Macrobid NDA 020064 Nitrofurantoin - SBA
2012-4789	07/03/2012 08/01/2012	FDA/OC/OES/DFOI/	Doe J	Individual Records
2012-4790	07/03/2012 08/01/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Wei-wei Chang NuTec Incorporated	Nitrofurantoin (monohydrate/macrocrystals) capsule, Sandoz ANDA 077066 - SBA
2012-4791	07/03/2012 08/01/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Wei-wei Chang NuTec Incorporated	Nitrofuantoin (monohydrate/macrocrystals) capsules ANDA 076648 Mylan - SBA
2012-4792	07/03/2012 08/01/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	GARDASIL - VAERs 4/1/2012 to 6/30/2012
2012-4793	07/03/2012 08/01/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ROTATEQ - VAERs 4/1/2012 to 6/30/2012
2012-4794	07/03/2012	FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16)	VICTRELIS - AERs 4/1/2012 to 6/30/2012

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	08/01/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MERCK & CO., INC.	
2012-4795	07/03/2012 08/01/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	DULERA - AERs 4/1/2012 to 6/30/2012
2012-4796	07/03/2012 08/01/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	JUVISYNC - AERs 4/1/2012 to 6/30/2012
2012-4797	07/03/2012 08/01/2012	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	BURGESS, BERNIE BURGESS, BERNIE	Assignment number 808885, attachment to establishment inspection report 2082851
2012-4798	07/05/2012 08/02/2012	FDA/OC/OES/DFOI/	BAUMANN, JEANNIE	CELL LEX STEM - 483
2012-4799	07/05/2012 08/02/2012	FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	Doe J	CMPLNT 126713 - INVESTIGATION RESULTS
2012-4800	07/05/2012 08/02/2012	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	RANIL M FERNANDO BIOSCREEN TESTING SERVICES INC	BIOSCREEN TESTING SERVICES INC, TORRANCE, CA - EIRS, 483S, WARNING LTRS, ETC
2012-4801	07/05/2012 08/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HARLAN M KRUMHOLZ YALE UNIVERSITY	RANDEXA (RANOLAZINE) NDA 21-526/S004 - APRVL, RVWS, LBLG, ETC
2012-4802	07/05/2012 08/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARIA A JOHNSON YALE UNIVERSITY	RANDEXA (RANOLAZINE) - NDA 021526/S004, APRVL, RVWS, LBLG ETC
2012-4803	07/05/2012 08/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOSEPH S ROSS, MD, MHS YALE UNIVERSITY	NDA 021526/S004 - APRVL, RVWS, LBLG ETC
2012-4804	07/05/2012	FDA/OMPT/CDER/ORP/DIDP/	FRED TROMBERG	NOVARTIS PHARMACEUTICALS - RECLAST (ZOLEDRONIC ACID 'INN' OR ZOLEDRONATE), AERS, RECS ETC 2005 TO

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	08/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LAW OFFICES OF FRED TROMBERG	PRESENT
2012-4805	07/05/2012 08/02/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	RANGER (RICHARD) D BAYER BAYER, RANGER (RICHARD D	HEMOGLOBIN STANDARDS & MAINTAINING ADEQUATE IRON STORES IN BLOOD DONATORS - PUBLIC WORKSHOP PRESENTATIONS 11/8-9/11
2012-4806	07/05/2012 08/02/2012	FDA/OMPT/CDRH/OCER/DFOI/	KATRINA FIEDLER CONVATEC	DPT LABS (HEALTHPOINT MEDICAL) - ALLCLENZ WOUND CLEANSER, K965120
2012-4807	07/05/2012 08/02/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	SHIN KANG, PHD WELLS FARGO SECURITIES	CINRYZE, SABQYUB, ANSTERDAM - EIR 9/19-28/11
2012-4808	07/05/2012 08/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	JAZZ - XYREM (SODIUM OXYBATE), NDA 21-196, PRE-CLINICAL TOXICOLOGICAL RECS
2012-4809	07/05/2012 09/13/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORACE-FO/BLT- DO/BLT-CB/ OC/ORACE/OCI/ OC/ORACE/OCI/	KERRIE WEBB KERSHAW CUTTER & RATINOF LLP	INDIVIDUAL RECS
2012-4810	07/05/2012 08/02/2012	FDA/OGROP/ORACE-FO/NYK- DO/NYK-DCB/ OC/ORACE/OCI/ OC/ORACE/OCI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORACE-FO/NYK- DO/NYK-DCB/	Doe J	COLUMBIA UNIV, NEW YORK, NY - EIRS, RECS, COMM ETC, 1/1/07 TO 7/2/12
2012-4811	07/05/2012 08/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	TEVA PHARMACEUTICALS - COPAXONE, CO RESP TO WARNING LTR, CORR ETC
2012-4812	07/05/2012 08/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOSE A DOS SANTOS POSTERNAK BLANKSTEIN ET AL	BANANA BOAT, SUN PHARMACETICALS CORP, ETC - AERS, RECS ETC

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2012-4813	07/05/2012 08/02/2012	FDA/OGROP/ORA/ORO/DIOP/	P. A. Scolnik Koru Naturals LLC	66-41 Import Alert 36 C
2012-4814	07/05/2012 08/02/2012	FDA/OC/OES/DFOI/ OC/ORA/ORM/ OC/ORA/ORM/	Linda A. Johnson THE ASSOCIATED PRESS	Johnson & Johnson- Listing of 483s, previously released 483s
2012-4815	07/05/2012 08/02/2012	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	DOUGLAS N BLUE II ZETETIC INC	LIFESCAN - ENTRY F23-9050001-5-1-1, 11/10/11, RECOVERY OF TEST STRIP SAMPLES TAKEN
2012-4816	07/05/2012 08/02/2012	FDA/OFVM/CFSAN/OCD/EOS/	Jheimbach LLC	Comment received by FDA/CFSAN/OFAS concerning GRAS Notice No. GRN 429
2012-4817	07/05/2012 08/02/2012	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	Matthias Mueller GENENTECH INC	Seattle Genetics, Inc., Bothell, WA, - 483 5/11, 7/11
2012-4818	07/05/2012 08/02/2012	OC/OA/OM/OMP/DDM/	Jennifer Brown INFOTRIEVE	67th ANTI-INFECTIVE DRUGS ADVISORY COMMITTEE paper
2012-4819	07/05/2012 08/02/2012	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	Linda Larsen Food Poisoning Bulletin	Mexicali Cheese Corp. - Recall and Investigation Records
2012-4820	07/05/2012 08/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michele Sinoway Lachman Consultants	Wockhardt, Aurangabad - EIR (2010)
2012-4821	07/05/2012 08/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	David Cluck ETSU Gatton College of Pharmacy	Linezolid - AERs
2012-4822	07/05/2012 08/02/2012	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	Individual Records
2012-4823	07/05/2012	FDA/OMPT/CDRH/OCER/DFOI/	KATE HERSH-BOYLE	BONET MFG CORP/BIOMET ORTHOPEDICS LLC - BIOMET

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	08/02/2012		HERSH & HERSH	VANGUARD PS OPEN BOX 62.T LEFTINTERLOCK; BIOMET VANGUARD MICROPLASTY SLIDEX FEMORAL 4-IN-1 BLOCK STAINLESS STEEL; VANGUARD DCM PS PLUS 16MM X 63/67MM T/BIAL BEARING AERS, DEFECTS, RECS ETC
2012-4824	07/05/2012 08/02/2012	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	Nina Chinery-Hesse/Christopher Both PRACS INSTITUTE, LTD.	Lawrence Galitz, MD - EIR (11/10/2011 - 12/01/2011)
2012-4825	07/05/2012 08/02/2012	FDA/OMPT/CDRH/OCER/DFOI/	Dr. David Lim Dr. David Lim	483s and EIRs for the month of June, 2012 issued by OC and OIVD of CDRH
2012-4826	07/05/2012 08/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lynn Reinholdt Reinholdt, Lynn	Lorcaserin - NDA
2012-4827	07/05/2012 08/02/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OES/DFOI/ OC/OA/OM/OMP/DDM/	KATHERINE B RILEY BARRETT LAW GROUP PA	DEL MONTE - FRUIT NATURALS PRODS, FRESHCUT VEGETABLE PRODS LBLG, INVESTIGATION, RECHNICAL RVWS, ETC
2012-4828	07/05/2012 08/02/2012	FDA/OC/OES/DFOI/	SHELLEY K SPOFFORD MCINTYRE & BARNES PLLC	H&P INDUSTRIES/TRIAD GROUP - EIRS & RECS 2009 AND PRIOR
2012-4829	07/05/2012 08/02/2012	OC/ORR/ OC/ORR/ OC/OCM/EMOPS/ FDA/OFVM/CFSAN/OCD/EOS/	LINDSEY B LAZOPOULOS K&L GATES	E COLI OUTBREAK - LETTUCE, EIRS, RECS, COMM ETC 10/09
2012-4830	07/05/2012 08/02/2012	FDA/OMPT/CTP/OD/	COVINGTON & BURLING LLP	DOMESTIC MFRS OF NEW TOBACCO PRODS, - INVESTIGATION RESULTS OF INTERSTATE COMMERCE SALE
2012-4831	07/05/2012 08/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	belldegrun, ron belldegrun, ron	Belviq - SBA
2012-4832	07/05/2012 08/02/2012	FDA/OMPT/CDRH/OCER/DFOI/	Noe M. Rivera Covidien- Product Monitoring	MAUDE Report 2516200
2012-4833	07/05/2012 08/02/2012	FDA/OMPT/CDRH/OCER/DFOI/	Abhijit Sharma DePaul University	K061993
2012-4834	07/05/2012 08/02/2012	FDA/OMPT/CTP/OD/ FDA/OC/OES/DFOI/	Saad Kamal CAPSTONE LLC	Menthol in Cigarettes

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2012-4835	07/05/2012 08/02/2012	FDA/OMPT/CDRH/OCER/DFOI/	Jeremy P. Oczek Bond, Schoeneck & King, PLLC	AirWare Holdings - submissions re: AIR ALLERGY; AIR BREATHE; AIR DECONGEST etc.
2012-4836	07/05/2012 08/02/2012	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	David Michail David Michail	PROSTHETIC SILICON BREAST IMPLANTS
2012-4837	07/05/2012 08/02/2012	FDA/OC/OES/DFOI/	Medacta USA	Orthopedics;
2012-4838	07/05/2012 08/02/2012	FDA/OO/OFBA/OAGS/	NATHAN M PEAK ASHCRAFT & GEREL LLP	PRECISION PANEL ERECTORS (GS11P10MKC0023); TSI/ARCHITECTURAL METALS INC (GS11P10MKCOO23); PRIME CONTRACTOR (GS11P10MKC0023) - CERTIFIED WKLY PAYROLLS 2010, 2011, 2012
2012-4839	07/05/2012 08/02/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/CVM/OCD/	ANN MARIE GAITAN SANDLER TRAVIS & ROSENBERG PA	USE OF GLUCOAMYLASE, PORTEASE, ALPHA-AMYLASE & DISTILLER GRAIN/DISTILLERS IN ANIMAL FEED - RECS, RVWS, MEMOS, ETC
2012-4840	07/05/2012 08/02/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	CLAUDIA ISING LOHMANN & RAUSCHER GMBH & CO	TISSUE REPAIR CO, SAN DIEGO, CA - EXCELLAGEN DRESSING, WOUND, DRUG K110318
2012-4841	07/05/2012 08/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOANNE S HAWANA ARENT FOX LLP	ISRS 8017300, 8103521, 8181160 ETC
2012-4842	07/05/2012 08/02/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	DOUGLAS N BLUE II ZETETIC	ENTRY EB515112945 - HEALTH & BEAUTY PRODS, RECS, PHOTOS ETC
2012-4843	07/05/2012 08/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	VAL SAWYER ZYMOGENETICS INC	ISR 8244360 - BOVINE THROMBIN/THROMBIN NOS/THROMBIN MOST RECENT
2012-4844	07/05/2012 08/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	MICHAEL L RICH PORZIO BROMBERG & NEWMAN PC	ALLIANCE LABS LLC - ENEMEEZ MINI ENEMA, ENEMEEZ PLUS MINI ENEMA, DOCUSOL MINI ENEMA ETC, AERS LAST 10 YRS
2012-4845	07/05/2012	FDA/OMPT/CDER/ORP/DIDP/	ELLEN GABLER	FDA DEBARMENT LIST - NAME OF FIRM, CITY, STATE ETC

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	08/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MILWAUKEE JOURNAL SENTINEL	
2012-4846	07/05/2012 08/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELAINE S WALLER SEATTLE GENETICS INC	GENETICS - ADCETRIS (BRENTUXIMAB VEDOTIN) ISRS 8131234, 8202828, 8250160
2012-4847	07/05/2012 08/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BENJAMIN P LEWIS MITSUBISHI TANABE PHARMA DEVELOPMENT OF AMERICA INC	MITSUBISHI TANABE PHARMA CORP - IND 101,322- NALFURAFINE HYDROCHLORIDE (TRK-820), SERIAL NOS 1-14
2012-4848	07/05/2012 08/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BENJAMIN P LEWIS MITSUBISHI TANABE PHARMA DEVELOPMENT OF AMERICA INC	MITSUBISHI TANABE PHARMA CORP - PRE-IND 72,361 NALFURAFINE HYDROCHLORIDE (TRK-820), SERIAL NOS 1-7; 10-31, 34-39 ETC 8/15/05
2012-4849	07/06/2012 08/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SUZANNE SPENCE MYLAN INSTITUTIONAL	ASTRAZENECA -FALODEX (FULVESTRANT) INJ NDA 21-344 SBA
2012-4850	07/06/2012 08/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SUZANNE SPENCE MYLAN INSTITUTIONAL	ABBOTT - CISATRICURIUM; BESYLATE ANDA-200-514; SANDOZ - CISATRICURIUM BESYLATE INJA NDA 200-154 ;/ SANDOZ - CISTRICURITUM BESYLATE INJ ANDA 200-159 SBA
2012-4851	07/06/2012 08/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RICK JS KIM LYNCH DASKAL EMERY LLP	BAYER AG - AVELOX, MEDWATCH SAFETY ALERTS, AERS, CORR, ETC 12/02 TO PRESENT
2012-4852	07/06/2012 08/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORACE-FO/BLT- DO/BLT-CB/	RICK J S KIM LYNCH DASKAL EMERY LLP	CB FLEET & COMPANY INC - FLEET SALINE ENEMA, FLEET ENEMA SALINE, FLEET ENEMA EXTRA; SODIUM PHOSPHATE BASED ENEMAS AERS, EIRS, AUDITS, ETC 12/02 TO PRESENT

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2012-4853	07/06/2012 08/03/2012	FDA/OMPT/CDRH/OCER/DFOI/	AMY ENGLEBERT PARKER HANNIFIN	PRE-SET 50/50 NITROUS OXIDE/OXYGEN MIXER - K760766; NITRONOX SCAVENGER (FRASER HARLAKE) - K821744; NITRONOX FIRST RESPONSE NITRONOX - K883833/A
2012-4854	07/06/2012 08/03/2012	FDA/OMPT/CDRH/OCER/DFOI/	KIM CHRISTIAN TELEFLEX MEDICAL	RESPIRATORY CARE INC - HUDSON RCI MODIFIED CONCHAATHERM III CONTROLLED HEATER K884150
2012-4855	07/06/2012 08/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SUZANNE SPENCE MYLAN INSTITUTIONAL	QOL MEDICALI - OLEATE INJ NDA 19-359 SBA
2012-4856	07/06/2012 08/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MCILLIAN NO 83854, CHARLES JEFFRE	LIST OF MURDERS/ATTEMPTED MURDERS/THREATS OF PHYSICAL ATTACKS WITH TRIAZOLAM - MEMO
2012-4857	07/06/2012 08/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	G SRINIVAS ZYDUS PHARMACEUTICALS USA INC	MERCAPTOPURINE TABS 50 MG NDA 09-053 - SBA
2012-4858	07/06/2012 08/03/2012	FDA/OGROP/OR/NE-FO/NYK- DO/NYK-DCB/	TRAVIS SCHAFTENAAR USB GLOBAL ASSET MANGEMENT	COOPER COMPANIES, WEST HENRIETTA, NY - 483S 10/14- 24/11
2012-4859	07/06/2012 09/07/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/OR/SE-FO/NOL- DO/NOL-CB/	KERRIE WEBB KERSHAW CUTTER & RATINOF LLP	INDIVIDUAL RECS
2012-4860	07/06/2012 08/03/2012	FDA/OMPT/CDRH/OCER/DFOI/ OC/OA/OM/OMP/DDM/ FDA/OGROP/OR/SE-FO/NOL- DO/NOL-CB/	KERRIE WEBB KERSHAW CUTTER & RATINOF LLP	WRIGHT MEDICAL TECHNOLOGY - CONSERVE PLUS QUADRA-FIX CUP RECS
2012-4861	07/06/2012 08/07/2012	FDA/OMPT/CDRH/OCER/DFOI/ OC/OA/OM/OMP/DDM/ FDA/OGROP/OR/SE-FO/NOL- DO/NOL-CB/	KERRIE WEBB KERSHAW CUTTER & RATINOF LLP	WRIGHT MEDICAL TECHNOLOGY - CONSERVE PLUS CUP RECS
2012-4862	07/06/2012 08/07/2012	FDA/OMPT/CDRH/OCER/DFOI/ OC/OA/OM/OMP/DDM/ FDA/OGROP/OR/SE-FO/NOL- DO/NOL-CB/	KERRIE WEBB KERSHAW CUTTER & RATINOF LLP	WRIGHT MEDICAL TECHNOLOGY - CONSERVE FEMORAL RESURFACING COMPONENT RECS

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2012-4863	07/06/2012 08/03/2012	FDA/OGROP/ORPA-FO/LOS-DO/LOS-CB/	DAVID LOHMAN SANESA PARTNERS	POLYPEPTIDE LABS, SAN DIEGO, CA -483W, UNTITLED LTRS, WARNING LTRS, ETC
2012-4864	07/06/2012 08/03/2012	FDA/OMPT/CDRH/OCER/DFOI/	SCANLAN, M KAY	SYNAPSE BIOMEDICAL - NEURX DIAGHEGN PACING SYS, H070003
2012-4865	07/06/2012 08/03/2012	FDA/OMPT/CDRH/OCER/DFOI/	SCANLAN, M KAY	SYNAPSE BIOMEDICAL - NEURX DIAGHREGM PACING SYS H100006
2012-4866	07/06/2012 08/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHASIN, KEITH	ZICAM - SAFETY RPT 3/1/10
2012-4867	07/06/2012 08/03/2012	FDA/OMPT/CDRH/OCER/DFOI/	Michele Sinoway LACHMAN CONSULTANT SERVICES, INC.	K030002
2012-4868	07/06/2012 08/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mara Goldstein CANTOR FITZGERALD	Adcetris (brentuximab vedotin) - AERs; PML (progressive multifocal leukoencephalopathy) - 01/13/2012
2012-4869	07/06/2012 08/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ISR NUMBER: # 7867543-X for JANUVIA (SITAGLIPTIN PHOSPHATE, MERCK)
2012-4870	07/06/2012 08/03/2012	OC/ORPA/ OC/ORPA/	Tara Hartung Hartung Brothers Inc	FEI Numbers
2012-4871	07/06/2012 08/03/2012	OC/OSMP/OOPD/ FDA/OMPT/OSMP/OOPD/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	Remicade (infliximab), BLA 103772 - Orphan Product Records
2012-4872	07/06/2012 08/03/2012	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	DESSART, SHONTAY K	FORENSICS CHEMISTRY CENTER - "CASE/SAMPLE SUMMARY RPT" TEST RESULTS, SHONTAY DESSART 391-92-1391 OR LORIS CAGNONI 17855, 9/1/08 TO 9/1/09
2012-4873	07/06/2012 08/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tamara Dalberg INDENA USA INC	Indena SpA (Settala, Italy) - EIR (March 2011)
2012-4874	07/06/2012	FDA/OMPT/CDRH/OCER/DFOI/	D. Younisian	K061477, K061478

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	08/03/2012		3s	
2012-4875	07/06/2012 08/03/2012	OC/OSMP/OOPD/	Angelia Slayton INC RESEARCH	Simponi (golimumab), BLA 125289 - Orphan Product Records
2012-4876	07/06/2012 08/03/2012	OC/OSMP/OOPD/	Angelia Slayton INC RESEARCH	Stelara (ustekinumab), BLA 125261 - Orphan Product Records
2012-4877	07/06/2012 08/03/2012	FDA/OGROP/ORAP/PA-FO/SAN-DO/SAN-CB/	Nicole A. Legrottaglie Palmer Kazanjian Wohl Hodson LLP	Blood Source, Mather, California - 482 (2009); Blood Source, Auburn, California - 482 (2009); Blood Source, Roseville, California - 482 (2009)
2012-4878	07/06/2012 08/03/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	SHIN KANG WELLS FARGO	SANQUIN AMSTERDAM - EIR9/19-28/11
2012-4879	07/06/2012 08/03/2012	OC/ORAP/ OC/ORAP/ FDA/OGROP/ORAP/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORAP/SW-FO/SWID/SWID-CB/	MAYNOR ORDONEZ INDUSTRIAS ALLMENTLCIAS KERN'S Y CLA SCA	MANGO, GYAVA, PINEAPPLE NECTARS ETC ENTRY M892-30829845 - ANALYTICAL RESULTS
2012-4880	07/06/2012 08/03/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	ABIGAIL MOSS BIOPHARM INSIGHT	DENDREON - CMC CORR
2012-4881	07/06/2012 08/03/2012	FDA/OGROP/ORAP/SE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAP/SE-FO/FLA-DO/FLA-CB/	Doe J	INDIVIDUAL RECS
2012-4882	07/06/2012 08/03/2012	FDA/OFVM/CFSAN/OCD/EOS/	FRANCIS, ANA MARGARITA	VAL/CONTINENTAL - FOOD FOR SALE RECS
2012-4883	07/06/2012 08/03/2012	FDA/OGROP/ORAP/SE-FO/ATL-DO/ATL-CB/	DANIEL H LEVI Paul Weiss Rifkind Wharton and Garrison LLP	SCIELE PHARMA INC, SHIONGI PHARMA INC, SHIONGI INC - EIRS, 483S, CO RESP 1/1/07 TO 12/31/10
2012-4884	07/06/2012 08/03/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORAP/SW-FO/DEN-DO/DEN-CB/	ADAM DIEDERICH SCHIFF HARDIN LLP	VALLEY MEAT CO, ROSWELL OR CHAVES CTY, NM - RECS REGARDING REQUESTS TO BECOME A RENDERING PLANT
2012-4885	07/06/2012 08/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SPITZ, CRAIG R	JANUVIA - AERS

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2012-4886	07/06/2012 08/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GERALD J OREHOSTKY ANTARES PHARMA INC	TESTOSTERONE ENANTHATE - DRUG APRVL PKG, ANDA 40-647
2012-4887	07/06/2012 08/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GERALD J OREHOSTKY ANTARES PHARMA INC	TESTOSTERONE CYPIONATE - DRUG APRVL PKG, ANDA 91-244
2012-4888	07/06/2012 08/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GERALD J OREHOSTKY ANTARES PHARMA INC	TESTOSTERONE ENANTHATE - DRUG APRVL PKG, NDA 99-165
2012-4889	07/09/2012 08/06/2012	FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/	GARY C COOPER GARY C COOPER LAW OFC	ENTRY #D52-0948587-4 - INVESTIGATION RPTS, EMAILS, SCHEDULES, ETC
2012-4890	07/09/2012 08/06/2012	FDA/OFVM/CFSAN/OCD/EOS/	THOMAS JANSSEN chemische fabrik budenheim	FCN 1144, FCN 699, FCN 1081, ETC
2012-4891	07/09/2012 08/06/2012	FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	DANAYI AZZARELLI COLE SCOTT AND KISSANE	INDIVIDUAL RECS
2012-4892	07/09/2012 08/06/2012	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	BIOMET MICROFIXATION - WALTER LORENTZ IMPLANT; STRICKER IMPLANT RECS
2012-4893	07/09/2012 08/06/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KIM STROUPE JETLINE-GEMINI MFG	FMI - UNSCENTED ANTIBACTERIAL HAND SANITIZER REGISTERED WITH FDA
2012-4894	07/09/2012 08/06/2012	OC/ORO/ OC/ORO/	ARMOUR, STEPHANIE	MOON MARINE US CORP, CUPERTINO, CA - LIST OF RESTAURANTS AND RETAILERS THAT RECEIVED YELLOWFIN TUNA, RECALL RECS 4/13/12; SALMONELLA OUTBREAK AT RESTAURANT CHAIN A 2010, ETC
2012-4895	07/09/2012 10/31/2012	FDA/OFVM/CFSAN/OCD/EOS/	TRUUS TIEMERSMA DSM AHEAD BV	NYLON 6, NYLON 6,6. NYLON 6,66 - COMPLETE PETITION
2012-4896	07/09/2012 08/06/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MICHAEL R COHEN RPH MS SCD INSTITUTE FOR SAFE MEDICATION PRACTICES	MEDWATCH RPTS CODED AS MEDICATION ERRORS 6/1-30/12

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2012-4897	07/09/2012 08/06/2012	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	MICHELLE RYBAK ROANOKE TRADE SERVICES INC	SBL GLOBAL INC - ENTRY #WUG-0154102-7 FDA NOTICES, NOTICES OF REFUSAL, FDA ACTION, ETC
2012-4898	07/09/2012 08/06/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	RUTH LAMLEY BAYER HEALTHCARE ANIMAL HEALTH DIVISION	BAYER, LA FELGUERA, SPAIN - EIRS, 483S, WARNING LTRS, ETC 11/06
2012-4899	07/09/2012 08/06/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	KATE WILLSON CENTER FOR PUBLIC INTEGRITY	KRIVROY ROG TISSUE BANK - DATE OF DE-REGISTRATION
2012-4900	07/09/2012 08/06/2012	FDA/OFVM/CFSAN/OCD/EOS/	SEAN HIGGINS ESQ ANDREWS THORNTON	JACK3D, OXYELITE PRO, MUSCLETECH NEUROCORE, ETC - CAERS
2012-4901	07/09/2012 08/06/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	NEEL, SCOTT	PFIZER - BOVINE THROMBIN JMI 4B RECS
2012-4902	07/09/2012 08/06/2012	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Travis Borchardt Schwabe North America	VitaQuest, West Caldwell, NJ - most recent 483, EIR, company response
2012-4903	07/09/2012 08/06/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	dr vipul shah R.P.Shah Memorial Trust for Disabled	Opioid Analgesics - side effects
2012-4904	07/09/2012 08/06/2012	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	Travis Borchardt Schwabe North America	Perrigo, Allegan, MI - most recent EIR, 483, company response
2012-4905	07/09/2012 08/06/2012	OC/CVM/OCD/	Gretchen Goetz FOOD SAFETY NEWS	Veterinary Drug Producers - corr re: withdrawal of antimicrobial new animal drugs and combination new animal drug products
2012-4906	07/09/2012 08/06/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Marie M. Kolp Theisen Bowers & Assoc-Atty Marie Kolp	PARNATE - AERs
2012-4907	07/09/2012	FDA/OMPT/CDER/GRP/DIDP/	dr vipul shah	Methotextrate - AERs

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2012-4908	07/09/2012 08/06/2012	FDA/OGROP/ORAN/FO/NYK-DO/NYK-DCB/	Travis Borchardt Schwabe North America	NBTY, Ronkonkoma, NY - most recent EIR, 483, company response
2012-4909	07/09/2012 08/06/2012	FDA/OGROP/ORAN/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORAN/PA-FO/LOS-DO/LOS-CB/	Travis Borchardt Schwabe North America	Pharmavite, Mission Hills, CA - EIR, 483, company response (most recent)
2012-4910	07/09/2012 08/06/2012	FDA/OGROP/ORAN/PA-FO/LOS-DO/LOS-CB/	Travis Borchardt Schwabe North America	Nutrillite, Buena Park, CA - EIR, 483, company response (most recent)
2012-4911	07/09/2012 08/06/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/OA/OM/OMP/DDM/	Mathieu Charvriat CEA / DSV / THERANEXUS	MODAFINIL - labeling, SBA, meeting minutes, etc.
2012-4912	07/09/2012 08/06/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/OA/OM/OMP/DDM/	Mathieu Charvriat CEA / DSV / THERANEXUS	MECLOFENAMIC ACID (MECLOMEN) - labeling, SBA, meeting minutes, etc.
2012-4913	07/09/2012 08/06/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/OA/OM/OMP/DDM/	Mathieu Charvriat CEA / DSV / THERANEXUS	MEFLOQUINE (LARIAM) - labeling, SBA, meeting minutes, etc.
2012-4914	07/09/2012 08/06/2012	FDA/OGROP/ORAN/SE-FO/ATL-DO/ATL-CB/	Travis Borchardt Schwabe North America	Nutra Manufacturing, Greenville, SC - EIR, 483, company response (most recent)
2012-4915	07/09/2012 08/06/2012	FDA/OGROP/ORAN/CE-FO/CIN-DO/CIN-CB/	Bowman Cox Elsevier Business Intelligence	Ben Venue Labs, Inc., Bedford, OH - EIRs, 483s, company responses (2007-present)
2012-4916	07/09/2012 08/06/2012	FDA/OC/OES/DFOI/	Bowman Cox Elsevier Business Intelligence	Ben Venue Labs, Bedford, OH - EIRs, 483s, company responses (2007-present)
2012-4917	07/09/2012 08/06/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Alice Chen UNIVERSITY OF CHICAGO	NCD - archives by quarter

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2012-4918	07/09/2012 08/06/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	dr vipul shah R.P.Shah Memorial Trust for Disabled	NSAIDS - side effects
2012-4919	07/09/2012 08/06/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Travis Borchardt Schwabe North America	Vita-Tech International, Inc., Tustin, CA - EIR, 483, company response (most recent)
2012-4920	07/09/2012 08/06/2012	FDA/OMPT/CDRH/OCER/DFOI/ OC/OCOS/OES/ OC/OCOS/OES/ FDA/OC/OCC/ OC/OA/OM/OMP/DDM/	Edward Michael Edward Michael	Quality System Regulation - look backs, reassessments or reevaluations of the economic impact assessment, etc.
2012-4921	07/10/2012 08/07/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	SCOTT R POOL GIBBS POOL & TURNER PC	HOSPIRA INC - LIFECARE PCA 3 V5.06 80MEA MDRS 4/21/10
2012-4922	07/10/2012 08/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	SCOTT R POOL GIBBS POOL & TURNER PC	HOSPIRA INC - LIFECARE PCA 3 V5.06 80MEA MDRS 3/7/10
2012-4923	07/10/2012 08/07/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	NELSON P LOPEZ GRIFOLS BIOLOGICALS INC	RUGER CHEMICAL COMPANY, LINDEN, NJ - EIRS, 483S 1/1/10 TO 7/1/12
2012-4924	07/10/2012 08/07/2012	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	BRANDON FERGUSON OC WEEKLY	OZELLE PHARMS - RESP TO WARNING LTR
2012-4925	07/10/2012 08/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	TOMOKO NAKAYAMA	PDM3 PERITONEAL DIALYSIS DVC - K974387
2012-4926	07/10/2012 08/07/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORASE-FO/FLADO/FLA-CB/	STEVEN J GERMAN ADELMAN GERMAN PLC	ARTHREX RADIOLUCENT RETRACTORS RECS
2012-4927	07/10/2012 08/07/2012	FDA/OC/OES/DFOI/	JOANNE L ZIMOLZAK MCKENNA LONG & ALDRIDGE LLP	2011-2430 - MINOR DELETIONS
2012-4928	07/10/2012 08/07/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	JEFFREY S KERR PETA FOUNDATION	PETA AND/OR INGRID ELIZABETH NEWKIRK - RECS, REPORTS, MEMOS ETC
2012-4929	07/10/2012 08/07/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAGLIANO #1070704, JOSEPH S	ELI LILLY & CO - ZYPREXA FRAUD ALLEGATIONS, REGULATORY VIOLATIONS, INJUNCTIONS, ETC

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2012-4930	07/10/2012 08/07/2012	FDA/OC/OES/DFOI/	LEA P VALDIVIA PODHURST ORSECK PA	ADVANCED MEDICAL OPTICS INC - COMPLETE MOISTUREPLUS MULTIPURPOSE CONTACT SOL, RECALLS 11/21/06 & 5/25/07 RECALL RECS, NON DISCLOSURE OF AERS OF ACANTHAMOEBA KERATITIS & OTHERS
2012-4931	07/10/2012 08/07/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GERALD J OREHOSTKY ANTARES PHARMA INC	TESTOSTERONE ENANTHATE - APRVL PKG RECS ANDA 040575
2012-4932	07/10/2012 08/07/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANDA 040575 ANTARES PHARMA INC	TESTOSTERONE ENANTHATE - APRVL PKG ANDA 085598
2012-4933	07/10/2012 08/07/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANDA 040575 ANTARES PHARMA INC	TESTOSTERONE ENANTHATE - APRVL PKG ANDA 085599
2012-4934	07/10/2012 08/07/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GERALD J OREHOSTKY ANTARES PHARMA INC	TESTOSTERONE ENANTHATE - APRVL PKG ANDA 040647
2012-4935	07/10/2012 08/07/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GERALD J OREHOSTKY ANTARES PHARMA INC	TESTOSTERONE ENANTHATE - APRVL PKG ANDA 083667
2012-4936	07/10/2012 08/07/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GERALD J. OREHOSTKY ANTARES PHARMA INC	TESTOSTERONE ENANTHATE ANDA 89-325 - APRVL LTRS, SUMMARY RVWS, LBLG, ETC
2012-4937	07/10/2012 08/07/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GERALD J. OREHOSTKY ANTARES PHARMA INC	TESTOSTERONE ENANTHATE ANDA 89-324 - APRVL LTRS, SUMMARY RVWS, LBLG, ETC

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2012-4938	07/11/2012 08/08/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SUZANNE SPENCE MYLAN INSTITUTIONAL	ASTRAZENECA - FASLODEX (FULVESTRANT) NDA 21-344 APRVL, CHEMISTRY RVW SUPPL
2012-4939	07/11/2012 08/08/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SUZANNE SPENCE MYLAN INSTITUTIONAL	QOL MEDCL - ETHAMOLIN (ETHANOLOAMINE OLEATE) NDA 19-357 APRVL, CHEMISTRY RVW SUPPL
2012-4940	07/11/2012 08/08/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SUZANNE SPENCE MYLAN INSTITUTIONAL	SANDOZ - CISATRICURIUM BESYLATE NDA 20-551, ANDA 200-154, ANDA 200-159 APRVL, CHEMISTRY RVW SUPPL
2012-4941	07/11/2012 08/08/2012	FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/	JENNIFER PARDUE AMENDIA INC	VERTICOR LTD - EIRS 2010
2012-4942	07/11/2012 08/08/2012	FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	JENNIFER PARDUE AMENDIA INC	NEW BUSINESS DEVELOPMENT LLC - EIRS 2004
2012-4943	07/11/2012 08/08/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	LEVAQUIN - SALES BROCHURE, VISUAL AID 2004, 2005
2012-4944	07/11/2012 08/08/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN AVELLANET CERULEAN LLC	ISRS 3410718-5, 3449694-8, 3469627-8, ETC
2012-4945	07/11/2012 08/08/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/OCOS/OES/ OC/OCOS/OES/ OC/OCOS/OL/	M ROY BRASWELL MCKINNEY, BRASWELL & BUTLER LLC	INTERNATIONAL ASSOCIATION OF COMPOUNDING PHARMACISTS - COUMPOUNDING OF DOMPERIDONE VIOLATES FEDERAL LAWS

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2012-4946	07/11/2012 08/08/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORO/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/	MARK PIFKO BARON & BUDD PC	ABBOTT LABORATORIES INC - ENSURE, MUSCLE HEALTH SHAKE, ENSURE CLINICAL STRENGTH CAERS, MEMOS, TRANS, ETC
2012-4947	07/11/2012 08/08/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOSEPH GAJDOSZ BUREAU OF PROFESSIONAL INVESTIGATIONS	COLLOIDAL SILVER - AERS
2012-4948	07/11/2012 08/08/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/	TINA SANTILLANES SANTILLANES & ASSOCIATES	ZIBO LITONG - EXAMINATION GLOVES ENTRY #916-2297101, #916-2191258-2 ANALYSIS
2012-4949	07/11/2012 08/08/2012	FDA/OC/OES/DFOI/	VICKY NGUYEN NBC Bay Area News (KNTV)	CHICKEN JERKY TREATS - CMLPNTS 1/07 TO 3/12
2012-4950	07/11/2012 08/08/2012	FDA/OGROP/ORO/NE-FO/NWE-DO/NWE-CB/	DIANE ZILKA GRANT & EISENHOFER PA	GENZYME CORP, ALLSTON, MA - 483S 5/09
2012-4951	07/11/2012 08/08/2012	FDA/OFVM/CFSAN/OCD/EOS/	DIANNE L CHAMBERS HOGAN LOVELLS US LLP	DRIVEN SPORTS - CRAVE CAERS
2012-4952	07/11/2012 08/08/2012	FDA/OFVM/CFSAN/OCD/EOS/	DIANNE L CHAMBERS HOGAN LOVELLS US LLP	BPI SPORTS - 1MR CAERS
2012-4953	07/11/2012 08/08/2012	FDA/OFVM/CFSAN/OCD/EOS/	DIANNE L CHAMBERS HOGAN LOVELLS US LLP	USP LABS - JACK 3D CAERS
2012-4954	07/11/2012 08/08/2012	FDA/OMPT/CDRH/OCER/DFOI/	CRISTINA CAMATS TALLADIUM INTERNATIONAL IMPLANTOLOGY	TALLADIUM ESPAFIA - INTERNATIONAL IMPLANTOGY ABUTMENTS XAM-MAR MANGRANE K090081
2012-4955	07/11/2012	FDA/OFVM/CFSAN/OCD/EOS/	DIANNE L CHAMBERS	MUSCLEPHARM - ASSAULT CAERS

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	08/08/2012		HOGAN LOVELLS US LLP	
2012-4956	07/11/2012 08/08/2012	FDA/OFVM/CFSAN/OCD/EOS/	DIANNE L CHAMBERS HOGAN LOVELLS US LLP	VPX - NO SHOTGUN, ANARCHY, CORALEX CAERS
2012-4957	07/11/2012 08/08/2012	FDA/OFVM/CFSAN/OCD/EOS/	DIANNE L CHAMBERS HOGAN LOVELLS US LLP	CELLUCOR - C3, NO3 EXTREME CAERS
2012-4958	07/11/2012 08/08/2012	FDA/OFVM/CFSAN/OCD/EOS/	DIANNE L CHAMBERS HOGAN LOVELLS US LLP	GASPARI NUTRITION - SUPERPUMP (250 AND MAX) - CAERS
2012-4959	07/11/2012 08/08/2012	FDA/OFVM/CFSAN/OCD/EOS/	DIANNE L CHAMBERS HOGAN LOVELLS US LLP	MUSCLETECH - NEUROCORE, NANOVAPOUR CAERS
2012-4960	07/11/2012 08/08/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	J. DONALD HENSON, SR Henson, J. Donald	MEDTRONIC - INSULIN PUMP P98002 A/C RVW ACTIONS
2012-4961	07/11/2012 08/08/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FLUTRA LIMANI AMABILE & ERMAN PC	AVONEX - AERS 2010 TO PRESENT
2012-4962	07/11/2012 08/08/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LANG, MILTON	OFLOXACIN OPHTHALMIC SOL; BAUSCH & LOMB - LOTEMAX (LOTEPREDNOL ETABOMATE OPHTHALMIC SOL - AERS
2012-4963	07/11/2012 08/08/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	ONFI - AERS
2012-4964	07/11/2012 08/08/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN F THOMPSON PHARM D ROBINSON & THOMPSON	GABAPENTIN - MYOCARDIAL INFARCTION RECS
2012-4965	07/11/2012 08/08/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	SHAUNAK DEEPAK JEFFERIES & CO	NISSHIN - 483S, REQUESTS FOR 483S
2012-4966	07/11/2012 08/08/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ryan L. Thompson Watts Guerra Craft LLP	Byetta study

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2012-4967	07/11/2012 08/08/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORO/ OC/ORO/ OC/ORO/OE/ OC/ORO/OE/ FDA/OGROP/ORO/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/ FDA/OGROP/ORO/CE-FO/DET-DO/DET-CB/ FDA/OC/OES/DFOI/ FDA/OGROP/ORO/SW-FO/DEN-DO/DEN-CB/ OC/ORO/ OC/ORO/ FDA/OC/OES/DFOI/	Matt Matt	Kaboom Action Strips - Recall, Lab Results
2012-4968	07/11/2012 08/08/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ryan L. Thompson Watts Guerra Craft LLP	Sitagliptin - 3 month pancreatic safety study
2012-4969	07/11/2012 08/08/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Matthew Mintz Mintz, Matthew L	RECORD study re: Avandia by GSK
2012-4970	07/11/2012 08/08/2012	FDA/OFVM/CFSAN/OCD/EOS/	Kim Wafford Andrew & Williamson Fresh Produce	Agricola EPSA S.A. De C.V. - Inspection Report 2/11
2012-4971	07/11/2012 08/08/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CANTOR FITZGERALD	Linacotide - Meeting minutes re: Phase II and pre-NDA

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		FDA/OMPT/CDER/GRP/DIDP/		
2012-4972	07/11/2012 08/08/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Revogenex Inc.	Tramadol - AERS
2012-4973	07/11/2012 08/08/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/ OC/ORO/ OC/ORO/	JoNel Aleccia MSNBC.COM	Dole Fresh Vegetable (04/14/2012 - 07/09/2012) - 483s, recall records
2012-4974	07/11/2012 08/08/2012	FDA/OGROP/ORO/NE-FO/NWE-DO/NWE-CB/	Mindy Du BioLife Cell Bank	BioCell Center, Medford, MA - 483
2012-4975	07/11/2012 08/08/2012	FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	Scott McCall TRS Labs Inc	TRS Labs - EIR (03/04/2010 - 08/31/2010)
2012-4976	07/11/2012 08/08/2012	FDA/OMPT/CDRH/OCER/DFOI/	David Dortch QIAGEN SCIENCES	QIAGEN - EIR (04/01/2012 - 06/01/2012); P110027/E002, P110030/E002; P110027/E003
2012-4977	07/11/2012 08/08/2012	FDA/OFVM/CFSAN/OCD/EOS/	Kim Wafford Andrew and Williamson Fresh Produce	Agricola Baja - Lab Report 2/11
2012-4978	07/11/2012 08/08/2012	FDA/OMPT/CDRH/OCER/DFOI/	Dennis Hansen Oppenheimer Wolff & Donnelly LLP	WATCHMAN - clinical trial records, PMA
2012-4979	07/11/2012 08/08/2012	FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	Scott McCall TRS Labs Inc	TRS Labs- EIR (06/11/2000 - 09/10/2010)
2012-4980	07/11/2012 10/04/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Jenny Yu Great Lakes	A list of current registered vaccines, blood and all other biologics manufacturers and a list of current approved vaccines, blood and all other biologics products
2012-4981	07/11/2012 08/08/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	Pfizer Clinical Research Unit, Singapore (03/06/2007 - 03/08/2007) - 483, EIR, response
2012-4982	07/11/2012 08/08/2012	OC/OA/OM/OMP/DDM/	Brent Johnson Widener University School of Law	Citizen's Petition from Indiana Medical Devices Manufacturers Council, Inc (61 FR 9181 under FDA Docket No. 95P-0110)
2012-4983	07/11/2012	FDA/OMPT/CDRH/OCER/DFOI/	Terry Thomas	K091333

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	08/08/2012		Terry Thomas of Behalf of GT LLC	
2012-4984	07/11/2012 08/08/2012	FDA/OMPT/CDRH/OCER/DFOI/	Megan Ohar TULANE UNIVERSITY	K991962
2012-4985	07/11/2012 08/08/2012	FDA/OMPT/CDRH/OCER/DFOI/	Terry Thomas Terry Thomas on behalf of GT, LLC	K0822159
2012-4986	07/11/2012 08/08/2012	FDA/OMPT/CDRH/OCER/DFOI/	Megan Ohar TULANE UNIVERSITY	K051408, K060014
2012-4987	07/11/2012 08/08/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Daven Mody Impax Laboratories, Inc.	Diastat and Diastat Acudial - Approval History, Letters, Reviews, and Related Documents
2012-4988	07/11/2012 08/08/2012	OC/ORO/ OC/ORO/	Matt Kavet Boston America Corp	E94-1127686-4/4/1A - test results
2012-4989	07/11/2012 08/08/2012	OC/OA/OM/OMP/DDM/	Becky Cooseman Brown & Crouppen, PC	ORTHOPEDIC AND REHABILITATION DEVICES PANEL TRANSCRIPT (CERTIFIED) - 9/8/05
2012-4990	07/11/2012 08/08/2012	FDA/OMPT/CDRH/OCER/DFOI/	Adrienne Misner REGSolutions, LLC	K904211 - Summary or Statement
2012-4991	07/11/2012 08/08/2012	FDA/OGROP/ORO/CE-FO/NWJ-DO/NWJ-CB/	Doe J	Stryker Recall Z-0072/73-08
2012-4992	07/11/2012 08/08/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Kevin Ustynik Parylene Coating Services	MAF 1176, DMF 15860
2012-4993	07/11/2012 08/08/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORO/NE-FO/NWE-DO/NWE-CB/	Brian Thompson McGinnis, Lochride and Kilgore	Fresenius Medical Care North America - Corr with FDA re: recall of Granuflo Acid Concentrate; AERs; Medwatch reports
2012-4994	07/11/2012 08/08/2012	OC/ORO/ OC/ORO/ OC/ORO/OE/	Jeff Overley Law360	Ethicon, Johnson & Johnson - Corr re: recall of transvaginal mesh products (06/01/2012 - 07/11/2012)

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		OC/ORAOE/		
2012-4995	07/12/2012 08/09/2012	FDA/OGROP/ORAOE-FO/DET-DO/DET-CB/	Alexander G. Barney The Karmel Law Firm	Hill-Rom, Inc., Batesville, IN - Inspection records (01/01/2012 - 07/11/2012)
2012-4996	07/12/2012 08/09/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Amanda Goodwin Eisai Inc.	Pimecrolimus (Elidel) NDA# 021302 - pediatric request
2012-4997	07/12/2012 08/09/2012	FDA/OC/OES/DFOI/	Deborah Austin BENNETT BIGELOW & LEEDOM PS	Certified Records
2012-4998	07/12/2012 08/09/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Amanda Goodwin Eisai Inc.	Protopic (tacrolimus) NDA# 050777 - pediatric request
2012-4999	07/12/2012 08/09/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 7/2-6/12
2012-5000	07/12/2012 08/09/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 6/25-29/12
2012-5001	07/12/2012 08/09/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 7/2-6/12
2012-5002	07/12/2012 08/09/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUEST 6/25-29/12
2012-5003	07/12/2012 08/09/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 7/2-6/12
2012-5004	07/12/2012 08/09/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUEST 6/25-29/12
2012-5005	07/12/2012 08/09/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	CLOSED FOIA REQUESTS 6/25-29/12
2012-5006	07/12/2012 08/09/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 7/2-6/12
2012-5007	07/12/2012 08/09/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 6/25-29/12

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2012-5008	07/12/2012 08/09/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	CLOSED FOIA REQUESTS 7/2-6/12
2012-5009	07/12/2012 08/09/2012	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	NELSON P LOPEZ GRIFOLS BIOLOGICALS INC	EASTMAN CHEMICAL CO, KINGSPORT, TN - EIRS, 483S 1/1/10 TO 7/1/12
2012-5010	07/12/2012 08/09/2012	FDA/OMPT/CDRH/OCER/DFOI/	RICHARD KELLER BRUNO INDEPENDENT LIVING AIDS INC	TRADE CMLPNT CPT1100211
2012-5011	07/12/2012 08/09/2012	FDA/OFVM/CFSAN/OCD/EOS/	JONES, DONNAMARIA R	ENERGY DRINKS, CAFFEINE - CAERS 1/05 TO 6/12
2012-5012	07/12/2012 08/09/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	AMY MITCHELL GLAXO SMITH KLINE	GLAXOSMITHKLINE, ARANDA - QUALITY ASSURANCE PROFILE (QAP)
2012-5013	07/12/2012 08/09/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELLIOT FAVUS MD FAVUS INSTITUTIONAL RESEARCH LLC	JAKAFI (RUXOLITINIB) - AERS 4/18/11 TO PRESENT
2012-5014	07/12/2012 08/09/2012	FDA/OC/OCC/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID LOHMAN SANESA PARTNERS	ELIZABETH DICKINSON, AMARIN - ORANGE BOOK MTG MINS, RECS 6/22/12
2012-5015	07/12/2012 08/09/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	LOAR, S BARTON	DPT LAKEWOOD INC, LYNBROOK, NY - 483 12/5/07
2012-5016	07/12/2012 08/09/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	LOAR, S BARTON	DPT LAKEWOOD INC, LAKEWOOD, NJ - 483S 4/13/05, 2/23/07, 3/18/08, ETC
2012-5017	07/12/2012 08/09/2012	FDA/OC/OES/DFOI/	DEBBIE ZAGER VENABLE LLP	MERCK - MMR II VACCINE IND 1016 EIRS
2012-5018	07/12/2012 08/09/2012	OC/CVM/OCD/	AMY RADKE PUTNEY INC	TEMARIL-P NADA 12-437 - SUMMARY
2012-5019	07/12/2012 08/09/2012	OC/CVM/OCD/	AMY RADKE PUTNEY INC	TELAZOL NADA 06-111 - SUMMARY
2012-5020	07/12/2012	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	KIM FINCH	CHOICE SPINE, KNOXVILLE, TN - EIR 8/11/08

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	08/09/2012		CHOICE SPINE LP	
2012-5021	07/12/2012 08/09/2012	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	MARY ROSENFELDT, RN, BSN XAVIER UNIV	B&B RIVERBOATS - FOODBORNE ILLNESS 4/12
2012-5022	07/12/2012 08/09/2012	OC/CVM/OCD/	AMY RADKE PUTNEY INC	TRESADERM NADA 42-633 - SUMMARY
2012-5023	07/12/2012 08/09/2012	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	MIKE RUSSELL DELAVAL MANUFACTURING	DEIBEL LABS OF ILLINOIS INC, LINCOLNWOOD, IL - EIR 2/23-4/21/11
2012-5024	07/12/2012 08/09/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARY B. SZALKOWSKI PRISMA CORP	INDAPAMIDE; PERINDOPRIL - AER SINCE 4/18/12
2012-5025	07/12/2012 08/09/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	EMIL M. DeGOMA, MD PENN MEDICINE	LOSARTAN (COZAAR), VALSARTAN (DIOVAN), AMLODIPINE (NORNASC), CLOPIDOGREL (PLAVIX), OMEPRAZOLE (PRILOSEC) - AER
2012-5026	07/12/2012 08/09/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michael K Flood Isaac, Wiles, Burkholder & Teetor	EMAILS FROM BOB RAPPAPORT OF FDA 1/95 TO PRESENT
2012-5027	07/12/2012 08/09/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	ANDRIA COLETTA TAYLOR DUANE BARTON & GILMAN LLP	BREG INC PAIN CARE - INFUSION PAIN PUMP INVESTIGATION 1/2000 TO PRESENT
2012-5028	07/12/2012 08/09/2012	FDA/OGROP/ORACE-FO/PHIDO/PHI-CB/	AARON M. WHITE Stern & Goldberg	ATTACHMENTS TO CORR
2012-5029	07/12/2012 08/09/2012	FDA/OMPT/CDRH/OCER/DFOI/	BENJAMIN L. ENGLAND, Esq. BENJAMIN L ENGLAND & ASSOCIATES LLC	ARGENTUM MEDICAL LLC - SILVERLON BRAND ISLAND DRESSING & ISLAND PAD K984208 CORR
2012-5030	07/12/2012 08/09/2012	OC/CVM/OCD/ FDA/OGROP/ORA/ORO/DIOP/ FDA/OC/OCC/ FDA/OC/OES/DFOI/	TIM SCHWAB Food and Water Watch	AQUA BOUNTY TECHNOLOGIES - AQUA ADVANTAGE SALMON CORR
2012-5031	07/12/2012 08/09/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PARAKKAL DEEPAK MD NORTHSHORE UNIV HEALTHSYSTEM	SEE EMAIL

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		FDA/OMPT/CDER/GRP/DIDP/		
2012-5032	07/12/2012 08/09/2012	FDA/OFVM/CFSAN/OCD/EOS/	BRUNER, RAISA	INSPECTIONS IN CHINA
2012-5033	07/12/2012 08/09/2012	FDA/OMPT/CDRH/OCER/DFOI/	LARRY HAMILTON THE PROMETHEUS GROUP	K030039
2012-5034	07/12/2012 08/09/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Jeff M. Hathaway Pin-Point Care Corp	K034021; K042290
2012-5035	07/12/2012 08/09/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	IPD Analytics, LLC	Tentative Approval Letter for ANDA No. 201801 for Zoledronic Acid Generic Drug
2012-5036	07/12/2012 08/09/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-3937 REQUEST LETTER
2012-5037	07/12/2012 08/09/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-3939 REQUEST LETTER
2012-5038	07/12/2012 08/09/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Self	Plavix - study results on brand v. generic
2012-5039	07/13/2012 08/10/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-4705 REQUEST LETTER
2012-5040	07/13/2012 08/10/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-3942 REQUEST LETTER
2012-5041	07/13/2012 08/10/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-4007 REQUEST LETTER
2012-5042	07/13/2012 08/10/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-4013 REQUEST LETTER
2012-5043	07/13/2012 08/10/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-4015 REQUEST LETTER
2012-5044	07/13/2012 08/10/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-4024 REQUEST LETTER
2012-5045	07/13/2012 08/10/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-4038 REQUEST LETTER

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2012-5046	07/13/2012 08/10/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-4063 REQUEST LETTER
2012-5047	07/13/2012 08/10/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-4088 REQUEST LETTER
2012-5048	07/13/2012 08/10/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-4115 REQUEST LETTER
2012-5049	07/13/2012 08/10/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-4188 REQUEST LETTER
2012-5050	07/13/2012 08/10/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-4515 REQUEST LETTER
2012-5051	07/13/2012 08/10/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-4237 REQUEST LETTER
2012-5052	07/13/2012 08/10/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-4293 REQUEST LETTER
2012-5053	07/13/2012 08/10/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-4271 REQUEST LETTER
2012-5054	07/13/2012 08/10/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-4451 REQUEST LETTER
2012-5055	07/13/2012 08/10/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-4087 REQUEST LETTER
2012-5056	07/13/2012 08/10/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-4105 REQUEST LETTER
2012-5057	07/13/2012 08/10/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-4125 REQUEST LETTER
2012-5058	07/13/2012 08/10/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-4156 REQUEST LETTER
2012-5059	07/13/2012 08/10/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-4497 REQUEST LETTER
2012-5060	07/13/2012 08/10/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-4542 REQUEST LETTER
2012-5061	07/13/2012 08/10/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-4505 REQUEST LETTER
2012-5062	07/13/2012	OC/OM/OMP/DDM/	ROSS RENDELMAN	DKT FDA-2012-P-0583

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	08/10/2012		HOGAN LOVELLS US LLP	
2012-5063	07/13/2012 08/10/2012	FDA/OC/OES/DFOI/	AMY KINCANON LEXIS NEXIS COURTLINK INC	2012-4549 - MOTLEY RICE LLC, WELLBUTRION, NDA 18-644/S33/S34
2012-5064	07/13/2012 08/10/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	KATE WILLSON ICIJ	REGISTERED BANKS IN UKRAINE - DNEPRODZERZHINK S, DEPT OF DNEPROPETROVSK REGIONAL FM BUREAU (DN2); STATE SCIENTIFIC MNFG ENTERPRISE BIOIMPLANT; GORLOVKA DEPT OF DONETZK REGIONAL FM BUREAU (GOR1) ETC
2012-5065	07/13/2012 08/10/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SUSANNE COLLINS PATHEON INC TRO	SASOL GERMANY GMBH, 58453 WITTEN, GERMANY - EIRS, 483S 5/09
2012-5066	07/13/2012 08/10/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SPIVY, ART .	LILLY - HISTALOG INJECTION 50MG/ML, SUMMARY OR APRVL LTRS
2012-5067	07/13/2012 08/10/2012	FDA/OC/OES/DFOI/	JEFFERIES & CO	HIGH POINT - 483S 1/1/11 TO PRESENT
2012-5068	07/13/2012 08/10/2012	OC/ORO/ORM/ OC/ORO/ORM/	GAIL LESSICK LACHNMAN CONSULTANT SERVICES INC	LIST OF DRUG COS, MED DEV MFRS, BIORESEARCHY MONITORING (BIMO) ETC, FOREIGN & DOMESTIC - 5/1-31/12
2012-5069	07/13/2012 08/10/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LOAR, S BARTON	INTERNATIONAL MEDICATIONS SYS LTD - ANDA 072076, SERIAL 000, D/012, S/013 (LBLG), & S/013 (FACILITY ADD'N)
2012-5070	07/13/2012 08/10/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LOAR, S BARTON	HOSPIRA - RVWS, ANDA 07-0254, 07-0256, & 07-0257
2012-5071	07/13/2012 08/10/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	LILLY - FORTEO (TERIPARATIDE RECOMBINANT HUMAN), NDA 02-1318, REMS DATA, 10-YR SAFETY UPDATE
2012-5072	07/13/2012 08/10/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	SORIN GROUP, MUNICH, GERMANY - EIRS, 483S, CO RESPS ETC 1/11 TO PRESENT

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2012-5073	07/13/2012 08/10/2012	FDA/OMPT/CDRH/OCER/DFOI/ OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SW-FO/DEN- DO/DEN-CB/	FOI Services, Inc.	SORIN GROUP, US & INTERNATIONAL FACILITIES - EIRS, 483S, CO RESPS ETC 1/11 TO PRESENT
2012-5074	07/13/2012 08/10/2012	FDA/OC/OES/DFOI/	GLADYS B. TONKIN WASHINGTON INFORMATION SOURCE	DAILY LOG 6/11-15/12
2012-5075	07/13/2012 08/10/2012	FDA/OC/OES/DFOI/	GLADYS B. TONKIN WASHINGTON INFORMATION SOURCE	DAILY LOG 6/18-22/12
2012-5076	07/13/2012 09/10/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	FOI Services, Inc.	CARIDIANBCT INC - TRIMA ACCEL AUTOMATED BLOOD COMPONENT COLLECTION SYS, BK08-0029
2012-5077	07/13/2012 08/10/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FOI Services, Inc.	STIEFEL LABS - FABIOR. MEDICAL/CLINICAL REVIEW NDA 20-2428
2012-5078	07/13/2012 08/10/2012	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 6/11-15/12
2012-5079	07/13/2012 08/10/2012	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 6/18-22/12
2012-5080	07/13/2012 08/10/2012	FDA/OMPT/CTP/OD/	FOI Services, Inc.	PHILIP MORRIS INTERNATIONAL VISIT (4/12 OR 5/12) - CORR, RECS ETC
2012-5081	07/13/2012 08/10/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 6/18-22/12
2012-5082	07/13/2012 08/10/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 6/18-22/12
2012-5083	07/13/2012 08/10/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 6/11-15/12
2012-5084	07/13/2012 08/10/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	RAMIREZ, HEIDI	LIST OF DRUGS CONTAINING SULFITES

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		FDA/OMPT/CDER/ORP/DIDP/		
2012-5085	07/13/2012 08/10/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 6/18-22/12
2012-5086	07/13/2012 08/10/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 6/11-15/12
2012-5087	07/13/2012 08/10/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 6/11-15/12
2012-5088	07/13/2012 08/10/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 6/11-15/12
2012-5089	07/13/2012 08/10/2012	FDA/OC/OES/DFOI/	INC RESEARCH CONSULTING & SUBMISSIONS	DAILY LOG 6/18-22/12
2012-5090	07/13/2012 08/10/2012	FDA/OC/OES/DFOI/	INC RESEARCH CONSULTING & SUBMISSIONS	DAILY LOG 6/11-15/12
2012-5091	07/13/2012 08/10/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 6/18-22/12
2012-5092	07/13/2012 08/10/2012	FDA/OFVM/CFSAN/OCD/EOS/	LAFLOWER 144854, BENJAMIN	NIACINE - STUDIES, CAERS, FINDINGS, ETC; FOOD ADDITIVES - CAERS
2012-5093	07/13/2012 08/10/2012	OC/ORA/ORM/ OC/ORA/ORM/	JOHNATHAN RICKMAN FDA NEWS	ALL 483'S FOR MEDICAL DVC MFG, CLNCL TRIAL FACILITIES 6/12
2012-5094	07/13/2012 08/10/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	KATE WILLSON INTERNATIONAL CONSORTIUM OF INVESTIGATIVE JOURNALISTS	FORM 3356 FOR KRIVOY ROG TISSUE BANK; NIKI TISSUE BANK
2012-5095	07/13/2012 08/10/2012	OC/ORA/OCI/ OC/ORA/OCI/ FDA/OGROP/ORA/SE-FO/SJN- DO/SJN-CB/	MICHAEL POMA DISCOVERY HEALTH ESTILOS CORP	DISCOVERY HEALTH ESTILOS CORP, BAYAMON, PR - VIOLATIONS 2006 TO PRESENT
2012-5096	07/13/2012 08/10/2012	FDA/OFVM/CFSAN/OCD/EOS/	BEN F PIERCE GORE ATTY	ADDITIONAL ATTACHMENTS REQUESTED - NUTRITION INITIATIVETECHNICAL RVW, 12/3/09; KATHLEEN LEWIS E- MAIL LBLS, 2/17/11; LINDA C COX E-MAIL LBLS, 3/3/11 ETC
2012-5097	07/13/2012 08/10/2012	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN-	CHARLES D STEINMAN KAMMHOLZ MESSINA LLP	TWENTY-NINE PALMS CALIFORNIA - CATFISH CARL'S GREY WASH CONTAMINATED TATTOO INK, INVESTIGATION RECS

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		DO/SAN-CB/		
2012-5098	07/16/2012 08/13/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ OC/OSMP/OOPD/	A FRANKLIN ROTHSCHILD PHD CENTER FOR CONTEMPORARY EQUINE STUDIES	RARE DISEASE THERAPEUTICS INC - ANASCORP ANTIVENOM INJ APRVL RECS, PROTOCOLS, PROCUREMENT, ETC
2012-5099	07/16/2012 08/13/2012	FDA/OC/OES/DFOI/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	SHAUBAK DEEPAK JEFFERIES & CO	VPHM, AMSTERDAM - EIRS, FOI REQUESTS
2012-5100	07/16/2012 08/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELSPETH CALLAHAN INDEPENDENCE LEGAL SUPPORT	ANGIOMAX (BIVALIRUDIN) INJ NDA 20-873/S022 - RECS
2012-5101	07/16/2012 08/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PAM HALSTEN ARMBRECHT JACKSON LLP	NARCAN (NALOXONE HCL) - AERS, CMLPNTS, DEAR DOCTOR LTRS, ETC
2012-5102	07/16/2012 08/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	COLLEEN GRACE DONOFRIO BABST CALLAND CLEMENTS ET AL	LALZHOU ZHONGDA CHEMICALS CO LTD, SHANDONG, CHINA - EIRS 2007 TO PRESENT
2012-5103	07/16/2012 08/13/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/OCOS/OES/ OC/OCOS/OES/	MONTE ROME INTERSHELL INTERNATIONAL CORP	NORTHERN PSP CLOSURE - RECS
2012-5104	07/16/2012 08/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID MOSSBURG MOSSBURG MEDIA INC	RELISTOR - AERS
2012-5105	07/16/2012 08/13/2012	FDA/OC/OES/DFOI/	MATTHEW DE PRETER ROCKEY & LYONS	THERMOTEK INC - NANOTHERM, VASCUTHERM K061866
2012-5106	07/16/2012 08/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SMITH, KIM	JAKAFI (RUXOLITINIB) - AERS
2012-5107	07/16/2012 08/13/2012	FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/	STELLA K HERRERA GRIFOLS BIOLOGICALS INC	B BRAUN MEDICAL, IRVINE, CA - EIRS, 483S 1/10 TO 6/12

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2012-5108	07/16/2012 08/13/2012	FDA/OGROP/ORO/PA-FO/SEA-DO/SEA-CB/ FDA/OMPT/CDRH/OCER/DFOI/	MIKE GALLAGHER GALLAGHER LAW FIRM LLP	GENERIC MEDICAL DEVICES INC - UNIVERSAL SLING WARNING LTRS, MEMOS, MINS, ETC
2012-5109	07/16/2012 08/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SI NGA MAN UNIV OF MACAU	PRESCRIPTION AND OTC DRUG PRODUCT PATENT AND EXCLUSIVITY LIST
2012-5110	07/16/2012 08/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHRISTINE BLUMHARDT BLUMHARDT CONSULTING	AZULIFIDINE (SULFASALAZINE) TABS,EN-TABS NDA 07-073, NDA 18-605, NDA 21-243 - APRVL RECS
2012-5111	07/16/2012 08/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Margaret Sapp Margaret Sapp	PDUFA - ADVISORY COMMITTEE AND APPROVAL DATES 2012
2012-5112	07/16/2012 08/13/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-3865 COMPLETE RESPONSE
2012-5113	07/16/2012 08/13/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-4468 COMPLETE RESPONSE
2012-5114	07/16/2012 08/13/2012	FDA/OC/OES/DFOI/	SYNTRON BIORESEARCH INC	510k
2012-5115	07/16/2012 08/13/2012	FDA/OC/OES/DFOI/	YOUNG, DIONNE E	FOI DAILY LOG 7/1/11 TO 7/1/12
2012-5116	07/16/2012 08/13/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	SYNTRON BIORESEARCH INC	K042723; K030286; K040437
2012-5117	07/16/2012 08/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	DIERINGER, CHARLES	PHASE III PROTOCOL CALHOUN VISION LAL, IOL - CONTRAINDICATION
2012-5118	07/16/2012 08/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRENT M. ARDAUGH, MPH, MS NORTHWESTERN UNIV FEINBERG SCHOOL OF MEDICINE	K852097A, K881604A, K760152, K771046
2012-5119	07/16/2012 08/13/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/	Guggenheim Securities, LLC	NDA, BLA SUBMISSIONS 2000-2012

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2012-5120	07/16/2012 08/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRENT M. ARDAUGH , MPH, MS NORTHWESTERN UNIV FEINBERG SCHOOL OF MEDICINE	K031328
2012-5121	07/16/2012 08/13/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Shin Kang WELLS FARGO	SANQUIN - FMD145 COVER LETTER FOR 9/19/2011- 9/28/2011 INSPECTION
2012-5122	07/16/2012 08/13/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Shin Kang WELLS FARGO	SANQUIN PLASMA PRODUCTS - CORR 01/01/2012 - 07/12/2012
2012-5123	07/16/2012 08/13/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-3633
2012-5124	07/16/2012 08/22/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Shin Kang WELLS FARGO	CAF-DCF, BRUSSELS, BELGIUM - EIR and FMD145 COVER LETTER
2012-5125	07/16/2012 08/13/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	LEERINK SWANN LLC	SANQUIN PLASMA PRODUCTS, AMSTERDAM - MOST RECENT EIR FOR MANUFACTURE OF CINRYZE
2012-5126	07/16/2012 08/13/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 7/2-6/2012
2012-5127	07/16/2012 08/13/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 7/9-13/2012
2012-5128	07/16/2012 08/13/2012	OC/ORO/ OC/ORO/ FDA/OFVM/CFSAN/OCD/EOS/	Justin Prochnow GREENBERG TRAURIG	NEW AGE BEVERAGES; XING BEVERAGE, LLC; XING TEA PRODUCTS - COMPLAINTS
2012-5129	07/16/2012 08/13/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-5154
2012-5130	07/16/2012 08/13/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-9215
2012-5131	07/16/2012 08/13/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-1924
2012-5132	07/16/2012 08/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	MICHAEL A LOCKE IMMUNOSTICS INC	MEDTEK DIAGNOSTICS LLC - LIFEGUARD K022755, HEMAWIPE SYS K912979/A, DIGIWIPE II SYS K853141, ETC
2012-5133	07/16/2012 08/13/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-2561

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2012-5134	07/16/2012 08/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	Steve Partono TECO DIAGNOSTICS	K070929
2012-5135	07/16/2012 08/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Brandy Dandy Brandy Dandy	REBIF, AVONEX, BETASERON ETC. - AERS
2012-5136	07/16/2012 08/13/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-2765
2012-5137	07/16/2012 08/13/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-3172
2012-5138	07/16/2012 08/13/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-3418
2012-5139	07/16/2012 08/13/2012	FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/	Lauren Sweeney WKMG-TV	NOVARTIS CONSUMER HEALTH INC., LINCOLN, NE - EIRS, CORR, ETC 07/01/2010 - 07/01/2012
2012-5140	07/16/2012 08/13/2012	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	RICHARD F. LOCKEY, MD UNIVERSITY OF SOUTH FLORIDA DEPT OF ALLERGY & CLINICAL IMMUNOLOGY	RICHARD LOCKEY MD, UNIV OF SOUTH FL - 483, WARNING LTR 6/8/89
2012-5141	07/16/2012 08/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Shelley Brooke Medical Products Laboratories, Inc.	NDA 021844 - CMC
2012-5142	07/16/2012 08/13/2012	FDA/OGROP/ORR/SE-FO/NOL-DO/NOL-CB/	LIZ DAY PROPUBLICA	CROWN HEALTH CARE LAUNDRY SERVICES - EIR, 483 11/17-25/09, CORR
2012-5143	07/16/2012 08/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Janet McChristion Fresenius Kabi-APP	ANDA 200154, ANDA 200159, ANDA 091488, ETC - APPROVAL LETTERS
2012-5144	07/16/2012 08/13/2012	OC/ORR/ OC/ORR/	LIZ DAY PROPUBLICA	INDUSTRIAL LAUNDRIES - CMLPNTS
2012-5145	07/16/2012 08/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mike Melillo MCDONALD HOPKINS LLC	TEV-TROPIN - APPROVAL LETTER

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2012-5146	07/16/2012 08/13/2012	FDA/OGROP/ORА/SE-FO/FLA-DO/FLA-CB/	DENNIS KEITH LEDFORD, MD UNIVERSITY OF SOUTH FLORIDA DEPT OF ALLERGY & CLINICAL IMMUNOLOGY	UNIV OF SOUTH FL, DENNIS KEITH LEDFORD MD - 483, WARNING LTR 10/17/88, 10/23/95
2012-5147	07/16/2012 08/13/2012	FDA/OGROP/ORА/PA-FO/SAN-DO/SAN-CB/	Jim Baumann - Senior Regulatory Specialist US WorldMeds, LLC	SOLSTICE NEUROSCIENCES, LLC, SOUTH SAN FRANCISCO, CA - EIR 2011
2012-5148	07/16/2012 08/13/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 6/18-22/12
2012-5149	07/16/2012 08/13/2012	FDA/OFVM/CFSAN/OCD/EOS/	Jim Lassiter Ingredient Identity	PUBLIC STAKEHOLDER MEETING MINUTES 5/06/03
2012-5150	07/16/2012 08/13/2012	FDA/OGROP/ORА/PA-FO/SEA-DO/SEA-CB/	Mary E. Lynn The Windward Company	SNBL USA, EVERETT, WA - EIR 11/16/2009 - 11/20/2009
2012-5151	07/16/2012 08/13/2012	FDA/OMPT/CTP/OD/	Allison Hoffman Shoe	FDA REPORT - MENTHOL CIGARETTES
2012-5152	07/16/2012 08/13/2012	FDA/OMPT/CTP/OD/	Allison Hoffman Shoe	MENTHOL CIGARETTES - NAMES OF PEER REVIEWERS
2012-5153	07/16/2012 08/13/2012	FDA/OMPT/CDER/ОР/DIDP/ FDA/OMPT/CDER/ОР/DIDP/ FDA/OMPT/CDER/ОР/DIDP/ FDA/OMPT/CDER/ОР/DIDP/	Ram Kapil Purdue Pharma L. P.	DR. RONAL FARKAS - PRESENTATION RE PRESCRIPTION SLEEP AID DRUGS 09/15/2011 - 09/15/2011
2012-5154	07/16/2012 08/13/2012	FDA/OMPT/CDER/ОР/DIDP/ FDA/OMPT/CDER/ОР/DIDP/ FDA/OMPT/CDER/ОР/DIDP/ FDA/OMPT/CDER/ОР/DIDP/	John Spaltro COVANCE	NDA 17-871 DEMSER - SBA
2012-5155	07/16/2012 08/13/2012	FDA/OGROP/ORА/SE-FO/FLA-DO/FLA-CB/	ROGER WILLIAMS FOX, MD UNIVERSITY OF SOUTH FLORIDA DEPT OF ALLERGY & CLINICAL IMMUNOLOGY	ROGER WILLIAMS FOXX MD, UNIV OF SOUTH FL - 483, WARNING LTR 2/7/95, 1/24/86
2012-5156	07/16/2012 08/13/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 6/11-15/12
2012-5157	07/16/2012 08/13/2012	FDA/OMPT/CDER/ОР/DIDP/ FDA/OMPT/CDER/ОР/DIDP/ FDA/OMPT/CDER/ОР/DIDP/ FDA/OMPT/CDER/ОР/DIDP/	JODY L. GREEN, PhD ROCKY MOUNTAIN POISON DRUG CTR	ISRS 8192874-6, 8196611-0, 9187126-6 COUGH AND COLD PREPARATIONS

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2012-5158	07/16/2012 08/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JODY L. GREEN, PhD. ROCKY MOUNTAIN POISON DRUG CTR	ISRS 8156428-X, 8157128-2, 8157427-4
2012-5159	07/16/2012 08/13/2012	FDA/OGROP/OIP/	Angelia Slayton INC RESEARCH	MICHAEL A. CHARLES - 10 MOST RECENT 483S SINCE 2009
2012-5160	07/16/2012 08/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JODY L. GREEN, PhD. ROCKY MOUNTAIN POISON DRUG CTR	ISRS 8019934-4, 8022172-2, 8023421-7
2012-5161	07/16/2012 08/13/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-1213
2012-5162	07/16/2012 08/13/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-3842
2012-5163	07/16/2012 08/13/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-3857
2012-5164	07/16/2012 08/13/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-3965
2012-5165	07/16/2012 08/13/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-4046
2012-5166	07/16/2012 08/13/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-4107
2012-5167	07/16/2012 08/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JODY L . GREEN, PhD. ROCKY MOUNTAIN POISON DRUG CTR	CAERS 8077579-4, 8081119-3, 8089532-5
2012-5168	07/16/2012 08/13/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-4140
2012-5169	07/16/2012 08/13/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-4324
2012-5170	07/16/2012 08/13/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-4323
2012-5171	07/16/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2012-4614

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	08/13/2012		MERCK & CO., INC.	
2012-5172	07/16/2012 08/13/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-4326
2012-5173	07/16/2012 08/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ALISON M. AGNEW PILLSBURY WINTHROP SHAW PTTMAN LLP	HP ACTHAR BULK, CHARLOTTETOWN, CANADA - DMF 17883; QUESTCOR PHARMS INC, BALTIMORE, MD - DMF 25341
2012-5174	07/16/2012 08/13/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	ALISON M. AGNEW PILLSBURY WINTHROP ET AL	QUESTCOR PHARMS INC - HP ACTHAR GEL - FOIA REQUESTS 4/30/12-7/12/12
2012-5175	07/16/2012 08/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PAMELA SHEPPARD TARO PHARMACEUTICALS USA INC	MERZ PHARMS - NAFTIN N 19-356 SUMMARY, RVWS, LBLG
2012-5176	07/16/2012 08/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	BENJAMIN L. ENGLAND, Esq. Benjamin L. England and Associates, LLC	ARGENTUM MEDICAL LLC - SILVERLON BRAND ISLAND DRESSING & ISLAND PAD K984208
2012-5177	07/16/2012 08/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	BENJAMIN L. ENGLAND, Esq. Benjamin L. England and Associates, LLC	ARGENTUM MEDICAL LLC - SILVERLON ASHESIVE STRIP & CALCIUM ALGINATE K023609, K023609
2012-5178	07/16/2012 08/13/2012	FDA/OC/OCC/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JENNIFER HSIEH HEALTHCARE RESEARCH CONSULTING GROUP	MTG BTWN ELIZABETH H DICKINSON ESQ, CHIEF COUNSEL AND HYMAN, PHELPS & MCNAMARA, AMARIN, COVINGTON & BURLING - ORANGE BOOK DISCUSSION TRANS 6/22/12
2012-5179	07/16/2012 08/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GERALD J. OREHOSTKY ANTARES PHARMA INC	TESTOSTERONE ENANTHATE ANDA 40-575 - APRVL
2012-5180	07/16/2012 08/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GERALD J. OREHOSTKY ANTARES PHARMA INC	TESTOSTERONE ENANTHATE ANDA 40-647 - APRVL

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2012-5181	07/17/2012 08/14/2012	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	PATRICIA L REGENYE Celgene Corporation	JOHN CATON JR, MD, WILLAMETTE VALLEY CANCER INSTITUTE, SPRINGFIELD, OR - EIRS, 483S, CO RESPS ETC 8/2/10 TO PRESENT
2012-5182	07/17/2012 08/14/2012	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	PATRICIA L REGENYE Celgene Corporation	MASSIMO CRISTOFANILLI, UNIV TEXAS MD ANDERSON CANCER CTR, HOUSTON, TX - EIRS, 483S, CO RESPS ETC 5/04 TO PRESENT
2012-5183	07/17/2012 08/14/2012	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	PATRICIA L REGENYE Celgene Corporation	RAVI VIJ, WASHINGTON UNIV SCH MED, ST. LOUIS, MO - EIRS, 483S, CO RESPS ETC, 12.11 TO PRESENT
2012-5184	07/17/2012 08/14/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Doe J	THROMBOCYTOPENIA VAERS - RESULTING FROM H1N1 FLU VACCINE
2012-5185	07/17/2012 08/14/2012	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	JOHN WALSH JAMES ALEXANDER CORP	PHARMCO-AAPER PRODUCTS INC, SHELBYVILLE, KY - EIRS, 483S, RECALL RECS, 7/09 TO PRESENT
2012-5186	07/17/2012 08/14/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FRATTI, JOHN	LEVAQUIN - OFF-LABEL, MISLEADING MARKETING RECS
2012-5187	07/17/2012 08/14/2012	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FRATTI, JOHN	JOHNSON & JOHNSON OR ORTHO-MCNEIL - LEVAQUIN CORR, RECS 1996 TO 2008
2012-5188	07/17/2012 08/14/2012	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	MUSCARELLA, LAWRENCE F	METHODIST HOSPITAL, HOUSTON TX - PSEUDOMONAS AERUGINOSA OUTBREAK RECS, 4/09
2012-5189	07/17/2012 08/14/2012	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	ALAN N GOLDBERG Stern & Goldberg	2012-4146 - PROTICA'S LTRS 2/23/12 & 6/1/12 ENCLOSURES & 4/18/12/LTR.
2012-5190	07/17/2012 08/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	JESSICA C DIXON PARKER POE ET AL LLP	MDRS 9610816-2008-00012, 9610816-2009-00028, 9610816-2010-00700, ETC
2012-5191	07/17/2012 08/14/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PRASANNA SUNTHANKER Revogenex Inc.	TRAMADOL - ISRS 4070975, 4197990,& 5656398 ETC
2012-5192	07/17/2012	FDA/OMPT/CDER/GRP/DIDP/	AMY KINCANON	MYLAN - TEMAZEPAM ANDA 70-920/S002,S003 RECS

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	08/14/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LEXISNEXIS COURTLINK INC	
2012-5193	07/17/2012 08/14/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PARAKAL DEEPAK MD CENTER FOR THE STUDY OF COMPLEX DISEASES	ISRS 3941741, 3942655, 6564651, ETC
2012-5194	07/17/2012 08/14/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PAMELA E ESHAM ARMBRECHT JACKSON LLP	NARCAN (NALOXONE HCL) - AERS, CMLPLNTS, WARNINGS, ETC
2012-5195	07/17/2012 08/14/2012	FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/	PAUL W TRIPP LINCARE INC	CAREFIRST OF FORT WAYNE INC (ADVANCED HEALTHCARE), IN, OH, MI - EIRS, 483S, WARNING LTRS, ETC 1/05 TO PRESENT
2012-5196	07/17/2012 08/14/2012	FDA/OMPT/CTP/OD/	AZIM CHOWDURY Keller and Heckman LLP	22ND CENTURY GROUP INC - NEW TOBACCO PROD APPLS, MODIFIED RISK TOBACCO PROD APPLS, MINOR MODIFICATION EXEMPTION REQUESTS, ETC
2012-5197	07/17/2012 08/14/2012	FDA/OGROP/ORA/PA-FO/SEA- DO/SEA-CB/ FDA/OMPT/CDRH/OCER/DFOI/	JOAN YAMADA MYOTRONICS	MYOTRONICS - CONFERENCE CALL MINS 5/15/12
2012-5198	07/17/2012 08/14/2012	FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/	Doe J	PRIME DISTRIBUTION SERVICES, PLAINFIELD, IN - INSP 5/12
2012-5199	07/17/2012 08/14/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	ARDAUGH, BRENT M	SOFRADIM PRODUCTION SA - PARIETEX SURGICAL MESH K982532
2012-5200	07/17/2012 08/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	ANNA DEMKOVIC ABBOTT LABORATORIES, INC.	NESTLE HEALTHCARE NUTRITION INC - NESTLE PUMP ADMINISTRATION SETS WITH SPIKERIGHT PLUS CONNECTORS CORR, MINS
2012-5201	07/17/2012 08/14/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/CE-FO/CIN- DO/CIN-CB/	DANAYI AZZARELLI COLE SCOTT AND KISSANE	EYE INFECTIONS/CONTAMINATIONS STEMMING FROM ADMINISTRATION OF AVASTIN IN KY 2007 TO PRESENT
2012-5202	07/17/2012 08/14/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	INDIVIDUAL RECS

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/		
2012-5203	07/17/2012 08/14/2012	FDA/OC/OES/DFOI/	DOYON, LAURIER JOSEPH	PAIN MANAGEMENT - POLICY DEFINITIONS
2012-5204	07/17/2012 08/14/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARK D KAMITOMO MARKAM GROUP INC PS	NIMBEX - AERS
2012-5205	07/17/2012 08/14/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 6/25-29/12
2012-5206	07/17/2012 08/14/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 7/2-6/12
2012-5207	07/17/2012 08/14/2012	FDA/OC/OES/DFOI/	JASON A CHERKIS HUFFINGTON POST	GLENN WATSON, JOHN HORTON, LEGITSCRIPT - CONTRACT HHSF223201000071C EMAILS, CORR 1/09 TO PRESENT
2012-5208	07/17/2012 08/14/2012	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	Ellen Peck VA Illiana Health Care System	VA ILLIANA HEALTH CARE SYSTEM BLOOD BANK - 483, 482 (5/11)
2012-5209	07/17/2012 08/14/2012	FDA/OFVM/CFSAN/OCD/EOS/	Angelia Slayton INC RESEARCH	FCN 1109
2012-5210	07/17/2012 08/14/2012	FDA/OFVM/CFSAN/OCD/EOS/	Angelia Slayton INC RESEARCH	FCN 545
2012-5211	07/17/2012 08/14/2012	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Branan Medical Corporation Branan Medical Corporation	BRANAN MEDICAL CORP - EIR 2011
2012-5212	07/17/2012 08/14/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/OER/OPA/ FDA/OC/OES/DFOI/ OC/OER/OPA/ FDA/OC/OEXA/OMA/	Jeanne Lenzer BMJ	INDIVIDUAL RECORDS

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2012-5213	07/17/2012 08/14/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Regina Brown Hemispherx Biopharma, Inc	HEMISPHERIX, NORTH BRUNSWICK, NJ - PRE-APPROVAL INSPECTION FOR NDA 22151 (11/2007)
2012-5214	07/17/2012 08/14/2012	FDA/OMPT/CTP/OD/ FDA/OC/OES/DFOI/ FDA/OMPT/CTP/OD/	Kimberly Elliott Shoe	LAWRENCE DEYTON - PERSONAL SCHEDULE RE: MENTHOL CIGARETTES MEETINGS
2012-5215	07/17/2012 09/18/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/CVM/OCD/	IKARIA INC	ZHEJIANG RUIBANG LABS, WENZHOU, CHINA - 483 7/28/11
2012-5216	07/17/2012 08/14/2012	OC/ORACE/ OC/ORACE/ OC/CVM/OCD/	Robin Taylor WPXI-TV	ONLINE PET PHARMACIES - COMPLAINTS 2002-2012
2012-5217	07/17/2012 08/14/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Nancy R. Meyers Ward Black Law	NDA 19645, NDA 19698 - ORIGINAL ACTION PACKAGES
2012-5218	07/17/2012 08/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	Sara K. Borrelli Jackson Walker L.L.P.	K063744
2012-5219	07/17/2012 08/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	Sara K. Borrelli Jackson Walker L.L.P.	P050028
2012-5220	07/17/2012 08/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	Sara K. Borrelli Jackson Walker L.L.P.	P110037
2012-5221	07/18/2012 08/15/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PATRICIA L. REGENYE Celgene Corporation	ISTITUTO EUROPEO DI ONCOLOGIA, MILANO, ITALY - 483, EIR 11/05 TO PRESENT
2012-5222	07/18/2012 08/15/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PATRICIA L. REGENYE Celgene Corporation	INSTITUTE GUSTAVE-ROUSSY DEPT OF MED, VILLEJUIF CEDEX, FRANCE - 483, EIR 6/10 TO PRESENT
2012-5223	07/18/2012 08/15/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	PATRICIA L. REGENYE Celgene Corporation	KATEDRA KLINIKA HEMATOL TRANSPLANTECJI SZPIKU AM W LUBLINIE & JACZEWSKIEGO, LUBLIN, POLAND - 483, EIR 1/10 TO PRESENT

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/		
2012-5224	07/18/2012 08/15/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CLARK G. SULLIVAN ARNALL GOLDEN & GREGORY, LLP	COBALAMIN - DESI RVW, APRVL
2012-5225	07/18/2012 08/15/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	SIMVASTATIN, MELOXICAM, CITALOPRAM - AER
2012-5226	07/18/2012 08/15/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRIAN B. WINEGAR PERDUE & KIDD LLP	ABBOTT LABS - HUMIRA RISK EVALUATION & MITIGATION STRATEGIES (REMS) RECS THROUGH 6/1/10
2012-5227	07/18/2012 08/15/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	BAYER, RANGE (RICHARD) D	BLOOD PRODUCTS A/C - RECOMMENDATION FOR CHANGE IN HEMOBLOBIN VALUES PRESENTATION 5/10/89
2012-5228	07/18/2012 08/15/2012	FDA/OMPT/CDRH/OCER/DFOI/	STACEY ELLUL NEUROPACE INC	DIABETES DATA MGMT SYS K032164
2012-5229	07/18/2012 08/15/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORO/OCI/ OC/ORO/OCI/	Laurie J. Wasserman Law Offices of Laurie J. Wasserman	INDIVIDUAL RECORDS
2012-5230	07/18/2012 10/03/2012	FDA/OMPT/CDRH/OCER/DFOI/	Jeffrey G. Thomas Jeffrey G. Thomas dba Thomas Law Company	PMA P080013 - S007; to PMA P080013 - S003, PMA P080013 - S002; ETC.
2012-5231	07/18/2012 08/15/2012	FDA/OGROP/ORO/SE-FO/ATL- DO/ATL-CB/	Jill Hyda Kemin Industries, Inc.	NC STATE, RALEIGH, NC - 483, EIR MARCH 2012
2012-5232	07/18/2012	FDA/OO/OFBA/OAGS/	Bill Hbranchak	HHSF223200831138P - START AND END DATES; OPTION YEARS; PRICING

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	08/15/2012		Neal R. Gross and Company	
2012-5233	07/18/2012 08/15/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Daven Mody Impax Laboratories, Inc.	IVERSINE (MECAMYLAMINE) - APPROVAL HISTORY, LETTERS, REVIEWS, ETC.
2012-5234	07/18/2012 08/15/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/OM/OFM/	THE BOSTON CONSULTING GROUP	PHARMACOVIGILANCE - BUDGET, STAFF 2011
2012-5235	07/18/2012 08/15/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	HUBER, MARIA	AMD 279 - SAP
2012-5236	07/18/2012 08/15/2012	FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/ FDA/OGROP/ORASE-FO/FLA- DO/FLA-CB/	Young, Stephen	FLYING FOOD GROUP, NEWARK, NJ - EIR, 483; FLYING FOOD GROUP, ORLANDO, FL - EIR, 483; FLYING FOOD GROUP, EAST GRANBY, CT - EIR, 483
2012-5237	07/18/2012 08/15/2012	FDA/OMPT/CDRH/OCER/DFOI/	Wei Huang Mid-Link International Inc	K102533
2012-5238	07/18/2012 08/15/2012	FDA/OMPT/CDRH/OCER/DFOI/	CANOPY MEDICAL INC	AESCLAP AG, TUTTLINGEN, GERMANY - EIR, 483, CORR (05/16/11)
2012-5239	07/18/2012 08/15/2012	OC/ORA/ OC/ORA/	SALLY HO SALLY HO	ENTRY NUMBER: BJU-1053246-5
2012-5240	07/18/2012 08/15/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARISA KALUHIOKALANI CENTRALIZED CLINICAL PHARMACY SERVICES	PRADAXA - AER
2012-5241	07/18/2012 08/15/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARISA KALUHIOKALANI CENTRALIZED CLINICAL PHARMACY SERVICES	XARELTO - AER

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2012-5242	07/18/2012 08/15/2012	OC/CVM/OCD/	Larry A Stobbs Larry A. Stobbs	PHIBRO SAUDE ANIMAL INTERNACIONAL LTDA, BRAZIL - EIRS, 483S, WARNING LETTERS, UNTITLED LETTERS RE: VIRGINIAMYCIN (2007-PRESENT)
2012-5243	07/18/2012 08/15/2012	FDA/OC/OES/DFOI/	WILLIAMS 780798, MICHAEL	AVAILABLE UNDER FOI
2012-5244	07/18/2012 08/15/2012	FDA/OFVM/CFSAN/OCD/EOS/	AMORY, MEADE	KOREAN SHELLFISH SANITATION PROGRAM - IPER 2010 TO 2012
2012-5245	07/18/2012 08/15/2012	OC/CVM/OCD/	Larry A Stobbs Larry A. Stobbs	PHIBRO SAUDE ANIMAL INTERNACIONAL LTDA, BRAZIL - EIRS, 483S, WARNING LETTERS, UNTITLED LETTERS RE: SALINOMYCIN (2007-PRESENT)
2012-5246	07/18/2012 08/15/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHANDRAN TIRUVATTAR DR REDDYS LABORATORIES INC	RANBAXY LABS LTD - XIMINO (MINOCYCLINE HYDROCHLORIDE) NDA 01-922 SBA
2012-5247	07/18/2012 08/15/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/OCOS/OES/ OC/OCOS/OES/ OC/OER/OPA/	ELENA HOWELL HOGAN LOVELLS LLP	FOOD SAFETY MODERNIZATION ACT - MTG MINS, CORR, MEMOS, ETC
2012-5248	07/18/2012 08/15/2012	FDA/OMPT/CDRH/OCER/DFOI/	LAUREN R. SILVIS SIDLEY AUSTIN LLP	CORR FROM ODE
2012-5249	07/18/2012 08/15/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GORDON JOHNSTON GORDON JOHNSTON	TEVA - PALONOSETRON HYDROCHLORIDE ANDA 90-713; HOSPIRA - LEVETIRACETAM ANDA 202-869; SAGENT - ACETAZOLAMIDE SODIUM ANDA 200-880
2012-5250	07/18/2012 08/15/2012	FDA/OMPT/CDRH/OCER/DFOI/	CATHERINE O'MARA-CHERUBIN MORRISON MAHONEY LLP	TRANSVAGINAL MESH - MDRS 2008 TO 1020
2012-5251	07/18/2012 08/15/2012	FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/	TRAVIS SCHAFTENAAR USB GLOBAL ASSET MANGEMENT	ANGIODYNAMICS, FREMONT, CA - 483 LAST 18 MTHS
2012-5252	07/18/2012 08/15/2012	FDA/OMPT/CDRH/OCER/DFOI/	STERN, CHERYL	JENS CHAPMAN MD - MDR SUBMISSIONS 1995 TO PRESENT; HARBORVIEW MEIDCAL CTR; UNIV OF WASHINGTON MEDICINE AFFILIATES - MDR SUBMISSIONS 2000 TO PRESENT, ETC
2012-5253	07/18/2012 10/24/2012	FDA/OGROP/ORO/SE-FO/NOL-DO/NOL-CB/ FDA/OMPT/CDER/ORP/DIDP/	DANAYI AZZARELLI CSK	AVASTIN - AER 2007 TO PRESENT

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2012-5254	07/18/2012 08/15/2012	FDA/OMPT/CDRH/OCER/DFOI/	Kristen Stewart DEUTSCHE BANK	PMA P100045
2012-5255	07/18/2012 08/15/2012	FDA/OC/OES/DFOI/	BURGESS, BERNIE	2010-5559, 2010-2940
2012-5256	07/19/2012 08/16/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PAMELA SHEPPARD TARO PHARMACEUTICALS USA INC	SANOFI AVENTIS - ALLEGRA (FEXOFENADINE HYDROCHLORIDE) N20-625
2012-5257	07/19/2012 08/16/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID T. LIN, Ph.D. BIOLOGICS CONSULTING GROUP	CESAMET (NABILONE) NDA 18-677 APRVL, RVWS
2012-5258	07/19/2012 08/16/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID T. LIN, Ph.D. BIOLOGICS CONSULTING GROUP	ABBOTT - MARINOL (DRONABINOL) NDA 18-651 APRVL, RVWS
2012-5259	07/19/2012 08/16/2012	OC/CVM/OCD/	SHELIA CROOKS PHIBRO ANIMAL HEALTH	TEVA ANIMAL HEALTH ANADA 200-344
2012-5260	07/19/2012 08/16/2012	OC/CVM/OCD/	SHELIA CROOKS PHIBRO ANIMAL HEALTH	TEVA ANMAL HEALTH ANADA 200-423
2012-5261	07/19/2012 08/16/2012	OC/CVM/OCD/	SHELIA CROOKS PHIBRO ANIMAL HEALTH	TEVA ANIMAL HEALTH ANADA 200-258
2012-5262	07/19/2012 08/16/2012	OC/CVM/OCD/	SHELIA CROOKS PHIBRO ANIMAL HEALTH	TEVA ANIMAL HEALTH ANADA 200-345
2012-5263	07/19/2012 08/16/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Kristen Stewart DEUTSCHE BANK	HALOZYME/BAXTER - BLA CORR

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2012-5264	07/19/2012 08/16/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECORDS
2012-5265	07/19/2012 08/16/2012	FDA/OC/OES/DFOI/	Greg Frisbee	KOMBUCHA - PRODUCT CLASSIFICATION
2012-5266	07/19/2012 08/16/2012	FDA/OMPT/CDRH/OCER/DFOI/	Anona Goebel KCI USA, Inc.	KCI MANUFACTURING, ATHLONE IRELAND - EIR 2/12
2012-5267	07/19/2012 08/16/2012	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	Sean Walsh Walsh, Sean C	OSO BIOPHARMACEUTICALS, NEW MEXICO - EIRS, 483 2012
2012-5268	07/19/2012 08/16/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	THOMAS J. WALZ HAHN WALZ AND KNEPP	DEPUY - ASR MODULAR ACETABULAR CUP SYS K040627 CORR
2012-5269	07/19/2012 08/16/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JACKSON, EVA JO.	IMANTINIB - AER, LBLG
2012-5270	07/19/2012 08/16/2012	FDA/OC/OES/DFOI/	BECKY COOSEMAN BROWN & CROUPPEN PC	CRONOBACTER SAKAZAKII - DENDROGRAMS
2012-5271	07/19/2012 08/16/2012	FDA/OMPT/CDRH/OCER/DFOI/	Wendi F May iSirona, LLC	K102974, K112282
2012-5272	07/20/2012 08/17/2012	OC/OM/OMP/DDM/	ROSS RENDELMAN HOGAN LOVELLS LLP	DKT FDA-2012-P-0538
2012-5273	07/20/2012 08/17/2012	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ OC/ORA/OCI/ OC/ORA/OCI/	CAITLIN L SALINAS Hilliard Munoz Gonzales LLP	SOUTH TEXAS COMPREHENSIVE CANCER CENTER, CORPUS CHRISTI, TX - COUNTERFEIT AVASTIN RECS, CORR
2012-5274	07/20/2012 08/17/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JODY L GREEN PHD ROCKY MOUNTAIN POISON & DRUG CENTER	COUGH AND COLD PREPARATIONS - ISRS 8019934-4, 8022172-2, 8023421-7, ETC
2012-5275	07/20/2012 08/22/2012	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	HENRY HADRY LEGAL RESEARCH INSTITUTE	PERSONAL CARE - NON-ACETONE NAIL POLISH REMOVER RECALL RECS

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2012-5276	07/20/2012 08/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	TIMOTHY R CONAWAY CONAWAY & CONAWAY PLLC	INSET TECHNOLOGIES INC - PROMETRA PROGRAMMABLE PUMP SYS, PROMETRA PUMP TRAY, INTRATHECAL CATHETER PERFORMANCE STANDARDS RECS
2012-5277	07/20/2012 08/17/2012	FDA/OC/OES/DFOI/	Doe J	DATABASES THAT INCLUDE RECS INDEXING HUMAN SUBJECTS RSEARCH
2012-5278	07/20/2012 08/17/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	ELYSSA M FRIED ESQ Finkelstein and Partners	LEONARD SPADA, PASQUAL PETRUZZO, NY GOURMET SALADS INC, BROOKLYN, NY - CORR, INVESTIGATIONS, LIST OF VENDORS, ETC 2009, 2010
2012-5279	07/20/2012 08/17/2012	OC/ORAN/ OC/ORAN/	VERA-LYNN KUBINEC CBC NEWS	SHIPMENTS FROM CANADA TURNED AWAY AT THE BORDER 1/09 TO PRESENT
2012-5280	07/20/2012 08/17/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	KATSUHIKO BABA SEIKO EPSON CORP	ERBE USA INC - HELIX HYDRO-JET K033590, HYBRID KNIFE K083608
2012-5281	07/20/2012 08/17/2012	OC/ORAN/ OC/ORAN/ FDA/OC/OES/DFOI/	MARIE MUNOZ SEADCO USA CORP	EXTRA JUMBO U-130 SPLS ENTRY #E4P-0020078-2 - LAB RESULTS
2012-5282	07/20/2012 08/17/2012	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	kevin giles Kevin Giles	PCI SYNTHESIS, NEWBURYPORT, MA - EIR 6/10, 8/11
2012-5283	07/20/2012 08/17/2012	OC/CVM/OCD/	Annette O'Connor IOWA STATE UNIVERSITY	NADA-113-232
2012-5284	07/20/2012 08/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	WANGYANG ANDON HEALTH CO LTD	SOOCHOW UNV, TESTING CENTER OF SANITATION AND ENVIRONMENT TECHNIC INSTITUTE - INSP, COMPLIANCE STATUS 5/30/11 TO 6/3/11
2012-5285	07/20/2012 08/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELLIOT FAVUS MD FAVUS INSTITUTIONAL RESEARCH LLC	NEUDEXTA - AERS 1/22/12 TO PRESENT
2012-5286	07/20/2012 08/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JULIE HOEHN BURKE HILL KERTSCHER & WHARTON LLP	ARCHER BIOSCIENCES INC - FILINGS FOR NDAS, IINVESTIGATOR INDS, EMERGENCY USE INDS, ETC 2008 TO PRESENT
2012-5287	07/20/2012 08/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	THIERRY FILLOUX TRISKEL INTEGRATED SERVICES	GONAL-F NDA 20-378 - SBA

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2012-5288	07/20/2012 08/17/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JAMES PEPPER - ELLIOTT GREENLEAF JAMES PEPPER - ELLIOTT GREENLEAF	ASTRAZENECA - CORR RE: QUETIAPINE, QT INTERVAL
2012-5289	07/23/2012 08/20/2012	FDA/OGROP/ORA/CE-FO/CIN- DO/CIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	RPH CONCEPTS, BEREA, KY - 483S 5/11/11-6/23/11
2012-5290	07/23/2012 08/20/2012	FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	NUSIL TECHNOLOGY LLC, BAKERSFIELD, CA - 483S 4/18/11-5/4/11
2012-5291	07/23/2012 08/20/2012	FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/	WALTER E CHALKLEY THOMSON REUTERS	EDGE BIOLOGICALS INC, MEMPHIS, TN - 483S 9/13-16/11
2012-5292	07/23/2012 08/20/2012	FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	CHRISTIAN HOSPITAL NORTHEAST-NORTHWEST (IRB), ST LOUIS, MO - 483S 12/11
2012-5293	07/23/2012 08/20/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	John McIntyre Ellipse Technologies, Inc.	K103560
2012-5294	07/23/2012 08/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	Danielle Wright Danielle Wright	K770768, K950461
2012-5295	07/23/2012 08/20/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Qiuhu Shi NEW YORK MEDICAL COLLEGE	K082481, K053501
2012-5296	07/23/2012 08/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	Gina Lento Pure Protein LLC	PMA P850020 - SSED
2012-5297	07/23/2012 08/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	Patty Williams Patricia Williams	OM3 GEL FOR ATRIUM C-QUR HERNIA MESH - APPROVAL RECS
2012-5298	07/23/2012 08/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	Mercedes LeGrand Mercedes LeGrand	AMP MD ROLLER - RODAN AND FIELDS
2012-5299	07/23/2012 09/06/2012	FDA/OC/OES/DFOI/	Lois Ritter Southern Regional Education Board	ADVERSE EVENTS
2012-5300	07/23/2012 08/20/2012	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	IPD Analytics, LLC	ANDA 078873 - EFFECTIVE APPROVAL LETTER
2012-5301	07/23/2012 08/20/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Stephanie Schutt Costello & Fera, LLC	ISOTRETINOIN - AERS

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2012-5302	07/23/2012 08/20/2012	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	WALTER E CHALKLEY THOMSON REUTERS	BIOMEDICAL RESEARCH INSTITUTE OF AMERICA, DBA BIOMED IRB, SAN DIEGO, CA - 483S 9/22/10-10/25/10, 8/8-19/11
2012-5303	07/23/2012 08/20/2012	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	LORICON TESTING, KEYPORT, NJ - 483S 8/5-12/10
2012-5304	07/23/2012 08/20/2012	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	DISCOVERY LABS, TOTOWA, NJ - 483S 1/24-31/12
2012-5305	07/23/2012 08/20/2012	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	TEVA PHARMACEUTICALS USA, SELLERSVILLE, PA - 483S 7/18-26/11
2012-5306	07/23/2012 08/20/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	MERCK SERONO, MODUGNO, BARI, ITALY - 483S 7/8-16/10
2012-5307	07/23/2012 08/20/2012	FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	WALTER E CHALKLEY THOMSON REUTERS	MERCK, ARECIBO, PR - 483S 10/25/10-11/3/10
2012-5308	07/23/2012 08/20/2012	FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	WALTER E CHALKLEY THOMSON REUTERS	MERCK, BARCELONETA, PR - 483S 4/16/09-5/21/09
2012-5309	07/23/2012 08/20/2012	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	WALTER E CHALKLEY THOMSON REUTERS	CARDINAL HEALTH, ORLANDO, FL - 483S 3/9-15/11
2012-5310	07/23/2012 08/20/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DON J MIZERK HUSCH BLACKWELL LLP	ACTAVIS ELIZABETH - INTUNIV ANDA 200881 APRVL LTR 6/29/12
2012-5311	07/23/2012 08/20/2012	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/ FDA/OMPT/CDER/GRP/DIDP/	WAYNE SADOWSKI NOVARTIS PHARMACEUTICAL CORP	DENISE YARDLEY MD, NASHVILLE, TN 3/27-29/12; MIKHAIL SHTIVELBAND MD, CHANDLER, AZ 4/9-10/12; JOSEPH BECK MD, FAYETTEVILLE, AR 4/17-19/12 - EIRS, 483S, 482S, ETC

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2012-5312	07/23/2012 08/20/2012	OC/CVM/OCD/	LINDA M DUPLÉ BIMEDA INC	COLORADO ANIMAL RESEARCH - PENICILLIN G PROCAINE NADA 065-505 BIOEQV STUDY 9/9/86, 5/26/88
2012-5313	07/23/2012 08/20/2012	OC/OM/OMP/DDM/	CAITLIN GIROUARD MCDERMOTT WILL & EMERY	DKT 1985P-0197, 1985P-0129, ETC.
2012-5314	07/24/2012 08/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jennifer Ensign Ensign, Jennifer D	NDA 074171
2012-5315	07/24/2012 08/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	IPD Analytics, LLC	ANDA 077707 - EFFECTIVE APPROVAL LETTER
2012-5316	07/24/2012 08/21/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Doe J	VAERS REPORT
2012-5317	07/24/2012 08/21/2012	FDA/OGROP/ORR/SE-FO/ATL- DO/ATL-CB/ FDA/OGROP/ORR/CE-FO/CIN- DO/CIN-CB/	Doe J	TALECRIS PLASMA RESOURCES - INSPECTION RECORDS 06/15/2012 - 06/23/2012
2012-5318	07/24/2012 08/21/2012	FDA/OGROP/ORR/ORO/DIOP/	Pablo A Scolnik Koru Naturals LLC	IMPORT ALERT 66-41 - PEARSON AND CRAIG PLACENTA SERUM
2012-5319	07/24/2012 08/21/2012	FDA/OGROP/ORR/CE-FO/DET- DO/DET-CB/	Al Jacks Al Jacks	COOK BIOTECH, WEST LAFAYETTE, IN - EIRS, 483 2007- 2012
2012-5320	07/24/2012 08/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Erika J. Harris Harris, Creech, Ward & Blackerby, P.A.	IV PHERNEGAN PACKAGE INSERT APRIL 2009
2012-5321	07/24/2012 08/21/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Oral BioTech	K103244, K053167
2012-5322	07/24/2012 08/21/2012	FDA/OGROP/ORR/CE-FO/DET- DO/DET-CB/	Max Harriger UBER FOODS, LLC	HEARTHSIDE FOOD SOLUTIONS - EIRS, 483S 4/19/10- 7/19/12

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		FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORAPA-FO/SEADO/SEA-CB/ FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/		
2012-5323	07/24/2012 08/21/2012	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Joan Friend AMERICAN RED CROSS	AMERICAN RED CROSS, WICHITA, KS - EIR 1/19/12
2012-5324	07/24/2012 08/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dennys Reyes, MD Cleveland Clinic Florida	RECLAST - AERS
2012-5325	07/24/2012 08/21/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	NANCY E. ANTHRACITE, MD WORLD VISTA	VISTA BLOOD ESTABLISHMENT COMPUTER SOFTWARE (VBECS)
2012-5326	07/24/2012 08/21/2012	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	DAVID LOHMAN SANESA PARTNERS	AKORN PHARM - 483S, UNTITLED LTRS, WARNING LTRS, ETC 1/12 TO PRESENT
2012-5327	07/24/2012 08/21/2012	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	DAVID L. PETITJEAN GROTH & ASSOCIATES	GRAMINEX, DESHLER, OH - EIR, CO RESP
2012-5328	07/24/2012 08/21/2012	OC/OCOS/OL/ OC/OCOS/OES/ OC/OCOS/OES/	REDLUND, PAUL G	STAFF REPORT ON GLAXO SMITH KLINE & THE DIBETES DRUG AVANDIA 3/30/10
2012-5329	07/24/2012 08/21/2012	FDA/OC/OES/DFOI/	JOHN CREWDSON PROJECT GOVRRNMENT OVERSIGHT	CORR WITH NAMED INDIVIDUALS
2012-5330	07/24/2012 08/21/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Adam Kuhn ProNova Solutions	K053641
2012-5331	07/24/2012 08/21/2012	FDA/OMPT/CDRH/OCER/DFOI/	Adam Kuhn ProNova Solutions, LLC	K100766
2012-5332	07/24/2012 08/21/2012	FDA/OMPT/CDRH/OCER/DFOI/	Adam Kuhn ProNova Solutions, LLC	K062891
2012-5333	07/24/2012 08/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ulrika Marking/ Koert Ritmeijer Medecins Sans Frontiers (MSF)	AMBISOME - AERS

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2012-5334	07/24/2012 08/21/2012	FDA/OMPT/CDRH/OCER/DFOI/	Adam Kuhn ProNova Solutions	K062891
2012-5335	07/24/2012 08/31/2012	FDA/OMPT/CDRH/OCER/DFOI/	BOBBY SCHOCHET OFW LAW	LAWRENCE H WEISS, ZYGO INDUSTRIES INC - LTR 8/7/95; WALT WOLTOSZ, WORLD + INC - 4/28/95
2012-5336	07/25/2012 08/22/2012	OC/OM/OMP/DDM/	RONA KRONENBERG RONA KRONENBERG	DKT FDA-2012-P-0760
2012-5337	07/25/2012 08/22/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Erica Weinstein LONG ISLAND UNIVERSITY	CAFEPIME - AERS
2012-5338	07/25/2012 08/22/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Stephanie Dube Thomas J Henry Law Firm	DR. MARK MOLITCH - ADVISORY COMMITTEE WAIVER STATEMENTS
2012-5339	07/25/2012 08/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	Lakshmi Padmanabhan St.Jude Medical Neuromodulation	P960009/S027, P960009S037, P960009/S065 - SAFETY AND EFFECTIVENESS DATA
2012-5340	07/25/2012 08/22/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Shalin Jani G&W Laboratories Inc.	NDA 018604 - SBA, CMC SUPP
2012-5341	07/25/2012 08/22/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	EVA GONSALVES FOI Services, Inc.	SANQUIN - CORR WITH FDA RE 09/11 INSPECTION
2012-5342	07/25/2012 09/18/2012	FDA/OMPT/CDRH/OCER/DFOI/	Maria Granquist/Chris Kilander Cook Medical	K092398
2012-5343	07/25/2012 08/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	Maria Granquist/Chris Kilander Cook Medical	K090832
2012-5344	07/25/2012 08/22/2012	OC/ORA/ OC/ORA/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORASE-FO/ATL- DO/ATL-CB/ FDA/OGROP/ORASW-FO/KAN- DO/KAN-CB/	GABRIEL H SCANNAPIECO JONES DAY	ABBOTT LABS - SIMILAC NEOSURE INFANT FORMULA CRONOBACTER SAKAZAKII TESTING METHODS, CORR, GUIDANCES, ETC
2012-5345	07/25/2012	FDA/OMPT/CTP/OD/	MARK E GREENWOLD	REQUESTS MADE BY FDA TO TOBACCO PROD MFRS 2009

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	08/22/2012		CAMPAIGN FOR TOBACCO-FREE KIDS	TO PRESENT
2012-5346	07/25/2012 08/22/2012	FDA/OC/OES/DFOI/	SHAUNAK DEEPAK JEFFERIES & CO	BANNER PHARMACAPS, HIGH POINT - 483S; FOI REQUESTS
2012-5347	07/25/2012 08/22/2012	FDA/OFVM/CFSAN/OCD/EOS/	LI ZHANG PHD BASF CORP	FCN 971
2012-5348	07/25/2012 08/22/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	JAMES T JACOB BLISPAK INC	BLISPAK ACQUISITION CORP, WHIPPANY, NJ - EIR 2012
2012-5349	07/25/2012 08/22/2012	OC/OA/OM/OMP/DDM/ FDA/OMPT/CDRH/OCER/DFOI/	GABRIEL B SHERMAN Hyman Phelps and McNamara PC	ORTHOPAEDIC AND REHABILITATION DVCS PANEL A/C - PMA SUBMITTED BY DEPUY ORTHOPAEDICS INC FOR COMPLETE ACETABULR HIP SYS P090002 TRANS 8/18/09, ETC
2012-5350	07/25/2012 08/22/2012	OC/OA/OM/OMP/DDM/	CARA WELCH PHD NATURAL PRODUCTS ASSOCIATION	DKT 1995S-0316
2012-5351	07/25/2012 08/22/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/ORM/ OC/ORO/ORM/	CARA WELCH PHD NATURAL PRODUCTS ASSOCIATION	CFSAN INTERNAL WEB-BASED TRAININGS FOR INSPECTORS - PRESENTATIONS RELATED TO FDA GMP FOR DIETARY SUPPLEMENTS 2011, 2012
2012-5352	07/25/2012 08/22/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	MATTHEW LOPER ORBIMED ADVISORS LLC	HI-TECH PHARMACAL - 483 10/11
2012-5353	07/25/2012 08/22/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANNELIEKE ROEST UNIV MEDICAL CENTER GRONINGEN	PROZAC (FLUOXETINE) NDA 18-936 - MEDICAL & STATISTICAL RVWS
2012-5354	07/25/2012 08/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	LEE H ROSEBUSH MORGAN LEWIS & BOCKIUS LLP	CALIBRA MEDICAL INC - FINESSE PERSONAL INSULIN DELIVERY PATCH K111924
2012-5355	07/25/2012 08/22/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RAMIREZ, HEIDI .	COMPLETE LIST OF ALL RX CONTAINING SULFITES
2012-5356	07/25/2012 08/22/2012	FDA/OFVM/CFSAN/OCD/EOS/	GARY J. BURIN, Ph.D. TECHNOLOGY SCIENCES GROUP INC	FCN 550 (disregard the fcn 556 in paragraph below).
2012-5357	07/25/2012 08/22/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OES/DFOI/	Megan Pickel BEVERIDGE & DIAMOND	CFSAN FOIA REQUESTS 6/22/12 TO PRESENT

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2012-5358	07/25/2012 08/22/2012	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	MARK L. WEINSTEIN DE VARONA ARANGO & WEINSTEIN LLC	UNIV OF MIAMI, DR SEAN SCULLY, RECAP TOTAL RESURFACING SYS - WARNING LTR
2012-5359	07/25/2012 08/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	LIZ DAY PROPUBLICA	SURGICAL DRAPE MFRS, DVC RE-PROCESSOR, CONTRACT STERILIZER - CMLPLNTS 1/02 TO PRESENT
2012-5360	07/25/2012 08/22/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 7/2-6/12
2012-5361	07/25/2012 08/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	CHERENE MASTROIANNI OLYMPUS AMERICA INC	OLYMPUS - EVIS EXERA II SYS 180 K100584
2012-5362	07/25/2012 08/22/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 6/25-29/12
2012-5363	07/25/2012 08/22/2012	FDA/OC/OES/DFOI/	INC RESEARCH CONSULTING & SUBMISSIONS	DAILY LOG 7/2-6/12
2012-5364	07/25/2012 08/22/2012	FDA/OC/OES/DFOI/	INC RESEARCH CONSULTING & SUBMISSIONS	DAILY LOG 6/25-29/12
2012-5365	07/25/2012 08/22/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 6/25-29/12
2012-5366	07/25/2012 08/22/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 7/2-6/12
2012-5367	07/25/2012 08/22/2012	FDA/OC/OES/DFOI/	WASHINGTON INFORMATION SOURCE	DAILY LOG 7/2-6/12
2012-5368	07/25/2012 08/22/2012	FDA/OC/OES/DFOI/	WASHINGTON INFORMATION SOURCE	DAILY LOG 6/25-29/12
2012-5369	07/25/2012 08/22/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/OCM/EMOPS/ OC/ORR/ OC/ORR/ FDA/OGROP/ORR/CE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORR/SE-FO/ATL-	PATTI WALLER MARLER CLARK ATTYS	SMILING HARA TEMPEH - SALMONELLA PARATYPHI B OUTBREAK RECS 4/12 TO 5/12

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		DO/ATL-CB/		
2012-5370	07/25/2012 08/22/2012	FDA/OC/OES/DFOI/	WASHINGTON INFORMATION SOURCE	DAILY LOG 6/26-29/12
2012-5371	07/25/2012 08/22/2012	FDA/OC/OES/DFOI/	WASHINGTON INFORMATION SOURCE	DAILY LOG 7/2-6/12
2012-5372	07/25/2012 08/22/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORO/SW-FO/SWID/SWID-CB/	SHIRLEY ROSS ROANOKE TRADE SERVICES INC	GRUPO CENTRAL DE DISCOS INC - ENTRY #MJ301585380 FDA ACTION, REDELIVERY NOTICES, NOTICES OF REFUSAL
2012-5373	07/25/2012 08/22/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 7/2-6/12
2012-5374	07/25/2012 08/22/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 6/25-29/12
2012-5375	07/25/2012 08/22/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 6/25-29/12
2012-5376	07/25/2012 08/22/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 7/2-6/12
2012-5377	07/25/2012 08/22/2012	OC/ORO/ORM/ OC/ORO/ORM/ OC/ORO/ OC/ORO/ OC/OM/OEO/	Mark Greenblatt ABC NEWS	COMMERCIAL AIRLINE CATERERS - LIST OF INSPECTIONS
2012-5378	07/25/2012 08/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	Troy Fleming Brown & Jennings, PLC	VALENTINE INTERNATIONAL LIMITED SHOWER CHAIR - MEDWATCH REPORT
2012-5379	07/25/2012 08/22/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SEAN L CORGAN LAVIN O'NEIL RICCI CEDRONE & DISIPIO	LEVAQUIN NDA 20-634, NDA 21-721 - MEDICATION GUIDE 2004 TO PRESENT
2012-5380	07/25/2012	FDA/OMPT/CDRH/OCER/DFOI/	TOSHIO MURATA	CARL ZEISS MEDITEC AG - CIRBUS PHOTO MODELS 600 &

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	08/22/2012		NIDEK INC	800 K112184
2012-5381	07/25/2012 08/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	K111454
2012-5382	07/25/2012 08/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	K120080
2012-5383	07/26/2012 08/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	IPD Analytics, LLC	ANDA 077437 - TENTATIVE APPROVAL LETTER
2012-5384	07/26/2012 08/23/2012	FDA/OC/OES/DFOI/	Paula Coxé 220 Laboratories, Inc.	220 LABS - EIR 6/4/12
2012-5385	07/26/2012 08/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	IPD Analytics, LLC	ANDA 076938 - TENTATIVE APPROVAL LETTER
2012-5386	07/26/2012 08/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	IPD Analytics, LLC	ANDA 077437 - TENTATIVE APPROVAL LETTER
2012-5387	07/26/2012 08/23/2012	OC/ORA/ OC/ORA/ FDA/OGROP/ORPA/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Jason A. Forge Robbins Geller -- Jason A. Forge	CONSUMER COMPLAINT 110480 - RECS
2012-5388	07/26/2012 08/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	Shweta Daga Voyage Medical, Inc.	K070051
2012-5389	07/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	Sharon Katzke	K100213

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	08/23/2012		Katzke, Sharon	
2012-5390	07/26/2012 08/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	IPD Analytics, LLC	ANDA 200160 - TENTATIVE APPROVAL LETTER
2012-5391	07/26/2012 08/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	STEVE W SUMMER STEVE W SUMMER ATTY AT LAW LLC	AMBIEN - MEDICATION GUIDE
2012-5392	07/26/2012 08/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	TRAMADOL - RECS
2012-5393	07/26/2012 08/31/2012	FDA/OGROP/ORP/SW-FO/DEN- DO/DEN-CB/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Doe J	INDIVIDUAL RECS
2012-5394	07/26/2012 08/23/2012	OC/OA/OM/OMP/DDM/	MAHMOUD AYESH Zx Pharma, LLC	DKT 1995S-0039
2012-5395	07/26/2012 08/23/2012	FDA/OFVM/CFSAN/OCD/EOS/	LOREN E S WALKER SCHRAMM WILLIAMS & ASSOCIATES INC	INDUSTRY PROPOSED STANDARDS OF IDENTITY FOR OLIVE OIL 1990 TO PRESENT
2012-5396	07/26/2012 08/23/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 7/9-13/12
2012-5397	07/26/2012 08/23/2012	FDA/OFVM/CFSAN/OCD/EOS/	JUDY MA HARRIS SPICE COMPANY INC	CB BADAR KENCANA, LAMPUNG, INDONESIA - EIRS, 483S
2012-5398	07/26/2012 08/23/2012	FDA/OFVM/CFSAN/OCD/EOS/	JUDY MA HARRIS SPICE COMPANY INC	PT SARIWIGUNA BINASENTOSA, JAKARTA, INDONESIA - EIRS, 483S
2012-5399	07/26/2012 08/23/2012	FDA/OFVM/CFSAN/OCD/EOS/	JUDY MA HARRIS SPICE COMPANY INC	CV PUTRA NUSA & CV PANEN BARU, JAKARTA, INDONESIA - EIRS, 483S
2012-5400	07/26/2012 08/23/2012	FDA/OFVM/CFSAN/OCD/EOS/	JUDY MA HARRIS SPICE COMPANY INC	PT AGRI SPICE INDONESIA, CENTRAL JAVA INDONESIA KLATAN, INDONESIA - EIRS, 483S
2012-5401	07/26/2012 08/23/2012	FDA/OFVM/CFSAN/OCD/EOS/	JUDY MA HARRIS SPICE COMPANY INC	PT BANGKA ALAM SEJAHTERA, PANGKALPINANG, INDONESIA - EIRS, 483S

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2012-5402	07/26/2012 08/23/2012	FDA/OFVM/CFSAN/OCD/EOS/	JUDY MA HARRIS SPICE COMPANY INC	PT PUTRABALI ADYAMULIA, BANDAR LAMPUNG, INDONESIA - EIRS, 483S
2012-5403	07/26/2012 08/23/2012	FDA/OFVM/CFSAN/OCD/EOS/	JUDY MA HARRIS SPICE COMPANY INC	PT NEKA BOGA PERISA, LAMPUNG INDONESIA - EIRS, 483S
2012-5404	07/26/2012 08/23/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	ELISA TOSTADO STRYKER SUSTAINABILITY SOLUTIONS	GYRUS ACMI - HALO PKS CUTTING FORCEPS K100896; GYRUS - BIPOLAR CUTTING FORCEPS K023492
2012-5405	07/26/2012 08/23/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MALIK M ADIL UNIV OF MINNESOTA DEPT OF NEUROLOGY	IMMUNE GLOBULIN INTRAVENOU - ISRS 602419, 6029419, 6386742, ETC
2012-5406	07/26/2012 08/23/2012	FDA/OFVM/CFSAN/OCD/EOS/	DANIEL R LUCKY LUCKY CONSULTANTS LLC	FCN 805
2012-5407	07/26/2012 08/23/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	SHEFT, LAURA L	SANOFI/DERMIK - SCULPTRA AERS
2012-5408	07/26/2012 08/23/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OES/DFOI/	FRYE 33719-183, LARRY	INDIVIDUAL RECS
2012-5409	07/26/2012 08/23/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PARAKKA DEEPAK CENTER FOR THE STUDY OF COMPLEX DISEASES	ISRS 3930462, 3949246, 3965051, ETC
2012-5410	07/26/2012 08/23/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ARTHUR C JOHNSON JOHNSON, JOHSON, LARSON ET AL	RELGAN (METOCOLOPRAMIDE) - WARNING LABEL CHANGES OR MEDICATION USAGE DEAR DOCTOR OR HEALTH CARE PROFESSIONAL LTRS
2012-5411	07/26/2012 08/23/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Jonathan Siegel Kingdon Capital Management	LUITPOLD PHARM, SHIRLEY, NY - 483S, EIRS, PREAPPROVAL INSPECTION RECS (8/11 TO PRESENT)
2012-5412	07/26/2012 08/23/2012	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	Marian Boardley Marian Boardley Consulting	SYNERGY CO, MOAB, UT - 483, EIR (5/11-5/12)
2012-5413	07/26/2012	FDA/OC/OES/DFOI/	Orin Kurtz	DIAMOND PET FOOD - 2012 RECALL RECORDS

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	08/23/2012		Orin Kurtz	
2012-5414	07/26/2012 08/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAN LITVIN GARWIN GERSTEIN & FISHER LLP	GLAXOSMITHKLINE - LAMICTAL CHEWABLES NDA 20-241, TABLET CHEWABLE ORAL NDA 20-764 APRVL, RVWS APRVL PKG, ETC
2012-5415	07/26/2012 08/23/2012	FDA/OFVM/CFSAN/OCD/EOS/	WILLIAM A OLSON PHD WASHINGTON INFORMATION SOURCE	FCN 1150
2012-5416	07/26/2012 08/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAN LITVIN GARWIN GERSTEIN & FISHER LLP	AUROBINIDO PHARMA - LAMOTRIGINE ANDA 90-401; TEVA LAMOTRIGINE ANDA 76-420 TABLET CHEWABLE ORAL; MYLAN - LAMOTRIGINE ANDA 76-630 TABLET CHEWABLE ORAL - APRVL, RVWS, APRVL PKG, ETC
2012-5417	07/26/2012 08/23/2012	FDA/OGROP/ORASE-FO/FLA- DO/FLA-CB/	PATRICIA L REGENYE Celgene Corporation	JEFFREY LANCET, H LEE MOFFITT CANCER & RESEARCH CTR, MIAMI, FL - 483S 4/05 TO PRESENT
2012-5418	07/26/2012 08/23/2012	FDA/OGROP/ORASE-FO/ATL- DO/ATL-CB/	PATRICIA L REGENYE Celgene Corporation	HANNA KHOURY, WINSHIP CANCER INSTITUTE, ATLANTA, GA - 483S 9/10 TO PRESENT
2012-5419	07/26/2012 08/23/2012	FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/	PATRICIA L REGENYE Celgene Corporation	GARY SCHILLER, UNIV CALIFORNIA LOS ANGELES SCH MED, LOS ANGELES, CA - 483S 11/11 TO PRESENT
2012-5420	07/26/2012 08/23/2012	FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/	PATRICIA L REGENYE Celgene Corporation	THOMAS KIPPS, UNIV CALIFORNIA SAN DIEGO, LA JOLLA, CA - 483S 3/09 TO PRESENT
2012-5421	07/26/2012 08/23/2012	FDA/OGROP/ORASW-FO/KAN- DO/KAN-CB/	AMY FEELY SPARBOE FARMS	NEW HORIZON COOP, BRITT, IA - EIR 7/20-22/11
2012-5422	07/26/2012 08/23/2012	FDA/OGROP/ORACE-FO/MIN- DO/MIN-CB/	AMY FEELY SPARBOE FARMS	SPARBOE FARMS, LITCHFIELD, MN - EIR 4/25/11-5/5/11
2012-5423	07/26/2012 08/23/2012	OC/OM/OMP/DDM/	CAROLYN DEAN COVINGTON & BURLING LLP	DKT. 1985P-0490
2012-5424	07/26/2012 08/23/2012	OC/OM/OMP/DDM/	MERLE ZIMMERMANN AMERICAN HERBAL PRODUCTS ASSOCIATION	DKT FDA-19995-S-0039
2012-5425	07/26/2012 08/23/2012	FDA/OGROP/ORASW-FO/KAN- DO/KAN-CB/	AMY FEELY SPARBOE FARMS	SPARBOE FARMS, GOODELL, IA - EIR 4/25-29/11
2012-5426	07/26/2012 08/23/2012	FDA/OGROP/ORASW-FO/KAN- DO/KAN-CB/	AMY FEELY SPARBOE FARMS	SPARBOE FARMS, HUMBOLDT, IA - EIR 6/20-21/11
2012-5427	07/26/2012	FDA/OGROP/ORACE-FO/NWJ-	VANESSA C JACKSON	GARDEN STATE NUTRITIONALS, WEST CALDWELL, NJ -

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	08/23/2012	DO/NWJ-CB/	Bactolac Pharmaceutical, Inc.	EIRS, 483S, 1/10 TO PRESENT
2012-5428	07/26/2012 09/07/2012	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OMPT/CDRH/OCER/DFOI/ OC/OA/OM/OMP/DDM/	MIRALSKY RODRIGUEZ FRIEDMAN RODMAN & FRANK PA	ZIMMER INC - NEXGEN COMPLETE KNEE SOL CORR, RISK ASSESSMENT, TRANS, ETC
2012-5429	07/26/2012 08/23/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	MARK S KACHNER KNOBBE MARTENS OLSON & BEAR	NONIN MEDICAL INC - AVANT MODEL 4000 DIGITALPULSE OXIMETRY SYS K052669
2012-5430	07/26/2012 08/23/2012	FDA/OC/OES/DFOI/	DEBORAH K AUSTIN BENNETT BIGELOW & LEEDOM PS	INFORMATION REGARDING TERMINATION & DISPOSITION OF CDC REQUESTED & FDA- ISSUED EUA PRODS RELENZA (ZANANAMIVIR), TAMIFLU (OSELTAMIVIR) CERTIFIED
2012-5431	07/26/2012 08/23/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	MARK D KACHNER KNOBBE MARTENS OLSON & BEAR	NONIN MEDICAL INC - MODEL 3100 WRISTOX PULSE OXIMETER K052829
2012-5432	07/26/2012 08/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	MARK D KACHNER KNOBBE MARTENS OLSON & BEAR	NONIN MEDICAL INC - MODEL 3150 WRISTOX2 K102350
2012-5433	07/26/2012 08/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	MARK D KACHNER KNOBBE MARTENS OLSON & BEAR	NONIN MEDICAL INC - MODEL 7500 DIGITAL PULSE OXIMETER K071285
2012-5434	07/26/2012 08/23/2012	OC/CVM/OCD/ OC/ORO/ OC/ORO/	VICKY NGUYEN KNTV	CHICKEN JERKY - CMLPLNTS 3/12 TO PRESENT
2012-5435	07/26/2012 08/23/2012	FDA/OC/OES/DFOI/	LIPSON, DEBRA	LIST OF ALL FOI REQUEST PERTAINING TO THE DEFINITON OF NATURAL FOOD LABEL CLAIMS 1/12 TO 6/12
2012-5436	07/26/2012 08/23/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	MARK D KACHNER KNOBBE MARTENS OLSON & BEAR	NONIN MEDICAL INC - AVANT 9600 PULSE OXIMETER K040589
2012-5437	07/26/2012 08/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	MARK D KACHNER KNOBBE MARTENS OLSON & BEAR	NONIN MEDICAL INC - MODEL 7500 DIGITAL PULSE OXIMETER K080255
2012-5438	07/26/2012 08/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	MARK D KACHNER KNOBBE MARTENS OLSON & BEAR	NONIN MEDICAL INC - MODEL AVANT 2120 PULSE OXIMETER AND NONINVASIVE BLOOD PRESSURE (NIBP) MONITOR K031487
2012-5439	07/26/2012	FDA/OGROP/ORO/ORO/DIOP/	JACKIE CALLAWAY	UNLICENSED BOTOX OR JUVEDERM - IMPORT ALERT 57-17, RPTS, PHOTOGRAPHS, VIDEO OF SHIPMENTS, ETC

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	08/23/2012	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ OC/ORAOOI/ OC/ORAOOI/	WFTS TV	
2012-5440	07/26/2012 08/23/2012	FDA/OC/OES/DFOI/	AL-MUJAHIDIN, MUHAMMAD	MK-4-TOP COP (MACE/TEAR GAS); MK-9-SABRE RED FOGGER (MACE/TEAR GAS); MK-4-SABRE RED (MACE/TEAR GAS) - INGREDIENTS, MFRS, AERS, ETC
2012-5441	07/26/2012 08/23/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	MARK D KACHNER KNOBBE MARTENS OLSON & BEAR	NONIN MEDICAL INC - MODEL 2500A PALMSAT PULSE OXIMETER K050056
2012-5442	07/26/2012 08/23/2012	FDA/OC/OES/DFOI/	VALSON, SILUS G-65198 B-3/21	INDUSTRIAL ARSENIC POISON - AERS, BROCHURES, PROCESS TO FILE COMPLAINT
2012-5443	07/26/2012 08/23/2012	FDA/OMPT/CDRH/OCER/DFOI/ OC/OA/OM/OMP/DDM/ OC/ORAOE/ OC/ORAOE/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	B KRISTIAN RASMUSSEN CORY WTSON ET AL	FRESENIUS MEDICAL CARE NORTH AMERICA - GRANUFLO POWDER & NATURALYTE LIQUID ACID CONCENTRATE RECALL NOTICES, MEMOS, RPTS, ETC
2012-5444	07/26/2012 08/23/2012	OC/ORAO/ OC/ORAO/	MARIA F MUNOZ SEADCO USA CORP	EXTRA JUMBO U-130 ENTRY #E4P-0020078-2 - LAB RESULTS
2012-5445	07/27/2012 08/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SUZIE KESCHAMRUS, MD, MBA AVANIR PHARMACEUTICALS INC	SEIZURE - AER 1/10 TO 1/12
2012-5446	07/27/2012 08/24/2012	OC/ORAO/ OC/ORAO/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	INDIVIDUAL RECORDS

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2012-5447	07/27/2012 08/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Wellington Regional Medical Center	MIOCHOL -E - AERS
2012-5448	07/27/2012 08/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Morin, Louis	PERTUZUMAB - BLA
2012-5449	07/27/2012 08/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CLARK G. SULLIVAN ARNALL GOLDEN GREGORY LLP	MALLINCKRODT PHARMA - PENNSAID NDA 020-947 FORM 3542, 3542A
2012-5450	07/27/2012 08/24/2012	OC/ORP/ OC/ORP/	Joseph N. Wilson Kona Cold Lobsters Ltd.	KONA COLD LOBSTERS - CFN OR FEI NUMBER
2012-5451	07/27/2012 08/24/2012	FDA/OMPT/CTP/OD/	Michael Felberbaum THE ASSOCIATED PRESS	LIST OF SE APPS SUBMITTED TO CTP, APPROVALS, REJECTIONS, ETC.
2012-5452	07/27/2012 08/24/2012	OC/ORP/ OC/ORP/	Maiken Cope Blue Ocean Mariculture LLC	BLUE OCEAN MARICULTURE LLC - FEI NUMBER
2012-5453	07/27/2012 08/24/2012	OC/OA/OM/OMP/DDM/	Donald A. Ecklund, Esq. Carella Byrne Cecchi Olstein Brody & Agn	DOCKET FDC-70, FR DOC 63-10752 (ORANGE JUICE)
2012-5454	07/27/2012 08/24/2012	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Eric Dahlin BRIGHAM YOUNG UNIVERSITY	CLINICAL TRIALS (DRUGS) TERMINATED 1990-2010
2012-5455	07/27/2012 08/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANNE MUTASHI HOGAN LOVELLS US LLP	BASIS FOR THE RECOMMENDATION FOR CONTROL OF PREGABALIN IN SCHEDULE V OF THE CONTROLLED SUBSTANCES ACT; BASIS FOR THE RECOMMENDATION FOR CONTROL OF ZOPICLONE AND ITS OPTICAL ISOMERS IN SCHEDULE IV OF THE CONTROLLED SUBSTANCES ACT - COPIES
2012-5456	07/27/2012	FDA/OMPT/CDER/ORP/DIDP/	PARAKKAL DEEPAK, MD	3941741, 3942655, 6564651

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	08/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CENTER FOR THE STUDY OF COMPLEX DISEASES	
2012-5457	07/27/2012 08/24/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	BAYER, RANGE (RICHARD) D	WORKSHOP ON BLOOD DONOR HEMOGLOBIN STANDARDS 6/11/90 - TRANSCRIPT
2012-5458	07/27/2012 08/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bennett Buchsieb Carti-Gen	ORANGE BOOK EQUIVALENT 086417 TESTOSTERONE; NDC 0009-0417 TESTOSTERONE CYPIONATE INJECTION; NDC:0409-4090 ZINC CHLORIDE INJECTION, ETC - NDA, INDA RECS, ETC
2012-5459	07/27/2012 08/24/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Lana Merriam Lana Merriam	SILICON DIOXIDE IN DRUGS, DEVICES AND FOODS
2012-5460	07/27/2012 08/24/2012	OC/OER/OPA/ FDA/OC/OEXA/OMA/	BRIAN VASTAG WASHINGTON POST	CORR BETWEEN HHS PRESS OFFICERS & NIH REGARDING NCI RESEACHER LAUREN V WOOD 7/16/12 - EMAILS
2012-5461	07/27/2012 12/24/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/ OC/OCOS/OES/ OC/OCOS/OES/ OC/OCOS/OL/ FDA/OC/OCC/ FDA/OC/OL/	GREGORY M. LUCE SKADDEN, ARPS, SLATE, MEAGHER & FLOM, LLP	POLICY ON PROMOTION OF MEDICAL DEVICES, PHARMACEUTICALS, BIOLOGICS FOR UNAPPROVED, UNCLEARED, OFF-LABEL USES 1/04 TO PRESENT
2012-5462	07/27/2012 08/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jeffrey Green / Alex Nussbaum at Healthcor HEALTHCOR MANAGEMENT LP	LUITPOLD, GALENICA - CORR RE SHIRLEY FACILITY AND COMPLETE RESPONSE LETTER

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		FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/		
2012-5463	07/27/2012 08/24/2012	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ALISON M. AGNEW PILLSBURY WINTHROP SHAW PTTMAN LLP	BEN VENUE LABS, BEDFORD, OH - 483 1/09 TO 7/25/12
2012-5464	07/27/2012 08/24/2012	OC/CVM/OCD/ FDA/OFVM/CFSAN/OCD/EOS/	JOSIE BALZAC BURDOCK GROUP	QUILLAJA SAPANARIA - REGULATORY STATUS, SAFETY
2012-5465	07/27/2012 08/24/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	UNIVERSITY OF NEW ENGLAND	VANCOMYCIN - REVIEW PACKAGES
2012-5466	07/27/2012 08/24/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 7/23-27/2012
2012-5467	07/27/2012 08/24/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 7/16-20/2012
2012-5468	07/27/2012 08/24/2012	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Doe J	INDIVIDUAL RECS
2012-5469	07/27/2012 08/24/2012	FDA/OO/OFBA/OAGS/	JEFF STACHEWICZ FOIA GROUP INC	CONTRACTOR PERFORMANCE RATING REPORTS SINCE 2009
2012-5470	07/27/2012 08/24/2012	FDA/OGROP/OIP/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	BRETT F. CLEMENTS HERZFELD RUBIN	RITE AID CORP, THRIFTY PAYLESS INC - LISTERIA TAINTED THRIFTY BRAND ICECREAM INVESTIGATION CORR, TESTING RECS, RPTS
2012-5471	07/30/2012 08/28/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OC/OES/DFOI/	KISH, NEAL	WHOLE BLOOD MONITORING, METHODS FOR DIAGNOSING HEMOSTASIS, NUMBER OF REQUESTS, ETC - CLNCL OR COMBAT SITUATION EVALUATION
2012-5472	07/30/2012 08/27/2012	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	SHERRI BATTTERSHELL WASHINGTON INFORMATION SOURCE	SYSTEMS ONE, STUART, FL - EIR, RESP LTRS, CORR 11/11
2012-5473	07/30/2012 08/27/2012	FDA/OMPT/CDRH/OCER/DFOI/	SHERRI BATTTERSHELL WASHINGTON INFORMATION SOURCE	HEARTWAY MEDICAL PRODUCTS, TAICHUNG, TAIWAN - 483, RESP LTRS, CORR 10/11
2012-5474	07/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	TINA WU	VENTANA MEDICAL MEDICAL SYSTEMS INC - VIRTUSO

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	08/27/2012		APTIV SOLUTIONS	SYS ICH HER2 K111543
2012-5475	07/30/2012 08/27/2012	FDA/OMPT/CDRH/OCER/DFOI/	TINA WU APTIV SOLUTIONS	APERIO TECHNOLOGIES - SCAN SCOPE XT SYS K080564
2012-5476	07/30/2012 08/27/2012	FDA/OMPT/CDRH/OCER/DFOI/	TINA WU APTIV SOLUTIONS	BIOIMAGENE INC - PATHIAM SYS WITH ISCAN FOR P53, KI-67 K092333
2012-5477	07/30/2012 08/27/2012	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	APP PHARM, SCHAUMBERG, IL - 483S 6/11 TO 7/11
2012-5478	07/30/2012 08/27/2012	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	APP PHARM, SCHAUMBERG, IL - EIRS 6/11 TO 7/11
2012-5479	07/30/2012 08/27/2012	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	COOPER SURGICAL INC, TRUMBULL, CT - EIRS 8/11 TO 9/11
2012-5480	07/30/2012 08/27/2012	FDA/OMPT/CDRH/OCER/DFOI/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	HEARTWAY MEDICAL PRODUCTS, TAICHUNG, TAIWAN - EIR, RESP LTRS, CORR 10/11
2012-5481	07/30/2012 08/27/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	COOPER SURGICAL INC, TRUMBULL, CT - 483S 8/11 TO 9/11
2012-5482	07/30/2012 08/27/2012	FDA/OMPT/CDRH/OCER/DFOI/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	OSYPKA MEDICAL GMBH, BERLINE, GERMANY - 483, RESP LTRS, CORR 11/11 TO 12/11

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2012-5483	07/30/2012 08/27/2012	FDA/OMPT/CDRH/OCER/DFOI/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	OSYPKA MEDICAL GMBH, BERLIN, GERMANY - EIR, RESP LTRS, CORR 11/11 TO 12/11
2012-5484	07/30/2012 08/27/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	FARMIA QUIMIA SA DE CV, IZCALLI, MEXICO - 483, RESP LTRS, CORR 9/11
2012-5485	07/30/2012 08/27/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	WEST-WARD PHARMACEUTICAL CORP, EATONTOWN, NJ - 483S 6/11
2012-5486	07/30/2012 08/27/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	WEST-WARD PHARMAECUTICALS CORP, EATONTOWN, NJ - EIRS 6/11
2012-5487	07/30/2012 08/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	LABOR L+S AG, BAD BOCKLET-GROSSENBRACH, GERMANY - 483S 7/11
2012-5488	07/30/2012 08/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	FARMA QUIMIA S A DE CV, IZCALI, MEXICO - 483S 9/11
2012-5489	07/30/2012 08/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	LABOR L+S AG, BAD BOCKLET-GROSSENBRACH, GERMANY - EIR, RESP LTRS, CORR 7/11
2012-5490	07/30/2012 08/27/2012	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	CHRISTIAN HOSPITAL NORTHWEST-NORTHEAST IRB, ST LOUIS, MO - 483S 12/11
2012-5491	07/30/2012 08/27/2012	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	ADVANCED ORTHOGONAL EQUIPMENT, ST PETERSBURG, FL - 483, RESP LTRS, CORR 8/11
2012-5492	07/30/2012 08/27/2012	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	ADVANCED ORTHOGONAL EQUIPMENT, ST PETERSBURG, FL - EIR, RESP LTRS, CORR 8/11

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2012-5493	07/30/2012 08/27/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	BIOCHEM LABS, LYNDHURST, NJ - 483, RESP LTRS, CORR 5/11 TO 6/11
2012-5494	07/30/2012 08/27/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	BIOCHEM LABS, LYNDHURST, NJ - EIR, RESP LTRS, CORR 5/11 TO 6/11
2012-5495	07/30/2012 08/27/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	DIANA LITTOV MOUNTAIN VIEW PEDIATRICS	GARDISIL VACCINE - VAERS
2012-5496	07/30/2012 08/27/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	GULF PHARMACEUTICAL INDUSTRIES, RAS AL KHAIMAH, UAE - 483, RESP LTRS, CORR
2012-5497	07/30/2012 08/27/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	GULF PHARMAVEUTICAL INDUSTRIES, RAS AL KHAIMAH, UAE - EIR, RESP LTRS, CORR
2012-5498	07/30/2012 08/27/2012	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	PROCYTE CORP, MONTGOMERYVILLE, PA - 483, RESP LTRS, CORR 8/11
2012-5499	07/30/2012 08/27/2012	FDA/OFVM/CFSAN/OCD/EOS/	GONZALEZ, FRANCESCA	HAIR DYE - AER
2012-5500	07/30/2012 08/27/2012	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	PROCYTE CORP, MONTGOMERYVILLE, PA - EIR, RESP LTRS, CORR 8/11
2012-5501	07/30/2012 08/27/2012	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	WASHINGTON INFORMATION SOURCE	CHRISTIAN HOSP NORTHWEST IRB, ST LOUIS, MO - EIR 12/11
2012-5502	07/30/2012 08/27/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WASHINGTON INFORMATION SOURCE	NOBILUS ENT, KUTNO, POLAND - 483 9/11
2012-5503	07/30/2012 08/27/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WASHINGTON INFORMATION SOURCE	NOBILUS ENT, KUTNO, POLAND - EIR 9/11

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2012-5504	07/30/2012 08/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WASHINGTON INFORMATION SOURCE	SELDER SA DE CV, COLONIA GUADALUPE, MEXICO - 483 9/11
2012-5505	07/30/2012 08/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WASHINGTON INFORMATION SOURCE	SELDER SA DE CV, COLONIA GUADALUPE, MEXICO - EIR 9/11
2012-5506	07/30/2012 08/27/2012	FDA/OGROP/ORR/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	SYSTEMSONE, STUART, FL - 483, RESP LTR, CORR 11/11
2012-5507	07/30/2012 08/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WASHINGTON INFORMATION SOURCE	MERCK SERONO, DARMSTADT, GERMANY - 483 6/11-7/11
2012-5508	07/30/2012 08/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WASHINGTON INFORMATION SOURCE	MERCK SERONO, DARMSTADT, GERMANY - EIR 6/11-7/11
2012-5509	07/30/2012 08/27/2012	FDA/OMPT/CDRH/OCER/DFOI/	WASHINGTON INFORMATION SOURCE	ADVANCED SURGICAL DESIGN & MANUFACTURE, ST LEONARDS, AUSTRALIA - 483 9/11
2012-5510	07/30/2012 08/27/2012	FDA/OMPT/CDRH/OCER/DFOI/	WASHINGTON INFORMATION SOURCE	ADVANCED SURGICAL DESIGN & MANUFACTURE, ST LEONARDS, AUSTRALIA - EIR 9/11
2012-5511	07/30/2012 08/27/2012	FDA/OMPT/CDRH/OCER/DFOI/	WASHINGTON INFORMATION SOURCE	PROBED MEDICAL TECHNOLOGIES, ABBOTSFORD, CANADA - EIR 9/11
2012-5512	07/30/2012 08/27/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI RESQUEST 7/9-13/12
2012-5513	07/30/2012 08/27/2012	FDA/OMPT/CDRH/OCER/DFOI/	WASHINGTON INFORMATION SOURCE	PROBED MEDICAL TECHNOLOGIES, ABBOTSFORD, CANADA - 483 9/11
2012-5514	07/30/2012	FDA/OMPT/CDER/ORP/DIDP/		WINTAC LTD, BANGALORE, INDIA - 483 9/11

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	08/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WASHINGTON INFORMATION SOURCE	
2012-5515	07/30/2012 08/27/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 7/16-20/12
2012-5516	07/30/2012 08/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WASHINGTON INFORMATION SOURCE	WINTAC LTD, BANGALORE, INDIA - EIR 9/11
2012-5517	07/30/2012 08/27/2012	FDA/OGROP/ORR/SE-FO/SJN-DO/SJN-CB/	WASHINGTON INFORMATION SOURCE	WARNER CHILCOTT CO, FAJARDO, PR - 483 6/11-7/11
2012-5518	07/30/2012 08/27/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOI REQUESTS 7/9-13/12
2012-5519	07/30/2012 08/27/2012	FDA/OGROP/ORR/SE-FO/SJN-DO/SJN-CB/	WASHINGTON INFORMATION SOURCE	WARNER CHILCOTT CO, FAJARDO, PR - EIR 6/11-7/11
2012-5520	07/30/2012 08/27/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOI REQUESTS 7/16-20/12
2012-5521	07/30/2012 08/27/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 7/9-13/12
2012-5522	07/30/2012 08/27/2012	FDA/OMPT/CTP/OD/	MARK E. GREENWOLD CAMPAIGN FOR TOBACCO-FREE KIDS	APPLICATIONS FOR DESIGNATION OF MODIFIED RISK TOBACCO PRODUCTS SUBMITTED BY CTP
2012-5523	07/30/2012 08/27/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	CLOSED FOI REQUESTS 7/16-20/12
2012-5524	07/30/2012 08/27/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	CLOSED FOI REQUESTS 7/9-13/12
2012-5525	07/30/2012 08/27/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 7/9-13/12
2012-5526	07/30/2012 08/27/2012	OC/OM/OMP/DDM/	CAROLYN DEAN COVINGTON & BURLING LLP	DKT 2000N-1625, 1994A-0388
2012-5527	07/30/2012	FDA/OC/OES/DFOI/	DEBI COHEN	CLOSED FOI REQUESTS 7/16-20/12

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	08/27/2012		WOLTERS KLUWER LAW & BUSINESS	
2012-5528	07/30/2012 08/27/2012	FDA/OFVM/CFSAN/OCD/EOS/	MARY ANN COMSTOCK UPS SUPPLY CHAIIN SOLUTIONS	DOCUMENTS WHICH NAME UPS SUPPLY CHAIN SOLUTIONS AS US AGENT UNDER BIOTERRORISM ACT OF 2002
2012-5529	07/30/2012 08/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WGM&Assoc.	AUROBINDO - 483S (1/12-5/12)
2012-5530	07/30/2012 08/27/2012	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Weiler, Kathleen	GENZYME, FRAMINGHAM, MA - MOST RECENT 483, WARNING LETTER
2012-5531	07/30/2012 08/27/2012	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORAOCI/ OC/ORAOCI/	Jackie Callaway WFTS TV	ILLEGAL BOTOX IN FLORIDA - CASES, REPORTS, INVESTIGATIONS, ETC. (01/01/2007- 7/20/2012)
2012-5532	07/30/2012 08/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Justin Bailey SANDERS LAW FIRM ATTY	NDA 019839
2012-5533	07/30/2012 08/27/2012	FDA/OC/OES/DFOI/	US Army Criminal Investigation Command	VAERS RECS
2012-5534	07/30/2012 08/27/2012	FDA/OMPT/CDRH/OCER/DFOI/	Lorraine Porto Adenta USA	K902646
2012-5535	07/30/2012 08/27/2012	OC/ORAO/ OC/ORAO/ FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ OC/CVM/OCD/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Therese Safranek	SAMPLE ANALYSIS - 732398, 732399

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2012-5536	07/30/2012 08/27/2012	FDA/OMPT/CDRH/OCER/DFOI/	Lorraine Porto Adenta USA	K902645
2012-5537	07/30/2012 08/27/2012	FDA/OC/OES/DFOI/	Catherine Ung THINC	CURRENT CV - VARIOUS FDA STAFF
2012-5538	07/30/2012 08/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Chris Neuger Chris Neuger	METHERGINE - AERS
2012-5539	07/30/2012 08/27/2012	FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/	Doe J	LIFEBANK USA - EIR, 483 2010
2012-5540	07/30/2012 08/27/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Shin Kang WELLS FARGO	SANQUIN, BELGIUM - CORR, 483 FOR 5/12 INSPECTION
2012-5541	07/30/2012 08/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kathleen Strausser Baptist Memorial Hospital for Women	METHERGINE RECS
2012-5542	07/30/2012 08/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MAURICE CHENIER MAURICE CHENIER	ROSIGLITAZONE, AVANDIA, AVANDAMET - SAFETY RECORDS RE: HEART ATTACK, STROKE, BLINDNESS
2012-5543	07/30/2012 08/27/2012	OC/ORACE/ OC/ORACE/ OC/CVM/OCD/	Rita Desollar Rita Desollar	WAGGIN TRAIN WHOLESOME CHICKEN JERKY LOT J4CA3756A - TESTING AND COLLECTION RECS
2012-5544	07/30/2012 08/27/2012	FDA/OMPT/CDRH/OCER/DFOI/	Stephen A Dunn Stephen A Dunn	K982110
2012-5545	07/30/2012 08/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Margie Overlake Hospital Medical Center	METHERGINE - RECS RE DELAY OF BREASTFEEDING
2012-5546	07/31/2012 08/28/2012	FDA/OC/OES/DFOI/	Linda Schalk Mortara Instrument	MEDWATCH FORM
2012-5547	07/31/2012 08/28/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Pat Moriarty HEALTHCOR MANAGEMENT LP	SALIX PHARM, PROGENICS PHARM - COMPLETE RESPONSE LETTER FOR RELISTOR

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2012-5548	07/31/2012 08/28/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	PROPECIA, PROSCAR - AERS, LABELING RECS
2012-5549	07/31/2012 08/28/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Hoss Ekrami Ekrami, Hossein	RELISTOR - AERS
2012-5550	07/31/2012 08/28/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OCC/	Matthew Natale Natale, Matthew T	MTG BTWN ELIZABETH DICKINSON AND BARBARA KURYS, AMARIN - CORR, AGENDA, ETC.
2012-5551	07/31/2012 08/28/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	VAERS 444540-1 , 451576 - MEDWATCH REPORTS, SOURCE DOCS
2012-5552	07/31/2012 08/28/2012	FDA/OMPT/CDRH/OCER/DFOI/	Elizabeth Sharpe Elizabeth Sharpe	CENTRAL VENOUS CATHETER TIP - SURVEILLANCE AND MONITORING DIRECTIVES
2012-5553	07/31/2012 08/28/2012	OC/OM/OMP/DDM/	FRANCIS QUAYNOR SIDLEY AUSTIN LLP	DKT FDA-2007-D-0369
2012-5554	07/31/2012 08/28/2012	FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	ELIZABETH HOUSER MD, AUSTIN, TX - EIRS 12/10 TO 1/11
2012-5555	07/31/2012 08/28/2012	FDA/OGROP/ORACE-FO/BLT- DO/BLT-CB/ FDA/OGROP/ORACE-FO/CHI- DO/CHI-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	ADVOCATE HEALTH CARE IRB, PARK RIDGE, IL - 483S 11/11
2012-5556	07/31/2012 08/28/2012	FDA/OMPT/CDRH/OCER/DFOI/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	AMPLIVOX LTD, OXFORD, UK - EIRS 12/11
2012-5557	07/31/2012 08/28/2012	FDA/OGROP/ORACE-FO/DET- DO/DET-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	ADVANCED ORTHO PRO, INDIANAPOLIS, IN - 483S 4/12
2012-5558	07/31/2012	FDA/OGROP/ORACE-FO/DET-	SHERRI BATTERSHELL	ADVANCED ORTHO PRO, INDIANAPOLIS, IN - EIRS 4/12

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	08/28/2012	DO/DET-CB/	WASHINGTON INFORMATION SOURCE	
2012-5559	07/31/2012 08/28/2012	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	INOVA BLOOD DONOR SERVICES, STERLING, VA - EIRS 1/12 TO 2/12
2012-5560	07/31/2012 08/28/2012	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	INOVA BLOOD DONOR SERVICES, STERLING, VA - 483S 1/12 TO 2/12
2012-5561	07/31/2012 08/28/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	GRAMERCY FERTILITY SERVICES, NEW YORK, NY - 483S 3/12
2012-5562	07/31/2012 08/28/2012	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	ADVOCATE HEALTH CARE IRB, PARK RIDGE, IL - EIRS, 11/11
2012-5563	07/31/2012 08/28/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	SELDER S A DE CV, COLONIA GUADALUPE, MEXICO - 483S 9/11
2012-5564	07/31/2012 08/28/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	SELDER S A DE C V, COLONIA GUADALUPE, MEXICO - EIRS 9/11
2012-5565	07/31/2012 08/28/2012	FDA/OMPT/CDRH/OCER/DFOI/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	AMPLIVOX LTD, OXFORD, UK - 483S 12/11
2012-5566	07/31/2012 08/28/2012	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	OKLAHOMA RESPIRATORY CARE, NORMAN, OK - EIRS 10/11
2012-5567	07/31/2012 08/28/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	PATRICIA L REGNEYE Celgene Corporation	GARY SCHILLER, UNIV CALIFORNIA LOS ANGELES SCH MED, LOS ANGELES, CA - EIRS, CORR 11/11 TO 7/12
2012-5568	07/31/2012 08/28/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/ OC/OCOS/OL/ FDA/OC/OCC/ FDA/OC/OL/	LINDSEY M WILLIAMS NATIONAL WHISTLEBLOWERS CENTER	TEXTS OF LOGON BANNERS OR STARTUP SCREENS THAT APPEARED ON FDA COMUPTERS 1/09 TO 1/12

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2012-5569	07/31/2012 08/28/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANNE MUTASHI HOGAN LOVELLS US LLP	BASIS FOR THE RECOMMENDATION FOR CONTROL OF PREGABALIN IN SCHEDULE V OF THE CONTROLLED SUBSTANCES ACT; BASIS FOR THE RECOMMENDATION FOR CONTROL OF ZOPICLONE AND ITS OPTICAL ISOMERS IN SCHEDULE IV OF THE CONTROLLED SUBSTANCES ACT
2012-5570	07/31/2012 08/28/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORAS/SW-FO/KAN-DO/KAN-CB/ OC/OCM/EMOPS/ OC/ORO/ OC/ORO/	NICHOLAS K PAROILISI JR LITCHFIELD CAVO LLP	ESTES HATCHERY - SALMONELLA MONTEVIDEO OUTBREAK EMAILS, MEMOS, RPTS, ETC 2/28/12-6/6/12
2012-5571	07/31/2012 08/28/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	OWEN C MURPHY OWEN MURPHY	BRISTOL-MYERS SQUIBB - KENALOG AERS, MEMOS, WARNINGS, ETC
2012-5572	07/31/2012 08/28/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PAM LARSON MEDIGENE, INC	ALPS PHARMACEUTICAL IND CO LTD, HIDA-SHI, GIFU, JAPAN - EIR 9/5-12/11
2012-5573	07/31/2012 08/28/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	DAVID J CARNEY ANAPOL SCHWARTZ	GLAXOSMITHKLINE - H1N1 LOT #AFLLA616 RECS
2012-5574	07/31/2012 09/21/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Doe J	INDIVIDUAL RECS
2012-5575	07/31/2012 08/28/2012	FDA/OMPT/CDRH/OCER/DFOI/	NATHAN A BEAVER FOLEY & LARDNER LLP	SHASER IPL HAIR REMOVAL SYS K120080
2012-5576	07/31/2012 08/28/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	NATHAN A BEAVER FOLEY & LARDNER LLP	SHASER IPL HAIR REMOVAL SYS K103560
2012-5577	07/31/2012 08/28/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	PICATO GEL - AERS

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2012-5578	07/31/2012 08/28/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SUZIE KESCHAMRUS MD MBA AVANIR PHARMACEUTICALS INC	AMPYRA (DALFAMPRIDINE) - AERS
2012-5579	07/31/2012 08/28/2012	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	SHAMROCK MEDICAL SOLUTIONS GROUP, LEWIS CENTER, OH - 483, RESP LTRS, CORR 8/11
2012-5580	07/31/2012 08/28/2012	FDA/OMPT/CDRH/OCER/DFOI/	Leann Christman MC3, Inc.	K964017
2012-5581	07/31/2012 08/28/2012	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	SHAMROCK MEDICAL SOLUTIONS GROUP, LEWIS CENTER, OH - EIR, RESP LTRS, CORR 8/11
2012-5582	07/31/2012 08/28/2012	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	ARROWHEAD MEDICAL DEVICE TECHNOLOGIES, COLLIERVILLE, TN - EIR, RESP LTRS, CORR 2/12
2012-5583	07/31/2012 08/28/2012	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	ARROWHEAD MEDICAL DEVICE TECHNOLOGIES, COLLIERVILLE, TN - 483, RESP LTRS, CORR 2/12
2012-5584	07/31/2012 08/28/2012	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	TANGO3 LLC, SIMPSONVILLE, KY - 483, RESP LTR, CORR 1/12 TO 2/12
2012-5585	07/31/2012 08/28/2012	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	TANGO3 LLC, SIMPSONVILLE, KY - EIR, RESP LTRS, CORR 2/12
2012-5586	07/31/2012 08/28/2012	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	ELIZABETH HOUSER MD, AUSTIN, TX - 483, RESP LTRS, CORR 12/10 TO 1/11
2012-5587	07/31/2012 08/28/2012	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	GRAMERCY FERTILITY SERVICES, NEW YORK, NY - EIR, RESP LTR, CORR 3/12
2012-5588	07/31/2012 08/28/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	COMPANIA INTERNACIONAL DE COMERCIO SA DE CV, DEL IZTAPALAPA, MEXICO - 483, RESP LTR, CORR 8/11
2012-5589	07/31/2012 08/28/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SHERRI BATTERSHELL WASHINGTON INFORMATION	COMPANIA INTERNACIONAL DE COMERCIO SA DE CV, DEL IZTAPALAPA, MEXICO - EIR, RESP LTR, CORR 8/11

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SOURCE	
2012-5590	07/31/2012 08/28/2012	FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	OKLAHOMA RESPIRATORY CARE, NORMAN, OK - 483, RESP LTRS, CORR 10/11
2012-5591	07/31/2012 08/28/2012	FDA/OMPT/CDRH/OCER/DFOI/	Pamela E. Deans Auxilium Pharmaceuticals, Inc	K102541
2012-5592	07/31/2012 08/28/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Simona Voic STRYKER SPINE	K102293, K080537
2012-5593	07/31/2012 08/28/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Truveris	ORANGE BOOK - DIGITAL ARCHIVES
2012-5594	07/31/2012 08/29/2012	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Kevin A Henry, Assistant Professor University of Utah, Dept of Geography	MAMMOGRAPHY FACILITIES - CERTIFICATION AND INSPECTION 2006-2010
2012-5595	07/31/2012 08/28/2012	FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/ FDA/OC/OES/DFOI/	Boris Friedman Kline & Co.	ABBOTT NUTRITION, STURGIS, MI - EIRS, EXHIBITS, ATTACHMENTS (2008-2012)
2012-5596	08/01/2012 08/29/2012	FDA/OMPT/CDRH/OCER/DFOI/	GOBER, THERON	MODIFICATION TO AUTOBAND LIGATOR - K083556
2012-5597	08/01/2012 08/29/2012	FDA/OMPT/CDRH/OCER/DFOI/	GOBER, THERON	AUTOBAND LIGATOR - K031236
2012-5598	08/01/2012 08/29/2012	FDA/OMPT/CDRH/OCER/DFOI/	GOBER, THERON	AUTOBAND LIGATOR - K081142
2012-5599	08/01/2012 08/29/2012	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	ANDREW HACK MILLENNIUM MANAGEMENT LLC	IMMUNOGEN INC - EIRS, 483S UNTITLED LTRS, ETC 1/12 TO PRESENT
2012-5600	08/01/2012 08/29/2012	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	ANDREW HACK MILLENNIUM MANAGEMENT LLC	AVANIR PHARMACEUTICALS INC - EIRS, 483S, UNTITLED LTRS, ETC 1/12 TO PRESENT
2012-5601	08/01/2012 09/17/2012	FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	ANDREW HACK MILLENNIUM MANAGEMENT LLC	THORATEC CORPORATION INC - EIRS, 483S, UNTITLED LTRS, ETC 1/12 TO PRESENT
2012-5602	08/01/2012 08/29/2012	FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	ANDREW HACK MILLENNIUM MANAGEMENT LLC	ISIS PHARMACEUTICALS INC - EIRS, 483S, UNTITLED LTRS, ETC 1/12 TO PRESENT
2012-5603	08/01/2012	FDA/OGROP/ORA/NE-FO/NWE-	ANDREW HACK	ALERE INC - EIRS, 483S, UNTITLED LTRS, ETC 1/12 TO

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	08/29/2012	DO/NWE-CB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	MILLENNIUM MANAGEMENT LLC	PRESENT
2012-5604	08/01/2012 08/29/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	ANDREW HACK MILLENNIUM MANAGEMENT LLC	REGENERON PHARMACEUTICALS INC - EIRS, 483S, UNTITLED LTRS, ETC 1/12 TO PRESENT
2012-5605	08/01/2012 08/29/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	ANDREW HACK MILLENNIUM MANAGEMENT LLC	QUESTCOR PHARMACEUTICALS INC - EIRS, 483S, UNTITLED LTRS, ETC 1/12 TO PRESENT
2012-5606	08/01/2012 08/29/2012	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	ANDREW HACK MILLENNIUM MANAGEMENT LLC	AUXILIUM PHARMACEUTICALS INC - EIRS, 483S, UNTITLED LTRS, ETC 1/12 TO PRESENT
2012-5607	08/01/2012 08/29/2012	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	ANDREW HACK MILLENNIUM MANAGEMENT LLC	ZIMMER HOLDINGS INC - EIRS, 483S, UNTITLED LTRS, ETC 1/12 TO PRESENT
2012-5608	08/01/2012 08/29/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	ANDREW HACK MILLENNIUM MANAGEMENT LLC	EDWARDS LIFESCIENCES CORP - EIRS, 483S, UNTITLED LTRS, ETC 1/12 TO PRESENT
2012-5609	08/01/2012 08/29/2012	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	ANDREW HACK MILLENNIUM MANAGEMENT LLC	NXSTAGE MEDICAL INC - EIRS, 483S, UNTITLED LTRS, ETC 1/12 TO PRESENT
2012-5610	08/01/2012 08/29/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	ANDREW HACK, MD, PhD MILLENNIUM MANAGEMENT LLC	DEX COM INC - EIRS, 483S, UNTITLED LTRS, 1/12 TO PRESENT
2012-5611	08/01/2012 08/29/2012	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	ANDREW HACK, MD, PhD MILLENNIUM MANAGEMENT LLC	ALIGN TECHNOLOGY INC - EIRS, 483S, UNTITLED LTRS, 1/12 TO PRESENT
2012-5612	08/01/2012 08/29/2012	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	ANDREW HACK, MD, PhD MILLENNIUM MANAGEMENT LLC	HEART WARE INTL INC - EIRS, 483S, UNTITLED LTRS, 1/12 TO PRESENT
2012-5613	08/01/2012 08/29/2012	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	ANDREW HACK, MD, PhD MILLENNIUM MANAGEMENT LLC	SEATTLE GENETICS INC - EIRS, 483S, UNTITLED LTRS, 1/12 TO PRESENT
2012-5614	08/01/2012 08/29/2012	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	ANDREW HACK, MD, PhD MILLENNIUM MANAGEMENT LLC	ABIOMED INC - EIRS, 483S, UNTITLED LTRS, 1/12 TO PRESENT
2012-5615	08/01/2012 08/29/2012	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	ANDREW HACK, MD, PhD MILLENNIUM MANAGEMENT LLC	INCYTE CORP - EIRS, 483S, UNTITLED LTRS, 1/12 TO PRESENT
2012-5616	08/01/2012 08/29/2012	FDA/OFVM/CFSAN/OCD/EOS/	A. SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 138947, 138957
2012-5617	08/01/2012 08/29/2012	FDA/OFVM/CFSAN/OCD/EOS/	KRISTI O. SMEDLEY, Ph.D. WASHINGTON INFORMATION SOURCE	SPIRULINA COLOR ADDITIVE PETITION 2C0293
2012-5618	08/01/2012	FDA/OGROP/ORACE-FO/PHI-	KATHY CONACHER	DRAEGER MEDICAL SYSTEMS INC, TELFORD, PA - EIRS

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	08/29/2012	DO/PHI-CB/	Draeger Medical Systems Inc	6/29/09-7/9/09
2012-5619	08/01/2012 08/29/2012	FDA/OMPT/CDRH/OCER/DFOI/	LINDA SCHALK Mortara Instrument	MORTARA INSTRUMENT INC - MEDWATCH RPT 3/12
2012-5620	08/01/2012 08/29/2012	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDRH/OCER/DFOI/	RAPHAEL LEWIS NORTH RUN CAPITAL LP	ABIOMED INC - CORR 1/00 TO PRESENT
2012-5621	08/01/2012 08/29/2012	FDA/OC/OES/DFOI/	DR. PAUL KOSTERS DEMCON ADVANCED MECHATRONICS BV	BMEYE BV - NEXFIN MODEL 2 K101123
2012-5622	08/01/2012 08/29/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Exane	NDA 21-654
2012-5623	08/01/2012 08/29/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	CLOSED REQUESTS 7/1-31/2012
2012-5624	08/01/2012 08/29/2012	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Allison Johnson Boehringer Ingelheim Vetmedica, Inc.	BAYER HEALTHCARE, SHAWNEE, KS - EIR, 483 (2012)
2012-5625	08/01/2012 08/29/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ketan Patell Fountain Valley regional Hospital	CARBOPLATIN - MEDWATCH DATA
2012-5626	08/01/2012 08/29/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	VAERS 451690-1, 457255-1 (ROTATEQ)
2012-5627	08/01/2012 08/29/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	ABBOTT LABS - BIAXIN CLNCL TRIALS
2012-5628	08/01/2012 08/29/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lidia Cristian Influmedix, inc	NDA 018101, NDA 019649
2012-5629	08/01/2012 08/29/2012	FDA/OMPT/CDRH/OCER/DFOI/	LIANE LaROCHELLE DEKA RESEARCH &	ROCHE DIAGNOSTICS - ACCU CHECK COMBO SYS K111353

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			DEVELOPMENT CORP	
2012-5630	08/01/2012 08/29/2012	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Mary F. Becker-Pasha Mary Becker-Pasha	GENE LOGIC INC., GAITHERSBURG, MD - EIRS (2006-2008); BRIDGE GLOBAL PHARM SERVICES, GAITHERSBURG, MD - EIRS (2006-2008)
2012-5631	08/01/2012 08/29/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	LESLIE MCHUGH LAWRENCE WORDEN RAINIS ET AL	PLUS IDE: G010245 (TC-PLUS SB SOL TIBIAL COMPONENT TI-PLASMA IDE ANNUAL RPT - DISCIPLINARY PROCEEDINGS, APPL FOR PREMARKET APRVL OR DVC APPL
2012-5632	08/01/2012 08/29/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	IPD Analytics, LLC	ANDA 077437 TENTATIVE APPROVAL LETTER, ETC.
2012-5633	08/01/2012 08/29/2012	FDA/OMPT/CDRH/OCER/DFOI/	Lavenia Ford CARDINAL HEALTH	K112805
2012-5634	08/01/2012 08/29/2012	FDA/OMPT/CDRH/OCER/DFOI/	Nancy Murphy Murphy, Nancy	ARRIVA BLOOD GLUCOSE MONITORING DEVICE - RECS 5/2/12-7/30/12
2012-5635	08/01/2012 08/29/2012	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BARNHILL 1596687, KYLE	ANTIDEPRESSANT - AER
2012-5636	08/01/2012 08/29/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	METFORMIN; ACTOS - AER
2012-5637	08/01/2012 08/29/2012	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	GERHARDT., NATHAN.	PRISMIC LIGHT INTL, MULFREESBORO, TN - 483, EIR 1/12
2012-5638	08/01/2012 08/29/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PETER ARHANGELSKY, Esq. EMORD & ASSOCIATES, P.C.	INVESTIGATIONAL DRUGS - TOTAL NUMBER OF SUBMISSIONS 2004 TO PRESENT
2012-5639	08/01/2012 08/29/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANDREW H. NAUER KLORES PERRY MITCHELL PC	ISRS 6737415; 7571678; 7983265

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2012-5640	08/01/2012 08/29/2012	FDA/OC/OES/DFOI/	ELENA HOWELL HOGAN LOVELLS LLP	2012-4120
2012-5641	08/01/2012 08/29/2012	OC/CVM/OCD/	Lyndsy Hassett Stason Pharmaceuticals, Inc	NADA 141-082
2012-5642	08/02/2012 08/30/2012	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	RACHEL GATEWOOD RETRACTABLE TECHNOLOGIES INC	BECTON DICKINSON AND CO - BD SYRINGES AND IV CATHETERS RPTS, TEST DATA, CO RESP, ETC 2004 TO PRESENT
2012-5643	08/02/2012 08/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	WATSON, SARAH	TRAINING STUDY LONGTERM P040043; EXACT STUDY PROTECT P040038; TAXUS ATLAS CABANA P060008, ETC
2012-5644	08/02/2012 08/30/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	AMY KINCANON LEXIS NEXIS COURTLINK INC	CYTOTEC (MISOPROSTOL) - AERS, SRS
2012-5645	08/02/2012 08/30/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	BENJAMIN P LEWIS PHD RPH MITSUBISHI TANABE PHARMA DEVELOPMENT OF AMERICA INC	TRK-820 (NALFURAFINE HCI INJ) IND 102,322, IND 72,361 RECS
2012-5646	08/02/2012 08/30/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	ROMAN ROZENFELD POINTSTATE CAPITAL LP	HOSPIRA, CLAYTON, NC 2012; BOULDER, CO 4/12 TO 6/12; AUSTIN, TX 6/12, ETC - 483S
2012-5647	08/02/2012 08/30/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PRASHANTH JAYARAM MAVERICK CAPITAL	AMARIN PHARMA INC - VASCEPA TRANS 6/22/12
2012-5648	08/02/2012 08/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	AMSINO MEDICA (KUNSHAN) CO LT, KUNSHAN CITY, CHINA - EIR 11/10
2012-5649	08/02/2012 08/30/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	2011-7554
2012-5650	08/02/2012 08/30/2012	FDA/OMPT/CTP/OD/	FOI Services, Inc.	PALL MALL BLACK, PALL MALL WHITE CIGARETTES - CORR, REQUESTS, PROD APPLS, ETC

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2012-5651	08/02/2012 08/30/2012	FDA/OMPT/CTP/OD/	FOI Services, Inc.	GRANDFATHERED TOBACCO PROD STATUS DETERMINATION CORR, SUMMARIES, RECS
2012-5652	08/02/2012 08/30/2012	FDA/OMPT/CTP/OD/	FOI Services, Inc.	TOBACCO PRODS FOR WHICH FDA ISSUED AN ORDER OF SUBSTANTIAL EQUIVALENCE
2012-5653	08/02/2012 08/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	ARROW INTERNATIONAL - ARROW EVOLUTION PRESSURE INJECTABLE PICC WITH CHLORAG+ARD ANTIMICROBIAL & ANTITHROMBOGENIC TECHNOLOGY K112896
2012-5654	08/02/2012 08/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	ARROW INTERNATIONAL - ARROW ANTIMICROBIAL PRESSURE INJECTABLE PERIPHERALLY INSERTED CENTRAL CATHETER K100635
2012-5655	08/02/2012 08/30/2012	FDA/OMPT/CTP/OD/	FOI Services, Inc.	TOBACCO ESTABLISHMENT REGISTRATIONS 6/12 TO PRESENT
2012-5656	08/02/2012 08/30/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	FOI Services, Inc.	ARROW INTERNATIONAL INC - ARROW ANTIMICROBIAL INJECTABLE PERIPHERALLY INSERTED CENTER CATHETER (PICC) K100635
2012-5657	08/02/2012 08/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	MEDTRONIC - KYPHON XPANDER II INFLATABLE BONE TAMP K101864
2012-5658	08/02/2012 08/30/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FOI Services, Inc.	JANSSEN PHARMS - RISPERDAL (RISPERIDONE) NDA 20-272/S036, NDA 20-588/S024, NDA 21-444/S008 APRVL RECS
2012-5659	08/02/2012 08/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FOI Services, Inc.	OTSUKA - ABILIFY (ARIPRAZOLE) NDA 21-436/S027 APRVL RECS
2012-5660	08/02/2012 08/30/2012	FDA/OC/OES/DFOI/	UNIV MEDICAL CENTER GRONINGEN	FOI DAILY LOGS LAST 2 YRS
2012-5661	08/02/2012 08/30/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/CHI-DO/CHI-CB/	Doe J	INDIVIDUAL RECS
2012-5662	08/02/2012 08/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	NOELLE C SUTTON Sutton, Noelle C	ANDA 40-541 - PACKAGING VALIDATION/DISTRIBUTION TESTING INSTRUCTIONS

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2012-5663	08/02/2012 08/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	Kim Washburn Kimberlee Washburn	K022364
2012-5664	08/02/2012 08/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	Corey Jaseph Ultradent Products, Inc.	K082470
2012-5665	08/02/2012 08/30/2012	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Doe J	COMPLAINT 127515
2012-5666	08/02/2012 08/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Kaylor The Law Offices of Keith Ligori	TRI-SPRINTEC - AERS
2012-5667	08/02/2012 08/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH	DR. SEUNGBONG, HONG, SAMSUNG MEDICAL HOSPITAL DEPARTMENT OF NEUROLOGY SEOUL, SOUTH KOREA - EIR, 483, RESPONSE (4/09)
2012-5668	08/02/2012 08/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	NDA 21-246 S-017, 21-087 S-030
2012-5669	08/02/2012 08/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	NDA 21-567 S-019
2012-5670	08/03/2012 08/31/2012	OC/OM/OMP/DDM/	ELENA NOWELL HOGAN LOVELLS LLP	DKT & DKT LOG OF FDA-1975-N-0336
2012-5671	08/03/2012 08/31/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	KANAI TORO MIC INTERNATIONAL CORP	BARCO NV - CORONIS FUSION K093197
2012-5672	08/03/2012 08/31/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	STINE KIHII-PLAMBEK SYMPHOGEN A/S	ONCOLOGIC DURGS A/C - TRANS 6/20/12
2012-5673	08/03/2012 08/31/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN F THOMPSON ROBINSON & THOMPSON	ISRS 4004716-0, 4211595-5, 4390735-1, ETC

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2012-5674	08/03/2012 08/31/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ALISON M AGNEW PILLSBURY WINTHROP SHAW PTTMAN LLP	LEUCOVORIN CALCIUM INJ - COMM, 1/10 TO 8/1/12
2012-5675	08/03/2012 08/31/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	TEDAC-MEIJ I FARMA, ALCALA DE HENARES, SPAIN - 483S 7/11
2012-5676	08/03/2012 08/31/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	TEDAC-MEIJ I FARMA, ALCALA DE HENARES, SPAIN - EIRS 7/11
2012-5677	08/03/2012 08/31/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	NOVALUNG GMBH, OBERSTENFELD, GERMANY - 483S 11/11
2012-5678	08/03/2012 08/31/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	NOVALUNG GMBH, OBERSTENFELD, GERMANY - EIRS 11/11
2012-5679	08/03/2012 08/31/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	B M P BULK MEDICINES & PHARMACEUTICALS, NORDERSTEDT, GERMANY - EIRS 11/11
2012-5680	08/03/2012 08/31/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	B M P BULK MEDICINES & PHARMACEUTICALS, NORDESTEDT, GERMANY - 483S 11/11
2012-5681	08/03/2012 08/31/2012	FDA/OGROP/ORACE-FO/MIN- DO/MIN-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	AD-TECH MEDICAL INSTRUMENT CORP, RACINE, WI - EIRS 12/11 TO 1/12
2012-5682	08/03/2012	FDA/OGROP/ORACE-FO/MIN-	SHERRI BATTERSHELL	AD-TECH MEDICAL INSTRUMENT CORP, RACINE, WI - 483S

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	08/31/2012	DO/MIN-CB/	WASHINGTON INFORMATION SOURCE	12/11 TO 1/12
2012-5683	08/03/2012 08/31/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	ACCORDA THERAPEUTICS, HAWTHORNE, NY - 483S 8/11
2012-5684	08/03/2012 08/31/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	SHSERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	ACCORDA THERAPEUTICS, HAWSTHORNE, NY - EIRS 8/11
2012-5685	08/03/2012 08/31/2012	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	WALTER E CHALKLEY THOMSON REUTERS	OKLAHOMA RESPIRATORY CARE INC, NORMAN, OK - 483S 10/19-28/11
2012-5686	08/03/2012 08/31/2012	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	WALTER E CHALKLEY THOMSON REUTERS	MYLAN, CAGUAS, PR - 483S 1/13/10-3/29/10
2012-5687	08/03/2012 08/31/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	WALTER E CHALKLEY THOMSON REUTERS	LUITPOLD PHARMS, SHIRLEY, NY - 483S 2/8/12-3/29/12
2012-5688	08/03/2012 08/31/2012	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	SURGICAL APPLIANCE INDUSTRIES, CINCINNATI, OH - 483S 5/11 TO 6/11
2012-5689	08/03/2012 08/31/2012	FDA/OC/OES/DFOI/ FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	WALTER E CHALKLEY THOMSON REUTERS	DOW CHEMICAL, MIDLAND, MI - 483S 6/13-16/11
2012-5690	08/03/2012 08/31/2012	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	WALTER E CHALKLEY THOMSON REUTERS	BBC BIOCHEMICAL, MT VERNON, WA - 483S 4/12-22/11
2012-5691	08/03/2012 09/06/2012	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	IMPAX LABS, HAYWARD, CA - EIRS, CORR 2/23/12-3/28/12
2012-5692	08/03/2012 08/31/2012	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	WALTER E CHALKLEY THOMSON REUTERS	CELLTEX THERAPEUTICS CORP, SUGARLAND, TX - EIRS 4/16-27/12
2012-5693	08/03/2012 08/31/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	THOMSON REUTERS	SANOPI PASTEUR S A, CAMPUS MERIEUX, MARCY L'ETOILE, FRANCE - 483S 3/19/12-4/2/12
2012-5694	08/03/2012 08/31/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	WALTER E CHALKLEY THOMSON REUTERS	SANOPI PASTEUR LTD, TORONTO, CANADA - 483SS 4/10-25/12
2012-5695	08/03/2012 08/31/2012	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	WALTER E. CHALKLEY THOMSON REUTERS	ELIZABETH E HOUSER MD, AUSTIN TEXAS - 12/6/10 TO 1/6/11
2012-5696	08/03/2012 08/31/2012	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	WALTER E. CHALKLEY THOMSON REUTERS	OUR LADY OF BELLEFONTE HOSP, ASHLAND, KY - 1/3/12 TO 1/6/12
2012-5697	08/03/2012	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	WALTER E. CHALKLEY	ADVOCATE HEALTH CARE, PARK RIDGE, IL - 11/7-30/11

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	08/31/2012	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	THOMSON REUTERS	
2012-5698	08/03/2012 08/31/2012	FDA/OGROP/ORASE-FO/FLADO/FLA-CB/	WALTER E. CHALKLEY THOMSON REUTERS	FRANCKS LAB INC, OCALA, FL - 3/9/2012 TO 5/11/12
2012-5699	08/03/2012 08/31/2012	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	WALTER E. CHALKLEY THOMSON REUTERS	MATTHEW P. MALCOLM, PhD, OTR, FORT COLLINS, CO - 2/10-16/12
2012-5700	08/03/2012 08/31/2012	FDA/OFVM/CFSAN/OCD/EOS/	NANDAKUMARA D SARMA, RPh, PhD UNITED STATES PHARMACOPEIA	ARGININE - AER 1/05 TO 7/12
2012-5701	08/03/2012 08/31/2012	FDA/OFVM/CFSAN/OCD/EOS/	HELEN A. OKETCH, Ph.D. UNITED STATES PHARMACOPEIA	RHODIOLA ROSEA - AER 1/05 TO 7/12
2012-5702	08/03/2012 08/31/2012	FDA/OFVM/CFSAN/OCD/EOS/	HELLEN A. OKETCH, PhD. UNITED STATES PHARMACOPEIA	N ACETYL GLUCOSAMINE - AER 1/05 TO 7/12
2012-5703	08/03/2012 08/31/2012	FDA/OFVM/CFSAN/OCD/EOS/	HELLEN A. OKETCH UNITED STATES PHARMACOPEIA	CALCIUM L 5 METHYLTETRAHYDROFOLATE - AER 1/05 TO 7/12
2012-5704	08/03/2012 08/31/2012	FDA/OFVM/CFSAN/OCD/EOS/	HELLEN A. OKETCH-R, PhD. UNITED STATES PHARMACOPEIA	ASTRAGALUS MEMBRANACEUS - AER 1/05 TO 7/12
2012-5705	08/03/2012 08/31/2012	FDA/OFVM/CFSAN/OCD/EOS/	HELLEN A. OKETCH, PhD. UNITED STATES PHARMACOPEIA	HOLY BASIL (OCIMUM SANCTUM OR OCIMUM TENUIFLORUM) - AER 1/05 TO 5/12
2012-5706	08/03/2012 08/31/2012	FDA/OFVM/CFSAN/OCD/EOS/	HELLEN A. OKETCH, PhD. UNITED STATES PHARMACOPEIA	ASTAXANTHIN - AER /05 TO 5/12
2012-5707	08/03/2012 08/31/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JENNIFER A. DAVIDSON KLEINFELD KAPLAN & BECKER	INTERMEZZO (ZOLPIDEM TARTRATE) NDA 22-328
2012-5708	08/03/2012 08/31/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OES/DFOI/	SHELDON T. BRADSHAW HUNTON & WILLIAMS LLP	DIETARY SUPPLEMENTS - AER
2012-5709	08/03/2012 08/31/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SEAN LYONS HENDLERLAW	VICTOZA (LIRAGLUTIDE) - AER

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2012-5710	08/03/2012 08/31/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DIANA R. COHEN ARNALL GOLDEN & GREGORY, LLP	KOWA COMPANY LTD - LIVALO (PITAVISTATIN) NDA 22-363
2012-5711	08/03/2012 08/31/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ROBERT E. SHAPIRO, MD, PhD UNIVERSITY OF VERMONT COLLEGE OF MEDICINE	ALLERGAN - ONABOTULINOTOXIN A AER
2012-5712	08/03/2012 08/31/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lisa Freeman MEDIMMUNE LLC	IND 103411 - SN0000, SN0003, SN0008
2012-5713	08/03/2012 08/31/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	VAERS 448946 (ROTATEQ)
2012-5714	08/03/2012 08/31/2012	FDA/OC/OES/DFOI/	James Schaefer Ortho Molecular Products	ENFORCEMENT RECORDS 01/01/2011 - 08/01/2012
2012-5715	08/03/2012 08/31/2012	FDA/OMPT/CDRH/OCER/DFOI/	Tina Mayer Lumenis, Inc.	K091064 - Navilus Laser System Operator Manual
2012-5716	08/03/2012 08/31/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sherry A. Leonard Ono Pharma USA, Inc.	FARMHISPANIA, S.A., MONTMELO, SPAIN - EIRS (4/09)
2012-5717	08/03/2012 08/31/2012	FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/	Ono Pharma USA, Inc.	GLATT AIR TECHNIQUES, RAMSEY, NJ - EIRS (11/09)
2012-5718	08/03/2012 08/31/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/	Sherry A. Leonard Ono Pharma USA, Inc.	GLATT AIR TECHNIQUES, RAMSEY, NJ - EIRS (12/11)
2012-5719	08/06/2012	FDA/OC/OES/DFOI/	LAUREN S BARR	CLOSED FOIA REQUESTS 7/16-20/12

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	09/04/2012		JH BARR & ASSOCIATES LLC	
2012-5720	08/06/2012 09/04/2012	FDA/OC/OES/DFOI/	LAUREN S BAR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 8/23-27/12
2012-5721	08/06/2012 09/04/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	CLOSED FOIA REQUESTS 7-23-27/12
2012-5722	08/06/2012 09/04/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 7/23-27-/12
2012-5723	08/06/2012 09/04/2012	FDA/OC/OES/DFOI/	SANDY FRIEDMAN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 7/23-27/12
2012-5724	08/06/2012 09/04/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 7/23-27/12
2012-5725	08/06/2012 09/04/2012	FDA/OMPT/CDRH/OCER/DFOI/	LINDA KARIYA NIHON KOHDEN AMERICA	CHEETAH MEDICAL INC - NICOM SYS K042144
2012-5726	08/06/2012 09/04/2012	FDA/OMPT/CDRH/OCER/DFOI/	LINDA KARYIA NIHON KOHDEN AMERICA	IMAGYN MEDICAL TECHNOLOGIES INC - ECOM (ENDOTRACHEAL CARDIC OUTPUT MONITORING) SYS K021174
2012-5727	08/06/2012 09/04/2012	FDA/OMPT/CDRH/OCER/DFOI/	RICHARD J FERGUS	LIFESTYLES LUBRICATED POLYISOPRENE MALE CONDOMS - K070800
2012-5728	08/06/2012 09/04/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	RICHARD J FERGUS	DUREX SYNTHETIC POLYISOPRENE MALE CONDOMS - K072169
2012-5729	08/06/2012 10/25/2012	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	CLARK H MCGEHEE JOHNSON & WARD ATTY AT LAW	ST JUDE MEDICAL - EON MINI MODEL 3788 SPINAL CORD STIMULATOR/IMPLANTABLE PULSE GENERATOR RECALL Z-1599-2010, LTRS, EMAILS, ETC
2012-5730	08/06/2012 09/04/2012	FDA/OMPT/CDRH/OCER/DFOI/	MILTON 561014, WILLIE A	BRONAM MEDICAL CORP - 3 PANEL DRUG KIT MONITECT RECS
2012-5731	08/06/2012 09/04/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KATHY MCGOWN FOXKISER	HORIZANT (GABAPENTIN ENACABIL) - NDA 22-399/S003 SBA
2012-5732	08/06/2012 09/04/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	COLLEEN GRACE DONOFRIO BABST CALLAD CLEMENTS ET AL	LAIZHOU XHONGDA CHEMICALS CO LTD, CHINA - MAGNESIUM SULFATE EXPORTS TO THE US RECS 7/07 TO PRESENT

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		FDA/OMPT/CDER/GRP/DIDP/		
2012-5733	08/06/2012 09/04/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PARAKKAL DEEPAK RESEARCH INSTITUTE CENTER FOR STUDY OF COMPLEX DISEASES	ISRS 3930462, 3949246, 3965051, ETC
2012-5734	08/06/2012 09/04/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LLOYD PRESTON PRESTON INNOVATIONS	TINACTIN FOOT POWDER SPRAY - LIST OF COMPANIES MFG THE CHEMISTRY & PKG
2012-5735	08/06/2012 09/04/2012	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	SHAMIKA R DALOMBA WICKER SMITH ET AL	CENTRAL ADMIXTURE PHARMACY SERVICES INC, ST JOSEPH'S HOSPITAL, TAMPA, FL - CARDIAC SURGICAL DVCS INVESTIGATION RPTS
2012-5736	08/06/2012 09/04/2012	FDA/OMPT/CDRH/OCER/DFOI/	LAVENIA FORD CARDINAL HEALTH	KINGUARD ONE STEP SSTERILIZATION WRAP - K112805
2012-5737	08/06/2012 09/04/2012	FDA/OFVM/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	IOVATE - HYDROXYCUT, SMARTBURN, RAPIDSLIM & RAPID SLIM, ETC CAERS 5/3/12 TO PRESENT
2012-5738	08/06/2012 09/04/2012	FDA/OMPT/CDRH/OCER/DFOI/	Gideon Granek Aposense	K101342
2012-5739	08/06/2012 09/04/2012	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Christina Graziano Kreindler & Kreindler, LLP	NATURALYTE, GRANUFLO DRY ACID CONCENTRATE - RECALL RECS 3/12
2012-5740	08/06/2012 09/04/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	John McIntyre Ellipse Technologies, Inc.	K011354
2012-5741	08/06/2012 09/04/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OC/OES/DFOI/	NORTHCOAST RESEARCH	FLU VACCINE LOT RELEASES 07/15/2011 - 03/31/2012
2012-5742	08/06/2012	FDA/OFVM/CFSAN/OCD/EOS/	Jason Tang	VALIDATION PROTOCOL FOR 21 CFR Part 172.886

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	09/04/2012		GBI Sourcing Limited	
2012-5743	08/06/2012 09/04/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Matt Sencenbaugh AppMedicine Inc	K062662, K051470, K061502 ETC
2012-5744	08/06/2012 09/04/2012	FDA/OC/OES/DFOI/	Marsha Lewis N/A	INDIVIDUAL RECS
2012-5745	08/06/2012 09/04/2012	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Boris Friedman Kline & Company	ABBOTT NUTRITION FACILITY, ALTA VISTA, VA - EIRS, EXHIBITS, ATTACHMENTS (01/01/2008 - 08/06/2012)
2012-5746	08/06/2012 09/04/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Kline & Co.	ABBOTT NUTRITION FACILITY, CASA GRANDE, AZ - EIRS, EXHIBITS, ATTACHMENTS (01/01/2008 - 08/06/2012)
2012-5747	08/06/2012 09/19/2012	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Kline & Co.	ABBOTT NUTRITION FACILITY, COLUMBUS, OH - EIRS, EXHIBITS, ATTACHMENTS (01/01/2008 - 08/06/2012)
2012-5748	08/06/2012 09/04/2012	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Robert Goldman CL King & Associates	INVACARE, OHIO - 483S (07/01/2011 - 08/01/2012)
2012-5749	08/06/2012 09/04/2012	FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECORDS
2012-5750	08/07/2012 09/05/2012	FDA/OC/OES/DFOI/	Mercy Health System	CONSUMER COMPLAINT 125760
2012-5751	08/07/2012 09/05/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Dr. Diane Sudduth Biovance	K103785
2012-5752	08/07/2012 09/05/2012	FDA/OMPT/CDRH/OCER/DFOI/	Mark Gardner DuVal & Associates, P.A.	K113656
2012-5753	08/07/2012 09/05/2012	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	James Schaefer Ortho Molecular Products	ORTHO MOLECULAR PRODUCTS, STEVENS POINT, WI; PROGRESSIVE LABS, IRVING, TX - SAMPLES, 483S, WARNING LETTERS, ETC.
2012-5754	08/07/2012 09/05/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Sheila A. Woolson Epstein Becker &Green, PC	KOBO PRODUCTS, INC., SOUTH PLAINFIELD, NJ - WARNING LETTERS, NOTICES OF VIOLATION, INSPECTIONS, ETC.
2012-5755	08/07/2012 09/05/2012	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	LaToya Fox NOW Foods, Inc.	DEERLAND-ENZYMES CO, KENNESAW, GA - EIR, 483, WARNING LETTER, ETC. (02/11-08/11)
2012-5756	08/07/2012 09/05/2012	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	David Fleshler South Florida Sun-Sentinel	COMMUNITY BLOOD CTR OF FLA, ONEBLOOD - CORR WITH FDA RE: 09/11-12/11 INSPECTION

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2012-5757	08/07/2012 09/05/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/OA/OM/OMP/DDM/ OC/OA/OM/OMP/DDM/	Franck Mouthon CEA	FLECAINIDE (FLECAINE) - LABELING CHANGES, SBA, MTG MINUTES, ETC.
2012-5758	08/07/2012 09/05/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	DOUGLAS E. CHABOT DECOF & DECOF PC	K991513
2012-5759	08/07/2012 09/05/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	DOUGLAS E. CHABOT DECOF & DECOF PC	K052117
2012-5760	08/07/2012 09/05/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	DOUGLAS E. CHABOT DECOF & DECOF PC	K023318
2012-5761	08/07/2012 09/05/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	DOUGLAS E. CHABOT DECOF & DECOF PC	K043456
2012-5762	08/07/2012 09/05/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	DOUGLAS E. CHABOT DECOF & DECOF PC	K023883
2012-5763	08/07/2012 09/05/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	DOUGLAS E. CHABOT DECOF & DECOF PC	K040337
2012-5764	08/07/2012 09/05/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	DOUGLAS E. CHABOT DECOF & DECOF PC	K051401
2012-5765	08/07/2012 09/05/2012	FDA/OFVM/CFSAN/OCD/EOS/	RYAN C. NUTE MYERS & COMPANY PLLC	HOYU AMERICA CO - DYE COLORING CAERS
2012-5766	08/07/2012 09/05/2012	OC/CVM/OCD/	ANA KOSTIC VETMEDIC	IVERMECTIN IVOMEK NADA - 128-409 EFFICACY & TOLERABILITY
2012-5767	08/07/2012 09/05/2012	FDA/OC/OES/DFOI/	SUSAN A. LONGACRE SAFETY RESEARCH & STRATEGIES INC	2012-4151, 2012-4120 - CERTIFIED RECS
2012-5768	08/07/2012 09/05/2012	FDA/OO/OFBA/OAGS/	STACHEWICZ, JEFF	HHSF223201210005I - CONTRACT, TECHNICAL PROPOSAL, SOW
2012-5769	08/07/2012 09/05/2012	FDA/OO/OFBA/OAGS/	STACHEWICZ, JEFF	HHSF22320120007I - CONTRACT, TECHNICAL PROPOSAL, SOW
2012-5770	08/07/2012 09/05/2012	FDA/OO/OFBA/OAGS/	STACHEWICZ, JEFF	HHSF223201210006I - CONTRACT, TECHNICAL PROPOSAL, SOW

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2012-5771	08/07/2012 09/05/2012	FDA/OC/OES/DFOI/	MICHAEL S. BARONE BASF CORP	BASF CORP, WASHINGTON, NJ - FOI REQUESTS 2007 TO 2012
2012-5772	08/07/2012 09/05/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	MICHAEL S. BARONE BASF CORP	BASF CORP, WASHINGTON, NJ - EIR 2007 TO 2012
2012-5773	08/08/2012 09/06/2012	OC/CVM/OCD/ FDA/OC/OCC/ FDA/OC/OES/DFOI/ OC/CVM/OCD/	PAIGE TOMASELLI CENTER FOR FOOD SAFETY	GENETICALLY ENGINEERED AEDES AEGYPTI MOSQUITOES - ENVIRONMENTAL PROTECTION AGENCY (EPA), FISH & WILDLIFE SERVICES (FWS), OXITEC, ETC COMM, RECS
2012-5774	08/08/2012 09/06/2012	FDA/OMPT/CTP/OD/	SAAD KAMAL CAPSTONE LLC	MINOR DELETIONS
2012-5775	08/08/2012 09/06/2012	FDA/OFVM/CFSAN/OCD/EOS/	FRANCIS, ANA MARGARITA	UNITED AIRLINES - WHAT HAPPENS TO PERISHABLE EDIBLES FROM 4 HOUR FLIGHTS
2012-5776	08/08/2012 09/06/2012	FDA/OMPT/CDRH/OCER/DFOI/	SCOTT S ADDISON PARKER POE ET AL LLP	MDRS MW5007891, MW50029192112667-2007-00059, ETC
2012-5777	08/08/2012 09/06/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WAYNE SADOWSKI NOVARTIS PHARMACEUTICALS CORP	NOVARTIS PHARMA AG, BASEL, SWITZERLAND - EIR, 482, 483, ETC 6/4-8/12
2012-5778	08/08/2012 09/06/2012	FDA/OC/OES/DFOI/	MATTHEW DE PRETER ROCKEY & LYONS	2012-5105
2012-5779	08/08/2012 09/06/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHNSON, KENT	CELEXA - AERS, RECS
2012-5780	08/08/2012 09/06/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHNSON, KENT	RASAGILINE - AERS, RECS
2012-5781	08/08/2012 09/06/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHNSON, KENT	KLONOPIN - AERS, RECS
2012-5782	08/08/2012	FDA/OMPT/CDER/ORP/DIDP/		CARBIDOPA-LEVODOPA - AERS, RECS

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	09/06/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHNSON, KENT	
2012-5783	08/08/2012 09/06/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHNSON, KENT	LIPITOR - AERS, RECS
2012-5784	08/08/2012 09/06/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHNSON, KENT	NEVIVOLOL - AERS, RECS
2012-5785	08/08/2012 09/06/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHNSON, KENT	CITALOPRAM HYDROBROMIDE - AERS, RECS
2012-5786	08/08/2012 09/06/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MICHAEL R COHEN RPH MS SCD INSTITUTE FOR SAFE MEDICATION PRACTICES	MEDWATCH RPTS CODED AS MEDICATION ERRORS 7/1-31/12
2012-5787	08/08/2012 09/06/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	Doe J	SHOPKO BRAND ONE A DAY VITAMINS FOR WOMEN OVER 50 - AERS
2012-5788	08/08/2012 09/06/2012	OC/CVM/OCD/	KRISTI O SMEDLEY PHD WASHINGTON INFORMATION SOURCE	CONDENSED EXTRACTED GLUTAMIC ACID FERMENTATION PROD - CORR, MEMOS, SUBMISSIONS, ETC
2012-5789	08/08/2012 09/06/2012	FDA/OC/OES/DFOI/	SCOTT HIRSCH CITADEL LLC	VALEANT PHARMS - 483S, WARNING LTRS 1/10 TO PRESENT
2012-5790	08/08/2012 09/06/2012	FDA/OMPT/CDRH/OCER/DFOI/	MEI DODSON HEALTHMATE INTERNATIONAL LLC	HI-DOW JQ-5C K102598
2012-5791	08/08/2012 09/06/2012	OC/ORO/ OC/ORO/	Doe J	METAMUCIL - CMLPNT

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		FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/		
2012-5792	08/08/2012 09/06/2012	FDA/OC/OES/DFOI/	Doe J	REHABILITATION CENTERS FOR NON-VIOLENT OFFENDERS - RECS, LEGISLATION, NEW LAWS
2012-5793	08/08/2012 09/06/2012	FDA/OMPT/CDRH/OCER/DFOI/	LAVENIA FORD CARDINAL HEALTH	KIMERLY-CLARK HEALTHCARE - KIMGUARD SMART-FOLD STERILIZATION WRAP K112300
2012-5794	08/08/2012 09/06/2012	FDA/OMPT/CDRH/OCER/DFOI/	DR VINCENZO PUTRONE AB ANALITICA	GI SUPPLY (DIVISION OF CHEK-MED SYSTEMS INC - HP-ONE RAPID UREA ASSAY K012411
2012-5795	08/08/2012 09/06/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dr Adil Sheraz Dermatology Medway Maritime Hospital	REVLIMID - AERS
2012-5796	08/08/2012 09/06/2012	FDA/OC/OES/DFOI/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CDRH/OCER/DFOI/ OC/ORAOCI/ OC/ORAOCI/	Mary Ann Roser AUSTIN AMERICAN-STATESMAN	LIPOTRON 3000
2012-5797	08/08/2012 09/06/2012	FDA/OC/OES/DFOI/	Alex Polishchuk Tharpe & Howell	INDIVIDUAL RECORDS
2012-5798	08/08/2012 09/06/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Monica Milam CADENCE PHARMACEUTICALS INC	LABORATORIES GRIFOLS, SA, BARCELONA, SPAIN - 483 07/12
2012-5799	08/08/2012 09/06/2012	OC/CVM/OCD/	vicky nguyen NBC Bay Area News (KNTV)	CHICKEN JERKY TREATS - CONSUMER COMPLAINTS SUBMITTED TO CVM
2012-5800	08/08/2012 09/06/2012	FDA/OC/OES/DFOI/	Alex Polishchuk Tharpe & Howell	MEDWATCH REPORT
2012-5801	08/08/2012	OC/ORAO/	Amanda E. Womack	INDIVIDUAL RECORDS

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	09/06/2012	OC/OROA/ FDA/OGROP/ORO/SW-FO/DAL- DO/DAL-CB/ OC/ORO/OCI/ OC/ORO/OCI/ OC/ORO/OCI/ OC/ORO/OCI/	Amanda E. Womack	
2012-5802	08/08/2012 09/06/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Adam Dalal none	ISOTRENTINOIN - AERS
2012-5803	08/08/2012 09/06/2012	FDA/OMPT/CDRH/OCER/DFOI/	Laura Boll Medovations Inc.	K102581
2012-5804	08/08/2012 09/06/2012	FDA/OMPT/CDRH/OCER/DFOI/	Laura Boll Medovations Inc.	K090851
2012-5805	08/08/2012 09/06/2012	FDA/OC/OES/DFOI/	KIK Custom Products, Inc. - Memphis Plant	KIK CUSTOM PRODUCTS, DANVILLE, IL - EIR 02/12
2012-5806	08/09/2012 09/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	Laura Boll Medovations Inc.	K070420
2012-5807	08/09/2012 09/07/2012	OC/ORO/ OC/ORO/ OC/ORO/ORM/ OC/ORO/ORM/	ROBERT W. BAIRD & CO INC	NUMBER OF 483S ISSUED IN 2011
2012-5808	08/09/2012 09/07/2012	FDA/OGROP/ORO/SW-FO/DAL- DO/DAL-CB/	Don Keck General Chemical LLC	GENERAL CHEMICAL, MIDLOTHIAN, TX - EIR 6/7/10
2012-5809	08/09/2012 09/07/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	BURZYNSKI CLINIC - HOLD RECS
2012-5810	08/09/2012 09/07/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-5212 REQUEST LTR

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2012-5811	08/09/2012 09/07/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-5225 REQUEST LTR
2012-5812	08/09/2012 09/07/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-5229 REQUEST LTR
2012-5813	08/09/2012 09/07/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-5264 REQUEST LTR
2012-5814	08/09/2012 09/07/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-5274 REQUEST LTR
2012-5815	08/09/2012 09/07/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-5299 REQUEST LTR
2012-5816	08/09/2012 09/07/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-5316 REQUEST LTR
2012-5817	08/09/2012 09/07/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-5393 REQUEST LTR
2012-5818	08/09/2012 09/07/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-5409 REQUEST LTR
2012-5819	08/09/2012 09/07/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-4058
2012-5820	08/09/2012 09/07/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-5456 REQUEST LTR
2012-5821	08/09/2012 09/07/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-4875 REQUEST LTR
2012-5822	08/09/2012 09/07/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-4885 REQUEST LTR
2012-5823	08/09/2012 09/07/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-4851 REQUEST LTR
2012-5824	08/09/2012 09/07/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-4944 REQUEST LTR
2012-5825	08/09/2012 09/07/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-4430
2012-5826	08/09/2012 09/07/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-4871 REQUEST LTR
2012-5827	08/09/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2012-4968 REQUEST LTR

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	09/07/2012		MERCK & CO., INC.	
2012-5828	08/09/2012 09/07/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-5017 REQUEST LTR
2012-5829	08/09/2012 09/07/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-5157 REQUEST LTR
2012-5830	08/09/2012 09/07/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-5158 REQUEST LTR
2012-5831	08/09/2012 09/07/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-5160 REQUEST LTR
2012-5832	08/09/2012 09/07/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-5202 REQUEST LTR
2012-5833	08/09/2012 09/07/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-5193 REQUEST LTR
2012-5834	08/09/2012 09/07/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-5308
2012-5835	08/09/2012 09/07/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-5307
2012-5836	08/09/2012 09/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	VY TRAN VARIAN MEDICAL SYSTEMS INC	VARIAN MEDICAL SYSTEMS, KELSINKI, FINLAND - 5/2-11/11; HAAN, GERMANY 5/9/11 EIRS
2012-5837	08/09/2012 09/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	MARK A KOPEC HABCO INC	PACIFIC PERCISION PRODUCTS - PORTABLE OXYGEN GENERATOR K120566
2012-5838	08/09/2012 09/07/2012	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	MARIANNA CARUSO CHARLES RIVER LABS	LAND O'LLAKES PURINA FEED LLC, RICHMOND, IN - EIR OR 483 5/19/12
2012-5839	08/09/2012 09/07/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARILYNN WHITNEY COVINGTON & BURLING LLP	HALAVEN (ERIBULIN MESYLATE) INJ NDA 201-532 APRVL/REPLACEMENT ACTION LTR 11/15/10 (CERTIFIED)
2012-5840	08/09/2012 09/07/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARILYNN WHITNEY COVINGTON BURLING LLP	HALAVEN (ERIBULIN) INJ NDA 201-532 - APRVL/REPLACEMENT ACTION LTR LBLG 11/15/10 (CERTIFIED)
2012-5841	08/09/2012 09/07/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GOONEWARDENA, PRASANNA	ZYPREXA, PAXIL, CLOZARIL (CLOZAPINE), ETC - AERS

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2012-5842	08/09/2012 09/07/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BOBBY SCHOCHET OLSSON FRANK WEEDA TERMAN MATZ PC	MYLAN INC - PIOGLITAZONE HCL, METFORMIN HCL (ACTOPLUS MET) ANDA 090-406 APRVL LTR 2/25/11
2012-5843	08/09/2012 09/07/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OGROP/ORANE-FO/NYK- DO/NYK-DCB/	SHARON M HANLON ZELMAN & HANLON PA	INTELLICELL BIOSCIENCES INC, NEW YORK, NY - WARNING LTR RESP TO CMLPLNTS, EMAIL TRANSMISSIONS, CORR 3/13/12
2012-5844	08/09/2012 09/07/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-4089
2012-5845	08/09/2012 09/07/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-4651
2012-5846	08/09/2012 09/07/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-4358
2012-5847	08/09/2012 09/07/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-4275
2012-5848	08/09/2012 09/07/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-4503
2012-5849	08/09/2012 09/07/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-4134
2012-5850	08/09/2012 09/07/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-4222
2012-5851	08/09/2012 09/07/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-2415
2012-5852	08/09/2012 09/07/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-4264
2012-5853	08/09/2012 09/07/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-4135
2012-5854	08/09/2012 09/07/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	King Lee King Lee	BOEHRINGER INGELHEIM PHARM - AMBROXOL RECS

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2012-5855	08/10/2012 09/10/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	QUINTILES IRELAND LTD, DUBLIN, IRELAND - EIR, 483, CORR 01/01/2002 TO PRESENT
2012-5856	08/10/2012 09/10/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	NDA 202343
2012-5857	08/10/2012 09/10/2012	FDA/OGROP/ORR/SE-FO/ATL- DO/ATL-CB/	Emory University, Office Rsch Compliance	EMORY UNIV RADIOACTIVE DRUG RESEARCH COMM - EIR 02/10
2012-5858	08/10/2012 09/10/2012	FDA/OGROP/ORR/CE-FO/CIN- DO/CIN-CB/ FDA/OC/OCC/ FDA/OMPT/CDRH/OCER/DFOI/	Robert Blinn Pura Vida Funds	INVACARE, ELYRIA, OH - CORR WITH FDA RE CONSENT DECREE
2012-5859	08/10/2012 09/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	Given Imaging	K111450
2012-5860	08/10/2012 09/10/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	NYCOMED GMGH, BADEN-WUERTTEMBERG, GERMANY - EIR 4/19/11
2012-5861	08/10/2012 09/10/2012	FDA/OMPT/CDRH/OCER/DFOI/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	K120109
2012-5862	08/10/2012 09/10/2012	FDA/OC/OES/DFOI/	none	TOWER SKINS - FBI FILE
2012-5863	08/10/2012 09/10/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	BENLYSTA - PRE-IND MEETING MATERIALS, BRIEFING PACKAGE
2012-5864	08/10/2012 09/10/2012	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	NDA 19908 S022

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		FDA/OMPT/CDER/ORP/DIDP/		
2012-5865	08/10/2012 01/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	Marta Gaia Zanchi Medinnovo LLC	K121677
2012-5866	08/10/2012 09/10/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Yuichi Utsumi Kyorin Pharmaceutical Co.,Ltd.	NDA 017788
2012-5867	08/10/2012 09/10/2012	FDA/OMPT/CDRH/OCER/DFOI/	PETER A TAKEA KYPHA INC	RANDOX LABORATORIES LTD - RANDOX COMPLEMENT C3 K000469
2012-5868	08/10/2012 09/10/2012	FDA/OMPT/CDRH/OCER/DFOI/ OC/OA/OM/OMP/DDM/ FDA/OMPT/CDRH/OCER/DFOI/	KENT L KLAUDT LIEF CABRASER HELMANN & BERNSTEIN LLP	MEDTRONIC INC - INFUSE BONE GRAFT P050053 FINANCIAL RELATIONSHIP WITH ANY INVESTIGATOR 1999 TO 2002; A/C TRANS 1/02, ETC
2012-5869	08/10/2012 09/10/2012	FDA/OMPT/CDRH/OCER/DFOI/	THEA LIND HealthPartners	FIBERS AND CONNECTORS USED IN A LASER FOR EVLA (VARICOSE VEIN PROCEDURE) - APRVL RECS
2012-5870	08/10/2012 09/10/2012	FDA/OMPT/CDRH/OCER/DFOI/	CHERENE MASTROIANNI OLYMPUS AMERICA INC	INVENDO MEDICAL GMBH - C20 COLONOSCOPY SYS K100624
2012-5871	08/10/2012 09/10/2012	FDA/OFVM/CFSAN/OCD/EOS/	CAITLIN WILCOX IOVATE HEALTH SCIENCES INTERNATIONAL INC	SLIM QUICK - CAERS
2012-5872	08/10/2012 09/10/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARY L GUERRERE PURDUE PHARMA LP	INTERMEZZO (ZOLPIDEM TARTRATE) NDA 22-328 - APRVL RECS
2012-5873	08/10/2012 09/10/2012	FDA/OGROP/ORAN/NE-FO/NYK- DO/NYK-DCB/	REBECCA MACIEL FoodScience Corporation	VENUS PHARM, HAUPPAUGE, NY - EIR 1/20/12
2012-5874	08/10/2012 09/10/2012	FDA/OC/OES/DFOI/	KRISTI O SMEDLEY PHD WASHINGTON INFORMATION SOURCE	2011-9295
2012-5875	08/10/2012 09/10/2012	FDA/OC/OES/DFOI/	JH BARR & ASSOCIATES LLC	DAILY LOG 7/23-27/12
2012-5876	08/10/2012 09/10/2012	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 7/16-20/12
2012-5877	08/10/2012 09/10/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION	DAILY LOG 7/9-13/12

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2012-5878	08/10/2012 09/10/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 7/16-20/12
2012-5879	08/10/2012 09/10/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 7/9-13/12
2012-5880	08/10/2012 09/10/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 7/16-20/12
2012-5881	08/10/2012 09/10/2012	FDA/OC/OES/DFOI/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	NUVASIVE INC - EIRS, 483S, UNTITLED LTRS,E TC 1/12 TO PRESENT
2012-5882	08/10/2012 09/10/2012	FDA/OC/OES/DFOI/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	WRIGHT MEDICAL GROUP INC - EIRS, 483S, UNTITLED LTRS, ETC 1/12 TO PRESENT
2012-5883	08/10/2012 09/10/2012	FDA/OC/OES/DFOI/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	ST JUDE MEDICAL INC - EIRS, 483S, UNTITLED LTRS, ETC 1/12 TO PRESENT
2012-5884	08/10/2012 09/10/2012	FDA/OC/OES/DFOI/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	CR BARD INC - EIRS, 483S, UNTITLED LTRS, ETC 1/12 TO PRESENT
2012-5885	08/10/2012 09/10/2012	FDA/OC/OES/DFOI/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	AMGEN INC - EIRS, 483S, UNTITLED LTRS, ETC 1/12 TO PRESENT
2012-5886	08/10/2012 09/10/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 7/9-13/12
2012-5887	08/10/2012 09/10/2012	FDA/OGROP/ORR/PA-FO/SAN-DO/SAN-CB/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	GILEAD SCIENCES INC - EIRS, 483S, UNTITLED LTRS, ETC 1/12 TO PRESENTS
2012-5888	08/10/2012 09/10/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 7/16-20/12
2012-5889	08/10/2012 09/10/2012	FDA/OC/OES/DFOI/	GLADYS B. TONKIN WASHINGTON INFORMATION SOURCE	DAILY LOG 7/16-20/12
2012-5890	08/10/2012 09/10/2012	FDA/OC/OES/DFOI/	GLADYS B. TONKIN WASHINGTON INFORMATION SOURCE	DAILY LOG 7/9-13/12
2012-5891	08/10/2012 09/10/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 7/16-20/12
2012-5892	08/10/2012	FDA/OC/OES/DFOI/	BARBARA JONES	DAILY LOG 7/9-13/12

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	09/10/2012		DOMINION GROUP INC	
2012-5893	08/10/2012 09/10/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 7/16-20/12
2012-5894	08/10/2012 09/10/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 7/9-13/12
2012-5895	08/10/2012 09/10/2012	FDA/OFVM/CFSAN/OCD/EOS/	Richard Tedford Tedford, Richard	FDA NO OBJECTION LETTER FOR RECYCLED PLASTICS 135
2012-5896	08/10/2012 09/10/2012	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORACE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORACE-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORACE-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORACE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORACE-FO/SJN-DO/SJN-CB/ FDA/OGROP/ORACE-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORACE-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORACE-FO/NYK-DO/NYK-DCB/	MARK P GREENBLATT ABC NEWS	AIRLINE CATERERS - INSPECTION RECORDS FOR FIRMS RECEIVING WARNING LETTERS OR OTHER ENFORCEMENT ACTIONS (7/25/09-7/25/12)
2012-5897	08/10/2012 09/10/2012	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORACE-FO/PHI-	MARK P GREENBLATT ABC NEWS	AIRLINE CATERERS - PHOTOS, VIDEOS FROM INSPECTIONS RESULTING IN A WARNING LETTER OR OTHER ENFORCEMENT ACTION

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		DO/PHI-CB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/		
2012-5898	08/13/2012 09/11/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tim Farley James Randi Educational Foundation	A NELSON, LONDON, UK - EIR, COMPANY RESPONSE (11/14/11-11/17/11)
2012-5899	08/13/2012 09/11/2012	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Tina Subrosa Investigations LLC	Z-MEDICA, CONNECTICUT - EIR, 483, COMPANY REPSONSE (2000-2012)
2012-5900	08/13/2012 09/11/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OC/OES/DFOI/ FDA/OO/OIM/OPILS/FDAHO/	Paul Reid Ocean Pharmaceuticals LLC	NYLOXIN (COBRA VENUM) - NDA
2012-5901	08/13/2012 09/11/2012	FDA/OMPT/CDRH/OCER/DFOI/	Juli Mann STEPTOE & JOHNSON	K082575
2012-5902	08/13/2012 09/11/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	ANDA 75737

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		FDA/OMPT/CDER/GRP/DIDP/		
2012-5903	08/13/2012 09/11/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Roman, Debbie J	ZYVOX - PATIENT REPORT
2012-5904	08/13/2012 09/11/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TECHNOLOGY CATALYSTS INTL	SHIRE - COMPLETE RESPONSE LETTER RE: VPRIV
2012-5905	08/13/2012 09/11/2012	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	Nancy Teasdale Regulatory Strategies and Solutions, Inc	BAXTER HEALTHCARE, CLEVELAND, MS; APP PHARM, LCC, GRAND ISLAND, NY - EIR, 483 (8/09-8/12)
2012-5906	08/13/2012 09/11/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	ANDA 75357
2012-5907	08/13/2012 09/11/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	ANDA 75598
2012-5908	08/13/2012 09/11/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	ANDA 75357
2012-5909	08/13/2012 09/11/2012	FDA/OMPT/CDRH/OCER/DFOI/	Michelle Sparks Carol L. Hepburn, P.S.	INDIVIDUAL RECORDS
2012-5910	08/13/2012 09/11/2012	FDA/OC/OES/DFOI/	Dr. Jack A. Shulman ACSA Advances Magazine	DRUG PRICES
2012-5911	08/13/2012 09/11/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sharif Ahmed Scinergist Pharmaceuticals LLC	NDA 017810 - CHEM RVW, BIOEQUIV RVW, PHARM/TOX
2012-5912	08/13/2012	FDA/OMPT/CDER/GRP/DIDP/	Sharif Ahmed	ANDA 201089 - BIOEQUIV RVW

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	09/11/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Scinergist Pharmaceuticals LLC	
2012-5913	08/13/2012 09/11/2012	FDA/OMPT/CDRH/OCER/DFOI/	SANDRA BROWN REICHERT TECHNOLOGIES	REICHERT INC, DEPEW, NY - PREFERENTIAL HYPERACULTY PERIMETER K050350; POD B-SCAN, ULTRASONIC PULSED ECHO IMAGING SYS K070884
2012-5914	08/13/2012 09/11/2012	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	MICHAEL H HINCKLE K&L GATES	INO THERAPEUTICS LLC (DBA IKARIA), MADISON, WI - EIRS 8/10, 10/11
2012-5915	08/13/2012 09/11/2012	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	MICHAEL H HNCKLE K&L GATES	INO THERAPEUTICS LLC (DBA IKARIA), 483S 8/10, 10/11
2012-5916	08/13/2012 09/11/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID L ROSEN FOLEY & LARDNER LLP	ORTHO TRI-CYCLEN LO NDA 021-241 - SUBMISSION FOR PATENT INFORMATION
2012-5917	08/13/2012 09/11/2012	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OC/OES/DFOI/	TYLER KENYON NORTHCOAST RESEARCH	ZIMMER HOLDINGS, WARSAW, IN - 483 MOST RECENT
2012-5918	08/13/2012 09/11/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARK D KAMITOMO MARKAM GROUP INC PS	ISRS 3019682, 3105840, 3137635, ETC
2012-5919	08/13/2012 09/11/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANIL SACHDEVA STRIDES INC	HOSPIRA -VITAMIN A PALMITATE NDA 006-823 SBA
2012-5920	08/13/2012 09/11/2012	FDA/OC/OES/DFOI/	NEWMAN J50399-A5-144, GEOFF	RADIONICS - RECS
2012-5921	08/13/2012 09/11/2012	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	ANTHONY P SCHIAVONE PHILIPS HOME HEALTHCARE SOLUTIONS	RESPIRONICS MANUFACTURING, MURRYSVILLE, PA - EIR 2012
2012-5922	08/13/2012 09/11/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Janet McChristion Fresenius Kabi USA	ANDA 200146, ANDA 202268, ANDA 200146, ETC - APPROVAL LTR

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2012-5923	08/13/2012 09/11/2012	FDA/OC/OES/DFOI/	WALTER TERRELL Terrell, Walter	HEALTH VIOLATIONS
2012-5924	08/13/2012 09/11/2012	FDA/OMPT/CTP/OD/	Michael Felberbaum THE ASSOCIATED PRESS	NEW TOBACCO PRODUCT APPS; APPROVED TOBACCO PRODUCT APPS; REJECTED TOBACCO PRODUCT APPS, ETC (6/09-8/12)
2012-5925	08/14/2012 09/12/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Robert Murdock Murdock & Associates	ZOLPIDEM - AERS
2012-5926	08/14/2012 09/12/2012	FDA/OGROP/ORPA/FO/SEA-DO/SEA-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Matthias Mueller Genentech	PIRAMAL, GRANGEMOUTH, SCOTLAND - EIR 06/11; SEATTLE GENETICS - EIR 05/11
2012-5927	08/14/2012 09/12/2012	FDA/OC/OES/DFOI/	Christina R Henning Canton City Health Department	CASE FARMS CHICKEN, CANTON, OH - TEST RESULTS
2012-5928	08/14/2012 09/24/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OC/OES/DFOI/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Sharon M Hanlon or Gina Cohen ZELMAN & HANLON PA	INTELLICELL BIOSCIENCES - EMAIL, CORR, COMPLAINTS, ETC.
2012-5929	08/14/2012 09/12/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	David McIntosh JAMES MINTZ GROUP INC	SHIONOGI, INC; SHIONOGI PHARMA, INC - REGISTRATION RECS
2012-5930	08/14/2012 09/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	Angie Hoover Findling Park & Associates	MEDTRONIC IMPLANTABLE CARDIOVERTER DEFIBRILLATOR - RPTS, CORR, MEMO, ETC (CERTIFIED)
2012-5931	08/14/2012 09/12/2012	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	KIK Custom Products, Inc. - Memphis Plant	KIK CUSTOM PRODS, DANVILLE, IL - EIR (01/11)
2012-5932	08/14/2012 09/12/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Alice Chen UNIVERSITY OF CHICAGO	DRUG REGISTRATION AND LISTING DATA 2000-2010

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2012-5933	08/14/2012 09/12/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Meeta Vete INSITE VISION	NDA 050722
2012-5934	08/14/2012 09/12/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	ALICE MEIKLE VITAL PHAMACEUTICALS INC	CYTOSPORT INC - INVESTIGATION RECS, WARNING LTR 6/29/11 RECS
2012-5935	08/14/2012 09/12/2012	FDA/OMPT/CDRH/OCER/DFOI/ OC/OA/OM/OMP/DDM/	SUZANNE O'SHEA FAEGRE BAKER DANIELS	DVC PROD CODE OQS, LAB DEVELOPMENT TEST - MEMOS, BRIEFING PKGS, RECS
2012-5936	08/14/2012 09/12/2012	FDA/OGROP/ORA/PA-FO/SEA- DO/SEA-CB/ FDA/OGROP/ORA/SW-FO/DEN- DO/DEN-CB/ FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	RICHARD LARNDER ASSOCIATED PRESS	MELALEUCA, IDAHO FALLS, ID 2001, 2005, 2007, ETC; 4LIFE RESEARCH, SANDY, UT 1/23-27/12; NUSKIN, PROVO, UT 3/11, ETC - INSPS
2012-5937	08/14/2012 09/14/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	LESLIE A KLAUSNER RN BSN MISHKIND LAW FIRM CO LPA	VAERS - INDIVIDUAL RECS
2012-5938	08/14/2012 09/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	CHRISTOPHER L YARBRO KENNEDY, KENNEDY, ROBBINS & YARBRO LC	CRYOLIFE - BIOGLUE SURGICAL ADHESIVE P010003 RPT 1063481-2004-00019
2012-5939	08/14/2012 09/12/2012	FDA/OC/OES/DFOI/	JEFF STACHEWICZ FOIA GROUP INC	DEEPWATER HORIZON - OIL, HYDROCARBONS, DISPERSANTS FROM THE MC262 WELL RECS
2012-5940	08/14/2012 09/12/2012	FDA/OC/OES/DFOI/	SALLEE, YARBI	HEPARIN - RECALL RECS
2012-5941	08/14/2012 09/12/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARY L REITZ GREENSFELDER HEMKER & GALE PC	STELARA - AERS
2012-5942	08/14/2012 09/12/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	G SRINIVAS ZYDUS PHARMACEUTICALS USA INC	HORIZON PHARMA USA - RAYOS TABS NDA 202-020 SBA
2012-5943	08/14/2012 09/12/2012	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	Anna Pappas Chipita America Inc	FEI 3007713859 - 482, NOTICE OF INSPECTION, FACTS ASSIGNMENT
2012-5944	08/15/2012	FDA/OC/OES/DFOI/	Shufen Ripperton	WATSON LABS, SALT LAKE CITY, UT - EIR 06/12

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	09/13/2012		Watson Laboratories, Inc.	
2012-5945	08/15/2012 09/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	abdul mateen Abdul Mateen	NEURX DPS DIAPHRAGM PACING SYSTEM (H100006) - DESIGN RECS
2012-5946	08/15/2012 09/13/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Alaska Burr NORTH RUN CAPITAL LP	ALERE INC, SAN DIEGO, CA - 483 (01/01/09 - 08/14/12), EMAILS, CORR
2012-5947	08/15/2012 09/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	XANAX - AERS
2012-5948	08/15/2012 09/13/2012	FDA/OC/OES/DFOI/	Alaksa Burr NORTH RUN CAPITAL LP	ALERE INC., SAN DIEGO, CA - 483 (01/01/09 - 08/14/12)
2012-5949	08/15/2012 09/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	David Mustra PWR	NDA 022328
2012-5950	08/15/2012 09/13/2012	FDA/OMPT/CTP/OD/	Joseph Manuppello PETA	MEETING RECS - CTP AND TOBACCO STAKEHOLDERS
2012-5951	08/15/2012 09/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	Vital Connect Inc.	K110809
2012-5952	08/15/2012 09/13/2012	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	KGO Television/ ABC NEWS	SAN FRANCISCO HERB & NATURAL FOOD CO, SOUTH FREMONT, CA - PHOTOS, VIDEO 05/12-08/12
2012-5953	08/15/2012 09/13/2012	OC/OM/OMP/DDM/	TOD MACK WESTLAW COURT EXPRESS	DKT FDA-2010-0526, FDA-2010P-0540, ETC.
2012-5954	08/15/2012 09/13/2012	OC/CVM/OCD/	EDWARD HAMMOND SUNSHINE PROJECT	RPTS REGARDING VIOLATIONS OF NIH GUIDELINES 1/01 TO PRESENT
2012-5955	08/15/2012 09/13/2012	FDA/OC/OES/DFOI/	LLOYD, WILLIAM	MEETING MINUTES RE: PERSONNEL ISSUE 3/30/12 & 4/2/12
2012-5956	08/15/2012 09/13/2012	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 7/23-27/12
2012-5957	08/15/2012 09/13/2012	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 7/30-8/3/12
2012-5958	08/15/2012	FDA/OC/OES/DFOI/		DAILY LOG 7/23-27/12

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	09/13/2012		WOLTERS KLUWER LAW & BUSINESS	
2012-5959	08/15/2012 09/13/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 7/30-83/12
2012-5960	08/15/2012 09/13/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 7/30-8/3/12
2012-5961	08/15/2012 09/13/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 7/23-27/12
2012-5962	08/15/2012 09/13/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP FOI Services, Inc.	DAILY LOG 7/23-27/12
2012-5963	08/15/2012 09/13/2012	FDA/OC/OES/DFOI/	CanReg, Inc.	DAILY LOG 7/30-8/3/12
2012-5964	08/15/2012 09/13/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 7/23-27/12
2012-5965	08/15/2012 09/13/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 7/30-8/3/12
2012-5966	08/15/2012 09/13/2012	FDA/OC/OES/DFOI/	GLADYS B. TONKIN WASHINGTON INFORMATION SOURCE	DAILY LOG 7/30-8/3/12
2012-5967	08/15/2012 09/13/2012	FDA/OC/OES/DFOI/	GLADYS B. TONKIN WASHINGTON INFORMATION SOURCE	DAILY LOG 7/23-27/12
2012-5968	08/16/2012 09/14/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 7/30/12-8/3/12
2012-5969	08/16/2012 09/14/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 7/30/12-8/3/12
2012-5970	08/16/2012 09/14/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 7/30/12-8/3/12
2012-5971	08/16/2012 09/14/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 8/6-10/12
2012-5972	08/16/2012 09/14/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 8/6-10/12

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2012-5973	08/16/2012 09/14/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 7/30/12-8/3/12
2012-5974	08/16/2012 09/14/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 7/30/12-8/3/12
2012-5975	08/16/2012 09/14/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 8/6-10/12
2012-5976	08/16/2012 09/14/2012	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	RICARDO RONQUILLO NEUROGE-SX	PRACS INSTITUTE, FARGO, ND - EIRS, 483S, WARNING LTRS, ETC 1/07 TO PRESENT
2012-5977	08/16/2012 09/14/2012	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	RICARDO RONQUILLO NEUROGE-SX	COMPARATIVE BIOSCIENCES, SUNNYVALE, CA - EIRS, 483S, WARNING LTRS, ETC 1/07 TO PRESENT
2012-5978	08/16/2012 09/14/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	JOHN WALSH JAMES ALEXANDER CORP	SUTHERLAND PACKAGING, ANDOVER, NJ - EIRS, 483S, RECALLS 8/09 TO PRESENT
2012-5979	08/16/2012 09/14/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHARLES CELESTE EAS Consulting Group, LLC	RAYOS DR TABS NDA 202-020 - APRVL LTR, LBLG, RVWS 7/26/12
2012-5980	08/16/2012 09/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	TATYANA BOGDAN CARDINAL HEALTH	HOWMEDICA OSTEONICS CORP - K063857
2012-5981	08/16/2012 09/14/2012	FDA/OFVM/CFSAN/OCD/EOS/	WILBUR JOHNSON JR COSMETIC INGREDIENT REVIEW	CHAMOMILE FLOWER (ANTHEMIS NOBILIS L), HUNGARIAN CHAMOMILE FLOWER OIL (MATRICARIA CHAMOMILLA L), ETC - CHEMICAL PROPERTIES, DERMAL PENETRATION, TOXICITY, ETC
2012-5982	08/16/2012 09/14/2012	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	GERHARDT, NATHAN	NUTRACEUTIX INC, LAFAYETTE, CO - 483 8/13/09
2012-5983	08/16/2012 09/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	WENDELL Y TONG SULLIVAN PAPAIN BLOCK ET AL	REJUVENATE MONOLITHIC SIZE 4 HIP STEM K091161
2012-5984	08/16/2012 09/14/2012	OC/OCOS/OL/	JACK GILLUM ASSOCIATED PRESS	REP PAUL RYAN - CORR 1/3/99 TO PRESENT
2012-5985	08/16/2012 09/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRENT M ARDAUGH MPH MS NORTHWESTERN UNIV FEINBERG SCHOOL OF MEDICINE	K982532
2012-5986	08/16/2012 09/14/2012	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	RONALD A ANDIO SCHIFF HARDIN LLP	DBA PATRON FARMS LLC, CANFIELD, OH - RECS, CORR 1/09 TO PRESENT
2012-5987	08/16/2012	FDA/OMPT/CDER/GRP/DIDP/	RICHARD L VANORE	TORADOL (KETOROLAC TROMETHAMINE NDA 19-698, NDA

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2012-5988	08/16/2012 09/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/OA/OM/OMP/DDM/	KIMBERLY H LANIER NELSON MULLINS RILEY & SCARBOROUGH LLP	TAKEDA - ACTOS NDA 21-073/S021,S024,S029 RVWS. MTG MINS, LBLG, ETC
2012-5989	08/16/2012 10/15/2012	FDA/OGROP/ORR/SW-FO/DEN- DO/DEN-CB/	JOAN M BECHTOLD SWEENEY & BECHTOLD LLC	CONMED CORP- EIR. COMM 2012
2012-5990	08/16/2012 09/14/2012	FDA/OC/OES/DFOI/	KATIE THOMAS NEW YORK TIMES	APP PHARMS, AMERICAN REGENT, HOSPIRA, ETC - 483S 1/08 TO PRESENT
2012-5991	08/16/2012 09/14/2012	FDA/OO/OFBA/OAGS/ OC/ORR/OCI/ OC/ORR/OCI/	JILL BONNIN LEGIT SCRIPT	CONTRACT #HHSF223201000071C - EMAILS, NOTES, MEMOS, ETC 9/1/11 TO 8/15/12
2012-5992	08/16/2012 09/14/2012	FDA/OGROP/ORR/NE-FO/NWE- DO/NWE-CB/	CATHERINE DAVIDSON PURDUE PHARMA LP	RHODES TECHNOLOGIES, COVENTRY, RI - EIRS MOST RECENT (CERTIFIED)
2012-5993	08/16/2012 09/14/2012	OC/ORR/ OC/ORR/ FDA/OGROP/ORR/PA-FO/LOS- DO/LOS-CB/	HOFFMANN, RALPH	CMPLNT
2012-5994	08/16/2012 09/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jeff Gerth PROPUBLICA	MCNEIL - PERIOD RPTS FOR 2011-2012 FOR ACETAMINOPHEN/TYLENOL
2012-5995	08/16/2012 09/14/2012	FDA/OGROP/ORR/CE-FO/NWJ- DO/NWJ-CB/	WHINERY, THOMAS V	DENTAL SAVINGS LLC, WEST NEW YORK, NJ - QUARTERLY RPTS OF INSPS
2012-5996	08/16/2012 09/14/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	LORI PFOHL TELEFLEX MEDICAL	AGENTO IC SILVER COATED ENDOTRACHEAL TUBE (INTERMEDIATE HIGH VOLUME LOW PRESSURE) K080170
2012-5997	08/16/2012 09/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SCOTT A HANNA ZUCKERMAN SPAEDER LLP	BENEDECTIN NDA 10-598 - LITIGATION RECS

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OCC/		
2012-5998	08/16/2012 09/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	David Lucking DL Consulting	NDA 22572
2012-5999	08/16/2012 09/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	David Miller none	ZYTIGA - AERS
2012-6000	08/16/2012 09/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	Lorraine Porto Adenta USA	K110275
2012-6001	08/16/2012 09/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Cathy Kelly Elsevier Business Intelligence	DRUG SAFETY OVERSIGHT BOARD MTG 5/17/12 - BACKGROUND RECS
2012-6002	08/16/2012 09/14/2012	FDA/OGROP/ORR/SW-FO/KAN- DO/KAN-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OCC/	Chris Quinn The Driscoll Firm, P.C.	CORR BTWN FDA AND KV PHARM AND/OR ETHEX CORP RE: CONSENT DECREE
2012-6003	08/16/2012 09/14/2012	FDA/OGROP/ORR/SE-FO/ATL- DO/ATL-CB/	Charles Dankwah Hawknad Manufacturing Industries, Inc.	CUSTOM ANALYTICS, INC., SUMTER, SC - LATEST 483
2012-6004	08/16/2012 09/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	Sandra White Aniara Diagnostica	HYPHEN BIOMED, NEUVILLE SUR OISE, FRANCE - EIR 06/12
2012-6005	08/16/2012 09/14/2012	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Larry A Stobbs Larry A. Stobbs	BEIJING KEYIFENG BIOTECH DEV CO - EIR 03/09
2012-6006	08/16/2012	FDA/OMPT/CDER/ORP/DIDP/	Jeff Gerth	PERIODIC RPTS 1995 OR 1996 BY MCNEIL FOR TYLENOL

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	09/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PROPUBLICA	
2012-6007	08/16/2012 09/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Darcy Gilson DBDG LLC	NDA 020632
2012-6008	08/17/2012 10/01/2012	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/CE-FO/CHIDO/CHI-CB/ FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/ FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/ FDA/OC/OES/DFOI/	BECKY COOSEMAN BROWN & CROUPPEN PC	MEAD JOHNSON NUTRITION - EIRS, 483S, WARNING LTRS, ETC 2002 TO PRESENT
2012-6009	08/17/2012 09/17/2012	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Doe J	INDIVIDUAL RECS
2012-6010	08/17/2012 09/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JAYA AYYAGARI DR REDDY'S LABORATORIES INC	DOUGLAS PHARMS - MYORISAN (ISOTRETINOIN) ANDA 76-485 SBA
2012-6011	08/17/2012	FDA/OFVM/CFSAN/OCD/EOS/	JONATHAN ALLEN	MULTI-STATE E COLI OUTBREAK - INVESTIGATION RECS 2009

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	09/17/2012	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	SNELL & WILMER LAW OFCS	
2012-6012	08/17/2012 09/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	METHADONE - AERS
2012-6013	08/17/2012 09/17/2012	FDA/OC/OES/DFOI/	JOSEPH H SAUNDERS SAUNDERS & WALKER PA	CR BARD INC, COVINGTON, GA 3/12/10; ETHICON GMBH, NORDERSTEDT, GERMANY 11/14-17/11; ETHICON LLC, LORENZO, PR 8/11/08-9/5/08, ETC - EIRS, 483S, CO RESP, ETC
2012-6014	08/17/2012 09/17/2012	FDA/OC/OES/DFOI/	AMY KINCANON LEXISNEXIS COURTLINK INC	2012-5407
2012-6015	08/17/2012 09/17/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/ORO/DIOP/	MARYBETH CONNER FALCON RESEARCH	NU SKIN, PHARMANEX - IMPORT REFUSALS, MDRS, WARNING LTRS 1/1/10 TO 8/15/12
2012-6016	08/17/2012 09/17/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ OC/OCOS/OES/ OC/OCOS/OES/	CANTU, KEVIN R	ANTHRAX VACCINATION PROGRAM - RECS
2012-6017	08/17/2012 09/17/2012	OC/OM/OMP/DDM/	MARILYNN WHITNEY COVINGTON & BURLING LLP	DKT 1977N-0094
2012-6018	08/17/2012 09/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	JOSH FEDERSPIEL ACUMED	SD TRANS-OSSEOUS FASTENER K9832354 - RECS, JOSEPH J SPRANZA CORR
2012-6019	08/17/2012 09/17/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	JOSHUA D SILVERMAN WILLIAMSON PETTY LC	BODYBUILDING.COM LLC - HAVOC (EPISTANE, EPITOSTANOL) CHEMICAL ANALYSIS, EIRS, WARNING LTRS, 1992 TO PRESENT
2012-6020	08/17/2012 09/17/2012	FDA/OFVM/CFSAN/OCD/EOS/	ANNA T FLOOD Keller and Heckman LLP	ARCH CHEMCALS INC - 2-PYRIDINETHIOL-1-OXIDE SODIUM FCN 175
2012-6021	08/17/2012 09/17/2012	FDA/OFVM/CFSAN/OCD/EOS/	ANNA T FLOOD Keller and Heckman LLP	ARCH CHEMICALS INC - ZINC PYRITHIONE FCN 1169
2012-6022	08/17/2012 09/17/2012	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	TORREANCE, TERRY	RON ANDIO, PATRON FARMS LLC, CANFIELD,OH - MEMOS, VIOLATIONS, INSP, ETC 4/3,5,30/12
2012-6023	08/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	THERESA SULLIVAN BARGER	MAMMOGRAPHY FACILITIES IN CT - INSPS THAT FOUND 1,

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	09/17/2012		CONNECTICUT HEALTH INVESTIGATIVE TEAM	2,3 LEVEL VIOLATIONS 2007 TO 2011
2012-6024	08/17/2012 09/17/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FRIEDMAN, INEZ C	RECLAST, INDERAL - AERS
2012-6025	08/17/2012 09/17/2012	OC/CVM/OCD/	GAMMONS, MARI ANNE	REVOLUTION (CANINE & FELINE) - PHARMACEUTICAL DETAIL SHEET
2012-6026	08/17/2012 09/17/2012	OC/OCOS/OES/ OC/OCOS/OES/	JENNIFER HSIEH HEALTHCARE RESEARCH CONSULTING GROUP	BILL GUYER, JOE GROGAN, GILEAD SCIENCES MTG - TRANS 8/16/12
2012-6027	08/17/2012 09/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	LAVENIA FORD CARDINAL HEALTH	KIMBERLY-CLARK HEALTHCARE - KIMGUARD ONE-STEP STERILIZATION WRAP K082177
2012-6028	08/17/2012 09/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	COLLEEN M DURAN Fresenius Medical Care North America	BAXTER HEALTHCARE - HOMECHOICE/HOMECHOICE PRO AUTOMATED PERSONAL CYCLER PERITONEAL DIALYSIS SYS K102936
2012-6029	08/17/2012 09/17/2012	FDA/OO/	JODIE RAE CURTIS FOX NEWS	AWARDS & BONUSES AWARDED TO FDA EMPLOYEES 1/06 TO PRESENT
2012-6030	08/17/2012 09/17/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Barbara Bernstein Bernstein, Barbara R	PROPECIA - AERS
2012-6031	08/17/2012 09/17/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dr. A. Thomas Taylor DOCTORS HOSPITAL	LACOSAMIDE - AERS
2012-6032	08/17/2012 09/17/2012	OC/ORO/ OC/ORO/	Gabriel Rodriguez A Customs Brokerage, Inc.	ENTRY MH9-0089620-9 - LAB RESULTS
2012-6033	08/17/2012 09/17/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	edwardsen, karen I	RECLAST - STUDIES, AERS
2012-6034	08/17/2012 09/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	Heather S. Lanza, Esq. The Law Office of David H. Jacobs	RETRACTABLE TECHNOLOGIES 1013 SYRINGE 1CC 27X.5 TB SAFE, ETC - 510K, PDA NUMBER, DEVICE LISTING NUMBER, ETC

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2012-6035	08/17/2012 09/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	Krantz, Katherine	K000881; K022730; K091989
2012-6036	08/17/2012 09/17/2012	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/ OC/ORASOCI/ OC/ORASOCI/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Adam Bobkin MILBERG LLP	K-V PHARM CO, ETHEX CO, THER-RX - 483S, WARNING LETTERS, RESPONSES
2012-6037	08/17/2012 09/17/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 7/30/2012 - 8/3/2012
2012-6038	08/17/2012 09/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	Trishia Dwyer GE Healthcare	K110646
2012-6039	08/17/2012 09/17/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 8/13-17/2012
2012-6040	08/17/2012 09/17/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 8/6-10/2012
2012-6041	08/17/2012 09/27/2012	FDA/OMPT/CDRH/OCER/DFOI/	Suzanne O'Shea FAEGRE BAKER DANIELS	CDRH - CORR RE: VALIDITY OF 510K AND LABELING OF CONTRAST AGENTS
2012-6042	08/17/2012 09/17/2012	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Frederick O. Cope Cope, Frederick O	PHARMALUCENCE - TECHNETIUM TC 99M SULFUR COLLOID INJ SNDA NDC 45567-0030-1
2012-6043	08/20/2012 09/18/2012	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	KELLEY UUSTAL Kelley Uustal	NDA 19304, 22224, 21656, ETC 21-203
2012-6044	08/20/2012 09/18/2012	OC/OCOS/OL/	Stifel Nicolaus & Co	RESPONSE TO SEN DURBIN RE CAFFEINE IN ENERGY DRINKS
2012-6045	08/20/2012 09/18/2012	FDA/OGROP/ORASORO/DIOP/ FDA/OGROP/ORASW-FO/SWID/SWID-CB/	Edward McPike Stifel Nicolaus & Co	NUSKIN ENTERPRISES, ESG PANATEC - CORR WITH FDA RE IMPORT REFUSAL
2012-6046	08/20/2012	FDA/OMPT/CDER/ERP/DIDP/	Joan Stitt (UG2CD-16)	ZIOPTAN - AERS (2/10/2012 - 6/30/2012)

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	09/18/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MERCK & CO., INC.	
2012-6047	08/20/2012 09/18/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	SAPHRIS - AERS (8/13/2009 - 6/30/2012)
2012-6048	08/20/2012 09/18/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	JANUMET - AERS (4/1/2010 - 6/30/2012)
2012-6049	08/20/2012 09/18/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	David R. Van Buskirk Leydig, Voit & Mayer LTD	NDA 050810 - FORM FDA 2253
2012-6050	08/20/2012 09/18/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ISENTRESS - AERS (11/1/2010 - 6/30/2012)
2012-6051	08/20/2012 09/18/2012	OC/OM/OMP/DDM/	SEAN WITZLING CITIZENS FOR HEALTH	DKT FDA-2010-P-0491
2012-6052	08/20/2012 09/18/2012	FDA/OMPT/CDRH/OCER/DFOI/	TECHNOLOGY SCIENCE GROUP INC	KIMBERLY - CLARK CORP, ROSWELL, GA - DEPEND FITTED BRIEF K854378
2012-6053	08/20/2012 09/18/2012	FDA/OMPT/CDRH/OCER/DFOI/	TECHNOLOGY SCIENCE GROUP INC	PROCTOR & GAMBLE MFG CO, CINCINNATI, OH - ATTENDS INCONTINENT BRIEF K873036
2012-6054	08/20/2012 09/18/2012	FDA/OGROP/ORASW-FO/KAN- DO/KAN-CB/ FDA/OGROP/ORASW-FO/DEN- DO/DEN-CB/ FDA/OGROP/ORASW-FO/DEN- DO/DEN-CB/ FDA/OC/OES/DFOI/ FDA/OGROP/ORASW-FO/KAN-	KRISTI O. SMEDLEY, Ph.D. WASHINGTON INFORMATION SOURCE	LLOYD LABS, IA - 483S 2012

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		DO/KAN-CB/		
2012-6055	08/20/2012 09/18/2012	FDA/OGROP/ORR/SW-FO/DEN-DO/DEN-CB/	DAVID LOHMAN SANESA PARTNERS	CORDEN PHARMA, BOULDER, CO - EIR 1/10 TO PRESENT
2012-6056	08/20/2012 09/18/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JIM FAUCETT NORTHWEST CLINICAL RESEARCH CTR	ADDERALL XR 30 NDA 21-303/S005;009 - SBA
2012-6057	08/20/2012 09/18/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	LOSARTAN POTASSIUM; FLECAINIDE ACETATE, WARFARIN SODIUM - AER
2012-6058	08/20/2012 09/18/2012	OC/ORR/ OC/ORR/ FDA/OGROP/ORR/SE-FO/SJN-DO/SJN-CB/	Doe J	CMLPNT
2012-6059	08/20/2012 09/18/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	QIAN ZHAO JOHNSON & JOHNSON CONSUMER & PERSONAL PRODUCTS WORLDWIDE	MINOXIDIL - AER
2012-6060	08/20/2012 09/18/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRENT M. ARDAUGH, MPH, MS NORTHWESTERN UNIV FEINBERG SCHOOL OF MEDICINE	K912144, K940489, K926344, K893626
2012-6061	08/20/2012 09/18/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRENT M. ARDAUGH, MPH, MS NORTHWESTERN UNIV FEINBERG SCHOOL OF MEDICINE	K031328
2012-6062	08/20/2012 09/18/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRENT M. ARDAUGH, MPH, MS NORTHWESTERN UNIV FEINBERG SCHOOL OF MEDICINE	K852097, K852097A, K870729
2012-6063	08/20/2012 09/18/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRENT M. ARDAUGH, MPH, MS NORTHWESTERN UNIV FEINBERG SCHOOL OF MEDICINE	K874096
2012-6064	08/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	FRANCISCO T. RIVAS, Esq.	ASCENT HEALTHCARE SOLUTIONS - LASER BASED

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	09/18/2012		SPECTRANETICS CORP	SINGLE USE CATHETERS PMA
2012-6065	08/21/2012 09/19/2012	FDA/OC/OES/DFOI/	KATIE THOMAS NEW YORK TIMES	APP HARMACEUTICALS, AMERICAN REGENT, BEN VENUE LABS, ETC - 483S 1/08 TO PRESENT
2012-6066	08/21/2012 09/19/2012	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/ FDA/OGROP/ORASE-FO/ATLDO/ATL-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	FOI Services, Inc.	HOSPIRA - 483S DOMESTIC & INTERNATIONAL 1/12/TO PRESENT
2012-6067	08/21/2012 09/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	GOTTEN INNOLIFE GROUP, TAIWAN - EIRS, 483S 3/5-8/12
2012-6068	08/21/2012 09/19/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	2012-4049
2012-6069	08/21/2012 09/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	COOK VASCULAR INC - EVOLUTION MECHANICAL DILATER SHEATH SET K061000
2012-6070	08/21/2012 09/19/2012	FDA/OMPT/CTP/OD/	FOI Services, Inc.	TOBACCO PRODS - AERS, SAFETY RECS 6/22/09 TO 7/31/12
2012-6071	08/21/2012 09/19/2012	FDA/OMPT/CTP/OD/	FOI Services, Inc.	CIGARETTE PRODS - AERS 6/22/09 TO 7/31/12
2012-6072	08/21/2012 09/19/2012	FDA/OMPT/CTP/OD/	FOI Services, Inc.	REYNOLDS AMERICAN INC CO (RJ REYNOLDS TOBACCO CO, AMERICAN SNUFF CO LLC, ETC) - CORR, INVESTIGATIONS RELATING TO MARKETING & ADVERTISING
2012-6073	08/21/2012 09/19/2012	FDA/OMPT/CTP/OD/	FOI Services, Inc.	PHILIP MORRIS - USE OF COLORS TO COMMUNICATE LIGHT CIGARETTES CORR
2012-6074	08/21/2012 09/19/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	LILLY - SYMBYAX (FLUOZETINE HCL, OLANZAPINE) NDA 21-520/S12 APRVL RECS 3/19/09
2012-6075	08/21/2012 09/19/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	PFIZER CONSUMER HEALTHCARE - ADVIL ALLERGY & CONGESTION RELIEF (CHLORPHENIRAMINE MALEATE; IBUPROFEN, PHENYLEPHRINE HCL) NDA 22-113 APRVL RECS 12/21/11

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2012-6076	08/21/2012 09/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	ETHICON - PDS PLATES K092590
2012-6077	08/21/2012 09/19/2012	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	FOI Services, Inc.	LEXINGTON INTERNATIONAL LLC, BOCA RATON, FL - EIRS, 483S CO RESP, ETC 1/11 TO PRESENT
2012-6078	08/21/2012 09/19/2012	FDA/OGROP/ORR/NE-FO/NYK-DO/NYK-DCB/	FOI Services, Inc.	AIRSEP, BUFFALO, NY - EIRS, 483S CO RESP, ETC 1/87 TO PRESENT
2012-6079	08/21/2012 09/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	ADVANCED STERILIZATION PRODS - STERRAD CYCLESURE BIOLOGICAL INDICATOR K103222
2012-6080	08/21/2012 09/19/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	FOI Services, Inc.	ADVANCED STERILIZATION PRODS - STERRAD 100NX TEST PACK K071537
2012-6081	08/21/2012 09/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	DANA PRODUCTS INC - REUSABLE TEST PACK FOR STEAM STERILIZATION FOR 10 MINUTE EXTENDED CYCLES K103321
2012-6082	08/21/2012 09/19/2012	OC/OSMP/OOPD/ FDA/OMPT/OSMP/OOPD/	FOI Services, Inc.	STANDARD OPERATING PROCEDURES & POLICES 420 TITLED ORPHAN DESIGNATION APPLS, RVWS OF REQUESTS - APPENDICES 11/9/10
2012-6083	08/21/2012 09/19/2012	FDA/OMPT/CTP/OD/	FOI Services, Inc.	REGULATIONS OF ELECTRONIC CIGARETTES (E CIGARETTES), GRANDFATHERED E CIGARETTE PRODS - COMM, RESP
2012-6084	08/21/2012 09/19/2012	FDA/OMPT/CTP/OD/ FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	COVIDIEN - SONICISION CORDLESS ULTRASONIC DISSECTION DVC K101797
2012-6085	08/21/2012 09/19/2012	FDA/OFVM/CFSAN/OCD/EOS/	FOI Services, Inc.	FCN 380
2012-6086	08/21/2012 09/19/2012	FDA/OFVM/CFSAN/OCD/EOS/	FOI Services, Inc.	LTRS OF NO-OBJECTION - MEMOS 1/10 TO PRESENT
2012-6087	08/21/2012 09/19/2012	FDA/OMPT/CTP/OD/	FOI Services, Inc.	TOTAL NUMBER OF EXEMPTIONS FROM THE REQUIREMENT OF DEMONSTRATING SUBSTANTIAL EQUIVALENCE UNDER THE FAMILY SMOKING PREVENTION & TOBACCO CONTROL ACT 8/4/11 TO PRESENT
2012-6088	08/22/2012 09/20/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	LORI PFOHL TELEFLEX MEDICAL	I-FLOW CORP - ON-Q CATHETER, ON-ANTIMICROBIAL CATHETER, SOAKER CATHETER K051401
2012-6089	08/22/2012 09/20/2012	FDA/OC/OES/DFOI/	REENERS, PATRICK	RECOMMENDATION OF .7 PPM FLOURIDE FOR PUBLIC WATER FLUORIDATION - RECS
2012-6090	08/22/2012 09/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	RECLAST - RECS

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		FDA/OMPT/CDER/GRP/DIDP/		
2012-6091	08/22/2012 09/20/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GORDON JOHNSTON GORDON JOHNSTON REGULATORY CONSULTANTS LLC	TEVA - PALONOSETRON HCL INJ ANDA 90-713; SANDOZ - CASPOFUNGIN ACETATE INJ ANDA 200-833 TENTATIVE APRVL LTR
2012-6092	08/22/2012 09/20/2012	FDA/OGROP/ORA/ORO/DIOP/ FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	NEIL F O'FLAHERTY OLSSON FRANK WEEDA TERMAN MATZ PC	DYNAVOX SYSTEMS LLC - ENTRY #AEK-6360716-6 IMPORT DETENTION RECS
2012-6093	08/22/2012 09/20/2012	OC/OM/OMP/DDM/	MARC NIELSEN SCHRAMM WILLIAMS & ASSOCIATES INC	DKT FDA-2012-P-0754, 1990P-0277
2012-6094	08/22/2012 09/20/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WILLIAM A GARVIN ESQ BUCHANAN INGERSOLL & ROONEY PC	LIBRAX (CHLORDIAZEPOXIDE AND CLIDINIUM) - SAFETY AND EFFICACY RECS
2012-6095	08/22/2012 09/20/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	NEIL ROCKIND NEIL ROCKIND PC	MARIJUANA - COMPASSIONATE USE INVESTIGATIONAL NEW DRUG PROGRAM RECS, DRYING AND CURING PROCESS, HUMAN CONSUMPTION STANDARDS, ETC 5/11 TO PRESENT
2012-6096	08/22/2012 09/20/2012	FDA/OMPT/CTP/OD/	MARK E GREENWOLD CAMPAIGN FOR TOBACCO-FREE KIDS	ALTRIA GROUP, PHILIP MORRIS USA INC - MODIFIED RISK TOBACCO PRODS RECS
2012-6097	08/22/2012 09/20/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	AMY KINCANON LEXISNEXIS COURTLINK INC	2012-1356
2012-6098	08/22/2012 09/20/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	AMY KINCANON LEXISNEXIS COURTLINK INC	2012-237
2012-6099	08/22/2012 09/20/2012	FDA/OC/OES/DFOI/	AMY KINCANON LEXISNEXIS COURTLINK INC	2012-1310
2012-6100	08/23/2012 09/21/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 8/6-10/12
2012-6101	08/23/2012 09/21/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 8/13-17/12
2012-6102	08/23/2012	FDA/OC/OES/DFOI/		FOI DAILY LOG 8/6-10/12

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	09/21/2012		FOI Services, Inc.	
2012-6103	08/23/2012 09/21/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 8/13-17/12
2012-6104	08/23/2012 09/21/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 8/6-10/12
2012-6105	08/23/2012 09/21/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 8/6-10/12
2012-6106	08/23/2012 09/21/2012	FDA/OC/OES/DFOI/	GLADYS B TONKIN WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 8/6-10/12
2012-6107	08/23/2012 09/21/2012	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 8/6-10/12
2012-6108	08/23/2012 09/21/2012	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	SUE CARLSON CARGILL ANIMAL NUTRITION	CARGILL ANIMAL NUTRITION, MONTGOMERY, AL - EIR 5/31/12
2012-6109	08/23/2012 09/21/2012	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	SUE CARLSON CARGILL ANIMAL NUTRITION	CARGILL INC, WINFIELD, PA - EIR 3/30/12
2012-6110	08/23/2012 09/21/2012	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	SUE CARLSON CARGILL ANIMAL NUTRITION	CARGILL ANIMAL NUTRITION, FLORA, IL - EIR 3/27/12
2012-6111	08/23/2012 09/21/2012	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	SUE CARLSON CARGILL ANIMAL NUTRITION	CARGILL ANIMAL NUTRITION, ELK RIVER, MN - EIR 3/1/12
2012-6112	08/23/2012 09/21/2012	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	SUE CARLSON CARGILL ANIMAL NUTRITION	CARGILL INC , SMITHTON, MO - EIR 2/28/12
2012-6113	08/23/2012 09/21/2012	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	SUE CARLSON CARGILL ANIMAL NUTRITION	CARGILL INC, BOVINA, TX - EIR 2/27/12
2012-6114	08/23/2012 09/21/2012	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	SUE CARLSON CARGILL ANIMAL NUTRITION	CARGILL INC, HARRISONBURG, VA - EIR 2/14/12
2012-6115	08/23/2012 09/21/2012	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	SUE CARLSON CARGILL ANIMAL NUTRITION	CARGILL ANIMAL NUTRITION, GARDEN CITY, KS - EIR 2/9/12
2012-6116	08/23/2012 09/21/2012	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	SUE CARLSON CARGILL ANIMAL NUTRITION	CARGILL ANIMAL NUTRITION, OKLAHOMA CITY, OK - EIR 1/9/12
2012-6117	08/23/2012 09/21/2012	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	DENISE RIEKER SANOFI PASTEUR	MERCK & CO, WEST POINT, PA - 483 2012
2012-6118	08/23/2012	FDA/OMPT/CBER/OCOD/DDOM/	DENISE RIEKER	CSL BIOTHERAPIES, PARKVILLE, VICTORIA, AUSTRALIA -

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	09/21/2012	ALFB/	SANOFI PASTEUR	483 2012
2012-6119	08/23/2012 09/21/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	DENISE RICKER SANOFI PASTEUR	MEDLMMUNE, SPEKE, LIVERPOOL, UK - 483 2012
2012-6120	08/23/2012 09/21/2012	FDA/OMPT/CDRH/OCER/DFOI/	DAVID BLOCH MEDTRONIC	ST JUDE MEDICAL - RIATA RIATA ST QUICKFLEX LV CRT, QUICKSITE LV CRT & DURATA ICD LEADS 522 POST-MARKET SUSRVEILANCE 2012
2012-6121	08/23/2012 09/21/2012	FDA/OMPT/CTP/OD/	MARILYNN WHITNEY COVINGTON BURLING LLP	TOBACCO PRODS - RPTS 3/23/11 TO PRESENT
2012-6122	08/23/2012 09/21/2012	FDA/OMPT/CDRH/OCER/DFOI/	GREGORY H. LEVINE ROPES GRAY LLP	CYNOSURE INC K111454
2012-6123	08/23/2012 09/21/2012	FDA/OGROP/ORASW-FO/DEN- DO/DEN-CB/	JOAN M. BECHTOLD SWEENEY & BECHTOLD LLC	CONMED ELECTROSURGERY - EIR 2012
2012-6124	08/23/2012 09/21/2012	FDA/OFVM/CFSAN/OCD/EOS/	KRISTI O. SMEDLEY, Ph.D. WASHINGTON INFORMATION SOURCE	INTRALYTIX INC - GRAS 435
2012-6125	08/23/2012 09/21/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/CVM/OCD/	KRISTI O. SMEDLEY, Ph.D. WASHINGTON INFORMATION SOURCE	MONSANTO - ETHOXYQUIN FAP 00001
2012-6126	08/23/2012 09/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANTHONY SOSCIA ATLANTIC PHARMACEUTICALS INC	ENDO - HYCODAN NDA 05-213 - LBLG, SUMMARY, TOXICOLOGY
2012-6127	08/23/2012 09/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	BENIEAR; APPROVEL; DIOVAN - AER
2012-6128	08/23/2012 09/21/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORASW-FO/FLA- DO/FLA-CB/	GREGORY H. ARABIAN GREGORY H ARABIAN & ASSOC PC	ENDO GIA STAPLING DVC - CORR, VIDEOS, DRAWINGS, ETC
2012-6129	08/23/2012 09/21/2012	FDA/OGROP/ORASW-FO/KAN- DO/KAN-CB/	SUE CARLSON CARGILL ANIMAL NUTRITION	CARGILL ANIMAL NUTRITION, MONTGOMERY CITY, MO - INSP FORM 2481 12/13/11
2012-6130	08/23/2012 09/21/2012	FDA/OC/OES/DFOI/	ELENA HOWELL HOGAN LOVELLS LLP	2012-5543
2012-6131	08/23/2012 09/21/2012	FDA/OC/OES/DFOI/	ELENA HOWELL HOGAN LOVELLS LLP	2012-4077

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2012-6132	08/23/2012 09/21/2012	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	MICHAEL E. TEPEDINO, MD CORNERSTONE EYE CARE	CORNERSTONE EYE CARE, HIGH POINT, NC - EIR 6/21/07
2012-6133	08/23/2012 09/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WILLIAM A. GARVIN, Esq. BUCHANAN INGERSOLL & ROONEY PC	LIBRAX - SAFETY, EFFICACY
2012-6134	08/23/2012 09/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVE R. VAN BUSKIRK LEYDIG VOIT & MAYER LTD	AZASITE NDA 50-810 - FORM 2253
2012-6135	08/23/2012 09/21/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	KIM HENDERSON SANOFI PASTEUR	NOVARTIS, SPEKE, LIVERPOOL UK - 483
2012-6136	08/23/2012 09/21/2012	FDA/OFVM/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 154425 7/24/12
2012-6137	08/23/2012 09/21/2012	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	SHAWN H. HUBER PROFESSIONAL HOSPITAL SUPPLY INC	ANDERSEN STERILIZERS INC, HAW RIVER, NC - INSP 5/16/12-8/21/12
2012-6138	08/23/2012 09/21/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	TONY G WOODS Animal & Plant Health Inspection Service - USDA	ANNUAL RPTS OF RESEARCH FACILITY 2011 - ATTACHMENTS
2012-6139	08/24/2012 09/24/2012	FDA/OMPT/CDRH/OCER/DFOI/	Travis Bendele Bendele Engineering	K090135, K101140, K102083
2012-6140	08/24/2012 09/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TRUDY LEHMANN Lehmann, Trudy	FORTEO - AERS
2012-6141	08/24/2012 09/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sam Chen Triplesea Technology (USA) Inc.	RELEVANT INTEGRILIN PHASE 1 CLINICAL STUDY
2012-6142	08/24/2012 09/24/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rankis, A. Arthur	K030004
2012-6143	08/24/2012	FDA/OGROP/ORR/SW-FO/DEN-		CHROMADEx - MTG MINS 08/15/12

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	09/24/2012	DO/DEN-CB/	ChromaDex Inc.	
2012-6144	08/24/2012 09/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sue Corbett THE RESEARCH INVESTMENT, INC.	NDA 17-555 ADDENDUM TO PHARMACOLOGIST REVIEW
2012-6145	08/24/2012 09/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Benjamin Lee COMPREHENSIVE DRUG ENTERPRISES LTD	NDA 22328
2012-6146	08/24/2012 09/24/2012	FDA/OGROP/ORR/SE-FO/FLA- DO/FLA-CB/	Liz DeAngelo THE INSTITUTE FOR TRANSFUSION MEDICINE	COMMUNITY BLOOD CENTERS OF FLORIDA - RESPONSE TO WARNING LETTER
2012-6147	08/24/2012 09/24/2012	FDA/OMPT/CDRH/OCER/DFOI/	Jake Stevens CE Medical Group	K000495
2012-6148	08/24/2012 09/24/2012	FDA/OGROP/ORR/NE-FO/NWE- DO/NWE-CB/	Jayson Bedford Raymond James, Attention: Jayson Bedford	ABIOMED - MTG MINUTES
2012-6149	08/24/2012 09/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lise Johnson, MD Brigham and Women's Hospital	METHERGINE - AERS
2012-6150	08/24/2012 09/24/2012	FDA/OMPT/CDRH/OCER/DFOI/	Kelly Jabbal AccessClosure, Inc.	P930038 S052
2012-6151	08/24/2012 09/24/2012	FDA/OC/OES/DFOI/	Joelle Lester Tobacco Control Legal Consortium	CTP FOIA REQUESTS
2012-6152	08/24/2012 10/09/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Peter W. Brolick Riggs Abney Neal Turpen Orbison & Lewis	PANHEMATIN - PACKAGE INSERTS 08/01/2001 - 12/31/2008
2012-6153	08/24/2012 09/24/2012	FDA/OGROP/ORR/CE-FO/CIN- DO/CIN-CB/	sonja meadows meadows, sonja	RONALD ANDIO DBA PATRON FARMS, CANFIELD, OH - RECS, PHOTOS OF INSPECTION 04/12
2012-6154	08/24/2012	FDA/OMPT/CDER/ORP/DIDP/		NDA 202611 - UNREDACTED REVIEW

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	09/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Astellas Pharma Global Development, Inc.	
2012-6155	08/24/2012 09/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rene Shen LEERINK SWANN & CO	XGEVA - MEDICAL REVIEW
2012-6156	08/24/2012 09/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michelle Palaro Will County Public Defender	TOPAMAX, NORTRIPTYLINE - WARNINGS (CERTIFIED)
2012-6157	08/24/2012 09/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Omobola Mudasiru ENVIRON INTERNATIONAL CORP	NDA 016912, NDA 016913, NDA 016948 - CLINICAL STUDIES
2012-6158	08/24/2012 09/24/2012	OC/CVM/OCD/ FDA/OO/OHR/ FDA/OC/OCC/	Scott Edwards F&WW, CLF	ARSENICALS - CORR, REPORTS, ETC BTWN FDA AND MANUFACTURERS 01/01/2008 - 09/21/2012
2012-6159	08/24/2012 09/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dr. Brian J. Hughes The Dow Chemical Company	RISPERIDONE - AERS
2012-6160	08/24/2012 09/24/2012	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	ve tay vuong PolyPeptide Laboratories, Inc.	BECKMAN RESEARCH INSTITUTE MASS SPECTROMETRY AND PROTEOMICS CORE FACILITY, LOS ANGELES, CA - EIR 2012
2012-6161	08/24/2012 09/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Meeta Vete INSITE VISION	JINAN JINDA PHARM CHEM CO LTD, SHANDONG PROVINCE, CHINA - EIR 07/10
2012-6162	08/24/2012 09/24/2012	FDA/OC/OES/DFOI/	Professor Stefan Elbe UNIVERSITY OF SUSSEX	ANTIVIRAL DRUG ADVISORY COMM - TRANSCRIPT 2/24/99
2012-6163	08/24/2012 09/24/2012	FDA/OMPT/CDRH/OCER/DFOI/	Richard Waite Innovative Trauma Care	K982439, K970439, K942425
2012-6164	08/24/2012	FDA/OGROP/OIP/	JoNel N. Aleccia	03/13/12 LTR TO DEPT OF SUPERVISION ON ANIMAL AND

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	09/24/2012		NBCNews.com	PLANT QUARANTINE, CHINA
2012-6165	08/24/2012 09/24/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sacman, Michele	STEPHEN BRINCAT, MALTA - EIR 08/10
2012-6166	08/24/2012 09/24/2012	FDA/OFVM/CFSAN/OCD/EOS/	Daniel Bjorkegren	FOOD LABEL AND PACKAGE SURVEY - DATA AND DOCUMENTATION
2012-6167	08/24/2012 09/24/2012	FDA/OMPT/CDRH/OCER/DFOI/	THE RESEARCH INVESTMENT, INC.	JOHNSON & JOHNSON - 1996 ETHICON COATED VICRYL SUTURE - LABEL INSERT
2012-6168	08/24/2012 09/24/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Thomas M. Burton THE WALL STREET JOURNAL	PRADAXA, XARELTO - SAFETY RVWS, AERS, CORR
2012-6169	08/24/2012 09/24/2012	FDA/OMPT/CDRH/OCER/DFOI/	DAVID BLOCH MEDTRONIC	ST JUDE MEDICAL, RIATA, RIATA ST - 2012 POST MARKET SURVEILLANCE
2012-6170	08/24/2012 09/24/2012	OC/OM/OMP/DDM/	KRISTI SMEDLEY WASHINGTON INFORMATION SOURCE	DKT FDA-2012-P-0072, FDA-2012-P-0313
2012-6171	08/24/2012 09/24/2012	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	NIKITA SETH NEURO THERM	NEURO THERM, MIDDLETON, MA - INSP 11/13 TO 12/4/08
2012-6172	08/24/2012 09/24/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MICHAEL BLAHNIK FRESHFORD CAPITAL MGMT	INNOPHARMA INC - COSYNTROPIN ANDA 202147 APRVL, SUMMARY RVW, LBLG 6/29/12
2012-6173	08/24/2012 09/24/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MICHAEL BLAHNIK FRESHFORD CAPITAL MGMT	AMPHASAR PHARMS - CORTROSYN NDA 16-750; INNOPHARMA INC - COSYNTROPIN ANDA 202147; 90-574
2012-6174	08/24/2012 09/24/2012	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	CAREY M. FISCHER CASEY M FISCHER PA	INDIVIDUAL RECS
2012-6175	08/24/2012 09/24/2012	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/CE-FO/MIN-	ROBERT VAN OSDEL Nexgen Pharma	21ST CENTURY, TEMPE, ARIZONA; ANS, CHANDLER, AZ; CORNERSTONE NUTRITIONAL LABS, FARMINGTON, UT - EIR

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		DO/MIN-CB/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OC/OES/DFOI/		
2012-6176	08/24/2012 09/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Robert Wolfangel Certus International, Inc.	NDA 019647 - PRESCRIBING INFORMATION, APPLICANT CONTACT INFORMATION, QUALITATIVE AND QUANTITATIVE COMPOSITION
2012-6177	08/24/2012 09/24/2012	FDA/OFVM/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 154779 8/6/12
2012-6178	08/24/2012 09/24/2012	FDA/OFVM/CFSAN/OCD/EOS/	Freelance journalist/author	MONSTER ENERGY DRINK - AERS, CORR
2012-6179	08/24/2012 09/24/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Robert Blaskiewicz Robert Blaskiewicz	BURZYNSKI RESEARCH INSTITUTE - PHASE III PROTOCOLS, APPROVAL RECORDS, IRB APPROVAL
2012-6180	08/24/2012 12/13/2012	FDA/OFVM/CFSAN/OCD/EOS/	ELIZABETH FISHER QUINN EMANUEL ET AL	COSMETIC TALC
2012-6181	08/24/2012 09/24/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Vesnaver, Mario	ALCON/LENSX, ALISO VIEJO, CA - 483 06/01/2012 - 08/23/2012
2012-6182	08/24/2012 09/24/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OGROP/ORACE-FO/PHI-	NATHANIEL L. ORENSTEIN BERMAN DEVALERIO ET AL	MERCK - MMR II EIR 1999 TO 2002

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		DO/PHI-CB/		
2012-6183	08/24/2012 09/24/2012	FDA/OFVM/CFSAN/OCD/EOS/	JOHN DOHERTY IOVATE HEALTH SCIENCES INTERNATIONAL INC	JACKED; OXY ELITE PRO; 1-MR - AER 5/23/12 TO PRESENT
2012-6184	08/24/2012 10/19/2012	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ OC/ORA/ OC/ORA/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OFVM/CFSAN/OCD/EOS/	Natalie J. Carlos Nature's Products, Inc.	NPI AMINO PEPTIDE BLEND RECS
2012-6185	08/24/2012 09/24/2012	FDA/OMPT/CDRH/OCER/DFOI/	Brianna Silverstein DRINKER BIDDLE & REATH LLP	K032456, K083502, K100501, ETC
2012-6186	08/24/2012 09/24/2012	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	SMART LIPO - AER
2012-6187	08/24/2012 09/24/2012	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jamie Galucci Gordon and Doner, P.A./Jamie Galucci	EPIPEN, EPIPEN JR. - PMA, RECALL RECS, INSPECTION RECS, ETC.
2012-6188	08/24/2012 09/24/2012	OC/OA/OM/OMP/DDM/	Joelle Lester Tobacco Control Legal Consortium	FDA2012D00710002
2012-6189	08/24/2012 09/24/2012	FDA/OMPT/CDRH/OCER/DFOI/	Qiuhu Shi NEW YORK MEDICAL COLLEGE	K102159, K102966
2012-6190	08/24/2012 09/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ralph Casale Ischemix	MEDICURE - AGREEMENT WITH FDA RE SPECIAL PROTOCOL ASSESSEMENT PROCESS FOR PHASE II MEND-CABG II STUDY
2012-6191	08/24/2012 09/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MaryBeth Conner FALCON RESEARCH	NDA 022432 and ANDA HP ACTHAR GEL

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		FDA/OMPT/CDER/GRP/DIDP/		
2012-6192	08/24/2012 09/24/2012	FDA/OMPT/CDRH/OCER/DFOI/	Jake Stevens CE Medical Group	K832233
2012-6193	08/24/2012 09/24/2012	FDA/OMPT/CDRH/OCER/DFOI/	Jake Stevens CE Medical Group	K090261
2012-6194	08/24/2012 09/24/2012	FDA/OMPT/CDRH/OCER/DFOI/	Jake Stevens CE Medical Group	K090261
2012-6195	08/24/2012 09/24/2012	FDA/OMPT/CDRH/OCER/DFOI/	Jake Stevens CE Medical Group	K061394, K073222
2012-6196	08/24/2012 09/24/2012	FDA/OMPT/CDRH/OCER/DFOI/	Jake Stevens CE Medical Group	K081446
2012-6197	08/24/2012 10/17/2012	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	CHRISTINE S. LIU LAW OFFICES OF CHRISTINE S LIU	INSP CONDUCTED BY ANDREW SLARVE AT CUPERTINO, CA 4/16-5/8/12
2012-6198	08/24/2012 09/24/2012	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	STHEFANY ARBELAEZ GREENDOM CORP	ENTRY NO 406-04749297
2012-6199	08/27/2012 09/25/2012	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Tyler, Joseph E	ALERE SAN DIEGO, INC - 483 06/12
2012-6200	08/27/2012 09/25/2012	OC/CVM/OCD/	ALIA LAYNE LAYNE, ALIA	NADA 141-175
2012-6201	08/27/2012 09/25/2012	OC/CVM/OCD/	ALIA LAYNE LAYNE, ALIA	NADA 141-204
2012-6202	08/27/2012 09/25/2012	OC/CVM/OCD/	ALIA LAYNE LAYNE, ALIA	NADA 141-205
2012-6203	08/27/2012 09/25/2012	OC/CVM/OCD/	ALIA LAYNE LAYNE, ALIA	ANADA
2012-6204	08/27/2012 09/25/2012	OC/OA/OM/OMP/DDM/	none	98P-0580/CP1, APPROVAL LETTER
2012-6205	08/27/2012 09/25/2012	FDA/OGROP/ORA/SW-FO/SWID/SWID-CB/	CHRISTINE RAMETTE SURETY CLAIMS INC	AZTECA CANDIES INC - ENTRY #BPX-0001139-1 INVOICES, PACKING LISTS, NOTICES OF ACTION, ETC
2012-6206	08/27/2012 09/25/2012	OC/CVM/OCD/ FDA/OFVM/CFSAN/OCD/EOS/	ADAM DIEDERICH SCHIFF HARDIN LLP	NATIONAL RESIDUE PROGRAM - TESTING OF SUBSTANCES BANNED FOR USE IN FOOD ANIMALS STUDIES, ANALYSES, TEST RESULTS, ETC
2012-6207	08/27/2012	OC/CVM/OCD/	LINDA M DUPLÉ	GENTAMICIN SULFATE SOL ANADA 200-115 - ORIGINAL

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	09/25/2012		BIMEDA INC	SUBMISSION 12/21/92, LTR CODE T0004, LTR TO FDA 6/1/93, ETC
2012-6208	08/27/2012 09/25/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	BRADSHAW, JILL	ALLERGAN INC - LUMIGAN (BIMATOPROST); PFIZER INC - XALATAN (LATANOPROST) APRVL LTR, RVWS, STUDIES, ETC
2012-6209	08/27/2012 09/25/2012	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	DAVID J GRYCZ SEDGWICK LLP	INDIVIDUAL RECS
2012-6210	08/27/2012 09/25/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	LORI PFOHL TELEFLEX MEDICAL	AGENTO IC SILVER COATED ENDOTRACHEAL TUBE K071365
2012-6211	08/27/2012 09/25/2012	FDA/OGROP/ORACE-FO/BLTDO/BLT-CB/ FDA/OGROP/ORACE-FO/CINDO/CIN-CB/ FDA/OGROP/ORACE-FO/NWJDO/NWJ-CB/ FDA/OGROP/ORACE-FO/PHIDO/PHI-CB/ FDA/OGROP/ORASE-FO/ATLDO/ATL-CB/ FDA/OGROP/ORASE-FO/FLADO/FLA-CB/ FDA/OGROP/ORASE-FO/NOLDO/NOL-CB/ FDA/OGROP/ORASW-FO/DALDO/DAL-CB/	FOI Services, Inc.	ROUSECO INC 6/27/12; S & M BRANDS INC 5/23/12; NATIONAL TOBACCO CO LP 3/23/12, ETC - EIRS, 483S, WARNING LTRS, ETC
2012-6212	08/27/2012 09/25/2012	FDA/OGROP/ORACE-FO/PHIDO/PHI-CB/	DEBORAH K ZAGER VENABLE LLP	MERCK & CO INC, WEST POINT, PA - EXHIBIT 2 RAW DATA FOR 600 SPLS, EXHIBIT 3 COLLECTION OF ASSAY PROCEDURES, EXHIBIT4 CURRENT PLATE INVENTORY
2012-6213	08/27/2012 09/25/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JEREMY TUBB FULLER TUBB BICKFORD & KRAHL PLLC	GSK, IPS RESEARCH CO, DR JEREMY COLES - HZA106827, HZA1066829, HZA113091, ETC COMM
2012-6214	08/27/2012 09/25/2012	FDA/OGROP/ORASE-FO/ATLDO/ATL-CB/	HILL, MELISSA .	2012-4641

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2012-6215	08/27/2012 09/25/2012	OC/OCOS/OES/ OC/OCOS/OES/	STEPHANIE NIELSEN DEMOCRATIC SENATORIAL CAMPAIGN COMMITTEE	GOV TOMMY G THOMPSON - CORR 2/05 TO PRESENT
2012-6216	08/27/2012 09/25/2012	OC/ORO/ OC/ORO/	STUART E GOLDENBERGER LICHTBLAU & GOLDENBERG PA	SLIMXTREME DIETARY SUPPLEMENT - LAB RESULTS
2012-6217	08/27/2012 09/25/2012	OC/ORO/ORM/ OC/ORO/ORM/	SCOTT THURM Dow Jones & Company	483S FOR US FACILITIES 2005 TO PRESENT
2012-6218	08/27/2012 09/25/2012	OC/OM/OMP/DDM/	KRISTI SMEDLEY WASHINGTON INFORMATION SOURCE	DKT FDA-1995-S-0039
2012-6219	08/27/2012 09/25/2012	OC/ORO/ORM/ OC/ORO/ORM/	SCOTT THURM Dow Jones & Company	483S FOR NON-US FACILITIES 2000 TO 2005
2012-6220	08/27/2012 09/25/2012	OC/ORO/ORM/ OC/ORO/ORM/	SCOTT THURM Dow Jones & Company	483S FOR US FACILITIES 2000 TO 2005
2012-6221	08/27/2012 09/25/2012	OC/ORO/ORM/ OC/ORO/ORM/	SCOTT THURM Dow Jones & Company	483S FOR NON-US FACILITIES 2005 TO PRESENT
2012-6222	08/27/2012 09/25/2012	OC/ORO/ORM/ OC/ORO/ORM/	GAIL LESSICK LACHMAN CONSULTANT SERVICES INC	DRUG COMPANIES, MEDICAL DVC MFRS, BIORESEARCH MONITORING (BIMO), ETC - DOMESTIC AND FOREIGN INSPS, 483S 6/1-30/12
2012-6223	08/27/2012 09/25/2012	FDA/OFVM/CFSAN/OCD/EOS/	STEM, DEREK	DYNAMICGREENS WHEATGRASS (WHEATGRASSJUICE.US) - WHEATGRASSJUICE TESTING RECS
2012-6224	08/27/2012 09/25/2012	FDA/OMPT/CDRH/OCER/DFOI/	KEVIN STRANGE WELLS FARGO SECURITIES	ST JUDE MEDICAL - RIATA, RIATA ST, RIATA ST OPTIM, ETC DEFIBRILLATOR LEADS 522 ORDER
2012-6225	08/27/2012 09/25/2012	OC/ORO/ORM/ OC/ORO/ORM/	THOMPSON, RAY	HUMAN DRUG, HUMAN MEDICAL DVC FIRMS - GMP, GLP, GCP INSPS 1/12 TO 7/12
2012-6226	08/27/2012 09/25/2012	FDA/OC/OES/DFOI/	Olmos #196384, Timothy	GOVERNMENTAL REQUIREMENTS FOR RESTAURANTS
2012-6227	08/27/2012 09/25/2012	FDA/OGROP/ORO/SE-FO/FLA- DO/FLA-CB/	JACKIE CALLAWAY ABC ACTION NEWS	IMPORT REFUSALS UNDER ALERT 57-17 IN FLORIDA LAST 5 YRS
2012-6228	08/27/2012 09/25/2012	FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECS
2012-6229	08/27/2012 09/25/2012	FDA/OMPT/CDRH/OCER/DFOI/	ENRICO BISSON NIDEK TECHNOLOGIES SRL	CENTERVUE SPA - MAIA MODEL 1 K092187
2012-6230	08/27/2012	FDA/OGROP/ORO/CE-FO/MIN-	Greg Poirier	APEX INTERNATIONAL, CHASKA, MIN - EIRS, COVER

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	09/25/2012	DO/MIN-CB/	Apex International	LETTER
2012-6231	08/27/2012 09/25/2012	FDA/OMPT/CDRH/OCER/DFOI/	Gina Lento Pure Protein LLC	P820033 S008, P830063 S006, P820033 S007
2012-6232	08/27/2012 09/25/2012	FDA/OFVM/CFSAN/OCD/EOS/	PERLA ALEXRIA Alexria, Perla	HERBALIFE DIETARY PRODUCTS - AERS
2012-6233	08/27/2012 09/25/2012	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Austin Nelson NELSON, AUSTIN	HOSPIRA, CLAYTON, NC - 483 02/12-PRESENT
2012-6234	08/27/2012 09/25/2012	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Austin Nelson NELSON, AUSTIN	HOSPIRA, AUSTIN, TX - 483 03/12 - PRESENT
2012-6235	08/27/2012 09/25/2012	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	Austin Nelson NELSON, AUSTIN	HOSPIRA, BOULDER, CO - 483 03/12-PRESENT
2012-6236	08/27/2012 09/25/2012	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	Austin Nelson NELSON, AUSTIN	HOSPIRA, LAKE FOREST, IL - 483 03/12-PRESENT
2012-6237	08/27/2012 09/25/2012	FDA/OMPT/CDRH/OCER/DFOI/	Art Rankis Rankis, A. Arthur	K070627
2012-6238	08/27/2012 09/25/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jennifer Sasaki ALKERMES, INC	NDA 20-732
2012-6239	08/28/2012 09/26/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	CLOSED FOIA REQUESTS 7/30/12-8/3/12
2012-6240	08/28/2012 09/26/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	CLOSED FOIA REQUESTS 8/6-10/12
2012-6241	08/28/2012 09/26/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	CLOSED FOIA REQUESTS 8/13-17/12
2012-6242	08/28/2012 09/26/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAD FDA WEBVIEW/FERDIC INC	CLOSED FOIA REQUESTS 8/20-24/12
2012-6243	08/28/2012 09/26/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 8/13-17/12
2012-6244	08/28/2012 09/26/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 8/10/24/12
2012-6245	08/28/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP	CLOSED FOIA REQUESTS 8/13-17/12

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	09/26/2012		CanReg, Inc.	
2012-6246	08/28/2012 09/26/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 8/20-24/12
2012-6247	08/28/2012 09/26/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 8/13-17/12
2012-6248	08/28/2012 09/26/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 8/20-14/12
2012-6249	08/28/2012 09/26/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 8/13-17/12
2012-6250	08/28/2012 09/26/2012	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	JOHNATHAN RICKMAN FDA NEWS	WATSON LABORATORIES INC, SALT LAKE CITY, UT; PARAGON MEDICAL, SMITHFIELD, UT; APPLIED WATER ENGINEERING INC, SALT LAKE CITY, UT - 483S 6/1-30/12
2012-6251	08/28/2012 09/26/2012	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OC/OES/DFOI/	JOHNATHAN RICKMAN FDA NEWS	ALLERGY LABORATORIES INC, OKLAHOMA CITY, OK - 483S 6/1-30/12
2012-6252	08/28/2012 09/26/2012	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	JOHNATHAN RICKMAN FDA NEWS	TEVA WOMENS HEALTH INC, CINCINNATI, OH; HMI INDUSTRIES INC, STRONGSVILLE, OH; PAIN MANAGEMENT TECHNOLOGIES INC, AKRON, OH, ETC - 483S 6/1-30/12
2012-6253	08/28/2012 09/26/2012	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	JOHNATHAN RICKMAN FDA NEWS	BAXTER HEALTHCARE CORP, ROUND LAKE, IL; PRECISION MEDICAL MANUFACTURING LLC, WHEELING, IL - 483S 6/1-30/12
2012-6254	08/28/2012 09/26/2012	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	JOHNATHAN RICKMAN FDA NEWS	PHARMACEUTICS INTERNATONAL INC, COCKEYSVILLE, MD; ADVANTAGEOUS MD LLC, VIRGINIA BEACH, VA - 483S 6/1-30/12
2012-6255	08/28/2012 09/26/2012	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	JOHNATHAN RICKMAN FDA NEWS	BANNER PHARMACAPS INC, HIGH POINT, NC; V-SAB MEDICAL LABS INC, CORNELIUS, NC; REMINGTON MEDICAL INC, ALPHARETTA, GA, ETC - 483S 6/1-30/12
2012-6256	08/28/2012 09/26/2012	OC/ORASW-FO/OC/ORASW-FO/	JOHNATHAN RICKMAN FDA NEWS	LISTING OF ALL NOTICES OF INSPECTIONAL OBSERVATIONS FOR PHARMS, BIOLOGICS & MEDICAL DVC MFG & CLNCL TRIAL FACILITIES BOTH IN THE US & OUTSIDE US - 483S 7/1-31/12
2012-6257	08/28/2012 09/26/2012	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	JOHNATHAN RICKMAN FDA NEWS	ACCRA PAC (DBA KIK CUSTOM PRODS), ELKHART, IN; VERTELLUS HEALTH & SPECIALTY PRODUCTS LLC, ZEELAND, MI; PFIZER INC, ROCHESTER, MI, ETC - 483S 6/1-30/12
2012-6258	08/28/2012 09/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	Chris Oldham PLANMED	K061834
2012-6259	08/28/2012	FDA/OMPT/CDRH/OCER/DFOI/	Suzanne O'Shea	CDRH CORR RE TRANSFERRING CONTRAST MEDIA OR SALINE BTW DRUG BULK CONTAINER AND A SYRINGE

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	10/09/2012		FAEGRE BAKER DANIELS	
2012-6260	08/28/2012 09/27/2012	FDA/OC/OES/DFOI/	Christopher Weaver THE WALL STREET JOURNAL	ST. JUDE MEDICAL - PREVIOUSLY RELEASED RECORDS 02/01/11 - 08/27/12
2012-6261	08/28/2012 09/26/2012	FDA/OGROP/ORPA/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/ FDA/OGROP/ORPA/PA-FO/SAN-DO/SAN-CB/	CJ Sylvester Lombard Odier	QUESTCOR - CORR 08/01/2008 - 08/27/2012
2012-6262	08/28/2012 09/26/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	IPD ANALYTICS LLC	ANDA 091558 - TENTATIVE AND EFFECTIVE APPROVAL LTRS
2012-6263	08/28/2012 09/26/2012	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORPA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	Christopher Weaver THE WALL STREET JOURNAL	ST JUDE MEDICAL - 483, 484 01/01/2005 - 08/27/2012
2012-6264	08/28/2012 09/26/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORA/ OC/ORA/	Beth Coronado SmithAmundsen LLC	SALMONELLA OUTBREAK 08/12 - REPORTS, NOTES, PHOTOS, ETC.
2012-6265	08/28/2012 09/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	Doug Bernstein PECA Labs	SHEHIGH PULMONIC VALVE CONDUIT MODEL NR-4000 - HDE RECS
2012-6266	08/28/2012 09/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	Doug Bernstein PECA Labs	CONTEGRA PULMONARY VALVED CONDUIT - HDE RECS
2012-6267	08/28/2012 09/26/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Yuki Kawase Panasonic Healthcare Co., Ltd.	NDA 20451, NDA 20451/S002, NDA 20451/S003 - APPROVAL PACKAGES

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2012-6268	08/28/2012 09/26/2012	FDA/OGROP/ORAP/PA-FO/SEA-DO/SEA-CB/	JOHNATHAN RICKMAN FDA NEWS	OREGON AESTHETIC TECHNOLOGIES INC, PORTLAND, OR - 483 6/12
2012-6269	08/28/2012 09/26/2012	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	JOHNATHAN RICKMAN FDA NEWS	MYLAN LLC, CAGUAS, PR; MSD INTL GMBH LLC, BARCELONETA, PA; TAPI PUERTO RICO INC, HUMACAO, PR - 483 6/12
2012-6270	08/28/2012 09/26/2012	FDA/OGROP/ORAP/PA-FO/SAN-DO/SAN-CB/	JOHNATHAN RICKMAN FDA NEWS	MEDIVATION INC, SAN FRANCISCO, CA; LAB VISION CORP, FREMONT, CA; MICROGENICS CORP, FREMONT, CA - 483 6/12
2012-6271	08/28/2012 09/26/2012	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	JOHNATHAN RICKMAN FDA NEWS	JANSSEN BIOTECH INC, MALVERN, PA; MIR COM PRODUCTS LLC, CENTRAL CITY, PA; ANSAR GROUP INC, PHILADELPHIA, PA - 483 6/12
2012-6272	08/28/2012 09/26/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	JOHNATHAN RICKMAN FDA NEWS	ALTAIRE PHARMS INC, AQUEBOGUE, NY; ASEPT PAK INC, MALONE, NY; CMP INDUSTRIES LLC, ALBANY, NY - 483 6/12
2012-6273	08/28/2012 09/26/2012	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	JOHNATHAN RICKMAN FDA NEWS	BAXTER HEALTHCARE CORP, CLEVELAND, MS; MEDTRONIC SOFAMOR DANEK USA MEMPHIS, TN; NAIMCO INC, CHATTANOOGA, TN - 483 6/12
2012-6274	08/28/2012 09/26/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	JOHNATHAN RICKMAN FDA NEWS	VILS PHARMA COATING INC, EDISON, NJ; AUSTARPHARMA LLC, EDISON, NJ; GUARDIAN DRUG CO INC, DAYTON, NJ - 483 6/12
2012-6275	08/28/2012 09/26/2012	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	JOHNATHAN RICKMAN FDA NEWS	THE PROMETHEUS GROUP, DOVER, NH; J PAC LLC, SOMERSWORTH, NH; ARMSTRONG PHARMACEUTICALS INC, CANTON, MA - 483 6/12
2012-6276	08/28/2012 09/26/2012	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	JOHNATHAN RICKMAN FDA NEWS	URIEL PHARMACY INC, EAST TROY, WI; SYBARITIC INC, BLOOMINGTON, MN; IMPLANT RESOURCE INC, BURNSVILLE, MN - 483 6/12
2012-6277	08/28/2012 09/26/2012	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	JOHNATHAN RICKMAN FDA NEWS	APTUIT LLC; HARRISONVILLE, MO; LLOYD INC OF IOWA, SHENANDOAH, IA; KELLER LABORATORIES INC, FENTON, MO - 483 6/12
2012-6278	08/28/2012 09/26/2012	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	JOHNATHAN RICKMAN FDA NEWS	220 LABORATORIES INC, RIVERSIDE, CA; OASIS MEDICAL INC, GLENDORA, CA; SEA SPINE INC, VISTA, CA - 483 6/12
2012-6279	08/28/2012 09/26/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	JOHNATHAN RICKMAN FDA NEWS	VISTA PHARM INC, LARGO, FL; DECIMAL INC, SANFORD, FL; INNOVIA LLC, MIAMI, FL - 483 6/12
2012-6280	08/28/2012 09/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	JOHNATHAN RICKMAN FDA NEWS	MEDART AS, HVIDOVRE, DENMARK; ELANA BV, UTRECHT, NETHERLANDS; MERIDIAN AG, THUN, SWITZERLAND - 483 6/12
2012-6281	08/28/2012 09/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHNATHAN RICKMAN FDA NEWS	PFIZER IRELAND PHARMS, DUBLIN PIKE, IRELAND - 483 6/12

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/		
2012-6282	08/28/2012 09/26/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHNATHAN RICKMAN FDA NEWS	CIPLA LTD, BANGALORE, KAMATAKA, INDIA; LUPIN LTD, INDORE MADHYA PRADESH, INDIA; PFIZER GMBH, FREIBERG, GERMANY - 483 6/12
2012-6283	08/28/2012 09/26/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/OA/OM/OMP/DDM/	ERIN E. SEDER VENABLE LLP	PANEL RPTS REGARDING SUNSCREEN
2012-6284	08/28/2012 09/26/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ROCKNEY S. TAVEAU BUTLER SNOW ET AL	ACETAMINOPHEN - AER
2012-6285	08/28/2012 09/26/2012	FDA/OGROP/ORR/SE-FO/NOL-DO/NOL-CB/	BRENDA M. GARTZ ELI LILLY & CO	DR ROBERT CONRY, UNIV OF ALABAMA COMPREHENSIVE CANCER CTR, BIRMINGHAM, AL - 483 6/17/04
2012-6286	08/28/2012 09/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	DRYMOND JY2525, ALBERT	TUBERCULOSIS TESTING - TYPE OF TESTS, MDRS; FACT SHEETS FOR CHRONIC RENAL DISEASE, TREATMENT, ETC
2012-6287	08/28/2012 09/26/2012	FDA/OGROP/ORR/PA-FO/SEA-DO/SEA-CB/	KINGSBAUER, DALTON	CMPLNT 125358 WISE WOMAN HERBALS - EIR, 483
2012-6288	08/28/2012 09/26/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MICHAEL NLAHNIK FRESHFORD CAPITAL MGMT	INNO PHARMA - COSYNTROPIN ANDA 02-147 APRVL
2012-6289	08/28/2012 02/19/2013	FDA/OFVM/CFSAN/OCD/EOS/	McKENZIE CATO Hyman, Phelps and McNamara	LALLEMAND INC - FAP 12/17/09
2012-6290	08/28/2012 09/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	WILLIAM C. LANHAM JOHNSON & WARD ATTY AT LAW	ADVANCED NEUROMODULATION SYSTEMS INC; EON MIMI MODEL 3788 IPG PMA
2012-6291	08/28/2012 09/26/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GOONEWARDENA, PRASANNA .	ZYPREXZ, PAXIL, CLOZARIL - AER

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2012-6292	08/28/2012 09/26/2012	FDA/OC/OES/DFOI/	HENLEY 56354-112, FRANK	PAIN MGMT - POLICY
2012-6293	08/29/2012 09/27/2012	OC/OM/OMP/DDM/	COLLEEN CAMPBELL SIDLEY AUSTIN LLP	DKT 1995N-0294
2012-6294	08/29/2012 09/27/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 8/13-17/12
2012-6295	08/29/2012 09/27/2012	FDA/OMPT/CDRH/OCER/DFOI/	NEWMAN, LEONARD	PREDICATE DVC - K990671
2012-6296	08/29/2012 09/27/2012	FDA/OMPT/CDRH/OCER/DFOI/	FLOD G LARSON PAXMED INTL	IMPLANT INOVATIONS INC - NANO TITE DENTAL IMPLANTS K062432
2012-6297	08/29/2012 09/27/2012	FDA/OMPT/CDRH/OCER/DFOI/	NATHAN A BEAVER FOLEY & LARDNER LLP	MEDICAL DVC LISTING & REGISTRATION DATABASE - 510KS, PMAS 2012
2012-6298	08/29/2012 09/27/2012	FDA/OMPT/CDRH/OCER/DFOI/	CHASE, STEPHEN C	STAXX CONVEX EXPANDALE - K090315, MDRS,
2012-6299	08/29/2012 09/27/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OGROP/ORAC/CE-FO/PHI- DO/PHI-CB/	Doe J	LIFE LINK TISSUE BANK, GLOBUS MEDICAL - BONE GRAFTS MDRS, RECALLS., ETC
2012-6300	08/29/2012 09/27/2012	FDA/OGROP/ORAC/PA-FO/SEA- DO/SEA-CB/	JANET A MCCORMICK INTERIOR ALASKA FISH PROCESSORS INC	YUTANA FISHERIES, MANLEY HOT SPRINGS, AK - EIRS 2007, 2008
2012-6301	08/29/2012 09/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	JIM FAUCETT NORTHWEST CLINICAL RESEARCH CTR	VYVANSE (LISDEXAMPHETAMINE) DIMESYLATE (VYVANSE) - SBA
2012-6302	08/29/2012 09/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PHIL L MILLMAN ETHICAL NUTRITONAL LLC	AKRON INC - CALCITROL INJ ANDA A078066, ANDA 78-066 NDA
2012-6303	08/29/2012	FDA/OMPT/CDER/ORP/DIDP/	PHIL LL MILLMAN	BAXTER HEALTHCARE CORP, BEDFORD LABS -

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	09/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	ETHICAL NUTRITONAL LLC	METHOCARBAMOL INJ NDA 11-790
2012-6304	08/29/2012 09/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ALISON M AGNEW PILLSBURY	QUESTCOR PHARMACEUTICALS INC - HP ACTHAR GEL - CMLNPTS, WARNING LTRS, RPTS
2012-6305	08/29/2012 09/27/2012	FDA/OGROP/ORAC/CE-FO/BLT- DO/BLT-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ALISON M AGNEW PILLSBURY WINTHROP SHAW PTTMAN LLP	BIO VECTRA INC, CHARLOTTOWN, CANADA - HP ACTHAR BULK, CHARLOTTETOWN CANADA; QUESTCOR PHARMACEUTICALS INC, BALTIMORE, MD - HP ACTHAR GEL (REPOSITORY CORTICOTRIPIN INJ) - RPTS EIRS, 483S, ETC 12/31/03 TO PRESENT
2012-6306	08/29/2012 09/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PHIL L MILLMAN ETHICAL NUTRITONAL LLC	APP PHARMACEUTICAL LLC - FAMIOTIDINE INK ANDA75- 709 NDA
2012-6307	08/29/2012 09/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	CLARK G SULLIVAN ARNALL GOLDEN & GREGORY, LLP	WATSON LABS - HYDROXOCOBALAMIN INJ ANDA 08- 5998, ANDA 08-528; ABRAXIS LABS - ANDA 084-921, ETC
2012-6308	08/29/2012 09/27/2012	OC/CVM/OCD/	JILLIAN NASH ALLTECH INC	EAST-MAN FEEDS, LETHBRIDGE, ALBERTA, WINNIPEG, MANITOBA - 483S PAST 10 YRS
2012-6309	08/29/2012 09/27/2012	OC/ORAC/ORM/ OC/ORAC/ORM/	TONY CHEN FDAZILLA	LIST OF 483S 1/1/12 TO 8/28/12
2012-6310	08/29/2012 09/27/2012	OC/OA/OM/OMP/DDM/	KRISTI O SMEDLEY WASHINGTON INFORMATION SOURCE	DKT 95G-0039 - APPENDICES
2012-6311	08/29/2012 09/27/2012	FDA/OC/OES/DFOI/	LAMOND, CHRIS	WHOLESALE PACKAGED ICE MFG FACILITIES, ICE VENDING MACHINES EIRS 7/11 TO PRESENT
2012-6312	08/29/2012 09/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	NATALIA DIAZ FREIDIN DORBRINSKY ATTY AT	LEVAQUIN - BLACK BOX WARNINGS, COMM, INTERNAL RECS, CASE RPTS, ETC

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2012-6313	08/29/2012 09/27/2012	FDA/OGROP/ORO/RO/DIOP/ FDA/OGROP/ORO/NE-FO/NYK- DO/NYK-DCB/	MICHELLE RYBAK ROANOKE TRADE SERVICES INC	PANAMERICAN FOODS CORP - ENTRY J37-00070652 FDA NOTICES, NOTICES OF REFUSAL, ETC
2012-6314	08/29/2012 09/27/2012	FDA/OGROP/ORO/RO/DIOP/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORO/SW- FO/SWID/SWID-CB/	Abel Sanchez Central Botanica del Nayar	CENTRAL BOTANICA DEL NAYAR, SA DE CV - EXPORT RECS, IMPORT REFUSALS, IMPORT ALERTS, ETC
2012-6315	08/29/2012 09/27/2012	FDA/OMPT/CDRH/OCER/DFOI/	Courtney Goldsworthy Courtney Goldsworthy, Esq.	COVIDIENT PERMACOL - MAUDE RPT
2012-6316	08/29/2012 09/27/2012	FDA/OGROP/ORO/SW-FO/DEN- DO/DEN-CB/ FDA/OGROP/ORO/SW-FO/KAN- DO/KAN-CB/	Ann Niedzinski LABS, Inc.	LABS, INC, CENTENNIAL, CO - EIR 07/10
2012-6317	08/29/2012 09/27/2012	FDA/OGROP/ORO/NE-FO/NYK- DO/NYK-DCB/	Ira Loss Wash	HI-TECH PHARM, AMITYVILLE, NY - 483 11/10
2012-6318	08/29/2012 09/27/2012	FDA/OMPT/CDRH/OCER/DFOI/	Dr. Michael Kretz none	K962218
2012-6319	08/29/2012 09/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Iroko Pharmaceuticals, LLC	NDA 020142 - SBA
2012-6320	08/29/2012 09/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bonnie Williams FOI Services, Inc.	ANDA 200675
2012-6321	08/29/2012 09/27/2012	FDA/OMPT/CDRH/OCER/DFOI/	Peter A. Takes Kypha, Inc.	K964842
2012-6322	08/29/2012 09/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bonnie Williams FOI Services, Inc.	RANBAXY - HHE

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2012-6323	08/29/2012 09/27/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 8/20-24/2012
2012-6324	08/29/2012 09/27/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Ira Loss Washington Analysis LLC	HI-TECH PHARM - FDA CORR RE WARNING LETTER VIOLATIONS 09/01/2011 - 09/06/2011
2012-6325	08/29/2012 09/27/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bonnie Williams FOI Services, Inc.	NDA 201739
2012-6326	08/29/2012 09/27/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Ira Loss Washington Analysis LLC	HI-TECH PHARM, AMITYVILLE, NY - 483 10/03/2011 - 10/19/2011
2012-6327	08/30/2012 09/28/2012	FDA/OMPT/CDRH/OCER/DFOI/	Meicler, Michele	ST JUDE MEDICAL - MITRAL VALVE 25MECJ-502 ADVERSE EVENTS, ETC
2012-6328	08/30/2012 09/28/2012	FDA/OMPT/CDRH/OCER/DFOI/	Bonnie Williams FOI Services, Inc.	K110639
2012-6329	08/30/2012 09/28/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Takeda Global Research & Development Cen	ALLOPURINOL ICSRS
2012-6330	08/30/2012 09/28/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Lisa Margulies Meyerson O'Neill	KLONOPIN - LABELS, DOCS, INSERTS TO DOCTORS OR PATIENTS
2012-6331	08/30/2012 09/28/2012	FDA/OMPT/CDRH/OCER/DFOI/	Premarket Notification Submission Documents Ultrapure & Industrial services, LLC	K102892
2012-6332	08/30/2012 09/28/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Marylyn Oparaugo Banner Pharmacaps Inc.	ANDA 090095
2012-6333	08/30/2012 09/28/2012	FDA/OMPT/CDRH/OCER/DFOI/	NATHAN A BEAVER FOLEY & LARDNER LLP	MDRS 1/98 TO PRESENT

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2012-6334	08/30/2012 09/28/2012	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/ FDA/OGROP/ORACE-FO/CINDO/CIN-CB/ FDA/OGROP/ORACE-FO/DETDO/DET-CB/ FDA/OGROP/ORACE-FO/NWJDO/NWJ-CB/ FDA/OGROP/ORACE-FO/PHIDO/PHI-CB/ FDA/OGROP/ORANE-FO/NYKDO/NYK-DCB/ FDA/OGROP/ORAPA-FO/LOSDO/LOS-CB/ FDA/OGROP/ORASE-FO/ATLDO/ATL-CB/ FDA/OGROP/ORASE-FO/NOLDO/NOL-CB/ FDA/OGROP/ORASE-FO/SJNDO/SJN-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/ FDA/OC/OES/DFOI/ FDA/OGROP/ORAPA-FO/LOSDO/LOS-CB/	KATIE THOMAS NEW YORK TIMES	HOSPIRA, LAKE FOREST, IL 7/13/12; BAXTER HEALTHCARE CORP 6/27/12; TEVA WOMEN'S HEALTH INC 6/4/12, ETC - 483S
2012-6335	08/30/2012 09/28/2012	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORAPA-FO/LOSDO/LOS-CB/	ELENA HOWELL HOGAN LOVELLS LLP	LUCKY COUNTRY INC - AUSSIE STYLE SOFT GOURMET LICORICE RECALL RECS
2012-6336	08/30/2012 09/28/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	PATTI DIVINCENZO WSB-TV	WHOLE BLOOD NUMBER 03LK44876 - RPT
2012-6337	08/30/2012 09/28/2012	FDA/OFVM/CFSAN/OCD/EOS/	NICHOLAS J PAROLISI JR LITCHFIELD CAVO LLP	ROMAINE AND/OR ICEBERG LETTUCE E COLI OUTBREAK - CORR, RPTS, ANALYTICAL STUDIES, ETC
2012-6338	08/30/2012	FDA/OFVM/CFSAN/OCD/EOS/	DAVID J MARTIN	RPTS OF ILLNESSES RESULTING FROM VIBRIO

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	09/28/2012		MEYERS RODBELL & ROSENBAUM PA	VULNIFICUS IN MD AND DE LAST 5 YRS
2012-6339	08/30/2012 09/28/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	ANNE Y BRODY GIBSON DUNN & CRUTCHER LLP	LIFETECH RESOURCES LLC - RAPIDLASH EYELASH RENEWAL SERUM, NEULASH CORR, CMLPNTS
2012-6340	08/30/2012 09/28/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	ANNE Y BRODY GIBSON DUNN & CRUTCHER LLP	ATHENA COSMETICS INC - REVITALASH EYELASH CONDITIONS, HAIR BY REEVITALASH, REVITABROW CMLPNTS, CORR
2012-6341	08/30/2012 09/28/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARCO DAMICI DAMici, Marco	LT 436,896 LABELS FOR TPR20
2012-6342	08/30/2012 09/28/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Carol Stephany Hospira, Inc.	ANDA 16366 S160
2012-6343	08/30/2012 09/28/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PAMELA SHEPPARD TARO PHARMACEUTICALS USA INC	AMNEAL PHARMS - FELBAMATE ANDA 201-680 SBA, LBLG, RVWS, ETC
2012-6344	08/30/2012 09/28/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PAMELA SHEPPARD TARO PHARMACEUTICALS USA INC	AMNEAL PHARMS - FELBAMATE ANDA 202-385 SBA, RVWS, LBLG, ETC
2012-6345	08/30/2012 11/01/2012	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	JENNIFER HSIEH HEALTHCARE RESEARCH CONSULTING GROUP	IMPAX PHARMS - RESP TO 483S 1/11 TO PRESENT
2012-6346	08/30/2012 11/01/2012	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	JENNIFER HSIEH HEALTHCARE RESEARCH CONSULTING GROUP	IMPAX LABS - RESP TO WARNING LTR 5/31/11
2012-6347	08/30/2012 09/28/2012	OC/ORAO/OCI/ OC/ORAO/OCI/	CONORS, ANTHONY ROBERT	RONALD LANCE KRAMER, THERMOLIFE - INVESTIGATION RECS
2012-6348	08/30/2012 09/28/2012	FDA/OMPT/CDRH/OCER/DFOI/	LAUREN R HEROLD MORGAN & MORGAN	GOLDEN BROTHERS, GOLDEN TECHNOLOGIES - CMLPNTS, WARRANTY ISSUES, INJURIES, ETC
2012-6349	08/30/2012	FDA/OMPT/CDER/GRP/DIDP/	LISA MARGUILES	KLONOPIN (CLONAZEPAM) NDA 17-533 LBLG 1/04 TO 12/05

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	09/28/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MEYERSON & O'NEILL ATTY	
2012-6350	08/30/2012 09/28/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	HUBER, MARIE	SIPULEUCEL-T BB-IND 6933 - TABLES, LISTINGS, FIGURES, ETC
2012-6351	08/30/2012 09/28/2012	FDA/OMPT/CDRH/OCER/DFOI/	MICEAL JOHANSSON MSC ETTEPLAN	HOLOGIC - SUROS ATEC K042290; BARD - FINESSE ULTRA K093068; ANGIOTECH - BIOPINCE K101832, ETC
2012-6352	08/30/2012 09/28/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 8/20-24/12
2012-6353	08/30/2012 09/28/2012	FDA/OMPT/CDRH/OCER/DFOI/	Vital Connect Inc.	K052489
2012-6354	08/30/2012 09/28/2012	FDA/OFVM/CFSAN/OCD/EOS/	Bonnie Williams FOI Services, Inc.	PAPER RECYCLING PROCESSES - NO OBJECTION LTRS
2012-6355	08/30/2012 09/28/2012	FDA/OGROP/ORAP/PA-FO/LOS- DO/LOS-CB/	Christopher Weaver THE WALL STREET JOURNAL	ST JUDE MEDICAL, SYLMAR, CA - 07/08/09 EIR EXHIBIT 11 CORRECTIVE AND PREVENTATIVE ACTION
2012-6356	08/30/2012 09/28/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/CVM/OCD/	Bonnie Williams FOI Services, Inc.	NORBROOK LABS, NEWRY, NORTHERN IRELAND - 483 2012
2012-6357	08/30/2012 09/28/2012	FDA/OMPT/CDRH/OCER/DFOI/	Tara Viviani Focus Diagnostics, Inc.	K120413 - CLIA ROUTING SLIP AND ATTACHMENTS
2012-6358	08/30/2012 09/28/2012	FDA/OFVM/CFSAN/OCD/EOS/	Bonnie Williams FOI Services, Inc.	FCN 380
2012-6359	08/30/2012 09/28/2012	FDA/OFVM/CFSAN/OCD/EOS/	Bonnie Williams FOI Services, Inc.	FCN 1108
2012-6360	08/31/2012 10/01/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	PATRICK A DAWSON COOPER FIRM	KING PHARMACUTICALS INC - EPIPEN EPINEPHRINE INJECTOR PENS LENGTH OF EXPIRATION DATE
2012-6361	08/31/2012 10/01/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PATRICK A DAWSON COOPER FIRM	MYLAN INC - EPIPEN EPINEPHRINE INJECTOR PENS LENGH OF EXPIRATION DATE

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2012-6362	08/31/2012 10/01/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PATRICK A DAWSON COOPER FIRM	DEY PHARMA LP - EPIPEN EPINEPHRINE INJECTOR PENS LENGTH OF EXPIRATION DATE
2012-6363	08/31/2012 10/01/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PATRICK A DAWSON COOPER FIRM	PFIZER - EPIPEN EPINEPHRINE INJECTOR PENS LENGTH OF EXPIRATION DATE
2012-6364	08/31/2012 10/01/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PATRICK A DAWSON COOPER FIRM	MERIDIAN MEDICAL TECHNOLOGIES INC - EPIPEN EPINEPHRINE INJECTOR PENS LENGTH OF EXPRIATION DATE
2012-6365	08/31/2012 10/01/2012	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	DENNIS KEITH LEDFORD UNIV OF SOUTH FLORIDA	DR DENNIS KEITH LEDFORD, UNIV OF SOUTH FLORIDA, ASTHMA, ALLERGY & IMMUNOLOGY CLNCL RESEARCH UNIT - AUDIT 10/17/88, 10/23/95
2012-6366	08/31/2012 10/01/2012	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	RICHARD FUNK LOCKEY UNIV OF SOUTH FLORIDA	DR RICHARD FUNK LOCKEY, UNIV OF SOUTH FLORIDA, ASTHMA, ALLERGY & IMMUNOLOGY CLNCL RESEARCH UNIT - AUDIT 6/8/89
2012-6367	08/31/2012 10/01/2012	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	ROGER WILLIAMS FOX UNIV OF SOUTH FLORIDA	DR ROGER WILLIAMS FOX, UNIV OF SOUTH FLORIDA, ASTHMA, ALLERGY & IMMUNOLOGY CLNCL RESEARCH UNIT - AUDIT 2/7/95, 1/24/86
2012-6368	08/31/2012 10/01/2012	FDA/OFVM/CFSAN/OCD/EOS/	ANNA T FLOOD Keller and Heckman LLP	PERMISSIBLE FOOD CONTACT USES FOR SODIUM PYRITHIONE (SODIUM OMADINE OR SODIUM SALT OF 1-HYDROXY 2 (1H)-PYRIDINETHIONE) - OPINIONS PRIOR TO 1995
2012-6369	08/31/2012 10/01/2012	FDA/OFVM/CFSAN/OCD/EOS/	ANNA T FLOOD Keller and Heckman LLP	PERMISSIBLE FOOD CONTACT USES FOR ZINC PYRITHIONE (ZINC OMADINE) - OPINIONS IN POLYMERS, ADHESIVES, SPONGES PRIOR TO 1995
2012-6370	08/31/2012 10/01/2012	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	G RICHARD JAMES LUCERNE FARMS	LUCERNE FARMS AT CARGIL ANIMAL NUTRITION, ALBANY, NY - EIRS, CMLPLNTS 3/11 TO 5/11
2012-6371	08/31/2012 10/01/2012	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	G RICHARD JAMES LUCERNE FARMS	LUCERNE FARMS AT DOVER SADDLERY RETAIL INC, CONCORD, NH - EIRS, CMLPLNTS 3/11 TO 5/11
2012-6372	08/31/2012 10/01/2012	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	G RICHARD JAMES LUCERNE FARMS	LUCERNE FARMS AT ANITA COONS AMESBURY, MA - EIRS, CMLPLNTS 3/11 TO 5/11

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2012-6373	08/31/2012 10/01/2012	FDA/OO/OFBA/OAGS/	SCOTT A HODES HODES, SCOTT A	INFORMATION AND COMPUTING TECHNOLOGIES FOR THE 21ST CENTURY PROGRAM (ICT21) - REQUEST FOR TASK ORDERS PROPOSALS 6/11 TO 5/12
2012-6374	08/31/2012 10/01/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	TAMIR SAGRE NEURO TECHNOLOGY SOLUTIONS LTD	QBTEST - K040894, GORDON DIAGNOSTIC SYS - K854903, OPTAX SYS - K020800
2012-6375	08/31/2012 10/01/2012	FDA/OMPT/CDRH/OCER/DFOI/	VICTORIA TAMARKIN IMAGING SCIENCES INTERNATIONAL	VATECH CO LTD - DNETAL COMPUTED TOMOGRAPHY X-RAY SYS K121412
2012-6376	08/31/2012 10/01/2012	FDA/OMPT/CDRH/OCER/DFOI/	JOSEPH KICEINA ABBOTT POINT OF CARE INC	HELENA LABS - CASCADE 480 K921363
2012-6377	08/31/2012 10/01/2012	OC/OSMP/OOPD/ FDA/OMPT/OSMP/OOPD/	LAUREN A FARRUGGIA Hyman, Phelps and McNamara	ACETADOTE (ACETYLEYSTEINE) NDA 21-539 APRVL
2012-6378	08/31/2012 10/01/2012	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WILLIAM A GARVIN BUCHANAN INGERSOL PC	LIBRAX (CHLORDIAZEPOXIDE, CLIDINIUM) - SAFETY AND EFFICACY RECS, DISCUSSIONS, EVALUATIONS
2012-6379	08/31/2012 10/01/2012	FDA/OMPT/CDRH/OCER/DFOI/	Paul D'Oyley Golden Family	ADVERSE EVENT REPORT - NORIAN CRS BONE CEMENT
2012-6380	08/31/2012 10/01/2012	FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/	Christopher Weaver THE WALL STREET JOURNAL	ST JUDE MEDICAL, SYMLAR, CA - EIR 09/30/06 EXHIBIT 2
2012-6381	08/31/2012 10/01/2012	FDA/OC/OES/DFOI/	Megan Pickel Beveridge & Diamond, PC	CFSAN FOIA REQUESTS 07/25/2012 - 08/30/2012
2012-6382	08/31/2012 10/01/2012	FDA/OGROP/ORR/CE-FO/CIN-DO/CIN-CB/	Edward W Skepnek Valnet Inc.	BATTELLE MEMORIAL INSTITUTE, COLUMBUS, OH - EIR 11/01/2011 - 01/31/2012
2012-6383	08/31/2012 10/01/2012	FDA/OMPT/CDRH/OCER/DFOI/	FDA Wood, Mary L	K120492
2012-6384	08/31/2012 10/01/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORR/SE-FO/NOL-DO/NOL-CB/	Sheila Schebek Schebek, Sheila M	MEDTRONIC INFUSE BONE GRAFT/LT-CAGE LUMBAR TAPERED FUSION DEVICE - INVESTIGATIONS, INQUIRIES, CORR, ETC
2012-6385	08/31/2012 10/01/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bonnie Williams FOI Services, Inc.	PERRIGO NTR GUM PRODUCTS - ANDAs, CORR, FOIA REQUESTS, ETC

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		FDA/OC/OES/DFOI/		
2012-6386	08/31/2012 10/01/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	Bonnie Williams FOI Services, Inc.	ZONNIC NRT GUM BRAND - APPLICATIONS, CORR, FOIA REQUESTS
2012-6387	08/31/2012 10/01/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	JERAMIE JONES INTERSTATE PLASTICS, INC.	MAF-300
2012-6388	08/31/2012 10/01/2012	FDA/OC/OES/DFOI/	Vicky Johnson Vicky Johnson	ADULTERATED EQUINE - WARNING LETTERS
2012-6389	09/04/2012 11/13/2012	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	JODIE L LWIZE JOHNSON JOHNSON LARSON ET AL	THORATEC HEARMATE II LEFT VENTRICULAR ASSIST SYS WITH THE SEALED OUTFLOW GRAFT - APRVL, RECALLS, COMM, ETC
2012-6390	09/04/2012 10/02/2012	FDA/OGROP/ORA/CE-FO/CHIDO/CHI-CB/ FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	ROGER BRINSER BIOLIFE PLASMA SERVICES	BIOLIFE PLASMA SERVICES, SHEBOYGAN, WI - EIR 3/19/12
2012-6391	09/04/2012 10/02/2012	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	LARKIN, LOREN	HOSPIRA, ROCKYMOUNT, NC, CLAYTON, NC, BOULDER, CO, ETC - 483S, WARNING LTRS 2012

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2012-6392	09/04/2012 10/02/2012	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	LARKIN, LOREN	LUITPOLD PHARMS - 483S LAST 3 YRS
2012-6393	09/04/2012 10/02/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DONALD S STEIN GREENBERG TRAUIG LLP	LIBERTY GOLD CO INC, SAN FRANCISCO, CA - LIGO SARDINES MFR, SHIPPER, IMPORTER, ETC
2012-6394	09/04/2012 10/02/2012	FDA/OO/OFBA/OAGS/	JAMES G DICKINSON FDA WEBVIEW/FERDIC INC	FDA BIOSCIENCE LIBRARY - FDA NEWS, FOOD CHEMICAL NEWS PURCHASE ORDER CONTRACTS, PRICE AGREED TO PAY FOR SITE LICENSE/SUBSCRIPTION
2012-6395	09/04/2012 10/02/2012	FDA/OFVM/CFSAN/OCD/EOS/	BROWN, ANET	BORAX (BROATE OF SODIUM) - CAERS
2012-6396	09/04/2012 10/02/2012	FDA/OC/OES/DFOI/	REED, JOHN H	FOI DAILY LOG 1/09 TO PRESENT
2012-6397	09/04/2012 10/02/2012	FDA/OC/OES/DFOI/	CHRIS WEAVER WALL STREET JOURNAL	MINOR DELETIONS - EIRS 6/26-29/06
2012-6398	09/04/2012 10/02/2012	FDA/OMPT/CDRH/OCER/DFOI/	Brian Kennedy Ayer Capital Management, LP	P950022 S030
2012-6399	09/04/2012 10/02/2012	FDA/OMPT/CDRH/OCER/DFOI/	Brian Kennedy Ayer Capital Management, LP	P950022 S025
2012-6400	09/04/2012 10/02/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Katsuhiko Baba SEIKO EPSON CORPORATION	K012464
2012-6401	09/04/2012 10/02/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Yu-Ju Chiang CHUNG YUAN CHRISTIAN UNIV/ DEPT OF ELECTRICAL ENGINERRING	K040904
2012-6402	09/04/2012 10/02/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jerry R. Ford	ORANGE BOOK - PRESCRIPTION AND OTC DRUG PRODUCT PATENT AND EXCLUSIVITY LIST FROM 17TH, 20TH, 23RD, 26TH, 29TH EDITION
2012-6403	09/04/2012 10/02/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Dr. Diane Sudduth Biovance	K111026

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2012-6404	09/04/2012 10/02/2012	FDA/OGROP/OROPA-FO/SAN-DO/SAN-CB/	mary nydegger Nydegger, Mary	ABCO LABORATORIES, FAIRFIELD, CA - INSPECTIONS REPORTS, WARNING LETTERS, ETC
2012-6405	09/04/2012 10/02/2012	OC/OROA/ OC/OROA/	Julie Putnam NBC UNIVERSAL	COMPLAINTS ON PET TREATS 2007-PRESENT - EXCEL FORMAT
2012-6406	09/04/2012 10/02/2012	FDA/OMPT/CDRH/OCER/DFOI/	Joshua Jennings Josh Jennings/Cowen and Company	P950022/S025, P950022/S030, P950022/S049
2012-6407	09/04/2012 10/02/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 8/27-31/2012
2012-6408	09/04/2012 10/02/2012	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Pharavee Jaiprasart University of Oklahoma HSC	CHEMICAL ENTITIES - CLINICAL TRIALS CONDUCTED OUTSIDE THE US 01/01/2005 - 08/31/2012
2012-6409	09/04/2012 10/02/2012	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Eisai Inc.	LORCASERIN HYDROCHLORIDE SCHEDULING RECOMMENDATION 06/25/12
2012-6410	09/04/2012 10/02/2012	FDA/OC/OES/DFOI/	Boris Friedman Kline & Company, attn: Boris Friedman	2012-5746 - MINOR DELETIONS
2012-6411	09/04/2012 10/02/2012	FDA/OMPT/CDRH/OCER/DFOI/	PaxMed International	K051461
2012-6412	09/04/2012 10/02/2012	FDA/OMPT/CDRH/OCER/DFOI/	Clarice Arruda Procedure Products Inc.	K884985
2012-6413	09/04/2012 10/02/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-5937 REQUEST LETTER
2012-6414	09/04/2012 10/02/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOIA REQUESTS CLOSED 8/1-31/2012
2012-6415	09/04/2012 10/02/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-5574 REQUEST LETTER
2012-6416	09/04/2012 10/02/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-5918 REQUEST LETTER
2012-6417	09/04/2012 10/02/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-5766 REQUEST LETTER

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2012-6418	09/04/2012 10/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	VIRGINIA BRADLEY Bradley, Virginia	IBUPROFEN - DEATH REPORTS
2012-6419	09/04/2012 10/02/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6030 REQUEST LETTER
2012-6420	09/04/2012 10/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Suzanne O'Shea FAEGRE BAKER DANIELS	NDA 20-845 - FORM 3542 AND/OR FORM 3542aFOR PATENT 5732693 AND PATENT 5752504
2012-6421	09/04/2012 10/02/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-5495 REQUEST LETTER
2012-6422	09/04/2012 10/02/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-5533 REQUEST LETTER
2012-6423	09/04/2012 10/02/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-5548 REQUEST LETTER
2012-6424	09/04/2012 10/02/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-5636 REQUEST LETTER
2012-6425	09/04/2012 10/02/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-5639 REQUEST LETTER
2012-6426	09/04/2012 10/02/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-5673 REQUEST LETTER
2012-6427	09/04/2012 10/02/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-5856 REQUEST LETTER
2012-6428	09/05/2012 10/03/2012	FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	KENNETH JONES BRASSELER USA	BRASSELER USA, SAVANNAH, GA - EIR 10/19/10
2012-6429	09/05/2012 10/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	BLA 125057 SUPP 16, 45, 46, 62, 71, 89, 95, 110, 114
2012-6430	09/05/2012 10/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	STELARA - AERS

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2012-6431	09/05/2012 10/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELLEN GABLER MILWAUKEE JOURNAL SENTINEL	WATSON, MYLAN, JOHNSON & JOHNSON, ETC - FENTANYL PATCHES SAFETY UPDATES
2012-6432	09/05/2012 10/03/2012	FDA/OGROP/ORACE-FO/PHI- DO/PHI-CB/	Sheila A. Woolson Epstein Becker & Green, PC	INOLEX CHEM CO, PHILADELPHIA, PA - VIOLATIONS, WARNING LETTERS, ENFORCEMENT ACTION, ETC
2012-6433	09/05/2012 10/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Christopher S. James, MD Retrophin, LLC	D-PENICILLAMINE (CUPRIMINE) - PK/PD DATA, TOXICITY DATA, PRECLINICAL DATA, ETC
2012-6434	09/05/2012 10/03/2012	OC/OA/OM/OMP/DDM/	MCKENZIE CAO Hyman Phelps and McNamara PC	DILUENTS IN COLOR ADDITIVE MIXTURES - COMMENT LTRS 10/8/64
2012-6435	09/05/2012 10/03/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/OCOS/OES/ OC/OCOS/OES/	Amy Silverstein REUTERS	FDA CORR WITH JUSTIN TEEGUARDEN RE BPA
2012-6436	09/05/2012 10/03/2012	FDA/OGROP/ORACE-FO/CHI- DO/CHI-CB/ FDA/OGROP/ORACE-FO/CIN- DO/CIN-CB/	Theodore Lapainis Theodore Lapainis	BATTELLE MEM INST - 483, CORR 12/12/2011 - 09/05/2012
2012-6437	09/05/2012 10/03/2012	OC/CVM/OCD/ OC/ORACE/ OC/ORACE/	Amy Silverstein REUTERS	DEL MONTE - FDA CORR RE CHICKEN JERKY
2012-6438	09/05/2012 10/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Takeda Global Research & Development Cen	ALLOPURINOL - 50 ISRS
2012-6439	09/05/2012 10/03/2012	FDA/OMPT/CDRH/OCER/DFOI/	MONIKA BHATT HODGSON RUSS LLP	NANO VIBRONIX LTD - PAINSHIELD MD K081075
2012-6440	09/05/2012 10/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PRASANNA SUNTHANKAR PHD REVOGENEX INC	TRAMADOL - ISRS 5134358, 5135730, 5327469, ETC
2012-6441	09/05/2012	FDA/OMPT/CDER/ORP/DIDP/	SAMUEL F COLIN MD	FERAHEME (FERUMOXYTOL) - AERS

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	10/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FIRST MANHATTAN CO	
2012-6442	09/05/2012 10/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jason Najdzinowicz Helsinn Therapeutics (U.S.), Inc.	JIANGXI KINGNORD INDUSTRIAL LTD, CHINA - EIR
2012-6443	09/05/2012 10/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Christopher S. James, MD Retrophin, LLC	SYPRINE NDA 019194 - PK/PD DATA, TOXICITY DATA, PRECLINICAL DATA ETC
2012-6444	09/05/2012 10/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	King Lee King Lee	PROSTRAKAN INC - SANCUSO
2012-6445	09/05/2012 10/03/2012	FDA/OMPT/CDRH/OCER/DFOI/	Dr. Diane Sudduth Biovance	K051214
2012-6446	09/05/2012 10/03/2012	FDA/OMPT/CDRH/OCER/DFOI/	Dr. Diane Sudduth Biovance	K102461
2012-6447	09/05/2012 10/03/2012	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	SHERRI MAIN ROQUETTE AMERICA INC	ROQUETTE AMERICA INC, KEOKUK, IA - FMD-145 3/6-7/12
2012-6448	09/05/2012 10/03/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	TORIGIAN LABS, QUEENS, NY - EIR, 483, CORR (1977)
2012-6449	09/05/2012 10/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 20670 S14
2012-6450	09/05/2012 10/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 21711
2012-6451	09/05/2012	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson	K092590

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	10/03/2012		FOI Services, Inc.	
2012-6452	09/05/2012 10/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	US PATENT 4,616,006, 4,628,051 - DECLARATIONS
2012-6453	09/05/2012 10/03/2012	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K051764
2012-6454	09/05/2012 10/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	BLA 125294
2012-6455	09/05/2012 10/03/2012	FDA/OGROP/ORAP/FO/SAN-DO/SAN-CB/	Rachel Johnson FOI Services, Inc.	GENENTECH, VACAVILLE, CA - 483 8/15/08, 9/28/09
2012-6456	09/05/2012 10/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 050740 - MANUFACTURING, IN VITRO EVALUATION
2012-6457	09/05/2012 10/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 050740 - MANUFACTURING, IN VITRO EVALUATION
2012-6458	09/05/2012 10/03/2012	FDA/OMPT/CDRH/OCER/DFOI/	NEURO TECHNOLOGY SOLUTIONS LTD	QBTECH AB - QBTEST K040894; CLINICAL DIAGNOSTIC INC - GORDON DIAGNOSTIC SYS K854903; OPTAX SYSTEM - OPTAX SYS K020800
2012-6459	09/05/2012 10/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DIETER LUELSORF ZETA PHARMACEUTICALS LLC	PHARMACEUTICAL INGREDIENT LIST OF LABELER CODES AND NAMES OF MFRS
2012-6460	09/05/2012 10/03/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/CVM/OCD/	JESSICA L LYON PHD MORGAN LEWIS & BOCKIUS LLP	FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS, FORMIC ACID
2012-6461	09/05/2012 10/03/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	BAYER, RANGE (RICHARD) D	BLOOD PRODS A/C - TOPIC III: WRITTEN STATEMENT OF UNDERSTANDING FOR BOOD DONORS PRESENTATIO PAPERS 4/29/11
2012-6462	09/05/2012	FDA/OFVM/CFSAN/OCD/EOS/		HANSEN NATURAL - MONSTER ENERGY DRINK CAERS

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	10/03/2012		CROSSLAND, WENDY	
2012-6463	09/05/2012 10/03/2012	FDA/OFVM/CFSAN/OCD/EOS/	CROSSLAND, WENDY	PEPSICO - ROCKSTAR ENERGY DRINK CAERS 2001 TO PRESENT
2012-6464	09/05/2012 10/03/2012	FDA/OFVM/CFSAN/OCD/EOS/	CROSSLAND, WENDY	RED BULL GMBH - RED BULL ENERGY DRINK CAERS 2011 TO PRESENT
2012-6465	09/05/2012 10/03/2012	FDA/OFVM/CFSAN/OCD/EOS/	CROSSLAND, WENDY	LIVING ESSENTIALS - 5-HOUR ENERGY CAERS 2004 TO PRESENT
2012-6466	09/05/2012 10/03/2012	FDA/OMPT/CDRH/OCER/DFOI/	IRENE K NAVIS MEDIGROUP INC	MEDIGROUP INC - MEDIGROUP LG-102 LIGHT GUIDE K923283
2012-6467	09/05/2012 10/03/2012	FDA/OMPT/CDRH/OCER/DFOI/	IRENE K NAVIS MEDIGROUP INC	MEDIGROUP - 2.2MM NEEDLESCOPE CANNULA K823295
2012-6468	09/05/2012 10/03/2012	FDA/OMPT/CDRH/OCER/DFOI/	IRENE K NAVIS MEDIGROUP INC	MEDIGROUP - MEDIGROUP LS-110 LIGHT SOURCE K823294
2012-6469	09/05/2012 10/03/2012	FDA/OMPT/CDRH/OCER/DFOI/	IRENE K NAVIS MEDIGROUP INC	MEDIGROUP - MEDDIGROUP ST-610 NEEDLESCOPE STERILIZATION TRAY K823297
2012-6470	09/05/2012 10/03/2012	FDA/OMPT/CDRH/OCER/DFOI/	IRENE K NAVIS MEDIGROUP INC	MEDIGROUP - QUILL CATHETER GUIDE K823303
2012-6471	09/05/2012 10/03/2012	FDA/OMPT/CDRH/OCER/DFOI/	IRENE K NAVIS MEDIGROUP INC	MEDIGROUP - DIALATORS PC-203 & 202 K823330
2012-6472	09/05/2012 10/03/2012	FDA/OMPT/CDRH/OCER/DFOI/	IRENE K NAVIS MEDIGROUP INC	MEDIGROUP - PC-204 TUNNELOR K823331
2012-6473	09/05/2012 10/03/2012	FDA/OMPT/CDRH/OCER/DFOI/	IRENE K NAVIS MEDIGROUP INC	MEDIGROUP - PC-205 TENCKHOFF CATHETER ROD OBTURATOR K823296
2012-6474	09/05/2012 10/03/2012	FDA/OMPT/CDRH/OCER/DFOI/	IRENE K NAVIS MEDIGROUP INC	MEDIGROUP - PERITONEAL DIALYSIS CATHETER CONNECTOR K974570
2012-6475	09/06/2012 10/04/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PATRICIA L REGENYE Celgene Corporation	ALEXANDER PATERSON, TOM BAKER CANCER CENTER, CALGARY AB, CANADA - 483S 12/04 TO 8/12
2012-6476	09/06/2012 10/04/2012	FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	PATRICIA L REGENYE Celgene Corporation	LINDA D BOSSERMAN, WILSHIRE ONCOLOGY MEDICAL GROUP INC, LA VERNE, CA - 483S 12/10 TO 8/12
2012-6477	09/06/2012 10/04/2012	FDA/OGROP/ORO/CE-FO/NWJ-DO/NWJ-CB/	PATRICIA L REGENYE Celgene Corporation	DAVID SIEGEL, HACKENSACK UNIV MEDICAL CENTER, HACKENSACK, NJ - EIRS, 483S, RESP, ETC 1/12 TO 8/12

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2012-6478	09/06/2012 10/04/2012	FDA/OGROP/ORR/SE-FO/NOL-DO/NOL-CB/	CHARLES CELESTE EAS Consulting Group, LLC	BAXTER HEALTHCARE, CLEVELAND, MS - EIRS 1/25/10-2/5/10
2012-6479	09/06/2012 10/04/2012	FDA/OGROP/ORR/SE-FO/NOL-DO/NOL-CB/	CHARLES CELESTE EAS Consulting Group, LLC	BAXTER HEALTHCARE, CLEVELAND, MS - EIRS, 483S 6/4-27/12
2012-6480	09/06/2012 10/04/2012	FDA/OMPT/CDRH/OCER/DFOI/	JEFFERY P FISHER EZ PEDO	NUSMILE PEDIATRIC CROWNS - NUSMILE ZR RESP TO TRADE CMLNT RECS 8/10/12
2012-6481	09/06/2012 10/04/2012	FDA/OMPT/CDRH/OCER/DFOI/	JEFFERY P FISHER EZ PEDO	KINDER KROWN ST LOUIS PARK, MN - SOLID ZIRCONIA PREFABRICATED CERAMIC CROWNS FOR CHILDREN ACTION TO TRADE CMLNT 8/10/12
2012-6482	09/06/2012 10/04/2012	FDA/OMPT/CDRH/OCER/DFOI/	APRIL LEE KODENT INC	CURASAN AG - CERASORB M ORTHO K040216
2012-6483	09/06/2012 10/04/2012	FDA/OGROP/ORR/NE-FO/NWE-DO/NWE-CB/	REBECCA NOSS BAXTER	APTIV SOLUTIONS, SOUTHBOROUGH, MA - 483 3/11 TO 5/11
2012-6484	09/06/2012 10/04/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LAUREN CUTLER GILEAD SCIENCES INC	RITIUXAN (RITUXMAB) BLA 10-3705 - SBA, MEDICAL RVWS 1/28/11
2012-6485	09/06/2012 10/04/2012	FDA/OFVM/CFSAN/OCD/EOS/	STERN, DEREK	EVERGREEN JUICES INC - WHEATGRASS JUICE HACCP MOST RECENT
2012-6486	09/06/2012 10/04/2012	OC/ORR/ OC/ORR/ FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORR/SW-FO/SWID/SWID-CB/	SAMANTHA MYERS ROANOKE TRADE SERVICES INC	GETMEX PRODUCTS LLC - ENTRY NUMBER 26045312625 BOND ENTRIES, NOTICES OF ACTIONS, COMMERCIAL INVOICES, ETC
2012-6487	09/06/2012 10/04/2012	OC/ORR/ORM/ OC/ORR/ORM/	JOHNATHAN RICKMAN FDA NEWS	PHARMACETICAL, BIOLOGICS, MEDICAL DVC MFG, CLNCL FACILITIES IN & OUTSIDE US - 483S 8/1-31/12
2012-6488	09/06/2012 10/05/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/ OC/ORR/ORM/	James Kenny Kenny, James	NEW FDA INVESTIGATOR TRAINING MATERIALS - CDRH, CDER,CBER

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		OC/ORR/ORM/		
2012-6489	09/06/2012 10/04/2012	FDA/OMPT/CDRH/OCER/DFOI/	IDx LLC	P100005
2012-6490	09/06/2012 10/04/2012	FDA/OFVM/CFSAN/OCD/EOS/	Jonathan Waldman	FCN - NEW COATING FOR BEVERAGE CANS
2012-6491	09/06/2012 10/04/2012	OC/CVM/OCD/	Carter Dillard ANIMAL LEGAL DEFENSE FUND	RACTOPAMINE - EFFECTS ON PIGS, CATTLE, TURKEYS, ETC
2012-6492	09/06/2012 10/04/2012	FDA/OC/OES/DFOI/	JAMES H LIDE HISTORY ASSOCIATES INC	2010-8410
2012-6493	09/06/2012 10/04/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	PARAXEL, PARAXEL CLINICAL PHARMACOLOGY, FARMOVS PARAXEL, BLOEMFONTEIN, SOUTH AFRICA - EIR, 483 01/01/2008 TO PRESENT
2012-6494	09/06/2012 10/04/2012	FDA/OC/OES/DFOI/	JOHN CREWDSON PROJECT ON GOVERNMENT OVERSIGHT	INDIVIDUAL RECS
2012-6495	09/06/2012 10/04/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Daniel Gofman SERRADO CAPITAL LLC	KYRPOLIS DMF
2012-6496	09/06/2012 10/04/2012	FDA/OMPT/CTP/OD/ FDA/OC/OES/DFOI/	Bonnie Williams FOI Services, Inc.	PALL MALL BLACK, PALL MALL WHITE - APPLICATIONS, CORR, REQUESTS ETC
2012-6497	09/06/2012 10/04/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Noreen Kelly Advocate Lutheran General Hospital	ALVIMOPAN (ENTEREG) - AERS
2012-6498	09/06/2012 10/04/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KINGRY 0687521, STEVEN	CIPRO - AERS 1989 TO PRESENT
2012-6499	09/06/2012 10/04/2012	FDA/OC/OES/DFOI/	Bonnie Williams FOI Services, Inc.	2012-4049
2012-6500	09/06/2012	FDA/OMPT/CDRH/OCER/DFOI/	Tamela White	SMITH AND NEPHEW JOURNEY UNI TIBIAL BASE PLATE - 510K, MDR, LABELING, ETC

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	10/04/2012		Farrell, White & Legg PLLC	
2012-6501	09/06/2012 10/04/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORO/OCI/ OC/ORO/OCI/	Ashley R. Palmer ROBBINS UMEDA LLP	DEPAKOTE - CORR RE: OFF LABEL USE
2012-6502	09/06/2012 10/04/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ross Laderman Kowa Research Institute, Inc.	NDA200675
2012-6503	09/06/2012 10/04/2012	OC/OM/OMP/DDM/	LAUREN FARRUGGIA Hyman Phelps and McNamara PC	DKT FDA-2012-P-0915
2012-6504	09/06/2012 10/04/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ellen Camos ANI Pharmaceuticals	ANDA 201916
2012-6505	09/06/2012 10/04/2012	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	Quentin Desein Brioschi Pharmaceuticals	BRIOSCHI, FAIR LAWN, NJ - EIRS 09/01/2000 - 09/01/2011
2012-6506	09/06/2012 10/04/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	David Lin BIOLOGICS CONSULTING GROUP	NEUTROVAL (BLA 125294) - APPROVAL PACKAGE
2012-6507	09/06/2012 10/04/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OCC/	Geoffrey Chambers Geoffrey R Chambers	JUNE 22, 2012 MEETING MINUTES RE ORANGE BOOK
2012-6508	09/06/2012 10/04/2012	FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/	III FFC	WINDY RIDGE DAIRY, FAIR OAKS, IN - EIR, CORR, 483 01/11 TO PRESENT
2012-6509	09/06/2012 10/04/2012	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	Parexel International	DR MICHAEL GOLDBERG, TRENTON, NJ - 483 3/8/1993, 11/27/1990
2012-6510	09/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	Peter A. Takes	K050955

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	10/05/2012		Kypha, Inc.	
2012-6511	09/07/2012 10/05/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Adam G. Husik, Esq. Hardin, Kundla, McKeon & Poletto, P.A.	GROW CO, INC, RIDGEFIELD, NJ - EIR, CORR 01/03/2000 - 09/06/2012
2012-6512	09/07/2012 10/05/2012	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Rachel Johnson FOI Services, Inc.	PAREXEL, PAREXEL CLINICAL PHARM, FARMOVS PAREXEL, ETC, BALTIMORE, MD - EIR, 483 01/01/09-PRESENT
2012-6513	09/07/2012 10/05/2012	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Rachel Johnson FOI Services, Inc.	PARAXEL, LOWELL, MA - EIR, 483 01/01/09 TO PRESENT
2012-6514	09/07/2012 10/05/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	PARAXEL, BERLIN, GERMANY - EIR, 483 01/01/2009 TO PRESENT
2012-6515	09/07/2012 10/05/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Rachel Johnson FOI Services, Inc.	PARAXEL, GLENDALE, CA - EIR, 483 01/01/09 TO PRESENT
2012-6516	09/07/2012 11/21/2012	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	P100018
2012-6517	09/07/2012 10/05/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Christine Woods Puma Biotechnology, Inc.	NDA 022334/S016 - ADMIN RECS, CORR, MED REVIEWS
2012-6518	09/07/2012 10/05/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Rachel Johnson FOI Services, Inc.	PAREXEL, SAN DIEGO, CA - EIR, 483 01/01/09 TO PRESENT
2012-6519	09/07/2012 10/05/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	John Ventosa Napoli Bern Ripka Shkolnik, LLP	LIPITOR - AERS
2012-6520	09/07/2012 10/05/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	IPD Analytics, LLC	AZELASTINE HYDROCHLORIDE - EFFECTIVE APPROVAL LTR
2012-6521	09/07/2012 10/05/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Marylyn Oparaugo Banner Pharmacaps Inc.	ANDA 090095, ANDA 202121 - APPROVAL LETTER, LABELING, ADMIN RECS ETC

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		FDA/OMPT/CDER/GRP/DIDP/		
2012-6522	09/07/2012 10/05/2012	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	TOBACCO ESTABLISHMENT REGISTRATIONS 08/01/12 TO PRESENT
2012-6523	09/07/2012 10/05/2012	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	TOBACCO PRODUCTS - DISCONTINUANCE OF DISTRIBUTION
2012-6524	09/07/2012 10/05/2012	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	TOBACCO - ORDERS OF SUBSTANTIAL EQUIVALENCE
2012-6525	09/07/2012 10/05/2012	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	TOBACCO PRODUCTS SOLD IN THE US AS OF JUNE 2012
2012-6526	09/07/2012 10/05/2012	OC/ORO/OCI/ OC/ORO/OCI/	FAST COMPANY MAGAZINE	HUMAN HOOKWORM INVESTIGATION
2012-6527	09/07/2012 10/05/2012	FDA/OC/OES/DFOI/ FDA/OGROP/ORA/ORO/DIOP/	KATE WILLSON CENTER FOR PUBLIC INTEGRITY	STATE ENTERPRISE FEI 3009204210, RTI BIOLOGICS FEI 3002719998, TUTOGEN MEDICAL FEI 3002487675, 3002924436
2012-6528	09/07/2012 10/05/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SUZANNE D. JENSEN KLEINFELD KAPLAN & BECKER	AVEDA ANDA 74-612 - CORR, BIOEQUIV, CHEMISTRY RVW
2012-6529	09/07/2012 10/05/2012	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	ARLENE NORDSTROM SEKISUI DIAGNOSTICS LLC	ALERE INC, SAN DIEGO, CA - 483
2012-6530	09/07/2012 10/05/2012	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	ROSE WINQUIST WINQUIST INVESTIGATIONS	BIOSIM LLC - RECS
2012-6531	09/07/2012 10/05/2012	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	INDIVIDUAL RECS
2012-6532	09/07/2012 10/05/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CROSBY T50417, COURTNEY	ACTOS - LBLG
2012-6533	09/07/2012 10/05/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	FRANK E. PISCITELLI, JR. PISCITELLI LAW FIRM	WHITE WAVE FOODS CO, BROOMFIELD, CO - INVESTIGATIONS
2012-6534	09/07/2012 10/05/2012	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	JOSEPH H. SAUNDERS SAUNDERS & WALKER PA	SOFRADIM PRODUCTION, TREVOUX, FRANCE - EC110486/E001; CR BARD INC, COVINGTON, GA - EC080229/E008; ETHICON GMBH, NORDERSTEDT, GERMANY - EC120028/E001

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/		
2012-6535	09/07/2012 10/05/2012	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	LIST OF OWNERS, OPERATORS WHO MANUFACTURE TOBACCO
2012-6536	09/07/2012 10/05/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	George Honda Panasonic Healthcare Co., Ltd.	NDA 19764 S035 - APPROVAL PACKAGE
2012-6537	09/07/2012 10/05/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/OCOS/OES/ OC/OCOS/OES/ OC/ORA/ OC/ORA/	ELENA HOWELL HOGAN LOVELLS US LLP	PEW CHARITABLE TRUSTS; CENTER FOR SCIENCE IN THE PUBLIC INTEREST; CONSUMER FEDERATION OF AMERICA - CORR
2012-6538	09/07/2012 10/05/2012	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	CHRISTINE M. BURNS DISCOVERY LABORATORIES INC	DISCOVERY LABS INC, WARRINGTON, PA FEI 3004898726 - 483 2/21-24/12
2012-6539	09/07/2012 10/05/2012	FDA/OFVM/CFSAN/OCD/EOS/	VERONICA S. KNAPP HOGAN LOVELLS LLP	MAUFACTURING WHOLE WHEAT FLOUR USING A RECONSTITUTION OR RECOMBINATION PROCESS - CORR
2012-6540	09/07/2012 10/05/2012	OC/OM/OMP/DDM/	MARILYNN WHITNEY COVINGTON & BURLING LLP	DKT FDA-2012-P-0317
2012-6541	09/07/2012 10/05/2012	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	GAITHER, CHARLES	NESTLE USA INC, BURLINGTON, WI - INSP
2012-6542	09/07/2012 12/17/2012	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	BROWN, JUNE	ALL CHILDREN'S HOSPITAL. ST PETERSBURG, FL - BONE MARROW TRANSPLANTATION RECSW 7/96; STUDY PROTOCOL - TREATMENT OF LYSOSOMAL AND PREOXISOMAL INBORN ERROS OF METABOLISM BY BONE MARROW TRANSPLANTATION 3/25/96, ETC
2012-6543	09/07/2012 10/05/2012	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	KYU MOK HWANG PHYSICAL PHARMACY LAB SKKU	K012354, K003219, K020431, K060075, K003221

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2012-6544	09/07/2012 10/05/2012	FDA/OMPT/CTP/OD/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LAFLOWER 144854, BENJAMIN .	NIACIN - AER
2012-6545	09/09/2012 10/05/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	SEROQUEL - AERS
2012-6546	09/09/2012 10/05/2012	FDA/OGROP/ORAN/NE-FO/NYK-DO/NYK-DCB/	Bonnie Williams FOI Services, Inc.	LUITPOLD PHARM, INC - UPDATE TO RESPONSE TO 05/18/12 483
2012-6547	09/09/2012 10/05/2012	FDA/OGROP/ORAN/NE-FO/NYK-DO/NYK-DCB/	Bonnie Williams FOI Services, Inc.	LUITPOLD PHARM, INC. - GMP SYSTEMS ENHANCEMENT ACTION PLANS 05/16/2011, 06/06/2011, 07/01/2011 ETC; RESPONSE TO WARNING LETTER 9/21/11
2012-6548	09/09/2012 10/05/2012	FDA/OMPT/CDRH/OCER/DFOI/	Karen Fan McKesson Medical Imaging Company	K051553, K061672
2012-6549	09/10/2012 11/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	GENO LLC - GENOSYL MV-1000 K120216
2012-6550	09/10/2012 10/09/2012	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	MEDACTA INTERNATIONAL SA - MYKNEE CUTTING BLOCKS K093806
2012-6551	09/10/2012 10/09/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	MATERIALISE NV - ZIMMER PATIENT SPECIFIC INSTRUMENTS, PATIENT SPECIFIC INSTRUMENTS PLANNER MODEL 1.1 K091263
2012-6552	09/10/2012 10/09/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	DEPUY ORTHOPAEDICS INC - TRI-LOCK BONE PRESERVATION STEM K073570
2012-6553	09/10/2012 10/09/2012	FDA/OFVM/CFSAN/OCD/EOS/	FOI Services, Inc.	INVISTA RESINS & FIBERS GMBH - NYLON MXD-6 (HEXAMEDIOLIC ACID PLYMER WITH 1,3 BENZENDIMETHANAMINE) FCN 1147
2012-6554	09/10/2012 10/09/2012	FDA/OFVM/CFSAN/OCD/EOS/	FOI Services, Inc.	FCN 380
2012-6555	09/10/2012 10/09/2012	OC/OSMP/OOPD/ FDA/OMPT/OSMP/OOPD/	FOI Services, Inc.	NITRIC OXIDE IN TREATMENT OF PULMONARY HYPERTENSION IN NEWBORNS -ORPAN DRUG APPL
2012-6556	09/10/2012	OC/ORAN/		LTRS THAT FDA SENT TO STATE CANCER REGISTRIES TO ENCOURAGE THEIR PARTICIPATION IN THE MTC

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	10/09/2012	OC/ORO/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	REGISTRY
2012-6557	09/10/2012 10/09/2012	FDA/OGROP/ORO/CE-FO/CIN-DO/CIN-CB/	PATRICIA L REGENYE Celgene Corporation	NASHAT GABRIAL, GABRAIL CANCER CENTER , CANTON, OH - 483S 12/09 TO 9/12
2012-6558	09/10/2012 10/09/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KATE PURCELL DOCUTRIEVAL INFORMATION SERVICES	SICORS - THO-FILGRASTIM BLA 12-5294 SBA
2012-6559	09/10/2012 10/09/2012	FDA/OFVM/CFSAN/OCD/EOS/	JAMES J MCGINLEY SONGWON INTERNATIONAL - AMERICAS INC	TRIS PHOSHITE - FCN 829
2012-6560	09/10/2012 10/09/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHAMBERS, GEOFFREY	VASCEPA ICOSAPENT ETHYL NDA 202-057 - EXCLUSIVITY SUMMARY
2012-6561	09/10/2012 10/09/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/OCOS/OES/ OC/OCOS/OES/ OC/OCOS/OL/	CHRISTOPHER BRENNAN WESTLAW COURT EXPRESS	FOREST LABORATORIES INC - SALES PRACTICES, PROMOTIONAL ACTIVITIES CORR 1/109 TO PRESENT
2012-6562	09/10/2012 11/06/2012	FDA/OFVM/CFSAN/OCD/EOS/	FATIMA ASLAN Keller and Heckman LLP	COLOR ADDITIVE PETITION (CAP) 2C0297
2012-6563	09/10/2012 10/09/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	A LUKE SMITH FARUQI & FARUQI LLP	TEVA PHARMACEUTICALS USA, WYETH PHARMACEUTICALS INC - ANDA 76-690 PATENT CORR 11/4/05
2012-6564	09/10/2012 10/09/2012	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	INDIVIDUAL RECS

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2012-6565	09/10/2012 10/09/2012	FDA/OMPT/CDRH/OCER/DFOI/	WALTER E CHALKLEY THOMSON REUTERS	COMPUMEDICS GERMANY GMBH, SINGEN, GERMANY - 483 3/19-22/12
2012-6566	09/10/2012 10/09/2012	FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	WALTER E CHALKLEY THOMSON REUTERS	ABBOTT PHARMS, BARCENOLETA, PR - 483 3/1-31/12
2012-6567	09/10/2012 10/09/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Christopher S. James Retrophin, LLC.	DEPEN - CMC DATA, PK/PD DATA, PRECLINICAL DATA, ETC
2012-6568	09/10/2012 10/09/2012	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	WALTER E CHALKLEY THOMSON REUTERS	CARDINAL HEALTH, BELTSVILLE, MD - 483 3/1-31/12
2012-6569	09/10/2012 10/09/2012	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	HOSPIRA, MCPHERSON, KS - 483 2/12
2012-6570	09/10/2012 10/09/2012	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	WALTER E CHALKLEY THOMSON REUTERS	PHARMACREAMS CORP, MIAMI, FL - 483 3/8-22/11
2012-6571	09/10/2012 10/09/2012	FDA/OMPT/CDRH/OCER/DFOI/	MILLER, CHRIS	K952737 - SUMMARY AND STATEMENT
2012-6572	09/10/2012 10/09/2012	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	WALTER E CHALKLEY THOMSON REUTERS	PHARMACEUTICS INTERNATIONAL, HUNT VALLEY, MD - 483 5/16-25/11
2012-6573	09/10/2012 10/09/2012	FDA/OFVM/CFSAN/OCD/EOS/	THOMAS J PEISTRUP Innoventions International	DIABESTEVIA - AERS, INVESTIGATION RECS
2012-6574	09/10/2012 10/09/2012	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	WALTER E CHALKLEY THOMSON REUTERS	ASEPT PAK INC, MALONE, NY - 483 6/11-20/12
2012-6575	09/10/2012 10/09/2012	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	WALTER E CHALKLEY THOMSON REUTERS	COMMED INC, VANCOUVER, WA - 483 3/26/12-4/2/12
2012-6576	09/10/2012 10/09/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	JIANGSU PROVINCE JIANERKANG MEDICAL DRESSING CO LTD, JIANGSU, CHINA - 483 9/13-19/11
2012-6577	09/10/2012 10/09/2012	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	WALTER E CHALKLEY THOMSON REUTERS	INFUPHARMA, HOLLYWOOD, FL - 483 7/18/11-9/27/11
2012-6578	09/10/2012	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	WALTER E CHALKLEY	CENTER FOR THE IMPROVEMEMNT OF HUMAN FUNCTIONING INTERNATIONAL (IRB), NEW YORK, NY - 483

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	10/09/2012	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	THOMSON REUTERS	7/6-8/11
2012-6579	09/10/2012 10/09/2012	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	WALTER E CHALKLEY THOMSON REUTERS	DAMIEN B SANDERLIN MD, LONE STAR CLNCL RSEARCH, HOUSTON, TX - 483 6/18/12-7/18/12
2012-6580	09/10/2012 10/09/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	NISSHIN PHARMA, JAPAN - 483 5/12
2012-6581	09/10/2012 10/09/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	TORRENT PHARM, GUJARAT, INDIA - 483 3/11
2012-6582	09/10/2012 10/09/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SANJAY H SHARMA PHD HETERO USA INC	VOTRIENT (PAZOPANIB TABS) - CHEMISTRY & BIOEQV RVWS, CORR, ETC
2012-6583	09/10/2012 10/09/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	DAVID LOHMAN SANESA PARTNERS	NORAC PHARMA, AZUSA, CA - EIRS 1/10 TO PRESENT
2012-6584	09/10/2012 10/09/2012	OC/OCOS/OES/ OC/OCOS/OES/ OC/OCOS/OL/ OC/OER/OPA/ OC/CVM/OCD/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CTP/OD/	GRETCHEN GOLDMAN UNION OF CONCERNED SCIENTISTS	NEW MEDIDA, SOCIAL MEDIA, PUBLIC AFFAIRS POLICY, ETC - MEMOS, INTERNET MATERIALS, EMPLOYEE HANDBOOKS, ETC

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		OC/ORO/ OC/ORO/		
2012-6585	09/11/2012 10/10/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	William Mestrandrea PFIZER	PHARM INSPECTORATE CURRICULUM - TRAINING MATERIALS, SUPPORTING DOCS
2012-6586	09/11/2012 10/10/2012	FDA/OMPT/CDRH/OCER/DFOI/	David Duersteler General Electric Medical Systems LLC	K103429
2012-6587	09/11/2012 10/10/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ron Schwarz Drug Process Licensing Associates, LLC	NDC CODES FOR APIS
2012-6588	09/11/2012 10/10/2012	OC/OA/OM/OMP/DDM/	Hao Ouyang Neutrogena COrportation	DOCKET 78N-0301 OTC PANEL SUBMISSION INDICES
2012-6589	09/11/2012 10/10/2012	FDA/OGROP/ORO/SE-FO/SJN-DO/SJN-CB/	Alisa Thomas VRx	MYLAN LLC - FOLLOW UP TO WARNING LETTER DATED 10/13/11
2012-6590	09/11/2012 10/10/2012	FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/	Matt Taylor TAYLOR, MATTHEW	HOSPIRA, AUSTIN TX, CLAYTON, NC - 483, WARNING LETTER 08/01/2012 - 09/10/2012
2012-6591	09/11/2012 10/10/2012	FDA/OFVM/CFSAN/OCD/EOS/	Edward Katz Mina Atramentum	CAP 8C0137, CAP 7C0251
2012-6592	09/11/2012 10/10/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jai-wei Fishman On-Site Patent Services LLC	ANDA 086069 - LABELING
2012-6593	09/11/2012 10/10/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Meeta Vete INSITE VISION	JINAN JINDA PHARM CHEM CO LTD, SHANDONG PROVINCE, CHINA - EIR 7/10
2012-6594	09/11/2012 10/10/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	CLOSED FOIA REQUESTS 9/3-7/12
2012-6595	09/11/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND	CLOSED FOIA REQUESTS 8/27/31/12

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	10/10/2012		FDA WEBVIEW/FERDIC INC	
2012-6596	09/11/2012 10/10/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 9/3-7/12
2012-6597	09/11/2012 10/10/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 8/27/31/12
2012-6598	09/11/2012 10/10/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 9/3-7/12
2012-6599	09/11/2012 10/10/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 8/27-31/12
2012-6600	09/11/2012 10/10/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 8/27-31/12
2012-6601	09/11/2012 10/10/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 9/3-7/12
2012-6602	09/11/2012 10/10/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUEST 9/3-7/12
2012-6603	09/11/2012 10/10/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 8/27-31/12
2012-6604	09/11/2012 10/10/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARK D KAMITOMO MARKAM GROUP INC PS	ISRS 3019682, 3105840, 3199360, ETC
2012-6605	09/11/2012 10/10/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORAP/PA-FO/LOS- DO/LOS-CB/	DEAN GRESHAM PAYNE MITCHELL LAW GROUP	NEUROBRANDS LLC - NEUROGASM, NEUROPASSION, NEUROSONIC, ETC LBLG, WARNING LTRS, NOTICES, ETC
2012-6606	09/11/2012 10/31/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PRENDERGAST, JOYCE E	CHANTIX (VERENICLINE) - ISRS 510170-8, 5182966-8, 5474701-0, ETC
2012-6607	09/11/2012 10/10/2012	FDA/OC/OES/DFOI/	CARLA R SCARMAZZI King & Spalding LLP	ABIOMED INC, DANVERS, MA - FOI REQUESTS 5/12 TO PRESENT
2012-6608	09/11/2012 10/10/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LAUREN DIPALI BRANCH LAW FIRM	DR JERI EL-HAGE - ACTOS (PIOGLITAZONE) RECS

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2012-6609	09/11/2012 10/10/2012	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	MARIAM HAFEZI QUALMAN KENNETH C CHESSICK MD LAW OFFICES	BIO-LIFE LLC (DUO-DENT DENTAL IMPLANT SYSTEMS LLC) - K923694
2012-6610	09/11/2012 10/10/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	CHRISTOPHER MARLBOROUGH FARUQI & FARUQI LLP	INNOVATION VENTURES LLC, WALLED LAKE, MI; LIVING ESSENTIALS LLC, FARMINGTON HILLS, MI - 5 HOUR ENERGY, CHASER, CHASER FOR WINE HEADACHES, ETC MISBRANDING, CAERS, CORR, ETC
2012-6611	09/11/2012 10/10/2012	FDA/OFVM/CFSAN/OCD/EOS/	MARK WOHLSCHLEDEL AMERICANS FOR LIMITED GOVERNMENT	CENTER FOR FOOD SAFETY, CENTER FOR ENVIRONMENTAL HEALTH - SAFETY REGULATIONS MTGS, CORR 1/11 TO PRESENT
2012-6612	09/11/2012 10/10/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	TRELSTAR INJ - AERS
2012-6613	09/11/2012 10/10/2012	OC/ORA/OCI/ OC/ORA/OCI/	CONNORS, ANTHONY ROBERT	INDIVIDUAL RECS
2012-6614	09/11/2012 10/10/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CRAIG TRAUTMAN INTAGRAS INC	ESTABLISHMENT REGISTRATIONS IN SPL FORMAT
2012-6615	09/11/2012 10/10/2012	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Doe J	CMPLNT
2012-6616	09/11/2012 10/10/2012	OC/OM/OMP/DDM/	CARLA SCARMAZZI KING & SPALDING	SRDP A/C 12/13/1979
2012-6617	09/11/2012 10/10/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	YARON FINKELSTEIN MD HOSPITAL FOR SICK CHILDREN	ZOFRAN (ONDANSETRON HCL) - AERS
2012-6618	09/11/2012 10/10/2012	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	LANGHANS, LINDA K	PROFESSIONAL HOSPITAL SUPPLY INC, TEMECULA, CA - INSP 4/20-29/11 RECS
2012-6619	09/11/2012	FDA/OC/OES/DFOI/		FOI DAILY LOG 2000 TO PRESENT

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	10/10/2012		REED, JOHN H	
2012-6620	09/11/2012 10/10/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KUICHI UTSUMI Kyorin Pharmaceutical Co.,Ltd.	DMSO (RIMSO-50) - APRVL RECS
2012-6621	09/12/2012 10/11/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Raluca Ciobanu Transcept Pharmaceuticals, Inc.	ZOFRAN - REVIEWS RE DATA FROM QT PROLONGATION STUDY
2012-6622	09/12/2012 10/11/2012	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	EDUARDO ALEMAN GENERAL DE SOLUBLES, S.A.	MCDANIEL'S COFFEE - CONSUMER COMPLAINT, LAB RESULTS
2012-6623	09/12/2012 10/11/2012	FDA/OMPT/CDRH/OCER/DFOI/	Michael Zalewski Intersurgical Incorporataed	K110019
2012-6624	09/12/2012 10/11/2012	FDA/OMPT/CDRH/OCER/DFOI/	Brian Bowman AMERIWATER	K093608 PERFORMANCE TESTING
2012-6625	09/12/2012 10/11/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dr. Pamela Kaleva Colorado Plains Medical Center Pharmacy	GENTAMICIN 10MG/ML NDA
2012-6626	09/12/2012 10/11/2012	FDA/OO/OFBA/OAGS/	Bill Hbranchak Neal R. Gross and Company	A MATTER OF RECORD - CONTRACTS FOR COURT REPORTING AND TRANSCRIPTION SERVICES
2012-6627	09/12/2012 10/11/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Warren Holmes Holmes, Warren	NDA 017861 ACTHAR GEL-SYNTHETIC - SBA
2012-6628	09/12/2012 10/11/2012	OC/OSMP/OOPD/ FDA/OMPT/OSMP/OOPD/	Allison Lowry Arbor Pharmaceuticals, Inc.	SOTALOL (IV) - ORPHAN DRUG DESIGNATION
2012-6629	09/12/2012 10/11/2012	FDA/OMPT/CDRH/OCER/DFOI/	Brian Bowman AMERIWATER	K974899 - PERFORMANCE TESTING
2012-6630	09/12/2012 10/11/2012	OC/CVM/OCD/	Jim Strickland WSB-TV	CHINESE CHICKEN JERKY PLANTS - INSPECTION RECS, PHOTOS, VIDEOS 01/01/2012 - 09/11/2012

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2012-6631	09/12/2012 10/11/2012	FDA/OGROP/ORA/ORO/DIOP/	Eastern Fisheries, Inc.	DALIAN FAR EASTERN SHORES SEAFOOD CO., LTD - ALERT 16-81 SALMONELLA
2012-6632	09/12/2012 10/11/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Carrie Ghose Columbus Business First	LYMPHOSEEK - COMPLETE RESPONSE LETTER
2012-6633	09/12/2012 10/11/2012	OC/ORO/ OC/ORO/	Jeff Gerth PROPUBLICA	MCNEIL CONSUMER HEALTH CARE - 483 12/09/2010 - 12/30/2010 (UNREDACTED)
2012-6634	09/12/2012 10/11/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/MIN-DO/MIN-CB/	Doe J	INDIVIDUAL RECS
2012-6635	09/12/2012 10/11/2012	FDA/OMPT/CDRH/OCER/DFOI/	Richard Waite Innovative Trauma Care	K970439
2012-6636	09/12/2012 10/11/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JEREMY TUBB FULLER TUBB BICKFORD & KRAHL PLLC	COMM BETWEEN DR JEREMY COLES, GLAXO SMITH KLINE & IPS RESEARCH CO - 11/11 TO PRESENT
2012-6637	09/12/2012 10/11/2012	FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/	SHAWN H. HUBER PROFESSIONAL HOSPITAL SUPPLY INC	CARDINAL HEALTH, EL PASO, TX - INSP MOST RECENT
2012-6638	09/12/2012 10/11/2012	FDA/OGROP/ORO/CE-FO/CHI-DO/CHI-CB/	SHAWN H. HUBER PROFESSIONAL HOSPITAL SUPPLY INC	CARDINAL HEALTH, MCGAW PARK, IL - INSP MOST RECENT
2012-6639	09/12/2012 10/11/2012	FDA/OMPT/CDRH/OCER/DFOI/	SHAWN H. HUBER PROFESSIONAL HOSPITAL SUPPLY INC	MEDLINE INDUSTRIES INC, TAMAUZIPAS, MEXICO - INSP MOST RECENT
2012-6640	09/12/2012 10/11/2012	FDA/OGROP/ORO/CE-FO/BLT-DO/BLT-CB/	SHAWN H. HUBER PROFESSIONAL HOSPITAL SUPPLY INC	AVID MEDICAL INC, TOANO, VA - INSP MOST RECENT
2012-6641	09/12/2012 10/11/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	SHELLY A. BLOOR BLACK MCLAUREN JONES ET AL	INDIVIDUAL RECS
2012-6642	09/12/2012 10/11/2012	FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/ OC/ORO/	DOUGLAS N. BLUE, II ZETETIC INC	ENTRY NO 30070573959 - MARS CHOCOLATE

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		OC/ORAI/		
2012-6643	09/12/2012 10/11/2012	FDA/OGROP/ORAI/SE-FO/FLA-DO/FLA-CB/ OC/ORAI/ OC/ORAI/	DOUGLAS N. BLUE, II ZETETIC	ENTRY NO 30070573942 - MARS CHOCOLATE
2012-6644	09/12/2012 10/11/2012	FDA/OGROP/ORAI/NE-FO/NYK-DO/NYK-DCB/	DOUGLAS N. BLUE, II ZETETIC	OTC PRODUCTS - ENTRY NO 10908519084
2012-6645	09/12/2012 10/11/2012	FDA/OC/OES/DFOI/	TROMP, STANLEY .	ESTIMATES OF RADIATION IN FISH RESULTING FROM 2011 EARTHQUAKE IN JAPAN
2012-6646	09/13/2012 11/07/2012	FDA/OGROP/ORAI/CE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORAI/CE-FO/CHI-DO/CHI-CB/ FDA/OGROP/ORAI/CE-FO/DET-DO/DET-CB/ FDA/OGROP/ORAI/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORAI/CE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORAI/NE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORAI/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORAI/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAI/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORAI/SE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORAI/SE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORAI/SW-FO/KAN-DO/KAN-CB/	Rachel Johnson FOI Services, Inc.	RISK EVALUATION AND MITIGATION STRATEGY INSPECTIONS - 483, EIR 01/01/10 TO 08/31/2012
2012-6647	09/13/2012 10/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K082177
2012-6648	09/13/2012 10/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	Earle Canty INTUITIVE SURGICAL	K090993 - EMAILS, ATTACHMENTS

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2012-6649	09/13/2012 10/12/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	ISRs - ADRENALIN, EPINEPHRINE, TWINJECT, ETC
2012-6650	09/13/2012 10/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K091685
2012-6651	09/13/2012 10/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	Charles Schepens	K760550
2012-6652	09/13/2012 10/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K112300
2012-6653	09/13/2012 10/12/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/DET- DO/DET-CB/	Doe J	INDIVIDUAL RECS
2012-6654	09/13/2012 10/12/2012	OC/OSMP/OOPD/	Jane Aoyagi Celgene Corporation	CYREVIA - ORPHAN DRUG DESIGNATION
2012-6655	09/13/2012 10/12/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Eric Gruff E4 Consulting	DOXIL - SBA
2012-6656	09/13/2012 10/12/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Charles Schepens	K760686, K941495
2012-6657	09/13/2012 10/12/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K112805
2012-6658	09/13/2012 10/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K112211
2012-6659	09/13/2012 10/12/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SW-FO/DAL- DO/DAL-CB/	Richard Stephens Stephens , Richard R	SAMPLE 754064
2012-6660	09/13/2012 10/12/2012	FDA/OGROP/ORO/SW-FO/DEN- DO/DEN-CB/	PAUL B CALLAHAN CHARLES RIVER LABS	DR LAWRENCE H ARP, BOULDER, CO - EIRS 6/4-5/12
2012-6661	09/13/2012 10/12/2012	FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/	PAUL B CALLAHAN CHARLES RIVER LABS	CHARLES RIVER LABORATORIES INC, RENO, NV - EIRS 7/18-25/12

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		FDA/OGROP/ORPA/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2012-6662	09/13/2012 10/12/2012	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	PAUL B CALLAHAN CHARLES RIVER LABS	CHARLES RIVER LABORATORIES, INC, DURHAM, NC - EIRS 7/24-27/12
2012-6663	09/13/2012 10/12/2012	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	PAU; B CALAHAN CHARLES RIVER LABS	CHARLES RIVER LABORATORIES INC, FREDERICK, MD - EIRS 7/30-31/12
2012-6664	09/13/2012 10/12/2012	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	PAUL B CALLAHAN CHARLES RIVER LABS	CHARLES RIVER LABORATORIES INC, CHICAGO, IL - EIRS 5/31/12-6/7/12
2012-6665	09/13/2012 10/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	JOHN PAUL HESSBURG KITCH DRUTCHAS ET AL	DIFFERENCES BETWEEN A HEARING AID & A PERSONAL SOUND AMPLIFER PROD - NOTICES, BULLETINS NEWSLETTERS, ETC 1/07 TO PRESENT
2012-6666	09/13/2012 10/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	JOHN PAUL HESSBURG KITCH DRUTCHAS ET AL	HEARING AID PROD BROCHURES -MFR, SELLER, DISTRIBUTOR, LTRS, EMAILS, COMM 1/07 TO PRESENT
2012-6667	09/13/2012 10/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	JOHN PAUL HESSBURG KITCH DRUTCHAS ET AL	INTERNET SALES OF HEARING AIDS OR PERSONAL SOUND AMPLIFER PRODS - LTRS, EMAILS, COMM 1/07 TO PRESENT
2012-6668	09/13/2012 10/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	JOHN PAUL HESSBURG KITCH DRUTCHAS ET AL	HEARING AID MEDICAL WAIVER REQUIREMENTS - LTRS, EMAILS, COMM, ETC 1/07 TO PRESENT
2012-6669	09/13/2012 10/12/2012	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	JOHN PAUL HESSBURG KITCH DRUTCHAS ET AL	HI HEALTHINNOVATIONS - HEARING TESTING, TESTING EQUIPMENT, HEARING AIDS, COMM, ETC 3/29/12 TO PRESENT
2012-6670	09/13/2012 10/16/2012	FDA/OMPT/CDRH/OCER/DFOI/	STEPHANIE PHILBIN GOODWIN PROCTER LLP	INSTRUMENTATION INDUSTRIES, BETHEL PARK, PA - COMM; JEM ENDOTRACHEAL TUBE CHANGER FROM CLASS III P8000068 K102127, LNZ PROD CODE
2012-6671	09/13/2012 10/12/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	SARAH GEISERT GENERAL MILLS	GENERAL MILLS, VINELAND, NJ - EIRS, 483S, CO RESP 11/08
2012-6672	09/13/2012 10/12/2012	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OC/OES/DFOI/	JESSICA FYE JPMorgan Chase	HOSPIRA, AUSTIN, TX - 483 8/12
2012-6673	09/13/2012 10/12/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OES/DFOI/	BINDRA, AMRIT P	CLARIANT CORP - FCN 356; CIBA SPECIATY CHEMICALS CORP - FCN 340; SUN CHEMICAL CORP - FCN 426

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		FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OES/DFOI/		
2012-6674	09/13/2012 10/12/2012	FDA/OFVM/CFSAN/OCD/EOS/	WOODALL, CHELSEA	GENETICALLY ENGINEERED FOODS - QUALITY CONTROL PROCEDURES, CMLPLNTS 1/1/10 TO 1/1/12
2012-6675	09/13/2012 10/12/2012	FDA/OFVM/CFSAN/OCD/EOS/	SUSAN MATTHEES GENERAL MILLS	DKT 2012C-0900
2012-6676	09/13/2012 10/12/2012	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	JEFF COLE WTFX-TV	AMOROSO BAKING CO, PHILADELPHIA, PA - 483 2/4/11
2012-6677	09/13/2012 10/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	REBECCA SHAMES-SCHULZ HOGAN LOVELLS LLP	INCISIVE INC - PINPOINTE FOOTLASER K093545; PINPOINTE USA INC - PINPOINTE FOOTLASER K093547
2012-6678	09/13/2012 10/12/2012	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	ANDREW MILLS BLUE WATER SEAFOOD DISTRIBUTORS	BLUE WATER SEAFOOD DISTRIBUTORS, BOHEMIA, NY - FOOD FACILITY REGISTRATION FEI/CFN NUMBER
2012-6679	09/13/2012 10/12/2012	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	ANDREW MILLS BLUE WATER SEAFOOD DISTRIBUTORS	MELFA COLD STORAGE LLC - FOOD FACILITY REGISTRATION FEI/CFN NUMBER
2012-6680	09/13/2012 10/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	DR PAUL KOSTERS DEMCON ADVANCED MECHATRONICS BV	BMEYE BV - NEXFIN MODEL 2 K101123
2012-6681	09/13/2012 01/07/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	R D SHARMA POLY MEDICURE LTD	BECTON DICKINSON MEDICAL, SANDY, UT - EIR 2005 TO 2012
2012-6682	09/13/2012 10/12/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	CIPROFLOXACIN - RECS
2012-6683	09/13/2012 10/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	Yu-Ju Chiang Chung Yuan Christian University	K050233
2012-6684	09/13/2012 10/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	Eileen Bailey Caliber Therapeutics, Inc.	ENDOGRAB - 510K
2012-6685	09/13/2012 10/12/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	COSTELLO, JANET	FLUZONE HIGH DOSE, PNEUMAVAX 23 - AERS

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2012-6686	09/13/2012 10/12/2012	OC/ORA/ OC/ORA/ FDA/OGROP/ORACE-FO/CHI- DO/CHI-CB/ FDA/OGROP/ORASE-FO/ATL- DO/ATL-CB/	ROBERT D FEAGIN III ROBERT D FEAGIN III LLC	VITA FOODS PRODUCTS INC, SAM'S CLUB - SALMONELLA POISONING INVESTIGATION RECS, Cmplnts, Medical RPTS, ETC
2012-6687	09/13/2012 11/19/2012	FDA/OGROP/ORAPA-FO/SAN- DO/SAN-CB/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	THORATEC - RECS 2011; GILEAD - 483S
2012-6688	09/13/2012 10/12/2012	FDA/OGROP/ORAPA-FO/SAN- DO/SAN-CB/	CHARLES CELESTE EAS Consulting Group, LLC	NOVARTIS VACCINES & DIAGNOSTICS, EMERYVILLE, CA - 483 3/12
2012-6689	09/13/2012 10/15/2012	FDA/OMPT/CDRH/OCER/DFOI/	PAM PUMMILL SYBRON DENTAL SPECIALTIES	LANGFORD IC SYSTEMS INC - MANZI MACH 1 INSTRUMENT CLEANER-PROCESSOR K060458
2012-6690	09/13/2012 10/15/2012	FDA/OMPT/CDRH/OCER/DFOI/	PAM PUMMILL SYBRON DENTAL SPECIALTIES	MINNTECH CORP - RENACLEAN SH DIALYZER CLEANING SYS K033505
2012-6691	09/13/2012 10/15/2012	FDA/OMPT/CDRH/OCER/DFOI/	PAM PUMMILL SYBRON DENTAL SPECIALTIES	POLYMER TECHNOLOGY (WILMINGTON PARTNERS LP) - BOSTON LIQUID ENZYMATC CLEANER K973217
2012-6692	09/14/2012 10/15/2012	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K113572
2012-6693	09/14/2012 10/15/2012	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2010-1600
2012-6694	09/14/2012 10/15/2012	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	F2011-1746
2012-6695	09/14/2012 10/15/2012	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K003425
2012-6696	09/14/2012 10/15/2012	FDA/OMPT/CDRH/OCER/DFOI/	Olivia Chan Branan Medical Corporation	K093879, K111206
2012-6697	09/14/2012 10/15/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Huffaker, Kirk	SPEEDGEL PRO, SPEEDGEL RX, TRANZGEL - NDA, CLINICAL TRIALS, ETC
2012-6698	09/14/2012	FDA/OMPT/CDER/ORP/DIDP/	Brady Huggett	GERON CORP - CORR RE PHASE 1 CLINICAL TRIAL

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	10/15/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	NATURE BIOTECHNOLOGY	
2012-6699	09/14/2012 10/15/2012	OC/OA/OM/OMP/DDM/ FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	JOINT MEETING OF PHARMACEUTICAL SCIENCE & PULMONARY-ALLERGY DRUG ADV COMM - SLIDES 08/16/1996
2012-6700	09/14/2012 10/15/2012	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2011-1642
2012-6701	09/14/2012 10/15/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Geoffrey R Chambers Geoffrey Chambers	AMARIN - CORR WITH FDA 09/07/12
2012-6702	09/14/2012 10/15/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rafe Lewis NORTH RUN CAPITAL LP	QUESTCOR - RECS, EMAIL RE MARKETING AND SALES COMPLAINTS
2012-6703	09/14/2012 10/15/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 8/20-24/12
2012-6704	09/14/2012 10/15/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 8/27-31/12
2012-6705	09/14/2012 10/15/2012	FDA/OC/OES/DFOI/	GLADYS B TONKIN WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 8/20-24/12
2012-6706	09/14/2012 10/15/2012	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 8/20-24/12
2012-6707	09/14/2012 10/15/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 8/20-24/12

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2012-6708	09/14/2012 10/15/2012	FDA/OMPT/CDRH/OCER/DFOI/	AMY KINCARION LEXIS NEXIS COURTLINK INC	JOHNSON & JOHNSON - ORTHO ALL FLEX DIAPHRAGM K080040
2012-6709	09/14/2012 10/15/2012	FDA/OMPT/CDRH/OCER/DFOI/	AMY KINCANON LEXIS NEXIS COURTLINK INC	WOMEN'S HEALTH GLOBAL PHARMACEUTICALS SUPPLY GROUP - CORR REGARDING ORTHO ALL FLEX DIAPHRAGM LBLG, PATIENT INSTRUCTIONS, ETC
2012-6710	09/14/2012 10/15/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 8/20-24/12
2012-6711	09/14/2012 10/15/2012	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAP/PA-FO/SAN-DO/SAN-CB/	Hui-Yun Wang HPC Foods, Ltd.	HPC FOODS LTD, HONOLULU, HI - 483
2012-6712	09/14/2012 10/15/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	THOMAS J MOORE INSTITUTE FOR SAFE MEDICATION PRACTICES	TIBOTEC - INTELENCE (ETRAVIRNE) NDA 22-187; REGENERON - ARCALYST (RILONACEPT) NDA 125-249; WYETH - PRISTIQ (DESVENLAFAXINE) NDA 021-992, ETC - CALENDER DATE ON WHICH THE ORIGINAL IND WAS FILED
2012-6713	09/14/2012 10/15/2012	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	DONALD S STEIN GREENBERG TRAURIG LLP	LIBERTY GOLD, SOUTH SAN FRANCISCO, CA - LIGO SARDINES NAMES OF MFR, SHIPPER, IMPORTER, ETC
2012-6714	09/14/2012 10/15/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 8/27-31/12
2012-6715	09/14/2012 10/15/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 8/20-24/12
2012-6716	09/14/2012 10/15/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 8/27-31/12
2012-6717	09/14/2012 10/15/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 8/27-31/12
2012-6718	09/14/2012 10/15/2012	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 8/27-31/12
2012-6719	09/14/2012 10/15/2012	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 8/27-31/12
2012-6720	09/14/2012 10/15/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 8/20-24/12
2012-6721	09/14/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP	FOI DAILY LOG 8/27-31/12

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	10/15/2012		CanReg, Inc.	
2012-6722	09/14/2012 10/15/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 9/10-14/2012
2012-6723	09/14/2012 10/15/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 9/3-7/2012
2012-6724	09/14/2012 10/17/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Liz Pretzinger Rawls McNelis + Mitchell	INDIVIDUAL RECS
2012-6725	09/14/2012 10/15/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sandra Baksys Baksys , Sandra A	ACTIVELLA LOW-DOSE (.5/.1) HRT - AERS, GENERIC EQUIVALENTS
2012-6726	09/14/2012 10/15/2012	OC/OM/OMP/DDM/	LAUREN NUSSBAUM LAUREN NUSSBAUM	FDA-1997-N-0067
2012-6727	09/14/2012 10/15/2012	OC/OM/OMP/DDM/	FRANCIS QUAYNOR SIDLEY AUSTIN LLP	DKT FDA-2012-P-0632
2012-6728	09/17/2012 10/16/2012	OC/CVM/OCD/	MARVIN SPERLING MY COWORKERS PETS LLC	LIST OF REGISTERED WHOLESALERS OF FLEA & TICK CONTROL PRODUCTS
2012-6729	09/17/2012 10/16/2012	OC/OM/OMP/DDM/	CHRIS CELESTE EAS Consulting Group, LLC	OTC VOLS. 160088, 160421, ETC.
2012-6730	09/17/2012 10/16/2012	FDA/OGROP/ORASE-FO/ATL- DO/ATL-CB/ FDA/OMPT/CDRH/OCER/DFOI/ OC/ORAO/OCI/ OC/ORAO/OCI/	MICHELE L. BUENATE MORGAN LEWIS COUNSELORS AT LAW	AM2PAT INC, ANGIER, NC - INVESTGATION 2007 TO 2008
2012-6731	09/17/2012 10/16/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MICHAEL R. COHEN INSTITUTE FOR SAFE MEDICATION PRACTICES	MEDWATCH MEDICATION ERRORS 8/12
2012-6732	09/17/2012 10/16/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	TRAVIS SCHAFTENAAR UBS GLOBAL ASSET MANAGEMENT	INTERGRA LIFESCIENCES ANDOVER, UK - 483 1/10 TO PRESENT

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2012-6733	09/17/2012 10/16/2012	FDA/OFVM/CFSAN/OCD/EOS/	MADHU G. SONI UBS GLOBAL ASSET MANAGEMENT	LEVOCAMITINE - GRAS 000362
2012-6734	09/17/2012 10/16/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORO/PA-FO/SAN- DO/SAN-CB/ FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/	WIESER, SCOTT	CMPLNT CC127201
2012-6735	09/17/2012 10/16/2012	FDA/OMPT/CDRH/OCER/DFOI/	COLLEEN MULLINS MEDTRONIC VASCULAR	ADVANCED VASCULAR DYNAMICS - RAD VASCULAR COMPRESSION DVC K092503
2012-6736	09/17/2012 10/16/2012	FDA/OMPT/CDRH/OCER/DFOI/	COLLEEN MULLINS MEDTRONIC VASCULAR	TERUMO MEDICAL CORP - TR BAND K070423
2012-6737	09/17/2012 10/16/2012	FDA/OMPT/CDRH/OCER/DFOI/	COLLEEN MULLINS MEDTRONIC VASCULAR	TERUMO CORP - GLIDESHEATH INTRODUCER K033681
2012-6738	09/17/2012 10/16/2012	FDA/OMPT/CDRH/OCER/DFOI/	COLLEEN MULLINS MEDTRONIC VASCULAR	TERUMO MEDICAL CORP - GLIDESHEATH INTRODUCER K082644
2012-6739	09/17/2012 10/16/2012	FDA/OMPT/CDRH/OCER/DFOI/	COLLEEN MULLINS MEDTRONIC VASCULAR	CORDIS CORP - AVANTI TRANS RADIAL CATHETER SHEATH INTRODUCER KIT K962746
2012-6740	09/17/2012 10/16/2012	FDA/OMPT/CDRH/OCER/DFOI/	COLLEEN MULLINS MEDTRONIC VASCULAR	ST JUDE MEDICAL - ULTIMUM ENGAGE TR INTRODUCER K091137
2012-6741	09/17/2012 10/16/2012	FDA/OMPT/CDRH/OCER/DFOI/	COLLEEN MULLINS MEDTRONIC VASCULAR	TERUMO MEDICAL CORP - RADIFOCUS OPTITORQUE ANGIOGRAPHIC CATHETER K082736
2012-6742	09/17/2012 10/16/2012	FDA/OMPT/CDRH/OCER/DFOI/	COLLEEN MULLINS MEDTRONIC VASCULAR	TERUMO CORP - HEARTRAIL III GUIDING CATHETER K092372
2012-6743	09/17/2012 10/16/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORO/NE-FO/NWE- DO/NWE-CB/	ANDREA CLISURA FARUQI & FARUQI LLP	JAMES M BLUM MD, MARSHALL BLUM HERBAL RESEARCH CLINIC - INSP
2012-6744	09/17/2012 10/16/2012	FDA/OFVM/CFSAN/OCD/EOS/	ANGELA SMYTH Iovate Health Sciences	CAERS 155488
2012-6745	09/18/2012 10/17/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/CVM/OCD/	Gary M. O'Bannon Balchem Corporation	POLY (2-VINYLPYRIDINE-CO-STYRENE) - GRAS RECS
2012-6746	09/18/2012	FDA/OMPT/CDER/ORP/DIDP/	Pat Moriarty	AVECIA - 483, WARNING LETTER

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	10/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	HEALTHCOR MANAGEMENT LP	
2012-6747	09/18/2012 10/17/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	MANDELL HORWITZ CONSULTANTS LLC	K855121
2012-6748	09/18/2012 10/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	Sara K. Borrelli Jackson Walker L.L.P.	P110030
2012-6749	09/18/2012 10/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	Sara K. Borrelli Jackson Walker L.L.P.	K113323
2012-6750	09/18/2012 10/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	Sara K. Borrelli Jackson Walker L.L.P.	K102911
2012-6751	09/18/2012 10/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	Richard Nuccitelli BioElectroMed Corp.	K100744
2012-6752	09/18/2012 10/17/2012	FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/ FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/	Rachel Johnson FOI Services, Inc.	ENTRY 235-1509680-0 LAB RESULTS
2012-6753	09/18/2012 10/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tom Burton THE WALL STREET JOURNAL	PRADAXA - LATEST ANALYSIS OR REPORT BY OFFICE OF SURVEILLANCE AND EPIDEMIOLOGY
2012-6754	09/18/2012 10/17/2012	FDA/OGROP/ORASE-FO/FLA- DO/FLA-CB/	Peter Katz NTSB Reporter	RICHARD K. VOGEL, ORMOND BEACH, FLA - 483, WARNING LETTER
2012-6755	09/18/2012 10/17/2012	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2011-3196
2012-6756	09/18/2012 10/17/2012	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2011-2931
2012-6757	09/18/2012 10/17/2012	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2011-3351
2012-6758	09/18/2012 10/17/2012	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	File# 2011-4043. Please see attached.;

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2012-6759	09/18/2012 10/17/2012	FDA/OGROP/ORR/SE-FO/NOL-DO/NOL-CB/	Rachel FOI Services, Inc.	WRIGHT MEDICAL TECHNOLOGIES, ARLINGTON, TN - EIR, 483, CORR 2003-2011
2012-6760	09/18/2012 10/17/2012	FDA/OGROP/ORR/SE-FO/NOL-DO/NOL-CB/	Rachel Johnson FOI Services, Inc.	WRIGHT MEDICAL TECHNOLOGY, ARLINGTON, TN - INVESTIGATOR DIARIES 2003-2011
2012-6761	09/18/2012 10/17/2012	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2011-4044
2012-6762	09/18/2012 10/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SANJAY H SHARMA HETERO USA INC	TOLVAPYSN TABS 15 MG, 30 MG, 60 MG - CHEMISTRY RVWS, BIOEQV RVWS, CORR, ETC
2012-6763	09/18/2012 10/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	SANJAY H SHARMA HETERO USA INC	FEBUXOSTAT TABS 40 MG, 80MG - CHEMISTRY RVWS, BIOEQV RVWS, CORR, ETC
2012-6764	09/18/2012 10/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CROSBY T50417, COURTNEY	RISPERIDONE - BLACK BOX WARNING
2012-6765	09/18/2012 10/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CROSBY, COURTNEY JEROME	ACTOS - BLACK BOX WARNING
2012-6766	09/18/2012 10/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	ERICK NAWROCKI GRYPHON STRATEGIES	CHELSEA THERAPEUTICS - NDA, RESP LTR 3/28/12
2012-6767	09/18/2012 10/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHANNES CZERNIN MD UNIV OF CALIFORNIA -LOS ANGELES	6 - (F-18) FLUORO DOPA IND APPL #30602 - AMENDMENTS
2012-6768	09/18/2012	FDA/OMPT/CDER/ORP/DIDP/		THELIN (SITAXENTAM SODIUM//S) IND #52-527 - PRE-

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	10/17/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	IKER NAVARRO MD	CLNCL SAFETY & TOXICOLOGY RPT SUMMARIES, SS&E, INVESTIGATOR'S BROCHURE
2012-6769	09/18/2012 10/17/2012	FDA/OFVM/CFSAN/OCD/EOS/	WILLIAM A OLSON WASHINGTON INFORMATION SOURCE	MITSUBISHI GAS CHEMICAL CO INC - NYLON NXD-6 FAP 3B4372
2012-6770	09/18/2012 10/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	RAIMUND OBERFOLL BIEDERMANN TECHNOLOGIES GMBH & CO KG	BIEDERMANN MOTECH GMBH, OLNEY, MD - TITANIUM SURGICAL MESH K900138
2012-6771	09/18/2012 10/17/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	THOMAS DEMELFI AMGEN	BOTOX BLA 103000/5215 - APRVL LTR, SUMMARY RVWS, MEDICAL RVWS, ETC
2012-6772	09/18/2012 10/17/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/OA/OM/OMP/DDM/	Fran Ehrlich Ehrlich, Fran E	NOLVADEX - SBA, MTG MINUTES
2012-6773	09/18/2012 10/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	Amy Taulbee Exactech, Inc	K120906
2012-6774	09/18/2012 10/17/2012	FDA/OFVM/CFSAN/OCD/EOS/	Elbert Anderson Elbert C. Anderson	COOGNA NEUTRACEUTICALS, INC - CORR RE GREY DEFENCE
2012-6775	09/18/2012 10/17/2012	FDA/OGROP/ORR/NE-FO/NWE-DO/NWE-CB/	Matt Wiechert Uni Exporter Co.	ST ACQUISITION COMPANY, STRATFORD, CT - EIRS, LAB RESULTS, RECALLS, ETC 2008-PRESENT
2012-6776	09/18/2012 10/17/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Allison Johnson Boehringer Ingelheim Vetmedica, Inc.	BUSHU PHARM, LTD - SAITAMA, JAPAN - EIR, 483 01/01/10-09/17/12
2012-6777	09/18/2012 10/17/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Helga Dimitrov Helga Dimitrov	FLOVENT - AERS
2012-6778	09/18/2012	FDA/OMPT/CDER/GRP/DIDP/	Jay Sirois	OTC METHYL SALICYLATE, MENTHOL, CAPSAICIN

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	10/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CONSUMER HEALTHCARE PRODUCTS ASSOCIATION	PRODUCTS - MEDWATCH FORMS FOR 43 CASES OF SERIOUS BURNS Date
2012-6779	09/18/2012 10/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/OA/OM/OMP/DDM/	Kurt Greve Kurt Greve	ZOLEDRONIC ACID - AERS, SAFETY COMMENTS, STUDIES, ETC
2012-6780	09/18/2012 10/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	DIANA LITTLEWOOD INTERMOUNTAIN VIEW PEDIATRICS	GARDISIL VACCINE - VAERS
2012-6781	09/18/2012 10/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CARMEN R RODRIGUEZ ANACOR	ACTAVIS MID ATLANTIC - ANDA 78-8046; APOTEX CORP- ANDA 78-172; G & W LABS - ANDA 78-233, ETC VIVO CLNCL STUDIES
2012-6782	09/19/2012 10/18/2012	FDA/OC/OES/DFOI/	K Knight K Knight	DICKINSON'S WEBVIEW, ELSEVIER BUSINESS INTELLIGENCE PINK SHEET, ELSEVIER INTELLIGENCE GRAY SHEET, ETC - INVOICES 2008-2012
2012-6783	09/19/2012 10/18/2012	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K101281 - SUMMARY
2012-6784	09/19/2012 10/18/2012	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	CTP - RECS RE CONGRESSIONAL REPORT
2012-6785	09/19/2012 10/18/2012	FDA/OO/OFBA/OAGS/	Kimbell & Associates	HHSF223200950098P
2012-6786	09/19/2012 10/18/2012	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K011238
2012-6787	09/19/2012 10/18/2012	FDA/OMPT/CDRH/OCER/DFOI/	Jean Menager Jean M. Menager, QA/RA Consultant	K992524
2012-6788	09/19/2012 10/18/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K040623 (CERTIFIED)

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2012-6789	09/19/2012 10/18/2012	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K963226 (CERTIFIED)
2012-6790	09/19/2012 10/18/2012	FDA/OMPT/CDRH/OCER/DFOI/	CIVCO Medical Solutions	K032015
2012-6791	09/19/2012 10/18/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K040537
2012-6792	09/19/2012 10/18/2012	OC/CVM/OCD/	Ernst Heinen Aratana Therapeutics	NADA 100-703 - FOIA SUMMARY
2012-6793	09/19/2012 10/18/2012	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	Jessica The Dinner Bell	BOO BOO'S DAWG HOUSE, BLOOMINGTON, IL - INSPECTIONS, COMPLAINTS SINCE 2010
2012-6794	09/19/2012 10/18/2012	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	CTP - CORR, DOCS, MEETING SUMMARIES, ETC WITH E-CIGARETTE MANUFACTURERS
2012-6795	09/19/2012 10/18/2012	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Mark Lepkowski Boehringer Ingelheim Pharmaceuticals Inc	BOEHRINGER-INGELHEIM PHARM, INC, RIDGEFIELD, CT - EIR, COVER SHEET (6/10)
2012-6796	09/19/2012 10/18/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	David Clayton, M.D. CFCG	NDA 21-427 - PEDIATRIC STUDIES
2012-6797	09/19/2012 10/18/2012	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Christina Graziano Kreindler & Kreindler LLP	FRESENIUS MEDICAL CARE NORTH AMERICA - 2008T AND 2008K HEMODIALYSIS MACHINES
2012-6798	09/19/2012 10/18/2012	FDA/OMPT/CDRH/OCER/DFOI/	Roxanna Massa Feldman, Fox & Morgado, P.A.	STRYKER ORTHOPAEDICS TRIATHLON KNEE SYSTEM - ADVERSE EVENTS, PRODUCT INSERTS, CORR ETC
2012-6799	09/19/2012 10/18/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ISR 7086037-5; 7086039-9; 7491291-1; ETC
2012-6800	09/19/2012 10/18/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OCC/	Bob Ortega THE ARIZONA REPUBLIC	BECTON DICKINSON & CO - PMA AND CORR RE: SUREPATH
2012-6801	09/19/2012 10/18/2012	OC/OER/OPA/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	MORGAN LISCINSKY - CORR WITH BLOOMBERG RE: VAGINAL MESH IMPLANT (CERTIFIED)
2012-6802	09/19/2012	FDA/OFVM/CFSAN/OCD/EOS/		ASPARTAME, STEVIA, SUCALOSE, ETC - SAFETY

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	10/18/2012		COUNCE #1615082, KENNETH	CONCERNS REGARDING COOKING
2012-6803	09/19/2012 10/18/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/NWJ- DO/NWJ-CB/	TERRENCE M POLIC CLIFFORD & RAIHALA SC	INDIVIDUAL RECS
2012-6804	09/19/2012 10/18/2012	FDA/OMPT/CDRH/OCER/DFOI/	JAY L BREAKSTONE PARKER & WAICHMAN ATTYS	MEDTRONIC - INFUSE BONE GRAFT LT-CAGE; LUMBAR TAPERED FUSION DVC MDRS, CORR, TESTING, ETC
2012-6805	09/19/2012 10/18/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	JOHN E HALL MEDICINE HALL	ZOLL MEDICAL INC - LIFE VEST WEARABLE CARDIAC DEFIBRILLATOR 510K CLEARANCE LTR
2012-6806	09/19/2012 10/18/2012	FDA/OC/OES/DFOI/	HOLMES, GLENN	COUNTRY OF ORIGIN WHERE WALMART GETS ITS BEEF, POULTRY, PORK 1/1/89 TO 8/25/12
2012-6807	09/19/2012 10/18/2012	OC/OM/OMP/DDM/	CHRIS CELESTE EAS Consulting Group, LLC	OTC VOLS. 160021, 160041, ETC.
2012-6808	09/19/2012 10/18/2012	FDA/OO/OFBA/OAGS/	JOHN FITZGERALD JOMEL NACAHA INC	LIST OF PERSONNEL IN POSSESSION OF A GOVERNMENT CREDIT CARD, AND PERSONNEL AUTHORIZED TO PURCHASE OFFICE SUPPLIES
2012-6809	09/19/2012 10/18/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SW-FO/KAN- DO/KAN-CB/	MARY LOU STOKKE GARDEN FRESH VEGETABLES LLC	ENGLISH CUCUMBERS - RPTS ON SPLS 9/10/12
2012-6810	09/19/2012 10/18/2012	OC/ORO/ORM/ OC/ORO/ORM/	GAIL LESSICK LACHMAN CONSULTANT SERVICES INC	DOMESTIC AND FOREIGN DRUG COMPANIES, MEDICAL DVC MFRS, BIORESEARCH MONITORING (BIMO), ETC - INSPS 7/1-31/12
2012-6811	09/19/2012 10/18/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 9/3-7/12
2012-6812	09/19/2012 10/18/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELLIOT FAVUS MD FAVUS INSTITUTIONAL RESEARCH LLC	ADCETRIS (BRENTUXIMAB VEDOTIN) - AERS
2012-6813	09/19/2012 10/18/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	RECLAST - AERS
2012-6814	09/19/2012 10/18/2012	FDA/OMPT/CDRH/OCER/DFOI/	JOHN PAUL HESSBURG KITCH DRUTCHAS ET AL	PERSONAL SOUND AMPLIFIER PROD REGARDING COMPLIANCE WITH VIOLATION OF FDA RULES - LTRS,

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				EMAILS, COMM 1/07 TO PRESENT
2012-6815	09/19/2012 10/18/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JIM DARNELL STAYMA CONSULTING SERVICES LLC	TERESINA HOLDLINGS LLC - NITROFURAN SUSPENSION ANDA 201-462 RECS
2012-6816	09/19/2012 10/18/2012	FDA/OMPT/CDRH/OCER/DFOI/	JOHN PAUL HESSBURG KITCH DRUTCHAS ET AL	PERSONAL SOUND AMPLIFIER PROD - MFR, DISTRIBUTOR, SELLER LTRS, EMAILS, COMM REGARDING COMPLIANCE WITH OR VIOLATION OF FDA RULES 1/07 TO PRESENT
2012-6817	09/19/2012 10/18/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JIM DARNELL STAYMA CONSULTING SERVICES LLC	TERESINA HOLDLINGS LLC - BUTALBITAL, ACETAMINOPHEN, CAFFEINE CAPS ANDA 200-184 RECS 3/10/10 TO PRESENT
2012-6818	09/19/2012 10/18/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JIM DARNELL STAYMA CONSULTING SERVICES LLC	TERESINA HOLDLINGS LLC - BUTALBITAL, ACETAMINOPHEN TABS ANDA 91-499 RECS 5/5/10 TO PRESENT
2012-6819	09/19/2012 10/18/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JIM DARNELL STAYMA CONSULTING SERVICES LLC	TERESINA HOLDLINGS LLC - HYDROCODONE BITARTRATE AND ACETAMINOPHEN ORALSOL ANDA 91-021 RECS 6/9/11 TO PRESENT
2012-6820	09/19/2012 01/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	ENN-LING CHEN HEART IMAGING TECHNOLOGIES LLC	MERGE OEM, ONTARIO, CANADA - K092915
2012-6821	09/19/2012 10/18/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JIM DARNELL STAYMA CONSULTING SERVICES LLC	TERESINA HOLDLINGS LLC - BUTALBITAL, ACETAMINOPHEN CAPS ANDA 202-018 RECS 6/25/10
2012-6822	09/19/2012 10/18/2012	FDA/OMPT/CTP/OD/	MARK E GREENWOLD CAMPAIGN FOR TOBACCO- FREE KIDS	LORILLAND INC - APPL TRACKING NUMBERS SE0003730, SE0003731 RECS
2012-6823	09/19/2012 10/18/2012	FDA/OMPT/CDRH/OCER/DFOI/	JENNY TUCKER WAGSTAFF & CARTMELL LLP	ORTHOPAEDIC & REHABILITATION DVC A/C - METAL ON METAL HIP IMPLANT SYS EXECUTIVE SUMM MEMO 6/27- 28/12
2012-6824	09/19/2012 10/18/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SANJAY H SHARMA HETERO USA INC	SAPHRIS (ASENAPINE) SUBLINGULA TABS- CHEMISTRY RVWS, BIOEQV RVWS, ADMINISTRATIVE RECS, ETC

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2012-6825	09/19/2012 10/18/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SANJAY H SHARMA HETERO USA INC	VITRAMUNE XR (NEVIRAPINE ER TABS) 400 MG (VITRAMUNE XR) - CHEMISTRY RVWS, BIOEQV RVWS, ADMINISTRATIVE RECS, ETC
2012-6826	09/19/2012 10/18/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SANJAY H SHASRMA HETERO USA INC	ONGLYA (SAXAGLIPTIN) TABS 2.5 MG, 5 MG (ONGLYZA) - CHEMISTRY RVWS, BIOEQV RVWS, ADMINISTRATIVE RECS, ETC
2012-6827	09/19/2012 10/18/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/	Doe J	THE VITAMIN SHOPPE, COLUMBIA, SC - SPIRUTEIN TROPICAL FRUIT PROTEIN POWDER CMLPNT
2012-6828	09/19/2012 10/18/2012	FDA/OMPT/CDRH/OCER/DFOI/	MICHAEL P QUINN DECOF & DECOF PC	BOSTON SCIENTIFIC CORP (BEI MEDICAL SYS) - HYDRO THERMABLATOR ENDOMETRIAL ABLATION SYS P000040/S001-S024
2012-6829	09/19/2012 10/18/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ALISON M AGNEW PILLSBURY WINTHROP SHAW PTTMAN LLP	BIO VECTRA INC, CHARLOTTESTOWN, CANADA - EIRS, 483S, CO RESP 8/10
2012-6830	09/19/2012 10/18/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LALITHA SUBRAMANIAN DR REDDY'S LABORATORIES INC	SANDOZ - ENOXAPARIN SODIUM SBA
2012-6831	09/19/2012 10/18/2012	FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	JASON GINSBERG SITARAS & ASSOCIATES PC	AIRSEP CORP, BUFFALO, NY - NEW LLIFE ELITE OXYGEN CONCENTRATOR RECS
2012-6832	09/19/2012 10/18/2012	FDA/OGROP/ORO/CE-FO/PHI-DO/PHI-CB/	DEBORAH JONES CARDIONET	CARDIONET INC, CHESTER, PA - EIR 7/10/12

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2012-6833	09/20/2012 10/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	Peter Pirsch Surveyor Capital	INSULET - PENDING 510K INSULIN INFUSION PUMP
2012-6834	09/20/2012 10/19/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Andrew Morgen Morgen, Andrew C	STATINS - PANCREATIC CANCER
2012-6835	09/20/2012 10/19/2012	FDA/OMPT/CTP/OD/	Joseph Manuppello PETA	CTP - MEETINGS WITH SHAREHOLDESR; LIST OF MEETING REQUESTS; DATES OF RESPONSE
2012-6836	09/20/2012 10/19/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Taylor Monroe Anh N Le DDS	DR ANH N LE - FORM 2597 FOR GENDEX 9000
2012-6837	09/20/2012 10/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	Paul MacDonald Nova Biomedical Corporation	K080641
2012-6838	09/20/2012 10/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	JIM CARPER Jim Carper	BREAST IMPLANT DEVICE - CURRENT PMA
2012-6839	09/20/2012 10/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	JIM CARPER Jim Carper	PMA - SILICONE IMPLANTS BY MENTOR, MCGHAN, DOW CORNING, ETC
2012-6840	09/20/2012 10/19/2012	OC/OA/OM/OMP/DDM/	Jim Carper	GUIDANCE FOR SALINE, SILICONE GEL AND ALTERNATIVE BREAST IMPLANTS; GUIDANCE FOR INDUSTRY AND FDA
2012-6841	09/20/2012 10/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	Jim Carper	SILICONE BREAST IMPLANT - PRODUCT SAFETY UPDATE REPORT 09/19/1991 - 09/19/1992
2012-6842	09/20/2012 10/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K040537
2012-6843	09/20/2012 10/19/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6207 REQUEST LETTER
2012-6844	09/20/2012 10/19/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6141 REQUEST LETTER
2012-6845	09/20/2012 10/19/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6144 REQUEST LETTER
2012-6846	09/20/2012 10/19/2012	FDA/OFVM/CFSAN/OCD/EOS/	Alec White HEALTHCOR MANAGEMENT LP	LIVING ESSENTIALS LLS - AERS
2012-6847	09/20/2012 10/19/2012	FDA/OFVM/CFSAN/OCD/EOS/	Alec White HEALTHCOR MANAGEMENT LP	MONSTER BEVERAGE CORP - AERS

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2012-6848	09/20/2012 10/19/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6182 REQUEST LETTER
2012-6849	09/20/2012 10/19/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6212 REQUEST LETTER
2012-6850	09/20/2012 10/19/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/OCOS/OES/ OC/OCOS/OES/ OC/OCOS/OL/	Anthony DeCarlo DeCarlo, Anthony M	TESTING OF GMO'S ON HUMAN BEINGS - SAFETY RECS
2012-6851	09/20/2012 10/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	Patrick H. Win, MD Win-Reed Medical Technologies	K031630, K011979, K003195, ETC
2012-6852	09/20/2012 10/19/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6117 REQUEST LETTER
2012-6853	09/20/2012 10/19/2012	FDA/OFVM/CFSAN/OCD/EOS/	Alec White HEALTHCOR MANAGEMENT LP	RED BULL GMBH - AERS
2012-6854	09/20/2012 10/19/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-5624
2012-6855	09/20/2012 10/19/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-5694
2012-6856	09/20/2012 10/19/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-4785
2012-6857	09/20/2012 10/19/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2010-582
2012-6858	09/20/2012 10/19/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-4261
2012-6859	09/20/2012 10/19/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-4817
2012-6860	09/20/2012 10/19/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-5485
2012-6861	09/20/2012 10/19/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-5352
2012-6862	09/20/2012 10/19/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-2320
2012-6863	09/20/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2012-3910

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	10/19/2012		MERCK & CO., INC.	
2012-6864	09/20/2012 10/19/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-4216
2012-6865	09/20/2012 10/19/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-5606
2012-6866	09/20/2012 10/19/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-5305
2012-6867	09/20/2012 10/19/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Harold J. Light LAW OFFICES OF HAROLD J. LIGHT	DILAUDID INJECTION 1 MG, 2 MG - LABELING, PACKAGE INSERT, RX INFO, ETC
2012-6868	09/20/2012 10/19/2012	FDA/OFVM/CFSAN/OCD/EOS/	JUSTINE HENKES Sure Pure	VITAMIN D2 BAKERS YEAST - FAP 9A4779
2012-6869	09/20/2012 10/19/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KINGRY 0687521, STEVEN	CIPRO - AERS 1989 TO PRESENT
2012-6870	09/20/2012 10/19/2012	OC/OM/OMP/DDM/	CHRIS CELESTE EAS Consulting Group, LLC	DKT LOG FDA-1995-S-0039
2012-6871	09/20/2012 10/19/2012	OC/OM/OMP/DDM/	JONATHAN BERMAN JONES DAY	DKT & DKT LOG OF 1978N-0038
2012-6872	09/20/2012 10/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	THEA LIND HealthPartners	ELVA - FIBERS & CONNECTORS APRVL
2012-6873	09/20/2012 10/19/2012	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HAWKINS, JUANITA M	CELEGENE CORP - EIR 4/11 TO 9/16/12

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2012-6874	09/20/2012 10/19/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	HUBER, MARIE .	D9902B - IND AMENDMENTS 1/3/08-1/18/09
2012-6875	09/20/2012 10/19/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	A. FRANK ROTHSCHILD, PhD. CENTER FOR CONTEMPORARY EQUINE STUDIES	2012-5098 MINOR DELETIONS
2012-6876	09/20/2012 10/19/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	NATHANIEL ENOS CONWAY HOMER & CHIN- CAPLAN PC	INDIVIDUAL RECS
2012-6877	09/20/2012 10/19/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ OC/ORO/OCI/ OC/ORO/OCI/ FDA/OGROP/ORO/NE-FO/NWE- DO/NWE-CB/	KATHRYN E. WHITE EPSTEIN BECKER & GREEN PC	GREENWICH HOSPITAL, GREENWICH, CT - BLOOD VIAIS INVESTIGATION 5/29/11 TO PRESENT
2012-6878	09/20/2012 10/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	JENNIFER D. NEWBERGER Hyman, Phelps & McNamara, P.C.	PALO VIA SKIN RENEWING LASER K090525 - WARNING LTRS, MDRS, COMPLNTS, ETC
2012-6879	09/21/2012 10/22/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	EISAI, JAPAN - EIR, 483,CORR 04/23/12-26/2012
2012-6880	09/21/2012 10/22/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	NDA 21356 S 025
2012-6881	09/21/2012 10/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	Dennis McLaughlin Philips Healthcare	K103489
2012-6882	09/21/2012 10/22/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SE-FO/ATL- DO/ATL-CB/	Doe J	KIRKLAND INFANT FORMULA - TEST RESULTS, REGISTRATION INFORMATION
2012-6883	09/21/2012 10/22/2012	OC/CVM/OCD/ OC/ORO/	Brad Armistead Arthur Dogswell	PET JERKY - COMPLAINTS SINCE 2007

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		OC/ORAI/		
2012-6884	09/21/2012 10/22/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Linda Awdishu UC San Diego	DRUG INDUCED KIDNEY INJURY - AERS
2012-6885	09/21/2012 10/22/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	James Hinson ROCKWELL MEDICAL TECHNOLOGIES INC	ANDA 075746, ANDA 075766. ANDA 077102, ETC - PACKAGE INSERTS
2012-6886	09/21/2012 10/22/2012	FDA/OC/OES/DFOI/	Brian Frenzel Tosk, Inc.	METHOTEXATE - SALES DATA
2012-6887	09/21/2012 10/22/2012	FDA/OC/OES/DFOI/	Brian Frenzel Tosk, Inc.	BLEOMYCIN - SALES DATA
2012-6888	09/21/2012 10/22/2012	OC/OA/OM/OMP/DDM/	Greg Hunt UNIVERSITY MEDICAL PHARMACEUTICALS CORP.	DOCKET 78N-03-1, VOL 060007-B THROUGH 060174
2012-6889	09/21/2012 10/22/2012	FDA/OC/OES/DFOI/	Brian Frenzel Tosk, Inc.	DOXORUBICIN - SALES DATA
2012-6890	09/21/2012 10/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	General Electric Co.	K103483
2012-6891	09/21/2012 10/22/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Liz Pretzinger Rawls McNelis + Mitchell	INDIVIDUAL RECS
2012-6892	09/21/2012 10/22/2012	OC/CVM/OCD/ OC/ORAI/ OC/ORAI/	Brad Armistead Arthur Dogswell	DOG FOOD COMPLAINTS SINCE 2007
2012-6893	09/21/2012 10/22/2012	FDA/OGROP/ORAI/SE-FO/FLA- DO/FLA-CB/	Branch Banking & Trust Company	COMMUNITY BLOOD CENTERS OF FLORIDA, INC. - WARNING LETTERS, CORR 01/01/2011 - 09/21/2012
2012-6894	09/21/2012 10/22/2012	FDA/OGROP/ORAI/CE-FO/MIN- DO/MIN-CB/	Steven Huff Board Surveyor or Cody Wiberg Executive Director Minnesota Board of Pharmacy	MINNESOTA INDEPENDENT COOPERATIVE - FIELD AUDIT 07/01/2012 - 09/21/2012
2012-6895	09/21/2012 10/22/2012	OC/ORAI/ OC/ORAI/	Balchem Corporation	BALCHEM, SLATE HILL, NY - FFR 10252541462
2012-6896	09/21/2012 10/22/2012	OC/ORAI/ OC/ORAI/	GARY M. O'BANNON Balchem Corporation	BALCHEM, VERONA, MO - FFR 18030626976

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2012-6897	09/21/2012 10/22/2012	OC/OROA/ OC/OROA/	GARY M. O'BANNON Balchem Corporation	BALCHEM, SALT LAKE CITY, UT - FFR 16918900624
2012-6898	09/21/2012 10/22/2012	OC/OROA/ OC/OROA/	GARY M. O'BANNON Balchem Corporation	BALCHEM, SAINT GABRIEL, LA - FFR 15674888176
2012-6899	09/21/2012 10/22/2012	OC/OROA/ OC/OROA/	GARY M. O'BANNON Balchem Corporation	BALCHEM, NEW HAMPTON, NY - FEI 11573438790
2012-6900	09/21/2012 10/22/2012	OC/OROA/ OC/OROA/	GARY M. O'BANNON Balchem Corporation	BALCHEM, MORRISBURG, ONTARIO CANADA - FFR 17704795344
2012-6901	09/21/2012 10/22/2012	OC/OROA/ OC/OROA/	GARY M. O'BANNON Balchem Corporation	BALCHEM, GREEN POND, SC - FFR 16922233078
2012-6902	09/21/2012 10/22/2012	OC/OROA/ OC/OROA/	GARY M. O'BANNON Balchem Corporation	BALCHEM, COVINGTON, VA - FFR 17143886916
2012-6903	09/21/2012 10/22/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/OROA/SW-FO/KAN- DO/KAN-CB/	MARY LOU STOKKE GARDEN FRESH VEGETABLES LLC	GARDEN FRESH VEGETABLES, O'NEIL, NE - ENGLISH CUCUMBER SAMPLE INVESTIGATION 9/10/12
2012-6904	09/24/2012 10/23/2012	FDA/OGROP/OROA/CE-FO/NWJ- DO/NWJ-CB/	Rachel Johnson FOI Services, Inc.	PF LABORATORIES, TOTOWA, NJ - EIR, 483, CORR
2012-6905	09/24/2012 10/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Cody Parsons, PharmD Canidate Miami Valley Hospital	PRADAXA, XARELTO - MEDWATCH REPORTS
2012-6906	09/24/2012 10/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	James R. Dennewill MED-LOGICS, Inc.	K082845
2012-6907	09/24/2012 10/23/2012	FDA/OGROP/OROA/NE-FO/NWE- DO/NWE-CB/	Rachel Johnson FOI Services, Inc.	RHODES TECHNOLOGIES, COVENTRY, RI - EIR, 483, CORR 04/15/2010 - 05/05/2010
2012-6908	09/24/2012 10/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	HUMANITARIAN USE DEVICES - APPLICANTS, INDICATIONS, YEAR APPROVED, ETC
2012-6909	09/24/2012 10/23/2012	OC/OROA/ORM/ OC/OROA/ORM/	SCOTT THURM WALL STREET JOURNAL	DRUG GMP INSPS WHERE 483S WERE ISSUED 2000 TO PRESENT
2012-6910	09/24/2012 10/23/2012	FDA/OMPT/CTP/OD/ OC/OCOS/OES/ OC/OCOS/OES/ OC/OCOS/OL/	ERIN E SEDER VENABLE LLP	ELECTRONIC CIGARETTES - RECS

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		OC/OA/OM/OMP/DDM/ FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2012-6911	09/24/2012 10/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	JOHN CREWDSON PROJECT ON GOVERNMENT OVERSIGHT	BAYER CORP - CIPROFLOXACIN CLNCL STUDIES 100169 AND 100201 INVESTIGATION RECS 10/22/08 TO PRESENT
2012-6912	09/24/2012 10/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	ANGELA SOZIO DANKER MILSTEIN & RUFFO PC	INDIVIDUAL RECS
2012-6913	09/24/2012 10/30/2012	FDA/OGROP/ORAP/PA-FO/LOS- DO/LOS-CB/	POLINA BERNSTEIN BERNSTEIN & FRIEDLAND PC	INDIVIDUAL RECS
2012-6914	09/24/2012 10/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN CREWDSON PROJECT ON GOVERNMENT OVERSIGHT	BAYER HEALTHCARE PHARMS - CIPRO (CIPROFLOXACIN HCI) IND 19-537 PROTOCOL #100169 INVESTIGATION RECS
2012-6915	09/24/2012 10/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	VAL SAWYER ZYMOGENETICS INC	BOVINE THROMBIN/THROMBIN NOS/THROMBIN LOCAL SOL - ISRS 8387210, 8394163, 8478069
2012-6916	09/24/2012 10/23/2012	FDA/OFVM/CFSAN/OCD/EOS/	SUE LANDSITTEL MORRISON & FOERSTER LLP	LEAD IN GRAPE JUICE - TEST RESULTS 1/06 TO PRESENT, CHAIN OF CUSTODY, QUALITY ASSURANCE, ETC
2012-6917	09/24/2012 10/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DON J MIZERK HUSCH BLACKWELL LLP	ACTAVIS ELIZABETH - INTUNIV ANDA 20-088 APRVL LTR 6/29/12
2012-6918	09/24/2012 10/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DON J MIZERK HUSCH BLACKWELL LLP	WATSON LABS INC - LIDODERM ANDA 200-675 APRVL LTR 8/23/12

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2012-6919	09/24/2012 10/23/2012	FDA/OC/OES/DFOI/	ANDREW KINDER JAMES MINTZ GROUP INC	BD - SUREPATH FLUID COLLECTION VIAL FOI REQUESTS
2012-6920	09/24/2012 10/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	ANDREW KINDER JAMES MINTZ GROUP INC	BECTON DICKINSON - BD SUREPATH FLUID COLLECTION VIAL EMAILS, LTRS, EXHIBITS, ETC 1/11 TO PRESENT
2012-6921	09/24/2012 10/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Iona Evans Labaton Sucharow LLP	NDA 050606, NDA 050606 S26, ANDA 06545, ETC - ACTION PACKAGES
2012-6922	09/24/2012 10/23/2012	FDA/OC/OES/DFOI/	DAVID P JORDAN THOMSON REUTERS	CONTRACT RESEARCH ORGANIZATION (CRO), DRUG MFRS, REPACKERS, ETC - FOREIGN AND DOMESTIC INSPS 4/12 TO PRESENT
2012-6923	09/24/2012 10/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	Nicholas Blank Blackpeak Group	SHANDONG WEIGAO MEDICAL POLYMER CO LTD, WEIHAI, CHINA - MOST RECENT EIR
2012-6924	09/24/2012 10/23/2012	OC/OER/OPA/	FOI Services, Inc.	BLOOMBERG NEWS ARTICLE - J&J SOLD VAGINAL MESH IMPLANT AFTER SALES HALT ORDERED CORR 6/26/12 (CERTIFIED)
2012-6925	09/24/2012 10/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SUZIE KESCHAMRUS MD AVANIR PHARMACEUTICALS INC	NUJEXTA (DESTROMETHORPHAN HYDROBROMIDE) NDA 21-879 - AERS
2012-6926	09/24/2012 10/23/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	CHRISTOPHER HENDEL CONSUMER REPORTS	SANOPI-PASTEUR - FLUZONE HIGH-DOSE INFLUENZA VACCINE VAERS 12/09 TO PRESENT
2012-6927	09/24/2012 10/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	CYMBALTA - AERS
2012-6928	09/24/2012 10/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PAMELA SCHANEEN SHIONOGI INC	VAGIFEM (ESTRADIOL VAGINAL TABS) NDA 20-908 - SBA
2012-6929	09/24/2012 10/23/2012	OC/OM/OMP/DDM/	JONES DAY	DKT 1978N-0038
2012-6930	09/24/2012 10/23/2012	FDA/OC/OES/DFOI/	GOONEWARDENA, PRASANNA	2012-6291 (CERTIFIED)

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2012-6931	09/24/2012 10/23/2012	FDA/OC/OES/DFOI/	ALI ABBASI MD PHARM D NCM USA	FLUDEOXYGLUCOSE F-18 INJ - NON-COMPLIANCES RPTS
2012-6932	09/24/2012 10/23/2012	FDA/OC/OES/DFOI/	ALI ABBASI MD PHARM D NCM USA	AMMONIA N13 - NON-COMPLIANCE RPTS
2012-6933	09/24/2012 10/23/2012	FDA/OC/OES/DFOI/	ALI ABBASI MD PHARM D NCM USA	SODIUM FLUORIDE F-18
2012-6934	09/25/2012 10/24/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 9/17-21/12
2012-6935	09/25/2012 10/24/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 8/6-10/12
2012-6936	09/25/2012 10/24/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	CLOSED FOIA REQUESTS 9/17-21/12
2012-6937	09/25/2012 10/24/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	CLOSED FOIA REQUESTS 9/10-14/12
2012-6938	09/25/2012 10/24/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 9/17-21/12
2012-6939	09/25/2012 10/24/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 9/10-14/12
2012-6940	09/25/2012 10/24/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 9/10-14/12
2012-6941	09/25/2012 10/24/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 9/17-21/12
2012-6942	09/25/2012 10/24/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 9/17-21/12
2012-6943	09/25/2012 10/24/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 9/17-21/12
2012-6944	09/25/2012 10/24/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 9/10-14/12
2012-6945	09/25/2012 10/24/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	TOSHIO MURATA NIDEK INC	LENSX LASER - 550 LASER SYS K082947, K092674; TECHNOLAS PERFECT VISION GMBH - VICTUS FEMTOSECOND LASER PLATFORM K120426; OPTIMEDICA CORP - CATALYS PRECISION LASER SYS K113479, ETC
2012-6946	09/25/2012	FDA/OMPT/CDER/ORP/DIDP/		GLAXOSMITH - FLOVENT HFA 220 MCG OTY12 INHALER

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	10/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SEDO, MARY	AERS
2012-6947	09/25/2012 10/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOANNE S HAWANA ARENT FOX LLP	BURNS ASSOCIATED WITH THE USE OF OTC TOPICAL MUSCLE & JOINT PAIN RELIEVERS (PATCHES, BALMS, & CREAMS) - AERS
2012-6948	09/25/2012 10/24/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	WILIAM SARRAILLE SIDLEY AUSTIN LLP	ST JUDE MEDICAL - FOIA REQUESTS & RESP 09/20/2011 to 09/20/2012
2012-6949	09/25/2012 10/24/2012	FDA/OGROP/ORR/SE-FO/SJN-DO/SJN-CB/ FDA/OGROP/ORR/SE-FO/SJN-DO/SJN-CB/	PATRICIA SABATINI PITTSBURGH POST-GAZETTE	MYLAN INC - RESP TO WARNING LTR, EIRS, 483S 10/13/11
2012-6950	09/25/2012 10/24/2012	FDA/OGROP/ORR/NE-FO/NWE-DO/NWE-CB/	GERHARDT, NATHAN	GLOBAL BIOTECHNOLOGIES INC, PORTLAND, ME - 483S 1/25/12-3/116/12
2012-6951	09/25/2012 10/24/2012	FDA/OGROP/ORR/NE-FO/NWE-DO/NWE-CB/ OC/OCOS/OL/ FDA/OC/OES/DFOI/	DAVID J D'ALOIA SAIBER ATTY	C R BARDS INC - RECALL EXTRA-LARGE SIZED COMPOSIX & LARGE OVAL LARGE CIRLE KUGEL PATCH PRODS, COMM, ETC 12/05, 1/06, 2/06, 3/06
2012-6952	09/25/2012 10/24/2012	OC/CVM/OCD/	VERONICA KNAPP HOGAN LOVELLS LLP	LALLEMAND ETHANOL TECHNOLOGY - TRANSFERM SAFETY RECS
2012-6953	09/25/2012 10/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	IPD Analytics, LLC	ANDA 078020 EFFECTIVE APPROVAL LTR
2012-6954	09/25/2012 10/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Thomas Perls MD, MPH BOSTON UNIVERSITY SCHOOL OF MEDICINE	CORR RE INCREASED CARDIOVASCULAR RISK ASSOCIATED WITH TESTOSTERONE ADMINISTRATION
2012-6955	09/25/2012 10/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Chris Hall PHT Corporation	DRUGS APPROVED BASED ON CLINICAL TRIAL DATE COLLECTED VIA ELECTRONIC PATIENT REPORTED OUTCOMES AND PAPER REPORTED OUTCOMES - DRUG NAME, SPONSOR, NDA DATE, ETC
2012-6956	09/25/2012	FDA/OMPT/CDER/ORP/DIDP/		INDIVIDUAL RECS

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	10/24/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	
2012-6957	09/25/2012 10/24/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SE-FO/NOL- DO/NOL-CB/	Kelly Warren International Specialty Supply, INC	SAMPLE RESULTS 720182
2012-6958	09/25/2012 10/24/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SW-FO/DEN- DO/DEN-CB/	Andy Frame FOOD SAFETY NEWS	JENSEN FARMS, COLORADO - INVESTIGATION RECS RE CANTALOUPE
2012-6959	09/25/2012 10/24/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2011-5107
2012-6960	09/25/2012 10/24/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	HUMIRA S 16, 45, 46
2012-6961	09/25/2012 10/24/2012	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2011-5106
2012-6962	09/25/2012 10/24/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SE-FO/NOL- DO/NOL-CB/	Kelly Warren International Specialty Supply, INC	SAMPLE RESULTS 760455
2012-6963	09/25/2012 10/24/2012	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2011-6042
2012-6964	09/25/2012 10/24/2012	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2011-5318
2012-6965	09/25/2012 10/24/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LEERINK SWANN & CO	TIOTROPIUM - REVIEW RECORDS RE APPROVAL OF EXACERBATION CLAIM
2012-6966	09/26/2012 10/25/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN CREWDSON PROJECT ON GOVERNMENT OVERSIGHT	BIORESEARCH MONITORING PROGRAM - LIST OF INVESTIGATIONS (HUMAN DRUGS) 1/07 TO PRESENT

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2012-6967	09/26/2012 10/25/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JASON T SAYERS VENABLE LLP	CEREBYX (FOSPHENYTOIN SODIUM) NDA 20-450 - LBLG, PI 1/02 TO PRESENT; FOSPHENYTOIN SODIUM ANDA 78-158 - LBLG, PI 1/06 TO PRESENT
2012-6968	09/26/2012 10/25/2012	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/ FDA/OMPT/CDRH/OCER/DFOI/	JAY L BREAKSTONE PARKER & WAICHMAN ATTYS	MEDTRONIC - INFUSE BONE GRAFT LT-CAGE; LT-CAGE LUMBAR TAPERED FUSION DVC CGMP REQUIREMENTS, CORR
2012-6969	09/26/2012 10/25/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	COLLINS, SARAH	MELATONIN - AERS
2012-6970	09/26/2012 10/25/2012	FDA/OFVM/CFSAN/OCD/EOS/	DAVID C STEINBERG STEINBERG & ASSOCIATES INC	UV GELS FOR NAIL ENHANCEMENT - CAERS
2012-6971	09/26/2012 10/25/2012	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/ FDA/OMPT/CDRH/OCER/DFOI/	KENNON DANIELS PHD BEAUFORT LLC	ORALDNA LABS INC, BRENTWOOD, TN 11/21-23/11; HEMOCUE A/B, ANGELHOLM, SWEDEN 10/24-26/11 - EIRS
2012-6972	09/26/2012 10/25/2012	FDA/OFVM/CFSAN/OCD/EOS/	KIM, GRACE	LIST OF COSMETIC BRAND NAMES LEGALLY SOLD IN THE US
2012-6973	09/26/2012 11/28/2012	FDA/OMPT/CDRH/OCER/DFOI/	LUCIAN GROVE MD PRIMARY CARE ASSOCIATES	DISCOVERY GROVE LLC - COMM
2012-6974	09/26/2012 10/25/2012	FDA/OC/OES/DFOI/	TIMOTHY M WHITING WHITING LAW GROUP LTD	SIMPLY THICK THICKENING GEL - RECS 2009 TO PRESENT
2012-6975	09/26/2012 10/25/2012	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	KATY MORTON TOPICA PHARMACEUTICALS INC	DPT LAKEWOOD LLC, LAKEWOOD, NJ - EIR 1/11 TO PRESENT
2012-6976	09/26/2012 10/25/2012	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	KATY MORTON TOPICA PHARMACEUTICALS INC	DPT LABORATORIES LTD, SAN ANTONIO, TX - EIR 1/11 TO PRESENT
2012-6977	09/26/2012 10/25/2012	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	KATY MORTON TOPICA PHARMACEUTICALS INC	DPT LABORATORIES LTD, BROOKS CITY-BASE, TX - EIR 1/11 TO PRESENT

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2012-6978	09/27/2012 10/26/2012	OC/OM/OMP/DDM/	MARILYNN WHITNEY COVINGTON & BURLING LLP	DKT FDA-2012-P-0904
2012-6979	09/27/2012 10/26/2012	OC/OM/OMP/DDM/	ROSS RENDELMAN HOGAN LOVELLS LLP	DKT 1986E-0118
2012-6980	09/27/2012 10/26/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rebecca Coleman Theravance, Inc.	ATROVENT - SBA
2012-6981	09/27/2012 10/26/2012	FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OCC/ OC/ORA/OCI/ OC/ORA/OCI/ FDA/OC/OES/DFOI/	Justin A. Steiner Bennett Bigelow & Leedom, P.S.	SYNTHES - REGULATORY FILINGS, RESPONSES, CORR, ETC.
2012-6982	09/27/2012 10/26/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PUBLIC CITIZEN	PRODUCT, ACTIVE INGREDIENT, APPLICATION NUMBER FOR DRUG OR BIOLOGICAL REVIEWED OR CONSULTED BY DIVISION OF CARDIOVASCULAR AND RENAL PRODUCTS ETC
2012-6983	09/27/2012 10/26/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K061445
2012-6984	09/27/2012 10/26/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	NYCOMED GMBH, BADEN-WUERTTEMBERG, GERMANY - EIR 4/19/12
2012-6985	09/27/2012 10/26/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KEN HEIDLER KEN HEIDLER	PRAVASTATIN - AERS
2012-6986	09/27/2012 10/26/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	HOSPIRA, INDIA - 483, EIR, CORR

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2012-6987	09/27/2012 10/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 22315 S3
2012-6988	09/27/2012 10/26/2012	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	LEERINK SWANN LLC	ALERE, SAN DIEGO, CA - 483 (06/01/2012 - 09/25/2012)
2012-6989	09/27/2012 10/26/2012	FDA/OO/OIM/OPILS/FDAHO/ FDA/OC/OEXA/OC/	Bernice Ridgeway Univ of Calif., Riverside Orbach Sci Lib	IDENTIFICATION OF AMPHETAMINE AND SOME RELATIVES 2/17/58
2012-6990	09/27/2012 10/26/2012	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	Garrett Dallas Coinstar	FOOD EVOLUTION, SCHILLER PARK, IL - COMPALAINTS, INSPECTIONS, RECALLS, ETC
2012-6991	09/27/2012 10/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Takeda Global Research & Development Cen	ALLOPURINOL - 23 ISRS FROM APPENDIX
2012-6992	09/27/2012 10/26/2012	FDA/OC/OES/DFOI/	CHRISTOPHER F. WOHL Palmer Kazanjian Wohl Hodson LLP	MINOR DELETIONS
2012-6993	09/27/2012 10/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	SHASUN PHARMA SOLUTIONS, NORTHUMBERLAND, ENGLAND - EIR, 483, CORR 02/01/12-07/31/12
2012-6994	09/27/2012 10/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	DAINIPPON SUMITOMO PHARMA, JAPAN - EIR, 483, CORR 02/01/12-07/31/12
2012-6995	09/27/2012 03/20/2013	FDA/OFVM/CFSAN/OCD/EOS/	Judy Negley Valspar, Corporation	FCN 1145
2012-6996	09/27/2012 10/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K090183
2012-6997	09/27/2012 10/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K110639
2012-6998	09/27/2012 10/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	INC RESEARCH CONSULTING &	3M HEALTHCARE, LEICESTERSHIRE, UK - EIR, 483, CORR 02/01/12-07/31/12

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2012-6999	09/27/2012 10/26/2012	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	INC RESEARCH CONSULTING & SUBMISSIONS	PATHEON, MANATI, PR - EIR, 483, CORR 02/01/12-07/31/12
2012-7000	09/27/2012 10/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	NYCOMED, SINGEN, GERMANY - EIR, 483, CORR 02/01/12-07/31/12
2012-7001	09/27/2012 10/26/2012	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	INC RESEARCH CONSULTING & SUBMISSIONS	ALMAC CLINICAL SERVICES, AUDUBON, PA - EIR, 483, CORR 02/01/12-07/31/12
2012-7002	09/27/2012 10/26/2012	FDA/OO/	Varjorie A. Leone Florida A&M University	HHS-FDA-ORA-DE-12-643713 - SUCCESSFUL RESUME, QUALIFICATIONS
2012-7003	09/27/2012 10/26/2012	FDA/OFVM/CFSAN/OCD/EOS/	Judy Negley Valspar Corporation	FCN 1177
2012-7004	09/27/2012 10/26/2012	FDA/OFVM/CFSAN/OCD/EOS/	Judy Negley Valspar Corporation	FCN 1188
2012-7005	09/27/2012 10/26/2012	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	LIZ WILLIAMS Williams, Liz	CHAMBERLAIN FARMS, OWENSVILLE, IN - 483 08/01/2012 - 09/26/2012
2012-7006	09/27/2012 10/26/2012	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	DONALD N. BLUE ZETETIC	ENTRY NO AVE 00279062, MIAMI, FL; AV3 - 00279039
2012-7007	09/27/2012 10/26/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K974788
2012-7008	09/27/2012 10/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K101797
2012-7009	09/27/2012 10/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K121550
2012-7010	09/27/2012 10/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K120729
2012-7011	09/27/2012 10/26/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	3M, NORTHRIDGE, CA - EIR, 438, CORR 02/01/12-07/31/12

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2012-7012	09/27/2012 10/26/2012	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Rachel Johnson FOI Services, Inc.	MERIDIAN MEDICAL TECHNOLOGIES, COLUMBIA, MD - EIR, 483, CORR 01/01/2000 TO PRESENT
2012-7013	09/27/2012 10/26/2012	FDA/OFVM/CFSAN/OCD/EOS/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	ABBOTT LIQUID PROTEIN DIETARY SUPP - PREMARKET NOTIFICATIONS, INTERNAL CORR, CORR WITH ABBOTT (2010-PRESENT)
2012-7014	09/27/2012 10/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	EPIPEN - CORR RE ADVERTISING
2012-7015	09/27/2012 10/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	EPIPEN - CORR RE WARNING STATEMENT
2012-7016	09/27/2012 10/26/2012	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	PPD LABORATORIES, MIDDLETON, WI - EIR, 483, CORR 02/01/12-07/31/12
2012-7017	09/27/2012 10/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	AEROCAN FRANCE SAS, BELLEGARDE, FRANCE - EIR, 483, CORR 02/01/12-07/31/12
2012-7018	09/27/2012 10/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	BESPAK EUROPE, NORFOLK, ENGLAND - EIR, 483, CORR 02/01/12-07/31/12
2012-7019	09/27/2012 10/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	RAND, ROGER .	BSN JOBST GMBH, EMMERICH, GERMANY - EIR 8/27-31/12
2012-7020	09/27/2012 10/26/2012	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	Garrett Dallas Garrett Dallas	FLYING FOOD GROUP, CHICAGO, IL - COMPLAINTS, INSPECTIONS, RECALL RECS ETC LAST TEN YEARS
2012-7021	09/27/2012 10/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K110074
2012-7022	09/27/2012 10/26/2012	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	CATALENT PHARMA SOLUTIONS, WOODSTOCK, IL - EIR, 483, CORR 02/01/12-07/31/12
2012-7023	09/27/2012	FDA/OGROP/ORACE-FO/DET-	Angelia Slayton	DOW CHEMICAL CO, MIDLAND, MI - EIR, 483, CORR

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	10/26/2012	DO/DET-CB/ FDA/OC/OES/DFOI/	INC RESEARCH CONSULTING & SUBMISSIONS	02/01/12-07/31/12
2012-7024	09/27/2012 10/26/2012	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	HOLOPACK, COLUMBIA, SC - EIR, 483, CORR 02/01/12- 07/31/12
2012-7025	09/27/2012 10/26/2012	FDA/OGROP/ORA/CE-FO/CIN- DO/CIN-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	PANTHEON, CINCINNATI, OH - EIR, 483, CORR 02/01/12- 07/31/12
2012-7026	09/27/2012 10/26/2012	FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	ABC LABORATORIES, COLUMBIA, MO - EIR, 483, CORR 02/01/12-07/31/12
2012-7027	09/27/2012 10/26/2012	FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	CELSIS LABORATORY GROUP, ST LOUIS, MO - EIR, 483, CORR 02/01/12-07/31/12
2012-7028	09/27/2012 10/26/2012	FDA/OFVM/CFSAN/OCD/EOS/	Maria Amodio ITTA	FCN 963
2012-7029	09/27/2012 10/26/2012	FDA/OFVM/CFSAN/OCD/EOS/	Maria Amodio ITTA	FCN 545
2012-7030	09/27/2012 10/26/2012	FDA/OC/OES/DFOI/	JAMI J. FARRIS PARKER POE ET AL LLP	MAUDE - 5777891, MW5002919, 2112667-2007-00059 ETC
2012-7031	09/27/2012 10/26/2012	FDA/OC/OES/DFOI/	JOHN CREWDSON PROJECT ON GOVERNMENT OVERSIGHT	WARNING LTRS 12-HFD-45-05-01, 10-HFD-45-11-04, 09- HFD-45-07-02
2012-7032	09/27/2012 10/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	ROB RAPAPORT COLUMBUS CIRCLE INVESTORS	ABIOMED STATISTICAL PLAN FROM PROJECT II STUDY
2012-7033	09/28/2012 10/29/2012	OC/OM/OMP/DDM/	AMY GAITHER LATHAM & WATKINS LLP	DKT FDA-2012-P-1028
2012-7034	09/28/2012 11/05/2012	FDA/OMPT/CDRH/OCER/DFOI/ OC/ORA/ OC/ORA/ FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/	FABRICE N VINCENT LIEF CABRASER HELMANN & BERNSTEIN LLP	MEDTRONIC - BIOPROSTHETIC VALVES MOSAIC AND HANCOCK VALVES MDRS. Cmplnts, CORR, ETC

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		FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/		
2012-7035	09/28/2012 10/29/2012	OC/OA/OM/OMP/DDM/	MAHMOUD AYESH Zx Pharma, LLC	DKT 1995S-0039
2012-7036	09/28/2012 10/29/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	SHARI O COVINGTON K&L GATES	REED-LANE INC, WAYNE, NJ - EIRS, 483S, WARNING LTRS, ETC
2012-7037	09/28/2012 10/29/2012	FDA/OC/OES/DFOI/	ALISON M AGNEW PILLSBURY WINTHROP SHAW PITTMAN LLP	ABIOMED INC - IMPELLA FOI REQUESTS 9/1-26/12; PRECUTANEOUS VENTRICULAR ASSITANCE DVCS (PVAD) FOI REQUESTS 9/1-26/12, ETC
2012-7038	09/28/2012 10/29/2012	FDA/OFVM/CFSAN/OCD/EOS/	ELENA HOWELL HOGAN LOVELLS LLP	ASSESSMENT OF THE AMOUNT OF CAFFEINE THAT PEOPLE IN THE US INGESTS - RPT
2012-7039	09/28/2012 10/29/2012	FDA/OMPT/CDRH/OCER/DFOI/	SUSSMAN, MARVIN L	DDAT (UK) LTD - DDAT OMT K050098
2012-7040	09/28/2012 10/29/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAWSON, WINNIE	EDETATE DISODIUM (EDTA), CETTIMONIUM BROMIDE NDA 12-645 - INGREDIENTS, LBLG, INDICATIONS, ETC
2012-7041	09/28/2012 10/29/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAWSON, WINNIE	NYLMERATE JELLY (PHENYLMERCURIC ACETATE AND BORIC ACID) NDA 05-773 - INGREDIENTS, INDICATIONS, LBLG, ETC
2012-7042	09/28/2012 10/29/2012	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OMPT/CDRH/OCER/DFOI/	LEWIS, WILLIAM	JOINT HEAT INC - HEATING POUCH MEMOS, LTRS, EMAILS, ETC 1/00 TO PRESENT
2012-7043	09/28/2012 10/29/2012	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OMPT/CDRH/OCER/DFOI/	LEWIS, WILLIAM	INDIVIDUAL RECS 1/00 TO PRESENT
2012-7044	10/01/2012 10/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 21455
2012-7045	10/01/2012 10/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	LAERDAL MEDICAL, STAVANGER, NORWAY - EIR, 483, CORR 06/20-23/2011
2012-7046	10/01/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Rita Choi	FINANCIAL CONFLICT WAIVERS, CDER AND CBER ADVISORY COMM MEETINGS - 1997 TO 2002

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2012-7047	10/01/2012 10/30/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 21858 - LABELING (CERTIFIEID)
2012-7048	10/01/2012 10/30/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	PATHEON, MISSISSAUGA, ONTARIO, CANADA - EIR, 483, CORR 02/01/12 TO 07/31/12
2012-7049	10/01/2012 10/30/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 21455 - LABELING (CERTIFIED)
2012-7050	10/01/2012 10/30/2012	FDA/OGROP/ORO/CE-FO/BLT-DO/BLT-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	EPIPEN - CORR RE MALFUNCTIONS OR EFFICACY
2012-7051	10/01/2012 10/30/2012	FDA/OFVM/CFSAN/OCD/EOS/	Maria Amodio ITTA	FCN 475
2012-7052	10/01/2012 10/30/2012	FDA/OFVM/CFSAN/OCD/EOS/	Maria Amodio ITTA	FCN 178
2012-7053	10/01/2012 10/30/2012	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	LIST OF TOBACCO PRODUCTS MANUFACTURED, PREPARED, COMPOUNDED ETC THAT HAVE NOTIFIED FDA OF DISCONTINUANCE
2012-7054	10/01/2012 10/30/2012	OC/ORO/ORM/ OC/ORO/ORM/	Joseph Anderson Joseph Anderson	LIST OF DOMESTIC AND INTERNATIONAL INSPECTIONS - SPONSOR, MONITOR, CRO 01/01/1990 - 12/31/2011
2012-7055	10/01/2012 10/30/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Takeda Global Research & Development Cen	ZYLOPRIM - AERS

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2012-7056	10/01/2012 10/30/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Margaret Schumacher	GARDISIL - VAERS
2012-7057	10/01/2012 10/30/2012	FDA/OGROP/ORACE-FO/BLT- DO/BLT-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	NEXT BREATH LLC, BALTIMORE, MD - EIR, 483, CORR 02/01/12-07/31/12
2012-7058	10/01/2012 10/30/2012	FDA/OGROP/ORACE-FO/DET- DO/DET-CB/ FDA/OC/OES/DFOI/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	PFIZER, INC, KALAMAZOO, MI - EIR, 483, CORR 02/01/12- 07/31/12
2012-7059	10/01/2012 10/30/2012	FDA/OGROP/ORANE-FO/NYK- DO/NYK-DCB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	NORWICH PHARM, NORWICH, NY - EIR, 483, CORR 02/01/12-07/31/12
2012-7060	10/01/2012 10/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	PATHEON, INC, ONTARIO, CANADA - EIR, 483, CORR 02/01/12-07/31/12
2012-7061	10/01/2012 10/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	PATHEON, INC, ONTARIO, CANADA - EIR, 483, CORR 02/01/12-07/31/12
2012-7062	10/01/2012 10/30/2012	FDA/OC/OES/DFOI/	Megan Pickel Beveridge & Diamond, PC	CFSAN FOIA REQUESTS 08/31/2012 - 09/27/2012
2012-7063	10/01/2012 10/30/2012	FDA/OGROP/ORASW-FO/KAN- DO/KAN-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	UNIVERSITY OF IOWA, PHARM SERVICES DIVISION, IOWA CITY, IA - EIR, 483, CORR 02/01/12-07/31/12
2012-7064	10/01/2012 10/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mary Lillian Walker Foltz Martin Hudson & Knapp, LLC	ISR 6545173, 7251443
2012-7065	10/01/2012 10/30/2012	FDA/OGROP/ORACE-FO/CIN- DO/CIN-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	WEST ANALYTICAL SERVICES, LLC - MAUMEE, OH EIR, 483, CORR 02/01/12-07/31/12
2012-7066	10/01/2012 10/30/2012	FDA/OGROP/ORACE-FO/BLT- DO/BLT-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	PHARMACEUTICS INTERNATIONAL, HUNT VALLEY, MD - EIR, 483, CORR 02/01/12-07/31/12

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2012-7067	10/01/2012 10/30/2012	FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORR/SW-FO/DEN-DO/DEN-CB/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/	HIGHSIDE CAPITAL MANAGEMENT	NUSKIN - INQUIRIES RE GALVANIC SPA DEVICE, AGELOC, ETC
2012-7068	10/01/2012 10/30/2012	FDA/OGROP/ORR/PA-FO/SAN-DO/SAN-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	MECOMM SOLUTIONS, EMERYVILLE, CA - EIR, 483, CORR 02/01/12-07/31/12
2012-7069	10/01/2012 10/30/2012	FDA/OGROP/ORR/PA-FO/SEA-DO/SEA-CB/	Doe J	TRIDENT SEAFOODS CORP, SEATTLE, WA - INSPECTION REPORTS, SAMPLE RESULTS, COMPLAINTS, ETC
2012-7070	10/01/2012 10/30/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michael Derby Norphan Pharmaceuticals, Inc.	IND SPONSOR - DEFLAZACORT IN TREATMENT OF DUCHENNE MUSCULAR DYSTROPHY
2012-7071	10/01/2012 10/30/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michael Salinas Michael Salinas	LASIX - AERS
2012-7072	10/01/2012 10/30/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OCC/ OC/OA/OM/OMP/DDM/	Iona Evans Labaton Sucharow LLP	VIROPHARMA - MEETINGS, MINUTES, CORR RE NDA 50606, AMENDMENTS, ACTION LETTER, ETC .
2012-7073	10/01/2012 10/30/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Chloe Bird and/or Fabian Zaccardo PCCA	LIST OF FOREIGN IMPORTED DRUG PRODUCTS, LIST OF NDC NUMBERS
2012-7074	10/01/2012 10/30/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Fort Lauderdale Sun-Sentinel Fort Lauderdale Sun-Sentinel	HCG - AERS

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/		
2012-7075	10/01/2012 10/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Janet McChristion Fresenius Kabi LLC USA	ANDA 200837, 201048, 202563, ETC - APPROVAL LETTERS
2012-7076	10/01/2012 10/30/2012	OC/CVM/OCD/	Kandarp Prajapati Advantagene Inc.	NADA 006475 - FOIA SUMMARY
2012-7077	10/01/2012 10/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	Amlendu Prabhakar ARIZONA STATE UNIVERSITY	K875029
2012-7078	10/01/2012 10/30/2012	FDA/OO/OIM/OPILS/FDAHO/ OC/OA/OM/OMP/DDM/ OC/OA/OM/OMP/DDM/	NORWEGIAN UNIV OF SCIENCE AND TECHNOLOGY	FDA-NIMN PSYCHOTOMIMETIC AGENCY ADVISORY COMM - MEETING RECS 01/01/1967 - 12/31/1975
2012-7079	10/01/2012 10/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mahi Deligianis Mahi Deligiannis	08/01/96 LTR FROM DDMAC TO PFIZER RE ZOLOFT
2012-7080	10/01/2012 10/30/2012	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	PHARMAGISTICS, LLC, SOMERSET, NJ - EIR, 483, CORR 02/01/12-07/31/12
2012-7081	10/01/2012 10/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	PATHEON INC, BOURGOIN-JALLIEU, CEDEX, FRANCE - EIR, 483, CORR 02/01/12-07/31/12
2012-7082	10/01/2012 10/30/2012	FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	PACE ANALYTICAL LIFE SCIENCES, LLC, OAKDALE, MN - EIR, 483, CORR 02/01/12-07/31/12
2012-7083	10/01/2012 10/30/2012	FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	UPS SUPPLY CHAIN SOLUTIONS (UNIT C&D), RENO, NV - EIR, 483, CORR 02/01/12-07/31/12
2012-7084	10/01/2012 10/30/2012	FDA/OGROP/ORA/CE-FO/CIN- DO/CIN-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	UPS SUPPLY CHAIN SOLUTIONS, LOUISVILLE, KY - EIR, 483, CORR 02/01/12-07/31/12
2012-7085	10/01/2012	FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/	Angelia Slayton	LANCASTER LABORATORIES, LANCASTER, PA - EIR, 483, CORR 02/01/12-07/31/12

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	10/30/2012		INC RESEARCH CONSULTING & SUBMISSIONS	
2012-7086	10/01/2012 10/30/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	KNIPPER & CO, INC, LAKEWOOD, NJ - EIR, 483, CORR 02/01/12-07/31/12
2012-7087	10/01/2012 10/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SANJAY H SHARMA HETERO USA INC	ACTONEL (RISEDRONATE) (SODIUM) TABS - CHEMISTRY RVWS, BIOEQV RVWS, ADMINISTRATIVE RECS, ETC
2012-7088	10/01/2012 10/30/2012	FDA/OMPT/CTP/OD/	LILI SAWAN Sawan, Lili	CIGARETTES - LIST OF INGREDIENTS
2012-7089	10/01/2012 10/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ADRIENNE E FAERBER DARTMOUTH INSTITUTE	ARICEPT (DONEPEZIL) NDA 20-690 - APRVL LTR, MEDICAL RVWS, STATITICAL RVWS, ADMINISTATIVE RVWS, ETC
2012-7090	10/01/2012 10/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	LABOR L & S AG, BAD BOCKLET-GROSSENBRACH, GERMANY - EIR, 483, CORR 02/01/12-07/31/12
2012-7091	10/01/2012 10/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JODY LL GREEN ROCKY MOUNTAIN POISON DRUG CTR	COUGH & COLD PREPARATIONS - ISRS 8255706-3, 8259298-4, 8261197-9, ETC
2012-7092	10/01/2012 10/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	MICRONISIERUNGS-KONTOR OBERROT GMBH, OBERROT, GERMANY - EIR, 483, CORR 02/01/12-07/31/12
2012-7093	10/01/2012 10/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	G CALEB ALEXANDER JOHN HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH	ABSTRAL(FENTANYL CITRATE) NDA 22-510; ACTIQ (FENTANYL CITRATE) NDA 20-747; BUTRANS (BUPRENOPHINE) NDA 21-306, ETC - EVALUATION, CORR, MEMOS, ETC
2012-7094	10/01/2012 10/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WAYNE SADOWSKI NOVARTIS PHARMACEUTICALS CORP	DR PREDRAG MINIC, BELGARDE, SERBIA 7/2-6/12; DR TORU SATOH, TOYKO, JAPAN 7/9-13/12; DR EKKEHARD GRUENIG, HEIDELBERG, GERMANY 7/23-27/12, ETC - EIRS, 483S, 482S, ETC

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		FDA/OMPT/CDER/ORP/DIDP/		
2012-7095	10/01/2012 10/30/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GORDON, KAREN	MINOXIDIL - AERS
2012-7096	10/01/2012 10/30/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	MICHAEL NAZERIAS PETNET SOLUTIONS INC	TRIAD, MACON, GA, MOBILE, AL, CHARLESTON, SC, ETC - EIRS, 483S
2012-7097	10/01/2012 10/30/2012	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	JOHN PAUL HUBBARD-HALL INC	HUBBARD-HALL INC, WATERBURY, CT - EIRS 10/13/10
2012-7098	10/01/2012 10/30/2012	FDA/OC/OES/DFOI/	NICHAEL NAZERIAS PETNET SOLUTIONS INC	BEAN APPLICATIONS, UNIONVILLE, NY; MCV MOLECULAR IMAGING CENTER, RICHMOND, VA, STERLING, VA, ETC - 483S
2012-7099	10/01/2012 10/30/2012	OC/OCOS/OL/ FDA/OC/OL/	MARK E GREENWOLD CAMPAIGN FOR TOBACCO-FREE KIDS	FAMILY SMOKING & TOBACCO CONTROL ACT OF 2009 - CORR, REGULATIONS OF NICOTINE REDUCTION THERAPY PRODS 6/22/09 TO PRESENT
2012-7100	10/01/2012 10/30/2012	FDA/OC/OES/DFOI/	ROBERT, THOMAS	21 USC 321 SECTION 201 CHAPTER 2 DEFINITIONS I (G) (CERTIFIED)
2012-7101	10/01/2012 10/30/2012	FDA/OC/OES/DFOI/	GISSENDAMMER, ROBIN	483S - MOST RECENT 2012
2012-7102	10/01/2012 10/30/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	Palmer Lambert GAINSBURGH BENJAMIN ET AL	BRILLIANT BLUE G COMPOUNDING AT FRANCK'S LAB, INC - INSPECTIONS, ENFORCEMENT RECS, CONTAMINATED LOTS, ETC
2012-7103	10/01/2012 10/30/2012	OC/OM/OMP/DDM/	JONATHAN BERMAN JONES DAY	DKT 1978N-0038
2012-7104	10/02/2012 10/31/2012	OC/OM/OMP/DDM/	ROSS RENDELMANN HOGAN LOVELLS LLP	DKT FDA-2012-P-1028
2012-7105	10/02/2012 10/31/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Stephen Jenkins Law office of Sybil Shainwald	LYBREL - AERS

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		FDA/OMPT/CDER/GRP/DIDP/		
2012-7106	10/02/2012 10/31/2012	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Shelburne Ellipse Technologies, Inc.	K111136
2012-7107	10/02/2012 10/31/2012	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Shelburne Ellipse Technologies, Inc.	K120291
2012-7108	10/02/2012 10/31/2012	FDA/OMPT/CDRH/OCER/DFOI/	TeraRecon, Inc.	K083423
2012-7109	10/02/2012 10/31/2012	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Shelburne Ellipse Technologies, Inc.	K110070
2012-7110	10/02/2012 10/31/2012	FDA/OFVM/CFSAN/OCD/EOS/	Robert Weissman Saretsky Katz Dranoff & Glass, LLP	DMAA - INVESTIGATION, RECS RE POTENTIAL HARM, ADVERSE EVENT REPORTS, ETC
2012-7111	10/02/2012 10/31/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lisa Suchar LASamatovicz	VIVITROL - REVIEW PACKAGE FOR S015
2012-7112	10/02/2012 10/31/2012	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Shelburne Ellipse Technologies, Inc.	K091445
2012-7113	10/02/2012 10/31/2012	FDA/OC/OES/DFOI/	LAUREN BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 8/6-10/12
2012-7114	10/02/2012 10/31/2012	FDA/OC/OES/DFOI/	LISA TARISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 9/10-14/12
2012-7115	10/02/2012 10/31/2012	FDA/OC/OES/DFOI/	LISA TARISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 9/3-7/12
2012-7116	10/02/2012 10/31/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 9/10-14/12
2012-7117	10/02/2012 10/31/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 9/3-7/12
2012-7118	10/02/2012 10/31/2012	FDA/OC/OES/DFOI/	WILLIAM A OLSON WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 9/10-14/12
2012-7119	10/02/2012 10/31/2012	FDA/OC/OES/DFOI/	WILLIAM A OLSON WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 9/3-7/12
2012-7120	10/02/2012	FDA/OC/OES/DFOI/	KEN REID	FOI DAILY LOG 9/10-14/12

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	10/31/2012		WASHINGTON INFORMATION SOURCE	
2012-7121	10/02/2012 10/31/2012	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 9/3-7/12
2012-7122	10/02/2012 10/31/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 9/10-14/12
2012-7123	10/02/2012 10/31/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 9/3-7/12
2012-7124	10/02/2012 10/31/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 9/10-14/12
2012-7125	10/02/2012 10/31/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 9/3-7/12
2012-7126	10/02/2012 10/31/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	DYNAMIT NOBEL GMBH, KALKSTRASSE, LEVERKUSEN, GERMANY - 02/01/12-07/31/12
2012-7127	10/02/2012 10/31/2012	FDA/OC/OES/DFOI/	Christina Colla Christina Marie Colla	PHARMACEUTICAL COMPANIES - VIOLATIONS
2012-7128	10/02/2012 10/31/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mendy Bolton Bolton, Mendy	ARMOUR THYROID - NONAPPROVAL DECISION RECS
2012-7129	10/02/2012 10/31/2012	FDA/OFVM/CFSAN/OCD/EOS/	Abigail Ross Keller and Heckman LLP	6/8/78 LTR FROM HW CHAO TO WL SCHLEYER; 5/22/61 LTR FROM FA CASSIDY RE CORROSION PREVENTATIVE IN WATER; ETC
2012-7130	10/02/2012 10/31/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	David Lin BIOLOGICS CONSULTING GROUP	NDA 202736 - APPROVAL PACKAGE
2012-7131	10/02/2012 10/31/2012	FDA/OMPT/CDRH/OCER/DFOI/	Nicola Kaiser IBL International GmbH	K102841
2012-7132	10/02/2012	FDA/OMPT/CDER/GRP/DIDP/	Hampus Rystedt	ALTU-237 - PRODUCT FILED BY ALTUS PHARM; ALLN-177

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	10/31/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRANN AB	- PRODUCT FILED BY ALLENA PHARM
2012-7133	10/02/2012 10/31/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHNSON, CYNTHIA	FOSAMAX - AER
2012-7134	10/02/2012 10/31/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	THOMAS DeMELFI Jr. AMGEN	TOPOMAX NDA 20-505/S-022, 20-844, S-019 - APRVL, MEDICAL RVW, CHEMISTRY RVW
2012-7135	10/02/2012 10/31/2012	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	RICHARD O. WOOD WOOD BURDITT GROUP	LEESAR REGIONAL SERVICE, FT MYERS, FL - 482, 483 LAST 5 YRS
2012-7136	10/02/2012 10/31/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DR. HONG SAJONZ Bayer HealthCare Pharmaceuticals	MULTIHANCE NDA 21-357/S011, NDA 21-358/S009
2012-7137	10/02/2012 10/31/2012	FDA/OGROP/ORA/CE-FO/CHI- DO/CHI-CB/	WILSON, MELISSA	JR CARLSON LABS - EIR, SUMMARY SPL QUESTIONS, CO RESP
2012-7138	10/02/2012 10/31/2012	FDA/OFVM/CFSAN/OCD/EOS/	MONTENEGRO, EBONY	CMPLNTS FROM SALON WORKERS
2012-7139	10/02/2012 10/31/2012	FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	BARRETT W. STETSON LAW FIRM OF BARRETT W STETSON	INDIVIDUAL RECS
2012-7140	10/02/2012 10/31/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHEA N. SHAVER REILLY POZNER LLP	ZOLOFT (SERTRALINE HYDROCHLORIDE) NDA 19-839 - CORR 9/1/05 TO PRESENT
2012-7141	10/02/2012 10/31/2012	FDA/OFVM/CFSAN/OCD/EOS/	DANIEL A. EDELMAN EDELMAN COMBS LATTURNER ET AL	LANCOME USA, L'OREAL - CO RESP, CORR, EFFICACY 9/7/12
2012-7142	10/02/2012 10/31/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ALLEN D. NICKOL ACTELION CLINICAL RESEARCH INC	NOLVADEX NDA 17-970/S000 - APRVL

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2012-7143	10/02/2012 11/13/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/OCOS/OES/ OC/OCOS/OES/ OC/OCOS/OL/ OC/OA/OM/OMP/DDM/	THOMAS P. KELLY LAW OFFICES OF PETER G ANGELOS	COLGATE PALMOLIVE CO - REGULATIONS, GUIDELINES, VIOLATIONS REGARDING COSMETIC TALCUM POWDER PRODS, ETC
2012-7144	10/02/2012 10/31/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHAW, CARISSA	NOVARTIS - METHERGINE WARNING LABEL
2012-7145	10/03/2012 11/01/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/	CARL R NIELSEN C NIELSEN CONSULTING LLC	NANTONG TIANLONG ANIMAL BY-PRODUCTS CO LTD, JIANGSU, CHINA - EIRS, ANALYTICAL RPTS, CMLNPTS, ETC
2012-7146	10/03/2012 11/01/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JASON G SHEASBY IRELL & MANELLA LLP	SEATTLE GENETICS - ADCETRIS (BRENTUXIMAB VEDOTIN) NON-CLNCL PHARMACOLOGY, TOXICOLOGY, HUMAN PHARMACOKINETICS, ETC
2012-7147	10/03/2012 11/01/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORO/CE-FO/MIN- DO/MIN-CB/ FDA/OGROP/ORO/CE-FO/DET- DO/DET-CB/	ROBERT J KING JR LOMMEN ABDO COLE KING STAGEBERG PA	ABBOTT LABS - CMLNPTS, INSPS, ETC; INDIVIDUAL RECS
2012-7148	10/03/2012 11/01/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MCKENZIE CATO Hyman, Phelps & McNamara P.C.	OFFICE OF GENERIC DRUGS - 180-DAY EXCLUSIVITY 2000-2012
2012-7149	10/03/2012 11/01/2012	FDA/OGROP/ORO/SW-FO/KAN- DO/KAN-CB/ FDA/OGROP/ORO/PA-FO/SAN- DO/SAN-CB/	ELENA HOWELL HOGAN LOVELLS US LLP	BRINKHOFF & MONOSON INC - ARCHER FARMS BRAND GROUND TURMERIC RECALL LOTS 1740901A, 2180902A, 2780906A, ETC

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2012-7150	10/03/2012 11/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	MARCIA L BENEDICT STERIS CORP	STERRAD NX DUO CYCLE TEST PACK K111391; STERRAD CYCLESURE 24 BIOLOGICAL INDICATOR K111375; STERRAD 100NX STERILIZER DUO CYCLE K1113777, ETC
2012-7151	10/03/2012 11/01/2012	FDA/OGROP/ORR/SE-FO/SJN-DO/SJN-CB/	TYLER KENYON NORTHCOAST RESEARCH	ZIMMER HOLDING, PONCE, PR - WARNING LTR 9/21/12
2012-7152	10/03/2012 11/01/2012	FDA/OFVM/CFSAN/OCD/EOS/	DR PETER D FOSTER HUHTAMAKI INC	JOHNSON POLYMERS - STYRENE-ACRYLIC COPOLYMERS FCN 130, FCN 231
2012-7153	10/03/2012 11/01/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	BLA 103772/S5113
2012-7154	10/03/2012 11/01/2012	OC/OSMP/OOPD/	Daven Mody Impax Laboratories, Inc.	NEURONEX INTRANASAL DIAZEPAM - ORPHAN DRUG DESIGNATION RECS
2012-7155	10/03/2012 11/01/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA202811
2012-7156	10/03/2012 11/01/2012	OC/OSMP/OOPD/ FDA/OMPT/OSMP/OOPD/	Daven Mody Impax Laboratories, Inc.	BOTOX, BENEFIX, GRALISE, ETC - ORPHAN DRUG DESIGNATION/EXCLUSIVITY RECS
2012-7157	10/03/2012 11/01/2012	FDA/OMPT/CDRH/OCER/DFOI/	Anne Mitchell Mitchell, Anne	RENAL SHOCKWAVE LITHOSTRIPSY - ADVERSE EVENTS
2012-7158	10/03/2012 11/01/2012	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	FOIA LOG 07/01/2012 to 09/30/2012
2012-7159	10/03/2012 11/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDRH/OCER/DFOI/	Louise Miller LRT Trading	STATENS SERUM INSTITUT, COPENHAGEN, DENMARK - INSPECTION RECS, RECALLS, CONSENT DECREE ETC
2012-7160	10/03/2012	FDA/OGROP/ORR/NE-FO/NWE-DO/NWE-CB/	Angelia Slayton	PFIZER, GROTON, CT - EIR, 493, CORR 05/04/09

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	11/01/2012		INC RESEARCH CONSULTING & SUBMISSIONS	
2012-7161	10/03/2012 11/01/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 9/17-21/2012
2012-7162	10/03/2012 12/14/2012	FDA/OFVM/CFSAN/OCD/EOS/	Richard Henrich Chemtura Corporation	FCN 1152
2012-7163	10/03/2012 11/01/2012	FDA/OFVM/CFSAN/OCD/EOS/	Avery Hartley Avery Hartley	AQUAFINCA ST PETER FISH, HONDURAS - COMPLAINTS, INSPECTION REPORTS
2012-7164	10/03/2012 11/01/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Linda Mota Shire Development LLC	BLA 103772, S5113; NDA 22000, S005; NDA 202811
2012-7165	10/03/2012 11/01/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HOLLINGSWORTHLLP	AMERICAN HOME PRODUCTS - WARNING LETTER 02/14/92
2012-7166	10/03/2012 11/01/2012	FDA/OMPT/CDRH/OCER/DFOI/	COVIDIEN	K120657
2012-7167	10/03/2012 11/01/2012	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2012-6560
2012-7168	10/03/2012 11/01/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sharon Myers ELI LILLY AND COMPANY - PHARMACEUTICAL DIVISION	ADENOSCAN - SBA
2012-7169	10/03/2012 11/01/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kim Wagner BIOPHARM DEVELOPMENT ASSOCIATES, LLC	NDA 202811 - REVIEWER REPORTS
2012-7170	10/03/2012 11/01/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sharon Myers ELI LILLY AND COMPANY - PHARMACEUTICAL DIVISION	ADENOCARD IV - SBA
2012-7171	10/03/2012	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/		PFIZER, GROTON, CT - EIR, 483, CORR 10/14/10

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	11/01/2012		INC RESEARCH CONSULTING & SUBMISSIONS	
2012-7172	10/03/2012 11/01/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOIA REQUESTS CLOSED 9/1/12-9/30/2012
2012-7173	10/03/2012 11/01/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 9/24-28/2012
2012-7174	10/03/2012 11/01/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 22000/S5
2012-7175	10/04/2012 11/02/2012	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	Richard O. Wood WOOD BURDITT GROUP	FLORIDA BIOLOGIX, ALUCHUA, FL - 482, 483, CORR ETC
2012-7176	10/04/2012 11/02/2012	FDA/OC/OES/DFOI/	Dr. Shiels / Amanda Bundy Children's Radiological Institute	FDA DRUG BULLETIN FDA JULY 1989;15-16
2012-7177	10/04/2012 11/02/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID PULLMAN Pullman, David	STATINS - AERS
2012-7178	10/04/2012 11/02/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	BLA 125360 S007
2012-7179	10/04/2012 11/02/2012	FDA/OMPT/CTP/OD/	KEVIN ALDRIDGE Aldridge, Kevin	LIST OF APPROVED CIGARETTE TUBE MANUFACTURERS FOR RYO
2012-7180	10/04/2012 11/02/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Laura F. Hron Law Office of Joel M. Fineberg	EPOGEN/PROCRIT - APPROVAL LETTER
2012-7181	10/04/2012 11/02/2012	FDA/OMPT/CDRH/OCER/DFOI/ OC/OCOS/OES/ OC/OCOS/OES/	Tom Burton THE WALL STREET JOURNAL	REPORT FOR OFFICE OF SPECIAL COUNSEL RE SAFETY OF MEDICAL DEVICES INCLUDING COLONAGRAPHY
2012-7182	10/04/2012 11/02/2012	FDA/OFVM/CFSAN/OCD/EOS/	Elizabeth Metcalf Morgan & Morgan, P.C.	SUAVE PROFESSIONALS KERATIN INFUSION KIT - COMPLAINTS, COMMUNICATIONS WITH UNILEVER

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2012-7183	10/04/2012 11/02/2012	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	The Windward Company	ISIS SERVICES, SAN CARLOS, CA - EIR 03/22/11-04/07/11
2012-7184	10/04/2012 11/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	Beverly Morrison Morrison, Beverly	K061011
2012-7185	10/04/2012 11/02/2012	OC/ORPA/ OC/ORPA/ FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	Robert McLennan Oregon Heritage Farms	SAMPLE 770367 - ANALYTICAL RESULTS
2012-7186	10/04/2012 11/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kimberly Calandriello	VENLAFAXINE ER, EFFEXOR XR - AERS
2012-7187	10/04/2012 11/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CenterWatch Monthly	NUMBER OF CLINICAL HOLDS APPLIED TO CLINICAL RESEARCH STUDY OR NEW DRUG APPLICATION DUE TO MISLEADING OR INCOMPLETE INVESTIGATOR BROCHURE
2012-7188	10/04/2012 11/02/2012	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	Richard O. Wood WOOD BURDITT GROUP	ORGAN RECOVERY SYSTEMS, ITASCA, IL - INSPECTION RECS
2012-7189	10/04/2012 11/02/2012	OC/CVM/OCD/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Horace Nalle Oriole Animal Health LLC	STUDIES OF SAFETY OR EFFICACY OF IBUPROFEN AND FAMOTIDINE IN DOGS
2012-7190	10/04/2012 11/02/2012	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	Avery Hartley Avery Hartley	TRIDENT SEAFOODS CORP - TEST RESULTS 2005 TO PRESENT
2012-7191	10/04/2012 11/02/2012	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	NIDIA NOEL EZEM CANADA	ABBOTT LABS, NORTH CHICAGO, IL - EIR MOST RECENT
2012-7192	10/04/2012 11/02/2012	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	JANET A. McCORMICK INTERIOR ALASKA FISH PROCESSORS INC	YUKON RIVER GOLD, KALTAG, AK - EIR 2007 TO 2010
2012-7193	10/04/2012	FDA/OMPT/CDER/ORP/DIDP/	BRITTANY LaPOINTE	ZOLOFT - APRVL

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	11/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DISCOVERY RESOURCE LITIGATION SUPPORT SERVICES	
2012-7194	10/04/2012 11/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OCC/ OC/OA/OM/OMP/DDM/	JAMES R.M. HEMMINGS SIDLEY AUSTIN LLP	DKTS 2007P-0358/CPI; FDA-2007-P-0111; 2007D-0168
2012-7195	10/04/2012 11/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORO/OCI/ OC/ORO/OCI/ FDA/OC/OCC/	WHITE, ROBERT W	PAXIL, DEPAKOTE, WELBUTRIN - OFF-LABEL PROMOTIONS, INVESTIGATION RECS REGARDING CHILDREN, TEENS, ETC
2012-7196	10/04/2012 11/02/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	ALISON M. AGNEW PILLSBURY WINTHROP SHAW PITTMAN LLP	INSULET CORP - OMNIPOD SINCE 2009
2012-7197	10/05/2012 11/05/2012	FDA/OGROP/ORO/CE-FO/DET-DO/DET-CB/ FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/ FDA/OFVM/CFSAN/OCD/EOS/	Becky Cooseman Brown & Crouppen, PC	INDIVIDUAL RECS
2012-7198	10/05/2012 11/05/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OO/ FDA/OO/OHR/	Doe J	INDIVIDUAL RECS
2012-7199	10/05/2012 11/05/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Robert E. Shapiro, MD, PhD UNIVERSITY OF VERMONT	ISRS 45767436, 4621628X, 65601858, 65985025

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2012-7200	10/05/2012 11/05/2012	FDA/OMPT/CDRH/OCER/DFOI/	Yves Arramon SpinalMotion	K110632
2012-7201	10/05/2012 11/05/2012	FDA/OMPT/CDRH/OCER/DFOI/	Shawn Esmaili Cercacor Labs	K112638
2012-7202	10/05/2012 11/05/2012	FDA/OMPT/CDRH/OCER/DFOI/	Yves Arramon SpinalMotion	K112036
2012-7203	10/05/2012 11/05/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Rachel Johnson FOI Services, Inc.	GE HEALTHCARE, SOUTH PLAINFIELD, NJ - EIRs 5/10/10, 3/10/11
2012-7204	10/05/2012 11/05/2012	FDA/OMPT/CDRH/OCER/DFOI/	Kerry King Intertox, Inc.	K932868
2012-7205	10/05/2012 11/05/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Rachel Johnson FOI Services, Inc.	BRACCO DIAGNOSTICS, PRINCETON, NJ - EIRs, 483s 3/11, 7/12
2012-7206	10/05/2012 11/05/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Alison Stuebe UNC School of Medicine	METHERGINE - AERS
2012-7207	10/05/2012 11/05/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2012-6487
2012-7208	10/05/2012 11/05/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2012-6270
2012-7209	10/05/2012 11/05/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2012-5921
2012-7210	10/05/2012 11/05/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2012-5686
2012-7211	10/05/2012 11/05/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2012-5601
2012-7212	10/05/2012 11/05/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2012-5604
2012-7213	10/05/2012 11/05/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2012-5307
2012-7214	10/05/2012 11/05/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2012-3134
2012-7215	10/05/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND	2012-6515

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	11/05/2012		FDA WEBVIEW/FERDIC INC	
2012-7216	10/05/2012 11/05/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2012-6271
2012-7217	10/05/2012 11/05/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2012-4694
2012-7218	10/05/2012 11/05/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2012-5841
2012-7219	10/05/2012 11/05/2012	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	JOHN WALSH JAMES ALEXANDER CORP	CARE FUSION, EL PASO, TX - EIRS, 483S, RECALLS 10/10 TO PRESENT
2012-7220	10/05/2012 11/05/2012	FDA/OC/OES/DFOI/	ROBERT A DORMER Hyman Phelps and McNamara PC	2012-5550, 2012-5647, 2012-6560, ETC
2012-7221	10/05/2012 11/05/2012	FDA/OFVM/CFSAN/OCD/EOS/	WILBUR JOHNSON JR COSMETIC INGREDIENT REVIEW	METHYL GLUCOSIDE COCONUT OIL ESTER (METHYL GLUCOSIDE SEQUICOCOATE) - CHEMICAL & PHYSICAL PROPERTIES, METABOLISM/BIOAVL, DERMAL PENETRATION, ETC
2012-7222	10/05/2012 11/05/2012	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/ORA/OCI/ OC/ORA/OCI/	ANN K RITTER MOTLEY RICE LLC	AMERISOURCE BERGEN CORP, FL - VIOLATION OF FDA AMENDMENTS ACT OF 2007 ; BELLCO DRUG CORP (AMERISOURCE BERGEN CORP) 2008 - EIRS
2012-7223	10/05/2012 11/05/2012	FDA/OFVM/CFSAN/OCD/EOS/	JAMES H HARTTEN ARENT FOX LLP	LANCOME USA - RESP TO WARNING LTR 9/7/12
2012-7224	10/05/2012 11/05/2012	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/OSMP/OOPD/ FDA/OC/OES/DFOI/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	ROBIN WINCHESTER KESSLERTOPAZ MELTZERCHECK LLP	QUESTCOR PHARMACEUTICALS INC - HP ACTHAR GEL EIRS, WARNING LTRS, APRVL, ETC

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2012-7225	10/05/2012 11/05/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Pam Brennan Pam Brennan	METHERGINE - AERS
2012-7226	10/09/2012 11/06/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jay Sirois CONSUMER HEALTHCARE PRODUCTS ASSOCIATION	ACETAMINOPHEN - MEDWATCH REPORTS
2012-7227	10/09/2012 11/06/2012	OC/ORA/ OC/ORA/ FDA/OGROP/ORANE-FO/NYK- DO/NYK-DCB/ FDA/OGROP/ORASW-FO/KAN- DO/KAN-CB/ FDA/OFVM/CFSAN/OCD/EOS/	Nicole Palen EMSL Analytical, Inc.	SAMPLE RESULTS
2012-7228	10/09/2012 11/06/2012	FDA/OFVM/CFSAN/OCD/EOS/	Merle Zimmermann AMERICAN HERBAL PRODUCTS ASSOCIATION	DIETARY SUPPLEMENTS - CAERS 07/01/2011 - 08/31/2012
2012-7229	10/09/2012 11/06/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Barry Weathers Barry E. Weathers	DEPO MEDROL - COMPLAINTS, CORR, AERS, ETC
2012-7230	10/09/2012 11/06/2012	FDA/OMPT/CDRH/OCER/DFOI/	Linda Kariya Nihon Kohden America, Inc.	K071969
2012-7231	10/09/2012 11/06/2012	FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/ OC/ORA/ OC/ORA/	DeAnne Brooks THE MOSES H. CONE MEMORIAL HOSPITAL	AMERIDOSE, WESTBOROUGH, MA - MOST RECENT EIR, 483
2012-7232	10/09/2012 11/06/2012	FDA/OFVM/CFSAN/OCD/EOS/	Donald Ecklund CARELLA BYRNE BAIN ET AL	LANCOME, L'OREAL - RESPONSE TO WL ISSUED 9/7/2012
2012-7233	10/09/2012 11/06/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Barry Necaise CBC Inc	K060656
2012-7234	10/09/2012 11/06/2012	FDA/OMPT/CDRH/OCER/DFOI/	Kathy Simpson Celleration, Inc.	K112782

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2012-7235	10/09/2012 11/06/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Irina Rivkind Irina Rivkind/Cantor Fitzgerald	JAZZ PHARMACEUTICALS - RESPONSE TO WARNING LETTER ISSUED 10/11/11
2012-7236	10/09/2012 11/06/2012	FDA/OMPT/CDRH/OCER/DFOI/	Matt Zepnick The Edelsteins, Faegenburg & Brown, LLP	TRANS1 AXIALIF 2L ANTERIOR SPINAL FIXATION MODEL NUMBER TR1-2316, EVENT DATE: 2/8/10; TRANS1 AXIALIF 2L ANTERIOR SPINAL FIXATION MODEL NUMBER TR1-2305, EVENT DATE: 11/23/09 - MAUDE REPORTS
2012-7237	10/09/2012 11/06/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jim Peace Peace, Jim	DHEA - AERS
2012-7238	10/09/2012 11/06/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	STACI M TROLIAN BIOMET INC	DR STEVEN MARK TRAINA - WARNING LTR CORR
2012-7239	10/09/2012 11/06/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	DENISE RIEKER SANOFI PASTEUR	VAERS - INDIVIDUAL RECS
2012-7240	10/09/2012 11/06/2012	FDA/OFVM/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 155912
2012-7241	10/09/2012 11/06/2012	OC/ORA/ORM/ OC/ORA/ORM/	JOHNATHAN RICKMAN FDA NEWS	PHARMACEUTICAL, BIOLOGICS, MEDICAL DVC MFG, CLNCL FACILITIES IN AND OUTSIDE THE US - 483S 9/1-30/12
2012-7242	10/09/2012 11/06/2012	OC/OA/OM/OMP/DDM/	MELISSA CERASO INFOTRIEVE INC	ANTIVIRAL A/C MTG - FIAU TOXICITY TRANS
2012-7243	10/09/2012 11/06/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/OIP/ OC/ORA/ OC/ORA/ FDA/OC/OES/DFOI/ OC/ORA/ORO/DFS/	SHERRIE A IRELAND FLASTER GREENBERG	FATTORIE CHIARAPPA SRL - FRESCOLINA SALATA CHEESE LISTERIA OUTBREAK RECALL RECS, TESTING, CORR, ETC

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		OC/ORO/ORO/DFS/		
2012-7244	10/09/2012 11/15/2012	FDA/OC/OES/DFOI/	ROABERT P CHARROW GREENBERG TRAUIG LLP	MEDTRONIC XOMED INC - LASER-SHIELD II ENDOTRACHEAL TUBE; LASER ENGINEERING INC - ULTRA MD 40 LASER SYS RECS
2012-7245	10/09/2012 11/06/2012	FDA/OFVM/CFSAN/OCD/EOS/	CARLA R SCARMAZZI KING & SPALDING	CITREM (CITRIC ACID ASTERS OF MONO- AND DIGLYCERIDES), MAGNESIUM L-ASPARTATE - RECS
2012-7246	10/09/2012 11/06/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHI WAI NG MEDICAL DEVELOPMENTS INTERNATIONAL LTD	METHOXYFLURANE - AERS
2012-7247	10/09/2012 11/06/2012	FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/	SHERI P COVINGTON K&L GATES	ACCUPAC, MAINLAND, PA - EIRS, 483S, WARNING LTRS, ETC 9/10 TO PRESENT
2012-7248	10/09/2012 11/06/2012	FDA/OMPT/CDRH/OCER/DFOI/	KAREN E PETERSON ENTELLUS MEDICAL	ENTRIGUE SURGICAL INC - ENTRIGUE SINUS DILATION SYS K121351
2012-7249	10/09/2012 11/06/2012	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DANIEL H LEVI PAUL WEISS RIFKIND WHARTON & GARRISON	SCIELE PHARMA INC, SHIONOGI PHARMA INC, SHIONOGA INC - REGULATORY MTG NOTES, MINS 1/07 TO 12/10, CMLNT
2012-7250	10/09/2012 11/06/2012	OC/ORO/ OC/ORO/ OC/ORO/OE/ OC/ORO/OE/	WILSON, DAWN	NUMBER OF LEVEL 1 RECALLS 2007-2012
2012-7251	10/09/2012 11/06/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MICHAEL R COHEN RPH MS SCD INSTITUTE FOR MEDICATION PRACTICES	MEDWATCH RPTS CODED AS MEDICATION ERRORS 9/1- 31/12
2012-7252	10/09/2012 11/06/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/ FDA/OGROP/ORA/SW- FO/SWID/SWID-CB/	SAMANTHA MYERS ROANOKE TRADE SERVICES INC	G & G PRODUCE LLC - ENTRY #BYX00430680 FDA NOTICE OF ACTION, INVOICES, BILLS OF LADING, ETC
2012-7253	10/09/2012	FDA/OMPT/CDER/ORP/DIDP/	VASSLLIOS	NDA 202-872 - RECS

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	11/06/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHRISTODOULOPOULOS SANDOZ CANADA INC.	
2012-7254	10/09/2012 11/06/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORA/SW-FO/DEN- DO/DEN-CB/ FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	RICHARD WANG TENZING GLOBAL	NU SKIN ENTERPRISES - AGELOC CMLPTS, INVESTIGATION
2012-7255	10/09/2012 11/06/2012	FDA/OO/OFBA/OAGS/	KIMBERLY LEGROW GRYPHON SCIENTIFIC	SOLICITATION FDA-12-223-SOL-00058 - PROPOSAL RVW PANEL RATING, NOTES
2012-7256	10/09/2012 11/06/2012	FDA/OGROP/ORA/PA-FO/SEA- DO/SEA-CB/	BRENDA M GARTZ ELI LILLY & CO	PETNET SOLUTIONS INC, KENT, WA - EIR, 483 2/12
2012-7257	10/09/2012 11/06/2012	OC/ORA/ORM/ OC/ORA/ORM/	GAIL LESSICK LACHMAN CONSULTANT SERVICES INC	DRUG COMPANIES, MEDICAL DVC MFRS, BIORESEARCH MONITORING (BIMO), ETC - FOREIGN AND DOMESTIC INSPS 8/1-31/12
2012-7258	10/09/2012 11/06/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GREGORY GREEN ESQ GREEN LAW FIRM PC	METHERGINE (METHYLERGONOVINE MALEATE) - AERS, LBLG, STORAGE RECS
2012-7259	10/09/2012 11/06/2012	FDA/OFVM/CFSAN/OCD/EOS/	TODD A HARRISON VENABLE LLP	BLACK COHOSH, SOY ISOFLAVONES - CAERS
2012-7260	10/09/2012 11/06/2012	FDA/OFVM/CFSAN/OCD/EOS/	TODD A HARRISON VENABLE LLP	PRIVATE-LABEL MENOPAUSE DIETARY SUPPLEMENT PRODS - CAERS
2012-7261	10/09/2012 11/06/2012	FDA/OFVM/CFSAN/OCD/EOS/	TODD A HARRISON VENABLE LLP	ONE-A-DAY WOMEN'S MENOPAUSE FORMULA DIETARY SUPPLEMENT PRODS - CAERS
2012-7262	10/09/2012 11/06/2012	FDA/OFVM/CFSAN/OCD/EOS/	TODD A HARRISON VENABLE LLP	ESTROVEN, ESTROVEN MAXIMUM STRENGTH, ESTROVEN NIGHTTIME, ETC - CAERS
2012-7263	10/09/2012 11/06/2012	FDA/OFVM/CFSAN/OCD/EOS/	TODD A HARRISON VENABLE LLP	REMIFEMIN, REMIFEMIN GOOD NIGHT - CAERS
2012-7264	10/09/2012 11/06/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TODD A HARRISON VENABLE LLP	BLACK COHOSH, SOY - CAERS

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2012-7265	10/09/2012 11/06/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 9/17-21/12
2012-7266	10/10/2012 11/07/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tyrah L. Miles DJA Global Pharmaceuticals, Inc	ZOMIG - SBA
2012-7267	10/10/2012 11/07/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tu Tu CSL BEHRING	NDA 020304 - SBA
2012-7268	10/10/2012 11/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	Elisabeth Neely St. Jude Medical	P840001/S185
2012-7269	10/10/2012 11/07/2012	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Makit apS Makit apS	K021356
2012-7270	10/10/2012 11/07/2012	FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	North Dallas Honey Company, LP	NORTH DALLAS HONEY CO - COMPLAINT
2012-7271	10/10/2012 11/07/2012	FDA/OGROP/ORA/CE-FO/CHI- DO/CHI-CB/	Travis Siverson BIRCHWOOD LABORATORIES INC	HYDROX CHEMICAL CO, ELGIN, IL - WARNING LETTERS, 483, RECALL, ETC01/01/2008 - 12/31/2009
2012-7272	10/10/2012 11/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	Richard O. Wood the Wood Burditt group	CDRH PROMOTION AND ADVERTISING UNTITLED LETTERS 01/01/2010 - 10/09/2012
2012-7273	10/10/2012 11/07/2012	OC/ORA/ OC/ORA/	Econ One Research	OFFICIAL ESTABLISHMENT INVENTORY RECORDS FOR INDUSTRY CODE 59
2012-7274	10/10/2012 11/07/2012	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/ OC/ORA/ OC/ORA/	Aaron Pressman Reuters News	NEW ENGLAND COMPOUNDING CENTER, FRAMINGHAM, MA - WARNING LETTER FOLLOW UP RECS
2012-7275	10/10/2012 11/07/2012	FDA/OMPT/CDRH/OCER/DFOI/ OC/OCOS/OES/ OC/OCOS/OES/ OC/OCOS/OL/ FDA/OC/OES/DFOI/	Lathrop & Gage LLP	SHASTA TECHNOLOGIES - CORR WITH FDA RE GENSTRIP ETC

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2012-7276	10/10/2012 11/07/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Richard O. Wood the Wood Burditt group	CBER PROMOTION AND ADVERTISING UNTITLED LETTERS 01/01/2010 - 10/09/2012
2012-7277	10/10/2012 11/07/2012	FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/	JOHNSON, JILL	ARKION LIFE SCIENCES, NEW CASTLE, DE - 483 4/11 TO PRESENT
2012-7278	10/10/2012 11/07/2012	FDA/OGROP/ORA/PA-FO/SEA- DO/SEA-CB/ FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/	JOHNSON, JILL .	STERLING TECHNOLOGIES, BROOKINGS, SD - 483 4/11 TO PRESENT
2012-7279	10/10/2012 11/07/2012	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	JOHNSON, JILL .	APS BIOGROUP, PHOENIX, AZ - 483 4/11 TO PRESENT
2012-7280	10/10/2012 11/07/2012	FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	JOHNSON, JILL .	LEGACY FOR LIFE, OKLAHOMA CITY, OK - 483 4/11 TO PRESENT
2012-7281	10/10/2012 11/07/2012	FDA/OGROP/ORA/SW-FO/DEN- DO/DEN-CB/	JOHNSON, JILL .	VMI NUTRITION, SALT LAKE CITY, UT - 483 4/11 TO PRESENT
2012-7282	10/10/2012 11/07/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	JOHNSON, JILL	SOFTGEL TECHNOLOGIES INC, LOS ANGELES, CA - 483 4/11 TO PRESENT
2012-7283	10/10/2012 11/07/2012	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	JOHNSON, JILL .	AMERICAN COPAK CORP, CHATSWORTH, CA - 483 4/11 TO PRESENT
2012-7284	10/10/2012 11/07/2012	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	SUSAN B. MILLS WEINBERG WHEELER ET AL	NATIONAL BEEF CALIFORNIA LP - EIR 1/09 TO PRESENT
2012-7285	10/10/2012 11/07/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	AHEARN, DONALD	IMMUNEX CORP - ENBREL ENTANERCEPT AER
2012-7286	10/10/2012 11/07/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OCC/	J. DONALD HENSON, SR Henson, J. Donald	MTG BETWEEN J DONALD HENSON CDRH AND CHIEF COUNSEL - DOCUMENTATION OF CONVERSATION 7/03/12
2012-7287	10/10/2012 11/07/2012	FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/	ELENA HOWELL HOGAN LOVELLS LLP	HALEDAMAN MILLS, MANHEIM, PA - YELLOW CORN MEAL RECALL
2012-7288	10/10/2012 11/07/2012	FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/	DONLAD N. BLUE ZETETIC INC	2 SOAP - ENTRY NO BGK- 0387652

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2012-7289	10/10/2012 11/07/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORAPA-FO/SEA- DO/SEA-CB/	GREGORY H. LEVINE ROPES & GRAY LLP	GEN1100033
2012-7290	10/10/2012 11/07/2012	FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/ OC/OCOS/OES/ OC/OCOS/OES/	MICHELLE JONES BURLESONS PURE HONEY	NATURE NATES HONEY, FRISCO, TX - FINES, JUDGEMENTS, CORR, ETC 3/30/12 TO 10/5/12
2012-7291	10/10/2012 11/07/2012	FDA/OMPT/CDRH/OCER/DFOI/ OC/OA/OM/OMP/DDM/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	JOHN P. HARLOE, JD, PhD FREESE & GOSS, PLLC	OBSTETRICS & GYNECOLOGY A/C MTG RE PELVIC MESH 9/8/11
2012-7292	10/10/2012 11/07/2012	FDA/OMPT/CDRH/OCER/DFOI/ OC/OA/OM/OMP/DDM/	JOHN P. HARLOE, JD, PhD FREESE & GOSS, PLLC	OBSTETRICS & GYNECOLOGY MEDICAL DVCS A/C 9/8/11 - JOURNAL ARTICLES, DATABASES, SPREADSHEETS, ETC
2012-7293	10/10/2012 11/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	JOHN P. HARLOE, JD, PhD FREESE & GOSS, PLLC	OBSTETRICS & GYNECOLOGY MEDICAL DVCS A/C 9/8/11 - JOURNAL ARTICLES, DATABASES, SPREADSHEETS, ETC
2012-7294	10/10/2012 11/07/2012	FDA/OGROP/ORASW-FO/KAN- DO/KAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	DAVID A. BORESI THURMAN LAW FIRM	MEDTRONIC INC - INFUSE BONE GROWTH ACCELERATOR PROD MDRS. CLNCL TRIAL RECS, PROTOCOLS, ETCPRO
2012-7295	10/10/2012 11/07/2012	FDA/OGROP/ORASW-FO/KAN- DO/KAN-CB/	SUSAN B. MILLS WEINBERG WHEELER ET AL	NATIONAL BEEF PACKAGING CO LLC - EIR 1/09 TO PRESENT
2012-7296	10/10/2012 11/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	CHRISTINA M. MIRACLE HILL ROM	K863047; K914351; K915779
2012-7297	10/10/2012 11/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	CHRISTINA M. MIRACLE HILL ROM	K921168; K926140; K944779
2012-7298	10/10/2012 11/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	McKENZIE CATO Hyman, Phelps & McNamara P.C.	SENTEHEART INC - LARIAT II SUTURE DELIVERY DEVICE K090385
2012-7299	10/10/2012 11/07/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORASE-FO/ATL- DO/ATL-CB/	MATTHEW A. ZEPNICK EDELSTEINS FAEGENBURG & BROWN LLP	INDIVIDUAL RECS
2012-7300	10/10/2012 11/07/2012	FDA/OGROP/ORASW-FO/KAN- DO/KAN-CB/	JEANETTE GOOGE MORTON SALT INC	MORTON SLT INC, SOUTH HUTCHINSON, KS - 483, EIR MOST RECENT
2012-7301	10/10/2012 11/07/2012	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	MATTHEW VENTRESCA MCMASTER UNIVERSITY	CODEINE USE IN CHILDREN - AERS

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		FDA/OMPT/CDER/GRP/DIDP/		
2012-7302	10/11/2012 11/08/2012	FDA/OC/OES/DFOI/	Surveyor Capital	BAXTER INTERNATIONAL INC, BAXTER HEALTHCARE CORP - 483 01/01/2009 - 10/04/2012
2012-7303	10/11/2012 11/08/2012	FDA/OC/OES/DFOI/	Fred Mamoun Fox Five News New York	JERKY PET TREATS - INSPECTIONS, COMPLAINTS 01/09/2007 - 10/09/2012
2012-7304	10/11/2012 11/08/2012	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/OCOS/OES/ OC/OCOS/OES/	T. Christian Miller PROPUBLICA	MCNEIL CONSUMER HEALTHCARE - CORR TO FDA 05/01/2009 - 08/30/2009
2012-7305	10/11/2012 11/08/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	EPOGEN - APPROVAL RECS
2012-7306	10/11/2012 11/08/2012	OC/OSMP/OOPD/ FDA/OMPT/OSMP/OOPD/	Rachel Johnson FOI Services, Inc.	NITRIC OXIDE - ORPHAN DRUG DESIGNATION
2012-7307	10/11/2012 11/08/2012	FDA/OC/OES/DFOI/	Johnathan Rickman FDA NEWS	FOIA LOG 09/24/2012 - 10/05/2012
2012-7308	10/11/2012 11/08/2012	FDA/OMPT/CDRH/OCER/DFOI/ OC/OCOS/OES/ OC/OCOS/OES/ OC/OCOS/OL/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Emily Bartkowicz AKERMAN SENTERFITT ATTYS	PELVIC MESH PRODUCTS - INVESTIGATION RECS, ANALYSIS
2012-7309	10/11/2012 11/08/2012	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	FCN 524, FAP 9B3477
2012-7310	10/11/2012 11/08/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Daniel Casaburi NPS PHARMACEUTICALS	NDA 21-847

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2012-7311	10/11/2012 11/08/2012	FDA/OFVM/CFSAN/OCD/EOS/	CBC (AMERICA) CORP	TRUEHOPE EMPOWERPLUS - AERS
2012-7312	10/11/2012 11/08/2012	FDA/OMPT/CTP/OD/	Kevin Aldridge Aldridge, Kevin	LIST OF REGISTERED CIGARETTE TUBE MANUFACTURERS
2012-7313	10/11/2012 11/08/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/ORO/ OC/ORO/	T. Christian Miller PROPUBLICA	JOHNSON & JOHNSON - MEETING MINUTES, AGENDAS, BRIEFING MATERIALS ETC FOR 02/19/2010 MTG WITH FDA
2012-7314	10/11/2012 11/08/2012	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Shelburne Ellipse Technologies, Inc.	K092318
2012-7315	10/11/2012 11/08/2012	FDA/OMPT/CDRH/OCER/DFOI/	Samantha Sledd Hall & Sethi, PLC	K042800
2012-7316	10/11/2012 11/08/2012	FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/ FDA/OMPT/CDRH/OCER/DFOI/ OC/OCOS/OES/ OC/OCOS/OES/ OC/OCOS/OL/ FDA/OC/OES/DFOI/	TORREY COPE SIDLEY AUSTIN LLP	KIMBERLY-CLARK CORP, ROSWELL, GA - CMLNRS, FOI REQUESTS, INSPS, ETC 3/20/10 TO 10/5/12
2012-7317	10/11/2012 11/08/2012	FDA/OMPT/CDRH/OCER/DFOI/	ALLISON M AGNEW PILLSBURY WINTHROP SHAW PITTMAN LLP	ABIOMED INC - IMPELLA DVC PROJECT II TRIAL STATISTICAL ANALYSIS PLAN
2012-7318	10/11/2012 11/08/2012	OC/OA/OM/OMP/DDM/	JAMES C MINGEE MINGEE & ASSOCIATES	GENERIC DRUG USER FEE AMENDMENTS MTG - TRANS 9/21/12
2012-7319	10/11/2012 11/08/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	NATHAN A BEAVER FOLEY & LARDNER LLP	DVC REGISTRATION AND LISTING DATABASE 2012
2012-7320	10/11/2012 11/08/2012	FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/ OC/ORO/OCI/ OC/ORO/OCI/ FDA/OFVM/CFSAN/OCD/EOS/	CONORS, ANTHONY ROBERT	INDIVIDUAL RECS

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		FDA/OGROP/ORA/SW-FO/SWID/SWID-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORA/OE/ OC/ORA/OE/		
2012-7321	10/11/2012 11/08/2012	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	GARY C COOPER GARY C COOPER LAW OFC	ENTRY #D52-0940626-8 - LAB RESULTS
2012-7322	10/11/2012 11/08/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WOODS 10B2776, LEON	PIREXICAM - AERS
2012-7323	10/11/2012 11/08/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/ OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	MICHELLE L MEJIA SANDLER TRAVIS & ROSENBERG PA	PERISHABLE SPECIALIST INC - ALL-0115379-0, ALL-0115922-7 NOTICES OF ACTION,REDELIVERY REQUESTS; SPIECH LLC - REFUSALS
2012-7324	10/11/2012 11/08/2012	FDA/OC/OES/DFOI/ OC/ORA/ OC/ORA/ FDA/OC/OES/DFOI/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ OC/CVM/OCD/	MICHELLE L MEJIA SANDLER TRAVIS & ROSENBERG PA	DEEP VALLEY FARM INC, FIGHT BAC - DRUG FACILITY REGISTRATION, WARNING TLRS, PROD LISTING; EMPACK - LIQUIDATED DAMAGES RECS, ETC
2012-7325	10/11/2012 11/08/2012	FDA/OC/OES/DFOI/	MICHAEL NAZERIAS PETNET SOLUTIONS INC	CARDINAL HEALTH 414 LLC, SEATTLE, WA; LAS VEGAS, NV, MEMPHIS, TN, ETC - EIRS, 483S
2012-7326	10/11/2012 11/15/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MCCASH, MARY	MICHAEL HAWOTTE, ALFACELL, CELEBREX, FLOMAX - RECS

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OO/OFBA/OAGS/		
2012-7327	10/11/2012 11/08/2012	FDA/OGROP/ORANE-FO/NYK- DO/NYK-DCB/	ONA SCANDURRA COUNTRY LIFE LLC	COUNTRY LIFE LLC, HAUPPAUGE, NY - EIRS, 483S 6/10 TO PRESENT
2012-7328	10/11/2012 11/08/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DR YA PING LEE CURTIN UNIV SCHOOL OF PHARMACY	ORAL PROTON PUMP INHIBITORS (PPI); OMEPRAZOLE, ESOMEPRAZOLE, ETC - AERS
2012-7329	10/11/2012 11/08/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LYNAE CHANG Boscogen, Inc.	SYN TECH PHARM AND TECH, SINYING CITY, TAIWAN - INSP 5/12
2012-7330	10/11/2012 11/08/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WILLIAM G GAINER TOLIVER & GAINER	RANBAXY PHARMS - MINOCYCLINE LBLG CHANGE, CORR, APRVL RECS, ETC
2012-7331	10/11/2012 11/08/2012	OC/ORANE/ORM/ OC/ORANE/ORM/	DAVID P JORDAN THOMSON REUTERS	FOREIGN & DOMESTIC DRUG MFRS, REPACKERS, LABELERS, ETC INSPS 1/11 TO 12/11
2012-7332	10/11/2012 11/08/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	GILLET #410314, TONY	IBOGAINE - RECS; STRANGE LOOKING MEAT SERVED BY GOVERNMENT EMPLOYEES - TESTING RECS
2012-7333	10/11/2012 11/08/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DUBECK B00004, ROBERT	XANAX, ZOLOFT, SLEEP AIDS, ETC - SLEEP DRIVING RECS
2012-7334	10/11/2012 11/08/2012	FDA/OGROP/ORANE-FO/NYK- DO/NYK-DCB/	TRAVIS SCHAFTENAAR UBS GLOBAL ASSET MANAGEMENT	ANGIODYNAMICS, QUEENSBURY, NY - 483 7/12 TO 9/12
2012-7335	10/11/2012 12/28/2012	FDA/OMPT/CDRH/OCER/DFOI/	ROYA BORAZJANI COOPER VISION, INC	DELEFILCON A SOFT CONTACT LENS K113168
2012-7336	10/11/2012	FDA/OMPT/CDRH/OCER/DFOI/	ROYA BORAZJANI	BAUSCH & LOMB - MESOFILCON A CONTACT LENS K113703

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	11/08/2012		COOPER VISION, INC	
2012-7337	10/11/2012 11/08/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARY B SZALKOWSKI PRISMA CORP	INDAPAMIDE AND PERINDOPRIL - AERS 7/21/12 TO PRESENT
2012-7338	10/11/2012 11/08/2012	OC/OA/OM/OMP/DDM/	MARY B SZALKOWSKI PRISMA CORP	NEUROPHARMACOLOGIC DRUGS A/C - TRANS 9/14/71
2012-7339	10/11/2012 11/08/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	NORBERT GOTTESMAN AVET CAPITAL MANAGEMENT LLC	EISAI INC - DECITABINE INJ OGD BIOEQV REQUIREMENTS
2012-7340	10/11/2012 11/08/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	NORBERT GOTTESMAN AVET CAPITAL MANAGEMENT LLC	CELGENE - AZACITIDINE INJECTABLE SUSPENSION - BIEQV RECS
2012-7341	10/12/2012 11/09/2012	OC/OM/OMP/DDM/	CARLA SCARMAZZI KING & SPALDING	DKT FDA-2012-N-0378
2012-7342	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	2012-5105
2012-7343	10/12/2012 11/09/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	JOHN HARLOE JD PHD FREESE & GOSS, PLLC	OBSTETRICS & GYNECOLOGY MEDICAL DVCS A/C - RECS 9/8/11
2012-7344	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	2012-6121
2012-7345	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	2012-5361
2012-7346	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	2012-5576
2012-7347	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	2012-2862
2012-7348	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	2012-5996
2012-7349	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	2011-7845

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2012-7350	10/12/2012 11/09/2012	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/ FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORACE-FO/PHIDO/PHI-CB/ FDA/OGROP/ORAPA-FO/LOSDO/LOS-CB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	SCHARBERG, DAVID L	GLAXOSMITHKLINE INC 8/9/12; EXPERIMENTAL PATHOLOGY LABS 8/14/12; TRS LABS INC 7/6/12, ETC - 483S 6/12 TO 8/12
2012-7351	10/12/2012 11/09/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	FOI Services, Inc.	2012-5751
2012-7352	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	2012-2638
2012-7353	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	2012-3213
2012-7354	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	2012-5728
2012-7355	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	2012-2920
2012-7356	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	2012-3057
2012-7357	10/12/2012 11/09/2012	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	PAUL W TRIPP LINCARE INC	FLEXLIFE HEALTH INC (ZIN MEDICAL INC), OH - EIRS, 483S, WARNING LTRS 1/05 TO PRESENT
2012-7358	10/12/2012	FDA/OC/OES/DFOI/		2012-3296

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	11/09/2012		FOI Services, Inc.	
2012-7359	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	2012-3494
2012-7360	10/12/2012 11/09/2012	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	BOOT, KEVIN	EMBRIA HEALTH SCIENCES LLC, ANKENY, IA - EIR 7/24/12
2012-7361	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 9/17-21/12
2012-7362	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 9/17-21/12
2012-7363	10/12/2012 11/09/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FOI Services, Inc.	PFIZER - VISINE PURE TEARS APRVL, CLNCL TRIAL, EFFICACY 2005
2012-7364	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 9/24-28/12
2012-7365	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 9/24-28/12
2012-7366	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 9/24-28/12
2012-7367	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 9/17-21/12
2012-7368	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 9/10-14/12
2012-7369	10/12/2012 11/09/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	S. TIRUVENDRA RA CHEM PHARMA LTD	RA CHEM PHARMA LTD, ANDHRA PRADESH, INDIA - EIR 3/26/12 TO 4/3/12
2012-7370	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOI REQUESTS 9/24-28/12
2012-7371	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	CLOSED FOI REQUESTS 9/24-28/12

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2012-7372	10/12/2012 11/09/2012	OC/CVM/OCD/ OC/OER/OPA/ FDA/OC/OEXA/OMA/	THOMAS E. SOULE EDELMAN COMBS LATTURNER ET AL	CANADIAN BRAODCASTING CORP INVESTIGATION OF IMPORTED CHICKEN JERKY USED AS PET FOOD
2012-7373	10/12/2012 11/09/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	mahlaqa patel PATEL, MAHLAQA	NDA 017871 - SBA
2012-7374	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 9/24-28/12
2012-7375	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 9/24-28/12
2012-7376	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 9/24-28/12
2012-7377	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOI REQUESTS 10/1-5/12
2012-7378	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	CLOSED FOI REQUESTS 10/1-5/12
2012-7379	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 10/1-5/12
2012-7380	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 10/1-5/12
2012-7381	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 10/1-5/12
2012-7382	10/12/2012 11/09/2012	FDA/OMPT/CDRH/OCER/DFOI/	AYAMI MARUYAMA CANON INC	BARCO - MAMMO TOMOSYNTHESIS K103792; CORONIS FUSION 10MP K093197; EIZO - REDIFORCE RX840-MG K093197
2012-7383	10/15/2012 11/13/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Laura Jacques Jacques, Laura A	INFLUENZA VACCINE - VAERS
2012-7384	10/15/2012 11/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Andrew Pollack NEW YORK TIMES COMPANY	NEW ENGLAND COMPOUNDING COMPANY - MEETING MINUTES, 483, REPORTS

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		OC/ORO/ OC/ORO/		
2012-7385	10/15/2012 11/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	David Hwang Mid-Link International Inc	SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD - 483 (4/9/2012 to 4/12/2012)
2012-7386	10/15/2012 11/13/2012	OC/OA/OM/OMP/DDM/	John Connell John Connell	PETITIONS RE ARENA PHARM LORCASERIN, QNEXA
2012-7387	10/15/2012 11/13/2012	FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/	David O'Connor PRACS INSTITUTE, LTD.	BA RESEARCH, HOUSTON, TX - EIRS (01/01/2005 - 12/31/2005)
2012-7388	10/15/2012 11/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sajjan Aryal ACCUCAPS INDUSTRIES LTD	IWAKI SEIYAKU CO LTD, KAKEGAWA CITY, JAPAN - EIR 10/08/2010
2012-7389	10/15/2012 11/13/2012	FDA/OC/OES/DFOI/	MOI, Inc.	RFQ 1103834-SOL-2012 - ARBEE ASSOCIATES, INC. PROPOSAL
2012-7390	10/15/2012 11/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Andrew Grant Benten Films	ZYPREXA, RISPERDAL - ISR
2012-7391	10/15/2012 11/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	Medinnovo LLC	K081147
2012-7392	10/15/2012 11/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	Scott Ki Idaho Business Review	IBX, CARDIOGRIP, ZONA PLUS, ZONA RX - 510K
2012-7393	10/15/2012 11/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Christopher Weaver THE WALL STREET JOURNAL	CANADA DRUGS, CANADADRUGS.COM - FDA CORR RE 9/21/12 WARNING LETTER ETC
2012-7394	10/15/2012 11/13/2012	FDA/OGROP/ORO/CE-FO/PHI-DO/PHI-CB/	Alka Chandna PETA	TRIPLE F FARMS, SAYRE, PA - EMAILS, LETTERS, REPORTS, ETC
2012-7395	10/15/2012 11/13/2012	FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	Bob Burns Talenti Gelato	JIMBO'S JUMBOS, INC, EDENTON, NC - EIRS (10/01/2009 - 10/11/2012)
2012-7396	10/15/2012 11/13/2012	FDA/OFVM/CFSAN/OCD/EOS/	Silvia Volkmann Orion Engineered Carbons GmbH	FAP 5B4464
2012-7397	10/15/2012	FDA/OFVM/CFSAN/OCD/EOS/	Steve Barwick	SILVER CONTAINING DIETARY SUPPLEMENTS - RECS RE

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	11/13/2012		Barwick, Steve	ABSORBING CERTAIN DRUGS
2012-7398	10/15/2012 11/13/2012	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Schraven, John	ALMASED - RESPONSE TO 01/18/12 WARNING LETTER
2012-7399	10/15/2012 11/13/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Paula Eichman APTALIS PHARMATECH INC	NATIONAL VITAMIN, CASA GRANDE, AZ - EIRS LAST TWO YEARS
2012-7400	10/15/2012 11/13/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Amanda E. De Vito, Couch White LLP Couch White LLP	SICAP INDUSTRIES, LLC, ALBANY, NY; GSC PRODUCTS LLC, ALBANY, NY; WAYNE PERRY - RECS 01/01/03 TO 10/11/12
2012-7401	10/15/2012 11/13/2012	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/ FDA/OMPT/CDRH/OCER/DFOI/ OC/ORA/OCI/ OC/ORA/OCI/	ROBERT G BERNHOFT BERNHOF LAW FIRM SC	INDIVIDUAL RECS
2012-7402	10/15/2012 11/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRANT WIGGER TRANSPHOTON CORP	APEX XL-4 K033001
2012-7403	10/15/2012 01/31/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	LAWRENCE A BOHM ESQ BOHM LAW GROUP	INDIVIDUAL RECS
2012-7404	10/15/2012 11/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ROBERT E COLLIER II COLLIER & ASSOCIATES LAW OFCS	TEVA PHARMACEUTICALS USA, TEVA NEUROSCIENCES INC - COPAXONE CMLPTS, RVWS, AERS, ETC
2012-7405	10/15/2012 11/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARTIN R PRINCE MD PHD Weill Medical College of Cornell University	GADOLINIUM - ISRS 6055003, 6238473, ETC
2012-7406	10/15/2012 11/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DOUGLAS P DOWD DOWD & DOWD PC	ABBOTT LABS - DEPAKOTE (DIVALPROEX SODIUM, VALPROIC ACID) AERS, WARNINGS, CO RESP, ETC
2012-7407	10/15/2012 11/13/2012	FDA/OGROP/ORARO/DIOP/ FDA/OGROP/ORASW-FO/SWID/SWID-CB/	CLAUDIA HORNBACK ROANOKE TRADE SERVICES INC	AGROSUN INC - ENTRY #DV101281900 NOTICES OF FDA REFUSAL
2012-7408	10/15/2012	OC/ORA/OCI/		INDIVIDUAL RECS

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	11/13/2012	OC/ORA/OCI/	Doe J	
2012-7409	10/15/2012 11/13/2012	FDA/OC/OES/DFOI/ FDA/OGROP/ORPA/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MEGHAN E RUESCH TRAUB LIEBERMAN STRAUS ET AL	USA FAR OCEAN GROUP INC - U-PROSTA NATURAL SUPPORT FOR PROSTATE HEALTH CORR, WARNING LTRS, CMLNPTS, ETC
2012-7410	10/15/2012 11/13/2012	FDA/OC/OES/DFOI/	ALISON M AGNEW PILLSBURY WINTHROP SHAW PITTMAN LLP	2012-6833
2012-7411	10/15/2012 11/13/2012	FDA/OC/OES/DFOI/	JOHN H REED MD WORLD INSTITUTE FOR SCIENTIFIC EXPLORATION	FOI DAILY LOG FY 1966 TO FY 1999
2012-7412	10/15/2012 11/13/2012	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	CRAIG ROUSH ROCKLINE INDUSTRIES	KLEEN TEST PRODUCTS CORP, PORT WASHINGTON, WI - EIR, 483, CORR 8/12
2012-7413	10/15/2012 11/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DOUGLAS P DOWD DOWD & DOWD PC	HOFFMAN-LAROCHE/ROCHE LABS - ACCUTANE AERS, WARNINGS, CO RESP, ETC
2012-7414	10/15/2012 11/13/2012	FDA/OFVM/CFSAN/OCD/EOS/	HALEY, KALA	FREE RANGE, CAGE FREE ANIMAL PRODS - DEFINITIONS, VIOLATIONS, FALSE ADVERTISING, ETC
2012-7415	10/15/2012 11/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	STUTE, HANK	CPT1200119
2012-7416	10/15/2012 12/06/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	JOHN RICHARSON Surveyor Capital	BAXTER HEALTHCARE CORP-BAXTER AG 1/21/10; BAXTER BIOSCIENCE 1/28/10; BAXTER MANUFACTURING SPA 9/1/09, ETC - 483S
2012-7417	10/15/2012 11/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	John Blewitt LIFECCELL CORPORATION	K080442
2012-7418	10/16/2012 11/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	Bernita Vick MPR Associates, Inc.	K012769
2012-7419	10/16/2012 11/14/2012	FDA/OFVM/CFSAN/OCD/EOS/	Judy Negley Valspar Corporation	FCN 1103
2012-7420	10/16/2012	OC/ORA/	Richard R. Stephens	TEST RESULTS

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	11/15/2012	OC/ORA/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Stephens, Richard R	
2012-7421	10/16/2012 11/14/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lee, Ellese N	ONCASPAR - AERS
2012-7422	10/16/2012 11/14/2012	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	THE NEW YORK TIMES	OASIS DATA
2012-7423	10/16/2012 11/14/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	LYNN R WEBSTER, SALT LAKE CITY, UT - MOST RECENT 483
2012-7424	10/16/2012 11/14/2012	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	Kathy Takeuchi, Pharm.D. HARBORVIEW MEDICAL CENTER	HYDROXUREA - AERS
2012-7425	10/16/2012 11/14/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Connie Romaine LSU Health Sciences Center in New Orleans	LSU HEALTH SCIENCES CENTER, NEW ORLEANS, LA - RESPONSE TO LETTER DATED 06/29/12
2012-7426	10/16/2012 11/14/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KMGH-TV	PRADAXA - AERS
2012-7427	10/16/2012 11/14/2012	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	Bethany Walls INTERTEK	FCN 1167
2012-7428	10/16/2012 11/14/2012	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	JOHNATHAN RICKMAN FDA NEWS	ACCURAY INC, SUNNYVALE, CA; MEDTRONIC ADVANCED ENERGY LLC, PALO, ALTO, CA; SKELETAL KINETICS LLC, CUPERTINO, CA, ETC - 483S 7/1-31/12
2012-7429	10/16/2012 11/14/2012	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	JOHNATHAN RICKMAN FDA NEWS	WYETH PHARMACEUTICAL CO (PFIZER CONSUMER HEALTHCARE), GUAYAMA, PR; ABBOTT BIOTECHNOLOGY LTD, BARCELONETA, PR; SURGICAL SPECIALTIES PUERTO RICO INC (ANGIOTECH PR INC), AGUADILLA, PR - 483S 7/1-31/12
2012-7430	10/16/2012	FDA/OMPT/CDER/GRP/DIDP/	Huan Tran	K102694

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	11/14/2012		Next Orthosurgical, Inc.	
2012-7431	10/16/2012 11/14/2012	FDA/OC/OES/DFOI/	Sarah Freishtat MEDILL SCHOOL OF JOURNALISM	MEDIA FOIA REQUESTS LAST SIX MONTHS
2012-7432	10/16/2012 11/14/2012	FDA/OGROP/ORPA/FO/SEA-DO/SEA-CB/	JOHNATHAN RICKMAN FDA NEWS	VIDCO INC, BEAVERTON, OR; KOREGON ENTERPRISES INC (NITE TRAIN'R), BEAVERTON, OR; ATOSSA GENETICS INC, SEATTLE, WA, ETC - 483S 7/1-31/12
2012-7433	10/16/2012 11/14/2012	FDA/OGROP/ORASE/FO/ATL-DO/ATL-CB/	Tracy Taylor Tracy Taylor	ROCHE CAROLINA, FLORENCE, SC - EIR, 483 03/01/2012 - 10/01/2012
2012-7434	10/16/2012 11/14/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	JOHNATHAN RICKMAN FDA NEWS	BAXTER MANUFACTURING SPA, RIETI, ITALY - 483S 7/1-31/12
2012-7435	10/16/2012 11/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHNATHAN RICKMAN FDA NEWS	HISUN PHARMACEUTICAL HANGZHOU CO LTD, FUYANG CITY, CHINA; ALCHEM INTERNATIONAL LTD, BALLABGARH, FARIDABAD, HARYANA, INDIA; CENEXI LABORATORIES THISSEN SA, BRAINE L'ALLEUD, BELGIUM, ETC - 483S 7/1-31/12
2012-7436	10/16/2012 11/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	JOHNATHAN RICKMAN FDA NEWS	TAIWAN KING STRONG CO LTD, TAICHUNG CITY, TAIWAN; XIANTAO RAYXIN MEDICAL PRODUCTS CO LTD, XIANTAO CITY, CHINA; VBM MEDIZINTECHNIK GMBH, SULZ AM NECKAR, GERMANY, ETC - 483S 7/1-31/12
2012-7437	10/16/2012 11/14/2012	FDA/OGROP/ORACE/FO/NWJ-DO/NWJ-CB/	JOHNATHAN RICKMAN FDA NEWS	BLOOMEX INTERNATIONAL INC, ELMWOOD PARK, NJ; INTEGRA LIFESCIENCES CORP, PLAINSBORO, NJ - 483S 7/1-31/12
2012-7438	10/16/2012 11/14/2012	FDA/OGROP/ORASE/FO/NOL-DO/NOL-CB/	JOHNATHAN RICKMAN FDA NEWS	SUNBEAM PRODUCTS INC (JARDEN CONSUMER SOLUTIONS), WAYNESBORO, MS; SOURCE PRODUCTION & EQUIPMENT CO INC, ST ROSE, LA; KNU LLC, LELAND, MS - 483S 7/1-31/12
2012-7439	10/16/2012 11/14/2012	FDA/OGROP/ORANE/FO/NWE-DO/NWE-CB/	JOHNATHAN RICKMAN FDA NEWS	GENZYME CORP, FRAMINGHAM, MA; TWINCRAFT INC, WINOSKI, VT; SPECIALTY MINERALS INC, ADAMS, MA, ETC - 483S 7/1-31/12
2012-7440	10/16/2012 11/14/2012	FDA/OGROP/ORASW/FO/DEN-DO/DEN-CB/	JOHNATHAN RICKMAN FDA NEWS	CORE LABS LLC, ENGLEWOOD, CO - 483S 7/1-31/12
2012-7441	10/16/2012 11/14/2012	FDA/OGROP/ORACE/FO/CIN-DO/CIN-CB/	JOHNATHAN RICKMAN FDA NEWS	NATURAL ESSENTIALS INC, STREETSBORO, OH; AMYLLIN OHINO LLC, WEST CHESTER, OH; SCOTTCARE CORP, CLEVELAND, OH - 483S 7/1-31/12
2012-7442	10/16/2012 11/14/2012	FDA/OGROP/ORACE/FO/CHI-DO/CHI-CB/	JOHNATHAN RICKMAN FDA NEWS	PRIMROSE CANDY CO, CHICAGO, IL; ABBOTT MOLECULAR, DES PLAINES, IL; HOSPIRA INC, LAKE FOREST, IL - 483S 7/1-31/12
2012-7443	10/16/2012	FDA/OMPT/CDER/ORP/DIDP/	KEVIN M FITZERLAND	ORTHO PHARMACEUTICAL, CORP; ORTHO-MCNEIL PHARMACEUTICALS INC; PRICARA, ETC - LEVAQUIN

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	11/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/OA/OM/OMP/DDM/	LEWIS SAUL & ASSOCS	AERS, TRANS, LTRS, ETC
2012-7444	10/16/2012 11/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/OA/OM/OMP/DDM/	KEVIN M FITZGERALD LEWIS SAUL & ASSOCS	SCHERING-PLOUGH CORP; SCHERING CORP; MERCK & CO INC - AVELOX AERS, TRANS, LTRS; ETC
2012-7445	10/16/2012 11/14/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	JOHNATHAN RICKMAN FDA NEWS	BRISTOL MYERS SQUIBB CO, EAST SYRACUSE, NY; MOGEN INSTRUMENTS, BROOKLYN, NY; SMARTPILL CORP, BUFFALO, NY - 483 7/12
2012-7446	10/16/2012 11/14/2012	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	JOHNATHAN RICKMAN FDA NEWS	VIRGINIA BLOOD SERVICES, RICHMOND, VA - 483 7/12
2012-7447	10/16/2012 11/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Justine Hager Biodel Inc.	NDA 018780
2012-7448	10/16/2012 11/14/2012	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	JOHNATHAN RICKMAN FDA NEWS	BANNER PHARMACAPS INC, HIGH POINT, NC; NEWTON LABORATORIES INC, CONYERS, GA; CR BARD INC, COVINGTON, GA - 483 7/12
2012-7449	10/16/2012 11/14/2012	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	JOHNATHAN RICKMAN FDA NEWS	POLYMER TECHNOLOGY SYS INC, INDIANAPOLIS, IN; AXIOBIONICS LLC, ANN ARBOR, MI - 483 7/12
2012-7450	10/16/2012 11/14/2012	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	JOHNATHAN RICKMAN FDA NEWS	ATLANTIC PRO NUTRIENTS INC, ORLANDO, FL; DEXTRUM LABORATORIES INC, MIAMI, FL; ADVANCED RADIATION MEASUREMENT INC, FT PIERCE, FL - 483 7/12
2012-7451	10/16/2012 11/14/2012	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	JOHNATHAN RICKMAN FDA NEWS	AUXILIUM PHARMA INC, HORSHAM, PA; PARTICLE SIZE TECHNOLOGY INC, QUAKERTOWN, PA; HERCON LABORATORIES CORP, EMIGSVILLE, PA - 483 7/12
2012-7452	10/16/2012 11/14/2012	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	JOHNATHAN RICKMAN FDA NEWS	MARCUS RESEARCH LAB INC, ST LOUIS, MO - 483 7/12
2012-7453	10/16/2012 11/14/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	JOHNATHAN RICKMAN FDA NEWS	HEALTH PLUS INC, CHINO, CA; LEVLAD LLC, CHATSWORTH, CA; BLAINE LABS INC, SANTA FE SPRINGS, CA - 483 7/12
2012-7454	10/16/2012 11/14/2012	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	JOHNATHAN RICKMAN FDA NEWS	WISCONSIN PHARMACAL CO LLC, JACKSON, WI; KLEEN TEST PRODUCTS CORP, PORT WASHINGTON, WI; AJD LABORATORIES INC, PARK RAPIDS, MN - 483 7/12

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2012-7455	10/16/2012 11/14/2012	OC/ORA/ OC/ORA/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHNATHAN RICKMAN FDA NEWS	TAKEDA PHARMACEUTICAL CO LTD, HIKARI, JAPAN - 483 7/12
2012-7456	10/16/2012 11/14/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 9/10-14/12
2012-7457	10/16/2012 11/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sue Corbett THE RESEARCH INVESTMENT, INC.	GUIDANCE CONJUGATED ESTROGEN TABLETS - IN VIVO BIOEQUIVALENCE, IN VITRO DRUG RELEASE
2012-7458	10/16/2012 11/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John Bonifield CNN	EPIDURAL INJECTION OF NECC PRODUCT - DATE OF EXPOSURE, NAME AND LOCATION OF FACILITY; TRANSPLANT PATIENTS - DATES OF EXPOSURE, NAME AND LOCATION OF FACILITIES
2012-7459	10/16/2012 11/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	K082298
2012-7460	10/16/2012 11/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	NDA 21520 S 012
2012-7461	10/16/2012 11/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Justine Hager Biodel Inc.	NDA 020928
2012-7462	10/16/2012 11/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Justine Hager Biodel Inc.	NDA 018780
2012-7463	10/16/2012 11/14/2012	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Susan Searles IKARIA INC	AVANTOR MATERIALS, CENTER VALLEY, PA - EIR (01/03/2011 - 10/16/2012)

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2012-7464	10/16/2012 11/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRENT M. ARDAUGH NORTHWESTERN UNIV FEINBERG SCHOOL OF MEDICINE	K963226, K931386, K915774
2012-7465	10/16/2012 11/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRENT M. ARDAUGH NORTHWESTERN UNIV FEINBERG SCHOOL OF MEDICINE	K831949, K923367, K926138
2012-7466	10/16/2012 11/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRENT M. ARDAUGH NORTHWESTERN UNIV FEINBERG SCHOOL OF MEDICINE	K083191
2012-7467	10/16/2012 11/14/2012	OC/ORA/ OC/ORA/	BRIAN HARTMAN ABC NEWS	SUNLAND INC - SALMONELLA OUTBREAK 2007 TO PRESENT
2012-7468	10/16/2012 11/14/2012	FDA/OGROP/ORASW-FO/DEN- DO/DEN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	INDIVIDUAL RECS
2012-7469	10/16/2012 11/14/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	NICOLAS 635504, ALBERT	PFIZER - LYRICA AER
2012-7470	10/16/2012 11/14/2012	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 10/1-5/12
2012-7471	10/17/2012 11/15/2012	FDA/OC/OES/DFOI/	Paul Knoepfler UNIVERSITY OF CALIFORNIA, DAVIS	CELLTEX, SUGARLAND, TX - WARNING LETTER
2012-7472	10/17/2012 11/15/2012	FDA/OFVM/CFSAN/OCD/EOS/	Mark Jackson ARCADIS	FCN 1096
2012-7473	10/17/2012 11/15/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Johnathan Rickman FDA NEWS	HOLOPACK, GERMANY - 483 2/24/2012

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2012-7474	10/17/2012 11/15/2012	FDA/OMPT/CDRH/OCER/DFOI/	Imran Karim	K101382
2012-7475	10/17/2012 11/15/2012	FDA/OFVM/CFSAN/OCD/EOS/	Wheeler, Lisa P	REPORT BY FDA TO HHS RE LABELING OF INFANT FORMULA 1981
2012-7476	10/17/2012 11/15/2012	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Drew Barlow Vertex Pharmaceuticals Incorporated	VERTEX PHARM INC. - QAP; EIR 12/21/11-01/13/12
2012-7477	10/17/2012 11/15/2012	OC/ORA/ OC/ORA/	James Andrews FOOD SAFETY NEWS	SUNLAND, INC - INSPECTION RECS 03/01/2009 - 10/16/2012
2012-7478	10/17/2012 11/15/2012	OC/ORA/ OC/ORA/	Cheryl Bernard Bernard, Cheryl	SUNLAND INC - EIR, 483, RESPONSES 08/01/2009 - 10/16/2012
2012-7479	10/17/2012 12/20/2012	FDA/OFVM/CFSAN/OCD/EOS/	Mark Jackson ARCADIS	FCN 1021
2012-7480	10/17/2012 11/15/2012	FDA/OFVM/CFSAN/OCD/EOS/	Mark Jackson ARCADIS	FCN 1020
2012-7481	10/17/2012 11/15/2012	FDA/OO/OFBA/OAGS/	Strategi Consulting	HHSF223201210029I - PROPOSAL, AWARDED CONTRACT, MODIFICATIONS
2012-7482	10/17/2012 11/15/2012	FDA/OMPT/CDRH/OCER/DFOI/	Gary Pekoe, Phd., or Kelley Creamer, Regulatory Affairs Mngr PluroGen Therapeutics, Inc.	PLUROGEL 45-5 CONCENTRATE CLEANSING PRODUCT - DEVICE CORR
2012-7483	10/17/2012 11/15/2012	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	LEERINK SWANN & CO	ALERE, SAN DIEGO, CA - RESPONSE TO 483 7/17/12
2012-7484	10/17/2012 11/15/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rob Disselkamp Rob Disselkamp	RISPERIDONE - AERS
2012-7485	10/17/2012 11/15/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rob Disselkamp Rob Disselkamp	DEPAKOTE - AERS
2012-7486	10/17/2012	FDA/OC/OES/DFOI/	AMY KINCANON	2009-8268

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	11/15/2012		LEXIS NEXIS COURTLINK INC	
2012-7487	10/17/2012 11/15/2012	FDA/OC/OES/DFOI/	AMY KINCANON LEXIS NEXIS COURTLINK INC	2010-2408
2012-7488	10/17/2012 11/15/2012	FDA/OC/OES/DFOI/	AMY KINCANON LEXIS NEXIS COURTLINK INC	2010-8869
2012-7489	10/17/2012 11/15/2012	FDA/OFVM/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	155879 - CAERS ADDITIONAL RECS
2012-7490	10/17/2012 11/15/2012	FDA/OFVM/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	155912 - CAERS ADDITIONAL RECS
2012-7491	10/17/2012 11/15/2012	FDA/OFVM/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	155912 - CAERS ADDITIONAL RECS
2012-7492	10/17/2012 11/15/2012	FDA/OFVM/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	155879 - CAERS ADDITIONAL RECS
2012-7493	10/17/2012 11/15/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	MARY BETH HENDERSON RCRI	THERMOCHEM-HT SYS - K993330
2012-7494	10/17/2012 11/15/2012	FDA/OC/OES/DFOI/	HENRY GLUCKSTERN HENRY GLUCK ATTY	SABIN TRIVALENT ORAL POLIO VACCINE - FOI REQUESTS 1/00 TO PRESENT
2012-7495	10/17/2012 11/15/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/CVM/OCD/	THOMAS D GOODRICH PHD PHARMAQ	SHANGHAI ZHONGXI SUNVE PHARMACEUTICAL CO LTD, SHANGHAI, CHINA - EIRS, 483S MOST RECENT
2012-7496	10/17/2012 11/15/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	JAY S TRIVEDI PATRIN PHARMA INC	MALLINCKRODT - METHYLPHENIDATE ORAL SOL NDA 21-419 10 MG, 5 ML 12/19/O2; TRISH PHARMA - METHYLPHENIDATE ORAL SOL ANDA 91-601 5 MG, 5 ML 7/23/10
2012-7497	10/17/2012 11/15/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LIA OBATA DOWD DOWD & DOWD PC	MERCK SHARP & DOHME CORP - FOSAMAX AERS, NDA, RESP

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		FDA/OMPT/CDER/ORP/DIDP/		
2012-7498	10/17/2012 11/15/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RITA BECHARA ACASTI PHARMA INC	AMARIN PHARMA INC - VASCEPA NDA 202-057 PRVL PKG 7/26/12
2012-7499	10/17/2012 11/15/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHESTER C STETFELT JR CHESTER C STETFELT JR OFC	PREMPRO, PROVERA - RECS
2012-7500	10/17/2012 11/15/2012	FDA/OGROP/ORACE-FO/MIN- DO/MIN-CB/ FDA/OMPT/CDRH/OCER/DFOI/ OC/OA/OM/OMP/DDM/ FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORASE-FO/SJN- DO/SJN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	YVONNE M FLAHERTY LOCKRIDGE GRINDAL NAUEN PLLP	PARADIGM QUICK-SET INFUSION SETS K011071 - EIRS, CMLPLNTS, ETC
2012-7501	10/17/2012 11/15/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/	PATI WALLER MARLER CLARK ATTYS	DOCTORS MEDICAL CENTER, MODESTO, CA - SALMONELLA IN INFANT FORMULA COMM, LAB RESULTS, RPTS, ETC 4/12, 5/12
2012-7502	10/17/2012 11/15/2012	OC/ORA/ OC/ORA/ FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/	MONTY DUCK BEF FOODS INC	BEF FOODS INC, SULPHUR SPRINGS, TX - LAB RESULTS 9/11/12
2012-7503	10/17/2012 01/11/2013	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORA/ OC/ORA/ OC/ORAOE/ OC/ORAOE/ OC/ORA/ORO/DFS/ OC/ORA/ORO/DFS/ FDA/OC/OES/DFOI/ FDA/OGROP/ORA/ORO/DIOP/ FDA/OGROP/ORAPA-FO/LOS-	CARRIE LUBINSKI GORDON & REES LLP	MANGOES OUTBREAK OF SALMONELLA - SPLS, LAB NOTEBOOKS, W/S, ETC 2012

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		DO/LOS-CB/ FDA/OGROP/ORO/PA-FO/SEA-DO/SEA-CB/ FDA/OGROP/ORO/SE-FO/NOL-DO/NOL-CB/		
2012-7504	10/17/2012 11/15/2012	OC/ORO/ OC/ORO/	MARY CLARE JALONICK ASSOCIATED PRESS	SUNLAND INC - OUTBREAK OF SALMONELLA IN PEANUT BUTTER 483S 2009, 2010, 9/12
2012-7505	10/17/2012 11/15/2012	OC/OCOS/OES/ OC/OCOS/OES/	VANESSA, STARKS	HHS MANDATED INVESTIGATION OF THE OC OR OO OFFICE OF MANAGEMENT RPT INCLUDING ANY RELATED RECS FOR OFFICE OF MANAGEMENT & OFFICE OF MANAGEMENT PROGRAMS
2012-7506	10/17/2012 11/15/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Diane Hawkins Hawkins, Diane	INDIVIDUAL RECS
2012-7507	10/17/2012 11/15/2012	FDA/OMPT/CDRH/OCER/DFOI/	Allison Komiyama PaxMed International	K002612
2012-7508	10/17/2012 11/15/2012	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Allison Komiyama PaxMed International	K001143
2012-7509	10/17/2012 11/15/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LESLEY S ZORK JACK H OLENDER LAW OFCS	INDIVIDUAL RECS
2012-7510	10/18/2012 11/16/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Allison Komiyama PaxMed International	K052168
2012-7511	10/18/2012 11/16/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORO/ OC/ORO/ FDA/OC/OES/ OC/OCOS/OL/ FDA/OC/OCC/ FDA/OC/OL/	Matthew Stone Cohen, Placitella & Roth	NEW ENGLAND COMPOUNDING CENTER - INVESTIGATION RECS

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2012-7512	10/18/2012 11/16/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Glen Spielmans Metropolitan State University - Psyc Dpt	SYMBYAX - REVIEW RECS
2012-7513	10/18/2012 11/16/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 21455 S7
2012-7514	10/18/2012 11/16/2012	FDA/OC/OES/DFOI/ FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	RBC CAPITAL MARKETS	ST JUDE MEDICAL, SOMAR, CA - 483 09/01/2012 - 11/30/2012
2012-7515	10/18/2012 11/16/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA50495 - TOXICOLOGY DATA
2012-7516	10/18/2012 11/16/2012	FDA/OMPT/CDRH/OCER/DFOI/	HemoSonics LLC	K083842
2012-7517	10/18/2012 11/16/2012	FDA/OFVM/CFSAN/OCD/EOS/	Aaron Kochman Lauren AgriSystems	ALLOWABLE CARBON BLACK LOADING 21 CFR 177.2600
2012-7518	10/18/2012 11/16/2012	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	Christopher Weaver THE WALL STREET JOURNAL	ST JUDE MEDICAL, SYLMAR, CA - CORR RE ONGOING INSPECTION
2012-7519	10/18/2012 11/16/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA202236
2012-7520	10/18/2012 11/16/2012	FDA/OC/OES/DFOI/	WINGARD, MICHELLE	FOIA REQUESTS 8/1/12 TO 9/1/12
2012-7521	10/18/2012 11/16/2012	FDA/OMPT/CDRH/OCER/DFOI/	ALLISON CHEN HARVEST CONSULTING CORP	HERAEUS KULZER LLC - GLUMA DESENSTITZER POWER GEL K093575
2012-7522	10/18/2012 11/16/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	ALLISON CHEN HARVEST CONSULTING CORP	COLGATE-PALMOLIVE CO - COLGATE DESENSTIZING DENTAL CREAM K103461
2012-7523	10/18/2012 11/16/2012	FDA/OMPT/CDRH/OCER/DFOI/	ALLISON CHEN HARVEST CONSULTING CORP	HOENIX DENTAL INC - SUPER SEAL TOOTH DESENSITZER K120109

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2012-7524	10/18/2012 11/16/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	ALLISON CHEN HARVEST CONSULTING CORP	JENERIC/PENTRON INC - QUELL DESENSTIZER K010957
2012-7525	10/18/2012 11/16/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	PIA MALBRAN CBS MIAMI	DETLOGIX ANNULOPLASTY RING - K083191
2012-7526	10/18/2012 11/16/2012	FDA/OMPT/CDRH/OCER/DFOI/	SANDRA BROWN REICHERT TECHNOLOGIES	REICHERT INC - POD PAC 20M CORNEAL PACHYETER SYS K030610
2012-7527	10/18/2012 11/16/2012	FDA/OGROP/ORACE-FO/DET- DO/DET-CB/	BAXTER PHARMACEUTICAL SOLUTIONS	BAXTER PHARMACEUTICAL SOLUTIONS, LLC, BLOOMINGTON, IN - EIR 01/03/2011 - 10/17/2012
2012-7528	10/18/2012 11/16/2012	FDA/OMPT/CDRH/OCER/DFOI/	Annette Nelson CooperVision, Inc.	K100456
2012-7529	10/18/2012 11/16/2012	FDA/OGROP/ORASE-FO/ATL- DO/ATL-CB/ FDA/OMPT/CDRH/OCER/DFOI/	MATHEW A ZEPNICK EDELSTEINS FAEGENBURG & BROWN LLP	TRANS1 AXIAL LIF 2L ANTERIOR SPINAL FIXATION - INVESTIGATIVE RECS 7/8/10
2012-7530	10/18/2012 11/16/2012	FDA/OMPT/CDRH/OCER/DFOI/	Annette Nelson CooperVision, Inc.	K100349
2012-7531	10/18/2012 11/16/2012	FDA/OMPT/CTP/OD/	THE ASSOCIATED PRESS	CTP - NUMBER OF EMPLOYEES WORKING ON REVIEW OF SUBSTANTIAL EQUIVALENCE APPLICATIONS
2012-7532	10/18/2012 11/16/2012	FDA/OMPT/CDRH/OCER/DFOI/	JOHN E HALL MEDICINE HALL	PHILIPS HEARTSTREAM - PHILIPS HEARTSTART HOME DEFIBRILLATOR K040904, K020715, K003565 CLEARANCE LTR & PROD INSERT
2012-7533	10/18/2012 11/16/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MATHERNE, MICHAEL MARK	CIPRO (CIPROFLOXACIN) - AERS
2012-7534	10/18/2012 11/16/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ASHLEY E BASS COVINGTON BURLING LLP	BUDEPRION XL 300 MG (WELLBUTRIN XL 300 MG) - MEETINGS, COMM, SUBMISSIONS, ETC
2012-7535	10/18/2012 11/16/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	THOMAS P VALET RHEINGOLD, VALET, ET AL	FDA SCIENCE BACKGROUND PAPER: ACUTE PHOSPHATE NEPHROPATHY & RENAL FAILURE ASSOCIATED WITH THE USE OF ORAL SODIUM PHOSPHATE BOWEL CLEANSING PRODS; FDA SAFETY INFORMATION/WARNING REGARDING FLEET PHOSPHO-SODA & FLEET ACCU-PREP 5/5/06 (CERTIFIED)

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2012-7536	10/18/2012 11/16/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	SANJAY H SHARMA HETERO USA INC	GLUCOTROL XL (GLIPIZIDE ER TABS) 2.5 MG, 10 MG - CHEMISTRY RVWS, SBA, BIOEQV
2012-7537	10/18/2012 11/16/2012	FDA/OFVM/CFSAN/OCD/EOS/	JONES 06-A-0604, VERNON	WHAT ANIMAL IS THE SURCE OF SOYA LECITHIM ARTIFICIAL COLORS ACID, ETC
2012-7538	10/18/2012 11/16/2012	FDA/OFVM/CFSAN/OCD/EOS/	LISA Y LEFFERTS CENTER FOR SCIENCE IN PUBLIC INTEREST	SEARLE LABS - TWO YR TOXICITY STUDY IN THE RAT, 104 WEEK 2 GENERATION IN UTERO STUDY IN RAT, 115 WEEK ORAL TUMORIGENCITY STUDY IN THE RAT CARCINOGENICITY STUDIES ON ASPARTAME
2012-7539	10/18/2012 11/16/2012	OC/ORO/ OC/ORO/	MARTINA BERNSTEIN PETA FOUNDATION	BOVINE SPONGIFORM ENCEPHALOPATHY - MEMOS, RPTS, EVALUATIONS, ETC
2012-7540	10/18/2012 11/16/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	MELANIE COURTOT UNIV OF BRITISH COLUMBIA	ADVERSE EVENTS FOLLOWING INFLUENZA A (H1N1) MONOVALENT VACCINES 10/09 TO 1/31/10
2012-7541	10/18/2012 11/16/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/	Doe J	DOLE CORP - SPINACH RECS
2012-7542	10/18/2012 11/16/2012	FDA/OC/OES/DFOI/	JEFF STACHEWICZ FOIA GROUP INC	MC252 WELL - IDENTIFYING COMPOSITON OF OIL, QUANTITY OF OIL, FATE & TRANSPORT, ETC
2012-7543	10/19/2012 11/19/2012	OC/OM/OMP/DDM/	MARILYNN WHITNEY COVINGTON & BURLING LLP	DKT FDA-2012-P-0904
2012-7544	10/19/2012 11/19/2012	OC/OM/OMP/DDM/	GABRIEL SHERMAN Hyman Phelps and McNamara PC	DKT FDA-2012-P-0939
2012-7545	10/19/2012 11/19/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	AnnMarie Beattie Harmonized Customs Brokers, Inc	ENTRY G76-0129053-7 - LAB RESULTS
2012-7546	10/19/2012 11/19/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Ofek Levin Via Surgical Ltd	K091900
2012-7547	10/19/2012 11/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	Ofek Levin Via Surgical Ltd	K093845
2012-7548	10/19/2012 11/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	Huan Tran Next Orthosurgical, Inc.	K110125

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2012-7549	10/19/2012 11/19/2012	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/ORA/ OC/ORA/	Molly Moore Leader, Bulso & Nolan	NEW ENGLAND COMPOUNDING PHARMACY - INVESTIGATIVE RECS, CORR, MEMOS, ETC.
2012-7550	10/19/2012 11/19/2012	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Rachel Johnson FOI Services, Inc.	MERCK , WEST POINT, PA- EIRs, 483s, CORR (01/01/2009-12/31/2010)
2012-7551	10/19/2012 11/19/2012	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Holli Baker Ridley, McGreevy & Winocur P.C.	REACTION NUTRITION, CARNEGIE, PA - 483, RESPONSE 4/22/2010 - 10/17/2012
2012-7552	10/19/2012 11/19/2012	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	TOBACCO PRODUCT LISTING FOR ALTRIA, PHILIP MORRIS, SMOKELESS TOBACCO
2012-7553	10/19/2012 11/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	Allison Komiyama PaxMed International	K112860
2012-7554	10/19/2012 11/19/2012	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	CORR BETWEEN CTP AND INDUSTRY RE CAPSULES IN CIGARETTES
2012-7555	10/19/2012 11/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	Allison Komiyama PaxMed International	K103254
2012-7556	10/19/2012 11/19/2012	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	LIST OF PRODUCTS - ALTRIA CLIENT SERVICES, PHILIP MORRIS USA INC, SMOKELESS TOBACCO LLC ETC
2012-7557	10/19/2012 11/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	Allison Komiyama PaxMed International	K083770
2012-7558	10/19/2012 11/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	Ofek Levin Via Surgical Ltd	K092483
2012-7559	10/19/2012 11/19/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Alexandra Perreiter Sharp Memorial Hospital	RIVAROXABAN - AERS
2012-7560	10/19/2012 11/19/2012	FDA/OFVM/CFSAN/OCD/EOS/	Michael Keegan WaterCensus	BOTTLED WATER COMPANIES - TESTING DATA RESULTS SUBMITTED TO FDA UNDER CURRENT REGULATIONS (01/01/2011 - 12/31/2011)
2012-7561	10/19/2012	FDA/OO/	John Crewdson	LIST OF MEDICAL OFFICERS AT FDA

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	11/19/2012		PROJECT ON GOVERNMENT OVERSIGHT	
2012-7562	10/19/2012 11/19/2012	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	JOHNATHAN RICKMAN FDA NEWS	UNITED I INTERNATIONAL LABORATORIES LLC, CARROLLTON, TX; HOSPIRA INC, AUSTIN, TX; MEDICA RENTS CO LTD, FORT WORTH, TX - 483 8/12
2012-7563	10/19/2012 11/19/2012	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	JOHNATHAN RICKMAN FDA NEWS	BARTON CAREY MEDICAL PRODUCTS INC, MAUMEE, OH; KDB INC, CRESENT SPRINGS, KY - 483 8/12
2012-7564	10/19/2012 11/19/2012	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	JOHNATHAN RICKMAN FDA NEWS	BLISTEX INC, OAK BROOK, IL; PHOENIX INSTRUMENTS INC, NAPERVILLE, IL - 483 8/12
2012-7565	10/19/2012 11/19/2012	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	JOHNATHAN RICKMAN FDA NEWS	ALLO SOURCE INC, CENTENNIAL, CO; MOOG MEDICAL DEVICES GROUP, SALT LAKE CITY, UT - 8/12
2012-7566	10/19/2012 11/19/2012	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	JOHNATHAN RICKMAN FDA NEWS	CARACO PHARMACEUTICAL LABORATORIES LTD, DETROIT, MI; PHARMACIA & UPJOHN LLC, KALAMAZOO, MI - 483 8/12
2012-7567	10/19/2012 11/19/2012	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	JOHNATHAN RICKMAN FDA NEWS	MDR FITNESS CORP, SUNRISE, FL; HILL DERMATEUTICALS INC, SANFORD, FL; NEPHRON PHARMACEUTICALS CORP, ORLANDO, FL - 483 8/12
2012-7568	10/19/2012 11/19/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	JOHNATHAN RICKMAN FDA NEWS	TAKEDA PHARMACEUTICAL CO LTD, OSAKA, JAPAN; UNITED BIOMEDICAL INC, HSIN CHU HSIEN, TAIWAN; CONCORD BIOTECH LTD, AHMEDABAD, GUHURAT STATE, INDIA - 483 8/12
2012-7569	10/19/2012 11/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	JOHNATHAN RICKMAN FDA NEWS	SUZHOU HUANQIU ACUPUNCTURE MEDICAL APPLIANCE CO LTD, SUZHIU CITY, CHINA; TONICA ELEKTRONIK AS FARUM, DENMARK; RICHWAY NF, SEOUL, KR - 483 8/12
2012-7570	10/19/2012 11/19/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	JOHNATHAN RICKMAN FDA NEWS	KC PHARMACEUTICALS INC, POMONA, CA; VITAMINERALS INC, GLENDALE, CA; BEAUTY HEALTH & SCIENCE INNOVATIONS INC, PICO RIVERA, CA - 483 8/12
2012-7571	10/19/2012 11/19/2012	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	JOHNATHAN RICKMAN FDA NEWS	INCONTROL MEDICAL LLC, BROOKFIELD, WI - 483 8/12
2012-7572	10/19/2012 11/19/2012	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	JHONATHAN RICKMAN FDA NEWS	VERTEX PHARMACEUTICALS INC, CAMBRIDGE, MA; ALEXION PHARMACEUTICALS INC, SMITHFIELD, RI; TENDER CORP, LITTLETON, NH - 483 8/12
2012-7573	10/19/2012 11/19/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	JOHNATHAN RICKMAN FDA NEWS	ELITE LABORATORIES INC; SUITE K VALUE ADDED SERVICES LLC, EDISON, NJ; WEST-WARD PHARMACEUTICAL CORP, EATONTOWN, NJ - 483 8/12
2012-7574	10/19/2012 11/19/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	JOHNATHAN RICKMAN FDA NEWS	ZION ORGANICS INC, SAINT ALBANS, NY; SAFETEC OF AMERICA INC, BUFFALO, NY; COLUMBIA PRESBYTERIAN

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				MEDICAL CTR, NEW YORK, NY - 483 8/12
2012-7575	10/19/2012 11/19/2012	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	JOHNATHAN RICKMAN FDA NEWS	GUARDIAN ANGEL PRODUCTS INC, HUNTINGDON VALLEY, PA; SPRING HEALTH PRODUCTS INC, NORRISTOWN, PA; GLYCADIA INC, PHILADELPHIA, PA - 483 8/12
2012-7576	10/19/2012 11/19/2012	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	JOHNATHAN RICKMAN FDA NEWS	TEXCHEM CHEMICAL CO, SACRAMENTO, CA; GENENTECH INC, SOUTH SAN FRANCISCO, CA; CONSESNSUS ORTHOPEDICS INC, EL DORADO HILLS, CA - 483 8/12
2012-7577	10/19/2012 11/19/2012	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	JOHNATHAN RICKMAN FDA NEWS	CANGENE BIOPHARMA INC, BALTIMORE, MD; HAWKNAD MANUFACTURING INDUSTRIES INC, ALEXANDRIA, VA; IBA MOLECULAR NORTH AMERICA INC, MORGANTOWN, WV - 483 8/12
2012-7578	10/19/2012 11/19/2012	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	JOHNATHAN RICKMAN FDA NEWS	GILES CHEMICAL, WAYNESVILLE, NC; CAROLON CO, RURAL HALL, NC, PERKIN ELMER HEALTH SCIENCES, SC - 483 8/12
2012-7579	10/19/2012 11/19/2012	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	JOHNATHAN RICKMAN FDA NEWS	PETNET SOLUTIONS INC, SPOKANE, WA; PARKS MEDICAL ELECTRONICS INC, ALOHA, OR; ELECTRODE STORE INC, BUCKLEY, WA - 483 8/12
2012-7580	10/19/2012 11/19/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/OA/OM/OMP/DDM/ FDA/OMPT/CDRH/OCER/DFOI/	JOHN P. HARLOE, JD, PhD FREESE & GOSS, PLLC	OBSTETRICS AND GYNECOLOGY MEDICAL DVCS A/C - PELVIC MESH RECS , CORR 9/8/11
2012-7581	10/19/2012 11/19/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	JOHN P. HARLOE, JD, PhD FREESE & GOSS, PLLC	PELVIC MESH STUDY PROTOCOLS, ENFORCEMENT ACTIONS, CORR, ETC
2012-7582	10/21/2012 11/19/2012	FDA/OFVM/CFSAN/OCD/EOS/	Bill Lesko Arizona Chemical, LLC	TETATOLOGICAL EVALUATION STUDIES OF FDA 71-28 (NATURALLY OCCURRING SUBSTANCE FROM PINE TREES)
2012-7583	10/21/2012 11/19/2012	FDA/OFVM/CFSAN/OCD/EOS/	Anna Edney BLOOMBERG NEWS	CAERS REPORTS - 01/01/2004 - 10/19/2012
2012-7584	10/21/2012 11/19/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OES/DFOI/ FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Nicki Steel Nicki Steel	KELLOGG'S MORNING STAR FARMS - CORR RE LABELING INFORMATION FOR SERVING SIZE OF MEAL STARTER CRUMBLES
2012-7585	10/21/2012 11/19/2012	OC/CVM/OCD/	JoNel Aleccia MSNBC.COM	YANTAI ASKA FOODS CO LTD, SHANDONG, CHINA - EIR 03/28/2012 - 03/30/2012
2012-7586	10/21/2012 11/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	CORIN USA	K922841

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2012-7587	10/21/2012 11/19/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6780 REQUEST LETTER
2012-7588	10/21/2012 11/19/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6487
2012-7589	10/21/2012 11/19/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6663
2012-7590	10/21/2012 11/19/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6271
2012-7591	10/21/2012 11/19/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6270
2012-7592	10/21/2012 11/19/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6118
2012-7593	10/21/2012 11/19/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-5604
2012-7594	10/21/2012 11/19/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-3211
2012-7595	10/21/2012 11/19/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2010-3929
2012-7596	10/21/2012 11/19/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6641 REQUEST LETTER
2012-7597	10/21/2012 11/19/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6956 REQUEST LETTER
2012-7598	10/21/2012 11/19/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6625 REQUEST LETTER
2012-7599	10/21/2012 11/19/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6685 REQUEST LETTER
2012-7600	10/21/2012 11/19/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6604 REQUEST LETTER
2012-7601	10/21/2012 11/19/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6824 REQUEST LETTER
2012-7602	10/21/2012 11/19/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6876 REQUEST LETTER
2012-7603	10/21/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2012-6891 REQUEST LETTER

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	11/19/2012		MERCK & CO., INC.	
2012-7604	10/22/2012 11/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRENT M ARDAUGH NORTHWESTERN UNIV FEINBERG SCHOOL OF MEDICINE	K926344
2012-7605	10/22/2012 11/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRENT M ARDAUGH NORTHWESTERN UNIV FEINBERG SCHOOL OF MEDICINE	K881604, K760152, K771046, ETC
2012-7606	10/22/2012 11/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRENT M ARDAUGH NORTHWESTERN UNIV FEINBERG SCHOOL OF MEDICINE	K880660, K863492, K905289, ETC
2012-7607	10/22/2012 11/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRENT M ARDAUGH NORTHWESTERN UNIV FEINBERG SCHOOL OF MEDICINE	K991764, K930428, K952684, ETC
2012-7608	10/22/2012 11/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRENT M ARDAUGH NORTHWESTERN UNIV FEINBERG SCHOOL OF MEDICINE	K893626
2012-7609	10/22/2012 11/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRENT M ARDAUGH NORTHWESTERN UNIV FEINBERG SCHOOL OF MEDICINE	K922164, K914350, K913641, ETC
2012-7610	10/22/2012 11/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRENT M ARDAUGH NORTHWESTERN UNIV FEINBERG SCHOOL OF MEDICINE	K942146, K885054, K953255, ETC
2012-7611	10/22/2012 11/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRENT M ARDAUGH NORTHWESTERN UNIV FEINBERG SCHOOL OF MEDICINE	K003358, K961160, K010726
2012-7612	10/22/2012 11/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARIE RUFRANO-WILSON CARDINAL HEALTH	CARDINAL HEALTH INC - LEADXER LABELER CODE 37205
2012-7613	10/22/2012	FDA/OMPT/CDER/ORP/DIDP/	MARIE RUFANO-WILSON	CARDINALHEALTH INC - THE MEDICINE SHOPPE LABELER

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	11/20/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CARDINAL HEALTH	CODE 49614
2012-7614	10/22/2012 11/20/2012	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	DOUGHLAS N BLUE II ZETETIC INC	SYNTHES SMP SA DECV CTO MEDICAL N 49, SATELITE NAUCALPAN, MEXICO - SYNTHES MEDICAL INSTRUMENTS ENTRY T9400573893
2012-7615	10/22/2012 11/20/2012	FDA/OGROP/ORR/NE-FO/NYK-DO/NYK-DCB/	DOUGLAS N BLUE II ZETETIC INC	TOILETRIES (COCOA LOTION, ALOE LOTION, ESSENTIAL MOISTURIZER) ENTRY 10908618795
2012-7616	10/22/2012 11/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRIAN BELL BOSTON SCIENTIFIC	A TABLE OF ALL MDRS IN MAUDE - MDR RPT KEY & THE PATIENT PROBLEM CODE
2012-7617	10/22/2012 11/20/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DDM/ FDA/OMPT/CDRH/OCER/DFOI/	HAMILTON PHD, LEROY L	CHANGES TO OR MODIFICATIONS OF FORM FDA 3429 GENERAL DVC CLASSIFICATION QUESTIONNAIRE - MEMO 5/12 TO PRESENT
2012-7618	10/22/2012 11/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	LISA R MORGAN ALERE DAN DIEGO INC	ROCHE DIAGNOSTICS - COAGUCHEK XS PLUS SYS APPL CLIA WAIVER
2012-7619	10/22/2012 11/20/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FRANCIS HY GREEN MD UNIV OF CALGARY/DEPT OF PATHOLOGY & LABORATORY MEDICINE	ALLIANCE PHARMS - IMAGENT GI PI
2012-7620	10/22/2012 11/20/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	ELISA TOSTADO STRYKER SUSTAINABILITY SOLUTIONS	HARMONIC ACE - 5MM DIAMETER SHEARS 23 K120729; HARMONIC ACE - LAPAROSCOPIC 5MM DIAMETER SHEARS 36 CM LENTH ADAPTIVE TISSUE TECNOLOGY K121550
2012-7621	10/22/2012 11/20/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WARREN WILLIAMS FOREST RESEARCH INSTITUTE	LINZESS (LINACLOTIDE) CAPS NDA 202-811 APRVL RECS 8/30/12
2012-7622	10/22/2012 11/20/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARIA RUFRANO-WILSON CARDINAL HEALTH	KINRAY INC - LABELER CODE 63777
2012-7623	10/22/2012 11/20/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GEORGE SHAMSOUN METHAPHARM INC	PRE-PEN - NDA 05-114 APRVL RECS, REVIEWER'S NOTES

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2012-7624	10/22/2012 12/03/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	GISSENDAMMER, ROBIN	CAMPBELL CO, CAMDEM, NJ - RECS, RESULTS 2008 TO 2012
2012-7625	10/22/2012 11/20/2012	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	JAMES A LOCHRIDGE JR PREIS & ROY	CREATIVE COMPOUNDS LLC - RPTS, TEST RESULTS, PHOTOGRAPHS, ETC 1/10, 2/10 (CERTIFIED)
2012-7626	10/22/2012 11/20/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OMPT/CDRH/OCER/DFOI/	STACI M TROLIAN BIOMET INC	DR MARK PHILLIPS FRIGGLE - WARNING LTR CORR, RECS
2012-7627	10/22/2012 11/20/2012	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OMPT/CDRH/OCER/DFOI/ OC/OA/OM/OMP/DDM/	NICKERSON HILL ALLERGAN MEDICAL	ANULEX TECHNOLOGIES - INSP 8/23/10-9/22/10, WARNING LTR RESP 3/3/11, FDA RESP TO K111261 6/20/11, ETC
2012-7628	10/22/2012 11/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	CHRISTINA M MIRACLE HILL-ROM	HILL-ROM INC - K001019, K001242, K003335, ETC
2012-7629	10/22/2012 11/20/2012	FDA/OFVM/CFSAN/OCD/EOS/	AHRENS, AMY	GENETICALLY MODIFIED CORN - BT BACTERIUM RECS
2012-7630	10/22/2012 11/20/2012	OC/CVM/OCD/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	STEVE D MATTERI CONTEMPORARY PRODUCTS INC	SICHUAN LONG MARCH PHARMACEUTICAL CO LTD, SICHUAN, CHINA - EIRS 9/9-15/09. 9/19-22/11
2012-7631	10/22/2012 11/20/2012	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	DOUGLAS M BLUE II ZETETIC INC	MARS CHOCOLATE PRODS ENTRY #30070573942 - RECS
2012-7632	10/22/2012 11/20/2012	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	DOUGLAS N BLUE II ZETETIC INC	MARS CHOCOLATE PRODS ENTRY #30070573959 - RECS
2012-7633	10/22/2012 11/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	PAM PUMMILL SYBRON DENTAL SPECIALTIES INC	MINNTECH CORP - RAPICIDE OPA-28 K120306
2012-7634	10/22/2012	FDA/OC/OCC/	JENNIFER HSIEH	SUPERNUS NDA DISCUSSION - TRANS 10/3/12

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	11/20/2012		HEALTHCARE RESEARCH CONSULTING GROUP	
2012-7635	10/22/2012 11/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	NICOLAS 635504, ALBERT	PFIZER, PARKER-DAVIS - LYRICA AERS, CLNCL STUDIES
2012-7636	10/22/2012 11/20/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	ARLENE MORALES BURDOCK GROUP	PECAN SHELL FLOUR - RPTS
2012-7637	10/22/2012 11/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HENLEY 56354-112, FRANK	ULTRAM (TRAMADOL HCL) - RECS
2012-7638	10/22/2012 12/04/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/ OC/OA/OM/OMP/DDM/ FDA/OMPT/CDRH/OCER/DFOI/	LUKE VELDERS UNIV OF PENNSYLVANIA/ABRAMSON CANCER CENTER	RESEARCH STUDIES THAT HAVE BEEN GRANTED A WAIVER OF INFORMATION CONSENT THAT ARE IN THE EMERGENCY MEDICAL SETTING PURSUANT TO 21CFR50.24 - TITLE OF STUDY, NAME OF INVESTIGATOR. EMAIL ADDRESS, ETC
2012-7639	10/22/2012 11/20/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SW-FO/DAL- DO/DAL-CB/ FDA/OGROP/ORO/SW- FO/SWID/SWID-CB/	CLAUDIA HORNBACK ROANOKE TRADE SERVICES INC	CHUENEG INC - NOTICES OF FDA REFUSAL ENTRY 53601525388
2012-7640	10/22/2012	FDA/OGROP/ORO/NE-FO/NYK-	SAMUEL F COLIN MD	LUITPOLD PHARMACEUTICALS INC, SHIRLEY, NY - 483S

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	11/20/2012	DO/NYK-DCB/	FIRST MANHATTAN CO	1/1/10 TO 10/17/62
2012-7641	10/22/2012 12/06/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Doe J	INDIVIDUAL RECS
2012-7642	10/22/2012 11/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jillian Keenan More Magazine	COMPOUNDED PRODUCTS - AERS
2012-7643	10/22/2012 11/20/2012	OC/ORA/ORO/DDFI/ OC/ORA/ORO/DDFI/	Stephen Watson The Buffalo News	APP PHARMACEUTICALS, GRAND ISLAND, NY - RECORDS RELEASED UNDER FOIA 10/19/02-10/19/12
2012-7644	10/22/2012 11/20/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	CORIN USA	K904448
2012-7645	10/22/2012 11/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Suzanne O'Shea FAEGRE BAKER DANIELS	NDA 20845 - FORM 3542/3542a FOR PATENT 8,282,966 AND RELATED CORR
2012-7646	10/22/2012 11/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John M. Nardo MD John M. Nardo MD	PROZAC - INITIAL MEDICAL REVIEWS 1987
2012-7647	10/22/2012 11/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORA/ OC/ORA/ FDA/OC/OES/ OC/OCOS/OL/ FDA/OC/OCC/ FDA/OC/OL/	Tom Burton THE WALL STREET JOURNAL	NECC, FRAMINGHAM, MASS - ALL RECS RE NECC AND MENINGITIS OUTBREAK (10/04/2012 - PRESENT)
2012-7648	10/22/2012 11/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John M. Nardo MD John M. Nardo MD	PAXIL - INITIAL REVIEWS FOR APPROVAL

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2012-7649	10/22/2012 11/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kenneth Douville Vertex Pharmaceuticals Incorporated	MICRO-SPHERE SA - QAP
2012-7650	10/22/2012 11/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jason Schnabel FAEGRE BAKER DANIELS	NDA 19430 - FORM 3542/3452A FOR PATENT 7449012, 7794432, 8048035
2012-7651	10/22/2012 11/20/2012	OC/ORA/ OC/ORA/	Christopher Weaver THE WALL STREET JOURNAL	ST JUDE MEDICAL, SYLMAR, CA - 483, EIR, EXHIBITS
2012-7652	10/22/2012 11/20/2012	OC/ORA/ OC/ORA/	RBC CAPITAL MARKETS	ST JUDE MEDICAL, SYLMAR, CA - 483 10/01/2012 - 10/19/2012
2012-7653	10/22/2012 11/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	Dr. Christopher Wilson NovioSense BV	MEDTRONIC CONTINUOUS GLUCOST MONITORING SYSTEMS RE PARADIGN REAL-TIME SYSTEM AND GUARDIAN REAL-TIME SYSTEM (P980022 S001 TO S122)
2012-7654	10/22/2012 11/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	Mr. Juha-Pekka Nuutinen Ozics Oy	K0909435
2012-7655	10/22/2012 11/20/2012	FDA/OFVM/CFSAN/OCD/EOS/	Kevin Goldberg Goldberg, Kevin I	MONSTER ENERGY DRINKS - AERS 01/01/2004 - 10/20/2012
2012-7656	10/23/2012 11/21/2012	FDA/OFVM/CFSAN/OCD/EOS/	Edward McPike Stifel Nicolaus & Co	DIET PEPSI - CAERS 2004 TO PRESENT
2012-7657	10/23/2012 11/21/2012	FDA/OMPT/CDRH/OCER/DFOI/	Clarice Arruda Procedure Products Inc.	K884885
2012-7658	10/23/2012 11/21/2012	FDA/OFVM/CFSAN/OCD/EOS/	Brian Hartman ABC NEWS	MONSTER ENERGY DRINK - AERS 01/01/2009 - 10/22/2012
2012-7659	10/23/2012 11/21/2012	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Tommy Bottoms LifePoint, INc.	LIFEPOINT, INC. WEST COLUMBIA, SC - EIR
2012-7660	10/23/2012 11/21/2012	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K121598
2012-7661	10/23/2012 11/21/2012	FDA/OFVM/CFSAN/OCD/EOS/	Edward McPike Stifel Nicolaus & Co	RED BULL - CAERS 2004 TO PRESENT
2012-7662	10/23/2012 11/21/2012	FDA/OFVM/CFSAN/OCD/EOS/	Edward McPike Stifel Nicolaus & Co	ROCKSTAR ENERGY - CAERS 2004 TO PRESENT
2012-7663	10/23/2012	FDA/OFVM/CFSAN/OCD/EOS/		ENERGY DRINKS - FIVE HEALTH CASES REFERENCED BY

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	11/21/2012		GOLDMAN SACHS	NEW YORK TIMES
2012-7664	10/23/2012 11/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	BLA 103949 S5153
2012-7665	10/23/2012 11/21/2012	FDA/OFVM/CFSAN/OCD/EOS/	Edward McPike Stifel Nicolaus & Co	COCA COLA, COKE, DIET COKE, ETC - CAERS 2004 TO PRESENT
2012-7666	10/23/2012 11/21/2012	FDA/OFVM/CFSAN/OCD/EOS/	Edward McPike Stifel Nicolaus & Co	MOUNTAIN DEW - CAERS 2004 TO PRESENT
2012-7667	10/23/2012 11/21/2012	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Rachel Johnson FOI Services, Inc.	GENZYME, FRAMINGHAM, MA - 483, EIR, CORR 2005; GENZYME, ALLSON LANDING, MA - 483, EIR, CORR 2005
2012-7668	10/23/2012 11/21/2012	FDA/OFVM/CFSAN/OCD/EOS/	Edward McPike Stifel Nicolaus & Co	DR PEPPER - CAERS 2004 TO PRESENT
2012-7669	10/23/2012 11/21/2012	FDA/OFVM/CFSAN/OCD/EOS/	Edward McPike Edward McPike	MONSTER ENERGY DRINKS - AERS
2012-7670	10/23/2012 11/21/2012	FDA/OFVM/CFSAN/OCD/EOS/	Edward McPike Stifel Nicolaus & Co	STARBUCKS - CAERS 2004 TO PRESENT
2012-7671	10/23/2012 11/21/2012	FDA/OFVM/CFSAN/OCD/EOS/	FORBES MAGAZINE	MONSTER ENERGY DRINKS - DEATH REPORTS
2012-7672	10/23/2012 11/21/2012	FDA/OFVM/CFSAN/OCD/EOS/	Edward McPike Stifel Nicolaus & Co	5 HOUR ENERGY PRODUCTS - CAERS 2004 TO PRESENT
2012-7673	10/23/2012 11/21/2012	FDA/OGROP/ORA/ORO/DIOP/	Frank Bednarz GOODWIN PROCTER LLP	IMPORTATION OF DESMOPRESSIN DRUG PRODUCTS SENT BY FERRING
2012-7674	10/23/2012 11/21/2012	FDA/OFVM/CFSAN/OCD/EOS/	EMILY MADOFF WOLF POPPER ROSS WOLF & JONES, L.L.P.	CORR RE WARNING LTR 9/7/12 TO LANCOME USA
2012-7675	10/23/2012 11/21/2012	OC/CVM/OCD/ FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	ADAM DIEDERICH SCHIFF HARDIN LLP	PATRON FARMS LLC, CANFIELD, OH - NON COMPLIANCE RECS, INVESTIGATIONS, WARNING LTRS SINCE 1/09 TO PRESENT
2012-7676	10/23/2012 11/21/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	JUSTIN LOVELACE TELEFLEX MEDICAL	PARKER MEDICAL INC - FLEX TIP TRACHEAL TUBE K984528; K100546
2012-7677	10/23/2012 11/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Synergy Pharmaceuticals, nc.	FDA SMG 4850.7

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		FDA/OMPT/CDER/GRP/DIDP/		
2012-7678	10/23/2012 11/21/2012	FDA/OFVM/CFSAN/OCD/EOS/	Kristy A. Schlesinger Kristy A. Schlesinger	MONSTER ENERGY - COMPLAINTS OF INJURY/DEATH
2012-7679	10/23/2012 11/21/2012	FDA/OFVM/CFSAN/OCD/EOS/	Kristy A. Schlesinger Kristy A. Schlesinger	STARBUCKS CAFFEINATED BEVERAGE - COMPLAINTS OF INJURY/DEATH
2012-7680	10/23/2012 11/21/2012	FDA/OFVM/CFSAN/OCD/EOS/	Kristy A. Schlesinger Kristy A. Schlesinger	RED BULL ENERGY BEVERAGE - COMPLAINTS OF INJURY/DEATH
2012-7681	10/23/2012 11/21/2012	FDA/OFVM/CFSAN/OCD/EOS/	Kristy A. Schlesinger Kristy A. Schlesinger	ROCKSTAR ENERGY BEVERAGE - COMPLAINTS OF INJURY/DEATH
2012-7682	10/23/2012 11/21/2012	FDA/OFVM/CFSAN/OCD/EOS/	Kristy A. Schlesinger Kristy A. Schlesinger	FULL THROTTLE ENERGY BEVERAGE - COMPLAINTS OF INJURY/DEATH
2012-7683	10/23/2012 11/21/2012	FDA/OFVM/CFSAN/OCD/EOS/	Kristy A. Schlesinger Kristy A. Schlesinger	AMP ENERGY BEVERAGE - COMPLAINTS OF INJURY/DEATH
2012-7684	10/23/2012 11/21/2012	FDA/OFVM/CFSAN/OCD/EOS/	Kristy A. Schlesinger Kristy A. Schlesinger	5 HOUR ENERGY - COMPLAINTS OF INJURY/DEATH
2012-7685	10/23/2012 11/21/2012	FDA/OMPT/CDRH/OCER/DFOI/	Ana Mlinar MESI, d.o.o.	K103693
2012-7686	10/23/2012 11/21/2012	FDA/OFVM/CFSAN/OCD/EOS/	Lara Yunaska INSIDE EDITION	MONSTER ENERGY DRINKS - AERS 2007 TO PRESENT
2012-7687	10/23/2012 11/21/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/ORO/ OC/ORO/	Jonathan Rockoff THE WALL STREET JOURNAL	NEW ENGLAND COMPOUNDING CENTER, AMERIDOSE, ALAUNUS, ETC - WARNING LETTERS, 483, ETC (01/01/1980 - 10/22/2012)
2012-7688	10/23/2012 11/21/2012	FDA/OC/OES/ OC/OCOS/OL/ FDA/OC/OCC/ FDA/OC/OES/DFOI/ OC/ORO/ OC/ORO/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Todd Wallack BOSTON GLOBE	NEW ENGLAND COMPOUNDING CENTER, AMERIDOSE, ALAUNUS PHARMACEUTICAL -- COMPLAINTS, INSPECTION RECS, CORR, ETC (01/01/2002 - 10/22/2012)

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OL/		
2012-7689	10/23/2012 11/21/2012	FDA/OC/OES/DFOI/	NICHOLS, JARROD	INDIVIDUAL RECS
2012-7690	10/23/2012 11/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/ OC/OCOS/OL/ FDA/OC/OCC/ OC/ORA/ OC/ORA/ FDA/OC/OL/	JUSTIN A. BROWNE, Esq. JANET, JENNER & SUGGS, LLC	NEW ENGLAND COMPOUNDING CTR - NVESTIGATION, WARNING LTR CORR, FUNGAL MENINGITIS OUTBREAK OF 2012 RECS, TEST RESULTS
2012-7691	10/23/2012 11/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/ OC/OCOS/OL/ FDA/OC/OCC/ OC/ORA/ OC/ORA/ FDA/OC/OL/	SEAN HIGGINS, Esq. ANDREWS & THORNTON	NEW ENGLAND COMPOUNDING CTR - MENINGITIS OUTBREAK RECS, MENINGITIS OUTBREAK FROM METHYLPREDNISOLONE, STERIOD INJ AERS, ETC
2012-7692	10/23/2012 11/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CORRENS, DOERTE	ISRS 2000 TO PRESENT - RPT TYPE, GENDER, MFR, ETC
2012-7693	10/23/2012 11/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SHIPMAN,, KIM	ISR 39770970001

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2012-7694	10/23/2012 11/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	C MPLNT
2012-7695	10/23/2012 11/21/2012	FDA/OMPT/CDRH/OCER/DFOI/	JOHN D. BRANSON PARKER POE ET AL LLP	MP70 INTELLIVUE - MDRS
2012-7696	10/23/2012 11/21/2012	OC/OA/OM/OMP/DDM/	ANGEL N. MOORE HENRY SPIEGEL MILLING LLP	DOC 44, 77N-0094
2012-7697	10/24/2012 11/22/2012	FDA/OFVM/CFSAN/OCD/EOS/	BILL KIRK Bill Kirk c/o UBS	MONSTER BEVERAGE CORP - AERS
2012-7698	10/24/2012 11/22/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	NDA 21660 S 31
2012-7699	10/24/2012 11/22/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/ OC/OCOS/OL/ FDA/OC/OCC/ OC/ORO/ OC/ORO/ FDA/OC/OL/	Tom Burton THE WALL STREET JOURNAL	NEW ENGLAND COMPOUNDING CENTER - CORR, MEMOS, INSPECTIONS, ETC (12/05/2006 - 10/03/2012)
2012-7700	10/24/2012 11/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	Xuan Liang Devon Medical Products	P910066
2012-7701	10/24/2012 12/21/2012	FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORO/	Fabian Zaccardo PROFESSIONAL COMPOUNDING CENTERS OF AMERICA (PCAA)	PROFESSIONAL COMPOUNDING CENTER OF AMERICA, HOUSTON, TX - 483, EIR, WARNING LETTERS, ETC (01/01/1990 - 10/01/2012)

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		OC/OR/ FDA/OGROP/OR/SW-FO/DAL- DO/DAL-CB/		
2012-7702	10/24/2012 11/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	Xuan Liang Devon Medical Products	P850007, S14, S16, S17
2012-7703	10/24/2012 11/22/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Parker Theuninck Meagher & Geer, P.L.L.P.	ALAVEN PHARMACEUTICALS, LCC - CORR RE REGLAN INVESTIGATION, BOXED WARNING
2012-7704	10/24/2012 11/22/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/OR/ OC/OR/	Kathleen McNerney WBUR	NEW ENGLAND COMPOUNDING CENTER - CORR WITH FDA 01/01/1999 - 10/23/2012
2012-7705	10/24/2012 11/22/2012	FDA/OGROP/OR/SE-FO/NOL- DO/NOL-CB/	Frank Truslow INDIVIDUAL	ENDO HEALTH SOLUTIONS HUNTSVILLE, AL - INSPECTION RECS 09/01/2010 - 12/31/2012
2012-7706	10/24/2012 11/22/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/OA/OM/OMP/DDM/	marjo gazak ELI LILLY AND COMPANY - PHARMACEUTICAL DIVISION	NDA 020599; PERIPHERAL AND CNS DRUGS ADVISORY COMMITTEE BRIEFING MATERIALS, MINUTES 09/18/95
2012-7707	10/24/2012 11/22/2012	FDA/OFVM/CFSAN/OCD/EOS/	Alec White HEALTHCOR MANAGEMENT LP	PEPSI CO - CAERS (01/01/2004 - 10/23/2012)
2012-7708	10/24/2012 11/22/2012	FDA/OGROP/OR/SE-FO/ATL- DO/ATL-CB/ FDA/OGROP/OR/SE-FO/NOL- DO/NOL-CB/	Frank Truslow INDIVIDUAL	QUALITEST, HUNTSVILLE, AL; QUALITEST, CHARLOTTE, NC - WARNING LETTER, 483, ETC (01/01/2009 - 12/31/2012)
2012-7709	10/24/2012 11/22/2012	FDA/OFVM/CFSAN/OCD/EOS/	Alec White HEALTHCOR MANAGEMENT LP	COCA COLA - CAERS (01/01/2004 - 10/23/2012)
2012-7710	10/24/2012 11/22/2012	FDA/OFVM/CFSAN/OCD/EOS/	Sharon Riley CONSUMER REPORTS ON HEALTH	NAIL POLISH, NAIL POLISH REMOVER, ARTIFICIAL NAILS, ETC - CAERS (01/01/2011 - 10/22/2012)
2012-7711	10/24/2012	FDA/OMPT/CDRH/OCER/DFOI/	Susan Anthoney	K120775

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	11/22/2012		AEGIS REGULATORY INC	
2012-7712	10/24/2012 11/22/2012	FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/	Tim McGlinn U. S. Steel & Carnegie Pension Fund	2012-6462
2012-7713	10/24/2012 11/22/2012	FDA/OMPT/CTP/OD/	MARK E GREENWOLD CAMPAIGN FOR TOBACCO-FREE KIDS	PHILIP MORRIS INTERNATIONAL - MODIFIED RISK TOBACCO PRODS RECS
2012-7714	10/24/2012 11/22/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	NORBERT GOTTESMAN AVET CAPITAL MANAGEMENT LLC	AZACITIDINE - DISSOLUTION TEST METHOD RECS; DECITABINE INJ - BIOEQV REQUIREMENTS
2012-7715	10/24/2012 11/22/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SCALES, DESSIE R	AMLODIPINE BESYLATE, ASPIRIN, JANUVIA, ETC - AERS
2012-7716	10/24/2012 11/22/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHRISTODOULOPOULOS VASSILIOS SANDOZ CANADA INC.	NDA 22-434/S012 - RECS
2012-7717	10/24/2012 11/22/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JUN LIMLENGCO MCGUFF PHARMACEUTICALS INC	MYLAN INSTITUTIONAL LLC, CO GALWAY, IRELAND, KILROE EAST, INVERIN, ETC - EIR, SUMMARY RPT 3/12
2012-7718	10/24/2012 11/22/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JUN LIMLENGCO MCGUFF PHARMACEUTICALS INC	BIONICHE PHARMA, KILROE EAST, INVERIN, CO GALWAY, IRELAND - SUMMARY RPT, EIR 10/09
2012-7719	10/24/2012 11/22/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHERYL A FISHER TIANO O'DELL	HYCODAN - AERS, MEDICATION ERROR RPTS
2012-7720	10/24/2012 11/22/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHERYL A FISHER TIANO O'DELL	TUSSINEX (TUSSIONEX) - AERS, MEDICATION ERROR RPTS

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		FDA/OMPT/CDER/GRP/DIDP/		
2012-7721	10/24/2012 11/22/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PATRICIA L REGENYE Celgene Corporation	PHILIP GOLD, SWEDISH CANCER INSTITUTE, SEATTLE, WA - EIRS, 483, CORR 10/10 TO PRESENT
2012-7722	10/24/2012 11/22/2012	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	PATRICIA L REGENYE Celgene Corporation	STEPHEN HANAUER, UNIV CHICAGO HOSPITAL MED CTR, CHICAGO, IL - 483 8/05 TO PRESENT
2012-7723	10/24/2012 11/22/2012	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	PATRICIA L REGENYE Celgene Corporation	OLIVIER RIXE, UNIV OF CINCINNATI CANCER INSTITUTE, CINCINNATI, OH - 483S 1/03 TO PRESENT
2012-7724	10/24/2012 11/22/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PATRICIA L REGENYE Celgene Corporation	ALESSANDRO TESTORI, ISTITUTO EUROPEO DI 1440, MILANO, ITALY - EIRS, 483S, CORR7/11 TO PRESENT
2012-7725	10/24/2012 11/22/2012	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	PATRICIA L REGENYE Celgene Corporation	MARK KIRSCHBAUM, CITY OF HOPE NATIONAL CANCER CENTER, DUARTE, CA - 483S 4/09 TO PRESENT
2012-7726	10/24/2012 11/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	CHRISTOPHER BRENNAN WESTLAW COURT EXPRESS	SMITH & NEPHEW - BHR BIRMINGHAM HIP RESURFACING SYS PO40033 MEMOS ETC
2012-7727	10/24/2012 11/22/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	PROMETHAZINE - MEDWATCH FORM 3500
2012-7728	10/24/2012 11/22/2012	FDA/OFVM/CFSAN/OCD/EOS/	MARK PIFKO BARON & BUDD PC	AVON PRODUCTS INC - ANEW REVERSALIST NIGHT RENEWAL CREAM, ANEW ULTIMATE 7S NIGHT CREAM, SOLUTIONS LIQUID BRA TONING GEL, ETC RECS
2012-7729	10/24/2012 11/22/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	STEPHEN D MUMFORD DRPH INTERNATIONAL SERVICES ASSISTANCE FUND	QUINACRINE HCL, IND 74,802 - EPIDEMIOLOGY RVW RECS
2012-7730	10/24/2012 11/22/2012	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	GERALD J OREHOSTKY ANTARES PHARMA INC	PHARMACEUTICS INTERNATIONAL INC - EIRS, 483S 1/06 TO PRESENT
2012-7731	10/24/2012 11/22/2012	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	ROBERT P CHARROW GREENBERG TRAUIG LLP	W L GORE & ASSOCIATES INC - GORE-TEX TISSUE REINFORCEMENT PATCH K820193, GORE-TEX SOFT TISSUE PATCH K914449, K930822, ETC
2012-7732	10/25/2012	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	Andrew T. Ryan	BOSTON SCIENTIFIC/GUIDANT - PACEMAKER INSPECTIONS; GUIDANT VITALITY 2 DR ICD IMPLANT

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	11/23/2012	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAP/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORAP/PA-FO/SEA-DO/SEA-CB/ FDA/OGROP/ORAP/SE-FO/SJN-DO/SJN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Ryan Law, APLC	MODEL T165; COMMUNICATIONS RE RECALL ETC
2012-7733	10/25/2012 11/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Wendy Tian LUNDBECK INC	NDA 20593 - SBA
2012-7734	10/25/2012 11/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Diana Rogers Diana Rogers	ELECON CREAM NDA REVIEWS
2012-7735	10/25/2012 11/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Barbara Swift UNIVERSITY OF FLORIDA	TERIFLUNOMIDE - SBA
2012-7736	10/25/2012 11/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Diana Rogers Diana Rogers	ELOCON OINTMENT NDA REVIEWS
2012-7737	10/25/2012 11/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Diana Rogers Diana Rogers	ELECON LOTION NDA REVIEWS
2012-7738	10/25/2012 11/23/2012	FDA/OFVM/CFSAN/OCD/EOS/	Chris Lahiff McDermott Will & Emery LLP	MONSTER BEVERAGES - AERS (01/01/2004 - 10/24/2012)
2012-7739	10/25/2012 11/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tom Burton THE WALL STREET JOURNAL	COMPOUNDING PHARMACIES - EMAILS, MEMORANDA, LEGAL ANALYSES, ETC BETWEEN OCC AND CDER COMPLIANCE

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2012-7740	10/25/2012 11/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kurt Greve Kurt W. Greve	NDA 21817 S 12
2012-7741	10/25/2012 11/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Robert DeGaetano Robert DeGaetano	METFORMIN - CLINICAL STUDIES RE B12 DEFICIENCY
2012-7742	10/25/2012 11/23/2012	FDA/OC/OES/DFOI/	Daniel Balaban Daniel Balaban	MCNEIL, JOHNSON & JOHNSON - TYLENOL INSPECTIONS, RECALL OF 2010, RESPONSE TO INVESTIGATION, ETC
2012-7743	10/25/2012 11/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	Keith Leland Preceptis Medical, Inc.	K103595
2012-7744	10/25/2012 11/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	QIAGEN SCIENCES	GREINER BIO-ONE GMBH - EIR (1/27/2003 - 01/30/2003)
2012-7745	10/25/2012 11/23/2012	FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/	Susan Dianne Luce Luce, Susan D	PRIDE OF AMERICA CRUISE SHIP HAWAIIAN ISLANDS - MOST RECENT INSPECTION REPORT
2012-7746	10/25/2012 11/23/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	William A. Scofield, Jr. Lathrop & Gage LLP	K021736
2012-7747	10/25/2012 11/23/2012	FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	QIAGEN SCIENCES	SCANTIBODIES, SANTEE, CA - EIR 2011
2012-7748	10/25/2012 11/23/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	William A. Scofield, Jr. Lathrop & Gage LLP	K003323
2012-7749	10/25/2012 11/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	John DeLucia ICAD INC	P100005/S001
2012-7750	10/25/2012 11/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	BLA 125276 S49
2012-7751	10/25/2012 11/23/2012	OC/ORO/ OC/ORO/	JULIA KUFMAN RBC CAPITAL MARKETS	ST JUDE MEDICAL, ARECIBO, PR - 483 (10/02/2012 - 10/02/2012)
2012-7752	10/25/2012	FDA/OGROP/ORO/SE-FO/ATL-	JOHNATHAN RICKMAN	PHARMACEUTICAL ASSOC INC, GREENVILLE, SC - 483 9/12

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	11/23/2012	DO/ATL-CB/	FDA NEWS	
2012-7753	10/25/2012 11/23/2012	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	JOHNATHAN RICKMAN FDANEWS	CB FLEET CO INC, LYNCHBURG, VA; PHIPPS & BIRD INC, RICHMOND, VA; INVITROCARE INC, FREDERICK, MD - 483 9/12
2012-7754	10/25/2012 11/23/2012	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	JOHNATHAN RICKMAN FDA NEWS	BLUE ISLAND PHENOL LLC, BLUE ISLAND, IL; MEDGYN PRODUCTS INC, ADDISON, IL; RICHARD WOLF MEDICAL INSTRUMENTS CORP, VERNON HILLS, IL - 483 9/12
2012-7755	10/25/2012 11/23/2012	FDA/OGROP/ORACE-FO/CINDO/CIN-CB/	JOHNATHAN RICKMAN FDA NEWS	CARDINAL HEALTH 414 LLC, WEST CHESTER, OH; KUTOL PRODUCTS CO, SHARONVILLE, OH; MEAS US LLC, DAYTON, OH - 483 9/12
2012-7756	10/25/2012 11/23/2012	FDA/OGROP/ORASW-FO/DALDO/DAL-CB/	JOHNATHAN RICKMAN FDA NEWS	ISO TEC DIAGNOSTICS INC, FRIENDSWOOD, TX; ST JUDE MEDICAL, PLANO, TX - 483 9/12
2012-7757	10/25/2012 11/23/2012	FDA/OGROP/ORASW-FO/DENDO/DEN-CB/	JOHNATHAN RICKMAN FDA NEWS	AMERICAN SLEEP ASSOC LLC, CEDAR CITY, UT; LED TECHNOLOGIES LLC, ELIZABETH, CO - 483 9/12
2012-7758	10/25/2012 11/23/2012	FDA/OGROP/ORACE-FO/DETD/DET-CB/	JOHNATHAN RICKMAN FDA NEWS	ELBA INC, TROY, MI; BAXTER PHARMACEUTICALS SOLUTIONS LLC, BLOOMINGTON, IN; AIRGAS GREAT LAKES LLC, LANSING, MI - 483 9/12
2012-7759	10/25/2012 11/23/2012	FDA/OGROP/ORASE-FO/FLADO/FLA-CB/	JOHNATHAN RICKMAN FDA NEWS	VITAL PHARMACEUTICALS INC, WESTON, FL; AMERICAN NATURAL PRODUCTS INC, MIAMI, FL; INVIVO CORP, ORLANDO, FL - 483 9/12
2012-7760	10/25/2012 11/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHNATHAN RICKMAN FDA NEWS	PFIZER HEALTH AB, STRANGNAS, SWEDEN; KANEBO COSMETICS INC, ODAWARA SHI KANAGAWA, JAPAN; AJANTA PHARMA LTD, AURANGABAD, INDIA - 483 9/12
2012-7761	10/25/2012 11/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	JOHNATHAN RICKMAN FDA NEWS	SEIKAGAKU CORP, IBARAKI, JAPAN; BPTRU MEDICAL DEVICES, COQUITAM, CANADA; SIGVARIS DO BRASIL, JUNDIAI, BRAZIL - 483 9/12
2012-7762	10/25/2012 11/23/2012	FDA/OGROP/ORASW-FO/KANDO/KAN-CB/	JOHNATHAN RICKMAN FDA NEWS	CARE TECH LABS INC, ST LOUIS, MO; MGP INGREDIENTS INC, ATCHISON, KS; GLOBAL MEDICAL HOLDINGS LLC, ADEL, IA - 483 9/12
2012-7763	10/25/2012 11/23/2012	FDA/OGROP/ORAPA-FO/LOSDO/LOS-CB/	JOHNATHAN RICKMAN FDA NEWS	BAXTER HEALTHCARE CORP, LOS ANGELES, CA; TITAN MEDICAL ENTERPRISES INC, SANTA FE SPRINGS, CA; IRENDIA CORP, LOS ANGELES, CA - 483 9/12
2012-7764	10/25/2012 11/23/2012	FDA/OGROP/ORACE-FO/MINDO/MIN-CB/	JOHNATHAN RICKMAN FDA NEWS	STEUART LABS, MABEL, MN; PETNET SOLUTIONS INC, MINNEAPOLIS, MN; HYDRITE CHEMICAL CO, MILWAUKEE, WI - 483 9/12
2012-7765	10/25/2012 11/23/2012	FDA/OGROP/ORANE-FO/NWEDO/NWE-CB/	JOHNATHAN RICKMAN FDA NEWS	CARDINAL HEALTH 414 LLC, WOBURN, MA; APLICATE INC, MERIDEN, CT; DAVOL INC, WARWICK, RI - 483 9/12
2012-7766	10/25/2012	FDA/OGROP/ORACE-FO/NWJ-	JOHNATHAN RICKMAN	JAMES ALEXANDER CORP, BLAIRSTOWN, NJ; LTS LOHMAN

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/ORP/ OC/ORP/		
2012-7780	10/26/2012 11/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K071343
2012-7781	10/26/2012 11/26/2012	FDA/OO/OFBA/OAGS/	Ryan Fothergill Primus Labs	FDA AGREEMENTS WITH IEH INTERNATIONAL (05/01/2009 - 10/25/2012)
2012-7782	10/26/2012 11/26/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	NATHANIEL ENOS CONWAY HOMER & CHIN- CAPLAN PC	VAERS - INDIVIDUAL RECS
2012-7783	10/26/2012 11/26/2012	FDA/OFVM/CFSAN/OCD/EOS/	MARILYNN WHITNEY COVINGTON BURLING LLP	MONSTER ENERGY PRODS - CAERS
2012-7784	10/26/2012 11/26/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	PATRICK KELLY CONWAY HOMER & CHIN- CAPLAN PC	VAERS - INDIVIDUAL RECS
2012-7785	10/26/2012 11/26/2012	FDA/OFVM/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 157049
2012-7786	10/26/2012 11/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	VINEET SARIN PHD KINAMED INC	K954219, K954213, K922247, ETC
2012-7787	10/26/2012 11/26/2012	FDA/OGROP/ORP/SE-FO/FLA- DO/FLA-CB/	WILLIAM S JOHNSON RN FLORIDA MEDICAL CLINIC	FLORIDA MEDICAL CLINIC, ZEPHYRHILLS, FL - AUDIT 8/6/12
2012-7788	10/26/2012 11/26/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/OCOS/OES/ OC/OCOS/OES/	DONALD E SEGAL ESQ ALSTON & BIRD LLP	USE OF LASER-ETCHING TECHNOLOGY ON EGGS AND A WALMART PILOT PROGRAM PERMITTING THE REPACKING OF EGGS AT THE RETAIL LEVEL - RECS, CORR
2012-7789	10/26/2012 11/26/2012	OC/ORP/ OC/ORP/ FDA/OGROP/ORP/ORO/DIOP/ FDA/OGROP/ORP/CE-FO/MIN- DO/MIN-CB/ FDA/OGROP/ORP/NE-FO/NWE- DO/NWE-CB/	LEIF LARSEN CBC MANITOBA	FRESH HEMP FOODS LTD - HEMP BLISS (NON DAIRY HEMP BEVERAGE) IMPORT REFUSAL RECS
2012-7790	10/26/2012 11/26/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	EDWARD GERARD ROBBINS UMEDA LLP	POLYMEDIX INC - PMX-60056 CLNCL TRIAL APRVL RECS

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2012-7791	10/26/2012 11/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/ OC/OCOS/OL/ FDA/OC/OCC/ OC/ORO/ OC/ORO/ FDA/OC/OL/	SEAN HIGGINS ESQ ANDREWS & THORNTON	ALANIS PHARM - METHYLPREDNISOLONE ACETATE MEMINGITIS OUTBREAK RECS 2012; AMERIDOSE LLC - STEROID INJ AERS 1/12 TO PRESENT, ETC
2012-7792	10/26/2012 11/26/2012	OC/ORO/ OC/ORO/ OC/OER/OPA/	M MELISSA BALTZ BUTLER SNOW ET AL	J&J MARKETED VAGINAL MESH IMPLANT WITHOUT US APPROVAL - CORR (CERTIFIED)
2012-7793	10/26/2012 11/26/2012	OC/ORO/ OC/ORO/ OC/OER/OPA/	M MELISSA BALTZ BUTLER SNOW ET AL	J&J SOLD VAGINAL MESH IMPLANT AFTER SALES HALT ORDERED - CORR (CERTIFIED)
2012-7794	10/26/2012 11/26/2012	OC/ORO/ OC/ORO/	KEVIN STRANGE WELLS FARGO SECURITIES	ST JUDE MEDICAL, SYLMAR, CA - 483 9/25/12-10/17/12
2012-7795	10/26/2012 11/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PAMELA SCHANEEN SHIONOGI INC	NAPRELAN (NAPROXEN SODIUM) NDA 20-353 - SBA
2012-7796	10/26/2012 11/26/2012	OC/ORO/ORM/ OC/ORO/ORM/	DAVID MANGIONE FDAZILLA	483S 8/23/12-10/24/12
2012-7797	10/26/2012 11/26/2012	FDA/OC/OES/DFOI/ OC/ORO/ OC/ORO/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	ST JUDE MEDICAL, SYLMAR, CA - EIRS, 483S, WARNING LTRS, ETC 1/12 TO PRESENT
2012-7798	10/26/2012 11/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JUN LIMLENGCO MCGUFF PHARMACEUTICALS INC	BIONICHE PHARMA, KILROE EAST, INVERIN, CO GALWAY, IRELAND - EIR 10/09; MYLAND INSTITUTIONAL LLC, KILROE EAST, INVERIN, CO GALWY, IRELAND - EIR 3/12

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2012-7799	10/26/2012 11/26/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	ALLISON CHEN HARVEST CONSULTING CORP	JENERIC/PENTRON INC - QUELL DESENSITIZER RECS
2012-7800	10/26/2012 11/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	ALLISON CHEN HARVEST CONSULTING CORP	HERAEUS KULZER LLC - GLUMA DESENSITIZER POWER GEL RECS
2012-7801	10/26/2012 11/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	ALLISON CHEN HARVEST CONSULTING CORP	COLGATE-PALMOLIVE CO - COLGATE DESENSITIZING DENTAL CREAM RECS
2012-7802	10/26/2012 11/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	ALLISON CHEN HARVEST CONSULTING CORP	HOENIX DENTAL INC - SUPER SEAL TOOTH DESENSITIZER RECS
2012-7803	10/26/2012 11/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PETER S REICHERTZ SHEPPARD MULLIN RICHTER & HAMPTON, LLP	AMAG PHARMACEUTICALS INC - FERAHEME (FERUMOXTOXOL INJ) NDA 22-180 AERS 10/09 TO PRESETN
2012-7804	10/26/2012 11/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PETER S REICHERTZ SHEPPARD MULLIN RICHTER & HAMPTON, LLP	WATSON PHARMS - NULECIT (IRON GLUCONATE & FERRIC GLUCONATE) ANDA 78-215 SBA 10/09 TO PRESENT
2012-7805	10/26/2012 11/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PETER S REICHERTZ SHEPPARD MULLIN RICHTER & HAMPTON, LLP	SANOFI-AVENTIS - FERRLECIT (IRON GLUCONATE & FERRIC GLUCONATE) NDA 17-44 SBA 10/09 TO PRESENT
2012-7806	10/26/2012 11/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PETER S REICHERTZ SHEPPARD MULLIN RICHTER & HAMPTON, LLP	LUITPOLD PHARMACEUTICALS INC - VENOFRER (IRON SUCROSE INJ) NDA 21-135 SBA 10/09 TO PRESENT
2012-7807	10/26/2012 11/26/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 10/1-5/12
2012-7808	10/26/2012 11/26/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 9/24-28/12
2012-7809	10/26/2012 11/26/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 10/8-12/12
2012-7810	10/29/2012 11/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ram Mohan Kathuroju INVAGEN PHARMACEUTICALS INC	ANDA 075753 - SBA

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2012-7811	10/29/2012 11/27/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JACOB JACOBSEN DUKE UNIVERSITY	5-HTP - AERS
2012-7812	10/29/2012 11/27/2012	FDA/OGROP/ORAN/NE-FO/NWE-DO/NWE-CB/	Ricky Campbell Journal Register Co.	NATUREMOST OF NEW ENGLAND, MIDDLETOWN, CT - CORR RE WARNING LETTER (05/24/2012 - 10/25/2012)
2012-7813	10/29/2012 11/27/2012	FDA/OFVM/CFSAN/OCD/EOS/	Barry Meier New York Times --Barry Meier	DIETARY SUPPLEMENTS - AERS (12/01/2008 - 10/01/2012); FDA NOTIFICATION OF AFFECTED COMPANIES OF RECEIPT OF FATALITY
2012-7814	10/29/2012 11/27/2012	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	GRANDFATHERED TOBACCO PRODUCT STATUS DETERMINATIONS - CORR, DOCUMENTATION, SUMMARIES (08/01/12 TO 10/29/12)
2012-7815	10/29/2012 11/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	Essex Industries, Inc.	K833994
2012-7816	10/30/2012 11/28/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6222
2012-7817	10/30/2012 11/28/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6055
2012-7818	10/30/2012 11/28/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-5914
2012-7819	10/30/2012 11/28/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-5887
2012-7820	10/30/2012 11/28/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-5683
2012-7821	10/30/2012 11/28/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6309
2012-7822	10/30/2012 11/28/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6250
2012-7823	10/30/2012 11/28/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6225
2012-7824	10/31/2012 11/29/2012	FDA/OFVM/CFSAN/OCD/EOS/	JEFFREY BARRACK Jeffrey Barrack	MONSTER ENERGY DRINKS - AERS; DEATH REPORTS (11/07 TO PRESENT)
2012-7825	10/31/2012	OC/ORAN/		M42-3142497-7 - TEST RESULTS

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	11/29/2012	OC/ORO/	Triunfo-Mex, Inc.	
2012-7826	10/31/2012 11/29/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DDM/	Doe J	SMITH AND NEPHEW - CORR WITH FDA RE BIRMINGHAM HIP RESURFACING DEVICE
2012-7827	10/31/2012 11/29/2012	FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORO/CE-FO/PHI-DO/PHI-CB/	Law Offices of Ronald A. Marron	HYLAND'S INC, STANDARD HOMEOPATHIC CO - CORR WITH FDA RE CALMS FORTE, TEETHING TABLETS, MIGRAINE HEADACHE RELIEF, ETC
2012-7828	10/31/2012 11/29/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Sheffield, Deborah	K965001
2012-7829	10/31/2012 11/29/2012	FDA/OC/OES/DFOI/	Megan Pickel BEVERIDGE & DIAMOND	CFSAN FOIA REQUESTS (09/27/2012 - 10/26/2012)
2012-7830	10/31/2012 11/29/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORO/ORM/ OC/ORO/ORM/ OC/ORO/ OC/ORO/	GMP Training Materials	FDA INVESTIGATOR TRAINING COURSE MATERIAL; DRUG GMP TRAINING COURSE MATERIAL (01/01/2011 - 10/26/2012)
2012-7831	10/31/2012 11/29/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	IPD ANALYTICS LLC	ANDA 091347 - EFFECTIVE APPROVAL LTR
2012-7832	10/31/2012 03/11/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Kelly Cycon Zeptomatrix (Formerly Cellular Products)	CELLULAR PRODUCTS HIV AND HTLV DIAGNOSTIC KITS - APPROVAL RECORDS (01/01/1985 - 12/31/1989)
2012-7833	10/31/2012 11/29/2012	FDA/OMPT/CDRH/OCER/DFOI/	Seawon Meditech Co., Ltd.	K111593
2012-7834	10/31/2012	FDA/OMPT/CDRH/OCER/DFOI/	Gary Syring	K082474

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	11/29/2012		Quality & Regulatory Associates, LLC	
2012-7835	10/31/2012 11/29/2012	FDA/OFVM/CFSAN/OCD/EOS/	Robert MacArthur Alternative Research Services, Inc.	MONSTER BEVERAGE CORP - REPORTS, INVESTIGATIONS, CORR
2012-7836	10/31/2012 11/29/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lia Obata Dowd Dowd & Dowd, PC	BOEHRINGER INGELHEIM PHARM, INC; BOEHRINGER INGELHEIM CORP; BOEHRINGER INGELHEIM USA, ETC - PRADAXA RECS, APPLICATIONS, AERS, ETC
2012-7837	10/31/2012 11/29/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	NDA 201803
2012-7838	10/31/2012 11/29/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	DIRECT REPORTS, MEDWATCH REPORTS, SOURCE DOCUMENTS -ISR 8404106-1
2012-7839	10/31/2012 11/29/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ISR NUMBERS 6673059-9, 6691992-9, 6709086-2 ETC
2012-7840	10/31/2012 11/29/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ISR 7267891-0, 8058598-0, 8099049-X ETC
2012-7841	10/31/2012 11/29/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HARPER #34654, JOHNATHAN SETH	PCP - AERS
2012-7842	10/31/2012 11/29/2012	FDA/OMPT/CDRH/OCER/DFOI/	ALAIN NIGON ALN IMPLANTS CHIRURGICAUX	WILLIAM COOK EUROPE APS - COOK CELECT VENA CAVA FILTER AND GUNTHER TULIP VENA CAVA FILTER RETRIEVAL SET K073374
2012-7843	10/31/2012 11/29/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CAROL DRURY ENDOMETRIOSIS ASSOCIATION	NUMBER OF THERAPIES APPROVED BY THE FDA FOR THE TREATMENT OF ENDOMETRIOSIS

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2012-7844	10/31/2012 11/29/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/OCOS/OES/ OC/OCOS/OES/ OC/OA/OM/OMP/DDM/	LEIGH A SANDERS CENTER FOR RESPONSIBLE SCIENCE	DKTS 2007P-0109, 2007P-0457; DRAFT GUIDANCE TO INDUSTRY REGARDING NON-ANIMAL TESTS FOR DRUG DEVELOPMENT PROGRAMS, ETC
2012-7845	10/31/2012 11/29/2012	FDA/OMPT/CDRH/OCER/DFOI/	M MELISSA BALTZ BUTLER SNOW ET AL	AMERICAN MEDICAL SYSTEMS - AMS ELEVATE APICAL AND POSTERIOR PROLAPSE REPAIR SYS WITH INTERPRO LITE, INTEXEN LP K082730 (CERTIFIED); SUBSTANTIAL EQUIVALENCE LTR 11/26/08 (CERTIFIED)
2012-7846	10/31/2012 11/29/2012	FDA/OMPT/CDRH/OCER/DFOI/	M MELISSA BALTZ BUTLER SNOW ET AL	AMERICAN MEDICAL SYSTEMS - AMS ELEVATE WITH INTEPRO LITE PROLAPSE REPAIR SYS, AMS ELEVATE WITH INTEXEN LP PROLAPSE REPAIR SYS K080185 (CERTIFIED); SUBSTANTIAL EQUIVALENCE LTR 4/10/08 (CERTIFIED)
2012-7847	10/31/2012 11/29/2012	FDA/OMPT/CDRH/OCER/DFOI/	M MELISSA BALTZ BUTLER SNOW ET AL	AMEICAN MEDICAL SYSTEMS - AMS APOGEE VAULT SUSPENSION SYS K040537 (CERTIFIED); SUBSTANTIAL EQUIVALENCE LTR 4/.22/04 (CERTIFIED)
2012-7848	10/31/2012 11/29/2012	FDA/OMPT/CDRH/OCER/DFOI/	M MELISSA BALTZ BUTLER SNOW ET AL	AMERICAN MEDICAL SYSTEMS - APOGEE AND PERIGEE SYSTEMS WITH INTEPRO LITE AND INTEXEN LP PELVIC FLOOR REPAIR SYS K082387 (CERTIFIED); SUBSTANTIAL EQUIVALENCE LTR 12/4/08 (CERTIFIED)
2012-7849	10/31/2012 11/29/2012	FDA/OMPT/CDRH/OCER/DFOI/	M MELISSA BALTZ BUTLER SNOW ET AL	BARD UROLOGICAL DIVISION - AVAULTA SOLO SUPPORT SYS, AVAULTA PLUE BIOSYNTHETIC SUPPORT SYS K063712 (CERTIFIED); SUBSTANTIAL EQUIVALENCE LTR 3/27/07 (CERTIFIED)
2012-7850	10/31/2012 11/29/2012	FDA/OMPT/CDRH/OCER/DFOI/	M MELISSA BALTZ BUTLER SNOW ET AL	BOSTON SCIENTIFIC CORP - PINNACLE PELVIC FLOOR REPAIR KIT K071957 (CERTIFIED); SUBSTANTIAL EQUIVALENCE LTR 1/13/09 (CERTIFIED)
2012-7851	10/31/2012 11/29/2012	FDA/OMPT/CDRH/OCER/DFOI/	M MELISSA BALTZ BUTLER SNOW ET AL	BARD UROLOGICAL DIVISION - AVAULTA SOLO SUPPORT SYS, AVAULTA PLUS BIOSYNTHETIC SUPPORT SYS K082571 (CERTIFIED); SUBSTANTIAL EQUIVALENCE LTR 9/30/08 (CERTIFIED)
2012-7852	10/31/2012 11/29/2012	FDA/OMPT/CDRH/OCER/DFOI/	M MELISSA BALTZ BUTLER SNOW ET AL	BOSTON SCIENTIFIC CORP - TBD SURGICAL MESH DVC K081048 (CERTIFIED); SUBSTANTIAL EQUIVALENCE LTR 8/22/08 (CERTIFIED)
2012-7853	10/31/2012 11/29/2012	FDA/OMPT/CDRH/OCER/DFOI/	M MELISSA BALTZ BUTLER SNOW ET AL	AMERICAN MEDICAL SYSTEMS - APOGEE AND PERIGEE SYTEMS WITH PC COATED INTEPRO LITE K081710

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				(CERTIFIED); SUBSTANTIAL EQUIVALENCE LTR 10/15/08 (CERTIFIED)
2012-7854	10/31/2012 11/29/2012	OC/OM/OMP/DDM/	THOMAS D. FITZGERALD FSI RESEARCH & SERVICES, INC.	DKT FDA-2012-P-0632, FDA-2012-P-1018
2012-7855	11/01/2012 11/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	Sevrina Ciucci Sevrina Ciucci	K061268
2012-7856	11/01/2012 11/30/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/	Doe J	CONSUMER COMPLAINT RECS
2012-7857	11/01/2012 11/30/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ OC/CVM/OCD/	Shane Baker Joint Investments LLC	MASCOMA CORP - RECOMBINANT YEAST PRODUCTS
2012-7858	11/01/2012 11/30/2012	FDA/OC/OES/DFOI/	Todd Wallack BOSTON GLOBE	NEW ENGLAND COMPOUNDING CENTER, AMERIDOSE - FOIA REQUESTS, RESPONSES (01/01/2004 - 10/30/2012)
2012-7859	11/01/2012 11/30/2012	FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/	Michael P. Krensavage Krensavage Asset Management	RTI BIOLOGICS, ALACHUA, FL - WARNING LETTER RECS
2012-7860	11/01/2012 11/30/2012	FDA/OC/OES/DFOI/	Jared MacCleary CROWELL & MORING	FOIA LOGS FOR CVM (04/01/2012 - 10/31/2012)
2012-7861	11/01/2012 11/30/2012	FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	Jose H. Lebron, Stat Rx QA Manager Stat Rx	STAT RX - 484, 483, EIR (01/01/2006 - 12/31/2011)
2012-7862	11/01/2012 11/30/2012	FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	LEERINK SWANN LLC	AUTOGENOMICS, VISTA, CA - EIR (09/01/2009 - 09/22/2009)
2012-7863	11/01/2012 11/30/2012	OC/ORO/ OC/ORO/	Andrew Kahn UNITE HERE	ST JUDE MEDICAL, SYLMAR, CA - 483 (09/01/2012 - 10/30/2012)
2012-7864	11/01/2012 11/30/2012	OC/CVM/OCD/	Rob Varese SHOTWELL & CARR, INC.	TYPE B AND TYPE C MEDICATED FEEDS - MICROBIOLOGICAL ASSAY METHOD
2012-7865	11/01/2012 11/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	M MELISA BALTZ BUTLER SNOW ET AL	C R BARD INC, COVINGTON, GA - AVAULTA SOLO SUPPORT SYS & AVAULTA PLUS BIOSYNTHETIC SUPPORT SYS K083839 (CERTIFIED)
2012-7866	11/01/2012 11/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	M MELISSA BALTZ BUTLER SNOW ET AL	AMERICAN MEDICAL SYSTEM, MINNETONKA, MN - AMS ELEVATE PC ANTERIOR & APICAL PROLAPSE REPAIR SYS WITH INTEPRO LITE K111118 (CERTIFIED)
2012-7867	11/01/2012	FDA/OMPT/CDRH/OCER/DFOI/	M MELISSA BALTZ	CALDERA MEDICAL INC, AGOURA HILLS, CA - ASCEND

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	11/30/2012		BUTLER SNOW ET AL	BLUE MESH AC & PC K101462 (CERTIFIED)
2012-7868	11/01/2012 11/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	M MELISSA BALTZ BUTLER SNOW ET AL	COLOPLAST A/S, HUMLEBAEK, DENMARK - EXAIR ANTERIOR & PROLAPSE REPAIR SYS K112386 (CERTIFIED)
2012-7869	11/01/2012 11/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	M MELISSA BALTZ BUTLER SNOW ET AL	AMERICAN MEDICAL SYSTEMS INC, MINNETONKA, MN - ELEVATE PC ANTERIOR & APICAL PROLAPSE REPAIR SYS WITH INTEPRO LITE & ELEVATE PC APICAL & POSTERIOR PROLAPSE REPAIR SYS WITH INTEPRO LITE K112842 (CERTIFIED)
2012-7870	11/01/2012 11/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	M MELISA BALTZ BUTLER SNOW ET AL	MPATHY MEDICAL DEVICES LTD, RAYNHAM, MA - RESTORELLE POLYPROPYLENE MESH K092207 (CERTIFIED)
2012-7871	11/01/2012 11/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	M MELISA BALTZ BUTLER SNOW ET AL	AMERICAN MEDICAL SYSTEMS, MINNETONKA, MN - ELEVATE ANTERIOR & APICAL PROLAPSE REPAIR SYS WITH INEPRO LITE K082677 (CERTIFIED)
2012-7872	11/01/2012 11/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	M MELISSA BALTZ BUTLER SNOW ET AL	CALDERA MEDICAL INC, AGOURA HILLS, CA - ASCEND SURGICAL MESH K083722 (CERTIFIED)
2012-7873	11/01/2012 11/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	M MELISSA BALTZ BUTLER SNOW ET AL	AMERICAN MEDICAL SYSTEMS, MINNETONKA, MN - ELEVATE PROLAPSE REPAIR SYSTEM WITH PC COATED INTEPRO LITE K090713 (CERTIFIED)
2012-7874	11/01/2012 11/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	M MELLISSA BALTZ BUTLER SNOW ET AL	AMERICAN MEDICAL SYSTEMS INC, MINNETONKA, MN - ELEVATE ANTERIOR & APICAL PROLAPSE REPAIR SYS, APICAL & POSTERIOR PROLAPSE REPAIR SYS, APICAL & POSTERIOR PROLAPSE REPAIR SYS WITH INTEXEN K121612 (CERTIFIED)
2012-7875	11/01/2012 11/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	M MELISSA BALTZ BUTLER SNOW ET AL	COLOPLAST A/S, HUMMLEBAEK, DENMARK - EXAIR ANTERIOR & EXAIR POSTERIOR PROLAPSE REPAIR SYS K083499 (CERTIFIED)
2012-7876	11/01/2012 11/30/2012	FDA/OGROP/ORR/SE-FO/SJN-DO/SJN-CB/	AMY WADE NOVARTIS ANIMAL HEALTH	CARDINAL HEALTH PR 410 INC, HUMACAO, PR - EIR 6/07-16/04
2012-7877	11/01/2012 11/30/2012	FDA/OFVM/CFSAN/OCD/EOS/	DANIEL R LUCKY LUCKY CONSULTANTS LLC	FCN 1162
2012-7878	11/01/2012 11/30/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SHERRY L. ROLLO HUSCH BLACKWELL LLP	SANDOZ - OLMESARTAN MEDOXOMIL NDA 90-237 APRVL LTR 9/16/09
2012-7879	11/01/2012 11/30/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SHERRY L. ROLLO HUSCH BLACKWELL LLP	MYLAN PHARMS INC - OLMESARTAN MEDOXOMIL APRVL 10/3/08, 5/15/12

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		FDA/OMPT/CDER/GRP/DIDP/		
2012-7880	11/01/2012 11/30/2012	FDA/OFVM/CFSAN/OCD/EOS/	MADHU SONI SONI & ASSOCIATES INC	CAFFEINE - CAERS 1/05 TO 3/12
2012-7881	11/01/2012 11/30/2012	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	CARSTON C. JOHANNSEN GOULD LAW OFFICES CHTD LLC	OPTIMAL PAIN CONTROL CREAM - AER SINCE 2010
2012-7882	11/01/2012 11/30/2012	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	CARSTON C. JOHANNSEN GOULD LAW OFFICES CHTD LLC	DICLOFENAC - AER SINCE 2009
2012-7883	11/01/2012 11/30/2012	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/ OC/ORA/OCI/ OC/ORA/OCI/	CARSTON C. JOHANNSEN GOULD LAW OFFICES CHTD LLC	FRANKLIN PHARMACY, ALABAMA & SHEFFIELD PHAMRCY & HOMECARE, FRANKLIN COUNTY, ALABAMA CONNECTION WITH DANIEL MITCHELL MD, HAWNEE MISSION MEDICAL CTR FOR PAIN MEDICINE, SHAWNEE MISSION, KS - RECS 2009 TO PRESENT
2012-7884	11/01/2012 11/30/2012	OC/CVM/OCD/	KRISTI O. SMEDLEY, Ph.D. WASHINGTON INFORMATION SOURCE	PHYTASE - RVW
2012-7885	11/01/2012 11/30/2012	OC/CVM/OCD/	KRISTI O. SMEDLEY, Ph.D. WASHINGTON INFORMATION SOURCE	GENENCOR - RVW
2012-7886	11/01/2012 11/30/2012	FDA/OC/OES/DFOI/	CHASTINE 12B2563, JAMES	FDA ORGANIZATIONAL CHART
2012-7887	11/01/2012 11/30/2012	OC/ORA/ OC/ORA/	KATIE THOMAS NEW YORK TIMES	ST JUDE MEDICAL, SYLMAR, CA - 483 10/17/12
2012-7888	11/01/2012 11/30/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORA/ OC/ORA/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	PATTI WALLER MARLER CLARK ATTYS	SALMONELLA ENTERIDITIS OUTBREAK 3/00 TO 4/00
2012-7889	11/01/2012 11/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARSHA JAFARY RECKITT BENCKISER INC	FLURBIPROFEN - AER 1/08 TO 10/20/12

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		FDA/OMPT/CDER/GRP/DIDP/		
2012-7890	11/01/2012 11/30/2012	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/ OC/OCOS/OL/ FDA/OC/OCC/ OC/ORAN/ OC/ORAN/ FDA/OC/OL/	KRISTEN FASO LAW OFFICES OF DAVID W HOLUB	NEW ENGLAND COMPOUNDING PHARMACY - RECALL; LICENSING MENINGITIS PRODUCING STERIOD MEDICATIONS
2012-7891	11/01/2012 11/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GURAL, MARILYN,	HOSPIRA, GUJARAT, INDIA; DR REDDYS, INDIA; SUN PHARMA, INDIA - 483, WARNING LTRS, EIR 1/07 TO 8/12
2012-7892	11/01/2012 11/30/2012	FDA/OFVM/CFSAN/OCD/EOS/	MARILYNN WHITNEY COVINGTON & BURLING LLP	MONSTER ENERGY - CAERS; MONSTER ENERGY PRODS 2004 TO PRESENT
2012-7893	11/01/2012 12/04/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/ FDA/OGROP/ORASW-FO/KANDO/KAN-CB/ FDA/OC/OES/DFOI/ OC/ORAN/ OC/ORAN/ FDA/OC/OES/DFOI/	MEG P. DADAY SEDGWICK LLP	CRONOBACTER SAKAZAKII - INVESTIGATION RECS, TESTING DATA, LAB SHEETS, ETC 1/11 TO PRESENT
2012-7894	11/01/2012 11/30/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORARORO/DIOP/ FDA/OGROP/ORACE-FO/CINDO/CIN-CB/ FDA/OGROP/ORACE-FO/DETDO/DET-CB/ FDA/OGROP/ORACE-FO/MIN-	LEIF LARSEN CBC NEWS	CHAMPION PET FOODS - ACANA GRASSLANDS DOG FOOD; STRAUSS HERBS - VITAMINS, MOISTURIZING HERBAL BODY WASH, HERBAL LOTION, ETC; BUNGE CANADA NIPAWIN - CANOLA MEAL, ETC IMPORT REFUSALS

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		DO/MIN-CB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/ FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/		
2012-7895	11/01/2012 11/30/2012	FDA/OFVM/CFSAN/OCD/EOS/	SCOTT W. ROONEY NEMES ROONEY ET AL	FIVE HOUR ENERGY - CAERS, INVESTIGATION RECS
2012-7896	11/02/2012 12/03/2012	FDA/OFVM/CFSAN/OCD/EOS/	CARLA R SCARMAZZI King & Spalding LLP	2012-6462, 2012-6463, 2012-6464, 2012-6465
2012-7897	11/02/2012 12/03/2012	FDA/OFVM/CFSAN/OCD/EOS/	CRAIG ROUSH ROCKLINE INDUSTRIES	LIST OF ACTIVE COSMETIC ESTABLISHMENTS
2012-7898	11/02/2012 12/03/2012	FDA/OO/OFBA/OAGS/ FDA/OC/OES/DFOI/	JEFF STACHEWICZ FOIA GROUP INC	HHSF223200830014I - CONTRACT, MODIFICATION, AMENDMENTS, ETC
2012-7899	11/02/2012 12/03/2012	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	DANIEL MACWILLIAMS WILSON ELSER MOSKOWITZ EDELMAN & DICKER LLP	FRANCK'S COMPOUNDING PHARMACY, OCALA, FL - BACTERIAL AND/OR MICROORGANISM GROWTH TESTING RECS
2012-7900	11/02/2012 12/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Elzie L Burgher Burgher, Elzie L	ORENCIA - AERS
2012-7901	11/02/2012 12/03/2012	FDA/OMPT/CDRH/OCER/DFOI/	Adam Sanders Adam Sanders, attorney for Insight Pharm	K941765, K936013, K934830 ETC
2012-7902	11/02/2012 12/03/2012	FDA/OFVM/CFSAN/OCD/EOS/ OC/OCOS/OES/ OC/OCOS/OES/	MARK MCAFEE RAW MILK INSTITUTE.ORG	DR GREGORY MILLER PHD, CALIFORNIA DAIRY RESEARCH FOUNDATION - MILK RELATED RESEARCH ACTIVITIES CORR
2012-7903	11/02/2012 12/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dennis W. Raisch UNIVERSITY OF NEW MEXICO SCHOOL OF MEDICINE	FINASTERIDE, DUTASTERIDE - AERS
2012-7904	11/02/2012	FDA/OMPT/CDER/ORP/DIDP/	Dennis W. Raisch	BRENTUXIMAB - AERS

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	12/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	UNIVERSITY OF NEW MEXICO	
2012-7905	11/02/2012 12/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORO/OCI/ OC/ORO/OCI/	Cynthia McHale Law Firm of McAfee & Taft	DERMAMEDICS, LLC - INVESTIGATION, INSPECTIONS OF LABELING, ADVERTISING, PRODUCT INFORMATION ETC (01/02/2012 - 11/01/2012)
2012-7906	11/02/2012 12/03/2012	FDA/OMPT/CDRH/OCER/DFOI/	Lavenia Ford Cardinal Health 200, LLC	K000442
2012-7907	11/02/2012 12/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Kelly Joohnson Fabyanske, Westra, Hart & Thomson, P.A.	HOSPIRA, SAN CRISTOBAL, DOMINICAN REPUBLIC - EIR (6/15/2009 - 12/15/2009)
2012-7908	11/02/2012 12/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PAMELA SHEPPARD TARO PHARMACEUTICALS USA INC	SANOFI PASTEUR - IVERMECTIN (SKLICE) LOTION NDA 202-736 SBA, MOR, LBLG, ETC
2012-7909	11/02/2012 12/14/2012	FDA/OGROP/ORO/PA-FO/SEA-DO/SEA-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/ OC/OCOS/OES/ OC/OCOS/OES/	Jim Gearhart QUORUM REVIEW	WESTERN INSTITUTIONAL REVIEW BOARD - CORR WITH FDA RE NEW REGULATIONS (07/01/1981 - 06/30/1982)
2012-7910	11/02/2012 12/03/2012	FDA/OMPT/CDRH/OCER/DFOI/	Paul Lee Johnson & Johnson Medical Products	K090821

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2012-7911	11/02/2012 12/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Macquarie	ADVATE - AERS (01/01/2000 - 11/01/2012)
2012-7912	11/02/2012 12/03/2012	FDA/OMPT/CTP/OD/	Aldridge, Kevin	CONTACT INFORMATION FOR CIGARETTE TUBE MANUFACTURER
2012-7913	11/02/2012 12/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mahadev Patel R&D Support Services Inc.	XYLO CHEM INDUSTRIES, NADIAD, INDIA - EIR (07/01/2011 - 07/16/2011)
2012-7914	11/02/2012 12/03/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/OA/OM/OMP/DDM/	Dawn M. Chmielewski Climaco Wilcox Peca Tarantino & Garofoli	MIRENA - AERS, DDMAC CORR, ADVISORY COMMITTEE TRANSCRIPTS, ETC (01/01/2000 - 11/02/2012)
2012-7915	11/02/2012 12/03/2012	FDA/OMPT/CDRH/OCER/DFOI/	Jack Cobourn Jack Cobourn	CLOPIDOGREL OR TICLOPIDINE-ELUDING STENTS USED IN ANGIOPLASTIES - AERS (03/01/2008 - 03/30/2010)
2012-7916	11/02/2012 12/03/2012	OC/OM/OMP/DDM/	JEFF GERTH PROPUBLICA	DKT 1977N-0094L
2012-7917	11/05/2012 12/04/2012	FDA/OMPT/CDRH/OCER/DFOI/	RICHARD KELLER BRUNO INDEPENDANT LIVING AIDS	TRADE CMLPNT - TRACKING NUMBER CPT1100211 CORR 5/12 TO PRESENT
2012-7918	11/05/2012 12/04/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN CREWDSON PROJECT ON GOVERNMENT OVERSIGHT	UNREDACTED RPTS OF FAERS (AERS) 1/06 TO PRESENT
2012-7919	11/05/2012 12/04/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELIZABETH BARBCHENN PUBLIC CITIZEN	ISR 3157839, 3767780, 3775034, ETC
2012-7920	11/05/2012 12/04/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MAHENDER KORAPATI MEDCORE PHARMA LLC	PFIZER -ANTIVERT (MECLIZINE HCL) ORAL TABS 12.5 MG, 25 MG, 50 MG NDA 10-721 APRVL RECS

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2012-7921	11/05/2012 12/04/2012	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/ FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	NATHAN A BEAVER FOLEY & LARDNER LLP	LIFESOUTH COMMUNITY BLOOD CENTERS 9/10/10, 7/24/12; AURORA AREA BLOOD BANK (HEARTLAND) 1/14/10; HEARTLAND BLOOD CENTERS INC, 11/28/11, ETC - 483'S WARNING LTRS, UNTITLED ENFORCEMENT LTRS, ETC
2012-7922	11/05/2012 12/04/2012	FDA/OFVM/CFSAN/OCD/EOS/	BETHANY WALLS Intertek Chemicals and Pharmaceuticals	PPG INDUSTRIES - CO-POLYMER OF METHACRYLIC ACID, ETHYL ACRYLATE, STYRENE, BUTYL METHACRYLATE & GLYCIDYL METHACRYLATE FCN 1177
2012-7923	11/05/2012 12/04/2012	FDA/OFVM/CFSAN/OCD/EOS/	ANGELA SMTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 142534, 144083, 144598, ETC
2012-7924	11/05/2012 12/04/2012	FDA/OFVM/CFSAN/OCD/EOS/	ADAMS, JACKSON	MONSTER ENERGY DRINKS - CAERS
2012-7925	11/05/2012 12/04/2012	FDA/OFVM/CFSAN/OCD/EOS/	PATTY LOVERA Food & Water Watch	AMERICAN DAIRY PRODUCTS INSTITUTE & THE US DAIRY EXPORT COUNCIL - GRASS NOTICE 444 MILK PROTEIN CONCENTRATE & MILK PROTEIN ISOLATE 9/25/12
2012-7926	11/05/2012 12/04/2012	FDA/OO/OFBA/OAGS/	PAYAL TAK TELESIS CORP	CHICKASAW NATION PROFESSIONAL SERVICES INC (SRA INTERNATIONAL INC) - HHSF2232009500261
2012-7927	11/05/2012 12/04/2012	FDA/OFVM/CFSAN/OCD/EOS/	CHRISTY CASPERS COPPERLEAF KITCHEN	COPPERLEAF KITCHEN, ALEXANDRIA, MN - NONPUBLIC RECS NAME OF FIRM, LTR DESTROY ALL HARD COPIES
2012-7928	11/05/2012 12/05/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/ FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORA/CE-FO/DET-	MERLE ZIMMERMANN AMERICAN HERBAL PRODUCTS ASSOCIATION	NUTRA MANUFACTURING, GREENVILLE SC 3/3-8/11; EVOL NUTRITION, KENNESAW, GA 7/13-29/11; VALENTINE ENTERPRISES INC, LAWRENCEVILLE, GA 10/5-11/11, ETC EIRS, 483S

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		DO/DET-CB/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OC/OES/DFOI/		
2012-7929	11/05/2012 12/04/2012	FDA/OFVM/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	LOVATE - HYDROXYCUT, SMARTBURN, RAPIDSLIM & RAPID SLIM, ETC CAERS 8/2/12 TO PRESENT
2012-7930	11/05/2012 12/04/2012	OC/ORAE/ OC/ORAE/	RICHARD D NEWMAN PHD RND SERVICES LLC	AMERIDOSE LLC - 483S 2012
2012-7931	11/05/2012 12/04/2012	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Pine Rebecca K Pine	K083767
2012-7932	11/05/2012 12/04/2012	FDA/OMPT/CDRH/OCER/DFOI/	Trishia Dwyer GE Healthcare	K113356

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2012-7933	11/05/2012 12/04/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Leola M. Anderson GERTLER LAW FIRM	K921224
2012-7934	11/05/2012 12/04/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 10/1-31/2012
2012-7935	11/05/2012 12/04/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	CLOSED FOIA REQUESTS 10/1-31/2012
2012-7936	11/05/2012 12/04/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	INDIVIDUAL RECS
2012-7937	11/05/2012 12/04/2012	FDA/OMPT/CDRH/OCER/DFOI/	Laurie Cartwright ARTHROCARE CORP	K120543
2012-7938	11/05/2012 12/04/2012	FDA/OMPT/CDRH/OCER/DFOI/	Laurie Cartwright ARTHROCARE CORP	K112040
2012-7939	11/05/2012 12/04/2012	FDA/OMPT/CDRH/OCER/DFOI/	Erin McCoy Tampa General Hospital	K121679
2012-7940	11/05/2012 12/04/2012	FDA/OMPT/CDRH/OCER/DFOI/	Laurie Cartwright ARTHROCARE CORP	K101823
2012-7941	11/05/2012 12/04/2012	FDA/OMPT/CDRH/OCER/DFOI/	Laurie Cartwright ARTHROCARE CORP	K103831
2012-7942	11/05/2012 12/04/2012	FDA/OMPT/CDRH/OCER/DFOI/	Laurie Cartwright ARTHROCARE CORP	K120078
2012-7943	11/05/2012 12/04/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Monica Hug Merck Consumer Care	ANDA 071739 - SBA
2012-7944	11/05/2012 12/04/2012	FDA/OFVM/CFSAN/OCD/EOS/	Doug Iten WFTS TV	MONSTER ENERGY DRINK - AERS (01/02/2007 - 11/01/2012)
2012-7945	11/05/2012 12/04/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jennifer Miles Frazer, Greene, Upchurch & Baker,	SULFASALAZINE - AERS WARNINGS, CORR ETC

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LLC	
2012-7946	11/05/2012 12/04/2012	FDA/OMPT/CDRH/OCER/DFOI/	Laura Boll Medovations Inc.	K111821
2012-7947	11/05/2012 12/04/2012	OC/ORO/OCI/ OC/ORO/OCI/	Jake Pearson Wired Magazine	GOOGLE INC ONLINE ADVERTISEMENT OF PHARMACIES - 2009 INVESTIGATION RECS
2012-7948	11/05/2012 12/04/2012	FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	Rachel Johnson FOI Services, Inc.	ALLERGAN, IRVINE, CA - EIR 05/24/2010; EIR 04/04/2008
2012-7949	11/06/2012 12/05/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Matt Daniel Prosight Capital	NCT01577654, NCT01170650 - ISRs
2012-7950	11/06/2012 12/05/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/	Mike Pagano Kraft Foods Global Inc.	KRAFT GREEN GODDESS SALAD DRESSING - SAMPLE RESULTS
2012-7951	11/06/2012 12/05/2012	FDA/OFVM/CFSAN/OCD/EOS/	Chris Lahiff McDermott Will & Emery LLP	MONSTER ENERGY DRINKS - CAERS
2012-7952	11/06/2012 12/05/2012	FDA/OMPT/CDRH/OCER/DFOI/	Dari Darabbeigi Persyst Development Corporation	K090019, K092039, K120485 ETC
2012-7953	11/06/2012 12/05/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 202428
2012-7954	11/06/2012 12/05/2012	FDA/OMPT/CDRH/OCER/DFOI/	Mark Patterson Lila Enterprise, LLC	K111501
2012-7955	11/06/2012 12/05/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Bruce Thompson Bruce Thompson	ISR 10482 10470 10471, ETC
2012-7956	11/06/2012 12/05/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Daniel Gofman SERRADO CAPITAL LLC	GASTROINTESTINAL DRUGS ADVISORY COMMITTEE TRANSCRIPT 10/16/12

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2012-7957	11/06/2012 12/05/2012	OC/OSMP/OOPD/ FDA/OMPT/OSMP/OOPD/	Diane Schulman The Indago Group Inc.	TETRACOSACTIDE HEXAACETATE - ORPHAN DRUG APPLICATION
2012-7958	11/06/2012 12/05/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Daryl Davis Davis, Daryl	BURZYNSKI RESEARCH INSTITUTE - DSI SUMMARY OF FINDINGS 08/01
2012-7959	11/06/2012 12/05/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	ANASTROZOLE - AER
2012-7960	11/06/2012 12/05/2012	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	JOHN L. HOLAHAN SIMPLY THICK LLC	SIMPLY THICK, WAKE COUNTY, NC; ST LOUIS, MO - SPL 656840, TEST RESULTS 6/2011
2012-7961	11/06/2012 12/05/2012	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	MARILYNN WHITNEY COVINGTON BURLING LLP	TOBACCO MFRS - EIRS, 483S AFTER 9/11
2012-7962	11/06/2012 12/05/2012	FDA/OMPT/CTP/OD/	MARILYNN WHITNEY COVINGTON & BURLING LLP	LIST OF TOBACCO PRODS FOR WHICH FDA ISSUED A SUBSTANTIAL EQUIVALENCE ORDER; SUMMARY OF ADVERSE HEALTH EFFECTS
2012-7963	11/06/2012	FDA/OGROP/ORA/SE-FO/FLA-	JOELLE G. NELSON	TOXIN TECHNOLOGY INC - ACTIVE PHARMACEUTICAL

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	12/05/2012	DO/FLA-CB/	JOHANSON & FAIRLESS LLP	INGREDIENT (API) TESTING LAB
2012-7964	11/06/2012 12/05/2012	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	SUSAN B. MILLS WEINBERG WHEELER ET AL	E COLI OUTBREAK AT CLEVELAND CO (NC) FAIR FROM 9/27 TO 10/7/12 - INVESTIGATION RECS, SPL SUMMARIES, TRACE BACK DATA, ETC
2012-7965	11/06/2012 12/05/2012	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KEVIN M. DWYER, Jr. LAW OFFICE OF KEVIN M DWYER JR	HARVARD CLNCL TRIAL RESEARCH INSTITUTE 12/09 INVESTIGATION OF THE FAILURE TO REPORT A SEVERE ADVERSE EVENT (SAE)
2012-7966	11/06/2012 12/05/2012	FDA/OMPT/CDRH/OCER/DFOI/	EILEEN BOYLE HOLOGIC INC	MEDIMAPS GROUP SA - TBS INSIGHT K121716
2012-7967	11/06/2012 12/05/2012	FDA/OFVM/CFSAN/OCD/EOS/	WALBAUM, RICHARD	NERIUM INTL LLC - NERIUM AD AGE DEFYING TREATMENT AER 8/11 TO PRESENT
2012-7968	11/06/2012 12/05/2012	FDA/OMPT/CDRH/OCER/DFOI/	EILEEN BOYLE HOLOGIC INC	ON DIAGNOSTICS - VIRTUOST K113725
2012-7969	11/06/2012 12/05/2012	FDA/OMPT/CDRH/OCER/DFOI/	BERRYMAN, THOMAS	UROMED PATCH K974600
2012-7970	11/06/2012 12/05/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	YVONNE M. FLAHERTY LOCKRIDGE GRINDAL NAUEN PLLP	PARADIGM QUICK SET INFUSION SETS K011071 CLASS I RECALL ACTION MEMO
2012-7971	11/06/2012 12/05/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	JANUVIA - AER
2012-7972	11/07/2012 12/06/2012	FDA/OC/OES/DFOI/	GLADYS B TONKINS WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 10/15-19/12
2012-7973	11/07/2012 12/06/2012	FDA/OC/OES/DFOI/	GLADYS B TONKIN WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 10/8-12/12
2012-7974	11/07/2012 12/06/2012	FDA/OC/OES/DFOI/	GLADYS B TONKINS WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 10/22-26/12
2012-7975	11/07/2012	FDA/OC/OES/DFOI/	GLADYS B TONKIN	FOI DAILY LOG 10/1-5/12

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	12/06/2012		WASHINGTON INFORMATION SOURCE	
2012-7976	11/07/2012 12/06/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 10/15-19/12
2012-7977	11/07/2012 12/06/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 10/22-26/12
2012-7978	11/07/2012 12/06/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 10/1-5/12
2012-7979	11/07/2012 12/06/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 10/8-12/12
2012-7980	11/07/2012 12/06/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 10/22-26/12
2012-7981	11/07/2012 12/06/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 10/1-5/12
2012-7982	11/07/2012 12/06/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 10/8-12/12
2012-7983	11/07/2012 12/06/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 10/15-19/12
2012-7984	11/07/2012 12/06/2012	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 10/8-12/12
2012-7985	11/07/2012 12/06/2012	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 10/15-19/12
2012-7986	11/07/2012 12/06/2012	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 10/1-5/12
2012-7987	11/07/2012 12/06/2012	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 10/1-5/12
2012-7988	11/07/2012 12/06/2012	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 10/22-26/12
2012-7989	11/07/2012 12/06/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW &	FOI DAILY LOG 10/22-26/12

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			BUSINESS	
2012-7990	11/07/2012 12/06/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 10/1-5/12
2012-7991	11/07/2012 12/06/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 10/8-12/12
2012-7992	11/07/2012 12/06/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 10/15-19/12
2012-7993	11/07/2012 12/06/2012	OC/ORO/OCI/ OC/ORO/OCI/	A CARIN WEINRICH SOREFF LAW	INDIVIDUAL RECS
2012-7994	11/07/2012 12/06/2012	FDA/OGROP/ORO/CE-FO/MIN-DO/MIN-CB/	PAUL W TRIPP LINCARE INC	GOLDEN SANDS RESPIRATORY CARE SERVICES INC,WI - EIRS, 483S, WARNING LTRS 1/05 TO PRESENT
2012-7995	11/07/2012 12/06/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	LOU CAPUTO EMORD & ASSOCIATES, P.C.	BLIS TECHNOLOGIES LTD - BLIS K-12 TRAVEL GUARD IMPORT REFUSAL NOTICE OF DETENTION & HEARING
2012-7996	11/07/2012 12/06/2012	FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/	LESLIE SHOJI INTEREX INDUSTRIES LTD	UNITED 1 INTERNATIONAL LABS, FARMERS BRANCH, TX; CEUTICAL LABS, FARMERS BRANCH, TX; MICROCONSULT INC, CARROLLTON, TX, ETC - EIRS
2012-7997	11/07/2012 12/06/2012	FDA/OO/ FDA/OO/OHR/	JOHN SANDERS BENEFIT COORDINATORS	LIST OF FDA EMPLOYEES - SUBORDINATE ELEMENTS, AGENCIES, FIELD COMPONENTS, ETC
2012-7998	11/07/2012 12/06/2012	FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	SUSAN B MILLS WEINBERG WHEELER ET AL	CLEVELAND COUNTY (NC) FAIR - E COLI OUTBREAK EIRS, TRACE BACK DATA, SPL SUMMARIES, ETC 9/27/12-10/7/12
2012-7999	11/07/2012 12/06/2012	FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/	SHANDIN KLOBE BAKER STERCHI COWDEN & RICE LLC	NEVADA HEART AND VASCULAR CENTER. LAS VEGAS, NV - PET SCANS INVESTIGATION RECS, INSP FINDINGS, CORR, ETC 1/05 TO PRESENT
2012-8000	11/07/2012 12/06/2012	FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/	SHANDIN KLOBE BAKER STERCHI COWDEN & RICE LLC	NEVADA HEART AND VASCULAR CENTER (LONGFORD MEDICAL CENTER), LAS VEGAS, NV - PET SCAN INVESTIGATION RECS, CORR, VIOLATIONS, ETC 1/05 TO PRESENT
2012-8001	11/07/2012 12/06/2012	FDA/OC/OES/DFOI/	JEFFREY J JONES JONES DAY	SCOTTS MIRACLE-GRO CO - WILD BIRD FOOD PRODS RECS 1/08 TO PRESENT
2012-8002	11/07/2012 12/06/2012	OC/CVM/OCD/ FDA/OGROP/ORO/CE-FO/CIN-	JEFFREY J JONES JONES DAY	INDIVIDUAL RECS

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2012-8003	11/07/2012 12/06/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/OIP/ OC/ORA/ OC/ORA/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	PATTI WALLER MARLER CLARK ATTYS	TANIMURA & ANTLE INC - ROMAINE LETTUCE RECALL COMM
2012-8004	11/07/2012 12/06/2012	FDA/OC/OES/DFOI/	Doe J	RULES, REGULATIONS ABOUT GLUTEN IN FOODS
2012-8005	11/07/2012 12/06/2012	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/OCOS/OES/ OC/OCOS/OES/	LISSETTE HOWARD POCHE UNIV OF TEXAS MD ANDERSON CANCER CENTER	ROBERT E YOUNG MD - CLNCL INVESTIGATOR DISQUALIFICATION PROCEEDINGS 10/15/82
2012-8006	11/07/2012 12/06/2012	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	ALAN G MINSK ARNALL GOLDEN GREGORY LLP	BENJAMIN BIOMEDICAL INC, ST PETERSBURG, FL - EIRS, CORR 2007
2012-8007	11/07/2012 12/06/2012	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	JONATHAN M RIVERA MANUEL A ROMERO PC	GOYA FOODS INC - CMLPNT
2012-8008	11/07/2012 12/06/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANDY WU UNIV OF PENNSYLVANIA WHARTON SCHOOL	ORANGE BOOK 1980 TO PRESENT

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		FDA/OMPT/CDER/GRP/DIDP/		
2012-8009	11/07/2012 12/06/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Matt Daniel Prosight Capital	VINTAFOLIDE - AERS (01/01/2000 - 11/06/2012)
2012-8010	11/07/2012 12/06/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Liz Pretzinger Rawls McNelis + Mitchell	INDIVIDUAL RECS
2012-8011	11/07/2012 12/06/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	McNerney, Jon	AZITHROMYACIN - AERS (01/01/1996 - 11/06/2012)
2012-8012	11/07/2012 12/06/2012	FDA/OFVM/CFSAN/OCD/EOS/	CAPSTONE LLC	MONSTER ENERGY DRINKS - AERS (01/01/2009 - 11/06/2012)
2012-8013	11/07/2012 12/06/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tammy Covert Simon Greenstone Panatier Bartlett, PC	TOLUENE, HYDROQUINONE IN HAIR AND NAIL PRODUCTS - CORR WITH COLOMER BEAUTY BRANDS USA, INC., CREATIVE NAIL DESIGNS, INC, LOREAL USA, ETC
2012-8014	11/07/2012 12/06/2012	FDA/OFVM/CFSAN/OCD/EOS/	Cdn Cosmetic Toiletry and Frag Assoc.	STUDY SUBMITTED TO FDA BY COSMETIC, TOILETRY AND FRAGRANCE ASSOCIATION - ABSORPTION, DISTRIBUTION, METABOLISM AND EXCRETION OF RED NO 9
2012-8015	11/07/2012 12/06/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K831004
2012-8016	11/07/2012 12/06/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jason Mallari Regis University	CRESTOR - AERS (08/29/2003 - 11/06/2012)
2012-8017	11/07/2012 12/06/2012	FDA/OFVM/CFSAN/OCD/EOS/	Paulina Do EXPONENT	CAP 4C0276
2012-8018	11/07/2012 12/06/2012	FDA/OC/OES/DFOI/	FREIFELDER, JACK FRANCIS	FOI REQUESTS 9/1/12-10/1/12
2012-8019	11/07/2012 12/06/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MICHAEL R COHEN RPH MS SCD INSTITUTE FOR SAFE MEDICATION PRACTICES	MEDWATCH RPTS CODED AS MEDICATION ERRORS 10/1-31/12

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2012-8020	11/07/2012 12/06/2012	FDA/OMPT/CDRH/OCER/DFOI/	DARI DARABBEIGI PERSYST DEVELOPMENT CORP	NATUS MEDICAL INC - NATUS NEUROWORKS K090010; OPTIMA NEUROSCIENCE INC - IDENTEVENT K092039; MOBERG RESEARCH INC - COMPONENT NEUROMONITORING SYS K080217, ETC
2012-8021	11/07/2012 12/06/2012	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	CHARLES CELESTE EAS Consulting Group, LLC	NOVARTIS VACCINES & DIAGNOSTICS, EMERYVILLE, CA - 483SS 4/12 TO PRESENT
2012-8022	11/07/2012 12/06/2012	OC/ORA/OCI/ OC/ORA/OCI/	Doe J	INDIVIDUAL RECS
2012-8023	11/08/2012 12/07/2012	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	steve caritis UNIV OF PITTSBURGH	COMPOUNDED MAKENA - LAB RESULTS
2012-8024	11/08/2012 12/07/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Robert Blaskiewicz Self	ANTINEOPLASTONS AS EXPERIMENTAL CANCER THERAPY - APPROVALS, WAIVERS
2012-8025	11/08/2012 12/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	HealthInterlink	K120941
2012-8026	11/08/2012 12/07/2012	FDA/OFVM/CFSAN/OCD/EOS/	Zafar Hayat Khan	ENERGY DRINKS - AERS (01/01/2010 - 11/07/2012)
2012-8027	11/08/2012 12/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	SOOJUNG MOON ENDOTEC INC.	K905262; K904870; K963100 ETC
2012-8028	11/08/2012	FDA/OMPT/CDRH/OCER/DFOI/	Bret Andre	P010019

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	12/07/2012		EyeReg Consulting, Inc.	
2012-8029	11/08/2012 12/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	HealthInterlink	K120941
2012-8030	11/08/2012 12/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	Danna Kehm HealthInterlink	K112858
2012-8031	11/08/2012 12/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	Bret Andre EyeReg Consulting, Inc.	K001962
2012-8032	11/08/2012 12/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	HealthInterlink	K072272
2012-8033	11/08/2012 12/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	Bret Andre EyeReg Consulting, Inc.	P980006
2012-8034	11/08/2012 12/07/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Parker Theuinck Meagher & Geer, PLLP	METOCLOPRAMIDE-CONTAINING PRODUCTS - NOTIFICATIONS 12/08
2012-8035	11/08/2012 12/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	Bret Andre EyeReg Consulting, Inc.	P040045
2012-8036	11/08/2012 12/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	Bret Andre EyeReg Consulting, Inc.	K100349
2012-8037	11/08/2012 12/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	Bret Andre EyeReg Consulting, Inc.	K032390
2012-8038	11/08/2012 12/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	Bret Andre EyeReg Consulting, Inc.	K002099
2012-8039	11/08/2012 12/07/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	ASHER KASSEL LIFEWATCH TECHNOLOGIES LTD	SOTERA WIRELESS - K122036, MONEBO TECHNOLOGIES - K062282
2012-8040	11/08/2012 12/07/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDRH/OCER/DFOI/	BOBBY SCHOCHET OLSSON FRANK WEEDA TERMAN MATZ PC	LTR TO CDRH OR CBER TO ANY CLNCL REGARDING LAB DEVELOPED TESTS (LTD) LAST 2 YRS
2012-8041	11/08/2012 12/07/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRANDON L. BOGLE LEVIN PAPANTONIO ET AL	MERCK & CO - FOSAMAX ATYPICAL FEMUR FRACTURES AERS, CLNCL TRIAL DATA

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2012-8042	11/08/2012 12/07/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	THOMAS WONG DEETH WILLIAMS WALL LLP	FDA APRVD DRUG PRODUCTS: WITH THERAPEUTIC EQUIVALENCE EVALUATIONS 16TH EDITION (1996); CUMULATIVE SUPPLEMENT 1/96 TO 7/96
2012-8043	11/08/2012 12/07/2012	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	DONALD N. BLUE ZETETIC INC	ENTRY NO AV3-00379904
2012-8044	11/08/2012 12/07/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BROWN 219191, KENYA	JOHNSON & JOHNSON/JANSSEN PHARMA - RESPERDAL (RESPIDOL) AER
2012-8045	11/08/2012 12/07/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	BRETT PARK CONWAY, HOMER & CHIN-CAPLAN PC	VAERS - INDIVIDUAL RECS
2012-8046	11/08/2012 12/07/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 10/15-19/12
2012-8047	11/08/2012 12/07/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 10/22-26/12
2012-8048	11/08/2012 12/07/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 10/8-12/12
2012-8049	11/08/2012 12/07/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 9/17-21/12
2012-8050	11/08/2012 12/07/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 10/8-12/12
2012-8051	11/08/2012 12/07/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 10/22-26/12
2012-8052	11/08/2012 12/07/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 10/15-19/12
2012-8053	11/08/2012 12/07/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 9/17-21/12

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2012-8054	11/08/2012 12/07/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCRAMP CanReg, Inc.	DAILY LOG 10/22-26/12
2012-8055	11/08/2012 12/07/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 10/15-19/12
2012-8056	11/08/2012 12/07/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 10/8-12/12
2012-8057	11/08/2012 12/07/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 9/24-28/12
2012-8058	11/08/2012 12/07/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	DAILY LOG 10/8-12/12
2012-8059	11/08/2012 12/07/2012	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 10/15-19/12
2012-8060	11/08/2012 12/07/2012	FDA/OC/OES/DFOI/	DAVID McFARLAND FDA WEBVIEW/FERDIC INC	DAILY LOG 10/22-26/12
2012-8061	11/08/2012 12/07/2012	FDA/OC/OES/DFOI/	DAVID McFARLAND FDA WEBVIEW/FERDIC INC	DAILY LOG 10/8-12/12
2012-8062	11/08/2012 12/07/2012	FDA/OC/OES/DFOI/	DAVID McFARLAND FDA WEBVIEW/FERDIC INC	DAILY LOG 10/15-19/12
2012-8063	11/08/2012 12/07/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 9/24-28/12
2012-8064	11/08/2012 12/07/2012	FDA/OC/OES/DFOI/	WILLIAM A. OLSON Center for Regulatory Services,Inc.	DAILY LOG 9/24-28/12
2012-8065	11/08/2012 12/07/2012	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 9/17-21/12
2012-8066	11/09/2012 12/10/2012	FDA/OFVM/CFSAN/OCD/EOS/	Michaela Laussegger Austrian Trade Commission	AUSTRALIAN TRADE COMMISSION - LIST OF ESTABLISHMENTS USING AS US AGENT FOR BIOTERRORISM FOOD REGISTRATION
2012-8067	11/09/2012 12/10/2012	FDA/OFVM/CFSAN/OCD/EOS/	LaVeeta Moten	INDIVIDUAL RECS
2012-8068	11/09/2012 12/10/2012	FDA/OFVM/CFSAN/OCD/EOS/	LaVeeta Moten LaVeeta Moten	CFSAN BUDGET EXECUTION AND ANALYSIS & REPORTING TEAM MEMBERS - NAMES, DUTIES, PROJECT TIMELINES, ETC (10/01/2009 - 11/08/2012)
2012-8069	11/09/2012 12/10/2012	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Glenn Irish Glenn Irish Consulting	SHIRE, LEXINGTON, MA - 483 (11/01/2011 - 11/08/2012)

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2012-8070	11/09/2012 12/10/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORO/CE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORO/SE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORO/SW-FO/KAN-DO/KAN-CB/ OC/ORO/ OC/ORO/	Kimberly Kindy THE WASHINGTON POST	CENTRAL ADMIXTURE PHARMACY INC, APOTHECURE, PHARMEDIUM SERVICES - INSPECTION RECS
2012-8071	11/09/2012 12/10/2012	FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	AMRI	BAXTER, MARION, NC - EIR MOST RECENT
2012-8072	11/09/2012 12/10/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OO/ FDA/OO/OHR/	Doe J	INDIVIDUAL RECS
2012-8073	11/09/2012 12/10/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OO/ FDA/OO/OHR/	LaVeeta Moten	CORR RE GS-14 TRAVEL LEAD POSITION WITHIN CFSAN
2012-8074	11/09/2012 12/10/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OO/ FDA/OO/OHR/	LaVeeta Moten	OFFICE OF MANAGEMENT SYSTEMS - TRAINING RECS
2012-8075	11/09/2012 12/10/2012	OC/ORO/ OC/ORO/ FDA/OC/OES/DFOI/	Kimberly Kindy THE WASHINGTON POST	CENTRAL ADMIXTURE PHARMACY SERVICES, PHARMEDIUM, APOTHECURE - INSPECTION RECS
2012-8076	11/09/2012 12/10/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	joseph barton joseph barton	ORANGE BOOK - CORTICOTROPIN
2012-8077	11/09/2012	FDA/OFVM/CFSAN/OCD/EOS/	Shailini Rao	MONSTER ENERGY DRINKS - AERS

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	12/10/2012		Eton Park Capital Management, L.P.	
2012-8078	11/09/2012 12/10/2012	OC/OA/OM/OMP/DDM/	Carrie Kahn CHEMRISK LLC	DKT 1975N-0190 - COMMENTS SUBMITTED BY THE SOCIETY OF THE PLASTICS INDUSTRY RE VINYL CHLORIDE EXPOSURE FROM CUTTING PVC PLASTIC FILM
2012-8079	11/09/2012 12/10/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Seongsoo Park DAEWOONG AMERICA INC	NDA 019594
2012-8080	11/09/2012 12/10/2012	OC/ORO/ORM/ OC/ORO/ORM/	JOHNATHAN RICKMAN FDA NEWS	PHARMACEUTICAL, BIOLOGICS, MEDICAL DVC MFG FACILITIES, ETC - 483S 10/1-31/12
2012-8081	11/09/2012 12/10/2012	FDA/OFVM/CFSAN/OCD/EOS/	FRANK E PISCITELLI JR PISCITELLI LAW FIRM	WHITE WAVE FOODS CO, BROOMFIELD, CO - HORIZON ORGANIC MILK PRODS INVESTIGATIVE RECS
2012-8082	11/09/2012 12/10/2012	FDA/OFVM/CFSAN/OCD/EOS/	LaVeeta Moten	IMPAC TRAINING SESSION - PRESENTERS, TRAINING MATERIALS
2012-8083	11/09/2012 12/10/2012	FDA/OFVM/CFSAN/OCD/EOS/	LaVeeta Moten	OFF ICE OF MANAGEMENT SYSTEMS - REPLACEMENT FOR DETAILS
2012-8084	11/09/2012 12/10/2012	OC/CVM/OCD/ FDA/OC/OCC/	AVINASH KAR NATURAL RESOURCES DEFENSE COUNCIL	VOLUME OF ANTIBIOTICS USED ANNUALLY IN FOOD-PRODUCING ANIMALS - RECS 2000 TO PRESENT
2012-8085	11/09/2012 12/10/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OO/ FDA/OO/OHR/	LaVeeta Moten	EDUCATION AND EXPERIENCE RECS - GOVERNMENT BUDGET
2012-8086	11/09/2012 12/10/2012	OC/ORO/ OC/ORO/	JUSTIN BROWNE ESQ JANET, JENNER & SUGGS, LLC	NEW ENGLAND COMPOUNDING CENTER - EIRS, 483S, TESTING RECS, ETC 10/26/12
2012-8087	11/09/2012 12/10/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LOU CAPUTO EMORD & ASSOCIATES, P.C.	BLIS TECHNOLOGIES LTD - BLIS K-12 TRAVEL GUARD IMPORT REFUSAL NOTICE OF DETENTION & HEARING
2012-8088	11/09/2012 12/10/2012	FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/	SHUGART, ROBERT M	REGENERATIVE TECHNOLOGIES INC - EIR, WARNING LTR 10/12
2012-8089	11/09/2012 12/10/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORO/CE-FO/DET-DO/DET-CB/ FDA/OGROP/ORO/SW-FO/KAN-	BECKY COOSEMAN BROWN & CROUPPEN PC	CRONOBACTER SAKAZAKII/CRONOBACTER SP/ENTEROBACTER SAKAZAKII - CORR, TESTING RECS, DENDROGRAMS, ETC; INDIVIDUAL RECS

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		DO/KAN-CB/		
2012-8090	11/09/2012 12/10/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRANDON L BOGLE LEVIN PAPANTONIO THOMAS ET AL	MERCK & CO INC - FOSAMAX (ALENDRONATE SODIUM) AERS, CLNCL RECS
2012-8091	11/09/2012 12/10/2012	FDA/OC/OES/DFOI/	COLLEEN K DUCAS SANOFI PASTEUR	2012-6926
2012-8092	11/09/2012 12/10/2012	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OMPT/CDRH/OCER/DFOI/	MICHAEL C SKOUTERIS SKOUTERIS & MAGEE PLLC	HILL-ROM COMPANY CORP, BATESVILLE, IN - DEFECTIVE HOSPITAL BEDS INVESTIGATION RECS, RECALL, WARNINGS, ETC
2012-8093	11/09/2012 12/10/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	NURIA MARCOS OLIVAN GLENMARK PHARMACEUTICALS MEXICO SA DE CV	AARTI INDUSTRIES LTD, THANE, INDIA; SYMBIOTEC PHARMALAB LTD, INDORE, INDIA; MATRIX LABORATORIES LTD, SECUNDERABAD, INDIA - EIRS, 483S
2012-8094	11/09/2012 12/10/2012	OC/ORACE/ OC/ORACE/	ANDREW KAHN DAVIS COWELL & BOWE LLP	ST JUDE MEDICAL INC, SYLMAR, CA - 483 10/12
2012-8095	11/09/2012 12/10/2012	FDA/OGROP/ORACE-FO/NYK-DO/NYK-DCB/	DOUGLAS N BLUE II ZETETIC INC	SIMILAC, ENFAMIL INFANT FORMULA ENTRY #DP406043860 - RECS
2012-8096	11/09/2012 12/10/2012	FDA/OMPT/CDRH/OCER/DFOI/	HELEN LEWIS DENTSPLY INTERNATIONAL, INC.	3M - ESPE LAVA CHAIRSIDE ORAL SCANNER K073199
2012-8097	11/09/2012 12/10/2012	FDA/OMPT/CDRH/OCER/DFOI/	HELEN LEWIS DENTSPLY INTERNATIONAL, INC.	3M - UNITEK LAVA CHAIRSIDE ORAL SCANNER K081961
2012-8098	11/09/2012 12/10/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	LIMIN ZHENG FISH & RICHARDSON PC	VYSIS - UROZYISION BLADDER CANCER RECURRENCE KIT K011031
2012-8099	11/09/2012 12/10/2012	FDA/OMPT/CDRH/OCER/DFOI/	LIMIN ZHENG FISH & RICHARDSON PC	ABBOTT MOLECULAR - UROVYISION BLADDER CANCER KIT P030052
2012-8100	11/09/2012 12/10/2012	OC/OA/OM/OMP/DDM/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JULIE NAUD GROUPE BNA CONSULTANT GROUP	BIOLOGICAL TESTING PROCEDURES FOR FLUORIDE DENTIFRICES - DKT 1980N-0042
2012-8101	11/09/2012	FDA/OMPT/CDER/ORP/DIDP/	CANDICE DURRENCE	OPTIMER PHARMACEUTICALS INC - DIFID (FIDAXOMICIN

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	12/10/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	OPTIMER PHARMACEUTICALS INC	TABS) NDA 201-699 AERS 4/27/12-11/7/12
2012-8102	11/09/2012 12/10/2012	FDA/OGROP/ORA/CE-FO/CIN- DO/CIN-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/	DONNIE ALLEN SNOW SKOUTERIS & MAGEE PLLC	HILL-ROM COMPANY CORP, BATESVILLE, IN - EIRS, 483S, MDRS, ETC
2012-8103	11/09/2012 12/10/2012	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	HANIF SACHEDEDINA CIPHER PHARMACEUTICALS INC	AIDERAX PHARMACEUTICALS INC, CORONA, CA - EIRS, 483S MOST RECENT
2012-8104	11/09/2012 12/10/2012	FDA/OMPT/CDRH/OCER/DFOI/	ROBB PERRY NORTH AMERICAN RESCUE LLC	COMBAT MEDICAL SYSTEMS LLC - COMBAT READY CLAMP K102025
2012-8105	11/09/2012 12/10/2012	FDA/OC/OES/DFOI/	ROBERT P CHARROW GREENBERG TRAUIG LLP	2006-15538, 2006-15634, 2012-3772
2012-8106	11/13/2012 12/11/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ORTAV YEHUDAI GREAT POINT PARTNERS LLC	SYNCO BIO PARTNERS BV, AMSTERDAM, NETHERLANDS - 483S 1/12 TO PRESENT
2012-8107	11/13/2012 12/11/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ORTSV YEHUDAI GREAT POINT PARTNERS LLC	BOEHRINGER INGELHEIM AUSTRIA GMBH, VIENNA, AUSTRIA - 483S 1/12 TO PRESENT
2012-8108	11/13/2012 12/11/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JAY H HENDERSON JAY HENDERSON PLLC	PARKE DAVIS - CEREBYX (FOSPHENYTOIN) NDA 20-450 LBLG OR LBLG CHANGES 1/1/07 TO 11/1/12
2012-8109	11/13/2012 12/11/2012	FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/	ORTAV YEHUDIA GREAT POINT PARTNERS LLC	APTUIT LLC, KANSAS CITY, MO; HARRISONVILLE, MO - 483S 1/12 TO PRESENT
2012-8110	11/13/2012 12/11/2012	FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/	ADAM DIEDERICH SCHIFF HARDIN LLP	KEATON WALKER, TRANSPORTATION LLC - SLAUGHTER OF HORSES CORR, LICENSES, PERMITS, ETC 1/11 TO PRESENT
2012-8111	11/13/2012 12/11/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	KYLA BERNNETT PUBLIC EMPLOYEES FOR ENVIRONMENTAL RESPONSIBILITY	EASTERN EQUINE ENCEPHALITIS VACCINE - RPTS, IND, SS&E, ETC

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2012-8112	11/13/2012 12/11/2012	FDA/OFVM/CFSAN/OCD/EOS/	CARLA R SCARMAZZI KING & SPALDING	HUMAN EXPOSURE TO CAFFEINE - RESP LTR 8/10/12
2012-8113	11/13/2012 01/09/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/ OC/ORO/ OC/ORO/	SCHRIFLER, JEFF	CDER OR CDRH FOREIGN INSP RECS
2012-8114	11/13/2012 12/11/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	ELIZBETH RICHARDS LATHAM & WATKINS LLP	EXCLUSIVE SUPPLEMENTS - BIORHYTHM SSIN JUICE; FAHRENHEIT NUTRITION - LEAN EFX; GASPARI NUTRITION - SPIRODEX, ETC RESP TO WARNING LTRS 4/24/12
2012-8115	11/13/2012 12/11/2012	FDA/OC/OES/DFOI/	DUCHNESKIE, STEPHANIE	LIST OF RECS REQUESTED BY PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS (PETA) 9/1/12 TO 10/1/12
2012-8116	11/13/2012 12/11/2012	OC/ORO/ORM/ OC/ORO/ORM/	TYLR KENYON NORTHCOAST RESEARCH	LIST OF EIRS, 483S - LAST SIX MONTHS
2012-8117	11/14/2012 12/12/2012	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	ALTRIA CLIENT SERVICES, PHILIP MORRIS USA INC, SMOKELESS TOBACCO COMPANY LLC - LIST OF PRODUCTS NOTIFIED FDA
2012-8118	11/14/2012 12/12/2012	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	ALTRIA CLIENT SERVICES, PHILIP MORRIS USA INC, SMOKELESS TOBACCO COMPANY LLC - PRODUCT LISTING
2012-8119	11/14/2012 12/12/2012	FDA/OMPT/CTP/OD/ OC/OM/OFM/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	QUARTERLY CTP USER FEES 10/01/11 TO PRESENT
2012-8120	11/14/2012 12/12/2012	FDA/OMPT/CTP/OD/ OC/OM/OFM/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	CTP USER FEES SINCE 10/01/11
2012-8121	11/14/2012 12/12/2012	FDA/OMPT/CTP/OD/ OC/OM/OFM/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	CTP USER FEES - MANUFACTURERS AND IMPORTERS ASSESSED 10/01/11 TO PRESENT
2012-8122	11/14/2012 12/12/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Christine Phillips, PhD, RAC ELI LILLY & CO	BLA 125276 S49

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		FDA/OMPT/CDER/GRP/DIDP/		
2012-8123	11/14/2012 12/12/2012	FDA/OFVM/CFSAN/OCD/EOS/	Shailini Rao Eton Park Capital Management, L.P.	MONSTER ENERGY - AERS
2012-8124	11/14/2012 12/12/2012	OC/CVM/OCD/	Mary Schwager News Pro Net TV	PET MEDICATIONS ERRORS - LAST THREE YEARS
2012-8125	11/14/2012 12/12/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	RON BELLDEGRUN belldegrun, ron	NDA 021610 - ABUK IMPURITY
2012-8126	11/14/2012 12/12/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Christine Phillips, PhD, RAC Eli Lilly and Company, Inc.	NDA 203214
2012-8127	11/14/2012 12/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	Ryan Gregerson American Sleep Association	K963591
2012-8128	11/14/2012 12/12/2012	FDA/OFVM/CFSAN/OCD/EOS/	Shailini Rao Eton Park Capital Management, L.P.	RED BULL - AERS
2012-8129	11/14/2012 12/12/2012	FDA/OFVM/CFSAN/OCD/EOS/	Shailini Rao Eton Park Capital Management, L.P.	ROCKSTAR ENERGY PRODUCTS - AERS
2012-8130	11/14/2012 12/12/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Geoffrey Robert Chambers Geoffrey R Chambers	VASCEPA EXCLUSIVITY DETERMINATION LETTER
2012-8131	11/14/2012 12/12/2012	FDA/OGROP/ORR/SE-FO/ATL- DO/ATL-CB/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	VISIUM FUNDS	IMMUCOR - NOTICE OF INTENT TO REVOKE; INSPECTION RECS
2012-8132	11/14/2012 12/12/2012	FDA/OGROP/ORR/SE-FO/FLA- DO/FLA-CB/ FDA/OC/OES/DFOI/	CARDINAL HEALTH	ANAZAOHEALTH CORP, TAMPA, FL - 483 (12/1/2009 - 12/23/2009)
2012-8133	11/14/2012 12/12/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Karen Anello DILWORTH PAXSON LLP	OXYCONTIN - AERS

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2012-8134	11/14/2012 12/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	Joe Braid EdgeOne Medical Inc	ABCO DEALERS, INC - GUAGE SPONGE X-RAY DETECTABLE X-RAY 510(K) NOTIFICATION
2012-8135	11/14/2012 12/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	Joe Braid EdgeOne Medical Inc	K071519
2012-8136	11/14/2012 12/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	Joe Braid EdgeOne Medical Inc	K821150
2012-8137	11/14/2012 12/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	UC-Care	K120187
2012-8138	11/14/2012 12/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	Joe Braid EdgeOne Medical Inc	K082703
2012-8139	11/14/2012 12/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	Joe Braid EdgeOne Medical Inc	K103641
2012-8140	11/14/2012 12/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	Joe Braid EdgeOne Medical Inc	K103641
2012-8141	11/14/2012 12/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	UC-Care	K122329
2012-8142	11/14/2012 12/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	UC-Care	K081093
2012-8143	11/14/2012 12/12/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dr. Merridee Wouters Deakin University	APPROVED DRUGS - LISTING
2012-8144	11/14/2012 12/12/2012	OC/ORAO/OE/ OC/ORAO/OE/	Oliver Yu Zymergi LLC	INSPECTION SPREADSHEET - UPDATE 03/30/2012 - 11/06/2012
2012-8145	11/14/2012 12/12/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/OA/OM/OMP/DDM/	Stephen Teti Scott+Scott, LLP	VIROPHARMA - CORR RE CITIZENS PETITIONS
2012-8146	11/14/2012 12/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	Angelia Slayton INC RESEARCH CONSULTING &	K950034

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			SUBMISSIONS	
2012-8147	11/14/2012 12/12/2012	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	PATRICIA MURPHY - 483, EIR, CORR
2012-8148	11/14/2012 12/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	K880047
2012-8149	11/14/2012 12/12/2012	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	DARIN S WIEGERS - EIR, 483, CORR
2012-8150	11/14/2012 12/12/2012	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Veronica Vogt Vogt, Veronica	ENBREL - COMPLAINTS, AERS, WARNINGS ETC
2012-8151	11/14/2012 12/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	Elisa D. Harvey, DVM, PhD CardioMed Device Consultants, LLC	K121083
2012-8152	11/14/2012 12/12/2012	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Paula A. Berezansky Diamond Pharmacy Services	SHAMROCK MEDICAL SOLUTIONS GROUP LLC - INSPECTIONS, VIOLATIONS, WARNING LETTER RECS, ETC
2012-8153	11/14/2012 12/12/2012	OC/CVM/OCD/	Aeree Lee Stason Pharmaceuticals, Inc.	ZHEJIANG JINHUA CONBA BIOPHARM CO - EIR (03/15/2010 - 03/19/2010)
2012-8154	11/14/2012 12/12/2012	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	ABBOTT LIQUID PROTEIN FORTIFIER - PREMARKET NOTIFICATIONS, CORR
2012-8155	11/14/2012 12/12/2012	FDA/OO/OFBA/OAGS/	Linda Ulrich - FDA Linda.Ulrich@fda.hhs.gov CHILDREN'S NATIONAL MEDICAL CENTER	PEDIATRIC DEVICE CONSORTIA GRANT - SUCCESSFUL GRANT APPLICATIONS RFA-FD-11-002
2012-8156	11/14/2012 12/12/2012	OC/CVM/OCD/ OC/ORO/ OC/ORO/ OC/ORO/OCI/ OC/ORO/OCI/ OC/ORO/OE/ OC/ORO/OE/	ALEX R LUMAGHI DOWD & DOWD PC	SCOTTS CO LLC - MIRACLE GRO MORNING SONG WILD BIRD SEED USE OF STORCIDE II AND ACTELIC 2E RECS
2012-8157	11/14/2012	FDA/OC/OES/DFOI/		OPERATION TRIPLE THREAT - POLICY RECS; INDIVIDUAL

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	12/12/2012		KASP 44179-424, GEORGE	RECS
2012-8158	11/14/2012 12/12/2012	FDA/OC/OES/	JENNIFER HSIEH HEALTHCARE RESEARCH CONSULTING GROUP	GILEAD SCIENCES MTG - ISSUES OF MUTIAL INTEREST EMAILS 8/6/12
2012-8159	11/14/2012 12/12/2012	OC/ORO/ORM/ OC/ORO/ORM/	GAIL LESSICK LACHMAN CONSULTANT SERVICES INC	DRUG COMPANIES, MEDICAL DVC MFRS, BIORESEARCH MONITORING (BIMO), ETC - DOMESTIC AND FOREIGN INSPS, 483S 9/1-30/12
2012-8160	11/14/2012 12/12/2012	FDA/OFVM/CFSAN/OCD/EOS/	MARILYNN WHITNEY COVINGTON BURLING LLP	RED BULL - CAERS 2004 TO 11/12/12
2012-8161	11/14/2012 12/12/2012	FDA/OFVM/CFSAN/OCD/EOS/	MARILYNN WHITNEY COVINGTON BURLING LLP	FIVE HOUR ENERGY - CAERS 2004 TO 11/12/12
2012-8162	11/14/2012 12/12/2012	FDA/OFVM/CFSAN/OCD/EOS/	MARILYNN WHITNEY COVINGTON BURLING LLP	ROCKSTAR - CAERS 2004 TO 11/12/12
2012-8163	11/14/2012 12/12/2012	FDA/OFVM/CFSAN/OCD/EOS/	MARILYNN WHITNEY COVINGTON BURLING LLP	NOS - CAERS 2004 TO 11/12/12
2012-8164	11/14/2012 12/12/2012	FDA/OFVM/CFSAN/OCD/EOS/	MARILYNN WHITNEY COVINGTON BURLING LLP	AMP - CAERS 2004 TO 11/12/12
2012-8165	11/14/2012 12/12/2012	FDA/OFVM/CFSAN/OCD/EOS/	MARILYNN WHITNEY COVINGTON BURLING LLP	REDLINE - CAERS 2004 TO 11/12/12
2012-8166	11/14/2012 12/12/2012	FDA/OFVM/CFSAN/OCD/EOS/	MARILYNN WHITNEY COVINGTON BURLING LLP	FULL THROTTLE - CAERS 2004 TO 11/12/12
2012-8167	11/14/2012 12/12/2012	FDA/OFVM/CFSAN/OCD/EOS/	OSTERHOLM, MICHAEL T	LEAFY GREEN PRODS - LISTERIA MONOSYTOGENES INVESTIGATION RECS
2012-8168	11/14/2012 12/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	Samantha K. Sledd Hall & Sethi, PLC	K042800
2012-8169	11/15/2012 12/13/2012	FDA/OC/OES/DFOI/	LaVeeta Moten	INDIVIDUAL RECS
2012-8170	11/15/2012 04/12/2013	FDA/OFVM/CFSAN/OCD/EOS/	LaVeeta Moten	OVERTIME AND COMPENSATORY TIME PAID TO OFFICE OF MANAGEMENT SYSTEMS (10/01/2009 - 11/08/2012)
2012-8171	11/15/2012 12/13/2012	FDA/OGROP/ORO/SW-FO/KAN- DO/KAN-CB/	Doe J	PINES INTERNATIONAL, INC, LAWRENCE, KS - 483, DETERMINATIONS, ETC
2012-8172	11/15/2012 12/13/2012	OC/OA/OM/OMP/DDM/	Doe J	INDIVIDUAL RECS
2012-8173	11/15/2012	OC/CVM/OCD/	Pamela Boner	NADA 135468

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	12/13/2012		PFIZER ANIMAL HEALTH	
2012-8174	11/15/2012 12/13/2012	OC/CVM/OCD/	Pamela Boner PFIZER ANIMAL HEALTH	NADA 9467
2012-8175	11/15/2012 01/29/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Mary Lynn The Windward Company	HMS VETERINARY DEVELOPMENT, TULARE, CA - EIR (02/12 - 05/12)
2012-8176	11/15/2012 12/13/2012	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Eden M Venti Incyte Corporation	INCYTE, WILMINGTON, DE - EIR (08/15/2011 - 08/19/2011)
2012-8177	11/15/2012 12/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	Austin McElroy Austin McElroy	K101239
2012-8178	11/15/2012 12/13/2012	OC/OA/OM/OMP/DDM/	Corinne Cohen Abiomed, Inc.	CIRCULATORY SYSTEMS DEVICES PANEL - TRANSCRIPTS 08/21/95
2012-8179	11/15/2012 12/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Emily Zeitler Emily Zeitler	DATA SUBMITTED TO FDA FROM MANUFACTURERS IN SUPPORT OF ANDAS FOR GENERIC CLOPIDOGREL
2012-8180	11/15/2012 12/13/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Yuwei Zhu VANDERBILT UNIVERSITY	INFLUENZA VIRUS VACCINE, TRIVALENT, TYPES A AND B INITIAL LOT RELEASE DATES 2006-2012
2012-8181	11/15/2012 12/13/2012	FDA/OFVM/CFSAN/OCD/EOS/	Cristy Jones jones, cristy j	BARE ESSENTIALS, BARE MINERALS, SEPHORA - CAERS
2012-8182	11/15/2012 12/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tina Babos IPD ANALYTICS LLC	ANDA 077742 - TENTATIVE APPROVAL LETTER 11/02/2012
2012-8183	11/15/2012 12/13/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	FOIA DAILY LOG 07/16-20/2012
2012-8184	11/15/2012 12/13/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Austin McElroy Austin McElroy	K081808
2012-8185	11/15/2012 01/16/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	none	NOVARTIS VACCINE, EMERYVILLE, CA - EIR, 483, WARNING LETTER, ETC
2012-8186	11/15/2012 12/13/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	LAKWOOD LLC, LAKWOOD, NJ - EIR, RESP LTR, CORR 2/12 TO 3/12

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2012-8187	11/15/2012 12/13/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	LAKEWOOD LLC, LAKEWOOD, NJ - 483, RESP LTR, CORR 2/12 TO 3/12
2012-8188	11/15/2012 12/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	FERCY PERSONAL CARE PRODUCTS, ZHEJIANG, CHINA - EIR, RESP LTR, CORR 3/12
2012-8189	11/15/2012 12/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	FERCY PERSONAL CARE PRODUCTS, ZHEJIANG, CHINA - 483S, RESP LTR, CORR 3/12
2012-8190	11/15/2012 12/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	PRINCE MEDICAL, ERCUIS, FRANCE - EIR, RESP LTR, CORR 3/12
2012-8191	11/15/2012 12/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	PRINCE MEDICAL, ERCUIS, FRANCE - 483, RESP LTR, CORR 3/12
2012-8192	11/15/2012 02/07/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	SUSAN B MILLS WEINBERG WHEELER ET AL	WEGMANS FOOD MARKETS INC, MONROE, NIAGARA, STEUBEN COUNTIES, NY, ETC - ORGANIC SPINACH & SPRING MIX BLEND E COLI OUTBREAK
2012-8193	11/15/2012 12/13/2012	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	MIR-COM PRODUCTS, CENTRAL CITY, PA - EIR, RESP LTR, CORR 6/12
2012-8194	11/15/2012 12/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	HEMOPARM A D, VRSAC, SERBIA - EIR, RESP LTR, CORR 11/11
2012-8195	11/15/2012 12/13/2012	OC/ORAE/ OC/ORAE/ FDA/OFVM/CFSAN/OCD/EOS/	CLAIRE KALTENBACH CHILDRESS AHLHEIM CARY LLC	MULTISTATE ROMAINE LETTUC E COLI OUTBREAK - INVESTIGATION RECS 2011
2012-8196	11/15/2012 12/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHERI BATTERSHELL WASHINGTON INFORMATION SOURCE	HEMOPARM AD, VRSAC, SERBIA - 483, RESP LTR, CORR 11/11

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2012-8197	11/15/2012 12/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/CVM/OCD/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	ZHONGNUO PHARMS, SHIJIAZHUANG, CHINA - EIR, RESP LTR, CORR 2011 TO 2012
2012-8198	11/15/2012 12/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PAMELA SHEPPARD TARO PHARMACEUTICALS USA INC	GENENTECH - ERIVEDGE (VISMODEGIB) NDA 203-388 SBA, RVWS, LBLG, ETC
2012-8199	11/15/2012 12/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHERI BATTERSHELL WASHINGTON INFORMATION SOURCE	ZHONGNUO PHARMACEUTICALS, SHIJIAZHUANG, CHINA - 483, RESP LTR, CORR 2012
2012-8200	11/15/2012 12/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	ERCROS SA, MADRID, SPAIN - EIR, RESP LTR, CORR 7/11
2012-8201	11/15/2012 12/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	ERCROS SA, MADRID, SPAIN - 483, RESP LTR, CORR 7/11
2012-8202	11/15/2012 12/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PAMELA SHEPPARD TARO PHARMACEUTICALS USA INC	ASTRAZENECA LP - BRILINTA (TICAGRELOR) NDA 22-433 SBA, RVWS, LBLG, ETC
2012-8203	11/15/2012 12/13/2012	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	SIEMENS HEALTHCARE DIAGNOSTICS, NEWARK, DE - 483, RESP LTR, CORR 12/11
2012-8204	11/15/2012 12/13/2012	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	SIEMENS HEALTHCARE DIAGNOSTICS, NEWARK, DE - EIR, RESP LTR, CORR 12/11
2012-8205	11/15/2012 12/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHRISTINE FORGUES MORGAN LEWIS & BOCKIUS LLP	VANCOMYCIN HCL CAPS - APRVL LTR 12/21/11

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2012-8206	11/15/2012 12/13/2012	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	NEUROTHERM INC, WILMINGTON, MA - EIR, RESP LTR, CORR 4/12
2012-8207	11/15/2012 12/13/2012	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	NEUROTHERM INC, WILMINGTON, MA - 483, RESP LTR, CORR 4/12
2012-8208	11/15/2012 12/13/2012	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	CENTER FOR THE IMPROVEMENT OF HUMAN FUCTIONING INTERNATIONAL, NEW YORK, NY - EIR, RESP LTR, CORR 7/11
2012-8209	11/15/2012 12/13/2012	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	CENTER FOR THE IMPROVEMENT OF HUMAN FUNCTIONING INTERNATIONAL, NEW YORK, NY - 483, RESP LTR, CORR 7/11
2012-8210	11/15/2012 12/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHERRIBATTERSHELL WASHINGTON INFORMATION SOURCE	A NELSON & CO LTD, LONDON, UK - EIR, RESP LTR, CORR 11/11
2012-8211	11/15/2012 12/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	A NELSON & CO LTD, LONDON, UK - 483, RESP LTR, CORR 11/11
2012-8212	11/15/2012 12/13/2012	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	INNOVACYN INC, RIALTO, CA - EIR, RESP LTR, CORR 11/11 TO 12/11

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2012-8213	11/15/2012 12/13/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	EILEEN DANNEMANN NATIONAL COALITION OF ORGANIZED WOMEN	MONOVALENT H1N1 INFLUENZA VAERS
2012-8214	11/15/2012 12/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	VIK BAJNATH ARTHREX INC	MW#5027281
2012-8215	11/15/2012 12/13/2012	FDA/OGROP/ORACE-FO/PHI- DO/PHI-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	MIR-COM PRODUCTS, CENTRAL CITY, PA - 483, RESP LTRS, CORR 6/12
2012-8216	11/15/2012 12/13/2012	FDA/OGROP/ORASE-FO/ATL- DO/ATL-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	BIOMERIEUX, DURHAM, NC - EIR, RESP LTRS, CORR 1/12 TO 3/12
2012-8217	11/15/2012 12/13/2012	OC/OM/OFM/	John Crewdson PROJECT ON GOVERNMENT OVERSIGHT	LIST OF PAYMENTS TO FDA PURSUANT TO PRESCRIPTION DRUG USERS FEE ACT
2012-8218	11/15/2012 12/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michele Sinoway LACHMAN CONSULTANT SERVICES, INC.	RESOLUTION CHEMICALS, STEVENAGE, UK - EIR 01/11
2012-8219	11/15/2012 12/13/2012	FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jeffrey Green / Alex Nussbaum at Healthcor HEALTHCOR MANAGEMENT LP	MAP PHARMACEUTICALS - COMPLETE RESPONSE LETTER RE LEVADEX, CORR, 483
2012-8220	11/15/2012 12/13/2012	FDA/OGROP/ORACE-FO/PHI- DO/PHI-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Theresa Appelbaum Padberg, Corrigan & Appelbaum	MEDRAD AVANTA FLUID MANAGEMENT INJECTION SYSTEM - INVESTIGATIONS, WARNING LETTERS, RECALLS, ETC
2012-8221	11/15/2012 12/13/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	BLA125276, NDA22383, NDA22433, ETC - RISK EVALUATION AND MITIGATION STRATEGY ASSESSMENTS
2012-8222	11/15/2012 12/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ISR 7361599, 7364893 - DIRECT REPORTS, MEDWATCH REPORTS, SOURCE DOCUMENTS

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2012-8223	11/15/2012 12/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ISR 7287296, 8227773, 8337499, 8374156 - DIRECT REPORTS, MEDWATCH REPORTS, SOURCE DOCUMENTS
2012-8224	11/15/2012 12/13/2012	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	BIOMERIEUX, DURHAM, NC - 483, RESP LTRS, CORR 1/12 TO 3/12
2012-8225	11/15/2012 12/13/2012	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	CELLTEX THERAPEUTICS CORP, SUGARLAND, TX - EIR, RESP LTRS, CORR 4/12
2012-8226	11/15/2012 12/13/2012	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	CELLTEX THERAPEUTICS CORP, SUGARLAND, TX - 483, RESP LTRS, CORR 4/12
2012-8227	11/15/2012 12/13/2012	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	INNOVACYN INC, RIALTO, CA - 483 11/11 TO 12/11
2012-8228	11/15/2012 12/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	LEISEGANG FEINMECHANIK-OPTIK, BERLIN, GERMANY - EIR 4/12
2012-8229	11/15/2012 12/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	LEISEGANG FEINMECHANIK OPTIK, BERLIN, GERMANY - 483 4/12
2012-8230	11/15/2012 12/13/2012	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	SPINEFRONTIER INC, BEVERLY, MA - EIR 5/12 TO 7/12
2012-8231	11/15/2012 12/13/2012	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	SPINEFRONTIER INC, BEVERLEY, MA - 5/12 TO 7/12
2012-8232	11/15/2012	FDA/OMPT/CBER/OCOD/DDOM/	SHERRI BATTERSHELL	SANOFI PASTEUR. MARCY L'ETOILE, FRANCE - EIR 3/12 TO

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	12/14/2012		TekTeam LLC.	
2012-8242	11/16/2012 12/14/2012	OC/OSMP/OOPD/ FDA/OMPT/OSMP/OOPD/	Holmes, Warren	ECULIZUMAB FOR THE TREATMENT OF IDIOPATHIC MEMBRANOUS GLOMERULAR NEPHROPATHY - ORPHAN DRUG DESIGNATION
2012-8243	11/16/2012 12/14/2012	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	CTP RECS COLLECTED FROM STATE HEALTH DEPARTMENTS ON ADVERSE EVENTS RE E-CIGARETTES
2012-8244	11/16/2012 12/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Marta Arcabell Laboratorios Lesvi, S.L.	INTERNATIONAL PHARMECEUTICAL RESEARCH CENTER, AMMAN, JORDAN - LAST TWO 483S
2012-8245	11/16/2012 12/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Matt Prokopczyk Dr. Reddys Laboratories Inc	SIMVASTATIN TABLETS USP - HEALTH HAZARD EVALUATION
2012-8246	11/16/2012 12/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	Sheetal Pandya TekTeam LLC.	K001284
2012-8247	11/16/2012 12/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DDD Ltd	VIPOR CHEMICALS LTD, INDIA - 483 (12/01/2006 - 12/31/2006)
2012-8248	11/16/2012 12/20/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OO/OIM/OPILS/FDAHO/	Henry Gluckstern HENRY GLUCKSTERN	ORAL POLIO VACCINE - TEST RESULTS (01/01/1960 - 12/31/1999)
2012-8249	11/16/2012 12/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CORRENS, DOERTE	SEPARATE RPTS OF ADVERSE SIDE EFFECTS 2000 TO PRESENT
2012-8250	11/16/2012 12/14/2012	FDA/OGROP/ORAP/PA-FO/SEA- DO/SEA-CB/	JAMES A LOCHRIDGE PREIS & ROY	KIRKMAN GROUP INC, KIRKMAN LABS - STEVIA SWEVIA, LIQUID ZINC LAB ANALYSIS 1/10
2012-8251	11/16/2012 12/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	PETER T ANDERSON ESQ ASHCRAFT & GEREL LLP	K030497
2012-8252	11/16/2012 12/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SHAPIRO, JOEL	DR BURZYNSKI, BURZYNSKI RESEARCH INSTITUTE (BRI) - NOTIFICATION LTR

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		FDA/OMPT/CDER/GRP/DIDP/		
2012-8253	11/16/2012 12/14/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KATHLEEN KOONS DJA GLOBAL PHARMACEUTICALS INC	SUBOXONE FILM NDA 22-410 - SBA
2012-8254	11/16/2012 12/14/2012	FDA/OC/OES/DFOI/	ELENA HOWELL HOGAN LOVELLS US LLP	2012-7560
2012-8255	11/16/2012 12/14/2012	FDA/OC/OES/DFOI/	DARREN BROWN PROVOST UMPHREY LAW FIRM	DR ERIC WILHELMSSEN, WILHELMSSEN CONSULTING - INGREDIENT DECLARATION FOR VARIOUS SWEETNERS FDA GUIDANCE LTR 5/8/2000
2012-8256	11/16/2012 12/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	M MELISSA BALTZ BUTLER SNOW ET AL	DR MED KURT LOBODASCH SURGICAL MESH LTR 8/3/12 (CERTIFIED)
2012-8257	11/16/2012 12/14/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PATRICK A DAWSON COOPER FIRM	EPIPEN EPINEPHRINE INJECTOR PEN - LBLG, EXPIRATION DATE
2012-8258	11/16/2012 12/14/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ERIN E SEDER VENABLE LLP	INTERNEURON PHARMACEUTICALS INC - IND APPLS 1990 TO 2000
2012-8259	11/16/2012 12/14/2012	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	DIANA R MARTINI VITAL THERAPIES	DR RAJULI PATEL, MARICOPA INTEGRATED HEALTH SYSTEM - 483 8/13/03
2012-8260	11/16/2012 12/14/2012	FDA/OC/OES/DFOI/ FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	Tony Collins-Kwong ALLINA HEALTH SYSTEM	PHARMEDIUM - 483S (01/01/2007 - 11/14/2012)
2012-8261	11/16/2012 12/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	CAITLIN CAREY MINER HARE WYNN NEWELL & NEWTON LLP	AMERICAN MEDICAL SYSTEMS INC - SURGICAL MESH RPTS
2012-8262	11/16/2012 12/14/2012	FDA/OFVM/CFSSAN/OCD/EOS/	JORDAN #B24482, VALDEZ	SOYA, SOYBEAN - CAERS, STUDIES, MEMOS, ETC
2012-8263	11/16/2012 03/11/2013	FDA/OGROP/ORA/CE-FO/CHI- DO/CHI-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	LARRY R ROGERS POWER ROGERS & SMITH PC	CYBERONICS MODEL 102 23437, MODEL 103 SN 19766 - INVESTIGATION, STUDIES, TEST MATERIALS, ETC

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2012-8264	11/16/2012 12/14/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 10/29/12-11/2/12
2012-8265	11/16/2012 12/14/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 10/22-26/12
2012-8266	11/16/2012 12/14/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OES/DFOI/	JOHN LYONS John Lyons	5-HOUR ENERGY, MONSTER ENERGY, VITAMIN WATER, ETC - AERS (11/01/2007 - 11/15/2012)
2012-8267	11/16/2012 12/14/2012	OC/OA/OM/OMP/DDM/	Desmond Jenson Tobacco Control Legal Consortium	FDA-2010-N-0568 - COMMENTS NOT AVAILABLE ON REGULATIONS.GOV
2012-8268	11/16/2012 12/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	Joy Frestedt FRESTEDT INCORPORATED	K112342
2012-8269	11/16/2012 12/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	elizabeth matovinovic matovinovic, elizabeth	ADVATE - AERS 07/15/03 TO PRESENT
2012-8270	11/16/2012 12/14/2012	FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	ROBERT MOSIER HODES MILMAN LIEBECK MOSIER, LLP	GRANUFLO AND NATURALYTE DRY ACID CONCENTRATE - RECALL RECS
2012-8271	11/16/2012 12/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	Reed Kathrein HAGENS BERMAN SOBOL SHAPIRO LLP	ABIOMED - CORR RE 02/24/12 MTG
2012-8272	11/16/2012 12/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	Reed Kathrein HAGENS BERMAN SOBOL SHAPIRO LLP	ABIOMED - FOLLOW UP TO WARNING LETTER (04/12)
2012-8273	11/16/2012 12/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	Reed Kathrein HAGENS BERMAN SOBOL SHAPIRO LLP	ABIOMED - ALL CORR RE IMPELLA CLAIMS, PROMOTIONS, MARKETING, ETC (01/12/2009 - 11/15/2012)
2012-8274	11/16/2012 12/14/2012	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	CTP REPORT RE MENTHOL CIGARETTES
2012-8275	11/16/2012	FDA/OC/OES/DFOI/	Reed Kathrein	ABIOMED - RECS RELEASED UNDER FOIA IN 2012

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	12/14/2012		HAGENS BERMAN SOBOL SHAPIRO LLP	
2012-8276	11/19/2012 12/17/2012	FDA/OFVM/CFSAN/OCD/EOS/	Peter Hsu Peter Hsu	CAERS REPORTS 139012, 139013
2012-8277	11/19/2012 12/17/2012	FDA/OFVM/CFSAN/OCD/EOS/	Scott, Michael	FCN 899, FCN 915 - SAFETY EVALUATION
2012-8278	11/19/2012 12/17/2012	OC/ORO/ OC/ORO/	Tom Burton WALL STREET JOURNAL	AMERIDOSE LLC, NEW ENGLANG COMPOUNDING CENTER - ORA RECS (01/03/2005 - 10/01/2012)
2012-8279	11/19/2012 12/17/2012	FDA/OC/OES/DFOI/	MADHU SONI SONI & ASSOCIATES INC	MONSTER ENERGY DRINKS - CAERS 1/12 TO PRESENT
2012-8280	11/19/2012 12/17/2012	FDA/OC/OES/DFOI/	RACHEL A AVAN LABATON SUCHAROW	MONSTER BEVERAGE CORP HANSEN NATURAL CORP) - ENERGY DRINKS CAERS
2012-8281	11/19/2012 12/17/2012	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	TOTAL NUMBER OF ORDERS OF SUBSTANTIAL EQUIVALENCE ISSUED UNDER FAMILY SMOKING PREVENTION AND TOBACCO ACT 09/01/12 TO 10/31/12
2012-8282	11/19/2012 12/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	ALELXANDER FILATOV PARASCRIPT LLC	ICAD - SECONDLOOK CAD SYS P010038/S013 USER MANUAL LBLG, SS&E
2012-8283	11/19/2012 12/17/2012	FDA/OFVM/CFSAN/OCD/EOS/	Michelle Minton The Competitive Enterprise Institute	CAERS - ALL FOOD AND DRINK PRODUCTS LAST FIVE YEARS
2012-8284	11/19/2012 12/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jake Nachmani, Esq. MORELLI RATNER PC	RISPERDAL - OFF-LABEL MARKETING RECS
2012-8285	11/19/2012 12/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	ALEXANDER FILATOV PARASCRIPT LLC	VUCOMP- MULTIPLE DIGITAL MAMMOGRAPHY SYS P100005/S001 MANUAL, LBLG, SS&E
2012-8286	11/19/2012 12/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kevin Koerner Ineos Barex	DMF 2343
2012-8287	11/19/2012 12/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Seongsoo Park DAEWOONG AMERICA INC	NDA019594 - MEDICAL RVW, CLINICAL TRIALS
2012-8288	11/19/2012	FDA/OMPT/CDER/ORP/DIDP/	Kristan Phillips	DR YUNG-JUE BANK, SEOUL NATIONAL UNIVERISTY

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	12/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MacroGenics	HOSPITAL, SEOUL, KOREA - EIR, 483 05/27/2011
2012-8289	11/19/2012 12/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	SBA 201739
2012-8290	11/19/2012 12/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	SBA 090358
2012-8291	11/19/2012 12/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	K110753
2012-8292	11/19/2012 12/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	K101612
2012-8293	11/19/2012 12/17/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Hannah Cheng MASSACHUSETTS INSTITUTE OF TECHNOLOGY	PIG WHIPWORMS - SUBMISSIONS PRIOR TO 2011
2012-8294	11/19/2012 12/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mark Wavrek Mark Wavrek	ACCUTANE - AERS
2012-8295	11/19/2012 12/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michelle Nuez / David Appleby, Esq. Hickey Law Firm	INDIVIDUAL RECS
2012-8296	11/19/2012 12/17/2012	FDA/OGROP/ORR/NE-FO/NYK- DO/NYK-DCB/	Debra Sweitzer Kythera Biopharmaceuticals, Inc	AMRI, RENSSELAER, NY - EIR (01/01/2006 - 11/16/2012)
2012-8297	11/19/2012 12/17/2012	OC/CVM/OCD/	Rachel Johnson FOI Services, Inc.	NADA 97222, NADA 108114 - SUPPLEMENTS
2012-8298	11/19/2012 12/17/2012	OC/CVM/OCD/	Algal Scientific Corporation	GRAS APPLICATIONS FOR YEAST OR MUSHROOM- DERIVED BETA GLUCAN PRODUCTS FOR USE AS ANIMAL FEED

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2012-8299	11/19/2012 12/17/2012	FDA/OGROP/ORPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Myron Levin FAIRWARNING	REVECOMED INTERNATIONAL, FULLERTON, CA; ADVANCED AESTHETIC CONCEPTS, FORT WORTH, TX - EIR, 483, WARNING LETTER (07/01/2012 - 11/16/2012)
2012-8300	11/19/2012 12/17/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	SBA 203214
2012-8301	11/19/2012 12/17/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	BLA 125276 S049
2012-8302	11/19/2012 12/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	RICHARD KELLER BRUNO INDEPENDANT LIVING AIDS	AMERIGLIDE, HANDICARE ACCESIBILITY, MAC LIFTGATE INC, ETC - WHEELCHAIR ELEVATORS MARKETED IN THE US NOT COMPLYING WITH FOOD DRUG & COSMETIC ACT & 21 CFR PART 800 TRADE CMLPNT INTERNAL OR EXTERNAL RECS, CORR, MAIL, ETC
2012-8303	11/19/2012 12/17/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	THOMAS CLUDERAY ENVIRONMENTAL WORKING GROUP	SUNSCREENS - CMLPNTS, AERS, CORR 1/08 TO PRESENT
2012-8304	11/19/2012 12/17/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHARLES F JOHNS STEPTOE & JOHNSON	HYDROCODONE - FAERS RPTS, CMLPNTS, QUESTIONAIRES, ETC
2012-8305	11/19/2012 12/17/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PATRICIA BOGERT BOGERT, PATRICIA	TRELSTAR - TRIPTORELINE AERS
2012-8306	11/19/2012 12/17/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KATE PURCELL DOCUTRIEVAL INFORMATION SERVICES	AUVI-Q NDA 201-739 - SBA

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2012-8307	11/19/2012 12/17/2012	FDA/OGROP/ORR/SE-FO/NOL-DO/NOL-CB/	KYLE SMITH NEEDLE SPECIALTY PRODUCTS CORP	NEEDLE SPECIALTY PRODUCTS CORP, BOYLE, MS - EIR 07/07/09
2012-8308	11/19/2012 12/17/2012	OC/ORR/ORM/ OC/ORR/ORM/	KIM C CAPONE PORZIO LIFE SCIENCES	LIST OF ALL INSP PURSUANT TO THE PRESCRIPTION DRUG MARKETING ACT (PDMA) 1/07 TO PRESENT
2012-8309	11/20/2012 12/18/2012	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	WAYNE GAJADHAR TROPICAL MARINE LTD	ENTRY NO AMG-0093132-3 LAB RPTS
2012-8310	11/20/2012 12/18/2012	FDA/OFVM/CFSAN/OCD/EOS/	WILLIAM A. OLSON, Ph.D. WASHINGTON INFORMATION SOURCE	NYLON MXD-6 RESINS (CAS REGISTRY NO 25718-70-1) PETITIONS
2012-8311	11/20/2012 12/19/2012	OC/ORR/ OC/ORR/ FDA/OGROP/ORR/CE-FO/DET-DO/DET-CB/	CLAUDIA HORNBACK ROANOKE TRADE SERVICES INC	GOLDEN STAR WHOLESALE INC - ENTRY NO G1710147845 REFUSAL, REDELIVERY
2012-8312	11/20/2012 12/18/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRIAN BELL BOSTON SCIENTIFIC CORP	TABLE OF MDRS AND PATIENT PROBLEM CODES 2006 TO PRESENT
2012-8313	11/20/2012 12/18/2012	FDA/OMPT/CDRH/OCER/DFOI/	HIROHIKO MURASE NSK AMERICA CORP	NSK AMERICA CORP, HOFFMAN ESTATES, IL - K052700
2012-8314	11/20/2012 12/18/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/	PABLO PERHACS JD, PhD SEARCY DENNEY ET AL	TEVA PHARMACEUTICALS - PROPOFOL INJECTABLE EMULSION TESTING & ANALYSIS 2005 TO 2009
2012-8315	11/20/2012 12/18/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PABLO PERHACS, JD Ph.D SEARCY DENNEY ET AL	TEVA PHARMACEUTICALS - PROPOFOL INJECTABLE EMULSION ANDA
2012-8316	11/20/2012 12/18/2012	FDA/OGROP/ORR/CE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PABLO PERHACS JD, Ph.D. SEARCY DENNEY ET AL	TEVA PHARMACEUTICALS - PROPOFOL INJECTABLE EMULSION EIR, 483, CO RESP, CORR 1/05 TO PRESENT

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		FDA/OMPT/CDER/GRP/DIDP/		
2012-8317	11/20/2012 12/18/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DISSELKAMP, ROBERT S	LAMICTAL - AERS 2007 TO PRESENT
2012-8318	11/20/2012 12/18/2012	FDA/OFVM/CFSAN/OCD/EOS/	JOHN DOHERTY IOVATE HEALTH SCIENCES INTERNATIONAL INC	FORTHANE, HEMORUSH, FASTIN, ETC - AERS
2012-8319	11/20/2012 12/18/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	BLA 125057 S0232
2012-8320	11/21/2012 12/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	ALEXANDER FILATOV PARASCRIPT LLC	ICAD - SECONDLOOK CAD SYS P010038/S013 USER MANUAL, LBLG, SS&E
2012-8321	11/21/2012 12/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	ALEXANDER FILATOV PARASCRIPT LLC	VUCOMP - MULTIPLE DIGITAL MAMMOGRAPHY SYS P100005/S001 USER MANUAL, LBLG, SS&E
2012-8322	11/21/2012 12/19/2012	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	DONALD N BLUE ZETETIC	CHOCOLATES - ENTRY SMLU3185964A PHOTOGRAGHS, OASIS SCREEN SHOTS, CBP FORM 3461
2012-8323	11/21/2012 12/19/2012	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	DONALD N BLUE ZETETIC	ENTRY D82-21238636 - PHOTOGRAPHS, OASIS SCREEN SHOTS, CBP FORM 3461
2012-8324	11/21/2012 12/19/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	THEO EMISON EMISON HULLVERSON LLP	DR MICHAEL DAKE, STANFORD UNIVERSITY - CHRONIC CEREBROSPINAL VENOUS INSUFFICIENCY IN THE USA COMM, INVESTIGATIONS, RPTS, ETC
2012-8325	11/21/2012 12/19/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	VICINO, WILLIAM	TOPOTECAN - AERS
2012-8326	11/21/2012 12/19/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	COX, JAMES E	DOMPERIDONE - AERS

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		FDA/OMPT/CDER/ORP/DIDP/		
2012-8327	11/21/2012 12/19/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	CHARLES SEIFE NEW YORK UNIV ARTS & SCIENCE	FABRICATED REC IN CLNCL TRIALS MUNNI SELAGAMSETTY 2/2/10, GHANDI SAADEH 12/08/08, HOWARD, MARKER 4/28/08, ETC - EIRS, 483S
2012-8328	11/21/2012 12/19/2012	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	KYLE SMITH NEEDLE SPECIALTY PRODUCTS CORP	NEEDLE SPECILTY PRODUCTS CORP, BOYLE, MS - EIR 7/07/09
2012-8329	11/21/2012 12/19/2012	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	ONA SCANDURRA COUNTRY LIFE LLC	RESP TO 483 1/10/12
2012-8330	11/21/2012 12/19/2012	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	ANTONIO MERCANTE DELIZIA FOODS INC	CHOCOLATE HAZELNUT SPREAD - RESULTS
2012-8331	11/21/2012 12/19/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/OIP/	GARDINER HARRIS NEW YORK TIMES	SPICE FARMS, INDIA - PROFILE RECS, NOTES, SUMMARIES, WARNING LTRS, ETC
2012-8332	11/21/2012 12/19/2012	FDA/OFVM/CFSAN/OCD/EOS/	KRISTI O SMEDLEY WASHINGTON INFORMATION SOURCE	MONSANTO - ETHOXYQUIN FAP 00001
2012-8333	11/21/2012 12/19/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	JOHN CREWDSON PROJECT ON GOVERNMENT OVERSIGHT	ZOSTAVAX - VAERS
2012-8334	11/21/2012 12/19/2012	FDA/OFVM/CFSAN/OCD/EOS/	Merle Zimmermann AMERICAN HERBAL PRODUCTS	NESTLE USA, KRAFT FOODS, JM SMUCKERS - CAERS (11/01/2010 - 10/31/2012)

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			ASSOCIATION	
2012-8335	11/21/2012 12/19/2012	FDA/OFVM/CFSAN/OCD/EOS/	Merle Zimmermann AMERICAN HERBAL PRODUCTS ASSOCIATION	COCA COLA COMPANY, PEPSICO - CAERS (11/01/2011 - 10/31/2012)
2012-8336	11/21/2012 12/19/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	Patrick Moriarty HEALTHCOR MANAGEMENT LP	RELISTOR - AERS; FOIA REQUESTS
2012-8337	11/21/2012 12/19/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gary J. McGarity Gary J. McGarity, PharmD	LUNESTA - AERS
2012-8338	11/21/2012 12/19/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Christine Ringler Esdaile, Barrett, Jacobs & Mone	INDIVIDUAL RECS
2012-8339	11/21/2012 12/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	Valerie Franck STRYKER INSTRUMENTS	K081047
2012-8340	11/21/2012 12/19/2012	FDA/OGROP/ORACE-FO/CIN- DO/CIN-CB/	Andrew Han VISIUM FUNDS	INVACARE, ELYRIA, OH - 483 (01/01/2012 - 12/19/2012)
2012-8341	11/21/2012 12/19/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John Lewis ACROMED CORP	SHOW FOR CLINICAL TRIAL PARTICIPANTS - INVESTIGATION RECS
2012-8342	11/21/2012 12/19/2012	FDA/OFVM/CFSAN/OCD/EOS/	Michelle R. Minton The Competitive Enterprise Institute	GORTON'S CRUNCHY BREADED FISH STICKS, GENERAL FOODS POP ROCKS, HERSHEY'S PAYDAY, ETC - CAERS (01/01/10-01/01/12)
2012-8343	11/21/2012 12/19/2012	FDA/OGROP/ORACE-FO/DET- DO/DET-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Ross Brooks Sanford Heisler, LLP	DEPUY ORTHOPAEDICS, INC ASR XL ACETABULAR HIP-REPLACEMENT SYSTEM - COMMUNICATIONS BETWEEN FDA AND DEPUY (10/07 TO 10/11)
2012-8344	11/21/2012 12/19/2012	FDA/OGROP/ORANE-FO/NYK- DO/NYK-DCB/ FDA/OFVM/CFSAN/OCD/EOS/	Mary Clare Jalonick THE ASSOCIATED PRESS	MARTE RICOTTA SALATA FRESCOLINA CHEESE - RECALL RECS, INSPECTIONS
2012-8345	11/21/2012 12/19/2012	FDA/OFVM/CFSAN/OCD/EOS/	John Shoemaker Visium	5 HOUR ENERGY - ADVERTISING INQUIRY
2012-8346	11/21/2012	FDA/OGROP/ORACE-FO/DET-	Tyler Kenyon	STRYKER INSTRUMENTS, PORTAGE, MI - 483 (6/18/2012);

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	12/19/2012	DO/DET-CB/	NORTHCOAST RESEARCH	STRYKER MEDICAL DIVISION OF STRYKER CORPORATION, PORTAGE, MI - 483 (6/26/2012); STRYKER INSTRUMENTS, PORTAGE, MI - 483 (11/09/2012)
2012-8347	11/21/2012 12/19/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Julie Myers Columbia University Medical Center	G.D. SEALE & COMPANY ORAL CONTRACEPTIVE - PACKAGE INSERT (1970)
2012-8348	11/21/2012 12/19/2012	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/ FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORA/OCI/ OC/ORA/OCI/	Doe J	COMPLAINT RECS
2012-8349	11/21/2012 12/19/2012	FDA/OC/OES/DFOI/	Benjamin Lesser Benjamin Lesser	ENERGY DRINKS ADVERSE EVENTS - FOIA REQUESTS (11/01/2011 - 11/20/2012)
2012-8350	11/21/2012 12/19/2012	FDA/OFVM/CFSAN/OCD/EOS/	Merle Zimmermann AMERICAN HERBAL PRODUCTS ASSOCIATION	COFFEE BEVERAGES AND CAFFEINE PRODUCTS - CAERS (11/1/2010 TO 10/31/2012)
2012-8351	11/21/2012 12/19/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mahidhar Chinta MICRO LABS USA INC	EFAVIRENZ, LAMIVUDINE, TENOFOVIR DISOPROXIL FUMARATE- SBA
2012-8352	11/21/2012 12/19/2012	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Tyler Kenyon NORTHCOAST RESEARCH	NORLAND, FORT ATKINSON, WI - 483 (7/30/2012); COOPERSURGICAL, STAFFORD, TX - 483 (8/06/2012)
2012-8353	11/21/2012 12/19/2012	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	Jane M. Hastedt G C HANFORD MFG CO	DOW CORNING HEALTHCARE INDUSTRIAL MATERIALS SITE, HEMLOCK, MI - EIR, 483 (05/01/2012 - 05/31/2012)
2012-8354	11/21/2012 12/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	Stephen Inglese Sleep Group Solutions	K011329, K921452
2012-8355	11/21/2012 12/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	Dari Darabbeigi Persyst Development Corporation	K092625

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2012-8356	11/23/2012 12/21/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Versabond AB Bone Cement Laboratorios SL S.A.	K022688
2012-8357	11/23/2012 12/21/2012	FDA/OFVM/CFSAN/OCD/EOS/	Kevin I. Goldberg Goldberg, Finnegan & Mester, LLC	MONSTER ENERGY DRINKS - FULL ADVERSE EVENT REPORTS (01/01/2004 - 10/23/2012)
2012-8358	11/23/2012 12/21/2012	FDA/OMPT/CDRH/OCER/DFOI/	Versabond AB Bone Cement Laboratorios SL S.A.	K022688
2012-8359	11/23/2012 12/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Amber Mynakha Northeast Regional Medical Center	DAPTOMYCIN - AERS (01/01/2003 - 11/01/2012)
2012-8360	11/23/2012 12/21/2012	OC/ORA/ORM/ OC/ORA/ORM/	David Mangione Govzilla, Inc.	LIST OF 483S ISSUED 08/29/2012 TO 11/21/2012
2012-8361	11/23/2012 12/21/2012	OC/ORA/ OC/ORA/	William Figueroa Southwind Foods LLC DBA Great American S	594-0230269-5 - COLLECTION REPORT, ANALYST WORKSHEET
2012-8362	11/23/2012 12/21/2012	FDA/OMPT/CTP/OD/	Hagens Berman Sobol Shapiro LLP HAGENS BERMAN SOBOL SHAPIRO LLP	TOBACCO PRODUCT MANUFACTURERS, IMPORTERS, AGENTS - REPORTS SUBMITTED 2012
2012-8363	11/23/2012 12/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Adrian Chew Pinsent Masons	FDA INACTIVE INGREDIENT GUIDE (1993)
2012-8364	11/23/2012 12/21/2012	FDA/OMPT/CDRH/OCER/DFOI/	Michael Pan Michael Pan	K122260
2012-8365	11/23/2012 12/21/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	SHELDON T. BRADSHAW HUNTON & WILLIAMS LLP	AVID HEATLH INC; NORTHWEST NATURAL PRODUCTS INC; SUPPLEMENT SCIENCES INC, VANCOUVER, WA - EIR, 483, RECALL 11/20/10 TO PRESENT
2012-8366	11/23/2012 12/21/2012	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Lesley Valle Boehringer Ingelheim	RODOLFO BORDONI, MARRIETTA, GA - 483 (08/28/95)
2012-8367	11/23/2012 12/21/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	DAVID HILZENRATH PROJECT ON GOVERNMENT OVERSIGHT	ZOSTAVAX - ACTION PACKAGE
2012-8368	11/23/2012 12/21/2012	FDA/OMPT/CDRH/OCER/DFOI/	David Dortch QIAGEN SCIENCES	PLEXUS, BAYAN LEPAS, MALAYSIA (01/01/2012 - 11/01/2012) - EIR

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2012-8369	11/23/2012 12/21/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Cubist Pharmaceuticals Cubist Pharmaceuticals	DAPTOMYCIN - RPTS FOR CASES OF EOSINOPHILIC PNEUMONIA (01/01/2004 - 12/31/2010)
2012-8370	11/23/2012 12/21/2012	FDA/OFVM/CFSAN/OCD/EOS/	Joseph Wilson joe wilson	MOUNTAIN DEW - CAERS (01/01/2000 - 11/21/2012)
2012-8371	11/23/2012 12/21/2012	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	William McPhail Woodard & Curran	EVERGREEN ORCHARD FARM, HAMILTON, NJ - EIR ATTACHMENTS (03/22/12)
2012-8372	11/23/2012 12/21/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Amber Mynakha Northeast Regional Medical Center	NOVOLOG, LANTUS - AERS (01/01/2000 - 11/01/2012)
2012-8373	11/23/2012 12/21/2012	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	DOUGLAS N. BLUE, II ZETETIC	BAUSCH & LOMB - 34 BUNDLES CONTAINING OTC ENTRY NO 51620481492
2012-8374	11/23/2012 12/21/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mahidhar Chinta MICRO LABS USA INC	NDA 203076 - SBA
2012-8375	11/23/2012 12/21/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mahidhar Chinta MICRO LABS USA INC	NDA 021971 - SBA
2012-8376	11/23/2012 12/21/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mahidhar Chinta MICRO LABS USA INC	NDA 022461 - SBA
2012-8377	11/23/2012 12/21/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MATHERNE, MICHAEL MARK	CIPRO - AER
2012-8378	11/23/2012 12/21/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	Alec White HEALTHCOR MANAGEMENT LP	STARBUCKS - ADVERSE EVENTS, CONSUMER COMPLAINTS

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2012-8379	11/23/2012 12/21/2012	FDA/OFVM/CFSAN/OCD/EOS/	Alec White HEALTHCOR MANAGEMENT LP	TEAVANA - CONSUMER COMPLAINTS, ADVERSE EVENTS, STUDEIS RE POTENTIAL PESTICIDE CONTAMINATION
2012-8380	11/23/2012 12/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mahidhar Chinta MICRO LABS USA INC	NDA 022459 - SBA
2012-8381	11/23/2012 12/21/2012	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	James Hurley HURLEY, JAMES	VEGETABLE JUICES, INC, BEDFORD PARK, IL - 483, COMPANY RESPONSE, EIR (03/01/2012 - 11/20/2012)
2012-8382	11/23/2012 12/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MICHELE L. BUENAFE MORGAN LEWIS	SANTYL (COLLAGENASE) APRVL, LBLG, CO RESP
2012-8383	11/23/2012 12/21/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	CooperVision, Inc. CooperVision, Inc.	COOPERVISION, PLEASANTON, CA - 483 (0 5/17/2012); COOPERVISION, W HENRIETTA, NY - 483 (05/29/12)
2012-8384	11/23/2012 12/21/2012	FDA/OFVM/CFSAN/OCD/EOS/	Shailini Rao Eton Patrk Capital Management	STARBUCKS - AERS
2012-8385	11/23/2012 12/21/2012	FDA/OFVM/CFSAN/OCD/EOS/	Sontakay, Suresh	FOOD CONTACT SUBSTANCE 15 4/00
2012-8386	11/23/2012 12/21/2012	FDA/OFVM/CFSAN/OCD/EOS/	Sontakay, Suresh	FOOD CONTACT SUBSTANCE 685 3/20/07
2012-8387	11/23/2012 12/21/2012	FDA/OFVM/CFSAN/OCD/EOS/	Sontakay, Suresh	FOOD CONTACT SUBSTANCE 889 7/3/09
2012-8388	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 10/29/12-11/2/12
2012-8389	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 11/5-9/12
2012-8390	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 11/12-16/12
2012-8391	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 11/5-9/12

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2012-8392	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 10/29/12-11/2/12
2012-8393	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 10/29/12-11/2/12
2012-8394	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 11/5-9/12
2012-8395	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 10/29/12-11/2/12
2012-8396	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 11/5-9/12
2012-8397	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/	GLADYS B TONKIN WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 10/29/12-11/2/12
2012-8398	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/	GLADYS B TONKIN WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 11/5-9/12
2012-8399	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 11/12/-16/12
2012-8400	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 11/5-9/12
2012-8401	11/26/2012 12/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	REO TANOSHIMA MD HOSPITAL FOR SICK CHILDREN	COPAXONE - AERS
2012-8402	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/	DAYTON, KATHRYN	DIETARY SUPPLEMENTS RECALLED DUE TO IMPROPER LBLG
2012-8403	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 10/29/12-11/2/12
2012-8404	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 10/27/12-11/2/12
2012-8405	11/26/2012	FDA/OC/OES/DFOI/	DEBI COHEN	FOI DAILY LOG 11/5-9/12

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	12/24/2012		WOLTERS KLUWER LAW & BUSINESS	
2012-8406	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	CLOSED FOIA REQUESTS 11/12-16/12
2012-8407	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	CLOSED FOIA REQUESTS 10/29/12-11/2/12
2012-8408	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	CLOSED FOIA REQUESTS 11/5-9/12
2012-8409	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 11/5-9/12
2012-8410	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 10/29/12-11/2/12
2012-8411	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 11/12-16/12
2012-8412	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 10/29/12-11/2/12
2012-8413	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 11/5-9/12
2012-8414	11/26/2012 12/24/2012	OC/ORO/OCI/ OC/ORO/OCI/	KAREN C KOSKI LAZARD CAPITAL MARKETS	ABIOMED - SUBPOENA 10/26/12 RECS
2012-8415	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	THEO EMISON EMISON HULLVERSON LLP	DR MICHAEL DRAKE, STANFORD UNIV - DIAGNOSIS AND/OR TREATMENT OF CHRONIC CEREBROSPINAL VENOUS INSUFFICIENCY (CCSVI) CORR, RPTS, INVESTIGATIONS, ETC
2012-8416	11/26/2012 12/24/2012	FDA/OMPT/CDRH/OCER/DFOI/	MEGAN STORRIE MELLINO ROBENALT LLC	INDIVIDUAL RECS - MAUDE RPT
2012-8417	11/26/2012 12/24/2012	FDA/OGROP/ORO/CE-FO/CIN-DO/CIN-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GABRIEL F ZAMBRANO FARMER JAFFE WEISSING EDWARDS FISTOS & LEHRMAN PL	BOEHRINGER INGELHEIM PHARMA GMBH & CO - PRADAXA CAPS (DEBIGATRAN ETEXILATE) NDA 22-512 RECALL RECS
2012-8418	11/26/2012 12/24/2012	FDA/OFVM/CFSAN/OCD/EOS/	DAVID W PLUNKETT JD JM CENTER FOR SCIENCE IN PUBLIC INTEREST	VIBRIO VULNIFICUS RISK CALCULATOR - MEMOS, EMAILS, TRANS, ETC 2007 TO PRESENT

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2012-8419	11/26/2012 12/24/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN BLOCH JOHNS HOPKINS MEDICINE DEPT OF NEUROLOGY	LORAZEPAM INTENSOL - ANDA RECS
2012-8420	11/26/2012 12/24/2012	FDA/OFVM/CFSAN/OCD/EOS/	CHRISTOPHER HENDEL CONSUMERS UNION OF THE U.S., INC	ENERGY DRNKS - CAERS 4/12/12 TO PRESENT
2012-8421	11/26/2012 02/01/2013	FDA/OC/OES/DFOI/ FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ OC/ORA/ OC/ORA/ FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/ FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/ FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	David Mangione FDAZILLA	PFIZER, PEARL RIVER, NY; HOSPIRA, ROCKY MOUNT, NC; CATALENT SOLUTIONS, BELGIUM - 483
2012-8422	11/26/2012 12/24/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GJ McGarity GJ McGarity	LYRICA - AERS
2012-8423	11/26/2012 12/24/2012	OC/OA/OM/OMP/DDM/	ronald piana Ronald Piana	ADVISORY COMMITTEE MEETING MINUTES - HYBRITECH INC. (06/29/93)
2012-8424	11/26/2012 12/24/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	Maryalice Gill The Telegraph of Nashua, NH	SMARTPHONE APPS - COMPLAINTS FROM NEW ENGLAND RESIDENTS (11/08/2012 - 11/14/2012)

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2012-8425	11/26/2012 12/24/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARIA GRAZIA VIMERCATI APTALIS PHARMA SRL	APTALIS PHARMA SRL, ITALY - QUALITY ASSURANCE PROFILE (QAP)
2012-8426	11/26/2012 12/24/2012	OC/CVM/OCD/ FDA/OC/OES/DFOI/	LYNNE TERRY OREGONIAN	JERKY PET TREATS FROM CHINA - INVESTIGATION RECS, LAB TESTS, NAMES OF MFRS, ETC 2007 TO PRESENT
2012-8427	11/26/2012 12/24/2012	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	MURIEL ASHIE MEDTRONIC INC	OSTEOTECH INC, SHREWSBURY, NJ - EIR 10/6/10-12/9/10
2012-8428	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/	Brian Lester MANNING & NAPIER ADVISORS INC	NOVARTIS, SANDOZ - 483 (06/11 TO PRESENT)
2012-8429	11/27/2012 12/26/2012	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Michael McBride Michael McBride	INDIVIDUAL RECS
2012-8430	11/27/2012 12/26/2012	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	Nicole M. Oliynyk ARIAD Pharmaceuticals Inc.	ASH STEVENS, RIVERVIEW, MI - EIR (01/01/2012 - 12/31/2012)
2012-8431	11/27/2012 12/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	Meredith Reynolds EPIMED INTERNATIONAL INC	K090995
2012-8432	11/27/2012 12/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Peter Breggin, M.D. Peter R. Breggin, M.D.	ACZONE - AERS (01/01/2004 - 11/26/2012)
2012-8433	11/27/2012 12/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORA/ OC/ORA/ FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/ FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Sarah Sorscher PUBLIC CITIZEN	COMPOUNDING PHARMACIES - 483S (04/01/2002 TO PRESENT)

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		FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/		
2012-8434	11/27/2012 12/26/2012	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Ashlea Surles WLOS-TV	BAXTER HEALTHCARE, MARION, NC - CORR, 483, WARNING LETTER, ETC (01/01/2012 - 11/26/2012)
2012-8435	11/27/2012 12/26/2012	OC/ORAE/ OC/ORAE/	Andrew Kahn UNITE HERE	ST JUDE MEDICAL, ARECIBO, PR - UNREDACTED 483 (09/17/2012 - 11/25/2012)
2012-8436	11/27/2012 12/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	joseph barton barton, joseph	CORTICOTROPIN/ACTH - ANNUAL FILINGS
2012-8437	11/27/2012 12/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mark Thomas Noseweek Magazine	TENOFIR 1% GEL - PROTOCOL
2012-8438	11/27/2012 12/26/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDRH/OCER/DFOI/	RICHARD N SHAPIRO RICHARD N SHAPIRO LAW OFCS	HOWMEDICA OSTEONICS CORP - ABG II MODULAR HIP REPLACEMENT K092406
2012-8439	11/27/2012 12/26/2012	FDA/OC/OES/DFOI/	CROSBY T50417, COURTNEY	ENERGY DRINKS - WARNINGS
2012-8440	11/27/2012 12/26/2012	FDA/OMPT/CTP/OD/	AUSTIN G STEEVES IV AUSTIN/TRAVIS COUNTY HEALTH AND HUMAN SERVICES	GENERAL SNUS, AUSTIN, TX - INVESTIGATION RECS
2012-8441	11/27/2012 12/26/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WAYNE SADOWSKI NOVARTIS PHARMACEUTICALS	NOVARTIS PHARMACEUTICALS CORP, EAST HANOVER, NJ - EIR, 483, CORR 8/13-23/12

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			CORP	
2012-8442	11/27/2012 12/26/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID C WEBER BEHREND & ERNSBERGER PC	MUTUAL PHARM - PREDNISONE ANNUAL RPT 1955 TO PRESENT
2012-8443	11/27/2012 12/26/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID C WEBER BEHREND & ERNSBERGER PC	UPJOHN PHARMS/PHARMACIA - DELTASONE ANNUAL RPTS 1955 TO PRESENT
2012-8444	11/27/2012 12/26/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID C WEBER BEHREND & ERNSBERGER PC	ROXANE LABS - PREDNISONE ANNUAL RPT 1955 TO PRESENT
2012-8445	11/27/2012 12/26/2012	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	RANIL M FERNANDO BIOSCREEN TESTING SERVICES INC	MICRO QUALITY LABS INC, BURBANK, CA - EIRS, 483S, WARNING LTRS LAST 5 YRS
2012-8446	11/27/2012 12/26/2012	OC/ORA/ OC/ORA/	DAVID BLOCH MEDTRONIC	ST JUDE MEDICAL, SYLMAR, CA - 483, CO RESP 10/17/12
2012-8447	11/27/2012 01/07/2013	FDA/OO/OFBA/OAGS/	JEFF STACHEWICZ FOIA GROUP INC	HHSF223200850014I - TASK ORDER HHS0001, AWARD TYPE, 2011 SPENDING, ETC
2012-8448	11/27/2012 12/26/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kenneth Woliner, MD Kenneth Woliner, MD	HCG - AERS (01/01/1973 - 12/01/2012)
2012-8449	11/27/2012 02/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	KEITH STONEBACK AGILE SCIENCES	SEMPRUS (TELEFLEX) - APRVL OF NEW MATERIAL FOR CATHETERS
2012-8450	11/27/2012 12/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	LISA ANDERSON CONMED CORP	BIRTCHEER MEDICAL SYSTEMS INC - HYFRECATOR K800617
2012-8451	11/27/2012 12/26/2012	FDA/OC/OES/DFOI/	Lauren Farruggia Hyman, Phelps and McNamara	ROCKSTAR ENERGY DRINKS - CAERS (01/01/04-10/23/12)

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2012-8452	11/27/2012 12/26/2012	FDA/OGROP/ORR/SW-FO/DEN-DO/DEN-CB/	Janie Gwinn WATSON LABORATORIES INC	WATSON PHARMACEUTICALS/LABORATORIES - MTG MINUTES
2012-8453	11/27/2012 12/26/2012	FDA/OFVM/CFSAN/OCD/EOS/	LAUREN FARRUGGIA Hyman, Phelps & McNamara, P.C.	COFFEE BEVERAGES - CAERS 1/1/04 TO 10/23/12
2012-8454	11/27/2012 12/26/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TONYA SAUSSER TARSA THERAPEUTICS INC	SANDOZ GMBH, KUNDL - 483 10/3-12/12
2012-8455	11/27/2012 12/26/2012	FDA/OFVM/CFSAN/OCD/EOS/	ELBEK, GAIL	SOY INFANT FORMULA & FOOD - CAERS
2012-8456	11/27/2012 12/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	NEELMEGH, RAMESH	MEDICVISION - SAFECT PICTURE ARCHIVING AND COMMUNICATIONS SYS
2012-8457	11/27/2012 12/26/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	SHAPIRO, ELAINE L	ZOSTAVAX - VAERS
2012-8458	11/27/2012 12/26/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Doe J	SILVER NITRATE - AERS
2012-8459	11/27/2012 12/26/2012	FDA/OFVM/CFSAN/OCD/EOS/	HELLEN A OKETCH PHD UNITED STATES PHARMACOPEIA	AGMATINE SULPHATE - CAERS 1/05 TO 5/12
2012-8460	11/27/2012 12/26/2012	FDA/OFVM/CFSAN/OCD/EOS/	HELLEN A OKETCH PHD UNITED STATES PHARMACOPEIA	N-ACETYL-D-GLUCOSAMINE - CAERS 1/05 TO 5/12
2012-8461	11/27/2012 12/26/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	2012-7908
2012-8462	11/27/2012 12/26/2012	FDA/OC/OES/DFOI/	BRIAN LESTER MANNING & NAPIER ADVISORS INC	SANDOZ, NOVARTIS - 483S, WARNING LTRS 6/11 TO PRESENT

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2012-8463	11/28/2012 12/27/2012	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K073556
2012-8464	11/28/2012 12/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	ANDA 090008 - TENTATIVE APPROVAL LETTER
2012-8465	11/28/2012 12/27/2012	FDA/OC/OES/DFOI/	Amy Kincanon LexisNexis CourtLink Document Retrieval	2012-7404
2012-8466	11/28/2012 12/27/2012	FDA/OC/OES/DFOI/	Amy Kincanon LexisNexis CourtLink Document Retrieval	2012-7914
2012-8467	11/28/2012 12/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	AMITIZA - AERS (11/02/2009 - 11/27/2012)
2012-8468	11/28/2012 12/27/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/PHI-DO/PHI-CB/	Helena Mateus-Martins J&K Fresh East a div of 721 Logistics	ENTRY 97E-0005593-0 - ANALYTICAL REPORT
2012-8469	11/28/2012 12/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mahlaqa LUNDBECK INC	NDA 11665 (MESTINON ER TABLETS) - SBA
2012-8470	11/28/2012 12/27/2012	FDA/OFVM/CFSAN/OCD/EOS/	Lauren Farruggia Hyman, Phelps and McNamara	ROCKSTAR ENERGY ADVERSE EVENTS - 83060, 86399, 87069, ETC
2012-8471	11/28/2012 12/27/2012	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/	Marie Sullivan and Suzanne Robinson Pain Consultants of West Florida, PA	SAMPLE RESULTS
2012-8472	11/28/2012 12/27/2012	FDA/OMPT/CDRH/OCER/DFOI/	Laura Boll Medovations Inc.	K090183
2012-8473	11/28/2012 12/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Paul J. Davis Paul J. Davis	PHENYTOIN - DETAILED REPORTS OF LEFT BUNDLE BRANCH BLOCK (01/01/2001 - 12/31/2011)

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2012-8474	11/28/2012 12/27/2012	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Laura Boll MEDOVATIONS INC	K061937
2012-8475	11/28/2012 12/27/2012	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	BIOMET MICROFIXATION - AER
2012-8476	11/28/2012 12/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GONZALES, GRACE	FORTICAL SPR - AER
2012-8477	11/28/2012 12/27/2012	FDA/OC/OES/DFOI/	JACKIE HERNDON ZAREMBA BROWNELL ET AL	CIPROFLOXACIN - RECS CERT
2012-8478	11/28/2012 12/27/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORAP/PA-FO/LOS- DO/LOS-CB/	Doe J	CMPLNT
2012-8479	11/28/2012 12/27/2012	FDA/OMPT/CDRH/OCER/DFOI/	KEVIN STRANGE WELLS FARGO SECURITIES	HEARTWARE VENTRICULAR ASSIST SYS - SAFETY & EFFECTIVENESS PMA P100047
2012-8480	11/28/2012 12/27/2012	FDA/OMPT/CDRH/OCER/DFOI/	R. SCOTT JENNINGS TRANSPHOTON CORP	APEX DETECTOR ELECTRONICS & ACQUISITION INTERFACE MODEL XL4 K033001
2012-8481	11/28/2012 12/27/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Doe J	MERCK - HIB VACCINE RECALL
2012-8482	11/28/2012 12/27/2012	FDA/OO/ FDA/OO/OHR/	MARK L. FLATTEN WASHINGTON EXAMINER	EMPLOYEE DATA - OFFICIAL TIME USE
2012-8483	11/29/2012 12/28/2012	FDA/OC/OES/DFOI/	Megan Pickel BEVERIDGE & DIAMOND	CFSAN FOIA REQUESTS (10/26/2012 - 11/28/2012)
2012-8484	11/29/2012 12/28/2012	FDA/OFVM/CFSAN/OCD/EOS/	Shailini Rao Eton Park Capital Management, L.P.	COCA COLA - AERS
2012-8485	11/29/2012 12/28/2012	FDA/OMPT/CDRH/OCER/DFOI/	Lisa Anderson ConMed Corporation	K33497
2012-8486	11/29/2012 12/28/2012	FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/	E Neely St. Jude Medical	BOSTON SCIENTIFIC - RESPONSE TO WARNING LETTER DATED 01/25/06
2012-8487	11/29/2012 12/28/2012	FDA/OGROP/ORACE-FO/MIN- DO/MIN-CB/	E neely St. Jude Medical	MEDTRONIC CDRM - WARNING LETTER RECS (11/09/2009 - 11/01/2012)

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2012-8488	11/29/2012 12/28/2012	FDA/OFVM/CFSAN/OCD/EOS/	Shailini Rao Eton Park Capital Management, L.P.	PEPSI - AERS
2012-8489	11/29/2012 12/28/2012	FDA/OMPT/CDRH/OCER/DFOI/	John P. Waters Whip Mix Corporation	K925375
2012-8490	11/29/2012 12/28/2012	FDA/OO/OFBA/OAGS/	Gina T Weismann TD Equipment Finance, Inc.	CONTRACTING OFFICER WARRANT OF AUTHORITY
2012-8491	11/29/2012 12/28/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rita Choi George Mason Law & Economic Center	APPROVABLE LETTERS, NOT APPROVABLE LETTERS, COMPLETE RESPONSE LETTERS FOR LISTED DRUGS (06/26/1997 - 11/28/2012)
2012-8492	11/29/2012 12/28/2012	FDA/OFVM/CFSAN/OCD/EOS/	Shailini Rao Eton Park Capital Management, L.P.	PEPSI ENERGY DRINKS - AERS
2012-8493	11/29/2012 12/28/2012	FDA/OGROP/ORACE-FO/MIN- DO/MIN-CB/	E Neely St. Jude Medical	GUIDANT CORPORATION, ST PAUL, MN - RESPONSE TO 483 ISSUED 2/09/06
2012-8494	11/29/2012 12/28/2012	FDA/OFVM/CFSAN/OCD/EOS/	Shailini Rao Eton Park Capital Management, L.P.	PEPSI - AERS
2012-8495	11/29/2012 12/28/2012	FDA/OFVM/CFSAN/OCD/EOS/	Omari Ramirez Water Island Capital, LLC	TEAVANA HOLDINGS - SAMPLE ANALYSIS
2012-8496	11/29/2012 12/28/2012	FDA/OMPT/CDRH/OCER/DFOI/	Kevin A Henry UNIVERSITY OF UTAH	MAMMOGRAPHY FACILITIES - NUMBERS OF MACHINES, CAPACITY, DIFFUSION, ETC (01/01/2003 - 12/31/2011)
2012-8497	11/29/2012 12/28/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KATE C BEARDSLEY ZUCKERMAN SPAEDER LLP	SUN PHARMACEUTICALL INDUSTRIES - SUMATRIPTAN AUTO-INJECTOR ANDA 09-0358 SBA, APRVL PKG
2012-8498	11/29/2012 12/28/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KATE C BEARDSLEY ZUCKERMAN SPAEDER LLP	INTELLIJECT - AUVI-Q (EPINEPHRINE INJ USP) NDA 20- 1739 SBA, APRVL PKG
2012-8499	11/29/2012 12/28/2012	FDA/OMPT/CDRH/OCER/DFOI/	HAMILTON, LEROY LESLIE	DESIGNATION FORM FDA 3429 - ALL VERSIONS THAT EXISTED PRIOR TO THE ASSIGNMENT OF THE FORM
2012-8500	11/29/2012	FDA/OMPT/CDER/GRP/DIDP/	JOHN B BRAUNSTEIN	ASACOL (MESALAMINE) - AERS

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	12/28/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	VOUTE LOHRFINK MAGRO LLP ET AL	
2012-8501	11/29/2012 12/28/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	JENNIFER GRAMLILNG SAMSTER KONKEL ET AL	WHEATON FRANCISCAN HEALTHCARE-FRANKLIN - TETANUS VACCINE RECS (CERTIFIED)
2012-8502	11/29/2012 12/28/2012	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/ OC/ORA/ OC/ORA/	PETER D LOFTUS Dow Jones & Company	OHM LABORATORIES, NEW BRUNSWICK, NJ - 483'S; RANBAXY LABS - ATORVASTIN CALICUM ANDA 07-6477 CO RESP 11/30/11 TO PRESENT
2012-8503	11/29/2012 12/28/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	NEIL SHEEHY NEIL SHEEHY	ETHICON (JOHNSON & JOHNSON CO) - FIBRIN PAD PROD LICENSE APPL RESP LTR, LBLG, CO RESP 10/5/12
2012-8504	11/29/2012 12/28/2012	FDA/OC/OES/	J. DONALD HENSON, SR Henson, J. Donald	LAURIE LENKEL - NAME & POSITION OF THE INDIVIDUAL GIVING THE ASSIGNMENT, CORR
2012-8505	11/29/2012 12/28/2012	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/ FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	CORBETT, SUZANNE	VOLUNTARY NATIONAL RETAIL FOOD REGULATORY PROGRAM STANDARDS, ASHFIELD, MA - RECIPIENTS OF FUNDING, COLLECTION FORM. LIST OF VENDORS, ETC
2012-8506	11/29/2012 12/28/2012	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Siobhan Briley Sullivan & Worcester LLP	AMERICAN DIAGNOSTICA, STAMFORD, CT - 510K SUBMISSIONS; 483, WARNING LETTERS, ETC
2012-8507	11/29/2012 12/28/2012	FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/	Tony Taylor AESCULAP	PREMIER RESEARCH, PHILADELPHIA, PA - 483 (01/01/2008 - 11/28/2012)
2012-8508	11/29/2012 12/28/2012	FDA/OMPT/CDRH/OCER/DFOI/	Liu Jimin Hexalotus Technology Pte Ltd	K110186, K122136
2012-8509	11/30/2012 12/31/2012	OC/CVM/OCD/ FDA/OFVM/CFSAN/OCD/EOS/	Carey Gillam/Reuters REUTERS	BNF 000124, DAS-68416-4, BNF 000125, MON 87708
2012-8510	11/30/2012 03/20/2013	FDA/OMPT/CTP/OD/ OC/OCOS/OES/ OC/OCOS/OES/	elliott favus FAVUS INSTITUTIONAL RESEARCH LLC	MENTHOL IN CIGARETTES - RECS (01/01/2011 - 12/31/2011)
2012-8511	11/30/2012 03/20/2013	FDA/OMPT/CTP/OD/ OC/OCOS/OES/ OC/OCOS/OES/	Elliot Favus FAVUS INSTITUTIONAL RESEARCH LLC	MENTHOL IN CIGARETTES - RECS (01/01/2012 - 11/29/2012)
2012-8512	11/30/2012	FDA/OMPT/CDER/GRP/DIDP/	pharmacokinetic data of Pitressin (vasopressin injection)	PITRESSIN - CLEARANCE DATA

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	12/31/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	UNIVERSITY OF HOUSTON COLLEGE OF OPTOMETRY	
2012-8513	11/30/2012 12/31/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JoNel N. Aleccia MSNBC.COM	NEW ENGLAND COMPOUNDING CENTER - MEDWATCH RPTS (05/21/2012 - 11/29/2012)
2012-8514	11/30/2012 12/31/2012	FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/ FDA/OMPT/CDRH/OCER/DFOI/ OC/OCOS/OES/ OC/OCOS/OES/ OC/OCOS/OL/ OC/OA/OM/OMP/DDM/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joanne Matusko NastLaw, LLC	MIRENA - APPLICATIONS, MANUALS, CORR, ETC
2012-8515	11/30/2012 12/31/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	David Friedman Morgan Stanley	XIAFLEX - STATISTICAL ANALYSIS PLAN FOR PHASE THREE
2012-8516	11/30/2012 12/31/2012	FDA/OFVM/CFSAN/OCD/EOS/	Josh James BRYAN CAVE LLP	OCEAN SPRAY CRAISINS, NISSIN TOP RAMEN, SABRA HUMMUS, ETC - CAERS
2012-8517	11/30/2012 12/31/2012	FDA/OGROP/ORASE-FO/FLA- DO/FLA-CB/	DAVID SCOTT BLUE ZETETIC INC	SEXY HAIR STYLING AND TREATMENT PRODS ENTRY #EHP00759408 - RECS
2012-8518	11/30/2012 12/31/2012	FDA/OMPT/CDRH/OCER/DFOI/	ALISON M AGNEW PILLSBURY WINTHROP SHAW PITTMAN LLP	2012-6833
2012-8519	11/30/2012 12/31/2012	FDA/OFVM/CFSAN/OCD/EOS/	GUBEN, ALISON	COCA COLA/DIET COKE, PEPSI COLA/DIET PEPSI, JOLT COLA, ETC - CAERS
2012-8520	11/30/2012 02/01/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OO/OFBA/OAGS/	DANIEL G JARCHO MCKENNA LONG & ALDRIDGE LLP	IEH LABORATORIES & CONSULTING GROUP - PATHOGEN PREVALENCE/BASELINE STUDY IN FRESH PRODUCE CONTRACTS, INVOICES, CORR, ETC

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2012-8521	11/30/2012 12/31/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TENECIA SULLIVAN SALAMANDRA LLC	METHYLENE BLUE - ISRS 3236013-5, 3839924-2, 3989080-5, ETC
2012-8522	11/30/2012 12/31/2012	FDA/OFVM/CFSAN/OCD/EOS/	GUBEN, ALISON	COFFEE - CAERS
2012-8523	11/30/2012 12/31/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joyce Lee MORRISON & FOERSTER LLP	LSD - APPROVALS, WARNING, DISCLOSURE
2012-8524	11/30/2012 12/31/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KATE PURCELL DOCUTRIEVAL INFORMATION SERVICES	PAR PHARMS - ANDA 91-340, ANDA 91-341 APRVL LTRS
2012-8525	11/30/2012 12/31/2012	OC/ORO/ OC/ORO/ FDA/OC/OES/DFOI/ FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	R IAN KLUGE Hyman Phelps and McNamara PC	FRESH FISH FILETS ENTRY #235-1509680-0 - SHIPPING & PACKING RECS
2012-8526	11/30/2012 12/31/2012	FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/ FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/	MCKENZIE CATO Hyman Phelps and McNamara PC	FLORIDA BIOLOGIX, ALACHUA, FL - RECS
2012-8527	11/30/2012 12/31/2012	FDA/OO/OFBA/OAGS/	FOI Services, Inc.	NATIONAL ENVIRONMENTAL HEALTH ASSN AWARD NUMBER U45FD 004325 - COOPERATIVE AGREEMENT 9/16/11, 8/14/12, 8/29/12, ETC
2012-8528	11/30/2012 12/31/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	PROSURG - EVA K001576
2012-8529	11/30/2012 12/31/2012	FDA/OGROP/ORO/SW-FO/KAN-DO/KAN-CB/	KRISTI O SMEDLEY PHD WASHINGTON INFORMATION SOURCE	SPARHAWK LABORATORIES INC, LENEXA, KS - EIRS, 4835 6/1/05 TO PRESENT
2012-8530	11/30/2012 12/31/2012	FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/	KIM C CAPONE PORZIO BROMBERG & NEWMAN PC	PFIZER INC, NEW YORK, NY - EIR, 483 101/15/12

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2012-8531	11/30/2012 12/31/2012	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDRH/OCER/DFOI/	DANIEL STEIN RICHARDS KIBBE & ORBE LLP	ABIOMED INC, DANVERS, MA - IMPELLA RECOVER LP 2.5 PERCUTANEOUS CARDIAC SUPPORT SYS CORR 1/1/08 TO PRESENT
2012-8532	12/03/2012 01/02/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	MIJIB U. QIDWAI GRIFOLS BIOLOGICALS INC	BAXTER, LOS ANGELES, CA - EIR, 483 10/12
2012-8533	12/03/2012 01/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	ROBBI PERRY NORTH AMERICAN RESCUE LLC	BELMONT INSTRUMENT CORP, BILLERICA, MA - BUDDY PLUS FLUID WARMER - K062774
2012-8534	12/03/2012 01/02/2013	FDA/OFVM/CFSAN/OCD/EOS/	ALVIN J LORMAN LAW OFC	FCN 1177
2012-8535	12/03/2012 01/02/2013	FDA/OFVM/CFSAN/OCD/EOS/	ALVIN J LORMAN LAW OFC	FCN 1188
2012-8536	12/03/2012 01/02/2013	FDA/OFVM/CFSAN/OCD/EOS/	ALVIN J LORMAN LAW OFC	FCN 1145
2012-8537	12/03/2012 01/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	JIM KUSTERS MORIA INC	K090626
2012-8538	12/03/2012 01/02/2013	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	McKENZIE CATO Hyman, Phelps and McNamara	ORGAN RECOVERY SYSTEMS INC - RECS
2012-8539	12/03/2012 01/14/2013	FDA/OGROP/ORACE-FO/DETDO/DET-CB/	STEVEN D. BROCK JOHNSON LAW PLC	INDIVIDUAL RECS
2012-8540	12/03/2012 01/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jing Ge Ge, Jing	HEARTWARE VENTRICULAR ASSIST DEVICE - STUDY DATA FOR 100 PATIENTS
2012-8541	12/03/2012 01/02/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Megan Mularczyk Pretzinger, Liz	INDIVIDUAL RECS
2012-8542	12/03/2012 01/02/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 21951
2012-8543	12/03/2012 01/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	Carey Folk New Country, LLC	K052732
2012-8544	12/03/2012 01/02/2013	FDA/OGROP/ORASE-FO/ATLDO/ATL-CB/	Dominic DeMuro PFIZER, INC	PFIZER, SANFORD, NC - EIR (11/2011)
2012-8545	12/03/2012 01/02/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KAVITA SRIVASTAVA TARO PHARMACEUTICALS USA INC	GLENMARK GENERICS - FLUTICASONE PROPIONATE SBA, CHEMISTRY RVW, LBLG, ETC

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2012-8546	12/03/2012 01/02/2013	FDA/OC/OES/DFOI/	Silvia Gambardella WTV-D-TV/ ABC	PET JERKY TREATS - COMPLAINTS FROM NORTH CAROLINA
2012-8547	12/03/2012 01/02/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	HYCAMTIN - APPROVAL, LABELING, MEDICAL REVIEW, ETC
2012-8548	12/03/2012 01/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	Emily Nugent Dickson Geesman LLP	K091057, K092356, K100403
2012-8549	12/03/2012 01/02/2013	FDA/OFVM/CFSAN/OCD/EOS/	Anna Edney BLOOMBERG NEWS	STARBUCKS COFFEE, HOSTESS TWINKIES - CAERS (01/01/2004 - 10/19/2012)
2012-8550	12/03/2012 01/02/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Yu-Ju Chiang Chung Yuan Christian University	K033474
2012-8551	12/03/2012 01/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	Robert Blinn Pura Vida Funds	P950022 S014
2012-8552	12/03/2012 01/02/2013	FDA/OC/OES/DFOI/	VIDA JOHNSON WONDER FIBER MASSAGE PRODUCT INC	HEALTH CARE THERAPEUTIC LIQUID - APRVL
2012-8553	12/03/2012 01/02/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Yu-Ju Chiang Chung Yuan Christian University	K011144
2012-8554	12/03/2012 01/02/2013	FDA/OFVM/CFSAN/OCD/EOS/	GUBEN, ALISON	RED BULL - AER 1/04 TO 11/1/12
2012-8555	12/04/2012 01/03/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SW-FO/SWID/SWID-CB/	BENJAMIN ENGLAND BENJAMIN L ENGLAND & ASSOCIATES LLC	HAINAN QINFU FOODS CO LTD - ENTRY #316-7043761-0 COLLECTION RPTS, STORAGE RECS, INVESTIGATIONS, ETC
2012-8556	12/04/2012 01/03/2013	FDA/OGROP/ORO/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORO/CE-FO/PHI-DO/PHI-CB/	PAUL W TRIPP LINCARE INC	MEDILINK HOMECARE INC, NJ, PA - EIRS, 483S, WARNING LTRS 1/105 TO PRESENT
2012-8557	12/04/2012 01/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANNE MUTASHI HOGAN LOVELLS LLP	FIRST VERSION, FINAL VERSION OF FORM FDA 356H

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2012-8558	12/04/2012 01/03/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANNE MUTASHI HOGAN LOVELLS US LLP	MARINOL NDA 18-651, DESYREL NDA 18-207, BUPRENEX NDA 18-401 - APRVL LTRS, FORM FDA 356H
2012-8559	12/04/2012 01/03/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANNE MUTASHI Hogan Lovells, ILP	CONTROLLED SUBSTANCES ACT - FDA DECISION TO INCLUDE ON THE FORM FDA 356H LANGUAGE THAT APPLIES TO PROPOSED DRUG SCHEDULING
2012-8560	12/04/2012 01/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	DANIEL B SNELLINGS PENTON LAW FIRM	INTUITIVE SURGICAL INC - DA VINCI SURGICAL SYS K081207 NOTICES, Cmplnts, MDRS, ETC
2012-8561	12/04/2012 01/03/2013	OC/OA/OM/OMP/DDM/	KRISTI O SMEDLEY PHD WASHINGTON INFORMATION SOURCE	DKT 1980N-0218
2012-8562	12/04/2012 01/03/2013	FDA/OC/OCC/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	GILEAD SCIENCES - MTG MINS, TRANS, AGENDA, ETC 11/8/12
2012-8563	12/04/2012 01/03/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID C WEBER BEHREND ERNSBEERGER, PC	UPJOHN PHARMS, MUTUAL PHARM, ROXANE LABS - PREDNISONE AERS, LBLG CHANGES
2012-8564	12/04/2012 01/03/2013	FDA/OGROP/ORAC/CE-FO/PHI-DO/PHI-CB/	OWEN, EVAN D	MCNEIL CONSUMER HEALTHCARE, FORT WASHINGTON, PA - EIR, VIDEOS, IMAGES, ETC 4/19/12
2012-8565	12/04/2012 01/03/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Yu-Ju Chiang Chung Yuan Christian University	K033474
2012-8566	12/04/2012 01/03/2013	FDA/OGROP/ORAC/CE-FO/MIN-DO/MIN-CB/	Sandy Stagge CTI Clinical Trial and Consulting Servic	SANDARAM HARIHARAN, MEDICAL COLLEGE OF WISCONSIN - 483 AND RESPONSE (6/12/2000)
2012-8567	12/04/2012 01/03/2013	FDA/OGROP/ORAC/CE-FO/CHI-DO/CHI-CB/	Sandy Stagge CTI Clinical Trial & Consulting Services	UNIVERSITY OF CHICAGO BIOLOGICAL SCIENCES DIVISION IRB - 483 AND RESPONSE (7/8/2009)
2012-8568	12/04/2012 01/03/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	TRETINOIN - AERS

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		FDA/OMPT/CDER/GRP/DIDP/		
2012-8569	12/04/2012 01/03/2013	FDA/OFVM/CFSAN/OCD/EOS/	Marvin Friedman TR Services	CAS 7773-06-0
2012-8570	12/04/2012 01/03/2013	FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/	Edward W Skepnek VALNET INC	MEDIVATORS, CONROE, TX - EIR (04/03/2010 - 04/15/2010)
2012-8571	12/04/2012 01/03/2013	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	Christopher M. Brown Remington Medical, Inc.	REMINGTON MEDICAL, INC, ALPHARETTA, GA - EIR (10/19/10 - 12/17/10)
2012-8572	12/04/2012 01/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 22580
2012-8573	12/04/2012 01/03/2013	FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/	Edward W Skepnek VALNET INC	MEDIVATORS, CONROE, TX - EIR (02/15/2009 - 03/15/2009)
2012-8574	12/04/2012 01/03/2013	FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/	Cindy Ingold AMERICAN RED CROSS BLOOD SERVICES	AMERICAN RED CROSS MISSOURI/ILLINOIS, ST PETERS, MO - EIR 10/27/11
2012-8575	12/04/2012 01/03/2013	FDA/OGROP/ORR/NE-FO/NWE-DO/NWE-CB/	Glenn Irish Glenn Irish Consulting	SHIRE, INC, LEXINGTON, MA - 483 (10/30/2011 - 11/30/2012)
2012-8576	12/04/2012 01/03/2013	FDA/OGROP/ORR/CE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORR/CE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORR/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORR/SE-FO/NOL-DO/NOL-CB/	Ben Eisler CBS This Morning	METOPROLOL SUCCEINATE, FUROSEMIDE, LEVERTIRACETAM, ETC - AERS, BIOAVAILABILITY RECS, INSPECTION RECS, ETC
2012-8577	12/04/2012 01/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/	John Crewdson PROJECT ON GOVERNMENT OVERSIGHT	SHINGLES PREVENTION STUDY - INVESTIGATIONS, AUDITS

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		ALFB/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/		
2012-8578	12/04/2012 01/03/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORA/ OC/ORA/	KANT, KRISHNA	BOOST-ULTRA - ANALYSIS
2012-8579	12/04/2012 01/03/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	BRENDA M GARTZ ELI LILLY & CO	ROCHE CAROLINA INC, FLORENCE, SC - 483 1/27/10
2012-8580	12/04/2012 01/03/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	BRENDA M GARTZ ELI LILLY & CO	MICROBAC SOUTHERN TESTING RESEARCH DIVISION, WILSON, NC - EIR, 483 2/10
2012-8581	12/04/2012 01/03/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	BRENDA M GARTZ ELI LILLY & CO	DPT LABS, SAN ANTONIO, TX - EIR, 483 10/18/10-11/12/10
2012-8582	12/04/2012 01/03/2013	FDA/OMPT/CTP/OD/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	ROTATIONAL WARNING PLANS FOR SMOKELESS TOBACCO PRODUCTS SUBMITTED BY ALTRIA CLIENT SERVICES, PHILIP MORRIS USA, US SMOKELESS TOBACCO COMPANY LLC ETC
2012-8583	12/04/2012 01/03/2013	FDA/OFVM/CFSAN/OCD/EOS/	STEPHEN J WEIN ESQ BATTAGLIA ROSS DICUS & WEIN PA	ZERXIS PHARMS - METANX, CEREFOLIN, DEPLIN, ETC CORR, SUBMISSION
2012-8584	12/04/2012 01/03/2013	FDA/OFVM/CFSAN/OCD/EOS/	STEPHEN J WEIN ESQ BATTAGLIA ROSS DICUS & WEIN PA	VIRTUS PHARMACEUTICALS LLC - METANX, CEREFOLIN, DEPLIN, ETC CORR, SUBMISSIONS
2012-8585	12/04/2012 01/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	Stephen Slavens GE Healthcare	K052345
2012-8586	12/04/2012 01/03/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kim Graves CRNA, ACNP, MSN Dayton Gastroenterology	PROPOVEN - AERS

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2012-8587	12/04/2012 01/03/2013	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	SUBSTANTIAL EQUIVALENCE FOR TOBACCO PRODUCTS
2012-8588	12/04/2012 01/03/2013	FDA/OC/OES/DFOI/	Karen Troutman Dewey Publications Inc.	ORGANIZATIONAL INFORMATION
2012-8589	12/04/2012 01/03/2013	FDA/OFVM/CFSAN/OCD/EOS/	STEPHEN J WEIN ESQ BATTAGLIA ROSS DICUS & WEIN PA	BRECKENRIDGE PHARMACEUTICAL INC - METANX, CEREFOLIN, DEPLIN, ETC CORR, SUBMISSIONS
2012-8590	12/04/2012 01/03/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kevin Kenney ENDO PHARMACEUTICALS	INDIVIDUAL SAFETY REPORTS
2012-8591	12/04/2012 01/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	Richard O. Wood the Wood Burditt group	CDRH 513(G) C033022
2012-8592	12/04/2012 01/03/2013	FDA/OFVM/CFSAN/OCD/EOS/	STEPHEN J WEIN ESQ BATTAGLIA ROSS DICUS & WEIN PA	PAMLAB LLC - METANX, CEREFOLIN, DEPLIN, ETC CORR, SUBMISSIONS
2012-8593	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7694 REQUEST LETTER
2012-8594	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7715 REQUEST LETTER
2012-8595	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7506 REQUEST LETTER
2012-8596	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7769 REQUEST LETTER
2012-8597	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7782 REQUEST LETTER
2012-8598	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7784 REQUEST LETTER
2012-8599	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 11/1-30/2012
2012-8600	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	CLOSED FOIA REQUESTS 11/1-30/2012

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2012-8601	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7734, 2012-7736, 2012-7737 REQUEST LETTER
2012-8602	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7641 REQUEST LETTER
2012-8603	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7509 REQUEST LETTER
2012-8604	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7693 REQUEST LETTER
2012-8605	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7133 REQUEST LETTER
2012-8606	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7328 REQUEST LETTER
2012-8607	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7239 REQUEST LETTER
2012-8608	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7403 REQUEST LETTER
2012-8609	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7497 REQUEST LETTER
2012-8610	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-4131
2012-8611	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7026
2012-8612	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7444 REQUEST LETTER
2012-8613	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7064 REQUEST LETTER
2012-8614	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6950
2012-8615	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7016
2012-8616	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7198 REQUEST LETTER
2012-8617	12/05/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2012-6436

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	01/04/2013		MERCK & CO., INC.	
2012-8618	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6382
2012-8619	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6538
2012-8620	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7189 REQUEST LETTER
2012-8621	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7468 REQUEST LETTER
2012-8622	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7199 REQUEST LETTER
2012-8623	12/05/2012 01/04/2013	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	BRENDA M GARTZ ELI LILLY & CO	HOLLISTER-STIER (JUBLIANT), SPOKANE, WA - EIRS 2/12
2012-8624	12/05/2012 01/04/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	BRENDA M GARTZ ELI LILLY & CO	PATHEON, CINCINNATI, OH - EIRS 12/11, 7/12
2012-8625	12/05/2012 01/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/CVM/OCD/	BRENDA M GARTZ ELI LILLY & CO	HISUM PHARMACEUTICAL COMPANY LTD, ZHEJIANG, CHINA - EIRS 9/11, 7/12
2012-8626	12/05/2012 01/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	M MELISSA BALTZ BUTLER SNOW ET AL	INIUITIVE SURGICAL INC, SUNNYVALE, CA -SURGICAL SYS & ENDOWRIST K050369, RESP LTR 4/29/05 (CERTIFIED)
2012-8627	12/05/2012 01/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	M MELISSA BALTZ BUTLER SNOW ET AL	DA VINCI SURGICAL SYS- DAVINCI SURGICAL SYS ENDOSCOPIC INSTRUMENTS K043288, RESP LTR 3/3/05 (CERTIFIED)
2012-8628	12/05/2012 01/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	CHANDRAN TIRUVATTAR DR REDDY'S LABORATORIES INC	WARNER CHILCOTT US - ESTRACE ANDA 08-069 SBA
2012-8629	12/05/2012 01/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHANDRAN TIRUATTAR DR REDDY'S LABORATORIES INC	VALEANT INTL - ZOVIRAX NDA 18-604 SBA

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2012-8630	12/05/2012 01/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JACKSON, EVA JO	ENALAPRIL MALEATE, METROPROLOL, NORTRIPTYLINE HCL, ETC - RECALL RECS, PI, AERS, ETC
2012-8631	12/05/2012 01/04/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	ANDREA CLISURA FARUQI & FARUQI LLP	CMPLNT 29667
2012-8632	12/05/2012 01/04/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Doe J	CAMPBELL - CREAM OF SHRIMP SOUP CMPLNT
2012-8633	12/05/2012 01/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARIAH MONTGOMERY CHANGE TO WIN	ALMUS PHARMACEUTICALS SINGAPORE PTE LTD; IMPORTS REFUSALS, EIRS,ETC 2005 TO PRESENT
2012-8634	12/05/2012 01/04/2013	FDA/OFVM/CFSAN/OCD/EOS/	MARILYNN WHITNEY COVINGTON BURLING LLP	CAFFEINE INTAKE BY THE US POPULATION 9/09
2012-8635	12/05/2012 01/04/2013	FDA/OFVM/CFSAN/OCD/EOS/	VERONICA S KNAPP HOGAN LOVELLS US LLP	SE RICHARD J DURBIN, CAFFEINE INTAKE BY US POPULATION 9/09
2012-8636	12/05/2012 01/04/2013	FDA/OFVM/CFSAN/OCD/EOS/	Desmonne Bennett BRYAN CAVE LLP	O.N.E. COCONUT WATER, ONE WORLD ENTERPRISES, ONE NATURAL EXPERIENCE - CAERS (03/01/2008 - 12/04/2012)
2012-8637	12/05/2012 01/04/2013	OC/ORA/ OC/ORA/	Nathan Ballard Sunrise Produce Inc.	SAMPLE RESULTS
2012-8638	12/05/2012 01/04/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Edward W Skepnek VALNET INC	FLEX MEDICAL, ASHEVILLE, NC - EIR 03/31/2011
2012-8639	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7056 REQUEST LETTER
2012-8640	12/05/2012 01/04/2013	FDA/OFVM/CFSAN/OCD/EOS/	Edward McPike Stifel Nicolaus & Co	ENERGY DRINKS - FULL CAERS REPORTS LISTED
2012-8641	12/05/2012 01/04/2013	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	FCN 546
2012-8642	12/05/2012 01/04/2013	FDA/OFVM/CFSAN/OCD/EOS/	Charles Sohn Sohn, Charles	FAP 3B3713
2012-8643	12/05/2012 01/04/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	David Mangione FDAZILLA	HOSPIRA, MCPHERSON, KS - 483 (10/24/2012)

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2012-8644	12/06/2012 01/07/2013	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	CLOSED FOIA REQUESTS 11/19-13/12
2012-8645	12/06/2012 01/07/2013	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	CLOSED FOIA REQUESTS 11/26-30/12
2012-8646	12/06/2012 01/07/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 11/19-23/12
2012-8647	12/06/2012 01/07/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 11/26-30/12
2012-8648	12/06/2012 01/07/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 11/19-23/12
2012-8649	12/06/2012 01/07/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 11/26-30/12
2012-8650	12/06/2012 01/07/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 11/9-23/12
2012-8651	12/06/2012 01/07/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 11/26-30/12
2012-8652	12/06/2012 01/07/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 11/19-23/12
2012-8653	12/06/2012 01/07/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 11/26-30/12
2012-8654	12/06/2012 01/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	BRENDA M GARTZ ELI LILLY & CO	PATHEON, FERENTINO, ITALY - 483S 5/11, 11/11
2012-8655	12/06/2012 01/07/2013	FDA/OGROP/ORO/CE-FO/MIN- DO/MIN-CB/	BRENDA M GARTZ ELI LILLY & CO	PHILIPS PLASTICS CORP, MENOMONIE, WI - EIRS 11/11
2012-8656	12/06/2012 01/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	BOEHRINGER INGELHEIM, VIENNA, AUSTRIA - EIRS 3/12

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2012-8657	12/06/2012 01/07/2013	FDA/OGROP/ORА/SE-FO/NOL-DO/NOL-CB/	PATRICIA L REGENYE Celgene Corporation	FARRELLL MENDELSON, CARDIOLOGY PC, BIRMINGHAM, AL - 483S 6/04 TO 11/12
2012-8658	12/06/2012 01/07/2013	FDA/OGROP/ORА/SE-FO/NOL-DO/NOL-CB/	PATRICIA L REGENYE Celgene Corporation	RICHARD KRAUSE, PARKRIDGE PROF PLZ SOUTH, CHATTANOOGA, TN - 483S 8/06 TO 11/12
2012-8659	12/06/2012 01/07/2013	FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/	SANJAY H SHARMA HETERO USA INC	MEPRON (ATOVAQUONE) ORAL SUSPENSION (MEPRON) - CHEMISTRY RVW, BIOQV RVW, ADMINSTRATIVE RECS
2012-8660	12/06/2012 01/07/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	M MELISSA BALTZ BUTLER SNOW ET AL	AMS APOGEE VAULT SUSPENSION SYS K040537 (CERTIFIED)
2012-8661	12/06/2012 01/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	CHRISTIE EVANS HILL ROM	STRYKER - IBED WIRELESS WITH IBED AWARENESS K103536
2012-8662	12/06/2012 01/07/2013	FDA/OC/OES/DFOI/	WASHINGTON, MARK A	POLICIES & PROCEDURES FOR THE GENERAL DISCHARGE OF ALL DEBT
2012-8663	12/06/2012 01/07/2013	FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/ FDA/OC/OES/DFOI/ FDA/OGROP/ORА/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORА/NE-FO/NWE-DO/NWE-CB/	GABRIEL F ZAMBRANO FARMER JAFFE WEISSING EDWARDS FISTOS & LEHRMAN PL	BOEHRINGER INGELHEIM PHARMS - PRADAXA CAPS (DABIGATRAN ETEXILATE MESYLATE) RECALL RECS, CORR, NOTICES, ETC
2012-8664	12/06/2012 01/07/2013	FDA/OFVM/CFSAN/OCD/EOS/	MICHELE MITAL OLSSON FRANK WEEDA TERMAN MATZ PC	CAFFEINE INTAKE BY THE US POPULATION - RPT 9/09
2012-8665	12/06/2012 01/07/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORА/CE-FO/DET-DO/DET-CB/	PATTI WALLER MARLER CLARK ATTYS	CHAMBERLAIN FARMS PRODUCE INC - SALMONELLA TYPHIMURIUM AND SALMONELLA NEWPORT MULTISTATE OUTBREAK CORR, LAB RESULTS, TRACE BACK, ETC
2012-8666	12/06/2012 01/07/2013	FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/	PARAKKAL DEEPAK MD CENTER FOR THE STUDY OF COMPLEX DISEASES	ISRS 3910189, 3931338, 3931346, ETC 1/03 to 6/12

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2012-8667	12/06/2012 01/07/2013	FDA/OFVM/CFSAN/OCD/EOS/	DIANNE L CHAMBERS HOGAN LOVELLS US LLP	DKT 2012F-0480 - FAP
2012-8668	12/06/2012 01/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	ELLIOT FAVUS MD FAVUS INSTITUTIONAL RESEARCH LLC	HEARTWARE VENTRICULAR ASSIST SYS - MDRS
2012-8669	12/06/2012 01/07/2013	OC/ORO/ORM/ OC/ORO/ORM/	GAIL LESSICK LACHMAN CONSULTANT SERVICES INC	DOMESTIC AND FOREIGN DRUG COMPANIES, MEDICAL DVC MFRS, BIORESEARCH MONITORING (BIMO), ETC - INSPS 10/1-31/12
2012-8670	12/06/2012 01/07/2013	OC/ORO/ OC/ORO/	Doe J	PURINA DOG FOOD - ALUMINUM POISONING CMLNT
2012-8671	12/06/2012 01/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	TERAZOSIN, HYTRIN - AERS
2012-8672	12/06/2012 01/07/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/ OC/OCOS/OES/ OC/OCOS/OES/ OC/OCOS/OL/	BRODY MULLINS WALL STREET JOURNAL	SAC CAPITAL, CR INTRINSIC - RECS, CORR 1/1/05 TO 12/1/12
2012-8673	12/06/2012 01/07/2013	OC/OM/OMP/DDM/	COLLEEN CAMPBELL SIDLEY AUSTIN LLP	DKT 1998P-0610
2012-8674	12/06/2012 01/07/2013	OC/ORO/ OC/ORO/	Doe J	RANBAXY - MEDICATION CONTAMINATION CMLNT
2012-8675	12/06/2012 01/07/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	JUDY F GORDON DVM CLINREG CONSULTING	TRUEVISION SYSTEMS INC - K101861

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			SERVICES INC	
2012-8676	12/06/2012 01/07/2013	OC/OM/OMP/DDM/	THOMAS FITZGERALD FSI RESEARCH & SERVICES, INC.	DKT 1985N-0548, 1976G-0073
2012-8677	12/06/2012 01/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Virginia Anello DOUGLAS & LONDON	K823115
2012-8678	12/06/2012 01/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Virginia Anello DOUGLAS & LONDON	K852310
2012-8679	12/06/2012 01/07/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Virginia Anello DOUGLAS & LONDON	K070177
2012-8680	12/06/2012 01/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	NYCOMED GMBH, BADEN-WUERTTEMBERG, GERMANY - EIR (04/19/12)
2012-8681	12/06/2012 01/07/2013	OC/OER/OPA/	XIN GE INDIVIDUAL	DR SHIMIN FANG - RECS RE INVITATION TO SPEAK AT FDA ON 11/10/12 SPEECH
2012-8682	12/06/2012 01/07/2013	OC/OA/OM/OMP/DDM/	Mehul Govani PL DEVELOPMENTS	1995-S-0039
2012-8683	12/06/2012 01/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Anna Edney BLOOMBERG NEWS	SIDNEY GILMAN - FINANCIAL DISCLOSURE FORMS (01/01/2002 - 12/05/2012)
2012-8684	12/06/2012 01/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	KYOCERA Medical Corporation KYOCERA Medical Corporation	K011533
2012-8685	12/06/2012 01/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Virginia Anello DOUGLAS & LONDON	K922005
2012-8686	12/06/2012 01/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/OA/OM/OMP/DDM/	Jennie Laton HASSARD BONNINGTON LLP	SKIN BLEACHING OTC DRUGS - PROPOSED RULE, TENTATIVE FINAL MONOGRAPH, NOTICE OF PROPOSED RULEMAKING, ETC
2012-8687	12/06/2012 01/07/2013	FDA/OC/OES/DFOI/	MARY SCHWAGER WHDH-TV INC	AIRLINE CATERERS - INSP LAST 3 YRS

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2012-8688	12/06/2012 01/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Virginia Anello DOUGLAS & LONDON	K030497
2012-8689	12/06/2012 01/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Virginia Anello DOUGLAS & LONDON	K810925
2012-8690	12/06/2012 01/07/2013	FDA/OC/OES/DFOI/	KRISTI O SMEDLEY PHD WASHINGTON INFORMATION SOURCE	2011-9188
2012-8691	12/06/2012 01/07/2013	FDA/OC/OES/DFOI/	KRISTI O SMEDLEY PHD WASHINGTON INFORMATION SOURCE	2011-4550
2012-8692	12/06/2012 01/07/2013	OC/ORO/ OC/ORO/	Brittany Freeman WSMV TV	AMERIDOSE - COMPLAINTS REFERENCED IN 483
2012-8693	12/06/2012 01/07/2013	FDA/OC/OES/DFOI/	KRISTI O SMEDLEY PHD WASHINGTON INFORMATION SOURCE	2011-8937
2012-8694	12/06/2012 01/07/2013	FDA/OFVM/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 151606, 151607, 151881, ETC
2012-8695	12/06/2012 01/07/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Willard Bond Wells III PRIVATE CITIZEN	AMARIN VASCEPA - RESPONSE LETTER CIRCULATED BY CDER EXCLUSIVITY BOARD
2012-8696	12/06/2012 01/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Shelburne Ellipse Technologies, Inc.	K031219
2012-8697	12/06/2012 01/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Shelburne Ellipse Technologies, Inc.	K010322
2012-8698	12/06/2012 01/07/2013	OC/ORO/ OC/ORO/	Brittany Freeman WSMV TV	NECC, AMERIDOSE - PHOTOS, VIDEOS TAKING DURING INSPECTIONS
2012-8699	12/06/2012 01/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	John Cody Medi USA, LP	K941926
2012-8700	12/06/2012 01/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Virginia Anello DOUGLAS & LONDON	K823115
2012-8701	12/06/2012 01/07/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Brittany Freeman WSMV TV	ZZZQUIL - AERS (01/01/2010 - 12/05/2012)

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2012-8702	12/06/2012 01/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANNE SOLKINEN ORION PHARMA	DR KIMMO INGRAM, ORION PHARMA R&D, ESPOO, FINLAND - ALPRAZOLAM TABS ANDA 200-818 EIR 10/18-22/10
2012-8703	12/06/2012 01/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	FERNANDO SABA Laboratorios SL S.A.	K103816
2012-8704	12/06/2012 01/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lauren Tornetta Endo Pharmaceuticals Inc.	NDA 18401 - SBA
2012-8705	12/06/2012 01/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	DAVID HILZENRATH PROJECT ON GOVERNMENT OVERSIGHT	ZOSTAVAX - CORR, MEMOS, EMAIL ETC RE RISK ASSESSMENT
2012-8706	12/06/2012 01/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANNE SOLKINEN ORION PHARMA	DR F H VAN HEUVELN, XENDO DRUG DEVELOPMENT BV, BIOTECH CENTER, GRONINGEN, NETHERLANDS - ALPRAZOLAM TABS ANDA 200-818 EIR 10/4-8/10
2012-8707	12/06/2012 01/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tom Burton WALL STREET JOURNAL	COMPOUNDING PHARMACIES - AERS
2012-8708	12/06/2012 01/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANNE SOLKINEN ORION PHARMA	STEPHAN M JAKOB MD, INSELPITAL, BERN, SWITZERLAND - RECEDEX (DEXMEDETOMIDINE HCL INJ) NDA 21-038 EIR 3/26-29/12
2012-8709	12/06/2012 01/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANNE SOLKINEN ORION PHARMA	ANTHONY DUGARD MD, HOSPITAL DUPUYTREN, LIMOGES, FRANCE - RECEDEX (DEXMEDETOMIDINE HC; INJ) NDA 21-038 EIR 3/19-23/12

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2012-8710	12/07/2012 01/08/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	JOHNATHAN RICKMAN FDA NEWS	KUTOL PRODUCTS CO, SHARONVILLE, OH; ACCUPAK MIDWEST INC, CINCINNATI, OH; MEDICAL QUANT USA INC, SOLON, OH - 483S 10/1-31/12
2012-8711	12/07/2012 01/08/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	JOHNATHAN RICKMAN FDA NEWS	GRESKO PRODUCTS INC, STAFFORD, TX; ADVANCED AESTHETIC CONCEPTS LP (PROFITSOLUTIONS MD), FT WORTH, TX - 483S 10/1-31/12
2012-8712	12/07/2012 01/08/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	JOHNATHAN RICKMAN FDA NEWS	CODY LABORATORIES INC, CODY, WY; CERAPEDICS INC, WESTMINSTER, CO - 483S 10/1-31/12
2012-8713	12/07/2012 01/08/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	JOHNATHAN RICKMAN FDA NEWS	DANMAR PRODUCTS INC, ANN ARBOR, MI; KREMERS URBAN PHARMACEUTICALS INC, SEYMOUR, IN; ENZYME SOLUTIONS INC, GARRETT, IN - 483S 10/1-31/12
2012-8714	12/07/2012 01/08/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	JOHNATHAN RICKMAN FDA NEWS	THEOCHEM LABORATORIES INC, TAMPA, FL; SRI SURGICAL, TAMPA, FL; ASO LLC, SARASOTA, FL, ETC - 483S 10-1-31/12
2012-8715	12/07/2012 01/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHNATHAN RICKMAN FDA NEWS	EXCELLA GMBH, FEUCHT, GERMANY; SANDOZ GMBH, KUNDL, AUSTRIA; UMAN PHARMA INC, CANDIAC, CANADA, ETC - 483S 10/1-31/12
2012-8716	12/07/2012 01/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHNATHAN RICKMAN FDA NEWS	MALEM MEDICAL, NOTTINGHAM, UK; OY AJAT LTD, ESPOO, FINLAND; CREASPINE SAS, PESSAC, FRANCE, ETC - 483S 10/1-31/12
2012-8717	12/07/2012 01/08/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	JOHNATHAN RICKMAN FDA NEWS	HOSPIRA INC, MCPHERSON, KS - 483S 10/1-31/12
2012-8718	12/07/2012 01/08/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	JOHNATHAN RICKMAN FDA NEWS	NEOMPS INC, SAN DIEGO, CA; DAKO NORTH AMERICA INC, CARPINTERIA, CA; INNOVATIVE MED INC, IRVINE, CA, ETC - 483S 10/1-31/12
2012-8719	12/07/2012 01/08/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	JOHNATHAN RICKMAN FDA NEWS	CONKLIN COMPANY INC, SHAKOPEE, MN; ZYGA TECHNOLOGY INC, MINNEAPOLIS, MN; DANE TECHNOLOGIES, BROOKLYN PARK, MN, ETC - 483S 10-1-31/12
2012-8720	12/07/2012 01/08/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	JOHNATHAN RICKMAN FDA NEWS	ORTHO CLINICAL DIAGNOSTICS INC, RARITAN, NJ; PACON MFG CORP, SOMERSET, NJ - 483S 10/1-31/12
2012-8721	12/07/2012 01/08/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	JOHNATHAN RICKMAN FDA NEWS	RADIUS MEDICAL LLC, HUDSON, MA; IKONISYS INC, NEW HAVEN, CT; KEYSTONE DENTAL INC, BURLINGTON, MA, ETC - 483S 10/1-31/12
2012-8722	12/07/2012 01/08/2013	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	JOHNATHAN RICKMAN FDA NEWS	HOWARD INSTRUMENTS INC, TUSCALOOSA, AL - 483S 10/1-31/12

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2012-8723	12/07/2012 01/08/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	JOHNATHAN RICKMAN FDA NEWS	CHEMBIO DIAGNOSTIC SYSTEM INC, MEDFORD, NY; PROPPER MFG CO INC, LONG ISLAND CITY, NY; BUSSE HOSPITAL DISPOSABLES, HAUPPAUGE, NY, ETC - 483S 10/1-31/12
2012-8724	12/07/2012 01/08/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	JOHNATHAN RICKMAN FDA NEWS	BEST MEDICAL INTERNATIONAL INC (BEST NOMOS), PITTSBURGH, PA - 483S 10/1-31/12
2012-8725	12/07/2012 01/08/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	JOHNATHAN RICKMAN FDA NEWS	AESTHETIC AND RECONSTRUCTIVE TECHNOLOGIES INC, RENO, NV; TERARECON INC, FOSTER CITY, CA; SCITON INC, PALO ALTO, CA - 483S 10/1-31/12
2012-8726	12/07/2012 01/08/2013	FDA/OFVM/CFSAN/OCD/EOS/	SEAN HIGGINS, Esq ANDREWS THORNTON	MONSTER REHAB GREEN TEA & ENERGY; DIETARY SUPPLEMENTS CONTAINING EPIGALLOCATECHIN 3 GALLATE - AER
2012-8727	12/07/2012 01/08/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PATRICK E. LUPINETTI FIRST DATABANK	BULK INGREDIENTS FOR HUMAN RX COMPOUNDING - LBLG
2012-8728	12/07/2012 01/08/2013	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	JOHNATHAN RICKMAN FDA NEWS	CUSTOM OCULAR PROSTHETICS INC, SEATTLE, WA; ELIXIR RESEARCH LLC, VASHON, WA; DE HOKANSON INC, BELLEVUE, WA - 483 10/12
2012-8729	12/07/2012 01/08/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	JOHNATHAN RICKMAN FDA NEWS	ABC COMPOUNDING CO INC, MORROW, GA; CAROLINA MEDICAL PRODUCTS CO, FARMVILLE, NC; CRYOLIFE INC, KENNESAW, GA - 483 10/12
2012-8730	12/07/2012 01/08/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	JOHNATHAN RICKMAN FDANEWS	AG ESSENCE INC, RICHMOND, VA; PHARMACEUTICALS INT'L INC, HUNT VALLEY, MD - 483 10/12
2012-8731	12/07/2012 01/08/2013	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	JOHNATHAN RICKMAN FDA NEWS	AKORN INC, DECATUR, IL; RAANI CORP, BEDFORD PARK, IL; HOME ACCESS HEALTH CORP, HOFFMAN ESTATES, IL - 483 10/12
2012-8732	12/07/2012 01/08/2013	FDA/OMPT/CTP/OD/	DESMOND JENSON Tobacco Control Legal Consortium	SMOKEMATE - ECIGARETTES INVESTIGATION
2012-8733	12/07/2012 01/08/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	PATRICIO T.D. BARRERA BARRERA & ASSOCIATES	KRAMER LABS INC - CORR, WARNING LTR, CASE FLA 06-05
2012-8734	12/07/2012 01/08/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RAVI DESHPANDE ACINO PRODUCTS LLC	TARO PHARMACEUTICALS - TERCONAZOLE VAGINAL SUPPOSITORY ANDA 077553, PROMETHAZINE HYDROCHLORIDE SUPPOSITORY ANDA 040603, PROMETHAZINE HYDROCHLORIDE SUPPOSITORY ANDA 040603 - SBA
2012-8735	12/07/2012 01/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	JAY WINCKLER WINCKLER & HARVEY LLP	LANX SPINAL FIXATION SYS K093285

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2012-8736	12/07/2012 01/08/2013	FDA/OFVM/CFSAN/OCD/EOS/ OC/OCOS/OES/ OC/OCOS/OES/ OC/OCOS/OL/	ERIKA DUTHELY ENVIRONMENTAL WORKING GROUP	BRAZILIAN BLOWOUT - CMLPTS, AER SINCE 1/11
2012-8737	12/07/2012 01/08/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHRISTOPHER HENDEL CONSUMER REPORTS	RELAXATION - AER, 1/04 TO PRESENT
2012-8738	12/07/2012 01/08/2013	FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/	VICTORIA SCOTT HEMISPHERX BIOPHARMA	HEMISPHERX BIOPHARMA INC - INSP 11/27-28/12
2012-8739	12/07/2012 01/08/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	MICHAEL LOUIK ROSEN LOUIK ET AL	DEPUY ORTHOPAEDICS INC - 3 PEG MOD ROT PATELLA CEMENTED
2012-8740	12/07/2012 01/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	WILSON, KATE	IVANO FRANKOVSK REGIONAL FORENSIC MEDICAL BUREAU, UKRAINE FEI 3007016079
2012-8741	12/10/2012 01/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	UNITED STATES SURGICAL CORP - LETTER FROM FDA RE RECLASSIFICATION OF NONABSORBABLE PET SUTURES (07/05/1990)
2012-8742	12/10/2012 01/09/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DDM/	Rachel Johnson FOI Services, Inc.	ADVANCED BIORESEARCH ASSOCIATES - PETITION FOR RECLASSIFICATION RE SURGICAL SUTURES
2012-8743	12/10/2012 01/09/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	KYOCERA Medical Corporation KYOCERA Medical Corporation	K050327
2012-8744	12/10/2012 01/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Shelburne Ellipse Technologies Inc	K023941
2012-8745	12/10/2012 01/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	JILL GOLDSTEIN GOLDSTEIN, JILL S	K122350
2012-8746	12/10/2012 01/09/2013	FDA/OGROP/ORACE-FO/BLT- DO/BLT-CB/	Charlotte Dannenfesler BD DIAGNOSTIC SYSTEMS	BD DIAGNOSTIC SYSTEMS, SPARKS, MD - EIR (04/23/10)
2012-8747	12/10/2012 01/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	INDIVIDUAL RECS

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2012-8748	12/10/2012 01/09/2013	FDA/OFVM/CFR/OC/EO/	Rachel Johnson FOI Services, Inc.	FCN 647
2012-8749	12/10/2012 01/09/2013	FDA/OC/OES/DFOI/	Maryann Ivie COSGRAVE VERGEER KESTER LLP	FOIA REQUESTS RE INVACARE (02/01/2008 - 11/30/2012)
2012-8750	12/10/2012 01/09/2013	FDA/OGROP/ORA/CE-FO/CIN- DO/CIN-CB/	Eric Gandhi Robeco Investment Mgmt.	INVACARE CORP, OHIO - 483 (06/01/2011 - 08/31/2011)
2012-8751	12/10/2012 01/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Robert Willimas Shire Pharmaceuticals	VYVANSE - AERS
2012-8752	12/10/2012 01/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Shelburne Ellipse Technologies, Inc.	K092138
2012-8753	12/10/2012 01/09/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K060119
2012-8754	12/10/2012 01/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Shelburne Ellipse Technologies, Inc.	K011354
2012-8755	12/10/2012 01/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Joakim Arwidson Hermes Medical Solutions	K093982
2012-8756	12/10/2012 01/09/2013	OC/OA/OM/OMP/DDM/ FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	GENERAL AND PLASTIC SURGERY DEVICES PANEL MEETING - SUPPORTING MATERIALS (10/20/1988)
2012-8757	12/10/2012 01/09/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	AnnMarie Beattie Harmonized Customs Brokers, Inc	ENTRY G76-0129576-7 - LAB RESULTS
2012-8758	12/10/2012 01/09/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Rachel Johnson FOI Services, Inc.	MIGUEL WENCASLAO TREGNAGHI, ARGENTINA - EIR, 483, WARNING LETTER, ETC
2012-8759	12/10/2012 01/09/2013	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOGS 11/12-16/12
2012-8760	12/10/2012 01/09/2013	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION	FOI DAILY LOG 11/19-23/12

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			SOURCE	
2012-8761	12/10/2012 01/09/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 11/12-16/22
2012-8762	12/10/2012 01/09/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 11/19-23/12
2012-8763	12/10/2012 01/09/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 11/12-16/12
2012-8764	12/10/2012 01/09/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DALILY LOG 11/19/23/12
2012-8765	12/10/2012 01/09/2013	FDA/OC/OES/DFOI/	GLADYS B TONKINS WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 11/12-16/12
2012-8766	12/10/2012 01/09/2013	FDA/OC/OES/DFOI/	GLADYS B TONKINS WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 11/19-12/12
2012-8767	12/10/2012 01/09/2013	FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 11/19/23/12
2012-8768	12/10/2012 01/09/2013	FDA/OC/OES/DFOI/	DEBI L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 11/12-16/12
2012-8769	12/10/2012 01/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHNATHAN A KNOLL COHEN & MALAD LLP	FRESSENIUS MEDICAL CARE NORTH AMERICA - NATURALYTE LIQUID ACID CONCENTRATE & NATURALYTE GRANUFLO (POWDER) ACID CONCENTRATE K30497, K023985, K911459, ETC (CERTIFIED)
2012-8770	12/10/2012 01/09/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	JONATHAN A KNOLL COHEN & MALAD LLP	FRESSENIUS MEDICAL CARE NORTH AMERICA - NATURALYTE LIQUID ACID CONCENTRATE & NATURALYTE GRANUFLO (POWDER) ACID CONCENTRATE MEMOS, CORR RECALL, ETC
2012-8771	12/10/2012 01/09/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	JOHN CREWDSON PROJECT ON GOVERNMENT OVERSIGHT	XIGRIS (DROTRECOGIN ALFA); MERIDA (SIBUTRAMINE); REDUCITIL (SIBUTRAMINE), ETC - CLNCL INSP SUMMARIES
2012-8772	12/10/2012 01/09/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	JOHN CREWDSON PROJECT ON GOVERNMENT	MERCK - ZOSTAVAX VACCINE OSI CLNCL INSP SUMMARIES

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			OVERSIGHT	
2012-8773	12/10/2012 01/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MICHAEL R COHEN INSTITUTE FOR SAFE MEDICATION PRACTICES	MEDWATCH RPTS CODES AS MEDICATION ERRORS 11/1-30/12
2012-8774	12/10/2012 01/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CANDICE DURENCE OPTIMER PHARMACEUTICALS INC	DIFICID (FIDAXOMICIN) NDA 201-699 - ISR 8652998, 8691126
2012-8775	12/10/2012 01/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	RINGELHEIM, A	PROLIA - AERS
2012-8776	12/10/2012 01/09/2013	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	LORI KERSEY CHARLESTON GAZETTE	YEAGER AIRPORT, CHARLESTON, WV; TRI-STATE AIRPORT, HUNTINGTON, WV; NORTH CENTAL WEST VIRGINA AIRPORT, CLARKSBURG, WV, ETC - EIRS 2011, 2012
2012-8777	12/10/2012 01/09/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	JANPAUL PORTAL FERRARO LAW FIRM	INDIVIDUAL RECS
2012-8778	12/10/2012 01/09/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	JOHN-MARK ZINI GIDEON COOPER & ESSARY	ARL LBIOPHARMA INC (ANALYTICAL RESEARCH LABS), OKAHOMA CITY, OK - 483S
2012-8779	12/10/2012 01/09/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OMPT/CDRH/OCER/DFOI/	STACI M TROLIAN BIOMET	DR MARK ALAN MIGHELL- CO RESP TO WARNING LTR 7/6/05
2012-8780	12/10/2012 01/09/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	JONATHAN A KNOLL COHEN & MALAD LLP	FRESSNIUS MEDICAL CARE NORTH AMERICA - NATURALYTE LIQUID ACID CONCENTRATE & NATURALYTE GRANUFLO (POWDER) ACID CONCENTRATE - EIRS, 483S 2006 (CERTIFIED)

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2012-8781	12/10/2012 01/09/2013	FDA/OMPT/CTP/OD/	DESMOND JENSON Tobacco Control Legal Consortium	METRO SUPER SAVER - SMOKELESS TOBACCO PROD, MARBORO LIGHTS INVESTIGATION & FOLLOW-UP ACTION
2012-8782	12/10/2012 01/09/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Kristan Phillips MacroGenics	MEDIVATION, SAN FRANCISCO, CA - 483 (06/27/12)
2012-8783	12/10/2012 01/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	John Crewdson PROJECT ON GOVERNMENT OVERSIGHT	OBSERVATIONAL POST-LICENSURE SAFETY STUDY FOR ZOSTOVAX IN A US HEALTH MAINTENANCE ORGANIZATION
2012-8784	12/10/2012 01/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	DAVID HILZENRATH PROJECT ON GOVERNMENT OVERSIGHT	POSTMARKET COMMITMENT 234570 - ANNUAL REPORT (6/18/2012), FINAL REPORT (12/30/2009)
2012-8785	12/10/2012 01/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Elisabeth Neely St. Jude Medical	P920015 S017
2012-8786	12/10/2012 01/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shannon Pettypiece BLOOMBERG NEWS	ATORVASTATIN - AERS
2012-8787	12/10/2012 01/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	E Neely St. Jude Medical	P920015 S090
2012-8788	12/10/2012 01/09/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	Rebecca Maciel FoodScience Corporation	ABH NATURE'S PRODUCTS, FARMINGDALE, NY - 483 (06/01/2012 - 06/30/2012)
2012-8789	12/10/2012 01/09/2013	FDA/OFVM/CFSAN/OCD/EOS/ OC/OA/OM/OMP/DDM/	Merle Zimmermann (ext 106) AMERICAN HERBAL PRODUCTS ASSOCIATION	NEW DIETARY INGREDIENTS - ALL RECS

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2012-8790	12/10/2012 01/09/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shannon Pettypiece BLOOMBERG NEWS	ATORVASTATIN - CORR BETWEEN FDA AND RANBAXY, OHM RE NOVEMBER 2012 RECALL
2012-8791	12/10/2012 01/09/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	Shannon Pettypiece BLOOMBERG NEWS	ENDO HEALTH SOLUTIONS, QUALITEST - CORR WITH FDA RE DECEMBER 2012 RECALL OF HYDROCODONE BITARTRATE AND ACETAMINOPHEN TABLETS
2012-8792	12/10/2012 01/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shannon Pettypiece BLOOMBERG NEWS	RANBAXY LABORATORIES, OHM LABORATORIES, TOANSA AND PUNJAB, INDIA - INSPECTION RECS (12/07/1995 - 12/07/2012)
2012-8793	12/10/2012 01/09/2013	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	Doe J	GC CORPORATION (GE AMERICA) - COMPLAINT FOLLOW UP
2012-8794	12/11/2012 01/10/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	BRENDA M. GARTZ ELI LILLY & CO	OSO BIOPHARMACEUTICALS, ALBUQUERQUE, NM - EIR 4/12
2012-8795	12/11/2012 01/10/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENDA M. GARTZ ELI LILLY & CO	LONZA, BRAIN, BELGIUM - EIR 6/12
2012-8796	12/11/2012 01/10/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	BRENDA M. GARTZ ELI LILLY & CO	EVONIK DEGUSSA CORP, LAFAYETTE, INDIANA - EIR 3/12
2012-8797	12/11/2012 01/10/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Dennis R. Gwaltney DePuy Orthopaedics, Inc.	DEPUY ORTHOPAEDICS, WARSAW, IN - EIR (05/10/2011 - 06/07/2011)
2012-8798	12/11/2012 01/10/2013	FDA/OFVM/CFSAN/OCD/EOS/	Justin J. Prochnow Justin J. Prochnow	VARIOUS PRODUCTS - CAERS (07/01/2004 - 10/23/2012)

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2012-8799	12/11/2012 01/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENDA M. GARTZ ELI LILLY & CO	GLAND PHARMA LTD, HYDERABAD, INDIA - EIR 8/12
2012-8800	12/11/2012 01/10/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	BRENDA M. GARTZ ELI LILLY & CO	GIRINDUS AMERICA INC, CINCINNATI, OH - EIR 2/12
2012-8801	12/11/2012 01/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dr. Michael Seminerio UNIVERSITY OF CHICAGO	TARCEVA - STUDY RESULTS
2012-8802	12/11/2012 01/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jeanna M Marraffa Pharm.D., DABAT Upstate NY Poison Center	LOPERAMIDE - AERS
2012-8803	12/11/2012 01/10/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	BRENDA M. GARTZ ELI LILLY & CO	FISHER CLNCL SERVICES, ALLENTOWN, PA - EIR 11/11
2012-8804	12/11/2012 01/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	Andrea Sudano Rocco Andrea Sudano	ANTIBIOTICS - WEIGHT LOSS AND AERS
2012-8805	12/11/2012 01/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Dr. Salvador Fornell Prez Dr. Fornell. Hospital Virgen del Rocío	EBI OSTEOGEN 20 - APPROVAL RECS
2012-8806	12/11/2012 01/10/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Samuel Medrano Private Individual	FRESENIUS MEDICAL CARE, BATTLE CREEK, MI - USE OF GRANUFLO AND NATURALYTE, SAFETY ISSUES
2012-8807	12/11/2012 01/10/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	John Chapman Stem Cell Partners LLC	BK110040
2012-8808	12/11/2012 01/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KEITH CHASIN LAW OFFICE OF KEITH CHASIN	INDIVIDUAL RECS

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2012-8809	12/11/2012 01/10/2013	FDA/OFVM/CFSAN/OCD/EOS/	Murray Carpenter Murray Carpenter	SUNKIST SODA - CAERS (09/01/2010 - 08/31/2011)
2012-8810	12/11/2012 01/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	ORI GOREN MOVING LIFE LTD	TZORA ACTIVE SYS LTD - ELITE ULTRA LIGHT COMPACT PORTABLE SCOOTER K052204; FREEFIDER LUGGIE SCOOTERS INC - MODEL 168-41T K110165; ELITE EXTRA LIGHT K052204
2012-8811	12/11/2012 01/10/2013	FDA/OFVM/CFSAN/OCD/EOS/	J. ANDREW MEYER, Esq. MORGAN & MORGAN	MARTEK BIOSCIENCES CORP - HORIZON ORGANIC MILK PLUS DHA OMEGA 3 DKT 2324
2012-8812	12/11/2012 01/10/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	CHRISTOPHER M. SHKRELI GOLDBERG SEGALLA	FOREVER CHEESE, LONG ISLAND, NY - FRESCOLINA RICOTTA SALATA LISTERIA OUTBREAK
2012-8813	12/11/2012 01/10/2013	OC/CVM/OCD/	STEVE D. MATTERI CONTEMPORARY PRODUCTS INC	SICHUAN LONG MARCH PHARMACEUTICAL CO LTD, LESHAN, SICHUAN, CHINA - EIR 9/09 TO 9/11
2012-8814	12/11/2012 01/10/2013	OC/OM/OMP/DDM/	THOMAS FITZGERALD FSI RESEARCH & SERVICES, INC.	DKT 1976G-0445, 1977G-0049
2012-8815	12/11/2012 01/10/2013	OC/OM/OMP/DDM/	CHRIS CELESTE EAS Consulting Group, LLC	DKT 1976N-0052
2012-8816	12/11/2012 01/10/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN CREWDSON PROJECT ON GOVERNMENT OVERSIGHT	MERCK SHARPE & DOHME CORP, WEST PT, PA - VACCINES & ALLERGENIC PRODUCTS; MERCK SERONO SPA, GUIDONIA MONTECELIO; MERCK SHARP & DOHME CORP, ELKTON, VA - VACCINES & ALLERGENIC PRODUCTS - RVWS, INSP
2012-8817	12/11/2012 01/10/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	MIKE SCHNEIDER BOOKHARDT & OTOOLE	KASEL, DENVER, CO - INSP12/11 TO PRESENT
2012-8818	12/11/2012 01/10/2013	FDA/OFVM/CFSAN/OCD/EOS/	D. GREGORY BLANKINSHIP MEISELMAN DENLEA ET AL	PLANT STEROLS - STUDIES

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2012-8819	12/11/2012 01/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SUSAN PRISET HARTLEY HAMPTON PC	SEMINAL EVENT RPT FILED BY MD ANDERSON RE INDIVIDUAL REC
2012-8820	12/11/2012 01/10/2013	FDA/OGROP/ORR/SW-FO/DEN- DO/DEN-CB/	BRENTON L. HORNER HORNER & ASSOCIATES	CORR BETWEEN FDA & WORLD HEALTH PRODUCTS LLC
2012-8821	12/11/2012 01/10/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	LAM, NELSON .	AGA MATRIX K103544
2012-8822	12/12/2012 01/11/2013	FDA/OFVM/CFSAN/OCD/EOS/	MARILYNN WHITNEY COVINGTON BURLING LLP	COCA-COLA - CAERS 1/04 TO PRESENT
2012-8823	12/12/2012 01/11/2013	FDA/OFVM/CFSAN/OCD/EOS/	MARILYNN WHITNEY COVINGTON BURLING LLP	PEPSI - CAERS 1/04 TO PRESENT
2012-8824	12/12/2012 01/11/2013	FDA/OFVM/CFSAN/OCD/EOS/	MARILYNN WHITNEY COVINGTON BURLING LLP	DR PEPPER - CAERS 1/04 TO PRESENT
2012-8825	12/12/2012 01/11/2013	FDA/OFVM/CFSAN/OCD/EOS/	MARILYNN WHITNEY COVINGTON BURLING LLP	MOUNTAIN DEW - CAERS 1/04 TO PRESENT
2012-8826	12/12/2012 01/11/2013	FDA/OFVM/CFSAN/OCD/EOS/	MARILYNN WHITNEY COVINGTON BURLING LLP	STARBUCKS COFFEE - CAERS 1/04 TO PRESENT
2012-8827	12/12/2012 01/25/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	WEAVER, JOHN D	HEK293 - APRVL RECS, BRIEFING RECS
2012-8828	12/12/2012 01/25/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	WEAVER, JOHN D	PER.C6 - APRVL RECS, BRIEFING RECS
2012-8829	12/12/2012 01/11/2013	FDA/OFVM/CFSAN/OCD/EOS/	ROBERT S MCQUATE GRAS ASSOCIATES LLC	FCN 736
2012-8830	12/12/2012 01/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	JASON SMITH BEDFONT SCIENTIFIC LTD	FIM MEDICAL - TABATABA CO TESTER CPT1200508 RECS
2012-8831	12/12/2012 01/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DOUG DIX UNIV OF HARTFORD	CANNABIS (MARIJUANA) - DRUG ENFORCEMENT APRVL RECS, FDA APRVL RECS

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2012-8832	12/12/2012 01/11/2013	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	MELINDA F LEVITT	NIH PROTOCOL 08-CH-0203 - EIR 10/11
2012-8833	12/12/2012 01/11/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	Doe J	AFTERSHOCK TATTOO, OLATHE, KS - TATTOO RPT
2012-8834	12/12/2012 01/11/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	JENNIFER CONNER AMERICAN CLAIMS MANAGEMENT	PRIME ORTHOPEDICS (PRIME MEDICAL RESOURCES) - APPL, DVC LISTING REGISTRATIONS, LICENSING, ETC 1/03 TO 12/12
2012-8835	12/12/2012 01/11/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	ROMAN LEBEDINSKIY TRAUB LIEBERMAN STRAUS ET AL	RAGE RV3, RAGE RV5, EPIO-PLEX, ETC - CORR, RECALL, RESP TO WARNING LTR, ETC 11/3/09
2012-8836	12/12/2012 01/11/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	STEPHEN HELLER HELLER LAW FIRM	BETANCOURT NUTRITION INC - RIPPED JUICE EX2 CMLNPTS, CAERS, COMM, ETC
2012-8837	12/12/2012 01/11/2013	FDA/OC/OES/DFOI/	Johnathan Rickman FDA NEWS	FOIA LOG (12/03/2012 - 12/07/2012)
2012-8838	12/12/2012 01/11/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OC/OES/DFOI/	Robert M. Goldman CL King & Associates	HILL-ROM, INC, BATESVILLE, IN - 483 (08/10/2011 - 12/10/2012)
2012-8839	12/12/2012 01/11/2013	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORA/ OC/ORA/	Richard O. Wood the Wood Burditt group	LIBRARY INFORMATION BULLETIN 4434 2; ACTION LEVEL, TOLERANCE, OR GUIDANCE LEVEL FOR TETRACYCLINE IN HONEY
2012-8840	12/12/2012 01/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	Gary Syring GRAY LTD	K955589, K010096, K110556
2012-8841	12/12/2012 01/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Suzanne O'Shea FAEGRE BAKER DANIELS	INO THERAPEUTICS - FORMS 3542 AND/OR 3542A RE NDA 20845 FOR PATENTS 8,291,904 AND 8,293,284; CORR
2012-8842	12/12/2012 01/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bernie Burgess BURGESS, BERNIE	IND 49105 GCP FILE 1840
2012-8843	12/12/2012	FDA/OMPT/CDER/GRP/DIDP/	Stacy Woeppel	DIPRIVAN (NDA 019627) - QUALITY REVIEW

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	01/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	B. Braun Medical Inc.	
2012-8844	12/13/2012 01/14/2013	FDA/OGROP/ORAN/NE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Kelly A. Fitzpatrick The Lanier Law Firm	FRESENIUS MEDICAL CARE - GRANUFLO/NATURALYTE RECS, CORR, MDRS ETC
2012-8845	12/13/2012 01/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ISR 7702455-3
2012-8846	12/13/2012 01/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	Michelle Meyer ATS Labs	K120306
2012-8847	12/13/2012 01/14/2013	FDA/OGROP/ORAN/SW-FO/DAL-DO/DAL-CB/	Angela STagg IMPULSE DYNAMICS	SURESH NEELAGARU, AMARILLO, TX - EIR, 483 RESPONSE, FINAL DETERMINATION (10/10/2012 - 10/19/2012)
2012-8848	12/13/2012 01/14/2013	FDA/OFVM/CFSAN/OCD/EOS/	Kevin D. Tucker EXPONENT	CONSULTATION DOCUMENT FOR MON 87460
2012-8849	12/13/2012 01/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	ATROVENT - MEDICAL OFFICER REVIEW
2012-8850	12/13/2012 01/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shannon Pettypiece BLOOMBERG NEWS	RANBAXY, PUNJAB, IN - 483 2009, 2011; EIR 2000, 2003
2012-8851	12/13/2012 01/14/2013	FDA/OGROP/ORAN/SW-FO/KAN-DO/KAN-CB/	Michael C. Cotugno Cotugno, Michael C	DYNALABS, ST LOUIS, MO - 483 MOST RECENT
2012-8852	12/13/2012 01/14/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOETTE GIOVINCO MD WTVT FOX 13	KERATIN COMPLEX SMOOTHING THERAPY, KERATIN COMPLEX PRODUCTS - AERS, COMPLAINTS, MONITORING STUDIES
2012-8853	12/13/2012	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson	FCN 527

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	01/14/2013		FOI Services, Inc.	
2012-8854	12/13/2012 01/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	Peter A. Takes Kypha, Inc.	K981783
2012-8855	12/13/2012 01/14/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Thomas W. Cooley Cooley, Thomas W	DYNALABS, ST LOUIS, MO - 483 (12/12/2011 - 12/11/2012)
2012-8856	12/13/2012 01/14/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	John Fanikos Fanikos, John	DYNALABS, ST LOUIS, MO - 483 MOST RECENT
2012-8857	12/13/2012 01/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA203214
2012-8858	12/13/2012 01/14/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	John Beasley MedTech Review, LLC	K100878
2012-8859	12/13/2012 01/14/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	Rachel Johnson FOI Services, Inc.	FRESCA FOODS, LOUISVILLE, CO - 483, WL
2012-8860	12/13/2012 01/14/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Katie Thomas NEW YORK TIMES	RANBAXY - EIR, 483, CORR (01/01/2012 - 12/12/2012)
2012-8861	12/13/2012 01/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	ShaeAnn Cavanagh AGFA Healthcare	K050228
2012-8862	12/13/2012 01/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Danielle Starr Foster & Eldridge	IMPORTANT DRUG WARNING CONCERNING UNAPPROVED USE OF INTRAVAGINAL OR ORAL MISOPROSTOL IN PREGNANT WOMEN FOR INDUCTION OR LABOR OR ABORTION (08/23/00)
2012-8863	12/13/2012 01/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	Dr. Diane Sudduth Biovance	K102461
2012-8864	12/13/2012 01/14/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Dr. Diane Sudduth Biovance	K092191
2012-8865	12/13/2012 01/14/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Janice Gardner ood Safe Pacific LLC	GATE GOURMET, INC, HONOLULU, HI - EIR MOST RECENT (01/02/2012 - 12/12/2012)

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2012-8866	12/13/2012 01/14/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORO/ OC/ORO/	Amy Shipley The Fort Lauderdale Sun-Sentinel	PHARMACIES IN FLORIDA - AERS, COMPLAINTS
2012-8867	12/13/2012 01/14/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	MICHAEL ROYBAL ROYBAL GLOBAL	DYNALABS - 483 2010 TO 2012
2012-8868	12/13/2012 01/14/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	MICHAEL ROYBAL ROYBAL GLOBAL	ANALYTICAL RESEARCH LABS - 483 2010 TO 2012
2012-8869	12/13/2012 03/12/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	CHARLES CELESTE EAS Consulting Group, LLC	GLAXO SMITH KLINE - INFANRIX BL 103647 LBLG, APRVL, CHEM RVW
2012-8870	12/13/2012 03/12/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	CHARLES CELESTE EAS Consulting Group, LLC	SANOFI PASTEUR - DALTACEL BL 103666 APRVL, LBLG, CHEM RVW
2012-8871	12/13/2012 03/12/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	CHARLES CELESTE EAS Consulting Group, LLC	GLAXO SMITH KLINE - ENGERIX BL 103239 APRVL, LBLG, CHEM RVW
2012-8872	12/13/2012 03/12/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	CHARLES CELESTE EAS Consulting Group, LLC	MERCK & CO - RECOMBIVAX HB BL 101066 APRVL, LBLG, CHEM RVW
2012-8873	12/13/2012 01/14/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M. GARTZ ELI LILLY & CO	VETTER PHARMA FERTIGUNG GMGH & CO, LANGENARGEN, GERMANY - EIR 7/12
2012-8874	12/13/2012 01/14/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M. GARTZ ELI LILLY & CO	VETTER PHARMA FERTIGUNG GMGH & CO, RAVENSBURG, GERMANY -EIR 4/12
2012-8875	12/13/2012 01/14/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	BRENDA M. GARTZ ELI LILLY & CO	TECH GROUP, TEMPE, AZ - EIR 10/11
2012-8876	12/13/2012 01/14/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M. GARTZ ELI LILLY & CO	SANDOZ, KUNDL, AUSTRIA - EIR 8/12
2012-8877	12/13/2012	FDA/OFVM/CFSAN/OCD/EOS/	PETER EISLER	PROTEIN POWDER/SHAKE FOR MUSTLE GROWTH - AER

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	01/14/2013		USA TODAY	
2012-8878	12/13/2012 01/14/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	MICHAEL D. MARRS CONYBEARE LAW OFFICE P C	DR SYBESMA, LAKELAND REGIONAL HEALTH SYS - PLEXUR M BONE GRAFT AER
2012-8879	12/13/2012 01/14/2013	FDA/OC/OES/DFOI/	BRODY MULLINS WALL STREET JOURNAL	WEDBUSH SECURITIES - FOI 1/10 TO PRESENT
2012-8880	12/13/2012 01/14/2013	OC/ORAC/ OC/ORAC/	ELCE M. ROGERS Dymatize Nutrition	CMPLNT 128733
2012-8881	12/13/2012 01/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KAYLEE WHITE SALAMANDRA LLC	MEDWATCH 7853733, 7853742
2012-8882	12/13/2012 01/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	VINEET SARIN, PhD. KINAMED INC	KINAMED INC, CAMARILLO, CA - K032950, K010101, K994214 NON REDACTED
2012-8883	12/13/2012 01/14/2013	OC/OM/OMP/DDM/	JENNIFER PELAIA COVINGTON BURLING LLP	DKT FDA-2012-P-0904
2012-8884	12/13/2012 01/14/2013	FDA/OO/OFBA/OAGS/	Fay Barnes - IQ Solutions IQ Solutions	OFFICE OF WOMEN'S HEALTH RFTOP NATIONAL WOMEN AND GIRLS HIV/AIDS AWARENESS DAY 2013 - RFP, STATEMENT OF WORK, MONTHLY REPORTS, ETC.
2012-8885	12/13/2012 01/14/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Doe J	INDIVIDUAL RECS
2012-8886	12/14/2012 01/15/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Dustin Strickland GREER LABORATORIES, INC.	GREER LABORATORIES, INC, LENOIR, NC - COMPLAINT
2012-8887	12/14/2012 01/15/2013	OC/ORAC/ OC/ORAC/	Amy Shipley The Fort Lauderdale Sun-Sentinel	FLORIDA PHARMACIES - INSPECTIONS 2009-2012; INFUPHARMA - INSPECTION RECS, CORR SINCE 7/30/12
2012-8888	12/14/2012 01/15/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Julie Donnelly Boston Business Journal	JUDGE ROTENBERG EDUCATIONAL CENTER, CANTON, MA - UNTITLED LETTER (05/23/2011)
2012-8889	12/14/2012 01/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	SUPPRELIN LA IMPLANT - SIDE EFFECTS
2012-8890	12/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	Steve Pardue	K092141; K090519

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	01/15/2013		Elevate Oral Care	
2012-8891	12/14/2012 01/15/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OC/OES/DFOI/	Dr. Paul Knoepfler UNIVERSITY OF CALIFORNIA, DAVIS	CELLTEX, RNL BIO, HUMAN BIOSTAR, ETC - APPROVAL RECS
2012-8892	12/14/2012 01/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Marcia L Zucker ZIVD, LLC	K121679
2012-8893	12/14/2012 01/15/2013	FDA/OMPT/CTP/OD/	Ryan Meyer HAGENS BERMAN SOBOL SHAPIRO LLP	HC0000048, HC0000067, HC0000068 ETC
2012-8894	12/14/2012 01/15/2013	OC/ORO/ OC/ORO/	Doe J	INDIVIDUAL RECS
2012-8895	12/14/2012 01/15/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tom Brakel Federated Investors	RELISTOR - AERS
2012-8896	12/14/2012 01/15/2013	OC/ORO/ OC/ORO/	Christy Wissman WhiteWave Foods	WHITEWAVE FOOD, MOUNT CRAWFORD, VA - TEST RESULTS
2012-8897	12/14/2012 01/15/2013	FDA/OFVM/CFSAN/OCD/EOS/	Nguyet Tran Tran Law Offices	USP LABS, LLC - WARNING LETTER (CERTIFIED)
2012-8898	12/14/2012 01/15/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kevin Butterfield Butterfield Technologies, LLC	K914190
2012-8899	12/14/2012 01/15/2013	FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/	Heather Neely, Sr. Director RA/QA Kinamed, Inc.	KINAMED, INC, CAMARILLO, CA - UNREDACTED EIRS (05/25/1993 - 12/11/1997)
2012-8900	12/14/2012 01/15/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K040985
2012-8901	12/14/2012 01/15/2013	FDA/OFVM/CFSAN/OCD/EOS/ OC/OCOS/OES/ OC/OCOS/OES/ FDA/OC/OES/DFOI/	Dale A. Scott Bell & Roper, P.A.	FOUR LOKO - GRAS REVIEW, CORR, SETTLEMENTS, ETC
2012-8902	12/14/2012 01/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	David Lin Shoprider Mobility Products, Inc.	MW5027704 SHOPRIDER STREAMER SPORT POWER CHAIR MODEL 888WA - SERIAL NUMBER, DATES OF USE

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2012-8903	12/14/2012 01/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Alison Mann Stuebe UNC School of Medicine	ISR 6617751, 6902283, 7016471, ETC
2012-8904	12/14/2012 01/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Alison Mann Stuebe UNC School of Medicine	DOMPERIDONE - FAERS
2012-8905	12/14/2012 01/15/2013	FDA/OFVM/CFSAN/OCD/EOS/	Dale A. Scott Bell & Roper, P.A.	PHUSION PROJECTS - CORR RE MANUFACTURE AND SALE OF ALCOHOLIC BEVERAGES CONTAINING CAFFEINE (11/13/09); CITY BREWING CO - CORR RE MANUFACTURE AND SALE OF ALCOHOLIC BEVERAGES CONTAINING CAFFEINE (11/13/09)
2012-8906	12/14/2012 01/15/2013	OC/ORO/ OC/ORO/ OC/CVM/OCD/	Kristina Worsham Worsham, Kristina	DIAMOND PET FOODS, KIRKLAND, COSTCO - COMPLAINTS FILED IN COLORADO (01/01/2012 - 12/13/2012)
2012-8907	12/14/2012 01/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Julie Donnelly Boston Business Journal	JUDGE ROTENBERG EDUCATIONAL CENTER - UNTITLED LETTER (06/29/2012)
2012-8908	12/14/2012 01/15/2013	OC/ORO/OE/ OC/ORO/OE/	George Ball UNIVERSITY OF MINNESOTA	MEDICAL DEVICE RECALL DATA (1994 TO PRESENT)
2012-8909	12/17/2012 01/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	JONATHAN REEVES MAKO SURGICAL CORP	ORTHO SOFT INC - STEROTAXIC INSTRUMENT K071714
2012-8910	12/17/2012 01/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	JONATHAN REEVES MAKO SURGICAL CORP	BLUE BELT TECHNOLOGIES - STEROTAXIC INSTRUMENTS K121936
2012-8911	12/17/2012 01/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	DAVID WARNICK MARK A ADAMS LLC	BOSTON SCIENTIFIC - SPINAL CORD STIMULATOR FORM 3500A 9/1/10 TO 10/31/10
2012-8912	12/17/2012 01/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JEFFREY A ROWE MURPHY BUTTERFIELD & HOLLAND PC	LISITING OF MORPHINE PRODS 2002
2012-8913	12/17/2012 01/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GARDINER HARRIS NEW YORK TIMES	LUPIN LTD, BHOPAL, INDIA - 11/12/08; ZENOTHECH LABORATORIES LTD, ANDHRA PRADESH, INDIA - 1/21/09; STERICON PHARMA PVT LTD, BANGALOR, KARNATAKA, INDIA 3/17/10, ETC - EIRS, 483S, WARNING LTRS LISTED IN THE NDC DIRECTORY

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		FDA/OC/OES/DFOI/		
2012-8914	12/17/2012 01/16/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELENA HOWELL HOGAN LOVELLS US LLP	SANDOZ INC - VORICONAZOLE (INJECTABLE IV INFUSION) NDA 90-0862, (TABLET ORAL) NDA 20-0265 CHEMISTRY RVWS
2012-8915	12/17/2012 01/16/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	MICHAEL P KRENSAVAGE Krensavage Asset Management	RTI BIOLOGICS - 483
2012-8916	12/17/2012 01/16/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	WALTER BROZOWISKI COKER SCHICKEL SORENSON ET AL	SANDOZ - PARENTA BRAND METHOTREXATE PROD RECALL 1/1/03 TO 12/12/12
2012-8917	12/17/2012 01/16/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	KATE WILLSON CENTER FOR PUBLIC INTEGRITY	RTI BIOLOGICS - 483 6/25/12 TO 7/11/12
2012-8918	12/17/2012 01/16/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	JOHN CREWSDON PROJECT ON GOVERNMENT OVERSIGHT	HEALTH-CARE PROVIDERS - VAERS
2012-8919	12/17/2012 01/16/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	DAVID HILZENRATH PROJECT ON GOVERNMENT OVERSIGHT	SHINGLES PREVENTION STUDY - VAERS
2012-8920	12/17/2012 01/16/2013	FDA/OFVM/CFSAN/OCD/EOS/	GARDINER HARRIS NEW YORK TIMES	VIET SPICES COMPANY LTD, MY PHUOC TOWN, VIETNAM - 9/21/10; INDIAN CHILLIES TRADING COMPANY LTD, VIRUDHUNAGAR, INDIA - 8/25/11; SWANI SPICE MILLS PVT LTD, NAVI MUMBAI, INDIA - 7/19/11, ETC - EIRS, 483'S, WARNING LTRS
2012-8921	12/17/2012 01/16/2013	FDA/OFVM/CFSAN/OCD/EOS/	BOBBY SHCHOCHET OLSSON FRANK WEEDA TERMAN BODE MATZ	INFANT FORMULA NOTIFICATION - CORR, MINS, EXHIBITS, ETC 6/1/12 TO PRESENT
2012-8922	12/17/2012 01/16/2013	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	2012-4541, 2012-4575, 2012-4694, ETC
2012-8923	12/17/2012 01/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Lakshmi Padmanabhan St.Jude Medical Neuromodulation	P840001/S076, P840001/S063, P960009/S035

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2012-8924	12/17/2012 01/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Chris Blowes Celgene Inc	NDA 022393 (ISTODAX) - CROSS DISCIPLINE TEAM LEADER'S REVIEW, MEDICAL REVIEW, STATISTICAL REVIEW, ETC
2012-8925	12/17/2012 01/16/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Julie M. Forte Ono Pharma, USA, Inc.	CBER BIOLOGICAL RESPONSE MODIFIERS ADVISORY COMMITTEE MEETING - PRESENTATION SLIDES (07/24/97)
2012-8926	12/17/2012 01/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Lakshmi Padmanabhan St.Jude Medical Neuromodulation	P970003/S065
2012-8927	12/17/2012 01/16/2013	FDA/OMPT/CTP/OD/	PAUL MENDOZA COMPANIA TABACALERA S.A	COMPANIA TABACALERA - LISTING OF INGREDIENTS IN TOBACCO PRODUCTS
2012-8928	12/17/2012 01/16/2013	FDA/OFVM/CFSAN/OCD/EOS/	Kerry King Intertox, Inc.	ODWALLA INCIDENT REPORT (10/30/96); PATHOGEN LEVELS OF LISTERIA IN APPLES (AUGUST 2012)
2012-8929	12/17/2012 01/16/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Tito Jankowski Self	K100040
2012-8930	12/17/2012 01/16/2013	FDA/OC/OES/DFOI/	Will Coggin CENTER FOR CONSUMER FREEDOM	ENVIRONMENTAL WORKING GROUP - FOIA REQUESTS (01/01/2012 - 12/14/2012)
2012-8931	12/17/2012 01/16/2013	OC/ORO/ OC/ORO/	Doe J	INDIVIDUAL RECS
2012-8932	12/17/2012 01/16/2013	OC/ORO/ORM/ OC/ORO/ORM/	David Mangione Govzilla, Inc.	LIST OF INSPECTIONS (11/22/2012 - 12/15/2012)
2012-8933	12/17/2012 01/16/2013	FDA/OGROP/ORO/SW-FO/KAN-DO/KAN-CB/	Bruce Metzger Bruce Metzger	DUTCHLAND FOODS, LESTER, IA - INSPECTION RECS (11/25/2012 - 12/15/2012)
2012-8934	12/17/2012 01/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Ditza Auerbach ditza auerbach	K082268
2012-8935	12/17/2012 01/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OCC/	Stephen Handal Independent	06/22/12 MEETING BETWEEN ELIZABETH DICKINSON AND KURT KARST - MEETING MINUTES, AMARIN RECS
2012-8936	12/17/2012 01/16/2013	FDA/OC/OES/DFOI/	Johnathan Rickman FDANEWS	FOIA REQUEST LOG (12/10/2012 - 12/14/2012)
2012-8937	12/18/2012	FDA/OMPT/CDRH/OCER/DFOI/	Michael Holbert	K101128

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	01/17/2013		Clean Coating Technologies LLC	
2012-8938	12/18/2012 01/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Janet McChristion Fresenius-kabi LLC USA	ANDA 079197, ANDA 200771, ANDA 202063, ETC - APPROVAL LTRS
2012-8939	12/18/2012 01/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Marie Getchell, Cre8MDI LLC Cre8MDI LLC	K070795
2012-8940	12/18/2012 01/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Marie Getchell, Cre8MDI LLC Cre8MDI LLC	K080670
2012-8941	12/18/2012 01/17/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Steve Pardue Elevate Oral Care	K041482
2012-8942	12/18/2012 01/17/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Marie Getchell, Cre8MDI LLC Cre8MDI LLC	K013434
2012-8943	12/18/2012 01/17/2013	OC/ORA/ OC/ORA/	Jen Wiczner Dow Jones/MarketWatch	DRUG PRODUCT CLASS I RECALLS (01/01/2005 - 12/17/2012)
2012-8944	12/18/2012 01/17/2013	FDA/OC/OES/DFOI/ FDA/OGROP/ORO/PA-FO/SEA-DO/SEA-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Traci S. Umberger PHYSIO-CONTROL, INC.	PHYSIO-CONTROL, INC - HEALTH HAZARD EVALUATION RE LIFEPAK 20, 20E
2012-8945	12/18/2012 01/17/2013	FDA/OGROP/ORO/PA-FO/SEA-DO/SEA-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Traci S. Umberger PHYSIO-CONTROL, INC.	PHYSIO-CONTROL INC, REDMOND, WA - HEALTH HAZARD ANALYSIS, 483 10/24/12
2012-8946	12/18/2012 01/17/2013	FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OC/OES/DFOI/	JoNel Aleccia NBCNews.com	RTI BIOLOGICS, ALACHUA, FL - INSPECTION RECS, WARNING LETTERS, CORR (12/17/2005 - 12/17/2012)
2012-8947	12/18/2012 01/17/2013	OC/OA/OM/OMP/DDM/	Jennifer Brown (2642660) INFOTRIEVE	ORALLY INHALED/INTRANASAL CORTICOSTEROIDS AND GROWTH IN CHILDREN (1998)
2012-8948	12/18/2012 01/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Liliane A Patton Patton, Liliane A	FORTEO - AERS
2012-8949	12/18/2012	FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/	LARA WEISS	FRANCK'S COMPOUNDING LAB, OCALA, FL - BRILLIANT BLUE G DYE RECS

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	01/17/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	GOLDBERG & GILLE LAW OFCS	
2012-8950	12/18/2012 01/17/2013	OC/OA/OM/OMP/DDM/	MICHAEL G REIN WELDON-LINNE & VOGT	DERMATOLOGIC AND OPHTHALMIC DRUGS A/C - TRANS 9/19/00 (CERTIFIED)
2012-8951	12/18/2012 01/17/2013	FDA/OGROP/OIP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CARMEN S SCOTT MOTLEY RICE LLC	MIRENA - AERS 1/09 TO PRESENT, CONTACT RPTS, LBLG, ETC
2012-8952	12/18/2012 01/17/2013	OC/ORO/ OC/ORO/	JOHN L HOLAHAN SIMPLY THICK LLC	SIMPLYTHICK PRODS - TEST RESULTS, SAMPLING
2012-8953	12/18/2012 01/17/2013	OC/ORO/ OC/ORO/	INGRID S MARTIN COLLORA LLP	NEW ENGLAND COMPOUNDING PHARMACY (NEW ENGLAND COMPOUNDING CENTER) - PROD SPLS TEST RESULTS
2012-8954	12/18/2012 01/17/2013	OC/CVM/OCD/	Constance N. White DVM PhD Fremont Veterinary Clinic	ENALAPRIL (NADA 141015)
2012-8955	12/18/2012 01/17/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Yu-Ju Chiang Chung Yuan Christian University	K001948, K080670, K020537
2012-8956	12/18/2012 01/17/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	GREG L DREVENSTEDT PHD VALMONT RESEARCH LLC	DENTAL DVC IMPORTERS - 807.41 ESTABLISHMENT REGISTRATION AND DVC LISTING
2012-8957	12/18/2012 01/17/2013	FDA/OGROP/ORO/CE-FO/CIN-DO/CIN-CB/	BRENDA M GARTZ ELI LILLY & CO	ALKERMES, WILMINGTON, OH - EIR 11/4/11
2012-8958	12/18/2012 01/17/2013	FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	BRENDA M GARTZ ELI LILLY & CO	DSM PHARMS, GREENVILLE, NC - EIR 4/11
2012-8959	12/18/2012 01/17/2013	FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	BRENDA M GARTZ ELI LILLY & CO	DSM PHARMS, GREENVILLE, NC - EIR 4/12
2012-8960	12/18/2012 01/17/2013	FDA/OGROP/ORO/PA-FO/SEA-DO/SEA-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Traci Umberger PHYSIO-CONTROL, INC.	PHYSIO-CONTROL INC, REDMOND, WA - HEALTH HAZARD ANALYSIS, 483 (10/24/12)
2012-8961	12/18/2012 01/17/2013	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	2010-7504, 2011-1983, 2011-5035, ETC
2012-8962	12/18/2012 01/17/2013	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	2012-1613, 2012-1963, 2012-1976, ETC

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2012-8963	12/18/2012 01/17/2013	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	2012-6067, 2012-6477, 2012-6663, ETC
2012-8964	12/19/2012 01/18/2013	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/ FDA/OMPT/CDRH/OCER/DFOI/	debra g speyer speyer, debra g	BAY IMAGING GROUP, NORTH FLORIDA - INSPECTION REPORTS, MQSA REVIEW, SUPERVISING PHYSICIAN, ETC (01/10/2008 - 12/31/2009)
2012-8965	12/19/2012 01/18/2013	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/ OC/OA/OM/OMP/DDM/	Thano Maceo Paris Thano Maceo Paris	GRADY HOSPITAL, ATLANTA, GA - INSPECTION, REPORT OF THE PUBLIC BOARD, TRANSCRIPT
2012-8966	12/19/2012 01/18/2013	OC/ORR/ OC/ORR/ FDA/OGROP/ORR/CE-FO/BLT-DO/BLT-CB/	Jennifer Szymanski Vitaflo USA	RENASTART - DISPOSAL OF RECALLED PRODUCT
2012-8967	12/19/2012 01/18/2013	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	PHILIP MORRIS/ALTRIA - CORR RE L&M, MARLBORO NXT, MARLBORO SELECT KING SIZE (06/22/2009 TO PRESENT)
2012-8968	12/19/2012 01/18/2013	OC/ORR/ OC/ORR/ FDA/OGROP/ORR/CE-FO/NWJ-DO/NWJ-CB/	Gloria Candelario N/A	SAMPLE RESULTS
2012-8969	12/19/2012 01/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ISR 8337594-X
2012-8970	12/19/2012 01/18/2013	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	2011-708, 2012-5498, 2012-5584, ETC
2012-8971	12/19/2012 01/18/2013	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	2012-8193, 2012-8215, 2012-970, ETC
2012-8972	12/19/2012 01/18/2013	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	2012-987, 2012-965, 2012-8187, ETC
2012-8973	12/19/2012 01/18/2013	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	2012-5587, 2012-5496, 2012-8227, ETC
2012-8974	12/19/2012	FDA/OC/OES/DFOI/	KEN REID	2011-1471, 2012-967, 2012-5558, ETC

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	01/18/2013		WASHINGTON INFORMATION SOURCE	
2012-8975	12/19/2012 01/18/2013	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	2012-5517, 2012-964, 2012-5562, ETC
2012-8976	12/19/2012 01/18/2013	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	2012-973, 2012-5683, 2012-8203
2012-8977	12/19/2012 01/18/2013	FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/	BRENDA M GARTZ ELI LILLY & CO	CARDINAL HEALTH, COLTON, CA - EIR 12/11
2012-8978	12/19/2012 01/18/2013	FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/	BRENDA M GARTZ ELI LILLY & CO	ANALYTICAL BIOCHEMISTRY LABS, COLUMBIA, MO - EIR 12/16/11
2012-8979	12/19/2012 01/18/2013	FDA/OGROP/ORR/CE-FO/DET-DO/DET-CB/	BRENDA M GARTZ ELI LILLY & CO	BAXTER PHARMACEUTICAL SOLUTIONS, BLOOMINGTON, IN - EIR 9/12
2012-8980	12/19/2012 01/18/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	JANICE M HOGAN HOGAN LOVELLS US LLP	SPINALMOTION INC - KINEFLEX C CERVICAL ARTIFICIAL DISC P100011 PANEL HOMEWORK ASSIGNMENTS, RISK/BENEFIT W/S
2012-8981	12/19/2012 02/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	ANDREA N WALLEN DELPHINUS MEDICAL TECHNOLOGIES INC	U-SYSTEMS INC, SUNNYVALE, CA - AUTOMATED BREAST ULTRASOUND SYS P110006 RECS
2012-8982	12/19/2012 01/18/2013	FDA/OGROP/ORR/SW-FO/DEN-DO/DEN-CB/	BRENTON LORNER HORNER & ASSOCIATES	WORLD HEALTH PRODUCTS LLC - DETOXAMIN SUPPOSITORIES CORR, RESP TO LTR 12/12.11
2012-8983	12/19/2012 01/18/2013	FDA/OGROP/ORR/NE-FO/NWE-DO/NWE-CB/	KAREN ANDERSON WBZ-TV	SPECIALITY MINERALS INC - 7/24/12; PHARMALUCENCE INC - 4/25/12; AMAG PHARMACEUTICALS INC - 5/24/12, ETC 483S
2012-8984	12/19/2012 01/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	AYAMI MARUYAMA CANON INC	REDIFORCE RX840-MG - K120451
2012-8985	12/19/2012 01/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELLIOT FAVUS FAVUS INSTITUTIONAL RESEARCH LLC	PONATINIB - AERS 1/10 TO PRESENT
2012-8986	12/19/2012 01/18/2013	FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/	Doe J	UNILEVER - WISHBONE SALAD DRESSING CMLPNT
2012-8987	12/19/2012 01/18/2013	OC/ORR/OE/ OC/ORR/OE/ OC/ORR/ORM/	Kevin McCoy USA TODAY	FOOD FACILITIES, BOTTLED WATER PLANTS - LIST OF INSPECTIONS, RECALLS (07/18/2006 - 12/18/2012)

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		OC/ORR/ORM/ OC/ORR/OE/ OC/ORR/OE/		
2012-8988	12/20/2012 01/22/2013	FDA/OGROP/ORR/CE-FO/BLT-DO/BLT-CB/	WALTER E. CHALKLEY THOMSON REUTERS	OCTAPharma PLASAM INC, VIRGINIA BEACH, VA - EIR, 483 2/3/12
2012-8989	12/20/2012 01/22/2013	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	WALTER E. CHALKLEY THOMSON REUTERS	MIRAMAR COSMETICS INC, DORAL, FL - EIR, 483 1/3/12
2012-8990	12/20/2012 01/22/2013	FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/	WALTER E. CHALKLEY THOMSON REUTERS	EXPERT CHEMICAL ANALYSIS INC, SAN DIEGO, CA - EIR, 483 1/28/11
2012-8991	12/20/2012 01/22/2013	FDA/OGROP/ORR/NE-FO/NYK-DO/NYK-DCB/	WALTER E. CHALKLEY THOMSON REUTERS	ALK ABELLO INC, PORT WASHINGTON, NY - 3/21/12
2012-8992	12/20/2012 01/22/2013	FDA/OGROP/ORR/PA-FO/SEA-DO/SEA-CB/	WALTER E. CHALKLEY THOMSON REUTERS	PETNET SOLUTIONS, KENT, WA - EIR, 483 2/12
2012-8993	12/20/2012 01/22/2013	FDA/OGROP/ORR/CE-FO/BLT-DO/BLT-CB/	WALTER E. CHALKLEY THOMSON REUTERS	JUBILANT CADISTA PHARMACEUTICALS, SALISBURY, MD - EIR, 483 3/14-23/12
2012-8994	12/20/2012 01/22/2013	FDA/OGROP/ORR/SE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORR/SE-FO/NOL-DO/NOL-CB/	WALTER E. CHALKLEY THOMSON REUTERS	TISSUE BANKS INT'L, MEMPHIS, TN - EIR, 483 6/18-20/12
2012-8995	12/20/2012 01/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	SHANGHAI HUHUI DAILY USE CHEMICAL PRODUCTS, SHANGHAI, CHINA - EIR, 483 2/6-10/12
2012-8996	12/20/2012 01/22/2013	FDA/OGROP/ORR/PA-FO/SEA-DO/SEA-CB/	WALTER E. CHALKLEY THOMSON REUTERS	SALEM HOSPITAL IRB, SALEM, OR - EIR, 483 6/6-25/12
2012-8997	12/20/2012 01/22/2013	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	WALTER E. CHALKLEY THOMSON REUTERS	RTI BIOLOGICS INC, ALACHUA, FL - EIR, 483 6/26-7/11/12
2012-8998	12/20/2012 01/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RUTH RIZKALLA, Esq. SIZEMORE LAW FIRM PLC	rhBMP-2 - LICENSE APPLICATION
2012-8999	12/20/2012 01/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	ALEX VEIZIS FDALIVE.COM	CHDR ADVISORY COMMITTEE MTG

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2012-9000	12/20/2012 01/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	JURGEN KALBER MEDENTIKA GMBH.	TI BASE ABUTMENT - NT TRADING GMBH AND CO KG, CLAREMONT, NH - K111935
2012-9001	12/20/2012 01/22/2013	FDA/OGROP/ORR/SE-FO/FLA- DO/FLA-CB/ FDA/OGROP/ORR/SE-FO/ATL- DO/ATL-CB/ FDA/OGROP/ORR/SE-FO/ATL- DO/ATL-CB/ FDA/OC/OES/DFOI/	GISSENDANNER, ROBIN	CMPLNT 120110
2012-9002	12/20/2012 01/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANDREW 017561, JOHN	SELENIUM SULFIDE LOTION; GELENIOM SOLFIDE TOPICAL SUSPENSION - RECALL
2012-9003	12/20/2012 01/22/2013	FDA/OC/OES/DFOI/	JH BARR & ASSOCIATES LLC	DAILY LOG 11/26-30/12
2012-9004	12/20/2012 01/22/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 11/19-23/12
2012-9005	12/20/2012 01/22/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 12/10-14/12
2012-9006	12/20/2012 01/22/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 12/3-7/12
2012-9007	12/20/2012 01/22/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 12/3-7/12
2012-9008	12/20/2012 01/22/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 12/10-14/12
2012-9009	12/20/2012 01/22/2013	FDA/OC/OES/DFOI/	DAVID MacFARLAND FDA WEBVIEW/FERDIC INC	DAILY LOG 12/3-7/12
2012-9010	12/20/2012 01/22/2013	FDA/OC/OES/DFOI/	DAVID MacFARLAND FDA WEBVIEW/FERDIC INC	DAILY LOG 12/10-14/12
2012-9011	12/20/2012 01/22/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 12/3-7/12
2012-9012	12/20/2012 01/22/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 12/10-14/12

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2012-9013	12/20/2012 01/22/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 12/10-14/12
2012-9014	12/20/2012 01/22/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 12/3-7/12
2012-9015	12/21/2012 01/23/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Lelia M. Fuentes CARDINAL HEALTH	POSITRON EMISSION TOMOGRAPHY DRUG MANUFACTURERS - EIRS(12/31/2010 - 12/31/2012)
2012-9016	12/21/2012 01/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kimberly Bulls TECHLAB, Inc.	K090700
2012-9017	12/21/2012 01/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kimberly Bulls TECHLAB, Inc.	K974651
2012-9018	12/21/2012 01/23/2013	FDA/OFVM/CFSAN/OCD/EOS/	Lena Gomez Keller and Heckman, LLP	CAFFEINE INTAKE BY THE US POPULATION
2012-9019	12/21/2012 01/23/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOSEPH WALKER Dow Jones & Company	INCIVEK - AERS
2012-9020	12/21/2012 01/23/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/OA/OM/OMP/DDM/ FDA/OC/OES/DFOI/	Emily Bartkowicz AKERMAN SENTERFITT ATTYS	TOPICAL ANTIFUNGAL DRUG PRODUCTS FOR OTC HUMAN USE - MEDICAL LITERATURE, JOURNALS, TESTING, ETC; KRAMER LABORATORIES, KRAMER CONSUMER HEALTHCARE - CORR WITH FDA

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2012-9021	12/21/2012 01/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kimberly Bulls TECHLAB, Inc.	K093295
2012-9022	12/21/2012 01/23/2013	FDA/OFVM/CFSAN/OCD/EOS/	Leslie H. Joyner, Esq. Marlin & Saltzman	HANSEN'S PREMIUM DIET SODA WITH ALL NATURAL FLAVORS - ALL RECS
2012-9023	12/21/2012 01/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	WELLSPRING, ONTARIO, CANADA - QAP
2012-9024	12/21/2012 01/23/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Dominique Huff Home Rule News	PLASMA DONATION - STATISTICAL DATA
2012-9025	12/21/2012 01/23/2013	FDA/OO/OFBA/OAGS/	Reindeer Charities Goedert, Matthew D	STOP GRANTS - JOIN TOGETHER NORTHERN NEVADA APPLICATION
2012-9026	12/21/2012 01/23/2013	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/ FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	Alexandra Ajmo LIFE EXTENSION	LIFE EXTENSION, NATURE'S VALUE INC, GEMINI PHARMACEUTICALS, ETC - EIRS
2012-9027	12/21/2012 01/23/2013	FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/	RO Wood the Wood Burditt group	PRESERVATION SOLUTIONS INC, ELKHORN, WI - 483, 482, EIR ETC
2012-9028	12/21/2012 01/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	Wendell Tong Tong, Wendell	STYKER REJUVENATE, STRYKER ABG - SUBMITTED RECS, REVIEWS, ADVERSE EVENTS ETC
2012-9029	12/21/2012 01/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CRISSEP #1258732, KENNETH	PREDISONE, ONCOVIN, MECHLORETHAMINE HCL, ETC - MFRS ADDRESS, DRUG INTERACTION RECS 1981 TO 1985, ETC
2012-9030	12/21/2012 01/23/2013	FDA/OC/OES/DFOI/	LATESHA R BAKER HINSHAW & CULBERTSON LLP	AVASTIN (BEVACIZUMAB) INJ, MIAMI-DADE COUNTY, FL - RECS 7/11
2012-9031	12/21/2012 01/23/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 10/8-12/12
2012-9032	12/21/2012 01/23/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 10/1-5/12
2012-9033	12/21/2012 01/23/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 10/15-19/12

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2012-9034	12/21/2012 01/23/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 10/22-26/12
2012-9035	12/21/2012 01/23/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 10/29/12-11/2/12
2012-9036	12/21/2012 01/23/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 11/5-9/12
2012-9037	12/21/2012 01/23/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 11/12-16/12
2012-9038	12/21/2012 01/23/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 11/19-23/12
2012-9039	12/21/2012 01/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN MANCINI ARIZONA STATE HOSPITAL	DECADRON PHOSPHATE INJ, DEXAMETHASONE SODIUM PHOSPHATE INJ - AERS
2012-9040	12/21/2012 01/23/2013	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/ OC/ORR/OCI/ OC/ORR/OCI/	Anderson, Carl	GAVIN SMITH, PRECISION PEPTIDES, LUTZ, FL - SALE OF PEPTIDES, ANABOLIC STEROIDS, HUMAN GROWTH HORMONE COMM 1/11 TO PRESENT
2012-9041	12/21/2012 01/23/2013	OC/CVM/OCD/	Douglass Oeller Douglass Oeller Consulting, Inc.	AAFCO FEED INGREDIENT DEFINITION FOR USE OF L-CARNITINE IN MILK REPLACER FOR RUMINANTS - STUDY DESIGN
2012-9042	12/21/2012 01/23/2013	OC/CVM/OCD/	Douglass Oeller Douglass Oeller Consulting, Inc.	AAFCO FEED INGREDIENT DEFINITION FOR THE USE OF CHROMIUM PROPIONATE IN CATTLE FEED - STUDY DESIGN
2012-9043	12/21/2012 01/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOSEPH WALKER Dow Jones & Company	ARANESP - AERS
2012-9044	12/21/2012 01/23/2013	OC/OA/OIM/ FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECS
2012-9045	12/26/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2012-7936 REQUEST LETTER

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	01/25/2013		MERCK & CO., INC.	
2012-9046	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8010 REQUEST LETTER
2012-9047	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7971 REQUEST LETTER
2012-9048	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7903 REQUEST LETTER
2012-9049	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8034 REQUEST LETTER
2012-9050	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8045 REQUEST LETTER
2012-9051	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8090 REQUEST LETTER
2012-9052	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7085
2012-9053	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8041 REQUEST LETTER
2012-9054	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8245 REQUEST LETTER
2012-9055	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8295 REQUEST LETTER
2012-9056	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8367 REQUEST LETTER
2012-9057	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8457 REQUEST LETTER
2012-9058	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8481 REQUEST LETTER
2012-9059	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8338 REQUEST LETTER
2012-9060	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8333 REQUEST LETTER
2012-9061	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7476

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2012-9062	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7066
2012-9063	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7065
2012-9064	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7058
2012-9065	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6664
2012-9066	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7566
2012-9067	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-3744
2012-9068	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8159
2012-9069	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7573
2012-9070	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-5150
2012-9071	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8360
2012-9072	12/26/2012 01/25/2013	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Ed Yoo Corporate Resolutions Inc.	PHELPS INDUSTRIES - VIOLATIONS; SANCTIONS (12/19/2002)
2012-9073	12/27/2012 01/28/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Tim Kelly BIOLIFE	K021062
2012-9074	12/27/2012 01/28/2013	OC/ORA/ OC/ORA/ OC/ORA/OE/ OC/ORA/OE/ FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Jen Wiczner Dow Jones/MarketWatch	DRUG RECALLS - LIST BEFORE CLASSIFICATION

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		FDA/OMPT/CDER/ORP/DIDP/ OC/ORA/OE/ OC/ORA/OE/		
2012-9075	12/27/2012 01/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Susan Winokur Winokur, Susan	HI-TECH PHARMACAL - BIOEQUIVALENCE STUDY AND RATING FOR LEVOCARNITINE
2012-9076	12/27/2012 01/28/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8462
2012-9077	12/27/2012 01/28/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8235
2012-9078	12/27/2012 01/28/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8080
2012-9079	12/27/2012 01/28/2013	OC/ORA/ OC/ORA/	Jeremy Finley WSMV-TV	FOREIGN OBJECTS IN FOOD - COMPLAINTS IN TENN
2012-9080	12/27/2012 01/28/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Leslie H. Joyner Esq. Marlin & Saltzman	OH SO CLEAN, CLEANWELL PRODUCTS - CONSUMER COMPLAINTS (10/25/2008 - 12/20/2012)
2012-9081	12/27/2012 01/28/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	Sandy Stagge CTI Clinical Trial & Consulting Services	HILLARD LAZARUS, CINCINNATI, OH - 483, CORR (08/01/1997 - 10/29/1997)
2012-9082	12/27/2012 01/28/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	Sandy Stagge CTI Clinical Trial & Consulting Services	UNIVERSITY HOSPITAL CASE MEDICAL CENTER IRB, CLEVELAND, OH - 483, CORR (11/30/2011 - 01/31/2012)
2012-9083	12/27/2012 01/28/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	Richard P. Dickey, MD, PhD The Fertility Institute of New Orleans	IVF CLINICS - FDA DISASTER RESPONSE INSPECTION REPORTS (10/21/12-10/30 2012)
2012-9084	12/27/2012 01/28/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	Richard P Dickey, MD, PhD Fertility Institute of New Orleans	FDA DISASTER RESPONSE INSPECTIONS OF IVF CLINICS (10/21/12-10/30/12)

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2012-9085	12/27/2012 01/28/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	Leslie H. Joyner, Esq. Marlin & Saltzman	NONGSHIM PRODUCTS - RECALLS, INSPECTIONS, ADVERSE EVENTS, ETC (12/19/2008 - 12/21/2012)
2012-9086	12/27/2012 01/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rowena Dodaro ALKERMES INC	VIVOTROL - 8379054-6, 8453511-6
2012-9087	12/27/2012 01/28/2013	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORA/ OC/ORA/ FDA/OGROP/ORA/CE-FO/CIN- DO/CIN-CB/ FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/ FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/ FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/ FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/ FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/ FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/	Leslie H. Joyner, Esq. Marlin & Saltzman	DIET 7UP - RECALL RECS, INSPECTION RECS, AERS, ETC (01/05/2009 - 12/21/2012)
2012-9088	12/27/2012 01/28/2013	FDA/OC/OES/DFOI/	Johnathan Rickman FDANEWS	FOIA LOG (12/17/2012 - 12/21/2012)
2012-9089	12/27/2012 01/28/2013	FDA/OGROP/ORA/CE-FO/CHI- DO/CHI-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kristina Farmer Segal McCambridge Singer & Mahoney	MERIX PHARMACEUTICAL, BARRINGTON, IL - ALL RECS

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2012-9090	12/27/2012 01/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mira Parekh UCSF Medical Center	LAMOTRIGINE - AERS
2012-9091	12/27/2012 01/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Evens Augustin Evens Augustin	K122356, K113514, K110704
2012-9092	12/28/2012 01/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mark Mathieu PAREXEL International Corp.	IND DATA
2012-9093	12/28/2012 01/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Munjal Sheladia PureTek Corporation	NDA 017010; ANDA 072354 - SUMMARY BASIS OF APPROVAL
2012-9094	12/28/2012 01/29/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Yvonne Higgins COPERNICUS GROUP IRB	COPERNICUS GROUP IRB, DURHAM, NC - 483, EIR (03/10)
2012-9095	12/28/2012 01/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rennae Lalwor Peninsula Regional Medical Center	XALERO - AERS (01/01/2012 - 12/26/2012)
2012-9096	12/28/2012 01/29/2013	FDA/OFVM/CFSAN/OCD/EOS/	LaVeeta Moten LaVeeta Moten	FUNDING ALLOCATED FOR OMS AWARDS; AWARD PROCEDURES; AWARD CORRESPONDENCE, ETC (01/01/2008 - 12/20/2012)
2012-9097	12/28/2012 01/29/2013	FDA/OC/OES/DFOI/	LaVeeta Moten LaVeeta Moten	INDIVIDUAL RECS
2012-9098	12/28/2012 01/29/2013	FDA/OFVM/CFSAN/OCD/EOS/	LaVeeta Moten LaVeeta Moten	REGULATION, POLICY, DIRECTIVE RE: SELECTION OF STAFF TO REVIEW RESUMES FOR GS-13 DETAILS AND PROMOTIONS WITHIN OMS; CORR RE: REVIEW OF APPLICATIONS OR RESUMES
2012-9099	12/28/2012 01/29/2013	FDA/OFVM/CFSAN/OCD/EOS/	LaVeeta Moten LaVeeta Moten	CFSAN BIRS SYSTEM - USE OR CORR RE NON-USE (01/01/2008 - 12/20/2012)
2012-9100	12/28/2012 01/29/2013	FDA/OFVM/CFSAN/OCD/EOS/	LaVeeta Moten LaVeeta Moten	CFSAN OSM - EMPLOYEE GRADE, TITLE, PROJECTS, ETC (01/01/2008 - 12/20/2012)
2012-9101	12/28/2012 01/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Alex Silverstein SIGMA CAPITAL MANAGEMENT	KALYDECO - AERS

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2012-9102	12/28/2012 01/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Alex Silverstein SIGMA CAPITAL MANAGEMENT LLC	BG-12 - AERS
2012-9103	12/28/2012 01/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Alex Silverstein SIGMA CAPITAL MANAGEMENT LLC	XTANDI - AERS
2012-9104	12/28/2012 01/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Alex Silverstein SIGMA CAPITAL MANAGEMENT LLC	KYPROLIS - AERS
2012-9105	12/28/2012 01/29/2013	OC/OM/OMP/DDM/	JANNA DEPORTER CENTER FOR SCIENCE IN THE PUBLIC INTEREST	DKT & DKT LOG OF 1999P-2630
2012-9106	12/31/2012 01/30/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Doe J	RHOGAM - VAERS (01/20/2009 - 12/28/2012)
2012-9107	12/31/2012 01/30/2013	OC/CVM/OCD/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	POLYSORBATE 80 - 05/21/08 LETTER FROM CVM
2012-9108	12/31/2012 01/30/2013	FDA/OC/OES/DFOI/	Johnathan Rickman FDANEWS	FOIA LOG (12/24/2012 - 12/28/2012)
2012-9109	12/31/2012 01/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	EFUDEX - AERS
2012-9110	12/31/2012 01/30/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	michael reilly integrity bio	DMF 12053 (LYOJECT)

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2012-9111	12/31/2012 01/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	Carl O. Magnell Valmed, S.A.	1000 MUSCLE STIMULATOR SYSTEM - 510K
2012-9112	12/31/2012 01/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	Luk Van Hecke TERUMO EUROPE NV	SYRINGE PUMP - MAUDE REPORTS (01/01/2012 - 12/27/2012)
2012-9113	12/31/2012 01/30/2013	OC/ORA/ OC/ORA/	Amandeep Singh RiaFragranceIncDBANaturalHoneyI mporters	SAMPLE RESULTS
2012-9114	12/31/2012 01/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Samuel Graham University of Wisconsin-Milwaukee	NDA 21446 S010
2012-9115	12/31/2012 01/30/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 11/5-9/12
2012-9116	12/31/2012 01/30/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 11/12-16/12
2012-9117	12/31/2012 01/30/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 12-3-7-12
2012-9118	12/31/2012 01/30/2013	FDA/OC/OES/DFOI/	LISA TARISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 12/3-7/12
2012-9119	12/31/2012 01/30/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 11/26-30/12
2012-9120	12/31/2012 01/30/2013	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 12/3-7/12
2012-9121	12/31/2012 01/30/2013	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 11/26-30/12
2012-9122	12/31/2012 01/30/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 12/3-7/12
2012-9123	12/31/2012 01/30/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 11/26-30/12
2012-9124	12/31/2012 01/30/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 12/3-7/12

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2012-9125	12/31/2012 01/30/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 11/26-30/12
2012-9126	12/31/2012 01/30/2013	FDA/OC/OES/DFOI/	GLADYS B TONKIN WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 11/26-30/12
2012-9127	12/31/2012 01/30/2013	FDA/OC/OES/DFOI/	GLADYS B TONKIN WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 12/3-7/12
2012-9128	12/31/2012 01/30/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 11/26-30/12
2012-9129	12/31/2012 01/30/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 12/3-7/12
2012-9130	12/31/2012 01/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	L LEE HICKS II MOORE & HICKS PC	ENCORE ORTHOPEDICS INC - TIBIAL INSERT K963028
2012-9131	12/31/2012 01/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	L LEE HICKS II MOORE & HICKS PC	ENCORE ORTHOPEDICS INC - FOUNDATION KNEE SYS TIBIAL COMPONENT K970031
2012-9132	12/31/2012 01/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	JULIE VAFIDES DEPUY MITEK	DEPUY MITEK - INTRAFIX TAPERED SCREW (INTRATUNNEL FIXATION FASTENER) K983560
2012-9133	12/31/2012 01/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ROTH, GAIL P	ABILIFY - AERS
2012-9134	12/31/2012 01/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/OA/OM/OMP/DDM/	DAVID C WEBER BEHREND ERNSBEERGER, PC	ROXANE LABS - PREDNISONE CITIZEN PETITIONS, PI, MEDICAL JOURNAL RPTS 1999 TO PRESENT
2012-9135	12/31/2012 01/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HELEY 56354-112, FRANK	ELAVIL - AERS
2012-9136	12/31/2012 01/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELAINE S WALLER SEATTLE GENETICS INC	ADCETRIC (BRENTUXIMAB VEDOTIN) - AERS 3/1/12 TO 11/30/12

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2012-9137	12/31/2012 01/30/2013	FDA/OFVM/CFSAN/OCD/EOS/	LISA Y LEFFERTS CENTER FOR SCIENCE IN PUBLIC INTEREST	BROMINATED VEGETABLE OIL - TOXICOLOGICAL STUDIES, TOXICITY CORR, AERS 1/70 TO PRESENT
2012-9138	12/31/2012 01/30/2013	FDA/OFVM/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CARES 159466 - ADDITIONAL RECS
2012-9139	12/31/2012 01/30/2013	FDA/OFVM/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 159466 - ADDITIONAL RECS
2013-1	01/02/2013 01/31/2013	FDA/OGROP/ORAP/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORAP/PA-FO/SAN- DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	JENNIFER CONNER AMERICAN CLAIMS MANAGEMENT	PRIME ORTHOPEDICS INC, PRIME MEDICAL RESOURCES - 483S, MDRS, ESTABLISHMENT REGISTRATION, ETC
2013-2	01/02/2013 03/04/2013	FDA/OMPT/CDRH/OCER/DFOI/ OC/OA/OM/OMP/DDM/ FDA/OC/OES/DFOI/	LOUIS S FRANECKE FRANECKE LAW GROUP	ST JUDE MEDICAL - RIATA, RIATA ST DEFIBRILLATION P950022/S006,S007,S008, ETC EIRS, 483S, RPTS, ETC
2013-3	01/02/2013 01/31/2013	FDA/OGROP/ORAP/PA-FO/LOS- DO/LOS-CB/	Meade, Doris	GM MANUFACTURING INC, GARDENA, CA - 483S 1/23/12- 2/13/12
2013-4	01/02/2013 01/31/2013	FDA/OMPT/CDRH/OCER/DFOI/	RANDY SCHERER PHD Cook Medical	MERIT MEDICAL INC - EMBOSPHERE MICROSPHERES INVESTIGATIONAL DVC EXEMPTION (IDE) APRVL LTR, PHASE III CLNCL STUDY PROTOCOL
2013-5	01/02/2013 01/31/2013	FDA/OMPT/CDRH/OCER/DFOI/	J. DONALD HENSON, SR Henson, J. Donald	MEDTRONIC - INSULIN PUMP P980022 RECS
2013-6	01/02/2013 01/31/2013	FDA/OFVM/CFSAN/OCD/EOS/	BETH CLAY CAPITOL STRATEGY CONSULTANTS	DIETARY SUPPLEMENTS - FDA REGISTRY DATA
2013-7	01/02/2013 01/31/2013	FDA/OGROP/ORAP/CE-FO/NWJ- DO/NWJ-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ALYSON OLIVER OLIVER LAW GROUP	PHARMACEUTICAL INNOVATIONS INC - ULTRA PHONIC CONDUCTIVITY GEL, SONIC GENERIC ULTRASOUND TRANSMISSION GEL, ULTRA PHONIC FONTANELLE SCANNING PAD, ETC INSP, LBLG, STERILIZATION, ETC

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		FDA/OMPT/CDRH/OCER/DFOI/ OC/OA/OM/OMP/DDM/ FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/		
2013-8	01/02/2013 01/31/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/	ALYSON OLIVER OLIVER LAW GROUP	MEDTRONIC - MOSAIC PROCINE BIOPROSTHETIC HEART VALVE PMA, RVWS, PROCEDURE MANUALS, ETC
2013-9	01/02/2013 01/31/2013	FDA/OGROP/ORASE-FO/NOL- DO/NOL-CB/	DOUGLAS N BLUE II ZETETIC	BEINING NOVARTIS PHARMA CO LTD - COARTEM 120 MG ENTRY #112-6851042-1 REFUSAL RECS
2013-10	01/02/2013 01/31/2013	FDA/OGROP/ORASE-FO/FLA- DO/FLA-CB/	DONALD N BLUE II ZETETIC	AV300384441 - RECS
2013-11	01/02/2013 01/31/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	KATY MORTON TOPICA PHARMACEUTICALS INC	KATAYAMA SEIYAKUSHYO CO LTD, TOYAMA, JAPAN - EIRS, 483S, WARNING LTRS, ETC 1/04 TO PRESENT
2013-12	01/02/2013 01/31/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	WILLIAM BRENNAN SEDGWICK LLP	COVIDIEN - ONYX LIQUID EMBOLIC SYS (ONYX HD-500) AERS
2013-13	01/02/2013 01/31/2013	FDA/OFVM/CFSAN/OCD/EOS/	CHRISTIE L GARZA ARMANDO DE DIEGO PC	FDA RETAIL AND FOOD SERVICE HACCP, FDA SEAFOOD HACCP 5/03 (CERTIFIED)
2013-14	01/02/2013 01/31/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ OC/CVM/OCD/	KATY MORTON TOPICA PHARMACEUTICALS INC	KATAYAMA SEIYAKUSHYO CO LTD, OSAKA, JAPAN - EIRS, 483S, WARNING LTRS, ETC 1/04 TO PRESENT
2013-15	01/02/2013 01/31/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	KARRAS, EDWARD	ACTOS, METFORMIN, PIOGLITAZONE - RECS
2013-16	01/02/2013 01/31/2013	FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/ OC/ORAOCI/	Anderson, Carl	DANIEL LANSDOWN, PURE PEPTIDES, HOUSTON, TX - ANABOLIC STEROIDS, HUMAN GROWTH HORMONE CORR 1/10 TO PRESENT

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		OC/ORO/OCI/		
2013-17	01/02/2013 01/31/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	RUTH RIZKALLA ESQ SIZEMORE LAW FIRM PLC	RHBMP-2 - BIOLOGICS, DRUG LICENSE APPL
2013-18	01/02/2013 01/31/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANDREWS D17561, JOHN	MORTON GROVE - SELENIUM SULFIDE LOTION; PERRIGO - SELENIUM SULFIDE TOPICAL SOL RECALL RECS
2013-19	01/02/2013 01/31/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tina Babos IPD ANALYTICS LLC	ANDA 202608 - APPROVAL LETTER
2013-20	01/02/2013 01/31/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	David Lin BIOLOGICS CONSULTING GROUP	NDA 202292 - APPROVAL PACKAGE
2013-21	01/02/2013 01/31/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Stephen R. Auten COZEN O'CONNOR	ANDA 202093 - FILING RECEIPT, CORR, PATENT CERTIFICATIONS ETC
2013-22	01/02/2013 01/31/2013	FDA/OC/OES/DFOI/	RONALD A. MARRON LAW OFFICES OF RONALD A MARRON	UNDREDACTED RECS
2013-23	01/02/2013 01/31/2013	OC/ORO/ORM/ OC/ORO/ORM/	JOHNATHAN RICKMAN FDA NEWS	ALL NOTICES TO PHARMACEUTICALS - 483'S 11/12
2013-24	01/02/2013 01/31/2013	FDA/OGROP/ORO/CE-FO/CHI- DO/CHI-CB/	SINEAD O'DONOGHUE GLOOR LAW GROUP LLC	ROLFS PATISSERIE, LINCOLNWOOD, IL - S AUREUS OUTBREAK SINCE 11/2/10
2013-25	01/02/2013 01/31/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	A. LUKE SMITH FARUQI & FARUQI LLP	RANBAXY, BATAMANDI - EIR 3/08
2013-26	01/02/2013 03/13/2013	FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	REZA TORKZADEH TORKZADEH LAW FIRM	PMA P950022
2013-27	01/02/2013	FDA/OMPT/CBER/OCOD/DDOM/	DAVID HILZENRATH	MERCK - ZOSTAVEX SHINGLES PATIENTS

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	01/31/2013	ALFB/	PROJECT ON GOVERNMENT OVERSIGHT	
2013-28	01/02/2013 01/31/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KIMBERLY D. ERNST COREPHARMA LLC	SANOBI - DIABETA NDA 17-532 SBA
2013-29	01/02/2013 01/31/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	VICTORIA SCOTT HEMISPHERX BIOPHARMA	HEMISPHERX BIOPHARMA INC, NEW BRUNSWICK, NJ - INSP CORR 10/12, 11/12
2013-30	01/02/2013 01/31/2013	FDA/OC/OES/DFOI/	REO TANOSHIMA, MD HOSPITAL FOR SICK CHILDREN	KEPPRA - AER
2013-31	01/02/2013 01/31/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SPENCER D29593, NATHAN	SEROQUEL - AER 2000 TO 2008
2013-32	01/02/2013 01/31/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	THOMAS T67081, KEITH	CANNABINOIDS - APRVL RPT
2013-33	01/02/2013 01/31/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	HENLEY 56354 112, FRANK	EFFEXOR - AER
2013-34	01/02/2013 01/31/2013	FDA/OC/OES/DFOI/	Megan Pickel BEVERIDGE & DIAMOND	CFSAN FOIA REQUESTS (12/01/2012 - 01/02/2013)
2013-35	01/02/2013 01/31/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	LIST OF CLOSED FOIA REQUESTS (1/1/2012 - 12/31/2012)
2013-36	01/02/2013 01/31/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	LIST OF CLOSED FOIA REQUESTS (12/1/12-12/31/12)
2013-37	01/02/2013 01/31/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG (12/1/12-12/31/2012)
2013-38	01/02/2013 01/31/2013	FDA/OC/OES/DFOI/	GLADYS B. TONKIN WASHINGTON INFORMATION SOURCE	DAILY LOG 12/10-14/12
2013-39	01/02/2013	FDA/OC/OES/DFOI/	GLADYS B. TONKIN	DAILY LOG 12/17-21/12

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	01/31/2013		WASHINGTON INFORMATION SOURCE	
2013-40	01/02/2013 01/31/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 12/17-21/12
2013-41	01/02/2013 01/31/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 12/10-12/12
2013-42	01/02/2013 01/31/2013	FDA/OC/OES/DFOI/	DEBRA L. COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 12/10-14/12
2013-43	01/02/2013 01/31/2013	FDA/OC/OES/DFOI/	DEBRA L. COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 12/17-21/12
2013-44	01/02/2013 01/31/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 12/10-14/12
2013-45	01/02/2013 01/31/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 12/17-21/12
2013-46	01/02/2013 01/31/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 12/10-14/12
2013-47	01/02/2013 01/31/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 12/17-21/12
2013-48	01/02/2013 01/31/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 12/17-21/12
2013-49	01/02/2013 01/31/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 12/10-14/12
2013-50	01/02/2013 01/31/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 12/10-14/12
2013-51	01/02/2013 01/31/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 12/17-21/12
2013-52	01/03/2013 02/01/2013	OC/OM/OMP/DDM/	MINDY B. DUANE INFOTECH DATA RESEARCH	DKT FDA- 1995-S-0039
2013-53	01/03/2013 02/01/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 12/17-21/12
2013-54	01/03/2013	FDA/OC/OES/DFOI/	DAVID MCFARLAND	CLOSED FOIA REQUESTS 12/17-21/12

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	02/01/2013		FDA WEBVIEW/FERDIC INC	
2013-55	01/03/2013 02/01/2013	FDA/OC/OES/DFOI/	LISA TARISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 12/17-21/12
2013-56	01/03/2013 02/01/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS12/17-21./12
2013-57	01/03/2013 02/01/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 12/17-21/12
2013-58	01/03/2013 02/01/2013	FDA/OC/OES/DFOI/	GLADYS B TONKIN WASHINGTON INFORMATION SOURCE	CLOSED FOIA REQUESTS 11/26-30/12
2013-59	01/03/2013 02/01/2013	FDA/OC/OES/DFOI/	GLADYS B TONKIN WASHINGTON INFORMATION SOURCE	CLOSED FOIA REQUESTS 12/3-7/12
2013-60	01/03/2013 02/01/2013	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/ FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	BRENDA M GARTZ ELI LILLY & CO	CARDINAL HEALTH, ORLANDO, FL - EIR 3/11
2013-61	01/03/2013 02/01/2013	FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/	BRENDA M GARTZ ELI LILLY & CO	HOSPIRA, MCPHERSON, KS - EIR 1/12, 5/12
2013-62	01/03/2013 02/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	MUSTAFA NEVZAT, YENIBONSNA, TURKEY - EIR 4/12
2013-63	01/03/2013 02/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	MUTSAFA NEVZAT LLAC SANAYII, ISTANBUL, TURKEY - EIR 11/10
2013-64	01/03/2013 02/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/CVM/OCD/	BRENDA M GARTZ ELI LILLY & CO	NORBROOK LABS, NEWRY, GB - EIR 4/12

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2013-65	01/03/2013 02/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	ORION CORP, ESPOO, FINLAND - EIR 6/11
2013-66	01/03/2013 02/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MAE WU NATURAL RESOURCES DEFENSE COUNCIL	COLGATE-PALMOLIVE - NDA 02-0231 RVWS, PHARMACOLOGY, TOXICOLOGY RECS
2013-67	01/03/2013 02/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KATE PURCELL DOCUTRIEVAL INFORMATION SERVICES	IMPAX - ANDA 76-298 APRVL LTR
2013-68	01/03/2013 02/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CASSELLS, KEITH	AVANDIA - AERS
2013-69	01/03/2013 02/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	SEAN HIGGINS ANDREWS THORNTON	JACK3D, OXYELITE PRO, NUTREX LIPO-6 BLACK PRODS, ETC - AERS 5/12 TO PRESENT
2013-70	01/03/2013 02/01/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	DAVID HILZENRATH PROJECT ON GOVERNMENT OVERSIGHT	MERCK SHARP & DOHME - ZOSTAVAX NDA 12-5123 ANNUAL RPTS 12/30/09, 6/18/12
2013-71	01/03/2013 02/01/2013	FDA/OFVM/CFSAN/OCD/EOS/ OC/OCOS/OES/ OC/OCOS/OES/	SHANNA DEVINE GOVERNMENT ACCOUNTABILITY PROJECT	CRUDE OIL, COREXIT 9500, COREXIT 9527 - TRANS, INTERVIEWS, STATEMENTS, ETC 4/20/10 TO 1/26/12
2013-72	01/03/2013 02/01/2013	FDA/OC/OES/DFOI/	YOIRA FERNANDEZ FREIDIN DORBRINSKY ATTY AT LAW	2012-6312 (CERTIFIED)
2013-73	01/03/2013 02/01/2013	OC/ORO/ OC/ORO/	Doe J	CMPLNT
2013-74	01/03/2013 02/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 202379 S5

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-75	01/03/2013 02/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	RICHARD O DEROBERTS DEROBERTS, RICHARD O	K111501
2013-76	01/03/2013 02/01/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	Rachel Nosowsky UNIVERSITY OF CALIFORNIA	COLUMBIA PRESBYTERIAN MEDICAL CENTER, NEW YORK, NY - 483, EIR, CORR (01/01/2011 - 01/01/2013)
2013-77	01/03/2013 02/01/2013	FDA/OFVM/CFSSAN/OCD/EOS/	Michelle Minton The Competitive Enterprise Institute	DIET COKE, MOUNTAIN DEW, COCA COLA, ETC - AERS (01/01/08 TO 01/01/13)
2013-78	01/03/2013 02/01/2013	OC/OA/OM/OMP/DDM/	Dan Litvin Garwin, Gerstein & Fisher LLP	DKT 2007-P-011, 2008-D-0369 (CERTIFIED)
2013-79	01/03/2013 02/01/2013	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	SUBSTANTIAL EQUIVALENT TOBACCO INFORMATION
2013-80	01/03/2013 02/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	Dolly Mistry COVIDIEN	K954300
2013-81	01/03/2013 02/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	BLA 125084 S153
2013-82	01/03/2013 02/01/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	Kara Morgenstern UNIVERSITY OF MICHIGAN	COLUMBIA PRESBYTERIAN HOSPITAL, NEW YORK, NY - 483 (07/01/2012 - 08/31/2012)
2013-83	01/03/2013 02/01/2013	OC/ORA/OE/ OC/ORA/OE/	WIEJIA DAI University of Maryland, College Park	MEDICAL DEVICE RECALL DATA (06/01/1976 - 12/31/2012)
2013-84	01/03/2013 02/01/2013	OC/CVM/OCD/	Julie putnam NBC UNIVERSAL	JERKY PET TREAT INSPECTIONS - VIDEOS, PHOTOS, ETC (MARCH/APRIL 2012)
2013-85	01/03/2013 02/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Thomas Perls MD, MPH BOSTON UNIVERSITY SCHOOL OF MEDICINE	GENOTROPIN, NORDITROPIN, NUTROPIN, ETC -ANNUAL DISTRIBUTION DATA REPORTS
2013-86	01/03/2013 02/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Steve Auten COZEN O'CONNOR	VALSARTAN FORFEITURE MEMO

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2013-87	01/03/2013 02/01/2013	FDA/OC/OES/DFOI/	WHITE, HORTENSE S	INDIVIDUAL RECS
2013-88	01/03/2013 02/01/2013	FDA/OC/OES/DFOI/	WHITE, HORTENSE S	INDIVIDUAL RECS
2013-89	01/04/2013 05/29/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OGROP/ORASW-FO/DEN- DO/DEN-CB/ FDA/OGROP/ORACE-FO/CHI- DO/CHI-CB/ FDA/OGROP/ORASE-FO/SJN- DO/SJN-CB/	GARCIA JR, NARCISO	INDIVIDUAL RECS
2013-90	01/04/2013 02/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	DANIEL W ERNSBERGER ESQ BEHREND ERNSBERGER, PC	BARD ACCESS SYSTEMS INC - POWER PICC CATHETERS MDRS
2013-91	01/04/2013 02/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	HELEN LEWIS DENTSPLY INTERNATIONAL	DAMON 4CLEAR K081415
2013-92	01/04/2013 02/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	HELEN LEWIS DENTSPLY INTERNATIONAL	EMPOWER CLEAR K122753
2013-93	01/04/2013 02/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	HELEN LEWIS DENTSPLY INTERNATIONAL	CLARITY MODIFIED CERAMIC BRACKETS K062305
2013-94	01/04/2013 02/04/2013	FDA/OFVM/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 150606, 150166
2013-95	01/04/2013 02/04/2013	FDA/OFVM/CFSAN/OCD/EOS/	Doe J	RED BULL, 5 HOUR ENERGY, MONSTER, ROCKSTAR ENERGY DRINKS - CAERS
2013-96	01/04/2013 02/04/2013	FDA/OC/OES/DFOI/	WHITE, HORTENSE S	INDIVIDUAL RECS
2013-97	01/04/2013 02/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOANNE S HAWANA ARENT FOX LLP	ISRS 8255707, 8439906, 8444371, ETC
2013-98	01/07/2013 03/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K121876
2013-99	01/07/2013 02/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K020791

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2013-100	01/07/2013 02/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K090435
2013-101	01/07/2013 02/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Deb Hogerman UCB, Inc.	NDA 21829 S 001, 002
2013-102	01/07/2013 02/05/2013	FDA/OFVM/CFSAN/OCD/EOS/	Becky Cooseman Brown & Crouppen, PC	MEAD JOHNSON NUTRITION - REPORTABLE FOOD REGISTRY REPORTING (01/01/2002 - 01/03/2013)
2013-103	01/07/2013 02/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Laird Forrest HylaPharm	ABRAXANE IND - 505(B)(2) APPLICATION
2013-104	01/07/2013 02/05/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Karin Desjardins COVIDIEN	K962577
2013-105	01/07/2013 02/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dan Litvin Garwin, Gerstein & Fisher LLP	ANDA 090596, 090402, 091195 ETC - SBA
2013-106	01/07/2013 02/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	Qiuhu Shi NEW YORK MEDICAL COLLEGE	K051672, K072625, K102159
2013-107	01/07/2013 02/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	Amy Weisman, Kennedy & Berris	K003363
2013-108	01/07/2013 02/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	SILICONE, GEL-FILLED AND SALINE BREAST IMPLANTS - CLNCL TRIALS, REGULATIONS
2013-109	01/07/2013 02/05/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	DAVID HILZENRATH PROJECT ON GOVERNMENT OVERSIGHT	MERCK - ZOSTAVAX SHINGLES PREVENTION STUDY SUMMARY MASTER FILE; BIOLOGICAL LICENSE APPL (BLA)
2013-110	01/07/2013 02/05/2013	OC/ORO/ORM/ OC/ORO/ORM/	GAIL LESSICK LACHMAN CONSULTANT SERVICES INC	DOMESTIC AND FOREIGN INSPECTIONS, 11/1-30/12, DRUG COMPANIES, MDM, BIMO AND GLP
2013-111	01/07/2013 02/05/2013	OC/OSMP/OOPD/ FDA/OMPT/OSMP/OOPD/	Laird Forrest HylaPharm	XALKORI - ORPHAN DRUG DESIGNATION
2013-112	01/07/2013	FDA/OMPT/CDER/ORP/DIDP/	Philip William Blair	CRESTOR - AERS

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	02/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Self	
2013-113	01/07/2013 02/05/2013	FDA/OFVM/CFSAN/OCD/EOS/ OC/OCOS/OES/ OC/OCOS/OES/	NICOLE C. ANDERSEN KREINDLER & KREINDLER	ENERGY DRINKS, DAWN RPT 11/22/11
2013-114	01/07/2013 02/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Eric H. Weinberg, Esq. Law Firm of Eric H. Weinberg	NDA 22512 S011
2013-115	01/07/2013 02/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DON J MIZERK HUSCH BLACKWELL LLP	MALLINKRODT INC - METHYLPHENIDATE HCL ANDA 202-608 APRVL LTR 12/28/12
2013-116	01/07/2013 02/05/2013	FDA/OMPT/CDRH/OCER/DFOI/ OC/OA/OM/OMP/DDM/ FDA/OMPT/CDRH/OCER/DFOI/	AudismFreeAmerica Audism Free America	EFFICACY OF COCHLEAR IMPLANTATION WITH YOUNG DEAF CHILDREN - REPORT OF EXPERT PANEL (06/26/85-06/28/85)
2013-117	01/07/2013 02/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	Marilyn Peguero-Fain freelance reporter	CRANIAL ORTHOSIS DEVICES - COMPLAINTS, FULL REPORTS
2013-118	01/07/2013 02/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELLIOT FAVUS, M.D. FAVUS INSTITUTIONAL RESEARCH LLC	XTANDI (ENZALUTAM DE, MDV3100) - AERS 1/1/10 TO PRESENT
2013-119	01/07/2013 02/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sajjan Aryal Accucaps Industries Limited	MSN LABORATORIES LTD, ANDHRA PRADESH, INDIA - EIR (03/5/12)
2013-120	01/07/2013 02/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Orange Book archive DATAMONITOR HEALTHCARE CONSULTING	ORANGE BOOK - 2006
2013-121	01/07/2013 02/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	THALIDOMIDE, THALOMID - COMMUNICATIONS, APPROVALS, RESTRICTIONS, ETC

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/OCOS/OES/ OC/OCOS/OES/ OC/OA/OM/OMP/DDM/		
2013-122	01/07/2013 02/05/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	MARY SCHWAGER WHDH-TV INC	D'ORO FOODS INC, MALDEN, MA; GATE GOURMET INC UNIT 231, EAST BOSTON, MA; DELTA AIR LINES INC, EAST BOSTON, MA, ETC - 483S
2013-123	01/07/2013 02/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Deb Hogerman UCB, Inc.	BLA 125160 S 080
2013-124	01/07/2013 02/05/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Doe J	INTRADERMAL VACCINE LOT NUMBER UT4463AA - VAERS
2013-125	01/07/2013 03/13/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Walter Kyle Walter Kyle	IPV, EIPV - UNPUBLISHED DATA AVAILABLE FROM SANOFI PASTEUR SA AND INC
2013-126	01/07/2013 02/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	Andrea McCready McCready, Andrea	K030765, K844550
2013-127	01/07/2013 02/05/2013	OC/OA/OM/OMP/DDM/	Walter Kyle Walter Kyle	VRBPAC - TRANSCRIPTS (07/29/85, 7/30/85)
2013-128	01/07/2013 02/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jonathon Doherty Milagro Community Care	XANAX - CLINICAL TRIALS, CORR
2013-129	01/07/2013 02/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Eric Schmidt COWEN AND COMPANY	BREAKTHROUGH CANDIDATES
2013-130	01/07/2013 02/05/2013	OC/ORO/ OC/ORO/	Doe J	INDIVIDUAL RECS
2013-131	01/07/2013 02/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	MONIKA BHATT HODGSON RUSS LLP	3M - LAVA ULTIMATE CAD/CAM RESTORATIVE K122569
2013-132	01/07/2013 04/04/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	MARTIN RUBENSTEIN HOWARD M FILE ATTY	INDIVIDUAL RECS - VAERS

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2013-133	01/07/2013 02/05/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	BRIANNE RIDEOUT ASHCRAFT & GEREL LLP	CELLULAR TELEPHONE DVCS- SCIENTIFIC STUDIES, CORR, INVESTIGATIONS, ETC
2013-134	01/07/2013 02/05/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	J. DONALD HENSON, SR Henson, J. Donald	MEDTRONIC - INSULIN PUMP P980022 RECS
2013-135	01/08/2013 02/06/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	KYOCERA Medical Corporation KYOCERA Medical Corporation	K041940
2013-136	01/08/2013 02/06/2013	FDA/OC/OES/DFOI/	JOHN A. HOWARD-ALGARIN BAMUNDO ZWAL ET AL	LAPAROSCOPIC TOCAR INJURIES RPT - CERTIFIED COPY
2013-137	01/08/2013 02/06/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Robert Harris Biosim	NDA 008372; NDA 017861; NDA 010831 ETC
2013-138	01/08/2013 02/06/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORO/OCI/ OC/ORO/OCI/	ANDERSON, CARL.	LABPE.COM - SALE OF PEPTIDES, ANABOLIC STEROIDS 1/11 TO PRESENT
2013-139	01/08/2013 02/06/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORO/OCI/ OC/ORO/OCI/	ANDERSON, CARL.	AJ GLOBAL LTD, DERL & EXTREME PEPTIDES.COM - SALE OF PEPTIDES, ANABOLIC STEROIDS 1/11 TO PRESENT
2013-140	01/08/2013 02/06/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bill Orr Bill Orr	CHANTIX - AERS
2013-141	01/08/2013 02/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	E.J. Smith Smith Associates	K060866
2013-142	01/08/2013 02/06/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dan Reed Celsus Laboratories, Inc.	SHENZHEN HEPALINK PHARMACEUTICAL CO LTD, GUANGDONG PROVINCE, CHINA - 483 , EIR (11/15/2008 - 01/07/2013)

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-143	01/08/2013 02/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	E.J. Smith Smith Associates	K001368
2013-144	01/08/2013 02/06/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Glenn Irish Glenn Irish Consulting	SHIRE HGT - 483 (11/07/2011 - 01/07/2013)
2013-145	01/08/2013 02/06/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	BioCare Biocare Enterprise Limited	K002712
2013-146	01/08/2013 02/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ismail Elchagea International Trading Pharmaceutical Lab	NEXAVAR TABLETS - IND, NDA
2013-147	01/08/2013 02/06/2013	OC/CVM/OCD/ OC/OCOS/OES/ OC/OCOS/OES/ OC/OA/OM/OMP/DDM/	ELISABETH HOLMES CENTER FOR FOOD SAFETY	ZILMAX (ZILPATEROL) APRVL, AER, WARNING LTRS
2013-148	01/08/2013 02/06/2013	FDA/OGROP/ORASW-FO/KAN- DO/KAN-CB/	BRENDA M. GARTZ ELI LILLY & CO	OZBURN HESSEY LOGISTICS WAREHOUSE, KANSAS CITY, MO - EIR 12/11
2013-149	01/08/2013 02/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENDA M. GARTZ ELI LILLY & CO	PATHEON BURLINGTON CENTURY OPERATIONS, BURLINGTON, CANADA - EIR 2/11
2013-150	01/08/2013 02/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENDA M. GARTZ ELI LILLY & CO	PATHEON TORONTO REGION OPERATIONS, MISSISSAUGA, CANADA - EIR 2/11
2013-151	01/08/2013 02/06/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	LEAH GOMEZ THE HUMANE SOCIETY OF THE UNITED STATES	ENVIRONMENTAL ENHANCEMENT PLAN FOR NON HUMAN PRIMATES BY HSUS
2013-152	01/08/2013 02/06/2013	OC/OSMP/OOPD/ FDA/OMPT/OSMP/OOPD/	Herriot Tabuteau Axsome Therapeutics, Inc.	CALCITONIN HUMAN FOR INJECTION - ORPHAN DESIGNATION
2013-153	01/08/2013 02/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ya Ping Lee School of Pharmacy Curtin University	OMEPRAZOLE, ESOMEPRAZOLE, LANSOPRAZOLEM ETC - AERS

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-154	01/08/2013 02/06/2013	FDA/OC/OES/DFOI/	Johnathan Rickman FDANEWS	FOIA LOG (12/31/2012 - 01/04/2013)
2013-155	01/08/2013 02/06/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Dan Reed Celsus Laboratories, Inc.	PHARMACIA HEPAR INC, FRANKLIN, OH - 483, EIR, CORR (01/01/2011 - 01/07/2013)
2013-156	01/08/2013 02/06/2013	FDA/OGROP/ORAPA-FO/SEADO/SEA-CB/	KRISTINA FRYE FRYE ELECTRONICS	FRYE ELECTRONICS, TIGARD, OR - EIR 6/22-7/3/12
2013-157	01/08/2013 02/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	E.J. Smith Smith Associates	K972527
2013-158	01/08/2013 02/06/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OC/OES/DFOI/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Richard P Dickey, MD, PhD Fertility Institute of New Orleans	IVF CLINICS - DISASTER RESPONSE INSPECTIONS (08/21/12-8/30/12)
2013-159	01/08/2013 02/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	LORAZEPAM; DIPHENHYDRAMINE; DOXEPIN; VALPROIC ACID SYRUP; MIRTAZAPINE - AER
2013-160	01/08/2013 02/06/2013	FDA/OGROP/ORA/ORO/DIOP/	DONALD BLUE GLOBAL TRADE INTELLIGENCE	IMPORT 20120103-1

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			INC	
2013-161	01/08/2013 02/06/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	MURIS DEMIROVIC FDA NEWS	MINDRAY DS USA INC, MAHWAY, NJ - 483 6/11/12 - 8/2/12
2013-162	01/08/2013 02/06/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	DAVID HILZENRATH PROJECT ON GOVERNMENT OVERSIGHT	MERCK - HERPEX ZOSTER RECORDED IN THE MINI SENTINEL DATABASE AER
2013-163	01/08/2013 02/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GAVIN ANDERSON AZAYA THERAPEUTICS INC	DOXIL NDA 50-718 - SUPPLEMENTAL NDA
2013-164	01/08/2013 02/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRUCE W. STECKLER STECKLER LAW LLP	AMGEN INC - EPOETIN ALFA (EPOGEN)
2013-165	01/08/2013 02/06/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	J. DONALD HENSON, SR Henson, J. Donald	PMA P980022
2013-166	01/08/2013 02/06/2013	OC/OM/OMP/DDM/	SEAN CRANSHAW THE PEW CHARITABLE TRUSTS	DKT 1993N-0029, 1980N-0446, ETC.
2013-167	01/09/2013 02/07/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Aaron Diamant WSB-TV	GATE GOURMET, ATLANTA HARTSFIELD JACKSON INTERNATIONAL AIRPORT - EIR, WARNING LETTER, CORR, ETC (12/01/2012 - 01/07/2013)
2013-168	01/09/2013 02/07/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Dan Reed Celsus Laboratories, Inc.	SCIENTIFIC PROTEIN LABORATORIES LLC, WAUNAKEE, WI - 483, EIR (12/09/2009 - 01/07/2013)
2013-169	01/09/2013 02/07/2013	OC/OM/OMP/DDM/	CARLA SCARMAZZI KING & SPALDING	DKT FDA-2012-N-0378
2013-170	01/09/2013 02/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dan Reed Celsus Laboratories, Inc.	NANKING KING-FRIEND BIOCHEMICAL PHARMACEUTICAL CO, JIANGSU - 483, EIR (09/01/2009 - 01/07/2013)
2013-171	01/09/2013 02/07/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Dan Reed Celsus Laboratories, Inc.	ORGANON API, INC, SIOUX CITY, IA - 483, EIR (02/01/2009 - 01/07/2013)
2013-172	01/09/2013 02/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dan Reed Celsus Laboratories, Inc.	BIOBERICA, SA, BARCELONA, SPAIN - 483, EIR (03/15/2009 - 01/07/2013)

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-173	01/09/2013 02/07/2013	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	Ann M. Carvalho McLarens Global Claim Services	SNYDER'S LANCE, CHARLOTTE, NC AND COLUMBUS, GA - INVESTIGATION RECS, REPORTS, INSPECTION RECS ETC (03/01/2012 - 01/07/2013)
2013-174	01/09/2013 02/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	K121598
2013-175	01/09/2013 02/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	James Collie J. R. Collie Associates, Inc.	K102758
2013-176	01/09/2013 02/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Betty Johnson Betty Johnson	K102727
2013-177	01/09/2013 02/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Betty Johnson Betty Johnson	K121091
2013-178	01/09/2013 02/07/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Betty Johnson Betty Johnson	K113479
2013-179	01/09/2013 02/07/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	K110735
2013-180	01/09/2013 02/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Mick Fenton Immunodiagnostic Systems Ltd	K831178
2013-181	01/09/2013 02/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	EMILY K STRUNK AKIN GUMP STRAUSS HAUER & FELD, LLP	XANDI (ENZALUTAMIDE) - AERS 8/31/12 TO PRESENT
2013-182	01/09/2013 02/07/2013	OC/OA/OM/OMP/DDM/	JANNA DEPORTER CENTER FOR SCIENCE IN PUBLIC INTEREST	DKT 1999P-2630
2013-183	01/09/2013 03/15/2013	OC/ORR/ OC/ORR/ FDA/OGROP/ORR/NE-FO/NWE-DO/NWE-CB/ FDA/OFVM/CFSAN/OCD/EOS/	PATTI WELLER MARLER CLARK ATTYS	STATE GARDEN INC - ORGANIC SPINACH AND SPRING MIX BLEND E COLI OUTBREAK INVESTIGATION RECS, LAB RESULTS, CORR, ETC11/2/12
2013-184	01/09/2013 02/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GAIL C TRABISH ESQ BOORNAZIAN JENSEN &	VALIDUS PHARMS - EQUETRO CORR, APRVL RECS, LBLG, ETC

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2013-185	01/09/2013 02/07/2013	FDA/OC/OES/DFOI/	ELENA HOWELL HOGAN LOVELLS US LLP	2012-8987
2013-186	01/09/2013 02/07/2013	FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	JENNIFER CONNER AMERICAN CLAIMS MANAGEMENT	BRIGHT REHAB SOLUTIONS INC, BAKERSFIELD, CA; GLENDALE, CA - IMPORTER REGISTRATION, EIRS, 483S, ETC 2009 TO PRESENT
2013-187	01/09/2013 02/07/2013	FDA/OFVM/CFSAN/OCD/EOS/	MARILYNN WHITNEY COVINGTON BURLING LLP	COCA-COLA - FULL THROTTLE & NOS; DR PEPPER- VENOM; PEPSICO - AMP & ADRENALINE RUSH CAERS
2013-188	01/09/2013 02/07/2013	FDA/OMPT/CTP/OD/	MARILYNN WHITNEY COVINGTON BURLING LLP	TOTAL NUMBER OF PROVISIONAL AND NON-PROVISIONAL TOBACCO PROD SUBSTANTIAL EQUIVLENCE (SE) RPTS, MODIFIED RISK TOBACCO PRODS, ETC
2013-189	01/09/2013 02/07/2013	FDA/OC/OES/DFOI/	JOHN CREWDSON PROJECT ON GOVERNMENT OVERSIGHT	RANBAXY, OHM - BLOOMBERG NEWS, NEW YORK TIMES ATORVASTATIN REQUESTS
2013-190	01/09/2013 02/07/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	DAVID HILZENRATH PROJECT ON GOVERNMENT OVERSIGHT	MEMOS, CORR, EMAIL WHICH DISCUSS THE INCIDENCE OF HERPES ZOSTER DURING THE POST-MARKETING PERIOD IN INDIVIDUALS VACCINATED WITH ZOSTAVAX
2013-191	01/09/2013 02/07/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Heuston, Brian	ADVIL PM - AERS
2013-192	01/09/2013 02/07/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Heuston, Brian	TYLENOL PM - AERS
2013-193	01/09/2013 02/07/2013	FDA/OGROP/ORO/CE-FO/CIN-DO/CIN-CB/	BRENDA M GARTZ ELI LILLY & CO	PROVIMI NORTH AMERICA, LEWISBURG, OH - EIRS 3/11, 10/11
2013-194	01/09/2013 02/07/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	QILU PHARMACEUTICAL FACTORY, JINAN, CHINA - EIR 7/11

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2013-195	01/09/2013 02/07/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	BRENDA M GARTZ ELI LILLY & CO	SANDOZ, WILSON, NC - EIR 6/11
2013-196	01/09/2013 02/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	LISA BURNS CHURCH & DWIGHT CO INC	SPD SWISS PRECISION DIAGNOSTICS GMBH - K112870
2013-197	01/09/2013 02/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ALBERTO ORTEGA UNIV OF FLORIDA WARRINGTON COLLEGE OF BUSINESS	ORANGE BOOK, NDC DIRECTORY 2001 TO 2011
2013-198	01/09/2013 02/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	C RICHARD MARSHALL C RICHARD MARSHALL LAW OFCS	TRAMADOL - AERS
2013-199	01/09/2013 02/07/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	JOHN WALSH JAMES ALEXANDER CORP	MP BIOMEDICALS LLC, SOLON, OH - EIRS, 488S, RECALLS 1/11 TO PRESENT
2013-200	01/09/2013 02/07/2013	OC/ORA/ OC/ORA/	INGRID S MARTIN COLLORA LLP	AMERIDOSE LLC - RAW MATERIAL, ENVIRONMENTAL SPL TEST RESULTS
2013-201	01/09/2013 02/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	CROSBY T-50417, COURTNEY	GRANUFLO, NATURLYT - BLACK BOX WARNING, RECALL RECS
2013-202	01/10/2013 02/08/2013	FDA/OFVM/CFSSAN/OCD/EOS/	Lena Gomez Keller and Heckman, LLP	FDA OPINION LETTER RE MILK PROTEIN CONCENTRATE
2013-203	01/10/2013 02/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	MAREK KUNECKI, LODZ, POLAND - 483 MOST RECENT
2013-204	01/10/2013 02/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Robert Oberlender Synthonics, Inc.	SINEMET, SINEMET CR - SBA
2013-205	01/10/2013	FDA/OGROP/ORA/NE-FO/NYK-	Leslie Paul	ALTARIE PHARMACEUTICALS, AQUEBOGUE, NY - EIR, 483

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	02/08/2013	DO/NYK-DCB/	PERRIGO CO	(2/01/2010 - 01/08/2013)
2013-206	01/10/2013 02/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	AYA NAGANO KYOCERA Medical Corporation	K120370
2013-207	01/10/2013 02/08/2013	OC/ORO/ OC/ORO/	Loren Larkin LARKIN, LOREN	ST JUDE MEDICAL, SYLMAR, CA AND SAN JUAN, PR - RESPONSE TO 483 (11/02/2012 - 01/09/2013)
2013-208	01/10/2013 02/08/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jonathan Zand, PharmD UpToDate a div of Wolters Kluwer Health	APIXABAN - SBA
2013-209	01/10/2013 02/08/2013	FDA/OFVM/CFSAN/OCD/EOS/	Judy Negley Valspar Corporation	FCN 635
2013-210	01/10/2013 02/08/2013	OC/OA/OM/OMP/DDM/	ronald piana Ronald Piana	IMMUNOLOGY DEVICES ADVISORY PANEL MEETING - TRANSCRIPT (12/09/1985)
2013-211	01/10/2013 02/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	jack rubinstein UNIVERSITY OF CINCINNATI	PROBENECID - APPROVAL RECS
2013-212	01/10/2013 02/08/2013	FDA/OFVM/CFSAN/OCD/EOS/	Ryan Simon CANTOX Health Sciences International	FRUIT/VEGETABLE JUICE COLORING - OPINION LETTERS AND CORR
2013-213	01/10/2013 02/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ketan Parekh Parekh, Ketan	IND 18004, NDA 019839
2013-214	01/10/2013 02/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dustin Block IPD Analytics, LLC	ANDA 200644 - EFFECTIVE APPROVAL LETTER
2013-215	01/10/2013 02/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Marie-Hlne Dancause pharmacist, Hôtel-Dieu de Lévis	VYVANSE - AERS

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2013-216	01/10/2013 02/08/2013	OC/CVM/OCD/ OC/OA/OM/OMP/DDM/	Michael Mlodzik Boehringer Ingelheim Vetmedica, Inc.	SUITABILITY PETITION 09P-0306/CPI
2013-217	01/10/2013 02/08/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	RICHARD C. BADEAUX DEGAN BLANCHARD EL AL	CREATIVE COMPOUNDS LLC, SCOTT CITY, MO - EIR 1/15/10 METAL ANTIMONY IN STEVIA LEAF EXTRACT
2013-218	01/10/2013 02/08/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	TEDD KESSLER LAW OFFICE OF TED KESSLER PC	STRYKER TRIDENT - CEMENTLESS CUPS, POLYETHYLENE SHELLS; SECUR FIT MAX STRYKER STEMS CMLPLNTS, WARNING LTR, MDRS 2005 TO PRESENT
2013-219	01/10/2013 02/08/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HEUSTON 240731, BRIAN	AMITRIPTYLINE - AER
2013-220	01/10/2013 02/08/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HEUSTON 240731, BRIAN	ELAVIL - AER
2013-221	01/10/2013 02/08/2013	FDA/OC/OES/DFOI/	ANDREWS D17561, JOHN	MORTON GROVE PHAMACEUTICAL - SELENIUM SULFIDE LOTION; PERRIGO - SELENIUM SULFIDE TOPICAL SUSPENSION
2013-222	01/10/2013 02/08/2013	OC/CVM/OCD/ FDA OC/OA/OM/OMP/DDM/	Michael Mlodzik Boehringer Ingelheim Vetmedica, Inc.	SUITABILITY PETITION 2-P-0945-0001
2013-223	01/10/2013 02/08/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ketan Parekh Parekh, Ketan	MIRENA - IND, NDA
2013-224	01/10/2013 02/08/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Rachel Johnson FOI Services, Inc.	INFLUENZA VACCINE - VAERS

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2013-225	01/10/2013 02/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kim Capone Porzio Life Sciences	SERAX - REGULATORY LETTER ISSUED BY THE DIVISION OF ADVERTISING, BUREAU OF DRUGS (01/01/1975 - 01/31/1975)
2013-226	01/10/2013 02/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	DEEP TMS BY BRAINSWAY - 510K
2013-227	01/10/2013 02/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Edward McPike Stifel Nicolaus & Co	NUSKIN - APPLICATION FOR CLEARANCE OF A FACIAL SPA UNIT
2013-228	01/10/2013 02/08/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ OC/ORA/OCI/ OC/ORA/OCI/	PAMELA BROOKS FIRST RECORDS RETRIEVAL	REFUSE OF SINGLE USE ENDOCAVITY NEEDLE GUIDES RECS 1/10 TO PRESENT
2013-229	01/10/2013 02/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/ FDA/OC/OES/DFOI/ OC/ORA/ OC/ORA/	PAUL W. SHAW K&L GATES	NEW ENGLAND COMPOUNDING CENTER, FRAMINGHAM, MA - INVESTIGATION RECS, LAB ANALYSES, TEST RESULTS, ETC 9/12 TO 10/12
2013-230	01/10/2013 02/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	A. LUKE SMITH FARUQI & FARUQI LLP	ANDA 40-445 APRVL
2013-231	01/10/2013 02/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	A. LUKE SMITH FARUQI & FARUQI LLP	ANDA 40-445 CROSS DISP RVW SUMMARY, SUMMARY RVW
2013-232	01/10/2013 02/08/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 12/24-28/12
2013-233	01/11/2013 02/11/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/	Tara J. Myslinski O'Connor, Carnathan & Mack, LLC	HEALTHPOINT - CORR RE HP802, ICX-SKN, OASIS, ETC

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2013-234	01/11/2013 02/11/2013	OC/OA/OM/OMP/DDM/	Sue Corbett THE RESEARCH INVESTMENT, INC.	SPECIAL REPORT TO FDA PUBLIC MEETING ON RE-EVALUATION OF RITODRINE LABELING (1992)
2013-235	01/11/2013 02/11/2013	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	Don Hammond Raymond Paul Johnson, A Law Corporation	EMBASSY SUITES, LA JOLLA, CA - PERMITS, COMPLAINTS, INSPECTION RECORDS ETC (05/22/2012 - 01/09/2013)
2013-236	01/11/2013 02/11/2013	FDA/OFVM/CFSAN/OCD/EOS/	Kayla Conroy Kayla Conroy	FOOD ADDITIVE PETITIONS FOR ARTIFICIAL SWEETENERS ETC
2013-237	01/11/2013 02/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joel Hoekstra Fresenius Kabi USA	NDA019952, NDA019953, NDA018609 ETC - SBA
2013-238	01/11/2013 02/11/2013	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/ FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAP/PA-FO/SAN-DO/SAN-CB/	Sarah Geisert GENERAL MILLS	GENERAL MILLS, WEST CHICAGO, IL - EIR 06/10; GENERAL MILLS, LODI, CA 08/10; GENERAL MILLS, BELVIDERE, IL - EIR 10/11
2013-239	01/11/2013 02/11/2013	OC/ORAO/OCI/ OC/ORAO/OCI/	Christopher Weaver THE WALL STREET JOURNAL	MEDIPLAN HEALTH CONSULTING, RXNORTH.COM - INVESTIGATION RECS
2013-240	01/11/2013 02/11/2013	OC/OSMP/OOPD/ FDA/OMPT/OSMP/OOPD/	HeeSun Lee Aclairo Pharmaceutical Development Group	ANATIBANT - ORPHAN PRODUCT DESIGNATION
2013-241	01/11/2013 02/11/2013	FDA/OC/OES/DFOI/	Christopher Weaver THE WALL STREET JOURNAL	MEDICAL DEVICE INOPERABILITY, SECURITY, CONNECTIVITY - FOIA REQUESTS AND STATUS (01/01/2011 - 01/10/2013)
2013-242	01/11/2013 02/11/2013	FDA/OC/OES/DFOI/	Christopher Weaver THE WALL STREET JOURNAL	COUNTERFEIT MEDICINES, MISBRANDED MEDICINES, UNAPPROVED MEDICINES - FOIA REQUESTS AND STATUS (01/01/2011 - 01/10/2013)
2013-243	01/11/2013 02/11/2013	FDA/OC/OES/DFOI/	Christopher Weaver THE WALL STREET JOURNAL	MASIMO CORP, COVIDIEN PLC, MINDRAY ETC - FOIA REQUESTS

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2013-244	01/11/2013 02/11/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Leslie Paul PERRIGO COMPANY	INTERNATIONAL VITAMIN CORP, FREEHOLD, NJ - 483, EIR (11/21/2011)
2013-245	01/11/2013 02/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Stephen From Eyegate Pharmaceuticals, Inc.	NDA 022212 (DUREZOL) - MEDICAL REVIEW
2013-246	01/11/2013 02/11/2013	OC/ORACE/OCI/ OC/ORACE/OCI/	Christopher Weaver THE WALL STREET JOURNAL	INVESTIGATION RECS
2013-247	01/11/2013 02/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 203752
2013-248	01/11/2013 02/11/2013	FDA/OFVM/CFSAN/OCD/EOS/ OC/OCOS/OES/ OC/OCOS/OES/	Alex Morrell Columbia School of Journalism	REGULATION OF DIETARY AND FITNESS SUPPLEMENTS - CAERS, EMAIL, MEMOS, ETC
2013-249	01/11/2013 02/11/2013	FDA/OGROP/ORACE-SW-FO/DAL-DO/DAL-CB/	Michael C. Cotugno Cotugno, Michael C	ANALYTICAL RESEARCH LABORATORIES, OKLAHOMA CITY, OK - 483 MOST RECENT(08/01/2012 - 01/10/2013)
2013-250	01/11/2013 02/11/2013	OC/OSMP/OOPD/ FDA/OMPT/OSMP/OOPD/	HeeSun Lee Aclairo Pharmaceutical Development Group	DEXANABINOL - ORPHAN DESIGNATION
2013-251	01/11/2013 02/11/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Joseph Thorpe Thorpe, Joseph	K993438, K011110, K042037 ETC
2013-252	01/11/2013 02/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GORDON JOHNSTON GORDON JOHNSTON REGULATORY CONSULTANTS LLC	HIKMA FARM - DILTIAZEM HCL ANDA 202-651; MYLAN LLC - TOPOTECAN HCL ANDA 201-166; ONCO THERAPIES LTD - CYTARABINE ANDA 201-784, ETC TENTATIVE APRVL LTR
2013-253	01/11/2013 02/11/2013	OC/ORACE/ORM/ OC/ORACE/ORM/	JOHNATHAN RICKMAN FDA NEWS	PHARMACEUTICAL, BIOLOGICS, MEDICAL DVC MFG, CLNCL TRIAL FACILITIES IN AND OUTSIDE THE US - 483S 12/1-31/12
2013-254	01/11/2013 02/11/2013	FDA/OGROP/ORACE-PA-FO/SEADO/SEA-CB/	JOHNATHAN RICKMAN FDA NEWS	PRECISION INTERCONNECT LLC (CONNECTIVITY MEDICAL), WILSONVILLE, OR; ADVANCED RENAL TECHNOLOGIES INC, BELLEVUE, WA - 483S 11/1-30/12
2013-255	01/11/2013 02/11/2013	FDA/OGROP/ORACE-SE-FO/SJN-DO/SJN-CB/	JOHNATHAN RICKMAN FDA NEWS	INTEGRA NEUROSCIENCES PR INC, ANASCO, PR - 483S 11/1-30/12

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2013-256	01/11/2013 02/11/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	JOHNATHAN RICKMAN FDA NEWS	BECTON DICKINSON AND CO, WILSON, NC; BEAUMONT PRODUCTS INC, KENNESAW, GA; DSM PHARMACEUTICALS INC, GREENVILLE, NC, ETC - 483S 11/1-30/12
2013-257	01/11/2013 02/11/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	JOHNATHAN RICKMAN FDA NEWS	ALEXZA PHARMACEUTICALS INC, MOUNTAIN VIEW, CA; NEVRO CORP, MENLO PARK, CA; CLAREBLEND INC, RENO, NV, ETC - 483S 11/1-30/12
2013-258	01/11/2013 02/11/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	JOHNATHAN RICKMAN FDANEWS	I HEALTH INC, WINDSOR, CT; ARTHROSURFACE INC, FRANKLIN, MA; ANIKA THERAPEUTICS INC, BEDFORD, MA - 483 11/12
2013-259	01/11/2013 02/11/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	JOHNATHAN RICKMAN FDA NEWS	PHOTOMEDEX INC, MONTGOMERYVILLE, PA; BIO-PHARM INC, LEVITTOWN, PA - 483S 11/1-30/12
2013-260	01/11/2013 02/11/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	JOHNATHAN RICKMAN FDA NEWS	FOUGERA PHARMACEUTICALS INC, HICKSVILLE, NY; NOVA HEALTH SYSTEMS INC, UTICA, NY; QUANTUM MEDICAL IMAGING LLC, RONKONKOMA, NY, ETC - 483S 11/1-30/12
2013-261	01/11/2013 02/11/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	JOHNATHAN RICKMAN FDA NEWS	CARMA LABORATORIES INC, FRANKLIN, WI; MODERN PRODUCTS INC, MEQUON, WI; NONIN MEDICAL INC, PLYMOUTH, MN - 483 11/12
2013-262	01/11/2013 02/11/2013	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	JOHNATHAN RICKMAN FDANEWS	VILEX IN TENNESSEE INC, MCMINNVILLE, TN; HEALTH SCIENCE PRODUCTS INC, HUEYTOWN, AL; AIONEX INC, GOODLETTSVILLE, TN, ETC - 483S 11/1-30/12
2013-263	01/11/2013 02/11/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	JOHNATHAN RICKMAN FDA NEWS	WATSON LABORATORIES INC, CORONA, CA; EVOFEM INC, SAN DIEGO, CA; RA MEDICAL SYS INC, CARLSBAD, CA - 483 11/12
2013-264	01/11/2013 02/11/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	JOHNATHAN RICKMAN FDA NEWS	APTUIT LLC, HARRISONVILLE, MO - 483 11/12
2013-265	01/11/2013 02/11/2013	OC/OR/ OC/OR/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHNATHAN RICKMAN FDA NEWS	ORION CORP, ESPOO, FINLAND; AARTI DRUGS LTD. MAHARASHTRA STATE, INDIA - 483 11/12
2013-266	01/11/2013 02/11/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	JHONATHAN RICKMAN FDA NEWS	OMRIX BIOPHARMACEUTICALS LTD, KIRYAT-ONO, ISRAEL; VETTER PHARMA FERTIGUNG GMBH & CO KG, RAVENSBURG, GERMANY; DOMINION BIOLOGICALS LTD, DARTMOUTH, CANADA - 483 11/12
2013-267	01/11/2013 02/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHNATHAN RICKMAN FDA NEWS	TABERNA PRO MEDICUM, LUENBURG, GERMANY; FISIOLINE SRL, VERDUNO, ITALY; LINET SPOL SRO, SLANY, CZECH REPUBLIC - 483 11/12
2013-268	01/11/2013	FDA/OGROP/ORACE-FO/NWJ-	JOHNATHAN RICKMAN	PHARMACEUTICAL INNOVATIONS INC, NEWARK, NJ;

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	02/11/2013	DO/NWJ-CB/	FDA NEWS	VECTRACOR INC, TOTOWA, NJ; BIPORE MEDICAL DEVICES INC, NORTHVALE, NJ, ETC - 483S 11/1-30/12
2013-269	01/11/2013 02/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MICHAEL R COHEN RPH MS SCD INSTITUTE FOR SAFE MEDICATION PRACTICES	MEDWATCH RPTS CODED AS MEDICATION ERRORS 12/1-31/12
2013-270	01/11/2013 02/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHNATHAN RICKMAN FDA NEWS	JIANGXI TIANXIN PHARMACEUTICAL CO LTD, LEPING, CHINA; CHIA GI LTD, CHIOS, GREECE; GRISI HNOS SA DE CV, MEXICO - 483 11/12
2013-271	01/11/2013 02/11/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	JOHNATHAN RICKMAN FDA NEWS	KATH KHEMICALS LLC, STERLING HEIGHTS, MI; STRYKER INSTRUMENTS, PORTAGE, MI; DEPUY ORTHOPAEDICS INC, WARSAW, IN - 483 11/12
2013-272	01/11/2013 02/11/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	JOHNATHAN RICKMAN FDA NEWS	DERMAZONE SOLUTIONS INC; SAINT PETERSBURG, FL; AIG TECHNOLOGIES INC, DEERFIELD BEACH, FL; VALJEAN CORP, INDIAN HARBOUR BEACH, FL - 483 11/12
2013-273	01/11/2013 02/11/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	JOHNATHAN RICKMAN FDA NEWS	NEXGEN PHARMA INC, COLORADO SPRINGS, CO; CARDINAL HEALTH 414 LLC; DENVER, CO; PARKWAY PRODUCTS INC, LOVELAND, CO - 483 11/12
2013-274	01/11/2013 02/11/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	JOHNATHAN RICKMAN FDANEWS	RX AIR INDUSTRIES LLC, FARMERS BRANCH, TX; AMERICAN AESTHETICS MEDICAL SUPPLY INC, DALLAS, TX; OHM PHARMACEUTICAL INC 414 INC, DALLAS, TX - 483 11/12
2013-275	01/11/2013 02/11/2013	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	JOHNATHAN RICKMAN FDA NEWS	FOREST PHARMACEUTICALS INC, CINCINNATI, OH; HUNT BROTHERS PRODUCTS, ZANESVILLE, OH; SYNAPSE BIOMEDICAL INC, OBERLIN, OH - 483 11/12
2013-276	01/11/2013 02/11/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	AMICUCCI, PHYLLIS	DR SAUD A SADIQ, MULTIPLE SCLEROSIS RESEARCH CENTER OF NEW YORK, NEW YORK, NY - CESSATION OF THE STEM CELL TRIAL RECS 2012
2013-277	01/11/2013 02/11/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	JOHNATHAN RICKMAN FDA NEWS	DANIELS SHARPSMART INC, CHICAGO, IL; CORPAK MEDSYSTEMS, BUFFALO GROVE, IL - 483 11/12
2013-278	01/11/2013 02/11/2013	OC/ORA/ OC/ORA/	MARIA MUNOZ SEADCO USA CORP	FROZEN PASTEURIZED EXTRA JUMBO MARISSIMO U-250, EXTRA JUMBO SEADCO U-130 ENTRY #E4P-0022287-7 - LAB RESULTS
2013-279	01/11/2013 02/11/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	JOHNATHAN RICKMAN FDA NEWS	CUSTOM HEALTHCARE SYSTEMS INC, RICHMOND, VA; FUTREX INC, HAGERSTOWN, MD; UPM PHARMS,

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				BALTIMORE, MD - 483 11/12
2013-280	01/11/2013 02/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/ OC/OCOS/OL/ FDA/OC/OES/DFOI/ OC/ORO/ OC/ORO/ FDA/OC/OL/	ALAN M FELDMAN FELDMAN SHEPHERD ET AL	ALAUNUS PHARMACEUTICAL LLC - RECALLS, Cmplnts, TRANS, ETC 1/95 TO PRESENT
2013-281	01/11/2013 02/11/2013	OC/OM/OMP/DDM/	MARILYNN WHITNEY COVINGTON BURLING LLP	DKT FDA-2012-P-0904
2013-282	01/11/2013 02/11/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 12/24-28/12
2013-283	01/11/2013 02/11/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 12/24-28/12
2013-284	01/11/2013 02/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/ OC/OCOS/OL/ FDA/OC/OES/DFOI/ OC/ORO/ OC/ORO/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OL/	ALAN M FELDMAN FELDMAN SHEPHERD ET AL	NEW ENGLAND COMPUNDING PHARMACY INC - RECALLS, Cmplnts, VIOLATION RPTS, ETC 1/95 TO PRESENT
2013-285	01/11/2013 02/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ALAN M FELDMAN FELDMAN SHEPHERD ET AL	AMERIDOSE LLC - RECALLS, Cmplnts, VIOLATION RPTS, ETC 1/95 TO PRESENT

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/ OC/OCOS/OL/ FDA/OC/OES/DFOI/ OC/ORA/ OC/ORA/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OL/		
2013-286	01/11/2013 02/11/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOI REQUESTS 12/24-28/12
2013-287	01/11/2013 02/11/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 12/24-28/12
2013-288	01/11/2013 02/11/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 12/24-28/12
2013-289	01/11/2013 02/11/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 12/24-28/12
2013-290	01/11/2013 02/11/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 12/24-28/12
2013-291	01/11/2013 02/11/2013	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	CLOSED FOI REQUESTS 12/24-28/12
2013-292	01/11/2013 02/11/2013	FDA/OC/OES/DFOI/	GLADYS B. TONKIN WASHINGTON INFORMATION SOURCE	DAILY LOG 12/24-28/12
2013-293	01/11/2013 02/11/2013	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 12/24-28/12
2013-294	01/11/2013 02/11/2013	FDA/OC/OES/DFOI/	JOHNATHAN RICKMAN FDA NEWS	DAILY LOG 12/17-21/12

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2013-295	01/11/2013 02/11/2013	FDA/OC/OES/DFOI/	JOHNATHAN RICKMAN FDA NEWS	DAILY LOG 12/24-28/12
2013-296	01/13/2013 02/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA21435
2013-297	01/13/2013 02/11/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	C Hartill RTI Biologics, Inc	MUSCULOSKELETAL TRANSPLANT FOUNDATION, EDISON, NJ - 483 (09/24/2012 - 12/31/2012)
2013-298	01/13/2013 02/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Chelsea A. Loughran Wolf Greenfield & Sacks, P.C.	ANTIVIPMYN, ANTIVENIN, ANTIVENOM - FORM 1571, FORM 1572, ETC
2013-299	01/13/2013 02/11/2013	OC/OSMP/OOPD/ FDA/OMPT/OSMP/OOPD/	HeeSun Lee Aclairo Pharmaceutical Development Group	TISSUE PLASMINOGEN ACTIVATOR - ORPHAN PRODUCT DESIGNATION
2013-300	01/13/2013 02/11/2013	OC/ORACE/ORM/ OC/ORACE/ORM/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	GLP INSPECTIONS, BIOEQUIVALENCE LABORATORIES, ANALYTICAL LABORATORIES - LIST OF INSPECTIONS 2011-2012
2013-301	01/13/2013 02/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Richard W. Gonnello Faruqi & Faruqi, LLP	BIOSANTE PHARMACEUTICALS LIBIGEL DRUG DEVELOPMENT PROGRAM - SPECIAL PROTOCOL ASSESSMENT, PHASE II CLINICAL TRIAL DATA, PHASE III EFFICACY CLINICAL TRIALS ETC
2013-302	01/13/2013 02/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	BLA 103780/5121
2013-303	01/13/2013 02/11/2013	OC/OSMP/OOPD/ FDA/OMPT/OSMP/OOPD/	HeeSun Lee Aclairo Pharmaceutical Development Group	NIMODIPINE - ORPHAN DRUG DESIGNATION
2013-304	01/13/2013 02/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sina Carlson Carlson, Sina	BINOSTO - BIOEQUIVALENCE STUDIES

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2013-305	01/13/2013 02/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ralph Harris SAMFORD UNIVERSITY	TACROLIMUS, CYCLOSPORIN - AERS
2013-306	01/13/2013 02/11/2013	OC/OSMP/OOPD/ FDA/OMPT/OSMP/OOPD/	HeeSun Lee Aclairo Pharmaceutical Development Group	CYCLOSPORINE - ORPHAN DRUG DESIGNATION
2013-307	01/13/2013 02/11/2013	FDA/OGROP/ORA/SW-FO/DEN- DO/DEN-CB/	Leslie Paul PERRIGO COMPANY	TWINLAB CORPORATION, AMERICAN FORK, UT - 483, EIR (11/01/2011 - 12/20/2011)
2013-308	01/13/2013 02/11/2013	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	Leslie Paul PERRIGO COMPANY	NUTRO LABORATORIES, S PLAINFIELD, NJ - EIR (01/15/2012 - 02/28/2012)
2013-309	01/13/2013 02/11/2013	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	Leslie Paul PERRIGO COMPANY	NBTY BOCA RATON, FL - 483, EIR (09/15/2010 - 10/30/2010)
2013-310	01/13/2013 02/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Mark Pregenzer Ronald Reagan UCLA Medical Center	OCUCOAT - APPROVAL ORDER, SUMMERY OF SAFETY AND EFFECTIVENESS
2013-311	01/13/2013 02/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	BLA 125104/33 - SUPPLEMENTAL APPROVAL INFORMATION
2013-312	01/13/2013 02/11/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	Leslie Paul PERRIGO COMPANY	PHARMAVITE LLC, VALENCIA, CA - EIR (11/15/2010 - 01/01/2011)
2013-313	01/13/2013 02/11/2013	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	Leslie Paul PERRIGO CO	NBTY, BOHEMIA, NY - 483, EIR (02/01/2012 - 03/10/2012)
2013-314	01/13/2013 02/11/2013	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	Leslie Paul PERRIGO COMPANY	CAPSULEWORKS, BAYPORT, NY - EIR (02/10/2009 - 03/25/2009)
2013-315	01/13/2013 02/11/2013	OC/OSMP/OOPD/ FDA/OMPT/OSMP/OOPD/	HeeSun Lee Aclairo Pharmaceutical Development Group	PROGESTERONE - ORPHAN DRUG DESIGNATION
2013-316	01/13/2013 02/11/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	Leslie Paul PERRIGO COMPANY	NBTY MANUFACTURING LLC, ANAHEIM, CA - EIR (06/01/2011 - 07/31/2011)
2013-317	01/13/2013	OC/OSMP/OOPD/	Stephen From	DUREZOL - ORPHAN DRUG DESIGNATION

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	02/11/2013	FDA/OMPT/OSMP/OOPD/	Eyegate Pharmaceuticals, Inc.	
2013-318	01/13/2013 02/11/2013	OC/OSMP/OOPD/ FDA/OMPT/OSMP/OOPD/	HeeSun Lee Aclairo Pharmaceutical Development Group	A POMORPHINE HYDROCHLORIDE - ORPHAN DRUG DESIGNATION
2013-319	01/13/2013 02/11/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Leslie Paul PERRIGO COMPANY	NBTY LLC, CARSON, CA - EIR (11/15/2010 - 01/05/2011)
2013-320	01/13/2013 02/11/2013	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	Leslie Paul PERRIGO COMPANY	NBTY, INC, CARBONDALE, IL - EIR (10/10/2011 - 11/10/2011)
2013-321	01/13/2013 02/11/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/ OC/ORA/OCI/ OC/ORA/OCI/	Gary Wittenberg Baranov & Wittenberg, LLP	FLANDERS PHARMACY, CLACKAMAS, OR; PACIFIC FRONTIER MEDICAL, REDWOOD CITY, CA - TEST RESULTS
2013-322	01/13/2013 02/11/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Michael Priest Self	CARGILL, INC, DES MOINES, IA - REPORT ABOUT FOOD SAFETY CONCERNS
2013-323	01/13/2013 02/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/OSMP/OOPD/ FDA/OMPT/OSMP/OOPD/	Richard W. Gonnello FARUQI & FARUQI LLP	CHELSEA THERAPEUTICS INTERNATIONAL - ORPHAN DRUG DESIGNATION, SPECIAL PROTOCOL ASSESSMENT, FAST TRACK STATUS, ETC
2013-324	01/13/2013 02/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ZOLPIDEM - CLINICAL TRIAL DATA, DRIVING SIMULATION STUDIES
2013-325	01/13/2013 02/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Peter R. Breggin, MD Center for the Study of Empathic Therapy	ZOLPIDEM - AERS
2013-326	01/14/2013 02/12/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORACE-FO/NWJ-	Doe J	NESTLE BENEALORIE NUTRITIONAL SUPPLEMENT - MANUFACTURING PROCESS

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		DO/NWJ-CB/ FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/		
2013-327	01/14/2013 02/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CARLO CASSULO MD ASCEND CAPITAL LLC	NUJEXTA (DEXTROMETHORPHAN HYDROBROMIDE & QUINIDINE SULFATE) CAPS - AERS 1/10 TO PRESENT
2013-328	01/14/2013 02/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CARLO CASULO MD ASCEND CAPITAL LLC	JAKAFI (RUXOLITINIB) - AERS 1/10 TO PRESENT
2013-329	01/14/2013 02/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CARLO CASULO MD ASCEND CAPITAL LLC	PONATINIB - AERS 1/10 TO PRESENT
2013-330	01/14/2013 02/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CARLO CASULO MD ASCEND CAPITAL LLC	ENZALUTAMIDE - AERS 1/10 TO PRESENT
2013-331	01/14/2013 02/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CARLO CASULO ASCEND CAPITAL LLC	QSYMIA (PHENTERMINE & TOPIRAMETE ER) CAPS - AERS 1/10 TO PRESENT
2013-332	01/14/2013 02/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CARLO CASULO MD ASCEND CAPITAL LLC	ABIRATERONE - AERS 1/10 TO PRESENT
2013-333	01/14/2013 02/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	SUSAN PATE CARESTREAM HEALTH INC	RIVERAIN MEDICAL GROUP - SOFTVEIW SYS K092363
2013-334	01/14/2013 02/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	FRANK E EPPERSON DDS	HYPODERMIC SYRINGE - GRANDFATHER DETERMINATION DISPOSABLE CARPULE
2013-335	01/14/2013 02/12/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	JUSTIN LOVELACE TELEFLEX MEDICAL	PALL MEDICAL - PALL UTIPOR ANESTHESIA BREATHING CIRCUIT SYS K013093

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2013-336	01/14/2013 02/12/2013	FDA/OMPT/CDRH/OCER/DFOI/ OC/ORA/ OC/ORA/	WILLIAM SARRAILLE SIDLEY AUSTIN LLP	ST JUDE - RESP TO 483, SUBMISIONS 7/1/12, 10/2/12
2013-337	01/14/2013 02/12/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	JASON MAHON PREMIER ORGANICS	PREMIER ORGANICS - NOTES, SUMMARIES, WARNINGS LTRS, ETC 1/07 TO 11/1/12
2013-338	01/14/2013 02/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MEROLA, ERIC	KURUME UNIVERSITY, KURUME, FUKUOKA PREFECTURE, JAPAN - REC 1988
2013-339	01/14/2013 02/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	AMBIEN - AERS
2013-340	01/14/2013 02/12/2013	FDA/OFVM/CFSAN/OCD/EOS/	STACY L CESLOWITZ SCHOEMAN UPDIKE & KAUFMAN LLP	MARLYN NUTRACEUTICALS INC - IMMUNE SYSTEM SUPPORT LEMON LIME TABS RECALL FDA SITE VISIT RECS 1988
2013-341	01/14/2013 02/12/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	STACY L CESLOWITZ SCHOEMAN UPDIKE & KAUFMAN LLP	MARLYN NUTRACEUTICALS INC - IMMUNE SYSTEM SUPPORT ORANGE TABS RECALL RECS 8/17/10
2013-342	01/14/2013 02/12/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	STACY L CESLOWITZ SCHOEMAN UPDIKE & KAUFMAN LLP	MARLYN NUTRACEUTICALS INC - AIR SHIELD PINK GRAPEFRUIT TABS RECALL RECS 8/17/10
2013-343	01/14/2013 02/12/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	STACY L CESLOWITZ SCHOEMAN UPDIKE & KAUFMAN LLP	NBTY ACQUISTION LLC (LEINER HEALTH PRODS INC) - AIR SHIELD ORANGE TABS RECALL RECS 8/17/10; MARLYN NUTRACEUTICALS INC - AFOREMENTIONED TABS COMM
2013-344	01/14/2013 02/12/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	STACY L CESLOWITZ SCHOEMAN UPDIKE & KAUFMAN LLP	NBTY ACQUISTION LLC (LEINER HEALTH PRODS INC) - AIRHEALTH ORANGE TABS, AIR PROTECTOR ORANGE TABS, AIR SHIELD ORANGE TABS, ETC RECALL RECS 8/17/10; MARYLN NUTRACEUTICALS INC - AFOREMENTIONED TABS COMM
2013-345	01/14/2013 02/12/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	STACY LL CESLOWITZ SCHOEMAN UPDIKE & KAUFMAN LLP	NBTY ACQUISTION LLC (LEINER HEALTH PRODS INC) - WALBORN LEMON LIME STICK PACK, AIRHEALTH LEMON LIME STICK PACK RECALL RECS 8/17/10;; MARLYN NUTRACEUTICALS INC - AFOREMENTIONED TABS COMM
2013-346	01/14/2013 02/12/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/NE-FO/NYK-	STACY L CESLOWITZ SCHOEMAN UPDIKE & KAUFMAN	NBTY ACQUISSTION LLC (LEINER HEALTH PROD INC) - AIRHEALTH LEMON-LIME TABS, AIR PROTECTOR LEMON-

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		DO/NYK-DCB/	LLP	LIME TABS, AIR SHIELD LEMON-LIME TABS RECALL, ETC RECS; MARLYN NUTRACEUTICALS INC - AFOREMENTIONED TABS COMM
2013-347	01/14/2013 02/12/2013	OC/ORO/ OC/ORO/	Doe J	CMLPNT
2013-348	01/14/2013 02/12/2013	FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/	PAUL B CALLAHAN CHARLES RIVER LABS	NOVARTIS VACCINES & DIAGNOSTICS INC, EMERYVILLE, CA - 483S 7/7-15/10
2013-349	01/14/2013 02/12/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	PAUL B CALLAHAN CHARLES RIVER LABS	GLAXOSMITHKLINE BIOLOGIS, DRSDEN, GERMANY - 483S 6/14-22/11
2013-350	01/14/2013 02/12/2013	FDA/OGROP/ORO/SE-FO/SJN-DO/SJN-CB/	PATRICIA SABATINI PITTSBURGH POST-GAZETTE	MYLAN INC - WARNING LTR RECS 11/9/12, 10/13/11
2013-351	01/14/2013 02/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	REMERON, WELLBUTRIN, GEODON - MED WATCH RPT
2013-352	01/14/2013 02/12/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	SAMANTHA MYERS ROANOKE TRADE SERVICES INC	SBL GLOBAL INC - ENTRY NUMBER WUG-01511467, WUG-01504843 NOTICES OF ACTION, COMMERCIAL INVOICES, BILLS OF LADING, ETC
2013-353	01/15/2013 02/13/2013	FDA/OC/OES/DFOI/	David Elder Parexel International	FOIA REQUEST LOG (07/01/2011 - 01/14/2013)
2013-354	01/15/2013 02/13/2013	FDA/OGROP/ORO/NE-FO/NWE-DO/NWE-CB/	Kristan Phillips MacroGenics	LONZA, PORTSMOUTH, NH - 483, EIR (01/01/2010 - 12/31/2010)
2013-355	01/15/2013 02/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gary Wolff SHIRE PHARMACEUTICALS INC	ISR 6786292, 6806987, 6810329, ETC
2013-356	01/15/2013 02/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Alison Sathe Ellman International	K040563
2013-357	01/15/2013 02/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Cynthia Wojtaszek BRISTOL-MYERS SQUIBB	BLA 103705/5332
2013-358	01/15/2013	FDA/OMPT/CDER/ORP/DIDP/	Eric H. Weinberg, Esq.	PRADAXA - SUBMISSIONS, CORR

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	02/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Law Firm of Eric Weinberg	
2013-359	01/15/2013 02/13/2013	FDA/OMPT/CTP/OD/	John Shoemaker Visium	ASSESSMENT OF THE IMPACT OF MENTHOLATED CIGARETTES ON SMOKING INITIATION, DEPENDENCE, AND CESSATION
2013-360	01/15/2013 02/13/2013	FDA/OFVM/CFSAN/OCD/EOS/	Kevin S. Fries COSMETIC INGREDIENT REVIEW	VOLUNTARY COSMETIC REGISTRATION PROGRAM UPDATE (01/14/2012 - 01/14/2013)
2013-361	01/15/2013 02/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Shelburne Ellipse Technologies, Inc.	K971783
2013-362	01/15/2013 02/13/2013	FDA/OFVM/CFSAN/OCD/EOS/	Alan Rappeport FINANCIAL TIMES	HERBALIFE PRODUCTS - AERS
2013-363	01/15/2013 02/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/OCOS/OES/ OC/OCOS/OES/ OC/ORR/ OC/ORR/	Thomas M. Burton THE WALL STREET JOURNAL	FDA CHINA AND INDIA OFFICES - CORR RE INSPECTIONS, SAFETY, AND COMPLIANCE OF DRUG OR API FACILITIES IN CHINA AND INDIA
2013-364	01/15/2013 02/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	KYPER, CHARLES H	MED-KHAN (USA) INC - LIPOKIT WITH DISPOSABLE 50CC AFT SYRINGE K083455
2013-365	01/15/2013 02/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	GABAPENTIN, NEURONTIN 300MG - AERS
2013-366	01/15/2013 02/13/2013	FDA/OFVM/CFSAN/OCD/EOS/	RAYMOND M DAVID PHD BASF CORP	D & C RED NO 9 ENTRY #237 IN CL NO 15585 - TOXICITY STUDY
2013-367	01/15/2013 02/13/2013	FDA/OGROP/ORR/CE-FO/NWJ-DO/NWJ-CB/	DR PHOEBE MOUNTS ESQ MORGAN LEWIS & BOCKIUS LLP	MUSCULOSKELETAL TRANSPLANT FOUNDATION - 483 12/12
2013-368	01/15/2013 02/13/2013	FDA/OGROP/ORR/CE-FO/PHI-DO/PHI-CB/	CATERINA GULYAS G&W LABORATORIES INC	BIO-PHARM INC, LEVITTOWN, PA - EIRS, 483S, CO RESP LAST 6 MONTHS
2013-369	01/15/2013 02/13/2013	FDA/OGROP/ORR/CE-FO/MIN-DO/MIN-CB/	CATERINA GULYAS G&W LABORATORIES INC	COUNTY LINE PHARMACEUTICALS LLC, BROOKFIELD, WI - EIRS, 483S, CO RESP LAST 6 MONTHS

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2013-370	01/15/2013 02/13/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	ANDREA SESSIONS ESQ FREDERICK W SMITH JR LAW OFCS	ABBOTT LABS, ABBOTT DIABETES CARE - GLUCOSE TEST STRIP RECALL 12/22/10, CMLNPTS, CORR, ETC
2013-371	01/15/2013 02/13/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	KELLI DUNLAP KERCSMAR & FELTUS PLLC	HALODROL LIQUIGELS - RECAL RECS
2013-372	01/15/2013 02/13/2013	OC/OROA/ OC/OROA/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	MICHAEL J WINER ESQ MICHAEL J WINER LAW OFC	INDIVIDUAL RECS
2013-373	01/15/2013 04/11/2013	OC/OROA/ OC/OROA/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	MANUEL A MOLINA FREEHILL HOGAN & MAHARR LLP	FROZEN SHRIMP ENTRY #MWCU6099637 - CORR, RPTS, TESTING, ETC
2013-374	01/15/2013 02/13/2013	FDA/OC/OES/DFOI/	A LUKE SMITH FARUQI & FARUQI LLP	ANDA 40-445 - APRVL RECS
2013-375	01/15/2013 02/13/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	GISSENDANNER, ROBIN	CMLNPT #120110
2013-376	01/15/2013 02/13/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	JENESSA G B COCCARO KERCSMAR & FELTUS PLLC	GASPARI NUTRITION INC - NOVEDX XT INVESTIGATION, RECALL RECS, TRANS, ETC

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2013-377	01/15/2013 02/13/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	JENESSA G B COCCARO KERCSMAR & FELTUS PLLC	GASPARI NUTRITION INC - M-ONE-T RPTS, NOTICES, MINS, ETC
2013-378	01/15/2013 02/13/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	JENESSA G B COCCARO KERCSMAR & FELTUS PLLC	GASPARI NUTRITION INC - ORASTA E RPTS, TRANS, NOTICES, ETC
2013-379	01/15/2013 02/13/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	JENESSA G B COCCARO KERCSMAR & FELTUS PLLC	GASPARI NUTRITION INC - OXAVAR RPTS, NOTICES, TRANS, ETC
2013-380	01/15/2013 02/13/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	JENESSA G B COCCARO KERCSMAR & FELTUS PLLC	GASPARI NUTRITION INC - ORASTAN A RPTS, TRANS, NOTICES, ETC
2013-381	01/15/2013 02/13/2013	FDA/OFVM/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 159461
2013-382	01/15/2013	FDA/OFVM/CFSAN/OCD/EOS/	ANGELA SMYTH	CAERS 159486

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	02/13/2013		IOVATE HEALTH SCIENCES INTERNATIONAL INC	
2013-383	01/15/2013 02/13/2013	FDA/OFVM/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 159218, 160158
2013-384	01/15/2013 02/13/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CTP/OD/	MICHAEL R SNEBERGER ESQ HBI INTERNATIONAL	HBI INTERNATIONAL - 905J RPTS SE0001698, SE0002348, SE0002350, ETC
2013-385	01/15/2013 02/13/2013	FDA/OC/OES/DFOI/	Amy Kincanon LexisNexis CourtLink Document Retrieval	2012-8911
2013-386	01/15/2013 02/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Art Rankis Art Rankis	K120306
2013-387	01/16/2013 02/14/2013	OC/OM/OMP/DDM/	JEFF GERTH PROPUBLICA	DKT 1977N-0094
2013-388	01/16/2013 02/14/2013	FDA/OGROP/ORAN/NE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Trevor C. Sanders AARON J. PRISBREY, P.C.	CODMAN DURAL GRAFT IMPLANT - MEMOS, REPORTS, STUDIES, ETC
2013-389	01/16/2013 02/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K123194
2013-390	01/16/2013 02/14/2013	OC/ORAN/ORM/ OC/ORAN/ORM/	Lee Ann Liss AbbVie	BIORESEARCH MONITORING - LIST OF DOMESTIC AND INTERNATIONAL INSPECTIONS (01/02/2001 - 12/31/2012)
2013-391	01/16/2013 02/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	Scott Conlin N/A	K102342, K120563
2013-392	01/16/2013 02/14/2013	FDA/OFVM/CFSAN/OCD/EOS/	Kathy Lee General Mills, Inc.	FOOD GMP MODERNIZATION WORKING GROUP: SUMMARY OF FOOD RECALLS; ANALYSIS OF FOOD RECALLS INITIATED IN 2008-2009 BY AN FDA CGMP WORKING GROUP
2013-393	01/16/2013 02/14/2013	FDA/OGROP/ORAN/NE-FO/NWE-DO/NWE-CB/	Rachel Johnson FOI Services, Inc.	PARAXEL, LOWELL, MA - EIR, 483 (01/01/09 TO PRESENT)
2013-394	01/16/2013 02/14/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Nancy Gunderson Veritox	FDA GUIDELINES FOR REPRODUCTION STUDIES FOR SAFETY EVALUATION OF DRUGS FOR HUMAN USE
2013-395	01/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	William Fisher	PMA 910066

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	02/14/2013		DJO, LLC	
2013-396	01/16/2013 02/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	Lourdes Coba Beckman Coulter, Inc.	K112605
2013-397	01/16/2013 02/14/2013	OC/OA/OM/OMP/DDM/	Doreen Frank ENVISAGE CONSULTING LLC	DKT 76N-052T
2013-398	01/16/2013 02/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Hassan Ahmad International Trading Pharmaceutical Lab	LEUCOVORIN - ANDA
2013-399	01/16/2013 02/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	OHAN ARAKELIAN COBEG WORLDWIDE, LLC	K871072, K871073, K871070 ETC
2013-400	01/16/2013 02/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENDA M. GARTZ ELI LILLY & CO	TETRA GENX ANALYTICAL LABORATORY, ST LAURENT QUEBEC- EIR 4/12
2013-401	01/16/2013 02/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENDA M. GARTZ ELI LILLY & CO	SMITH KLINE BEECHAM, WORTHING WEST SUXXES, UK - EIR 3/11
2013-402	01/16/2013 02/14/2013	FDA/OGROP/ORAP/PA-FO/SEA- DO/SEA-CB/	BRENDA M. GARTZ ELI LILLY & CO	SHEPPARD WOOD DISTRIBUTORS INC, NAMPE, ID - EIR 12/11
2013-403	01/16/2013 02/14/2013	FDA/OGROP/ORAP/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORAP/PA-FO/LOS- DO/LOS-CB/	BURGESS, BERNIE	EXHIBITS FOR 2012-4657
2013-404	01/16/2013 02/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	Ward Komers Golden West Biologicals, Inc.	K110641
2013-405	01/16/2013 02/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	Ward Komers Golden West Biologicals, Inc.	K113177
2013-406	01/16/2013 02/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jason Walton Fogless International AB	K962714, K043160, K945407
2013-407	01/16/2013 02/14/2013	FDA/OC/OES/DFOI/	Johnathan Rickman FDANEWS	FOIA REQUEST LOG (01/07/2013 - 01/11/2013)
2013-408	01/16/2013	FDA/OMPT/CDER/GRP/DIDP/	Audrey Spolarich	LEVAQUIN - AERS

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	02/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	audrey Spolarich	
2013-409	01/16/2013 02/14/2013	FDA/OMPT/CDRH/OCER/DFOI/ OC/ORA/ OC/ORA/ FDA/OGROP/ORA/CE-FO/CHI- DO/CHI-CB/	Sarah A. Ferrill SALVI SCHOSTOK & PRITCHARD PC	INDIVIDUAL RECS
2013-410	01/16/2013 02/14/2013	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Tony Taylor Aesculap, Inc.	D-TARGET, QUINCY MA; D-TARGET, SWITZERLAND - 483, REPORTS
2013-411	01/16/2013 02/14/2013	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	SAMUEL F. COLIN MD FIRST MANHATTAN CO	LUITPOLD PHARMACEUTICALS INC - 483 2/9/11 TO 3/15/11
2013-412	01/16/2013 02/14/2013	FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/	ROBERT M. GOLDMAN CL King & Associates	HILL ROM INC, BATESVILLE, IN - 483 12/12 TO PRESENT
2013-413	01/16/2013 02/14/2013	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	BETSY REDDINGTON LIGHT AGE INC	FEI 2246844
2013-414	01/16/2013 02/14/2013	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	A. LUKE SMITH FARUQI & FARUQI LLP	OHM LABS, NJ - 483 2008 TO 2009
2013-415	01/16/2013 02/15/2013	OC/OCOS/OES/ OC/OCOS/OES/	JIM MORRIS CENTER FOR PUBLIC INTEGRITY	CORR BETWEEN AMERICAN CHEMISTRY COUNCIL & FDA 1/09 TO PRESENT
2013-416	01/16/2013 02/14/2013	FDA/OC/OES/DFOI/	DONALD F. SEGAL ALSTON & BIRD LLP	FOOD ADDITIVE PETITION FOIA SUBMITTED BY GRUMA CORP; SPINA BIFIDA ASSOC; MARCH OF DIMES FOUNDATION
2013-417	01/16/2013 02/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHANDRA TIRUVATTAR DR REDDY'S LABORATORIES INC	PHARMAFORCE - BROMFENAC SODIUM ANDA 02-030 SBA
2013-418	01/17/2013 02/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K884834

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2013-419	01/17/2013 02/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K112672
2013-420	01/17/2013 02/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K110030
2013-421	01/17/2013 02/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K030302
2013-422	01/17/2013 02/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K112198
2013-423	01/17/2013 02/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K070129
2013-424	01/17/2013 02/15/2013	OC/CVM/OCD/	SAYED AHMED PFIZER ANIMAL HEALTH	ZILPATEROL TYPE B AND TYPE C FEED ASSAY METHODS; TIAMULIN TYPE B AND TYPE C FEED ASSAY METHODS; MONENSIN TYPE B AND TYPE C FEED ASSAY METHODS
2013-425	01/17/2013 02/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K103668
2013-426	01/17/2013 02/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K101030
2013-427	01/17/2013 02/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K030618
2013-428	01/17/2013 02/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K083330
2013-429	01/17/2013 02/15/2013	FDA/OC/OES/DFOI/	ELLIOT FAVUS MD FAVUS INSTITUTIONAL RESEARCH LLC	2012-4834, 2012-5151, 2012-5152, ETC
2013-430	01/17/2013 02/15/2013	FDA/OC/OES/DFOI/	KYLE SAMPSON HUNTON & WILLIAMS LLP	MYLAN LABORATORIES INC - FOI REQUESTS REGARDING WARNING LTR 10/31/11
2013-431	01/17/2013 02/15/2013	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/ OC/ORO/	JORDAN FEIN UNITE HERE	XYIENCE ENERGY DRINK, SUPPLEMENTS - CMLPNTS, RPTS, CORR, ETC
2013-432	01/17/2013 02/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	LEX PEARCE ICU MEDICAL INC	BECTON DICKINSON & CO - CLOSED ATINEOPLASTIC AND HAZARDOUS RECONSTITUTION AND TRANSFER SYS K123213
2013-433	01/17/2013 02/15/2013	OC/ORO/ OC/ORO/	DOUGLAS N BLUE II ZETETIC INC	STARBURST, CHEWING GUM, SKITTLES ENTRY #AV300384136 - RECS
2013-434	01/17/2013	OC/ORO/	DOUGLAS N BLUE II	IINFANT FORMULA ENTRY #DP406171638 - RECS

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	02/15/2013	OC/OR/ FDA/OGROP/OR/NE-FO/NYK- DO/NYK-DCB/	ZETETIC INC	
2013-435	01/17/2013 02/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	MANISH AHUJA BIOTEX INC	K012366
2013-436	01/17/2013 02/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	MANISH AHUJA BIOTEX INC	K090240
2013-437	01/17/2013 02/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	MANISH AHUJA BIOTEX INC	K992304
2013-438	01/17/2013 02/15/2013	OC/OR/ OC/OR/ FDA/OGROP/OR/PA-FO/LOS- DO/LOS-CB/ OC/OR/ OC/OR/ OC/OR/ OC/OR/	Doe J	DIETARY SUPPLEMENT WOW - LAB RPT
2013-439	01/17/2013 02/15/2013	OC/OA/OM/OMP/DDM/	BAYER, RANGE (RICHARD) D	DKT 2011D-0722
2013-440	01/17/2013 02/15/2013	FDA/OGROP/OR/NE-FO/NYK- DO/NYK-DCB/	JOHN WALSH JAMES ALEXANDER CORP	MOD-PAC, BUFFALO, NY - EIRS, 483S, RECALL RECS 1/11 TO PRESENT
2013-441	01/17/2013 02/15/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	STEWART, JAMES M	ETHYL ALCOHOL, TRICLOSAN, CHLOROXYLENOL - SAFETY RECS
2013-442	01/17/2013 02/15/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	BELLWYCK PACKAGING SOLUTIONS, MISSISSAUGA, ONTARIO - EIR MOST RECENT
2013-443	01/17/2013 02/15/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	CILAG AG, SCHAFFHAUSEN, SWITZERLAND - EIR 2010
2013-444	01/17/2013	FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ	CATALENT UK SWINDON ZYDIS LTD, SWINDON, WILTSHIRE

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	02/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELI LILLY & CO	- EIR 11/11
2013-445	01/17/2013 02/15/2013	FDA/OFVM/CFSAN/OCD/EOS/	CHASTINE 12B2563, JAMES	SODIUM CASEINATE - LIST OF INGREDIENTS
2013-446	01/17/2013 02/15/2013	FDA/OC/OES/DFOI/	ELLIOT FAVUS MD FAVUS INSTITUTIONAL RESEARCH LLC	CTP FOIA REQUESTS 2010-2012
2013-447	01/17/2013 02/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	WEIJIA DAI UNIVERSITY OF MARYLAND	EARLY COLLABORATION MEETINGS FOR PMA
2013-448	01/17/2013 02/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	WEIJIA DAI UNIVERSITY OF MARYLAND	PMA, 510K - DATA ON WITHDRAWN AND DENIED APPLICATIONS
2013-449	01/18/2013 02/19/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Kim Finch CHOICE SPINE LP	510KS - INDICATIONS FOR USE, DEVICE DESCRIPTION, SUBSTANTIAL EQUIVALENCE ETC
2013-450	01/18/2013 02/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tonya Sausser Tarsa Therapeutics Inc.	SANDOZ GMBH, KUNDL, AUSTRIA - 483 (10/01/2012 - 11/01/2012)
2013-451	01/18/2013 02/19/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Brent Ardaugh Framingham Heart Study	K004043
2013-452	01/18/2013 02/19/2013	OC/CVM/OCD/ OC/ORO/ OC/ORO/	Abigail Sterling KPIX/CBS5	CHICKEN JERKY TREATS FOR DOGS - INTERNAL MEMOS
2013-453	01/18/2013 02/19/2013	FDA/OGROP/ORO/SE-FO/ATL- DO/ATL-CB/	Linda Bowen SANOFI	CAPSUGEL, GREENWOOD, SC - EIR JUNE 2012
2013-454	01/18/2013 02/19/2013	FDA/OMPT/CTP/OD/	Desmond Jenson Public Health Law Center	CTP FOIA REQUEST LOG (08/22/2012 - 01/17/2013)
2013-455	01/18/2013 02/19/2013	OC/OA/OM/OMP/DDM/	Desmond Jenson Public Health Law Center	FDA-2012-N-1148
2013-456	01/18/2013 02/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	David Lin BIOLOGICS CONSULTING GROUP	ISOLYTE E (NDA 019718)

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2013-457	01/18/2013 02/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jennifer Ensign Ensign, Jennifer D	ANDA APPLICATION FOR GENERIC 1G MESALAMINE SUPPOSITORY COMPARISON TO THE BRAND DRUG CANASA FILED BY SANDOZ IN 2007
2013-458	01/18/2013 02/19/2013	OC/ORR/ORM/ OC/ORR/ORM/	David Mangione FDAZILLA	LIST OF INSPECTIONS (11/01/2011 - 01/15/2013)
2013-459	01/18/2013 02/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Larry Morris MORRIS, LARRY	THALLIUM CHLORIDE - CLINICAL TRIAL STUDIES INCLUDING SIDE EFFECTS
2013-460	01/18/2013 02/19/2013	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	John Beasley MedTech Review, LLC	OSCOR, INC, PALM HARBOR, FL - 483, RESPONSES (07/27/2010 - 08/31/2010)
2013-461	01/18/2013 02/19/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	David Weissburg OSS Bo	K953339, K915774, K051879
2013-462	01/18/2013 02/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Eric Norrington, PharmD, BCPS Clark Memorial Hospital Pharmacy	LEVOFLOXACIN AND AMIODARONE - REPORTED CASES OF TORSADES AND OTHER SERIOUS CARDIAC ARYTHMIAS
2013-463	01/18/2013 02/19/2013	FDA/OC/OES/DFOI/	Christopher Weaver THE WALL STREET JOURNAL	REATA PHARMACEUTICALS INC, BARDOXOLONE, UNIVERSITY OF TEXAS MEDICAL CENTER - FOIA REQUESTS
2013-464	01/18/2013 02/19/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 12/31/12-1/4/13
2013-465	01/18/2013 02/19/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 12/31/12-1/4/13
2013-466	01/18/2013 02/19/2013	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDID INC	CLOSED FOIA REQUESTS 12/31/12-1/4/13
2013-467	01/18/2013 02/19/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 12/31/12-1/4/13
2013-468	01/18/2013 02/19/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 12/31/12-1/4/13
2013-469	01/18/2013 02/19/2013	FDA/OGROP/ORR/CE-FO/DET-DO/DET-CB/	BRENDA M GARTZ ELI LILLY & CO	CLARITA KETELS, ST CLAIR SHORES, MI - 483 10/24/11

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2013-470	01/18/2013 02/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	HAMELN PHARMACEUTICALS GMBH, HAMELN, GERMANY - 483 6/4/12
2013-471	01/18/2013 02/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	FRED FIORE HYDROFERA LLC	HYDROFERA, WILLIMANTIC, CT - WOUND CARE PRODS K013462, K023138
2013-472	01/18/2013 02/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORA/OCI/ OC/ORA/OCI/	ANDERSON, CARL.	INJECTABLE PEPTIDES - MARKETING & SALES RECS, COMM
2013-473	01/18/2013 02/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORA/OCI/ OC/ORA/OCI/	ANDERSON, CARL.	PEPTIDELELABS.COM - ANABOLIC STEROIDS OR HUMAN GROWTH HORMONE COMM 1/11 TO PRESENT
2013-474	01/18/2013 02/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CLAUDINE Q HOMOLASH SHELLER LAW OFCS	PROTOCOL INH-189-003 - MEDWATCH FILINGS
2013-475	01/18/2013 02/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOANNE GIGORGIO THERAVANCE INC	REGLAN (METOCLOPRAMIDE HCL) NDA 17-854, NDA 17-862 - SBA
2013-476	01/18/2013 02/19/2013	FDA/OFVM/CFSAN/OCD/EOS/	REBECCA LL DANNENBERG FRANKLIN & PROKOPIK	PHUSION PROJECTS - FOUR LOKO WARNING LTR INVESTIGATION, Cmplnts, Rulings, etc 11/10
2013-477	01/18/2013 02/19/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	AIMEE DOYLE, ESQ. KOTCHEN & LOW LLP	BLIS TECHNOLOGIES LTD, FRUTARON LTD - FORMS 7512, 3499, MISBRANDING & UNAPPROVED NEW DRUG, ETC

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		FDA/OGROP/ORO/ORO/DIOP/		
2013-478	01/18/2013 02/19/2013	OC/CVM/OCD/	TIM SCHWAB Food & Water Watch	AQUABOUNTY - NADA LTR
2013-479	01/18/2013 02/19/2013	FDA/OFVM/CFSAN/OCD/EOS/	ERIC F GREENBERG ERIC F GREENBERG PC	CHOCO TREASURE LLC OR CANDY TREASURE LLC, ETC - CHOCOLATE SURPRISE EGG (SURPRISE EGG OR CHOCO TREASURE) SUBMISSIONS, CORR, RVWS LAST 4 YRS
2013-480	01/22/2013 02/20/2013	FDA/OFVM/CFSAN/OCD/EOS/	BETHANY KENNEDY EMORD & ASSOCIATES, P.C.	WAL-MART STORE'S INC - GREAT VALUE ENERGY SHOT CAERS
2013-481	01/22/2013 02/20/2013	FDA/OFVM/CFSAN/OCD/EOS/	BETHANY KENNEDY EMORD & ASSOCIATES, P.C.	COSTCO WHOLESALE CORP - KIRKLAND SIGNATURE ENERGY SHOT CAERS
2013-482	01/22/2013 02/20/2013	FDA/OFVM/CFSAN/OCD/EOS/	RICHARD E GUTTING JR REDMON PEYTON & BRASWELL LLP	ANTARTIC TOOTHFISH (DISSOSTICHUS MAWSONI) - MARKET NAMES RECS
2013-483	01/22/2013 02/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ECKHARD MILSMANN PHD DIAPHARM GMBH & CO KG	HAMELN PHARMACEUTICALS GMBH - 483 6/4-14/12
2013-484	01/22/2013 02/20/2013	FDA/OGROP/ORO/NE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Doe J	NATURALLY TE - BLACK BOX WARNING, REGULATORY HISTORY, RECALL RECS
2013-485	01/22/2013 02/20/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	LORI PFOHL TELEFLEX MEDICAL	MELKER EMERGENCY CRICOTHYROTOMY CATHETER KIT K013916
2013-486	01/22/2013 02/20/2013	OC/ORO/ OC/ORO/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KYRIAKIDIS, JOANNA	PHARMEDIUM SERVICES LLC - WARNING LTRS, EIRS, 483S, ETC 2010 TO PRESENT; AMERIDOSE LLC - EIR 7/21/08, ETC
2013-487	01/22/2013 02/20/2013	OC/ORO/ OC/ORO/	MARLA F MUNOZ SEADCO USA CORP	FROZEN PASTEURIZED EXTRA JUMBO SEADCO U-130, EXTRA JUMBO MARISSIMO U-250 ENTRY #E49-0022287-7 - LAB RESULTS

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2013-488	01/22/2013 02/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SCOTT #JY1512/L-27, SEAN	AMBIEN, SEROQUEL - AERS
2013-489	01/22/2013 02/20/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	ANTOINETTE PERRY ADAMMAS CONSULTING LLC	PAREXEL/PERCEPTIVE, BILERICA, MA - EIRS, 483S, CO RESP 2/14-23/12
2013-490	01/22/2013 02/20/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Innetta Walker ESTECH	K090385, K060721, K093679 ETC
2013-491	01/22/2013 02/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Catherine Shachaf Orlucent	VIZILITE BLUE ORAL EXAMINATION - APPROVAL RECS
2013-492	01/22/2013 02/20/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Judy Sadler IU Health Goshen Hospital	IU HEALTH GOSHEN HOSPITAL - 483, EIR (11/01/2012 - 11/06/2012)
2013-493	01/22/2013 02/20/2013	FDA/OC/OES/DFOI/	Johnathan Rickman FDA NEWS	FOIA REQUEST LOG (01/14/2013 - 01/18/2013)
2013-494	01/22/2013 02/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Madalyn Duncan Impact medical, LLC	K113399, K110086, K071035
2013-495	01/22/2013 02/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jan Petranek Petranek, Jan	SINEQUAN - POST MARKETING SAFETY ISSUE RECS (01/01/2000 - 01/01/2013)
2013-496	01/22/2013 02/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jan Petranek Petranek, Jan	SEROQUEL - POST MARKETING SAFETY ISSUE RECS (01/01/2000 - 01/01/2013)
2013-497	01/22/2013 02/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	michele hong michele hong	CRESTOR, ZOCOR, LIPITOR, ETC - SUPPLEMENTAL NEW DRUG APPLICATION PROCESS RECS
2013-498	01/22/2013 04/08/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Christopher Rush FDA Quality and Regulatory Consultants	CHRISTOPHER RUSH - BIMO INSPECTIONS (01/01/2002 - 01/01/2008)
2013-499	01/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Mick Fenton	K070788

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	02/20/2013		Immunodiagnostic Systems Ltd	
2013-500	01/22/2013 02/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Charlie Zhou Living Stream Food and Drug Consulting	QSYMIA CAPSULE - CMC AND BIOPHARMACEUTICAL REVIEW
2013-501	01/22/2013 02/20/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Angela Turner Turner, Angela	LLOYD, INC, SHENANDOAH, IA - EIR (MAY 2012)
2013-502	01/22/2013 02/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Walt Brittle FDA Compliance Help Desk Inc	LINA MEDICAL APS, GLOSTRUP, DENMARK - 483, EIR, CORR (01/01/2006 to 01/01/2013)
2013-503	01/22/2013 02/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Brandie R Durrett Durrett, Brandie R	NUVIGIAL - AERS
2013-504	01/22/2013 02/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bill Webster UNIVERSITY OF SYDNEY	GUIDELINES FOR REPRODUCTION STUDIES FOR SAFETY EVALUATION OF DRUGS FOR HUMAN USE (1966)
2013-505	01/22/2013 02/20/2013	OC/ORAS/ OC/ORAS/	Richard O. Wood the Wood Burditt group	144-4574669-8 - LAB RESULTS
2013-506	01/22/2013 02/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Benjamin Drosman REGENERON PHARMACEUTICALS INC	LUCENTIS - APPROVAL PACKAGE
2013-507	01/22/2013 02/20/2013	OC/CVM/OCD/ OC/ORAS/ OC/ORAS/ FDA/OC/OES/DFOI/	Steven A Roach FOOD ANIMAL CONCERNS TRUST	Date Range: 08/01/2001 - 01/14/2013; Records related to the feed investigation of a domestic United States cow that was reported as infected with Bovine Spongiform Encephalopathy on April 24, 2012. Specifically records related to the firm described as "One facility processed and manufactured with poultry waste in the report "Final Feed Investigation Summary - California BSE Case - July 2012" which is available on the FDA website. The focus of our request is whether or not the infected cow was likely exposed to ruminant meat and bone meal through the feeding of the form of poultry waste known as poultry litter. In addition we would like to better understand FDAs risk communication about the feed particularly how FDA chose to communicate to the public whether or not the cow was actually exposed to ruminant meat and bone meal through poultry litter. A more detailed

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				request and a request for a fee waiver are included in the attached file. The wide date range of records is aimed at capturing feed investigations that occurred during the life of the cow, but before it was identified as being infected. ;
2013-508	01/22/2013 02/20/2013	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	TOBACCO ESTABLISHMENT REGISTRATIONS AND TOBACCO PRODUCT LISTINGS
2013-509	01/22/2013 02/20/2013	FDA/OFVM/CFSAN/OCD/EOS/	Brian Kennedy AYER CAPITAL	MONSTER BEVERAGE - EMAILS, SLIDES, OTHER RECS RE 11/30/12 MEETING WITH FDA
2013-510	01/22/2013 02/20/2013	FDA/OGROP/ORPA/PA-FO/LOS-DO/LOS-CB/	Barbara Kowinsky KOWINSKY, BARBARA	THIBIANT INTERNATIONAL - EIR, WARNING LETTER, 483 (01/01/2012 - 01/11/2013)
2013-511	01/22/2013 02/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	DYMISTA - SBA 202236 000
2013-512	01/22/2013 02/20/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	JOSE HERNANDEZ - 483 (01/01/10 TO PRESENT)
2013-513	01/22/2013 02/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K110699
2013-514	01/22/2013 02/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K121194
2013-515	01/22/2013 02/20/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Bayer HealthCare LLC Animal Health (Ruth Lamley) Bayer HealthCare LLC Animal Health	BOEHRINGER INGELHEIM, ELWOOD, KS - 483, EIR (4/2/2010, 11/23/2009, 11/6/2008, ETC)
2013-516	01/22/2013 02/20/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Law Offices of Ronald A. Marron Law Offices of Ronald A. Marron	NATURE'S WAY/SCHWABE NORTH AMERICA - CORR WITH FDA
2013-517	01/22/2013 02/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gen Li personal use	CLINICAL INVESTIGATOR DATA - FORM 1572 HUMAN DRUGS

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-518	01/23/2013 02/21/2013	OC/OM/OMP/DDM/	MARILYNN WHITNEY COVINGTON BURLING LLP	DKT FDA-2006-P-0007, FDA-2007-D-0433, ETC.
2013-519	01/23/2013 02/21/2013	OC/OM/OMP/DDM/	WESILEY ALBUQUERQUE NATIONAL CORPORATE RESEARCH	OTC VOL. 070280, 070270, 070238, ETC.
2013-520	01/23/2013 02/21/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Adam S. Morgenthau, MD MOUNT SINAI MEDICAL CENTER	KVIEM-SILTZBACH SKIN TEST - IND
2013-521	01/23/2013 02/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Gary Wolff SHIRE PHARMACEUTICALS INC	VYVANSE - FAERS 6601306, 6615751, 6650425 ETC
2013-522	01/23/2013 02/21/2013	OC/CVM/OCD/	Ruth Lamley Bayer HealthCare LLC Animal Health	GRINDEX, LATVIA - 483, EIR (04/27/2007)
2013-523	01/23/2013 02/21/2013	FDA/OGROP/ORR/NE-FO/NWE- DO/NWE-CB/	Robert Haggerty, Sr. VP Corporate QA/QC Lyophilization Services of New England	LYOPHILIZATION SERVICES OF NEW ENGLAND, BEDFORD, NH - EIR UNREDACTED (06/02/2011 - 06/09/2011)
2013-524	01/23/2013 02/21/2013	FDA/OGROP/ORR/SE-FO/FLA- DO/FLA-CB/	Lauren Farruggia Hyman, Phelps and McNamara	TG UNITED, INC, BROOKSVILLE, FL - 483, EIR WARNING LETTERS, ETC
2013-525	01/23/2013 02/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ISR 4457069-8, 3197882-0, 5874061-7 ETC
2013-526	01/23/2013 02/21/2013	FDA/OGROP/ORR/CE-FO/CHI- DO/CHI-CB/	Carole Kempfer RADIANT RESEARCH	DYNAVAX - INSPECTION REPORT (10/18/2012 - 11/16/2012)
2013-527	01/23/2013 02/21/2013	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 12/31/12-1/4/13
2013-528	01/23/2013	FDA/OC/OES/DFOI/	DEBI COHEN	FOI DAILY LOG 12/3/12-1/4/13

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	02/21/2013	FDA/OC/OES/DFOI/	WOLTERS KLUWER LAW & BUSINESS	
2013-529	01/23/2013 02/21/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DEBI COHEN CanReg, Inc.	FOI DAILY LOG 12/3/12-1/4/13
2013-530	01/23/2013 02/21/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	WILLIAM A OLSON WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 12/31/12-1/4/13
2013-531	01/23/2013 02/21/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 12/31/12-1/07/13
2013-532	01/23/2013 02/21/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 12/31/12-1/4/13
2013-533	01/23/2013 02/21/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 12/31/12-1/4/13
2013-534	01/23/2013 02/21/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/	DONALD N BLUE ZETETIC	CHOCOLATES SMLU3185964A - PHOTOGRAPHS, OASIS SCREEN SHOTS, CBP FORM 3461
2013-535	01/23/2013 02/21/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/	DONALD N BLUE ZETETIC	CHOCOLATES SMLU3152799A - PHOTOGRAPHS, OASIS SCREEN SHOTS, CBP FORM 3461
2013-536	01/23/2013 02/21/2013	FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/ OC/ORO/ OC/ORO/	DONALD N BLUE ZETETIC	CHOCOLATES SMLU3179805A - PHOTOGRAPHS, OASIS SCREEN SHOTS, CBP FORM 3461
2013-537	01/23/2013 02/21/2013	FDA/OGROP/ORO/CE-FO/CHI-DO/CHI-CB/	PAUL W TRIPP LINCARE INC	THH ACQUISTION LLC (TOTAL HOME HEALTH) - EIRS. 483S, WARNING LTRS 1/04 TO PRESENT
2013-538	01/23/2013 02/21/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Carol Wasteney The Mentholatum Company	ROHTO-MENTHOLATUM, THUAN AN TOWN, VIETNAM - EIR (05/15/12 TO 01/22/2013)
2013-539	01/23/2013 02/21/2013	FDA/OGROP/ORO/CE-FO/MIN-DO/MIN-CB/	Doe J	INDIVIDUAL RECS
2013-540	01/23/2013	FDA/OMPT/CBER/OCOD/DDOM/	DAVID HILZENRATH	MERCK - ZOSTAVAX FINAL PROTOCOL, RPTS 11/06.5/07,

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	03/27/2014	ALFB/	PROJECT ON GOVERNMENT OVERSIGHT	11/10, 5/11
2013-541	01/24/2013 02/22/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Gary Koenig Gary Koenig	BAXTER TISSEAL - 510K
2013-542	01/24/2013 02/22/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shannon James Northern Navajo Medical Center	ANCEF - APPROVAL HISTORY; LABELING REVISION HISTORY
2013-543	01/24/2013 02/22/2013	OC/OA/OM/OMP/DDM/	Michael Slater Merrimack Pharmaceuticals, Inc.	DOXORUBICIN HYDROCHLORIDE - COMMENTS ON DRAFT GUIDANCE
2013-544	01/24/2013 02/22/2013	FDA/OGROP/ORR/NE-FO/NWE- DO/NWE-CB/	Rachel Johnson FOI Services, Inc.	LSNE, BEDFORD, NH - EIR (6/2/11)
2013-545	01/24/2013 02/22/2013	FDA/OGROP/ORR/CE-FO/BLT- DO/BLT-CB/	Sandy Stagge CTI Clinical Trial & Consulting Services	JOHNS HOPKINS UNIVERSITY SCHOOL OF MEDICINE IRB - 483, RESPONSE (01/07/11)
2013-546	01/24/2013 02/22/2013	FDA/OFVM/CFSAN/OCD/EOS/	Murray Carpenter Murray Carpenter	STARBUCKS COFFEE, TEA - CAERS (01/01/2004 - 12/31/2012)
2013-547	01/24/2013 02/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	INDIVIDUAL RECS
2013-548	01/24/2013 02/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 202292
2013-549	01/24/2013 02/22/2013	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORR/ OC/ORR/ FDA/OGROP/ORR/CE-FO/NWJ- DO/NWJ-CB/	Michael Atkins Atkins Intellectual Property, PLLC	B&B INTERNATIONAL, LINDEN, NJ - PACKING PERMITS AND RECS
2013-550	01/24/2013 02/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dustin Block IPD Analytics, LLC	ANDA 079040 - EFFECTIVE APPROVAL LETTER

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/		
2013-551	01/24/2013 02/22/2013	FDA/OC/OES/DFOI/	MUJIB U. QIDWAI GRIFOLS BIOLOGICALS INC	OCTAPHARMA AB, STOCKHOLM, SWEDEN - EIR, 483 1/11
2013-552	01/24/2013 02/22/2013	FDA/OC/OES/DFOI/	MUJIB U. QUIWAI GRIFOLS BIOLOGICALS INC	CSL BEHRING, VICTORIA, AUSTRALIA - EIR, 483 1/10 TO 12/31/12
2013-553	01/24/2013 02/22/2013		BRENDA M. GARTZ ELI LILLY & CO	RECORDATI, CAMPOVERDE, ITALY - EIR 7/10
2013-554	01/24/2013 02/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENDA M. GARTZ ELI LILLY & CO	JANSSEN BIOLOGICS, LEIDEN, NETHERLANDS - EIR MOST RECENT
2013-555	01/24/2013 02/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENDA M. GARTZ ELI LILLY & CO	DAITO PHARMACEUTICAL CO LTD, TOYAMA CITY, JAPAN - EIR 9/11
2013-556	01/24/2013 02/22/2013	FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	PATRICIA L. REGENYE Celgene Corporation	ANNELIESE GONZALEZ, CORPUS CHRISTI, TX - 483 11/08 TO PRESENT
2013-557	01/24/2013 02/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PATRICIA L. REGENYE Celgene Corporation	MUHAMMAD SALIM, ALLAN BLAIR CANCER CTR, REGINA, CANADA - 483 12/03 TO PRESENT
2013-558	01/24/2013 02/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	CAROLYN L. WAGNER CARESTREAM HEALTH INC	SHIMADZU CORP - DAR7000 RADSPEED SAFIRE K050925
2013-559	01/24/2013 02/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	CAROLYN L. WAGNER CARESTREAM HEALTH INC	FUJUFILM SYSTEMS USA INC - FDR ACCELERATE STATIONARY XRAY SYS K093427
2013-560	01/24/2013 02/22/2013	OC/CVM/OCD/	KRISTI O. SMEDLEY, Ph.D. WASHINGTON INFORMATION SOURCE	FAP OA4200
2013-561	01/24/2013 02/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SMITH, KIMBERLY .	XTANDI A - AER

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2013-562	01/24/2013 02/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	SUSSMAN, MARVIN L	RADIONICS MEDICAL INC - SPECTRUM ANALYZER 8000 K810851
2013-563	01/24/2013 03/15/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	BAYER, RICHARD	BLOOD PRODCUTS A/C BPAC 9/10/08, 7/27/10, 4/29/11
2013-564	01/24/2013 02/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ROXANNE OZAWA AFFYMAX INC	AUDREY GUREVICH, ST PETERSBURG MEDICAL ACADEMY, ST PETERSBURG, RUSSIA - EIR 12/11
2013-565	01/24/2013 02/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ROXANNE OZAWA COULON AFFYMAX INC	DR KONSTATIN GUREVICH, ST ELIZABETH CITH HOSPITAL, ST PETERSBURG, RUSSIA - 483, EIR 11/11
2013-566	01/24/2013 02/22/2013	FDA/OGROP/ORO/PA-FO/SAN- DO/SAN-CB/	ROXANNE OZAWA COULON AFFYMAX INC	AFFYMAX INC, PALO ALTO, CA - EIR 10/11
2013-567	01/24/2013 02/22/2013	FDA/OGROP/ORO/SE-FO/FLA- DO/FLA-CB/	ROXANNE OZAWA COULON AFFYMAX INC	EDOUARD MARTIN, MD, FLORIDA RESEARCH INSTITUTE, LAUDERDALE LAKES, FL - 483, EIR 9/11
2013-568	01/24/2013 02/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID L. ROSEN FOLEY & LARDNER LLP	SOFGEN PHARMACEUTICALS - PROGESTERONE ORAL CAPSULES ANDA 200456
2013-569	01/24/2013 02/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID L. ROSEN FOLEY & LARDNER LLP	TEVA PHARMACEUTICALS - PROGESTERONE ORLA CAPSULES SBA ANDA 202121
2013-570	01/24/2013 02/22/2013	FDA/OFVM/CFSAN/OCD/EOS/	FREDERICK A. STEARNS Keller and Heckman LLP	NONO LABORATORIES INC GRASP 5G0297
2013-571	01/24/2013 02/22/2013	FDA/OFVM/CFSAN/OCD/EOS/	KELLY STAROSTA HILL Keller and Heckman LLP	STARLINGER & CO - NOL 160
2013-572	01/24/2013 02/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	BENJAMIN L. ENGLAND, Esq. BENJAMIN L ENGLAND & ASSOCIATES LLC	SILVERLON - CONTACT WOUND DRESSING K981299; WOUND PACKING STRIPS K984210
2013-573	01/24/2013 02/22/2013	FDA/OGROP/ORO/NE-FO/NWE- DO/NWE-CB/ FDA/OMPT/CDRH/OCER/DFOI/	TIMOTHY P. COON, Esq. WILK AUSLANDER	CORR BETWEEN FDA & MIRA INC 9/11 TO 12/12

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2013-574	01/24/2013 02/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	BORIS REYDEL, MD INVENTIO LLC	K112698
2013-575	01/24/2013 02/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	BORIS REYDEL, MD INVENTIO LLC	K112698 UNREDACTED
2013-576	01/24/2013 02/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KATE PURCELL DOCUTRIEVAL INFORMATION SERVICES	MINIVELLE NDA 03-752 SBA
2013-577	01/24/2013 02/22/2013	FDA/OGROP/ORR/SE-FO/FLA- DO/FLA-CB/	PATRICIO T.D. BARRERA BARRERA & ASSOCIATES	KRAMER LABORATORIES INC - EXHIBITS, ATTACHMENTS
2013-578	01/24/2013 02/22/2013	OC/CVM/OCD/ OC/OA/OM/OMP/DDM/	GABRIEL SCOTT CASCADIA WILDLANDS	DCK FDA 2011-N-0899
2013-579	01/24/2013 02/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	BRADFORD P. KLAGER LAW OFFICES OF DOUGLAS A ALLISON	MI GWANG POLYMACON CONTACT LENSES - CORR
2013-580	01/25/2013 02/25/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Javier Collazo RespCare	K071560
2013-581	01/25/2013 02/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Francine Vero Francine Vero -Towne, Ryan & Partners PC	NOVASURE INPEDANCE CONTROLLED ENDOMETRIAL ABLATION SYSTEM - MANUALS, INSTRUCTIONS, TRAINING ETC
2013-582	01/25/2013 02/25/2013	OC/CVM/OCD/	Application document for animal drug using nitenpyram SUMITOMO CHEMICAL CO LTD	NITENPYRAM - APPROVAL RECS
2013-583	01/25/2013 02/25/2013	FDA/OGROP/ORR/CE-FO/PHI- DO/PHI-CB/	Gene Partin ZOLL Lifecor Corporation	ZOLL LIFECORE CORPORATION - EIR EXHIBITS (08/28/2001 - 08/28/2001)
2013-584	01/25/2013 02/25/2013	FDA/OGROP/ORR/PA-FO/LOS- DO/LOS-CB/	Azuka L. Uzoh Law Office of Azuka L. Uzoh	TEVA PARENTERAL MEDICINES, INC, IRVINE, CA - EIR, 483, SHUTDOWN ORDERS (08/02/2007 - 07/31/2010) (CERTIFIED)
2013-585	01/25/2013 02/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Maria Makarich Makarich, Maria	OXARBAZEPINE 300/5 SUSPENSION - BIOEQUIVALENCE DATA
2013-586	01/25/2013 02/25/2013	FDA/OGROP/ORR/SE-FO/ATL- DO/ATL-CB/	Sandy Stagge CTI Clinical Trial & Consulting Services	AMELIA LANGSTON, ATLANTA, GA - 483, RESPONSE (08/01/2006 - 10/01/2006)

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2013-587	01/25/2013 02/25/2013	OC/ORO/ OC/ORO/ OC/ORO/OE/ OC/ORO/OE/	Theresa Thompson UIC c/o Theresa Thompson	MEDICAL DEVICE AND RAD HEALTH RECALL EVENTS
2013-588	01/25/2013 02/25/2013	FDA/OFVM/CFSAN/OCD/EOS/	LaVeeta Moten LaVeeta Moten	NOTICE RE WORK ON LAPTOPS FROM COLLEGE PARK DESKTOP SUPPORT
2013-589	01/25/2013 02/25/2013	FDA/OGROP/ORO/SE-FO/NOL- DO/NOL-CB/	Sandy Stagge CTI Clinical Trial & Consulting Services	JEFFREY SOSMAN, MD - 483, RESPONSE (09/01/2010 - 12/01/2010)
2013-590	01/25/2013 02/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K041711
2013-591	01/25/2013 02/25/2013	FDA/OGROP/ORO/CE-FO/MIN- DO/MIN-CB/	Jens Saakvitne South Dakota Lions Eye and Tissue Bank	LIFESOURCE, MINNEAPOLIS, MN - 483 (01/01/2011 - 12/31/2011)
2013-592	01/25/2013 02/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Katherine Giannamore Law Office of Katherine Giannamore, P.A.	ANDA 074731
2013-593	01/25/2013 02/26/2013	OC/CVM/OCD/ FDA/OGROP/ORO/CE-FO/CIN- DO/CIN-CB/ FDA/OGROP/ORO/SW-FO/DAL- DO/DAL-CB/ FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/	Jeffrey Jones, Counsel for The Scotts Miracle-Gro Company The Scotts Miracle-Gro Company	SCOTT'S MIRACLE GRO COMPANY - TESTING RE HARM TO BIRDS, WILD BIRD FOOD, ETC
2013-594	01/25/2013 02/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Walters AtriCure, Inc.	K101961, K111064
2013-595	01/25/2013 02/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Katherine Giannamore Law Office of Katherine Giannamore, P.A.	ANDA 075357
2013-596	01/25/2013 02/25/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Katherine Giannamore Law Office of Katherine Giannamore, P.A.	ANDA 074924

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-597	01/25/2013 02/25/2013	OC/OA/OM/OMP/DDM/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bijal Pandhi NOVARTIS PHARMACEUTICAL CORP	SALMON CALCITONIN - ENDOCRINOLOGIC AND METABOLIC ADVISORY COMMITTEE MATERIALS 1991, 1994
2013-598	01/25/2013 02/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Katherine Giannamore Law Office of Katherine Giannamore, P.A.	ANDA 074588
2013-599	01/25/2013 02/25/2013	FDA/OGROP/ORACE-FO/DET- DO/DET-CB/	Hillary M Estes NESTLE USA INC	NESTLE USA, ANDERSON, IN - EIR (05/14/2010 - 11/05/2010)
2013-600	01/25/2013 02/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Javier Collazo Respacare	K102404
2013-601	01/25/2013 02/25/2013	FDA/OGROP/ORACE-FO/CHI- DO/CHI-CB/	Jeri Hill DMS Holding, Inc., Dba/Briggs Healthcare	DMS HOLDING, INC DBA BRIGGS HEALTHCARE, WAUKEGAN, IL - EIR (6/15/2011 - 06/16/2011)
2013-602	01/25/2013 02/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Anthony Lenza, Esq. Amabile & Erman, P.C.	265782, 10455-10-2002-00021, 1045510-2002-00027 ETC - MAUDE REPORTS AND INVESTIGATION RECS
2013-603	01/25/2013 02/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sandy Stagge CTI Clinical Trial & Consulting Services	JOHAN MAERTENS, BELGIUM - EIR (06/01/2004 - 08/30/2004)
2013-604	01/25/2013 02/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	FDA RESPONSE TO 06/28/2001 LETTER FROM INTUITIVE SURGICAL
2013-605	01/25/2013 02/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	UQUIFA, SPAIN; UQUIFA, MEXICO - EIR, 483, WARNING LETTER, ETC
2013-606	01/25/2013 02/25/2013	FDA/OC/OES/DFOI/	DARREN L BROWN PROVOST UMPHREY LAW FIRM	DR ERIC WILHELMSSEN, WILHELMSSEN CONSULTING - GUIDANCE LTR ON INGREDIENT DECLARATION FOR VARIOUS SWEETENERS 5/8/00; HILLEL S ROBERTS, UPSCALE FOODS, INC - WARNING LTR 11/15/04, ETC (CERTIFIED)
2013-607	01/25/2013	FDA/OMPT/CDER/GRP/DIDP/		BUSPAR (BUSPICONE HCL) - MARKETING, SALES, MFG

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	02/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRYAN #254638, T TERRELL	RECS
2013-608	01/25/2013 02/25/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	REO TANOSHIMA MD HOSPITAL FOR SICK CHILDREN	KEPPRA (LEVETIRACETAM) - AERS
2013-609	01/25/2013 02/25/2013		VIELHABER, LINDA	SAFETY RPT #1027508
2013-610	01/25/2013 02/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	AMY TAYLOR INFOTRIEVE INC	GUIDANCE FOR CLNCL EVALUATION OF COMBINATION ESTROGEN/PROGESTIN-CONTAINING DRUG PRODS
2013-611	01/25/2013 02/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	CHRISTOPHER L ROBINSON MORRISON & FOERSTER LLP	LEPU MEDICAL TECHNOLOGY (BEIJING) CO LTD - RADIAL ARTERY COMPRESSION TOURNIQUET K111837
2013-612	01/25/2013 02/25/2013	FDA/OFVM/CFSAN/OCD/EOS/	Jason DeYoung WESTERN MICHIGAN UNIVERSITY	FOOD AND BEVERAGE FIRMS IN MI, IN, OH - COMPANY NAMES, CONTACT, EMAIL ETC
2013-613	01/25/2013 02/25/2013	OC/ORO/ OC/ORO/	PETER D WEINSTEIN ESQ COLE SCOTT AND KISSANE	INFUPHARMA LLC, HOLLYWOOD, FL - INVESTIGATION RPT 1/17/12
2013-614	01/25/2013 02/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	CAROL NAKAGAWA MERGE HEALTHCARE	AYCAN DIGITALSYSTEME GMBH - AYCAN MOBILE K122260
2013-615	01/25/2013 02/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ARIANNA OBERMEIER FLORIDA BLUE	ORANGE BOOK - EXCLUSIVITY AND PATENT FILES
2013-616	01/25/2013 02/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	RENAE N FEO INTEGRA YORK PA INC	JARIT ENDOSCOPES K944870
2013-617	01/25/2013 09/17/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORO/CE-FO/DET-DO/DET-CB/	CRYSTAL SPIVEY WILDEMAN KAHN DEES DONOVAN & KAHN LLP	MEAD JOHNSON NUTRITION CO - ENFAMIL PREMIUM INFANT, ENFAMIL GENTLEASE, ENFAMIL AR RECS 2009 TO PRESENT
2013-618	01/25/2013 02/25/2013	FDA/OGROP/ORO/NE-FO/NWE-DO/NWE-CB/	STEPHEN D ELLIS ELLIS BOXER & BLAKE PLLC	AADCO MEDICAL INC, RANDOLPH, VT - EIRS, WARNINGS, REGISTRATIONS, ETC

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2013-619	01/25/2013 02/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	KATHERINE STRONG CARNER SIDLEY AUSTIN LLP	OFFICE OF IN VITRO DIAGNOSTIC DEVICE EVALUATION AND SAFETY (OIVD) - UNTITLED LTRS SENT TO A CLNCL LAB, LAB SELLING ANALYTE SPECIFIC REAGENTS (ASR), ETC
2013-620	01/25/2013 02/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ABEBE #285447, UNULA B	MAXZIDE, NAPROXEN, NIFEDIPINE, ETC - RECS
2013-621	01/25/2013 02/25/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	JOHN D HENDERSON JOHN D HENDERSON PSC	SOUTHERN STATES CAMPBELLSVILLE SERVICE, CAMPBELLSVILLE, KY, HARGIS TRUCKING INC, COLUMBIA, KY - DELIVERY OF UREA CONTAMINATED FEED TO SMITH FARMS 12/09
2013-622	01/25/2013 02/25/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	MARSHA GREEN DANIEL POWELL & BREWER LLC	RAW CLOVER SPROUTS E COLI OUTBREAK AT JIMMY JOHN'S RESTAURANTS INVESTIGATION RECS 12/25/11 TO 3/3/12
2013-623	01/25/2013 02/25/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	BRENDA M GARTZ ELI LILLY & CO	SYNERGY HEALTH, SAN DIEGO, CA - EIR 2/12
2013-624	01/25/2013 02/25/2013	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	BRENDA M GARTZ ELI LILLY & CO	ANDERSON PACKAGING, ROCKFORD, IL - EIR 4/18/12
2013-625	01/25/2013 02/25/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	BRENDA M GARTZ ELI LILLY & CO	APTUIT INC, KANSAS CITY, MO - EIR 3/24/10
2013-626	01/25/2013 02/25/2013	FDA/OC/OES/DFOI/	JOHNATHAN RICKMAN FDA NEWS	FOI DAILY LOG 1/7-11/13
2013-627	01/25/2013 02/25/2013	FDA/OFVM/CFSAN/OCD/EOS/	JOHN R ERICKSON BASF CORP	CFSAN CANCER ASSESSMENT CIMMITTEE MEMO CAP 9C0096 4/21/89
2013-628	01/28/2013 02/26/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OC/OES/DFOI/	Melissa Hirst JONES DAY	NURSERY WATER, WELL WATER - TESTING RECS; COMPLAINT; ETC

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		FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/		
2013-629	01/28/2013 02/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Chris Cano Agile Therapeutics	NORLESTRIN 21 2.5/50 - MEDICAL OFFICER REVIEW AND OTHER REVIEWS
2013-630	01/28/2013 02/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OO/OIM/OPILS/DDM/	michele hong michele hong	NDA 21366 S10
2013-631	01/28/2013 02/26/2013	FDA/OFVM/CFSAN/OCD/EOS/	Chris Lahiff McDermott Will & Emery LLP	CONTAMINATED DRIED FRUITS - ADVERSE EVENTS (01/01/2000 - 01/25/2013)
2013-632	01/28/2013 02/26/2013	OC/ORAS/ OC/ORAS/	Janice M. Rizzi Radagast Pet Food, Inc.	CONSUMER COMPLAINT 129691
2013-633	01/28/2013 02/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Curtis Obert CASE WESTERN RESERVE UNIVERSITY	RADIATION EMITTING MACHINES IN HOSPITALS - NUMBER, INSTALATION
2013-634	01/28/2013 02/26/2013	FDA/OGROP/ORASSE-FO/ATL-DO/ATL-CB/	Brian Roemer Gate Gourmet	GATE GOURMET - CONSUMER COMPLAINT RECS
2013-635	01/28/2013 02/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Chris Cano Agile Therapeutics	NORLESTRIN 21 1/50 - MEDICAL OFFICER REVIEW
2013-636	01/28/2013 02/26/2013	FDA/OFVM/CFSAN/OCD/EOS/	Zoi Pappayiannis N/A (CONSUMER)	MOLYBDENUM, NICKEL, COBALT, VANADIUM, AND STRONTIUM IN TOTAL DIET
2013-637	01/28/2013 02/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/OA/OM/OMP/DDM/	Jennifer Brown INFOTRIEVE INC	PLACEBO-CONTROLLED CLINICAL TRIALS DATABASE FOR SUICIDALITY AND PREPARING DATA SETS FOR ANALYSIS BY FDA - DRAFT GUIDANCE
2013-638	01/28/2013 02/26/2013	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORAS/ OC/ORAS/	Travis J. Jacobs, Esq. The Jacobs Law, LLC	MANUKA HONEY, WEDDERSPOON ORGANIC - REPORTS, TEST RESULTS, APPLICATION, ETC (01/01/2005 - 01/25/2013)

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		FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/		
2013-639	01/28/2013 02/26/2013	OC/CVM/OCD/ FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Jason A. Forge Robbins, Geller, Rudman & Dowd	SCOTTS MIRACLE GRO - CORR WITH FDA RE RECALLS; TELEPHONE CALLS
2013-640	01/28/2013 03/14/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Mary Gustafson PLASMA PROTEIN THERAPEUTICS ASSOCIATION	POST DONATION FATALITY REPORTS
2013-641	01/28/2013 02/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	ERAN BEN-TAL BIOCEP LTD	VERIDEX - CELL TRACKS AUTO PREP SYS K122821; K110406; K100684; IMMUNICON - CELL TRACKS AUTO PREP SYS K040077
2013-642	01/28/2013 02/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELLIOTT FAVUS, M.D. FAVUS INSTITUTIONAL RESEARCH LLC	ARIAD PHARMACEUTICALS - RIDAFOROLIMUS SPA
2013-643	01/28/2013 02/26/2013	FDA/OFVM/CFSAN/OCD/EOS/	GREENBERG, BEATRICE .	FOOD LBLG POLICY REGARDING HUMAN FOOD 9/11 TO PRESENT
2013-644	01/28/2013 02/26/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	PATRICIA L. REGENYE Celgene Corporation	SHAKER DAKHIL, CA CTR KANSAS, WICHITA, KS - 483 3/12 TO PRESENT
2013-645	01/28/2013 02/26/2013	OC/ORAOE/ OC/ORAOE/	MARY CLARE JALONICK ASSOCIATED PRESS	SALMONELLA, E COLI, LISTERIA AT FOOD FACILITIES - 483S
2013-646	01/28/2013 02/26/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	ZIMMERER, CHARLES	APEX ENERGETICS INC, IRVINE, CA - RECS
2013-647	01/28/2013 02/26/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	ZIMMERER, CHARLES	ARMEN SIMONIAN, ORANGE COUNTY, CA - RECS
2013-648	01/28/2013 02/26/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	ZIMMERER, CHARLES	BLOOD NUTRITION INSTITUTE INC, SANTA ANA, CA - RECS
2013-649	01/28/2013 02/26/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	ZIMMERER, CHARLES	PRINCIPAL LAB INC, SANTA ANA, CA - RECS
2013-650	01/28/2013 02/26/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	ZIMMERER, CHARLES	HEALTH SCIENCES INVESTMENT GROUP, PHOENIX, AZ - RECS
2013-651	01/28/2013 02/26/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	ZIMMERER, CHARLES	ARMOND SIMONIAN, ORANGE COUNTY, CA - RECS

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2013-652	01/28/2013 02/26/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	ZIMMERER, CHARLES	CYREX LABORATORIES LLC, PHOENIX, AZ - RECS
2013-653	01/28/2013 02/26/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	ZIMMERER, CHARLES	BLOOD NUTRITION SOFTWARE INC - RECS
2013-654	01/28/2013 02/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	HOBBS 134225, BRIAN	AMBIEN (ZOLPIDEM) - AERS
2013-655	01/28/2013 02/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LAURA HOBBS LEXIS NEXIS COURTLINK INC	AMOUNT OF 14 HYDROXYCODEINONE PERMITTED IN OXYCODONE HCL ACTIVE PHARMACEUTICAL INGREDIENT (API) - RECS
2013-656	01/28/2013 02/26/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDRH/OCER/DFOI/	NANETTE CANEPA BECKMAN COULTER INC	HEMOCCULT TEST FOR RECAL OCCULT BLOOD
2013-657	01/28/2013 03/12/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/OCOS/OL/ FDA/OC/OCC/ OC/ORO/ OC/ORO/ FDA/OC/OL/ FDA/OMPT/CDRH/OCER/DFOI/	ABRAHAM PAYTON AMERICAN BRIDGE 21ST CENTURY	CORR BETWEEN FDA COMMISSIONER, THE DEPUTY COMMISSIONER FOR FOODS AND VETERINARY MEDICINE, IVACARE CORP
2013-658	01/28/2013 02/26/2013	OC/CVM/OCD/	DAN ASHE PATTERSON BELKNAP WEBB & TYLER	FELINE HAIRBALLS; FELINE UNIARY TRACT HEALTH - LBLG, NO OBJECTION LTRS
2013-659	01/28/2013 02/26/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	DOUGLAS N. BLUE ZETETIC	ENTRY NO AV300383518
2013-660	01/28/2013	FDA/OMPT/CDER/GRP/DIDP/	COLEEN KLASMEIER	PFIZER INC - ZOLOFT WARNING LTR 8/1/96

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	02/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SIDLEY AUSTIN LLP	
2013-661	01/28/2013 03/05/2013	FDA/OO/OFBA/OAGS/	FOI Services, Inc.	ABBOTT LAB V797P-5057B; ELI LILLY V797P-2237D; GENENTECH V797P-5067B
2013-662	01/28/2013 02/26/2013	FDA/OC/OES/DFOI/	ERIN E. SEDER VENABLE LLP	AZO GESIC; AZO SEPTIC; AZO STANDARD - AER 2005 TO PRESENT
2013-663	01/28/2013 02/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PETER S. REICHERTZ SHEPPARD MULLIN ET AL	VENOFER AER
2013-664	01/28/2013 02/26/2013	FDA/OC/OES/DFOI/	TRISH McGRADE PRITZKER OLSEN	SIMPLY THICK - NECROITIZING ENTEROCOLITIS INSP, RPTS, CORR 1/10 TO PRESENT
2013-665	01/28/2013 02/26/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/ OC/ORO/ OC/ORO/ OC/ORO/OE/ OC/ORO/OE/ FDA/OGROP/ORO/CE-FO/PHI- DO/PHI-CB/ FDA/OGROP/ORO/NE-FO/NWE- DO/NWE-CB/ FDA/OGROP/ORO/SE-FO/SJN- DO/SJN-CB/	J SCOTT NABERS BLIZZARD MCCARTHY & NABERS LLP	WYETH LABORATORIES INC, PFIZER INC - 483S, WARNING LTRS; EFFEXOR XR LBLG CHANGES, FINES, ETC
2013-666	01/28/2013 02/26/2013	FDA/OGROP/ORO/CE-FO/NWJ- DO/NWJ-CB/	SHERI O. COVINGTON K&L GATES	JK SUCRALOSE INC, EDISON, NJ - EIR, 483, WARNING LTR, CORR SINCE 2005
2013-667	01/28/2013 02/26/2013	FDA/OGROP/ORO/CE-FO/CHI- DO/CHI-CB/	SHERI O. COVINGTON K&L GATES	JM HUBER CORP - EIR, 483, WARNING LTR, CORR SINCE 2005

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2013-668	01/29/2013 02/27/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	JOHN CREWDSON PROJECT ON GOVERNMENT OVERSIGHT	RE-LY (NCT 0262600), RELY-ABLE (NCT 00808060), TRIALS - EIRS, 483S, FDA FORM 1572
2013-669	01/29/2013 02/27/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN CREWDSON PROJECT ON GOVERNMENT OVERSIGHT	PRADAXA (DABIGATRAN) - APRVL PKG, A/C, AGENDAS, ETC
2013-670	01/29/2013 02/27/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN CREWDSON PROJECT ON GOVERNMENT OVERSIGHT	BOEHRINGER INGELHEIM PHARMACEUTICALS - RELY-ABLE TRIAL RESULTS, RPTS 12/12
2013-671	01/29/2013 02/27/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID HILZENRATH PROJECT ON GOVERNMENT OVERSIGHT	BOEHRINGER INGELHEIM PHARMACEUTICALS - RE-LY & RELY-ABLE TRIALS USER FEES; MERCK & CO INC - SHINGLES PREVENTION STUDY RVWS, USER FEES
2013-672	01/29/2013 02/27/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	DAVID HILZENRATH PROJECT ON GOVERNMENT OVERSIGHT	HERPES ZOSTER VACCINE - VAERS 283902, 316387, 277377, ETC
2013-673	01/29/2013	FDA/OMPT/CDER/GRP/DIDP/		AKRIMAX - TIROSINT 50 MG CMLPNT

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	02/27/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVIS, DAWN	
2013-674	01/29/2013 02/27/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FRANCISCO JAVIER DAVALOS FARRIMOND CASTILLO & BRESNAHAN PC	VIGOR-25 - MFR NAMES, CONTACT RECS, DISTRIBUTORS NAMES, ETC
2013-675	01/29/2013 02/27/2013	FDA/OC/OES/DFOI/	CHRIS WEAVER WALL STREET JOURNAL	2011-7792, 2011-7791, 2011-7790, ETC
2013-676	01/29/2013 02/27/2013	FDA/OC/OES/DFOI/	CAROLLO, RUSSELL	FOI DAILY LOG 1/03 TO PRESENT
2013-677	01/29/2013 02/27/2013	FDA/OC/OES/DFOI/	SCHONHOFT, BRAD	PFIZER INC, (ZOETIS), KALAMAZOO, MI - 483S, WARNINGS 1/1-25/13
2013-678	01/29/2013 02/27/2013	FDA/OGROP/ORACE-FO/BLT- DO/BLT-CB/ FDA/OGROP/ORACE-FO/CHI- DO/CHI-CB/ FDA/OGROP/ORACE-FO/CIN- DO/CIN-CB/ FDA/OGROP/ORACE-FO/DET- DO/DET-CB/ FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORACE-FO/NYK- DO/NYK-DCB/ FDA/OGROP/ORACE-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORACE-FO/SAN- DO/SAN-CB/ FDA/OGROP/ORACE-FO/SEA- DO/SEA-CB/ FDA/OGROP/ORACE-FO/ATL- DO/ATL-CB/ FDA/OGROP/ORACE-FO/FLA- DO/FLA-CB/	MOLLY SHEARER UNITEHERE!	GATE GOURMET, BOSTON, MA, NEW YORK, NY, ELIZABETH, NJ, ETC - AIRPORT KITCHEN EIRS, VIOLATIONS, CMLPNTS RPTS, ETC

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		FDA/OGROP/ORR/SE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/		
2013-679	01/29/2013 02/27/2013	FDA/OGROP/ORR/CE-FO/CHI-DO/CHI-CB/	DAVID B SUDZUS DRINKER BIDDLE REATH LLP	MARLENE LANTZ, MCHENRY COUNTY, IL, FDA CHICAGO FIELD OFFICE - MEMOS, MTG MINS, SUMMARIES, ETC 2005
2013-680	01/30/2013 02/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Gary Wolff SHIRE PHARMACEUTICALS INC	7345315, 7389965, 7419534 ETC - FAERS DETAILED RPTS
2013-681	01/30/2013 02/28/2013	OC/CVM/OCD/ FDA/OGROP/ORR/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORR/PA-FO/SAN-DO/SAN-CB/	Ryan T. Kearney COZEN O'CONNOR	MILO'S KITCHEN CHICKEN JERKY RECALL - INSPECTIONS, TESTING, RECALL RECS, ETC
2013-682	01/30/2013 03/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/	B Burges BURGESS, BERNIE	INTERNAL CORR RE CLINICAL TRIAL COMPLAINT
2013-683	01/30/2013 02/28/2013	FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/ORR/ OC/ORR/	b. Burges BURGESS, BERNIE	FACTS ASSIGNMENT 808885 - TRAVEL VOUCHERS, RECEIPTS, EXPENSES, ETC
2013-684	01/30/2013 02/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	b burges BURGESS, BERNIE	PROTOCOL, BACKGROUND INFORMATION SENT TO DISTRICT OFFICE FOR FACTS ASSIGNMENT 808885
2013-685	01/30/2013	FDA/OFVM/CFSAN/OCD/EOS/	Megan Pickel	CFSAN FOIA REQUESTS (01/04/2013 - 01/28/2013)

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	02/28/2013	FDA/OC/OES/DFOI/	Beveridge & Diamond, PC	
2013-686	01/30/2013 02/28/2013	OC/ORА/OCI/ OC/ORА/OCI/	Doe J	INDIVIDUAL RECS
2013-687	01/30/2013 02/28/2013	FDA/OO/OHR/	Doe J	INDIVIDUAL RECS
2013-688	01/30/2013 02/28/2013	FDA/OGROP/ORА/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/ FDA/OGROP/ORА/PA-FO/LOS-DO/LOS-CB/	b. burgess BURGESS, BERNIE	CORR RE CSO AND SUPERVISOR FOR FACTS ASSIGNMENT 808885
2013-689	01/30/2013 02/28/2013	FDA/OGROP/ORА/CE-FO/DET-DO/DET-CB/	Alexander Barney The Karmel Law Firm	HILL-ROM, INC, BATESVILLE, IN - INSPECTION RECS (03/01/2011 - 1/28/13)
2013-690	01/30/2013 02/28/2013	FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/	Jeff Overley Law360	RANBAXY ATORVASTATIN - AERS (11/01/2012 - 01/28/2013)
2013-691	01/30/2013 02/28/2013	FDA/OC/OES/DFOI/	Johnathan Rickman FDANEWS	FOIA REQUEST LOG (01/21/2013 - 01/25/2013)
2013-692	01/30/2013 02/28/2013	FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/	Lynn Walsh WPTV 5	NUVARING, YAZ, YASMIN - AERS (01/01/2009 - 01/28/2013)
2013-693	01/30/2013 02/28/2013	OC/ORА/ OC/ORА/	David Hanson N/A	NUTRO PET FOOD - LAB RESULTS SINCE JAN 2012
2013-694	01/30/2013 02/28/2013	FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDRH/OCER/DFOI/	Courtney Burgess Sugarman & Sugarman, P.C.	SCULTPRA - PACKAGE AND PRODUCT INSERTS (01/01/2009 - 01/28/2013)

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2013-695	01/30/2013 02/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Richard Gonnello FARUQI & FARUQI LLP	AETERNA ZENTARIS INC, KERYX BIOPHARMACEUTICALS - PHASE 2 AND PHASE 3 TRIALS TESTING PERIFOSINE FOR TREATMENT OF COLORECTAL CANCER
2013-696	01/30/2013 03/08/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Anne-Solenne Rolland Sutton Law Group, P.A.	VACCINE LOT NUMBERS R05172, 471804, 469395
2013-697	01/30/2013 02/28/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Bob Bowers OBT	K112946
2013-698	01/30/2013 02/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Jim Petricek Harpeth Advisors	OSTEOCEL, TRINITY - AERS
2013-699	01/30/2013 02/28/2013	FDA/OO/OHR/	Doe J	INDIVIDUAL RECS
2013-700	01/30/2013 02/28/2013	OC/OA/OM/OMP/DDM/	Kathryn del Real The Cavanagh Law Firm	GUIDE TO INFORMED CONSENT - INFORMATION SHEET 2004
2013-701	01/30/2013 02/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Christopher Lotito Biotechnology Dashboard	PREDNISONE - AERS (01/01/2012 - 01/28/2013)
2013-702	01/30/2013 02/28/2013	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	FCN 725
2013-703	01/30/2013 02/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kevin Sill Intezyne	IND 104117 - CORR
2013-704	01/30/2013 02/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K113188
2013-705	01/30/2013 02/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K090995
2013-706	01/30/2013 02/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Laura Boll Medovations Inc.	K112994

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2013-707	01/30/2013 02/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kevin Sill Intezyne	IND 104861 - CORR
2013-708	01/30/2013 02/28/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K854334
2013-709	01/30/2013 02/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	ANDA 74531 S1
2013-710	01/30/2013 02/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	ANDA 091328
2013-711	01/30/2013 02/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jeff Wurtsbaugh PromoLogics, Inc.	K922187
2013-712	01/30/2013 02/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Krista Brown (Pharmacist) Krista Brown (pharmacist, BRHA)	QUETIAPINE - AERS
2013-713	01/30/2013 02/28/2013	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/ OC/CVM/OCD/ FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	Ryan T. Kearney COZEN O'CONNOR	IMS TRADING CORP - INSPECTIONS, INVESTIGATIONS, RECALLS ETC
2013-714	01/30/2013 02/28/2013	OC/CVM/OCD/ FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORA/SW-FO/DEN- DO/DEN-CB/ FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/ FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/	Ryan T. Kearney COZEN O'CONNOR	WAGGIN TRAIN, CANYON CREEK - INSPECTIONS, INVESTIGATIONS, RECALLS ETC
2013-715	01/30/2013	OC/CVM/OCD/	Ryan T. Kearney	CADET CHICKEN JERKY PET TREATS - INSPECTION,

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	02/28/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	COZEN O'CONNOR	INVESTIGATION, TESTING ETC
2013-716	01/30/2013 02/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BORON, MELANIE	VASCEPA (ICOSAPENT ETHYL) - PHARMACODYNAMIC & PHARMACOKINETIC DATA, PHASE 1 & PHASE 2 TESTING, ETC
2013-717	01/30/2013 02/28/2013	FDA/OC/OES/DFOI/	ROSS D PLONT GRUEL MILLS NIMS & PYLMAN LLP	ALLEGIANCE HEALTHCARE CORP - EXCHANGE TRANSFUSION TRAY PROCEDURE TRAY FDA FORM 3500A, RPTS, MEMOS, ETC
2013-718	01/30/2013 02/28/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OFVM/CFSAN/OCD/EOS/	CLAUDIA NUNN BURDOCK GROUP	ALOE VERA - REGULATORY STATUS, CONSUMPTION, SAFETY RECS, ETC
2013-719	01/30/2013 02/28/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	TRAVIS SCHAFTENAAR UBS GLOBAL ASSET MANAGEMENT	HILL-ROMM, BATESVILLE, IN - 483S 10/12, 11/12
2013-720	01/30/2013 02/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOSEPH M LANE MD HOSPITAL FOR SPECIAL SURGERY	DENOSUMAB BLA 125320 - APRVL RECS
2013-721	01/30/2013 02/28/2013	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	THOMPSON, RAY	AKORN INC, DECATUR, IL 5/14-25/12; ABBOTT MOLECULAR, DES PLAINES, IL 7/2-11/12; BIOSYNERGY INC, ELK GROVE VILLAGE, IL 2/27/12-3/2/12, ETC - 483S
2013-722	01/30/2013 02/28/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	THOMPSON, RAY	PAIN MANAGEMENT TECHNOLOGIES INC, AKRON, OH 6/4-8/12; CASCO MANUFACTURING SOLUTIONS INC, CINCINNATI, OH 5/7-10/12; REESE PHARMACEUTICAL CO, CLEVELAND, OH 12/14/11-1/11/12, ETC - 483S
2013-723	01/30/2013 02/28/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	THOMPSON, RAY	KIMBERLY CLARK CORP, CONWAY, AR 4/23-27/12; ENCOMPASS GROUP LLC, ADDISON, TX 1/18-20/12; MISSION PHARMACAL CO, BOERNE, TX 5/9-25/12. ETC - 483S
2013-724	01/30/2013 02/28/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	THOMPSON, RAY	ACELLA PHARMACEUTICALS LLC, ALPHARETTA, GA 3/19-22/12; REMINGTON MEDICAL INC, ALPHARETTA, GA 5/21/12-6/6/12; BANNER PHARMACAPS INC, HIGH POINT, NC 6/25/12-7/2/12, ETC - 483S
2013-725	01/30/2013 02/28/2013	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	WALTER E CHALKLEY THOMSON REUTERS	PETNET SOLUTIONS INC - EIRS, 483S, CO RESP 2/12

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2013-726	01/30/2013 02/28/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	THOMPSON, RAY	BECTON DICKINSON MEDICAL SYSTEMS, CANAAN, CT 3/14-16/12; PFIZER INC, GROTON, CT 2/21-24/12; Z-MEDICA CORP, WALLINGFORD, CT 3/29/12-4/11/12, ETC - 483S
2013-727	01/30/2013 02/28/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	THOMPSON, RAY	ALTAIRE PHARMACEUTICALS INC, AQUEBOGUE, NY 3/15-19/12; AMNEAL PAHRMACEUTICALS OF NEW YORK LLC, HAUPPAUGE, NY 5/8-15/12; FOREST LABORATORIES INC, COMMACK, NY 2/15-22/12, ETC - 483S
2013-728	01/30/2013 02/28/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	THOMPSON, RAY	CIANNA MEDICAL INC, ALISO VIEJO, CA 12/14/11-1/9/12; REVITOL CORP, BURBANK, CA 4/24/12-6/1/12; PURQUALITY LLC, TEMPE, AZ 1/10-30/12, ETC - 483S
2013-729	01/30/2013 02/28/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	THOMPSON, RAY	PHARMATEC LLC, DAVIE, FL 1/12-24/12; BECKMAN COULTER INC, HIALEAH, FL 7/16-20/12; PACE TECH INC, CLEARWATER, FL 3/15-19/12, ETC - 483S
2013-730	01/30/2013 02/28/2013	FDA/OC/OES/DFOI/	WALTER E CHALKLEY THOMSON REUTERS	2012-7518
2013-731	01/30/2013 02/28/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	WALTER E CHALKLEY THOMSON REUTERS	ST MARY'S HOSPITAL & MEDICAL CENTER INC, GRAND JUNCTION, CO - EIRS, 483S, CO RESP 6/4-15/12
2013-732	01/30/2013 02/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	TAIWAN THREE MAST PHARMACEUTICAL CO LTD, TAINAN CITY, TAIWAN - EIRS, 483S, CO RESP 4/23-27/12
2013-733	01/30/2013 02/28/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	THOMPSON, RAY	APHENA PHARMA SOLUTIONS-MARYLAND LLC, EASTON, MD 1/9-13/12; MYLAN PHARMACEUTICALS INC, MORGANTOWN, WV 1/23/12-2/2/12; BOEHRINGER INGELHEIM CHEMICALS INC, PETERSBURG, VA 3/22/12-4/4/12 - 483S
2013-734	01/30/2013 02/28/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	RUGER CHEMICAL, LINDEN, NJ - EIRS, 483S, CO RESP 9/22/11-10/11/11
2013-735	01/30/2013 02/28/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	THOMPSON, RAY	AMGEN INC, BOULDER, CO 12/14/11-1/6/12; ADAPTA MEDICAL INC, COLORADO SPRINGS, CO 1/23-26/12; NELSON LABORATORIES INC, SALT LAKE CITY, UT 3/5-9/12, ETC - 483S
2013-736	01/30/2013 02/28/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	THOMPSON, RAY	GLOBUS MEDICAL INC, AUDUBON, PA 4/18/12-5/1/12; AUXILIUM PHARMACEUTICALS INC, HORSHAM, PA 6/25/12-7/6/12; MUTUAL PHARMACEUTICAL CO INC 1/9-27/12, ETC - 483S
2013-737	01/30/2013 02/28/2013	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	THOMPSON, RAY	SAGE PHARMACEUTICALS INC, SHREVEPORT, LA 2/14-17/12; HAWTHORN PHARMACEUTICALS INC, MADISON, MS 1/30/12-2/15/12; ONYX MEDICAL CORP, LMEMPHIS, TN 2/1-13/12, ETC - 483S

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2013-738	01/30/2013 02/28/2013	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	THOMPSON, RAY	MIRGEN PHARMACEUTICAL, BOISE, ID 1/9-30/12; GENETECH INC, HILLSBORO, OR 6/19-27/12; GYNEX CORP, REDMOND, WA 7/16-20/12, ETC - 483S
2013-739	01/30/2013 02/28/2013	OC/ORAP/ORM/ OC/ORAP/ORM/	THOMPSON, RAY	HUMAN DRUG, MEDICAL DVC FIRMS - GMP, GLP, GCP INSPS 8/1/12-12/31/12
2013-740	01/30/2013 02/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	THOMPSON, RAY	HERBRAND PHARMACHEMICALS GMBH, GENGENBACH, GERMANY 6/11-15/12; SCICAN BHT, GERSTHOFEN, GERMANY 7/16-19/12; BASF PHARMACHEMIKALIEN GMBH & CO KG, MINDEN GERMANY 2/6-10/12,ETC - 483S
2013-741	01/30/2013 03/15/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	WALTER E CHALKLEY THOMSON REUTERS	JHP PHARMACEUTICALS LLC, ROCHESTER, MI - EIR, 483, CO RESP 3/12
2013-742	01/30/2013 02/28/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	GUARDIAN DRUG CO, DAYTON, NJ - EIR, 483, CO RESP 3/12
2013-743	01/30/2013 02/28/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	THOMPSON, RAY	NOVO NORDISK A/S, GENTOFTE, DENMARK 6/28-26/12; NOVO NORDISK A/S, HILLEROED, DENMARK 3/21/12; NOVO NORDISK A/S, KALUNDBORG, DENMARK 3/5-9/12 - 483S
2013-744	01/30/2013 02/28/2013	FDA/OC/OES/DFOI/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	WALTER E CHALKLEY THOMSON REUTERS	RTI BIOLOGICS, ALACHUA, FL - EIR, CORR 6.25/12-7/11/12
2013-745	01/30/2013 02/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	THOMPSON, RAY	GENZYME FLANDERS NV, GEEL, BELIGIUM 1/16/24/12; HOSPIRA COSTA RICA LTD, LA AURORA DE HEREDIA, COSTA RICA 4/16-19/12; BRISTOL-MYERS SQUIBB, ANAGNI, ITALY 3/5-8/12, ETC - 483S
2013-746	01/30/2013 02/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	THOMPSON, RAY	BECTON DICKINSON DE MEXICO, CUAUTITLAN IZCALLI, MEXICO 1/16-19/12; AKZO NOBEL CHEMICALS SA DE CV, LOS REYES LA PAZ EDO, MEXICO 3/26-30/12 - 483S
2013-747	01/30/2013 02/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	THOMPSON, RAY	SHIONGI & CO LTD, AMAGASAKI-SHI, JAPAN 2/10-15/12; TAKEDA PHARMACEUTICAL CO LTD, HIKARI, JAPAN 7/17-20/12 - 483S

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		FDA/OC/OES/DFOI/		
2013-748	01/30/2013 02/28/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	THOMPSON, RAY	DEPUY (IRELAND) LOUGHBEG, RINGASKIDDY, IRELAND 1/23-26/12; JANSSEN BIOLOGICS (IRELAND) BARNAHELY, RINGASKIDDY, IRELAND 6/12-18/12 - 483S
2013-749	01/30/2013 02/28/2013	FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORAPA-FO/SAN- DO/SAN-CB/ FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/	WALTER E CHALKLEY THOMSON REUTERS	DR MALCOLM PAUL, NEWPORT BEACH, CA 6/14/12-7/17/12; DR RICHARD D'AMICO, ENGLEWOOD, NJ 10/11/12-11/12/12, ETC - EIR, 483, CO RESP
2013-750	01/30/2013 02/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	THOMPSON, RAY	ASTRAZENCA, MACCLESFIELD, CHESHIRE, UK 3/12-16/12; DEPUY INTERNATIONAL LTD, LEEDS, UK 2/13-16/12 - 483S
2013-751	01/30/2013 02/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	HAMELN PHARMACEUTICALS GMBH, HAMELN, GERMANY - EIR, 483, CO RESP 6/4-14/12
2013-752	01/30/2013 02/28/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	THOMPSON, RAY	NOVARTIS PHARMA BPO, HUNINGUE, FRANCE 1/23-31/12; SANOFI CHIMIE, PLOERMEL, FRANCE 3/26-30/12 - 483S
2013-753	01/30/2013 02/28/2013	FDA/OGROP/ORANE-FO/NYK- DO/NYK-DCB/	WALTER E CHALKLEY THOMSON REUTERS	APP PHARMS, GRAND ISLAND, NY - EIR, 483, CORR 10/2- 19/12
2013-754	01/30/2013 02/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	THOMPSON, RAY	BOEHRINGER INGELHEIM RCV GMBH, VIENNA, AUSTRIA 3/15/23/12; DSM FINE CHEMICALS AUSTRIA GMBH NFG GMBH & CO KG, LLINZ, AUSTRIA 5/29-12-6/1/12 - 483S

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2013-755	01/30/2013 02/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	THOMPSON, RAY	POLYMED THERAPEUTICALS INC, ERLANG, CHINA 5/21-23/12; CHONGQING KANGLE PHARMACEUTICAL CO LTD, CHONGQING, CHINA 4/23-26/12 - 483S
2013-756	01/30/2013 02/28/2013	FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	THOMPSON, RAY	ABBOTT BIOTECHNOLOGY LTD, BARCELONETA, PR 6/26/12-7/12/12; BIO LAB-ST JOSEPH CORP, BAYAMON, PR 4/17/12-5/9/12; ABBOTT DIAGNOSTICS INTERNATIONAL LTD, BARCELONETA, PR 1/18-12-3/12/12, ETC - 483S
2013-757	01/30/2013 02/28/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	THOMPSON, RAY	IMPLANT RESOURCE INC, BURNSVILLE, MN 5/16-12-6/17/12; MEDTRONIC NEUROMODULATION, MINNEAPOLIS, MN 3/14/12-5/9/12; BOSTON SCIENTIFIC CRM CORP, SAINT PAUL, MN 3/19/12-4/16/12, ETC
2013-758	01/30/2013 02/28/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	THOMPSON, RAY	GLAXOSMITHKLINE CONSUMER HEALTHCARE LP, CLIFTON, NJ 12/20/11 TO 1/9/12; AUSTARPHARMA LLC, EDISON, NJ 5/30/12-6/5/12; ACTAVIS ELIZABETH LLC, ELIZABETH, NJ 12/13/11 TO 1/13/12, ETC - 483S
2013-759	01/30/2013 02/28/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	THOMPSON, RAY	NOVARTIS VACCINE & DIAGNOSTICS INC, EMERYVILLE, CA 3/20-30/12; IMMUNETECH INC, FOSTER CITY, CA 3/12-23/12; BIOGENEX LABORATORIES INC, FREMONT, CA 12/20/11 TO 1/6/12, ETC - 483S
2013-760	01/30/2013 02/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	THOMPSON, RAY	SANDOZ PRIVATE LTD (NOVARTIS), NAVI MUMBIA, INDIA 1/2-9/12; CADILA HEALTHCARE LTD, AHMEDABAD CITY, INDIA 2/13-23/12; CIPLALTD, BANGALORE, KARNATAKA, INDIA 6/21-28/12, ETC - 483S
2013-761	01/30/2013 02/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	THOMPSON, RAY	NOVARTIS PHARMA AG, BASEL, SWITZERLAND 7/19-26/12; CILAG AG, SCHAFFHAUSEN, SWITZERLAND 4/20-27/12; NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND 6/11-22/12, ETC - 483S
2013-762	01/30/2013 02/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	THOMPSON, RAY	APOTEX FERMENTATION INC, WINNIPEG, CANADA 6/4-7/12; CONTRACT PHARMACEUTICALS LTD (CPL), MARKHAM, CANADA 1/31/12 TO 2/2/12; CARDIOMED SUPPLIES INC, LINDSAY, CANADA 2/20-23/12 - 483S
2013-763	01/30/2013 02/28/2013	FDA/OFVM/CFSAN/OCD/EOS/	CYNTHIA B LIEBERMAN Keller and Heckman LLP	FCN 1206
2013-764	01/30/2013	FDA/OGROP/ORA/PA-FO/SEA-	BRENDA M GARTZ	PETNET SOLUTIONS, KENT, WA - EIR 2/12

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	02/28/2013	DO/SEA-CB/	ELI LILLY & CO	
2013-765	01/30/2013 02/28/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	BRENDA M GARTZ ELI LILLY & CO	BACHEM INC, TORRANCE, CA - EIR 1/20/12
2013-766	01/30/2013 02/28/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	BRENDA M GARTZ ELI LILLY & CO	PETNET SOLUTIONS, ST LOUIS, MO - EIR 2/11
2013-767	01/30/2013 02/28/2013	FDA/OC/OES/DFOI/	CHRISTOPHER WEAVER WALL STREET JOURNAL	2008-1744, 2011-7185, 2012-3210, ETC
2013-768	01/30/2013 02/28/2013	FDA/OC/OES/DFOI/	CHRISTOPHER WEAVER WALL STREET JOURNAL	2008-3812, 2012-3360, 2012-3741
2013-769	01/30/2013 02/28/2013	FDA/OC/OES/DFOI/	BERNIE BURGESS BURGESS, BERNIE	RECS RE: FOI REQUEST
2013-770	01/30/2013 02/28/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OC/OES/DFOI/	THOMPSON, RAY	ADVANCED ORTHOPRO INC, INDIANAPOLIS, IN 4/6-26/12; L PERRIGO CO, ALLEGAN, MI 4/17/12-5/8/12; ACUMEDIA MANUFACTURERS INC, LANSING, MI 12/19/11-1/9/12, ETC - 483S
2013-771	01/31/2013 03/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	Richard Superfine Rheomics, Inc.	K062604
2013-772	01/31/2013 03/01/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Rachel Johnson FOI Services, Inc.	OSCAR GOODMAN, NEVADA CANCER CENTER, LAS VEGAS, NV - EIR (6/25/2012 - 07/03/2012)
2013-773	01/31/2013 03/01/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Rachel Johnson FOI Services, Inc.	MEDIVATION, SAN FRANCISCO, CA - EIR 06/08/12
2013-774	01/31/2013 03/15/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Michael Feiler Kulling Selander Lownds Winslett & Moser	INVACARE - INSPECTION RECS, CORR, UNTITLED LETTER ETC
2013-775	01/31/2013 03/01/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Linda Bowen SANOFI	GENENTECH, HILLSBORO, OR; GENENTECH, SAN FRANCISCO; GENENTECH, VACAVILLE, CA ETC - 483
2013-776	01/31/2013 03/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	Juan Herrera AIDI Biomedical	AIDI BIOMEDICAL - MDR SINCE 01/01/2013
2013-777	01/31/2013	OC/ORAI/	Joshua A. Leach	SYNOVIS DURA-GUARD - SAMPLE RESULTS

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	03/01/2013	OC/OR/ FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Baxter Healthcare Corp.	
2013-778	01/31/2013 03/01/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Rachel Johnson FOI Services, Inc.	ANDREW ARMSTRONG, DUKE UNIVERSITY MEDICAL CENTER, DURHAM, NC - EIR (6/13/12)
2013-779	01/31/2013 03/01/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Laura Hass Hass, Laura	ETHICON, ETHICON ENDO-SURGERY GASTRIC BYPASS SURGERY STAPLERS - COMPLAINTS, INVESTIGATIONS, REPORTS ETC
2013-780	01/31/2013 03/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mahidhar Chinta MICRO LABS USA INC	NDA 203491
2013-781	01/31/2013 03/01/2013	FDA/OO/OFBA/OAGS/	Shadonna Messiah United Union Of Security Guards	HSH-QEC-12-D-00002
2013-782	01/31/2013 03/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jay Wrobel, Ph.D. Fox Chase Chemical Diversity Center	RILUZOLE - SUMMARIES OF IN VITRO AND ANIMAL SAFETY PHARMACOLOGY AND TOXICOLOGY STUDIES
2013-783	01/31/2013 03/01/2013	FDA/OFVM/CFSAN/OCD/EOS/ OC/CVM/OCD/	Josh Jendza BASF - The Chemical Company	FAP 2269
2013-784	01/31/2013 03/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	Tomas Friend KIPA AB	AGA MEDICAL CORP - MATERIALS SUBMITTED FOR OCCLUDER OR OCCLUSION DEVICE (01/02/1996 - 01/02/2001)
2013-785	01/31/2013 03/01/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Xiang Liu Blackrock	HILL-ROM, BATESVILLE, IN - 483 (09/01/2012 - 01/01/2013)
2013-786	01/31/2013 03/01/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	LIFE EXTENSION - Alexandra Ajmo Ajmo, Alexandra	US PHARMA LAB INC, NORTH BRUNSWICK, NJ - EIR (01/01/2012 - 01/01/2013)
2013-787	01/31/2013 03/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	Tomas Friend KIPA AB	PMA P000039

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2013-788	01/31/2013 03/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	Cathy Shachaf Orlucent	K014018
2013-789	01/31/2013 03/01/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	JOHNATHAN RICKMAN FDA NEWS	RSA CORP, DANBURY, CT; ALLERQUEST LLC, PLAINVILLE, CT; PCI SYNTHESIS, NEWBURYPORT, MA, ETC - 483S 12/1-31/12
2013-790	01/31/2013 03/01/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	JOHNATHAN RICKMAN FDA NEWS	GUY & O'NEILL INC, FREDONIA, WI; BRUNO INDEPENDENT LIVING AIDS INC, OCONOMOWOC, WI - 483S 12/1-31/12
2013-791	01/31/2013 03/01/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	JOHNATHAN RICKMAN FDA NEWS	CUSTOM COMPOUNDING CENTERS, LOS ALAMITOS, CA; SCIENTIFIC PHARMACEUTICALS INC, POMONA, CA; BIOSEAL CORP. PLACENTIA, CA, ETC - 483S 12/1-31/12
2013-792	01/31/2013 03/01/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	JOHNATHAN RICKMAN FDA NEWS	NESHER PHARMACEUTICALS (USA) LLC, BRIDGETON, MO; NESHER PHARMACEUTICALS (USA), LLC, SAINT LOUIS, MO; WEXFORD LABS INC, KIRKWOOD, MO - 483S 12/1-31/12
2013-793	01/31/2013 03/01/2013	OC/ORA/ OC/ORA/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHNATHAN RICKMAN FDANEWS	ORION CORP, ESPOO, FINLAND - 483S 12/1-31/12
2013-794	01/31/2013 03/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHNATHAN RICKMAN FDANEWS	AMERICAN ORTHO-TECH (P) LTD, CHENNAI, TAMBARAM, INDIA; UNOMEDICAL LSDN BHD, SUNGAI PETANI, KEDAH, MALAYSIA; GARAVENTA (CANADA) LTD, ST SURREY, CANADA, ETC - 483S 12/1-31/12
2013-795	01/31/2013 03/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHNATHAN RICKMAN FDA NEWS	BSP PHARMACEUTICALS SRL, LATINA SCALO, ITALY; FARMHISPANIA SA, MONTMELO, SPAIN; SICOR SRL, SANTHIA (VC), ITALY, ETC - 483S 12/1-31/12
2013-796	01/31/2013 03/01/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	JOHNATHAN RICKMAN FDA NEWS	PETNET SOLUTIONS INC, FORT LAUDERDALE, FL; CFS DENTAL INC, HIALEAH, FL; VYCOR MEDICAL INC, BOCA RATON, FL, ETC - 483S 12/1-31/12
2013-797	01/31/2013 03/01/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	JOHNATHAN RICKMAN FDA NEWS	PFIZER INC, ROCHESTER, MI; EXCEL MEDICAL PRODUCTS INC, FENTON, MI - 483S 12/1-31/12
2013-798	01/31/2013 03/01/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	JOHNATHAN RICKMAN FDA NEWS	BENCHMARK MEDICAL INC, SALT LAKE CITY, UT; WATSON LABORATORIES INC, SALT LKE CITY, UT; FRESENIUS MEDICAL CARE NORTH AMERICA, OGDEN, UT, ETC
2013-799	01/31/2013 03/01/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	JOHNATHAN RICKMAN FDANEWS	AMERICAN PHARMACEUTICALS & COSMETICS INC, FORT WORTH, TX; CYBERONICS INC, HOUSTON, TX; MEDRO SYSTEMS INC, MCKINNEY, TX, ETC - 483S 12/1-31/12

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2013-800	01/31/2013 03/01/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	JOHNATHAN RICKMAN FDA NEWS	PEMCO INC, INDEPENDENCE, OH; NORMAN NOBLE INC, HIGHLAND HEIGHTS, OH; HAVELS INC, CINCINATI, OH, ETC - 483S 12/1-31/12
2013-801	01/31/2013 03/01/2013	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	JOHNATHAN RICKMAN FDA NEWS	MEDFIL INC, GLENDALE HEIGHTS, IL; LATTICE INC, WHEATION, IL; DEL MEDICAL INC, ROSELE, IL - 483S 12/1-31/12
2013-802	01/31/2013 03/01/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	JOHANTHAN RICKMAN FDANEWS	RX SOUTH LLC (DBA RX3 PHARMACY), CHESTER, VA; HEMAGEN DIAGNOSTICICS INC, COLUMBIA, MD; ACELL INC, COLUMBIA, MD - 483S 12/1-31/12 - 483S 12/1-31/12
2013-803	01/31/2013 03/01/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	JOHNATHAN RICKMAN FDANEWS	SUMMIT INDUSTRIES, MARRIETA, GA; HEAVENLY HARVEST INC, MOULTRIE, GA - 483S 12/1-31/12
2013-804	01/31/2013 03/01/2013	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	JOHNATHAN RICKMAN FDANEWS	BLOOD BANK COMPUTER SYSTEMS INC, AUBURN, WA; CARDINAL LHEAL 414 INC, SEATTLE, WA; MALONEY'S CUSTOM OCULAR PROSTHETICS, LAKE OSWEGO, OR, ETC - 483S 12/1-31/12
2013-805	01/31/2013 03/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LEO STERNLICHT RIDGEBACK CAPITAL MANAGEMENT LLC	SALIX PHARMACEUTICALS - RELISTOR (METHYLNALTREXONE BROMIDE) CO RESP
2013-806	01/31/2013 03/01/2013	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	MASSEY, GEORGE	INDIVIDUAL RECS
2013-807	01/31/2013 03/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KYRIAKIDIS, JOANNA	LTR TO KAREN TANNERT, RPH TX DEPT OF STATE HEALTH SERVICES 5/4/05
2013-808	01/31/2013 03/01/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	JOHNATHAN RICKMAN FDA NEWS	NU WORLD CORP, CARTERET, NJ; OHM LABORATORIES INC, NEW BRUNSWICK, NJ; CATALENT PHARMA SOLUTIONS LLC, SOMERSET, NJ - 483 12/12
2013-809	01/31/2013 03/01/2013	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	JOHNATHAN RICKMAN FDA NEWS	BD CARIBE LTD, CAYEY, PR; KNOLL LLC, JAYUYA, PR - 483 12/12
2013-810	01/31/2013 03/01/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	JOHNATHAN RICKMAN FDANEWS	INTERSECT ENT INC, PALO ALTO, CA; AMPAC FINE CHEMICALS LLC, RANCHO CORDOVA, CA; NATUREX INC, SHINGLE SPRINGS, CA - 483 12/12
2013-811	01/31/2013 03/01/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	JOHNATHAN RICKMAN FDA NEWS	B BRAUN MEDICAL INC, ALLENTOWN, PA - 483 12/12
2013-812	01/31/2013 03/01/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	JOHNATHAN RICKMAN FDANEWS	ASCENT PHARMACEUTICALS INC, CENTRAL ISLIP, NY; HI TECH PHARMACAL CO INC, AMITYVILLE, NY; NOVARTIS PHARMACEUTICALS CORP, SUFFERN, NY - 483 12/12

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2013-813	01/31/2013 03/01/2013	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	JOHNATHAN RICKMAN FDANEWS	CRYOSURGERY INC, NASHVILLE, TN; AXIS HEALTH CARE LLC, MONTGOMERY, AL - 483 12/12
2013-814	01/31/2013 03/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	CHRISTOPHER B. SPUCHES, Esq. EHRENSTEIN CHARBONNEAU ET AL	CANNULATED BONE SCREW K061620; BONE FIXATION DEVICE K071035; PROFILE PLATES SCREWS & WASHERS K110086
2013-815	01/31/2013 03/01/2013	FDA/OFVM/CFSAN/OCD/EOS/	ROBERT A. DeCAMP DERINGER LOGISTICS CONSULTING GROUP	AN DERINGER INC - LTR SHOWING CO AS AN AGENT OF THE US
2013-816	01/31/2013 03/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	SARA BEARDSLEY SIDLEY AUSTIN LLP	ACIST ANGIOGRAPHIC CONTRAST MGMT INJECTORSYS MODEL CMS2000 k991103; ACIST ANGIOGRAPHIC INJECTION SYS, MODEL R2000 CMS (K010390); ACIST ANGIOGRAPHIC CONTRAST MGMT SYS (K984231)
2013-817	01/31/2013 03/01/2013	FDA/OC/OES/DFOI/	ROSS D. PLONT GRUEL MILLS NIMS & PYLMAN LLP	CARDINAL HEALTH EXCHANGE TRANSFUSION TRAY 6/13/07
2013-818	01/31/2013 03/01/2013	FDA/OC/OES/DFOI/	ROSS D. PLONT GRUEL MILLS NIMS & PYLMAN LLP	ALLEGIANCE HEALTHCARE PHARMASEAL EXCHANGE TRANSFUSION TRAY 2/20/02
2013-819	01/31/2013 03/01/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARK SCHOOF PRO PUBLICA	RESPONSE LTR FROM FDA TO CETERO RESEARCH 7/26/11
2013-820	01/31/2013 03/01/2013	OC/ORAOCI/ OC/ORAOCI/	COLOSI, JOSEPH A	INDIVIDUAL RECS
2013-821	02/01/2013 03/04/2013	OC/CVM/OCD/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Ryan T. Kearney COZEN O'CONNOR	HARTZ CHICKEN CHEWS, HARTZ OINKIE PIG SKIN WRAPPED WITH CHICKEN - INVESTIGATION, INSPECTIONS, TESTING, ETC
2013-822	02/01/2013 03/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bobbie Sanderson Sanderson, Bobbie	FORTEO - NUMBER OF MEDWATCH RPTS FOR OSTEOSARCOMA, BONE CANCER
2013-823	02/01/2013 03/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	KARIM FIZAZI, INSTITUTE GUSTAVE-ROUSSY, VILLEJUIF, FRANCE - EIR (07/30/2012 - 08/03/2012)

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2013-824	02/01/2013 03/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	WOLFGANG LOIDL, LINZ UROLOGIE ABTEILUNG, LINS, AUSTRIA - EIR (08/2012)
2013-825	02/01/2013 03/04/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/DET-DO/DET-CB/ FDA/OFVM/CFSAN/OCD/EOS/	Becky Cooseman Brown & Crouppen, PC	SAMPLE 661933 - ALL RECS
2013-826	02/01/2013 03/04/2013	FDA/OC/OES/DFOI/	MINTZ GROUP	SUREPATH FLUID COLLECTION VIAL - FOI REQUESTS
2013-827	02/01/2013 03/04/2013	FDA/OFVM/CFSAN/OCD/EOS/ OC/OCOS/OES/ OC/OCOS/OES/ OC/OA/OM/OMP/DDM/	CHARLOTTE VALLAEYS CORNUCOPIA INSTITUTE	DKT 2008P-0347
2013-828	02/01/2013 03/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORO/ OC/ORO/	REBECCA FIELD EMERSON MITTS LAW LLC	PHARMEDIUM SERVICES LLC - WARNING LTRS, APRVL RECS, INSPS, ETC 1/07 TO PRESENT
2013-829	02/01/2013 03/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORO/ OC/ORO/	REBECCA FIELD EMERSON MITTS LAW LLC	CENTRAL ADMIXTURE PHARMACY SERVICES INC, B BRAUN MEDICAL INC - WARNING LTRS, APRVL RECS, INSPS, ETC 1/07 TO PRESENT
2013-830	02/01/2013 03/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RAVI DESHPANDE ACINO PRODUCTS LLC	JANSSEN PHARMA - TERAZOL 3 (TERCONAZOLE) VAGINAL SUPPOSITORY NDA 19-641; PERRIGO NEW YORK - TERCONAZOLE VAGINAL SUPPOSITORY ANDA 77-149 SBA

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2013-831	02/01/2013 03/04/2013	FDA/OMPT/CTP/OD/	FOI Services, Inc.	NAMES OF ESTABLISHMENTS ENGAGED IN THE MANUFACTURE, PREPARATION, COMPOUNDING OF TOBACCO PRODS
2013-832	02/01/2013 03/04/2013	FDA/OFVM/CFSAN/OCD/EOS/	DAVID C STEINBERG STEINBERG & ASSOCIATES INC	HAIR STRAIGHTENER COSMETICS - CAERS 2000 TO PRESENT
2013-833	02/01/2013 03/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OC/OES/DFOI/	CURTIN, DENNIS D	OCTAPharma AB, STOCKHOLM, SWEDEN - 483 1/11
2013-834	02/01/2013 03/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/OA/OM/OMP/DDM/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Empire State Consumer Project, Inc	DKT 2012P-0566
2013-835	02/01/2013 03/04/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	CONKLIN COMPANY INC - EIR, 483, CO RESP 10/12
2013-836	02/01/2013 03/04/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORACE-FO/DEN-DO/DEN-CB/	Doe J	INDIVIDUAL RECS
2013-837	02/01/2013 03/04/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORACE-FO/LOS-DO/LOS-CB/	Lorraine Shelton Exova Inc.	AAI PHARMA SERVICES, EDISON, NJ - EIR 3/15/12; IRVINE PHARM SERVICES, IRVINE, CA - EIR 11/24/09, 4/2/12; NORTH AMERICAN SCIENCE ASSOC INC, IRVINE, CA - EIR 10/14/11; NORTH AMERICAN SCIENCE ASSOC, NORTHWOOD, OH - EIR 12/9/11
2013-838	02/01/2013	OC/OM/OMP/DDM/	GLORIA GASKINS	DKT FDA-1975-N-0355

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	03/04/2013		KLEINFELD KAPLAN & BECKER	
2013-839	02/01/2013 03/04/2013	OC/OM/OMP/DDM/	ANGELIA SLAYTON INC RESEARCH CONSULTING & SUBMISSIONS	OTC VOLS. 160414, 160397
2013-840	02/03/2013 03/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mara Goldstein Cantor Fitzgerald/Mara Goldstein	CELLDEX THERAPEUTICS CDX-011 - MINUTES FROM END OF PHASE 2 MTGS
2013-841	02/03/2013 03/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Christopher Weaver THE WALL STREET JOURNAL	BARDOXOLONE METHYL - IND SAFETY AND EFFECTIVENESS RECS
2013-842	02/03/2013 03/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	CLOSED FOIA REQUESTS (01/012013-01/31/2013)
2013-843	02/03/2013 03/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG (12/31/2012 - 2/1/2013)
2013-844	02/03/2013 03/04/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	VAERS 270905, 271928, 272975 ETC
2013-845	02/03/2013 03/04/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORR/SE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORR/CE-FO/MIN-DO/MIN-CB/	JEROME LEW MEDTRONIC (INFUSE BMP)	OFF LABEL USE OF MEDTRONIC INFUSE BMP IN THE CERVICAL SPINE AND IMPROPER SUBMISSION OF HUMAN SUBJECTS INTO CLINICAL TRIALS OR STUDIES - INVESTIGATION RECS
2013-846	02/03/2013 03/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Andrew Ellis PRIVATE CITIZEN	VIDEX, VIDEX EC -REPORTS RE PORTAL HYPERTENTION
2013-847	02/03/2013 03/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kelli Chan Kelli Chan	LEVAQUIN, CIPRO, AVELOX, ETC - AERS
2013-848	02/03/2013 03/04/2013	FDA/OGROP/ORR/CE-FO/PHI-DO/PHI-CB/	Tonya Bechtel Tarsa Therapeutics, Inc.	SHARP, ALLENTOWN, PA - EIR (APRIL 2011)
2013-849	02/03/2013	FDA/OMPT/CDER/ORP/DIDP/	Kimberly Clarke	HCG INJECTIONS - AERS

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	03/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dr.Emma's Corporation	
2013-850	02/03/2013 03/04/2013	OC/OA/OM/OMP/DDM/	Chris Lahiff Chris Lahiff c/o McDermott Will & Emery	MEMORANDUM TO THE RECORD 2012 REFERENCED IN STANDARDS FOR THE GROWING, HARVESTING, PACKING AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION
2013-851	02/03/2013 03/04/2013	OC/ORO/ OC/ORO/	Christopher Weaver THE WALL STREET JOURNAL	SAMPLE RESULTS FROM INDUSTRY CODES 56, 57, 60-66
2013-852	02/03/2013 03/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mara Goldstein Cantor Fitzgerald/Mara Goldstein	ADCETRIS - AERS
2013-853	02/03/2013 03/04/2013	OC/OSMP/OOPD/ FDA/OMPT/OSMP/OOPD/	Rachel Johnson FOI Services, Inc.	HUMATE-P - ORPHAN DRUG DESIGNATION
2013-854	02/03/2013 03/04/2013	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/	Michael Atkins Atkins Intellectual Property, PLLC	ZAO GRUPPA PEDPRIYATIJ OST, ZAO OST AQUA, LTD AQUA LIFE - IMPORTATION, DISTRIBUTION, PACKING, SALE ETC
2013-855	02/03/2013 03/04/2013	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/	Michael G. Atkins Atkins Intellectual Property, PLLC	DUCHESSE, DIOWEC DUSHESSE, EXTRA-CIDER ETC - IMPORTATION, DISTRIBUTION, PACKING ETC
2013-856	02/03/2013 03/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Chris Letter Odom & Des Roches, LLP	NDA 76436, 76905, 76905 ETC - TENTATIVE APPROVAL LETTERS
2013-857	02/03/2013 03/04/2013	FDA/OGROP/ORO/NE-FO/NWE-DO/NWE-CB/	Mark W. Sherman LRP PUBLICATIONS	JUDGE ROTENBERG CENTER, CANTON, MA - CORR 5/23/11, 6/29/12
2013-858	02/03/2013 03/04/2013	FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/	Nanci Martinez for Martinez Food Company Martinez Food Company	MARTINEZ FOOD CO, ELGIN, TX - INSPECTION RECS (01/01/2013 - 01/31/2013)
2013-859	02/03/2013 03/04/2013	OC/ORO/OCI/ OC/ORO/OCI/	Christopher Weaver THE WALL STREET JOURNAL	CANADA DRUGS, KRIS THORKELSON - RELEASABLE RECS IN CRIMINAL CASE
2013-860	02/03/2013	FDA/OMPT/CDER/ORP/DIDP/	Ole Pedersen	ANDA 077850

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	03/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Alkalon AS	
2013-861	02/03/2013 03/04/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Janet Horn BD Diagnostic Systems / Janet Horn	LIST OF ALL FDA REGISTERED DRUG COMAPNIES, COSMETIC/PERSONAL CARE COMPANIES
2013-862	02/03/2013 03/04/2013	OC/OSMP/OOPD/ FDA/OMPT/OSMP/OOPD/	Rachel Johnson FOI Services, Inc.	WILATE - ORPHAN DRUG APPLICATION
2013-863	02/03/2013 03/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Teresa Porter not applicable	VIMPAT - AERS
2013-864	02/03/2013 03/04/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Anthony Lenza, Esq. Amabile & Erman, P.C.	HILL-ROM CLINITRON CII RECALL Z-0989-03 - DOCS, LETTERS, RPTS
2013-865	02/03/2013 03/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Attorney Gary Liquori Powers & Liquori, Attys at Law	METHADONE PUBLIC HEALTH ADVISORY 11/27/2006 (CERTIFIED)
2013-866	02/03/2013 03/04/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rebecca Shelburne Ellipse Technologies Inc	K083458
2013-867	02/03/2013 03/04/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	David Kim David Kim	NOVO NORDISK, DENMARK - WARNING LETTER, 483 (01/01/2012 - 12/31/2012)
2013-868	02/03/2013 03/04/2013	FDA/OC/OES/DFOI/	Amy Kincanon LexisNexis CourtLink Document Retrieval	2011-3365

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2013-869	02/03/2013 03/04/2013	FDA/OC/OES/DFOI/	Amy Kincanon LexisNexis CourtLink Document Retrieval	2009-6614
2013-870	02/03/2013 03/04/2013	FDA/OC/OES/DFOI/	Amy Kincanon LexisNexis CourtLink Document Retrieval	2010-7304
2013-871	02/03/2013 03/04/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	B Burgess BURGESS, BERNIE	FACTS 808885 - 482
2013-872	02/03/2013 03/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kristina Hahn-Major B. Braun Medical Inc.	ANDA 200222
2013-873	02/03/2013 03/04/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Rachel Johnson FOI Services, Inc.	TEXAS BIOMEDICAL RESEARCH, SAN ANTONIO, TX - 483 (09/01/2012 - 10/31/2012)
2013-874	02/03/2013 03/04/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Rachel Johnson FOI Services, Inc.	PHARMANET, PRINCETON, NJ - 483 (09/01/2012 - 10/31/2012)
2013-875	02/03/2013 03/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	Richard A Conlen MD R&G Medical and Development Corp.	K080464
2013-876	02/03/2013 03/04/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Doe J	BAXTER HEALTHCARE IV DIVISION, MARION, NC - 483, SAMPLE RESULTS
2013-877	02/03/2013 03/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	Greg Nagle Aurora Photonics Inc.	K011244
2013-878	02/04/2013 03/05/2013	FDA/OFVM/CFSAN/OCD/EOS/	TIMOTHY J REULAND SPEERS REULAND & CIBULSKIS PC	CANTALOUPE DNA FINGERPRINT RECS
2013-879	02/04/2013 03/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LAURA HOBBS LEXISNEXIS COURTLINK INC	AMOUNT OF 14-HYDROXYCODEINONE PERMITTED IN OXYMORPHONE HCL ATIVE PHARMACEUTICAL INGREDIENT (API) - RECS
2013-880	02/04/2013 03/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PATRICK E MA OD MD UNIV OF BRITISH COLUMBIA	PATRICK MA MD - UNTITLED LTR, EIR, 483 5/22/00

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2013-881	02/04/2013 03/05/2013	OC/OCOS/OES/ OC/OCOS/OES/ FDA/OC/OES/DFOI/ OC/ORA/OCI/ OC/ORA/OCI/	Doe J	INDIVIDUAL RECS
2013-882	02/04/2013 03/05/2013	FDA/OC/OES/DFOI/	KELLY A FITZPATRICK LANIER LAW FIRM	2012-8844 - MINOR DELETIONS
2013-883	02/04/2013 03/05/2013	FDA/OC/OES/DFOI/	ROSS D PLONT GRUEL MILLS NIMS & PYLMAN LLP	CARDINAL HEALTH - EXCHANGE TRANSFUSION FORM FDA 3500A, RPTS, MEMOS, ETC
2013-884	02/04/2013 03/05/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	COLAS, BRIAN	ISRS 3177015-7, 3412365-8, 3208564-0, ETC
2013-885	02/04/2013 03/05/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	AZIM CHOWDHURY Keller and Heckman LLP	NICORETTE NDA 18-612/S022 - FIVE USAGES STUDIES, RVW MEMOS
2013-886	02/04/2013 03/05/2013	FDA/OFVM/CFSAN/OCD/EOS/	ANNA FLOOD Keller and Heckman LLP	FCN 1233
2013-887	02/04/2013 03/05/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	BRETT PARK CONWAY HOMER & CHIN- CAPLAN PC	INDIVIDUAL RECS - VAERS
2013-888	02/04/2013 03/06/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	BRETT PARK CONWAY HOMER & CHIN- CAPLAN PC	INDIVIDUAL RECS - VAERS
2013-889	02/04/2013 03/05/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	CHRISTINA CIAMPOLILLO ESQ CONWAY HOMER & CHIN- CAPLAN PC	MERCK & CO INC - GARDASIL POST-MARKETING REQUIREMENTS, RPTS, STUDIES, ETC
2013-890	02/04/2013 03/05/2013	FDA/OFVM/CFSAN/OCD/EOS/	MITCHELL A CHEESEMAN STEPTOE & JOHNSON	HERCULES INC - FAP 0B2442
2013-891	02/04/2013 03/05/2013	FDA/OFVM/CFSAN/OCD/EOS/	ALBA 89560-012, DENNIS	ASPARTAME - RECS, CAERS
2013-892	02/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	GERALD MOSS	K910912, K890871

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	03/05/2013		MOSS MEDICAL PRODUCTS INC	
2013-893	02/04/2013 03/05/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDRH/OCER/DFOI/	COLEEN KLASMEIER SIDLEY AUSTIN LLP	LIFECCELL CORP - EIRS, 483S, COR RESP, ETC 5/6/11 TO 1/30/13
2013-894	02/04/2013 03/05/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	Doe J	MEDTRONIC - SYNCHROMED II BACLOFEN INFUSION PUMP RECALL RECS
2013-895	02/04/2013 03/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	COLAS, BRIAN	ABBOTT LABS - BIAXIN (CLARITHROMYCIN) CHANGES BEING EFFECTED (CBE), POST-MARKETING RPTS, DEAR DOCTOR LTRS
2013-896	02/04/2013 03/07/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	JANE CARROLL COMMUNITY TISSUE SERVICES	MUSCULOSKELETAL TRANSPLANT FOUNDATION - EIR MOST RECENT
2013-897	02/04/2013 03/05/2013	FDA/OFVM/CFSAN/OCD/EOS/	TAMI DALBERG INDENA USA INC	FLAVEX NATUREXTRAKTE GMBH, REHLINGEN, GERMANY - EIR 4/19-20/12
2013-898	02/04/2013 03/05/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	BRENDA M GARTZ ELI LILLY & CO	PETNET SOLUTIONS, JACKSONVILLE, FL - EIR 3/11
2013-899	02/04/2013 03/05/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	BRENDA M GARTZ ELI LILLY & CO	PETNET SOLUTIONS, DALLAS, TX - EIR 3/11
2013-900	02/04/2013 03/05/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	BRENDA M GARTZ ELI LILLY & CO	PETNET SOLUTIONS, ATLANTA, GA - EIR 2/11
2013-901	02/05/2013 03/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	Adam Cole Excel Medical Products, Inc.	K884327
2013-902	02/05/2013 03/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	An Wending Hisun Pharmaceuticals USA Inc.	TYPE II DRUG MASTER FILES SUBMITTED TO FDA (2007-2012)
2013-903	02/05/2013 03/06/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OFVM/CFSAN/OCD/EOS/	Michelle Celarier Michelle Celarier, New York Post	HERBALIFE FORMULA ONE, HERBALIFE PERSONALIZED PROTEIN POWDER - COMPLAINTS, INVESTIGATIONS (01/01/2005 - 02/04/2013)
2013-904	02/05/2013	FDA/OGROP/ORASE-FO/FLA-	Peter Nesbitt	QUASAR BIO-TECH, SILVER BAY LLC, SARASOTA, FL -

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	03/06/2013	DO/FLA-CB/ FDA/OC/OES/DFOI/	Quasar Bio-Tech Inc., aka Silver Bay LLC	REPORTS, LETTERS, EMAIL ETC
2013-905	02/05/2013 03/06/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lakshmi Raghavan DermPathe Pharmaceuticals	ZOVIRAX OINTMENT FORMULATION INFORMATION
2013-906	02/05/2013 03/06/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	EMCURE PHARMACEUTICALS, PUNE, INDIA - EIR (JUNE 2011)
2013-907	02/05/2013 03/06/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	FERRIC CITRATE - LIST OF NDA, ANDA
2013-908	02/05/2013 03/06/2013	FDA/OC/OES/DFOI/	Steven F. Napolitano Skadden, Arps, Slate, Meagher & Flom LLP	FOIA REQUESTS RE ZOLOFT
2013-909	02/05/2013 03/06/2013	OC/CVM/OCD/ FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/	Marc Selinger EXAMINER.COM	COMPLAINT 130061
2013-910	02/05/2013 03/06/2013	FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Melissa Henderson Melissa Henderson	DANIEL H PRESENT, NEW YORK, NY - MEMO TO FILE
2013-911	02/05/2013 03/06/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/	james mcgovern MCGOVERN, JAMES J	DR J TENNAT - FOLLOW UP OR CLOSE OUT TO WARNING LETTER DATED 2/15/05
2013-912	02/05/2013 03/06/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS Consulting Group, LLC	PULMOZYME BLA 103532 APRVL, LBLG, PHARMACOLOGY RVW, CHEMISTY RVW

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2013-913	02/05/2013 03/06/2013	OC/ORO/ OC/ORO/	FAVID BLOCH MEDTRONIC	ST JUDE MEDICAL, SYLMAR, CA - CO RESP 1/10/13
2013-914	02/05/2013 03/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	GERALD MOSS MOSS MEDICAL PRODUCTS INC	BARD MOSS GASTROSTOMY TUBE K890871
2013-915	02/05/2013 03/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	GERALD MOSS MOSS MEDICAL PRODUCTS INC	BIOSEARCH MEDICAL PRODUCTS INC K935045; K923474
2013-916	02/05/2013 03/06/2013	FDA/OGROP/ORO/CE-FO/NWJ- DO/NWJ-CB/ FDA/OMPT/CDRH/OCER/DFOI/	HU, QIYONG	MINDRAY MEDICAL INT'L, NY; CHINA - INSP LAST 5 YRS, WARNING LTRS, CO RESP
2013-917	02/05/2013 03/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	KELLY HEMPEL VIGIL LAW FRIM	OLYMPUS LF-GP FIBEROPTIC INTUBATION SCOPE - CORR 1/08 TO PRESENT
2013-918	02/05/2013 04/19/2013	FDA/OGROP/ORO/SW-FO/DEN- DO/DEN-CB/	KELLY HEMPEL VIGIL LAW FRIM	INDIVIDUAL RECS
2013-919	02/05/2013 03/06/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OES/DFOI/	SINEAD O'DONOGHUE GLOOR LAW GROUP LLC	CHARGE BEVERAGES CORP - LIQUID CHARGE; UNITED BRANDS COMPANY INC - JOOSE; PHUSION PROJECTS LLC - FOUR DOCS
2013-920	02/05/2013 03/06/2013	FDA/OFVM/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	IOVATE, HYDROXYCUT, SMARTBURN, ETC - AER SINCE 10/31/12
2013-921	02/05/2013 03/06/2013	FDA/OGROP/ORO/CE-FO/NWJ- DO/NWJ-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JENESSA G.B. COCCARO KERCSMAR & FELTUS PLLC	GARPARI NUTRITION INC - HALODROL LIQUIGELS & HALODROL MT, NOVEDEX XT; ORASTAN A - AER, CMLNPTS 1/05 TO 12/11
2013-922	02/05/2013 03/06/2013	FDA/OC/OES/DFOI/	BRODY MULLINS WALL STREET JOURNAL	2012-2751, 2012-8672
2013-923	02/05/2013 03/06/2013	OC/CVM/OCD/ OC/OCOS/OES/ OC/OCOS/OES/ FDA/OC/OCC/ OC/OA/OM/OMP/DDM/	ELISABETH HOLMES CENTER FOR FOOD SAFETY	RACTOPAMINE - AER
2013-924	02/05/2013 03/06/2013	FDA/OFVM/CFSAN/OCD/EOS/	FOI Services, Inc.	CFR 21, FOOTNOTE 4, PAGE 53
2013-925	02/05/2013	FDA/OGROP/ORO/CE-FO/DET-	KEVIN NOYES	NEW LIFE GENERATION, INDIANAPOLIS, IN - EIR, 483,

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	03/06/2013	DO/DET-CB/	AMERICAN DONOR SERVICES	WARNING LTRS, CO RESP
2013-926	02/05/2013 04/08/2013	FDA/OC/OES/DFOI/	ALISON YOUNG USA TODAY	DIETARY SUPPLEMENT - 483 2009 TO PRESENT
2013-927	02/05/2013 03/06/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OCC/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OCC/	ANDRREW KINDER MINTZ GROUP	SURE PATH FLUID COLLECTION VIAL - TESTING USE 1/05 TO PRESENT
2013-928	02/06/2013 03/07/2013	OC/OM/OMP/DDM/	ROSS RENDELMAN HOGAN LOVELLS LLP	DKT FDA-2013-D-0045
2013-929	02/06/2013 03/07/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Phil Sanderson NIH/NCATS	PRAZQUANTEL - SBA
2013-930	02/06/2013 03/07/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Taraneh Norouzi National Institutes of Health (NIH)	MAYO CLINIC NUCLEAR MEDICINE, DEPARTMENT OF RADIOLOGY, MINNESOTA - 483 (01/01/2010 - 01/31/2013)
2013-931	02/06/2013 03/07/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John Crewdson PROJECT ON GOVERNMENT OVERSIGHT	RECORD 1, 2, 3, 4 TRIALS - INSPECTIONS, AUDITS, INVESTIGATIONS BY OFFICE OF SURVEILLANCE AND EPIDEMIOLOGY
2013-932	02/06/2013 03/07/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John Crewdson PROJECT ON GOVERNMENT OVERSIGHT	RE-LY, RECORD 1, 2, 3, 4 TRIALS - INFORMED CONSENT FORMS
2013-933	02/06/2013 03/07/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Daniel Burnett Theranova, LLC	K052025, K061333, K101847
2013-934	02/06/2013 03/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Nisha Arora ARCIM Advisors LLC	K062915, K002233
2013-935	02/06/2013 03/07/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Marielena Groeger PROPUBLICA	ORANGE BOOK - DATE FILES (01/01/1980 - 12/31/2012)
2013-936	02/06/2013 03/07/2013	FDA/OMPT/CTP/OD/ OC/OM/OFM/	Rachel Johnson FOI Services, Inc.	MANUFACTURERS, IMPORTERS OF TOBACCO PRODUCTS ASSESSED USER FEES (10/01/2012 TO PRESENT)

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		FDA/OC/OES/DFOI/		
2013-937	02/06/2013 03/07/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K073656
2013-938	02/06/2013 03/07/2013	FDA/OMPT/CTP/OD/ OC/OM/OFM/ FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	MANUFACTURERS, IMPORTERS OF TOBACCO PRODUCTS FOR WHICH USER FEE WAS RECEIVED (10/01/2012 TO PRESENT)
2013-939	02/06/2013 03/07/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Simon Fairbrass HEALTHCOR MANAGEMENT LP	LONZA BIOLOGICS, HOPKINTON, MA - WARNING LETTER, 483, CORR ETC
2013-940	02/06/2013 03/07/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DDM/	Carrie Engleman SRI INTERNATIONAL	K081754 - DE NOVO PETITION
2013-941	02/06/2013 03/07/2013	FDA/OFVM/CFSAN/OCD/EOS/ OC/OR/ OC/OR/	Leslie Patton BLOOMBERG NEWS	MCDONALDS - NON-EMERGENCY FOOD PROBLEM REPORTS
2013-942	02/06/2013 03/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Dr. Diane Sudduth Biovance	K102478
2013-943	02/06/2013 03/07/2013	FDA/OFVM/CFSAN/OCD/EOS/ OC/OR/ OC/OR/	Leslie Patton BLOOMBERG NEWS	YUM! BRAND RESTAURANTS - NON-EMERGENCY FOOD PROBLEMS
2013-944	02/06/2013 03/07/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Rachel Johnson FOI Services, Inc.	BLA 125156 S0076
2013-945	02/06/2013 03/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K112342
2013-946	02/06/2013 03/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K032734
2013-947	02/06/2013 03/07/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Esther Lee Horizon NJ Health	OXYTROL FOR WOMEN - APPROVAL RECS
2013-948	02/06/2013 03/07/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K061848
2013-949	02/06/2013	FDA/OMPT/CDER/ERP/DIDP/	Tai-Li Chang, MD	COMPOUNDS CONTAINING FERRIC CITRATE, FERRIC

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	03/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Venrock Associates	AMMONIUM CITRATE - REGULATORY DECISIONS AND ACTIONS, APPROVALS, GUIDANCE ETC
2013-950	02/06/2013 03/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Aleksandr Rabodzey PFM (Attn: Alex Rabodzey)	PFIZER LYRICA STUDY - ENDPOINT ON PLACEBO
2013-951	02/06/2013 03/07/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OGROP/ORO/ORO/DIOP/	Mary Gustafson PPTA	IMPORT ALERT 57-01 BLOOD AND BLOOD COMPONENTS INCLUDING HUMAN PLASMA SERUM
2013-952	02/06/2013 03/07/2013	FDA/OC/OES/DFOI/	Johnathan Rickman FDANEWS	FOIA LOG 01/28/2013 TO 02/01/2013
2013-953	02/06/2013 03/07/2013	FDA/OMPT/CDRH/OCER/DFOI/ OC/OCOS/OL/ FDA/OC/OES/DFOI/ FDA/OC/OL/	CAROLLO, RUSSELL	VERISANTE AURA - RECS
2013-954	02/06/2013 03/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	W E CHALKLEY THOMSON REUTERS	APTALIS PHARMA US - URSO 250 (URSODIOL) NDA 20-675 APRVL RECS
2013-955	02/06/2013 03/07/2013	FDA/OGROP/ORO/NE-FO/NWE-DO/NWE-CB/	Sarah Nugent BioSphere Medical, Inc.	BIOSPHERE MEDICAL, ROCKLAND, MA - EIR JUNE 2011
2013-956	02/06/2013 03/07/2013	FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/	KATHY NGUYEN ZONARE MEDICAL SYSTEMS INC	EVOLVE MANUFACTURING TECHNOLOGIES INC, MOUNTAIN VIEW, CA - EIR
2013-957	02/06/2013 03/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PROJECT ON GOVERNMENT OVERSIGHT	BOEHRINGER INGELHEIM PHARMACEUTICALS INC - PRADAXA (DABIGATRAN ETEXILATE MESYLATE) ANNUAL AND FINAL RPT
2013-958	02/06/2013 03/07/2013	FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	DARCI TEOBALDI HOGAN LOVELLS LLP	ADVANCED BIONICS CORP, SYLMAR, CA - 483 9/15/04, WARNING LTR 2/1/05, RECALL RECS, ETC

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2013-959	02/06/2013 03/07/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John Crewdson PROJECT ON GOVERNMENT OVERSIGHT	RE-LY TRIAL - INSPECTION RECS BY DSI
2013-960	02/06/2013 03/22/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	MARKER GROUP INC	INDIVIDUAL RECS - VAERS
2013-961	02/06/2013 03/07/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John Crewdson PROJECT ON GOVERNMENT OVERSIGHT	RE-LY TRIAL - INSPECTIONS, INFORMED CONSENT, PRINCIPAL INVESTIGATOR CONTACT INFORMATION
2013-962	02/06/2013 03/07/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CALLE M MENDENHALL FREESE & GOSS, PLLC	ACTOS (PIOGLITAZONE) NDA 21-073 - AERS, CORR, WARNING LTRS, ETC
2013-963	02/06/2013 03/07/2013	FDA/OGROP/ORA/PA-FO/SEA- DO/SEA-CB/	GRAHAM J GILBERT SMITH HARTVIGSEN PLLC	RANGEN INC - CMLPNTS, CORR, WARRANTS, ETC
2013-964	02/06/2013 03/07/2013	OC/ORA/ OC/ORA/ OC/ORA/ORO/DFS/ OC/ORA/ORO/DFS/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/ FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/	TONY COVENY SIMON & LUKE LLP	CRIMSON CLOVER SPROUTS SEEDS - E COLI OUTBREAK IN AR, KS, IA, MO, WI 12/25/11 TO 1/15/12 RECS
2013-965	02/06/2013 03/07/2013	FDA/OO/OHR/	J. DONALD HENSON, SR Henson, J. Donald	JOB DESCRIPTION FOR CDRH SENIOR RVW INDIVIDUAL OF P980022/S010,S011,S015; JOB DESCRIPTION FOR FDA OFFICE OF COMMISSIONER OMBUDSMAN, ETC
2013-966	02/06/2013 03/07/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	COLLEEN BOSWELL BIOLASE TECHNOLOGY INC	BIOLASE TECHNOLOGY INC, IRVINE, CA - EIR 8/2-4/11
2013-967	02/06/2013 03/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	COLLEEN BOSWELL BIOLASE TECHNOLOGY INC	BIOLASE TECHNOLOGY INC - LASER PROD RPTS, ANNUAL RPTS ON RADIATION SAFETY TESTING OF LASER PRODS, ETC
2013-968	02/06/2013 03/07/2013	FDA/OC/OES/DFOI/	BRODY MULLINS WALL STREET JOURNAL	FOI REQUESTS SUBMITTED FOR FY2008 TO FY2012

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2013-969	02/06/2013 03/07/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RICHARD HAY RICHARD HAY LAW OFC	METFORMIN - AERS 2000 TO 2013
2013-970	02/06/2013 03/07/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	SONG-SIK CHOI SHINHWA ELECTRON CO LTD	TANDA SKINCARE SYS K080591; TANDA MAX OTC SYS K110735; ME K121598
2013-971	02/06/2013 03/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	EPPERSON, FRANK	DENTAL SYRINGE - SAFETY FEATURES RECS
2013-972	02/06/2013 03/07/2013	OC/ORO/ORM/ OC/ORO/ORM/	GAIL LESSICK LACHMAN CONSULTANT SERVICES INC	DRUG COMPANIES, MEDICAL DVC MFRS, BIORESEARCH MONITORING (BIMO), ETC - DOMESTIC & FOREIGN INSPS 12/1-31/12
2013-973	02/06/2013 03/07/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARY ANDERSON SHIRE PHARMACEUTICALS INC	NOVARTIS PHARMACEUTICALS CORP - NDA 21-882/S015 SBA
2013-974	02/06/2013 03/07/2013	FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/	CHARLES CELESTE EAS Consulting Group, LLC	NX GENERATION LTD, HAUPPAUGE, NY - 483 7/18,23,25/12
2013-975	02/06/2013 03/07/2013	FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	MARK C STANZIANO CHANFRAU & CHANFRAU	WHITNEY LABS, ORMOND BEACH, FL - EIRS 6/09 TO 6/11
2013-976	02/07/2013 03/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K121846
2013-977	02/07/2013 03/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Alan Rezach MEDTRONIC	K851935 - SUMMARY
2013-978	02/07/2013 03/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Alan Rezach MEDTRONIC	K914269 - SUMMARY
2013-979	02/07/2013 03/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Alan Rezach MEDTRONIC	K915672 - SUMMARY
2013-980	02/07/2013 03/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Alan Rezach MEDTRONIC	K801080 - SUMMARY
2013-981	02/07/2013 03/08/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sharon Barclay Kime Genentech, Inc.	NDA 021436 S027 SBA

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2013-982	02/07/2013 03/08/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Doe J	INDIVIDUAL RECS
2013-983	02/07/2013 03/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Orsan Medical Technologies Osraen Medical Technologies	K981846, K962928, K103206
2013-984	02/07/2013 03/08/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tina M. Babos IPD Analytics, LLC	FERRIC CITRATE - APPROVED LABELING, SUMMARY REVIEW
2013-985	02/07/2013 03/08/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sanja Ilic sanja ilic	MEDWATCH TPA2009A02453
2013-986	02/07/2013 03/08/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OC/OES/DFOI/	Doe J	RHOGAM - RECALL RECS
2013-987	02/07/2013 03/08/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORAPA-FO/SEA- DO/SEA-CB/	Lytton Smith KARR TUTTLE CAMPBELL LAW OFFICES	TATTOO INK - SKIN INFECTIONS IN WASHINGTON STATE
2013-988	02/07/2013 03/22/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Gyasi Bourne LightIntegra Technology Inc.	BK080014, BK070004, BK050034
2013-989	02/07/2013 03/08/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sharon Barclay Kime Genentech, Inc.	NDA 021444 S08 SBA
2013-990	02/07/2013 03/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K122027
2013-991	02/07/2013 03/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K111374
2013-992	02/07/2013 03/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K113059
2013-993	02/07/2013 03/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K122690
2013-994	02/07/2013 03/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Gabe Johnson Keyence Corporation	LASERS - PRODUCT REPORTS

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2013-995	02/07/2013 03/08/2013	FDA/OFVM/CFSAN/OCD/EOS/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	ROQUETTE FRERES SA, LESTREM, FRANCE - 483 2012
2013-996	02/07/2013 03/08/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nostrum Laboratories, Inc. NOSTRUM LABORATORIES INC	CARAFATE SUSPENSION - CMC, CLINICAL STUDIES
2013-997	02/07/2013 03/21/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Gyasi Bourne LightIntegra Technology Inc.	BK110066
2013-998	02/07/2013 03/08/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-9039 REQUEST LETTER
2013-999	02/07/2013 03/08/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8808
2013-1000	02/07/2013 03/08/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8783 - REQUEST LETTER
2013-1001	02/07/2013 03/08/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8747 REQUEST LETTER
2013-1002	02/07/2013 03/08/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8816 REQUEST LETTER
2013-1003	02/07/2013 03/08/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8772 - REQUEST LETTER
2013-1004	02/07/2013 03/08/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8705 REQUEST LETTER
2013-1005	02/07/2013 03/08/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8541 REQUEST LETTER
2013-1006	02/07/2013 03/08/2013	FDA/OFVM/CFSAN/OCD/EOS/ OC/OCOS/OES/ OC/OCOS/OES/ OC/OCOS/OL/ OC/OA/OM/OMP/DDM/ FDA/OC/OL/	Megan Pickel Beveridge & Diamond, PC	BIOTECH, BIENGINEERED, GENETICALLY MODIFIED FOOD LABELING - MEMOS, MINUTES, NOTES ETC LAST TWO YEARS
2013-1007	02/07/2013 03/08/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John M. Nardo MD John M. Nardo MD	NDA 019839

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-1008	02/07/2013 03/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Susan Plank Allergan, Inc.	CONJUNCTIN - NDA RECS
2013-1009	02/07/2013 03/08/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	SUE CARLSON CARGILL ANIMAL NUTRITION	CARGILL ANIMAL NUTRITION, NEW RICHLAND, MN - EIR, 10/24/12
2013-1010	02/07/2013 03/08/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	SUE CARLSON CARGILL ANIMAL NUTRITION	CARGILL ANIMAL NUTRITION, HEREFORD, TX - EIR 7/17/12
2013-1011	02/07/2013 03/08/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	SUE CARLSON CARGILL ANIMAL NUTRITION	CARGILL ANIMAL NUTRITION, CASA GRANDE, AZ - EIR 8/1/12
2013-1012	02/07/2013 03/08/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	SUE CARLSON CARGILL ANIMAL NUTRITION	CARGILL ANIMAL NUTRITION, STOCKTON, CA - EIR 8/6/12
2013-1013	02/07/2013 03/08/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	SUE CARLSON CARGILL ANIMAL NUTRITION	CARGILL ANIMAL NUTRITION, LITTLE CHUTE, WI - EIR 9/11/12
2013-1014	02/07/2013 03/08/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	SUE CARLSON CARGILL ANIMAL NUTRITION	CARGILL ANIMAL NUTRITION, LECOMPTE, LA - EIR 9/12/12
2013-1015	02/07/2013 03/08/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	SUE CARLSON CARGILL ANIMAL NUTRITION	CARGILL ANIMAL NUTRITION, SIOUX CITY, IA - EIR 9/26/12
2013-1016	02/07/2013 03/08/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	SUE CARLSON CARGILL ANIMAL NUTRITION	CARGILL INC, BATAVIA, NY - EIR 7/10/12
2013-1017	02/07/2013 03/08/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	SUE CARLSON CARGILL ANIMAL NUTRITION	CARGILL ANIMAL NUTRITION, GIDDINGS, TX - EIR 6/6/12
2013-1018	02/07/2013 03/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	REO TANOSHIMA, MD HOSPITAL FOR SICK CHILDREN	COPAXONE (GLATIRAMER ACETATE) - ISRS 6833424, 7246939, 7530249
2013-1019	02/07/2013 03/08/2013	OC/ORA/OCI/ OC/ORA/OCI/ OC/OM/OFM/	CHRIS CANTERGIANI SCRIPPS HOWARD NEWS SERVICE	STOLEN AGENCY ITEMS 2007 TO 2012
2013-1020	02/07/2013	FDA/OGROP/ORA/CE-FO/CHI-	GREGORY A. BEDELL	EVANGERS DOG & CAT FOOD CO - WARNING LTR

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	04/15/2013	DO/CHI-CB/ FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	KNABE KRONING ET AL	QUESTIONS
2013-1021	02/07/2013 03/08/2013	FDA/OFVM/CFSAN/OCD/EOS/	ELOIT HARRISON LEWIS & HARRISON	FCN 567
2013-1022	02/07/2013 03/08/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	TIFFANY K. HANNUS LOMMEN ABDO COLE KING STAGEBERG PA	INDIVIDUAL RECS
2013-1023	02/07/2013 03/08/2013	FDA/OC/OES/DFOI/	Doe J	NATURALYTE, GRANUFLO - AERS
2013-1024	02/07/2013 03/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ALEX VEIZIS FDALIVE.COM	IMPACT OF APRVD DRUG ON CHRONIC OPIOID THERAPY - PUBLIC HEARING
2013-1025	02/08/2013 03/27/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Laurie Ricketts Dempsey & KingSLand	INDIVIDUAL RECS
2013-1026	02/08/2013 03/11/2013	OC/ORACE/ OC/ORACE/ FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	ASHA LAMBATOS AVALON RISK MANAGEMENT INC	ENTRY #274-02109477 - NOTICE OF FDA ACTION #1
2013-1027	02/08/2013 03/11/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	VAL SAWYER MEDICINES CO	BOVINE THROMBIN/THROMBIN NOS/THROMBIN LOCAL SOL - ISRS 8532937, 8524621, 8504612
2013-1028	02/08/2013 03/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/ORACE/OCI/ OC/ORACE/OCI/	PETER J TOMAO ESQ PETER J TOMAO ESQ	ALTUZAN, AVASTIN - TESTING TO DETERMINE IF THEY ARE COUNTERFEIT BEVACIZUMAB
2013-1029	02/08/2013 03/11/2013	FDA/OGROP/ORACE-FO/FLA-DO/FLA-CB/	JAMES K GIBSON JR PHD INTEGRITY LIFE SCIENCES	EXCITE MEDICALCORP, TAMPA,FL - EIR, 482, 483
2013-1030	02/08/2013 08/12/2013	FDA/OFVM/CFSAN/OCD/EOS/	ALISA BOUCHER BASF CORP	COGNIS, HENKEL CORP - VEGETABLE OIL ACIDS RECS
2013-1031	02/08/2013 03/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARY ANDERSON SHIRE INC	WARNER CHILCOTT - DELZICOL NDA 204-412

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2013-1032	02/08/2013 03/11/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 1/21-25/13
2013-1033	02/08/2013 03/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	MURALI GAVINI - 483S 2012 TO PRESENT
2013-1034	02/08/2013 03/11/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 1/21-25/13
2013-1035	02/08/2013 03/11/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SHCRAMP CanReg, Inc.	CLOSED FOI REQUESTS 1/21-25/13
2013-1036	02/08/2013 03/11/2013	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	CLOSED FOI REQUESTS 1/21-25/13
2013-1037	02/08/2013 03/11/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 1/21-25/13
2013-1038	02/08/2013 03/11/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 1/21-25/13
2013-1039	02/08/2013 03/11/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 1/21-25/13
2013-1040	02/08/2013 03/11/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 1/21-25/13
2013-1041	02/08/2013 03/11/2013	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 1/21-25/13
2013-1042	02/08/2013 03/11/2013	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 1/21-25/13
2013-1043	02/08/2013 03/11/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 1/21-25/13
2013-1044	02/08/2013 03/11/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 1/21-25/13

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2013-1045	02/11/2013 03/12/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Rachel Johnson FOI Services, Inc.	FISHER WALLACE, NEW YORK, NY - EIR MOST RECENT
2013-1046	02/11/2013 03/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Pauliana Hall PCH integrated Regulatory Services, Inc.	NDA 17821 S0000 - APPROVAL PACKAGE OR SBA
2013-1047	02/11/2013 03/12/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Brent Ardaugh Framingham Heart Study	K880660, K863138
2013-1048	02/11/2013 03/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Andrew Berks Nostrum Laboratories, Inc.	ANDA 201374 - FINAL APPROVAL LETTER
2013-1049	02/11/2013 03/12/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Ann Williams WILLIAMS, ANN B	AP PHARMA, INC, REDWOOD CITY, CA - 483, EIR, WARNING LETTER ETC
2013-1050	02/11/2013 03/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	Beverly Laird 3D Medical Concepts, LLC	K925635
2013-1051	02/11/2013 03/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Vinayagam Kannan JHP Pharmaceuticals, LLC	ANDA 011145 - SBA
2013-1052	02/11/2013 03/12/2013	FDA/OC/OES/DFOI/	Michael P. Krensavage Krensavage Asset Management LLC	CRYOLIFE, KENNESAW, GA - 483, WARNING LETTER
2013-1053	02/11/2013 03/12/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dale B. Adams Majestic Publishers	LINDANE - APPROVAL RECS
2013-1054	02/11/2013 03/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jeff O'Donnell Jr O'Donnell Partners	K101734
2013-1055	02/11/2013 03/12/2013	FDA/OC/OES/DFOI/	David Elder PAREXEL	FOIA REQUEST LOG (01/13/2013 - 02/07/2013)

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2013-1056	02/11/2013 03/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sherwin Sattarzadeh Genzyme, A Sanofi Company	NDA 21348
2013-1057	02/11/2013 03/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angela Vagotis Vagotis, Angela T	PAXIL - AERS
2013-1058	02/11/2013 03/12/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORR/SW-FO/DAL- DO/DAL-CB/	Robert Blaskiewicz Robert Blaskiewicz	BURZYNSKI CLINIC, HOUSTON, TX - 483 (01/01/1985 - 12/31/2012)
2013-1059	02/11/2013 03/12/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Brent Ardaugh Framingham Heart Study	K870622, K102496, K052161 ETC
2013-1060	02/11/2013 03/12/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Brent Ardaugh Framingham Heart Study	K914972, K780568, K792441 ETC
2013-1061	02/11/2013 03/12/2013	FDA/OGROP/ORR/CE-FO/DET- DO/DET-CB/ FDA/OC/OES/DFOI/	Brian Harrison Brian Harrison	JHP PHARMACEUTICALS, ROCHESTER, MI - 483 (3/13/12-3/29/12)
2013-1062	02/11/2013 03/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Karen Schultz The Dominion Group	NDA 204412 - SBA
2013-1063	02/11/2013 03/12/2013	OC/CVM/OCD/	Dr. Diane Sudduth Biovance	NADA 014366
2013-1064	02/11/2013 03/12/2013	OC/OSMP/OOPD/ FDA/OMPT/OSMP/OOPD/	Lauren Farruggia Hyman, Phelps & McNamara P.C.	VELCADE - ORPHAN DRUG DESIGNATION FILE
2013-1065	02/11/2013 03/12/2013	OC/OA/OM/OMP/DDM/	Pauliana Hall PCH integrated Regulatory Services, Inc.	NONPRESCRIPTION DRUGS AND ARTHRITIS ADVISORY COMMITTEES BRIEFING DOCS 07/20/1999
2013-1066	02/11/2013 03/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K110617
2013-1067	02/11/2013 03/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	Ashley Driscoll Diazyme Laboratories	K050574
2013-1068	02/11/2013	FDA/OMPT/CDER/ORP/DIDP/	Gary Wolff	ISR 6884596, 6912897, 7010082 ETC

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	03/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHIRE PHARMACEUTICALS INC	
2013-1069	02/11/2013 03/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K122662
2013-1070	02/11/2013 03/12/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/	Rachel Johnson FOI Services, Inc.	RICHARD WASSERMAN, DALLAS, TX - EIR (08/13-17/2012)
2013-1071	02/11/2013 03/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K103095
2013-1072	02/11/2013 03/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tonya Bechtel Tarsa Therapeutics, Inc.	SANDOZ KUNDL, SCHAFTENAU - 483, WARNING LETTER (01/03/2011 - 09/28/2012)
2013-1073	02/11/2013 03/12/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Karen Weigand BEAUMONT HOSPITAL	BOVINE THROMBIN JMI PRODUCT 4B - AERS
2013-1074	02/11/2013 03/12/2013	OC/OSMP/OOPD/ FDA/OMPT/OSMP/OOPD/	Todd Phillips BECKLOFF ASSOCIATES INC	ADALIMUMAB - ORPHAN DESIGNATION REVIEW
2013-1075	02/11/2013 03/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	510(k) Summary for K834400
2013-1076	02/11/2013 03/12/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Brent Ardaugh Framingham Heart Study	K955349, K905496, K770835 ETC
2013-1077	02/11/2013 03/12/2013	FDA/OGROP/ORACE-FO/BLT- DO/BLT-CB/	Jarusha A. Bonitz Pharmaceutics International, Inc.	PHARMACEUTICS INTERNATIONAL INC, COCKEYSVILLE, MD, HUNT VALLEY, MD - EIR 05/19-28/10, 05/22/12-06/01/12, 10/01-22/12
2013-1078	02/11/2013 03/12/2013	FDA/OGROP/ORAPA-FO/SAN- DO/SAN-CB/	SHERRY RAE OREGON CHERRY GROWERS INC	DIANA FRUIT CO - WARNING LTR 7/27/11, CLOSING LTR 11/11/12
2013-1079	02/11/2013 03/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MICHAEL R. COHEN INSTITUTE FOR SAFE MEDICATION PRACTICES	MEDWATCH RPTS CODED AS MEDICATION ERRORS 1/1-31/13
2013-1080	02/11/2013 03/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	THOMAS, DAVID .	VALPROIC ACID; DILANTIN - AER

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2013-1081	02/11/2013 03/12/2013	FDA/OC/OES/DFOI/	BURGESS, BERNIE	2007-3879
2013-1082	02/11/2013 03/12/2013	OC/OM/OMP/DDM/	LINDA COLLER LINDA COLLER	DKT 1988P-0179
2013-1083	02/11/2013 03/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MURIS DEMIROVIC MANNING & NAPIER ADVISORS INC	NOVO NORDISK, NONO ALLE, BAGSVAERD DENMARK - 483 3/12-20/12
2013-1084	02/11/2013 03/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	JAMES L. FORD, Sr. JAMES LEE FORD	MCGHAN STYLE 468 SALINE FILLED BREAST IMPLANT - PMA APRVL
2013-1085	02/11/2013 03/12/2013	FDA/OMPT/CTP/OD/ FDA/OC/OPP/OP/	RICHARD G. DANNER JR ATTY	FDA SETS THE VALUE OF LIFE IN PROPOSING WARNING LABELS ON CIGARETTES - FINDINGS (CERTIFIED)
2013-1086	02/11/2013 03/12/2013	OC/ORR/ORM/ OC/ORR/ORM/	JOHNATHAN RICKMAN FDA NEWS	PHARMACEUTICALS, BIOLOGICS & MEDICAL DVC MFG, CLNC FACILITIES IN & OUTSIDE THE US - 483 1/1-31/13
2013-1087	02/11/2013 03/12/2013	OC/OCOS/OL/	JACK GILLUM ASSOCIATED PRESS	CORR TO SEN ROBERT MENENDEZ 1/07 TO PRESENT
2013-1088	02/11/2013 03/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN BLOCH JOHNS HOPKINS SCHOOL OF MEDICINE	ROXANE LABORATORIES - DIAZEPAM INTERSOL ANDA
2013-1089	02/11/2013 03/12/2013	FDA/OFVM/CFSSAN/OCD/EOS/	NNEKA LEIBA ENVIRONMENTAL WORKING GROUP	PRIORITY-BASED ASSESSMENT OF FOOD ADDITIVES DATABASE
2013-1090	02/11/2013 03/12/2013	OC/CVM/OCD/	HUGHES, LAURA	D-LIMONENE - AERS LAST 10-15 YRS
2013-1091	02/12/2013 03/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Donna Seifarth Swiftwater Group, LLC	SUVEN LIFE SCIENCES, INDIA - QAP, 483, WARNING LETTERS ETC (01/01/2008 - 02/11/2013)
2013-1092	02/12/2013 03/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	joseph costa white mountain toxicology services llc	JUXTAPID NDA REVIEW

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2013-1093	02/12/2013 03/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Brent Ardaugh Framingham Heart Study	K033337, K974098, K980483
2013-1094	02/12/2013 03/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K023960
2013-1095	02/12/2013 03/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anil Goyal, PhD Qualiber, Inc.	GEMZAR IND
2013-1096	02/12/2013 03/13/2013	OC/OER/OPA/	XIN GE INDIVIDUAL	DR SHIMIN FANG - FDA APPROVAL FOR SPEECH
2013-1097	02/12/2013 03/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	CIVCO Medical Solutions CIVCO Medical Solutions	K120882
2013-1098	02/12/2013 03/13/2013	OC/CVM/OCD/	Becky Armfield Novartis Animal Health US, Inc.	ANALYTICAL METHOD FOR DETERMINATION OF RACTOPAMINE HYDROCHLORIDE IN FEED SAMPLES
2013-1099	02/12/2013 03/13/2013	FDA/OC/OES/DFOI/	Johnathan Rickman FDANEWS	FOIA REQUEST LOG (02/04/2013 - 02/08/2013)
2013-1100	02/12/2013 03/13/2013	FDA/OC/OES/DFOI/	SHARI SMITH Smith, Shari D	NEW ENGLAND COMPOUNDING CENTER - INVESTIGATIONS, REPORTS, LETTERS ETC (2002-PRESENT)
2013-1101	02/12/2013 03/13/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	Doe J	INDIVIDUAL RECS
2013-1102	02/12/2013 03/13/2013	FDA/OC/OES/DFOI/	STEVEN F NAPOLITANO SKADDEN, ARPS, SLATE, MEAGHER & FLOM, LLP	2000-23647, 2000-23649, 2000-23650, ETC
2013-1103	02/12/2013 03/13/2013	FDA/OC/OES/DFOI/	BRENTON L HORNER HORNER & ASSOCIATES	UNREDACTED RECS
2013-1104	02/12/2013 03/13/2013	FDA/OFVM/CFSAN/OCD/EOS/	MERLE ZIMMERMANN AMERICAN HERBAL PRODUCTS ASSOCIATION	DIETARY SUPPLEMENTS - CAERS 138702, 138704, 138707, ETC 1/12 TO 8/12
2013-1105	02/12/2013 03/13/2013	FDA/OGROP/ORO/CE-FO/BLT-DO/BLT-CB/	JOHN CREWSDON PROJECT ON GOVERNMENT	BOEHRINGER INGELHEIM ROXANE INC, DANBURY, CT 11/10/08; BOEHRINGER INGELHEIM ROXANE INC,

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		FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	OVERSIGHT	COULMBUS,OH 5/6/09; BOEHRINGER INGELHEIM CHEMICALS INC, PETERSBURG, VA 5/13/09, ETC - EIRS
2013-1106	02/12/2013 03/13/2013	OC/ORAI/ OC/ORAI/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	BENJAMIN L ENGLAND ESQ BENJAMIN L ENGLAND & ASSOCIATES LLC	SGMP COMPANY LTD - ENTRY #EJK-0030361-1 TEST RESULTS
2013-1107	02/12/2013 03/13/2013	FDA/OC/OES/DFOI/	WILLIAM SARRAILLE SIDLEY AUSTIN LLP	ST JUDE MEDICAL - WARNING LTR RESP FOI REQUESTS 1/10/13 TO PRESENT
2013-1108	02/12/2013 03/13/2013	OC/CVM/OCD/	RYAN T KEARNEY COZEN O'CONNOR	DEL MONTE FOODS - MILO'S KITCHEN CHICKEN JERKY, CHICKEN GRILLERS INVESTIGATION , TESTING, RECALL RECS
2013-1109	02/12/2013 03/13/2013	OC/CVM/OCD/	RYAN T KEARNEY COZEN O'CONNOR PC	NESTLE PURINA PETCARE CO (WAGGIN TRAIN LLC) - CHICKEN JERKY PET TREATS RESIDUAL ANTIBIOTICS INVESTIGATION, TESTING, RECALL RECS
2013-1110	02/12/2013 03/13/2013	OC/CVM/OCD/	RYAN T KEARNEY COZEN O'CONNOR	HARTZ MOUNTAIN CORP - CHICKEN CHEWS, OINKIE PIG SKIN TWISTS RESIDUAL ANTIBIOTICS INVESTIGATIONS, TESTING, RECALL RECS 2012
2013-1111	02/12/2013 03/13/2013	FDA/OC/OES/DFOI/	BOWEN #887936, ALTON	MEDWATCH FORM
2013-1112	02/13/2013 03/14/2013	OC/ORAI/ OC/ORAI/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Doe J	INDIVIDUAL RECS
2013-1113	02/13/2013 03/14/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/ OC/OCOS/OL/ FDA/OC/OES/DFOI/ OC/ORAI/ OC/ORAI/ FDA/OC/OL/	Michael Kaplan CBS NEWS/60 MINUTES	NEW ENGLAND COMPOUNDING CENTER - EMAILS, MEMOS, REPORTS

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2013-1114	02/13/2013 03/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K962696
2013-1115	02/13/2013 03/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	Diane Horwitz MANDELL HORWITZ CONSULTANTS LLC	K012990
2013-1116	02/13/2013 03/14/2013	OC/OA/OM/OMP/DDM/	Sara Warren Turner Environmental Law Clinic	STANDARDS FOR THE GROWING, HARVESTING, PACKING, AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION - REFERENCE 266 (01/03/2012 - 02/12/2013)
2013-1117	02/13/2013 03/14/2013	FDA/OO/OHR/	Viviana Bolton Viviana Bolton	HHS-FDA-14-533201
2013-1118	02/13/2013 03/14/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/ FDA/OC/OES/DFOI/	Thomas Sanders COLLEGE OF WILLIAM AND MARY	BRAVO FARMS CHEESE, LLC - INSPECTION RECS 2010
2013-1119	02/13/2013 03/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K033080
2013-1120	02/13/2013 03/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	Diane Horwitz MANDELL HORWITZ CONSULTANTS LLC	K060888
2013-1121	02/13/2013 03/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	Diane Horwitz MANDELL HORWITZ CONSULTANTS LLC	K103648
2013-1122	02/13/2013 03/14/2013	FDA/OFVM/CFSAN/OCD/EOS/	Alec White HEALTHCOR MANAGEMENT LP	MONSTER BEVERAGE, LIVING ESSENTIALS, RED BULL - CAERS (01/01/2000 - 02/12/2013)
2013-1123	02/13/2013 03/14/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tomas Kiselak RA CAPITAL MANAGEMENT	DRUG PRODUCTS BY ACTIVE INGREDIENT, INDICATIONS FOR NDA 00623, 01285, 01885 ETC, LABELING, ETC
2013-1124	02/13/2013 03/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	Bonnie Williams FOI Services, Inc.	K093661
2013-1125	02/13/2013 03/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	Bonnie Williams FOI Services, Inc.	K123444
2013-1126	02/13/2013 03/14/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	SBA 203263

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-1127	02/13/2013 03/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	Diane Horwitz MANDELL HORWITZ CONSULTANTS LLC	K970266
2013-1128	02/13/2013 03/14/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Marc C. Sanchez Contract In-House Counsel and Consultant	K102598, K011880, K091933
2013-1129	02/13/2013 03/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Deb Hogerman UCB, Inc.	NDA 21829 - MEDICAL, STATISTICAL, CMC REVIEWS (UNREDACTED)
2013-1130	02/13/2013 03/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	BAUEREIND GMBH - VENOTRAIN COLOR COMPRESSION STOCKINGS & PANTYHOSE K860826
2013-1131	02/13/2013 05/03/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	FOI Services, Inc.	CARIDIAN BCT INC - TRIMA ACCEL AUTOMATED BLOOD COMPONENT COLLECTION SYS BK080029
2013-1132	02/13/2013 03/14/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FOI Services, Inc.	NDA 21077/S3
2013-1133	02/13/2013 03/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	EXCEL TECH LTD - XLTEK EVOKED POTENTIAL HEADBOX MODEL EP16 SPS 1 STATIC PRESERVATION SOLUTION K992313
2013-1134	02/13/2013 03/14/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	FOI Services, Inc.	RYMED TECHNOLOGIES INC - IN VISION PLUS NANO W/NEUTRAL ADVANTAGE TECHNOLOGY K093489
2013-1135	02/13/2013 03/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	THOMAS, JEFFREY G	DURALSEAL SPINAL SEALANT - POST APRVL
2013-1136	02/13/2013 03/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	MATERIALISE	D4D TECHNOLOGIES - E4D COMPASS K110511
2013-1137	02/13/2013 03/14/2013	FDA/OGROP/ORAP/PA-FO/LOS- DO/LOS-CB/	DAN HANSEN CONSTELLATION BRANDS	TURNER ROAD VINTNERS, LODI, CA - 482 11/28/12
2013-1138	02/13/2013 03/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GEORGE R. SYZMANSKI LAW OFFICES OF GEORGE R SZYMANSKI	TYLENOL ARTHRITIS PAIN - CMLPNTS

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-1139	02/13/2013 03/14/2013	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/ FDA/OMPT/CDRH/OCER/DFOI/	RICHARD N SHAPIRO LAW OFCS	HOWMEDICA OSTEONICS CORP, MAHWAH, NJ - K092406 2009, 2010, 2011, 2012
2013-1140	02/13/2013 03/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JODY L. GREEN, Ph.D. ROCKY MOUNTAIN POISON DRUG CTR	8481354, 8491845, 8492420, ETC - AERS
2013-1141	02/13/2013 03/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	R MARK BORTNER SOCKOL & ASSOCIATES PA	PROFESSIONAL THERAPY PRODUCTS - DOCS
2013-1142	02/13/2013 03/14/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	P RICHARD WARBURTON CHEMDAQ INC	ADVANCED STERILIZATION PRODUCTS - STERRAD NX STERILIZER K042116
2013-1143	02/13/2013 03/14/2013	FDA/OFVM/CFSAN/OCD/EOS/	EASLEY 103481, KENT A	SOY - AER
2013-1144	02/13/2013 03/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN CREWDSON PROJECT ON GOVERNMENT OVERSIGHT	OSE RPTS OF INVESTIGATIONS OF RE-LY TRIAL
2013-1145	02/13/2013 03/14/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	Doe J	INDIVIDUAL RECS
2013-1146	02/13/2013 03/14/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	MARSH, JAMES	CMPLNT 128274
2013-1147	02/14/2013 03/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jeff O'Donnell Jr O'Donnell Partners	K072879, K040604
2013-1148	02/14/2013 03/15/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Bonnie Williams FOI Services, Inc.	K990144
2013-1149	02/14/2013 03/15/2013	FDA/OO/OFBA/OAGS/	William Hbranchak Neal R. Gross and Company	HHSF223201010156G
2013-1150	02/14/2013	FDA/OGROP/ORA/SE-FO/ATL-	Sarah Schober	DIETARY SUPPLEMENT COMPANIES IN NORTH CAROLINA -

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	03/15/2013	DO/ATL-CB/	BioNetwork	483 (02/13/2012 - 02/12/2013)
2013-1151	02/14/2013 03/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Norie Young WINTHROP UNIVERSITY HOSPITAL	AVANDIA - COMPLAINTS 2007
2013-1152	02/14/2013 03/15/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Suzanne Meintzer WILSON ELSER MOSKOWITZ EDELMAN & DICKER LLP	SAN FRANCISCO HERB & NATURAL FOOD CO - ALL RECS (01/01/2011 - 12/31/2013)
2013-1153	02/14/2013 03/15/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	Lydia Mulvany MILWAUKEE JOURNAL SENTINEL	ECHO LAKE FOODS, BURLINGTON, WI - INSPECTION RECS 11/13/09
2013-1154	02/14/2013 03/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	DUPHASTON - AERS
2013-1155	02/14/2013 03/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	BLA 125057 S0071
2013-1156	02/14/2013 03/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	David Hermelin Xeragenx LLC	NDA 019722
2013-1157	02/14/2013 03/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	David Hermelin Xeragenx LLC	ANDA 084264
2013-1158	02/14/2013 03/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tim Barder Blend Therapeutics	NDA 21063, NDA 21492
2013-1159	02/14/2013 03/15/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORA/PA-FO/LOS-	Gary Mackinnon Alvogen Group	BAYER HEALTHCARE - EIR (02/02/2009 - 03/08/2012)

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		DO/LOS-CB/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORASW-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORASW-FO/LOS-DO/LOS-CB/		
2013-1160	02/14/2013 03/15/2013	FDA/OGROP/ORASW-FO/SAN-DO/SAN-CB/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OES/DFOI/	BRETT F CLEMENTS HERZFELD RUBIN	CFSAN EMAIL CONCERNING LISTERIA MONOCYTOGENES FOUND IN THRIFTY ICE CREAM (CERTIFIED)
2013-1161	02/14/2013 03/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DOUGLAS F FORMAN DR REDDY'S LABORATORIES INC	DR REDDY'S LABORATORY INC - TIZANIDINE HCI TABS ANDA 76-286 CMLPNT
2013-1162	02/14/2013 03/15/2013	OC/CVM/OCD/	ELISABETTA LAMBERTINI UNIV OF MARYLAND	ANIMAL FEED INGREDIENTS, PET FOODS, PET TREATS - MICROBIOLOGICAL TESTS
2013-1163	02/14/2013 03/15/2013	FDA/OFVM/CFSAN/OCD/EOS/ OC/OER/OPA/ FDA/OC/OES/	BOBBY SCHOCHET OLSSON FRANK & WEEDA	COOPERATIVE AGREEMENTS BTWN FDA AND OUTSIDE PARTIES CONCERNING FOOD SAFETY 2009 TO PRESENT
2013-1164	02/14/2013 03/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GAVIN ANDERSON AZAYA THERAPEUTICS INC	SUN PHARMA GLOBAL FZE - LIPODOX (DOXORUBICIN HCL LIPOSOMAL INJ) ANDA 203-263 RECS
2013-1165	02/14/2013 04/03/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORASW-FO/PHI-DO/PHI-CB/	ROBERT WELCH ANSAR INC	ANSAR INC - MTG MINS, NOTES, TRANS, ETC
2013-1166	02/14/2013 03/22/2013	FDA/OGROP/ORASW-FO/DET-DO/DET-CB/ FDA/OMPT/CDRH/OCER/DFOI/	JOSEPH H SAUNDERS SAUNDERS & WALKER PA	BIOMET INC, WARSAW, IN; BIOMET UK LTD, SOUTH WALES, UK - EIRS, 482S, 483S; MOM HIP ARTHROPLASTY SYS CONGRESSIONAL CORR, ETC
2013-1167	02/14/2013	FDA/OMPT/CDER/GRP/DIDP/		CHANTIX (VERENICLINE) - AERS 6/1/12 TO 2/5/13

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	03/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PRENDERGAST, JOYCE E	
2013-1168	02/14/2013 03/15/2013	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	JAMIE J FINIZIO BASCOMBE FINIZIO LAW CENTER	STEAMER SPORT 888WA WHEELCHAIR - CMLPNTS, RECALL RECS, SAFETY ALERTS, ETC
2013-1169	02/14/2013 03/15/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	DONALD N BLUE ZETETIC	SHAMPOO CONDITIONERS HAIR PREPARATIONS BILL OF LADING # SMLU3261238A - RECS
2013-1170	02/14/2013 03/15/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	DOUGLAS N BLUE ZETETIC	HAIR SHAMPOO & CONDITIONERS BILL OF LADING #SMLU3270088A - RECS
2013-1171	02/14/2013 03/15/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	DOUGLAS N BLUE ZETETIC	SHAMPOO CONDITIONERS HAIR PREPARATIONS BILL OF LADING # SMLU3249949A - RECS
2013-1172	02/14/2013 03/15/2013	FDA/OFVM/CFSAN/OCD/EOS/	BETTY BEHRENS REGAN ZAMBRI LONG & BERTRAM PLLC	INDIVIDUAL RECS
2013-1173	02/14/2013 03/15/2013	FDA/OFVM/CFSAN/OCD/EOS/	BETTY BEHRENS REGAN ZAMBRI LONG & BERTRAM PLLC	INDIVIDUAL RECS
2013-1174	02/14/2013 03/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	BIOMET - HIP PROTHESIS MDRS
2013-1175	02/14/2013 03/15/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Doe J	FLU VACCINE - INDIVIDUAL RECS
2013-1176	02/14/2013 03/15/2013	OC/CVM/OCD/	HUGHES, LAURA	D-LIMONENE - AERS
2013-1177	02/14/2013 03/15/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	BRYAN W BLACK DERREVERE, HAWAKES, BLACK ET AL	AMERICAN CASIEN CO, BURLINGTON, NJ - INSPS 2007 TO 2011
2013-1178	02/14/2013 03/15/2013	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	BRYAN W BLACK DERREVERE, HAWAKES, BLACK ET AL	NATROL INC, CHATSWORTH, CA - INSPS 2007 TO 2011
2013-1179	02/14/2013	FDA/OGROP/ORAP/PA-FO/LOS-	BRYAN W BLACK	COMMERCIAL PROTEINS CORP, LAKE ARROWHEAD, CA -

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	03/15/2013	DO/LOS-CB/	DERREVERE, HAWAKES, BLACK ET AL	INSPS 2007 TO 2011
2013-1180	02/14/2013 03/15/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	BRYAN W BLACK DERREVERE, HAWAKES, BLACK ET AL	FCC PRODUCTS, LIVINGSTON, NJ - INSPS 2007 TO 2011
2013-1181	02/14/2013 03/15/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	BRYAN W BLACK DERREVERE, HAWAKES, BLACK ET AL	NATURE'S PRODUCTS INC, SUNRISE, FL - INSPS 2007 TO 2011
2013-1182	02/14/2013 03/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	NOVO NORDISK A/S, BAGSVAERD, DENMARK - 483 3/12-20/12
2013-1183	02/14/2013 03/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	NOVO NORDISK A/S, BAGSVAERD, DENMARK - EIR 3/12-20/12
2013-1184	02/14/2013 03/15/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Willis, Jerome	SCHWARZ PHARMA - FORMS IN WHICH REGLAN IS MANUFACTURED
2013-1185	02/15/2013 03/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	Suzanne Grenier TERUMO CARDIOVASCULAR SYSTEMS CORP	K992785
2013-1186	02/15/2013 03/18/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jeff Overley Law360	HOSPIRA INC - 483 (07/01/2012 - 02/13/2013)
2013-1187	02/15/2013 03/18/2013	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	Thomas Sanders COLLEGE OF WILLIAM AND MARY	QUESERIA BENDITA, YAKIMA, WA - EIR (01/01/2010 - 12/31/2010)
2013-1188	02/15/2013 03/18/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Carla Johnson ASSOCIATED PRESS	HOSPIRA INC - 483 (01/01/2011 - 02/14/2013)

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/		
2013-1189	02/15/2013 03/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	Suzanne Grenier TERUMO CARDIOVASCULAR SYSTEMS CORP	K922356
2013-1190	02/15/2013 03/18/2013	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	Thomas Sanders COLLEGE OF WILLIAM AND MARY	SETTON INTERNATIONAL FOODS, INC., COMMACK, NY - EIR 2009
2013-1191	02/15/2013 03/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Adam Deisinger Rocah Brown	REQUIP - DEAR HEALTHCARE PROFESSIONAL LETTERS
2013-1192	02/15/2013 04/12/2013	FDA/OGROP/ORA/SW-FO/DEN- DO/DEN-CB/	Kathleen Rowe Rowe, Kathleen	BONFILS BLOOD CENTER, DENVER, CO - 483 (02/01/2010 - 02/14/2013)
2013-1193	02/15/2013 03/18/2013	FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	Thomas Sanders COLLEGE OF WILLIAM AND MARY	BASIC FOOD FLAVORS, LAS VEGAS, NV - EIR 2010
2013-1194	02/15/2013 03/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	Imran Karim Imran Karim	K120737
2013-1195	02/15/2013 03/18/2013	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	Thomas Sanders COLLEGE OF WILLIAM AND MARY	AZTECA, BROOKLYN, NY - EIR 2010
2013-1196	02/15/2013 03/18/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	Kenneth Cusack CERTIFIED LABORATORIES INC	52309790336 - LAB RESULTS
2013-1197	02/15/2013 03/18/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	Thomas Sanders COLLEGE OF WILLIAM AND MARY	SETTON PISTACHIO, TERRA BELLA, CA - EIR 2009
2013-1198	02/15/2013	FDA/OFVM/CFSAN/OCD/EOS/	Natasha Singer	DIETARY SUPPLEMENTS CONTAINING DMAA - ADVERSE EVENTS (01/01/2009 - 02/14/2013)

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	03/18/2013		THE NEW YORK TIMES	
2013-1199	02/15/2013 03/18/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Thomas Sanders COLLEGE OF WILLIAM AND MARY	QUESERIA CHIPILO, PASSAIC, NJ - EIR 2010
2013-1200	02/15/2013 03/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	Imran karim Imran Karim	K103472
2013-1201	02/15/2013 03/18/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Susan Zakarian PRA INTERNATIONAL	ANDREW L CHAN, SACRAMENTO, CA - 483 (04/09/2012 - 05/31/2012) ;
2013-1202	02/15/2013 03/18/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Sarah Schober BioNetwork	GAIA HERBS, BREVARD, NC - 483 2/16/11
2013-1203	02/15/2013 03/18/2013	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	TOBACCO SUBSTANTIAL EQUIVALENCE DATA
2013-1204	02/15/2013 03/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	David Hermelin Xeragenx LLC	NDA 016635 - APPROVAL HISTORY, LABELING
2013-1205	02/15/2013 03/18/2013	OC/OA/OM/OMP/DDM/	Sarah Sorscher PUBLIC CITIZEN	INTRA-AORTIC BALLOON PUMP DEVICES; EXTRACORPOREAL MEMBRANE OXYGENATION DEVICES; EXTERNAL CARDIAC COMPRESSOR DEVICES - COMMENTS; FDA-2009-M-0101-0093 (UNREDACTED)
2013-1206	02/15/2013 03/18/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Thomas Sanders COLLEGE OF WILLIAM AND MARY	SETTON INTERNATIONAL FOODS, INC, TERRA BELLA, CA - EIR (01/01/2010 - 12/31/2010)
2013-1207	02/15/2013 03/18/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Thomas Sanders COLLEGE OF WILLIAM AND MARY	PEANUT CORPORATION, LYNCHBURG, VA - EIR (01/01/2009 - 12/31/2009)
2013-1208	02/15/2013 03/18/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Thomas Sanders COLLEGE OF WILLIAM AND MARY	PEREGRINA CHEESE CORPORATION, BROOKLYN, NY - EIR (01/01/2009 - 12/31/2009)
2013-1209	02/15/2013 03/18/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Thomas Sanders COLLEGE OF WILLIAM AND MARY	WRIGHT COUNTY EGG AKA QUALITY EGG, GALT, IA - EIR (01/01/2010 - 12/31/2010)
2013-1210	02/15/2013	OC/CVM/OCD/	Dane Martin	MILO'S KITCHEN - CORR BETWEEN FDA AND NY STATE

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	03/18/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ OC/ORA/ OC/ORA/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Shank & Hamilton, P.C.	DEPT OF AGRICULTURE; INTERNAL CORR; CORR TO OR FROM MILO'S KITCHEN, DEL MONTE CORP, ETC
2013-1211	02/15/2013 03/18/2013	OC/CVM/OCD/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ OC/ORA/ OC/ORA/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Dane Martin Shank & Hamilton, P.C.	WAGGIN TRAIN, CANYON CREEK - COMM BETWEEN FDA AND NY STATE DEPT OF AGRICULTURE; INTERNAL CORR; CORR WITH WAGGIN TRAIN, NESTLE PURINA PETCARE COMPANY ETC
2013-1212	02/15/2013 03/18/2013	FDA/OFVM/CFSAN/OCD/EOS/	wendy crossland CROSSLAND, WENDY	NOS ENERGY DRINKS - AERS (02/23/2007 - 02/15/2013)
2013-1213	02/15/2013 03/18/2013	FDA/OFVM/CFSAN/OCD/EOS/	wendy crossland CROSSLAND, WENDY	NO FEAR ENERGY DRINKS - AERS (02/16/2007 - 02/15/2013)
2013-1214	02/15/2013 03/18/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Doe J	CMPLNT 130363
2013-1215	02/15/2013 03/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHNATHAN REEVES MAKO SURGICAL CORP	STANMORE IMPLANTS WORLDWIDE LTD - SCULPTOR ROBOTIC GUIDANCE ARM K121765
2013-1216	02/15/2013 03/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LAURA KILGORE WATSON LABORATORIES INC	GONAL F RFF PEN NDA 21-684/S-019, 21-684/S023, 21-684/S-024 APRVL LTRS
2013-1217	02/15/2013 03/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	MICHAEL TREAS HOLLWOG LLC	ETHICON INC - TEMPORARY CARDIAC PACING WIRE K822155
2013-1218	02/15/2013 03/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BROTHER 1273700, HENRI	VALTERAN (DICLOFENAC), ALTRAM (TRAMADOL) - AERS

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2013-1219	02/15/2013 03/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PAMELA SCHANEEN SHIONOGI INC	SALIX PHARMACEUTICALS - RELISTOR (METHYLNALTREXONE BROMIDE) NDA 21-964 CORR 12/6/12
2013-1220	02/15/2013 03/18/2013	FDA/OC/OES/DFOI/	HEATHER GALE OFW LAW	UNTITLED LTRS 12/1/11 TO PRESENT
2013-1221	02/15/2013 03/18/2013	FDA/OC/OES/DFOI/	HEATHER GALE OFW LAW	PREVIOUSLY RELEASED UNTITLED LTRS FROM CDRH
2013-1222	02/15/2013 03/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	K BARNES BIOPHARM INSIGHT	NOVO - NORDISK A/S - 483, CO RESP 12/12/12
2013-1223	02/15/2013 03/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	KARL NITTINGER DENTSPLY INTERNATIONAL	DMC COMPOSITE 2 K103351
2013-1224	02/15/2013 03/18/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	SEAN GREENWOOD GAUTHIER HOUGHTALING ET AL	INDIVIDUAL RECS - VAERS
2013-1225	02/15/2013 03/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	MELISSA A. JONES LAW OFFICES OF RICHARD N SHAPIRO	STRYKER IRELAND LTD OSTEONICS - EIR, FORM 3500, FORM 3500A
2013-1226	02/15/2013 03/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHANDRAN TIRUVATTAR DR REDDY'S LABORATORIES INC	PERRIGO ISRAEL - MINOXIDIL ANDA 91-344 SBA
2013-1227	02/15/2013 03/18/2013	FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Doe J	INDIVIDUAL RECS
2013-1228	02/15/2013 03/18/2013	FDA/OGROP/ORO/CE-FO/BLT- DO/BLT-CB/	DONALD N. BLUE ZETETIC	ENTRY NO WFX12307470
2013-1229	02/15/2013 03/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MERLE ZIMMERMANN AMERICAN HERBAL PRODUCTS ASSOCIATION	DIETARY SUPPLEMENT - CAERS 7/1/10 TO 6/30/11

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		FDA/OFVM/CFSAN/OCD/EOS/		
2013-1230	02/15/2013 03/18/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Doe J	INDIVIDUAL RECS - VAERS (CERTIFIED)
2013-1231	02/15/2013 03/18/2013	FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/	ANNE E. SCHMIDT JIM BRADY AND ASSOCIATES PC	OLIVE GARDEN, FOXBORO, MA - FOOD POISONNG 1/8/13
2013-1232	02/15/2013 03/18/2013	OC/OCOS/OL/ FDA/OC/OL/	JENNIFER HABERKORN POLITICO	CORR BTWN HOUSE, SENATE & HHS 11/6/12 TO 2/14/13
2013-1233	02/15/2013 03/18/2013	OC/OCOS/OES/ OC/OCOS/OES/	JOSEPH DEDVUKAJ JOSEPH DEDVUKAJ FIRM PC	BELVIQ (LORCASERIN HCI) - DRUG CLASSIFICATION EVALUATION & SCHEDULING PROCESS RECS, CORR, ETC
2013-1234	02/15/2013 03/18/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	GABRIEL BRIER QUINN EMANUEL ET AL	NDA 00-623, 01-285, 01-885
2013-1235	02/19/2013 03/19/2013	FDA/OFVM/CFSAN/OCD/EOS/	wendy crossland CROSSLAND, WENDY	FULL THROTTLE ENERGY DRINK - AERS (02/02/2007 - 02/14/2013)
2013-1236	02/19/2013 03/19/2013	FDA/OFVM/CFSAN/OCD/EOS/	wendy crossland CROSSLAND, WENDY	AMP ENERGY DRINKS - AERS (02/15/2007 - 02/14/2013)
2013-1237	02/19/2013 03/19/2013	FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/	Michael A. Carome, M.D. PUBLIC CITIZEN'S HEALTH RESEARCH GROUP	REVECO INTERNATIONAL, FULLERTON, CA; ADVANCED AESTHETIC CONCEPTS, FORT WORTH, TX; PROFIT SOLUTIONS MD, FORT WORTH, TX - 483 12/31/09 TO PRESENT
2013-1238	02/19/2013 03/19/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Diane Horwitz MANDELL HORWITZ CONSULTANTS LLC	K910944
2013-1239	02/19/2013 03/19/2013	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	FEDERAL EXCISE TAX PAYED BY INDUSTRY FOR REMOVAL OF CIGARETTE PAPER AND TUBES
2013-1240	02/19/2013 03/19/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Emily Settlemoir Reliable Biopharmaceutical Corporation	PHARMACOSMOS ROERVANGSVEJ, HOLBAEK, DENMARK - MOST RECENT EIR
2013-1241	02/19/2013 03/19/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Chris Cano Agile Therapeutics	OBSTETRICS AND GYNECOLOGY ADVISORY COMMITTEE MEETINGS - MEETING MINUTES, AGENDAS 1975

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		FDA/OMPT/CDER/GRP/DIDP/ OC/OA/OM/OMP/DDM/		
2013-1242	02/19/2013 03/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jennifer Wong St. Jude Medical	BOSTON SCIENTIFIC PRECISION SPECTRA SYSTEM - SUBMISSION, LABELING (P030017 S134)
2013-1243	02/19/2013 03/19/2013	FDA/OFVM/CFSAN/OCD/EOS/ OC/OCOS/OES/ OC/OCOS/OES/ FDA/OC/OCC/	Gregory Jaffe Center for Science in the Public Interest	GENETICALLY ENGINEERED ORGANISMS - MEETINGS BETWEEN FDA AND INDUSTRY ON OR AROUND 01/11/13
2013-1244	02/19/2013 03/19/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rebecca Shames HOGAN LOVELLS US LLP	K122389, K111454, K102541
2013-1245	02/19/2013 03/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K894369
2013-1246	02/19/2013 03/19/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/NE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORO/CE-FO/PHI-DO/PHI-CB/	Lorcan Carleton Carleton, Lorcan	CONSUMER COMPLAINT 130581
2013-1247	02/19/2013 03/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Slvia Aguiar Oliveira Rosa São José Hospital	DONEPEZIL - AERS
2013-1248	02/19/2013 03/19/2013	FDA/OFVM/CFSAN/OCD/EOS/	Lynn P. Tordo Thor Specialties, Inc.	FCN 1169
2013-1249	02/19/2013 03/19/2013	FDA/OC/OES/DFOI/	Kelly Yamanouchi Atlanta Journal-Constitution	GATE GOURMET, ATLANTA, GA - 483 (10/31/2012 - 02/15/2013)
2013-1250	02/19/2013 03/19/2013	FDA/OGROP/ORO/CE-FO/DET-DO/DET-CB/	Kimberly Kiker Calhoun City Schools	BEST EXPRESS FOODS, INC - RECS, WARNING LETTER, CLEARANCE
2013-1251	02/19/2013 03/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dr. Frederick O. Cope Dr. Frederick O. Cope	AMYVID - APPLICATION, ANALYSIS, REVIEW
2013-1252	02/19/2013 03/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Anne Crossley Reckitt Benckiser Healthcare UK	ADVIL COLD & FLU COATED TABLETS - NDA

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-1253	02/19/2013 03/19/2013	FDA/OO/OHR/	Jairaj Mehta JM Pharma Solutions, LLC	RUSSELL G KATZ, MD - RESUME
2013-1254	02/19/2013 03/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Dr. Yossi Muncher Dr. Yossi Muncher	K931946
2013-1255	02/19/2013 03/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Gabriel Zimmerman The Sheba Medical Center	CIPRODEX(R) - SBA
2013-1256	02/19/2013 03/19/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ OC/ORA/OCI/ OC/ORA/OCI/ FDA/OC/OES/DFOI/	Louis Jefferson PROMETHEUS LABS	PROMETHEUS LABORATORIES, INC - COMPLAINTS, INVESTIGATIONS, RESULTS OF COMPLAINTS (01/01/2008 - 01/01/2013)
2013-1257	02/19/2013 03/19/2013	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	Caroline Hartill RTI Biologics, Inc	UNIVERSITY OF MIAMI TISSUE BANK - 483 (02/01/2012 - 02/18/2013)
2013-1258	02/19/2013 03/19/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Ellen Zimmerman ClearView Diagnostics Incorporated	K070477
2013-1259	02/19/2013 03/19/2013	OC/CVM/OCD/	Larry Stobbs Stobbs Consulting Inc.	FEED ASSAY METHOD FOR MGA
2013-1260	02/19/2013 03/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	BLA 125160 S080 - APPROVAL LETTER, LABELING, MEDICAL REVIEW, ETC
2013-1261	02/19/2013 03/19/2013	OC/CVM/OCD/	Larry Stobbs Stobbs Consulting Inc.	RACTOPAMINE ASSAY METHOD B04372
2013-1262	02/19/2013 03/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHARLES CELESTE EAS Consulting Group, LLC	PULMOZYNE (DORMASE ALFA) BLA 103532 APRVL LTR, LBLG, MOR, ETC
2013-1263	02/19/2013 05/24/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	RUTH WOLFSON PHD BIOLOGICS CONSULTING GROUP	GLASSIA - ORIGINAL BLA, CLNCL PHARMACOLOGY RVW, SAFETY TESTING, ETC

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2013-1264	02/19/2013 03/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CORNELL, CAITLIN	ANDROSCIENCE CORP - TOPICAL ASC-19 CREAM FOR ACNE IND
2013-1265	02/19/2013 03/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SUSAN PRIEST HARTLEY HAMPTON PC	INDIVIDUAL RECS
2013-1266	02/19/2013 03/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	THAO PHAN CARL ZEISS MEDITEC INC	RIGHTMEDICAL PRODUCTS LLC - RIGHTON SOOM SLIT LAMP NS-2D K110129; TOPCON MEDICAL SYSTEMS INC - TOPCON SLIT LAMP SL-2G K110489, ETC
2013-1267	02/19/2013 03/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ERIC H WEINBERG ERIC H WEINBERG ESQ	BOEHRINGER INGELHEIM PHARMACEUTICALS INC - PRDAXA (DABIGATRAN ETEXILATE MESYLATE) NDA 22-512/S004 CORR, MINS, NOTES, ETC
2013-1268	02/19/2013 03/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	UCERIS NDA 203-634 - APRVL LTR, LBLG, MOR, ETC
2013-1269	02/19/2013 03/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELENA VIBOCH KEARNY VENTURE PARTNERS	FERRIC NITRATE - TRADE NAMES
2013-1270	02/19/2013 03/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KUHLMANN, DAVID	DIVISION OF NEUROLOGY PRODUCTS - MEMBERS CONFLICT OF INTEREST RECS
2013-1271	02/19/2013 03/19/2013	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	STELLA K HERRERA GRIFOLS BIOLOGICALS INC	HOSPIRA, ROCKY MOUNT, NC - EIRS, 483S 1/11 TO 1/13
2013-1272	02/19/2013 03/19/2013	FDA/OGROP/ORR/CE-FO/PHI-DO/PHI-CB/	J HOWISON SCHROEDER NEURO KINETICS INC	NEURO KINETICS INC, PITTSBURGH, PA - EIR 4/15-20/10
2013-1273	02/20/2013 03/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tim McCarthy Kingdon Capital Management	XTANDI - FAERS (09/10/2012 - 02/19/2013)

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-1274	02/20/2013 03/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	BLA 103795 S1004 (ENBREL)
2013-1275	02/20/2013 03/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Emily Settlemoir Reliable Biopharmaceutical Corporation	ST PHARM CO LTD, GYEONGGI-DO, KOREA - EIR MOST RECENT
2013-1276	02/20/2013 03/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	BLA 103705 S5256 (RITUXAN)
2013-1277	02/20/2013 03/20/2013	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	Michael Laszek Healthpoint Biotherapeutics	LONZA WALKERVILLE, WALKERVILLE, MD - 483 AND/OR EIR (12/01/2011 - 12/31/2011)
2013-1278	02/20/2013 03/20/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/ FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/ OC/CVM/OCD/	Jenn Strathman WEWS-TV - Jenn Strathman	BENEFUL, PURINA DOG FOOD - CONSUMER COMPLAINTS, INSPECTION REPORTS, MEMOS ETC (01/01/2010 - 02/18/2013)
2013-1279	02/20/2013 03/20/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Brian Walsworth NA	DR JONATHAN FIELDING, LOS ANGELES, CA - ALL CORR (01/01/2002 - 02/15/2013)
2013-1280	02/20/2013	FDA/OMPT/CDER/GRP/DIDP/	Dr. Frederick O. Cope	DATSCAN - COMMENTS, SUMMARIES

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	03/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dr. Frederick O. Cope	
2013-1281	02/20/2013 03/20/2013	FDA/OFVM/CFSAN/OCD/EOS/	Andrew Breza AMERICAN UNIVERSITY	OIL OF MELALEUCA INC - REGULATORY ACTIONS (01/01/1981 - 12/01/1986)
2013-1282	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	Johnathan Rickman FDANEWS	FOIA REQUEST LOG (02/11/2013 to 02/15/2013)
2013-1283	02/20/2013 03/20/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Alina Poulsen Happy Products llc	K920240
2013-1284	02/20/2013 03/20/2013	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	FCN 429, 545, 594 ETC
2013-1285	02/20/2013 03/20/2013	FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/	Rachel Johnson FOI Services, Inc.	CENTOCOR, RADNOR, PA - EIR, 483 09/08
2013-1286	02/20/2013 03/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Ratinder Brar St. Jude Medical	P960009 S051
2013-1287	02/20/2013 03/20/2013	FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/	Tyler Kenyon NORTHCOAST RESEARCH	HILL-ROM, BATESVILLE, IN - MONTHLY UPDATES (10/30/2012 - 02/19/2013)
2013-1288	02/20/2013 03/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Deborah Cohen BMJ	EXENATIDE, LIRAGLUTIDE, SITIGLIPTIN - REPORTS, STUDIES, MEMOS ETC
2013-1289	02/20/2013 03/20/2013	FDA/OFVM/CFSAN/OCD/EOS/ OC/CVM/OCD/	Mike Smith Truth in Food/Custom Publications LLC	MILK SAMPLING FIELD ASSIGNMENTS - SUMMARY OR INTERIM STATUS REPORTS
2013-1290	02/20/2013 05/09/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Raymond R. Blanche NST Consulting, LLC	K113097
2013-1291	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	BRODY MULLINS WALL STREET JOURNAL	2013-968 SPREADSHEET
2013-1292	02/20/2013 03/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	WILLIAM H. WALL WALL MEDICAL INC	WALL MEDICAL INC, BUFORD, GA - SET ADMINISTRATION INTRAVASCULAR K940689
2013-1293	02/20/2013 03/20/2013	OC/CVM/OCD/	LAMBERTINI, ELISBETTA	SALMONELLA - ANIMAL FEED INGREDIENTS, PET FOODS 2002 TO 2009
2013-1294	02/20/2013	FDA/OGROP/ORA/SE-FO/SJN- DO/SJN-CB/		CONSUMER CMLPNT

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	03/20/2013		FLORES MOJICA, FELICITA	
2013-1295	02/20/2013 03/20/2013	OC/CVM/OCD/	TOM NASH MUCKROCK NEWS	GENETICALLY ENGINEERED SALMON 2000 TO 2012
2013-1296	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 1/28/13 - 2/1/12
2013-1297	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	WEEKLY CLOSED LOG 1/28/13 - 2/1/13
2013-1298	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 1/14-18/13
2013-1299	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 1/14-18/13
2013-1300	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	LISA TARRISON SCHRAMP CanReg, Inc.	DAILY LOG 1/7-11/13
2013-1301	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 1/7-11/13
2013-1302	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 1/28/13 - 2/1/13
2013-1303	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	CLOSED LOG 1/28/13 - 2/1/13
2013-1304	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	CLOSED LOG 1/14-18/13
2013-1305	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 1/14-18/13
2013-1306	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 1/7-11/13
2013-1307	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	Lauren Briese Williams, Craig	2012-1997
2013-1308	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	CLOSED LOG 1/7-11/13
2013-1309	02/20/2013 03/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Felicia Ruley TechLab Inc	K982315
2013-1310	02/20/2013 03/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jairaj U. Mehta JM Pharma Solutions, LLC	ORGANIZATIONAL CHART DIVISION OF NEUROLOGY PRODUCTS, DIVISION OF PSYCHIATRY PRODUCTS (02/20/2008 - 02/20/2013)

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2013-1311	02/20/2013 03/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Bradley Wendorff UW-Madison dept Biomedical Eng.	K061256
2013-1312	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED LOG 1/14-18/13
2013-1313	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 1/14-18/13
2013-1314	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 1/7-11/13
2013-1315	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED LOG 1/7-11/13
2013-1316	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED LOG 1/28-2/1/13
2013-1317	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 1/28-2/1/13
2013-1318	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	FDA NEWS	DAILY LOG 1/28-2/1/13
2013-1319	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	DAVID McFARLAND FDA REVIEW/FDA WEBVIEW	DAILY LOG 1/14-18/13
2013-1320	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	DAVID McFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED LOG 1/7-11/13
2013-1321	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	GLADYS B. TONKIN WASHINGTON INFORMATION SOURCE	DAILY LOG 1/7-11/13
2013-1322	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	GLADYS B. TONKIN WASHINGTON INFORMATION SOURCE	DAILY LOG 1/14-18/13
2013-1323	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	GLADYS B. TONKIN WASHINGTON INFORMATION SOURCE	DAILY LOG 1/28-2/1/13
2013-1324	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 1/7-11/13

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2013-1325	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 1/14-18/13
2013-1326	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 1/28-2/1/13
2013-1327	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 1/14-18/13
2013-1328	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	DEBRA L. COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 1/14-18/13
2013-1329	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 1/7-11/13
2013-1330	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 1/7-11/13
2013-1331	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 1/28/13 - 2/1/13
2013-1332	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 1/28/13 - 2/1/13
2013-1333	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 1/7-11/13
2013-1334	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 1/14-18/13
2013-1335	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 1/28/13 - 2/1/13
2013-1336	02/20/2013 03/20/2013	OC/CVM/OCD/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ OC/OR/ OC/OR/	REBECCA FIELD EMERSON MITTS LAW LLC	WEDGEWOOD VILLAGE PHARMACY INC - WARNING LTR SINCE 1/09
2013-1337	02/20/2013	OC/CVM/OCD/	REBECCA FIELD EMERSON	DIRECT VET MARKETING INC - WARNING LTRS SINCE 1/09

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	03/20/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	MITTS LAW LLC	
2013-1338	02/20/2013 03/20/2013	OC/CVM/OCD/ OC/OR/ OC/OR/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	NICOLE A. VENO IZARD NOBEL LLP	PURINA BENEFUL - AERS 2007 TO PRESENT
2013-1339	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	DNALD E. SEGAL ALSTON & BIRD LLP	CRYOLIFE INC, KENNESAW, GA - EIR, 483, WARNING LTR, CORR 1/12 TO PRESENT
2013-1340	02/20/2013 03/20/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	MEADE, DORIS .	UPSLABS LLC, DALLAS, TX - 483 2/7-21/12
2013-1341	02/21/2013 03/21/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	ANa Maria Saaibi Biomedika Consulting	K062270
2013-1342	02/21/2013 03/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	Felicia Ruley TechLab Inc	K083464
2013-1343	02/21/2013 03/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	Darren Reeves DP DISTRIBUTION & CONSULTING, LLC	K082554
2013-1344	02/21/2013 03/21/2013	OC/CVM/OCD/ FDA/OC/OCC/	Genna Reed Food & Water Watch	MTG BETWEEN MICHAEL DOYLE AND FDA RE OXITEC - RECS, AGENDA, NOTES, ETC
2013-1345	02/21/2013 03/21/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Aaron Diamant WSB-TV	GATE GOURMET, ATLANTA, GA - EIR, 483, WARNING LETTER ETC (06/01/2009 - 12/31/2012)

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2013-1346	02/21/2013 03/21/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OCC/	ANGIE SALVATIERRA US LEGAL SUPPORT INC	ANTHREX - TIGHTROPE CLNCL STUDIES, APRVL RECS, SS&E, ETC
2013-1347	02/21/2013 03/21/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RAVI DESHPARIDE ACINO PRODUCTS LLC	TARO PHARMS - TERCONAZOLE VAGINAL SUPPOSITORY ANDA 77-553 SBA
2013-1348	02/21/2013 03/21/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OPP/OP/	VERONICA S KNAPP HOGAN LOVELLS LLP	PARTIALLY HYDROGENATED VEGETABLE OILS - GRAS STATUS
2013-1349	02/21/2013 03/21/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	HOLLY J BAYNE BAYNE & ASSOCIATES	INC AGENCY BV, LOOSDRECHT, NETHERLANDS - EIR 9/10-13/12 CORR, TRANS, MTG NOTES, ETC
2013-1350	02/21/2013 03/21/2013	FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECS
2013-1351	02/21/2013 03/21/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MICHELE K POWERS BRASSEL ALEXANDER & RICE LLC	JOHNS HOPKINS MEDICINE - PHARMACODYNAMIC TRIAL OF PRE-PROSTATECTOMY LOVASTATIN RPTS, APRVL, MEMOS, ETC
2013-1352	02/21/2013 03/21/2013	FDA/OFVM/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 160966
2013-1353	02/21/2013 03/21/2013	FDA/OFVM/CFSAN/OCD/EOS/ OC/OA/OM/OMP/DDM/	SHERRY L FISHER HUNTON & WILLIAMS LLP	VISIT TO PAPER BOARD PLANTS IN CONNECTION WITH PCB FINDINGS IN TOTAL DIET SAMPLE 7/14/71 (CERTIFIED)
2013-1354	02/21/2013 03/21/2013	OC/CVM/OCD/	JANET L DEFILIPPIS HERRIS GROUP LLC	BACITRACIN, LINCOMYCIN, AMPROLIUM HCI - RECS
2013-1355	02/21/2013	FDA/OC/OES/DFOI/	ROSS D PLONT	CARDINAL HEALTH - EXCHANGE TRANSFUSION TRAY

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	03/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	GRUEL MILLS NIMS & PYLMAN LLP	FORM FDA 3500A, MEMOS, RPTS, NARRATIVES, ETC
2013-1356	02/21/2013 03/21/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	ROSS D PLONT GRUEL MILLS NIMS & PYLMAN LLP	CARDINAL HEALTH - EXCHANGE TRANSFUSION TRAY STOPCOCK FORM FDA 3500A, MEMOS, RPTS, NARRATIVES, ETC
2013-1357	02/21/2013 03/21/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	ROSS D PLONT GRUEL MILLS NIMS & PYLMAN LLP	ALLEGIANCE HEALTHCARE CORP - EXCHANGE TRANSFUSION PROCEDURE TRAY FORM FDA 3500A, MEMOS, RPTS, NARRATIVES, ETC
2013-1358	02/21/2013 03/21/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	ROSS D PLONT GRUEL MILLS NIMS & PYLMAN LLP	ALLEGIANCE HEALTHCARE - PHARMASEAL EXCHANGE TRANSFUSION TRAY FORM FDA 3500A, MEMOS, RPTS, NARRATIVES, ETC
2013-1359	02/22/2013 03/22/2013	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	Dave Braggs ISIS Pharmaceuticals	PYRAMID LABORATORIES, COSTA MEDA, CA - EIR (01/01/2010 - 01/01/2013)
2013-1360	02/22/2013 03/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Gary Wolff SHIRE PHARMACEUTICALS INC	MEDWATCH REPORTS WITH CONTACT INFORMATION UNREDACTED
2013-1361	02/22/2013 03/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Gary Liquori, Esq. Powers & Liquori, Attys at Law	METHADONE - UPDATED GUIDELINES ON PRESCRIBING, PACKAGE INSERTS, CONVERSION CHARTS
2013-1362	02/22/2013 03/22/2013	OC/ORAP/ORM/ OC/ORAP/ORM/	David Mangione Govzilla, Inc.	LIST OF INSPECTIONS (01/01/08 - 02/20/2013)
2013-1363	02/22/2013 03/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Adam P. Deisinger, Esq. Roach, Brown, McCarthy & Gruber, P.C.	REQUIP - CERTIFIED RECS
2013-1364	02/22/2013 03/22/2013	FDA/OGROP/ORAP/CE-FO/NWJ-DO/NWJ-CB/	Alyssa Smirz BioGenesis Nutraceuticals Inc	GARDEN STATE NUTRITIONALS - EIR (01/01/2007 - 02/21/2013)
2013-1365	02/22/2013 03/22/2013	FDA/OGROP/ORAP/CE-FO/DET-DO/DET-CB/ FDA/OC/OES/DFOI/	Jason DeVoght Jason DeVoght	EXCEL MEDICAL PRODUCTS, FENTON, MI - 483 (07/03/2012 - 02/21/2013)
2013-1366	02/22/2013 03/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Edward J Kaplan MD Microspherix LLC	ONCOGEL PACLITAXEL/REGEL ABSORBABLE GEL - PRECLINICAL IN VITRO AND IN VIVO TOXICOLOGY AND PHARMACOKINETIC TESTING

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-1367	02/22/2013 03/22/2013	FDA/OC/OES/DFOI/	Amy Kincanon LEXISNEXIS COURTLINK INC	2013-1018
2013-1368	02/22/2013 03/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Philip Almeter University of Kentucky - UK Chandler	THROMBIN-JMI, RECOTHROM - AERS
2013-1369	02/22/2013 03/22/2013	FDA/OFVM/CFSAN/OCD/EOS/	Haruya Kato Kato Business Consulting	BASF - UNTITLED LETTER RECS (02/21/2013 - 03/15/2013)
2013-1370	02/22/2013 03/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tim McCarthy Kingdon Capital Management	ZYTIGA - AERS
2013-1371	02/22/2013 03/22/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Amy Kincanon LEXISNEXIS COURTLINK INC	2012-8401
2013-1372	02/22/2013 03/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kevin Colquitt Standly & Hamilton, LLP	K982347, K983853, K984458 ETC - MAUDE REPORTS
2013-1373	02/22/2013 03/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Edward J Kaplan MD Microspherix LLC	GLIADEL - PRECLINICAL IN VITRO AND IN VIVO TOXICOLOGY AND PHARMACOKINETIC STUDIES
2013-1374	02/22/2013 03/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sandeep Patil Theravance, Inc.	FENCAMFAMIN - DEA SCHEDULE IV STATUS; NDA/IND; SAE
2013-1375	02/22/2013 03/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OCC/	Steven Napolitano Napolitano, Steven	VASCEPA - NCE RECS (06/01/2013 - 02/21/2013)
2013-1376	02/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	GREGORY H. LEVINE	CYNOSURE INC - AFFIRM DO DIODE LASER K101601

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	03/22/2013		ROPES & GRAY LLP	
2013-1377	02/22/2013 03/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	GREGORY H. LEVINE ROPES & GRAY LLP	CYNOSURE INC - YAG FAMILY LASER K031690
2013-1378	02/22/2013 03/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	GREGORY H. LEVINE ROPES & GRAY LLP	CYNOSURE INC - YAG MIR FAMILY LASER K053421
2013-1379	02/22/2013 03/22/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	MARC CHAFETZ BELTWAY LAW GROUP LLP	FRESNIUS - GRANUFLO; NATURLYTE COMPLIANCE
2013-1380	02/22/2013 03/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LAURA KILGORE WATSON LABORATORIES INC	GONAL F RFF NDA 21-684/S-028; NDA 21-684/S-029
2013-1381	02/22/2013 03/22/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	ONA SCANDURRA COUNTRY LIFE LLC	US PHARMA LAB INC, NORTH BRUNSWICK, NJ; ASPIRE PHARMACEUTICALS, SOMERSET NJ - 483, EIR 6/09 TO PRESENT
2013-1382	02/22/2013 03/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KRISTIN DAVENPORT GOODWIN PROCTER LLP	CARDIOGEN 82 NDA 19-414 - APRVL RECS, RVWS
2013-1383	02/22/2013 03/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KATE CADDY DSM Bright Science. Brighter living	POSH CHEMICALS PRIVATE LTD, INDIA - EIR, 483 CO RESP SINCE 2008
2013-1384	02/22/2013 03/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	LIANE LaROCHELLE DEKA RESEARCH & DEVELOPMENT CORP	FRESENIUS, HOME HEMODIALYSIS MACHINE K121421
2013-1385	02/22/2013 03/22/2013	FDA/OO/OHR/	KENDRA L. SHELTON PROADVOCATE GROUP	HOWARD SKLAMBERG; ALYSON SABEN; DALI BORDEN - DECLARATION OF STATEMENT W/EMPLOYEE
2013-1386	02/22/2013 03/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	SANDY MASTROIANNI ITC	ITC, PISCATAWAY, NJ - K040190 SUBMISSION
2013-1387	02/22/2013 03/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	SANDY MASTROIANNI ITC	MICROCOAGULATION ACTIVATED CLOTTING TIME PLUS TEST K941007 1994
2013-1388	02/22/2013 03/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GVOZD, VLADIMIR	CATER WALLACE INC - FELBATOL (FELBAMATE) SUBMISSION

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-1389	02/22/2013 03/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LAURA HOBBS LEXIS NEXIS COURTLINK INC	NORAMCO, RHODES TECHNOLOGIES, JOHNSON MATTHEY - 14 HYDROXYCODEINONE (UNSATURATED KETONE IMPURITY) CORR SINCE 2010, oxycodone hydrochloride
2013-1390	02/22/2013 03/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CURTIS A. THURSTON , Jr. THURSTON LAW OFFICES	SEPTOCAINE NDA 20-971/S-001; 20-971/S-023 - CORR
2013-1391	02/22/2013 03/22/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	VIRGIL L. UMPHENOUR INTERIOR ALASKA FISH PROCESSORS INC	BONSILA, ANVIK, AK - EIR 2009
2013-1392	02/22/2013 03/22/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BARRY J. GAINEY GAINEY & MCKENNA	RANBAXY - ATORVASTATIN (GENERIC LIPITOR) CORR
2013-1393	02/22/2013 03/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WILLIAM W. HOWARD, Ph.D., MBA ALITAIR PHARMACEUTICALS INC	ROBERTS PHARMACEUTICAL CORP, EATONTOWN, NJ - MAXIVENT (DOXOFYLLINE) NDA
2013-1394	02/25/2013 03/25/2013	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2012-7067
2013-1395	02/25/2013 03/25/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	Shibani Malhotra Malhotra, Shibani	HOSPIRA, INC, LAKE FOREST, IL - 483, UNTITLED LETTER (06/01/2012 - 02/22/2013)
2013-1396	02/25/2013 03/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Brent Ardaugh Framingham Heart Study	K941546, K980176, K890100
2013-1397	02/25/2013 03/25/2013	FDA/OFVM/CFSAN/OCD/EOS/	Lauren A. Farruggia Hyman, Phelps and McNamara	US AGENT FOR REGISTERED FOREIGN FOOD FACILITIES
2013-1398	02/25/2013 03/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Brent Ardaugh Framingham Heart Study	K932673, K910859, K882378 ETC
2013-1399	02/25/2013 03/25/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Daryl DeValerio Andrews BERMAN DEVALERIO ET AL	ABIOMED, INC - COMMUNICATIONS WITH FDA RE IMPELLA RECOVER LP 2.5 PERCUTANEOUS CARDIAC SUPPORT

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		FDA/OMPT/CDRH/OCER/DFOI/		SYSTEM
2013-1400	02/25/2013 03/25/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Kelly Jabbal AccessClosure, Inc.	ACCESSCLOSURE, MOUNTAIN VIEW, CA - EIR (08/01/2011 - 08/30/2011)
2013-1401	02/25/2013 03/25/2013	FDA/OFVM/CFSAN/OCD/EOS/	Josh Kleckner Alfa Laval Tank Equipment	FCN 302, FCN 297
2013-1402	02/25/2013 03/25/2013	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2013-227
2013-1403	02/25/2013 03/25/2013	FDA/OFVM/CFSAN/OCD/EOS/	Robert Weissman Saretsky Katz Dranoff & Glass, LLP	DMAA CONTAINING PRODUCTS - AERS (06/01/2012 - 02/22/2013)
2013-1404	02/25/2013 03/25/2013	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2012-7254
2013-1405	02/25/2013 03/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Sami Woo C & H International Co.	K020851
2013-1406	02/25/2013 03/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Brent Ardaugh Framingham Heart Study	K903315, K830654, K912573 ETC
2013-1407	02/25/2013 03/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Erica Winter Erica Winter, Noven Pharmaceuticals	ANSAID - PHARMACOLOGY REVIEW, MEDICAL/SAFETY REVIEW, CLINICAL PHARMACOLOGY
2013-1408	02/25/2013 03/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Brent Ardaugh Framingham Heart Study	K921777, K934722, K934311 ETC
2013-1409	02/25/2013 03/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Brandon Stempo B. Braun Medical Inc.	NDA 17643 - SBA, MEDICAL REVIEW, CLINICAL/PHARMACOLOGY REVIEW
2013-1410	02/25/2013 03/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Brent Ardaugh Framingham Heart Study	K896095, K862158, K900773 ETC
2013-1411	02/25/2013 03/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	ANDA 203263
2013-1412	02/25/2013 03/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	HAMELN PHARMACEUTICALS, HAMELN, GERMANY - EIR, 483 (06/04/12-06/14/12)

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2013-1413	02/25/2013 03/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Brandon Stempo B. Braun Medical Inc.	NDA 18786
2013-1414	02/25/2013 03/25/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORO/ORO/DIOP/	Shibani Malhotra Malhotra, Shibani	HOSPIRA, INC - IMPORT BAN (11/02/2012 - 02/22/2013)
2013-1415	02/25/2013 03/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	JANUVIA - PEDIATRIC WRITTEN REQUEST FOR STUDIES AND AMENDMENTS
2013-1416	02/25/2013 03/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michael Mlodzik Boehringer Ingelheim Vetmedica, Inc.	AUROBINDO PHARMA LTD, HYDERABAD, INDIA - EIR (09/17/2012 - 02/22/2013)
2013-1417	02/25/2013 03/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Eduardo E. Kelly MD Steptoe Therapeutics Inc.	TBO -FILGRASTIM - SBA
2013-1418	02/25/2013 03/25/2013	OC/ORA/ OC/ORA/ OC/CVM/OCD/	Phyllis Entis eFoodAlert	KASEL ASSOCIATED INDUSTRIES, DENVER, CO - 483, 423(A) LETTER
2013-1419	02/25/2013 03/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Michael Muelly Michael Muelly	K081304
2013-1420	02/25/2013 03/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Benjamin P. Mouton McGlynn, Glisson & Mouton	AMNISURE INTERNATIONAL, LLC - MEDICAL DEVICE CORRECTION LETTER 10/01/07
2013-1421	02/25/2013 03/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ERIN E SEDER VENABLE LLP	AZO GESIC, AZO SEPTIC, AZO STANDARD, ETC - AERS
2013-1422	02/25/2013	FDA/OGROP/ORO/CE-FO/NWJ-	EDWARD BRENNAN	FLAVOR DEVELOPMENT CORP, NORWOOD, NJ - EIR 11/11

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	03/25/2013	DO/NWJ-CB/	FLAVOR DEVELOPMENT CORP	
2013-1423	02/25/2013 03/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHNATHAN RICKMAN FDA NEWS	GLOCHEM INDUSTRIES LTD, ANDRHA PRADESH, INDIA; SEVEN STAR PHARMACEUTICAL CO LTD, TAIPEI HSIENG, TAIWAN; BEIJING TAIYANG PHARMACEUTICAL INDUSTRY CO LTD, BEIJING, CHINA, ETC - 483S 1/1-31/13
2013-1424	02/25/2013 03/25/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	JOHNATHAN RICKMAN FDA NEWS	BIOMET CO LTD, SEOUL, KOREAN; RUBIMED AG, HERGISWIL, SWITZERLAND - 483S 1/1-31/13
2013-1425	02/25/2013 03/25/2013	FDA/OGROP/ORASE-FO/FLA- DO/FLA-CB/	JOHNATHAN RICKMAN FDANEWS	PRIME ENTERPRISES INC, HIALEAH, FL; BELCHER PHARMACEUTICALS LLC, LARGO, FL; GADAL LABORATORIES INC, MIAMI, FL, ETC - 483S 1/1-31/13
2013-1426	02/25/2013 03/25/2013	FDA/OGROP/ORASW-FO/KAN- DO/KAN-CB/	JOHNATHAN RICKMAN FDANEWS	LINCARE INC, OTTAWA, KS; MOBIUS THERAPEUTICS LLC, ST LOUIS, MO; RELIABLE BIOPHARMACEUTICAL CORP, OVERLAND, MO, ETC - 483S 1/1-31/13
2013-1427	02/25/2013 03/25/2013	FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/	JOHNATHAN RICKMAN FDANEWS	ALPHA MEDICAL INSTRUMENTS LLC, MISSION VIEJO, CA; HELIX MEDICAL LLC, CARPINTERIA, CA; ACUFOCUS INC, IRVINE, CA - 483S 1/1-31/13
2013-1428	02/25/2013 03/25/2013	FDA/OGROP/ORACE-FO/MIN- DO/MIN-CB/	JOHNATHAN RICKMAN FDANEWS	BIRCHWOOD LABORATORIES INC, EDEN PRAIRIE, MN; FRONTIER MEDICAL PRODUCTS INC, PORT WASHINGTON, WI; ELECTRO KINETIC TECHNOLOGIES LLC, GERMANTOWN, WI - 483S 1/1-31/13
2013-1429	02/25/2013 03/25/2013	FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/	JOHNATHAN RICKMAN FDA NEWS	BIO-CONCEPT LABORATORIES INC, SALEM, NH; BFS PHARMA INC, RANDOLPH, MA; CENTRAL ADMIXTURE PHARMACY SERVICES INC, WOBURN, MA, ETC - 483S 1/1- 31/13
2013-1430	02/25/2013 03/25/2013	FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/	JOHNATHAN RICKMAN FDANEWS	CONTRACT COATING INC, HACKENSACK, NJ; MEDI PHYSICS INC, SOUTHFIELD PLAINFIELD, NJ; OMEGA PACKAGING CORP, TOTOWA, NJ, ETC - 483S 1/1-31/13
2013-1431	02/25/2013 03/25/2013	FDA/OGROP/ORASE-FO/NOL- DO/NOL-CB/	JOHNATHAN RICKMAN FDANEWS	LIFESOUTH COMMUNITY BLOOD CENTERS INC, MADISON, AL; PETNET SOLUTIONS INC, COVINGTON, LA; GAC TECHNO CENTER, BIRMINGHAM, AL - 483S 1/1-31/13
2013-1432	02/25/2013 03/25/2013	FDA/OGROP/ORANE-FO/NYK- DO/NYK-DCB/	JOHNATHAN RICKMAN FDANEWS	AMES GOLDSMITH CORP, GLENS FALLS, NY; ADVANCE PHARMACEUTICAL INC, HOLTSMVILLE, NY; FRESENIUS KABI USA LLC, GRAND ISLAND, NY, ETC - 483S 1/1-31/13
2013-1433	02/25/2013 03/25/2013	FDA/OGROP/ORACE-FO/PHI- DO/PHI-CB/	JOHNATHAN RICKMAN FDANEWS	DRECHER ENTERPRISES INC, UPPER DARBY, PA; PIRAMAL CRITICAL CARE INC, BETHLEHEM, PA - 483S 1/1-31/13
2013-1434	02/25/2013 03/25/2013	FDA/OGROP/ORAPA-FO/SAN- DO/SAN-CB/	JOHNATHAN RICKMAN FDANEWS	XLUMENA INC, MOUNTAIN VIEW, CA; AMEDICA BIOTECH INC, HAYWARD, CA; INVUITY INC, SAN FRANCISCO, CA - 483S 1/1-31/13
2013-1435	02/25/2013	FDA/OGROP/ORASE-FO/SJN-	JOHNATHAN RICKMAN	MSD INTERNATIONAL GMBH PUERTO RICO BRANCH LLC,

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	03/25/2013	DO/SJN-CB/	FDA NEWS	ARECIBO, PR; CARDINAL HEALTH PR 218 INC, ANASCO, PR - 483S 1/1-31/13
2013-1436	02/25/2013 03/25/2013	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	JOHNATHAN RICKMAN FDANEWS	BEZWECKEN INC, WILSONVILLE, OR; COMFORT ACRYLICS INC, CAMAS, WA; VANGUARD EMS INC, BEAVERTON, OR, ETC - 483S 1/1-31/13
2013-1437	02/25/2013 03/25/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	JOHNATHAN RICKMAN FDANEWS	WAYNE CONCEPT MANUFACTURING CO INC, FORT WAYNE, IN; CARACO PHARMACEUTICAL LABORATORIES INC, DETROIT, MI - 483S 1/1-31/13
2013-1438	02/25/2013 03/25/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	JOHNATHAN RICKMAN FDA NEWS	SHIPPERT ENTERPRISES LTD, CENTENNIAL, CO - 483S 1/1-31/13
2013-1439	02/25/2013 03/25/2013	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	SCOTT WILKIN UBS GLOBAL ASSET MANAGEMENT	INTEGRA, ANASCO, PR - 483 10/12 TO 11/12
2013-1440	02/25/2013 03/25/2013	FDA/OFVM/CFSAN/OCD/EOS/	CHARLES CELESTE EAS CONSULTING GROUP LLC	SUNTORY LTD - ACUTE TOXICITY TEST HGT-94-23; HGT-94-26
2013-1441	02/25/2013 03/25/2013	FDA/OFVM/CFSAN/OCD/EOS/	FAUST 01B2507, BRIAN	POTASSIUM - AER
2013-1442	02/25/2013 03/25/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	JOHNATHAN RICKMAN FDANEWS	MID-CONTINENT PACKAGING INC, ENID, OH; FRESENIUS MEDICAL CARE NORTH AMERICA TEXAS, IRVING, TX; RAPID TRAUMA LLC, SAN ANTONIO, TX, ETC - 43S 1/1-31/13
2013-1443	02/25/2013 03/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	EARL GOEHRING, Jr. DEGGE GROUP LTD	ISRS 7362873, 7388962, 7389714, ETC
2013-1444	02/25/2013 03/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	EARL GOEHRING, Jr. DEGGE GROUP LTD	ISRS 8438483, 8438487, 8438491 ETC
2013-1445	02/25/2013 03/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	EARL GOEHRING, Jr. DEGGE GROUP LTD	ISRS 8122655, 8130611, 8130617 ETC
2013-1446	02/25/2013 03/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	EARL GOEHRING, Jr. DEGGE GROUP LTD	ISRS 7616861, 7621864, 7630337, ETC

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2013-1447	02/25/2013 03/25/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/ORO/DIOP/	MICHAEL G. ATKINS Atkins Intellectual Property, PLLC	B&B INTERNATIONAL, NY, NY - VIOLATIONS 200 TO 10/04
2013-1448	02/25/2013 03/25/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/ORO/DIOP/	MICHAEL G. ATKINS Atkins Intellectual Property, PLLC	OST AQUA ZAO, CHERNOGOLOVKA, RUSSIA - VIOLATIONS 2000 TO PRESENT
2013-1449	02/25/2013 03/25/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/ORO/DIOP/	MICHAEL G. ATKINS Atkins Intellectual Property, PLLC	AQUA LIFE , CHEMOGOLOVKA, RUSSIA - VIOLATIONS 2000 TO PRESENT
2013-1450	02/25/2013 03/25/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	JOHNATHAN RICKMAN FDANEWS	WRENCARE, MIDDLETOWN, OH; DIAGNOSTIC HYBRIDS INC, ATHENS, OH; SCM TRUE AIR TECHNOLOGIES LLC, LOUISVILLE, KY, ETC - 483S
2013-1451	02/25/2013 03/25/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	JOHNATHAN RICKMAN FDA NEWS	CORPAK MEDSYSTEMS INC, BUFFALO GROVE, IL; ALMA LASERS INC, BUFFALO GROVE, IL - 483S 1/1-31/13
2013-1452	02/25/2013 03/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORA/ OC/ORA/	TINA MARIE HARRIS TRAUB LIEBERMAN STRAUS ET AL	FRANCKS LAB INC - BRILLIANT BLUE G; TRIAMCINOLONE INJECTION
2013-1453	02/25/2013 03/25/2013	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	JOHNATHAN RICKMAN FDA NEWS	JOHNS HOPKINS UNIV PET CENTER, BALTIMORE, MD; HUMAN BIOSCIENCES INC, GAITHERSBURG, MD; VISIONARY OPTICS LLC, FRONT ROYAL, VA - 483S 1/1-31/13
2013-1454	02/25/2013 03/25/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	JOHNATHAN RICKMAN FDANEWS	MEDI-FARE DRUG AND HOME HEALTH CENTER, BLACKSBURG, SC; NCONTRACT SURGICAL INC, MORRISVILLE, NC - 483S 1/1-31/13
2013-1455	02/25/2013 03/25/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	RICHARD H. WAGNER WAGNER LYNN ET AL	DA VITA HEALTHCARE PARTNERS INC - INVESTIGATION RECS
2013-1456	02/25/2013 03/25/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	FLYNN P. CAREY GALLAGHER & KENNEDY PA	THERMOLIFE INTERNATIONAL LLC - PUMP BOL, E BOL, T, BOL - CORR, INVESTIGATIONS, AER 1/05 TO 12/11
2013-1457	02/25/2013 03/25/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 2/4-8/13
2013-1458	02/25/2013 03/25/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 2/4-8/13
2013-1459	02/25/2013	FDA/OC/OES/DFOI/		CLOSED FOI REQUESTS 2/4-8/13

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	03/25/2013		FOI Services, Inc.	
2013-1460	02/25/2013 03/25/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 2/4-8/13
2013-1461	02/25/2013 03/25/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 2/4-8/13
2013-1462	02/25/2013 03/25/2013	FDA/OC/OES/DFOI/	SANDY FRIEDMAN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 2/4-8/13
2013-1463	02/25/2013 03/25/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOI REQUESTS 2/4-8/13
2013-1464	02/25/2013 03/25/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 2/4-8/13
2013-1465	02/25/2013 03/25/2013	FDA/OC/OES/DFOI/	GLADYS B. TONKIN WASHINGTON INFORMATION SOURCE	DAILY LOG 2/4-8/13
2013-1466	02/25/2013 03/25/2013	FDA/OC/OES/DFOI/	DAVID McFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOI REQUESTS 2/4-8/13
2013-1467	02/25/2013 03/25/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 2/4-8/13
2013-1468	02/25/2013 03/25/2013	FDA/OC/OES/DFOI/	BARBARA JONES WASHINGTON INFORMATION SOURCE	DAILY LOG 2/4-8/13
2013-1469	02/25/2013 03/25/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OES/DFOI/	Megan Pickel BEVERIDGE & DIAMOND	CFSAN FOIA REQUESTS (02/01/2013 - 02/25/2013)
2013-1470	02/26/2013 03/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	John Stocking Stocking, John	K081697
2013-1471	02/26/2013 03/26/2013	FDA/OC/OES/DFOI/	Brent Arbogast Brent Arbogast	FREQUENTLY REQUESTED RECORDS
2013-1472	02/26/2013 03/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Brent Ardaugh Framingham Heart Study	K120834, K060967, K924125 ETC
2013-1473	02/26/2013 03/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Brent Ardaugh Framingham Heart Study	K063696, K041191, K010566 ETC
2013-1474	02/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Ann Thomas	K980431

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	03/26/2013	FDA/OC/OES/DFOI/	TauTona Group	
2013-1475	02/26/2013 03/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Ann Thomas TauTona Group	K992991
2013-1476	02/26/2013 03/26/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Ann Thomas TauTona Group	K013625
2013-1477	02/26/2013 03/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Ann Thomas TauTona Group	K050246
2013-1478	02/26/2013 03/26/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/	Brad N Sommer SOMMER LAW GROUP, PC	RODAN & FIELDS AMP MR MICRO-NEEDLE ROLLER - CLASSIFICATION RECS
2013-1479	02/26/2013 03/26/2013	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	P.Caro TissueNet	ALLOGRAFT INNOVATIONS, GAINESVILLE, FL - 483 (11/01/2012 - 02/25/2013)
2013-1480	02/26/2013 03/26/2013	FDA/OC/OES/DFOI/	Johnathan Rickman FDA NEWS	FOIA LOG (02/18/2013 - 02/22/2013)
2013-1481	02/26/2013 03/26/2013	FDA/OMPT/CTP/OD/	Donald Graff CELERION	TAR AND NICOTINE CONTENT OF CIGARETTES
2013-1482	02/26/2013 03/26/2013	OC/CVM/OCD/	Rachel Johnson FOI Services, Inc.	TYPE C FEED ASSAY FOR NICARB 25%
2013-1483	02/26/2013 03/26/2013	FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/	Doe J	INVESTIGATION RECS
2013-1484	02/26/2013 03/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	BARRY STANIFORD NIPRO Diagnostics	MW5009109
2013-1485	02/26/2013 03/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	BARRY STANIFORD NIPRO Diagnostics	MW5027038
2013-1486	02/26/2013 03/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	BARRY STANIFORD NIPRO Diagnostics	MW5016600
2013-1487	02/26/2013 03/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	BARRY STANIFORD NIPRO Diagnostics	MW5009261
2013-1488	02/26/2013 03/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	BARRY STANIFORD NIPRO Diagnostics	MW5017757
2013-1489	02/26/2013 03/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	BARRY STANIFORD NIPRO Diagnostics	MW5012580
2013-1490	02/26/2013 03/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	BARRY STANIFORD NIPRO Diagnostics	MW5019215

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2013-1491	02/26/2013 03/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	BARRY STANIFORD NIPRO Diagnostics	MW5019473
2013-1492	02/26/2013 03/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	BARRY STANIFORD NIPRO Diagnostics	MW5005390
2013-1493	02/26/2013 03/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	BARRY STANIFORD NIPRO Diagnostics	MW5009108
2013-1494	02/26/2013 03/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	BARRY STANIFORD NIPRO Diagnostics	MW5002772
2013-1495	02/26/2013 03/26/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	HEATHER GALE OLSSON FRANK WEEDA TERMAN MATZ PC	CDRH UNTITLED LTRS 12/1/11 TO PRESENT
2013-1496	02/26/2013 03/26/2013	FDA/OC/OES/DFOI/	HEATHER GALE OLSSON FRANK WEEDA TERMAN MATZ PC	CDRH UNTITLED LTRS
2013-1497	02/26/2013 03/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OCC/ FDA/OC/OES/DFOI/	SCOTT #JY1512/L-27, SEAN	ASTRAZENECA PHARMS - SEROQUEL OFF-LABEL MARKETING, SETTLEMENT AGREEMENT, CMLPNTS, ETC
2013-1498	02/26/2013 04/17/2013	FDA/OGROP/ORAP/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORAP/PA-FO/SAN- DO/SAN-CB/	DANIEL G JARCHO MCKENNA LONG & ALDRIDGE LLP	NATURAL SELECTION FOODS, EARTHBOUND FARMS, TAYLOR FARMS - EIRS, 483S 1/06 TO PRESENT
2013-1499	02/26/2013 03/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORAP/CE-FO/PHI- DO/PHI-CB/ FDA/OGROP/ORAP/NE-FO/NYK- DO/NYK-DCB/ FDA/OGROP/ORAP/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORAP/SE-FO/ATL- DO/ATL-CB/	DAVID HILZENRATH PROJECT ON GOVERNMENT OVERSIGHT	PRADAXA - AERS; BOEHRINGER INGELHEIM, DANBURY, CT; COLUMBUS, OH, PETERSBURG, VA - EIRS; RE-LY TRIALS - CLNCL SITES, NAMES OF INVESTIGATORS, ETC

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		FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/		
2013-1500	02/26/2013 03/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	NAPROXEN - AERS
2013-1501	02/26/2013 03/26/2013	FDA/OFVM/CFSAN/OCD/EOS/	STEVE OTWELL PHD UNIV OF FLORIDA COLLEGE OF AGRICULTURE AND LIFE SCIENCES	ASSESSMENT OF THE NET EFFECTS OF FISH CONSUMPTION DURING PREGNACY - FINAL DRAFT
2013-1502	02/26/2013 03/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CLARK, CHRISTY	PROPRANOLOL - AERS
2013-1503	02/26/2013 03/26/2013	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORR/OCI/ OC/ORR/OCI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	E KIRK WOOD WOOD LAW FIRM LLC	IDS SPORTS - MASS TABS INVESTIGATION RECS
2013-1504	02/26/2013 03/26/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	FAYGIE SACKS SMC DIRECT LLC	BINAX CLEARVIEW ADVANCED STRAP A K091489 - CLIA WAIVER APPL
2013-1505	02/26/2013 03/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	BARRY STANIFORD SMC DIRECT LLC	WAMPOLE LABS - CLEARVIEW HCG COMBO K992187 CLIA WAIVER APPL
2013-1506	02/26/2013 03/26/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	FAYGIE SACKS SMC DIRECT LLC	BINAX - NOW STREP A CARD K960712 CLIA WAIVER APPL
2013-1507	02/26/2013 03/26/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	FAYGIE SACKS SMC DIRECT LLC	WAMPOLE LABS - CLEARVIEW HCG II K953988 CLIA WAIVER APPL
2013-1508	02/27/2013 03/27/2013	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2012-5936
2013-1509	02/27/2013	FDA/OC/OES/DFOI/	Rachel Johnson	2012-6045

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	03/27/2013		FOI Services, Inc.	
2013-1510	02/27/2013 03/27/2013	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2012-2938
2013-1511	02/27/2013 03/27/2013	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2012-6015
2013-1512	02/27/2013 03/27/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	John D. Morris 4LIFE RESEARCH LC	CSBNUTRITION, LINDON, UT - WARNING LETER, 483 (07/02/2012 - 12/28/2012)
2013-1513	02/27/2013 03/27/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Patricia Mullins The SWAIM390 Companies	WISDOM PROTEINS INC, SAN DIEGO, CA - INSPECTION RECS (01/01/2009 - 12/31/2012)
2013-1514	02/27/2013 03/27/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jennifer Wong St. Jude Medical	P030017 S134
2013-1515	02/27/2013 03/27/2013	FDA/OFVM/CFSAN/OCD/EOS/	Tony G. Mendoza Crowell & Moring LLP	FCN 246
2013-1516	02/27/2013 03/27/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Alec White HEALTHCOR MANAGEMENT LP	APP PHARMACEUTICALS, LLC, GRAND ISLAND - CORR (01/01/2010 - 02/26/2013)
2013-1517	02/27/2013 03/27/2013	OC/ORAS/OC/ORAS/	Richard Newman RND Services, LLC	CENTRAL ADMIXTURE PHARMACY SERVICES, INC, WOBURN, MA - 483 2013
2013-1518	02/27/2013 03/27/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Fang Liu G&W Labs	ANDA 064022, ANDA 062124 - SBA
2013-1519	02/27/2013 03/27/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Cathy Kitzmiller Eisai Inc.	EISAI, RESEARCH TRIANGLE PARK, NC - EIR (07/01/2011 - 12/31/2011)
2013-1520	02/27/2013 03/27/2013	FDA/OFVM/CFSAN/OCD/EOS/	Justin O'Connor Justin O'Connor	ASPARTAME IN MILK, DAIRY PRODUCTS (01/01/2008 - 02/26/2013)
2013-1521	02/27/2013 03/27/2013	FDA/OMPT/CDRH/OCER/DFOI/	Bill Chin Masep Infini	K111862
2013-1522	02/27/2013 03/27/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K110012
2013-1523	02/27/2013 03/27/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Leonard Krause Compliance Specialists, LLC	SIMILASAN CORPORATION, HIGHLANDS RANCH, CO; SIMILASAN AG, JONEN SWITZERLAND - 483 (04/08/2011 - 05/27/2011)

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2013-1524	02/27/2013 03/27/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K100818
2013-1525	02/27/2013 03/27/2013	FDA/OMPT/CDRH/OCER/DFOI/	Bill Chin Masep Infini	K102915
2013-1526	02/27/2013 03/27/2013	FDA/OMPT/CDRH/OCER/DFOI/	Ginger R Neil Ripple LLC	K090957
2013-1527	02/27/2013 03/27/2013	FDA/OMPT/CDRH/OCER/DFOI/	Ginger R Neil Ripple LLC	K123255
2013-1528	02/27/2013 03/27/2013	FDA/OGROP/ORR/SE-FO/ATL- DO/ATL-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jeff Varelman Jeff Varelman	KING BIO INC, ASHEVILLE, NC - INSPECTION RECORDS, ADVERSE EVENT REPORTS, ETC (01/01/2009 - 01/01/2013)
2013-1529	02/27/2013 03/27/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Ginger R Neil Ripple LLC	K082629
2013-1530	02/27/2013 03/27/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tina M. Babos IPD ANALYTICS LLC	LETTER DATED 04/28/1988 FROM C PECK OF CDER RE 5 YEAR STATUTORY EXCLUSIVITY
2013-1531	02/27/2013 03/27/2013	OC/CVM/OCD/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bryan Sanders N/A	CIS-TESTOSTERONE - APPROVAL RECS, DATES FOR HUMAN AND ANIMAL DRUGS; DESI RECS
2013-1532	02/27/2013 03/27/2013	FDA/OGROP/ORR/SE-FO/SJN- DO/SJN-CB/	DIAZ, BRENDA LIZ	SAMPLE RESULTS
2013-1533	02/27/2013 03/27/2013	OC/OM/OMP/DDM/	GLORIA GASKINS KLEINFELD KAPLAN & BECKER	DKT 2001P-0586, 2002P-0469
2013-1534	02/27/2013 03/27/2013	FDA/OGROP/ORR/NE-FO/NWE- DO/NWE-CB/	CARLO CASULO, MD ASCEND CAPITAL LLC	ABIOMED - CLOSE OUT LTR 6/10/11

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2013-1535	02/27/2013 03/27/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	CMPLNT 10846
2013-1536	02/27/2013 03/27/2013	FDA/OC/OES/DFOI/	Doe J	SCHIYGOHRENIA - CAUSES
2013-1537	02/27/2013 03/27/2013	FDA/OC/OES/DFOI/	ELLOITT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	2013 DRUG REQUEST LOG
2013-1538	02/27/2013 03/27/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELLIOT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	PONATINIB (ICLUSIG) - AER 2012 TO PRESENT
2013-1539	02/27/2013 03/27/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	OAKES, TIMOTHY	TANDEM DIABETES CARE INC - INSULIN DELIVERY SYS K111210
2013-1540	02/27/2013 03/27/2013	FDA/OMPT/CDRH/OCER/DFOI/	OLIVE O'DRISCOLL CORK INSTITUTE OF TECHNOLOGY	ACCLARENT INC, MENLO PK, CA - K082188
2013-1541	02/27/2013 03/27/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	OLIVE O'DRISCOLL CORK INSTITUTE OF TECHNOLOGY	ACCLARENT INC, MENLO PARK, CA - K103595
2013-1542	02/27/2013 03/27/2013	FDA/OGROP/ORO/CE-FO/CHI- DO/CHI-CB/	LIANE LaROCHELLE DEKA RESEARCH & DEVELOPMENT CORP	HOSPIRA INC, LAKE FOREST, IL - 483 1/13
2013-1543	02/27/2013 03/27/2013	FDA/OGROP/ORO/SE-FO/FLA- DO/FLA-CB/	DAVID SCOTT BLUE ZETETIC	ENTRY NO EHP00765942
2013-1544	02/27/2013 03/27/2013	FDA/OGROP/ORO/SE-FO/FLA- DO/FLA-CB/ FDA/OMPT/CDRH/OCER/DFOI/	KURT E. LEE JUDD ULRICH ET AL	SILVER BAY LLC - RECALL, AER
2013-1545	02/27/2013 03/27/2013	FDA/OGROP/ORO/SE-FO/FLA- DO/FLA-CB/ FDA/OMPT/CDRH/OCER/DFOI/	KURT E. LEE JUDD ULRICH ET AL	QUASAR BIO-TECH INC - RECALL, AER

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2013-1546	02/27/2013 03/27/2013	FDA/OMPT/CDRH/OCER/DFOI/	GARY O'HARA THERMOMEDICS	THERMOMEDICS - K080759, K090361
2013-1547	02/27/2013 03/27/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	ELENA HOWELL HOGAN LOVELLS LLP	2012-8987
2013-1548	02/27/2013 03/27/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	K. MICHELLE VASSALLO LINCARE INC	PURE OXYGEN LLC, OHIO; PA - 483, EIR, WARNING LTR 1/05 TO PRESENT
2013-1549	02/27/2013 03/27/2013	OC/ORACE/OCI/ OC/ORACE/OCI/	GEORGE A. STAMBOULIDIS BAKER & HOSTETLER, LLP	DR ANTHONY GALEA - INVESTIGATION
2013-1550	02/27/2013 03/27/2013	FDA/OFVM/CFSAN/OCD/EOS/	EASLEY 103481, KENT A	SOY - AER
2013-1551	02/28/2013 03/28/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Matt Cheatham SL Chapman LLC	AMS 800 URINARY CONTROL PUMP WITH INHIBIZONE; RESERVOIR, PENILE PROSTHESIS 100 CC, IMPLANT, EXTENDER 100 CC ETC - ALERTS, RECALLS, SAGETY COMMUNICATIONS
2013-1552	02/28/2013 03/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Brent Ardaugh Framingham Heart Study	K792281, K820193, K923657
2013-1553	02/28/2013 03/28/2013	OC/ORACE/ OC/ORACE/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Jeffrey A. Pribanic, Esquire Pribanic & Pribanic, L.L.C.	INDIVIDUAL RECS
2013-1554	02/28/2013 03/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	Lauren Specter NBC NEWS	DMAA - AERS (01/01/2006 - 02/27/2013)
2013-1555	02/28/2013 03/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	Sarah Tracy UNIVERSITY OF TORONTO	MSG - AERS (01/01/1985 - 12/31/2012)
2013-1556	02/28/2013 03/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Emily Morris Georgia Tech Research Institute	K944765
2013-1557	02/28/2013	FDA/OFVM/CFSAN/OCD/EOS/	Lauren Specter	USPLABS, JACK3D - AERS (2006-2013)

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	03/28/2013		NBC NEWS	
2013-1558	02/28/2013 03/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ryan Gaspar UH Hilo College of Pharmacy	IMNM WITH HMG-COA REDUCTASE INHIBITOR THERAPY - AERS (01/01/1987 - 02/27/2013)
2013-1559	02/28/2013 03/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Caitlin Senter Remington Medical, Inc.	K990519
2013-1560	02/28/2013 03/28/2013	FDA/OC/OES/DFOI/	WHITE, HORTENSE S	SPICES, FOOD DYES - RECS
2013-1561	02/28/2013 03/28/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	MARY D LEWIS MARY D LEWIS LLC	INDIVIDUAL RECS
2013-1562	02/28/2013 03/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	NATALIE N SANDERS LATHAM & WATKINS LLP	KARMELSONIX (ISONEA) - PERSONAL WHEEZOMETER K090863; PULMOTRACK 5050 K101022
2013-1563	02/28/2013 03/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/OA/OM/OMP/DDM/	JOHN E FITZPATRICK III ODOM & DES ROCHES LLP	DKT 2012P-1028; ACTAVIS ELIZABETH LLC - ANDA 91-422, AMNEAL PHARMS - ANDA 203-136
2013-1564	02/28/2013 03/28/2013	FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/	MEADE, DORIS .	BEEHIVE BOTANICALS INC, HAYWARD, WI - 483 7/23-25/12
2013-1565	02/28/2013 03/28/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/ORO/DIOP/ FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MAYA FOA REPRIEVE	PENTOBARBITAL SODIUM POWDER - IMPORT RECS 7/12 TO PRESENT
2013-1566	02/28/2013 03/28/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	HEIDI L REILLY CLARKE LAW OFFICES	INDIVIDUAL RECS
2013-1567	02/28/2013 03/28/2013	FDA/OFVM/CFSAN/OCD/EOS/	ELIZABETH FLOCK MUCKROCK NEWS	OCEANA - SEAFOOD FRAUD IN AMERICA RECS 2/21/13

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2013-1568	02/28/2013 03/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	ISOSORBIDE (DINITRATE AND/OR MONONITRATE) - API/BULK PROD LISTINGS 1/10 TO PRESENT
2013-1569	02/28/2013 03/28/2013	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	ANDRES G MONTERO SUAREZ & MONTERO LAW OFCS	MALTA HATUEY BEVERAGE - RECALL RECS, RPTS, PRESS RELEASES, ETC
2013-1570	03/01/2013 03/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Alan Buchwald, M.D. Alan Buchwald, M.D., Inc.	BODY BUILDING PRODUCTS AND HIDDEN STEROIDS: ENFORCEMENT BARRIERS - REFERENCES, ADVERSE EVENTS
2013-1571	03/01/2013 03/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Garet Heintz Pacira Pharmaceuticals, Inc.	EXPAREL - SBA
2013-1572	03/01/2013 03/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	LABOR L+S, GERMANY - INVESTIGATOR DIARIES (01/24/2013 - 02/01/2013)
2013-1573	03/01/2013 03/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	LABOR L+S, GERMANY - EIR, 483, RESPONSE, ETC (01/24/2013 - 02/01/2013)
2013-1574	03/01/2013 03/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	peter m stevens md Morphographics, LLC	K031493
2013-1575	03/01/2013 03/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Naomi Wells UNIVERSITY OF ILLINOIS AT CHICAGO	SAVELLA - AERS (01/01/2003 - 02/28/2013)
2013-1576	03/01/2013 05/09/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Dr. Paul Effler Paul Effler MD	SUMMARY BASIS FOR REGULATORY ACTION CSL LIMITED INFLUENZA VIRUS VACCINE
2013-1577	03/01/2013 03/29/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Bernie R Silvers ORIGEN BIOMEDICAL	K991864
2013-1578	03/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson	K121270

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	03/29/2013		FOI Services, Inc.	
2013-1579	03/01/2013 03/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K121270
2013-1580	03/01/2013 03/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	AMY PAGNOZZI SMC DIRECT LLC	BINAX, CLEARVIEW ADVANCED STREP A MODEL 737-430 K091489; BINAX, NOW STREP A TEST K960712; ACON, QUICK A RAPID TEST STRIP K010582
2013-1581	03/01/2013 04/18/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	JENNIFER O'BRIEN BATTELLE	INDIVIDUAL RECS
2013-1582	03/01/2013 03/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	LENORE FAULHABER, Ph.D. PROCTER & GAMBLE COMPANY	UROMED IMPRESS SOFTPATCH - UNREDACTED
2013-1583	03/01/2013 03/29/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	CLOSED FOI LOG 2/11-15/13
2013-1584	03/01/2013 03/29/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 2/11-15/13
2013-1585	03/01/2013 03/29/2013	FDA/OC/OES/DFOI/		DAILY LOG 2/11-15/13
2013-1586	03/01/2013 03/29/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI LOG 2/11-15/13
2013-1587	03/01/2013 03/29/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 2/11-15/13
2013-1588	03/01/2013 03/29/2013	FDA/OC/OES/DFOI/	SANDY FRIEDMAN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 2/11-15/13
2013-1589	03/01/2013 03/29/2013	FDA/OC/OES/DFOI/	DEBRA COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 2/11-15/13
2013-1590	03/01/2013 03/29/2013	FDA/OC/OES/DFOI/	LISA TARRISON SCHRAMP CanReg, Inc.	CLOSED REQUESTS LOG 2/11-15/13
2013-1591	03/01/2013 03/29/2013	FDA/OC/OES/DFOI/	LISA TARRISON SCHRAMP CanReg, Inc.	DAILY LOG 2/11-15/13
2013-1592	03/01/2013 03/29/2013	FDA/OC/OES/DFOI/	GLADYS B. TONKIN WASHINGTON INFORMATION SOURCE	DAILY LOG 2/11-15/13
2013-1593	03/01/2013 03/29/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION	DAILY LOG 2/11-15/13

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2013-1594	03/01/2013 03/29/2013	FDA/OC/OES/DFOI/	DAVID McFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED REQUESTS LOG 2/11-15/13
2013-1595	03/01/2013 03/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NOTICES SENT BY FDA IN 1985 TO MANUFACTURERS OF NEUROLEPTIC DRUGS REGARDING LABEL WARNINGS FOR TARDIVE DYSKINESIA
2013-1596	03/01/2013 03/29/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Jeff White Saint Joseph's Translational Research In	AMERICAN PRECLINICAL SERVICES, MINNEAPOLIS, MN - 483 (01/01/2011 - 03/01/2013)
2013-1597	03/01/2013 03/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gabriel Brier QUINN EMANUEL ET AL	PRESCRIPTION DRUG WRAP-UP LIST
2013-1598	03/01/2013 03/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dana Annunziato NOVEN PHARMACEUTICALS INC	NDA 018766 - MEDICAL RVW
2013-1599	03/01/2013 03/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	A full copy of the 510(k) medical device K083087 and K052643 Ei Inc.	K083087, K052643
2013-1600	03/01/2013 03/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	SBA 202608
2013-1601	03/04/2013 04/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Molly Juhlin Oregon Health Sciences University	VASCEPA - SUMMARY REVIEW
2013-1602	03/04/2013 04/01/2013	FDA/OGROP/ORACE-FO/SEA-DO/SEA-CB/	Mitchell A. Goldstein Babener & Associates	PULSE HEALTH, LLC - WARNING LETTER RECS (01/03/2012 - 02/28/2013)
2013-1603	03/04/2013 04/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	5663073 6221105 7285819 ETC - MEDWATCH RPTS (SINGULAIR)

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2013-1604	03/04/2013 04/01/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OMPT/CDRH/OCER/DFOI/	Pete Bevan Chromogenex Technologies Limited	ADVANCED PHOTONICS SYSTEMS LED SYSTEMS - FDA ACTIONS (10/29/2012 - 02/28/2013)
2013-1605	03/04/2013 06/14/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Professor Paul Effler Paul Effler, MD	CSL INFLUENZA VACCINE - REGISTRATION, LICENSE RECS (01/01/1989 - 01/01/2012)
2013-1606	03/04/2013 04/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	SBA 20589, S009, 015, 017, 019
2013-1607	03/04/2013 04/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	Robert Langreth BLOOMBERG NEWS	MEDSUN SAFETY SURVEY ON SURGEONS AND HOSPITAL USE OF INTUITIVE SURGICAL ROBOTIC EQUIPMENT AND MEDICAL PRODUCT SAFETY NETWORK; MEDICAL PRODUCT SAFETY NETWORK SMALL SAMPLE SURVEY ON DA VINCI SURGICAL SYSTEM
2013-1608	03/04/2013 04/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	NDA 20589
2013-1609	03/04/2013 04/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kevin Minnich B. Braun Medical Inc.	K111275
2013-1610	03/04/2013 04/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bridgette Kunst B&H Consulting Services, Inc.	NDA 020207 - SBA
2013-1611	03/04/2013 04/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bridgette Kunst B&H Consulting Services, Inc.	NDA 014691 - SBA
2013-1612	03/04/2013 04/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	PEDIATRIC WRITTEN REQUEST FOR STUDIES AND RELATED AMENDMENTS FOR VICTOZA
2013-1613	03/04/2013 04/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING &	PEDIATRIC WRITTEN REQUEST FOR STUDIES AND RELATED AMENDMENTS FOR BYETTA

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2013-1614	03/04/2013 04/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	PEDIATRIC WRITTEN REQUEST FOR STUDIES AND RELATED AMENDMENTS FOR AMARYL
2013-1615	03/04/2013 04/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	SBA 20944 S002, 003
2013-1616	03/04/2013 04/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	NDA 20944 - RECS NOT INCLUDED IN RELEASABLE SBA
2013-1617	03/04/2013 04/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kim Thorson Medical Products Laboratories, Inc.(MPL)	ANDA 202470 SEQUENCE 0001
2013-1618	03/04/2013 04/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Chris Cano Agile Therapeutics	NDA 17354, NDA 17355, NDA 17875 - MEDICAL OFFICE REVIEW
2013-1619	03/04/2013 04/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Richard Beasley Beasley, Richard	NDA 20723
2013-1620	03/04/2013 04/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORP/NE-FO/NWE- DO/NWE-CB/ FDA/OC/OES/DFOI/	Law Offices of Ronald A. Marron Law Offices of Ronald A. Marron	NELSON BACH USA LTD - CORR, COMM WITH FDA

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2013-1621	03/04/2013 04/01/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Kevin Minnich B. Braun Medical Inc.	K110535
2013-1622	03/04/2013 04/01/2013	OC/ORO/ORM/ OC/ORO/ORM/	Jason DeYoung WESTERN MICHIGAN UNIVERSITY	LIST OF INSPECTIONS IN MICHIGAN, INDIANA, OHIO (01/04/2010 - 03/01/2013)
2013-1623	03/04/2013 04/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	Ellen Zimmerman ClearView Diagnostics Incorporated	K012084
2013-1624	03/04/2013 04/01/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Barry Newberger Conley Rose P.C.	LENSX LASERS INC, ALCON LENSX, INC, ALCON RESEARCH, LTD - 510K RECS
2013-1625	03/04/2013 04/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	Josh Sweren FARALLON CAPITAL MANAGEMENT LLC	INTUITIVE SURGICAL, DA VINCI ROBOT - EMAILS, LETTERS TO OR FROM FDA RE SAFETY, COMPLICATIONS, ADVERSE EVENTS; PHYSICIANS, HOSPITALS WHO WERE SENT A SURVEY IN 2012 OR 2013 RE DA VIN CI ROBOT PRODUCT SAFETY ISSUES (09/30/12-03/01/2013)
2013-1626	03/04/2013 04/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mario A. Inchiosa, Jr., Ph.D. NEW YORK MEDICAL COLLEGE	PHENOXYBENZAMINE - AERS
2013-1627	03/04/2013 04/01/2013	FDA/OC/OES/DFOI/	Jasmine Bager Columbia Journalism School	FIVE HOUR ENERGY DRINK - FOIA REQUESTS (03/01/2000 - 03/01/2013)
2013-1628	03/04/2013 04/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K123845
2013-1629	03/04/2013 04/01/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K090312
2013-1630	03/04/2013 04/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	INVERNESS MEDICAL, INVERNESS, SCOTLAND - EIR PAGES 5 TO 7; 483 PAGES 1 TO 2 (04/19/04-4/22/04)
2013-1631	03/04/2013 04/01/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K120737
2013-1632	03/04/2013 04/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K122280
2013-1633	03/04/2013 04/01/2013	FDA/OGROP/ORO/NE-FO/NYK- DO/NYK-DCB/ FDA/OGROP/ORO/SE-FO/NOL- DO/NOL-CB/ FDA/OGROP/ORO/SW-FO/DAL- DO/DAL-CB/	Elaine Noblit United Therapeutics Corporation	ROBYN J BARST, NEW YORK, NY - EIR 02/02/01; ROBERT C BOURGE, BIRMINGHAM, AL - EIR 01/08/01; ADAANI E FROST, HOUSTON, TX - EIR 01/18/01

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2013-1634	03/04/2013 04/01/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORR/SE-FO/NOL- DO/NOL-CB/	Murray Carpenter Murray Carpenter	12/05/12 MTG BETWEEN MICHAEL LANDA AND HYMAN, PHELPS, MCNAMARA, INTERTEK CONTOX, RE ENERGY DRINKS - MINUTES; CORR; ROCKSTAR CORR WITH FDA AFTER 05/12 WARNING LETTER
2013-1635	03/04/2013 04/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K110301
2013-1636	03/04/2013 04/01/2013	FDA/OO/OFBA/OAGS/	Rose Santos FOIA GROUP INC	HHSF223200850014I ORDER 3 HHS0001 - CONTRACT, MODIFICATIONS
2013-1637	03/04/2013 04/17/2013	FDA/OO/OFBA/OAGS/	Rose Santos FOIA Group, Inc.	HHSF223201110030I
2013-1638	03/04/2013 04/01/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-171 REQUEST LETTER
2013-1639	03/04/2013 04/01/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-497 REQUEST LETTER
2013-1640	03/04/2013 04/01/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-547 REQUEST LETTER
2013-1641	03/04/2013 04/01/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 2/1/2013 - 3/1/2013
2013-1642	03/04/2013 04/01/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-620 REQUEST LETTER
2013-1643	03/04/2013 04/01/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOIA REQUESTS CLOSED 02/01/13-02/28/2013
2013-1644	03/04/2013 04/01/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-89 REQUEST LETTER
2013-1645	03/04/2013 04/01/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-692 REQUEST LETTER
2013-1646	03/04/2013 04/01/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-298 REQUEST LETTER
2013-1647	03/04/2013 04/01/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-351 - REQUEST LETTER
2013-1648	03/04/2013 04/01/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-132 REQUEST LETTER
2013-1649	03/04/2013 04/01/2013	FDA/OGROP/ORR/CE-FO/CIN- DO/CIN-CB/	JASON A FORGE ROBBINS GELLER ET AL	USA V SCOTTS MIRACLE-GRO CO - INVESTIGATION RECS, RPTS, MEMOS, ETC

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2013-1650	03/04/2013 04/01/2013	OC/CVM/OCD/	Nathan Bahill Stetson University School of Law	GENETICALLY ALTERED ATLANTIC SALMON - LIST OF STUDIES AND DATA RE MIXING, BREEDING WITH WILD OR NATURAL ATLANTIC SALMON
2013-1651	03/04/2013 04/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOSHUA M GLASSER ARNOLD & PORTER	ERIVEDGE (VISMODEGIB) CAPS NDA 20-3388 - APRVL LTR 1/30/12
2013-1652	03/04/2013 04/01/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	DAVID W GERDT PHD EMPIRICAL T ECHNOLOGIES CORP	TL-300 T-LINE K123446, NEXFIN M ODE 1014 K072049, CC NEXFIN K101123, ETC
2013-1653	03/04/2013 04/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LAURA HOBBS LEXISNEXIS COURTLINK INC	NORAMCO, RHODES TECHNOLOGIES, MALLINCKRODT/COVIDIEN, ETC - 14-HYDROXYCODEINONE RESP, SUBMISSIONS, CORR, ETC
2013-1654	03/04/2013 04/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/OA/OM/OMP/DDM/	ELIZABETH MOCCALDI BUTLER, SNOW, O'MARA, STEVENS & CANNADA, PLLC ATTORNEYS AT LAW	PROSCAR, PROPECIA - CITIZEN PETITIONS
2013-1655	03/04/2013 04/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	REO TANOSHIMA MD HOSPITAL FOR SICK CHILDREN	COPAXONE (GLATIRAMER ACETATE) - ISRS 6868065, 6853352, 7236316, ETC
2013-1656	03/04/2013 04/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	JUDY F GORDON DVM CLINREG CONSULTING SERVICES INC	CIBA VISION - K073459
2013-1657	03/04/2013 08/19/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/ FDA/OMPT/CDRH/OCER/DFOI/	LEIGH SANDERS CENTER FOR RESPONSIBLE SCIENCE	ANIMAL TESTING - INTERNAL ANALYSIS, TRADE SECRETS, PATENTS, ETC
2013-1658	03/04/2013	FDA/OMPT/CDER/ORP/DIDP/	TYRAH L MILES	OSPHENA (OSPEMIFENE) - SBA

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	04/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DJA GLOBAL PHARMACEUTICALS INC	
2013-1659	03/04/2013 04/01/2013	FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/	Doe J	INDIVIDUAL RECS
2013-1660	03/04/2013 04/01/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ OC/OA/OM/OMP/DDM/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARC RENDELL MD ASNDI	NOVO NORDISK - INSULIN DEGLUDEC APRVL RLECS, INVESTIGATION, A/C MTG
2013-1661	03/04/2013 04/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ROSETTE, FRANK	GRISEOFULVIN - AERS
2013-1662	03/04/2013 04/18/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Doe J	INDIVIDUAL RECS - VAERS
2013-1663	03/04/2013 04/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CARLO CASULO MD ASCEND CAPITAL LLC	STRIDE ARCO LABS - 483, WARNING LTRS, CLOSE OUT LTRS 1/1/10 TO 2/27/13
2013-1664	03/04/2013 04/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	BARBARA J WHITMAN INTEGRA LIFESCIENCES CORP	INTEGRA LIFESCIENCES CORP - COLLASTAT ABSORBABLE COLLAGEN HEMOSTATIC AGENT P810006/S002
2013-1665	03/04/2013 04/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	BARBARA J WHITMAN INTEGRA LIFESCIENCES CORP	HELISTAT ABSORBABLE COLLAGEN HEMOSTATIC SPONGE P850010/S005
2013-1666	03/04/2013 04/01/2013	FDA/OFVM/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 161330
2013-1667	03/04/2013 04/01/2013	FDA/OFVM/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 155879, 157049, 161089
2013-1668	03/04/2013 04/01/2013	FDA/OC/OES/DFOI/ OC/ORAI/	Smith, Shari D	NECC 4/16/02 INSPECTION - EXHIBITS

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		OC/ORAI/		
2013-1669	03/05/2013 04/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kelly Jabbal AccessClosure, Inc.	P930038 S052
2013-1670	03/05/2013 04/02/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	William Carroll BRINKS HOFER GILSON & LIONE	US PATENT 8,372,872 - ORANGE BOOK SUBMISSION
2013-1671	03/05/2013 04/02/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	BLA 125118 S122
2013-1672	03/05/2013 04/02/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	1 Rosales, Ruth R	COLISTIN - CLINICAL STUDIES
2013-1673	03/05/2013 04/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jane Keathley Keathley and Company LLC	K113853
2013-1674	03/05/2013 04/02/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Maninder Chopra Kirax Corp	HYDROCODONE, HYDORCODONE/ACETAMINOPHEN - NDA RECS
2013-1675	03/05/2013 04/02/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORAI/PA-FO/LOS- DO/LOS-CB/	Law Offices of Ronald A. Marron Law Offices of Ronald A. Marron	TADIN CORP - CORR, COMM WITH FDA (12/28/2008 - 03/04/2013)
2013-1676	03/05/2013 04/02/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	BLA 103795 S 5110
2013-1677	03/05/2013 04/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	C J Pillar CJP Consulting, Inc.	K120135
2013-1678	03/05/2013 04/02/2013	FDA/OGROP/ORAI/SW-FO/DEN- DO/DEN-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Law Offices of Ronald A. Marron Law Offices of Ronald A. Marron	SIMILASAN - CORR, COMM WITH FDA (1/01/2003 - 03/04/2013)

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2013-1679	03/05/2013 04/02/2013	FDA/OFVM/CFSAN/OCD/EOS/	Law Offices of Ronald A. Marron Law Offices of Ronald A. Marron	IOVATE - CORR, COMM WITH FDA
2013-1680	03/05/2013 04/02/2013	FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	Wayne Thuna FMC Distributors, Inc.	FMC DISTRIBUTORS, INC, PONCE, PR - EIR (12/08/2009 - 12/11/2009)
2013-1681	03/05/2013 04/02/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	VIVELLE DOT - AERS
2013-1682	03/05/2013 04/02/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	Joseph Anderson Joseph Anderson	DR MICHAEL RING - EIR AUGUST 2012
2013-1683	03/05/2013 04/02/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	NDA 20812
2013-1684	03/05/2013 04/02/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	SBA 20812 S007, 011
2013-1685	03/05/2013 04/02/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	NDA 20267
2013-1686	03/05/2013 04/02/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	SBA 20267, S005
2013-1687	03/05/2013 04/02/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	QILU PHARMACEUTICAL, JINAN, CHINA - EIR, 483, WARNING LETTER, ETC (06/28/2010-07/01/2010)

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2013-1688	03/05/2013 04/02/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Richard Leon Neumedicines Inc.	G-CSF (NEUPOGEN) - EMERGENCY USE AUTHORIZATION APPLICATIONS
2013-1689	03/05/2013 04/02/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Richard Leon Neumedicines Inc.	CYTOKINES - IND, EMERGENCY USE AUTHORIZATIONS
2013-1690	03/05/2013 04/02/2013	FDA/OGROP/ORAC/CE-FO/PHI-DO/PHI-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANGELA E MCGRAW FLEISHMAN & SHAPIRO PC	MERCK & CO INC - INVANZ RECALL RECS
2013-1691	03/05/2013 04/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN NICPON CMP INDUSTRIES LLC	DURAFLEX K063626
2013-1692	03/05/2013 04/02/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	COREY B RUBENSTEIN STETLER DUFFY & ROTERT LTD	TOTAL NUMBER OF INVESTIGATIONAL NEW DRUG APPLICATIONS (INDA) FILED, CLNCL HOLDS FOR CBER AND CDER 2007 TO 2010, ETC
2013-1693	03/05/2013 04/02/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARIA MATTERN GLAXO SMITH KLINE	FINASTERIDE - ISRS 3055449-9, 3076713-3, 3505197-3, ETC
2013-1694	03/05/2013 04/02/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOANNE S HAWANA ARENT FOX LLP	SEPTOCAINE INJ, ARTICAINE HCL - ISRS 8480724, 8529551, 8530048, ETC
2013-1695	03/05/2013 04/02/2013	FDA/OFVM/CFSAN/OCD/EOS/	LISA P ALSOBROOK Keller and Heckman LLP	CHITEC TECHNOLOGY CO LTD, HANSON GROUP LLC - FCN 537, FCN 935 CHEMISTRY & TOXICOLOGY MEMOS

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2013-1696	03/05/2013 04/02/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	SAMUEL F COLIN MD FIRST MANHATTAN CO	LUITPOLD PHARMACEUTICALS INC - 483S, WARNING LTRS, CO RESP 2/1/13 TO PRESENT
2013-1697	03/05/2013 04/02/2013	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	MICHAEL CODY APHENA PHARMA SOLUTIONS	BLU CARIBE INC, DORADO, PR - EIR 10/12
2013-1698	03/05/2013 04/02/2013	FDA/OFVM/CFSAN/OCD/EOS/	DAVID C STEINBERG STEINBERG & ASSOCIATES INC	HAIR STRAIGHTENER COSMETICS REGISTERED WITH FDA UNDER VCRP BASED ON THIOGLYCOLIC ACID, SALTS, ESTERS - CAERS 2000 TO PRESENT
2013-1699	03/05/2013 04/02/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TOM BURTON WALL STREET JOURNAL	OMONTYS (PEGINESATIDE) - AERS
2013-1700	03/05/2013 04/02/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	WALTER E. CHALKLEY THOMSON REUTERS	HOSPIRA COSTA RICA LTD, LA AURORA de HEREDIA - EIR, 483, CO RESP 4/12
2013-1701	03/05/2013 04/02/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	XYLO CHEM INDUSTRIES, NADIAD, INDIA - EIR, 483, CO RESP 6/11
2013-1702	03/05/2013 04/02/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	BULK MEDICINES & PHARMACEUTICALS GMBH, NORDERSTEDT, GERMANY - EIR, 483, CO RESP 11/11
2013-1703	03/05/2013 04/24/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E. CHALKLEY THOMSON REUTERS	COREPHARMA LLC - EIR, 483, CO RESP 6/12
2013-1704	03/05/2013 04/02/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	NOVO NORDISK AS, BAGSVAERD, DENMARK - EIR, 483, CO RESP 3/12-20/12
2013-1705	03/05/2013 04/02/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	BEANNE CHEMICAL CO, TAICHUNG CITY , TAIWAN - EIR, 483, CO RESP 5/2-4/12

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2013-1706	03/05/2013 04/02/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	PA BENJAMIN MAUFACTURING CO LTD, KINGSTON, JAMAICA - EIR, 483, CO RESP 5/5-11/12
2013-1707	03/05/2013 04/02/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	WALTER E. CHALKLEY THOMSON REUTERS	SINGING RIVER HEALTH SYS IRB, PASCAGOULA, MS - EIR, 483, CO RESP 7/2-23/12
2013-1708	03/05/2013 04/02/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	WALTER E. CHALKLEY THOMSON REUTERS	ADVANCED SPECIALTY PHARMACY, BESSEMER, AL - EIR, 483, CO RESP 3/23-25/11
2013-1709	03/05/2013 05/07/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	WALTER E. CHALKLEY THOMSON REUTERS	SOVEREIGN PHARMACEUTICALS LLC, ST FORT WORTH, TX - EIR, 483, CO RESP - 1/18 TO 2/2/12
2013-1710	03/05/2013 04/02/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	WALTER E. CHALKLEY THOMSON REUTERS	THE AMERICAN NATIONAL RED CROSS, DOUGLASVILLE, GA - EIR, 483, CO RESP 6/12
2013-1711	03/05/2013 04/02/2013	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	WALTER E. CHALKLEY THOMSON REUTERS	CHI RHO CLIN INC - BURTONSVILLE, MD - EIR, 483, CO RESP 4/12
2013-1712	03/05/2013 04/02/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	WALTER E. CHALKLEY THOMSON REUTERS	CRESENDO THERAPEUTICS LLC, VISTA, CA - EIR, 483, CO RESP 1/12
2013-1713	03/05/2013 04/02/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	WALTER E. CHALKLEY THOMSON REUTERS	BAXTER HEALTHCARE CORP, CLEVELAND MS - EIR, 483, CO RESP 6/12
2013-1714	03/05/2013 04/02/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	WALTER E. CHALKLEY THOMSON REUTERS	NORTHERN INDIANA CANCER RESEARCH CONSORTIUM IRB, SOUTH BEND IN - EIR, 483, CO RESP 2/12
2013-1715	03/05/2013 04/02/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	WALTER E. CHALKLEY THOMSON REUTERS	STAT RX USA, GAINESVILLE, CA - EIR, 483, CO RESP 2/12
2013-1716	03/05/2013 04/02/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	WALTER E. CHALKLEY THOMSON REUTERS	GENERITECH CORP, FRESNO, CA - EIR, 483, CO RESP 4/12
2013-1717	03/05/2013 04/02/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	WALTER E. CHALKLEY THOMSON REUTERS	APPLIED CONSUMER SERVICES INC, HILEAH GARDENS, FL - EIR, 483, CO RESP 1/12
2013-1718	03/05/2013 04/02/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	WALTER E. CHALKLEY THOMSON REUTERS	HILL DERMACEUTICALS INC, SANDFORD, FL - EIR, 483, CO RESP 3/12
2013-1719	03/05/2013 04/02/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	WALTER E. CHALKLEY THOMSON REUTERS	HEMARUS LLC, JACKSONVILLE, FL - EIR, 483, CO RESP 3/12

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2013-1720	03/05/2013 04/24/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E. CHALKLEY THOMSON REUTERS	COREPHARMA LL, MIDDLESEX, NJ - EIR, 483, CO RESP 2/11
2013-1721	03/05/2013 04/02/2013	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	WALTER E. CHALKLEY THOMSON REUTERS	HOSPIRA, LAKE FOREST, IL - EIR, 483, CO RESP 1/13
2013-1722	03/05/2013 04/02/2013	FDA/OGROP/ORACE-FO/PHIDO/PHI-CB/	WALTER E. CHALKLEY THOMSON REUTERS	ABBEY COLOR INC, PHILADELPHIA, PA - EIR, 483, CO RESP 3/13-23/12
2013-1723	03/05/2013 04/02/2013	FDA/OGROP/ORAPA-FO/SEADO/SEA-CB/	WALTER E. CHALKLEY THOMSON REUTERS	MICHAEL E. RING MD, SPOKANE, WA - EIR, 483, CO RESP 8/23/12
2013-1724	03/05/2013 04/02/2013	FDA/OGROP/ORASE-FO/FLADO/FLA-CB/	WALTER E. CHALKLEY THOMSON REUTERS	MARK PINSKY MD, PALM BEACH GARDENS, FL - EIR, 483, CO RESP 9/17-28/12
2013-1725	03/05/2013 04/02/2013	OC/CVM/OCD/	KRISTI O. SMEDLEY, Ph.D. WASHINGTON INFORMATION SOURCE	ANHYDROUS AMMONIA - CATTLE FOOD ADDITIVE PETITION CORR, RVWS, APRVL
2013-1726	03/05/2013 04/02/2013	OC/CVM/OCD/	KRISTI O. SMEDLEY, Ph.D. WASHINGTON INFORMATION SOURCE	ANHYDROUS AMMONIA - FOOD ADDITIVE PETITION MF 3673 CORR, RVW, APRVL
2013-1727	03/05/2013 04/02/2013	OC/CVM/OCD/	KRISTI O. SMEDLEY, Ph.D. WASHINGTON INFORMATION SOURCE	ANHYDROUS AMMONIA - DAIRY FOOD ADDITIVE PETITION MF 3555 CORR, RVWS, APRVL
2013-1728	03/05/2013 04/02/2013	OC/ORORM/ OC/ORORM/	GAIL LESSICK LACHMAN CONSULTANT SERVICES INC	DRUG COMPANIES, MEDICAL DVC MANUFACTURING, BIORESEARCH MONITORING - INSP 1/13
2013-1729	03/07/2013 04/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Peter Gallagher ZBI	VALEANT PHARMACEUTICALS - COMPLAINTS RE SAFETY, MARKETING, GMP COMPLIANCE (03/01/2008 - 03/01/2013)
2013-1730	03/07/2013 04/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7350
2013-1731	03/07/2013 04/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-1919
2013-1732	03/07/2013 04/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8176
2013-1733	03/07/2013 04/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-5493

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2013-1734	03/07/2013 04/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-4172
2013-1735	03/07/2013 04/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7572
2013-1736	03/07/2013 04/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	VILDAGLIPTON - PEDIATRIC WRITTEN REQUEST FOR STUDIES
2013-1737	03/07/2013 04/04/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/ FDA/OGROP/ORA/SW-FO/DEN- DO/DEN-CB/	Jim McNair Jim McNair	FDA RESPONSE TO MAUDE REPORT
2013-1738	03/07/2013 04/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jim McNair Jim McNair	FDA RESPONSE TO MAUDE REPORT
2013-1739	03/07/2013 04/04/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tang S. Peng ChemWerth, Inc.	MICROTROL STERILIZATION SERVICES PVT LTD, KARNATAKA, INDIA - EIR
2013-1740	03/07/2013 04/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Doe J	APLISOL - AERS (03/05/2010 - 03/05/2013)
2013-1741	03/07/2013 04/04/2013	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	Catherine Bowen Barclays Research	HOSPIRA - 483 (02/25/2013 - 03/04/2013)
2013-1742	03/07/2013 04/04/2013	FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Jim McNair Jim McNair	DA VINCI ROBOTIC SURGICAL SYSTEM - LETTERS, MEMOS, REPORTS RE SAFETY CONCERNS
2013-1743	03/07/2013 04/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	AVANDIA - PEDIATRIC WRITTEN REQUEST FOR STUDIES

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-1744	03/07/2013 04/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	NASONEX 50 MCG - AERS
2013-1745	03/07/2013 04/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	Tycho Peterson J.P. Morgan Securities LLC	INTUITIVE SURGICAL, DA VINCI SURGERY - COMM BTWN FDA AND HOSPITALS, PHYSICIANS AS PART OF MEDSUN FROM 1/2006 TO PRESENT; SURVEY RECS
2013-1746	03/07/2013 04/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	QILU, JINAN, CHINA - EIR, WARNING LETTER, COMPANY RESPONSE ETC (06/28/2010 - 07/01/2010)
2013-1747	03/07/2013 04/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	AVANDIA - PEDIATRIC WRITTEN REQUEST FOR STUDIES
2013-1748	03/07/2013 04/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	TRAJENTA - PEDIATRIC WRITTEN REQUEST FOR STUDIES
2013-1749	03/07/2013 04/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	ONGLYZA - PEDIATRIC WRITTEN REQUEST FOR STUDIES
2013-1750	03/07/2013 04/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lakshmi Raghavan DermPathe Pharmaceuticals	ZOVIRAX OINTMENT - OPEN MANUFACTURING PROCESS IN NDA
2013-1751	03/07/2013 04/04/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	David Mangione Govzilla, Inc.	CATALENT PHARMA SOLUTIONS LLC, MORRISVILLE, NC - 483 (02/14/2013 - 02/14/2013)
2013-1752	03/07/2013 04/04/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Barbara Kowinsky KOWINSKY, BARBARA	THIBIANT LABORATORIES, CHATSWORTH, CA - EIR, WARNING LETTER, VIOLATIONS (01/03/2011 - 03/30/2012)
2013-1753	03/07/2013 04/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING &	AVANDAMENT - PEDIATRIC WRITTEN REQUEST FOR STUDIES

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SUBMISSIONS	
2013-1754	03/07/2013 04/04/2013	FDA/OGROP/ORO/SE-FO/ATL- DO/ATL-CB/	Jessica Fye J.P. Morgan Securities LLC	HOSPIRA, ROCKY MOUNT, NC - 483 (02/01/2013 - 03/05/2013)
2013-1755	03/07/2013 04/04/2013	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	SUBSTANTIAL EQUIVALENCE FOR TOBACCO PRODUCTS FEB 2013
2013-1756	03/07/2013 04/04/2013	FDA/OC/OES/DFOI/	Johnathan Rickman FDANEWS	FOIA REQUEST LOG (02/25/2013 - 03/01/2013)
2013-1757	03/07/2013 04/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jim McNair Jim McNair	FDA CONCERNS ABOUT DA VINCI SURGICAL SYSTEM SAFETY
2013-1758	03/07/2013 04/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Hana Camarillo Pacific University School of Pharmacy	XARELTO - POSTMARKETING SAFETY DATA FOR TWO NEW INDICATIONS
2013-1759	03/07/2013 04/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	KOMBIGLYZE - PEDIATRIC WRITTEN REQUEST FOR STUDIES
2013-1760	03/07/2013 04/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	JANUMET - PEDIATRIC WRITTEN REQUEST FOR STUDIES
2013-1761	03/07/2013 04/04/2013	FDA/OGROP/ORO/SE-FO/ATL- DO/ATL-CB/	Chris Kuehnle LEERINK SWANN & CO	HOSPIRA, ROCKY MOUNT, NC - 483 (02/28/2013 - 03/06/2013)
2013-1762	03/07/2013 04/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	JENTADUETA - PEDIATRIC WRITTEN REQUEST FOR STUDIES
2013-1763	03/07/2013 04/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	JUVISYNC - PEDIATRIC WRITTEN REQUEST FOR STUDIES
2013-1764	03/07/2013	FDA/OGROP/ORO/SE-FO/ATL-	Michael Marini	CAPSUGEL INC, GREENWOOD, SC - EIR (06/21/2011 -

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	04/04/2013	DO/ATL-CB/	Capsugel Inc.	12/31/2011)
2013-1765	03/07/2013 04/04/2013	FDA/OGROP/ORPA-FO/SAN-DO/SAN-CB/	Tom East Tom East Consulting	IMPAX LABORATORIES, HAYWARD, CA - 483 (01/07/2013 - 03/05/2013)
2013-1766	03/07/2013 04/04/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Shibani Malhotra RBC CAPITAL MARKETS	HOSPIRA, ROCKY MOUNT, NC - (03/01/2013 - 03/06/2013)
2013-1767	03/07/2013 04/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	AVANDARYL - PEDIATRIC WRITTEN REQUEST FOR STUDIES
2013-1768	03/07/2013 04/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/OM/OMP/DDM/	Bethany Farmer INFOTRIEVE	PRESENTATION OF EFFICACY RESULTS OF SINGLE-DOSE ANALGESICS FOR STUIES USING ACUTE PAIN MODELS
2013-1769	03/07/2013 04/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	Joyce Dobervich Estill Medical Technologies, Inc.	K012031
2013-1770	03/07/2013 04/04/2013	OC/ORPA/ OC/ORPA/ FDA/OGROP/ORPA-FO/LOS-DO/LOS-CB/	Mark Prinz Registrar Corp	ENTRY NUMBER DO7-8403124-0
2013-1771	03/07/2013 04/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K121216
2013-1772	03/07/2013 04/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K102788
2013-1773	03/07/2013 04/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K071187
2013-1774	03/07/2013 04/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K010051
2013-1775	03/07/2013 04/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K002172
2013-1776	03/07/2013 04/04/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dr. Christine James Sound Sleep Health	HCG FOR WEIGHT LOSS - AERS (01/01/2000 - 02/28/2013)

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2013-1777	03/07/2013 04/04/2013	OC/OSMP/OOPD/ FDA/OMPT/OSMP/OOPD/	Rachel Johnson FOI Services, Inc.	MOD-423 ORPHAN DESIGNATION
2013-1778	03/07/2013 04/04/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	Brian Brown Carlson, Gaskey & Olds	ANSAR GROUP, PHILADELPHIA, PA - WARNING LETTER RECS, INVESTIGATION (01/01/2010 - 03/06/2013)
2013-1779	03/07/2013 04/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K093799
2013-1780	03/07/2013 04/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	Ellen Zimmerman ClearView Diagnostics In.	K080935
2013-1781	03/07/2013 04/04/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	Pinar Cakir EKIN KIMYA TIC. LTS. STI.	AVANTOR PERFORMANCE MATERIALS, PARIS, KY - EIR 12/2010
2013-1782	03/07/2013 04/04/2013	FDA/OFVM/CFSAN/OCD/EOS/	Lauren Farruggia Hyman, Phelps and McNamara	COFFEE BEVERAGES - CAERS (01/01/2004 - 10/23/2012)
2013-1783	03/07/2013 05/30/2013	FDA/OC/OES/DFOI/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	David Mangione Govzilla, Inc.	PFIZER, PEARL RIVER, NY; HOSPIRA, ROCKY MOUNT, NC; CRUCELL, BERNE, SWITZERLAND, ETC - INSPECTION RECS
2013-1784	03/08/2013 04/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Daniel Kantor Daniel Kantor	GILENYA - AERS

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2013-1785	03/08/2013 04/05/2013	FDA/OFVM/CFSAN/OCD/EOS/	Daniel Tokar Pinnacle Foods LLC	TROPIJUGOS, SA, SANTO DOMINGO, DR - EIR, 483 (02/01/2013 - 03/01/2013)
2013-1786	03/08/2013 04/05/2013	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	HERBALIFE - AERS
2013-1787	03/08/2013 04/05/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Rachel Johnson FOI Services, Inc.	HERBALIFE - EIR, 483 FROM LOS, SAN, ATL (01/01/2003)
2013-1788	03/08/2013 04/05/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Yigal Nochomovitz Morgan Stanley	HOSPIRA, ROCKY MOUNT, NC - 483 (02/12/2013 - 03/01/2013)
2013-1789	03/08/2013 04/05/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	David Gregoire ALGORITHMHE PHARMA INC	PHARMANET CANANDA, QUEBEC, CANADA; PHARMA MEDICA RESEARCH INC MISSISSAUGA, CANADA; PRACS INSTITUTE LTD, S FARGO, ND ETC - 483 (01/01/10)
2013-1790	03/08/2013 04/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FARAH JAVID-MAJD University of Houston College of Pharmac	IV ZOLEDRONIC ACID, PAMIDRONATE - MEDWATCH RECS
2013-1791	03/08/2013 04/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	David Hermelin Xeragenx LLC	NDA 016635, ANDA 084264, NDA 016635 ETC
2013-1792	03/08/2013 04/05/2013	FDA/OC/OES/DFOI/	Pam Williams Williams, Pam	HOSPIRA - 483, WARNING LETTERS (01/03/2011 - 03/29/2013)
2013-1793	03/08/2013	OC/ORA/OE/	Kaitlin Wowak	RECALL DATA SPREADSHEETS (01/01/2004 - 03/07/2013)

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	04/05/2013	OC/ORAOE/	UNIVERSITY OF NOTRE DAME	
2013-1794	03/08/2013 04/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Leo Trevino Liquidia Technologies, Inc.	XALATAN - SBA
2013-1795	03/08/2013 04/05/2013	FDA/OGROP/ORAOCE-FO/DET-DO/DET-CB/	Ed Silverman PHARMALOT	PFIZER, TERRE HAUTE, IN - 483 (01/03/2012 - 12/31/2013)
2013-1796	03/08/2013 04/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dustin Block IPD ANALYTICS LLC	ANDA 090999 - EFFECTIVE APPROVAL LETTER
2013-1797	03/08/2013 04/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K770717
2013-1798	03/08/2013 04/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PAMELA SHEPPARD TARO PHARMACEUTICALS USA INC	LEO PHARMA AS - DOVONEX (CALCIPOTRIENE) CREAM NDA 20-554 SBA
2013-1799	03/08/2013 04/05/2013	FDA/OC/OES/DFOI/	ARMOUR, STEPHANIE	SALMONELLA, E COLI, LISTERIA OUTBREAKS ASSOCIATED WITH RESTAURANTS, RETAILERS, FARMS 2009 TO 7/6/12
2013-1800	03/08/2013 04/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN G BERGMAN HELSELL FETTERMAN LLP	GLAXOSMITHKLINE - LAMICTAL TABS NDA 20-241 APRVL LTR, RVWS, LBLG, ETC
2013-1801	03/08/2013 04/05/2013	FDA/OC/OES/DFOI/ OC/ORAO/ OC/ORAO/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	TONY CORBO Food & Water Watch	KASEL ASSOCIATED INDUSTRIES INC, DENVER. CO - INSPS, PROD TESTING 2/13

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		FDA/OC/OES/DFOI/ FDA/OGROP/ORACE-FO/DET-DO/DET-CB/		
2013-1802	03/08/2013 04/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	FRANZ MENEAN MEDAGENT INC	K112121 - LBLG, INSTRUCTIONS FOR USE, IFU STATEMENTS
2013-1803	03/08/2013 04/05/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	STEVE STROUPHAUER BD LEE LABS	LEE LABS, GRAYSON, GA - EIR 9/6-28/07
2013-1804	03/08/2013 04/05/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	ROMAN ROZENFELD POINTSTATE CAPITAL LP	HOSPIRA, ROCKY MOUNT - 483 2/13
2013-1805	03/08/2013 04/05/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	GENENTECH INC - EIR, 483, CO RESP 8/12
2013-1806	03/08/2013 04/05/2013	FDA/OFVM/CFSAN/OCD/EOS/	DEENA KALAI PLLC	CHANEL, LANCOME, CLINIQUE, ETC - COSMETIC PROD INGREDIENT STATEMENTS
2013-1807	03/08/2013 04/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARC RENDELL MD ASNDI	NOVO NORDISK - INSULIN DEGLUDEC APRVL RECS
2013-1808	03/08/2013 04/05/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	MICHAEL R COHEN RPH MS SCD INSTITUTE FOR SAFE MEDICATION PRACTICES	MEDWATCH RPTS CODED AS MEDICATION ERRORS 2/1-28/13
2013-1809	03/08/2013 04/05/2013	FDA/OC/OES/DFOI/	CHARLIE NETTLETON HEALTHCOR MANAGEMENT LP	HOSPIRA INC - EIRS, 483S, UNTITLED LTRS, ETC 3/1/10 TO 3/1/13
2013-1810	03/08/2013 04/05/2013	OC/CVM/OCD/	KRISTI O SMEDLEY PHD WASHINGTON INFORMATION SOURCE	NATIONAL COTTONSEED PRODUCTS ASSN - FAP 2172
2013-1811	03/08/2013 04/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	THOMPSON JR, THOMAS W	DENTAL FLOSS - CLNCL TESTINGS, STANDARDS, CLASSIFICATION, ETC
2013-1812	03/08/2013 04/05/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	CHRISTINE S RICHARD INDAGO GROUP	INTUITIVE SURGICAL INC, SUNNYVALE, CA - DA VINCI ROBOTIC SURGERY SYS SAFETY, MDRS, TRAINING RECS
2013-1813	03/08/2013	FDA/OMPT/CDER/ORP/DIDP/	ELAINE S WALLER PHARM D	ADCETRIS (BRENTUXIMAB VEDOTIN) - ISRS 8454532,

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	04/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MBA SEATTLE GENETICS INC	8486800, 8621754, ETC
2013-1814	03/08/2013 04/05/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	MARGARET M GROVES JD DUKE UNIV/SCHOOL OF MEDICINE	KIMBERLY BLACKWELL MD, DUKE UNIV MEDICAL CTR, DURHAM, NC - EIR, CLOSE OUT LTR 6/5-7/12
2013-1815	03/08/2013 04/05/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	MARGARET MGROVES JD DUKE UNIV/SCHOOL OF MEDICINE	SARAH H LISANDBY MD, DUKE UNIV MEDICAL CTR, DURHAM, NC - EIR 10/11-129/12
2013-1816	03/08/2013 04/05/2013	OC/ORA/ OC/ORA/	Matt Cine/Jeremy Cain GIDEON COOPER & ESSARY	CENTRAL ADMIXTURE PHARMCY SERVICES INC, CHICAGO, IL - EIRS 1/1/10 TO PRESENT
2013-1817	03/08/2013 04/24/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OC/OES/DFOI/	CAHRLES CELESTE EAS CONSULTING GROUP LLC	NOVARTIS VACCINES & DIAGNOSTICS, EMERYVILLE, CA - EIR 5/12
2013-1818	03/08/2013 04/05/2013	OC/ORA/ OC/ORA/	JOHN-MARK ZINI GIDEON COOPER & ESSARY	WEDGEWOOD PHARMACY, SWEDESBORO, NJ - EIRS 1/1/10 TO PRESENT
2013-1819	03/08/2013 04/05/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	CHARLES CELESTE EAS CONSULTING GROUP LLC	ORASURE TECHNOLOGIES, BETHLEHEM, PA - 483, EIR, CO RESP, WARNING LTR 1/03 TO PRESENT
2013-1820	03/08/2013 04/05/2013	OC/ORA/ OC/ORA/	JOHN-MARK ZINI GIDEON COOPER & ESSARY	APOTHECURE INC, SALLAS, TX - EIRS 1/1/10 TO PRESENT
2013-1821	03/08/2013 04/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	TONY HURTADO Liberty Mutual Fire Insurance Company	NATIONAL MARKETING LLC, ANAHEIM, CA - ESTABLISHMENT REGISTRATION, LICENSING RECS, CORR, ETC
2013-1822	03/08/2013 04/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	TONY HURTADO Liberty Mutual Fire Insurance Company	ASPEN MEDICAL RESOURCES LLC, ANAHEIM, CA - ESTABLISHMENT REGISTRATION, LICENSING RECS, CORR, ETC
2013-1823	03/08/2013 04/15/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	CHARLES CELESTE EAS CONSULTING GROUP LLC	SIEMENS HEALTH CARE DIAGNOSTICS INC, TARRYTOWN, NY - 483, EIR, WARNING LTR, CO RESP 1/03 TO PRESENT
2013-1824	03/08/2013 04/05/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	CHARLES CELESTE EAS CONSULTING GROUP LLC	SIEMENS HEALTHCARE DIAGNOSTICS INC, BERKELEY, CA - EIR, 483, WARNING LTR, CO RESP 1/03 TO PRESENT
2013-1825	03/08/2013 04/05/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	CHARLES CELESTE EAS CONSULTING GROUP LLC	ORTHO CLINICAL DIAGNOSTICS INC, ROCHESTER, NY - EIR, 483, WARNING LTR, CO RESP 1/03 TO PRESENT
2013-1826	03/08/2013 08/08/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CBER/OCOD/DDOM/	CHARLES CELESTE EAS CONSULTING GROUP LLC	ORTHO CLINICAL DIAGNOSTICS INC, RARITAN, NJ - 483, EIR, WARNING LTR, CO RESP 1/03 TO PRESENT

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		ALFB/		
2013-1827	03/08/2013 04/24/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	CHARLES CELESTE EAS CONSULTING GROUP LLC	ABBOTT LABS POINT OF CARE, PRINCETON, NJ - 483, EIR, WARNING LTR, CO RESP 1/03 TO PRESENT
2013-1828	03/08/2013 04/05/2013	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	CHARLES CELESTE EAS CONSULTING GROUP LLC	ABBOTT DIAGNOSTICS, LAKE FOREST, IL - 483, EIR, WARNING LTR, CO RESP 1/03 TO PRESENT
2013-1829	03/08/2013 04/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	CHARLES CELESTE EAS CONSULTING GROUP LLC	ABBOTT, WIESBADEN, GERMANY - EIR, 483, WARNING LTR, CO RESP 1/03 TO PRESENT
2013-1830	03/08/2013 04/05/2013	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	CHARLES CELESTE EAS CONSULTING GROUP LLC	ABBOTT MOLECULAR, DES PLAINES, IL - EIR, 483, WARNING LTR, CO RESP 1/03 TO PRESENT
2013-1831	03/08/2013 04/05/2013	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/ FDA/OC/OES/DFOI/	CHARLES CELESTE EAS CONSULTING GROUP LLC	ABBOTT LABS, ABBOTT PARK, IL - EIR, 483, WARNING LTR, CO RESP 1/03 TO PRESENT
2013-1832	03/08/2013 04/05/2013	OC/CVM/OCD/	Scott Krygier BASF Corp.	FORMIC ACID, FORMATE - ANIMAL SAFETY STUDIES
2013-1833	03/08/2013 04/05/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Michael Rich Raymond James & Associates	HOSPIRA, ROCKY MOUNT, NC - 483 (03/01/2013 - 03/08/2013)
2013-1834	03/08/2013 04/05/2013	FDA/OC/OES/DFOI/	STEVE RITTKE BALYASNY ASSET MANAGEMENT	ST JUDE MEDICAL, SYLMAR, CA - 483 1/12 TO 3/5/13
2013-1835	03/08/2013 04/05/2013	FDA/OC/OES/DFOI/	STEVE RETTKE BALYASNY ASSET MANAGEMENT	HOSPIRA INC, ROCKY MOUNT, NC - 483 1/12 TO 3/5/13
2013-1836	03/08/2013 04/05/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	STEVE RETTKE BALYASNY ASSET MANAGEMENT	IMPAX LABS, HAYWARD, CA - 483 1/12 TO 3/5/13
2013-1837	03/08/2013 04/05/2013	OC/ORACE-FO/DET-DO/DET-CB/	JOHN MARK ZINI GIDEON COOPER & ESSARY	PHARMEDIUM LLC, LAKE FOREST, IL - EIR SINCE 1/10
2013-1838	03/08/2013 04/05/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	JOHN MARK ZINI GIDEON COOPER & ESSARY	PHARMACIA UPJOHN, KALAMAZOO, MI - EIR 2002
2013-1839	03/08/2013 04/05/2013	OC/ORACE-FO/DET-DO/DET-CB/	JOHN-MARK ZINI GIDEON COOPER & ESSARY	LEE SILSBY COMPOUNDING PHARMACY , CLEVELAND HEIGHTS, OH - EIR SINCE 1/10

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2013-1840	03/08/2013 04/05/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	MANOJ K. GARG HEALTHCO	HOSPIRA, ROCKY MOUNT, NC - 483 3/1/13
2013-1841	03/08/2013 04/05/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	CYNTHIA PATINO LEWIS BRISBOIS ET AL	POMONA VALLEY HOSPITAL CTR - INSP, CMLPNTS, CORR 2002 TO PRESENT
2013-1842	03/08/2013 04/05/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	BETH RYAN LOMMEN ABDO COLE KING STAGEBERG PA	INDIVIDUAL RECS
2013-1843	03/08/2013 04/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SUZANNE KETTERIDGE NEW HAMPSHIRE PUBLIC DEFENDER	FETANYL PATCHES - AER 1997 TO 2013
2013-1844	03/08/2013 04/05/2013	FDA/OC/OES/DFOI/	WENEEKE, HURLEY	GENERIC DRUG APPLICATIONS & DENIALS
2013-1845	03/11/2013 04/08/2013	OC/OR/ OC/OR/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Cheryl CONSUMER	ZI XIU TANG BEE POLLEN - MANUFACTURER
2013-1846	03/11/2013 04/08/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Law Offices of Ronald A. Marron Law Offices of Ronald A. Marron	NATURE'S INNOVATION, INC - CORR, COMM WITH FDA (12/19/2008 - 03/06/2013)
2013-1847	03/11/2013 04/08/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Law Offices of Ronald A. Marron Law Offices of Ronald A. Marron	HEEL, INC. - CORR, COMM WITH FDA
2013-1848	03/11/2013 04/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Walter Cordiglia ReflexionHealth, Inc	K943430
2013-1849	03/11/2013 04/08/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Law Offices of Ronald A. Marron Law Offices of Ronald A. Marron	DIAL CORPORATION - CORR, COMM WITH FDA (01/01/2009 - 03/06/2013)

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-1850	03/11/2013 04/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Del Stringham Stringham, Del J	LEVOTHRYOXINE - IN VIVO BIOAVAILABILITY DATA, TABLET DISSOLUTION DATA
2013-1851	03/11/2013 04/08/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Robert Langreth BLOOMBERG NEWS	INTUITIVE SURGICAL DA VINCI SURGICAL SYSTEM - CORR, EMAILS, RECS RE APPROVAL, CLEARANCE
2013-1852	03/11/2013 04/08/2013	FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	Kasie Davis Davis, Kasie L	COVENANT HEALTH SYSTEM, LUBBOCK, TX - DEATHS (01/01/2009 - 12/31/2011)
2013-1853	03/11/2013 04/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Andrew Keyser Keyser, Andrew L	AMBIEN - EFFECTIVE DOSE, CONCENTRATION , STUDIES
2013-1854	03/11/2013 04/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Brent Ardaugh Framingham Heart Study	K903205, K914190, K801589 ETC
2013-1855	03/11/2013 04/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Brent Ardaugh Framingham Heart Study	K823351
2013-1856	03/11/2013 04/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K110824
2013-1857	03/11/2013 04/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Brent Ardaugh Framingham Heart Study	K983393, K896919, K003819
2013-1858	03/11/2013 04/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Brent Ardaugh Framingham Heart Study	K970481, K955628, K955854 ETC
2013-1859	03/11/2013 04/08/2013	FDA/OGROP/ORA/CE-FO/CHI- DO/CHI-CB/ FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/ FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	Jessica Wong GENERAL MILLS	GENERAL MILLS, WEST CHICAGO, IL; GENERAL MILLS, MUFREESBORO, TN; GENERAL MILLS, BELVIDERE, IL; ETC - EIR, 483, RESPONSE

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		FDA/OGROP/ORPA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/		
2013-1860	03/11/2013 04/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Thuc Quyen Nguyen Thuc Quyen Nguyen	SUMATRIPTAN - AERS
2013-1861	03/11/2013 04/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	JD Webb The OrthoMedix Group, Inc.	K112736
2013-1862	03/11/2013 04/08/2013	OC/OSMP/OOPD/ FDA/OMPT/OSMP/OOPD/	Faryal Hasan Hyman, Phelps & McNamara P.C.	COLCHINE - ORPHAN DRUG DESIGNATION RECS
2013-1863	03/11/2013 04/08/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	Law Offices of Ronald A. Marron Law Offices of Ronald A. Marron	NATURAL BALANCE, NUTRACEUTICAL - COMM, CORR WITH FDA(1/01/2006 - 03/08/2013)
2013-1864	03/11/2013 04/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Brent Ardaugh Framingham Heart Study	K872235, K860540, K803676
2013-1865	03/11/2013 04/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Alan S. Ryan, PhD Sancilio and Company, Inc.	FLUOGUM - SBA
2013-1866	03/11/2013 04/08/2013	FDA/OC/OES/DFOI/	GREENBERG, K BEN	ARICEPT - RECS
2013-1867	03/11/2013 04/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	INDIVIDUAL RECS
2013-1868	03/11/2013 04/08/2013	OC/ORPA/ OC/ORPA/ FDA/OGROP/ORPA/PA-FO/LOS-DO/LOS-CB/	CHRISTOPHER M KANE SIMON GLUCK & KANE LLP	FOOD AND SWEETS TRADING GMBH, OESCHGEN, SWITZERLAND - INSPECTOR NOTES, EMAILS, LAB RESULTS, ETC
2013-1869	03/11/2013 04/08/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	PETER J SOMERA JR SOMERA & SILVA LLP	STRYKER - NEPTUNE S ULTRA WASTE MANAGEMENT SYS MDRS, RECALLS, APRVLS, ETC

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2013-1870	03/11/2013 04/08/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORANE-FO/NYK- DO/NYK-DCB/ FDA/OGROP/ORA/ORO/DIOP/	MICHAEL J VILLEGIANTE ESQ WELTIN STREB & WELTIN	MOON MARINE CORP, MOON FISHERY PVT LTD, OCEAN QUEEN SEAFOOD INC, ETC - SALMONELLA OUTBREAK INVESTIGATION RECS, CORR 2012
2013-1871	03/11/2013 04/08/2013	FDA/OGROP/ORASE-FO/FLA- DO/FLA-CB/	K MICHELLE VASSALLO LINCARE INC	RX STAT INC, FL - EIRS, 483S, WARNING LTRS 1/1/05 TO PRESENT
2013-1872	03/11/2013 04/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	ROGER SONNENBURG BAYER HEALTHCARE LLC	MILES LABS - K831600
2013-1873	03/11/2013 04/08/2013	FDA/OGROP/ORASW-FO/KAN- DO/KAN-CB/	VICTOR GREEN KCAS LLC	KCAS LLC, SHAWNEE, KS - EIR 7/18-22/11
2013-1874	03/11/2013 04/08/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	WENDY JO ROGERS CORSON & JOHNSON LAW FIRM	AMIODARONE - AERS 1/1/01 TO PRESENT
2013-1875	03/11/2013 04/08/2013	FDA/OO/OHR/	JOCELYN SKINNER ESQ HOUSE OF RUTH MARYLAND INC	INDIVIDUAL RECS
2013-1876	03/11/2013 04/08/2013	FDA/OFVM/CFSAN/OCD/EOS/	MICHELLE LEVINSON NATURAL RESOURCES DEFENSE COUNCIL	PRIORITY BASED ASSESSMENT OF FOOD ADDITIVE DATABASE (PAFA)
2013-1877	03/11/2013 04/08/2013	FDA/OGROP/ORASE-FO/FLA- DO/FLA-CB/	DOUGLAS N BLUE II ZETETIC INC	CASES OF CHOCOLATES SMLU3281673 - RECS
2013-1878	03/11/2013 04/08/2013	FDA/OGROP/ORASE-FO/FLA- DO/FLA-CB/	DOUGLAS N BLUE II ZETETIC INC	CASES OF CHOCOLATES SMLU3135013A - RECS
2013-1879	03/11/2013 04/08/2013	FDA/OFVM/CFSAN/OCD/EOS/	GREENBERG, BEATRICE	CORN REFINERS ASSN, WASHINGTON, DC - CORR REGARDING USE OF THE TERM NATURAL TO DESCRIBE HIGH FRUCTOSE CORN SYRUP
2013-1880	03/11/2013 04/08/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	CHARLES CELESTE EAS Consulting Group, LLC	ORTHO0CLINICAL DIAGNOSTICS INC/JOHNSON & JOHNSON, WYCOMBE, BUCKINGHAMSHIRE, UK - EIRS, 483S, WARNING LTRS, ETC 1/103 TO PRESENT
2013-1881	03/11/2013 04/08/2013	FDA/OGROP/ORACE-FO/CHI- DO/CHI-CB/	CHARLES CELESTE EAS CONSULTING GROUP LLC	ABBOTT LABS, ABBOTT PARK, IL - EIRS, 483S, WARNING LTRS, ETC 1/03 TO PRESENT
2013-1882	03/11/2013 04/08/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	SCOTT A HANNA ZUCKERMAN SPAEDER LLP	IRON-O-VITA NDA 01-885, VITABLE NDA 01-285 - APRVL RECS

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2013-1883	03/11/2013 04/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	MARK A KOPEC HABCO INDUSTRIES LLC	PACIFIC PRECISION PRODUCTS - PORTABLE OXYGEN GENERATOR K120566
2013-1884	03/11/2013 04/08/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	JUBILANT HOLLISTER STIER, QUEBEC, CANADA - 483 3/19-26/12
2013-1885	03/11/2013 04/08/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	JUBILANT HOLLISTER STIER, QUEBEC, CANADA - EIR 3/19-26/12
2013-1886	03/11/2013 04/08/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	MUJIB U QIDWAI GRIFOLS BIOLOGICALS INC	OCTAPharma AB, STOCKHOLM, SWEDEN - EIR, 483 1/10-20/11
2013-1887	03/11/2013 04/08/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	MUJIB U QIDWAI GRIFOLS BIOLOGICALS INC	CSL BEHRING, VICTORIA, AUSTRALIA - EIRS, 483S 1/10 TO 12/12
2013-1888	03/11/2013 04/08/2013	OC/OM/OMP/DDM/	ROSS RENDELMANN HOGAN LOVELLS LLP	DKT FDA-2013-P-0070, FDA-2012-P-1103
2013-1889	03/11/2013 04/08/2013	OC/OM/OMP/DDM/	ROSS RENDELMAN HOGAN LOVELLS LLP	DKT FDA-2013-P-0058
2013-1890	03/11/2013 04/08/2013	OC/OM/OMP/DDM/	FATIMA ASLAM Keller and Heckman LLP	DKT FDA-2012-S-1178, FDA-199-S-0039
2013-1891	03/11/2013 04/08/2013	OC/OM/OMP/DDM/	MARILYNN WHITNEY COVINGTON BURLING LLP	DKT FDA-2012-P-0904
2013-1892	03/12/2013 04/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Heather Neely Kinamed Incorporated	K102834, K013982, K072250 ETC
2013-1893	03/12/2013 04/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jeanne Truitt Smiths-Medical	DRUG FOR TISSUE DAMAGE, EXTRAVASATION - AERS
2013-1894	03/12/2013 04/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	AMANTADINE - AERS

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2013-1895	03/12/2013 04/09/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	Doe J	ORTHO DIAGNOSTIC SYSTEMS, RARITAN, NY - EIR, AERS
2013-1896	03/12/2013 04/09/2013	FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	Brent Arbogast Critical Process Filtration	AGRIFLU - 483, COMPARABILITY STUDY, ETC (07/10/2008 - 03/08/2013)
2013-1897	03/12/2013 04/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Juha-Pekka Nuutinen Mectalent Medical Services	K053225
2013-1898	03/12/2013 04/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	FLECTOR - PATENT TERM EXTENSION CORR
2013-1899	03/12/2013 04/09/2013	FDA/OFVM/CFSAN/OCD/EOS/	Douglas Barasatian citizens petition	BLEACHED WHITE FLOUR - APPROVAL AGENTS
2013-1900	03/12/2013 04/09/2013	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	Scott Talbot Gavis Pharmaceuticals, LLC	GAVIS PHARMACEUTICALS, SOMERSET, NJ - EIR (03/05/2010)
2013-1901	03/12/2013 04/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Deborah Sontag THE NEW YORK TIMES	SUBOXONE, SUBUTEX, BUTRANS - AERS (10/08/2002 - 03/10/2013)
2013-1902	03/12/2013 04/09/2013	FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/ FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Charles Hunger Charles Hunger	BOSTON SCIENTIFIC PROTEGEN MESH SLING - RECALL LETTER 1/22/99, CORR
2013-1903	03/12/2013 04/09/2013	FDA/OFVM/CFSAN/OCD/EOS/	Mike Snodgrass TriSep Corporation	EXEMPTION FILE 97-016 FOOD CONTACT
2013-1904	03/12/2013 04/09/2013	FDA/OFVM/CFSAN/OCD/EOS/	Andrew Sullivan WINSTON & STRAWN LLP	WESTERN SUGAR COOPERTATIVE, MICHIGAN SUGAR COMPANY, MICHIGAN SUGAR COMPANY ETC - CORR RE HIGH FRUCTOSE CORN SYRUP (01/01/2005 - 03/11/2013)
2013-1905	03/12/2013	FDA/OMPT/CDER/GRP/DIDP/	Kyle Davis	SSRI DRUGS - AERS

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	04/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MICHIGAN STATE UNIVERSITY	
2013-1906	03/12/2013 04/09/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	John D. Morris 4LIFE RESEARCH LC	CBS NUTRITION, LINDON, UT - EIR AUGUST 2012
2013-1907	03/12/2013 04/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	gerald cagle cagle, gerald d	AMYVID - SBA
2013-1908	03/12/2013 04/09/2013	FDA/OFVM/CFSAN/OCD/EOS/	Andrew Sullivan WINSTON & STRAWN LLP	CAPRI SUN MOUNTAIN COOLER - CORR RE SUGAR
2013-1909	03/12/2013 04/09/2013	FDA/OFVM/CFSAN/OCD/EOS/	Doe J	PHENYLKETONURIS, ASCOBIC ACID - CAERS
2013-1910	03/12/2013 04/09/2013	OC/CVM/OCD/	JEFFREY S GULLEY GOVERNMENT ACCOUNTABILITY PROJECT	SALE OF ANTIMICROBIAL DRUGS FOR USE IN FOOD-PRODUCING ANIMALS - RECS
2013-1911	03/12/2013 04/09/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	CATHY L BURGESS ALSTON & BIRD LLP	HOSPIRA, ROCKY MOUNT, NC - 483, CORR 1/13 TO PRESENT
2013-1912	03/12/2013 04/17/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/ FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/ OC/ORA/ORO/DFS/	BENJAMIN L ENGLAND ESQ BENJAMIN L ENGLAND & ASSOCIATES LLC	TRICYCLAZOLE, BUPROFEZIN, ISOPROTHIOLANE IN RICE - METHODOLOGY VALIDATION TESTING

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		OC/ORO/ORO/DFS/		
2013-1913	03/12/2013 04/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	ELIZABETH A BATTS ULMER & BERNE LLP	DR 180-II K001288, HOLTER FOR WINDOWS K930564, DR 180+OXY K004007 (CERTIFIED)
2013-1914	03/12/2013 04/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	PETER HUMPHRIES DUNCAN BASHEER HANNON	DEPUY - LCS3PEG MOD ROT PATELLA POROCOAT, LCS INSET TROCHLEAR CMPLNTS, MDRS
2013-1915	03/12/2013 04/09/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	JAMES J GIBSON JR PHD INTEGRITY LIFE SCIENCES	EXCITE MEDICAL CORP - 482S, 483S, CORR, ATTACHMENTS, ETC
2013-1916	03/12/2013 04/09/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	K MICHELLE VASSALLO LINCARE INC	RAYTEL CARDIAC SERVICES INC (PHILIPS REMOTE CARDIAC SERVICES), CT - EIRS, 483S, WARNING LTRS 1/05 TO PRESENT
2013-1917	03/12/2013 04/09/2013	OC/OSMP/OOPD/	CORBIN, D JONATHAN	PRIMOCURE PHARMA INC - 3-BROMOPYRUVATE RECS
2013-1918	03/12/2013 04/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	LORI SMITH MERIAL	THIODIPROPIONIC ACID, DILAURYL & DISTEARYL ESTERS - PHARMACOLOGY & TOXICOLOGY FINAL RPT
2013-1919	03/12/2013 04/09/2013	FDA/OMPT/CTP/OD/	REGINALD C BARRETT JR CAROLINA TOBACCO MANUFACTURERS LLC	ALTERNATIVE BRANDS INC - INGREDIENT LIST
2013-1920	03/12/2013 04/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	DEAN IRWIN RA MEDICAL SYSTEMS INC.	SPECTRANETICS - CVX-300 EXCIMER SYS SERIVCE MANUAL
2013-1921	03/12/2013 04/09/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	KAREN DONOVAN MEDPHARMA PARTNERS LLC	SAFECOR HEALTH LLC, COLUMBUS, OH - EIRS, 483S, WARNING LTRS 2010-2012
2013-1922	03/12/2013 04/09/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	KAREN DONOVAN MEDPHARMA PARTNERS LLC	SAFECOR HEALTH LLC, WOBURN, MA - EIRS, 483S, WARNING LTRS 2010-2012
2013-1923	03/12/2013 04/09/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	KAREN DONOVAN MEDPHARMA PARTNERS LLC	UDL LABS, ROCKFORD, IL - EIRS, 483S, WARNING LTRS 2010-2012
2013-1924	03/12/2013 04/09/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	KAREN DONOVAN MEDPHARMA PARTNERS LLC	CARDINAL HEALTH, ZANESVILLE, OH - EIRS, 483S, WARNING LTRS 2010-2012
2013-1925	03/12/2013 04/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Nanette LoDolce Baker Botts	K924969
2013-1926	03/12/2013	FDA/OMPT/CDER/GRP/DIDP/	Heather Munro Prescott	NDA 18680

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	04/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OO/OIM/OPILS/DDM/	CENTRAL CONNECTICUT STATE UNIVERSITY	
2013-1927	03/13/2013 04/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Joanna Veres ClearView Diagnostics Inc.	K993802
2013-1928	03/13/2013 04/10/2013	FDA/OC/OES/DFOI/	Johnathan Rickman FDANEWS	FOIA REQUEST LOG (03/04/2013 - 03/08/2013)
2013-1929	03/13/2013 04/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Andrew Goldsmith CANACCORD GENUITY	REMODULIN - COMPLETE RESPONSE LETTER
2013-1930	03/13/2013 04/10/2013	FDA/OGROP/ORR/SE-FO/ATL- DO/ATL-CB/	Thomas McGrath AMRI-Burlington	DSM PHARMACEUTICALS, INC, GREENVILLE, NC - WARNING LETTER AND REPSONSES (04/02/2012 - 03/12/2013)
2013-1931	03/13/2013 04/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachael Flanagan Leopold Law, PA	GLOBUS MEDICAL, INC TRANSITION 2 LEVEL IMPLANT - ADVERSE EVENTS, IMPLANT TRACKING STICKERS, LOT NUMBERS ETC (07/13/2012 - 03/12/2013)
2013-1932	03/13/2013 04/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	7748236 7750172 7752230 ETC - MEDWATCH REPORTS
2013-1933	03/13/2013 04/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	jesse polansky jmp	CRESTOR - SUBMISSION AND APPROVAL RECS
2013-1934	03/13/2013 04/10/2013	FDA/OGROP/ORR/NE-FO/NYK- DO/NYK-DCB/	William D. Sanders McGivney & Kluger, P.C.	NBTY - RECALL RECS
2013-1935	03/13/2013 04/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dr. Ross Ross, Kevin	AMBIEN - PEDIATRIC WRITTEN REQUEST
2013-1936	03/13/2013 05/06/2013	OC/ORR/ OC/ORR/	Carol Reynolds Reynolds, Carol A	NUTRO - COMPLAINTS (08/01/2012 - 03/11/2013)

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2013-1937	03/13/2013 04/10/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Mary Gustafson PPTA	PLASMA DONOR FATALITIES - TABLE OF FINAL CONCLUSIONS FY12
2013-1938	03/13/2013 04/10/2013	FDA/OO/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Shin Kang WELLS FARGO SECURITIES	KALYDECO - AERS
2013-1939	03/13/2013 04/10/2013	OC/CVM/OCD/	John Hallberg Hallberg, John W	NADA 134930 FOIA SUMMARY
2013-1940	03/13/2013 04/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	3696536 3755232 4040349 ETC - MEDWATCH REPORTS
2013-1941	03/13/2013 04/10/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/SEA- DO/SEA-CB/	Doe J	COMPLAINT 130596, FOLLOW UP
2013-1942	03/13/2013 04/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Stryker Sustainability Solutions STRYKER SUSTAINABILITY SOLUTIONS	K121240, K032676, K122511
2013-1943	03/13/2013 04/10/2013	FDA/OMPT/CTP/OD/	Lauren Channell Siegfried & Jensen	ELECTRONIC CIGARETTES - ADVERSE EVENTS
2013-1944	03/13/2013 04/10/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Stryker Sustainability Solutions STRYKER SUSTAINABILITY SOLUTIONS	K31011,K092879
2013-1945	03/13/2013 04/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	PROMETRIUM - AERS
2013-1946	03/13/2013 04/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Paul Banwatt Gilbert's LLP	DEAR HEALTH CARE PROFESSIONAL LETTER RE DRUGS 2/3/89
2013-1947	03/13/2013	FDA/OMPT/CDER/ORP/DIDP/	JACQUELINE KILLEN	ADDERALL XR - APRVL

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	04/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HILLYARD WAHLBERG ET AL	
2013-1948	03/13/2013 04/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JACQUELINE KILLEN HILLYARD WAHLBERG ET AL	AMPHETAMINE; DEXTROAMPHETAMINE - APRVL
2013-1949	03/13/2013 04/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JACQUELINE KILLEN HILLYARD WAHLBERG ET AL	ADDERALL - APRVL
2013-1950	03/13/2013 04/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	ELISA TOSTADO STRYKER SUSTAINABILITY SOLUTIONS	REPROCESSED ENDOSCOPITC TROCARS K121240; ENDOPATH BLADELESS TROCAR K032676; ENDOPATH BLADELESS TROCAR K122511
2013-1951	03/13/2013 04/10/2013	FDA/OGROP/ORAP/PA-FO/SAN-DO/SAN-CB/	MATTHEW E. KONOSKY UBS GLOBAL ASSET MANAGEMENT	IMPAX LABS, HAYWARD, CA - 483
2013-1952	03/13/2013 04/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN GREENHAM SYSTAGENIX	RADIOMETER COMBINED O2, CO2, SP02 K043003; PERIMED TRANSCUTANEOUS O2, CO2 MONITOR K990960
2013-1953	03/13/2013 04/10/2013	FDA/OGROP/ORAP/CE-FO/PHI-DO/PHI-CB/	ALEXIS ERAZO MEDCOMP INC	MEDCOMP, HARLEYSVILLE, PA - EIR 5/03
2013-1954	03/13/2013 04/10/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	ELLIOT FAVUS, M.D. FAVUS INSTITUTIONAL RESEARCH LLC	BAXTER - GAMMA GARD LIQUID VAERS 1/06 TO PRESENT
2013-1955	03/13/2013 04/10/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	LIANE LaROCHELLE DEKA RESEARCH & DEVELOPMENT CORP	LIFESCAN INC - ONE TOUCH VERIO BLOOD GLUCOSE MONITORING SYS INC K093745
2013-1956	03/13/2013 04/10/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORAP/CE-FO/PHI-DO/PHI-CB/	BRUCE D. GOODMAN STEINBERG GOODMAN & KALISH	SYNTHES - PANGEA SYS APRVL, MDRS, EIRS, ETC 2000 TO PRESENT
2013-1957	03/13/2013 04/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID C. WEBER BEHREND & ERNSBERGER PC	PRENISONONE - LBLG CHANGES 1990 TO PRESENT
2013-1958	03/13/2013	FDA/OMPT/CDER/ORP/DIDP/	SUZANNE KETTERIDGE	FETANYL - AERS 1997 TO 2013

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	04/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	NEW HAMPSHIRE PUBLIC DEFENDER	
2013-1959	03/13/2013 04/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	JEANNE BAKER DEPUY ORTHOPAEDICS INC	HIP REPLACEMENT CONTENT
2013-1960	03/13/2013 04/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	REA TANOSHIMA, MD HOSPITAL FOR SICK CHILDREN	KEPPRA (LEVETIRACETAM) - ISRS 6549236, 3853599, 7155070, ETC
2013-1961	03/14/2013 04/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	HUMIRA - SUPPEMENTAL APPROVAL RECS
2013-1962	03/14/2013 04/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Marc Tewey Cerium Pharmaceuticals	CORTROSYN - SBA
2013-1963	03/14/2013 04/11/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Tina O'Brien Terumo BCT	BK090058
2013-1964	03/14/2013 04/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	Augusta Cerny Shire Regenerative Medicine	K061711
2013-1965	03/14/2013 04/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tina Babos IPD ANALYTICS LLC	ANDA 078813, ANDA 078817, ANDA 090849 ETC - APPROVAL LETTERS
2013-1966	03/14/2013 04/11/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OO/OIM/OPILS/DDM/	Kevin Wyckoff ORTHO CLINICAL DIAGNOSTICS INC	RECEPTAN-N - RECLASSIFICATION PETITION
2013-1967	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	Amy Kincanon LEXISNEXIS COURTLINK INC	2012-7732
2013-1968	03/14/2013 04/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Arvinder Singh Kirax Corp.	HYDROCODONE, ACETAMINOPHEN, HYDROCODONE - NDA RECS

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		FDA/OMPT/CDER/ORP/DIDP/		
2013-1969	03/14/2013 04/11/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Michelle D. Johnson Johnson, Michelle D	INFLUENZA VACCINE - ADVERSE EVENTS IN MARYLAND (01/01/2009 - 01/01/2013)
2013-1970	03/14/2013 04/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jennifer Dittman Vertex Pharmaceuticals Incorporated	BLA 125427
2013-1971	03/14/2013 04/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	EXELON - PROMOTIONAL RECS
2013-1972	03/14/2013 04/11/2013	FDA/OO/OFBA/OAGS/	MICHAEL MORISY MUCKROCK NEWS	BOOZ ALLEN HAMILTON - CONTRACTS, FINAL RPTS LAST 5 YRS
2013-1973	03/14/2013 04/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORASE-FO/ATL- DO/ATL-CB/ FDA/OC/OES/DFOI/	A LUKE SMITH FARUQI & FARUQI LLP	SANDOZ - SKELAXIN ANDA 40-445 EIRS, CORR, RECS
2013-1974	03/14/2013 04/11/2013	FDA/OGROP/ORASE-FO/ATL- DO/ATL-CB/	RACK, RALPH	CYCLE-TEX INC, DALTON, GA - REMOVAL OF MEDICAL DVCS PHOTOS, CORR, RECS
2013-1975	03/14/2013 04/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	RICHARD KELLER BRUNO INDEPENDENT LIVING AIDS INC	WHEELCHAIR ELEVATORS MARKETED IN THE US - TRADE CMLNT 9/5/12
2013-1976	03/14/2013 04/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELSPETH CALLAHAN INDEPENDENCE LEGAL SUPPORT	PALATIN TECHNOLOGIES - PT141 (BREMELANOTIDE) PHASE III CLNCL TRIAL APPL LTR 8/07
2013-1977	03/14/2013 04/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	COLCORD, JARED S	BAVITUXIMAB - APRVL OF BREAKTHROUGH DESIGNATION APPL
2013-1978	03/14/2013	FDA/OMPT/CBER/OCOD/DDOM/		BIOVEST - BIOVAX ID MTG TRANS 11/2/12

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	04/11/2013	ALFB/	HILL, MICHAEL	
2013-1979	03/14/2013 04/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	KIM FINCH CHOICE SPINE LP	EBI LLC - SOLITAIRE-C CERVICAL SPACER SYS K113796
2013-1980	03/14/2013 04/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	KIM FINCH CHOICE SPINE LP	SYNTHES SPINE CO LP - SYNTHES ZEO-P K112459
2013-1981	03/14/2013 04/11/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	KIM FINCH CHOICE SPINE LP	RSB SPINE LLC - INTERPLATE C K092070
2013-1982	03/14/2013 04/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	KIM FINCH CHOICE SPINE LP	RSB LLC - INTERPLATE INTERBODY FUSION DVC K071922
2013-1983	03/14/2013 04/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	KIM FINCH CHOICE SPINE LP	STRYKER CORP - HOFFMANN 3 MODULAR EXTERNAL FIXATION SYS K121252
2013-1984	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2010-2061
2013-1985	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-1546
2013-1986	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2010-8205
2013-1987	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2010-2951
2013-1988	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-5871
2013-1989	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-3578
2013-1990	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2010-7023
2013-1991	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2010-3778
2013-1992	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-3884
2013-1993	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-1039
2013-1994	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-6310

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2013-1995	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2010-8374
2013-1996	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-4231
2013-1997	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	DAVID MacFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOI LOG 2/25/13-3/1/13
2013-1998	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	DAVID MacFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOI LOG 2/18-22/13
2013-1999	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	CLOSED FOI LOG 2/18-22/13
2013-2000	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	CLOSED FOI LOG 2/25/13-3/1/13
2013-2001	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 2/25/13-3/1/13
2013-2002	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	FOI LOG 2/18-22/13
2013-2003	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	FOI LOG 2/25/13-3/1/13
2013-2004	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 2/18-22/13
2013-2005	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI LOG 2/25/13-3/1/13
2013-2006	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 2/18/13-2/22/13
2013-2007	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 2/25/13-3/1/13
2013-2008	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 2/18-22/13
2013-2009	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 2/18-22/13
2013-2010	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 2/25/13-3/1/13

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2013-2011	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 2/18-22/13
2013-2012	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	DEBRA L. COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 2/25/13-3/1/13
2013-2013	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 2/25/13-3/1/13
2013-2014	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	SANDY FRIEDMAN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 2/18-22/13
2013-2015	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 2/25/13-3/1/13
2013-2016	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 2/18-22/13
2013-2017	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY CLOSED LOG 2/25/13-3/1/13
2013-2018	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 2/18-22/13
2013-2019	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	GLADYS B. TONKIN WASHINGTON INFORMATION SOURCE	DAILY LOG 2/18-22/13
2013-2020	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	GLADYS B. TONKIN WASHINGTON INFORMATION SOURCE	DAILY LOG 2/25/13-3/1/13
2013-2021	03/15/2013 04/12/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	THOMAS O HELTON BAKER DONELSON ET AL	MIR-CON LLC, CENTRAL CITY, PA - EIR, 483 6/7/12, CORR 6/19/12, ETC
2013-2022	03/15/2013 04/12/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	GORDON JOHNSTON GORDON JOHNSTON REGULATORY CONSULTANTS LLC	HOSPIRA, ROCKY MOUNT, NC - 483 1/1-31/13, 2/20/13-3/10/13
2013-2023	03/15/2013 04/12/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	K MICHELLE VASSALLO LINCARE INC	CARDIAC EVALUATION SERVICES INC, CT - ERIS, 483S, WARNING LTRS 1/05 TO PRESENT
2013-2024	03/15/2013 04/12/2013	OC/ORAOE/ OC/ORAOE/	GREENBERG, BEATRICE	TOTAL NUMBER OF CLASS I AND CLASS II FOOD RECALLS FY2012

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2013-2025	03/15/2013 04/12/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	JAMES J GIBSON JR INTEGRITY LIFE SCIENCES	HILL LABS, FRAZER, PA - EIRS, 482S, 483S, ETC 1/09 TO PRESENT
2013-2026	03/15/2013 04/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	JAMES J GIBSON JR INTEGRITY LIFE SCIENCES	HTRD GROUP HONG KONG LTD, HONG KONG, CHINA - EIRS, 482S, 483S, ETC 1/09 TO PRESENT
2013-2027	03/15/2013 04/12/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	JAMES J GIBSON JR INTEGRITY LIFE SCIENCES	ADVANCED BACK TECHNOLOGIES INC, HAUPPAUGE, NY - EIRS, 482S, 483S, ETC 1/09 TO PRESENT
2013-2028	03/15/2013 04/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	JAMES J GIBSON JR INTEGRITY LIFE SCIENCES	UNIVERSAL PAIN TECHNOLOGY CANADA INC, PRINCE GEORGE, CANADA - EIRS, 482S, 483S, ETC 1/09 TO PRESENT
2013-2029	03/15/2013 04/12/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	JAMES J GIBSON JR INTEGRITY LIFE SCIENCES	NORTH AMERICAN MEDICAL CORP, MARIETTA, GA - EIRS, 482S, 483S, ETC 1/09 TO PRESENT
2013-2030	03/15/2013 04/12/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN K GRANT ROBBINS GELLER ET AL	IMPAX LABORATORIES INC - RYTARY (IPX066) CMLNLS, INVESTIGATIONS,RPTS, ETC 2010 TO 2013
2013-2031	03/15/2013 04/12/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	JOHN K GRANT ROBBINS GELLER ET AL	IMPAX LABORATORIES INC - 483S, COMM, WARNING LTRS 2010- TO 2013
2013-2032	03/15/2013 04/12/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OES/	LAURA TURNER JUDICIAL WATCH	GLUTEN-FREE LBLG - CORR, CONTACTS WITH CELIAC DIEASE ALLIANCE, PAMELA'S PRODUCTS, OFFICE OF INFORMATION AND REGULATORY AFFAIRS (OIRA), ETC
2013-2033	03/15/2013 04/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	JASON SMITH BEDFONT SCIENTIFIC LTD	TABATABA BREATH CO MONITOR K080278
2013-2034	03/15/2013 04/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KOBAYASHI, RIEKO	GUIDELINES FOR CLINICAL EVALUATION OF LIPID-ALTERING AGENTS IN ADULTS AND CHILDREN
2013-2035	03/15/2013 04/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELLIOT FAVUS MD FAVUS INSTITUTIONAL	ADCETRIS (BRENTUXIMAB VEDOTIN) - AERS 5/12 TO PRESENT

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RESEARCH LLC	
2013-2036	03/15/2013 04/12/2013	FDA/OO/OFBA/OAGS/	ROSE SANTOS FOIA GROUP INC	HHSF2232008500151 - CONTRACT, MODIFICATIONS, ORDERS
2013-2037	03/15/2013 04/12/2013	FDA/OO/OFBA/OAGS/	ROSE SANTOS FOIA GROUP INC	HHSF2232008500211 - CONTRACT, MODIFICATIONS, ORDERS
2013-2038	03/15/2013 04/12/2013	FDA/OO/OFBA/OAGS/	ROSE SANTOS FOIA GROUP INC	HHSF2232008500191 - CONTRACT, MODIFICATIONS, ORDERS
2013-2039	03/15/2013 04/12/2013	FDA/OO/OFBA/OAGS/	ROSE SANTOS FOIA GROUP INC	HHSF2232008500201 - CONTRACT, MODIFICATIONS, ORDERS
2013-2040	03/15/2013 04/12/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-5860
2013-2041	03/15/2013 04/12/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-4677
2013-2042	03/15/2013 04/12/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-5904
2013-2043	03/15/2013 04/12/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-5494
2013-2044	03/15/2013 04/12/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-5632
2013-2045	03/15/2013 04/12/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-5653
2013-2046	03/15/2013 04/12/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-4156
2013-2047	03/15/2013 04/12/2013	FDA/OGROP/ORP/SW-FO/KAN-DO/KAN-CB/	David Mangione Govzilla, Inc.	HOSPIRA, MCPHERSON, KS - EIR (10/01/2012 - 11/01/2012)
2013-2048	03/15/2013 04/12/2013	OC/ORP/OCI/ OC/ORP/OCI/ FDA/OGROP/ORP/PA-FO/LOS-DO/LOS-CB/	JOSEPH MASI SPORTS RESEARCH IN SAN PEDRO CALIFORNIA	SPORTS RESEARCH - INVESTIGATION
2013-2049	03/15/2013 04/12/2013	FDA/OGROP/ORP/SE-FO/ATL-DO/ATL-CB/	David Mangione Govzilla, Inc.	CATALENT PHARMA SOLUTIONS LLC, MORRISVILLE, NC - EIR 02/14/13
2013-2050	03/15/2013	FDA/OC/OES/DFOI/	David Mangione	483S RELEASED SINCE 04/13/2012

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	04/26/2013		Govzilla, Inc.	
2013-2051	03/18/2013 04/15/2013	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	HOSPIRA, ROCKY MOUNT, NC - EIR, 483, WARNING LETTER
2013-2052	03/18/2013 04/15/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Aegis Regulatory Inc. AEGIS REGULATORY INC	CAROL COLE COMPANY TRINITY WRINKLE REMOVER DEVICE - USER MANUAL, PREDICATE CHART, OUTER LABEL
2013-2053	03/18/2013 04/15/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Deborah Hilts Cenestra, LLC	RILUZOLE - SBA
2013-2054	03/18/2013 04/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Thomas Hirte Boston Scientific Endoscopy	K050578
2013-2055	03/18/2013 04/15/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ryan Thompson Watts Guerra Craft LLP	NESINA (ALOGLIPTIN BENZOATE - AERS, ANALYSIS, DETAILED REPORTS, SAFETY/EPIDEMIOLOGY REPORTS
2013-2056	03/18/2013 04/15/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ryan Thompson Watts Guerra Craft LLP	TRADJENTA (LINAGLIPTIN) - AERS, ANALYSIS, DETAILED REPORTS, ETC
2013-2057	03/18/2013 04/15/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Scott Fawcett Carroll Quality Consult, Inc.	NDA 022029
2013-2058	03/18/2013 04/15/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Christine Garner RECORDTRAK	NATIONAL MEDICAL SERVICES LABS, WILLOW GROVE, PA - 483, LAB RESULTS (01/03/2006 - 03/14/2013)
2013-2059	03/18/2013 04/15/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Jennifer Moore Regard Law Group	FEED SAMPLE 750441
2013-2060	03/18/2013 04/15/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Christine Garner RECORDTRAK	MEDTOX LABORATORIES, ST PAUL, MN - 483, EIR (01/03/2006 - 03/14/2013)
2013-2061	03/18/2013 04/15/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Azanta A/S Azanta A/S	METRONIDAZOLE - SBA

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2013-2062	03/18/2013 04/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Augusta Cerny Shire Regenerative Medicine	K113104
2013-2063	03/18/2013 04/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Richard Wright Wright, Richard	STRYKER REJUVENATE, STRYKER ABG - INSTRUCTIONS FOR USE
2013-2064	03/18/2013 04/15/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	Linda Bowen SANOFI	DOW CHEMICAL CO, PLAQUEMINE, LA - EIR (02/07/2013 - 02/13/2013)
2013-2065	03/18/2013 04/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Augusta Cerny Shire Regenerative Medicine	K123356
2013-2066	03/18/2013 04/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Melanie Johnson none	K103392
2013-2067	03/18/2013 04/15/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Peter Gallagher ZIFF BROTHERS INVESTMENTS	VALEANT PHARMACEUTICALS - AERS
2013-2068	03/18/2013 04/15/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Kristan Phillips MacroGenics	GENENTECH - 483 (03/01/2012 - 03/14/2013)
2013-2069	03/18/2013 04/15/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Melanie Johnson none	K013931
2013-2070	03/18/2013 04/15/2013	FDA/OFVM/CFSAN/OCD/EOS/	Maria Jesus Perez Columbia University (student)	ENERGY DRINKS - AERS, COMPLAINTS
2013-2071	03/18/2013 06/07/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	TYLER KENYON NORTHCOAST RESEARCH	STRYKER CORP, PORTAGE, MI - WARNING LTR 11/12; INTEGRA LIFESCIENCES, PALINSBORO, NJ - WARNING LTR; INTEGRA LIFESCIENCES, PUERTO RICO - CO RESP
2013-2072	03/18/2013 04/15/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	MICHAL KAHAN LEV EL DIAGNOSTICS OF HEART DISEASES LTD	LEV EL LTD - HEARTTRENDS K021825; BIOSENSOR CORP - AMBULATORY (HOLTER) RECORDING SYS K950944
2013-2073	03/18/2013 04/15/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	MARGARET M. GROVES, JD. DUKE UNIV/SCHOOL OF MEDICINE	DR KENNETH W MAHAFFEY, DUKE CLNCL RESEARCH INSTITUTE, DURHAM, NC - EIR 8/20-24/12
2013-2074	03/18/2013 04/15/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SE-FO/ATL-	HAYGOOD, TRACY	INDIVIDUAL RECS

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		DO/ATL-CB/		
2013-2075	03/18/2013 04/15/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HOLLAND, CHRIS	MARQIBO KIT (VINCRISTINE SULFATE) NDA 202497 APRVL
2013-2076	03/18/2013 04/15/2013	FDA/OGROP/ORAP/PA-FO/SAN-DO/SAN-CB/	MATTHEW E. KONOSKY UBS GLOBAL ASSET MANAGEMENT	IMPAX LABS, HAYWARD, CA - 483 7/09 TO 8/09
2013-2077	03/18/2013 04/15/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PEGGY J. BERRY AMARIN PHARMA INC	VASCEPA (ICOSAPENT ETHYL) NDA 202-057 - UNREDACTED RVW
2013-2078	03/18/2013 04/15/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN K. GRANT ROBBINS GELLER ET AL	IMPAX LABS INC - FENOFIBRATE ANDA 75-868 Cmplnts, INVESTIGATIONS 2010 TO 2013
2013-2079	03/18/2013 04/15/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN K. GRANT ROBBINS GELLER ET AL	IMPAX LABS INC - CONCERTA NDA 21-121 Cmplnts, INVESTIGATIONS 2010-2013
2013-2080	03/18/2013 04/15/2013	FDA/OFVM/CFSAN/OCD/EOS/	GERALDINE E. EDENS BAKER & HOSTETLER, LLP	ALBEMARLE CORP - FCN 1197
2013-2081	03/18/2013 04/15/2013	FDA/OFVM/CFSAN/OCD/EOS/	GERALDINE E. EDENS BAKER & HOSTETLER, LLP	ENVIRO TECH CHEMICAL SERVICES INC - FCN 944
2013-2082	03/18/2013 04/15/2013	FDA/OFVM/CFSAN/OCD/EOS/	GERALDINE E. EDENS BAKER & HOSTETLER, LLP	ENVIRO TECH CHEMICAL SERVICES INC - FCN 1098
2013-2083	03/18/2013 04/16/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORAP/SE-FO/ATL-DO/ATL-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORAP/SE-FO/ATL-DO/ATL-CB/	TRISH McGRADE PRITZKER OLSEN	SIMPLY THICK - INSP RECS, CORR
2013-2084	03/18/2013 07/19/2013	FDA/OGROP/ORAP/PA-FO/SAN-DO/SAN-CB/	WILLIAM S. NORTON MOTLEY RICE LLC	HOSPIRA - INSP, INVESTIGATIONS 6/08 TO 1/12

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		FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/		
2013-2085	03/18/2013 04/15/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	JONES, GERALDINE	SANOFI-AVENTIS GROUP - FLUZONE VAERS
2013-2086	03/19/2013 04/16/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Law Offices of Ronald A. Marron Law Offices of Ronald A. Marron	NATURAL BALANCE, NATURE'S BALANCE, DIAL CORPORATION, ETC - COMM, CORR WITH FDA (01/01/2004 - 03/14/2013)
2013-2087	03/19/2013 04/16/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ryan Thompson Watts Guerra Craft LLP	A 3 MONTHS PANCREATIC STUDY IN A DIABETIC RODENT TREATED WITH SITAGLIPTIN - RESULTS, CONCLUSIONS
2013-2088	03/19/2013 04/16/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ryan Thompson Watts Guerra Craft LLP	A PROSPECTIVE OBSERVATIONAL COHORT STUDY TO EXAMINE THE INCIDENCE OF PANCREATIC MALIGNANCY AND THYROID NEOPLASM IN PATIENTS WITH TYPE 2 DIABETES MELLITUS INITIATED ON BYETTA COMPARED TO PATIENTS INITIATED OTHER ANTIDIABETIC AGENTS
2013-2089	03/19/2013 04/16/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ryan Thompson Watts Guerra Craft LLP	JANUMET, JANUMET XR - OSE REVIEWS OR REPORTS RE AERS, ANALYSIS OF AERS, DETAILED AERS ETC
2013-2090	03/19/2013 04/16/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ryan Thompson Watts Guerra Craft LLP	ONGLYZA - OSE REVIEWS OR REPORTS RE AERS, ANALYSIS OF AERS, DETAILED AERS ETC

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-2091	03/19/2013 04/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ryan Thompson Watts Guerra Craft LLP	BYDUREON - OSE REVIEWS OR REPORTS RE AERS, ANALYSIS OF AERS, DETAILED AERS ETC
2013-2092	03/19/2013 04/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ryan Thompson Watts Guerra Craft LLP	JUVISYNC - OSE REVIEWS OR REPORTS RE AERS, ANALYSIS OF AERS, DETAILED AERS ETC
2013-2093	03/19/2013 04/16/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	John Shoemaker Visium	ALERE, SAN DIEGO, CA - 483, RESPONSE (01/01/2012 - 03/14/2013)
2013-2094	03/19/2013 04/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ryan Thompson Watts Guerra Craft LLP	JANUVIA - OSE REVIEWS OR REPORTS RE AERS, ANALYSIS OF AERS, DETAILED AERS ETC
2013-2095	03/19/2013 04/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ryan Thompson Watts Guerra Craft LLP	BYETTA - OSE REVIEWS OR REPORTS RE AERS, ANALYSIS OF AERS, DETAILED AERS ETC
2013-2096	03/19/2013 04/16/2013	FDA/OC/OES/DFOI/ FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	LORI MISCOE LORI MISCOE	COMPLAINT
2013-2097	03/19/2013 04/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ryan Thompson Watts Guerra Craft LLP	VICTOZA - OSE REVIEWS OR REPORTS RE AERS, ANALYSIS OF AERS, DETAILED AERS ETC
2013-2098	03/19/2013 04/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ryan Thompson Watts Guerra Craft LLP	OSENI - OSE REVIEWS OR REPORTS RE AERS, ANALYSIS OF AERS, DETAILED AERS ETC
2013-2099	03/19/2013 04/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Robert W Caverly Indirect Cost	COMPASSIONATE INVESTIGATIONAL DRUG APPLICATION FOR CANNIBIS USE THROUGH THE 1968 DRUG SUPPLY PROGRAM

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2013-2100	03/19/2013 04/16/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ni Sun Alkermes, Inc.	ABILIFY MAINTENA - SBA
2013-2101	03/19/2013 04/16/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sheila Albeke Oregon Health Science Center	NESINA, KAZANO, OSENI - APPROVAL PACKAGE
2013-2102	03/19/2013 04/16/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kathy McGown FOXKISER	ELECTRONIC VERSION OF THE 32ND ANNUAL EDITION OF THE ORANGE BOOK
2013-2103	03/19/2013 04/16/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Heather Goldman Goldman, Heather	HUMIRA - AERS
2013-2104	03/19/2013 05/17/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Rachel Johnson FOI Services, Inc.	BK090058
2013-2105	03/19/2013 04/16/2013	FDA/OFVM/CFSAN/OCD/EOS/	Jack Beidleman Idahoan Foods, LLC	CAERS162495
2013-2106	03/19/2013 04/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K033181
2013-2107	03/19/2013 04/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K090871
2013-2108	03/19/2013 04/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Michelle Garcia Garcia, Michelle	ESSURE - CLASSIFICATION AS CLASS III DEVICE, PREMARKET APPROVAL
2013-2109	03/19/2013 04/16/2013	FDA/OFVM/CFSAN/OCD/EOS/	Sage Leehey University of Nevada, Reno	FDA'S DECISION TO RECOGNIZE GENETICALLY MODIFIED FOOD ORGANISM AS GENERALLY RECOGNIZED AS SAFE
2013-2110	03/19/2013 04/16/2013	FDA/OC/OES/DFOI/	Andrew Finkelstein Susquehanna Financial Group	HOSPIRA, ROCKY MOUNT, NC - 483 MARCH 2013
2013-2111	03/19/2013	FDA/OGROP/ORO/SE-FO/FLA-	Scott Fawcett	KAPPA LABORATORIES, MIAMI, FL - 483, EIR 2003 TO 2013

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	04/16/2013	DO/FLA-CB/	Carroll Quality Consult, Inc.	
2013-2112	03/19/2013 04/16/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	CELESTONE 6MG INJECTABLE STEROID - AERS
2013-2113	03/19/2013 04/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Thomas Rehorst Dentaurum, Inc.	K942667
2013-2114	03/19/2013 04/16/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ryan Thompson Watts Guerra Craft LLP	ALOGLIPTIN - OSE REVIEWS OR REPORTS RE AERS, ANALYSIS OF AERS, DETAILED AERS ETC
2013-2115	03/19/2013 04/16/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ryan Thompson Watts Guerra Craft LLP	JENTADUETO - OSE REVIEWS OR REPORTS RE AERS, ANALYSIS OF AERS, DETAILED AERS ETC
2013-2116	03/19/2013 04/16/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ryan Thompson Watts Guerra Craft LLP	KOMBIGLYZE XR - OSE REVIEWS OR REPORTS RE AERS, ANALYSIS OF AERS, DETAILED AERS ETC
2013-2117	03/19/2013 04/16/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ryan Thompson Watts Guerra Craft LLP	PANCREATIC CANCER, PANCREATITIS - SAFETY OR EPIDEMIOLOGICAL STUDIES, SAFETY CONCERNS, AND INCRETIN MIMETIC CLASS OF DRUGS
2013-2118	03/19/2013 04/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Elisa Hebb Elisa Hebb	K112119 SAFETY AND EFFECTIVENESS SUMMARY
2013-2119	03/19/2013 04/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	E.J. Smith Smith Associates	K983016
2013-2120	03/19/2013 04/16/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	ANDA 77991
2013-2121	03/19/2013 04/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	E.J. Smith Smith Associates	K050906

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2013-2122	03/19/2013 04/16/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	YVONNE M FLAHERTY LOCKRIDGE GRINDAL NAUEN PLLP	ST JUDE MEDICAL, SYLMAR, CA - EIR EXHIBITS 1-42, CMLNPTS, INVESTIGATIONS, ETC
2013-2123	03/19/2013 04/16/2013	FDA/OFVM/CFSAN/OCD/EOS/	KEVIN W LEONARD GRUNFELD DESIDERIO ET AL	SEIKO MARINE SDN BHD, MALAYSIA - INTERNATIONAL INSPS 1993 TO PRESENT
2013-2124	03/19/2013 04/16/2013	OC/ORA/ OC/ORA/ OC/ORA/OCI/ OC/ORA/OCI/	DANIEL R LAPINSKI ESQ WILENTZ GOLDMAN & SPITZER PA	RAM MEDICAL INC - COUNTERFEIT POLYPROPYLENE SURGICAL MESH RECS
2013-2125	03/19/2013 04/16/2013	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	DONALD N BLUE ZETETIC INC	CTNS SIM SENS IOSMIL SOY TSCW10592719 - RECS
2013-2126	03/19/2013 04/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	NATALIE N SANDERS LATHAM & WATKINS LLP	ISONEA (KARMELOSONIX) - PULMOTRACK 2020 SYS K102229
2013-2127	03/19/2013 04/16/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Doe J	INDIVIDUAL RECS
2013-2128	03/19/2013 04/16/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	CHARLES CELESTE EAS CONSULTING GROUP LLC	HERBS OF LIGHT, ALACHUA, FL - 483S 8/1/12-10/1/12
2013-2129	03/19/2013 04/16/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	THOMAS T67081, KEITH	MARINOL. CANNABINOIDS - SBA, ADDRESS OF MFRS, CLNCL RECS, ETC
2013-2130	03/19/2013 04/16/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	CHLOE BOWER SYNGEN INC	MEDTRONIC SOFAMOR DANEK USA INC - MAGELLAN AUTOLOGOUS PLATELET SEPARATOR SYS BK040068
2013-2131	03/19/2013 04/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	VIK BAJNATH ARTHREX INC	MDR 2963226
2013-2132	03/19/2013 04/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	DAVID BLOCH MEDTRONIC	CARDIOMEMS - WARNING LTR RESP
2013-2133	03/19/2013 04/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	BARRY G STANIFORD NIPRO Diagnostics	MW5029053
2013-2134	03/19/2013 04/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	CHRISTINE FORGUES MORGAN LEWIS & BOCKIUS LLP	SILVERSTEAM AND DERMASEPT K093227
2013-2135	03/19/2013 04/16/2013	OC/ORA/ OC/ORA/	NORAH BURTON FOODMATCH INC	ENTRY #DP4-0615057-4 - LAB ANALYSIS

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2013-2136	03/19/2013 04/16/2013	OC/ORO/ OC/ORO/	NORAH BURTON FOODMATCH INC	GREEN CASTEL VETRANO OLIVES ENTRY #NE9-9502212-0/10-1 - LAB ANALYSIS
2013-2137	03/19/2013 04/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	ROBIN L ROWE STRYKER CORP	BLUE BELL TECHNOLOGIES INC - NAVIOPFS K121936
2013-2138	03/19/2013 04/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	ROBIN L ROWE STRYKER INCUBATION OF MEDICAL TECHNOLOGY	STANMORE IMPLANTS WORLDWIDE LTD - SCULPTOR ROBOTIC GUIDANCE ARM K121765
2013-2139	03/19/2013 04/16/2013	FDA/OGROP/ORO/CE-FO/BLT-DO/BLT-CB/	PATRICIA L REGENYE Celgene Corporation	HERBERT BARAF, ARTHRITIS RHEUMATISM ASSOC, WHEATON, MD - 483S 3/07 TO PRESENT
2013-2140	03/19/2013 04/16/2013	FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	PATRICIA L REGENYE Celgene Corporation	MARTIN MOLLEN, ARIZONA RES CTR, PHOENIX, AZ - 483S 3/02 TO PRESENT
2013-2141	03/19/2013 04/16/2013	FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/	PATRICIA L REGENYE Celgene Corporation	BARRY WINSTON, NORTH HOUSTON GASTROENTEROLOGY CLIN, HOUSTON, TX - 483S 4/05 TO PRESENT
2013-2142	03/19/2013 04/16/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PATRICIA L REGENYE Celgene Corporation	DANA TEGZOVA, RHEUMA INST, PRAGUE, CZE - 483S 10/10 TO PRESENT
2013-2143	03/19/2013 04/16/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PATRICIA L REGENYE Celgene Corporation	REMO PANACCIONE, PETER LOUGHEED CTR, CALGARY, CANADA - 483S 1/07 TO PRESENT
2013-2144	03/19/2013 04/16/2013	FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/	PATRICIA L REGENYE Celgene Corporation	DALE BRAMLET, FLORIDA ORTHO ASSOC, ST PETERSBURG, FL - 483S 6/06 TO PRESENT
2013-2145	03/20/2013 04/17/2013	FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Sabrina Korber CNBC Business News	INTUITIVE SURGICAL - CORR WITH FDA (01/01/1997 - 03/19/2013)
2013-2146	03/20/2013 04/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Neos Surgery S.L. Neos Surgery S.L.	K091432
2013-2147	03/20/2013 04/17/2013	FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	Rachel Johnson FOI Services, Inc.	HERBALIFE INTERNATIONAL, LOS ANGELES, CA - EIR ATTACHMENTS 05/18/07-05/22/2007
2013-2148	03/20/2013 04/17/2013	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	HERBALIFE, SUZHOU, CHINA - EIR, 483
2013-2149	03/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Ginger Neil	K071364

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	04/17/2013		Ripple, LLC	
2013-2150	03/20/2013 04/17/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/NWJ- DO/NWJ-CB/	JoNel Aleccia MSNBC.COM	MED PREP CONSULTING INC, TINTON FALLS, NJ - 483 (03/19/2001 - 03/19/2013)
2013-2151	03/20/2013 04/17/2013	OC/ORO/ OC/ORO/	Prashanth Jayaram CIG	ST JUDE MEDICAL - FIRST UPDATE TO 01/01/2013 WARNING LETTER
2013-2152	03/20/2013 04/17/2013	OC/ORO/ORM/ OC/ORO/ORM/	David Mangione Govzilla, Inc.	LIST OF 483S 02/21/2013 TO 03/19/2103
2013-2153	03/20/2013 04/17/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORO/SW-FO/KAN- DO/KAN-CB/	Rachel Johnson FOI Services, Inc.	KAN PAK, ARKANSAS CITY, KAN - 483, EIR TWO MOST RECENT
2013-2154	03/20/2013 04/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Bio-Matrix Scientific Group, Inc. / Regen BioPharma, Inc Schayltz, Seth	BIO-MATRIX SCIENTIFIC GROUP, INC, HEMAXELLERATE, REGEN BIOPHARMA - IND RECS
2013-2155	03/20/2013 04/17/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ana Cabrera KMGH-TV	HGH - AERS; REQUESTS TO USE DRUG OFF-LABEL (1/01/2008 - 03/19/2013)
2013-2156	03/20/2013 04/17/2013	FDA/OGROP/ORO/CE-FO/MIN- DO/MIN-CB/	Lori Hays Merz Aesthetics, Inc.	MERZ AESTHETICS, FRANKSVILLE, WI - EIR (3/14/2011 - 04/08/2011)
2013-2157	03/20/2013 04/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Courtney Goldsworthy Witt & Goldsworthy, PLLC	COVIDIEN PERMACOL - UNTITLED LETTERS, WARNING LETTERS, RECALLS ETC
2013-2158	03/20/2013 04/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ivan King Qi Oncology LLC	NDA 018154
2013-2159	03/20/2013 05/15/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Wendy Samford ThermoGenesis Corp.	BK940022
2013-2160	03/20/2013	FDA/OC/OES/DFOI/	Robert King	FOIA REQUEST LOG (03/11/2013 - 03/15/2013)

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	04/17/2013		FDANEWS	
2013-2161	03/20/2013 05/03/2013	FDA/OMPT/CTP/OD/ FDA/OC/OES/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	APPOINTMENT OF MITCH ZELLER AS CTP DIRECTOR
2013-2162	03/20/2013 04/17/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDRH/OCER/DFOI/	Pam Hayden NORTH AMERICAN SPINE SOCIETY	POWERPOINT PRESENTATIONS AT NASS SPINE FORUM
2013-2163	03/20/2013 04/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	E.J. Smith Smith Associates	K021939
2013-2164	03/20/2013 04/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	E.J. Smith Smith Associates	K023872
2013-2165	03/20/2013 04/17/2013	FDA/OC/OES/DFOI/	michael gibson gibson, michael	HOSPIRA, ROCKY MOUNT, NC - 483 (02/01/2013 - 03/19/2013)
2013-2166	03/20/2013 04/17/2013	FDA/OFVM/CFSAN/OCD/EOS/	Doe J	MAXGXL - RECS RE BAN ON PRODUCT
2013-2167	03/20/2013 04/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	E.J. Smith Smith Associates	K021938
2013-2168	03/20/2013 04/17/2013	FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/	Rachel Johnson FOI Services, Inc.	INAMED, SANTA BARBARA, CA - EIR, 483
2013-2169	03/20/2013 04/17/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	E.J. Smith Smith Associates	K060109
2013-2170	03/20/2013 04/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	E.J. Smith E.J. Smith	K040916
2013-2171	03/20/2013 04/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	E.J. Smith Smith Associates	K031748
2013-2172	03/20/2013 04/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	ANDA 77170
2013-2173	03/20/2013	FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson	ANDA 90922

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	04/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	
2013-2174	03/20/2013 04/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	E.J. Smith Smith Associates	K992289
2013-2175	03/20/2013 04/17/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	Sonya Cressman The British Columbia Cancer Agency	HISTORICAL PRODUCT LABEL, MEDICAL REVIEW, STATISTICAL REVIEW FOR 11 NDA/ BLA FILES
2013-2176	03/20/2013 04/17/2013	FDA/OGROP/ORAC/CE-FO/PHI- DO/PHI-CB/	Lauren Hubbard CTI	DR STEPHAN GRUPP, CHILDREN'S HOSPITAL OF PHILADELPHIA - 483 (3/21/2005-3/24/2005)
2013-2177	03/20/2013 04/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GHORMLEY 138287, ANTHONY	DEPAKOTE - AER
2013-2178	03/20/2013 04/17/2013	FDA/OFVM/CFSAN/OCD/EOS/	ROBERT S. McQUATE, Ph.D. GRAS ASSOCIATES LLC	FCN 880
2013-2179	03/20/2013 04/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KIM C. CAPONE PORZIO LIFE SCIENCES	WYETH - SERAX LTR 4/23/75
2013-2180	03/20/2013 04/17/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	TOSHIO MURATA NIDEK INC	CARL ZEISS MEDITEC AG - FORUM, FORUM ARCHIVE, FORUM VIEWER K122938; TOPCON CORP- IMAGENET PROFESSIONAL PC SOFTWARE SYS K082364; TOPCON MEDICAL SYS INC - SYNERGY K093313
2013-2181	03/20/2013 04/17/2013	FDA/OGROP/ORAC/CE-FO/NWJ- DO/NWJ-CB/	WAYNE SADOWSKI NOVARTIS PHARMACEUTICAL CORP	NOVARTIS PHARMACEUTICALS, EAST HANOVER, NJ - 483, CORR
2013-2182	03/20/2013 04/17/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FRIEDMAN, ROBERT .	XANTHAN GUM - AER 1969 TO 2013

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-2183	03/20/2013 04/17/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	John Morris 4LIFE RESEARCH LC	USANA HEALTH SCIENCES, SALT LAKE CITY, UT - EIR
2013-2184	03/20/2013 04/17/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	John Morris 4LIFE RESEARCH LC	NEWAYS INTERNATIONAL, SPRINGVILLE, UT - EIR (01/01/2012 - 03/19/2013)
2013-2185	03/20/2013 04/17/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	John Morris 4Life	NATURE'S SUNSHINE PRODUCTS, PROVO, UT - EIR (01/01/2012 - 03/19/2013)
2013-2186	03/20/2013 04/17/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	John Morris 4LIFE RESEARCH LC	WASATCH PRODUCT DEVELOPMENT LLC, DRAPER, UT - EIR (01/02/2012 - 03/19/2013)
2013-2187	03/20/2013 04/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID HOFFMEISTER, Esq WILSON SONSINI ET AL	ANDA D77302
2013-2188	03/20/2013 04/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID HOFFMEISTER, Esq. WILSON SONSINI ET AL	180 DAY MARGETING EXCLUSIVITY - MTG MINUTES, CORR
2013-2189	03/20/2013 04/17/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	John Morris 4LIFE RESEARCH LC	NELSON NUTRACEUTICAL, SALT LAKE CITY, UT; NELSON NUTRACEUTICAL, IRWINDALE, CA - EIR (01/01/2012 - 03/19/2013)
2013-2190	03/20/2013 04/17/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	John Morris 4Life	ALVITA HERBAL TEAS, AMERICAN FORK, UT - EIR (01/03/2012 - 03/19/2013)
2013-2191	03/20/2013 04/17/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Mike Conley The McDowell News	BAXTER HEALTHCARE, NORTH COVE, NC - INSPECTION RECS 01/20/2012 - 03/20/2013
2013-2192	03/20/2013 04/17/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	ROQUETTE FRERES SA, LESTREM, FRANCE - EIR 2008
2013-2193	03/20/2013 04/17/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	John Morris 4Life	UNICITY NETWORK, EAST OREM, UT - EIR (01/02/2012 - 03/19/2013)
2013-2194	03/20/2013	FDA/OMPT/CDER/GRP/DIDP/	DAVID HOFFMEISTER, Esq.	ANDA 77858

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	04/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WILSON SONSINI ET AL	
2013-2195	03/20/2013 04/17/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	John Morris 4Life	NUTRA FORCE, INC PARK CITY, UT - EIR (01/01/2012 - 03/19/2013)
2013-2196	03/20/2013 04/17/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Doe J	COMPLAINT RECS
2013-2197	03/20/2013 04/17/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	Dennis Graves Avanti Polar Lipids, Inc.	AVANTI POLAR LIPIDS, INC, ALABASTER, AL - PREAPPROVAL INSPECTION (11/01/2012 - 01/31/2013)
2013-2198	03/20/2013 04/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	ALYSON OLIVER OLIVER LAW GROUP	PHARMACEUTICAL INNOVATIONS INC - SONIC ULTRASOUND TRANSMISSION GEL CORR, CMLPLNTS
2013-2199	03/20/2013 04/17/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	TOBACCO MANUFACTURERS - EIR, 483 (08/08/2012-03/18/2013)
2013-2200	03/20/2013 04/17/2013	FDA/OFVM/CFSAN/OCD/EOS/	AMI V. GADHIA CONSUMERS UNION	INORGANIC & ORGANIC ARSENIC CONCENTRATIONS IN RICE & RICE PRODUCTS - TEST RESULTS
2013-2201	03/20/2013 04/17/2013	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORA/ OC/ORA/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/ FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	PEARD, BILLY	PINNACLE FOODS GROUP LLC - LOG CABIN SYRUP & BIRDS EYE FROZEN CORN CORR 2003 TO PRESENT
2013-2202	03/20/2013 04/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	PEYTON R. BIDDLE, III OSTERHOUDT PRILLAMAN ET AL	K031106

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2013-2203	03/20/2013 04/17/2013	FDA/OC/OES/DFOI/	MARTINA BERNSTEIN PETA FOUNDATION	BOVINE SPONGIFORM ENCEPHALOPATHY - RPTS, STUDIES 1/08 TO PRESENT
2013-2204	03/20/2013 04/17/2013	FDA/OC/OES/DFOI/	DAVID GRYZC SEDGWICK LLP	INFANT FORMULA RECS
2013-2205	03/20/2013 04/17/2013	OC/ORO/ORM/ OC/ORO/ORM/	ROBERT KING FDANEWS	PHARMACEUTICAL, BIOLOGICS, MEDICAL DVC, CLNCL TRIAL FACILITIES - 483S 2/1-28/13
2013-2206	03/20/2013 04/17/2013	FDA/OFVM/CFSAN/OCD/EOS/	SANDRA PIERCE BARON & BUDD PC	RESP TO LTR FROM WASHINGTON DEPT OF AGRICULTURE RE REPORTED FINDINGS OF LOW LEVELS OF LEAD IN SOME FOOD PRODUCTS COMMONLY CONSUMED BY CHILDREN
2013-2207	03/21/2013 04/18/2013	FDA/OGROP/ORO/SW-FO/DEN-DO/DEN-CB/	John Morris 4Life	NUTRACEUTICAL INTERNATIONL, PARK CITY, UTAH - EIR (01/01/2012 - 03/19/2013)
2013-2208	03/21/2013 04/18/2013	FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	Doe J	HTL STREFA, MARIETTA, GA - INSPECTION RESULTS (01/15/2013 - 03/01/2013)
2013-2209	03/21/2013 04/18/2013	FDA/OGROP/ORO/SW-FO/DEN-DO/DEN-CB/	JOhn Morris 4Life	LIVING ESSENTIAL OILS, LEHI, UT - EIR (01/02/2012 - 03/19/2013)
2013-2210	03/21/2013 04/18/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	ROQUETTE FRERES SA, LESTREM, FRANCE - EIR 2012
2013-2211	03/21/2013 04/18/2013	OC/OSMP/OOPD/ FDA/OMPT/OSMP/OOPD/	Beatrix Taylor Omeros Corporation	SOLIRIS - ORPHAN DRUG DESIGNATION APPLICATION, OOPD REVIEW OF REQUEST FOR ORPHAN DRUG DESIGNATION
2013-2212	03/21/2013 04/18/2013	FDA/OGROP/ORO/SW-FO/KAN-DO/KAN-CB/	Angela Turner Turner, Angela	NOVARTIS CONSUMER HEALTH, INC, LINCOLN, NE - 483 (01/21/2013 - 02/22/2013)
2013-2213	03/21/2013 04/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Beatrix Taylor Omeros Corporation	BLA 125166 - REVIEW SUMMARY
2013-2214	03/21/2013 04/18/2013	FDA/OGROP/ORO/SW-FO/DEN-DO/DEN-CB/	John Morris 4Life	TWIN LABS, AMERICAN FORK, UT - EIR (01/01/2012 - 03/19/2013) ;
2013-2215	03/21/2013 04/18/2013	FDA/OGROP/ORO/SW-FO/DEN-DO/DEN-CB/	John Morris 4Life	SCHIFF NUTRITION INTERNATIONAL, SALT LAKE CITY, UT - EIR (01/2012 - 03/19/2013)
2013-2216	03/21/2013	FDA/OMPT/CDER/ORP/DIDP/	PETER S REICHERTZ	CELESTONE SOLUSPAN (BETAMETHASONE

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	04/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHEPPARD MULLIN RICHTER & HAMPTON, LLP	ACETATE/BETAMETHASONE SODIUM PHOSPHATE INJ) NDA 14-602/S056 - RECS
2013-2217	03/21/2013 04/18/2013	FDA/OFVM/CFSAN/OCD/EOS/	BACKMAN, ARI I	SA CONFISERIE LEONIDAS, ANDERLECHT, BELGIUM 8/16/12; BRUXELLES, BELGIUM 8/14/12 - EIRS
2013-2218	03/21/2013 04/18/2013	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	JOHN WALSH JAMES ALEXANDER CORP	POLYMER CONVERSIONS INC, ORCHARD PARK, NY - EIRS, 483S, RECALLS 1/11 TO PRESENT
2013-2219	03/21/2013 04/18/2013	FDA/OGROP/ORA/CE-FO/BLT- DO/BLT-CB/	JOHN WALSH JAMES ALEXANDER CORP	FILTRONA FIBERTEC, COLONIAL HEIGHTS, VA - EIRS, 483S, RECALLS 4/11 TO PRESENT
2013-2220	03/21/2013 04/18/2013	FDA/OGROP/ORA/CE-FO/CHI- DO/CHI-CB/	JOHN WALSH JAMES ALEXANDER CORP	CHEM-IMPEX INTERNATIONAL, WOOD DALE, IL - EIRS, 483S, RECALLS 4/09 TO PRESENT
2013-2221	03/21/2013 04/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	ROBERT STEELE STRYKER MEDICAL	LINET SPOL SRO, SLANY, CZECH REPUBLIC - 483 10/29/12- 11/1/12
2013-2222	03/21/2013 04/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARK SCHOOF PROPUBLICA	CETERO, HOUSTON, TX - RESEARCH VIOLATIONS RECS
2013-2223	03/21/2013 04/18/2013	FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/ FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/ FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/ FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/ FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/ FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN CREWDSON PROJECT ON GOVERNMENT OVERSIGHT	DAVID SALERNO, CHATTANOOGA HEART INST 1/28/92; RONALD MILLER, UNIV OF CALIFORNIA SAN FRANCISCO, SAN FRANCISCO, CA; VIRENDA DESAI, PHYSICIAN ALLIANCE RESEARCH CENTER, LONG BEACH, CA 3/17/08, ETC - 483S

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2013-2224	03/22/2013 04/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Joanne Beique Joanne Beique	K113544
2013-2225	03/22/2013 04/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 202971
2013-2226	03/22/2013 04/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Joanne Beique Joanne Beique	K072123
2013-2227	03/22/2013 04/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Melissa Luras Watson Laboratories, Inc.	SKYLA NDA 203159 - CHEMISTRY REVIEW; MICROBIOLOGY REVIEW; SUMMARY REVIEW ETC
2013-2228	03/22/2013 04/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kimberlee Washburn Kimberlee Washburn	K050438
2013-2229	03/22/2013 04/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	EVISTA - AERS
2013-2230	03/22/2013 04/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Martin N. Preiser GOLDBERG & GOLDBERG	METHADONE 10 MG - PACKAGE INSERTS
2013-2231	03/22/2013 04/19/2013	FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/	Richard Bilton BBC News	BURZYNSKI CLINIC, BURZYNSKI RESEARCH INSTITUTE - 483(01/01/1995 - 03/21/2013)
2013-2232	03/22/2013 04/19/2013	FDA/OGROP/ORR/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/	Defense Nutrition Salmas Law Group	WISDOM PROTEINS INC, SAN DIEGO, CA - LABEL, PHOTOS
2013-2233	03/22/2013 04/19/2013	FDA/OGROP/ORR/SW-FO/DEN-DO/DEN-CB/	4Life 4LIFE RESEARCH LC	EXCEL INTERNATIONAL, INC, SANDY, UT - EIR
2013-2234	03/22/2013 04/19/2013	FDA/OGROP/ORR/SW-FO/DEN-DO/DEN-CB/	John Morris 4Life	XANGO, LLC, LEHI, UT - EIR (01/02/2012 - 03/20/2013)
2013-2235	03/22/2013 04/19/2013	FDA/OFVM/CFSAN/OCD/EOS/	Adrian Giraldo Soto Ecoflora SAS	CAP 2CO293

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2013-2236	03/22/2013 04/19/2013	FDA/OFVM/CFSAN/OCD/EOS/	Elena De Marco Mataluni SpA	FAP 9A4779
2013-2237	03/22/2013 04/19/2013	FDA/OC/OES/DFOI/	Heather Greenslate BALYASNY ASSET MANAGEMENT	FDA FOIA LOG (01/01/2011 - 03/21/2013)
2013-2238	03/22/2013 04/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Terrence J. Donahue, Jr. McGlynn Glisson & Mouton	METOCLOPRAMIDE - MEDICAL REVIEWS
2013-2239	03/22/2013 04/19/2013	FDA/OMPT/CDRH/OCER/DFOI/ OC/ORA/ OC/ORA/ FDA/OGROP/ORACE-FO/CIN- DO/CIN-CB/	Doe J	INDIVIDUAL RECS
2013-2240	03/22/2013 04/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Clint Matthews UNIVERSITY OF MISSOURI	K101793
2013-2241	03/22/2013 04/19/2013	FDA/OGROP/ORASW-FO/KAN- DO/KAN-CB/	Patti Waller Marler Clark Law Firm	FDA SAMPLE #708461 LABORATORY TESTING RESULTS
2013-2242	03/22/2013 04/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	INDIVIDUAL RECS
2013-2243	03/22/2013 04/19/2013	FDA/OC/OES/DFOI/	Heather Greenslate BALYASNY ASSET MANAGEMENT	FOIA LOGS (08/02/2007 - 12/31/2010)
2013-2244	03/22/2013 04/19/2013	FDA/OO/OIM/OPILS/DDM/ OC/OM/OMP/DDM/	Alex Silverstein SIGMA CAPITAL MANAGEMENT LLC	JAZZ PHARMACEUTICALS - CITIZENS PETITIONS, REPSONSES
2013-2245	03/22/2013 04/19/2013	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	ELSEVIER, ELSEVIER SCIENCE, REED TECHNOLOGIES - FOIA INVOICECS 01/01/2007 TO 12/21/2011
2013-2246	03/22/2013 04/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Joanne Beique Joanne Beique	K110518
2013-2247	03/22/2013 04/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Alex Silverstein SIGMA CAPITAL MANAGEMENT LLC	JAKAFI - AERS

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2013-2248	03/22/2013 04/19/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	John Morris 4Life	AGEL, LEHI, UT - EIR (01/02/2012 - 03/20/2013)
2013-2249	03/22/2013 04/19/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	John Morris 4LIFE RESEARCH LC	NU SKIN ENTERPRISES, PROVO, UT - EIR (01/02/2012 - 03/20/2013)
2013-2250	03/22/2013 04/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ERYN M. PEDDICORD PEDDICORD AND TOWNSEND LLC	MISOPROSTOL (CYTOTEC) LBLG
2013-2251	03/22/2013 04/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SIDNEY M. WOLFE, MD PUBLIC CITIZEN HEALTH RESEARCH GROUP	SITAGLIPTIN - OES RVW 6/09
2013-2252	03/22/2013 04/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Leon Lambry Surgical Information Systems	K930492
2013-2253	03/22/2013 04/19/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	PATRICIA L. REGENYE Celgene Corporation	THOMAS ERVIN, FLORIDA CANCER SPECIALISTS, FT MYERS, FL - EIR, 483, CO RESP 4/12 TO PRESENT
2013-2254	03/22/2013 04/19/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Lynn Cox Sinclair Research Center LLC	SINCLAIR RESEARCH CENTER, AUXVASSE, MO - EIR (06/09/2008 - 03/20/2013)
2013-2255	03/22/2013 04/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kimberlee Washburn Kimberlee Washburn	K003111
2013-2256	03/22/2013 04/19/2013	FDA/OFVM/CFSAN/OCD/EOS/	Barbara Blakistone National Fisheries Institute	SURVEILLANCE SAMPLING OF MAHI MAHI FROM TAIWAN FOR PAST THREE YEARS
2013-2257	03/22/2013 04/19/2013	FDA/OO/OFBA/OAGS/	CHRISTOPHER E. POWELL MARATHON	09-223-SOL-0052
2013-2258	03/22/2013 04/19/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	John Morris 4Life	ASEPTIC SOLUTIONIS, CORONA, CA - EIR (01/02/2012 - 03/20/2013)
2013-2259	03/22/2013 04/19/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	John Morris 4LIFE RESEARCH LC	BASIC RESEARCH, SALT LAKE CITY, UT - EIR (1/02/2012 - 03/20/2013)
2013-2260	03/22/2013 04/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sofia Bruera Blizzard & Nabers, LLP	TYSABRI - AERS
2013-2261	03/22/2013	FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton	SBA 21087 S-040/ 21246 S-027 (TAMIFLU)

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	04/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	INC RESEARCH CONSULTING & SUBMISSIONS	
2013-2262	03/22/2013 04/19/2013	FDA/OGROP/ORR/SW-FO/DEN- DO/DEN-CB/	John Morris 4LIFE RESEARCH LC	DESERET LABORATORIES, ST GEORGE, UT - EIR (01/02/2012 - 03/20/2013)
2013-2263	03/22/2013 04/19/2013	OC/ORR/ OC/ORR/ FDA/OGROP/ORR/SW- FO/SWID/SWID-CB/	DONALD N. BLUE ZETETIC	ENTRY NO D01-0842601-2 - MARS CHOCOLATES
2013-2264	03/22/2013 04/19/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	SBA 21087 S048, 049/ 21246 S034, S035 (TAMIFLU)
2013-2265	03/22/2013 04/19/2013	OC/ORR/ OC/ORR/ FDA/OGROP/ORR/SW- FO/SWID/SWID-CB/	DONALD N. BLUE ZETETIC	ENTRY NO D01-0842682-2 - MARS CHOCOLATES
2013-2266	03/22/2013 04/19/2013	OC/ORR/ OC/ORR/ FDA/OGROP/ORR/SW- FO/SWID/SWID-CB/	DONALD N. BLUE ZETETIC	D01-0842143-5 - MARS CHOCOLATES
2013-2267	03/22/2013 04/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	SBA 21087 S056/ 21246 S039 (TAMIFLU)
2013-2268	03/22/2013 04/19/2013	OC/ORR/ OC/ORR/ FDA/OGROP/ORR/SW- FO/SWID/SWID-CB/	DONALD N. BLUE ZETETIC	ENTRY NO D01-0842622-8 - UNCLE BENS RICE
2013-2269	03/22/2013 04/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	SBA 21087 S062/ 21246 S045 (TAMIFLU)

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2013-2270	03/22/2013 04/19/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Marc C. Sanchez Contract In-House Counsel and Consultant	K060846
2013-2271	03/22/2013 04/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHISTINE P. BUMP GOODWIN PROCTER LLP	OTSUKA PHARMCEUTICAL CO LTD - ABILIFY MAINTENA KIT NDA 202-971 APRVL, LBLG, MED RVWS
2013-2272	03/22/2013 04/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KATHRYN L. BIBERSTEIN ALKERMES INC	OTSUKA PHARM CO - ABILIFY MAINTENA KIT APRVL, LBLG, MEDICAL RVW
2013-2273	03/22/2013 04/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SOFIA BRUERA Blizzard & Nabers, LLP	TYSABRI (NATALIZUMAB) AER 1/05 TO 1/1/13
2013-2274	03/22/2013 04/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	S ALBERT EDWARDS, PHARM D	ACTAMINOPHEN & CODEINE PHOSPHATE ORAL SOLUTION; POTASSIUM CHLORIDE ORAL SOLUTION RED; ANTISPASMODIC ELIXIR, ETC - EVALUATION
2013-2275	03/22/2013 04/19/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	COLLEEN K. DUCAS SANOFI PASTEUR	MERIEUX SERUMS ET VACCINS - DCT C-3301
2013-2276	03/22/2013 04/19/2013	FDA/OC/OES/DFOI/	JOHNATHAN RICKMAN FDANEWS	ST JUDE MEDICAL PUERTO RICO LLC, ARECIBO, PR - 483 10/12
2013-2277	03/22/2013 04/19/2013	FDA/OC/OES/DFOI/	AMY DELINE SIDLEY AUSTIN LLP	ST JUDE MEDICAL - ALL REQUESTS RELATED TO 522 SURVEILLANCE
2013-2278	03/25/2013 04/22/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-969 REQUEST LETTER
2013-2279	03/25/2013 04/22/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1022 REQUEST LETTER
2013-2280	03/25/2013 04/22/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1415 REQUEST LETTER ONLY
2013-2281	03/25/2013 04/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K022718

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2013-2282	03/25/2013 04/22/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Alan Rorke Dr Alan Rorke	K053228
2013-2283	03/25/2013 04/22/2013	OC/OSMP/OOPD/ FDA/OMPT/OSMP/OOPD/	Herriot Tabuteau Axsome Therapeutics Inc.	RALOXIFENE (EVISTA) - ORPHAN DESIGNATION REVIEW
2013-2284	03/25/2013 04/22/2013	FDA/OC/OL/	Jonathan J. Darrow Harvard Law Schol	REPORT TO CONGRESS REQUIRED BY SECTION 904 OF THE FDAAA
2013-2285	03/25/2013 04/22/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K100349
2013-2286	03/25/2013 04/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K091733
2013-2287	03/25/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K102860
2013-2288	03/25/2013 04/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Luigi Xerri VenatoRx Pharmaceuticals, Inc.	MEROPENEM - IND RECS
2013-2289	03/25/2013 04/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	Debanjana Bhattacharya UNIVERSITY OF SOUTH DAKOTA	DEPLIN - APPROVAL PACKAGE
2013-2290	03/25/2013 04/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K100221
2013-2291	03/25/2013 04/22/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SW-FO/KAN-DO/KAN-CB/	Myrna Booth Blank Park Zoo	SAMPLE 761686
2013-2292	03/25/2013 04/22/2013	FDA/OFVM/CFSAN/OCD/EOS/	Kris Callaert Techniplast Projects	FCN 631
2013-2293	03/25/2013 04/22/2013	FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/ FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	JOSEPH I. MARCHESE Bursor & Fisher, P.A.	ST JUDE MEDICAL - RECS RE PREMATURE EROSION IN RIATA AND RIATA ST (01/01/2005 - 03/22/2013)

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2013-2294	03/25/2013 04/22/2013	OC/ORa/OCI/ OC/ORa/OCI/	Ken Cummings NA	WHITEHALL SPECIALTIES, WHITEHALL, WI, LACROSSE, WI, DMV USA - INVESTIGATION RECS
2013-2295	03/25/2013 04/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	INDIVIDUAL RECS
2013-2296	03/25/2013 04/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Elizabeth Woodling OXiGENE, Inc.	DR REDDY'S LABORATORY, INDIA - 483 01/01/07 TO 06/01/10
2013-2297	03/25/2013 04/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kacie Carroll RN Barr & Mudford LLP	BODY BUILDING PRODUCTS AND HIDDEN STEROIDS: ENFORCEMENT BARRIERS - REPORT FROM MICHAEL LEVY ESQ TO SENATE SUBCOMMITTEE 2009
2013-2298	03/25/2013 04/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jonathan Zhu Asia Dynamics Inc.	K952414
2013-2299	03/25/2013 04/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Alex Silverstein SIGMA CAPITAL MANAGEMENT LLC	XTANDI - AERS
2013-2300	03/25/2013 04/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Alex Silverstein SIGMA CAPITAL MANAGEMENT LLC	ICLUSIG - AERS
2013-2301	03/25/2013 04/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Alex Silverstein SIGMA CAPITAL MANAGEMENT LLC	KYPROLIS - AERS
2013-2302	03/25/2013 04/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	AMY MITCHELL GLAXO SMITH KLINE	GLAXO SMITH KLINE, WORTHING, UK - QAP
2013-2303	03/25/2013	FDA/OMPT/CDER/ORP/DIDP/	WALTER E. CHALKLEY	FABBRICA ITALIANA SINTETICI, MONTECCHIO, MAGGIORE,

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	04/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	THOMSON REUTERS	ITALY - EIR, 483, CO RESP 3/12
2013-2304	03/25/2013 04/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	NEDD, CUTHBERT	CHEMOTHERAPY DRUGS - APRVD LIST
2013-2305	03/25/2013 04/22/2013	FDA/OC/OES/DFOI/	DONALD E. SEGAL ALSTON & BIRD LLP	CRYO LIFE, KENNESAW, GA - EIR, 483, WARNING LTR
2013-2306	03/25/2013 04/22/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDRH/OCER/DFOI/	JOSHUA KINCANNON, Esq. KEEFE BARTELS CLARK ATTY AT LAW	STRYKER ORTHOPAEDICS 0 REJUVENATE MODULAR NECK STEMS K092561
2013-2307	03/25/2013 04/22/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDRH/OCER/DFOI/	JOSHUA KINCANNON, Esq. KEEFE BARTELS CLARK ATTY AT LAW	STRYKER ORTHOPAEDICS - ABG II MODULAR NECK STEMS K092406
2013-2308	03/25/2013 04/22/2013	FDA/OO/OIM/OPILS/DDM/ FDA/OC/OES/DDM/	LAURA S. SUTTELL PHILLIPS LYTLE ET AL	DCT 75N-0062
2013-2309	03/25/2013 04/22/2013	FDA/OMPT/CTP/OD/	MARILYNN WHITNEY COVINGTON BURLING LLP	SE RVW PROCESS
2013-2310	03/25/2013 04/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WHITE W101640, JONATHAN	LEVETIRACETAM - AER
2013-2311	03/25/2013 04/22/2013	OC/OM/OMP/DDM/ OC/OM/OMP/DDM/	EAS CONSULTING GROUP LLC	DKT LOG 1990N-0200
2013-2312	03/25/2013 04/22/2013	OC/OM/OMP/DDM/	CHRIS CELESTE EAS Consulting Group, LLC	DKT 1990N-0200
2013-2313	03/26/2013 04/23/2013	FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA REQUEST LOG (03/18/2013 - 03/22/2013)
2013-2314	03/26/2013 04/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jerome Lew JEROME LEW	INFUSE BONE GRAFT - AERS, NON-COMPLIANCE OF IRB, RESPONSES ETC
2013-2315	03/26/2013 04/23/2013	OC/ORACE/ OC/ORACE/	Sarah Sellers q-Vigilance, LLC	MEDI-FARE PHARMACY - 483 (12/01/2012 - 01/31/2013)
2013-2316	03/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Camilla Recke	K953239

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	04/23/2013		BioPorto Diagnostics A/S	
2013-2317	03/26/2013 04/23/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/	Richard O. Wood the Wood Burditt group	97Y-0007131-4/1-1 (STERILE NON-ADHERENT PAD 2 X 3), 97Y-0007131-4/2-1 (STERILE NON-ADHERENT PAD 3 X 4), 97Y-0007131-4/16-1 (DK T-DRAIN SPONGE ECO 4X4 6PLY ST 2/PK 25PK/TY 12TY/CS)
2013-2318	03/26/2013 04/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	E.J. Smith Smith Associates	K982901
2013-2319	03/26/2013 04/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	E.J. Smith Smith Associates	K983716
2013-2320	03/26/2013 04/23/2013	FDA/OC/OES/DFOI/	Amy Kincanon LexisNexis CourtLink Document Retrieval	2013-218
2013-2321	03/26/2013 04/23/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ni Sun Alkermes, Inc.	TECFIDERA - SBA
2013-2322	03/26/2013 04/23/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Saagar Patel Whitney Medical Solutions	K032065, K050322, K052395
2013-2323	03/26/2013 04/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	Robert Buehler TEI Biosciences Inc.	RAW DATA TO SUPPORT ADVERSE EVENT TABLE
2013-2324	03/26/2013 04/23/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Alvin Washington Alvin Washington	CYTOMEL - AERS
2013-2325	03/26/2013 04/23/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Timothy Joy RMC Pharmaceutical Solutions, Inc	SYNCO BIO PARTNERS VC, AMSTERDAM - 483, EIR, RESPONSE (04/01/2012 - 03/01/2013)
2013-2326	03/26/2013 04/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1581 REQUEST LETTER
2013-2327	03/26/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2013-1265 - REQUEST LETTER

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	04/23/2013		MERCK & CO., INC.	
2013-2328	03/26/2013 04/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1224 REQUEST LETTER
2013-2329	03/26/2013 04/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-960 REQUEST LETTER
2013-2330	03/26/2013 04/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	AMY L GOERSS HODGSON RUSS LLP	PRISMATIK DENTALCRAFT INC - OBSIDIAN CERAMIC BLOCKS K100781
2013-2331	03/26/2013 04/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	AMY L GOERSS HODGSON RUSS LLP	IVOCLAR USA INC - HIGH GOLD PALLADIUM FREE CERAMIC SOLDER K012877
2013-2332	03/26/2013 04/23/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	GILBERT R WEINER ADVANCED PHARMA CR LLC	CETERO RESEARCH - EIR 2007
2013-2333	03/26/2013 05/13/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/ OC/ORA/ OC/ORA/ OC/ORA/OE/ OC/ORA/OE/ FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	ANTHONY M ELEFTHERI LEWIS WAGNER LLC	CHAMBERLAIN FARMS INC, OWENSVILLE, IN - SALMONELLA OUTBREAK INSPS, 483S, NOTES, RECALL RECS, ETC 2012
2013-2334	03/26/2013 04/23/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARY B SZALKOWSKI PRISMA CORP	INDAPAMIDE AND PERINDOPRIL - AERS 12/7/12 TO PRESENT
2013-2335	03/26/2013 04/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	ZIEBOL, LOIS	CONCENTRIC MEDICAL INC - CONCENTRIC BALLOON GUIDE CATHETER K112404
2013-2336	03/26/2013 06/17/2013	FDA/OFVM/CFSAN/OCD/EOS/	BECKY COOSEMAN BROWN & CROUPPEN PC	CRONOBACTER INVESTIGATIONS - LAB W/S, EPIDEMIOLOGY FILES, DENDROGRAMS, ETC 2009 TO 2012
2013-2337	03/26/2013 04/23/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/ FDA/OMPT/CDRH/OCER/DFOI/ OC/ORA/ OC/ORA/ OC/ORA/OE/ OC/ORA/OE/	PATRICK N BROYLES BROYLES LAW FIRM	ZIMMER - FITMORE HIP STEM DESIGN CHANGES, PACKAGING, CLEARANCE FOR MARKETING, ETC

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		FDA/OGROP/ORACE-FO/DET-DO/DET-CB/		
2013-2338	03/26/2013 04/23/2013	FDA/OMPT/CDRH/OCER/DFOI/ OC/ORACE/ OC/ORACE/ OC/ORACE/OE/ OC/ORACE/OE/ FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	PATRICK N BROYLES BROYLES LAW FIRM	ZIMMER - POROLOCK MIS STEM K071723 INSTRUCTIONS FOR USE, CLEARANCE FOR MARKETING, WARNINGS, ETC
2013-2339	03/26/2013 04/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	YVONNE M FLAHERTY LOCKRIDGE GRINDAL NAUEN PLLP	ST JUDE MEDICAL - RIATA, RIATA ST DEFIBRILLATOR LEADS CORPORATE QUALITY SYSTEM IMPROVEMENT PLANT (QSIP), CORPORATE QSIP STEERING COMMITTEE, ETC ATTACHMENTS, EXHIBITS, MINS, ETC
2013-2340	03/26/2013 04/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	YVONNE M FLAHERTY LOCKRIDGE GRINDAL NAUEN PLLP	ST JUDE MEDICAL - UPDATE TO 483 9/3/09, EXHIBITS, ATTACHMENTS, RECS, ETC
2013-2341	03/26/2013 04/23/2013	FDA/OFVM/CFSAN/OCD/EOS/	MITCHELL A CHEESEMAN PHD STEPTOE & JOHNSON	ECOLAB INC - FAP 2A4785 RVW MEMO
2013-2342	03/26/2013 04/23/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OO/OHR/	DUNCAN, HILARIO R	ANNOUNCEMENT PH-NM-13-764407 SUPERVISORY PARALEGAL SPECIALIST - CORR
2013-2343	03/26/2013 04/23/2013	FDA/OGROP/ORACE-SW-FO/DAL-DO/DAL-CB/	JOHN WALSH JAMES ALEXANDER CORP	HALTERMANN, HOUSTON, TX - EIRS, 483S, PROD RECALLS
2013-2344	03/26/2013 04/23/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	TOSHIO MURATA NIDEK INC	CENTERVUE SPA - MAIA MODEL 1 K092187
2013-2345	03/26/2013 04/23/2013	FDA/OGROP/ORACE-SW-FO/DEN-DO/DEN-CB/	DOMINGO, VANESSA	COLORADO BIOLABS INC - EIR MOST RECENT
2013-2346	03/26/2013 04/23/2013	FDA/OGROP/ORACE-SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	PATRICIA L REGENYE Celgene Corporation	HOWARD SCHWARTZ, MIAMI RES ASSOC, MIAMI, FL - 483S 10/05 TO PRESENT
2013-2347	03/26/2013 05/17/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	MITCHELL, ERIC	ONE LAMBDA INC - MICROSSP HLA KIT BK960062
2013-2348	03/26/2013 04/23/2013	FDA/OGROP/ORACE-PA-FO/LOS-DO/LOS-CB/	ERNIE MOLINA AMERICOLOR CORP	AMERICOLOR CORP, PLACENTIA, CA - EIR, 483 9/13/12
2013-2349	03/26/2013 04/23/2013	FDA/OFVM/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES	CAERS 138930, 139159, 140919, ETC

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			INTERNATIONAL INC	
2013-2350	03/26/2013 04/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	OLIVE O'DRISCOLL CORK INSTITUTE OF TECHNOLOGY	K955433
2013-2351	03/26/2013 04/23/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	OLIVE O'DRISCOLL CORK INSTITUTE OF TECHNOLOGY	K974295
2013-2352	03/26/2013 04/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	OLIVE O'DRISCOLL CORK INSTITUTE OF TECHNOLOGY	K942315
2013-2353	03/26/2013 04/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	OLIVE O'DRISCOLL CORK INSTITUTE OF TECHNOLOGY	K896087
2013-2354	03/26/2013 04/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	OLIVE O'DRISCOLL CORK INSTITUTE OF TECHNOLOGY	K895041
2013-2355	03/26/2013 04/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	OLIVE O'DRISCOLL CORK INSTITUTE OF TECHNOLOGY	K092886
2013-2356	03/26/2013 04/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	OLIVE O'DRISCOLL CORK INSTITUTE OF TECHNOLOGY	K113576
2013-2357	03/26/2013 04/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	OLIVE O'DRISCOLL CORK INSTITUTE OF TECHNOLOGY	K771219
2013-2358	03/26/2013 04/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	OLIVE O'DRISCOLL CORK INSTITUTE OF TECHNOLOGY	K051522
2013-2359	03/26/2013 04/23/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	OLIVE O'DRISCOLL CORK INSTITUTE OF TECHNOLOGY	K000801
2013-2360	03/26/2013 04/23/2013	FDA/OC/OES/DFOI/	MITCHELL A CHEESEMAN PHD STEPTOE & JOHNSON	2010-763, 2009-9561
2013-2361	03/27/2013 04/24/2013	FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/	Dale Misczynski Monebo Technologies, Inc.	MONEBO, AUSTIN, TX - MTG RECS (12/10/2012 - 12/30/2012)
2013-2362	03/27/2013	FDA/OMPT/CDER/ORP/DIDP/	Tom Burton	AFFYMAX INC - ANAYLSES, MEMOS, LETTERS RE

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	04/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALL STREET JOURNAL	ADVERSE EVENTS (02/01/2013 - 03/26/2013)
2013-2363	03/27/2013 04/24/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OO/OHR/ OC/ORO/ OC/ORO/ OC/ORO/ OC/ORO/	Doe J	INDIVIDUAL RECS
2013-2364	03/27/2013 04/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jodi Kimble ProMedTek, Inc.	K083433
2013-2365	03/27/2013 04/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Buck Brown iScreen Vision	PEDIAVISION INC SPOT VS100 - INVESTIGATION RECS
2013-2366	03/27/2013 04/24/2013	FDA/OC/OES/	Geoffrey R Chambers Geoffrey R. Chambers	FDA MEETING RE PATIENT-CENTRIC PROVISIONS OF FDASIA - MINUTES
2013-2367	03/27/2013 04/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Cora Sim Ellipse Technologies, Inc.	K032097
2013-2368	03/27/2013 04/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Cora Sim Ellipse Technologies Inc.	K020885
2013-2369	03/27/2013 04/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Srividya Sukadev Pan Medical	K122533
2013-2370	03/27/2013 04/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Srividya Sukadev Pan Medical	K981251
2013-2371	03/27/2013 04/24/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-889 REQUEST LETTER
2013-2372	03/27/2013 04/24/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-884 - REQUEST LETTER
2013-2373	03/27/2013 04/24/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1561 REQUEST LETTER
2013-2374	03/27/2013 04/24/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1288 REQUEST LETTER
2013-2375	03/27/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2013-847 REQUEST LETTER

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	04/24/2013		MERCK & CO., INC.	
2013-2376	03/27/2013 04/24/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2010-8135
2013-2377	03/27/2013 04/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Mr. Katsuhiko Baba (New Business Strategy Group) SEIKO EPSON CORPORATION	K093981
2013-2378	03/27/2013 04/24/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Yu-Ju Chiang Chung Yuan Christian University	K013434, K093192, K982707
2013-2379	03/27/2013 04/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Cora Sim Ellipse Technologies, Inc.	K101438
2013-2380	03/27/2013 04/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jodi Kimble ProMedTek, Inc.	K022458
2013-2381	03/27/2013 04/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Karen Griffin HOSPIRA INC	D-096-2013 - HHE, RISK ASSESSMENT
2013-2382	03/27/2013 04/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Karen Griffin Hospira, Inc.	Z-0069-2013 - HHE, RISK ASSESSMENT
2013-2383	03/27/2013 04/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	LEVINE, AMY L	SMITH & NEPHEW, BIRMINGHAM, AL - HIP RESURFACING DVC P04033 POST APRVL STUDY PROTOCOL, PROGRESS RPTS, STATUS DETERMINATION, ETC
2013-2384	03/27/2013 04/24/2013	FDA/OMPT/CDRH/OCER/DFOI/ OC/OM/OMP/DDM/ FDA/OC/OES/DDM/	DINGLE, DAN	CPG 305.100 ACUPUNCTURE DVC & ACCESSORIES, DKT 94P-0443, ANESTHESIOLOGY DVC ADVISORY PANEL MEETING, 6/15/76, 3/22/78, 10/1/80, ETC
2013-2385	03/27/2013 04/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GREGORY B BREDLOVE CUNNINGHAM BOUNDS ET AL	AZULFINDE(SUFASALAZINE) APLASTIC ANEMIA- AERS LAST 20 YRS
2013-2386	03/27/2013 04/24/2013	FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	ANN M CARVALHO McLarens Global Claim Services	SNYER'S LANCE, COLUMBUS, GA - EIRS 2011, 9/2012, 10/2012
2013-2387	03/27/2013 04/24/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/	CHRISTOPHER M KANE SIMON GLUCK & KANE LLP	MITIGATION GUIDELINES - VIOLATIONS
2013-2388	03/27/2013	FDA/OFVM/CFSAN/OCD/EOS/	UDI GROFMAN	HERBALIFE INTERNATIONAL - INVESTIGATION,

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	04/24/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	PAUL WEISS RIFKIND WHARTON & GARRISON	ENFORCEMENT ACTION, COMPLIANCE ACTION 5/1/12 TO 3/22/13
2013-2389	03/27/2013 04/24/2013	FDA/OC/OES/DFOI/	DONALD E SEGAL ALSTON & BIRD LLP	CRYOLLIFE INC, KENNESAW, GA - EIRS, 483S, WARNING LTRS, ETC 1/13 TO PRESENT
2013-2390	03/27/2013 04/24/2013	OC/ORAI/ OC/ORAI/ OC/ORAI/ORO/ OC/ORAI/ORO/ FDA/OGROP/ORAI/ORO/DIOP/	DONALD BLUE GLOBAL TRADE INTELLIGENCE INC	IMPORTS UNDER USFDA OVERSIGHT - 20130325-1 1/13 TO PRESENT
2013-2391	03/27/2013 04/24/2013	OC/ORAI/ OC/ORAI/ OC/ORAI/ORO/ OC/ORAI/ORO/ FDA/OGROP/ORAI/ORO/DIOP/	DONALD BLUE GLOBAL TRADE INTELLIGENCE INC	IMPORTS UNDER USFDA OVERSIGHT - 20130325-2 1/1/11-12/31/11
2013-2392	03/27/2013 04/24/2013	FDA/OC/OES/DFOI/	ELENA HOWELL HOGAN LOVELLS US LLP	2013-1908
2013-2393	03/27/2013 04/24/2013	FDA/OMPT/CTP/OD/ FDA/OO/OFBA/OAGS/ FDA/OMPT/CTP/OD/	CATHERINE MACRUM HUGHES HUBBARD & REED	INITIATION WITH MENTHOL CIGARETTES & YOUTH SMOKING UPTAKE - SUMM, RPTS, CORR, ETC FINAL RPT 11/10
2013-2394	03/27/2013 04/24/2013	FDA/OFVM/CFSAN/OCD/EOS/	MICHELLE LEVINSON NATURAL RESOURCES DEFENSE COUNCIL	PRIORITY BASED ASSESSMENT OF FOOD ADDITIVES (PAFA) DATABASE - RECS
2013-2395	03/28/2013 04/25/2013	OC/ORAI/ OC/ORAI/ FDA/OGROP/ORAI/NE-FO/NWE-DO/NWE-CB/	Joce Sterman WMAR/ABC-2	AMERICAN CRUISE LINES - INSPECTION REPORTS (01/01/2008 - 03/01/2013)
2013-2396	03/28/2013 04/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DDM/	Darwin Tandam Neutraderm, Inc	UNDECYLENIC ACID - CLINICAL DATA FOR NAIL FUNGUS TREATMENT
2013-2397	03/28/2013 04/25/2013	FDA/OGROP/ORAI/SW-FO/DAL-DO/DAL-CB/	Robert Blaskiewicz Robert Blaskiewicz	STANISLAW BURZYNSKI, HOUSTON, TX - 483 (01/01/2013 - 04/01/2013)
2013-2398	03/28/2013	FDA/OFVM/CFSAN/OCD/EOS/	Haruya Kato	BASF - UNTITLED LETTER RECS (02/06/2007 - 03/26/2013)

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	04/25/2013		Kato Business Consulting	
2013-2399	03/28/2013 04/25/2013	FDA/OGROP/ORPA-FO/SAN-DO/SAN-CB/	Mark Fenton TAKEDA PHARMACEUTICALS NORTH AMERICA INC	AMERISOURCE BERGEN, SACRAMENTO, CA - 483 (01/01/2012 - 12/31/2012)
2013-2400	03/28/2013 04/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Adrienne E. Faerber, PhD Dartmouth Inst. Cent. For Med. Media.	ANDRODERM - INITIAL APPROVAL RECS
2013-2401	03/28/2013 04/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Cora Sim Ellipse Technologies, Inc.	K100312
2013-2402	03/28/2013 04/25/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Cora Sim Ellipse Technologies, Inc.	K971783
2013-2403	03/28/2013 04/25/2013	OC/ORPA/ OC/ORPA/ FDA/OGROP/ORPA/CE-FO/MIN-DO/MIN-CB/	Shawn Stoley All American Foods, Inc.	SAMPLE RESULTS AND REPORT
2013-2404	03/28/2013 04/25/2013	FDA/OGROP/ORPA/CE-FO/CIN-DO/CIN-CB/	Felix Briaud Camicas Productions	RONALD ANDIO DBA PATRON FARMS LLC - WARNING LETTER FOLLOW UP RECS (07/09/2012 - 07/09/2012)
2013-2405	03/28/2013 04/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Cora Sim Ellipse Technologies, Inc.	K980854
2013-2406	03/28/2013 04/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Christopher Buck, Ph.D., Esq. Pribanic & Pribanic, L.L.C.	NEURONTIN - APPROVAL LETTER
2013-2407	03/28/2013 04/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Valerie Franck STRYKER INSTRUMENTS	K123188
2013-2408	03/28/2013 04/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	REQUIP NDA 20658/S13 - MEDICAL OFFICER RVW
2013-2409	03/28/2013 04/25/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Casey A. Metzger STRYKER INSTRUMENTS	K040485
2013-2410	03/28/2013 04/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K030286

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2013-2411	03/28/2013 04/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Ashley Driscoll Diazyme Laboratories	K121232
2013-2412	03/28/2013 04/25/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Donald Barry MEDICA CORPORATION	K022158
2013-2413	03/28/2013 04/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Casey A. Metzger STRYKER INSTRUMENTS	K102971
2013-2414	03/28/2013 04/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Melanie Bell Scilucent, LLC	PERTZYE - SBA
2013-2415	03/28/2013 04/25/2013	FDA/OGROP/ORAP/PA-FO/LOS- DO/LOS-CB/	WALTER E CHALKLEY THOMSON REUTERS	CRESCENDO THERAPEUTICS LLC, VISTA, CA - EIRS, 483S, CO RESP 4/11
2013-2416	03/28/2013 04/25/2013	FDA/OGROP/ORAP/PA-FO/SAN- DO/SAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	GENENTECH INC - EIRS, 483S, CO RESP 8/12
2013-2417	03/28/2013 04/25/2013	FDA/OGROP/ORAP/CE-FO/CHI- DO/CHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	PFIZER INC - EIRS, 483S, CO RESP 12/12
2013-2418	03/28/2013 04/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	XYLO CHEM INDUSTRIES, NADIAD, INDIA - EIRS, 483S, CO RESP 7/11
2013-2419	03/28/2013 05/09/2013	FDA/OGROP/ORAP/CE-FO/MIN- DO/MIN-CB/ FDA/OGROP/ORAP/CE-FO/DET- DO/DET-CB/ FDA/OC/OES/DFOI/	WALTER E CHALKLEY THOMSON REUTERS	ENZYME SOLUTIONS INC - EIRS, 483S, CO RESP 10/12
2013-2420	03/28/2013 04/25/2013	FDA/OGROP/ORAP/SE-FO/FLA- DO/FLA-CB/	WALTER E CHALKLEY THOMSON REUTERS	DEXTRUM LABORATORIES INC - EIRS, 483S, CO RESP 7/12
2013-2421	03/28/2013 04/25/2013	FDA/OGROP/ORAP/CE-FO/PHI- DO/PHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	MERCK SHARPE & DOHME CORP, WEST POINT, PA - EIRS, 483S CO RESP 9/12
2013-2422	03/28/2013 04/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	LUPIN CHEMICALS, TARAPUR, INDIA - EIRS, 483S, CO RESP 6/12
2013-2423	03/28/2013	FDA/OGROP/ORAP/SE-FO/ATL-	WALSTER E CHALKLEY	BAXTER HEALTHCARE CORP, MARION, NC - EIRS, 483S,

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	04/25/2013	DO/ATL-CB/	THOMSON REUTERS	CO RESP 8/12
2013-2424	03/28/2013 04/25/2013	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	WALTER E CHALKLEY THOMSON REUTERS	LACLEDE INC, RANCHO DOMINGUEZ, CA - EIRS, 483S, CO RESP 6/19-27/12
2013-2425	03/28/2013 04/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	JUBILANT HOLLISTERSTIER GENERAL PARTNERSHIP, KIRKLAND QUEBEC, CANADA - EIRS, 483S, CO RESP 3/19-26/12
2013-2426	03/28/2013 04/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	APOTEX INC, TORONTO, ON , CANADA - EIRS, 483S, CO RESP 8/13-24/12
2013-2427	03/28/2013 04/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	WALTER E CHALKLEY THOMSON REUTERS	CSL BEHRING, MARBURG, GERMANY - EIRS, 483S, CO RESP 1/27/12
2013-2428	03/28/2013 04/25/2013	FDA/OGROP/ORAP/SE-FO/ATL-DO/ATL-CB/	WALTER E CHALKLEY THOMSON REUTERS	HOSPIRA, ROCKY MOUNT, NC - EIRS, 483S, CO RESP 2/12/13-3/13/13
2013-2429	03/28/2013 04/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SAMUEL F. COLIN, M.D. FIRST MANHATTAN CO	DAIICHI SANKYO - BENICAR CORR
2013-2430	03/28/2013 04/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SAMUEL F. COLIN, M.D. FIRST MANHATTAN CO	NOVARTIS - DIOVAN CORR
2013-2431	03/28/2013 04/25/2013	FDA/OFVM/CFSAN/OCD/EOS/	FRAN SILVERMAN TRUTH IN ADVERTISING INC	NOURISH LIFE LLC - SPEECH NUTRIENTS SPEAK CMLPNTS
2013-2432	03/28/2013 04/25/2013	FDA/OFVM/CFSAN/OCD/EOS/	FRAN SILVERMAN TRUTH IN ADVERTISING INC	NOURISH LIFE LLC - SUPPLEMENTS CMLPNTS
2013-2433	03/28/2013 04/25/2013	FDA/OFVM/CFSAN/OCD/EOS/	WILLIAM A. OLSON, Ph.D. WASHINGTON INFORMATION SOURCE	FCN 141

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2013-2434	03/28/2013 04/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	MARILYNN WHITNEY WASHINGTON INFORMATION SOURCE	UNTITLED CDRH LTRS FROM 1/12
2013-2435	03/28/2013 04/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOSEPH L MARCHESE BURSOR & FISHER PA	ST JUDE MEDICAL INC - RIATA & RIATA ST MODEL 1560, 1561, 1562, ETC RECS
2013-2436	03/28/2013 04/25/2013	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	COURTNY GERRISH TODAYS TMJ4 WTMJ-TV	MEALS FOR FLIGHTS OUT OF MILWAUKEES MITCHELL INT'L AIPIORT & CHICAGO OHARE 1/4/10-12/2/12 - INSP; LSG SKY CHEFS & GATE GOURMET FACILITIES 1/4/10-12/28/12
2013-2437	03/28/2013 04/25/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ALBERTINE LUGINBUHL LIBRAIRIE MEDI SCIENCES	RPT FSR FOR HO407G
2013-2438	03/28/2013 05/15/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	MITCHELL, ERIC	PEL FREEZE CLNCL SYS - UNITRAY SSP HLA TYPING KITS BK000019
2013-2439	03/28/2013 04/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	LORI COHEN GREENBERG TRAUIG LLP	CR BARD INC - AVAULTA SUPPORT SYS; SOFRADIM PRODUCTION - UGYTEX DUAL KNIT MESH CORR
2013-2440	03/28/2013 04/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID M. HOFFMEISTER WILSON SONSINI ET AL	LOESTRIN 24 FE ANDA 078-267 - APRVL
2013-2441	03/28/2013 04/25/2013	FDA/OFVM/CFSAN/OCD/EOS/	UDI GROFMAN PAUL WEISS ET AL	HERBALIFE LTD - INVESTIGATIONS 5/12 TO 3/22/13
2013-2442	03/28/2013 04/25/2013	FDA/OMPT/CDRH/OCER/DFOI/ OC/ORACE/OCI/ OC/ORACE/OCI/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	DANIEL P. LAPINSKI WILENTZ GOLDMAN & SPITZER PA	RAM MEDICAL INC - COUNTERFEIT POLYPROPYLENE SURGICAL MESH PRODUCTS CORR
2013-2443	03/29/2013 04/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Melanie Bell Scilucet, LLC	ULTRESA - SBA

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2013-2444	03/29/2013 04/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Alex Silverstein Sigma Capital Management	PML ETC - AERS
2013-2445	03/29/2013 04/26/2013	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	Matthew Wallace CARGILL	GILMAN FARM SERVICE CENTER - PHOTOS (03/22/2013 - 03/22/2013)
2013-2446	03/29/2013 04/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jennifer Caggiano Sidney P. Cominsky Trial Lawyers LLC	OSP - WARNINGS (CERTIFIED)
2013-2447	03/29/2013 04/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Mark Priz Registrar Corp	RADIATION EMITTING DEVICES REPORTED TO CDRH UNDER AN INITIAL RADIATION SAFETY REPORT (01/01/2008 - 12/31/2012)
2013-2448	03/29/2013 04/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Casey A. Metzger STRYKER INSTRUMENTS	K972832
2013-2449	03/29/2013 04/26/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORACE-FO/NYK-DO/NYK-DCB/	KS ChetakSF	ENTRY 551-2353070-7
2013-2450	03/29/2013 04/26/2013	FDA/OGROP/ORACE-FO/NWE-DO/NWE-CB/	Stephen Willey Stifel Nicolaus & Co	ALEXION PHARMACEUTICALS, SMITHFIELD, RI - WARNING LETTER RECS
2013-2451	03/29/2013 07/31/2013	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	FCN 939
2013-2452	03/29/2013 04/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	ANDA 78267 - APPROVAL, TENTATIVE APPROVAL
2013-2453	03/29/2013 04/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Linda Giles - Regulatory Specialist DenTek Oral Care, Inc.	K942633
2013-2454	03/29/2013 04/26/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Alan Brett Mindways Software, Inc.	K983273
2013-2455	03/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	Charlie Mack	K122120

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	04/26/2013		IRC KOREA	
2013-2456	03/29/2013 04/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jenna Groves Genesis Biosystems, Inc.	K965256
2013-2457	03/29/2013 04/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Linda Giles DenTek Oral Care, Inc.	K964976
2013-2458	03/29/2013 04/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jenna Groves Genesis Biosystems, Inc.	K963204
2013-2459	03/29/2013 04/26/2013	OC/ORA/ OC/ORA/	RAVNITZKY, MICHAEL	GENERAL MILLS CORP - RECS
2013-2460	03/29/2013 04/26/2013	OC/ORA/OE/ OC/ORA/OE/	ALISON YOUNG USA TODAY	DIETRARY SUPPLEMENTS - RECAL RECS
2013-2461	03/29/2013 04/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	MITCHELL A GOLDSTEIN Babener & Associates	NU SKIN ENTERPRISES INC (PHARMANEX) - NANOCOQ10 CLAIMS NOTIFICATIONS
2013-2462	03/29/2013 04/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID M HOFFMEISTER WILSON SONSINI ET AL	ANDA 78-267 - APRVL TLR
2013-2463	03/29/2013 04/26/2013	FDA/OFVM/CFSAN/OCD/EOS/	TODD S STEWART TODD S STEWART LAW OFCS	PELICAN SEAFOOD CO, MACY'S SMOKED FISH & DIP LLC, FORT PIERCE, FL, ETC - CIGUATERA POISONING RECS, EIRS, ATTACHMENTS, ETC
2013-2464	03/29/2013 04/26/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	TODD BOWLUS HARRY S COHEN & ASSOCIATES PC	INDIVIDUAL RECS
2013-2465	03/29/2013 04/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DON J MIZERK HUSCH BLACKWELL LLP	ANCHEN PHARMACEUTICALS INC - LUVOX CR ANDA 91-476 APRVL LTR 3/13/13
2013-2466	03/29/2013 04/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WARREN WILLIAMS FOREST RESEARCH INSTITUTE	DIV OF BIOEQUIVALENCE GUIDANCE FOR IN VIVO BIOEQUIVALENCE STUDIES OF METAPROTERENOL SULFATE AND ALBUTEROL (METERED DOSE INHALERS)

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2013-2467	03/29/2013 04/26/2013	OC/CVM/OCD/	ADAM DIEDERICH SCHIFF HARDIN LLP	RESIDUE TESTING OF HORSES AND HORSE MEAT 1/1/11 TO PRESENT
2013-2468	03/29/2013 04/26/2013	FDA/OGROP/ORO/ORO/DIOP/	MAYA FOA REPRIEVE	SODIUM THIOPENTAL POWDER - IMPORTS 1/1/12 TO PRESENT
2013-2469	03/29/2013 04/26/2013	FDA/OGROP/ORO/NE-FO/NWE-DO/NWE-CB/	WANDA CARPINELLA NAVILYST MEDICAL	NAVILYST MEDICAL INC, MARLBOROUGH, MA - EIRS 9/16/11
2013-2470	03/29/2013 04/26/2013	FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/	WANDA CARPINELLA NAVILYST MEDICAL	NAVILYST MEDICAL INC, GLENS FALLS, NY - EIRS 9/8-21/09, 4/30/10-5/27/10, 7/5-11/11
2013-2471	03/29/2013 04/26/2013	FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	SHADLE, PAULA	RHEIN BIOTECH GMBH, DUSSELDORF, GERMANY; DYNVAX TECHNOLOGIES INC, BERKELEY, CA - EIRS, 483S 2012, CO RESP 2/25/13
2013-2472	03/29/2013 04/26/2013	FDA/OGROP/ORO/NE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	ALEXION PHARMACEUTICALS INC, CHESHIRE, CT - EIRS, 483S, WARNING LTRS, ETC 1/1/11 TO PRESENT
2013-2473	04/01/2013 04/29/2013	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/CHI-DO/CHI-CB/ FDA/OGROP/ORO/SE-FO/SJN-DO/SJN-CB/	Merritt Lentz Lentz, Earl M	MOTIONS PROFESSIONAL HAIR RELAXER REGULAR - CONSUMER COMPLAINTS, ADVERSE EVENTS, INVESTIGATIONS ETC
2013-2474	04/01/2013 04/29/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mihir Taneja Belcher Pharmaceuticals, LLC	NDA 005897, NDA 006135, NDA 006012 ETC
2013-2475	04/01/2013 04/29/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Chris Cano Agile Therapeutics	QUARTETTE - MEDICAL OFFICER REVIEW, SUMMARY REVIEW
2013-2476	04/01/2013 04/29/2013	FDA/OFVM/CFSAN/OCD/EOS/	Cambria Roth Insight Magazine	PESTICIDE TESTS - FRUITS AND VEGETABLES

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2013-2477	04/01/2013 04/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sarah Buduson WEWS - NewsChannel5	MIRENA - AERS
2013-2478	04/01/2013 04/29/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Indeep Aulak Response Point of Care Inc.	K021317, K030286, K042890 ETC
2013-2479	04/01/2013 04/29/2013	FDA/OFVM/CFSAN/OCD/EOS/	Amy Taylor Infotrieve, Inc	PATHOLOGY REPORT ON OSBORNE-MENDEL RATS FED PHENETHYL SENOCIOATE IN RATIONS FOR FOUR MONTHS
2013-2480	04/01/2013 04/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Deb Hubers Deb Hubers	CYANOCOBALAMIN INJECTION USP 1000 MCG/ML - APPROVAL RECS
2013-2481	04/01/2013 04/29/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/CHI-DO/CHI-CB/	Tanisha Breton Tanisha Breton	PETAG - DATA, LAB RESULTS, COMMUNICATIONS ETC (01/01/2009 - 03/28/2013)
2013-2482	04/01/2013 04/29/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/MIN-DO/MIN-CB/	Melissa Stillson Stillson, Melissa	SWEET P'S COOKIES - COMPLAINT RECS (11/01/2012 - 01/01/2013)
2013-2483	04/01/2013 04/29/2013	FDA/OGROP/ORO/NE-FO/NWE-DO/NWE-CB/	Shin Kang WELLS FARGO SECURITIES	ALEXION PHARMACEUTICALS - 483, RESPONSE LETTERS, WARNING LETTER (08/01/2012 - 03/28/2013)
2013-2484	04/01/2013 04/29/2013	FDA/OGROP/ORO/NE-FO/NWE-DO/NWE-CB/ FDA/OC/OES/DFOI/	Patrick Moriarty HEALTHCOR MANAGEMENT LP	ALEXION PHARMACEUTICALS - WARNING LETTER, 483, COMMUNICATIONS, ETC (03/06/2009 - 03/28/2013)
2013-2485	04/01/2013 04/29/2013	FDA/OGROP/ORO/NE-FO/NWE-DO/NWE-CB/	Kumaraguru Raja Citi Research	ALEXION PHARMACEUTICALS - WARNING LETTER, 483 (08/06/2012 - 03/28/2013)
2013-2486	04/01/2013 04/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C THORNTON ANDREWS & THORNTON	BIOMET INC - METAL ON METAL ACETABULAR SYS K993438
2013-2487	04/01/2013 04/29/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	JOHN C THORNTON ANDREWS & THORNTON	BIOMET INC - M2A MAGNUM SYS K042037
2013-2488	04/01/2013 04/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C THORNTON ANDREWS & THORNTON	BIOMET INC - M2A MAGNUM 12/14 TAPER INSERTS & ONE-PIECE MODULAR HEADS K061423

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2013-2489	04/01/2013 04/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C THORNTON ANDREWS & THORNTON	BIOMET INC - M2A 32MM TAPER SYS K003363
2013-2490	04/01/2013 04/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C THORNTON ANDREWS & THORNTON	BIOMET INC - M2A-MAGNUM TRI-SPIKE ACETABULAR COMPONENT K062995
2013-2491	04/01/2013 04/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C THORNTON ANDREWS & THORNTON	BIOMET INC - M2A C2A ACETABULAR SYS KK042841
2013-2492	04/01/2013 04/29/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	JOHN C THORNTON ANDREWS & THORNTON	BIOMET INC - M2A ACETABULAR SYS K011110
2013-2493	04/01/2013 04/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C THORNTON ANDREWS & THORNTON	BIOMET INC - METAL-ON-METAL HIP SYS K113271
2013-2494	04/01/2013 04/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C THORNTON ANDREWS & THORNTON	BIOMET INC - TAPERLOC 12/14 TAPER FEMORAL COMPONENTS K042537
2013-2495	04/01/2013 04/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C THORNTON ANDREWS & THORNTON	BIOMET INC - M2A 28MM RINGLOC ACETABULAR LINER K002379
2013-2496	04/01/2013 04/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	GERALD R KOLB BENDCABLE	LIST OF CERTIFIED MAMMOGRAPHY SITES UNDER THE MAMMOGRAPHY QUALITY STANDARDS ACT (MQSA) AS OF MOST RECENT DATE AVAILABLE
2013-2497	04/01/2013 04/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C THORNTON ANDREWS & THORNTON	BIOMET INC - METAL-ON-METAL HIP SYS EXPANDED CONTRAINDICATIONS K082446
2013-2498	04/01/2013 04/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	ZHEJIANG XIANJU PHARMS, ZHEJIANG, CHINA - 483S 7/18-21/11
2013-2499	04/01/2013 04/29/2013	FDA/OC/OES/DFOI/	BRODY MULLINS WALL STREET JOURNAL	2010-3861, 2010-3977, 2010-4021, ETC
2013-2500	04/01/2013 04/29/2013	FDA/OC/OES/DFOI/	BRODY MULLINS WALL STREET JOURNAL	2012-2179, 2012-2188, 2012-2685, ETC
2013-2501	04/01/2013 04/29/2013	FDA/OC/OES/DFOI/	BRODY MULLINS WALL STREET JOURNAL	2013-339, 2013-876, 2013-159, ETC
2013-2502	04/01/2013 04/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHRIS CANO Agile Therapeutics	TEVA - QUARTETTE (LEVNORGESTREL/ETHINYL ESTRADIOL & ESTRADIOL) TABS MEDICAL OFFICERS RVWS, SUMMARY RVWS
2013-2503	04/01/2013	FDA/OMPT/CDER/ORP/DIDP/	EDWARD R MCNICHOLAS	VIFOR PHARMA LTD - IRON SUCROSE ANDA 78-215 APRVL

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	04/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SIDLEY AUSTIN LLP	RECS, PUBLIC LOG RECEIPT
2013-2504	04/01/2013 04/29/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	MEADE, DORIS .	S & S FLAVORS, ST BREA, CA - EIR; 2/11
2013-2505	04/01/2013 04/29/2013	OC/ORA/ OC/ORA/ OC/ORA/ORM/ OC/ORA/ORM/	ROBERT KING FDA NEWS	LIST OF 483S NOTICES OF INSPECTIONAL OBSERVATIONS FOR PHARMACEUTICALS, BIOLOGICS & MEDICAL DVC MFG FACILITIES IN THE USA & OUTSIDE OF THE USA 2/1-28/13
2013-2506	04/01/2013 04/29/2013	FDA/OGROP/ORA/CE-FO/CHI- DO/CHI-CB/ OC/ORA/ OC/ORA/ FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/	Doe J	CMPLNT - TOMATO PASTE
2013-2507	04/01/2013 04/29/2013	OC/CVM/OCD/	Doe J	CMPLNT - PURINA BENEFULL DOG FOOD
2013-2508	04/01/2013 04/29/2013	OC/OM/OMP/DDM/	SETH MAILHOT SHEPPARD MULLIN	DKT 1995S-0316
2013-2509	04/01/2013 04/29/2013	OC/OM/OMP/DDM/	LYNN DITTIDRAI GIBSON DUNN & CRUTCHER LLP	FDC-70 DKT LOG, FDC-77 TR, EXHIBITS
2013-2510	04/02/2013 04/30/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	LUO, LUCY	CMPLNT 131355
2013-2511	04/02/2013 04/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	THOMAS M. BURTON WALL STREET JOURNAL	IN VITRO DIAGNOSTICS - AERS
2013-2512	04/02/2013 04/30/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHRISTINE JAMES, ND Sound Sleep Health	ATTIX - HCG AER
2013-2513	04/02/2013	FDA/OMPT/CDER/ORP/DIDP/	KATHY M. McGOWN	QUARTETTE (LEVONORGESTREL/ETHINYL ESTRADIOL) NDA 204-061 SBA

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	04/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FO XKISER	
2013-2514	04/02/2013 04/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CAZARES, MARCUS .	DAVROCET - BAN
2013-2515	04/02/2013 04/30/2013	FDA/OGROP/OR A/NE-FO/NWE-DO/NWE-CB/	ANDREW HACK, MD, PhD. MILLENNIUM MANAGEMENT LLC	ALEXION PHARMACEUTICALS INC, CHESHIRE, CT; SWITZERLAND; RI - 483, EIR, WARNING LTR, UNTITLED LTRS 1/11 TO PRESENT
2013-2516	04/02/2013 04/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN F. THOMPSON, PHARM D, FCP ROBINSON & THOMPSON	PROPYLTHIOURACIL - AER
2013-2517	04/02/2013 04/30/2013	FDA/OGROP/OR A/CE-FO/PHI-DO/PHI-CB/ FDA/OGROP/OR A/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/OR A/CE-FO/PHI-DO/PHI-CB/	PATRICIA L. REGENYE Celgene Corporation	CHERIAN VERGHESE, ALBERT EINSTEIN MED CTR, PHILADELPHIA, PA - 483 2/07 TO 3/13
2013-2518	04/02/2013 04/30/2013	OC/CVM/OCD/ FDA/OGROP/OR A/SE-FO/ATL-DO/ATL-CB/ FDA/OGROP/OR A/SE-FO/FLA-DO/FLA-CB/ FDA/OGROP/OR A/SW-FO/KAN-DO/KAN-CB/	DEB WINKLER PUTNEY INC	PFIZER ANIMAL HEALTH, LINCOLN NE; BAYER HEALTHCARE LLC; SHAWNEE, KS; BAYER, JOSEPH, MO - 483 MOST RECENT
2013-2519	04/02/2013 04/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HOLLY EMRICK SVETZ WOMBLE CARLYLE ET AL	SHIRE DEVELOPMENT INC - PROAMATINE CORR
2013-2520	04/02/2013 04/30/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/OR A/CE-FO/NWJ-DO/NWJ-CB/ OC/OR A/ OC/OR A/	GENEVIEVE M. SPIRES PORZIO BROMBERG & NEWMAN PC	WELCHS FOODS INC - FRUIT SNACK 5/11 TO 6/11

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2013-2521	04/02/2013 04/30/2013	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	DAVID A. CHAPPELLE NFI DISTRIBUTION	NFI DISTRIBUTION, TAMPA, FL - EIR 2/27/13
2013-2522	04/02/2013 04/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	SARA BEARDSLEY SIDLEY AUSTIN LLP	STRYKER SUSTAINABILITY SOLUTIONS - REPROCESSED STEERABLE INTRODUCER K123334
2013-2523	04/02/2013 04/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	LUCA VESCOVO PARAMED SRL	MR OPEN K101295
2013-2524	04/02/2013 04/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANA CABRERA KMGH-TV	PHYSICIANS, PHARMACIES SEEKING PERMISSION TO USE HGH PAST 10 YRS
2013-2525	04/02/2013 04/30/2013	FDA/OC/OES/DFOI/	MARIA STISO PREMIER INVESTIGATORS	DANIELE INT'L V. WHOLESOME SPICE & SEASONINGS - SALMONELLA 2009
2013-2526	04/03/2013 05/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BETH ZIEMBA CELL THERAPEUTICS INC	RUXOLITINIB - MEDWATCH 3500A
2013-2527	04/03/2013 05/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORR/CE-FO/NWJ-DO/NWJ-CB/	JAMES F SWINDOLL JAMES F SWINDOLL LAW OFCS	CLARIS LIFESCIENCE, CLARIS LIFESCIENCE INC - IV METRONIDAZOLE RECALL RECS
2013-2528	04/03/2013 05/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Elspeth Callahan INDEPENDENCE LEGAL SUPPORT	AUGUST 2007 LETTER TO PALATIN TECHNOLOGIES RE BREMELANOTIDE; CLINICAL TRIAL DATA
2013-2529	04/03/2013 05/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/OM/OMP/DDM/ FDA/OC/OES/DDM/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	ABUK IMPURITIES IN OXYCODONE HCI PRODUCTS

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2013-2530	04/03/2013 05/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DON J MIZERK HUSCH BLACKWELL LLP	ANCHEN PHARMACEUTICALS INC - LUVOX CR ANDA 91-476 APRVL LTR 3/13/13
2013-2531	04/03/2013 05/01/2013	FDA/OMPT/CTP/OD/ FDA/OC/OL/ FDA/OMPT/CTP/OD/	MARK GREENWOLD CAMPAIGN FOR TOBACCO-FREE KIDS	CENTER FOR TOBACCO PRODUCTS MTG - REQUIREMENTS FOR TESTING OF HARMFUL CONSTITUENTS REQUIRED BY SECTION 904 OF THE TOBACCO CONTROL ACT
2013-2532	04/03/2013 05/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SIDNEY WOLFE MD PUBLIC CITIZEN	ISRS 6865332, 7031713, 7031715, ETC
2013-2533	04/03/2013 05/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	BOSTON SCIENTIFIC CORP - SOLYX SIS SYS K081275 CMLNPTS, 510K CLEARANCE
2013-2534	04/03/2013 05/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	BOSTON SCIENTIFIC CORP - ADVANTAGE TRANSVAGINAL MID URETHRAL SLING SYS K020110 CMLNPTS, 510K CLEARANCE, ETC
2013-2535	04/03/2013 05/01/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	BOSTON SCIENTIFIC CORP - PINNACLE PELVIC FLOOR REPAIR KITS K071957 CMLNPTS, 510K CLEARANCE, ETC
2013-2536	04/03/2013 05/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	BOSTON SCIENTIFIC CORP - PREFYX PPS SYS K040787 CMLNPTS, 510K CLEARANCE, ETC
2013-2537	04/03/2013 05/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	BOSTON SCIENTIFIC CORP - ADVANTAGE FIT SYS K020110 CMLNPTS, 510K CLEARANCE, ETC
2013-2538	04/03/2013 05/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	BOSTON SCIENTIFIC CORP - LYNX SUPRAPUBIC MID URETHRAL SLING SYS K020110 CMLNPTS, 510K CLEARANCE, ETC
2013-2539	04/03/2013 05/01/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	BOSTON SCIENTIFIC CORP - UPHOLD VAGINAL SUPPORT SYS K081048 CMLNPTS, 510K CLEARANCE, ETC
2013-2540	04/03/2013 05/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	BOSTON SCIENTIFIC CORP - OBTRYX TRANSOBTURATOR MID URETHRAL SLING SYS K040787 CMLNPTS, 510K CLEARANCE, ETC
2013-2541	04/03/2013 05/01/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OES/DFOI/	Benjamin Essner crossover Healthcare Fund	MEETING TRANSCRIPTS
2013-2542	04/03/2013 05/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	Dr. C. J. Kaiser gke-GmbH	K113302
2013-2543	04/03/2013	FDA/OC/OES/DFOI/	Megan Pickel	CFSAN FOIA REQUESTS (02/26/2013 - 03/29/2013)

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	05/01/2013		BEVERIDGE & DIAMOND	
2013-2544	04/03/2013 05/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John Newman JMP Securities	NDA 204063
2013-2545	04/03/2013 05/01/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Ken Reid Washington Information Source Co.	ALEXION PHARMACEUTICALS, RHODE ISLAND - 483, EIR, RESPONSE (08/02/2012 - 03/29/2013)
2013-2546	04/03/2013 05/01/2013	OC/ORA/ OC/ORA/	James A. Robson Cash, Krugler & Fredericks LLC	CLINICAL SPECIALTIES LLC AKA CLINICAL SPECIALTIES COMPOUNDING PHARMACY - RECALL RECS MARCH 2013
2013-2547	04/03/2013 05/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John Newman JMP Securities	NDA 202379 S005
2013-2548	04/03/2013 05/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jason Leckerman; Marcel Pratt BALLARD SPAHR LLP	ANDA 77415
2013-2549	04/03/2013 05/01/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	William Hite Columbia Management	ALEXION - WARNING LETTER (03/27/2013 - 03/28/2013)
2013-2550	04/03/2013 05/01/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	JONATHAN KLEIN SULLIVAN & COLLINS LLC	ASR TAPER SLEEVE ADAPTER SIZE 12/14+2 - RPTS, CORR, RECALL RECS, ETC
2013-2551	04/03/2013 05/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Alex Silverstein Sigma Capital Management	ISR 8917306, 9191334, 9126116
2013-2552	04/03/2013 05/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	JONATHAN KLEIN SULLIVAN & COLLINS LLC	DEPUY - ASR XL ACETABULAR SYS RPTS, CORR, RECALL RECS, ETC
2013-2553	04/03/2013 05/01/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Chris Wubbolt QACV Consulting, LLC	AMERICAN DENTAL PARTNERS, INC, WAKEFIELD, MA - EIR (1/31/2013 - 3/29/2013)
2013-2554	04/03/2013	FDA/OMPT/CDER/ORP/DIDP/	Daan De Coster	INHALED BECLOMETHASONE, BECLOMETASONE - DRUG MARKETING AUTHORIZATIONS

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	05/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Department of Primary Care and Population Health, University College London	
2013-2555	04/03/2013 05/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mathijs de Vaan Columbia University	QUARTERLY DATA FILES FROM AERS
2013-2556	04/03/2013 05/01/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORACE-FO/DET- DO/DET-CB/	JONATHAN KLEIN SULLIVAN & COLLINS LLC	DEPUY - ASR ACETABULAR CUP RPTS, CORR, RECALL RECS, ETC
2013-2557	04/03/2013 05/01/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORACE-FO/DET- DO/DET-CB/	JONATHAN KLEIN SULLIVAN & COLLINS LLC	DEPUY - ASR UNI FEMORAL IMPLANT RPTS, CORR, RECALL RECS, ETC
2013-2558	04/03/2013 05/01/2013	FDA/OFVM/CFSAN/OCD/EOS/	BRIAN H ELDRIDGE Segal McCambridge Singer & Mahoney	NUTRICIA NORTH AMERICA INC - NEOCATE E028 SPLASH CAERS, CMLPTS, TESTING, ETC
2013-2559	04/03/2013 05/01/2013	FDA/OFVM/CFSAN/OCD/EOS/	BRIAN H ELDRIDGE Segal McCambridge Singer & Mahoney	NUTRICIA NORTH AMERICA INC - NEOCATE JUNIOR CAERS, CMLPTS, TESTING, ETC
2013-2560	04/03/2013 05/01/2013	FDA/OFVM/CFSAN/OCD/EOS/	BRIAN H ELDRIDGE Segal McCambridge Singer & Mahoney	NUTRICIA NORTH AMERICA INC - NEOCATE INFANT RPTS, CORR, RECALL RECS, ETC
2013-2561	04/03/2013 05/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	MERCK - SINGULAIR (MONTELUKAST) ISRS 4660916, 7509835
2013-2562	04/03/2013 05/01/2013	FDA/OC/OES/DFOI/	ROBERT KING FDA NEWS	FOI DAILY LOG 3/25-29/13
2013-2563	04/03/2013 05/01/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORAPA-FO/SEA- DO/SEA-CB/	O'NEILL, KIT	NEW DAY FISHERIES INC - EIR, CLOSEOUT LTR, CO RESP, ETC 2004 TO PRESENT
2013-2564	04/04/2013 05/02/2013	OC/OM/OMP/DDM/	GLORIA GASKINS KLEINFELD KAPLAN & BECKER	DKT FDA-2012-P-1103
2013-2565	04/04/2013 05/02/2013	OC/OM/OMP/DDM/	DOREEN FRANK ENVISAGE CONSULTING LLC	DKT 1978N-1520, OTC VOL 060024, ETC.

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2013-2566	04/04/2013 05/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	(Mr) Taro Kanai (First Name/Last Name) MIC International Corp.	K121622
2013-2567	04/04/2013 05/02/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/OM/OMP/DDM/ FDA/OC/OES/DDM/	Jason Leckerman; Marcel Pratt BALLARD SPAHR LLP	DRAFT GUIDANCE ON BUPROPRION HYDROCHLORIDE - ADMIN FILE
2013-2568	04/04/2013 05/02/2013	FDA/OGROP/ORAN/NE-FO/NWE-DO/NWE-CB/	Alethia Young DEUTSCHE BANK	ALEXION - 483 ASSOCIATED WITH MARCH 27, 2013 483
2013-2569	04/04/2013 05/02/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jason Leckerman; Marcel Pratt BALLARD SPAHR LLP	FDA FINDING THAT BUDEPRION XL 300 MG WAS NOT THERAPEUTICALLY EQUIVALENT TO WELBUTRIN XL 300 MG
2013-2570	04/04/2013 05/02/2013	OC/OM/OMP/DDM/ FDA/OC/OES/DDM/	William Miller DepuySynthes	GENERAL AND PLASTIC SURGERY DEVICES PANEL OF THE MEDICAL DEVICE ADVISORY COMMITTEE - MTG MINUTES RE DOWN CLASSIFICATION OF PET SUTURES ; FEDERAL REGISTER
2013-2571	04/04/2013 05/02/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Chloe Bird PROFESSIONAL COMPOUNDING CENTERS OF AMERICA (PCAA)	LIST OF FOREIGN IMPORTED DRUG PRODUCTS; LISTING OF NDC NUMBERS (01/03/2012 - 04/02/2013)
2013-2572	04/04/2013 05/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kathryn A. Jayne SomnoMed, Inc.	K050592
2013-2573	04/04/2013 05/02/2013	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	CLOSED FOIA REQUESTS 3/1-31/13
2013-2574	04/04/2013 05/02/2013	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 3/31/13
2013-2575	04/04/2013 05/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	DREW HILL STAGE 2 CONTRACT ENGINEERING LLC	K122154
2013-2576	04/04/2013 05/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	DREW HILL STAGE 2 CONTRACT ENGINEERING	K092435

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2013-2577	04/04/2013 05/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	DREW HILL STAGE 2 CONTRACT ENGINEERING	K081359
2013-2578	04/04/2013 05/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	DREW HILL STAGE 2 CONTRACT ENGINEERING	K052611
2013-2579	04/04/2013 05/02/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	DREW HILL STAGE 2 CONTRACT ENGINEERING	K003469
2013-2580	04/04/2013 05/02/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	DREW HILL STAGE 2 CONTRACT ENGINEERING	K012141
2013-2581	04/04/2013 05/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	DREW HILL STAGE 2 CONTRACT ENGINEERING	K020857
2013-2582	04/04/2013 05/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	DREW HILL STAGE 2 CONTRACT ENGINEERING	K021340
2013-2583	04/04/2013 05/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	DREW HILL STAGE 2 CONTRACT ENGINEERING LLC	K030532
2013-2584	04/04/2013 05/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	DREW HILL STAGE 2 CONTRACT ENGINEERING	K030587
2013-2585	04/04/2013 05/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	DREW HILL STAGE 2 CONTRACT ENGINEERING LLC	K033617
2013-2586	04/04/2013 05/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	DREW HILL STAGE 2 CONTRACT ENGINEERING LLC	K033657
2013-2587	04/04/2013 05/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	DREW HILL STAGE 2 CONTRACT ENGINEERING	K050172
2013-2588	04/04/2013 05/02/2013	FDA/OC/OES/DFOI/	MARY STIPANCIC PHARMA MEDICA RESEARCH INC	COVANCE INC, MADISON, WA - EIRS, 483S
2013-2589	04/04/2013	FDA/OGROP/ORAC/CE-FO/CIN-	K MICHELLE VASSALLO	ON DEMAND HOME MEDICAL LLC, OH - EIRS, 483S,

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	05/02/2013	DO/CIN-CB/	LINCARE INC	WARNING LTRS, ETC 1/05 TO PRESENT
2013-2590	04/04/2013 05/02/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KIMBERLY SMITH	PONATINIB/ICLUSIG - AERS
2013-2591	04/04/2013 05/02/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/ OC/ORO/OCI/ OC/ORO/OCI/	Sakal, John	ALBUTEROL - TEST RESULT 2/3/12
2013-2592	04/04/2013 05/02/2013	FDA/OFVM/CFSAN/OCD/EOS/	KRISTI O SMEDLEY PHD WASHINGTON INFORMATION SOURCE	SYNGENTA SEEDS INC - BNF 95
2013-2593	04/04/2013 05/02/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARY K BLASY Robbins, Geller, Rudman & Dowd	VENTRUS - VEN 309 (IFERANSERIN OINTMENT) - COMM, RPTS, INTERNAL RECS
2013-2594	04/04/2013 05/02/2013	FDA/OFVM/CFSAN/OCD/EOS/	LISA M RAVE WHYTE, HIRSHBOECK AND DUDEK, S.C.	QUALITYEGG LLC, GALT, IA - CORR 1/1/10 TO 12/31/11
2013-2595	04/04/2013 05/02/2013	FDA/OFVM/CFSAN/OCD/EOS/	MATEA GOLD LOS ANGELES TIMES	INTERAGENCY WORKING GROUP - FOOD MARKETED TO CHILDREN CORR, EMAILS, COMM
2013-2596	04/04/2013 05/02/2013	FDA/OFVM/CFSAN/OCD/EOS/	R CRAIG MCLAUGHIN ELK & ELK	RIVER RANCH FRESH FOODS PRODUCTS - LISTERIA EIRS, PHOTOGRAPHS, VIDEOTAPES, ETC
2013-2597	04/04/2013 05/02/2013	OC/OM/OMP/DDM/	GLORIA GASKINS KLEINFELD KAPLAN & BECKER	DKT 2002P-0435
2013-2598	04/04/2013 05/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	tom watkins CNN	INSULIN PUMP MALFUNCTIONS, INCENTIVES TO PRESCRIBE
2013-2599	04/04/2013	FDA/OMPT/CDER/ORP/DIDP/	Ortav Yehudai	CAMBREX PROFARMACO MILANO, MILAN, PAULLO, IT - 483

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	05/02/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Great Point Partners, LLC	(04/03/2012 - 04/01/2013)
2013-2600	04/05/2013 05/03/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Chris Elam Diabetes OneStop	DR SHERWYN L SCHWARTZ, SAN ANTONIO, TX - 483, RESPONSES, LETTERS (01/27/1995 - 08/31/2009)
2013-2601	04/05/2013 05/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tracie Carey, Regulatory Program Director Roche TCRC, Inc.	ISR 5662103, 4490357, 6410825 ETC
2013-2602	04/05/2013 05/03/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Brienne Kugler Morgan Stanley	ALEXION - WARNING LETTER, 483
2013-2603	04/05/2013 05/03/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Blake C. Arnold Robert W. Baird & Co.	ALEXION PHARMACEUTICALS - 483, RESPONSE (08/01/2012 - 12/25/2012)
2013-2604	04/05/2013 05/03/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Emily Bartkowicz AKERMAN SENTERFITT ATTYS	SURGICAL MESH - CORR, MEDICAL LITERATURE, INSPECTION RECS, ETC
2013-2605	04/05/2013 05/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Debbie Cabrera Agile Therapeutics	QUARTETTE - MEDICAL OFFICER REVIEW AND SUMMARY REVIEW
2013-2606	04/05/2013 05/03/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Jeff Pecoraro Pecoraro, Jeffery A	INDIVIDUAL RECS
2013-2607	04/05/2013 05/03/2013	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 3/4-8/13
2013-2608	04/05/2013 05/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	HAYNES, JANE ISBELL	FORTEO - AERS 2000 TO 4/3/13
2013-2609	04/05/2013 05/03/2013	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	WILLIAM SLEVIN NORTH AMERICAN RESCUE LLC	H&H ASSOCIATES INC, ORDINARY, VA - EIRS, 483S 2012 MOST RECENT

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2013-2610	04/05/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	LAVENIA FORD CARDINAL HEALTH	KIMBERLY-CLARK - KC 200, KC300 FACE MASK K111402
2013-2611	04/05/2013 05/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	H DAVID BLAIR BLAIR & STROUD ATTYS	SMITH & NEPHEW - R3 ACETABULAR SYS K083566
2013-2612	04/05/2013 05/03/2013	FDA/OC/OES/DFOI/	AMY KINCANON LEXISNEXIS COURTLINK INC	2011-7417
2013-2613	04/05/2013 05/03/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	SARA BEARDSLEY SIDLEY AUSTIN LLP	PRODUCT CODE ONB - CLOSED ANTINEOPLASTIC AND HAZARDOUS DRUG RECONSTITUTION AND TRANSFER SYSTEMS
2013-2614	04/05/2013 05/03/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JACOB MCDOWELL WEINBERG GROUP INC	ABBOTT - HUMIRA BLA 125057 APRVL LTR, FINAL LBLG, MOR, ETC
2013-2615	04/05/2013 05/03/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID PENG PHD Stifel Nicolaus & Co	ARIAD PHARMS - ICLUSIG CLNCL TRIALS RECS
2013-2616	04/05/2013 05/03/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	THOMAS J MOORE INSTITUTE FOR SAFE MEDICATION PRACTICES	ETRAVIRINE, RILONACEPT, DESVENLAFAXINE, ETC - NDA'S 22-187, NDA 12-5249, NDA 21-992POSTMARKETING COMMITMENTS, ETC
2013-2617	04/05/2013 05/03/2013	FDA/OC/OES/DFOI/	SAMUEL FRIEDMAN SAMUEL FRIEDMAN ATTORNEY AT LAW	2009-4918, 2009-9429 (CERTIFIED)
2013-2618	04/05/2013 05/03/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	JOHN C THORNTON ESQ ANDREWS THORNTON	DEPUY INC - ZIRCONIA ARTICUL/EZE FEMORAL BALLS K952088
2013-2619	04/05/2013 05/03/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	JOHN C THORNTON ESQ ANDREWS THORNTON	BIOMET INC - FREEDOM CONSTRAINED LINERS K030047

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		FDA/OC/OES/DFOI/		
2013-2620	04/05/2013 05/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C THORNTON ESQ ANDREWS & THORNTON	BIOMET INC - FULL HEMISPHERE RINGLOC LINER K920640
2013-2621	04/05/2013 05/03/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	JOHN A BERANBAUM BERANBAUM MENKEN LLP	LTR TO NEW YORK DOWNTOWN HOSPITAL 8/12
2013-2622	04/05/2013 05/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	INTUITIVE SURGICAL ENDOSCOPIC INSTRUMENT CONTROL SYS K090993
2013-2623	04/05/2013 05/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	INTUITIVE SURGICAL DA VINCI SI SURGICAL SYS - K081137
2013-2624	04/05/2013 05/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	INTUITIVE SURGICAL DA VINCI ENDOSCOPIC INSTRUMENTS, CONTROL SYS & ENDOWRIST STABILIZER K080291
2013-2625	04/05/2013 05/03/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	INTUITIVE SURGICAL DA VINCI SINGLE SITE INSTRUMENTS & ACCESSORIES K112208
2013-2626	04/05/2013 05/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C THORNTON ESQ ANDREWS & THORNTON	BIOMET INC - SHP HIP SYS K960984
2013-2627	04/05/2013 05/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	MODIFICATION TO INTUITIVE SURGICAL DA VINCI SURGICAL SYS & ENDOSCOPIC INSTRUMENTS - K043288
2013-2628	04/05/2013 05/03/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	JOHN C THORNTON ESQ ANDREWS & THORNTON	DEPUY INC - ULTIMA METAL-ON-METAL ACETABULAR CUP K001523
2013-2629	04/05/2013 05/03/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	JOHN C THORNTON ESQ ANDREWS THORNTON	DEPUY INC - ULTIMA UNIPOLAR HEAD AND ADAPTER SLEEVES K965156
2013-2630	04/05/2013 05/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C THORNTON ESQ ANDREWS & THORNTON	JOINT MEDICAL PRODUCTS CORP - ZTT I AND II ACETABULAR CUP OF THE S-ROM TOTAL HIP SYS K951000
2013-2631	04/05/2013 05/03/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DDM/	JOHN C THORNTON ESQ ANDREWS & THORNTON	MCKEE-FARRAR METAL-ON-METAL HIP - RECS
2013-2632	04/05/2013 05/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C THORNTON ESQ ANDREWS & THORNTON	RING METAL-ON-METAL HIP - RECS
2013-2633	04/05/2013 05/03/2013	OC/OM/OMP/DDM/	LAUREN FAMIGGIA Hyman, Phelps & McNamara, P.C.	DKT FDA-2009-N-0205, FDA-2010-N-0475, ETC.
2013-2634	04/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C THORNTON ESQ	SIVASH METAL-ON-METAL TOTAL HIP PROTHESES -

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	05/03/2013		ANDREWS & THORNTON	RECS
2013-2635	04/05/2013 05/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C THORNTON ESQ ANDREWS & THORNTON	SULZER ORTHOPEDICS INC - INTER-OP METASUL ACETABULAR SYS K974728
2013-2636	04/05/2013 05/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C THORNTON ESQ ANDREWS & THORNTON	WRIGHT MEDICAL TECHNOLOGY INC - CONSERVE PLUS SPIKED SHELL AND CONSERVE TOTAL 56MM FEMORAL HEAD K031963
2013-2637	04/05/2013 05/03/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	JOHN C THORNTON ESQ ANDREWS THORNTON	WRIGHT MEDICAL TECHNOLOGY INC - METAL TRANSCEND ARTICULATION SYS K004043
2013-2638	04/05/2013 05/03/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	JOHN C THORNTON ESQ ANDREWS & THORNTON	WRIGHT MEDICAL TECHNOLOGY INC - METAL TRANSCEND ARTICULATION SYS K021349
2013-2639	04/05/2013 05/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C THORNTON ESQ ANDREWS & THORNTON	SMITH & NEPHEW INC - REFLECTION CERAMIC ACETABULAR SYS -P030022
2013-2640	04/05/2013 05/03/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	JOHN C THORNTON ESQ ANDREWS & THORNTON	ENCORE ORTHOPEDICS INC - FOUNDATION POROUS COATED FLARED RIM ACETABULAR CUP K974095
2013-2641	04/05/2013 05/03/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	JOHN C THORNTON ESQ ANDREWS THORNTON	ENCORE ORTHOPEDICS INC - FOUNDATION POROUS COATED HEMISPHERICAL ACETABULAR K974093
2013-2642	04/05/2013 05/03/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	JOHN C THORNTON ESQ ANDREWS & THORNTON	ENCORE ORTHOPEDICS INC - FMP METAL/METAL ACETABULAR INSERT K003250
2013-2643	04/05/2013 05/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C THORNTON ESQ ANDREWS & THORNTON	HOWMEDICAL OSTEONICS CORP - STRYKER MODULAR HIP SYS K071082
2013-2644	04/05/2013 05/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C THORNTON ESQ ANDREWS & THORNTON	HOWMEDICA OSTEONICS CORP - REJUVENATE MODULAR STEM K081044
2013-2645	04/05/2013 05/03/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	JOHN C THORNTON ESQ ANDREWS & THORNTON	HOWMEDICA OSTEONICS CORP - ABG II MODULAR HIP STEM K092406
2013-2646	04/05/2013 05/03/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	JOHN C THORNTON ESQ ANDREWS THORNTON	ZIMMER GMBH - DUROM ACETABULAR COMPONENT AND METASUL LDH LARGE DIAMETER HEADS K053536

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		FDA/OC/OES/DFOI/		
2013-2647	04/05/2013 05/03/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	JOHN C THORNTON ESQ ANDREWS THORNTON	CENTERPULSE ORTHOPEDICS INC - EPSILON METASUL ACETABULAR INSERT AND METASUL MODULAR FEMORAL HEAD K033634
2013-2648	04/05/2013 05/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C THORNTON ESQ ANDREWS & THORNTON	BIOMET INC - UNIVERSAL ACETABULAR CUP, METAL ON METAL ACETABULAR SYS K993438
2013-2649	04/05/2013 05/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C THORNTON ESQ ANDREWS & THORNTON	BIOMET INC - TITANIUM MULLER TOTAL HIP K780357
2013-2650	04/05/2013 05/03/2013	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 3/11-15/13
2013-2651	04/05/2013 05/03/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 3/4-8/13
2013-2652	04/05/2013 05/03/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 3/11-15/13
2013-2653	04/05/2013 05/03/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 3/4-8/13
2013-2654	04/05/2013 05/03/2013	FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 3/4-8/13
2013-2655	04/05/2013 05/03/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 3/11-15/13
2013-2656	04/05/2013 05/03/2013	FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 3/11-15/13
2013-2657	04/05/2013 05/03/2013	FDA/OC/OES/DFOI/	GLADYS B TONKIN WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 3/11-15/13
2013-2658	04/05/2013 05/03/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 3/4-8/13
2013-2659	04/05/2013 05/03/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 3/11-15/13

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2013-2660	04/05/2013 05/03/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 3/4-8/13
2013-2661	04/05/2013 05/03/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 3/11-15/13
2013-2662	04/05/2013 05/03/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 3/11-15/13
2013-2663	04/05/2013 05/03/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 3/4-8/13
2013-2664	04/05/2013 05/03/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 3/4-8/13
2013-2665	04/05/2013 05/03/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 3/11-15/13
2013-2666	04/05/2013 05/03/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 3/4-8/13
2013-2667	04/05/2013 05/03/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 3/11-15/13
2013-2668	04/05/2013 05/03/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 3/4-8/13
2013-2669	04/05/2013 05/03/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOFIF DAILY LOG 3/11-15/13
2013-2670	04/05/2013 05/03/2013	FDA/OC/OES/DFOI/	GLADYS B TONKIN WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 3/4-8/13
2013-2671	04/05/2013 05/03/2013	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 3/11-15/13
2013-2672	04/05/2013 05/03/2013	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC	CLOSED FOIA REQUESTS 3/4-8/13
2013-2673	04/08/2013 05/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ingrid Hoos HORIZON PHARMA INC	NDA 202020
2013-2674	04/08/2013 05/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Trupti Shah TAKEDA PHARMACEUTICALS NA INC	OMONTYS - AERS

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2013-2675	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	Christopher Corridan Alden Medical LLC	K892329
2013-2676	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	Dion Brandt TIDI Products, LLC	K953672
2013-2677	04/08/2013 05/06/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Donald Parriott County College of Morris	USER GUIDE FOR CBER'S ELECTRONIC SIGNATURE PROCESS
2013-2678	04/08/2013 05/06/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jacquelin M. Cronin Jacobi & Chamberlain LLP	KLONOPIN - WARNINGS, LABELS, APPLICATIONS ETC
2013-2679	04/08/2013 05/06/2013	FDA/OC/OES/DFOI/	Desmond Jenson Public Health Law Center	CTP FOIA REQUEST LOG
2013-2680	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	Joseph T. Shen, MD Premier Heart, LLC	K992703
2013-2681	04/08/2013 05/06/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CARTER GOULD JMP Securities	ICLUSIG - ARES
2013-2682	04/08/2013 05/06/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	KLONIPIN - AERS
2013-2683	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Carl Jenkins WOOD BURDITT GROUP	K110131
2013-2684	04/08/2013 05/06/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gene Hall Gene Hall	DMF 15062
2013-2685	04/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Steve Pardue	K945794

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	05/06/2013		Elevate Oral Care	
2013-2686	04/08/2013 05/06/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Angela Turner Turner, Angela	NOVARTIS CONSUMER HEALTH INC, LINCOLN, NE - EIR (01/21/2013 - 02/28/2013)
2013-2687	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	Mihir Zaveri UC Berkeley Graduate School of Journalism	K083191; K923367; K831949 ETC
2013-2688	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	Steve Pardue Elevate Oral Care	K102808
2013-2689	04/08/2013 05/06/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Angela Turner Turner, Angela	NOVARTIS CONSUMER HEALTHCARE INC, LINCOLN, NE - RESPONSE TO 483 MARCH 2013
2013-2690	04/08/2013 05/06/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Sigal Melamed-Gal Teva Pharmaceuticals Company	PRILOSEC - SBA
2013-2691	04/08/2013 05/06/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Maryann Vigliotta Annovation Biopharma	AMIDATE - SBA
2013-2692	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	Aleq Rojas Aleqtro Global, L.L.C.	K994095
2013-2693	04/08/2013 05/06/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Garry Pogil Law Office of Garry Pogil	TRAVATAN - AERS
2013-2694	04/08/2013 05/06/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	shin kang WELLS FARGO	JAKAFI - AERS
2013-2695	04/08/2013 05/06/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Mitchell A. Goldstein Babener & Associates	NU SKIN ENTERPRISES AKA PHARMANEX - COMM WITH FDA RE NANOCOQ10
2013-2696	04/08/2013 05/06/2013	OC/ORAS/ OC/ORAS/ FDA/OGROP/ORACE-FO/DET-	Pradeepan Srinivasan Yem Foods LLC	ENTRY 11279475193 - REPORT OF PESTICIDE ANALYSIS

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		DO/DET-CB/		
2013-2697	04/08/2013 05/06/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Healthy Life Purity First Healthy Life Purity First	HEALTHY LIFE PURITY FIRST - COMPLAINTS
2013-2698	04/08/2013 05/06/2013	FDA/OC/OES/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OL/	Eric Lipton THE NEW YORK TIMES	HEMISPHERX BIOPHARMA (01/01/2012 - 06/01/2013) - CORR OUTSIDE NDA PROCESS
2013-2699	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	EMILY KRISTEN STRUNK AKIN GUMP STRAUSS HAUER & FELD, LLP	INRANGE REMOTE MEDICATION MANAGEMENT SYS K051338
2013-2700	04/08/2013 05/06/2013	FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OFVM/CFSAN/OCD/EOS/	EASLEY 103481, KENT A	PHENYLKETONURICS - RECS
2013-2701	04/08/2013 05/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHANDRAN TIRUWATTAR DR REDDY'S LABORATORIES INC	MYLAN PHARMS INC - ACYCLOVIR OINTMENT ANDA 202-459 CHEMISTRY RVW
2013-2702	04/08/2013 05/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARYLEE LAWREY WATSON LABORATORIES INC	CINDAMYCIN CAPS ANDA 63-083, PROBENECID TABS ANDA 84-442, CORTICOTROPIN INK ANDA 88-772 - BIO SECTION
2013-2703	04/08/2013 05/06/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Doe J	INDIVIDUAL RECS
2013-2704	04/08/2013 05/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHRISTINE JAMES ND Sound Sleep Health	ATTIX - HCG AERS
2013-2705	04/08/2013 05/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MICHAEL R COHEN RPH MS SCD INSTITUTE FOR SAFE MEDICATION PRACTICES	MEDWATCH CODED AS MEDICATION ERROS 3/1-31/13

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2013-2706	04/08/2013 05/06/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	MERCK - ISENTRESS (RALTEGRAVIR) ISRS 7234397, 8365298
2013-2707	04/08/2013 05/06/2013	FDA/OGROP/ORR/SW-FO/DEN-DO/DEN-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARK S JAFFE JAFFE LAW FRIM	DR HENRY LIN - INVESTIGATION RECS, VIOLATIONS REFERENCED IN WARNING LTR 3/8/10, STATUS OF ENFORCEMENT PROCEEDINGS, ETC
2013-2708	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	AMY PAGNOZZI SMC DIRECT LLC	HENRY SCHEIN - ONE STEP+ HCG TEST K953988; IMMUNOCARD STAT! - HCG COMBO ADVANTAGE PREGNACY TEST K9992187
2013-2709	04/08/2013 05/06/2013	FDA/OC/OES/ FDA/OFVM/CFSAN/OCD/EOS/	TOM NASH MUCKROCK NEWS	WALMART - CORR MENTIONING GMO, GENETICALLY MODIFIED, LBLG, ETC
2013-2710	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	MUNA KEA TECHNOLOGIES - CELLVIZIO 100 SERIES, CELLVIZIO SYSTEMS WITH CONFOCAL MINIPROBES K122042
2013-2711	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	MUNA KEA TECHNOLOGIES - CELLVIZIO 100 SERIES SYS, CELLVIZIO SYS WITH CONFOCAL MINIPROBES K120208
2013-2712	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	MUNA KEA TECHNOLOGIES - CELLVIZIO 100 SERIES SYS WITH CONFOCAL MINPROBES K111047
2013-2713	04/08/2013 05/06/2013	FDA/OFVM/CFSAN/OCD/EOS/	FOI Services, Inc.	EASTMAN CHEMICAL CO - FCN 1041
2013-2714	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	PENTAX MEDICAL CO - CONFOCAL VIDEO COLONOSCOPE K042741
2013-2715	04/08/2013 05/06/2013	OC/CVM/OCD/	FOI Services, Inc.	ELANCO ANIMAL HEALTH - TYPE B AND TYPE C REGULATORY ASSAY METHODS FOR TYLAN (TYLOSIN PHOSPHATE) NADA 12-491
2013-2716	04/08/2013 05/06/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	BIOGEN IDEC - TECFIDERA (DIMETHYL FUMARATE) N204063
2013-2717	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C. THORNTON, Esq. ANDREWS & THORNTON	BIOMET INC - BIO MOORE ENDO HEADS K984028

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2013-2718	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C. THORNTON, Esq. ANDREWS & THORNTON	BIOMET INC - CFE TOTAL HIP FEMORAL COMPONENT K830313
2013-2719	04/08/2013 05/06/2013	FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/	TRUDY FLOURNOY STEPTOE & JOHNSON	2011-6947
2013-2720	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C. THORNTON, Esq. ANDREWS & THORNTON	BIOMET INC - METAL ACETABULAR SYS K993438
2013-2721	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C. THORNTON, Esq. ANDREWS & THORNTON	BIOMET INC - NON CEMENTED POROUS COATED TOTAL HIP PROSTHESES K030055
2013-2722	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C. THORNTON, Esq. ANDREWS & THORNTON	BIOMET INC - PF ACETABULAR COMPONENT K861114
2013-2723	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C. THORNTON, Esq. ANDREWS & THORNTON	BIOMET INC - MALLORY HEAD TOTAL HIP SYS K853259
2013-2724	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C. THORNTON, Esq. ANDREWS & THORNTON	BIOMET INC - TAPERLOC FEMEROL STEM & UNIVERSAL ACETABULAR COMPONENT K921301
2013-2725	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C. THORNTON, Esq. ANDREWS & THORNTON	DEPUY INC - FOCUS TOTAL HIP SYS K883460
2013-2726	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C. THORNTON, Esq. ANDREWS & THORNTON	DEPUY INC - ARTICUL EZE FEMORAL HEADS K980513
2013-2727	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C. THORNTON, Esq. ANDREWS & THORNTON	SMITH & NEPHEW INC - HYDROXYAPATITE COATED REFLECTION ACETABULAR SHELL & HA COATED REFLECTION INTERFIT SHELL K990666
2013-2728	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C. THORNTON, Esq. ANDREWS & THORNTON	SMITH & NEPHEW INC - REFLECTION ACETABULAR COMPONENT K932755
2013-2729	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C. THORNTON, Esq. ANDREWS & THORNTON	SMITH & NEPHEW INC - MODULAR ACETABULAR CUP SYS K920430
2013-2730	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	JOHN C. THORNTON, Esq. ANDREWS & THORNTON	SMITH & NEPHEW INC - RELECTION 3 ACETABULAR SYS K070756
2013-2731	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C. THORNTON, Esq. ANDREWS & THORNTON	SMITH & NEPHEW INC - REFLECTION 3 ACETABULAR SYS K061253
2013-2732	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C. THORNTON, Esq. ANDREWS & THORNTON	SMITH & NEPHEW INC - REFLECTION DUAL DIMENSION SHELL K960094
2013-2733	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	JOHN C. THORNTON, Esq. ANDREWS & THORNTON	SULZER ORTHOPEDICS INC - INTER OP DURASUL ACETABULAR INSERT K983509
2013-2734	04/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C. THORNTON, Esq.	SULZER ORTHOPEDICS INC - INTER OP DURASUL

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	05/06/2013		ANDREWS & THORNTON	ACETABULAR INSERTS & COCR FEMORAL HEADS K993259
2013-2735	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C. THORNTON, Esq. ANDREWS & THORNTON	BIOMET INC - BIO MOORE ENDO HEAD TAPER ADAPTER K002106
2013-2736	04/08/2013 05/06/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	FRAN SILVERMAN TRUTH IN ADVERTISING INC	NOURISH LIFE LLC - CMLPNTS
2013-2737	04/08/2013 05/06/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	FRAN SILVERMAN TRUTH IN ADVERTISING INC	NOURISH LIFE LLC - SPEECH NUTRIENTS CMLPNTS
2013-2738	04/08/2013 05/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	HOWZE, BRITTANY	PROJECTS CONDUCTED BY DR JACQUELINE LEUNG, UCSF MEDICAL CTR 5R01AG031795 - 04, 5R01AG031795-03, 5R01AG031795-02
2013-2739	04/08/2013 05/06/2013	OC/ORACE/ORM/ OC/ORACE/ORM/	ROBERT KING FDANEWS	483 NOTICES FOR PHARMACEUTICAL, BIOLOGICS, MEDICAL DVC, CLNCL TRIAL FACILITIES 3/13
2013-2740	04/08/2013 05/06/2013	FDA/OO/OIM/OPILS/FDAHO/ FDA/OC/OES/DFOI/	ALISON YOUNG USA TODAY	REUMOFAN - DOCS
2013-2741	04/08/2013 05/06/2013	FDA/OO/OFBA/OAGS/ FDA/OMPT/CDRH/OCER/DFOI/	PATRICK CHENG CHILDRENS NATIONAL MEDICAL CENTER	MICHIGAN PEDIATRIC DVC CONSORTIUM, ANN ARBOR, MI; MISTRAL DVC CONSORTIUM, MENLO PK, NJ; PEDIATRIC CARDIOVASCULAR DVC CONSORTIUM, BOSTON, MA ETC - 2009 TO 2012
2013-2742	04/08/2013 05/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CATHY PETTERSEN MULLIN LAW GROUP PLLC	TRI SPRINTEC - AER
2013-2743	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	THOMAS S. MURPHY ANDOVER HEALTHCARE INC	MEDICAL PRODS INACCURATELY LABELED AS LATEX FREE - RECS
2013-2744	04/08/2013 05/06/2013	FDA/OGROP/ORACE-FO/ATL-DO/ATL-CB/	Jim Strickland WSB-TV	NESTLE PURINA PETCARE, FAIRBURN, GA - 483 (01/03/2010 - 04/03/2013)
2013-2745	04/08/2013 05/06/2013	FDA/OGROP/ORACE/ORO/DIOP/ FDA/OGROP/OIP/	Derick Lucas AGILENT TECHNOLOGIES	CHEMICAL CONTAMINANTS IN FOOD FROM FOREIGN POSTS
2013-2746	04/09/2013 05/07/2013	OC/OM/OMP/DDM/	DOREEN FRANK ENVISAGE CONSULTING LLC	OTC VOL. 060030, 060031, ETC.
2013-2747	04/09/2013 05/07/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	ANN WATERHOUSE HILL-ROM	HILL-ROM, MICHAEL MURPHY MTG - TRANS 3/28/13

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		FDA/OMPT/CDRH/OCER/DFOI/ OC/ORO/ OC/ORO/ FDA/OC/OCC/		
2013-2748	04/09/2013 05/07/2013	FDA/OGROP/ORO/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/	Doe J	INDIVIDUAL RECS
2013-2749	04/09/2013 05/07/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ERIC H WEINBERG ERIC H WEINBERG ESQ	BOEHRINGER INGELHEM PHARMACEUTICAL INC - PRADAXA (DABIGATRAN ETEXILATE MESYLATE) NDA 22-512/S0101 CORR, MINS, AMENDMENTS, ETC
2013-2750	04/09/2013 05/07/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ERIC H WEINBERG ERIC H WEINBERG ESQ	BOEHRINGER INGELHEM PAHRMACEUTICAL INC - PRADAXA (DABIGATRAN ETEXILATE MESYLATE) NDA 22-512/S009 AMENDMENTS, WARNINGS, CORR, ETC
2013-2751	04/09/2013 05/07/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ERIC H WEINBERG ERIC H WEINBERG ESQ	BOEHRINGER INGELHEM PAHRMACEUTICAL INC - PRADAXA (DABIGATRAN ETEXILATE MESYLATE) NDA 22-512/S007 AMENDMENTS, CORR, MINS, ETC
2013-2752	04/09/2013 05/07/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ERIC H WEINBERG ERIC H WEINBERG ESQ	BOEHRINGER INGELHEM PAHRMACEUTICAL INC - PRADAXA (DABIGATRAN ETEXILATE MESYLATE) NDA 22-512/S005 RISK EVALUATION AND MITIGATION STRATEGY (REMS), CORR, MINS, ETC
2013-2753	04/09/2013 05/07/2013	FDA/OC/OES/DFOI/	ANN WATERHOUSE HILL-ROM	HILL-ROM, BATESVILLE, IN - 483 2/1/13
2013-2754	04/09/2013 05/07/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GHORMLEY 138287, ANTHONY	VISTARIL - AERS
2013-2755	04/09/2013 05/07/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/ FDA/OFVM/CFSSAN/OCD/EOS/	VALERIE HANNIG OPPENHEIMER GROUP	COMPANIES LISTING DAVID OPPENHEIMER, OPPENHEIMER GROUP AS US AGENT (FRUIT & VEGETABLE IMPORTER)

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2013-2756	04/09/2013 05/07/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	AUBAGIO - AERS
2013-2757	04/09/2013 05/07/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	ENBREL BLA 103795 - APRVL RECS, MEDICAL RVWS
2013-2758	04/09/2013 05/07/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SAMUEL F COLIN MD FIRST MANHATTAN CO	VIVUS INC - QSYMIA AERS 9/15/12 TO PRESENT
2013-2759	04/09/2013 05/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	MARK PRINZ Registrar Corp	LIST OF FOREIGN RADIATION EMITING DVC MFRS 1/08 TO 12/12
2013-2760	04/09/2013 05/07/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	MICHELLE BODIEN QUIDEL CORPORATION	CLINICAL INNOVATIONS LLC - ROM PLUS AND ROM PLUS CONTROLS K110605
2013-2761	04/09/2013 05/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	MICHELLE BODIEN QUIDEL CORPORATION	METRIKA INC - DRX QT HCG & DRX QT HCG CONTROL SET K991532
2013-2762	04/09/2013 05/07/2013	FDA/OC/OES/	MARILYNN WHITNEY COVINGTON & BURLING LLP	LIVING ESSENTIALS - 5-HOUR ENERGY; PEPSICO INC - AMP ENERGY; FUZE BEVERAGE LLC - FULL THROTTLE, ETC OFFICE OF THE COMMISSIONER CORR 2/1/13 TO PRESENT
2013-2763	04/09/2013 05/07/2013	FDA/OFVM/CFSAN/OCD/EOS/	MARILYNN WHITNEY COVINGTON & BURLING LLP	LIVING ESSENTIALS - 5-HOUR ENERGY; PEPSICO INC - AMP ENERGY; FUZE BEVERAGE - FULL THROTTLE, ETC CENTER FOR FOOD SAFETY AND APPLIED NUTRITION CORR 2/1/13
2013-2764	04/09/2013 05/07/2013	FDA/OC/OL/	MARILYNN WHITNEY COVINGTON & BURLING LLP	LIVING ESSENTIALS - 5-HOUR ENERGY; PEPSICO INC - AMP ENERGY; FUZE BEVERAGE - FULL THROTTLE, ETC - OFFICE OF LEGISLATION CORR 2/1/13
2013-2765	04/09/2013 05/07/2013	FDA/OFVM/CFSAN/OCD/EOS/	Steven Burman Steven Burman	HAIR DYE INDUSTRY CONSENT AGREEMENT
2013-2766	04/10/2013 05/08/2013	OC/OM/OMP/DDM/	MARILYNN WHITNEY COVINGTON BURLING LLP	DKT & DKT LOG OF 1996N-0082
2013-2767	04/10/2013 05/08/2013	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	JONATHAN CARLSON WNCN-TV	FOOD FACILITY INSPS AT AIRLINE CATERING FACILITIES AT RALEIGH DURHAM INTERNATIONAL AIRPORT, MORRISVILLE, NC - RECS 1/11 TO 4/13

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2013-2768	04/10/2013 05/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	CARRIE WELCH RN DICKINSON PRUD'HOMME ADAMS & INGRAM LLP	MDRS 1847269, 1847254, 1068225, ETC 1/1/08 TO 4/1/13
2013-2769	04/10/2013 05/08/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHRIS DIMITROPOULOS ELION INVESTMENTS	ISIS PHARMS - SMNRX PRE-IND MTG MINS
2013-2770	04/10/2013 05/08/2013	FDA/OGROP/ORANE-FO/NYK- DO/NYK-DCB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALIA, PARMINDER SINGH	VERITAS HEALTHCARE LLC, NY - CLNCL INVESTIGATOR LIST, FINANCIAL DISCLOSURE STATEMENT, HIPAA AUTHORIZATION, ETC PRIOR TO 10/14/11
2013-2771	04/10/2013 05/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	KELLY K IVERSON COHEN & GRIGSBY PC	MEDTRONIC - THORACIC STENT GRAFT SYS P070007 CORR, APRVL LTRS, LBLG, ETC
2013-2772	04/10/2013 05/08/2013	FDA/OC/OES/DFOI/	JEFFREY J JONES JONES DAY	SCOTTS COMPANY LLC, GUTWEIN & CO INC - WILD BIRD FOOD PRODS FOI REQUESTS 1/08 TO PRESENT
2013-2773	04/10/2013 05/08/2013	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORA/ OC/ORA/ OC/ORA/OE/ OC/ORA/OE/	JOSH LONG VIRGO PUBLISHING	DIETARY SUPPLEMENT FACILITIES - 483S, WARNING LTRS, ENFORCEMENT ACTIONS, ETC FY 2010 TO FY 2012
2013-2774	04/10/2013 05/08/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ALAN R BENNETT ESQ ROPES & GRAY LLP	SUN PHARMA GLOBAL FZE - DOXORUBICIN HYDROCHLORIDE LIPOSOME INJ ANDA 203-263 REVIEWER MEMO
2013-2775	04/10/2013 05/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOCELYN J IVERSON NIELSEN ZEHE & ANTAS PC	AGFA CORP - DRYSTAR 4500M IMAGER MDRS
2013-2776	04/10/2013 05/08/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ruby Holder Greywall Asset Management	ADO-TRASTUZUMAB EMTANSINE - AERS
2013-2777	04/10/2013 05/08/2013	OC/CVM/OCD/ FDA/OC/OES/DFOI/	JEANNIE PERRON COVINGTON BURLING LLP	PHYTASE USE IN ANIMAL FEED - SAFETY ASSESSMENT

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2013-2778	04/10/2013 05/08/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nathan Sadeghi-Nejad Palkon Capital Management	ICLUSIG - AERS
2013-2779	04/10/2013 05/08/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Christine Piette Durrance UNC Chapel Hill	FDA APPROVED EMERGENCY CONTRACEPTIVES - NDC CODES
2013-2780	04/10/2013 05/08/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ruby Holder Greywall Asset Management	PONATINIB HYDROCHLORIDE (ICLUSIG) - AERS
2013-2781	04/10/2013 05/08/2013	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/OCI/ OC/ORO/OCI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	UDI GROFMAN PAUL WEISS RIFKIND WHARTON & GARRISON LLP	CARL ICAHN, ICAHN ENTERPRISES, ICAHN PARTNERS, ICAHN & CO - INVESTIGATION RECS, ENFORCEMENT ACTIONS 5/1/12 TO 3/22/13
2013-2782	04/10/2013 05/08/2013	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	Kevin P. Farrell WILSON ELSE ET AL	APHENA PHARMA SOLUTIONS MARYLAND FNA CELESTE CONTRACT PACKAGING, EASTON, MD - INVESTIGATIONS, INSPECTIONS, ENFORCEMENT ETC (04/01/2009 - 04/01/2013)
2013-2783	04/10/2013 05/08/2013	FDA/OFVM/CFSAN/OCD/EOS/	Dayun Ko Ko, Dayun	FCN 475
2013-2784	04/10/2013 05/08/2013	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/OCI/ OC/ORO/OCI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	UDI GROFMAN PAUL WEISS RIFKIND WHARTON & GARRISON LLP	ROBERT CHAPMAN, CHAPMAN CAPITAL - INVESTIGATION RECS, ENFORCEMENT ACTION, COMPLIANCE ACTION 5/1/12 TO 3/22/13
2013-2785	04/10/2013	FDA/OMPT/CBER/OCOD/DDOM/	Veronika Pesheva	ANTHRAX VACCINE IMMUNIZATION PROGRAM FOR

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	05/20/2013	ALFB/	Pesheva, Veronika	MILITARY UNITS - PROTOCOLS
2013-2786	04/10/2013 05/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Vassilios Christodoulopoulos SANDOZ CANADA INC.	NDA 203168
2013-2787	04/10/2013 05/08/2013	OC/CVM/OCD/	Dena White Boehringer Ingelheim Vetmedica, Inc.	NADA 009505, NADA 098379, NADA 140856 ETC - FOI SUMMARIES
2013-2788	04/10/2013 05/08/2013	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/OCI/ OC/ORO/OCI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	UDI GROFMAN PAUL WEISS RIFKIND WHARTON & GARRISON LLP	DANIEL S LOEB, THIRD POINT LLC - INVESTIGATION RECS, ENFORCEMENT ACTION, COMPLIANCE ACTION 5/1/12 TO 3/22/13
2013-2789	04/10/2013 05/08/2013	FDA/OGROP/ORO/SW-FO/KAN-DO/KAN-CB/	Lesley Valle Boehringer Ingelheim	JOHN DIPERSIO, WASHINGTON UNIVERSITY SCHOOL OF MEDICINE, ST LOUIS, MO - 483 (01/01/1983 - 04/09/2013)
2013-2790	04/10/2013 05/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Monica Reckless Salix Pharmaceuticals, Inc.	NDA 203634
2013-2791	04/10/2013 05/08/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	Jason Tsai KPC Products, Inc.	ENTRY FS2-1098058-7
2013-2792	04/10/2013 05/08/2013	FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/	Chris Elam Diabetes and Glandular Disease Clinic	DR MARK KIPNES, SAN ANTONIO, TX - 483 1998, 2000, 2012
2013-2793	04/10/2013 05/08/2013	FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/	Lesley Valle Boehringer Ingelheim	MD ANDERSON CANCER CENTER, HOUSTON, TX - 483 (01/01/1981 - 04/08/2013)
2013-2794	04/10/2013 05/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Monica Reckless Salix Pharmaceuticals, Inc.	NDA 203634 - PHARMACOLOGY REVIEW

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		FDA/OMPT/CDER/ORP/DIDP/		
2013-2795	04/10/2013 05/08/2013	FDA/OC/OES/DFOI/	MATTHEW PEARLMAN PCMG INC	LIST OF FDA PURCHASE CARD HOLDERS
2013-2796	04/10/2013 05/08/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DUSTIN BLOCK IPD ANALYTICS LLC	ETHINYL ESTRADIOL, NORETHINDRONE ACETATE ANDA 78-267 APRVL 9/1/09; ZOLEDRONIC ACID ANDA 91-363, ANDA 201-801 EFFECTIVE APRVL LTR 3/29/13
2013-2797	04/10/2013 05/08/2013	FDA/OFVM/CFSAN/OCD/EOS/	JAMES BLOOM NORM BLOOM & SON LLC	PROGRAM ELEMENT EVALUATION RPT OF GROWING AREA CLASSIFICATION ELEMENT FOR CT, PROGRAM ELEMENT EVALUATION RPT OF THE PLANT AND SHIPPING COR CT, ANNUAL PROGRAM EVALUATION RPT FOR CT FY 2006 TO FY 2012
2013-2798	04/10/2013 05/08/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SHWETA PATEL HETERO USA INC	BENICAR (OLMESARTAN MEDOXOMIL TABS - LBLG
2013-2799	04/10/2013 05/08/2013	FDA/OC/OES/DFOI/	JULIA G YOUNG STRICK LAW FIRM PLLC	DAVOL INC - MESH COMPOSIX KUGEL PATCH RPTS
2013-2800	04/10/2013 05/08/2013	FDA/OO/OHR/	SANTORI, AGNES M	INDIVIDUAL RECS
2013-2801	04/10/2013 05/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	STEVE SCHIEFER COMPASS MOLDED PRODUCTS LLC	ROTONICS MFG - SHARPS PLUS 5 GALLON PLUS CONTAINER K980179
2013-2802	04/10/2013 05/08/2013	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORR/NE-FO/NYK-DO/NYK-DCB/	KRISTEN CULTRARA DIETRICH LAW FIRM PC	FARM RICH (RICH FOODS) - RECALL RECS
2013-2803	04/10/2013 05/08/2013	FDA/OC/OES/DFOI/	Abraham, Troy	OPERATION MIND CONTROL - RECS
2013-2804	04/10/2013 05/08/2013	OC/CVM/OCD/ OC/ORR/ OC/ORR/ FDA/OGROP/ORR/CE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORR/CE-FO/CHI-DO/CHI-CB/	NICOLE A VENO IZARD NOBEL LLP	NESTLE PURINA PETCARE CO - BENEFUL BRAND DOG FOOD MYOTOXINS TEST SPLS 318110-0, 318111-0, 318112-0, ETC ANALYTICAL W/S, CORR

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		FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/		
2013-2805	04/11/2013 05/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	deborah gross Lympha Press USA	K120972
2013-2806	04/11/2013 05/09/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OFVM/CFSAN/OCD/EOS/	Cyndi Ivy Professional Liability Insurance Services, Inc.	SUNLAND, INC RAW AND ROASTED PEANUTS - RECALL RECS (09/14/2012 - 04/09/2013)
2013-2807	04/11/2013 05/09/2013	FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/	roland@treeoflifeherbals.com Tree of Life Herbals	NATURAL WELLNESS LLC - STRUCTURE/FUNCTION CLAIMS UNDER DSHEA
2013-2808	04/11/2013 05/09/2013	FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/	roland@treeoflifeherbals.com Tree of Life Herbals	LIFES2GOOD INC - STRUCTURE/FUNCTION CLAIMS UNDER DSHEA
2013-2809	04/11/2013 05/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Vikas Gokhale BIO-Pace Technology Inc	SSED FOR PACEMAKERS VIGOR-DR, BROMOS-DR
2013-2810	04/11/2013 05/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sunil Patel Livwel Therapeutics Inc.	DRUG MASTER FILES 14327, 17411
2013-2811	04/11/2013 05/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Virginia Beakes-Read Eisai Inc.	FDA/HHS RECOMMENDATION OF SCHEDULING UNDER THE CONTROLLED SUBSTANCES ACT SENT TO DEA RE FYCOMPA TABLETS
2013-2812	04/11/2013 05/09/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Jeffrey Dupont Iron Workers	SIBLEY MEMORIAL HOSPITAL, WASHINGTON, DC - EIRS (09/18/2009 - 07/15/2011)
2013-2813	04/11/2013 05/09/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Shin Kang WELLS FARGO	DRUGS GRANTED BREAKTHROUGH THERAPIES (10/01/2012 - 04/09/2013)
2013-2814	04/11/2013	FDA/OGROP/ORACE-FO/CIN-	MaryAnn Ivie	INVACARE CORPORATION - INSPECTIONS, WARNING

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	05/09/2013	DO/CIN-CB/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	COSGRAVE VERGEER KESTER LLP	LETTERS, TESTING ETC (04/01/2004 - 04/01/2012)
2013-2815	04/11/2013 05/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dennis W. Raisch UNIVERSITY OF NEW MEXICO	PEGINISATIDE - ANAPHYLAXIS OR HYPERSENSITIVITY
2013-2816	04/11/2013 05/09/2013	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	Becky Armfield NOVARTIS ANIMAL HEALTH US INC	EX-LAX, INC, HUMACAO, PR - EIR MOST RECENT (03/05/2013 - 03/07/2013)
2013-2817	04/11/2013 05/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Skadden - Steven Napolitano Skadden, Arps, Slate, Meagher & Flom LLP	ANDA 074843
2013-2818	04/11/2013 06/06/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Jonathan R. Sanford Nanobiosym Diagnostics, Inc.	BK030033
2013-2819	04/11/2013 05/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jason Hughes Dianna Hughes	GLYBURIDE - AERS
2013-2820	04/11/2013 05/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	WELCHOL - OCP REVIEW OF DDI STUDIES
2013-2821	04/11/2013 05/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Corey Pugliese Purcell & Ingraio	SOTRADECOL - AERS
2013-2822	04/11/2013 05/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Timothy Bassett Pura Vida Investments	DELZICOL - REVIEW RECS (03/10/2011 - 02/10/2013)
2013-2823	04/11/2013	FDA/OFVM/CFSSAN/OCD/EOS/	Jeannette Cooperman	SIMPLY THICK - FIRST COMMUNICATION RE POSSIBLE

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	05/09/2013		St. Louis Magazine	PROBLEM
2013-2824	04/11/2013 06/03/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Lesley Valle Boehringer Ingelheim	UNIVERSITY OF MICHIGAN, SOUTHWEST ONCOLOGY GROUP - 483 (01/01/1981 - 04/10/2013)
2013-2825	04/11/2013 05/09/2013	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Laurence Paskowitz Paskowitz Law Firm P.C.	HOSPIRA, LAKE FOREST, IL; CLAYTON, NC; ROCKY MOUNT, NC ETC - EIRS (01/01/2009 - 04/10/2013)
2013-2826	04/11/2013 05/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Skadden - Steven Napolitano Skadden, Arps, Slate, Meagher & Flom LLP	ANDA 040507
2013-2827	04/11/2013 06/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	MANISH AHUJA BIOTEX INC	P12005
2013-2828	04/11/2013 05/09/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Eve Damiano Damiano Consulting Associates	SCIENTIFIC PROTEIN LABORATORIES, LLC, WAUNAKEE, WI - EIRS
2013-2829	04/11/2013 05/09/2013	FDA/OC/OES/DFOI/	CHRIS HURLEY COAST TO COAST	LIST OF FDA PURCHASE CARD HOLDERS
2013-2830	04/11/2013 05/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Eli Werner GE MEDICAL SYSTEMS ISRAEL, FUNCTIONAL IMAGING	K082588
2013-2831	04/11/2013 05/09/2013	FDA/OFVM/CFSAN/OCD/EOS/	Ron Leisner PPG Industries, Inc.	FCN 1060
2013-2832	04/11/2013 05/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	MANISH AHUJA BIOTEX INC	P050012
2013-2833	04/11/2013 06/06/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Jonathan R. Sanford Nanobiosym Diagnostics, Inc.	BK000038
2013-2834	04/11/2013 05/09/2013	FDA/OC/OES/DDM/	Desmond Jenson Tobacco Control Legal Consortium	FDA-2012-N-1032 - COMMENTS
2013-2835	04/11/2013	FDA/OMPT/CDER/ORP/DIDP/	WALTER E. CHALKLEY	ENBREL BLA 103-795/S1001 - CLNCL RVW

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	05/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	THOMSON REUTERS	
2013-2836	04/11/2013 05/09/2013	FDA/OC/OES/DDM/	Peter R. Breggin, MD Center for the Study of Empathic Therapy	PSYCHOPHARMACOLOGIC DRUGS ADVISORY COMMITTEE - TRANSCRIPT (02/24/1984)
2013-2837	04/11/2013 05/09/2013	FDA/OFVM/CFSAN/OCD/EOS/ USA TODAY	ALISON YOUNG	DIETARY SUPPLEMENTS - CAERS 1/08 TO 12/31/12
2013-2838	04/11/2013 05/09/2013	FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	BEIL, LAURA	CELLTEX THERAPEUTICS, HOUSTON, TX - CORR, EIRS, AERS
2013-2839	04/11/2013 05/09/2013	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORAS/ OC/ORAS/	VERONICA S KNAPP HOGAN LOVELLS US LLP	CANDY TREASURE LLC - CHOCO TREASURE EGGS SAFETY RECS
2013-2840	04/11/2013 05/09/2013	OC/ORAS/ORM/ OC/ORAS/ORM/	GAIL LESSICK LACHMAN CONSULTANT SERVICES INC	LIST OF DOMESTIC & FOREIGN INSP FOR DRUG COMPANIES, MEDICAL DVC MANUFACTURERS, BIORESEARCH MONITORING ETC 2/13
2013-2841	04/11/2013 05/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JAMES R JOHNSON HOGAN LOVELLS US LLP	SANDRIL NDA 09-376, SERPANRAY NDA 09-391, SERPASIL NDA 09-115, ETC - APRVL LTR
2013-2842	04/11/2013 05/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JAMES R JOHNSON HOGAN LOVELLS US LLP	RESERPINE - APRVL LTR
2013-2843	04/11/2013 05/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JAMES R JOHNSON HOGAN LOVELLS US LLP	PHENDIMETRAZINE TARTRATE ER, 105MG PHENDIMETRAZINE TARTRATE CAPS - APRVL LTR
2013-2844	04/11/2013 05/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HUTAR, CLAIRE	HUMAN EXPERIMENTS PERTAINING TO CONTRACEPTION 1/1900 TO 1/2000

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2013-2845	04/11/2013 05/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	IBRAHIM, ALEXANDRA	ISOTRETINOIN (ACCUTANE) - AER
2013-2846	04/11/2013 05/09/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	MEADE, DORIS.	NATUREX, SHINGLE SPRINGS, CA - 483, EIR 12/17/12
2013-2847	04/11/2013 05/09/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	SAMUEL FRIEDMAN, PC SAMUEL FRIEDMAN ATTORNEY AT LAW	EDWARD B BEHARRY & CO LTD, LACYTOWN, GUYANA - GINGERMINT BOZ-0018528-6 CERTIFIED
2013-2848	04/11/2013 05/09/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	SAMUEL FRIEDMAN, PC SAMUEL FRIEDMAN ATTORNEY AT LAW	EDWARD B BEHARRY & CO LTD, LACYTOWN, GUYANA - CONFECTIONS 113-2105994-8 CERTIFIED
2013-2849	04/11/2013 05/09/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	SAMUEL FRIEDMAN, PC SAMUEL FRIEDMAN ATTORNEY AT LAW	EDWARD B BEHARRY CO, LACYTOWN, GUYANA - INDI CURRY POWDER DM9-3010657-8 CERTIFIED
2013-2850	04/11/2013 05/09/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	SAMUEL FRIEDMAN, PC SAMUEL FRIEDMAN ATTORNEY AT LAW	EDWARD B BEHARRY CO, LACYTOWN, GUYANA - COUGH DROPS CANDY 406-0371077-9 CERTIFIED
2013-2851	04/11/2013 05/09/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	SAMUEL FRIEDMAN, PC SAMUEL FRIEDMAN ATTORNEY AT LAW	EDWARD B BEHARRY CO, LACYTOWN, GUYANA - TATTOO CHEWING GUM 406-0371007-9 CERTIFIED
2013-2852	04/11/2013 05/09/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	SAMUEL FRIEDMAN, PC SAMUEL FRIEDMAN ATTORNEY AT LAW	EDWARD B BEHARRY CO, LACYTOWN, GUYANA - GARAM MASALA 406-0443921-2 CERTIFIED
2013-2853	04/11/2013 05/09/2013	OC/ORA/ OC/ORA/	SAMUEL FRIEDMAN, PC SAMUEL FRIEDMAN ATTORNEY AT LAW	EDWARD B BEHARRY CO, LACYTOWN, GUYANA - CONFECTIONERY CONFECTIONS FOR CNSMPTION 916-2065571-1 CERTIFIED

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		FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/		
2013-2854	04/11/2013 05/09/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	SAMUEL FRIEDMAN, PC SAMUEL FRIEDMAN ATTORNEY AT LAW	EDWARD B BEHARRY & CO LTD, LACYTOWN, GUYANA - COUGH DROPS BOZ-0018528-6 CERTIFIED
2013-2855	04/11/2013 05/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	HEATHER BRADLEY EISAI INC	FYCOMPA (PERAMPANEL) NDA 202-834 10/22/12
2013-2856	04/11/2013 05/09/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	MEADE, DORIS. .	NATUREX, HACKENSACK, NJ - EIR, 483 5/17/12
2013-2857	04/11/2013 05/09/2013	FDA/OO/OHR/	BOB STEEVES DICKINSON'S FDA WEBVIEW	LIST OF FDA EMPLOYEES PAID WITH GOVT APPROPRIATIONS
2013-2858	04/11/2013 05/09/2013	FDA/OFVM/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	163394 - CAERS
2013-2859	04/11/2013 05/09/2013	FDA/OFVM/CFSAN/OCD/EOS/	DEVON Wm. HILL Keller and Heckman, LLP	REVIEW OF THE SUMMARY OF TABLE OF TOXICITY STUDIES ON DEHT
2013-2860	04/11/2013 05/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	MANISH AHUJA BIOTEX INC	P980022
2013-2861	04/11/2013 05/09/2013	FDA/OO/OFBA/OAGS/	BELLE NEUMANN AB SCIEX	SOLICITATION RFQ762600 - RESPONSE
2013-2862	04/12/2013 05/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Eric H. Weinberg The Law Firm of Eric H. Weinberg	NDA 22512
2013-2863	04/12/2013 05/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Brady Johnson TULANE UNIVERSITY	K122356
2013-2864	04/12/2013 05/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ian McClellan Oregon Health & Science University	CANAGLIFLOZIN - REVIEW PACKET
2013-2865	04/12/2013	FDA/OMPT/CDER/GRP/DIDP/	Eric H. Weinberg	NDA 22512

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	05/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	The Law Firm of Eric H. Weinberg	
2013-2866	04/12/2013 05/10/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kacie Carroll RN Barr & Mudford LLP	INCREDIBLE BULK, XCELER8-DHB, MASS XTREME ETC - AERS
2013-2867	04/12/2013 05/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORO/ OC/ORO/ OC/ORO/OE/ OC/ORO/OE/	Pat Williams Newman & McIntosh, LLC	DEXTROAMPHETAMINE/AMPHETAMINE 20 MG TABLETS, BARR LABORATORIES - RECALL RECS
2013-2868	04/12/2013 05/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	David M. Gottfried Law Office of David M. Gottfried	CORR FROM ROBERT SKIP CUMMINS TO FDA RE CYBERONICS AND A VEGUS NERVE STIMULATION IMPLANTATION DEVICE 2004 - 04/30/2005
2013-2869	04/12/2013 05/10/2013	FDA/OC/OES/DDM/	Katherine Giannamore Law Office of Katherine Giannamore, P.A.	52 FR 8831
2013-2870	04/12/2013 05/10/2013	FDA/OMPT/CTP/OD/	Desmond Jenson Tobacco Control Legal Consortium	CORR WITH FDA RE LETTER FROM RJ REYNOLDS TO ANN SIMONEAU AND BEVERLY CHERNAIK; FOLLOW UP MEETING (01/10/2012 - 04/10/2013)
2013-2871	04/12/2013 05/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	HYDROCODONE - AERS
2013-2872	04/12/2013 05/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Patrick Murphy LaserPointerSafety.com	LASER REGULATION AS DEMONSTRATION LASERS OR SLA
2013-2873	04/12/2013 05/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lauren Farruggia Hyman, Phelps & McNamara, P.C.	ANDA 090358 - SBA

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2013-2874	04/12/2013 05/10/2013	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	Lesley Valle Boehringer Ingelheim	VANDERBILT UNIVERSITY - 483 (01/01/1984 - 04/11/2013)
2013-2875	04/12/2013 05/10/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Evelyn Robertson ORGANOGENESIS INC	PROPPER MANUFACTURING, LONG ISLAND CITY, NY - EIR (01/01/2012 - 04/11/2013)
2013-2876	04/12/2013 05/10/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Evelyn Robertson ORGANOGENESIS INC	AVANTOR PERFORMANCE MATERIALS, PARIS, KY - EIR (08/01/2012 - 01/11/2013)
2013-2877	04/12/2013 05/10/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Michael Tomsic WFAE, NPR station in Charlotte, N.C.	BAXTER PHARMACEUTICALS, NORTH CAROLINA - INSPECTION RECS, WARNING LETTERS, ENFORCEMENT ACTIONS (12/01/2012 - 04/11/2013)
2013-2878	04/12/2013 05/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sammy Almashat MD Public Citizen Health Research Group (HRG)	LIRAGLUTIDE - 16 AERS
2013-2879	04/12/2013 05/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Franz-Josef Braun Meda Pharma GmbH & Co. KG	GLENMARK'S GENERIC OF ALDARA CREAM - THERAPEUTIC EQUIVALENCE STUDIES
2013-2880	04/12/2013 05/10/2013	FDA/OFVM/CFSAN/OCD/EOS/	PRESCOTT PAULIN 300 BELOW INC	TUNGSTEN DISULFIDE - APRVL
2013-2881	04/12/2013 05/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	SEAN BUNDY COCHLEAR AMERICAS	SOPHONO INC - OTOMAG BONE CONDUCTION HEARING SYS MODEL ALPHA1 S & M K102199
2013-2882	04/12/2013 05/10/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	CHEN, JOHN	SAMUEL CS CHANG, FINEMOST CORP, CERRITOS, CA - WARNING LTR, 483
2013-2883	04/12/2013 05/10/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	CHEN, JOHN	MAO L YANG, GM MANUFACTURING INC, GARDENA, CA - WARNING LTR, 483
2013-2884	04/12/2013 05/10/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	MANGEL, DAVID A	CMLPNT 124067
2013-2885	04/12/2013 05/10/2013	FDA/OO/OFBA/OAGS/	AMY TONG STRATEGI CONSULTING LLC	NETIMPACT STRATEGIES INC - CONTRACT #HHSF223201210029I
2013-2886	04/12/2013 05/10/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	K. MICHELLE VASSALLO LINCARE INC	LONGCAP DNS LLC, FL - EIR, 483, WARNING LTR 1/05 TO PRESENT
2013-2887	04/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	JUDY F. GORDON	FPT FRESCO PHOSPHENE TONOMETER K991840

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	05/10/2013		CLINREG CONSULTING SERVICES INC	
2013-2888	04/12/2013 05/10/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	LAUREL KOESTER WAVELIGHT LASER TECHNOLOGIE AG	WAVELIGHT GMBH, PRESSATH, GERMANY - EIR 1/28-31/13
2013-2889	04/12/2013 05/10/2013	OC/CVM/OCD/ OC/CVM/OCD/	MICHAEL J. SWEENEY DICKIE MCCAMEY & CHILCOTE	WESTERN CHEMICAL INC - PARASITE S (FORMALIN) NADA 140-989 APRVL, RVWS
2013-2890	04/12/2013 05/10/2013	OC/CVM/OCD/	MICHAEL J. SWEENEY DICKIE MCCAMEY & CHILCOTE	ARGENT CHEMICAL LABS INC - PARACIDE F (FORMALIN) NADA 140-831 APRVL, RVWS
2013-2891	04/12/2013 05/10/2013	OC/CVM/OCD/	MICHAEL J. SWEENEY DICKIE MCCAMEY & CHILCOTE	NATCHEZ ANIMAL SUPPLY CO - FORMALIN F (FORMALIN) NADA 137-687 APRVL, RVWS
2013-2892	04/12/2013 05/10/2013	OC/CVM/OCD/	MICHAEL J. SWEENEY DICKIE MCCAMEY & CHILCOTE	BL MITCHELL INC - FORMACIDE B (FORMALIN) NADA 200-414 APRVL, RVWS
2013-2893	04/15/2013 05/13/2013	FDA/OO/OFBA/OAGS/	Terrence M OConnor #2 Terrence M OConnor	ORACLE - CONTRACTS RECS (01/01/2010 - 04/10/2013)
2013-2894	04/15/2013 05/13/2013	FDA/OO/OFBA/OAGS/	Terrence M OConnor #3Revised Terrence M OConnor	ORACLE - CONTRACT DEBRIEFING SUMMARIES (01/01/2010 - 04/10/2013)
2013-2895	04/15/2013 05/13/2013	FDA/OO/OFBA/OAGS/	Terrence M OConnor #1 Terrence M OConnor	CORR BETWEEN FDA AND ORACLE RE FEDERAL BUSINESS SYSTEMS CORP, DLT-FBSC, SOLARIS ETC (01/01/2010 - 04/10/2013)
2013-2896	04/15/2013 05/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Paul Farrell Greene Ketchum	MEDICAL DEVICES WITH 510K CLEARANCE DATES BETWEEN 5/10/99 AND 4/30/04 THAT HAVE BEEN RECALLED
2013-2897	04/15/2013 05/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Eric H. Weinberg The Law Firm of Eric H. Weinberg	NDA 22512
2013-2898	04/15/2013 05/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Eric H. Weinberg The Law Firm of Eric H. Weinberg	NDA 22512
2013-2899	04/15/2013 05/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K111543
2013-2900	04/15/2013 05/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 50706 - PHARMACOLOGY, TOXICOLOGY

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-2901	04/15/2013 05/13/2013	FDA/OGROP/ORR/SW-FO/DAL- DO/DAL-CB/	ROBRRT KING FDA NEWS	OAKDELL PHARMACY INC, SAN ANTONIO TX; HOME INTENSIVE CARE PHARMACY INC, SAN ANTONIO, TX; RECKITT BENCKISER INC, FORT WORTH, TX, ETC - 483S 3/1-31/13
2013-2902	04/15/2013 05/13/2013	FDA/OGROP/ORR/CE-FO/CIN- DO/CIN-CB/	ROBERT KING FDANEWS	BRAINMASTER TECHNOLOGIES, BEDFORD, OH; NEOGEN CORP, LEXINGTON, KY; GEBAUER CO, CLEVELAND, OH - 483S 3/1-31/13
2013-2903	04/15/2013 05/13/2013	FDA/OGROP/ORR/CE-FO/CHI- DO/CHI-CB/	ROBERT KING FDA NEWS	HYDRITE CHEMICALS, UNIVERSITY PARK, IL; MAR COR PURIFICATION CHICAGO, DOWNERS GROVE, IL; MEDIFIX INC, MORTON GROVE, IL - 483S 3/1-31/13
2013-2904	04/15/2013 05/13/2013	FDA/OGROP/ORR/CE-FO/BLT- DO/BLT-CB/	ROBERT KING FDA NEWS	AMERICAN ANIBIOTICS INC, BALTIMORE, MD; AUTOMATED OPHTHALMICS, INC, COLUMBIA, MD; CALVARY SPINE LLC, TOWSON, MD - 483S 3/1-31/13
2013-2905	04/15/2013 05/13/2013	FDA/OGROP/ORR/SE-FO/ATL- DO/ATL-CB/	ROBERT KING FDANEWS	STEWART COMPOUNDING PHARMACY, FAYETTEVILLE, NC - 483S 3/1-31/13
2013-2906	04/15/2013 05/13/2013	FDA/OGROP/ORR/PA-FO/SAN- DO/SAN-CB/	PATRICIA L REGENYE Celgene Corporation	JONAHTAN BERNSTEIN,HEMOPHILIA TREATMENT CENTER OF LAS VEGAS, LAS VEGAS, NV - 483S 2/10/10 TO PRESENT
2013-2907	04/15/2013 05/13/2013	FDA/OGROP/ORR/CE-FO/CHI- DO/CHI-CB/	PATRICIA L REGENYE Celgene Corporation	LEONARD VALENTINO,RUSH CHILDREN'S HOSPITAL, CHICAGO, IL - 483S 5/29/08, 6/30/08, 7/18/12, ETC
2013-2908	04/15/2013 05/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANTON AMANN ROXANE LABORATORIES INC	DIPHENHYDRAMINE HCI CAPS ANDA 80-635 - RECS
2013-2909	04/15/2013 05/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CURITIS A THURSTON JR THURSTON LAW OFFICES	SEPTOCAINE NDA 20-9718/S009, NDA 20-971/S013 - CORR, STUDIES, RPTS, ETC
2013-2910	04/15/2013 05/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	RONALD S GOLDSER ZIMMERMAN REED PLLP	ST JUDE MEDICAL - RIATA ICD LEADS P950022/S14; RITATA ST ICD LADS P950022/S24 RECS
2013-2911	04/15/2013 05/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	ROBBI PERRY NORTH AMERICAN RESCUE LLC	SAM MEDICAL PRODUCTS, WILSONVILLE, OR - SAM JUNCTIONAL TOURNIQUET K123694
2013-2912	04/15/2013 05/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KAHLES, ANDRE	ORANGE BOOK - 2001-2010

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-2913	04/15/2013 05/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PETER S REICHERTZ SHEPPARD MULLILN RICHTER ET AL	LUITPOLD PHARMACEUTICALS INC - SPRIX, (KETOROLAC TROMETHAMINE) NASAL SPRAY NDA 22-382 5/1/10 TO PRESENT
2013-2914	04/15/2013 05/13/2013	FDA/OC/OES/DFOI/	Doe J	MEDICATION FOR NERVE DAMAGE - RECS
2013-2915	04/15/2013 05/13/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	THOMAS J MCKENNA GAINEY MCKENNA & EGGLESTON	PEREGRINE PHARMACEUTICALS INC - BAVITUXIMAB PHASE II CLNCL TRIAL PROTOCOL
2013-2916	04/15/2013 05/13/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	THOMAS J MCKENNA GAINEY MCKENNA & EGGLESTON	CLINICAL SUPPLIES MANAGEMENT INC - STANDARD OPERATING PROCEDURE (SOP), CLNCL PROTOCOLS, RPTS, ETC
2013-2917	04/15/2013 05/13/2013	FDA/OFVM/CFSAN/OCD/EOS/	NICOLE BROCHU SUN-SENTINEL	TEMPORARY HENNA TATTOOS, ORGANIC DYES IN PERMANENT TATTOOS - CMLPNTS 1/1/11 TO 4/1/13
2013-2918	04/15/2013 05/13/2013	FDA/OFVM/CFSAN/OCD/EOS/	WILLIAM A OLSON PHD WASHINGTON INFORMATION SOURCE	SABIC INNOVATIVE PLASTICS - FCN 831
2013-2919	04/15/2013 05/13/2013	FDA/OC/OES/DFOI/	JOHN BONIFELD CNN	TRIAMCINOLONE INJ - DATE OF EXPOSURE, LOCATION OF FACILITY, TRANSPLANT PATIENTS, ETC
2013-2920	04/15/2013 05/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MUNDINE, JEREMY	PAXIL - AERS
2013-2921	04/15/2013 05/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MUNDINE, JEREMY	DEPAKOTE, SEROQUEL - AERS

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2013-2922	04/15/2013 05/13/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	OLIVIA T LUK NIRO SCAVONE HALLER & NIRO	PREMIER LABS, AUSTIN, TX - GMP
2013-2923	04/15/2013 05/13/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	OLIVIA T LUK NIRO SCAVONE HALLER & NIRO	QUANTUM NUTRITIONAL LABS - GMP
2013-2924	04/15/2013 05/13/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	KROMENAKER, FRANK FRITZ	KIMBERLY-CLARK - WARNING LTRS 3/9/01, 6/4/08, 8/8/2012
2013-2925	04/15/2013 05/13/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	S ALBERT EDWARDS S ALBERT EDWARDS, PHARM D	EDWARDS LIFESCIENCES LLC, IRVINE, CA - EIRS, 483S 2006 TO 2009
2013-2926	04/15/2013 05/13/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	JACKIE CALLAWAY ABC ACTION NEWS	ADORA BODY SCULPTING CLINIC, TAMPA, BRANDON, WESLEY CHAPEL. PALM HARBOR, FL - INSP PAST 12 MONTHS
2013-2927	04/15/2013 05/13/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	MARK C STANZIANO CHANFRAU & CHANFRAU	WHITNEY LABS, ORMOND BEACH, FL - RPTS
2013-2928	04/15/2013 05/13/2013	FDA/OFVM/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 163796
2013-2929	04/15/2013 05/13/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	ROBERT KING FDA NEWS	AMGEN INC, LONGMONT, CO; NOVARAD CORP, AMERICAN FORK,UT; SORIN GROUP USA INC, ARVADA, CO, ETC - 483S 3/1-31/13
2013-2930	04/15/2013 05/13/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	ROBERT KING FDANEWS	PORTAGE PHARMACY INC, PORTAGE, MI; DOW ARGOSCIENCES LLC, HARBOR BEACH, MI; BIOMEDIX INC, BLOOMINGTON, IN, ETC - 483S 3/1-31/13
2013-2931	04/15/2013 05/13/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	ROBERT KING FDANEWS	INSIGHT INSTRUMENTS INC, STUART, FL; AXIUM HEALTHCARE PHARMACY INC, LAKE MARY, FL; PINOOK-USA, ORLANDO, FL, ETC - 483S 3/1-31/13
2013-2932	04/15/2013 05/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Cagla KURFALI, Cagla	K032845, K013226, K101538
2013-2933	04/15/2013 05/13/2013	FDA/OMPT/CTP/OD/	Desmond Jenson Tobacco Control Legal Consortium	CTP INDEPENDENT REVIEW OF AVAILABLE SCIENCE RELATED TO THE IMPACT OF MENTHOL CIGARETTES ON PUBLIC HEALTH (03/17/2011 - 04/12/2013)
2013-2934	04/15/2013 05/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Stephanie Wright The Wright Family	EFFEXOR, EFFEXOR XR - AERS

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-2935	04/15/2013 05/13/2013	OC/CVM/OCD/ FDA/OFVM/CFSAN/OCD/EOS/	Dr Ryan M. Yamka Blue Buffalo Company	FIBER FOR HAIRBALL CLAIMS IN FELINE FOODS - WHITE PAPERS, REPORTS, ETC (04/01/2003 - 04/12/2013)
2013-2936	04/15/2013 05/13/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Benjamin Mettey Boston Biomedical Consultants, Inc.	APPLICATION OF ADVANCES IN NUCLEIC ACID AND PROTEIN BASED DETECTION METHODS TO MULTIPLEX DETECTION OF TRANSFUSION-TRANSMISSIBLE AGENTS AND BLOOD CELL ANTIGENS IN BLOOD DONATIONS - WORKSHOP TRANSCRIPTS
2013-2937	04/15/2013 05/13/2013	FDA/OC/OES/DDM/ FDA/OFVM/CFSAN/OCD/EOS/	Jeffrey Gordon Quinn Emanuel Urquhart & Sullivan, LLP	07/11/86 LETTER FROM JW SWANSON TO PHILLIPPE DOUILLETT, DOCKET NUMBER 83P-0404; 07/31/73 MEMO FROM DR ALFRED WEISSLER RE ASBESTOS IN TALC 2
2013-2938	04/15/2013 05/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ROBERT KING FDA NEWS	CIPLA LTD, DHAR, INDIA; CHEMAGIS LTD, BEER SHEVA, ISRAEL, AMGEN TECHNOLOGY IRELAND, DUBLIN IRELAND, ETC - 483S 3/1-31/13
2013-2939	04/15/2013 05/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LIEBSCHUTZ Isabelle LABORATOIRES PLASTO SANTE	LABORATOIRES FOURNIER, FRANCE - INSPECTION REPORT 5/19/98
2013-2940	04/15/2013 05/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	ROBERT KING FDA NEWS	USCOM LTD, SYDNEY, AUSTRALIA; ALPINION MEDICAL SYSTEMS, SEOUL, SOUTH KOREA; LIGHTMED CORP, SHULIN DISTRICT, NEW TAIPEI CITY, TAIWAN, ETC - 483S 3/1-31/13
2013-2941	04/15/2013 05/13/2013	FDA/OGROP/ORR/SW-FO/KAN- DO/KAN-CB/ FDA/OGROP/ORR/SW-FO/KAN- DO/KAN-CB/	ROBERT KING FDANEWS	MERIDIAN MEDICAL TECHNOLOGIES, BRENTWOOD, MO; CONTINENTAL MANUFACTURING CHEMIST INC, MADRID, IA; MEGA SUN INC, ST LOUIS, MO, ETC - 483S 3/1-31/13
2013-2942	04/15/2013 05/13/2013	FDA/OGROP/ORR/PA-FO/LOS- DO/LOS-CB/	ROBERT KING FDANEWS	CA BOTANA INTERNATIONAL INC, SAN DIEGO, CA; NEXGEN PHARMA INC, IRVINE, CA; PACIRA PHARMACEUTICALS INC, SAN DIEGO, CA, ETC - 483S 3/1-31/13
2013-2943	04/15/2013 05/13/2013	FDA/OGROP/ORR/CE-FO/MIN- DO/MIN-CB/	ROBERT KING FDA NEWS	STEARNS PACKAGING CORP, MADISON, WI; PRISM CLINICAL IMAGING INC, ELM GROVE, WI; ESCALON MEDICAL CORP, NEW BERLIN, WI, ETC - 483S 3/1-31/13
2013-2944	04/15/2013 05/13/2013	FDA/OGROP/ORR/NE-FO/NWE- DO/NWE-CB/	ROBERT KING FDANEWS	BIOGEN IDEC INC, CAMBRIDGE, MA; REMOTE TECHNOLOGIES INC, GREENWICH, CT; HEMEDEX INC, CAMBRIDGE, MA, ETC - 483S 3/1-31/13
2013-2945	04/15/2013 05/13/2013	FDA/OGROP/ORR/CE-FO/NWJ- DO/NWJ-CB/	ROBERT KING FDANEWS	DIMENSIONAL MERCHANDISING INC, WHARTON, NJ; SIEGFRIED USA LLC, MIDDLESEX, NJ; ULTRARAD CORP, WEST BERLIN, NJ, ETC - 483S 3/1-31/13

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2013-2946	04/15/2013 05/13/2013	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	ROBERT KING FDA NEWS	SHOWA BEST GLOVE INC, FAYETTE, AL; TINGLE X-RAY PRODUCTS INC, COTTONSALE, AL; EXXON MOBIL CHEMICAL CO, BATON ROUGE, LA, ETC - 483S 3/1-31/13
2013-2947	04/15/2013 05/13/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	ROBERT KING FDANEWS	INVAGEN PHARMACEUTICALS INC, HAUPPAUGE, NY; IMMCO DIAGNOSTICS INC, BUFFALO, NY; PREMIER HEART LLC, PORT WASHINGTON, NY, ETC - 483S 3/1-31/13
2013-2948	04/15/2013 05/13/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	ROBERT KING FDANEWS	SPRAY-TEK INC, BETHLEHEM, PA - 483S 3/1-31/13
2013-2949	04/15/2013 05/13/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	ROBERT KING FDANEWS	FVS HOLDINGS INC (GREEN VALLEY DRUGS), HENDERSON, NV; NEUROPACE INC, MOUNTAIN VIEW, CA; SENTRELHEART INC, REDWOOD CITY, CA, ETC - 483S 3/1-31/13
2013-2950	04/15/2013 05/13/2013	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	ROBERT KING FDA NEWS	CERAMCO MANUFACTURING BV, LAS PIERDAS, PR; NEOLPHARMA INC, CAGUAS, PR; AGROPHARMA LABORATORIES INC, SALINAS, PR - 483S 3/1-31/13
2013-2951	04/15/2013 05/13/2013	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	ROBERT KING FDANEWS	MIRADOR BIOMEDICAL INC, SEATTLE, WA; MICROSURGICAL TECHNOLOGY INC, REDMOND, WA; INOVISE MEDICAL INC, BEAVERTON, OR, ETC - 483S 3/1-31/13
2013-2952	04/15/2013 05/13/2013	OC/ORA/ OC/ORA/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	ROBERT KING FDA NEWS	BHARAT ENTERPRISES, DELHI, INDIA - 483S 3/1-31/13
2013-2953	04/15/2013 05/13/2013	FDA/OC/OES/DFOI/	ADAM BUTSCHEK CAUSE OF ACTION	DISCRETIONARY, NON-FORMULA GRANTS, GRANT RECIPIENTS, ETC - RECS
2013-2954	04/16/2013 05/14/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tang Peng ChemWerth, Inc.	MICROTROL STERILIZATION SERVICES PVT LTD, KARNATAKA, INDIA - EIR 10/25/12
2013-2955	04/16/2013 05/14/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	A&S Pharmaceutical Corp A&S Pharmaceutical Corp	NOVACYL LIMITED, THAILAND - EIR, 483 (01/01/2012 - 04/01/2013)
2013-2956	04/16/2013	FDA/OGROP/ORASE-FO/ATL-	Aaron D Schneider	DOLE FRESH VEGETABLES, INC, BESSEMER CITY, NC -

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	05/14/2013	DO/ATL-CB/	Dole Fresh Vegetables, Inc.	DIARY NOTES (06/29/2012 - 07/03/2012)
2013-2957	04/16/2013 05/14/2013	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	Aaron Schneider Dole Fresh Vegetables, Inc.	DOLE FRESH VEGETABLES, INC, BESSEMER CITY, NC - DIARY NOTES (03/18/2013 - 03/21/2013)
2013-2958	04/16/2013 05/14/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Marlena S Fejzo UCLA	STUDY ON DICLECTIN/DICLEGIS EFFECTIVENESS, SAFETY, SIDE EFFECTS ETC
2013-2959	04/16/2013 05/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	Diane Horwitz MANDELL HORWITZ CONSULTANTS LLC	K910944
2013-2960	04/16/2013 05/14/2013	FDA/OGROP/ORR/ORO/DIOP/ OC/ORR/ORO/DFS/ OC/ORR/ORO/DFS/	Kari Umholtz Umholtz, Kari A	SEAFOOD IMPORTED FROM CHINA - ILLEGAL NITROFURANS, MALACHITE RESIDUE, MELAMINE, ETC
2013-2961	04/16/2013 05/14/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gopal Reddy Palvatla EASTERN MICHIGAN UNIVERSITY	FENTORA, FENTANYL CITRATE - MEDWATCH RPTS (01/01/2003 - 12/31/2012)
2013-2962	04/16/2013 05/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	Cora Sim Ellipse Technologies, Inc.	K082018
2013-2963	04/16/2013 05/14/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dheeresh Pathak Self	WOCKHARDT, INDIA - 483 (01/01/2013 - 04/14/2013)
2013-2964	04/16/2013 05/14/2013	FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/	Robert Blaskiewicz Skeptics for the Protection of Cancer Patients	BURZYNSKI CLINICAL - RESPONSES TO 483 (09/14/2012 - 05/14/2013)
2013-2965	04/16/2013 05/14/2013	FDA/OGROP/ORR/CE-FO/DET-DO/DET-CB/ FDA/OC/OES/DFOI/	Matt Jordan STRYKER MEDICAL	HILL-ROM COMPANY - 01/11/13 RESPONSE TO 483 AND RELATED RECS
2013-2966	04/16/2013 05/14/2013	FDA/OC/OES/DFOI/	Donald Segal ALSTON & BIRD LLP	FOIA REQUESTS FOR FAP 2A4796 (01/01/2013 - 04/15/2013)
2013-2967	04/16/2013 05/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOANNE CONDE XODUS MEDICAL	UNIMED SURGICAL - UNITED COATED LAPAROSCOPIC ARTHROSCOPY SUCTION IRRIGATION ELECTRODE K970066
2013-2968	04/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOANNE CONDE	UNIMED SURGICAL PRODUCTS INC - UNIMED COATED

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	05/14/2013		XODUS MEDICAL	NEEDLE ELECTRODE, COATED BLADE ELECTRODE, COATED BALL ELECTRODE K962935
2013-2969	04/16/2013 05/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	JAONNE CONDE XODUS MEDICAL	MEGADYNE MEDICAL PRODUCTS INC - EZ CLEAN ELECTRODE K913473
2013-2970	04/16/2013 05/14/2013	FDA/OGROP/ORR/SW-FO/DEN-DO/DEN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	JOANNE CONDE XODUS MEDICAL	MEGADYNE MEDICAL PRODUCTS INC - EZ CLEAN LAPAROSCOPIC ELECTRODE K913281
2013-2971	04/16/2013 05/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOANNE CONDE XODUS MEDICAL	AMERICAN MEDICAL PRODUCTS INC - EZ CLEAN K862221
2013-2972	04/16/2013 05/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOANNE CONDE XODUS MEDICAL	MEGADYNE MEDICAL PRODUCTS INC - EZ CLEAN ELECTROSURGICAL ELECTRODE K081791
2013-2973	04/16/2013 05/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOANNE CONDE XODUS MEDICAL	MEGADYNE MEDICAL PRODUCTS INC - EZ CLEAN ELECTROSURGICAL ELECTRODE K081791
2013-2974	04/16/2013 05/14/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	JOANNE CONDE XODUS MEDICAL	UNIMED SURGICAL PRODUCTS INC, LARGO, FL - AUDITS 1/10 TO 1/12
2013-2975	04/16/2013 05/14/2013	FDA/OFVM/CFSAN/OCD/EOS/	A. YOUNG USA TODAY	REUMOFAM; WOW - CAERS 1/13 TO 4/13
2013-2976	04/16/2013 05/14/2013	FDA/OFVM/CFSAN/OCD/EOS/	ELBEK, GAIL	SOY INFANT FORMULA - CAERS
2013-2977	04/16/2013 05/14/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	STEVEN NAPOLITANO SKADDEN ARPS SLATE MEAGHER & FLOM	PROPOXYPHENE HYDROCHLORIDE ANDA 040-908 APRVL
2013-2978	04/16/2013 05/14/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHANDRAN TIRUVATTAR DR REDDY'S LABORATORIES INC	TARO PHARMA - TOPICORT NDA 204-141 SBA
2013-2979	04/16/2013 05/14/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LISA CHIARINI HUGHES HUBBARD & REED	PROLENSA NDA 20-3168
2013-2980	04/16/2013	FDA/OMPT/CDER/ORP/DIDP/	MICHAEL D. SHUMSKY	TECFIDERA NDA 204-063

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	05/14/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KIRKLAND & ELLIS LLP	
2013-2981	04/16/2013 05/14/2013	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	STEPHEN J. CARR AKERMAN SENTERFITT ATTYS	ELECTROSTIM MEDICAL SERVICES INC - EIR
2013-2982	04/17/2013 05/15/2013	FDA/OMPT/CTP/OD/ FDA/OO/OFBA/OFO/OFM/BTAMS / FDA/OMPT/CTP/OD/ FDA/OC/OES/DDM/	Desmond Jenson Tobacco Control Legal Consortium	TOBACCO MANUFACTURER AND IMPORTER USER FEES ASSESSED BY FDA CTP - ALL RECS AND CORR (06/22/2009 - 04/15/2013)
2013-2983	04/17/2013 05/15/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Dr Mike Williams Dr. Mike Williams	K061688, K092942, K090503
2013-2984	04/17/2013 05/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Cora Sim Ellipse Technologies Inc.	K993956
2013-2985	04/17/2013 05/15/2013	FDA/OGROP/ORR/NE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	William Hite Columbia Management	LONZA BIOLOGICS, PORTSMOUTH, NH - DRUG QUALITY ASSURANCE REVIEW, 483
2013-2986	04/17/2013 05/15/2013	FDA/OMPT/CTP/OD/	Allison O'Donnell Campaign for Tobacco Free Kids	MTG BETWEEN TOBACCO MANUFACTURERS AND FDA 5/2/12 - SUBMISSIONS, DISCUSSIONS, ATTENDENCE, ETC
2013-2987	04/17/2013 05/15/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Keli Renner Renner, Keli C	ZOSTAVAX - VAERS
2013-2988	04/17/2013 05/15/2013	FDA/OC/OES/DFOI/	Robert King FDA NEWS	FOIA REQUEST LOG (04/08/2013 - 04/12/2013)
2013-2989	04/17/2013 05/15/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michael Zupke Michael Zupke	BUPROPION - BIOEQUIVALENCE
2013-2990	04/17/2013 05/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Bonnie Williams FOI Services, Inc.	K102924
2013-2991	04/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Amy Kincanon	K092561

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	05/15/2013		LexisNexis CourtLink Document Retrieval	
2013-2992	04/17/2013 05/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Bonnie Williams FOI Services, Inc.	K101996
2013-2993	04/17/2013 05/15/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Amy Kincanon LexisNexis CourtLink Document Retrieval	K071082
2013-2994	04/17/2013 05/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Bonnie Williams FOI Services, Inc.	K110599
2013-2995	04/17/2013 05/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Atul Khare Akorn, Inc.	ANDA 078711
2013-2996	04/17/2013 05/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Diana L. Martone CORIN USA	K963043
2013-2997	04/17/2013 05/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Amy Kincanon LexisNexis CourtLink Document Retrieval	K100866
2013-2998	04/17/2013 05/15/2013	OC/ORO/ORM/ OC/ORO/ORM/	David Mangione Govzilla, Inc.	LIST OF 483, EIR, INSPECTIONS (03/20/2013 - 04/15/2013)
2013-2999	04/17/2013 05/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Bonnie Williams FOI Services, Inc.	K122698
2013-3000	04/17/2013 05/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Matthew Miller MEYERSON & O'NEILL ATTY	INFUSE BONE GRAFT IN DENTAL AND SINUS AUGMENTATION PROCEDURES - SAFETY AND EFFICACY
2013-3001	04/17/2013 05/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Howard Brittain Howard Brittain	NITROFURATOIN - AERS (01/01/2008 - 01/01/2013)
2013-3002	04/17/2013 05/15/2013	FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	MEADE, DORIS.	FINEMOST CORP (QUALIHERB), CERRITOS, CA - 483 9/12-21/12
2013-3003	04/17/2013 05/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	AMY C CHAMBERS RONALD R BENJAMIN LAW OFC	INDIVIDUAL RECS

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2013-3004	04/17/2013 05/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	NORMAN W PAULI JR PAULI LAW FIRM	INDIVIDUAL RECS
2013-3005	04/17/2013 05/15/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	JOLENE LAKEY Glanbia Nutritionals (NA)	GLANBIA NUTRITIONALS, SPRINGFIELD, MO - EIR 8/28/12
2013-3006	04/17/2013 05/15/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	TOM HAUERTER ORTHO DEVELOPMENT CORP	K050210
2013-3007	04/17/2013 05/15/2013	FDA/OC/OL/	RORY CAMPBELL DEMOCRATIC SENATORIAL CAMPAIGN COMMITTEE	CONGRESSMAN STEVE KING - CORR 6/1/11 TO 4/11/13
2013-3008	04/17/2013 05/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CROSBY T-50417, COURTNEY	PRADAXA - DEAR DOCTOR LTRS, PRESCRIBING INFO
2013-3009	04/17/2013 05/15/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	SARAH SCHARF ROSS MEDICAL	K072558, K071995
2013-3010	04/17/2013 05/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	NATHAN JORGENSEN, Ph.D. Stifel Nicolaus & Co	AMPYRA - EFFICACY
2013-3011	04/17/2013 05/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	LILLY ELIZABETH DWARKA EQUIPMENTS PVT LTD	MYCO MEDICAL - GLASS VAN GLASS SYRINGE K963364; PROCEDURE PRODUCTS INC - GLASS SYRINGE, DRUG LUER K820384, ETC
2013-3012	04/17/2013 05/15/2013	FDA/OO/OFBA/OAGS/	ROSE SANTOS FOIA GROUP INC	HHSF223200830014I - TASK ORDERS, WINNING PROPOSAL, CONTRACT, ETC
2013-3013	04/17/2013 05/15/2013	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	MICHAEL NAZERIAS PETNET SOLUTIONS INC	ION BEAM APPLICATIONS, UINIONVILLE, NY; RICHMOND, VA; SOMERSET, NJ, ETC - 483S

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		FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/		
2013-3014	04/17/2013 05/15/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	MICHAEL NAZERIAS PETNET SOLUTIONS INC	ION BEAM APPLICATIONS, MACON, GA; MOBILE, AL; CHARLESTON, SC, ETC - 483S
2013-3015	04/17/2013 05/15/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	MERZ PHARMS - XEOMIN (INCOBOTULINUMTOXIN A) BLA 125360/007 APRVL LTR
2013-3016	04/17/2013 05/15/2013	OC/ORASW-FO/ OC/ORASW-FO/	WALTER E CHALKLEY THOMSON REUTERS	LIST OF INSPS 1996
2013-3017	04/17/2013 05/15/2013	OC/ORASW-FO/ OC/ORASW-FO/	TOM CORWIN AUGUSTA CHRONICLE	CLINICAL SPECIALTIES COMPOUNDING PHARMACY, AUGUSTA, GA; MARTINEZ, GA - INSPS 3/13
2013-3018	04/17/2013 05/15/2013	OC/ORASW-FO/ OC/ORASW-FO/	ALISON YOUNG USA TODAY	DIETARY SUPPLEMENT FIRMS - 483S 1/08 TO PRESENT
2013-3019	04/17/2013 05/15/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LEIGH SANDERS CENTER FOR RESPONSIBLE SCIENCE	MATTEK - EPIDERM, EPIOCULAR ANIMAL TESTING RECS
2013-3020	04/18/2013 05/16/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Birgitta Gassner REDL Life Science Patent Attorneys	FORMULATION DEVELOPMENT OF REMODULIN, JUSTIFICATION FOR FINAL COMPOSITION OF SOLUTION FOR INFUSION
2013-3021	04/18/2013 05/16/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OGROP/ORAPASW-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	Jim McNair none	ALIGN TECHNOLOGY, BIOMET INC, DUPUY ETC - 483 (07/01/2012 - 04/15/2013)

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		FDA/OC/OES/DFOI/		
2013-3022	04/18/2013 05/16/2013	FDA/OMPT/CTP/OD/	Desmond Jenson Tobacco Control Legal Consortium	TOBACCO ESTABLISHMENT REGISTRATION AND TOBACCO PRODUCT LISTING - ALL RECS AND CORR (06/22/2009 - 04/16/2013)
2013-3023	04/18/2013 05/16/2013	FDA/OC/OES/DDM/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jason Leckerman; Marcel Pratt BALLARD SPAHR LLP	FDA'S CONSIDERATION AND ANALYSIS OF VALEANT PHARMACEUTICALS INTERNATIONAL INC'S CITIZEN PETITION
2013-3024	04/18/2013 05/16/2013	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	Melanie Jackson Fresenius Kabi USA, LLC	PQ CORPORATION, UTICA, IL - MOST RECENT 483 AND RESPONSE
2013-3025	04/18/2013 05/16/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Trupti Shah Takeda TAKEDA PHARMACEUTICALS NA INC	TAKEDA AFFYMAX - LISTING OF 156 CASES
2013-3026	04/18/2013 05/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Amy Kincanon LexisNexis CourtLink Document Retrieval	K091423
2013-3027	04/18/2013 05/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Amy Kincanon LexisNexis CourtLink Document Retrieval	K041114
2013-3028	04/18/2013 05/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Amy Kincanon LexisNexis CourtLink Document Retrieval	K021346
2013-3029	04/18/2013 05/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Amy Kincanon LexisNexis CourtLink Document Retrieval	K121308
2013-3030	04/18/2013 05/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Amy Kincanon LexisNexis CourtLink Document Retrieval	K092406
2013-3031	04/18/2013 05/16/2013	FDA/OFVM/CFSAN/OCD/EOS/	Dr. Byron Shock Scientific Ecological Services, Inc.	OUTBREAK DATABASE DATA
2013-3032	04/18/2013 05/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Traci Lillyroot Mortara Instrument, Inc	MEDWATCH FORM DEVICE EVENT KEY 2168692
2013-3033	04/18/2013	FDA/OFVM/CFSAN/OCD/EOS/	Mallory Shiflett	CENTREVILLE VA WAREHOUSE MANUFACTURING ZI XIU TANG BEE POLLEN - INVESTIGATION RECS (10/01/2012 -

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	05/16/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/ORACE/ OC/ORACE/	Shiflett, Mallory E	04/16/2013)
2013-3034	04/18/2013 05/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Mihir Zaveri UC Berkeley Graduate School of Journalism	RECALL Z-1896-2009, Z-3056-2011 - HHE; HRA FOR RESOLUTION CLIP MODEL M00522600, M00522601, M00522602 ETC
2013-3035	04/18/2013 05/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Amy Kincanon LexisNexis CourtLink Document Retrieval	K081044
2013-3036	04/18/2013 05/16/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORACE-FO/NYK-DO/NYK-DCB/	Bruce McKeeman SUMMIT TO SEA LLC	INVESTIGATION OF FRAUDULENT EMAIL RE MEDWATCH REPORT (07/16/2012 - 04/16/2013)
2013-3037	04/18/2013 05/16/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Eileen Berbary Berbary, Eileen	WILLIAM BEAUMONT HOSPITAL RESEARCH DEPARTMENT, KELLY SAWYER, SIMON DIXON - 483, WARNING LETTER (04/01/2000 - 04/16/2013)
2013-3038	04/18/2013 05/16/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MITTAL SUTARIA Sutaria, Mittal	LIST OF NDA OR BLA SUBMITTED FOR NEW MOLECULAR ENTITIES SINCE JANUARY 2012; LIST OF NDA OR BLA CURRENTLY UNDER REVIEW; LIST OF NDA OR BLA TO BE DISCUSSED AT UPCOMING ADVISORY MEETINGS
2013-3039	04/18/2013 05/16/2013	FDA/OFVM/CFSAN/OCD/EOS/	John Hilgren ECOLAB INC	FCN 1025
2013-3040	04/18/2013 05/16/2013	FDA/OFVM/CFSAN/OCD/EOS/	John Hilgren ECOLAB INC.	FCN 1035
2013-3041	04/18/2013 05/16/2013	FDA/OFVM/CFSAN/OCD/EOS/	John Hilgren ECOLAB INC	FCN 1094
2013-3042	04/18/2013 05/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Saket Bhatt COVIDIEN	K934193
2013-3043	04/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	Andrew Goodenough	K110962

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	05/16/2013		Integrated Technologies Ltd	
2013-3044	04/18/2013 05/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Art Rankis Art Rankis	K060537
2013-3045	04/18/2013 05/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Sara Borrelli Jackson Walker L.L.P.	K922457
2013-3046	04/18/2013 05/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Art Rankis Art Rankis	K012031
2013-3047	04/18/2013 05/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Art Rankis Art Rankis	K052547
2013-3048	04/18/2013 05/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K112161
2013-3049	04/18/2013 05/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Laura Boll Medovations Inc.	K111262
2013-3050	04/18/2013 05/16/2013	OC/ORA/ OC/ORA/	Elizabeth Engebretson Engebretson, Elizabeth	PHARMEDIUM - 483 (02/01/2013 - 04/17/2013)
2013-3051	04/18/2013 05/16/2013	FDA/OC/OES/DDM/	LAURA S SUTTELL PHILLIPS LYTLER ET AL	DKT 1975-N-0301
2013-3052	04/18/2013 05/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	ROBBI PERRY NORTH AMERICAN RESCUE LLC	KENDALL CO, MANSFIELD, MA - EXCILON AMD AMTIMICROBIAL SPONGE K011941
2013-3053	04/18/2013 05/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	STEPHANIE YUTKIN STEPHANIE YUTKIN COUNSELOR AT LAW	BIOENTERICS CORP - LAP-BAND SYS POST-MARKET US STUDY PMA APRVL APPLICATION, SUPPL TO PMA 5/25,31/01
2013-3054	04/18/2013 05/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	SARA BEARDSLEY SIDLEY AUSTIN LLP	NEMOTO KYORINDO CO LTD - SONIC SHOT GX CONTRAST DELIVERY SYS K091734
2013-3055	04/18/2013 05/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	HAMILTON PHD, LEROY L	CDRH OMBUDSMAN - POSITION DESCRIPTION
2013-3056	04/18/2013 05/16/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RICHARD NORTON INNOVATIVE PHARMACEUTICALS	NDA 50-703 - SBA
2013-3057	04/18/2013 05/16/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MANUEL A MOLINA FREEHILL HOGAN & MAHARR LLP	SANDHYA MARINES LTD, INDIA - FROZEN SHRIMP EIRS, WARNING LTRS, UNTITLED LTRS

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/ORO/DIOP/		
2013-3058	04/18/2013 05/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	FRANK DONATH SOCRATEC R&D	SOCRATEC R&D,ERFURT, GERMANY - EIRS 8/27-31/12
2013-3059	04/18/2013 05/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SUZIE KESCHAMRUS AVANIR PHARMACEUTICALS INC	NUJEXTA (DEXTROMETHORPHAN HYDROBROMIDE) NDA 21-879 - AERS
2013-3060	04/18/2013 05/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/ORA/ OC/ORA/ FDA/OGROP/ORA/ORO/DIOP/	JANET Y SANTANA FEDERAL PUBLIC DEFENDER TENNESSEE	PENTOBARBITAL (DEA CODE 2270) & NONCONTROLLED ACTIVE INGREDIENT (DEA CODE 2271) - IMPORT, TRANSPORT, NOTICE OF ACTION, ETC
2013-3061	04/18/2013 05/16/2013	OC/CVM/OCD/ FDA/OC/OES/DFOI/	KRISTI O SMEDLEY Center for Regulatory Services,Inc.	TILMICOSIN ANADA 200-509 - LBLG PKG
2013-3062	04/18/2013 05/16/2013	FDA/OC/OES/	LIPPERT #B74054, DON	ILLINOIS CORRECTIONAL INDUSTRIES- FOOD & DAIRY PROCESSING PLANTS LAST 5 YRS
2013-3063	04/18/2013 05/16/2013	FDA/OMPT/OSMP/OOPD/	CHRISTOPHER P ADAMAS ANDARIX PHARMACEUTICALS INC	IMMUNOMEDICS INC, MORRIS PLAINS, NJ - CEA-CIDE (MN14 MONOCLONAL ANTIBODY TO CARCINOEMBRYONIC ANTIGEN) DRUG APPLICATION 9/18/98
2013-3064	04/18/2013 05/16/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	CHEN, JOHN	FINEMOST CORP (QUALIHERB), CERRITOS, CA - WARNING LTR 32-1 483, VIOLATIONS, RESP TO 483, ETC
2013-3065	04/18/2013 05/16/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	KIRSTEN CULTRARA DIETRICH LAW FIRM PC	FARM RICH FOODS OR RICH PRODUCTS - RECALL INVESTIGATION

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2013-3066	04/18/2013 05/16/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	CHEN, JOHN	GM MANUFACTURING INC, GARDENA, CA - WARNING LTR 2912 483, VIOLATION, RESP TO WARNING LTR, ETC 7/23/12
2013-3067	04/18/2013 05/16/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	JOHN A BERANBAUM BERANBAUM MENKEN LLP	NEW YOR DOWNTOWN HOSPITAL - LTR 8/12
2013-3068	04/18/2013 05/16/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	SINGULAR MONTELUKAST TABS - AERS
2013-3069	04/18/2013 05/16/2013	FDA/OO/OFBA/OAGS/	ROSE SANTOS FOIA GROUP INC	HHSF22301110044G
2013-3070	04/18/2013 05/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Diana L. Martone CORIN USA	K963046
2013-3071	04/18/2013 05/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Andrew Goodenough Integrated Technologies Ltd	K093186
2013-3072	04/18/2013 05/16/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/ORAOCI/ OC/ORAOCI/	Doe J	BOTOX - RECS 1/11 TO PRESENT
2013-3073	04/19/2013 05/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KEITH MCWHA MCCARTER & ENGLISH LLP	HOSPIRA - DAPTOMYCIN NDA 203-797 RECS
2013-3074	04/19/2013 05/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PAMELA SHEPPARD TARO PHARMACEUTICALS USA INC	MYLAN PHARMS INC - ACYCLOVIR ANDA 202-459 SBA
2013-3075	04/19/2013 06/11/2013	FDA/OC/OES/ FDA/OMPT/CTP/OD/	JOEL KURTZBERG CAHILL GORDON & REINDEL	FDA EXPERIEMNTAL STUDY OF GRAPHIC CIGARETTE WARNING LABELS - RECS

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2013-3076	04/19/2013 05/17/2013	FDA/OGROP/ORR/SE-FO/NOL-DO/NOL-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/	AVDEEF, STEPHEN M	CDC, SAM'S CLUB, WALMART, ETC - BURKHOLDERIA CAPACIA RECALL, CORR, RPTS, ETC 2006
2013-3077	04/19/2013 05/17/2013	FDA/OC/OES/DFOI/	ELLIOT FAVUS MD FAVUS INSTITUTIONAL RESEARCH LLC	CDER FOIA REQUEST LOG 1/13 TO PRESENT
2013-3078	04/19/2013 07/31/2013	FDA/OFVM/CFSAN/OCD/EOS/	KRISTI O CMEDLEY PHD WASHINGTON INFORMATION SOURCE	COGNIS DEUTSCHLAND GMBH & CO KG - FCN 618
2013-3079	04/19/2013 05/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	XIMENA VAN DEN ENDEN ricoh orthodontic appliances inc	K113516
2013-3080	04/19/2013 05/17/2013	FDA/OFVM/CFSAN/OCD/EOS/	ARLENE MORALES BURDOCK GROUP	VITAMIN K-1 (PHYRONADIONE) - REGULATORY STATUS, CONSUMPTION, SAFETY RECS, ETC
2013-3081	04/19/2013 05/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Adrienne E Faerber, PhD The Dartmouth Institute Ctr for Med and Media	ESIDRIX NDA 11793; HYDRODIURIL NDA 11835; ORETIC NDA 11971 ETC - APPROVAL RECS
2013-3082	04/19/2013 05/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Diana L. Martone CORIN USA	K963044
2013-3083	04/19/2013 05/17/2013	FDA/OFVM/CFSAN/OCD/EOS/	ARLENE MORALES BURDOCK GROUP	SODIUM MOLYBDATE DEHYDRATE - REGULATORY STATUS, CONSUMPTION, SAFETY RECS, ETC
2013-3084	04/19/2013 05/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Eileen Flowers Jefferies, LLC	ICLUSIG - AERS
2013-3085	04/19/2013 05/17/2013	FDA/OFVM/CFSAN/OCD/EOS/	ARLENE MORALES BURDOCK GROUP	DISODIUM SELENITE - REGULATORY STATUS, CONSUMPTION, SAFETY RECS, ETC
2013-3086	04/19/2013 05/17/2013	FDA/OMPT/CTP/OD/	Desmond Jenson Tobacco Control Legal Consortium	SUBSTANTIAL EQUIVALENT ORDER LETTERS AND NON-SUBSTANTIAL ORDER LETTERS ISSUED BY CTP 06/22/2009 - 04/17/2013

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2013-3087	04/19/2013 05/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Please help me Alliance institute	QBD IMPLEMENTED PDR FOR GLIMEPIRIDE
2013-3088	04/19/2013 05/17/2013	FDA/OFVM/CFSAN/OCD/EOS/	ARLENE MORALES BURDOCK GROUP	CHROMIUM CHLORIDE - REGULATORY STATUS, CONSUMPTION, SAFETY RECS, ETC
2013-3089	04/19/2013 05/17/2013	FDA/OC/OES/ FDA/OC/OPP/OP/ FDA/OMPT/CDRH/OCER/DFOI/	Peter Spaulding Peter Spaulding	CORR BETWEEN FDA AND DR ALVARO PASCUAL-LEONE RE CRANIAL ELECTROTHERAPY STIMULATION DEVICES NEUROLOGICAL DEVICES PANEL 08/01/2011 TO PRESENT
2013-3090	04/19/2013 05/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	John Reichard Shamrock Medical Solutions Group, LLC	SHAMROCK MEDICAL SOLUTIONS GROUP, LLC - UNREDACTED HEALTH HAZARD EVALUATIONS
2013-3091	04/19/2013 05/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Laura Boll Medovations Inc.	K913881
2013-3092	04/19/2013 05/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Diana L. Martone CORIN USA	K994152
2013-3093	04/19/2013 05/30/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Edward K. Phillips International Marine Products Los Angeles	IMP FOODS, SAN MATEO, CA - EIR, 483, IMPORT ALERT (11/01/2010 - 04/17/2013)
2013-3094	04/19/2013 05/17/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Ed Skepnek Valnet Inc.	MEDIVATORS, CONROE, TX - EIR (11/15/2012 - 01/15/2013)
2013-3095	04/19/2013 05/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Natalie Corrick AstraZeneca Pty Ltd	CAMBREX KARLSOGA - EIR (01/01/2011 - 01/31/2011)
2013-3096	04/19/2013 05/17/2013	OC/ORA/ OC/ORA/ OC/ORA/ OC/ORA/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Doe J	INDIVIDUAL RECS
2013-3097	04/19/2013 05/17/2013	FDA/OC/OES/DDM/ FDA/OFVM/CFSAN/OCD/EOS/	Jeffrey Gordon Quinn Emanuel Urquhart &	7/11/86 LETTER FROM JW SWANSON TO PHILLIPPE DOUILLET, 83P-0404; 7/31/73 MEMO FROM ALFRED

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			Sullivan, LLP	WEISSLER RE TALC (CERTIFIED)
2013-3098	04/19/2013 05/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Francois Binette, Ph.D. BioTime	K070496
2013-3099	04/19/2013 05/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Nathan A. Beaver FOLEY & LARDNER LLP	K955556
2013-3100	04/19/2013 05/17/2013	OC/ORO/OCI/ OC/ORO/OCI/	Patricia Perez Perez, Patricia L	OCI 2006-MIF-705-0298 - CERTIFIED RECS
2013-3101	04/19/2013 05/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Nathan A. Beaver FOLEY & LARDNER LLP	K801036
2013-3102	04/19/2013 05/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Nathan A. Beaver FOLEY & LARDNER LLP	K934085
2013-3103	04/19/2013 05/17/2013	FDA/OFVM/CFSAN/OCD/EOS/	Jim Faller Valley Chemical Solutions, Inc.	FAP 2A4736, FAP 6A4767
2013-3104	04/19/2013 05/17/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 3/25-29/13
2013-3105	04/19/2013 05/17/2013	FDA/OGROP/ORO/NE-FO/NWE-DO/NWE-CB/	Jonathan Harrington Olympus Biotech Corporation	STERIS ISOMEDIX SERVICES, NORTHBOROUGH, MA 0- EIR (10/17/2011 - 10/19/2011)
2013-3106	04/19/2013 05/17/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 3/25-29/13
2013-3107	04/19/2013 05/17/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 3/25-29/13
2013-3108	04/19/2013 05/17/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 3/25-29/13
2013-3109	04/19/2013 05/17/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 3/18-22/13
2013-3110	04/19/2013 05/17/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 3/18-22/13
2013-3111	04/19/2013 05/17/2013	FDA/OC/OES/DFOI/	WILLIAM A. OLSON, Ph.D. WASHINGTON INFORMATION SOURCE	DAILY LOG 3/25-29/13
2013-3112	04/19/2013	FDA/OC/OES/DFOI/	WILLIAM A. OLSON, Ph.D.	DAILY LOG 3/18-22/13

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	05/17/2013		WASHINGTON INFORMATION SOURCE	
2013-3113	04/19/2013 05/17/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 3/18-22/13
2013-3114	04/19/2013 05/17/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 3/25-29/13
2013-3115	04/19/2013 05/17/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 3/18-22/13
2013-3116	04/19/2013 05/17/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 3/18-22/13
2013-3117	04/19/2013 05/17/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 3/25-29/13
2013-3118	04/19/2013 05/17/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 3/25-29/13
2013-3119	04/19/2013 05/17/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 3/18-22/13
2013-3120	04/19/2013 05/17/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 3/18-22/13
2013-3121	04/19/2013 05/17/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 3/25-29/13
2013-3122	04/19/2013 05/17/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 3/18-22/13
2013-3123	04/19/2013 05/17/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 3/25-29/13
2013-3124	04/19/2013 05/17/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY CLOSED LOG 3/25-29/13
2013-3125	04/19/2013 05/17/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY CLOSED LOG 3/18-22/13
2013-3126	04/19/2013 05/17/2013	FDA/OC/OES/DFOI/	DAVID MacFARLAND FDA REVIEW/FDA WEBVIEW	DAILY CLOSED LOG 3/18-22/13
2013-3127	04/19/2013 05/17/2013	FDA/OC/OES/DFOI/	DAVID MacFARLAND FDA REVIEW/FDA WEBVIEW	WEEKLY CLOSED LOG 3/25-29/13

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2013-3128	04/19/2013 05/17/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 3/18-22/13
2013-3129	04/22/2013 05/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tony Fiorino Greywall Asset Management	EXPAREL - STATISTICAL REVIEW, UNREDACTED MEDICAL REVIEW
2013-3130	04/22/2013 05/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Nathan A. Beaver FOLEY & LARDNER LLP	K955557
2013-3131	04/22/2013 05/20/2013	FDA/OMPT/CTP/OD/	Desmond Jenson Tobacco Control Legal Consortium	ALL ORDERS ISSUED PURSUANT TO SECTION 911 OF THE FDCA APPROVING OR DENYING APPLICATION TO MARKET A TOBACCO PRODUCT AS A MODIFIED RISK TOBACCO PRODUCT (06/22/09 TO PRESENT)
2013-3132	04/22/2013 05/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	David Lin BIOLOGICS CONSULTING GROUP	TZ-3 APPROVAL PACKAGE
2013-3133	04/22/2013 05/20/2013	FDA/OGROP/ORO/CE-FO/CIN-DO/CIN-CB/	Sarah Tribble THE PLAIN DEALER	BEN VENUE - WARNING LETTERS, INSPECTION REPORTS, CONSENT DECREES ETC SINCE 01/01/13
2013-3134	04/22/2013 05/20/2013	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	SUBSTANTIAL EQUIVALENT ORDERS ISSUED UNDER SECTION 910(a)(2)(A) OF THE FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT, IDENTITY OF PRODUCT, IDENTITY OF MANUFACTURER 03/01/13 TO 3/31/13
2013-3135	04/22/2013 05/20/2013	FDA/OC/OES/ FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORO/ OC/ORO/	Robert D. Sullivan, Jr. Wilson, Elser, Moskowitz, Edelman & Dicker LLP	RECS RE THREE LOTS OF PRESERVATIVE-FREE METHYLPREDNISONONE ACETATE MANUFACTURED BY NECC ASSOCIATED WITH THE MULTI-STATE OUTBREAK OF FUNGAL MENINGITIS
2013-3136	04/22/2013 05/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	David Lin BIOLOGICS CONSULTING GROUP	NDA 019355 - APPROVAL RECS

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2013-3137	04/22/2013 05/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	ADVANCED BIONICS HIFOCUS MID-SCALA ELECTRODE - APPLICATION SUBMISSION DATE
2013-3138	04/22/2013 05/20/2013	FDA/OMPT/CTP/OD/	Desmond Jenson Tobacco Control Legal Consortium	MODIFIED RISK TOBACCO APPLICATIONS JUNE 22, 2009 TO PRESENT
2013-3139	04/22/2013 05/20/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Rachel Johnson FOI Services, Inc.	ANIMAS, WEST CHESTER, PA - 483 (07/18/2011 - 08/10/2011)
2013-3140	04/22/2013 05/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	07/20/1984LETTER FROM DR PAUL LEBER TO SPONSORS OF NEUROLEPTIC DRUGS RE TARDIVE DYSKINESIA WARNINGS, SUBSEQUENT CORR
2013-3141	04/22/2013 05/20/2013	FDA/OGROP/ORACE-FO/DEN-DO/DEN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Garrison Wells THE GAZETTE OF THE DEMONCRATIC SOCIALIST REPUBLIC OF SRI LANKA	MEDWATCH MESSAGES SENT TO FDA RE WARFARIN AND CONCERNS THAT DOSAGES HARMING PATIENTS IN COLORADO SPRINGS
2013-3142	04/22/2013 05/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Laura Boll Medovations Inc.	K934985
2013-3143	04/22/2013 05/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Laura Boll Medovations Inc.	K992485
2013-3144	04/22/2013 05/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Laura Boll MEDOVATIONS INC	K103707
2013-3145	04/22/2013 05/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Laura Boll Medovations Inc.	K020135
2013-3146	04/22/2013 05/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Elaine Duncan Paladin Medical, Inc.	K111920
2013-3147	04/22/2013 05/20/2013	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	SAMUEL GOLDBERGER BLUE BEVERAGE	BERNER FOOD AND BEVERAGE, DAKOTA, ILLINOIS - 483
2013-3148	04/22/2013 05/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOSEPH KICEINA ABBOTT POINT OF CARE INC	I-STAT CELITE ACT CARTIDGE - K992571; I-STAT KAOLIN ACT CARTIDE - K023582
2013-3149	04/22/2013 05/20/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	NATHAN A BEAVER FOLEY & LARDNER LLP	LIST OF CURRENT MEDICAL DVCS - 510KS, PMAS 2013

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2013-3150	04/22/2013 05/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	SAGENT STRIDES - BACITRACIN INJ; FERA PHARMS - NEOMYCIN, POLYMYXIN B SULFATES anda 90-211 & BACITRACIN ZINC OINTMENT ANDA 60-764 - AERS
2013-3151	04/22/2013 05/20/2013	FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	Rachel Johnson FOI Services, Inc.	NYPRO, NC - EIR, 483, WARNING LETTER ETC (01/01/2009 TO PRESENT)
2013-3152	04/22/2013 05/20/2013	FDA/OMPT/CTP/OD/	Desmond Jenson Tobacco Control Legal Consortium	COMMONWEALTH BRANDS - FOLLOW UP RECS (07/20/2010 - 04/19/2013)
2013-3153	04/22/2013 05/20/2013	FDA/OMPT/CTP/OD/	Desmond Jenson Tobacco Control Legal Consortium	PHILIP MORRIS USA - FOLLOW UP TO 6/17/10 LETTER RE MARKETING MARLBORO LIGHT
2013-3154	04/22/2013 05/20/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LAUREN MILLER ARNOLD AND PORTER	PERJETA (VISMODEGIB) BLA 12-5409 - APRVL LTR (CETIFIED)
2013-3155	04/22/2013 05/20/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	BRETT PARK CONWAY HOMER & CHIN-CAPLAN PC	INDIVIDUAL RECS
2013-3156	04/22/2013 05/20/2013	FDA/OFVM/CFSAN/OCD/EOS/	ELIZABETH SWEIS INTERTEK	ENZYME BIO SYSTEMS LTD - FAP 9A4175
2013-3157	04/22/2013 05/20/2013	FDA/OFVM/CFSAN/OCD/EOS/	DONNAMARIA R JONES UNIFORMED SERVICES UNIVERSITY OF HEALTH SCIENCES	CAFFEINE & ENERGY DRINKS - CAERS 1/12 TO 12 /12
2013-3158	04/22/2013 05/20/2013	OC/ORO/ORM/ OC/ORO/ORM/	WALTER E CHALKLEY THOMSON REUTERS	LIST OF INSP - COMPANY, LOCATION, INSPECTORS 1999
2013-3159	04/22/2013 05/20/2013	OC/ORO/ OC/ORO/	KYRIALKDIS, JOANNA	RONALD CHESMORE - JOHN M HAMMOND, C EDWARD WEBB, MAUDE BABINGTON, ETC LTR 7/29/92
2013-3160	04/22/2013 05/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	SUSAN PATE CARESTREAM HEALTH INC	CURVEBEAM LLC - PEDCAT K113548
2013-3161	04/22/2013 05/20/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	SUSAN PATE CARESTREAM HEALTH INC	PLANMED OY - PLANMED VERITY K121418
2013-3162	04/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	SHERRI RUARK	ZOLL MEDICAL CORP - AED PLUS MDRS 1/02 TO 12/02

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	05/20/2013		BRUER WOODDELL & HARRELL	
2013-3163	04/22/2013 05/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORA/ORO/DIOP/	JANET Y SANTANA FEDERAL PUBLIC DEFENDER TENNESSEE	IMPORTATION OF PHENOBARBITAL DEA SCHEDULE IV CONTROLLED SUSTANCE DEA CODE #2285 - IMPORT, ENTRY NOTICE OF FDA ACTION, ETC
2013-3164	04/22/2013 05/20/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	DONALD N BLUE ZETETIC	BOXES PREPAERATIONS FORHAIR SHAMPOO & HAIR CONDITIONER IN 8 PALLETS ENTRY NUMBER EHP-0076994-4 - PHOTOGRAPHS, OASIS SCREEN SHOTS
2013-3165	04/22/2013 05/20/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	DONALD N BLUE ZETETIC	PALLETS CONTAINING SHAMPOO CONDITIONERS HAIR PREPARATIONS ENTRY NUMBER EHP-0076949-8 - PHOTOGRAPHS & OASIS SCREEN SHOTS
2013-3166	04/23/2013 05/21/2013	OC/ORA/ OC/ORA/	Chris Kaiser Kaiser, Chris	CONCORD PHARMACY, SUWANEE, GA - (03/01/2013 - 04/19/2013)
2013-3167	04/23/2013 05/21/2013	OC/ORA/ OC/ORA/ OC/CVM/OCD/	Mark Greenblatt SCRIPPS HOWARD NEWS SERVICE	PUBLICLY RELEASABLE FIELDS OR TABLES OF DATA RE PET FOOD COMPLAINTS
2013-3168	04/23/2013 05/21/2013	FDA/OC/OES/DFOI/ FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	John Reinke John Reinke	PET AG FORMULAS
2013-3169	04/23/2013 05/21/2013	OC/CVM/OCD/	Mark Greenblatt SCRIPPS HOWARD NEWS SERVICE	ADVERSE EVENTS REPORTED TO CVM FOR DRUGS GIVEN TO ANIMALS OR PETS (01/01/2008 - 04/19/2013)
2013-3170	04/23/2013 05/21/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michael Novod Nordea Markets	DIABETES DRUGS - AERS (01/01/2009 - 04/19/2013)
2013-3171	04/23/2013 05/21/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Stan Kisiel Mercer St Warehouse LLC	INTERNATIONAL FOOD AND CANDY, HIGHTSTOWN, NJ; INTERNATIONAL FOOD AND CANDY, EAST BRUNSWICK, NJ - INSPECTIONS, VIOLATIONS, CORR ETC (01/01/2010 - 04/19/2013)
2013-3172	04/23/2013 05/21/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	methylnaltrexone Université Joseph Fourier	METHYLNALTREXONE - AERS; SAFETY STUDY NCT 00804141
2013-3173	04/23/2013	FDA/OC/OES/DFOI/	Amy Kincanon	2013-2535

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	05/21/2013		LexisNexis CourtLink Document Retrieval	
2013-3174	04/23/2013 05/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Karen Schultz The Dominion Group	NDA 022406 S001, NDA 022406 S003 - SBA, REVIEW
2013-3175	04/23/2013 05/21/2013	OC/ORO/OCI/ OC/ORO/OCI/	Doe J	INVESTIGATION RECS
2013-3176	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	Cora Sim Ellipse Technologies, Inc.	K072161
2013-3177	04/23/2013 05/21/2013	FDA/OGROP/ORO/CE-FO/DET-DO/DET-CB/	Michelle Masson TRILLIUM HEALTH CARE PRODUCTS INC	SPI PHARMA, GRAND HAVEN, MI - EIR (05/01/2011 - 04/30/2013)
2013-3178	04/23/2013 05/21/2013	FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA REQUEST LOG (04/15/2013 - 04/19/2013)
2013-3179	04/23/2013 05/21/2013	FDA/OGROP/ORO/CE-FO/PHI-DO/PHI-CB/	Michelle Masson TRILLIUM HEALTH CARE PRODUCTS INC	SPI PHARMA, LEWES, DE - EIR (09/01/2012 - 04/30/2013)
2013-3180	04/23/2013 05/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	prashanth jayaram JAYARAM, PRASHANTH	SAREPTA THERAPEUTICS - MINUTES FROM MARCH 2013 TYPE B END-OF-PHASE II MEETINGS
2013-3181	04/23/2013 05/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Trupti Shah TAKEDA PHARMACEUTICALS NA INC	INCRETIN-BASED ANTI-DIABETIC AGENT - AERS
2013-3182	04/23/2013 05/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Melissa Burkhart Melissa Burkhart	DESOGESTREL, APRI/DESOGEN - SIDE EFFECTS
2013-3183	04/23/2013 05/21/2013	OC/ORO/ OC/ORO/ OC/ORO/OE/ OC/ORO/OE/	Mark Greenblatt SCRIPPS HOWARD NEWS SERVICE	ELECTRONIC LISTING OF ALL PET FOOD MANUFACTURERS INSPECTED BY FDA (01/01/2008 - 04/22/2013)

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		OC/ORO/ORM/ OC/ORO/ORM/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORO/CE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORO/CE-FO/CHIDO/CHI-CB/ FDA/OGROP/ORO/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORO/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORO/CE-FO/PHIDO/PHI-CB/ FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORO/SE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORO/SW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORO/SW-FO/KAN-DO/KAN-CB/ FDA/OGROP/ORO/SW-FO/SWID/SWID-CB/ OC/CVM/OCD/		
2013-3184	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	Patricia Reuter Patricia Reuter	WYETH INFUSE BONE GRAFT - POST APPROVAL REPORTS
2013-3185	04/23/2013 05/21/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	b. burgess BURGESS, BERNIE	INTERNAL FDA MEMO, EMAIL CORR FOR JAN/FEB 2007 FOR DAN MY-CHU
2013-3186	04/23/2013 05/21/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	b. burgess BURGESS, BERNIE	INSPECTIONAL CLASSIFICATION FOR FACTS 808885 BY CDER

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		FDA/OMPT/CDER/ORP/DIDP/		
2013-3187	04/23/2013 05/21/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	b. Burgess BURGESS, BERNIE	BACKGROUND INFORMATION PROVIDED BY CDER DSI TO CONDUCT INSPECTION 808885
2013-3188	04/23/2013 05/21/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	b. Burgess BURGESS, BERNIE	BACKGROUND INFORMATION PROVIDED BY CDER DSI FOR FACTS 808885
2013-3189	04/23/2013 05/21/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Stryker Sustainability Solutions STRYKER SUSTAINABILITY SOLUTIONS	RECALL Z-0941-2013 - RECALL RECS
2013-3190	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	KELLY K MCNABB PRITZKER OLSEN	AMERICAN MEDICAL SYSTEMS - APOGEE AND PERIGEE WITH INTEPRO LITE AND INTEXEN LP K082387
2013-3191	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	KELLY K MCNABB PRITZKER OLSEN	AMERICAN MEDICAL SYSTEMS INC - AMS ELEVATE ANTERIOR AND APICAL PROLAPSE REPAIR SYS WITH INTEPRO LITE K082677
2013-3192	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/ PRITZKER OLSEN	KELLY K MCNABB PRITZKER OLSEN	AMERICAN MEDICAL SYSTEMS INC - MINIARC PRECISE SINGLE-INCISION SLING K100807
2013-3193	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/ PRITZKER OLSEN	KELLY K MCNABB PRITZKER OLSEN	AMERICAN MEDICAL SYSTEMS INC - AMS ELEVATE PC APICAL AND POSTERIOR PROLAPSE REPAIR SYS WITH INTEPRO LITE, ANTERIOR AND APICAL PROLAPSE REPAIR SYS WITH INTEPRO LITE K111118
2013-3194	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	KELLY K MCNABB PRITZKER OLSEN	AMERICAN MEDICAL SYSTEMS INC - AMS APOGEE VAULT SUSPENSION SYS K040537
2013-3195	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/ PRITZKER OLSEN	KELLY K MCNABB PRITZKER OLSEN	AMERICAN MEDICAL SYSTEMS INC - SPARC, MONARC, BIOARC SP, BIOARC TO SLING SYS K041948
2013-3196	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/ PRITZKER OLSEN	KELLY K MCNABB PRITZKER OLSEN	AMERICAN MEDICAL SYSTEMD INC - URETHRAL SLING, SURGICAL MESH K051530
2013-3197	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/ PRITZKER OLSEN	KELLY K MCNABB PRITZKER OLSEN	AMERICAN MEDICAL SYSTEMS INC - AMS ELEVATE APICAL AND POSTERIOR PROLAPSE REPAIR SYS WITH INTEPRO LITE, AMS ELEVATE APICAL AND POSTERIOR PROLAPSE REPAIR SYS WITH INTEXEN LP K082730
2013-3198	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	KELLY K MCNABB PRITZKER OLSEN	AMERICAN MEDICAL SYSTEMS INC - AMS MINIARC SLING SYS K071902
2013-3199	04/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	CHARLES M. HART	HOLOGIC INC - FULL FIELD DIGITAL X RAY

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	05/21/2013		HART CONSULTING LLC	MAMMOGRAPHIC CONTRAST ENHANCED DIGITAL MAMMOGRAPHY SYS K123873
2013-3200	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	CHARLES M. HART HART CONSULTING LLC	HOLOGIC INC - SYS XRAY MAMMOGRAPHIC LORAD AFFIRM BREAST BIOPSY GUIDANCE SYS K122836
2013-3201	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	KELLY K MCNABB PRITZKER OLSEN	AMERICAN MEDICAL SYSTEMS INC - AMS MINIARC SLING SYS K073703
2013-3202	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	CHARLES M. HART HART CONSULTING LLC	HOLOGIC INC - SYS X RAY MAMMOGRAPIC LORAD DIGITAL SPOT MAMMOGRAPHY SYS K040884
2013-3203	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	KELLY K MCNABB PRITZKER OLSEN	AMERICAN MEDICAL SYSTEMS INC - AMS ELEVATE PC APICAL AND POSTERIOR PROLAPSE REPAIR SYS WITH INTEPRO LITE, AMS ELEVATE PC ANTERIOIR AND APICAL PROLAPSE SYS WITH INTEPRO LITE K112842
2013-3204	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	CHARLES M. HART HART CONSULTING LLC	MICROSPACE PTY LTD - GENERATOR PULSE PACEMAKER EXTERNAL PROGRAMMABLE CARDIAC STIMULATOR K072200
2013-3205	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	KELLY K MCNABB PRITZKER OLSEN	AMERICAN MEDICAL SYSTEMS INC - AMS ELEVATE WITH INTEPRO LITE PROLAPSE REPAIR SYS, AMS ELEVATE WITH INTEXEN LP PROLAPSE REPAIR SYS K080185
2013-3206	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	CHARLES M. HART HART CONSULTING LLC	EP MEDSYSTEMS - GENERATOR PULSE PACEMAKER EXTERNAL PROGRAMMABLE EP 4 CARDIAC STIMULATOR K092913
2013-3207	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	KELLY K MCNABB PRITZKER OLSEN	AMERICAN MEDICAL SYSTEMS INC - SPARC SYS, MONARC SYS, MONARC+ SYS, MONARC C SYS K081613
2013-3208	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	KELLY K MCNABB PRITZKER OLSEN	AMERICAN MEDICAL SYSTEMS INC - APOGEE AND PERIGEE SYS WITH PC COATED INTEPRO LITE K081710
2013-3209	04/23/2013 05/21/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JAMES FARES NURO PHARMACEUTICALS INC	MYSOLINE NDA 10-401/S10 UNREDACTED
2013-3210	04/23/2013 05/21/2013	FDA/OFVM/CFSAN/OCD/EOS/	CHASTINE12B2563, J	FISH; SHELLFISH - MERCURY CONTENT
2013-3211	04/23/2013 05/21/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	JEREMY JOHNSON Traditional Medicinals, Inc.	BI NUTRACEUTICALS, LONG BEACH, CA; ISLANDIA, NY - EIR, 483, RECALL 1/12 TO PRESENT
2013-3212	04/23/2013 05/21/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORACE-FO/NWJ-	JEREMY JOHNSON Traditional Medicinals, Inc.	MARTIN BAUER GROUP, SECAUCUS, NJ; GERMANY - EIR, 483, RECALL 1/12 TO PRESENT

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		DO/NWJ-CB/		
2013-3213	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	KELLY K MCNABB PRITZKER OLSEN	AMERICAN MEDICAL SYSTEMS INC - SPARC SLING SYS K013355
2013-3214	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	KELLY K MCNABB PRITZKER OLSEN	AMERICAN MEDICAL SYSTEMS INC - SPARC SLING SYS K021263
2013-3215	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	KELLY K MCNABB PRITZKER OLSEN	AMERICAN MEDICAL SYSTEMS INC - SPARC SLING SYS K020663
2013-3216	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	KELLY K MCNABB PRITZKER OLSEN	AMERICAN MEDICAL SYSTEMS INC - MINIARC PRO SINGLE-INCISION SLING SYS K12164
2013-3217	04/23/2013 05/21/2013	FDA/OFVM/CFSAN/OCD/EOS/	JEREMY JOHNSON Traditional Medicinals, Inc.	WORLEE NATURPRODUKTE GMBH, HAMBURG, GERMANY - EIR, 483, RECALL 1/12 TO PRESENT
2013-3218	04/23/2013 05/21/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OFVM/CFSAN/OCD/EOS/	JEREMY JOHNSON Traditional Medicinals, Inc.	HIGH QUALITY ORGANICS, RENO, NV - EIR, 483, RECALL 1/12 TO PRESENT
2013-3219	04/23/2013 05/21/2013	FDA/OFVM/CFSAN/OCD/EOS/	JEREMY JOHNSON Traditional Medicinals, Inc.	MOTHER PARKERS SANDRA TEA & COFFEE LTD, MISSISSAUGA, ONTARIO - EIR, 493, RECALL 1/12 TO PRESENT
2013-3220	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	KELLY K. McNABB PRITZKER OLSEN	AMERICAN MEDICAL SYS INC - PELVIC MESH PRODUCTS MONARC SLING SYS K023516
2013-3221	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	KELLY K. McNABB PRITZKER OLSEN	AMERICAN MESH SYS INC - PELVIC MESH SYS K121612
2013-3222	04/23/2013 05/21/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	KELLY K. McNABB PRITZKER OLSEN	AMERICAN MEDICAL SYS INC - PELVIC MESH PRODUCTS K090713
2013-3223	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	KELLY K. McNABB PRITZKER OLSEN	AMERICAN MEDICAL SYS INC - PELVIC MESH PRODUCTS K011251
2013-3224	04/23/2013 05/21/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	KELLY K. McNABB PRITZKER OLSEN	AMERICAN MEDICAL SYS INC - PELVIC MESH PRODUCTS K040623
2013-3225	04/23/2013 05/21/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID L. ROSEN FOLEY & LARDNER LLP	OXYTOCIN NDA 02-272/S-014 LBLG
2013-3226	04/23/2013 05/21/2013	FDA/OFVM/CFSAN/OCD/EOS/	MERLE ZIMMERMANN AMERICAN HERBAL PRODUCTS ASSOCIATION	DIETARY SUPPLEMENTS - AER 7/10

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2013-3227	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Heather Luna Aphena Pharma Solutions	K-Y LUBRICATING JELLY - 510K
2013-3228	04/24/2013 05/22/2013	FDA/OMPT/CTP/OD/	Desmond Jenson Tobacco Control Legal Consortium	2012-8781 UPDATED
2013-3229	04/24/2013 05/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Marc C. Sanchez, Esq. Contract In-House Counsel and Consultants, LLC	COLLODIAL SILVER - NUMBER OF DEATHS, ALLERGIC REACTIONS, DRUG INTERACTIONS ETC
2013-3230	04/24/2013 05/22/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Scott Fawcett Carroll Quality Consult, Inc.	PHARMATECH, LCC; MEDIPHARM LABORATORIES (06/01/2002 - 04/22/2013)
2013-3231	04/24/2013 05/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachelle Lyon Janus Capital Group Attn: Rachelle Lyon	XTANDI - CNS AERS
2013-3232	04/24/2013 05/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	AMY GONZALES AMGEN INC	MN PHARMACEUTICALS, INSTANBUL, TURKEY - EIR MAY 2012
2013-3233	04/24/2013 05/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORACE/OCI/ OC/ORACE/OCI/	Joanne Moskovic Moskovic & Associates, Ltd.	SYMBAX - INVESTIGATION RECS
2013-3234	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Heather Luna Aphena Pharma Solutions	VAST RESOURCES/TOPCO SALES PERSONAL LUBRICATING JELLY - 510K
2013-3235	04/24/2013 05/22/2013	OC/ORACE/ OC/ORACE/ FDA/OGROP/ORACE-FO/LOS-DO/LOS-CB/	AnnMarie Beattie Harmonized Customs Brokers, Inc.	ENTRY G76-0129969-4 - LAB RESULTS

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2013-3236	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Tim M. Lohnes ORCHID DESIGN	K122470
2013-3237	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	GENESIS RETAIL GENESIS RETAIL INC	K12171
2013-3238	04/24/2013 05/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tomisha LeClair LECLAIR, TOMISHA	ZOFRAN - AERS
2013-3239	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Cora Sim Ellipse Technologies, Inc.	K041393
2013-3240	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Yuta Kawakatsu TOYOBO U.S.A., INC.	K103081
2013-3241	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K953509
2013-3242	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K051956
2013-3243	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K070874
2013-3244	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Barry Callahan RJL SYSTEMS	K874361
2013-3245	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K121426
2013-3246	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K960455
2013-3247	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K965241
2013-3248	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K993655
2013-3249	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	AMERICAN MEDICAL SYSTEMS INC - APOGEE VAULT SUSPENSION SYS K040537
2013-3250	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	AMERICAN MEDICAL SYSTEMS INC - SPARC SYS; MONARC SYS; MONARC+SYS, ETC K081613
2013-3251	04/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	AARON L EMBREY	AMERICAN MEDICAL SYSTEMS INC - BIOARC SP SLING KIT

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	05/22/2013		ANDRUS HOOD & WAGSTAFF PC	K030123
2013-3252	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	AMERICAN MEDICAL SYSTEMS INC - IN-FAST BONE SCREW SYS K011910
2013-3253	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	AMERICAN MEDICAL SYSTEMS INC - SPARC SLING SYS K013355
2013-3254	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	AMERICAN MEDICAL SYSTEMS INC - SPARC SLING SYS K011251
2013-3255	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	AMERICAN MEDICAL SYSTEMS INC - SINGLE INCISION SLING SYS K070065
2013-3256	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	AMERICAN MEDICAL SYSTEMS INC - SPARC SLING SYS K021263
2013-3257	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	AMERICAN MEDICAL SYSTEMS INC - SPARC SLING SYS K020663
2013-3258	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	AMERICAN MEDICAL SYSTEM INC - MINIARC SLING SYS K071902
2013-3259	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	AMERICAN MEDICAL SYSTEMS INC - PERIGE TM SYS K040623
2013-3260	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	AMERICAN MEDICAL SYSTEMS INC - MONARC SLING SYS K023516
2013-3261	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	AMERICAN MEDICAL SYSTEMS INC - ELEVATE PROLAPSE REPAIR SYS WITH PC COATED INTEPRO LITE K090713
2013-3262	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	AMERICAN MEDICAL SYSTEMS INC - APOGEE & PERIGEE SYS WITH PC COATED INTEPRO LITE K081710
2013-3263	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	AMERICAN MEDICAL SYS INC - SPARC, MONARC BIOARC SP & BIOARC TO SLING SYS K041948
2013-3264	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	AMERICAN MEDICAL SYSTEMS INC - MINIARC PRECISE T SINGLE-INCISION SLING K0100807
2013-3265	04/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	AARON L EMBREY	AMERICAN MEDICAL SYSTEMS INC - MONARC & BIOARC

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	05/22/2013		ANDRUS HOOD & WAGSTAFF PC	TO SUBFASCIAL HAMMOCKS K051530
2013-3266	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	AMERICAN MEDICAL SYSTEMS INC - MINIARC SLING SYSTEM K073703
2013-3267	04/24/2013 05/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	AMY MITCHELL GLAXO SMITH KLINE	PATHEON PHARMS, CINCINNATI, OH - QAP
2013-3268	04/24/2013 05/22/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	JAMES DORE DORE DEUTSCHER LAW GROUP PLLC	TOCOMA RADIOLOGICAL ASSOCIATES , LAKEWOOD, WA - INSPS 1999 TO 2010
2013-3269	04/24/2013 05/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sinem Tan MN Pharmaceuticals-Mustafa Nevzat Ilac	MUSTAFA NEVZAT - EIR 04/20/12 TO 05/03/12
2013-3270	04/24/2013 05/22/2013	OC/ORA/OCI/ OC/ORA/OCI/	Roger Farmer Nation Treasury Employees Union	INTERNAL AFFAIRS INVESTIGATION
2013-3271	04/24/2013 05/22/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	Anthony Sansone Anthony M. Sansone	FOOD SAMPLE 798264 - DETENTION RECS
2013-3272	04/24/2013 05/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Karen Seta-Aust Camargo Pharmaceutical Services	FDA STAFF MANUAL GUIDE 4850.7
2013-3273	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Chiara Cunico Brainlab AG	BRAINLAB - EIR (01/01/2008 - 12/31/2012)
2013-3274	04/24/2013 05/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Aida Durmo Bosnalijek d.d.	IND-SWIFT, PUNJAB, INDIA - EIR (01/01/2011 - 04/24/2013)
2013-3275	04/24/2013 05/22/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Mario Vesnaver Mario Vesnaver	LENSX - RESPONSE TO WARNING LETTER
2013-3276	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	James Keller CooperSurgical, Inc	K110288

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2013-3277	04/24/2013 05/22/2013	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	Lauren Farruggia Hyman, Phelps and McNamara	CHATTEM, INC - WARNING LETTER RECS
2013-3278	04/24/2013 05/22/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	CRAIG ROUSH ROCHLINE INDUSTRIES	PAXICO LLC, BATAVIA, OH - EIRS, 483S, CORR 1/08 TO PRESENT
2013-3279	04/24/2013 05/22/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ OC/OR/ OC/OR/	JACK WEATHERLY ARKANSAS DEMOCRAT GAZETTE	2004-DAL-WL-02 - RECS
2013-3280	04/24/2013 05/22/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Doe J	CMPLNT
2013-3281	04/24/2013 05/22/2013	FDA/OFVM/CFSAN/OCD/EOS/	LAURA J STEVENS PURDUE UNIV/NUTRITION SCIENCE DEPT	NATIONAL RESEARCH COUNCIL - SURVEY OF INDUSTRY ON THE USE OF FOOD ADDITIVES VOL 3 10/31/79
2013-3282	04/24/2013 05/22/2013	FDA/OO/OHR/	REICHLER, VIRGIL D	HHS-FDA-ORA-MP-13-861909 - RESUMES
2013-3283	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K113527
2013-3284	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kathleen Selover Selover, Kathleen	K022807
2013-3285	04/24/2013 05/22/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	Sahil Bhatia Manning and Napier Advisors	COOPER COMPANIES, COOPERVISION, COOPER SURGICAL - 483 (01/01/2012 - 04/24/2013)
2013-3286	04/24/2013 05/22/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	JHP PHARMACEUTICALS, ROCHESTER, MI - EIR, 483 01/01/11 TO 3/20/13
2013-3287	04/25/2013 05/23/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Eagle Pharmaceuticals, Inc. Eagle Pharmaceuticals, Inc.	CIPLA LIMITED UNIT V, VIII, AND IX VERNA INDUSTRIAL ESTATE, VERNA, COA, INDIA - EIR, 483 (01/01/2010 - 05/31/2013)

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-3288	04/25/2013 05/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Alexander M M Shepherd MD PhD UTHSCSA	OXYCODONE - AERS
2013-3289	04/25/2013 05/23/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Dora Fong KARL STORZ ENDOSCOPY AMERICA INC	K063345
2013-3290	04/25/2013 05/23/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Dora Fong KARL STORZ ENDOSCOPY AMERICA INC	K042961
2013-3291	04/25/2013 05/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jennifer Kiblinger DiaPharma	K103555
2013-3292	04/25/2013 05/23/2013	FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	Joshua Malamud Hyman, Phelps & McNamara, P.C.	ICON DEVELOPMENT SOLUTIONS - 483, EIR (01/01/2008 - 04/24/2013)
2013-3293	04/25/2013 05/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Benjamin Burgin Salix Pharmaceuticals, Inc.	NDA 21908 S011
2013-3294	04/25/2013 05/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Brienne Kugler Morgan Stanley	JAKAFI - AERS
2013-3295	04/25/2013 05/23/2013	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	Fulbright & Jaworski FULBRIGHT & JAWORSKI LLP	DERMA SCIENCE, PRINCETON, NJ - WARNING LETTERS, EIR, 483 ETC (01/01/2007 - 04/24/2013)
2013-3296	04/25/2013 05/23/2013	FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/	Jeanne Whalen WALL STREET JOURNAL	NOVARTIS, LINCOLN, NE - 483 (01/01/2011 - 04/24/2013)
2013-3297	04/25/2013 05/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1867 REQUEST LETTER
2013-3298	04/25/2013 05/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2089, 2013-2092, 2013-2094 - REQUEST LETTER
2013-3299	04/25/2013 05/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1690 REQUEST LETTER

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2013-3300	04/25/2013 05/23/2013	FDA/OC/OES/DFOI/	201300165 MERCK & CO., INC.	2013-1842 REQUEST LETTER
2013-3301	04/25/2013 05/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1760 REQUEST LETTER
2013-3302	04/25/2013 05/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1763 REQUEST LETTER
2013-3303	04/25/2013 05/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2295 REQUEST LETTER
2013-3304	04/25/2013 05/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1654 REQUEST LETTER
2013-3305	04/25/2013 05/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1662 REQUEST LETTER
2013-3306	04/25/2013 05/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1693 REQUEST LETTER
2013-3307	04/25/2013 05/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2251 REQUEST LETTER
2013-3308	04/25/2013 05/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2421 REQUEST LETTER
2013-3309	04/25/2013 05/23/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	vinu Self	PEANUT OIL/PROTEIN IN VACCINES
2013-3310	04/25/2013 05/23/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Francisco Polonio Laboratorios Lesvi, S.L.	ALGORITHME PHARMA INC, CANADA - 483 NOVEMBER 2012
2013-3311	04/25/2013 05/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	Chris Card none	K082819, K072870
2013-3312	04/25/2013 05/23/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 202497
2013-3313	04/25/2013 05/23/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORPA-FO/SAN- DO/SAN-CB/	Roger Golden Roger N. Golden, a Professional Corporation	RICHWAY, INC, NEVADA - FOOD INSPECTIONS, REGISTRATION

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2013-3314	04/25/2013 05/23/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAP/PA-FO/SAN-DO/SAN-CB/	Roger N. Golden Roger N. Golden, A Prof. Corp.	ASIACORP, CALIFORNIA - FOOD INSPECTIONS, REGISTRATION
2013-3315	04/25/2013 05/23/2013	FDA/OFVM/CFSAN/OCD/EOS/	WILLIAM A OLSON, Ph.D. WASHINGTON INFORMATION SOURCE	IMPACT MODIFIED NYLON MXD-6 RESINS - PETITIONS
2013-3316	04/25/2013 05/23/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELLIOT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	MINUTES FROM SEREPTA THERAPEUTICS TYPE B END OF PHASE II MTGS 3/13
2013-3317	04/25/2013 05/23/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	ELLIOT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	ALEXION PHARMACEUTICALS, CHESHIRE, CT - EIR, 483, WARNING LTR 1/11 TO PRESENT
2013-3318	04/25/2013 05/23/2013	FDA/OC/OES/DFOI/	ELLIOT FAVUS, MD. FAVUS INSTITUTIONAL RESEARCH LLC	2013-1813
2013-3319	04/25/2013 05/23/2013	FDA/OFVM/CFSAN/OCD/EOS/	ELIZABETH SWEIS INTERTEK	FAP 9A4175
2013-3320	04/25/2013 05/23/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	BRIAN WILLIAMSON JCB Laboratories	JCB LABS, WICHITA, KS - EIR 2/12
2013-3321	04/25/2013 05/23/2013	FDA/OC/OES/DFOI/	LAW OFFICES OF RONALD A MARRON	UNREDACTED RECORDS
2013-3322	04/25/2013 05/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	SYDNEY FREEDBERG BLOOMBERG NEWS	CHALRES OSHAUGHNESSY WARNING LTR
2013-3323	04/25/2013 05/23/2013	FDA/OC/OES/DFOI/	LAW OFFICES OF RONALD A MARRON	UNREDACTED RECS
2013-3324	04/25/2013 05/23/2013	FDA/OC/OES/DFOI/	LAW OFFICES OF RONALD A MARRON	UNREDACTED RECS
2013-3325	04/25/2013 05/23/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FLYNN P. CAREY MITCHELL STEIN CAREY PC	THERMO LIFE INTL LLC - RECALL, INVESTIGATIONS

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-3326	04/25/2013 05/23/2013	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/	FLYNN P. CAREY GALLAGHER & KENNEDY PA	THERMO LIFE - CORR 1/00 TO 12/11
2013-3327	04/25/2013 05/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	AL-MUJAHIDIN 103968, MUHAMMAD	LIST OF VITAMINS; HALDON, THORAZINE, BOSPAR - AER
2013-3328	04/25/2013 05/23/2013	FDA/OGROP/ORO/CE-FO/PHI- DO/PHI-CB/ FDA/OMPT/CDRH/OCER/DFOI/	RONALD J LANGA PA	SYNTHES USA HQ, WEST CHESTER, PA - CLICK X 3D POLYAXIAL HEADS; PEDICLE SCREWS; N HANCE RODS CMLNT
2013-3329	04/25/2013 05/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	NIEVE ANJOMI RODMAN LAW GROUP LLC	PROSTATE 63 CANCER DIAGNOSTIC TEST K050063
2013-3330	04/25/2013 05/23/2013	FDA/OFVM/CFSAN/OCD/EOS/ OC/CVM/OCD/	PAIGE TOMASELLI CENTER FOR FOOD SAFETY	REN O SAL TABLETS ROXARSONE, ZOCO POULTRY TABLETS, KORUM IMPROVED FORMULA ETC - SAFETY & EFFECTIVENESS STUDIES, CMLNTS 2009 TO PRESENT
2013-3331	04/25/2013 05/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CURTIS A. THURSTON, Jr. THURSTON LAW OFFICES	SEPTOCAINE NDA 20-971/S-009; 20-971/S-013
2013-3332	04/25/2013 05/23/2013	FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORO/SE-FO/ATL- DO/ATL-CB/ FDA/OGROP/ORO/SW-FO/KAN- DO/KAN-CB/	BEN EISLER CBS This Morning	QUINTILES INC - AER 2009 TO PRESENT
2013-3333	04/26/2013 05/24/2013	FDA/OC/OES/DFOI/	Jeanne Whalen WALL STREET JOURNAL	NOVARTIS - FOIA REQUESTS (01/01/2011 - 04/25/2013)
2013-3334	04/26/2013 05/24/2013	FDA/OGROP/ORO/NE-FO/NWE- DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31, 2013 for: Shire Human Genetic Therapies, Lexington, MA
2013-3335	04/26/2013 05/24/2013	FDA/OGROP/ORO/NE-FO/NWE- DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING &	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31,

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			SUBMISSIONS	2013 for: Amgen Inc, Woburn, MA.
2013-3336	04/26/2013 05/24/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31, 2013 for: Bristol-Meyers-Squibb, Devens, MA
2013-3337	04/26/2013 05/24/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31, 2013 for: Cubist Pharmaceuticals, Lexington, MA
2013-3338	04/26/2013 05/24/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31, 2013 for: Amgen Inc, West Greenwich, RI
2013-3339	04/26/2013 05/24/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31, 2013 for: Biogen Idec, Cambridge, MA
2013-3340	04/26/2013 05/24/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31, 2013 for: Alexion Pharmaceuticals, Smithfield, RI
2013-3341	04/26/2013 05/24/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31, 2013 for: AMAG Pharmaceuticals, Inc., Cambridge, MA
2013-3342	04/26/2013 05/24/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31, 2013 for: Abbott Laboratories, Worcester, MA
2013-3343	04/26/2013 05/24/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31, 2013 for: Lonza Biologics, Inc., Newington, NH
2013-3344	04/26/2013 05/24/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31, 2013 for: Genzyme, Allston, MA
2013-3345	04/26/2013 05/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31, 2013 for: Dynamit Nobel GmbH, Kalkstrasse, Leverkusen, Germany
2013-3346	04/26/2013 05/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31, 2013 for: Labor L & S AG, Bad Bocklet-Grossenbrach, Germany

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2013-3347	04/26/2013 05/24/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31, 2013 for: ImmunoGen, Norwood, MA
2013-3348	04/26/2013 05/24/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31, 2013 for: Genzyme, Northborough, MA
2013-3349	04/26/2013 05/24/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31, 2013 for: Vertex Pharmaceuticals, Cambridge, MA
2013-3350	04/26/2013 05/24/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31, 2013 for: Alexion Pharmaceuticals, Cheshire, CT
2013-3351	04/26/2013 05/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31, 2013 for: Micronisierungs-Kontor Oberrot GmbH (MCKO, Oberot, Germany)
2013-3352	04/26/2013 05/24/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31, 2013 for: AstraZeneca Pharmaceuticals LP, Westborough, MA
2013-3353	04/26/2013 05/24/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31, 2013 for: Genzyme, Cambridge, MA
2013-3354	04/26/2013 05/24/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31, 2013 for: Lonza Group Ltd., Hopkinton, MA
2013-3355	04/26/2013 05/24/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31, 2013 for: Infinity Pharmaceuticals, Cambridge, MA
2013-3356	04/26/2013 05/24/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31, 2013 for: Stryker Biotech, Hopkinton, MA
2013-3357	04/26/2013 05/24/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31, 2013 for: Merrimack Pharmaceuticals Inc., Cambridge, MA
2013-3358	04/26/2013 05/24/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING &	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31, 2013 for: Genzyme Science Center, Framingham, MA

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			SUBMISSIONS	
2013-3359	04/26/2013 05/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA16131
2013-3360	04/26/2013 05/24/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31, 2013 for: Millenium (Takeda), Cambridge, MA
2013-3361	04/26/2013 05/24/2013	FDA/OFVM/CFSAN/OCD/EOS/	DEVON HILL Keller and Heckman LLP	EASTMAN CHEMICAL CO - FCN 224, FCN 440, FCN 597 TOXICOLOGY MEMO
2013-3362	04/26/2013 05/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	Meade, Doris	NORTHEAST PHARMACEUTICAL GROUP CO LTD, LIAONING PROVINCE, CHINA - 483 7/12
2013-3363	04/26/2013 05/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CURTIS A THURSTON JR THURSTON LAW OFFICES	SEPTOCAINE NDA 20-971/S009,S013 - DEAR HEALTH CARE PROFESSIONAL LTR
2013-3364	04/26/2013 05/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PAMELA SHEPPARD TARO PHARMACEUTICALS USA INC	GALDERMA LABS LP - ADAPALENE (DIFFERIN) NDA 20-338 SBA
2013-3365	04/26/2013 05/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	BARRY J STANIFORD NIPRO Diagnostics	MW5029708
2013-3366	04/26/2013 05/24/2013	FDA/OC/OES/DFOI/	ELENA HOWELL HOGAN LOVELLS LLP	2013-2507
2013-3367	04/26/2013 05/24/2013	FDA/OC/OES/DFOI/	ELENA HOWELL HOGAN LOVELLS US LLP	2013-2804
2013-3368	04/26/2013 05/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	THOMAS T67081, KEITH	UNIMED - MARINOL SBA, PSYCHOACTIVE COMPONENT OF THC, MFR ADDRESS, ETC

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2013-3369	04/26/2013 05/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	VIK BAJNATH ARTHREX INC	MW5029745
2013-3370	04/26/2013 05/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Alan Schwartz Schwartz Imaging	ULTRASOUND STANDOFF PAD DEVICE - MEDICAL SAFETY DEVICE SHEET
2013-3371	04/26/2013 05/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tony Fiorino Greywall Asset Management	EXPAREL - AERS
2013-3372	04/26/2013 05/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ranbaxy Ranbaxy Inc.	ANDA 062479
2013-3373	04/26/2013 05/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Francisco Polonio Laboratorios Lesvi, S.L.	Algorithme Pharma Inc, Canada - 483 01/2011
2013-3374	04/26/2013 05/24/2013	FDA/OFVM/CFSAN/OCD/EOS/	EYASSU G ABEGAZ PHD AJINOMOTO NORTH AMERICA INC	ASPARTAME - CAERS 1995 TO 2012
2013-3375	04/26/2013 05/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Pat Walicke MD, PhD SteadyMed Therapeutics	REMODULIN - MEDWATCH REPORTS
2013-3376	04/26/2013 05/24/2013	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/	JESSICA WICHA BAKER & MCKENZIE	NAVARO PECAN COMPANY INC, CORSICANA, TX; CAMILLA COMMODITY SERVICES INC, CAMILLA, GA - EIRS. 483S CORR, ETC 2007 TO PRESENT
2013-3377	04/29/2013 05/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	ALAIN GUILLAUMOT LANDANGER SA	K014207
2013-3378	04/29/2013 05/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Epimed International - For Wallach PainBlocker Epimed International, Inc.	K854334
2013-3379	04/29/2013 05/28/2013	OC/ORR/ OC/ORR/	Todd Wendt Seatech Corporation	ENTRY 603-1096062-4

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		FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/		
2013-3380	04/29/2013 05/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Ashley tuan Nexis Vision	K083921
2013-3381	04/29/2013 05/28/2013	FDA/OC/OES/DFOI/	Megan Pickel Beveridge & Diamond, PC	FOIA REQUESTS FOR CFSAN (04/01/2013 - 04/26/2013)
2013-3382	04/29/2013 05/28/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Rachel Johnson FOI Services, Inc.	H LEE MOFFITT CANCER CENTER, TAMPA, FL - EIR
2013-3383	04/29/2013 05/28/2013	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2013-2260, 2013-2273
2013-3384	04/29/2013 05/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Stephanie Edwin St. John Hospital and Medical Center	RIVAROXABAN - AERS
2013-3385	04/29/2013 05/28/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Stephanie Fullard Porex Corporation	POREX CORPORATION - EIR (11/28/2012 - 02/20/2013)
2013-3386	04/29/2013 05/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	ABUSE DETERRENCE OR TAMPER RESISTENCE TESTING TO SUPPORT APPROVAL OF NEW DRUG APPLICATION FOR OXYCONTIN
2013-3387	04/29/2013 05/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jeffrey Newman Law Offices of Jeffrey A. Newman & Associates	LC BEAD MICROSPHERES, BEADBLOCK MICROSPHERE - ADVERSE EVENTS 2006 TO PRESENT
2013-3388	04/29/2013 05/28/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Jennifer C. Smith-Parker BIOPHARM INSIGHT	ALEXION PHARMACEUTICALS - RESPONES TO WARNING LETTER ISSUED 03/22/2013
2013-3389	04/29/2013 05/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jeffrey Newman Law Offices of Jeffrey A. Newman & Associates	DUXORUBICIN HYDROCHLORIDE - AERS JANUARY 2006 TO PRESENT
2013-3390	04/29/2013 05/28/2013	OC/ORAO/ORM/ OC/ORAO/ORM/ OC/ORAO/OE/ OC/ORAO/OE/	Querida Anderson BIOPHARM INSIGHT	CLINICAL INVESTIGATIONS - LIST OF INSPECTIONS (01/01/2013 - 03/31/2013)
2013-3391	04/29/2013	FDA/OFVM/CFSAN/OCD/EOS/	Marcella Garsetti	DATA ON MARGARINES AND SPREADS

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	05/28/2013		Unilever Canada	
2013-3392	04/29/2013 05/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Stephen Teti Teti, Stephen	VENTRUS BIOSCIENCES, INC - RECS AND COMM WITH FDA RE IFERANSERIN, VEN 309 ETC
2013-3393	04/29/2013 05/28/2013	FDA/OC/OES/DFOI/	TURIEL, MIWTCHELL R	EXCEDRIN'S REMOVAL FROM THE SHELVES - RECS
2013-3394	04/29/2013 05/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Ann Waterhouse HILL-ROM	LUNG ASSIST INC - K120277
2013-3395	04/29/2013 05/28/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	MIKE BYROM BIOEDEN INC	COOK GENERAL BIO TECHNOLOGY LLC, INDIANAPOLIS, IN - EIRS, 483S, CO RESP 2010 TO PRESENT
2013-3396	04/29/2013 05/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DHSDHSNKK UPSFHYE SEYFARTH SHAW LLP	JANSSEN PHARMS - NUCYNTA NDA 22-304 FORMS 356(H), 3542, 3542(A), JAPEUTADOL HCL ETC
2013-3397	04/29/2013 05/28/2013	FDA/OFVM/CFSAN/OCD/EOS/	JEFF GREAVES FOOD INGREDIENT SOLUTIONS LLC	GNT - SPIRULINA CONCENTRATE PETITION
2013-3398	04/29/2013 05/28/2013	FDA/OC/OES/DDM/ FDA/OFVM/CFSAN/OCD/EOS/	JEFF GREAVES FOOD INGREDIENT SOLUTIONS LLC	MARS INC - SPIRULINA BLUE PETITION
2013-3399	04/29/2013 05/28/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	BRENDAN J FLAHERTY PRITZKER OLSEN	WHOLE FOODS, EAST LIBERTY, PA - PERRIN EDEL DE CLERON CHEESE FOODBORNE PATHOGEN OUTBREAK TESTING, INSP RPTS, ENFORCEMENT ACTIONS, ETC 1/11 TO PRESENT
2013-3400	04/29/2013 05/28/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	MICHAEL J VILLEGGIANTE WELTIN STREB & WELTIN	MOON FISHERY (INDIA) PVT LTD, MOON MARINE (USA) CORP, MOON MARINE INTERNATIONAL CO LTD, ETC - RPTS, CORR 1/08 TO PRESENT; INSPS 2010 TO PRESENT, ETC
2013-3401	04/29/2013 05/28/2013	FDA/OFVM/CFSAN/OCD/EOS/	CHRISTOPHER LEN NY/NJ BAYKEEPER	NJ SHELLFISH PROGRAM - ANNUAL PROGRAM EVALUATION RPTS FY2009
2013-3402	04/29/2013 05/28/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	PATRICIA L REGENYE Celgene Corporation	SCOTT SMITH, LOYOLA UNIV CHICAGO, MAYWOOD, IL - 483S 5/11 TO PRESENT
2013-3403	04/29/2013 05/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN CREWDSON PROJECT ON GOVERNMENT	CORR BTWN DR. DOV LINZER & DIVISION OF SCIENTIFIC INVESTIGATIONS

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	OVERSIGHT	
2013-3404	04/29/2013 05/28/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Doe J	ROCHE MOLECULAR SYSTEMS, ALAMEDA, CA - INVESTIGATOR'S INTERIM AND FINAL RPTS, CORR 2003
2013-3405	04/29/2013 05/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SHIPMAN, KIM	ISRS 4668141, 4532649, 7748365
2013-3406	04/29/2013 05/28/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Doe J	CHILDREN'S HOSPITAL OAKLAND RESEARCH INSTITUTE (CHORI) - INVESTIGATOR'S INTERIM AND FINAL RPTS, CORR
2013-3407	04/29/2013 05/28/2013	FDA/OMPT/CTP/OD/	CHARLES CELESTE EAS CONSULTING GROUP LLC	TOBACCO ESTABLISHMENTS REGISTERED WITH THE FDA PER THE REQUIREMENTS UNDER SECTION 905 OF THE ACT
2013-3408	04/29/2013 05/28/2013	FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/	CHARLES CELESTE EAS CONSULTING GROUP LLC	FOOD FACILITIES REGISTERED WITH THE FDA AS PER THE REQUIREMENTS UNDER THE FD&C ACT, BIOTERRORISM ACT AND FSMA
2013-3409	04/30/2013 05/29/2013	FDA/OC/OES/DFOI/	Jake McDowell The Weinberg Group	FOIA DAILY LOG (01/01/2010 - 04/01/2013)
2013-3410	04/30/2013 05/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	Muhammad arif SIMPLE DIAGNOSTICS	K121224
2013-3411	04/30/2013 05/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable EIR for the April 2012 for inspection of: Nycomed GmbH: A Takeda Company, Robert-Bosch Strasse 8, Singen (Hohentwiel), Baden-Wuerttemberg 78224, Germany
2013-3412	04/30/2013 05/29/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firms correspondence from January 1, 2005 to December 31, 2010 for: Colorado State University, Endocrine Laboratory, Colorado
2013-3413	04/30/2013 05/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the approval letter, labeling, medical review, chemistry review, pharmacology review, statistical review, and all other releasable documents for: Invega (paliperidone), NDA 21-999 S-004, manufactured by Ortho McNeil Janssen, and approved 12/22/09
2013-3414	04/30/2013 05/29/2013	FDA/OFVM/CFSAN/OCD/EOS/	Wu Chen Wu, Chen	SANTE INTERNATIONAL - ADVERSE EVENTS (04/01/1985 - 04/27/2013)
2013-3415	04/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	Deval Patel	K050766

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	05/29/2013		STRYKER CORP	
2013-3416	04/30/2013 05/29/2013	FDA/OC/OES/	Jim McElhatton FEDERAL TIMES	FDA SEQUESTRATION PLAN (10/01/2012 - 04/26/2013)
2013-3417	04/30/2013 05/29/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firms correspondence from January 1, 2005 to December 31, 2010 for: Research Pathology Services, New Britain, Pennsylvania
2013-3418	04/30/2013 05/29/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Terrie Cowley THE TMJ ASSOCIATION, LTD	TMJ CONCEPTS, INC, TMJ MEDICAL, INC, BIOMET MICROFIXATION - MOST RECENT INSPECTION RECS, NUMBER OF HDE REQUESTED (02/07/2010 - 04/26/2013)
2013-3419	04/30/2013 05/30/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	TYLER KENYON NORTHCOAST RESEARCH	HILL ROM HOLDINGS, BATESVILLE, IN; INTEGRA LIFE SCIENCES MGMT, ANASCO, PR - RESP LTR 3/12
2013-3420	04/30/2013 05/29/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	P. MOLLY FORD MARANGA MORGENSTERN LAW CORP	VALLEY SURGICAL CTR VS COUNTY OF LOS ANGELES - TIFFINY BURROWS INVESTIGATION
2013-3421	04/30/2013 05/29/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	P. MOLLY FORD MARANGA MORGENSTERN LAW CORP	VALLEY SURGICAL CTR VS COUNTY OF LOS ANGELES - INVESTIGATION OF JULIAN OMIDI
2013-3422	04/30/2013 05/29/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	P. MOLLY FORD MARANGA MORGENSTERN LAW CORP	VALLEY SURGICAL CTR VS COUNTY OF LOS ANGELES - INVESTIGATION OF MICHAEL OMIDI
2013-3423	04/30/2013 05/29/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	P. MOLLY FORD MARANGA MORGENSTERN LAW CORP	VALLEY SURGICAL CTR VS COUNTY OF LOS ANGELES - INVESTIGATION OF MORTON ELLIOTT ALPERT
2013-3424	04/30/2013 05/29/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	P. MOLLY FORD MARANGA MORGENSTERN LAW CORP	VALLEY SURGICAL CTR VS COUNTY OF LOS ANGELES - INVESTIGATION OF TOP SURGEONS LLC
2013-3425	04/30/2013 05/29/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	P. MOLLY FORD MARANGA MORGENSTERN LAW CORP	VALLEY SURGICAL CTR VS COUNTY OF LOS ANGELES - INVESTIGATION OF BAKERSFIELD SURGERY INSTITUTE INC
2013-3426	04/30/2013 05/29/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	P. MOLLY FORD MARANGA MORGENSTERN LAW	VALLEY SURGICAL CTR VS COUNTY OF LOS ANGELES - INVESTIGATION OF WOODLAKE AMBULATORY SURGERY

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			CORP	CTR
2013-3427	04/30/2013 05/29/2013	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	P. MOLLY FORD MARANGA MORGENSTERN LAW CORP	VALLEY SURGICAL CTR VS COUNTY OF LOS ANGELES - INVESTIGATION OF NEW LIFE SURGERY CTR
2013-3428	04/30/2013 05/29/2013	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	P. MOLLY FORD MARANGA MORGENSTERN LAW CORP	VALLEY SURGICAL CTR VS COUNTY OF LOS ANGELES - INVESTIGATION ALMONT AMBULATORY SURGERY CTR
2013-3429	04/30/2013 05/29/2013	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	P. MOLLY FORD MARANGA MORGENSTERN LAW CORP	VALLEY SURGICAL CTR VS COUNTY LOS ANGELES - INVESTIGATION OF BEVERLY HILLS SURGICAL CTR
2013-3430	04/30/2013 05/29/2013	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	P. MOLLY FORD MARANGA MORGENSTERN LAW CORP	VALLEY SURGICAL CTR VS COUNTY OF LOS ANGELES - INVESTIGATION OF VALLEY SURGICAL CTR LLC
2013-3431	04/30/2013 05/29/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	David Mangione Govzilla, Inc.	BEN VENUE LABORATORIES, BEDFORD, OH - EIR, 483 (03/29/2013 - 03/29/2013)
2013-3432	04/30/2013 05/29/2013	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	P. MOLLY FORD MARANGA MORGENSTERN LAW CORP	VALLEY SURGICAL CTR VS COUNTY OF LOS ANGELES - INVESTIGATION OF 1800 GET SLIM
2013-3433	04/30/2013 05/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	Alejandro Gonzalez Della Valle, MD Alejandro Gonzalez Della Valle, MD	ZIMMER LONGEVITY - ADDITIONAL MAUDE INFORMATION
2013-3434	04/30/2013 05/29/2013	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	P. MOLLY FORD MARANGA MORGENSTERN LAW CORP	VALLEY SURGICAL CTR VS COUNTY OF LOS ANGELES - INVESTIGATION OF SAN DIEGO AMBULATORY CTR LLC
2013-3435	04/30/2013 05/29/2013	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	P. MOLLY FORD MARANGA MORGENSTERN LAW CORP	VALLEY SURGICAL CTR VS COUNTY OF LOS ANGELES - INVESTIGATION OF COSMOPOLITIAN PLASTIC & RECONSTRUCTION SURGERY
2013-3436	04/30/2013 05/29/2013	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	P. MOLLY FORD MARANGA MORGENSTERN LAW CORP	VALLEY SURGICAL CTR VS COUNTY OF LOS ANGELES - INVESTIGATION PALMDALE AMBULATORY CTR
2013-3437	04/30/2013 05/29/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAP/PA-FO/SEA-DO/SEA-CB/ FDA/OMPT/CDER/ORP/DIDP/	Shin Kang WELLS FARGO	GILEAD SCIENCES - 483, EIR, WARNING LETTER (04/01/2012 - 04/29/2013)

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2013-3438	04/30/2013 05/29/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	P. MOLLY FORD MARANGA MORGENSTERN LAW CORP	VALLEY SURGICAL CTR VS COUNTY OF LOS ANGELES - INVESTIGATION VALENCIA AMBULATORY CTR LLC
2013-3439	04/30/2013 05/29/2013	FDA/OC/OES/DFOI/	PHINNY, C WENDY	TEVA PHARMACEUTICALS - PALONOSETRON HYDROCHLORIDE INJECTION NDA 202-224 CORR
2013-3440	04/30/2013 05/29/2013	FDA/OC/OES/DFOI/	Jeanne Whalen Wall Street Journal and Dow Jones	2013-2212; 2012-1390; 2012-5139
2013-3441	04/30/2013 05/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	b. Burgess BURGESS, BERNIE	FACTS ASSIGNMENT ISSUED BY CDER GOOD CLINICAL PRACTICE TO LOS
2013-3442	04/30/2013 05/29/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	INDIVIDUAL RECS
2013-3443	04/30/2013 05/29/2013	FDA/OC/OES/DDM/	Kathy Osgerby Taylor Wessing LLP	DISCUSSION FOR DESIGNING CLINICAL PROGRAMS FOR DEVELOPING DRUGS, DEVICES, OR BIOLOGICAL PRODUCTS ETC
2013-3444	04/30/2013 05/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Ray Jozwik Coeur Inc.	K003398
2013-3445	04/30/2013	FDA/OMPT/CDER/ORP/DIDP/	Erin Hendrick	ABELCET - MEDWATCH REPORTS

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	05/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GRADY HEALTH SYSTEM	
2013-3446	04/30/2013 05/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Denise Miller Denise Miller	PHENTERMINE - AERS
2013-3447	04/30/2013 05/29/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Doe J	INDIVIDUAL RECS
2013-3448	05/01/2013 05/30/2013	FDA/OGROP/ORR/SE-FO/ATL- DO/ATL-CB/	DONNA BONFIGHO RHODIA INC	RHODIA INC, SPARTANBURG, SC - EIR 11/28/12-12/5/12
2013-3449	05/01/2013 05/30/2013	FDA/OGROP/ORR/CE-FO/CHI- DO/CHI-CB/	BETTINA CAMCIGIL Humane Society of the United States	RICHARD J CZIMER JR, CZIMER FOODS INC, HOMER GLEN, IL - INVESTIGATIONS, LICENSING, INSPS, ETC
2013-3450	05/01/2013 05/30/2013	FDA/OGROP/ORR/CE-FO/MIN- DO/MIN-CB/	DEBRA A DULYN MURNANE BRANDT	CUT FRUIT EXPRESS INC, INVER GROVE HEIGHTS, MN - INSPS, RECALLS, WARNING LTRS, ETC
2013-3451	05/01/2013 05/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	MERZ PHARMS - XEOMIN (INCOBOTULINUMTOXIN A) BLA 125360/007
2013-3452	05/01/2013 05/30/2013	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORR/ OC/ORR/ FDA/OGROP/ORR/CE-FO/CHI- DO/CHI-CB/	WILLIAMS SR, GARY	PLASTIC BAGS, PLASTIC WRAP USED TO STORE AND SERVE FOOD - RECALLS, INVESTIGATIONS, COMPLNTS, ETC
2013-3453	05/01/2013 05/30/2013	FDA/OGROP/ORR/CE-FO/CIN- DO/CIN-CB/	MICHAEL D LEVIN HEALTH BUSINESS STRATEGIES	CBA PHARMA INC, LEXINGTON, KY - EIRS, 483S, WARNING LTRS, ETC
2013-3454	05/01/2013 05/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	RANEXA - AERS
2013-3455	05/01/2013 05/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DISSANAYAKE, SANJEEVA	ASTRAZENACA - LONG-ACTING BETA-AGONISTS BRIEFING DOCUMENTATION FOR THE JOINT A/C 12/08

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-3456	05/01/2013 05/30/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	KIM HENDERSON SANOFI PASTEUR	GLAXOSMITHKLINE BIOLOGICALS, RIXENSART, BELGIUM - 483
2013-3457	05/01/2013 05/30/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	KIM HENDERSON SANOFI PASTEUR	GLAXOSMITHKLINE BIOLOGICALS, DRESDEN, GERMANY - 483 2012
2013-3458	05/01/2013 05/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOE E MATTHEWS JR OLIVER MANER LLP	SIMVISTATIN WITH VORICONAZOLE - AERS
2013-3459	05/01/2013 05/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOE E MATTHEWS JR OLIVER MANER LLP	VFEND (VORICONAZOLE) WITH VYTORIN - AERS
2013-3460	05/01/2013 05/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOE E MATTHEWS JR OLIVER MANER LLP	VFEND (VORICONAZOLE) WITH VYTORIN - AERS
2013-3461	05/01/2013 05/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOE E MATTHEWS JR OLIVER MANER LLP	SIMIVSTATIN - APRVL RECS, DEVELOPMENT, EVALUATION, ETC
2013-3462	05/01/2013 05/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOE E MATTHEWS JR OLIVER MANER LLP	EZETIMIBE WITH VORICONAZOLE - DEVELOPMENT, EVALUATION, APRVL, ETC
2013-3463	05/01/2013 06/24/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SW-FO/DEN- DO/DEN-CB/	AMS Health Sciences LLC AMS Health Sciences	COMPLAINT 1600095
2013-3464	05/01/2013 05/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michele Sinoway Lachman Consultants	NDA 050684

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2013-3465	05/01/2013 05/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michele Sinoway Lachman Consultants	NDA 050684
2013-3466	05/01/2013 06/24/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SW-FO/DEN- DO/DEN-CB/	AMS Health Sciences LLC AMS Health Sciences	COMPLAINT 164176
2013-3467	05/01/2013 05/30/2013	FDA/OGROP/ORO/CE-FO/CHI- DO/CHI-CB/	Lesley Valle Boehringer Ingelheim	LOYOLA UNIVERSITY MEDICAL CENTER, LOYOLA UNIVERSITY, CHICAGO, IL - 483 (04/01/1980 - 04/30/2013)
2013-3468	05/01/2013 05/30/2013	OC/CVM/OCD/	Ruth Lamley Bayer HealthCare LLC Animal Health	NADA 034254
2013-3469	05/01/2013 05/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Jill Woods McRoberts Security Technologies	MEDWATCH 5025529
2013-3470	05/01/2013 05/30/2013	FDA/OGROP/ORO/CE-FO/BLT- DO/BLT-CB/	Michele Sinoway Lachman Consultants	CAPRICORN PHARMA INC - RESPONSE TO WARNING LETTER (04/21/2010 - 03/15/2011)
2013-3471	05/01/2013 05/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 4/1-30/2013
2013-3472	05/01/2013 05/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	CLOSED FOIA REQUESTS
2013-3473	05/01/2013 05/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	REMS ASSESSMENT FOR BYDUREON, FORTEO
2013-3474	05/01/2013 05/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	REMS ASSESSMENT FOR ACTEMRA, ARCAPTA NEOHALER, DULERA, ETC
2013-3475	05/01/2013 06/04/2013	OC/ORO/ OC/ORO/	fiona nelson wedderspoon organic USA	MANUKA HONEY, WEDDERSPOON ORGANIC - COMPLAINTS (01/01/2011 - 01/01/2013)

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2013-3476	05/01/2013 05/30/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Infab Corporation Infab Corporation	BLOX-R CORPORATION - INVESTIGATION RECS (01/01/2013 - 04/30/2013)
2013-3477	05/01/2013 05/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELODIE PALYSWIT Camicas Productions	BOTOX - AERS
2013-3478	05/01/2013 05/30/2013	OC/ORASORM/ OC/ORASORM/ FDA/OGROP/ORASPA-FO/LOS-DO/LOS-CB/	b. burgess bernie burgess	LIST OF FOR-CAUSE INSPECTIONS CONDUCTED BY LOS-DO 2006, 2007
2013-3479	05/01/2013 05/30/2013	FDA/OGROP/ORASPA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	b burgess bernie burgess	FACTS ASSIGNMENT 808885 - LETTER TO VA PROJECT OFFICER
2013-3480	05/01/2013 05/30/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORASPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORASPA-FO/SEADO/SEA-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	Alex Nussbaum HEALTHCOR MANAGEMENT LP	GILEAD SCIENCES - 483 LAST 12 MONTHS; COMPLETE RESPONSE LETTER; FOIA REQUESTS
2013-3481	05/01/2013 05/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 201281
2013-3482	05/01/2013 05/30/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OMPT/CDRH/OCER/DFOI/	Francine Vero Towne, Ryan & Partners, PC	NOVASURE INPEDANCE CONTROLLED ENDOMETRIAL ABLATION SYSTEM - CORR WITH FDA, NOVACEPT, INC, HOLOGIC TO NATHAN LITTAUER HOSPITAL OR DR ANDREW SAMACH

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2013-3483	05/02/2013 05/31/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	GIOVANNI PARRINELLO, Ph.D. MACLEOD PHARMACEUTICALS INC	MACLEOD PHARMACEUTICALS - EIR 12/18 TO 12/21/12
2013-3484	05/02/2013 05/31/2013	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	SHERI O. COVINGTON K&L GATES	HEM CARE OF OREGON INC - WARNING LTR, 483 2011 TO PRESENT
2013-3485	05/02/2013 05/31/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	lisa suchar self-employed	NDA 202813 - SBA
2013-3486	05/02/2013 05/31/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Deborah Sontag THE NEW YORK TIMES	SUBOXONE - CASE REPORTS 7247578 766 7903972 8169325 ETC
2013-3487	05/02/2013 05/31/2013	OC/ORAS/ OC/ORAS/ OC/ORAS/ORM/ OC/ORAS/ORM/ OC/ORAS/OE/ OC/ORAS/OE/	Debra Dressel Dressel, Debra A	LIST OF APPLE CIDER FACILITIES WITH HACCP INSPECTIONS LAST FIVE YEARS; VIOLATIONS CITED
2013-3488	05/02/2013 05/31/2013	FDA/OFVM/CFSAN/OCD/EOS/ OC/CVM/OCD/	Kyle Herink Kemin Industries, Inc.	FAP FOR SELENIUM YEAST SUBMITTED BY ALLTECH, INC
2013-3489	05/02/2013 06/05/2013	FDA/OC/OES/	Emily Flitter Reuters News	COMMISSIONER MARGARET HAMBURG - AGENDA, CALENDAR, APPOINTMENTS ETC (01/01/2011 - 05/01/2013)
2013-3490	05/02/2013 05/31/2013	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	Kim Barton Watson Laboratories, Inc.	WARNER CHILCOTT CO, LLC, FAJARDO, PR - EIR (03/01/2013 - 04/30/2013)
2013-3491	05/02/2013 05/31/2013	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection report for the September 2012 inspection for: University of Arkansas for Medical Sciences (UAMS) Myeloma Institute for Research & Therapy, Little Rock, AR
2013-3492	05/02/2013 05/31/2013	FDA/OFVM/CFSAN/OCD/EOS/	Carmon Yusten Yusten, Carmon D	CREATINE ETHYL ESTHER HCI - NEW DIETARY INGREDIANT RECS
2013-3493	05/02/2013 05/31/2013	FDA/OC/OES/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Emily Flitter Reuters News	ETEPLIRSEN, SAREPTA THERAPEUTICS - COMMUNICATIONS (1/01/2011 - 05/01/2013)

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		FDA/OGROP/ORAP/PA-FO/SEA-DO/SEA-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OL/		
2013-3494	05/02/2013 05/31/2013	FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA DAILY LOG (04/01/2013 - 04/05/2013)
2013-3495	05/02/2013 05/31/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	MELANIE COURTOT TERRY FOX LABORATORY BCCRC	BOTSIS - VAERS
2013-3496	05/03/2013 06/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/ORAP/OCI/ OC/ORAP/OCI/	EDWARD F BRUNO BRUNO & WEINER	PHYSICIAN LICENSED OR PRACTICING MEDICINE IN THE US REGARDING BOTOX PURCHASES - LTR, NOTICE, CEASE & DESIST ORDER, ETC 11/30/12, 1/13/12
2013-3497	05/03/2013 06/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LOLLAR, EVELYN	DIPHENOXYLATE HCL, ATROPINE SULFATE TABS - AERS
2013-3498	05/03/2013 06/03/2013	FDA/OC/OES/DFOI/	MICHAEL P MANAPOL BRIAN D WITZER INC	SOLODYN (MINOCYCLINE HCL) NDA 50-808 - ISRS 4172850, 6464532, 6638697, ETC 4/23/08 TO 4/23/13
2013-3499	05/03/2013 06/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARIO A INCHIOSA NEW YORK MEDICAL COLLEGE/DEPT OF PHARMACOLOGY	ISRS 4054799, 4133493, 6077511
2013-3500	05/03/2013 06/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FRANCIS J MARTIN DELPOR INC	ALZA CORP (JOHNSON & JOHNSON PHARMS) - VIADUR (LEUPROLIDE ACETETE IMPLANT) NDA 21-088 SBA
2013-3501	05/03/2013 06/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	G SRINIVAS ZYDUS PHARMACEUTICALS USA	BAUSCH & LOMB - FLUNISOLIDE NASAL SPRAY ANDA 74-805 SBA

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	INC	
2013-3502	05/03/2013 06/03/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	HYDROCODONE - AERS
2013-3503	05/03/2013 06/03/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Adrian Chowdhary UCB Pharma Ltd	CATALENT, BRUSSELS, BELGIUM - MOST RECENT EIR
2013-3504	05/03/2013 06/03/2013	FDA/OC/OES/DFOI/	Desmond Jenson Tobacco Control Legal Consortium	2011-5643, 2012-1704, 2012-5451 ETC
2013-3505	05/03/2013 06/03/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 21196 PRELIMINARY CLINICAL SAFETY REVIEW
2013-3506	05/03/2013 06/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	Joanna Veres ClearView Diagnostics Inc.	K123901
2013-3507	05/03/2013 06/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	Joanna Veres ClearView Diagnostics In.	K063391
2013-3508	05/03/2013 06/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K123700
2013-3509	05/03/2013 06/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	Michele Sacman Sacman, Michele	TARGOS MOLECULAR PATHOLOGY GMBH, KASSEL, GERMANY - EIR (08/01/2010 - 08/31/2010)
2013-3510	05/03/2013 06/03/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	PATRICK KELLY CONWAY, HOMER & CHIN- CAPLAN PC	INDIVIDUAL RECS (CERTIFIED)
2013-3511	05/03/2013 06/03/2013	FDA/OFVM/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	IOVATE - HYDROXYCUT, SMARTBURN, RAPIDSLIM & RAPID SLIM, ETC CAERS 2/13 TO PRESENT

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2013-3512	05/06/2013 06/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	Goldy Singh Profound Medical Inc.	K120561
2013-3513	05/06/2013 06/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	BLA 103795 5356
2013-3514	05/06/2013 06/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	Stephen Griffin INNOVAQUARTZ INC	K050108
2013-3515	05/06/2013 06/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	Joanna Veres ClearView Diagnostics Inc.	K123420
2013-3516	05/06/2013 06/04/2013	FDA/OC/OES/DDM/	Susan Todd West-Ward Pharmaceutical Corp.	DOCKET 85D-0249
2013-3517	05/06/2013 06/04/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	HYDROQUINONE AS SKIN LIGHTENER
2013-3518	05/06/2013 06/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Robert Brod BURG SIMPSON ET AL	DEPAKOTE, DEPAKOTE ER - LABELS
2013-3519	05/06/2013 06/04/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Doe J	INDIVIDUAL RECS
2013-3520	05/06/2013 06/04/2013	FDA/OFVM/CFSAN/OCD/EOS/	Doe J	AXE BODY SPRAY - INGREDIENTS
2013-3521	05/06/2013 06/04/2013	FDA/OFVM/CFSAN/OCD/EOS/	Jon Whelan Net Return, Inc.	AXE BODY SPRAY - INGREDIENTS
2013-3522	05/06/2013 06/04/2013	FDA/OC/OES/ FDA/OFVM/CFSAN/OCD/EOS/	Katharine Mieszkowski The Center for Investigative Reporting	CORR RE ADDED SUGAR AND ADDED SUGAR NUTRITIONAL LABELING WITH SUGAR ASSOCIATION, CORN REFINERS ASSOCIATION, AMERICAN BAKERS ASSOCIATION ETC (05/02/2008 - 05/02/2013)
2013-3523	05/06/2013	FDA/OGROP/ORACE-FO/NWE-DO/NWE-CB/	Rachel Johnson	LONZA, NH, MA - 483, EIR, CORR

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	06/04/2013		FOI Services, Inc.	
2013-3524	05/06/2013 06/04/2013	FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/	Martin Robbins THE GUARDIAN	DR STANISLAW BURZYNSKI, HOUSTON, TX - INSPECTIONS, COMPLIANCE, ENFORCEMENT (01/01/1977 - 12/31/1986)
2013-3525	05/06/2013 06/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	B&H Consulting Services, Inc. B&H Consulting Services, Inc.	INDIVIDUAL CASE SAFETY REPORTS
2013-3526	05/06/2013 06/04/2013	FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORR/SW-FO/SWID/SWID-CB/	b burgess bernie burgess	SAMPLE SUMMARY, MEMO OF RESULTS OF ANALYSIS FACTS 808885
2013-3527	05/06/2013 06/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Paul Goldberg The Cancer Letter	TIVOZANIB - PRE-NDA MEETING DATE, ATTENDEES, AGENDA
2013-3528	05/06/2013 06/04/2013	FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORR/CE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORR/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORR/NE-FO/NWE-DO/NWE-CB/	Rachel Johnson FOI Services, Inc.	LONZA - EIR, 483, CORR
2013-3529	05/06/2013 06/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	b. burgess BURGESS, BERNIE	INTERNAL DSI CORR FROM DLW TO LKB 11/29/07
2013-3530	05/06/2013	OC/ORR/	Mark Greenblatt	IMPORT REFUSAL DATA (01/01/2008 - 05/02/2013)

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	06/04/2013	OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/	SCRIPPS HOWARD NEWS SERVICE	
2013-3531	05/06/2013 06/04/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	hollie telford hollie telford	DRUG AND HEALTH FOOD MANUFACTURERS REGISTERED WITH FDA
2013-3532	05/06/2013 06/04/2013	FDA/OGROP/ORO/PA-FO/SAN- DO/SAN-CB/	Shin Kang WELLS FARGO	GILEAD SCIENCES, FOSTER CITY - 483 (01/01/2012 - 05/02/2013)
2013-3533	05/06/2013 06/04/2013	FDA/OC/OES/DDM/	Rachel Johnson FOI Services, Inc.	Slides, briefing materials for Peripheral & Central Nervous System Drugs AC Meeting 06/06/2001
2013-3534	05/06/2013 06/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	Presentation given at NADDI National Conference
2013-3535	05/06/2013 06/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	NIDIA NOEL EZEM CANADA	HAORUI PHARMA CHEM INC - EIR, 483, CO RESP 7/13-16/11
2013-3536	05/06/2013 06/04/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORO/CE-FO/CHI- DO/CHI-CB/ FDA/OGROP/ORO/SE-FO/FLA- DO/FLA-CB/ FDA/OGROP/ORO/SW-FO/DAL- DO/DAL-CB/ FDA/OGROP/ORO/SW-FO/KAN- DO/KAN-CB/	SANDRA M. BOGENRIEF, RN, LNC LOMMEN ABDO COLE KING STAGEBERG PA	CRONOBACTER INFECTION 2011
2013-3537	05/06/2013 06/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARC RENDELL, MD ASNDI	BEOHRINGER INGELHEIM - LINAGLIPTIN APRVL, ADVISORY MTG
2013-3538	05/06/2013 06/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	MATT CLAUSEN MEDLINE INDUSTRIES INC	MEDLINE INDUSTRIES INC - TENDER WET WOUND DRESSING K991755

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2013-3539	05/06/2013 06/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	EMILY SETTLEMOIR Reliable Biopharmaceutical Corporation	SIGMA ALDRICH, BUCHS, SWITZERLAND - 483
2013-3540	05/06/2013 06/04/2013	FDA/OC/OES/DDM/	MERAV AKNIN MACCABI HEALTHCARE SERVICES	NERVOUS SYS DRUGS ADVISORY COMMITTEE MTG 1989
2013-3541	05/06/2013 06/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	GREGORY H. LEVINE ROPES & GRAY LLP	SYNERON MEDICAL LTD - BEAUTY ME K123845
2013-3542	05/06/2013 06/04/2013	FDA/OC/OES/ FDA/OC/OES/DDM/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	HUNTER J. SHKOLNIK Napoli Bern Ripka Shkolnik, LLP	REPRODUCTIVE HEALTH A/C; PUBLIC CITIZENS REQUEST FOR A BAN OF THIRD GENERATION COMBINATION ORAL CONTRACEPTIVES CONTAINING DESOGESTREL
2013-3543	05/06/2013 06/04/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	BAILEY A. BLAIR HUFF POWELL & BAILEY	THE PERRY HOSPITAL, HOUSTON, TX - INSP 5/10
2013-3544	05/06/2013 06/04/2013	FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECS
2013-3545	05/06/2013 06/04/2013	FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECS
2013-3546	05/06/2013 06/04/2013	FDA/OC/OES/ FDA/OMPT/CDRH/OCER/DFOI/	KATHERINE STRONG CARNER SIDLEY AUSTIN LLP	CORR SENT TO INSTITUTIONAL RVW BOARDS FORM 1/11 TO PRESENT
2013-3547	05/06/2013 06/04/2013	FDA/OFVM/CFSAN/OCD/EOS/	CATHERINE R. NEILSEN Keller and Heckman LLP	NO OBJECTION LTR FROM EUGENE COLEMAN 4/13/94
2013-3548	05/07/2013 06/05/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	AGENSIAN HEALTHCARE, FOND DU LAC, WI - EIRS, 483S CO RESP 11/07-13/12
2013-3549	05/07/2013 06/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	PEKING MEDICINE MANUFACTORY, TSUEN WAN, NEW TERRITORIES, HONG KONG - EIRS, 483S, CO RESP 04/30/12-05/04/12
2013-3550	05/07/2013	FDA/OGROP/ORA/SW-FO/DAL-	WALTER E CHALKLEY	PHYSICIANS TOTAL CARE INC, TULSA, OK - EIRS,483S, CO

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	06/05/2013	DO/DAL-CB/	THOMSON REUTERS	RESP 01/24/12-02/24/12
2013-3551	05/07/2013 06/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	WYETH LEDERLE, CATANIA, ITALY - EIRS, 483S, CO RESP 07/09-20/12
2013-3552	05/07/2013 06/05/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	WALTER E CHALKLEY THOMSON REUTERS	PUGET SOUND BLOOD CENTER & PROGRAM, SEATTLE, WA - EIRS, 483S, CO RESP 01/14/13-02/15/13
2013-3553	05/07/2013 06/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	INSTITUTO MASSONE SA, BUENOS AIRES, ARGENTINA - EIRS, 483, CO RESP 11/12, 11/13
2013-3554	05/07/2013 06/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	ORGANO SINTESIS S A DE CV, MEXICO - EIRS, 483S, CO RESP 10/12
2013-3555	05/07/2013 06/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	LABORATORIOS LIOMONT SA DE CV, MEXICO - EIRS, 483S, CO RESP 10/12
2013-3556	05/07/2013 06/05/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	WALTER E CHALKLEY THOMSON REUTERS	ALLERGAN, IRVINE, CA - EIRS, 483S, CO RESP 08/26/93
2013-3557	05/07/2013 06/05/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	WALTER E CHALKLEY THOMSON REUTERS	ALLERGAN, IRVINE, CA - EIRS, 483S, CO RESP 03/27/96
2013-3558	05/07/2013 06/05/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	WALTER E CHALKLEY THOMSON REUTERS	ALLERGAN, IRVINE, CA - EIRS, 483S, CO RESP 04/27/98
2013-3559	05/07/2013 06/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	ASADA MILLING CO LTD, GUNMA, JAPAN - EIRS, 483S, CO RESP 10/09-12/12

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2013-3560	05/07/2013 06/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	ANGIE BEYER AIRLIQUIDE	EZ-OX PLUS - K053117
2013-3561	05/07/2013 09/04/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OGROP/ORACE-FO/BLT- DO/BLT-CB/ OC/OR/ OC/OR/ FDA/OC/OES/	CHRISTA C COTTRELL KIRKLAND & ELLIS LLP	PLASMA PROTEIN THERAPETICS ASSOCIATION (INTERNATIONAL PLASMA PRODUCTS INDUSTRY ASSOCIATION) - MFG OF PLASMA-DERIVED PROTEIN THERAPIES ASSOCIATION (INTRAVENOUS IMMUNOGLOBULIN & ALBUMIN) ACTIONS TO IMPLEMENT GMP, FACILITY SHUT DOWNS, PROD QUARANTINES OR MFG CONSENT DECREES, ETC 1996 TO 2002, 1997 TO 2002
2013-3562	05/07/2013 06/05/2013	FDA/OC/OL/	MICHAEL MORISY MUCKROCK NEWS	CONGRESSIONAL COMMITTEES - RESP 1/08 TO PRESENT
2013-3563	05/07/2013 06/05/2013	FDA/OGROP/ORACE-FO/SJN- DO/SJN-CB/	Doe J	CMPLNT - APPLE JUICE
2013-3564	05/07/2013 06/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	YVONNE M FLAHERTY LOCKRIDGE GRINDAL NAUEN PLLP	ST JUDE MEDICAL - RIATA, RIATA ST DEFIBRILLATOR LEADS 522 APPL NUMBER PS12011 LEAD EXTERNALIZATION AND ABRASION P950022
2013-3565	05/07/2013 06/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ROBERT A COHEN DECHERT LLP	HOSPIRA INC, JAVELIN PHARMACEUTICALS INC - DYLOJECT CORR 10/07 TO PRESENT
2013-3566	05/07/2013 06/05/2013	FDA/OFVM/CFSAN/OCD/EOS/	MAE WU NATURAL RESOURCES DEFENSE COUNCIL	TOTAL DIET STUDY INDUSTRIAL CHEMICAL RESIDUE MONITORING 2004 TO 2012
2013-3567	05/07/2013 06/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELENA HOWELL Hogan Lovells, LLP	TEVA PHARMACEUTICALS USA - PALONOSETRON HCL ANDA 202-224 CORR
2013-3568	05/07/2013 06/05/2013	OC/OR/ OC/OR/ FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/	Doe J	CHURCH & DWIGHT COMPANY INC - ARM & HAMMER PEROXIDE CARE TOOTHPASTE CMPLNTS LAST 5 YRS
2013-3569	05/07/2013 06/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	GREGORY H LEVINE ROPES & GRAY LLP	SYNERON MEDICAL LTD - ME HAIR2GO K121598
2013-3570	05/07/2013 06/05/2013	OC/OR/ OC/OR/	Stuart Warner YALE-NEW HAVEN HOSPITAL	MED PREP PHARMACY INC, TINTON FALLS, NJ - TESTING INFORMATION AND FINDINGS

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2013-3571	05/07/2013 06/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	MATTHEW L CANTWELL PICOLIFE TECHNOLOGIES LLC	TANDEM - T:SLIM K111210; MEDTRONIC - MINIMED K990801; NIPRO - AMIGO K071613
2013-3572	05/07/2013 06/05/2013	OC/ORO/ OC/ORO/	Stuart Warner YALE-NEW HAVEN HOSPITAL	CENTRAL ADMIXTURE PHARMACY SERVICES, INC, WALLINGFORD, CT - PLAN OF CORRECTION (02/19/2013 - 05/07/2013)
2013-3573	05/07/2013 06/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	ANDA 202224
2013-3574	05/07/2013 06/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	DAvid Knasack Orthocon, Inc	K111538
2013-3575	05/07/2013 06/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Adrienne E Faerber Dartmouth Institute Ctr for Med Media	AMBIEN CR, LIPITOR, LOPRESSOR, ETC - APPROVAL RECS FOR NDA SUPPLEMENTS
2013-3576	05/07/2013 06/05/2013	FDA/OGROP/ORO/NE-FO/NWE-DO/NWE-CB/	Shirley Duggan Smiths Medical ASD, Inc.	SMITHS MEDICAL ASD, ROCKLAND, MA - EIR (01/18/2011 - 01/28/2011)
2013-3577	05/07/2013 06/05/2013	FDA/OGROP/ORO/CE-FO/NWJ-DO/NWJ-CB/	Sylvester Williams III WuXi AppTec Inc.	MUSCULOSKELETAL TRANSPLANT FOUNDATION, EDISON, NJ - EIR, 483 (09/17/2012 - 12/30/2012)
2013-3578	05/07/2013 06/05/2013	FDA/OC/OES/DDM/	Rachel Johnson FOI Services, Inc.	Script and Video for Xyrem Prescription and Distribution Process submitted to FDA by Orphan Medical on 05/30/2001 for the FDAsPeripheral and Central Nervous System Drugs Advisory Committee meeting on 06/06/2001
2013-3579	05/07/2013 06/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	b. burgess bernie burgess	Internal FDA correspondence or letter received by DSI on 9/27/07
2013-3580	05/07/2013 06/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	Lois Chandler CARDIUM THERAPEUTICS	K072113
2013-3581	05/07/2013 06/05/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Brent Ardaugh Framingham Heart Study	K980482, K972651, K955349 ETC
2013-3582	05/07/2013 06/05/2013	FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	b. burgess bernie burgess	ORIGINAL SIGNED EIR FOR 94092
2013-3583	05/07/2013	FDA/OFVM/CFSAN/OCD/EOS/	Kathi Prudente	COMFREY IN BURT'S LIP BALM (08/23/2012 - 05/06/2013)

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	06/05/2013	OC/ORA/ OC/ORA/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	Prudente, Kathi	
2013-3584	05/07/2013 06/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	Lois Chandler CARDIUM THERAPEUTICS	K083440
2013-3585	05/07/2013 06/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Francisco Polonio Laboratorios Lesvi, S.L.	ALGORITHMHE PHARMA, CANADA - ALL INSPECTION RECS 01/01/2011 TO PRESENT
2013-3586	05/07/2013 06/05/2013	OC/ORA/OCI/ OC/ORA/OCI/	Kathleen Martin-Weis MERCK & CO., INC.	COUNTERFEIT CRIXIVAN - LAB ANALYSIS
2013-3587	05/07/2013 06/05/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	Julie Butler Olive Oil Times	AVB-2080130-0/1/1 OLIVOS GIDA YAG TARIM SAN. ITH.IHR. VE TIC A.S.
2013-3588	05/07/2013 06/05/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	Brendan Ryan WARNER CHILCOTT	BAXTER HEALTHCARE, CLEVELAND, MS - EIR (01/01/2010 - 12/31/2010)
2013-3589	05/07/2013 06/05/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Lena Gomez Keller and Heckman, LLP	FORMOR INC, CONWAY, ARK - 483, RESPONSE TO WARNING LETTER
2013-3590	05/07/2013 06/05/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Manfred Abel Greiner Bio-One	BK070029 SUMMARY
2013-3591	05/07/2013 06/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	JULIA G YOUNG STRICK LAW FIRM PLLC	DAVOL INC - MESH COMPOSIX KUGEL PATCH RECS
2013-3592	05/07/2013 06/05/2013	OC/ORA/ORM/ OC/ORA/ORM/	GAIL LESSICK LACHMAN CONSULTANT SERVICES INC	FOREIGN & DOMESTIC DRUG COMPANIES, MEDICAL DVC MFRS, BIORESEARCH MONITORING (BIMO), ETC - 483S 3/1-31/13
2013-3593	05/07/2013 06/05/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	MIKE RUSSELL DELAVAL MANUFACTURING	WEST AGRO INC, HAMILTON, NY - EIR, 483S 2/27/12-3/7/12
2013-3594	05/07/2013	FDA/OGROP/ORA/CE-FO/CIN-	LAUREN HANSON	HILLS NUTRITION, BOWLING GREEN, NY - SALMONELLA

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	06/05/2013	DO/CIN-CB/	WBKO TV	INVESTIGATION 1/13
2013-3595	05/07/2013 06/05/2013	FDA/OO/OFBA/OAGS/	KIM, MARLENE	BIG ENTERPRISES INC, WALDORF, MD - CONTRACT OR GRANT APPLS FUNDED BY HHS AND FDA
2013-3596	05/07/2013 06/05/2013	FDA/OC/OES/DFOI/	GUMPERT, DAVID .	DELETIONS TO OCC RESPONSE
2013-3597	05/08/2013 06/06/2013	FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA REQUEST LOG (04/29/2013 - 05/03/2013)
2013-3598	05/08/2013 06/06/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/CVM/OCD/	Deb Winkler Putney, Inc.	NOROCARP - APPROVAL LETTER
2013-3599	05/08/2013 06/06/2013	OC/ORAOE/ OC/ORAOE/	Brent Ardaugh Framingham Heart Study	FDA ENFORCEMENT REPORT - RECALL NOTICE OF MICROVASIVE UROLOGY PRODUCTS PROTEGEN COLLAGEN IMPREGNATED SLING AND VESICA SLING KITS WITH PROTEGEN 3/17/99
2013-3600	05/08/2013 06/06/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Shelf life of Actigall (Ursodiol 300mg capsule) Daewoong America Inc.	ACTIGALL - SHELF LIFE
2013-3601	05/08/2013 06/06/2013	FDA/OGROP/ORAOE/NE-FO/NYK-DO/NYK-DCB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Eric Lim Meng How Crystal Aesthetics	BACTOLAC PHARMACEUTICAL, HAUPPAUGE, NY - CGMP CERTIFICATION, LICENSE
2013-3602	05/08/2013 06/06/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Trupti Shah TAKEDA PHARMACEUTICALS NA INC	CASE REPORTS
2013-3603	05/08/2013 06/06/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Adrienne E Faerber Dartmouth Institute Ctr for Med Media	NDA 20553, NDA 20622

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2013-3604	05/08/2013 06/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Adrienne E Faerber Dartmouth Institute Ctr for Med Media	COPAXONE, CELEBREX, NEXIUM ETC - APPROVAL RECS FOR SUPPLEMENTS
2013-3605	05/08/2013 06/06/2013	FDA/OC/OL/	Jake Sherman POLITICO	COMM WITH REP ERIC CANTOR RE STAR SCIENTIFIC, JOHNNIE R WILLIAMS
2013-3606	05/08/2013 06/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	Ratinder Brar St. Jude Medical	K970943 - SUMMARY
2013-3607	05/08/2013 06/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	Ratinder Brar St. Jude Medical	K981820 - SUMMARY
2013-3608	05/08/2013 06/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	ANDA 78702 APPROVAL LETTER
2013-3609	05/08/2013 06/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jeff Schaffer Bloomington Drug	NDA 009925
2013-3610	05/08/2013 06/06/2013	OC/ORA/OE/ OC/ORA/OE/	Justin Fregia ValueScope, Inc.	FDA ENFORCEMENT WEEKLY REPORTS 1991-2003
2013-3611	05/08/2013 06/06/2013	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2013-3238
2013-3612	05/08/2013 06/06/2013	FDA/OFVM/CFSAN/OCD/EOS/	HELLEN A. OKETCH, Ph.D. US PHARMACOPEIAL CONVENTION	CALCIUM MAGNESIUM PHYTATE - CAERS 2/05; 4/13
2013-3613	05/08/2013 06/06/2013	FDA/OFVM/CFSAN/OCD/EOS/	HELLEN A. OKETCH, Ph.D. US PHARMACOPEIAL CONVENTION	METHYLCOBALAMIN - CAERS 1/05; 4/13
2013-3614	05/08/2013 06/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KATY MORTON TOPICA PHARMACEUTICALS INC	YONEZAWA HAMARI CHEMICALS CO LTD, YAMAGATA, JAPAN - EIR 1/12 TO PRESENT
2013-3615	05/08/2013	FDA/OMPT/CDER/GRP/DIDP/	LIBBE ENGLANDER, Ph.D	8403630-5; 8458718-X; 6643895-3 - MEDWATCH RPT

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2013-3616	05/08/2013 06/06/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TAMI DALBERG INDENA USA INC	SICOR DE MEXICO SA DE CV, LERME, MEXICO - EIR 11/25/09
2013-3617	05/08/2013 06/06/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TAMI DALBERG INDENA USA INC	SICOR ITALY, SANTHIA, ITALY - EIR 12/16/10
2013-3618	05/08/2013 06/06/2013	FDA/OFVM/CFSAN/OCD/EOS/	CYNTHIA M. BARBER PBM Nutritionals LLC	MEAD JOHNSON NUTRITION - INFANT FORMULA
2013-3619	05/08/2013 06/06/2013	FDA/OFVM/CFSAN/OCD/EOS/	CYNTHIA M. BARBER PBM PRODUCTS LLC	ABBOTT LABS - INFANT FORMULA
2013-3620	05/08/2013 06/06/2013	FDA/OGROP/ORACE-FO/PHI- DO/PHI-CB/	DAVID C. WEBER BEHREND & ERNSBERGER PC	MUTUAL PHARMACEUTICAL CO - PREDNISONE EIR 1993 TO PRESENT
2013-3621	05/08/2013 06/06/2013	FDA/OGROP/ORACE-FO/CIN- DO/CIN-CB/	PAUL B. CALLAHAN CHARLES RIVER LABS	WIL RESEARCH. ASHLAND OH - 483 3/12
2013-3622	05/08/2013 06/06/2013	FDA/OFVM/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 164646 4/23/13
2013-3623	05/08/2013 06/06/2013	FDA/OC/OES/DDM/ FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RICHARD A. WRIGHT, Esq. CORY WATSON ET AL	OMONTYS - EIRS, 483S, WARNING LTRS, ETC
2013-3624	05/08/2013 06/06/2013	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORACE-FO/ OC/ORACE-FO/	AVDEEF, STEPHEN	CORR BETWEEN SAMS CLUB & CDC REGARDING 2006 BURKHOLDERIA CEPACIA RECALL
2013-3625	05/08/2013 06/06/2013	FDA/OC/OES/DFOI/	JOHN CREWDSON PROJECT ON GOVERNMENT OVERSIGHT	2003-2337; 4834; 11319 ETC

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2013-3626	05/09/2013 06/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Gary J. Syring Quality & Regulatory Associates, LLC	K860219
2013-3627	05/09/2013 06/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachelle Lyon Lyon, Rachelle	XTANDI, ZYTIGA - AERS
2013-3628	05/09/2013 06/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Tim waldron Univeristy of Iowa Hospital & Clinics	K852612
2013-3629	05/09/2013 06/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Stephen Griffin INNOVAQUARTZ INC	K110685
2013-3630	05/09/2013 06/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michelle Albright Lexicon Pharmaceuticals, Inc.	NDA 020386
2013-3631	05/09/2013 06/07/2013	FDA/OGROP/ORR/CE-FO/CHI-DO/CHI-CB/	Samuel Coe, Assistant Corporate Attorney Newly Weds Foods, Inc.	NEWLY WED FOODS INC, YORKVILLE, IL - ALL INSPECTION RECS (01/01/2013 - 05/08/2013)
2013-3632	05/09/2013 06/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Candice Durrence Optimer Pharmaceuticals, Inc.	DIFICID - AERS
2013-3633	05/09/2013 06/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Patrick Mevs Martin Clearwater & Bell, LLP	Clinical trials of chemotherapy by Super-Selective Intraarterial Intracranial Infusion of Temozolomide (Temodar)
2013-3634	05/09/2013 06/07/2013	FDA/OGROP/ORR/CE-FO/MIN-DO/MIN-CB/	Vicki E. Babbert Ice Miller, LLP	Investigation and Testing of Instant Milk Protein Concentrate 80% (IMPC-80) at Plainview Milk Products Cooperative, Plainview, Minnesota
2013-3635	05/09/2013	FDA/OMPT/CDER/GRP/DIDP/	Ivan King	NDA 18154

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	06/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Qi Oncology LLC	
2013-3636	05/09/2013 06/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Sasha Gelfand ControlRad Systems Ltd	K031597
2013-3637	05/09/2013 06/07/2013	FDA/OFVM/CFSAN/OCD/EOS/	MARY ANN COMSTOCK UPS SUPPLY CHAIIN SOLUTIONS	UPS SUPPLY CHAIN SOLUTIONS INC, UNITED PARCEL SERVICE INC, UNITED PARCEL SERIVCE OF AMERICA INC, ETC LISTED AS US AGENT UNDER THE BIOTERRORISM ACT OF 2002 AND/OR FOOD SAFETY MODERNIZATION ACT
2013-3638	05/09/2013 06/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	ANDREA S DELAND KITCH DRUTCHAS ET AL	HI HEALTHINNOVATIONS - HEARING TESTING, HEARING AIDS FITTING, SALES, ETC 3/2912
2013-3639	05/09/2013 06/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOE E MATTHEWS JR OLIVER MANER LLP	VFEND, VYTORIN, ZOCOR, ETC - AERS
2013-3640	05/09/2013 06/07/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	WILLIAMS, NATHANIA M	CMPLNT 131379
2013-3641	05/09/2013 06/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	HELTON, SHARLA	ALLERGAN - BOTOX, BOTOX COSMETIC AERS
2013-3642	05/09/2013 06/07/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	LIZ WOOL QD-QUALITY AND TRAINING SOLUTIONS	DYNAVAX - EIR, 483, CO RESP, ETC 2012
2013-3643	05/09/2013 06/07/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	LIZ WOOL QD-QUALITY AND TRAINING SOLUTIONS	JANSSEN ALZHEIMER IMMUNOTHERAPY - EIR, 483S, CO RESP, ETC 2010 TO 2012
2013-3644	05/09/2013 06/07/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	LIZ WOOL QD-QUALITY AND TRAINING SOLUTIONS	TALON THERAPEUTICS (HANA BIOSCIENCE) - EIR, 483, CO RESP, ETC 2011-2012
2013-3645	05/09/2013 06/07/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	LIZ WOOL QD-QUALITY AND TRAINING SOLUTIONS	OXIGENE - EIR, 483, CO RESP, ETC 2011-2012
2013-3646	05/09/2013	FDA/OGROP/ORA/CE-FO/NWJ-	LIZ WOOL	BRISTOL MYERS SQUIBB - EIR, 483, CO RESP, ETC 2011-

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	06/24/2013	DO/NWJ-CB/	QD-QUALITY AND TRAINING SOLUTIONS	2012
2013-3647	05/09/2013 06/07/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	LIZ WOOL QD-QUALITY AND TRAINING SOLUTIONS	JANSSEN/JOHNSON AND JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT - EIR, 483S, CO RESP, ETC 2008-2012
2013-3648	05/09/2013 06/07/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	LIZ WOOL QD-QUALITY AND TRAINING SOLUTIONS	REGENERON, TARRYTOWN, NY - EIR, 483, CO RESP, ETC 2011-2012
2013-3649	05/09/2013 06/07/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	LIZ WOOL QD-QUALITY AND TRAINING SOLUTIONS	BIOGEN-IDEC, BOSTON, MA - EIR, 483, CO RESP, ETC 2010-2012
2013-3650	05/09/2013 06/07/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	LIZ WOOL QD-QUALITY AND TRAINING SOLUTIONS	PFIZER, GROTON, CT - EIR, 483, CO RESP, ETC 2008-2012
2013-3651	05/10/2013 06/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K062048
2013-3652	05/10/2013 06/10/2013	FDA/OC/OES/DFOI/	Bob Mitchell - Req1 Executive Leadership Services, LLC	HHSF223200830014I
2013-3653	05/10/2013 06/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	PIP SALINE IMPLANTS - LETTER TO DOCTORS
2013-3654	05/10/2013 06/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Candice Durrence Optimer Pharmaceuticals, Inc.	DIFICID - APPROVAL RECS
2013-3655	05/10/2013 06/10/2013	FDA/OC/OES/DFOI/	Bob Mitchell Req2 Executive Leadership Services, LLC	HHSF223200830014I - PROPOSAL RECS
2013-3656	05/10/2013 06/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Emily Settlemoir Reliable Biopharmaceutical Corporation	QUIMICA SINTETICA SA, SPAIN - EIR OR 483
2013-3657	05/10/2013 06/10/2013	FDA/OC/OES/DFOI/	Andrew D. Cardon NATIONAL ASSOCIATION FOR BIOMEDICAL RESEARCH	FOIA REQUEST LOG 05/09/2012 - 05/09/2013
2013-3658	05/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Diane Horwitz - Medskin	K072113

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	06/10/2013		MANDELL HORWITZ CONSULTANTS LLC	
2013-3659	05/10/2013 06/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Megan Burns DEPUY ORTHOPAEDICS INC	K111863, K121640, K122053
2013-3660	05/10/2013 06/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Chris Chitemerere Stratdigm	ORANGE BOOK DATA (01/02/2001 - 12/12/2002)
2013-3661	05/10/2013 06/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 200153
2013-3662	05/10/2013 06/10/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Natalie Morrison BIOPHARM INSIGHT	ASTRAZENECA, MACCLESFIELD, UK - INSPECTION RECS, WARNING LETTERS
2013-3663	05/10/2013 06/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Laura Salcedo Jonathan Paul Eyewear	FGZ INTERNATIONAL, INC, DIOPTICS MEDICAL PRODUCTS,LIVE EYEWEAR, INC - REGISTRATION RECS
2013-3664	05/10/2013 06/10/2013	FDA/OFVM/CFSAN/OCD/EOS/	Luz Agana San Francisco Asthma Task Force	21 CFR 178.1010 - STUDY INFORMATION
2013-3665	05/10/2013 06/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	BOEHRINGER INGELHEIN PHARMA GMBH & CO KG, INGELHEIM AM RHEIN, GERMANY - 483 MOST RECENT
2013-3666	05/10/2013 06/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	BOEHRINGER INGLHEIM PHARMA GMBH & CO KG, BIBERACH AN DER RISS, GERMANY - 483 MOST RECENT
2013-3667	05/10/2013 06/10/2013	FDA/OFVM/CFSAN/OCD/EOS/	DATZ, JANIS	AVON PRODUCTS INC - WARNING LTR 10/5/12
2013-3668	05/10/2013 06/10/2013	FDA/OFVM/CFSAN/OCD/EOS/	DATZ, JANIS	LANCOME USA - WARNING LTR 9/7/12

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2013-3669	05/10/2013 06/10/2013	FDA/OC/OES/DDM/	TESS M SCHOENTHAL UNIV OF CALIFORNIA BERKELEY	DKT 1978N-1665
2013-3670	05/10/2013 06/10/2013	FDA/OC/OES/DDM/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN S BAKER LIGHTFOOT FRANKLIN & WHITE LLC	TESTOPEL - RECS
2013-3671	05/10/2013 06/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	SANDI L PRUITT UNIV OF TEXAS SOUTHWEST MEDICAL CTR	LIST OF MAMMOGRAPHY FACILITIES, TX 1990 TO 2013
2013-3672	05/10/2013 06/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLIE LITTON UNEMED	LIST OF ANNUAL HISTORICAL RECS REGARDING THE NUMBER OF ANTIBIOTIC DRUG APPL & THE NUMBER OF ANTIBIOTIC DRUG APRVL IN HUMANS 1960 TO PRESENT
2013-3673	05/10/2013 06/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CANDICE CHARTAIN MCINTOSH LAW FIRM PC	LYPRON NDA 20-517; SYNAREL NDA 19-886; MEGCE NDA 20-264 - PI, MEDICATION GUIDES
2013-3674	05/10/2013 06/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	WENDY LOU JONES ROYAL KNIGHT INC	BAXTER HEALTHCARE CORP (BAXTER HYLAND), GLENDALE, CA -CEPROTEIN (PROTEIN-C) CONCENTRATE RECS
2013-3675	05/10/2013 06/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MICHAEL R COHEN INSTITUTE FOR SAFE MEDICATION PRACTICES	MEDWATCH RPTS CODED AS MEDICATION ERRORS 4/1-30/13
2013-3676	05/10/2013 06/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	NICK BUDNICK OREGONIAN	PATRICK WITHAM, PATRICK H WITHAM, PARAGON BIOTECH, ETC - NDAS, COMMENTS, RVWS, ETC
2013-3677	05/10/2013 06/10/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	GILBERT R WEINER ADVANCEDPHARMA	CETERO RESEARCH - EIRS, CLASSIFICATION LTR

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2013-3678	05/10/2013 06/10/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	LATESHA R BAKER HINSHAW & CULBERTSON LLP	VAERS 48310, 480899, 485907
2013-3679	05/10/2013 06/10/2013	OC/ORO/ORM/ OC/ORO/ORM/	ROBERT KING FDA NEWS	PHARMACEUTICALS, BIOLOGICS & MEDICAL DVC MFG & CLNCL TRIAL FACILITIES BOTH INSIDE & OUTSIDE THE USA - 483S 4/1-30/13
2013-3680	05/10/2013 06/10/2013	FDA/OC/OES/DDM/	GAYLEC SHULTZ KIRKLAND & ELLIS LLP	ODAC A/C TR MIN 06/17/1993
2013-3681	05/10/2013 06/10/2013	FDA/OC/OES/DDM/	CYNTHIA MEYER KLEINFELD, KAPLAN & BECKER	DKT 2002P-0435
2013-3682	05/10/2013 06/10/2013	FDA/OC/OES/DDM/	MARILYNN WHITNEY COVINGTON & BURLING LLP	DKT 1977N-0094
2013-3683	05/10/2013 06/10/2013	FDA/OC/OES/DDM/	JOYCE MUTCHERSON-RIDLEY WOLTERS KLUWER	DKT FDA-2011-S-0932, FDA-2012-S-1144, ETC.
2013-3684	05/10/2013 06/10/2013	FDA/OC/OES/DDM/	MARILYNN WHITNEY COVINGTON & BURLING LLP	DKT FDA-2013-P-0283
2013-3685	05/10/2013 06/10/2013		FATIMA ASLAM Keller and Heckman LLP	DKT FDA-1985-G-0511
2013-3686	05/10/2013 06/10/2013	FDA/OC/OES/DDM/	FATIMA ASLAM Keller and Heckman LLP	DKT FDA-1985-G-0511
2013-3687	05/10/2013 06/10/2013	FDA/OGROP/ORO/CE-FO/MIN- DO/MIN-CB/	Matthew Welsch ThermaSolutions, Inc.	EIGHT MEDICAL CORPORATION, HEI CORPORATION - INSPECTION RECS (09/03/2012 - 05/07/2013)
2013-3688	05/10/2013 06/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	SBA 50718 S 020, 029 DOXIL
2013-3689	05/10/2013 06/10/2013	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	CORR WITH CONSOLIDATED FLAVOR CORP
2013-3690	05/10/2013 06/10/2013	FDA/OC/OES/DDM/	CHRIS CELESTE EAS CONSULTING GROUP LLC	OTC VOL. 080173, 080174, ETC.
2013-3691	05/10/2013 06/10/2013	FDA/OC/OES/DDM/	GEORGE O'BRIEN HOGAN LOVELLS LLP	DKT FDA-2013-P-0058
2013-3692	05/10/2013	FDA/OC/OES/DDM/	CHRIS CELESTE	OTC VOL. 080010, 080057, ETC.

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	06/10/2013		EAS Consulting Group, LLC	
2013-3693	05/10/2013 06/10/2013	FDA/OC/OES/DDM/	CHRIS CELESTE EAS Consulting Group, LLC	OTC VOL. 080064, 080085, ETC.
2013-3694	05/10/2013 06/10/2013	FDA/OC/OES/DDM/	CHRIS TURNER CITIZENS FOR HEALTH	DKT FDA-2010-P-0491, FDA-2012-P-0904, ETC.
2013-3695	05/13/2013 06/11/2013	FDA/OFVM/CFSAN/OCD/EOS/	CYNTHIA B LIEBERMAN Keller and Heckman LLP	DUPONT DOW ELASTOMERS LLC - FCN 368; MITSUI CHEMICALS INC - FCN 806, FCN 917, FCN 1120 CHEMISTRY, TOXICOLOGY, ENVIRONMENTAL RVW MEMOS
2013-3696	05/13/2013 06/11/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	DONALD N BLUE ZETETIC INC	SHAMPOOS AND PREPARATIONS FOR USE ON THE HAIR ENTRY #EHP-00771985-8 - RECS
2013-3697	05/13/2013 09/03/2013	FDA/OC/OES/ FDA/OFVM/CFSAN/OCD/EOS/	BOBBY SCHOCHET OLSSON FRANK WEEDA TERMAN MATZ PC	FDA, HHS ASSISTANT SECRETARY FOR PLANNING AND EVALUATION - FRONT-OF-PACKAGE LBLG SYS RECS FY2014
2013-3698	05/13/2013 09/03/2013	FDA/OC/OES/ FDA/OFVM/CFSAN/OCD/EOS/	BOBBY SCHOCHET OLSSON FRANK WEEDA TERMAN MATZ PC	GROCERY MFRS ASSN - FRONT-OF-PACKAGING (FOP) LBLG SYS
2013-3699	05/13/2013 06/11/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	ACTIENT PHARMACEUTICALS INC - EIRS, 483S, UNTITLED LTRS, ETC 1/12 TO PRESENT
2013-3700	05/13/2013 06/11/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	AUXILIUM PHARMACEUTICALS INC - EIRS, 483S, UNTITLED LTRS, ETC 1/12 TO PRESENT
2013-3701	05/13/2013 06/11/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	INTUITIVE SURGICAL INC - EIRS, 483S, UNTITLED LTRS, ETC 1/12 TO PRESENT
2013-3702	05/13/2013 06/11/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	THORATEC CORP - EIRS, 483S, UNTITLED LTRS, ETC 1/12 TO PRESENT
2013-3703	05/13/2013 06/11/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	ABAXIS INC - EIRS, 483S, UNTITLED LTRS, ETC 1/12 TO PRESENT
2013-3704	05/13/2013 06/11/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	MEDIVATION INC - EIRS, 483S, UNTITLED LTRS, ETC 1/12 TO PRESENT
2013-3705	05/13/2013 06/11/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	NPS PHARMACEUTICALS INC - EIRS, 483S, UNTITLED LTRS, ETC 1/12 TO PRESENT
2013-3706	05/13/2013 06/11/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	WRIGHT MEDICAL GROUP INC - EIRS, 483S, UNTITLED LTRS, ETC 1/12 TO PRESENT
2013-3707	05/13/2013	FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson	AERS 8237200

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	06/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FOI Services, Inc.	
2013-3708	05/13/2013 06/11/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	RESMED INC - EIRS, 483S, UNTITLED LTRS, ETC 1/12 TO PRESENT
2013-3709	05/13/2013 06/11/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	HEARTWARE INTERNATIONAL INC - EIRS, 483S, UNTITLED LTRS, ETC 1/12 TO PRESENT
2013-3710	05/13/2013 06/11/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Angelina Slayton INC RESEARCH CONSULTING & SUBMISSIONS	SHELDON FREEDMAN, MD, LAS VEGAS, NV - EIR, 483 06/01/2012-07/25/2012
2013-3711	05/13/2013 06/11/2013	FDA/OMPT/CTP/OD/	Doe J	TOP CIGARETTE TOBACCO, BUGLER TOBACCO - INGREDIENTS
2013-3712	05/13/2013 06/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Loxitane NDA Watson Laboratories, Inc.	NDA 17525
2013-3713	05/13/2013 06/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	Chantal Frontczak Hemodia SAS	K925160, K954465, K951843 ETC
2013-3714	05/13/2013 06/11/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	BIOMARIN PHARMACEUTICAL INC - EIRS, 483S, UNTITLED LTRS, ETC 1/12 TO PRESENT
2013-3715	05/13/2013 06/11/2013	OC/CVM/OCD/	Blaine Baker, Regulatory Manager Virbac AH, Inc	NADA 140869
2013-3716	05/13/2013 06/11/2013	FDA/OC/OES/DFOI/	Michael Moss THE NEW YORK TIMES	FOOD AND BEVERAGE FOIA REQUESTS (05/10/2011 - 05/10/2013)
2013-3717	05/13/2013 06/11/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	SEATTLE GENETICS INC - EIRS, 483S, UNTITLED LTRS, ETC 1/12 TO PRESENT
2013-3718	05/13/2013 06/11/2013	FDA/OC/OES/DFOI/ OC/ORA/ OC/ORA/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Eric Young Kessler Topaz Meltzer & Check, LLP	ST JUDE, SYLMAR, CA - INSPECTION RECS, CORR
2013-3719	05/13/2013 06/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	b. burgess BURGESS, BERNIE	CDER/DSI GCP C/R/S 1840

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-3720	05/13/2013 06/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	EPOGEN - APPROVAL RECS
2013-3721	05/13/2013 06/11/2013	FDA/OC/OES/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	b. burgess bernie burgess	EMAILD DATED 9/26/2011 TO OSI RE COMPLAINT TO COMMISSIONER
2013-3722	05/13/2013 06/11/2013	OC/ORP/ OC/ORP/	Tony Collins-Kwong ALLINA HEALTH SYSTEM	PHARMERICA - 483 (01/01/2011 - 05/10/2013)
2013-3723	05/13/2013 06/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Brian Overstreet AdverseEvents, Inc.	AERS 8002028, 7917378, 7064380, ETC
2013-3724	05/13/2013 06/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	b burgess bernie burgess	CORR FROM BEHR ON 2/14/11 TO OSI RE DISPUTE
2013-3725	05/13/2013 06/11/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Christine Livoti BIOPHARM INSIGHT	DRUGS FOR WHICH BT DESIGNATION APPLICATIONS WERE FILED, APPROVED, NAMES OF SPONSORS (07/09/2012 - 04/30/2013)
2013-3726	05/13/2013 06/11/2013	OC/ORP/ OC/ORP/ FDA/OGROP/ORP/SW-FO/DAL- DO/DAL-CB/	Eric Puente Puente, Eric	HEB TOMATO SAMPLES
2013-3727	05/13/2013 06/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	Donna Stauffer TELA Bio, Inc.	K061982
2013-3728	05/13/2013 06/13/2013	FDA/OC/OES/DFOI/	Mark Prinz Registrar Corp	FOREIGN FOOD FACILITY INSPECTIONS - 483 (10/01/2011 - 12/31/2012)

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2013-3729	05/13/2013 06/11/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Collin L. Freer Berman Fink Van Horn P.C.	SEED BIOTECH, DALLAS, TX - FILINGS, REGISTRATION, ETC
2013-3730	05/13/2013 06/11/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Jorge Hernn Ramrez Universidad Icesi	RNS60 - APPROVAL FOR STUDIES, IND
2013-3731	05/13/2013 06/11/2013	OC/ORAS/ OC/ORAS/ FDA/OFVM/CFSAN/OCD/EOS/ OC/ORAS/OCI/ OC/ORAS/OCI/	Cheryl Cheryl	ZI XIU TANG BEE POLLEN - FINDINGS OF SIBUTRAMINE, WARNING LETTER (09/01/2012 - 06/01/2013)
2013-3732	05/13/2013 06/11/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Jacques Jentel DuPage Medical Group / Jacques Jentel, M.D.	ULTRAM, ULTRAM ER, TRAMADOL, ETC - AERS
2013-3733	05/13/2013 06/11/2013	FDA/OC/OES/DDM/	Advisory Committee Meetings Orthopaedic and Rehab Devices Peter Boone	ORTHOPAEDIC AND REHABILITATION DEVICES - TRANSCRIPTS 7/22/1994-7/23/1994
2013-3734	05/13/2013 06/11/2013	FDA/OC/OES/DFOI/	ELLIOT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	2013-1123, 1571, 1729 ETC
2013-3735	05/13/2013 06/11/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OC/OES/DFOI/	ELLIOT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	PONATINIB (ICLUSIG) AER 1/13 TO PRESENT
2013-3736	05/13/2013 06/11/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OC/OES/DFOI/	ELLIOT FAVUS FAVUS INSTITUTIONAL RESEARCH LLC	ADCETRIS (BRENTUXIMAB VEDOTIN) AER 1/13 TO PRESENT
2013-3737	05/13/2013	FDA/OFVM/CFSAN/OCD/EOS/	BRIAN M. OVERSTREET	HYDROXYUREA AER9/12 TO PRESENT

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	06/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ADVERSE EVENTS	
2013-3738	05/13/2013 06/11/2013	FDA/OC/OES/DFOI/	THORNHILL 322084, CHRIS	NUTRITIONAL CALORIE VALUE
2013-3739	05/13/2013 06/11/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GOINS 302385, MICHAEL	BENTY; REMRON; VISTONL ETC - AER
2013-3740	05/13/2013 06/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PATRICIA L. REGENYE Celgene Corporation	MARGRIT SIMON, BERLIN, GERMANY - 483 10/09 TO PRESENT
2013-3741	05/13/2013 06/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	WATTS, LEWIS	PUBLIC WORKSHOP - LBLG 4/29-30/13
2013-3742	05/13/2013 06/11/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/	HAROLD G. FURLOW HAROLD G FURLOW ATTORNEY AT LAW	ZIMUSSU0221 7/15/05; ZIMUSSRO37 9/8/05 - ENTRY DOCS
2013-3743	05/13/2013 06/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	INDIVIUAL RECS
2013-3744	05/13/2013 06/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BETH ZIEMBA CELL THERAPEUTICS INC	8681891, 8917306, 9023966 ETC - MEDWATCH

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-3745	05/13/2013 06/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN CREWDSON PROJECT ON GOVERNMENT OVERSIGHT	PHARMACOVIGILANCE RVW 12/15/11 - UNREDACTED PAGE 33
2013-3746	05/13/2013 06/17/2013	FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/	ERIN E. SEDER VENABLE LLP	ALL DIETARY SUPPLEMENT & OTC DRUG COMPANIES TO DISCUSS AER - 483 6/09 TO PRESENT; NUMBER OF AER 2008 TO PRESENT
2013-3747	05/13/2013 06/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	LUCINDA J. TODD HILL-ROM	LINET SPOL SRO - 483 10/29/12 TO 11/2/12
2013-3748	05/13/2013 06/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WENDY JO ROGERS CORSON & JOHNSON LAW FIRM	AMIODARONE - NDA; PEACE HEALTH RIVER BEND HOSPITAL, EUGENE, OREGON 2008 TO 2013; FAERS RPT
2013-3749	05/14/2013 06/12/2013	FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA REQUEST LOG - (05/06/2013 - 05/10/2013)
2013-3750	05/14/2013 06/12/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Rebecca Britton Oregon Health & Science University Hospitals and Clinics	BERIPLEX P/N - TRIAL RECS
2013-3751	05/14/2013 06/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Erik van den Akker Erik van den Akker	NCT00046020 - STUDY DATA
2013-3752	05/14/2013 06/12/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Doe J	HOSPITAL UNIVERSITARIO, DR JOSE E GONZALEZ, MONTERREY, MEXICO - INSPECTION RECS (05/02/2007 - 05/02/2013)
2013-3753	05/14/2013 06/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ramanareddy Posam Self	PREDNISONE - CLINICAL TRIALS, AERS

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2013-3754	05/14/2013 06/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	James Bush Vertex Pharmaceuticals, Incorporated	AESICA PHARMACEUTICALS LIMITED - QAP PROFILE
2013-3755	05/14/2013 06/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	James Bush Vertex Pharmaceuticals, Incorporated	AESICA PHARMACEUTICALS GMBH - QAP
2013-3756	05/14/2013 06/12/2013	FDA/OGROP/ORACE-FO/CIN- DO/CIN-CB/	Brendan Ryan WARNER CHILCOTT	EMERALD PERFORMANCE MATERIALS - EIR (05/13/2010 - 05/13/2013)
2013-3757	05/14/2013 06/12/2013	FDA/OMPT/OSMP/OOPD/	Scott Wilkin UBS AG	PROCYSBI - ORPHAN DRUG DESIGNATION
2013-3758	05/14/2013 06/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Molly Juhlin OREGON HEALTH SCIENCES UNIVERSITY	ITRACONAZOLE WITH SAQUINAVIR - TRIAL RECS
2013-3759	05/14/2013 06/12/2013	FDA/OGROP/ORACE-FO/ATL- DO/ATL-CB/	Amber Baker BioNetwork	GAIA HERBS, BREVARD, NC - 483 (05/01/2009 - 05/13/2013)
2013-3760	05/14/2013 06/12/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 4/15-19/13
2013-3761	05/14/2013 06/12/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 4/22-26/13
2013-3762	05/14/2013 06/12/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 4/15-19/13
2013-3763	05/14/2013 06/12/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 4/22-26/13
2013-3764	05/14/2013 06/12/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 4/15-19/13
2013-3765	05/14/2013 06/12/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 4/22-26/13
2013-3766	05/14/2013 06/12/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW &	FOI DAILY LOG 4/15-19/13

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			BUSINESS	
2013-3767	05/14/2013 06/12/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 4/22-26/13
2013-3768	05/14/2013 06/12/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 4/15-19/13
2013-3769	05/14/2013 06/12/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 4/22-26/13
2013-3770	05/14/2013 06/12/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 4/15-19/13
2013-3771	05/14/2013 06/12/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 4/22-26/13
2013-3772	05/14/2013 06/12/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 4/15-19/13
2013-3773	05/14/2013 06/12/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 4/22-26/13
2013-3774	05/14/2013 06/12/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 4/15-19/13
2013-3775	05/14/2013 06/12/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 4/22-26/13
2013-3776	05/14/2013 06/12/2013	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 4/15-19/13
2013-3777	05/14/2013 06/12/2013	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 4/22-26/13
2013-3778	05/14/2013 06/12/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 4/15-19/13
2013-3779	05/14/2013 06/12/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 4/22-26/13
2013-3780	05/14/2013 06/12/2013	FDA/OC/OES/DFOI/	GLADYS B TONKIN WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 4/15-19/13
2013-3781	05/14/2013 06/12/2013	FDA/OC/OES/DFOI/	GLADYS B TONKIN WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 4/22-26/13

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2013-3782	05/14/2013 06/12/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 4/15-19/13
2013-3783	05/14/2013 06/12/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 4/22-26/13
2013-3784	05/14/2013 06/12/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	STEVEN C GLICKMAN GLICKMAN & GLICKMAN LAW OFCS	BOTULISM INVESTIGATION - INDIVIDUAL RECS
2013-3785	05/14/2013 06/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID HOFFMEISTER ESQ WILSON SONSINI ET AL	BANNER - ANDA 200-899; ROXANE - ANDA 202-204; SANDOZ - ANDA 202-660 TENTATIVE APRVL LTRS
2013-3786	05/14/2013 06/12/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OMPT/CDRH/OCER/DFOI/	SHELLY S JOCK RALPH C JONES LAW OFCS	OLYMPUS - SURGMASTER ELECTROSURGICAL UNIT (UES-40) CLASS 2 RECALL
2013-3787	05/14/2013 06/12/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	KIMBERLY A GRABBE MAGLIO CHRISTOPHER & TOALE LAW FIRM	INDIVIDUAL RECS
2013-3788	05/14/2013 06/12/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Doe J	CMLPNT
2013-3789	05/14/2013 06/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	LAVENIA FORD CARDINAL HEALTH	AVERY DENNISON CORP - K113836
2013-3790	05/14/2013 06/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PHINNY, C WENDY	TEVA PHARMACEUTICALS USA - PALONOSETRON HCL ANDA 202-224 CORR
2013-3791	05/14/2013 06/12/2013	FDA/OC/OES/DDM/	FATIMA ASLAM Keller and Heckman LLP	DKT FDA-1985-G-0511
2013-3792	05/14/2013 06/12/2013	FDA/OC/OES/DDM/	FATIMA ASLAM Keller and Heckman LLP	DKT FDA-1985-G-0511
2013-3793	05/15/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2011-5611

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	06/13/2013		MERCK & CO., INC.	
2013-3794	05/15/2013 06/13/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-5589
2013-3795	05/15/2013 06/13/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-4763
2013-3796	05/15/2013 06/13/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8712
2013-3797	05/15/2013 06/13/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2009-3073
2013-3798	05/15/2013 06/13/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8717
2013-3799	05/15/2013 06/13/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-3064
2013-3800	05/15/2013 06/13/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8021
2013-3801	05/15/2013 06/13/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-1082
2013-3802	05/15/2013 06/13/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7578
2013-3803	05/15/2013 06/13/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7708
2013-3804	05/15/2013 06/13/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7433
2013-3805	05/15/2013 06/13/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8750
2013-3806	05/15/2013 06/13/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8581
2013-3807	05/15/2013 06/13/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7281
2013-3808	05/15/2013 06/13/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6988
2013-3809	05/15/2013 06/13/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7022

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2013-3810	05/15/2013 06/13/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-9523
2013-3811	05/15/2013 06/13/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-7008
2013-3812	05/15/2013 06/13/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7429
2013-3813	05/15/2013 06/13/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Scott A. Hodes Scott A. Hodes, Attorney at Law	GILEAD SCIENCES, FOSTER CITY - 483 (01/01/2013 - 05/15/2013)
2013-3814	05/15/2013 06/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Amy Gonzales AMGEN INC.	MUSTAFA NEVZAT PHARMACEUTICALS, TURKEY - EIR (01/03/2012 - 05/14/2013)
2013-3815	05/15/2013 06/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Christine Nichols Boston Biomedical Associates	K113313
2013-3816	05/15/2013 06/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Scott Hodes Scott A. Hodes, Attorney at Law	ICLUSIG - AERS
2013-3817	05/15/2013 06/13/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Dora Fong KARL STORZ ENDOSCOPY AMERICA INC	K091515
2013-3818	05/15/2013 06/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	KATHLEEN BERNHARD GEORGIA INSTITUTE OF TECHNOLOGY	K913882, K981851, K974653 - SUMMARY
2013-3819	05/15/2013 06/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Andrew Ellis Andrew Ellis	VIDEX, VIDEX EC - AERS (01/01/1990 - 12/31/2006)
2013-3820	05/15/2013 06/13/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Art Rankis Art Rankis	K082217
2013-3821	05/15/2013 06/13/2013	FDA/OC/OES/DFOI/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORAPA-FO/LOS-	Eric Young Kessler Topaz Meltzer & Check, LLP	ST JUDE MEDICAL - INSPECTION RECS RE LEAD PRUDUCTS

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		DO/LOS-CB/ FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/		
2013-3822	05/15/2013 06/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Nathan Bryson CYNAPSUS THERAPEUTICS INC.	APOKYN - POSTMARKETING COMMITMENTS, PROTOCOLS, FINAL REPORTS
2013-3823	05/15/2013 06/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Dora Fong KARL STORZ ENDOSCOPY AMERICA INC	K061871
2013-3824	05/15/2013 06/13/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Doe J	SAMPLE 783279 - TEST RESULTS
2013-3825	05/15/2013 06/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Thomas Zarembinski BioTime, Inc.	K112568, K022995, K945835 ETC
2013-3826	05/15/2013 06/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Calvin Lin UOC USA INC.	K123339
2013-3827	05/15/2013 06/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kate Gitter Plexus Corp.	PLEXUS MANUFACTURING, PENANG, MALYSIA - EIR JAN 2009
2013-3828	05/15/2013 06/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Holm Uhlig UNIVERSITY OF OXFORD	ZAVESCA - ISR 5599512, 5587626, 5681080 ETC
2013-3829	05/15/2013 06/13/2013	FDA/OC/OL/	Susanna Monseau, Associate Professor, TCNJ Susanna Monseau	RESPONSES TO REP ISSA RE MCNEIL CONSENT DECREE
2013-3830	05/15/2013 06/13/2013	FDA/OC/OES/DDM/	ELENA HOWELL HOGAN LOVELLS LLP	DKT FDA-2006-P-0010
2013-3831	05/15/2013 06/13/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	STEVE D. MATTERI CONTEMPORARY PRODUCTS INC	VETERINARY SERVICE INC, FRESNO, CA - EIR 3/23/10
2013-3832	05/15/2013	FDA/OGROP/ORAPA-FO/SAN-	STEVE D. MATTERI	VETERINARY SERVICE INC, MODESTO, CA - EIR 6/4/10

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	06/13/2013	DO/SAN-CB/	CONTEMPORARY PRODUCTS INC	
2013-3833	05/15/2013 06/13/2013	FDA/OC/OES/DDM/	AMY WILLMAN XLEAR	DCK 80N-0042
2013-3834	05/15/2013 06/13/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	ANNA McCUTCHEN RYMED TECHNOLOGIES INC	BIOPATCH K003229
2013-3835	05/15/2013 06/13/2013	FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/	THOMAS P. RIEDERER PE TRUE VISION SYSTEMS INC	TRUE VISION SYS, GOLETA, CA - EIR 3/11-12/13
2013-3836	05/15/2013 06/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HILL, CYNTHIA	TRADJENTA - RECS
2013-3837	05/15/2013 06/13/2013	FDA/OGROP/ORACE-FO/BLT- DO/BLT-CB/ FDA/OGROP/ORACE-FO/DET- DO/DET-CB/ FDA/OGROP/ORACE-FO/MIN- DO/MIN-CB/ FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORAPA-FO/SAN- DO/SAN-CB/	ANDREW HACK, MD, PhD. MILLENNIUM MANAGEMENT LLC	COVANCE INC - 483, EIR, UNTITLED LTRS 1/12 TO PRESENT
2013-3838	05/15/2013 06/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	ELIZABETH A. BATTS ULMER BERNE LLP	ROZINN ELECTRONICS INC - NETLINK K020213
2013-3839	05/15/2013 06/13/2013	FDA/OGROP/ORASW-FO/DEN- DO/DEN-CB/	LOPER, MATTHEW	ALLO SOURCE - WARNING LTR 2010 TO PRESENT
2013-3840	05/15/2013 06/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	CARMELA R. WITMER ATLEE HALL BROOKHART LLP	THOMAS MEDICAL PRODUCTS INC, MALVERN, PA - BARD CHANNEL FX TRANSSEPTAL SHEATH KIT - ALL DOCUMENTS
2013-3841	05/15/2013 06/13/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORAPA-FO/LOS-	STUTE, HANK.	CMPLNT CPT1200119

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		DO/LOS-CB/		
2013-3842	05/15/2013 06/13/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/	CHRISTOPHER M. KANE SIMON GLUCK & KANE LLP	ENTRY NO EYD-0105093-3
2013-3843	05/15/2013 06/13/2013	FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORASE-FO/ATL- DO/ATL-CB/ FDA/OGROP/ORASW-FO/KAN- DO/KAN-CB/ FDA/OGROP/ORACE-FO/BLT- DO/BLT-CB/ FDA/OGROP/ORAPA-FO/SEA- DO/SEA-CB/	ALANA ZUSIS SMITH AMUNDSEN LLC	THERMO PAC LLC - SIMPLY THICK DOCS
2013-3844	05/15/2013 06/13/2013	FDA/OGROP/ORACE-FO/CIN- DO/CIN-CB/	SHANNON BUDNICK STOCK YARDS BANK & TRUST CO	LOUISVILLE REPRODUCTION CENTER, LOUISVILLE, KY - INSP
2013-3845	05/15/2013 06/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	SUSAN PATE, RAC STOCK YARDS BANK & TRUST CO	XORAN TECHNOLOGIES INC - XCAT SYS K061834
2013-3846	05/15/2013 06/13/2013	FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORASW-FO/KAN- DO/KAN-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANDREW HACK, MD, PhD. MILLENNIUM MANAGEMENT LLC	CELGENE CORP - 483, EIR, UNTITLED LTRS, CORR
2013-3847	05/15/2013 06/13/2013	FDA/OC/OES/DFOI/	INEZ CAMPBELL SANDOZ	OWEN MUNFORD, MARIETTA, GA - AUTOJET II K013362
2013-3848	05/15/2013 06/13/2013	OC/CVM/OCD/ OC/OCS/NCTR/OD/	DR. WOLFGANG STENGEL EUROPEAN COALITION TO END ANIMAL EXPERIMENTS	SUB CHRONIC TOXICITY STUDY ON TRIPHENYL PHOSPHATE
2013-3849	05/15/2013 06/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	LAUREN SILVIS SIDLEY AUSTIN LLP	ODE RESPONSES TO RECIPIENTS ON 7/10/12
2013-3850	05/15/2013	FDA/OMPT/CDER/ORP/DIDP/	JOSH LEE	WEST WARD PHARMACEUTICALS INC, EATONTOWN, NJ -

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	06/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORA/ OC/ORA/ FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	FEDERAL PUBLIC DEFENDER ARKANSAS	INSP, WARNING LTRS, CORR 1/10 TO PRESENT
2013-3851	05/15/2013 06/13/2013	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORA/ OC/ORA/	HEATHER GALE OLSSON FRANK & WEEDA	REPORTABLE FOOD REGISTRY - UPDATED INTERNAL INSP GUIDANCE PAGE 7
2013-3852	05/15/2013 06/13/2013	FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/	MEADE, DORIS.	HILLESTAD PHARMACEUTICALS USA INC, WOODRUFF, WI - 483 7/25-27/12
2013-3853	05/16/2013 06/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	Dion Brandt TIDI Products, LLC	K962288
2013-3854	05/16/2013 06/14/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	Eric Young Kessler Topaz Meltzer & Check, LLP	ST JUDE MEDICAL, INC, SYLMAR, CA - INSPECTION RECS 6/8/09
2013-3855	05/16/2013 06/14/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Gary Syring Quality & Regulatory Associates, LLC	K870450
2013-3856	05/16/2013 06/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kaori Asakawa EXPERIEN GROUP LLC	K961385
2013-3857	05/16/2013 06/14/2013	FDA/OMPT/OSMP/OOPD/	Rachel Johnson FOI Services, Inc.	GRALISE - ORPHAN DRUG DESIGNATION
2013-3858	05/16/2013 06/14/2013	FDA/OMPT/OSMP/OOPD/	Rachel Johnson FOI Services, Inc.	HORIZANT - ORPHAN DRUG DESIGNATION
2013-3859	05/16/2013 06/14/2013	FDA/OGROP/ORA/SW-FO/DEN- DO/DEN-CB/	Aaron Sorensen doterra	YOUNG LIVING, SPANISH FORK, UT - 483 (06/15/2012 - 06/22/2012)
2013-3860	05/16/2013 06/14/2013	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	GRANDFATHERED TOBACCO PRODUCT STATUS DETERMINATIONS ISSUED BY CTP (10/30/2012 to 05/10/2013)
2013-3861	05/16/2013 06/14/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nazmin Khan Khan, Nazmin	DELZICOL - CLINICAL REVIEW, CLINICAL PHARMACOLOGY AND BIOPHAMACEUTICAL REVIEW ETC

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-3862	05/16/2013 06/14/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	CHRISTOPHER BERRY ANIMAL LEGAL DEFENSE FUND	ROCK ISLAND REFRIGERATED DISTRIBUTORS INC, PETALUMA, CA - EIRS, CO RESP, WARNING LTRS, ETC LAST 5 YRS
2013-3863	05/16/2013 06/14/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	CHRISTOPHER BERRY ANIMAL LEGAL DEFENSE FUND	STEVEN MAHARTIPETALUMA FARMS; PETALUMA, CA - EIRS, CO RESP, WARNING LTR, ETC
2013-3864	05/16/2013 06/14/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	BRENTON L HORNER HORNER & ASSOCIATES	WORLD HEALTH PRODCTS LLC, SALT LAKE CITY, UT - IMPORT REFUSAL RPT 1/06
2013-3865	05/16/2013 06/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHANNON L TURNER GlaxoSmithKline	GLAXOSITHKLINE - EVRUX, WARE -QUALITY ASSURANCE PROFILE (QAP)
2013-3866	05/16/2013 06/14/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	ROBERT ROMIG NUTRITIONAL LABORATORIES INTL	USANA; NATURE SUNSHINE - EIRS
2013-3867	05/16/2013 06/14/2013	FDA/OC/OES/DDM/ FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	OMAR S RIVERO Thomas J Henry Law Firm	BRISTOL-MYERS SQUIBB (INHIBITEX INC) - HEPATITIS C BMS-986094 (INX-08189) FORM 1571, FORM 1572, PRE-CLNCL STUDIES, ETC(CERTIFIED)
2013-3868	05/16/2013 06/14/2013	FDA/OC/OES/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	mohammad 96A3015, MALLK	TEGRETOL, REMORAN, CELEXA - AERS, RECS
2013-3869	05/17/2013 06/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Thomas Valentine Elekta Inc.	K102915, K111862
2013-3870	05/17/2013 06/17/2013	FDA/OC/OES/ FDA/OMPT/CTP/OD/	Anna Edney BLOOMBERG NEWS	MARGARET HAMBURG, MITCHELL ZELLER, LEONA BRENNER-GATI - EMAILS (09/01/2012 - 05/16/2013)
2013-3871	05/17/2013	FDA/OMPT/CDER/GRP/DIDP/	Jens Kristensen	VIREAD - POST APPROVAL SAFETY DATA

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	06/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	kristensen	
2013-3872	05/17/2013 06/17/2013	FDA/OGROP/ORAN/FO/NWE- DO/NWE-CB/	Michael Scott Cognate BioServices, Inc.	PHASE 2 MEDICAL MANUFACTURING, ROCHESTER, NH - EIR, 483 (01/01/2006 - 12/31/2006)
2013-3873	05/17/2013 06/17/2013	FDA/OGROP/ORAN/CE-FO/PHI- DO/PHI-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Barry Sands RQMIS Inc.	OLYMPUS GYRUS ACMI, OLYMPUS AMERICA - COMM RE INSPECTIONS, RECALL (05/02/2012 - 05/15/2013)
2013-3874	05/17/2013 06/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Stewart Siskin, PharmD Erie County Medical Center Corporation	BLA 103172
2013-3875	05/17/2013 06/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Adrienne E Faerber Dartmouth Inst. Cent. For Med. Media.	NDA 22426, NDA 203414
2013-3876	05/17/2013 06/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kimberlee Washburn WASHBURN, KIMBERLEE	P100047
2013-3877	05/17/2013 06/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jens Kristensen kristensen	HESPERA - POST MARKETING SAFETY DATA
2013-3878	05/17/2013 06/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Eric Lim Meng How Crystal Aesthetics	BACTOLAC PHARMACEUTICAL - CERTIFIED REGISTRATION
2013-3879	05/17/2013 06/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	AMY L. GOERSS HODGSON RUSS LLP	ZIMMER DENTAL INC - ZFX DENTAL CAD SYS K121709
2013-3880	05/17/2013 06/17/2013	FDA/OGROP/ORAN/CE-FO/CIN- DO/CIN-CB/	SHANNON BUDNICK STOCK YARDS BANK & TRUST CO	LOUISVILLE REPRODUCTIVE CTR, LOUISVILLE, KY - 483 5/6/13
2013-3881	05/17/2013 06/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JUSTIN DIMARTINO RETROPHIN INC	NOVARTIS PHARMACEUTICALS - SYNTOCINON (OXYTOCIN NASAL SPRAY) NDA 12/285 CLNCL RVV, MEDICAL RVV

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2013-3882	05/17/2013 06/17/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	GRAY, SCHERLY D	CMP LNT 132014
2013-3883	05/17/2013 06/17/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	SHELLY S. JOCK LAW OFFCIES OF RALPH C JONES	OLYMPUS GYRUS ACMI INC - WARNING LTRS, INSP, 7/10 TO 8/2/12
2013-3884	05/17/2013 06/17/2013	FDA/OFVM/CFSAN/OCD/EOS/	CHRISTINE FORGUES MORGAN LEWIS & BOCKIUS LLP	WACKER BIOCHEM CORP - GRN 000074
2013-3885	05/17/2013 06/17/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/ FDA/OMPT/CDRH/OCER/DFOI/	SHELLY S. JOCK LAW OFFCIES OF RALPH C JONES	OLYMPUS - ENDOSCOPIC ELECTROSURGICAL UNIT RECALL
2013-3886	05/17/2013 06/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID G. ADAMS VENABLE LLP	CNF DESMO PK 200301 - 1/03 TO PRESENT
2013-3887	05/20/2013 06/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	Henry Dao HSP USA LLC	K100918, K123072
2013-3888	05/20/2013 06/18/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Brian Duncan Brian Duncan	SANDOZ, WILSON, NC - 483 (03/01/2013 - 05/17/2013)
2013-3889	05/20/2013 06/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Patrick Mevs Martin Clearwater & Bell, LLP	TEMODAR - CLINICAL TRIAL RECS
2013-3890	05/20/2013 06/18/2013	FDA/OO/OHR/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	MARY CAROLE CRANE MUNSON ROWLETT MOORE BOONE	INDIVIDUAL RECS (CERTIFIED)
2013-3891	05/20/2013	FDA/OO/OHR/	DANIEL H MOSS	INDIVIDUAL RECS

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	06/18/2013		JOELSON ROSENBERG MOSS COHEN WARREN & DRASNIN PLC	
2013-3892	05/20/2013 06/18/2013	FDA/OO/OHR/	DARIN L RUMER JOSEPH GREENWALD & LAAKE PA	INDIVIDUAL RECS
2013-3893	05/20/2013 06/18/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	WALTER E CHALKLEY THOMSON REUTERS	ORGANON - HTLV-I P21E ANTIGEN (HUMAN T- LYMPHOTROPIC VIRUS I & II) APRVL LTR
2013-3894	05/20/2013 08/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	WALTER E CHALKLEY THOMSON REUTERS	MERCK SANTE SAS - CYANOKIT (HYDROXOCOBALAMIN) NDA 22-041/S008,S009 APRVL LTR
2013-3895	05/20/2013 06/18/2013	FDA/OGROP/ORANE-FO/NYK- DO/NYK-DCB/	TAKACS, TRACI	FEDERAL LABORATORIES CORP, ALDEN, NY - INSPS, HEALTH VIOLATIONS, INSP RESULTS LAST 15 YRS
2013-3896	05/20/2013 06/18/2013	OC/ORO/ORM/ OC/ORO/ORM/	THOMPSON, RAY	HUMAN DRUG, HUMAN MEDICAL DVC FIRMS - GMP, GLP, GCP INSPS 1/13 TO 3/13
2013-3897	05/20/2013 06/18/2013	FDA/OC/OES/DFOI/	CROSBY T-50417, COURTNEY	LIST OF DRUG AND HEALTH AIDS RECALLS
2013-3898	05/20/2013 06/18/2013	FDA/OFVM/CFSAN/OCD/EOS/	MCKENZIE #300416, LEROY A	EDIBLE PROTEIN FIBERS, TEXTURIZED FOOD PRODS, PROCESSED POULTRY PRODS, ETC - COMPOSITION QUALITY STANDARDS
2013-3899	05/21/2013 06/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michele Sinoway Lachman Consultants	ANDA 062-737
2013-3900	05/21/2013 06/19/2013	FDA/OGROP/ORACE-FO/MIN- DO/MIN-CB/ FDA/OMPT/CDRH/OCER/DFOI/ OC/ORO/OE/ OC/ORO/OE/	Jake Lovato, through his counsel the Kelin Law Firm P.C. Kelin Law Firm P.C.	MEDTRONIC ENPULSE IPG - RECALL RECS; MEDTRONIC PACEMAKERS AND LEADS - RECALL CLASSIFICATION LETTERS; RECALL EFFECTIVENESS CHECKS; ETC (02/20/2004 - 05/20/2013)
2013-3901	05/21/2013 06/19/2013	FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA REQUEST LOG (05/13/2013 - 05/17/2013)

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2013-3902	05/21/2013 06/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	PMA 890023 S 7
2013-3903	05/21/2013 06/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K063359
2013-3904	05/21/2013 06/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michele Sinoway Lachman Consultants	ANDA 61490
2013-3905	05/21/2013 06/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Omobola Mudasiru ENVIRON International Corporation	LIBRIUM NDA
2013-3906	05/21/2013 06/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michele Sinoway Lachman Consultants	ANDA 61395
2013-3907	05/21/2013 06/19/2013	FDA/OGROP/ORO/SE-FO/ATL- DO/ATL-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Prashanth Jayaram Prashanth Jayaram	CARDIOMEMS - WARNING LETTER CORR (06/15/2012 - 05/20/2013)
2013-3908	05/21/2013 06/19/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/ORM/ OC/ORO/ORM/	Mark Prinz Registrar Corp	FOREIGN FOOD FACILITIES
2013-3909	05/21/2013 06/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michele Sinoway Lachman Consultants	ANDA 62901
2013-3910	05/21/2013 06/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michele Sinoway Lachman Consultants	ANDA 61490
2013-3911	05/21/2013 06/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michele Sinoway Lachman Consultants	ANDA 62901

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2013-3912	05/21/2013 06/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michele Sinoway Lachman Consultants	ANDA 61395
2013-3913	05/21/2013 06/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michele Sinoway Lachman Consultants	ANDA 62738
2013-3914	05/21/2013 06/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michele Sinoway Lachman Consultants	ANDA 62732
2013-3915	05/21/2013 06/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Benita Chappell Cericon, LLC	K111275
2013-3916	05/21/2013 06/19/2013	FDA/OC/OES/ FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/ OC/ORO/ FDA/OC/OPP/OP/ FDA/OGROP/OIP/	Joseph L. Satran The Huffington Post	MSFA - INTERNAL EMAILS, FAXES, EMAIL ETC
2013-3917	05/21/2013 06/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Michelle Jump STRYKER CORPORATION	K123188 SUMMARY
2013-3918	05/21/2013 06/19/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/SEA- DO/SEA-CB/	Doe J	INDI VIDUAL RECS
2013-3919	05/21/2013 06/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Holly Lambert Holly Lambert	K023967, K014234
2013-3920	05/21/2013 07/02/2013	FDA/OC/OPP/OP/	Peter Spaulding Peter Spaulding	PETER LURIE - CORR WITH PUBLIC CITIZEN (08/01/2011 - 05/17/2013)
2013-3921	05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	Peter Spaulding	DR PASCUAL-LEONE - ABSENCE OR RECUSAL FROM 2/10/12 NEUROLOGICAL DEVICES PANEL

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	06/19/2013	FDA/OC/OES/DFOI/	Peter Spaulding	
2013-3922	05/21/2013 06/19/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	ROBERT KING FDANEWS	S & B PHARMA (DBA NORAC PHARMA), AZUSA, CA; MARIETTA CORP, VERNON, CA; PHYSICIANS FORMULA INC, CITOOF INDUSTRY, CA, ETC - 483S 4/1-30/13
2013-3923	05/21/2013 06/19/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	ROBERT KING FDA NEWS	MILBAR LABORATORIES INC, EAST HAVEN, CT; TOM'S OF MAINE INC, SANFORD, ME; IMMUCELL CORP, POTLAND, ME, ETC - 483S 4/1-30/13
2013-3924	05/21/2013 06/19/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	ROBERT KING FDANEWS	MEDSTRONIC NEUROMODULATION, MINNEAPOLIS, MN; NE'S INK INC, WAUKESHA WI; CEDARBURG PHARMACEUTICALS INC, GRAFTON, WI, ETC - 483S 4/1-30/13
2013-3925	05/21/2013 06/19/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	ROBERT KING FDA NEWS	MED PREP CONSULTING INC, TINTON FALLS, NJ; FRUTAROM USA INC, NORTH BERGEN, NJ.; P F LABORATORIES INC, TOTOWA, NJ, ETC - 483S 4/1-30/13
2013-3926	05/21/2013 06/19/2013	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	ROBERT KING FDA NEWS	TRIAD ISOTOPES INC, MOBILE AL; CARDINAL HEALTH 414 LLC, BIRMINGHAM, AL; PETER SCHIFF ENTERPRISES, COOKEVILLE, TN, ETC - 483S 4/1-30/13
2013-3927	05/21/2013 06/19/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	ROBERT KING FDA NEWS	TOPIDERM INC, NORTH AMITYVILLE, NY; JEROME STEVENS PHARMACEUTICALS INC, BOHEMIA, NY; BLUE LIGHT INC, ITHACA, NY, ETC - 483S 4/1-30/13
2013-3928	05/21/2013 06/19/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	ROBERT KING FDA NEWS	AIR LIQUIDE ELECTRONICS US LP, MORRISVILLE, PA - 483S 4/1-30/13
2013-3929	05/21/2013 06/19/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	ROBERT KING FDA NEWS	GENERITECH CORP, FRESNO, CA; HOTSPUR TECHNOLOGIES, MOUNTAIN VIEW, CA; CONNECT IMAGING INC, HONOLULU, HI - 483S 4/1/30/13
2013-3930	05/21/2013 06/19/2013	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	ROBERT KING FDA NEWS	WARNER CHILCOTT COMPANY LLC, FAJARDO, PR; FENWAL A FRESENIUS-KABY CO, MARICAO, PR - 483S 4/1/30/13
2013-3931	05/21/2013 06/19/2013	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	ROBERT KING FDA NEWS	OMEGA TECH LABS LLC, GARDEN DITY, ID; SKIN BIOLOGY INC, BELLEVUE, WA; ACUTE INNOVATIONS LLC, HILLSBORO OR, ETC - 483S 4/1/30/13
2013-3932	05/21/2013 06/19/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	ROBERT KING FDA NEWS	CLINICAL SPECIALTIES COMPOUNDING PHARMACY, AUGUSTA, GA; SANDOZ INC, WILSON, NC; ENCOMPASS GROUP LLC, MCDONOUGH, GA - 483S 4/1-30/13
2013-3933	05/21/2013 06/19/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	ROBERT KING FDA NEWS	PINK INC (DBA HEARTEN), RICHMOND, VA; BELL-MORE LABORATORIES INC, HAMPSTEAD, MD - 483S 4/1-30/13
2013-3934	05/21/2013 06/19/2013	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	ROBERT KING FDA NEWS	FINISH LINE INC, BENSENVILLE, IL; VVVF ILLINOIS SERVICES LLC, MONTGOMERY, IL; CONCEPT LABORATORIES, INC, CHICAGO, IL, ETC - 483S 4/1-30/13
2013-3935	05/21/2013	FDA/OGROP/ORACE-FO/CIN-	ROBERT KING	HITACHI MEDICAL SYSTEMS AMERICA INC, TWINSBURG,

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	06/19/2013	DO/CIN-CB/	FDA NEWS	OH; SO-LOW ENVIRONMENTAL EQUIPMENT CO INC, CINCINNATI, OH; ASTRO MEDICAL DEVICES, MENTOR, OH - 483S 4/1-30/13
2013-3936	05/21/2013 06/19/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	ROBERT KING FDA NEWS	BEAUTY MANUFACTURING SOLUTIONS CORP, DALLAS, TX; DPT LABORATORIES LTD, SAN ANTONIO, TX; APOTHECURE INC, DALLAS, TX, ETC - 483S 4/1-30/13
2013-3937	05/21/2013 06/19/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	ROBERT KING FDA NEWS	FISCHER MEDICAL TECHNOLOGIES INC, BROOMFIELD, CO; CAO GROUP INC, WEST JORDAN, UT - 483S 4/1-30/13
2013-3938	05/21/2013 06/19/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	ROBERT KING FDA NEWS	AMERIFLO CORP, CARMEL, IN; HEALTHMARK INDUSTRIES, CO INC, FRASER, MN
2013-3939	05/21/2013 06/19/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	ROBERT KING FDA NEWS	TROPICHEM RESEARCH LABS INC, JUPITER, FL; MEDICAL ENERGY INC, PENSACOLA, FL; ZANDER SCIENTIFIC INC, VERO BEARCH, FL - 483S 4/1-30/13
2013-3940	05/21/2013 06/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ROBERT KING FDA NEWS	PROMED EXPORTS PRIVATE LTD, VILLAGE KHERA NIHLA, INDIA; ALEMBIA LTD, VADODARA, INDIA; RUBICON RESEARCH PRIVATE LTD, KAYLAN, INDIA, ETC - 483S 4/1-30/13
2013-3941	05/21/2013 06/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	ROBERT KING FDA NEWS	TORINER SAS MONTBONNOT, ST MARTIN, FRANCE; HUBEI WEIKANG PROTECTIVE PRODUCTS CO LTD, XIANTAO CITY, CHINA; WONJIN MULSAN CO LTD, INCHEON REPUBLIC OF SOUTH KOREA, ETC - 483S 3/1-30/13
2013-3942	05/21/2013 06/19/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	ROBERT KING FDANEWS	VVF KANSAS SERVICES LLC, KANSAS CITY, KS; LLOYD INC OF IOWA, SHENANDOAH, IA; EMERALD 3 ENTERPRISE INC, CAMDENTON, MO, ETC - 483S 4/1-30/13
2013-3943	05/21/2013 06/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jake McDowell The Weinberg Group Inc.	NDA 203826 SBA
2013-3944	05/21/2013 06/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Cynthia S Gilbert Perfectly Legal Inc	TAXOTERE - NOTICES, LETTERS, REPORTS RE MISLABELING (01/01/2009 - 12/31/2012)
2013-3945	05/21/2013 06/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Cynthia S Gilbert Perfectly Legal, Inc	AVASTIN - NOTICES, LETTERS, REPORTS, ETC RE MISLABELING (01/01/2009 - 12/31/2012)

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-3946	05/21/2013 06/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Cynthia S. Gilbert Perfectly Legal, Inc.	HERCEPTIN - NOTICES, LETTERS, REPORTS ETC RE MISLABELING (01/01/2009 - 12/31/2012)
2013-3947	05/21/2013 06/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Cynthia S Gilbert Perfectly Legal, Inc	ALOXI - NOTICES, LETTERS, REPORTS ETC RE MISLABELING (01/01/2009 - 12/31/2012)
2013-3948	05/21/2013 06/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Cynthia S. Gilbert Perfectly Legal Inc	VELCADE - NOTICES, LETTERS, REPORTS ETC RE MISLABELING (01/01/2009 - 12/31/2012)
2013-3949	05/21/2013 06/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Cynthia S Gilbert Perfectly Legal Inc	MABTHERA - NOTICES, LETTERS, REPORTS ETC RE MISLABELING (01/01/2009 - 12/31/2012)
2013-3950	05/21/2013 06/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Cynthia S Gilbert Perfectly Legal Inc.	MHRA - INFORMATION PROVIDED TO FDA RE NON-FDA CANCER DRUGS
2013-3951	05/21/2013 06/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Cynthia S. Gilbert Perfectly Legal Inc	GEMZAR - NOTICES, LETTERS, REPORTS ETC RE MISLABELING (01/01/2009 - 12/31/2012)
2013-3952	05/21/2013 06/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shalin Jani Aerie Pharmaceuticals Inc.	NDA 020597
2013-3953	05/22/2013 06/20/2013	FDA/OGROP/ORP/SE-FO/FLA-DO/FLA-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	ABDALA F KALIL MD, VITALITY INSTITUTE - RECS

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-3954	05/22/2013 06/20/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OGROP/ORA/CE-FO/BLT- DO/BLT-CB/ FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/	BRUCE C HERRON LOSCO & MARCONI PA	RITCHIE C SHOEMAKER MD, POCOMOKE CITY, MD - CMLPNTS, STUDIES, RPTS, ETC
2013-3955	05/22/2013 06/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PAMELA SHEPPARD TARO PHARMACEUTICALS USA INC	GALDERMA LABS LP - CLOBEX (CLOBETASOL PROPIONATE) NDA 21-835; PADDOCK LLC - CLOBETASOL PROPIONATE ANDA 90-898 SBA, MOR, LBLG, ETC
2013-3956	05/22/2013 07/12/2013	FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	JESSHILL E LOVE ESQ ROPER MAJESKI KOHN & BENTLEY	FUJINO ENTERPRISES INC (DBA BLUE OCEAN SMOKEHOUSE), PRINCETON-BY-THE-SEA, CA - LICENSE STATUS, WARINGS, VIOLATIONS, ETC
2013-3957	05/22/2013 06/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	OLIVIA M FLEMING ESQ BARNES & THORNBURG LLP	BIOLASE TECHNOLOGY INC - WATERLASE MD ER,CR:YSGG K083927
2013-3958	05/22/2013 06/20/2013	FDA/OC/OES/DDM/	JOHN DILLARD OFW LAW	DKT 1980P-0226
2013-3959	05/22/2013 06/20/2013	FDA/OC/OES/DDM/	MARILYNN WHITNEY COVINGTON & BURLING LLP	DKT 1975N-0244
2013-3960	05/22/2013 06/20/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	Richard Dijkman Protocol Naturals	LIQUID HEALTH, MURIETTA, CA - EIR, WARNING LETTER RESPONSE (07/08/2012 - 01/03/2013)
2013-3961	05/22/2013 06/20/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Susan M. Bonapace ALEXION PHARMACEUTICALS	BOEHRINGER INGELHEIM PHARMA GMBH & CO - WARNING LETTER, 483, COMPANY RESPONSE ETC (11/01/2012 - 05/17/2013)
2013-3962	05/22/2013 06/20/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/	ADAM DIEDERICH SCHIFF HARDIN LLP	KEATON WALKER, TRAVIS BOUSLOG, RESPONSIBLE TRANSPORTATION, SIGOURNEY, IA - RECS 1/10 TO PRESENT
2013-3963	05/22/2013 06/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Ryan Lambert New Look Laser College	K110370, K033259
2013-3964	05/22/2013 06/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kate Vassilkova INDEPENDENCE LEGAL	INACTIVE INGREDIENT GUIDE (01/01/1998 - 12/31/1999)

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2013-3965	05/22/2013 06/20/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORASW-FO/KAN- DO/KAN-CB/	ADAM DIEFERICH SCHIFF HARDIN LLP	ROSEWOOD FARMS, SIGOURNEY, IA - RECS 1/08 TO RPRESENT
2013-3966	05/22/2013 06/20/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORASW-FO/KAN- DO/KAN-CB/	ADAM DIEDERICH SCHIFF HARDIN LLP	DAVID RAINS, RAINS NATURAL MEAT, GALLATIN, MO - RECS 1/08 TO PRESENT
2013-3967	05/22/2013 06/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	CHERENE J. MASTROIANNI OLYMPUS AMERICA INC	PENTAX - VIDEO PROCESSOR EPK-15010 K122470
2013-3968	05/22/2013 06/20/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORASW-FO/KAN- DO/KAN-CB/	DAM DIEDERICH SCHIFF HARDIN LLP	WEST LIBERTY FOODS, MOUNT PLEASANT FOODS, SIGOURNEY FOODS, SIGOURNEY, IA - RECS 1/08 TO PRESENT
2013-3969	05/22/2013 06/20/2013	FDA/OC/OES/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Imani Gandy RH Reality Check	7/19/12 MTG BTWN JANET WOODCOCK AND RESEARCH AND CHIEF MEDICAL OFFICERS OF PHARMACEUTICAL FIRMS; 3/22-23/12 MEETING BTWN JANET WOODCOCK AND RESEARCH AND CHIEF MEDICAL OFFICERS, JANE AXELRAD ETC; 6/10/10 MTG BETWEEN JOSH SHARFSTEIN AND TEVA DRUGS RE GENERIC DRUGS - MINUTES, NOTES, PRESENTATION MATERIALS
2013-3970	05/22/2013 06/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Doe J	CINRYZE - AER
2013-3971	05/22/2013 06/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Terri Meredith NATIONAL COUNCIL FOR PRESCRIPTION DRUG PROGRAMS	NDC - NUMBER OF LABELER CODES WITH 5 OR LESS DIGITS ETC
2013-3972	05/22/2013 06/20/2013	OC/ORASORM/ OC/ORASORM/	David Mangione Govzilla, Inc.	LIST OF 483S, INSPECTIONS, EIR IN EXCEL FORMAT 4/16/13 TO 5/18/13
2013-3973	05/22/2013 06/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	COVIDIEN INC - PATIENT RETURN ELECTRODE; GROUNDING PADS INJURIES 1/95 TO PRESENT
2013-3974	05/22/2013 06/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Todd Cartee Penn State Hershey Medical Center	LMX-4, 20% BENZOCAINE CREAM - APPROVAL LABELS

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2013-3975	05/22/2013 06/20/2013	FDA/OC/OES/ FDA/OFVM/CFSAN/OCD/EOS/ OC/CVM/OCD/ FDA/OC/OCC/	Bruce Burk CITIZEN	GENETICALLY MODIFIED ORGANISMS - TESTS, REVIEWS, STUDIES ETC
2013-3976	05/22/2013 06/20/2013	OC/CVM/OCD/	HUGHES, LAURA .	DLIMONENE - AER
2013-3977	05/22/2013 06/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jennifer Burgan Smith & Nephew, Inc.	K110546, K101793, K081584 ETC
2013-3978	05/22/2013 06/20/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/	RONALD KALISH STEINBERG GOODMAN & KALISH	SMITH & NEPHEW - EMPERION FEMORAL COMPONENT APRVL, EIR, LBLG ETC 2000 TO PRESENT
2013-3979	05/22/2013 06/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	VIK BAJNATH ARTHREX INC	MW #5029745
2013-3980	05/22/2013 07/22/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORA/ OC/ORA/ FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	MARK F. SCHOTTINGER KIRKLAND & ELLIS LLP	EASTERN MAGNESIA TALC CO - STUDIES, CORR, INPS, ETC 1967 TO 1990
2013-3981	05/22/2013 06/20/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/CE-FO/BLT- DO/BLT-CB/	Doe J	INDIVIDUAL RECS
2013-3982	05/22/2013 06/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KIMBERLY MANHARD ARDEA BIOSCIENCES	CLNCL TRIAL SITE CLOSURE
2013-3983	05/22/2013 06/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	STEPHANIE PHILBIN GOODWIN PROCTER LLP	COOKS INC - ZILVER PTX DRUG ELUTING PERIPHERAL STENT P100022 MINS, RVWS MEMOS, TELEPHONE MEMOS

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2013-3984	05/22/2013 06/20/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	MIMEDX GROUP INC - EIRS, 483S, UNTITLED LTRS 1/10 TO PRESENT
2013-3985	05/22/2013 06/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	ROBBI PERRY NORTH AMERICAN RESCUE LLC	COMBAT MEDICAL SYSTEMS LLC - COMBAT READY CLAMP K130482
2013-3986	05/22/2013 06/20/2013	FDA/OC/OES/DFOI/ OC/ORAO/OCI/ OC/ORAO/OCI/	BRANDON L. BOGLE LEVIN PAPANTONIO THOMAS ET AL	REPORTED VIOLATIONS OF 21 CFR 1/08 TO PRESENT
2013-3987	05/22/2013 06/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WOOSTER, ANNALEE	RETYLANE, RETYLANE-L - AERS 1/04 TO PRESENT
2013-3988	05/22/2013 06/20/2013	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORAO/ OC/ORAO/	NANCY WATZMAN SUNLIGHT FOUNDATION	CFSAN MTG MINS 1/4/11 TO 5/20/13
2013-3989	05/22/2013 06/20/2013	FDA/OC/OL/	NANCY WATZMAN SUNLIGHT FOUNDATION	CORR BETWEEN FDA & MEMBERS OF CONGRESS RE FOOD MODERNIZATION ACT 1/4/11 TO 5/20/13
2013-3990	05/22/2013 06/20/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARILEE KARTJE Teva Pharmaceuticals	STEVEN WEINMAN, LARRY AUSTIN - 483S 2012, 2013
2013-3991	05/23/2013 06/21/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firms available correspondence from January 1 2012 to July 31 2012 for: Alexion Pharmaceuticals, Smithfield, RI
2013-3992	05/23/2013	FDA/OGROP/ORANE-FO/NWE-	Angelia Slayton	A copy of the releasable inspection reports, 483s, and the firms

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	06/21/2013	DO/NWE-CB/	INC RESEARCH CONSULTING & SUBMISSIONS	available correspondence from January 1 2012 to July 31 2012 for: Abbott Laboratories, Worcester, MA
2013-3993	05/23/2013 06/21/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firms available correspondence from January 1 2012 to July 31 2012 for: AMAG Pharmaceuticals, Inc., Cambridge, MA
2013-3994	05/23/2013 06/21/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firms available correspondence from January 1 2012 to July 31 2012 for: Amgen Inc, West Greenwich, RI
2013-3995	05/23/2013 06/21/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firms available correspondence from January 1 2012 to July 31 2012 for: Amgen Inc, Woburn, MA
2013-3996	05/23/2013 06/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shalin Jani Aerie Pharmaceuticals Inc.	NDA 018086 - SBA
2013-3997	05/23/2013 06/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dan Hariharan PATRIN PHARMA INC	NDA 019452 - SBA
2013-3998	05/23/2013 06/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Cynthia S Gilbert Perfectly Legal Inc	PACLITAX - NOTICES, REPORTS, LETTERS ETC RE MISLABELING (01/01/2009 - 12/31/2012)
2013-3999	05/23/2013 06/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	Larry Hamilton THE PROMETHEUS GROUP OF NEW HAMPSHIRE LIMITED	K842514, K864690
2013-4000	05/23/2013 06/21/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Martin Robbins THE GUARDIAN	DR STANISLAW BURZYNSKI, HOUSTON, TX - INSPECTIONS, COMPLIANCE, ENFORCEMENT ETC (01/01/2003 - 05/31/2013)
2013-4001	05/23/2013 06/21/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Martin Robbins THE GUARDIAN	DR STANISLAW BURZYNSKI, BURZYNSKI RESEARCH INSTITUTE, BURZYNSKI CLINIC - INSPECTIONS, COMPLIANCE, ENFORCEMENT ETC (01/01/1987 - 12/31/2002)
2013-4002	05/23/2013 06/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	Allison Scott ANSON GROUP	K120033, K063692, K063740
2013-4003	05/23/2013 06/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	Scott R. Lambert EMORY UNIVERSITY	IDE G020021

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2013-4004	05/23/2013 06/21/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ayesha Adil The Weinberg Group	ANDA 90358
2013-4005	05/23/2013 06/21/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 203098
2013-4006	05/23/2013 06/21/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	JOHN WALSH JAMES ALEXANDER CORP	APLICARE INC, PRICHARD, WV - EIRS, 483S, RECALLS 5/11 TO PRESENT
2013-4007	05/23/2013 06/21/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	JOHN WALSH JAMES ALEXANDER CORP	MICROBIOLOGICAL CONSULTANTS INC, WEST VIRGINIA, WV - EIRS, 483S, RECALLS 4/11 TO PRESENT
2013-4008	05/23/2013 06/21/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	BENDA M GARTZ ELI LILLY & CO	FISHER BIOSERVICES, ROCKVILLE, MD - EIRS 2010 TO PRESENT
2013-4009	05/23/2013 06/21/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	BRENDA M GARTZ ELI LILLY & CO	TREK DIAGNOSTICS SYSTEMS (DBA THERMO FISHER SCIENTIFIC), SUN PRAIRIE, WI - 483S 2010 TO PRESENT
2013-4010	05/23/2013 06/21/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	BRENDA M GARTZ ELI LILLY & CO	TREK DIAGNOSTICS SYSTEMS INC (DBA THERMO FISHER SCIENTIFIC), SUN PRAIRIE, WI - EIRS 2010 TO PRESENT
2013-4011	05/23/2013 06/21/2013	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	FISHER CLINICAL SERVICES, GUJARAT, INDIA, ALLENTOWN, PA, BUENOS AIRES, ARGENTINA, ETC - EIRS 2010 TO PRESENT
2013-4012	05/23/2013 06/21/2013	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	FISHER CLINICAL SERVICES, GUJARAT, INDIA, ALLENTOWN, PA, BUENOS AIRES, ARGENTINA, ETC - 483S 2010 TO PRESENT

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2013-4013	05/23/2013 06/21/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	THEROMO FISHER SCIENTIFIC (FISHER SCIENTIFIC CO), FAIRPORT, NY, MIDDLETOWN, VA, SHANGHAI, CHINIA, ETC - 483S
2013-4014	05/23/2013 06/21/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	THERMO FISHER SCIENTIFIC (FISHER SCIENTIFIC CO), FAIRPORT, NY, MIDDLETOWN, VA, SHANGHAI, CHINA, ETC - EIRS 2010 TO PRESENT
2013-4015	05/23/2013 06/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	RICHARD HAY LAW OFC	ZIMMER - NATURAL NAIL SYS; CEPHALAMEDULARY FERORAL NAIL MDRS
2013-4016	05/23/2013 06/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	ROBBINS	TROVAGENE - HPV HIGH-RISK TEST GEN 1300246
2013-4017	05/23/2013	FDA/OMPT/CDER/ORP/DIDP/	ELENA HOWELL	PERRIGO ISRAEL - TESTOSTERONE APRVL PKG NDA 203-

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	06/21/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HOGAN LOVELLS LLP	098
2013-4018	05/23/2013 06/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	LORI COHEN GREENBERG TRAURIG LLP	SOFRADIM PRODUCTION - UGTEXMESH K033376; DAVOL INC (CR BARD INC) - COLLAMEND IMPLANT K052322; CR BARD INC - PELVISOFIT ACELLULAR COLLAGEN BIOMESH K031332, ETC
2013-4019	05/23/2013 06/21/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN W GETSINGER MEDTRONIC	ALLERGAN INC - BOTOX LAST FIVE YRS
2013-4020	05/23/2013 06/21/2013	FDA/OGROP/ORAC/CE-FO/DET-DO/DET-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANGELA E MCGRAW FLEISHMAN & SHAPIRO PC	MERCK & CO INC - INVANZ RECALL LTR
2013-4021	05/23/2013 06/21/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JENINIFER HSIEH DEERFIELD INSTITUTE	MANNKIND CORP - AFREZZA COMPLETE RESP LTRS
2013-4022	05/23/2013 06/21/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID HILZENRATH PROJECT ON GOVERNMENT OVERSIGHT	BOEHRINGER INGELHEIM - PRADAXA (DABIGATRAN) CORR
2013-4023	05/23/2013 06/21/2013	FDA/OFVM/CFSAN/OCD/EOS/	FATIMA ASLAM Keller and Heckman LLP	FRUITE JUICE, VEGTABLE JUICE - LTRS 1/94 TO PRESENT
2013-4024	05/23/2013 06/21/2013	FDA/OO/OIM/OPILS/FDAHO/	BYLER, LARIEA	ORAL HISTORY TRANS - DVD
2013-4025	05/23/2013 06/21/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	AMBIEN, AMBIEM CR - AERS
2013-4026	05/23/2013	FDA/OC/OES/DDM/	GEORGE O'BRIEN	DKT FDA-2013-P-0070

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	06/21/2013		HOGAN LOVELLS LLP	
2013-4027	05/24/2013 06/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Laura Bleyendaal DePuy Synthes Spine	K071922
2013-4028	05/24/2013 06/24/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Donna Stauffer TELA Bio, Inc.	K980431
2013-4029	05/24/2013 06/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Donna Stauffer TELA Bio, Inc.	K062697
2013-4030	05/24/2013 06/24/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Donna Stauffer TELA Bio, Inc.	K070560
2013-4031	05/24/2013 06/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Holly Imes MOOG MEDICAL DEVICES GROUP	K121613
2013-4032	05/24/2013 06/24/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firms available correspondence from January 1 2012 to July 31 2012 for: Cubist Pharmaceuticals, Lexington, MA
2013-4033	05/24/2013 06/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Joel Chic RGI Medical	INTAVENT LARYNGEAL MASK - 510K SUMMARY
2013-4034	05/24/2013 06/24/2013	FDA/OMPT/CTP/OD/	Ryan Meyer HAGENS BERMAN SOBOL SHAPIRO LLP	TOBACCO PRODUCT ANALYSIS: SCIENTIFIC PUBLIC WORKSHOP - TRANSCRIPT (04/01/2012 - 04/30/2012)
2013-4035	05/24/2013 06/24/2013	FDA/OC/OES/DFOI/	Jaime Vassallo LEXISNEXIS COURTLINK INC	2013-2157
2013-4036	05/24/2013 06/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jessica Sparks Lilley Vanderbilt Children's Hospital	STATIN THERAPY - AERS
2013-4037	05/24/2013 06/24/2013	FDA/OGROP/ORASE-FO/FLADO/FLA-CB/	Derek Auito MCKENNA LONG & ALDRIDGE LLP	RECALL D-1652-2012
2013-4038	05/24/2013 06/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Joshua M. Robinson Joshua M. Robinson	DR DURRAN - ADVERSE EVENTS
2013-4039	05/24/2013 06/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Robert Langreth BLOOMBERG NEWS	RESULTS OF MEDICAL PRODUCT SAFETY NETWORK SMALL SAMPLE SURVEY RE INTUITIVE DA VINCE SURGICAL SYSTEM
2013-4040	05/24/2013	FDA/OMPT/CDER/ORP/DIDP/	Lawrence W. Masten, PhD, DABT	PAXIL - AERS

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	06/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lawrence W. Masten, PhD, DABT	
2013-4041	05/24/2013 06/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Cynthia S Gilbert Perfectly Legal, Inc.	ZOMETA - NOTICES, REPORTS, LETTERS RE MISLABELING (01/01/2009 - 12/31/2012)
2013-4042	05/24/2013 06/24/2013	FDA/OFVM/CFSAN/OCD/EOS/	Amy Shipley Fort Lauderdale Sun Sentinel	PRO SUPPS HYDE, CELLUCOR C4 EXTREME, BSN N.O-XPLODE - AERS, WARNING LETERS (01/01/2010 - 05/15/2013)
2013-4043	05/24/2013 07/24/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Rachel Johnson FOI Services, Inc.	BLA 103649/5107
2013-4044	05/24/2013 06/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Cynthia S. Gilbert Perfectly Legal Inc	ELOXATIN - NOTICES, REPORTS, LETTERS RE MISLABELING (1/01/2009 - 12/31/2012)
2013-4045	05/24/2013 06/24/2013	FDA/OGROP/ORAP/PA-FO/LOS- DO/LOS-CB/	David Shaw SHAW, DAVID	ST JUDE MEDICAL IESD UPDATE REPORT TO WARNING LETTER AND 483 RESPONSES (04/14/2013 - 05/22/2013)
2013-4046	05/24/2013 06/24/2013	FDA/OGROP/ORAP/PA-FO/SAN- DO/SAN-CB/	Matt Mezvinsky Ridgeback Capital Management, LLC	GILEAD, FOSTER CITY, CA - 483, WARNING LETTER (01/01/2012 - 05/22/2013)
2013-4047	05/24/2013 06/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michele Sinoway LACHMAN CONSULTANT SERVICES INC	ANDA 062-737, 061-490, ANDA 062-738, 061, ANDA 062-901 ETC - LABELING
2013-4048	05/24/2013 06/24/2013	FDA/OGROP/ORAP/NE-FO/NWE- DO/NWE-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Chris Lewis Scion Medical Technologies, LLC	ACCESS CARDIOSYSTEMS Z-0199-05, Z-0203-05, Z-0201-05 ETC - RECALL CORR
2013-4049	05/24/2013 06/24/2013	FDA/OGROP/ORAP/CE-FO/PHI- DO/PHI-CB/	Dan Michaeli Sirona Dental Systems, Inc.	IMAGING SCIENCES I-CAT FLX SCANNER - CONSUMER COMPLAINT RECS
2013-4050	05/24/2013 06/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	George Kontos SPK	CERVICORE INTERVERTEBRAL DISC - CLINICAL TRIAL RECS
2013-4051	05/24/2013 06/24/2013	FDA/OGROP/ORAP/SE-FO/FLA- DO/FLA-CB/	Michael Scott Cognate BioServices, Inc.	CURASCRIPT SD, LAKE MARY, FL - FOLLOW UP INSPECTION TO WARNING LETTER

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2013-4052	05/24/2013 06/24/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Lisa Torkelson Old Country Farms Co-op	CLOVERLEAF BRAND MUENSTER - DESTRUCTION RECS (4/20/2013 - 05/20/2013)
2013-4053	05/24/2013 06/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Scott Groner TRIS PHARMA INC	HYCODAN - APPROVAL RECS
2013-4054	05/24/2013 06/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Richard Wiard PhysioWave Inc.	ATCOR MEDICAL XCEL PWA/PWV - 510K
2013-4055	05/24/2013 06/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Beau Bassett Pura Vida Investments	JETREA - AERS
2013-4056	05/24/2013 06/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dustin Block IPD Analytics, LLC	ANDA 202571 - EFFECTIVE APPROVAL LETTER
2013-4057	05/24/2013 06/24/2013	FDA/OC/OES/DDM/	CARLA SCARMAZZI KING & SPALDING	DKT FDA-2013-N-0227
2013-4058	05/24/2013 06/24/2013	FDA/OC/OES/DDM/	MERLE ZIMMERMANN AMERICAN HERBAL PRODUCTS ASSOCIATION	DKT FDA-2012-S-1178, FDA-2013-S-0023
2013-4059	05/24/2013 06/24/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	WALTER E. CHALKLEY THOMSON REUTERS	CSL BEHRING, BERN SWITZERLAND - EIR, 483, CO RESP 2/12
2013-4060	05/24/2013 06/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	NOVO NORDISK A/S. SOEBORD, DENMARK - 483, EIR, CO RESP 5/12
2013-4061	05/24/2013 06/24/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	WALTER E. CHALKLEY THOMSON REUTERS	TEVA PHARMACEUTICALS USA INC, MEXICO, MO - 483, EIR, CO RESP 2/12
2013-4062	05/24/2013 06/24/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	WALTER E. CHALKLEY THOMSON REUTERS	NOVARTIS VACCINE & DIAGNOSTICS INC, EMERYVILLE, CA - EIR, 483, CO RESP 3/12
2013-4063	05/24/2013 06/24/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	WALTER E. CHALKLEY THOMSON REUTERS	MALLINCKRODT INC, MARYLAND HEIGHTS, MO - EIR, 483, CO RESP 8/12

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2013-4064	05/24/2013 08/28/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	WALTNER E. CHALKLEY THOMSON REUTERS	FRESENIUS MEDICAL CARE, OGDEN, UT - EIR, 483, CO RESP
2013-4065	05/24/2013 06/24/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER CHALKLEY THOMSON REUTERS	BRISTOL MYERS SQUIBB, PRINCETON, NJ - EIR, 483, CO RESP 1/12
2013-4066	05/24/2013 07/09/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	WALTER E. CHALKLEY THOMSON REUTERS	MCLAREN HEALTH CARE IRB, BURTON, MI - EIR, 483, CO RESP 7/12
2013-4067	05/24/2013 06/24/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	WALTER E. CHALKLEY THOMSON REUTERS	JOHN O FLEMING MD, MADISON, WI - EIR, 483, CO RESP 6/12
2013-4068	05/24/2013 06/27/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E. CHALKLEY THOMSON REUTERS	DAVA PHARMACEUTICALS INC, FORT LEE, NJ - EIR, 483, CO RESP 7/12
2013-4069	05/24/2013 06/24/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	WALTER E. CHALKLEY THOMSON REUTERS	MYLAN PHARMACEUTICALS INC, MORGANTOWN, WV - EIR, 483, CO RESP 7/12
2013-4070	05/24/2013 06/24/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	WALTER E. CHALKLEY THOMSON REUTERS	ALEXION PHARMACEUTICALS INC, CHESHIRE, CT - EIR, 483, CO RESP 8/12
2013-4071	05/24/2013 06/24/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	WALTER E. CHALKLEY THOMSON REUTERS	SANOFI PASTEUR INC, SWIFTWATER, PA - EIR, 483, CO RESP 8/12
2013-4072	05/24/2013 06/24/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E. CHALKLEY THOMSON REUTERS	MERCK & CO, SPRINGFIELD, NJ - EIR, 483, CO RESP 5/12
2013-4073	05/24/2013 06/24/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	WALTER E. CHALKLEY THOMSON REUTERS	AMERICAN NATIONAL RED CROSS, FAIRFAX, VA - EIR, 483, CO RESP 3/12
2013-4074	05/24/2013 06/24/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	WALTER E. CHALKLEY THOMSON REUTERS	INDICUS PHARMA LLC, RALEIGH, NC - EIR, 483, CO RESP 9/12
2013-4075	05/24/2013 06/26/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	WALTER E. CHALKLEY THOMSON REUTERS	CARDINAL HEALTH LLC, LAS VEGAS, NV - EIR, 483, CO RESP 9/12
2013-4076	05/24/2013 06/24/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	WALTER E. CHALKLEY THOMSON REUTERS	BAXTER PHARMACEUTICALS SOLUTIONS, BLOOMINGTON, IN - EIR, 483, CO RESP 9/12
2013-4077	05/24/2013 06/24/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	WALTER E. CHALKLEY THOMSON REUTERS	ALL AMERICAN WELDING SUPPLY INC, PLYMOUTH, IN - EIR, 483, CO RESP 9/12
2013-4078	05/24/2013 06/24/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	WALTER E. CHALKLEY THOMSON REUTERS	AIRGAS USA LLC, DALLAS, TX - EIR, 483, CO RESP 9/12
2013-4079	05/27/2013 06/24/2013	OC/CVM/OCD/ FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Tom Amoss Tom amoss	AHC PRODUCTS, WINCHESTER, KY - INSPECTION RECORDS, ADVERSE EVENTS (12/01/2011 - 05/22/2013)

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2013-4080	05/27/2013 06/24/2013	FDA/OGROP/ORPA/FO/SAN-DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Robert Langreth BLOOMBERG NEWS	CORR BETWEEN FDA AND INTUITIVE SURGICAL RE JAN 2013 MEDICAL PRODUCT SAFETY NETWORK SMALL SAMPLE SURVEY RE DA VINCE SURGICAL SYSTEM ETC
2013-4081	05/27/2013 06/24/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CDRH/OCER/DFOI/	David Shaw SHAW, DAVID	ST JUDE MEDICAL - CORR, RESPONSES TO 6/26/09 WARNING LETTER FOR NEUROMODULATION DIVISION AND FACILITIES IN PLANO, TX AND HACKETTSTOWN, NJ
2013-4082	05/27/2013 06/24/2013	FDA/OC/OES/DDM/ FDA/OFVM/CFSAN/OCD/EOS/	Joshua Valero Capstone Law APC	MOTT'S LLP NUTRIENT CLAIM PETITIONS (05/23/2008 - 05/23/2013)
2013-4083	05/27/2013 06/24/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kip Nelson SMITH MOORE LEATHERWOOD LLP	NESHER PHARMACEUTICALS - FIELD ALERT RECS, MEETING RECS, 483 (01/01/2010 - 05/23/2013)
2013-4084	05/28/2013 06/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bao Le ARIAD Pharmaceuticals, Inc	ICLUSIG - VOLUNTARY DIRECT REPORTS
2013-4085	05/28/2013 06/25/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firms available correspondence from January 1 2012 to July 31 2012 for: AstraZeneca Pharmaceuticals LP, Westborough, MA
2013-4086	05/28/2013 06/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Tom J Healy VITALOGRAPH (IRELAND) LTD	VITALOGRAPH - EIR (09/12/2011 - 09/16/2011)
2013-4087	05/28/2013 06/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA20427
2013-4088	05/28/2013 06/25/2013	OC/ORAA/ORM/ OC/ORAA/ORM/	Jason DeYoung DeYoung, Jason	HOSPITALS INSPECTED IN MI, IN, OH (05/04/2010 - 05/23/2013)
2013-4089	05/28/2013 06/25/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firms available correspondence from January 1 2012 to July 31 2012 for: Alexion Pharmaceuticals, Cheshire, CT
2013-4090	05/28/2013	FDA/OGROP/ORANE-FO/NWE-	Angelia Slayton	A copy of the releasable inspection reports, 483s, and the firms

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	06/25/2013	DO/NWE-CB/	INC RESEARCH CONSULTING & SUBMISSIONS	available correspondence from January 1 2012 to July 31 2012 for: Bristol-Meyers-Squibb, Devens, MA
2013-4091	05/28/2013 06/25/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firms available correspondence from January 1 2012 to July 31 2012 for: Biogen Idec, Cambridge, MA
2013-4092	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	Desmond Jenson Tobacco Control Legal Consortium	CTP FOIA REQUEST LOG 06/22/2009 - 05/24/2013
2013-4093	05/28/2013 06/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K121174
2013-4094	05/28/2013 06/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K102003
2013-4095	05/28/2013 06/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORAO/RO/DIOP/	Bowman Cox Elsevier Business Intelligence	HOSPIRA HEALTHCARE INDIA - CORR RE ADDITIONAL AND REMOVAL OF PRODUCTS (01/01/2012 - 05/24/2013)
2013-4096	05/28/2013 06/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K121943
2013-4097	05/28/2013 06/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kevin Johnston Johnston, Kevin	NDA 201922 - SBA
2013-4098	05/28/2013 06/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Natalie Morrison BIOPHARM INSIGHT	ASTRAZENICA, MACCLESFIELD - 483, RESPONSE MARCH 2012
2013-4099	05/28/2013 06/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Gloria Reyes Gloria Reyes International Journalism	NDA 020240
2013-4100	05/28/2013 06/25/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	BTran Tran Associates	K122356
2013-4101	05/28/2013 06/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Gloria Reyes Gloria Reyes International	NDA 019886

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Journalism	
2013-4102	05/28/2013 06/25/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	BTran Tran & Associates	K090363
2013-4103	05/28/2013 06/25/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/	Wang Tangshan Huiyuan Food Co., Ltd.	TANGSHAN HUIYUAN FOOD CO LTD, CHINA - IMPORT INFORMATION
2013-4104	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	Christopher Brennan WESTLAW COURT EXPRESS	RECORDS PROVIDED TO KATHERINE EBAN RE DIRTY MEDICINE
2013-4105	05/28/2013 06/25/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDRH/OCER/DFOI/ OC/ORO/ OC/ORO/ FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/	Richard Chun the Wood Burditt group	M50-0271820-8, M50-0281400-7 - CFSAN RECORDS
2013-4106	05/28/2013 06/25/2013	FDA/OGROP/ORO/CE-FO/NWJ-DO/NWJ-CB/	Richard Wilson Hartford Steam Boiler Inspection & Insurance Co	ROYAL FOOD DISTRIBUTORS, HEIGHTSTOWN, NJ - CONDEMNATION RECS (04/01/2012 - 06/30/2012)
2013-4107	05/28/2013 06/25/2013	FDA/OGROP/ORO/CE-FO/NWJ-DO/NWJ-CB/	Lauren DePompei Ben Venue Laboratories	WELCH, HOLME AND CLARK, NEWARK, NJ - EIR (10/01/2010 - 01/01/2011)
2013-4108	05/28/2013 06/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K112506
2013-4109	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOGS 4/29/13-5/3/13
2013-4110	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 4/29/13-5/3/13
2013-4111	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOGS 5/6-10/13
2013-4112	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 5/6-10/13
2013-4113	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 4/29/13-5/3/13
2013-4114	05/28/2013	FDA/OC/OES/DFOI/		CLOSED FOIA REQUESTS 4/29/13-5/3/13

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	06/25/2013		WOLTERS KLUWER LAW & BUSINESS	
2013-4115	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 5/6-10/13
2013-4116	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 5/6-10/13
2013-4117	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 4/29/13-5/3/13
2013-4118	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 5/6-10/13
2013-4119	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 5/6-10/13
2013-4120	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 4/29/13-5/3/13
2013-4121	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 4/29/13-5/3/13
2013-4122	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 5/6-10/13
2013-4123	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 5/6-10/13
2013-4124	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 4/29/13-5/3/13
2013-4125	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIRA REQUESTS 5/6-10/13
2013-4126	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 4/29/13-5/3/13
2013-4127	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 4/29/13-5/3/13
2013-4128	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 5/6-10/13
2013-4129	05/28/2013 06/25/2013	FDA/OC/OES/DDM/ FDA/OFVM/CFSAN/OCD/EOS/	MITCHELL S FUERST ESQ FUERST ITTLEMAN PL	DKT 1996N-0050, ADVANCED NOTICE OF PROPOSED RULEMAKING FOR THE REGULATION OF MEDICAL FOODS, ETC

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2013-4130	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	GLADYS B TONKIN WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 4/29/13-5/3/13
2013-4131	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	GLADYS B TONKIN WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 5/6-10/13
2013-4132	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 4/29/13-5/3/13
2013-4133	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	KLEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 5/6-10/13
2013-4134	05/28/2013 06/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	HOLLY RAMIREZ BOSTON SCIENTIFIC CORP	BOSTON SCIENTIFIC CORP - RIO ASPIRATION CATHETER K051880
2013-4135	05/28/2013 07/11/2013	FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/	KEVIN H KONO DAVIS WRIGHT TREMAINE LLP	MOON MARINE, CUPERTINO, CA - EIR 4/16/12-5/8/12
2013-4136	05/28/2013 06/25/2013	FDA/OFVM/CFSAN/OCD/EOS/	LA TOYA SUTTON MANATT PHELPS & PHILLIPS LLP	DEHYDRATED BEET (BEET POWDER) AND TUMERIC - RECS
2013-4137	05/28/2013 06/25/2013	FDA/OGROP/ORO/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	ANTOON, DAVID	INTUITIVE SURGICAL INC - ROBOTIC DA VINCI DVC INVESTIGATION, CLEVELAND CLINIC FOUNDATION SURGERY FINDINGS
2013-4138	05/28/2013 06/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ROBERT POLLOCK LACHMAN CONSULTANT SERVICES INC	ARGENT, NEXGEN, MANCHESTER PHARMS - INVERSINE (MECAMYLAMINE HCL) NDA 10-251 RECS, MEDICAL NECESSITY
2013-4139	05/28/2013 06/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PETER S REICHERTZ SHEPPARD MULLIN RICHTER & HAMPTON	VASOPRESSIN INJ - AERS
2013-4140	05/28/2013 06/25/2013	FDA/OFVM/CFSAN/OCD/EOS/	IOVATE HEALTH SCIENCES RESEARCH INC	CAERS 153519, 158001

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2013-4141	05/28/2013 06/25/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	ANDRENE HERON Roche Diagnostics Operations, Inc.	ACCU-CHEK COMBO K111353, ACCU-CHEK INFORM II K121679, ACCU-CHEK NANO SMARTVIEW SYS K113131, ETC
2013-4142	05/28/2013 06/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	ANGIE BEYER AIRLIQUIDE	AGA LINDE HEALTHCARE - MEDICYL-E-LITE PORTABLE OXYGEN SYS K033897
2013-4143	05/28/2013 06/25/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	WALTER E CHALKLEY THOMSON REUTERS	DANIEL M SULLIVAN MD, MELISSA ALSINA MD, H LEE MOFFITT CANCER CENTER AND RESEARCH INSTITUTE, TAMPA, FL - EIR, 483, CO RESP 8/04
2013-4144	05/28/2013 06/25/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	WALTER E CHALKLEY THOMSON REUTERS	HUSSAIN I SABA MD, H LEE MOFFITT CANCER CENTER AND RESEARCH INSTITUTE, TAMPA, FL - EIR, 483, CO RESP 2/06
2013-4145	05/28/2013 06/25/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	WALTER E CHALKLEY THOMSON REUTERS	HUSSAIN I SABA MD, H LEE MOFFITT CANCER CENTER AND RESEARCH INSTITUTE, TAMPA, FL - EIR, 483, CO RESP 5/05
2013-4146	05/28/2013 06/25/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	WALTER E CHALKLEY THOMSON REUTERS	VERNON K SONDAK MD, H LEE MOFFITT CANCER CENTER AND RESEARCH INSTITUTE, TAMPA, FL - EIR, 483, CO RESP 10/11
2013-4147	05/28/2013 06/25/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	WALTER E CHALKLEY THOMSON REUTERS	JAVIER PINILA-IBARZ, H LEE MOFFITT CANCER CENTER AND RESEARCH INSTITUTE, TAMPA, FL - EIR, 483, CO RESP 9/12
2013-4148	05/28/2013 06/25/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	JOHN WALSH JAMES ALEXANDER CORP	STERIS ISOMEDIX SERVICES INC, SOUTH PLAINFIELD, NJ - EIRS, 483S, RECALL RECS 5/11 TO PRESENT
2013-4149	05/28/2013 06/25/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	JOHN WALSH JAMES ALEXANDER CORP	PLASTICS TECHNOLOGY LABORATORIES INC, PITTSFIELD, MA - EIRS, 483S, RECALL RECS 5/11 TO PRESENT
2013-4150	05/28/2013 06/25/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	JOHN WALSH JAMES ALEXANDER CORP	MOCON INC, MINNEAPOLIS, MN - EIRS, 483S, RECALL RECS 5/11 TO PRESENT
2013-4151	05/28/2013 06/25/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	JOHN WALSH JAMES ALEXANDER CORP	GILBRALTAR LABS, FAIRFIELD, NJ - EIRS, 483S, RECALL RECS 5/11 TO PRESENT
2013-4152	05/28/2013 06/25/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	JOHN WALSH JAMES ALEXANDER CORP	WHITEHOUSE ANALYTICAL LABS, WHITEHOUSE, NJ - EIRS, 483S, RECALL RECS 10/08 TO PRESENT
2013-4153	05/28/2013 06/25/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	JOHN WALSH JAMES ALEXANDER CORP	WHITEHOUSE ANALYTICAL LABS, WHITEHOUSE, NJ - EIRS, 483S, RECALL RECS 5/11 TO PRESENT
2013-4154	05/28/2013 06/25/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	JOHN WALSH JAMES ALEXANDER CORP	OLIVER-TOLAS HEALTHCARE PACKAGING, FEASTERVILLE, PA - EIRS, 483S, RECALL RECS 5/11 TO PRESENT

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2013-4155	05/28/2013 06/25/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	JOHN WALSH JAMES ALEXANDER CORP	MIDWEST FILTRATION CO, CINCINNATI, OH - EIRS, 483S, RECALL RECS 5/11 TO PRESENT
2013-4156	05/28/2013 06/25/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	JOHN WALSH JAMES ALEXANDER CORP	UFP TECHNOLOGIES, DENVER, CO - EIRS, 483S, RECALL RECS 5/11 TO PRESENT
2013-4157	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA REQUEST LOG (5/20/2013 - 5/24/2013)
2013-4158	05/29/2013 06/26/2013	FDA/OC/OES/DDM/	GEORGE O'BRIEN HOGAN LOVELLS LLP	DKT FDA-2013-P-0471
2013-4159	05/29/2013 06/26/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firms available correspondence from January 1 2012 to July 31 2012 for: Genzyme, Northborough, MA
2013-4160	05/29/2013 06/26/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firms available correspondence from January 1 2012 to July 31 2012 for: Genzyme Science Center, Framingham, MA
2013-4161	05/29/2013 06/26/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firms available correspondence from January 1 2012 to July 31 2012 for: Genzyme, Allston, MA
2013-4162	05/29/2013 06/26/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firms available correspondence from January 1 2012 to July 31 2012 for: Genzyme, Cambridge, MA
2013-4163	05/29/2013 06/26/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	Kenneth Lum Seafood Products Association	LABORATORY REPORT 803495
2013-4164	05/29/2013 06/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	B. burgess BURGESS, BERNIE	TRANSCRIPT OF TELEPHONE CALL 1/24/07 FROM DAN-MY CHU RE COMPLAINT
2013-4165	05/29/2013 06/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	HILLUSA CORPORATION HILLUSA CORPORATION	K940975
2013-4166	05/29/2013 06/26/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDER/ORP/DIDP/	Tom Standifer Self	HAAS PHARMACEUTICALS, LLC - INSPECTIONS, FILINGS, APPLICATIONS ETC (01/01/1985 - 05/28/2013)

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2013-4167	05/29/2013 06/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Saagar Patel Whitney Medical Solutions	K820692
2013-4168	05/29/2013 06/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kim Thorson Medical Products Laboratories, Inc.	K040098
2013-4169	05/29/2013 06/26/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	Steve Schroeder Schroeder Law	EVANGER'S DOG AND CAT FOOD, WHEELING, IL - ALL RECS (01/01/2010 - 05/28/2013)
2013-4170	05/29/2013 06/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kristin Hinton METHAPHARM INC	FAERS REPORTS
2013-4171	05/29/2013 06/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sean Stewart Concordia University Wisconsin School of Pharmacy	STATINS - CASE REPORTS
2013-4172	05/29/2013 06/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	B. Burgess B. Burgess	INTERNAL MEMO OR CONSULT REFERENCED IN LETTER FROM MS AUTOR
2013-4173	05/29/2013 06/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kirsty Barnes BIOPHARM INSIGHT	WOCKHARDT LIMITED, AURANGABAD - 483, WARNING LETTER
2013-4174	05/29/2013 06/26/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/NE-FO/NWE-	Kirsty Barnes BIOPHARM INSIGHT	EXEMPLAR - 483, WARNING LETTER

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		DO/NWE-CB/		
2013-4175	05/29/2013 06/26/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7948
2013-4176	05/29/2013 06/26/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2554 - REQUEST LETTER ONLY
2013-4177	05/29/2013 06/26/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2842 - REQUEST LETTER ONLY
2013-4178	05/29/2013 06/26/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3447 - REQUEST LETTER ONLY
2013-4179	05/29/2013 06/26/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2987 - REQUEST LETTER ONLY
2013-4180	05/29/2013 06/26/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3068 - REQUEST LETTER ONLY
2013-4181	05/29/2013 06/26/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3003 - REQUEST LETTER ONLY
2013-4182	05/29/2013 06/26/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3182 - REQUEST LETTER ONLY
2013-4183	05/29/2013 06/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	KILPATRICK, PETE	BIO-MEDICAL RESEARCH LTD, WEST GALWAY, REPUBLIC OF IRELAND - NEURO TECH TYPE 410 K024258
2013-4184	05/29/2013 06/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	KATHY A STETTS KEMP JONES & L COULTHARD	SUNRISE HOSPITAL & MEDICAL CENTER, LAS VEGAS, NV - MDRS, LTRS, RECALLS, ETC 1/1/09 TO 12/31/10
2013-4185	05/29/2013 06/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MICHAELE K POWERS BRASSEL ALEXANDER & RICE LLC	JOHN HOPKINS MEDICINE - PHARMACODYNAMIC TRIAL OF PRE-PROSTATECTOMY LOVASTATIN IND, AMENDMENTS, MINS, ETC
2013-4186	05/29/2013 06/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DDM/	CATHERINE M DICKENSON BRYAN CAVE LLP	DKT 2007P-0190
2013-4187	05/29/2013 06/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	VETTER, RAVENSBURG, SCHUENTZENTRASSE, GERMANY - EIRS 10/29/12-11/9/12

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		FDA/OMPT/CDER/ORP/DIDP/		
2013-4188	05/29/2013 06/26/2013	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	BJIAN ESFANDIARI BAUM HEDLUND PC	POMONA VALLEY HOSPITAL MEDICAL CENTER - DRAFT & FINAL RPT, NOTES, VIOLATIONS, ETC 9/24/12
2013-4189	05/29/2013 06/26/2013	OC/ORAP/ORM/ OC/ORAP/ORM/	DAVID P JORDAN THOMSON REUTERS	LIST OF FOREIGN & DOMESTIC INSP 10/12 TO PRESENT
2013-4190	05/29/2013 06/26/2013	OC/CVM/OCD/	AMI V GADHIA CONSUMERS UNION	NARMS RETAIL MEAT PROGRAM - LABEL CLAIMS 1/03 TO 2011
2013-4191	05/29/2013 06/26/2013	FDA/OC/OES/DFOI/	ANNE WEISMANN CITIZENS FOR RESPONSIBILITY & ETHICS IN WASHINGTON	COST OF EACH TRIP & COST OF TRAVEL BY FDA EMPLOYEE - RECS 10/12 TO PRESENT
2013-4192	05/30/2013 06/27/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	SARAH KARLIN ELSEVIER PINK SHEET	MCFI REGULATORY SYMPOSIUM - LESSONS LEARNED FROM H1N1 TO ENHANCE TODAY'S PANDEMIC INFLUENZA VACCINE PREPAREDNESS SLIDE PRESENTATION 5/29/13
2013-4193	05/30/2013 06/27/2013	FDA/OMPT/CDRH/OCER/DFOI/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	5N PLUS LUBECK GMBH, LUBECK, GERMANY - EIR, 483, CO RESP 7/12
2013-4194	05/30/2013 07/25/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	WALTER E CHALKLEY THOMSON REUTERS	COMMONWEALTH SERUM LABORATORIES (CSL) LTD, PARKVILLE, AUSTRALIA - EIR, 483, CO RESP 4/22
2013-4195	05/30/2013 06/27/2013	FDA/OGROP/ORAP/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	WALTER E CHALKLEY THOMSON REUTERS	220 LABORATORIES INC, RIVERSIDE, CA - EIR, 483, CO RESP 6/12
2013-4196	05/30/2013 06/27/2013	FDA/OGROP/ORAP/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	WALTER E CHALKLEY THOMSON REUTERS	21ST CENTURY ONCOLOGY INC, NAPLES, FL - EIR, 483, CO RESP 4/12
2013-4197	05/30/2013 06/27/2013	FDA/OGROP/ORAP/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	WALTER E CHALKLEY THOMSON REUTERS	21ST CENTURY ONCOLOGY INC, PORT CHARLOTTE, FL - EIR, 483, CO RESP 4/12
2013-4198	05/30/2013 06/27/2013	FDA/OGROP/ORAP/SW-FO/KAN-DO/KAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	AAI PHARMA ANALYTICAL SERVICES ST LOUIS INC, AFFTON, MO - EIR, 483, CO RESP 2/12
2013-4199	05/30/2013 06/27/2013	FDA/OGROP/ORAP/CE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	AAI PHARMA SERVICES, EDISON, NJ - EIR, 483, CO RESP 3/12
2013-4200	05/30/2013 06/27/2013	FDA/OGROP/ORAP/SE-FO/ATL-DO/ATL-CB/	WALTER E CHALKLEY THOMSON REUTERS	AAI PHARMA SERVICES, WILMINGTON, NC - EIR, 483, CO RESP 3/12
2013-4201	05/30/2013	FDA/OGROP/ORAP/PA-FO/SAN-	WALTER E CHALKLEY	AARON INDUSTRIES INC, LYNWOOD, CA - EIR, 483, CO

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	06/27/2013	DO/SAN-CB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	THOMSON REUTERS	RESP 4/12
2013-4202	05/30/2013 06/27/2013	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	WALTER E CHALKLEY THOMSON REUTERS	ABBOTT BIOTECHNOLOGY LTD, BARCELONETA, PR - EIR, 483, CO RESP 7/12
2013-4203	05/30/2013 06/27/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	ACCELERATED ANALYTICAL LABORATORIES INC, MILWAUKEE, WI - EIR, 483, CO RESP 6/12
2013-4204	05/30/2013 06/27/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	ACTAVIS ELIZABETH LLC, ELIZABETH, NJ - EIR, 483, CO RESP 1/12
2013-4205	05/30/2013 06/27/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	WALTER E CHALKLEY THOMSON REUTERS	ADVANCED APOTHECARIES INC, FORT SMITH, AR - EIR, 483, CO RESP 1/12
2013-4206	05/30/2013 06/27/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	ANTIGEN LABORATORIES-COLUMBUS, COLUMBUS, OH - EIR, 483, CO RESP 6/12
2013-4207	05/30/2013 06/27/2013	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	CSL PLASMA, DECATUR, IL - EIR, 483, CO RESP 3/12
2013-4208	05/30/2013 06/27/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	CSL PLASMA, COLUMBUS, OH - EIR, 483, CO RESP 8/12
2013-4209	05/30/2013 06/27/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	CSL PLASMA INC, LAWRENCE, KS - EIR, 483, CO RESP 2/12
2013-4210	05/30/2013 06/27/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	WALTER E CHALKLEY THOMSON REUTERS	CSL PLASMA INC, ALBUQUERQUE, NM - EIR, 483, CO RESP 6/12
2013-4211	05/30/2013 06/27/2013	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	WALTER E CHALKLEY THOMSON REUTERS	CSL PLASMA INC, PORTLAND, OR - EIR, 483, CO RESP 1/12
2013-4212	05/30/2013 06/27/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	WALTER E CHALKLEY THOMSON REUTERS	DANIEL J MERENSTEIN MD, WASHINGTON, DC - EIR, 483,CO RESP 3/12
2013-4213	05/30/2013 06/27/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	WALTER E CHALKLEY THOMSON REUTERS	DENNIS S RIFF MD, ANAHEIM, CA - EIR, 483,CO RESP 8/12
2013-4214	05/31/2013 06/28/2013	FDA/OMPT/CTP/OD/	Desmond Jenson Tobacco Control Legal Consortium	GRANDFATHERED TOBACCO PRODUCT STATUS DETERMINATION - CORR, SUMMARIES RE REYNOLDS AMERICAN OR RJ REYNOLDS TOBACCO CO
2013-4215	05/31/2013 06/28/2013	FDA/OMPT/CTP/OD/	Desmond Jenson Tobacco Control Legal Consortium	LIST OF SUBSTANTIAL EQUIVALENCE APPLICATIONS SUBMITTED BY REYNOLDS AMERICAN OR RJ REYNOLDS TOBACCO CO (06/22/2009 - 05/29/2013)

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2013-4216	05/31/2013 06/28/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Thomas Valentine Elekta Inc.	K111106, K061140, K102650, ETC
2013-4217	05/31/2013 06/28/2013	FDA/OC/OES/DFOI/	Megan Pickel Beveridge & Diamond, PC	CFSAN FOIA REQUESTS 04/30/2013 TO PRESENT
2013-4218	05/31/2013 06/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Joshua A. Malamud Hyman, Phelps & McNamara P.C.	PS100006 - RESPONSE TO SECTION 522 REQUEST DATED 7/21/2010
2013-4219	05/31/2013 06/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Carol Schmidt Seattle Genetics, Inc.	IBRUTINIB MANTLE CELL LYMPHOMA - BREAKTHROUGH THERAPY APPLICATION AND CORR
2013-4220	05/31/2013 06/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Art Rankis Art Rankis	K973741
2013-4221	05/31/2013 06/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mani Krishnan EMD Millipore Corporation	DMF 24055
2013-4222	05/31/2013 07/29/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Art Rankis Art Rankis	BK020043
2013-4223	05/31/2013 06/28/2013	FDA/OO/OFBA/OAGS/	Rose Santos FOIA Group, Inc.	HHSF223200830014I MONTHLY REPORTS, ANNUAL REPORTS
2013-4224	05/31/2013 06/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANDA 074110 Arrastia, Capote & Phang, LLP	ANDA 074110
2013-4225	05/31/2013 06/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANDA 087639 Arrastia, Capote & Phang, LLP	ANDA 087639
2013-4226	05/31/2013 06/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANDA 074106 Arrastia, Capote & Phang, LLP	ANDA 074106
2013-4227	05/31/2013	FDA/OMPT/CDER/ORP/DIDP/	ANDA 087632	ANDA 087632

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	06/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Arrastia, Capote & Phang, LLP	
2013-4228	05/31/2013 06/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	8664812 8679576 8702172 ETC
2013-4229	05/31/2013 06/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	8663616 8709294 8724649 ETC
2013-4230	05/31/2013 06/28/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Indeep Aulak Response Point of Care Inc.	K100130
2013-4231	05/31/2013 06/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	DIRECT REPORTS, MEDWATCH REPORTS, SOURCE DOCUMENTS 8715487
2013-4232	05/31/2013 07/03/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Anne Myers Kaufman Dolowich Voluck LLP	SYNTHES USA - CORR WITH FDA RE FAILURE TO ABIDE BY CORPORATE INTEGRITY AGREEMENT
2013-4233	05/31/2013 06/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joshua Malamud Hyman, Phelps & McNamara, P.C.	NDA 021998 S002 - SBA
2013-4234	05/31/2013 06/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	DIRECT REPORTS, MEDWATCH REPORTS, ANY SOURCE - 8697566 8746664
2013-4235	05/31/2013 06/28/2013	OC/CVM/OCD/ FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Tom Amoss Tom amoss	AHC PRODUCTS - INSPECTIONS, ADVERSE EVENTS 2011 TO PRESENT
2013-4236	05/31/2013 06/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	J.D. Webb The OrthoMedix Group, Inc.	K112470
2013-4237	05/31/2013	FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16)	DIRECT REPORTS, MEDWATCH REPORTS, ANY SOURCE

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	06/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MERCK & CO., INC.	DOCUMENTS 8746477
2013-4238	05/31/2013 06/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kristine Kim Neurocrine Biosciences, Inc.	NDA 21894
2013-4239	05/31/2013 07/03/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	Anne Myers Kaufman Dolowich Voluck LLP	SYNTHES USA - CORR RE WARNING LETTER (04/02/2012 - 05/29/2013)
2013-4240	05/31/2013 06/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mani Krishnan EMD Millipore Corporation	DMF 3557, DMF 3561, DMF 9831 ETC
2013-4241	05/31/2013 07/03/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Anne Myers Kaufman Dolowich Voluck LLP	SYNTHES USA - CORR WITH FDA EXCLUDING MAUDE REPORTS RE SCREWS, GUIDEWIRES, DRILL BITS (04/01/2012 - 05/28/2013)
2013-4242	05/31/2013 06/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	DIRECT REPORTS, MEDWATCH REPORTS, ANY SOURCE DOCUMENTS 8713701 8750425
2013-4243	05/31/2013 06/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANDA 087617 Arrastia, Capote & Phang, LLP	ANDA 087617
2013-4244	05/31/2013 06/28/2013	FDA/OC/OES/DDM/	Desmond Jenson Tobacco Control Legal Consortium	FDA-2013-N-0227 - COMMENTS TO DOCKET
2013-4245	05/31/2013 06/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K121710
2013-4246	05/31/2013 06/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Melissa Whalen Hutton & Hutton Law Office	INDIVIDUAL RECS
2013-4247	05/31/2013 06/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANDA 088856 Arrastia, Capote & Phang, LLP	ANDA 088856

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-4248	05/31/2013 06/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	THOMAS P VALET ESQ RHEINGOLD, VALET, ET AL	HEALTHCARE PROFESSIONAL SHEET, FDA ALERT - ORAL SODIUM PHOSPHATE (OSP) PRODUCTS FOR BOWEL CLEANSING
2013-4249	05/31/2013 06/28/2013	FDA/OO/OFBA/OAGS/	FRANK J CHILLI CENTURION RESEARCH SOLUTIONS	AQUILENT - TASK ORDER HHSF223201210959G AWARDED UNDER CONTRACT GS35F472G
2013-4250	05/31/2013 06/28/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	BRETT PARK CONWAY HOMER & CHIN-CAPLAN PC	INDIVIDUAL RECS
2013-4251	05/31/2013 07/12/2013	FDA/OFVM/CFSAN/OCD/EOS/	RUBY E BURNER Keller and Heckman LLP	DAI-ICHI KOGYO SEIYAKU CO LTD - FCN 1257
2013-4252	05/31/2013 06/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID HOFFMEISTER ESQ WILSON SONSINI ET AL	PLAN B ONE-STEP (LEVONORGESTREL) TABS NDA 21-998/S002
2013-4253	05/31/2013 06/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	KIM THORSON Medical Products Laboratories, Inc.	VARNISHAMERICA - K040098
2013-4254	05/31/2013 06/28/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	MICHELLE POULK BURLESONS PURE HONEY	NATURE NATE'S HONEY, NORTH DALLAS HONEY CO, FRISCO, TX - WARNING LTRS, CORR, ORDERS, ETC 3/20/12 TO 5/31/13; CMLPNT 125652
2013-4255	05/31/2013 09/17/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Doe J	INDIVIDUAL RECS
2013-4256	05/31/2013 06/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID HILZENRATH PROJECT ON GOVERNMENT OVERSIGHT	DPV-I - PHARMACOVIGILANCE RVW 12/15/11
2013-4257	05/31/2013 06/28/2013	FDA/OFVM/CFSAN/OCD/EOS/	CHARLES CELESTE EAS CONSULTING GROUP LLC	FAP 0A4705
2013-4258	05/31/2013 06/28/2013	FDA/OFVM/CFSAN/OCD/EOS/	CHARLES CELESTE EAS CONSULTING GROUP LLC	FAP 9A4692
2013-4259	05/31/2013 06/28/2013	FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECS

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2013-4260	05/31/2013 06/28/2013	FDA/OFVM/CFSAN/OCD/EOS/	CHARLES CELESTE EAS CONSULTING GROUP LLC	FAP 1A4729
2013-4261	05/31/2013 06/28/2013	FDA/OC/OES/DFOI/	HOLLIS 377055/D2205, ANTHONY	PANCREAS - AER
2013-4262	05/31/2013 06/28/2013	FDA/OC/OES/DFOI/	HOLLIS 377055/D2205, ANTHONY	HYPERTENSION DRUG RECALLS
2013-4263	05/31/2013 06/28/2013	FDA/OC/OES/DFOI/	HOLLIS 377055/D2205, ANTHONY	NEUROLOGY RECALL MEDICATIONS
2013-4264	05/31/2013 06/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID HILZENRATH PROJECT ON GOVERNMENT OVERSIGHT	MINI SENTINEL PRADAXA STUDY 2011
2013-4265	05/31/2013 06/28/2013	FDA/OGROP/ORA/CE-FO/CIN- DO/CIN-CB/	JIM FANGMAN HILL ROM	SCM TRUE AIR TECHNOLOGIES LLC, LOUISVILLE, KY - 483
2013-4266	05/31/2013 06/28/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/	NORMAN M. GOLDFARB JOURNAL OF CLINICAL RESEARCH BEST PRACTICES	QUESTIONS AND ANSWERS FDA PROVIDED THROUGH GCPQUESTIONS@OC.FDA.GOV 2012
2013-4267	05/31/2013 06/28/2013	FDA/OGROP/ORA/PA-FO/SEA- DO/SEA-CB/	DAVE EISENHUT NORPAC FOODS	HHE 8452
2013-4268	05/31/2013 06/28/2013	FDA/OC/OES/DFOI/	HOLLIS 377055/D2205, ANTHONY	DIABETES MEDICATIONS AER
2013-4269	05/31/2013 06/28/2013	FDA/OC/OES/DFOI/	JACK A. KRAMER WESTLAND KRAMER BENNETT PC	HEALTHCARE PROFESSIONAL SHETT 3/06; SCIENCE BACKGROUND PAPER 5/06; ALERT 12/11/08
2013-4270	05/31/2013 06/28/2013	FDA/OGROP/ORA/CE-FO/CHI- DO/CHI-CB/ FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/ FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/ FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/ FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/ FDA/OMPT/CDRH/OCER/DFOI/	JOY J. LIU ROPES GRAY LLP	DENTAL EZ INC; RAMVAC DENTAL PRODUCTS INC; CUSTOM AIR - EIRS, 483S, MDRS, ETC 2008 TO 2013

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2013-4271	05/31/2013 06/28/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	HOOVER, BRIAN S	AUTISM & BIOPSY STUDY; IMMUNIZATIONS & DEVELOPMENT STUDY
2013-4272	06/03/2013 07/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	LATANIA BLACK MEDTRONIC	STERLING IF SCREW EYELET & STERLING CROSS-PIN EYELET - K063584
2013-4273	06/03/2013 07/01/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	LATANIA BLACK MEDTRONIC	STERLING INTERFERENCE SCREW HT & STERLING INTERFERENCE SCREW ST - K060253
2013-4274	06/03/2013 07/01/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	JEAN DOMENICO SANDOZ	OWEN MUNFORD, MARIETTA, GA - AUTOJECT II - CLEARANCE LTR
2013-4275	06/03/2013 07/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARC CHAFETZ AMERICAN LAW PARTNERS	AVASTIN - RPTS OF OFF LABEL USE
2013-4276	06/03/2013 07/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	CHRISTOPHER J GANSEN GANSEN LAW GROUP	ADVATE - HEPATITIS C AERS
2013-4277	06/03/2013 07/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SCOTT A HODES Scott A. Hodes, Attorney at Law	ICULSIG (PONATINIB) - AERS DETAILED RPT
2013-4278	06/03/2013 07/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARC CHAFETZ AMERICAN LAW PARTNERS	ANGIOTENSIN RECEPTOR BLOCKERS (ARB) - RPTS
2013-4279	06/03/2013 07/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	HOLGER WEIS DEMEXX INC	IND #39680 - RECS
2013-4280	06/03/2013 07/01/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	CHRISTOPHER J GANSEN GANSEN LAW GROUP	HEMOFIL (ANITHEMOPHILIC FACTOR HUMAN) - HEPATITIS C VAERS
2013-4281	06/03/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	REO TANOSHIMA	COPAXONE (GLATIRAMER ACETATE) - ISRS 3035510, 3163637, 3151816, ETC

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	07/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	HOSPITAL FOR SICK CHILDREN	
2013-4282	06/03/2013 07/01/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ OC/ORO/ OC/ORO/ FDA/OGROP/ORO/NE-FO/NWE- DO/NWE-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORO/CE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORO/PA-FO/SAN- DO/SAN-CB/	Doe J	ENOXAPARIN SODIUM - SPL #781-587-7466, SPL #740431 - TEST RESULTS
2013-4283	06/03/2013 07/01/2013	FDA/OGROP/ORO/NE-FO/NWE- DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firms available correspondence from January 1 2012 to July 31 2012 for: Lonza Biologics, Inc., Newington, NH
2013-4284	06/03/2013 07/01/2013	FDA/OGROP/ORO/NE-FO/NWE- DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firms available correspondence from January 1 2012 to July 31 2012 for: ImmunoGen, Norwood, MA
2013-4285	06/03/2013 07/01/2013	FDA/OGROP/ORO/NE-FO/NWE- DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firms available correspondence from January 1 2012 to July 31 2012 for: Infinity Pharmaceuticals, Cambridge, MA
2013-4286	06/03/2013 07/01/2013	FDA/OGROP/ORO/NE-FO/NWE- DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firms available correspondence from January 1 2012 to July 31 2012 for: Lonza Group Ltd., Hopkinton, MA
2013-4287	06/03/2013 07/01/2013	FDA/OGROP/ORO/NE-FO/NWE- DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firms available correspondence from January 1 2012 to July 31 2012 for: Shire Human Genetic Therapies, Lexington, MA
2013-4288	06/03/2013 07/01/2013	FDA/OGROP/ORO/NE-FO/NWE- DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firms available correspondence from January 1 2012 to July 31 2012 for: Stryker Biotech, Hopkinton, MA

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2013-4289	06/03/2013 07/01/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firms available correspondence from January 1 2012 to July 31 2012 for: Vertex Pharmaceuticals, Cambridge, MA
2013-4290	06/03/2013 07/01/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firms available correspondence from January 1 2012 to July 31 2012 for: Millenium (Takeda), Cambridge, MA
2013-4291	06/03/2013 07/01/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firms available correspondence from January 1 2012 to July 31 2012 for: Merrimack Pharmaceuticals Inc., Cambridge, MA
2013-4292	06/03/2013 07/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANDA 088857 Arrastia, Capote & Phang, LLP	ANDA 088857
2013-4293	06/03/2013 07/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANDA 088855 Arrastia, Capote & Phang, LLP	ANDA 088855
2013-4294	06/03/2013 07/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANDA 087616 Arrastia, Capote & Phang, LLP	ANDA 087616
2013-4295	06/03/2013 07/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANDA 088853 Arrastia, Capote & Phang, LLP	ANDA 088853
2013-4296	06/03/2013 07/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sharon Taylor Taylor, Sharon	LEVOQUIN - AERS
2013-4297	06/03/2013	FDA/OMPT/CDER/GRP/DIDP/	Tina M. Babos	ANDA 201-578 - EFFECTIVE APPROVAL LETTER

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	07/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	IPD ANALYTICS LLC	
2013-4298	06/03/2013 07/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Susan Todd West-Ward Pharmaceutical Corp.	GETZ PHARMA RESEARCH PVT, LTD, INDIA - 483 MAY 2013
2013-4299	06/03/2013 07/01/2013	OC/CVM/OCD/	B-TERA B-TERA	IFA-11-317
2013-4300	06/03/2013 07/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Constantine Panagotacos Dunn & Panagotacos LLP	CITANEST PLAIN DENTAL 4% - WARNINGS, TESTING, DANGERS
2013-4301	06/03/2013 07/01/2013	FDA/OFVM/CFSAN/OCD/EOS/	Jeff Goehring YOUNG & THOMPSON	CHLORELLA - SUBMISSION FOR APPROVAL AS FOOD SUBSTANCE
2013-4302	06/03/2013 07/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Susan Todd West-Ward Pharmaceutical Corp.	CIPLA, LTD, MUMBIA, INDIA - 483 MAY 2013
2013-4303	06/03/2013 07/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Christina Patullo Long Pharmaceuticals, LLC	NDA 013960 - SBA
2013-4304	06/03/2013 07/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LuLu HEC PARIS	NDA 018780 - APPROVAL RECS
2013-4305	06/03/2013 07/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	James Bradbury SUMMIT MEDICAL LTD	K071520
2013-4306	06/03/2013 07/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dennis W. Raisch UNIVERSITY OF NEW MEXICO	VICTRELIS, BOCEPREVIR - AERS

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2013-4307	06/03/2013 07/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	Sean Cho TaoNetworks Int'l., Inc.	K121700
2013-4308	06/03/2013 07/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	Gil Shapira G.N.S neoLaser Ltd	K120938
2013-4309	06/03/2013 07/01/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 5/1-31/2013
2013-4310	06/03/2013 07/01/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	CLOSED FOIA REQUESTS (5/1-31/2013)
2013-4311	06/03/2013 07/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dennis W. Raisch UNIVERSITY OF NEW MEXICO	INCIVEK, TELAPREVIR - AERS
2013-4312	06/04/2013 07/02/2013	FDA/OFVM/CFSAN/OCD/EOS/	DAN FREEMAN WELLS ANDERSON & RACE LLC	TABZ TEA CLEAN - CMLNPTS, CORR, NOTES, ETC
2013-4313	06/04/2013 07/02/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN S BAKER LIGHTFOOT FRANKLIN & WHITE LLC	TESTOPEL - ISR 8178925
2013-4314	06/04/2013 07/02/2013	FDA/OGROP/ORAN/NE-FO/NWE- DO/NWE-CB/ FDA/OGROP/ORAN/SE-FO/ATL- DO/ATL-CB/	ROSE H GOLDMAN MD MPH HARVARD SCHOOL OF PUBLICH HEALTH	THALLIUM IN NALTREXONE - RECS
2013-4315	06/04/2013 07/02/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID HOFFMEISTER ESQ WILSON SONSINI ET AL	BANNER PHARMACAPS - DUTASTERIDE CAPS ANDA 200- 899 FINAL APRVL LTR
2013-4316	06/04/2013 07/02/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORAN/CE-FO/MIN- DO/MIN-CB/	HOLLY J BAYNE BAYNE & ASSOCIATES	NESTLE HEALTHCARE NUTRITION - BOOST KID ESSENTIALS NUTRITIONALLY COMPLETE DRINK MEDICAL FOOD WARNING LTR 12/3/09; BIOENERGY INC - CORVALEN M, CORVALEN, CORVALEN CHEWABLE WAFER CORR, MEMOS, TRANS, ETC
2013-4317	06/04/2013 07/02/2013	FDA/OC/OES/DFOI/	RAFE LEWIS NORTH RUN CAPITAL LP	ABIOMED INC, MEDICARE ADMINISTRATIVE CONTRACTORS, HHS - IMPELLA CORR
2013-4318	06/04/2013 07/02/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HATTON 1519223, ROLAND	BOEHRINGER-INGELHEIM - DOPAMINE AGONISTS, MIRAPEX (PRAMIPEXOLE HCL) AERS, CORR 1997 TO 2005

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-4319	06/04/2013 07/02/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GREGORY H LEVINE ROPES & GRAY LLP	OMS721 - CMLPNT LTRS SUBMITTED TO THE OFFICE OF PRESCRIPTION DRUG PROMOTION 4/8/13, 4/22/13
2013-4320	06/04/2013 07/02/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JAMES R JARROW BAKER STERCHI COWDEN & RICE LLC	BDI - CARDIOGEN-82 NDA 19-414 INVESTIGATION, VIOLATIONS, CORR, ETC 3/1/11 TO PRESENT
2013-4321	06/04/2013 07/02/2013	OC/ORO/ORM/ OC/ORO/ORM/	GAIL LESSICK LACHMAN CONSULTANT SERVICES INC	DRUG COMPANIES, MEDICAL DVC MFRS, BIORESEARCH MONITORING (BIMO), ETC - DOMESTIC AND FOREIGN INSPS, 483S 4/1-30/13
2013-4322	06/04/2013 07/02/2013	FDA/OGROP/ORO/SW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORO/SW-FO/DEN-DO/DEN-CB/	KOSNETT, MICHAEL J	LIFE VANTAGE - PROTANDIM RECALL RECS
2013-4323	06/04/2013 07/02/2013	FDA/OC/OES/DDM/	MARILYNN WHITNEY COVINGTON & BURLING LLP	DKT 2003P-0064
2013-4324	06/05/2013 07/03/2013	FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/ FDA/OMPT/CDRH/OCER/DFOI/	MARIA K. TOUGAS SCOTT & SCOTT	PHILLIPS - LIFELINE MEDICAL ALERT DVC CMLPNTS
2013-4325	06/05/2013 07/03/2013	FDA/OMPT/CTP/OD/	JOE MAPOTHER TOBACCO JOURNAL INTERNATIONAL	NEW APPLICATIONS FILED IN CTP
2013-4326	06/05/2013 07/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	HENNING, CHARLES	TAMSULOSIN HCL - AER
2013-4327	06/05/2013 07/03/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	FRAN SILVERMAN TRUTH IN ADVERTISING.ORG	VERVA NUTRITION CO, SCOTTSDALE, AZ - VERVE; NEXT CMLPNTS
2013-4328	06/05/2013 07/03/2013	FDA/OC/OES/DFOI/	HOLZERLAND, WILLIAM	SECURITY CAMERA FOOTAGE AT FDA
2013-4329	06/05/2013	FDA/OMPT/CDER/GRP/DIDP/	THOMAS FAHEY	ABILIFY - BRISTOL MYERS SQUIBB COMM, EFFICACY,

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	07/03/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	NATIONAL CORPORATE RESEARCH	LBLG, APRVL 2002 TO 2007
2013-4330	06/05/2013 07/03/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	JOSHUA TURNER GOLDWATER INSTITUTE	APPLICTIONS FOR COMPASSIONATE USE 1/05 TO PRESENT
2013-4331	06/06/2013 07/05/2013	FDA/OGROP/ORACE-FO/BLT- DO/BLT-CB/	WALTER E CHALKLEY THOMSON REUTERS	VALLEY HEALTH INSWTITUTIONAL REVIEW BOARD, WINCHESTER, VA - EIRS, 483S, CO RESP 1/29/13-2/01/13
2013-4332	06/06/2013 08/07/2013	FDA/OGROP/ORAPA-FO/SAN- DO/SAN-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORAPA-FO/SAN- DO/SAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	JOSE JOSEPH-VEMPILLY MD, FRESNO, CA - EIRS, 483S, CO RESP 9/13/12-10/11/12
2013-4333	06/06/2013 07/05/2013	FDA/OGROP/ORAPA-FO/SAN- DO/SAN-CB/ FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/	WALTER E CHALKLEY THOMSON REUTERS	INNOVATIVE MED INC, IRVINE, CA - EIRS, 483S, CO RESP 10/03-09/12
2013-4334	06/06/2013 07/05/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	CMI COSMETIC MANUFACTURERS INC, CONCORD, ONTARIO, CANADA - EIRS, 483S, CO RESP 10/12
2013-4335	06/06/2013 07/05/2013	FDA/OGROP/ORASE-FO/ATL- DO/ATL-CB/	WALTER E CHALKLEY THOMSON REUTERS	V-SAB MEDICAL LABS INC, CORNELIUS, NC - EIRS, 483S, CO RESP 5/22/12-6/20/12
2013-4336	06/06/2013 07/05/2013	FDA/OGROP/ORACE-FO/BLT- DO/BLT-CB/	WALTER E CHALKLEY THOMSON REUTERS	LONZA WALKERVILLE, WALKERVILLE, MD - EIRS, 483S, CO RESP 12/11
2013-4337	06/06/2013 07/05/2013	FDA/OGROP/ORAPA-FO/SAN- DO/SAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	IMPAX LABS, HAYWARD, CA - EIRS, 483S, CO RESP 3/13

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2013-4338	06/06/2013 07/05/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	WALTER E CHALKLEY THOMSON REUTERS	ACORDA THERAPEUTICS, HAWTHORNE, NY - EIRS, 483S, CO RESP 8/15/11-09/09/11
2013-4339	06/06/2013 07/05/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	WAWLTER E CHALKLEY THOMSON REUTERS	CATALENT PHARMA SOLUTIONS, MORRISVILLE, NC - EIRS, 483S, CO RESP 2/13
2013-4340	06/06/2013 07/05/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	MEDTRONIC SPINAL & BIOLOGICS, WEXFORD, PA - EIRS, 483S, CO RESP 01/23/12
2013-4341	06/06/2013 07/05/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	LIFESOURCE-UPPER MIDWEST OPO, SAINT PAUL, MN - EIRS, 483S, CO RESP 01/24/12
2013-4342	06/06/2013 07/05/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	GLAXOSMITHKLINE CONSUMER HEALTHCARE, LP, CLIFTON, NJ - EIRS, 483S, CO RESP 01/09/12
2013-4343	06/06/2013 07/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	GENZYME FLANDERS NV, GEEL, BELGIUM - EIRS, 483S, CO RESP 01/24/12
2013-4344	06/06/2013 07/05/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	WALTER E CHALKLEY THOMSON REUTERS	MICHAEL DESANTIS, HICKORY, NC - EIRS, 483S, CO RESP 01/05/12
2013-4345	06/06/2013 09/10/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	WALTER E CHALKLEY THOMSON REUTERS	AMGEN INC, BOULDER, CO - EIRS, 483S, CO RESP 01/06/12
2013-4346	06/06/2013 07/05/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	WALTER E CHALKLEY THOMSON REUTERS	AMGEN INC, WEST GREENWICH, RI - EIRS, 483S, CO RESP 01/20/12
2013-4347	06/06/2013 07/25/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	ALLURE LABORATORIES, INC, HAYWARD, CA - EIRS, 483S, CO RESP 01/12/12
2013-4348	06/06/2013 07/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	WALTER E CHALKLEY THOMSON REUTERS	BAXTER BIOSCIENCE, VIENNA, AUSTRIA - EIRS, 483S, CO RESP 01/19/12
2013-4349	06/06/2013 08/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	BAXTER HEALTHCARE CORP, BAXTER AG, WIEN, AUSTRIA - EIRS, 483S, CO RESP 01/31/12

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2013-4350	06/06/2013 07/05/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	WALTER E CHALKLEY THOMSON REUTERS	BIO RAD LABORATORIES INC, WOODINVILLE, WA - EIRS, 483S, CO RESP 01/31/12
2013-4351	06/06/2013 07/05/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	CAPITAL HEALTH, TRENTON, NJ - EIRS, 483S, CO RESP 1/27/12
2013-4352	06/06/2013 07/05/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	WALTER E CHALKLEY THOMSON REUTERS	GLAXOSMITHKLINE CONSUMER HEALTHCARE (GLAXOSMITHKLINE), AIKEN, SC - EIRS, 483S, CO RESP 01/27/12
2013-4353	06/06/2013 07/05/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	WALTER E CHALKLEY THOMSON REUTERS	GRAFT SOURCE LLC, GRAPEVINE, TX - EIRS, 483S, CO RESP 01/11/12
2013-4354	06/06/2013 07/05/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	HACKENSACK UNIVERSITY MEDICAL CENTER, BLOOD BANK, HACKENSACK, NJ - EIRS, 483S, CO RESP 01/24/12
2013-4355	06/06/2013 07/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/CVM/OCD/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	HUSASHU PHARMACEUTICAL CORP, SHIJAZHUANG, CHINA - EIRS, 483S, CO RESP 01/12/12
2013-4356	06/06/2013 07/05/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	WALTER E CHALKLEY THOMSON REUTERS	OCTAPharma PLASMA INC, PETERSBURG, VA - EIRS, 483S, CO RESP 01/24/12
2013-4357	06/06/2013 07/05/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	WALTER E CHALKLEY THOMSON REUTERS	OCTAPharma PLASMA INC, KALAMAZOO, MI - EIRS, 483S, CO 01/23/12
2013-4358	06/06/2013 07/05/2013	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	WALTER E CHALKLEY THOMSON REUTERS	AMERICAN RED CROSS BLOOD SERVICES TENNESSEE VALLEY REGION, NASHVILLE, TN - EIRS, 483S, CO RESP 01/05/12
2013-4359	06/06/2013 07/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	BOEHRINGER-INGELHEIM PHARMA GMBH, INGELHEIM AM RHEIN, GERMANY - EIRS, 483S, CO RESP 11/05-12/12
2013-4360	06/06/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	WALTER E CHALKLEY	ACELL INC, COLUMBIA, MD - EIRS, 483S, CO RESP 11/28/12-12/20/12

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	07/05/2013		THOMSON REUTERS	
2013-4361	06/07/2013 07/08/2013	FDA/OGROP/OR/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	Paul Blackburn Cubist Pharmaceuticals	PALM SPRINGS RESEARCH INSTITUTE, INC, HIALEAH, FL - EIR, 483, RESPONSE 6/6/2011
2013-4362	06/07/2013 07/08/2013	FDA/OGROP/OR/CE-FO/NWJ-DO/NWJ-CB/	Paul Blackburn Cubist Pharmaceuticals	CHRISTOPHER J LUCASTI DO, SOMERS POINT, NJ - EIR, 483, RESPONSES (10/15/2007 - 12/30/2007)
2013-4363	06/07/2013 07/08/2013	FDA/OGROP/OR/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Paul Blackburn Cubist Pharmaceuticals	MOHAMED BIDAIR, MD, LA MESA, CA - EIR, 483, RESPONSES (03/16/2011 - 03/16/2011)
2013-4364	06/07/2013 07/08/2013	FDA/OGROP/OR/CE-FO/MIN-DO/MIN-CB/	Paul Blackburn Cubist Pharmaceuticals	CHRISTIAN G SCHROCK, MD, MINNEAPOLIS, MN - EIR, 483, RESPONSES (03/14/2007 - 12/01/2007)
2013-4365	06/07/2013 07/08/2013	FDA/OGROP/OR/CE-FO/NWJ-DO/NWJ-CB/	Paul Blackburn Cubist Pharmaceuticals	CHRISTOPHER J LUCASTI, SOMERS POINT, NJ - EIR, 483, RESPONSES (04/11/2007 - 04/11/2007)
2013-4366	06/07/2013 07/08/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Paul Blackburn Cubist Pharmaceuticals	VERONIKA B POPOVA, MD, ST PETERSBURG, RUSSIA - EIR, 483, RESPONSES (02/18/2008 - 12/01/2008)
2013-4367	06/07/2013 07/08/2013	FDA/OGROP/OR/SE-FO/NOL-DO/NOL-CB/	Paul Blackburn Cubist Pharmaceuticals	AHMAD A HAIDAR, MD, PICAYUNE, MS - EIR, 483, RESPONSES (04/04/2005 - 04/04/2005)
2013-4368	06/07/2013 07/08/2013	OC/OR/ OC/OR/	Melissa Hipolit WJHL-TV	COMPOUNDING PHARMACIES IN TENNESSEE - INSPECTION REPORTS (05/30/2012 - 05/30/2013)
2013-4369	06/07/2013 07/08/2013	FDA/OGROP/OR/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/OR/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/OR/SE-FO/SJN-DO/SJN-CB/	Eric Young Kessler Topaz Meltzer & Check, LLP	ST JUDE MEDICAL - INSPECTION RECS RE LEADS (09/01/2009 - 12/31/2009)
2013-4370	06/07/2013 07/08/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Michael P. Manapol, Esq. Law Offices of Brian D. Witzer, Inc.	EOSINOPHILIA - AERS
2013-4371	06/07/2013	FDA/OGROP/OR/NE-FO/NWE-	Penny Northcutt/REGSolutions, LLC	BLANCHARD CONTACT LENS INC, NH - EIR JUNE 2011

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	07/08/2013	DO/NWE-CB/	REGSolutions, LLC	
2013-4372	06/07/2013 07/08/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Derek Auito MCKENNA LONG & ALDRIDGE LLP	LABORATORIOS ANDROMACO SA, SANTIAGO, CHILE - REGISTRATION WITH DECRS DATABASE (01/01/2010 - 05/01/2013)
2013-4373	06/07/2013 07/08/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	MERCK & CO - COMPLIANCE RECORDS FOR IMPORTS INTO THE US 2012-2013
2013-4374	06/07/2013 07/08/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	Marc C. Sanchez, Esq. Contract In-House Counsel and Consultants, LLC	COMFREY - AERS, SCIENTIFIC DATA, CLINICAL STUDIES RE ADVISORY
2013-4375	06/07/2013 07/08/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Duloxetine for major depressive disorder The Nordic Cochrane Centre	DULOXETINE WITH THE INDICATION DEPRESSIVE DISORDER - FULL TRIAL PROTOCOLS, AMENDMENTS, REPORTS ETC
2013-4376	06/07/2013 07/31/2013	FDA/OMPT/CTP/OD/ FDA/OC/OES/	Yltzchak Jacobovitz CAPSTONE LLC	CORR BETWEEN CTP AND OMB, MEETINGS, MENTHOL CIGARETTE RECS (01/01/2011 - 05/31/2013)
2013-4377	06/07/2013 07/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	LM Hanley Navilyst Medical, Inc	LETTER TO MANUFACTURERS OF 510K CLEARANCES FOR PROCEDURE DXT (07/01/2012 - 07/15/2012)
2013-4378	06/07/2013 07/08/2013	FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	b. burgess BURGESS, BERNIE	UNTITLED LETTER ISSUED 2008 RE ASSIGNMENT NUMBER 808885
2013-4379	06/07/2013 07/08/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	b. burgess B. Burgess	LETTER TO CDER EXEC SEC FROM L BALL RE COMPLAINT 1639
2013-4380	06/07/2013 07/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Patrick Tillino Patrick Tallino	K123769

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2013-4381	06/07/2013 07/08/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tracy O'Neill Tracy O'Neill	XARELTO - AERS
2013-4382	06/07/2013 07/08/2013	OC/CVM/OCD/	Gaurav Shah BioResource International, Inc	GM FEED ENZYMES EXPRESSED IN GENETICALLY MODIFIED EXPRESSION SYSTEMS - SAFETY INFORMATION
2013-4383	06/07/2013 07/08/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORR/SE-FO/NOL-DO/NOL-CB/	Patrick Tallino Patrick Tallino	K113621
2013-4384	06/07/2013 07/08/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Shaheen Wirk Palkon Capital Management	NCT00708201 - STUDY RESULTS
2013-4385	06/07/2013 07/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K000515
2013-4386	06/07/2013 07/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Christine Nichols Boston Biomedical Associates	K873643, K840532
2013-4387	06/07/2013 07/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K070897
2013-4388	06/07/2013 07/08/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Gary Syring SYRING, GARY J	K082629
2013-4389	06/07/2013 07/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Julie Perkins AgaMatrix, Inc	K121291
2013-4390	06/07/2013 07/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Gary Syring SYRING, GARY J	K883149
2013-4391	06/07/2013 07/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Gary Syring SYRING, GARY J	K111717
2013-4392	06/07/2013 07/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Gary Syring SYRING, GARY J	K883149
2013-4393	06/07/2013 07/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Gary Syring SYRING, GARY J	K885306
2013-4394	06/07/2013 07/08/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jennifer Brooks Microbiotix, Inc.	NDA 050347 - SBA

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/		
2013-4395	06/07/2013 07/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Aftab Ahmad Neurowave Medical Technology	K020020, K040512
2013-4396	06/07/2013 07/08/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Karin Desjardins COVIDIEN	K993691
2013-4397	06/07/2013 07/08/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Jason Lam New Horizon Enterprises Ltd.	ENTRY NUMBER D52-9005145-2
2013-4398	06/07/2013 07/08/2013	FDA/OC/OES/DFOI/	Esther Farber Labaton Sucharow, LLP	2010-3944, 2012-6036
2013-4399	06/07/2013 07/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Andrew Kumamoto HelixIP LLP	LAZANDA - FAERS
2013-4400	06/07/2013 07/08/2013	FDA/OC/OES/DFOI/	Stephen Roos ASE Direct Inc.	PCARD HOLDERS
2013-4401	06/07/2013 07/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Ian Marsden CONSUMER	K123237
2013-4402	06/07/2013 07/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Ian Marsden CONSUMER	K120257
2013-4403	06/07/2013 07/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Marge Walls-Walker Cook Medical	K112454
2013-4404	06/07/2013 07/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Joanna Veres ClearView Diagnostics Inc.	K050846
2013-4405	06/07/2013 07/08/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	Joy Flynn flynn, joy	AVANTOR, PARIS, KY - EIR (01/02/2012 - 06/06/2013)
2013-4406	06/07/2013 07/08/2013	FDA/OFVM/CFSAN/OCD/EOS/	Amy Shipley The Fort Lauderdale Sun Sentinel	DRIVEN SPORTS CRAZE, GASPARI NUTRITION DETONATE - ADVERSE EVENTS, COMPLAINTS, WARNING LETTERS
2013-4407	06/07/2013 07/08/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Kimberly D. Goodman Cooperstein, Esquire Murray, Kelly & Bertrand, P.C.	PALLIMED SOLUTIONS, INC, WOBURN, MA - COMPLAINT 132017, PUBLIC RECS

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2013-4408	06/07/2013 07/08/2013	OC/CVM/OCD/ OC/ORO/ OC/ORO/	Julie Putnam NBC Bay Area News (KNTV)	PET TREAT COMPLAINTS (01/01/2013 - 06/04/2013)
2013-4409	06/07/2013 07/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Anthony Castellazzo AMICUS THERAPEUTICS	BOEHRINGER INGELHEIM, RHEIN, GERMANY - EIR (11/05/2012 - 11/12/2012)
2013-4410	06/07/2013 07/08/2013	FDA/OGROP/ORO/SW-FO/DEN-DO/DEN-CB/	Caron McEWan Mountain Country Foods	SAMPLE RESULTS - MOUNTAIN COUNTRY FOODS, SPANISH FORK, UT
2013-4411	06/07/2013 07/08/2013	FDA/OC/OES/ FDA/OMPT/CDRH/OCER/DFOI/	Peter Spaulding Peter Spaulding	FDA CORR WITH JEFFREY LIEBERMAN, SARAH "HOLLY" LISANBY, JAMES H. SCULLY JR (01/01/2008 - 06/03/2013)
2013-4412	06/07/2013 07/08/2013	FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	Andres Cabrera Grunenthal LatAm	MALLINCKRODT, RALEIGH, NC - 483, EIR (06/01/2009 - 06/03/2013)
2013-4413	06/07/2013 07/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Scott Talbot Gavis Pharmaceuticals, LLC	HOSPIRA HEALTHCARE INDIA PVT LTD - 483 (10/03/2012 - 10/10/2012)
2013-4414	06/07/2013 07/08/2013	OC/ORO/ORM/ OC/ORO/ORM/	b. burgess BURGESS, BERNIE	LIST OF INSPECTIONS CONDUCTED BY LOS ANGELES DISTRICT IN FY 2006
2013-4415	06/07/2013 07/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michael S. Sawaya Altaire Pharmaceuticals, Inc.	NDA 018299
2013-4416	06/07/2013 07/10/2013	FDA/OC/OES/DDM/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORO/CE-FO/PHI-DO/PHI-CB/	Brad D Hewett The Mike Kelly Law Group	RESPIRONICS, INC SMARTMONITOR2
2013-4417	06/07/2013 07/30/2013	FDA/OGROP/ORO/CE-FO/DET-DO/DET-CB/	David Mangione Govzilla, Inc.	BAXTER PHARMACEUTICAL SOLUTIONS LLC, BLOOMINGTON, IN - EIR, 483 (05/10/2013 - 05/10/2013)
2013-4418	06/07/2013 07/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michele Sinoway Lachman Consultants	WOCKHARDT INDIA FACILITIES - 483 (12/17/2010 - 02/28/2012)

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-4419	06/07/2013 07/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Gloukhova Svetlana AbbVie Inc	915 REVIEW OF FINGOLIMOD
2013-4420	06/07/2013 07/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ashley Yeager The Simon Law Firm	BENTYL - AERS, CASE REPORTS 6124897, 6534658
2013-4421	06/07/2013 07/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dan Himmelfarb Mayer Brown LLP	TESTOSTERONE - APPROVAL RECS
2013-4422	06/07/2013 07/08/2013	FDA/OC/OES/DFOI/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Blake Goodner Bridger Corporation	GILEAD SCIENCES, FOSTER CITY, CA - 483, WARNING LETTERS, RESPONSE LETTERS (01/01/2012 TO PRESENT)
2013-4423	06/07/2013 07/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bao Le ARIAD Pharmaceuticals, Inc	ICLUSIG - AERS
2013-4424	06/07/2013 07/08/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	Michael R. McCann Michael R. McCann, P.A.	COMPLAINT 130549
2013-4425	06/07/2013 07/08/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Patti Krofft Pettit Kohn Ingrassia & Lutz	NATIONAL VITAMIN COMPANY, INC - TESTING RECS
2013-4426	06/07/2013 07/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Larry Hagerman HAGERMAN INFORMATION SERVICES	BOEHRINGER INGELHEIM PHARMA GMBH & CO - CDER HHE REQUEST AND CONSULT
2013-4427	06/07/2013 07/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Geoffrey May May, Geoffrey	NCT00140179 - DATA ANALYSIS, STUDY RESULTS

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2013-4428	06/07/2013 07/08/2013	FDA/OC/OES/DFOI/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kip Nelson SMITH MOORE LEATHERWOOD LLP	NESHER PHARMACEUTICALS (USA) LLC - 483, EIR, FIELD REPORT ETC
2013-4429	06/07/2013 07/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Lori Hays Merz Aesthetics, Inc.	ANTEIS SA, PLAN-LES-OATES - EIR 2/5/13
2013-4430	06/07/2013 07/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Angela Birchall Bio Products Laboratory Limited	BIO PRODUUCTS LABORATORY LTD, ELSTREE, UK - EIR 6/13/11, ADVERSE EVENTS
2013-4431	06/07/2013 07/08/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Christine Livoti BioPharm Insight	BLA ACCEPTED FOR REVIEW, COMPLETE RESPONSE LETTERS FOR CMC RELATED ISSUES, NAMES AND INDICATIONS OF BIOLOGICS, ETC
2013-4432	06/07/2013 07/08/2013	FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA REQUEST LOG 5/27/2013 to 5/31/2013
2013-4433	06/07/2013 07/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kathrin Simmons Kathrin Simmons	K895365
2013-4434	06/07/2013 07/08/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Ilona W Surick EISAI INC	ESAI, WOODCLIFF LAKE, NJ - EIR (01/01/2013 - 02/25/2013)
2013-4435	06/07/2013 07/08/2013	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	FOIA REQUESTS RE RANBAXY DATA INTEGRITY, CGMP
2013-4436	06/07/2013 07/08/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Rachel Johnson FOI Services, Inc.	RANBAXY, GLOVERSVILLE, NY - EIR, 483, RESPONSES ETC 01/01/04 TO PRESENT
2013-4437	06/07/2013 07/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	RANBAXY, INDIA - EIR, 483, RESPONSES ETC

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-4438	06/07/2013 07/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Timothy Bassett Pura Vida Investments	JUXTAPID - AERS
2013-4439	06/07/2013 07/08/2013	FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECS
2013-4440	06/07/2013 07/08/2013	OC/ORR/ORM/ OC/ORR/ORM/	ROBERT KING FDA NEWS	MEDICAL DVC, PHARMACEUTICAL, BIOLOGIC FACILITIES - 483S 5/13
2013-4441	06/07/2013 07/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	COOPER 328257, JACK .	DICCYLOMINE; KETAMINE; HALDOL; BENEDRYL - AER
2013-4442	06/07/2013 07/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PERLMUTTER, SUZY	BOTOX AER
2013-4443	06/07/2013 07/08/2013	FDA/OGROP/ORR/SE-FO/SJN-DO/SJN-CB/	JOHN VARONE ROYAL FOOD IMPORT CORPORATION	ENTRY NO E5R-1009888-2
2013-4444	06/07/2013 07/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	MARILYNN WHITNEY COVINGTON BURLING LLP	CDRH UNTITLED LTRS SINCE 1/12
2013-4445	06/07/2013 07/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MICHAEL R. COHEN INSTITUTE FOR SAFE MEDICATION PRACTICES	MEDWATCH MEDICATION ERRORS 5/1-31/13
2013-4446	06/07/2013 07/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	SARI E. KOLATCH COHEN TAUBER ET AL	SHIONOGI PHARMA INC - 483, EIR 1/30 TO 2/8/12
2013-4447	06/07/2013 07/08/2013	FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/	DOROTHY A O'BRIEN ATTY AT	ARCHER DANIELS MIDLAND CO, CLINTON, IA - EIR 2009 TO PRESENT

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			LAW PLC	
2013-4448	06/07/2013 07/08/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JASON T. SAYERS VENABLE LLP	PHENYTOIN SODIUM ANDA 84-307 - LBLG 1/00
2013-4449	06/07/2013 07/08/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KATHLEEN S. HARDWAY VENABLE LLP	BEDFORDS - KETOROLAC TROMETHAMINE ANDA 75-222 - LBLG SINCE 1/11; HOSPIRA - KETOROLAC TROMETHAMINE ANDA 74-801 - LBLG SINCE 1/97
2013-4450	06/10/2013 07/09/2013	OC/ORO/ OC/ORO/	Katrina Reiling Parexel International	MP143 COMPUTER AIDED INSPECTIONS - ORA U COURSE MATERIALS
2013-4451	06/10/2013 07/09/2013	OC/ORO/ OC/ORO/	Katrina Reiling Parexel International	DV201 BASIC MEDICAL DEVICE - ORA U COURSE MATERIALS
2013-4452	06/10/2013 07/09/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Christine Livoti BioPharm Insight	NUMBER OF NDAS ACCEPTED FOR REVIEW, NUMBER OF COMPLETE RESPONSE LETTERS RE CMC ISSUES, NAMES AND INDICATIONS OF DRUGS, ETC
2013-4453	06/10/2013 07/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Andrew Flock Flock, Andrew J	BUDEPRION XL 300 MG - BIOEQUIVALENCE STUDY
2013-4454	06/10/2013 07/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Shirley Francis- Fraser SHIRLEY T ATTY	EXELON NDA 022083 SUPP 016 - REVIEW RECS
2013-4455	06/10/2013 07/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Melissa Jeffries Boston Scientific Neuromodulation	MAUDE DATA - FIELD F10 PATIENT PROBLEM CODES
2013-4456	06/10/2013 07/09/2013	OC/ORO/ OC/ORO/	Katrina Reiling Parexel International	DG201BASIC DRUG SCHOOL - ORA U COURSE MATERIALS
2013-4457	06/10/2013 07/09/2013	OC/ORO/ OC/ORO/	Rachel Johnson FOI Services, Inc.	ORA U COURSE MATERIALS - DV303, DG307

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2013-4458	06/10/2013 07/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mahidhar Chinta Micro Labs USA, Inc	ANDA 091563 - SBA
2013-4459	06/10/2013 07/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Joel Barr Stericycle, Inc.	K950899, K950898, K950897
2013-4460	06/10/2013 07/09/2013	FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/	Jim Cassi, VP QA ResMed Corporation	RESMED CORPORATION - EIR (02/02/2009 - 02/27/2009)
2013-4461	06/10/2013 07/09/2013	OC/ORR/OE/ OC/ORR/OE/	Jacob Harris THE NEW YORK TIMES	FOOD RECALL DATA
2013-4462	06/10/2013 07/09/2013	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	TOTAL NUMBER OF SUBSTANTIAL EQUIVALENCE ORDERS UNDER FSPTCA, IDENTITY OF PRODUCTS
2013-4463	06/10/2013 07/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Daan De Coster University College London and Cochrane Collaboration	BECLOMETASONE INHALERS IN COPD - TRIALS USED TO SUPPORT UNSUCCESSFUL APPLICATIONS (01/01/1970 - 01/01/2006)
2013-4464	06/10/2013 07/09/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Daan De Coster University College London and Cochrane Collaboration	BECLOMETASONE - TRIALS USED TO SUPPORT UNSUCCESSFUL APPLICATIONS (01/01/1970 - 01/01/2006)
2013-4465	06/10/2013 07/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kelly Rowan Sitlinger, McGlinchy & Theiler	ST JUDE RIATA LEADS - PMA, SUPPLEMENT, CORR ETC
2013-4466	06/10/2013 07/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Evan Luxon TheraNova LLC	K110518
2013-4467	06/10/2013 07/09/2013	OC/ORR/ OC/ORR/	Katrina Reiling Parexel International	MP143 COMPUTER AIDED INSPECTIONS, DV201 BASIC MEDICAL DEVICE, DG201 BASIC DRUG SCHOOL - ORR U COURSE MATERIALS
2013-4468	06/10/2013 07/09/2013	FDA/OFVM/CFSAN/OCD/EOS/	Joshua Valero Capstone Law APC	MONSTER BEVERAGE CORPORATION - NUTRIENT CONTENT CLAIM PETITIONS LAST FIVE YEARS
2013-4469	06/10/2013 07/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Susan Zolnier MannKind Corporation	DIOSYNTH FRANCE SA, EURAGNY-SUR-EPTE - EIR (01/02/2013 - 05/31/2013)
2013-4470	06/10/2013	FDA/OMPT/CDER/GRP/DIDP/	Marc Wezowski	NDA 17716, 18217, 17576 ETC - CMC

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	07/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Leydig, Voit & Mayer LTD	
2013-4471	06/10/2013 07/09/2013	FDA/OFVM/CFSAN/OCD/EOS/	Joshua Valero Capstone Law APC	HANSEN NATURAL CORPORATION - NUTRIENT CONTENT CLAIM PETITIONS LAST FIVE YEARS
2013-4472	06/10/2013 07/09/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Jason A Dean Hulsey Oliver & Mahar, LLP	JARCHEM INDUSTRIES INC - CORR, REGISTRATIONS, INSPECTIONS
2013-4473	06/10/2013 07/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	BTran Tran & Associates	MACROLANE - PRE-IDE, IDE, PMA ETC
2013-4474	06/10/2013 07/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Bao Tran Tran & Associates	JUVEDERM - PRE-IDE, IDE, PMA, ETC
2013-4475	06/10/2013 07/09/2013	FDA/OC/OES/ FDA/OC/OES/DDM/ FDA/OFVM/CFSAN/OCD/EOS/	Sara D. Avila Avila, Sara D	GMO - CITIZEN PETITION, REFERRALS
2013-4476	06/10/2013 07/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Fergus E McKiernan MARSHFIELD CLINIC PEDIATRICS DEPT	PROLIA - AERS
2013-4477	06/10/2013 07/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Bao Tran Tran Associates	RETYLANE INJECTABLE GEL - PRE-IDE, IDE, PMA ETC
2013-4478	06/10/2013 07/09/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	BTran Tran & Associates	K110318
2013-4479	06/10/2013 07/09/2013	OC/CVM/OCD/	Bryndis Stefansdottir Isteka ehf.	ITSEKA EHF - EIR (06/20/2011 - 05/28/2013)
2013-4480	06/10/2013 07/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	INDIVIDUAL RECS
2013-4481	06/10/2013	FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson	USA V. RANBAXY RECS, CONSENT DECREE

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	07/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OCC/ OC/ORA/OCI/ OC/ORA/OCI/	FOI Services, Inc.	
2013-4482	06/10/2013 07/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	RANBAXY - DATA INTEGRITY EXPERT
2013-4483	06/10/2013 07/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	PRE-SUBMISSION AUDITS OF APPLICATIONS OF RANBAXY APPPLICATIONS
2013-4484	06/10/2013 07/09/2013	FDA/OC/OES/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	COMMUNICATIONS BETWEEN FDA AND DINESH THAKUR RE RANBAXY
2013-4485	06/10/2013 07/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OCC/ OC/ORA/OCI/ OC/ORA/OCI/	Rachel Johnson FOI Services, Inc.	RECS RE THAKUR V. RANBAXY
2013-4486	06/10/2013 07/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OCC/ OC/ORA/OCI/ OC/ORA/OCI/	Rachel Johnson FOI Services, Inc.	USA V. RANBAXY USA - PLEA AGREEMENT, PLEA SUPPLEMENT

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2013-4487	06/10/2013 07/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORO/ OC/ORO/	Rachel Johnson FOI Services, Inc.	RANBAXY - RECS RE 9/16/08 IMPORT ALERT
2013-4488	06/10/2013 07/09/2013	FDA/OC/OES/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OCC/ OC/ORO/OCI/ OC/ORO/OCI/	Rachel Johnson FOI Services, Inc.	RANBAXY - APPLICATION INTEGRITY POLICY, CAOP
2013-4489	06/10/2013 07/09/2013	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	RANBAXY - MEDIA FOIA REQUESTS
2013-4490	06/10/2013 07/09/2013	OC/CVM/OCD/	JENNIFER VRIONIS, MS KINDRED BIOSCIENCES NC	AYERST LABORATORIES INC, NEW YORK, NY - PRIMIDONE TABS NADA 009-392 DRUG EFFICACY STUDY IMPLEMENTATION (DESI) RVW RPT
2013-4491	06/10/2013 07/09/2013	OC/CVM/OCD/	JENNIFER VRIONIS, MS KINDRED BIOSCIENCES NC	FORT DODGE LABORATORIES INC, FORT DODGE, IA - MYLEPSIN TABS NADA 010-091 DRUG EFFICACY STUDY IMPLEMENTATION (DESI) RVW RPT
2013-4492	06/10/2013 07/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	WILLIAM REYNOLDS FIRST I INVESTIGASTIONS	U&I CORPORATION , SOUTH KOREA -OPTIMA SPINAL PEDICLE FIXATION; ZS SPINAL FIXATION SYS; DYNESY SEST SCREWS, ETC MDRS
2013-4493	06/10/2013 07/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	WILLIAM REYNOLDS FIRST I INVESTIGASTIONS	U&I CORP - OPTIMA SPINAL SYS K024096
2013-4494	06/10/2013 07/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	MONIKA BHATT HODGSON RUSS LLP	AUTOMATED OPHTHALMIC INC - SOFTIPS K992998, ACCUTOME ULTRASOUND INC - ACCUPEN K083377
2013-4495	06/10/2013 07/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KIM HENDERSON SANOFI PASTEUR	EBEWE PHARMA GES MBH NFG UNTERACH AM ATTERSEE, AUSTRIA - 483S 10/15-23/12
2013-4496	06/10/2013 07/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	STOBAUGH, A DERRICK	TNF-A INIBITORS -ISRS 4035003, 5668246, 5850508, ETC

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-4497	06/10/2013 07/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	T CHRISTIAN MILLER PROPUBLICA	MCNEIL CONSUMER HEALTHCARE - 7147034, 7380883, 3782721 ISRS ETC
2013-4498	06/10/2013 07/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	BONNIE BASHAM CAPITAL IDEAS	MEDAFOR INC - ARISTA AH ABSORBABLE HEMOSTAT P050038 IX SUMMARY PRE-CLNCL STUDIES
2013-4499	06/10/2013 07/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELAINE S WALKER SEATTLE GENETICS INC	ADCETRIS (BRENWTUXIMAB VEDOTIN) - AERS 9/1/12 TO 5/31/13
2013-4500	06/10/2013 07/09/2013	FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/	THOMAS F SPENADER	VI-JON LABORATORIES INC - EIRS, 483S, WARNING LTRS 4/07 TO PRESENT
2013-4501	06/10/2013 07/09/2013	FDA/OGROP/ORR/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/	BOB FRANKSON LEVLAD LLC	LEVLAD LLC, CHATSWORTH, CA - EIRS 9/2-9/10
2013-4502	06/10/2013 07/09/2013	FDA/OC/OES/DDM/ FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHERYL B SHAPIRO CLEARY GOTTLIEB STEEN ET AL	ENDOCRINOLOGIC & METABOLIC DRUGS A/C 6/13-07 - RIMONABANT NDA 21-888 REC, RVWS, APRVL, ETC
2013-4503	06/10/2013 07/09/2013	OC/ORR/ OC/ORR/ FDA/OGROP/ORR/NE-FO/NYK-DO/NYK-DCB/	AMY BOJIE LI FUZHOU GOLDEN BANYAN FOODSTUFFS CO LTD	ENTRY ES6-4014665-1/8/1 - DETENTION NOTICE
2013-4504	06/10/2013 07/09/2013	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORR/ OC/ORR/	Erika Knudsen Center for Science in the Public Interest	CONSUMER COMPLAINTS. REQUESTS FOR ENFORCEMENT ACTION FOR MISBRANDED PRODUCTS 06/01/2008 UNDER 402, 403 OF THE FDCA, 21 CFR PART 101
2013-4505	06/11/2013 07/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	CORR RE 02/25/2009 MEMO BY JANET WOODCOCK RE RANBAXY DATA INTEGRITY

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-4506	06/11/2013 07/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Bernard Bedor spinal resources inc	CAPTIVA SPINE, JUPITER, FL - REPACKAGING, RELABELING
2013-4507	06/11/2013 07/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Alaska Burr NORTH RUN CAPITAL LP	WOCKHART LTD, AURANGABAD, WALUG - 483, CORR (01/01/2010 - 06/07/2013)
2013-4508	06/11/2013 07/10/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Alaska Burr NORTH RUN CAPITAL LP	WOCKHARDT - 483, CORR (01/01/2010 - 06/07/2013)
2013-4509	06/11/2013 07/10/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	b. burgess BURGESS, BERNIE	FACTS 808885 - FINANCIAL RECS
2013-4510	06/11/2013 07/10/2013	FDA/OC/OES/DFOI/	b.burgess BURGESS, BERNIE	DFOI CORR WITH DIANE F WALKER RE 2007-3879
2013-4511	06/11/2013 07/10/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	b. burgess B. Burgess	FACTS 808885 - FMD 145 LETTER
2013-4512	06/11/2013 07/10/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	b. burgess BURGESS, BERNIE	EI ENDORSEMENT FOR FACTS 808885
2013-4513	06/11/2013 07/10/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Andrew Buckler vascuVis Inc.	K043111
2013-4514	06/11/2013 07/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Andrew Buckler vascuVis Inc.	K073156
2013-4515	06/11/2013 07/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Amanda Goodwin EISAI INC	TYSABRI BLA 125104 - SBA
2013-4516	06/11/2013 07/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	ANDA 40091

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-4517	06/11/2013 07/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jerry Lee True Diagnostics	K023642
2013-4518	06/11/2013 07/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mahidhar Chinta Micro Labs USA, Inc	ANDA 074460 - SBA
2013-4519	06/11/2013 07/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Andrew Buckler vascuVis Inc.	K082607
2013-4520	06/11/2013 07/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Andrew Buckler vascuVis Inc.	K071331
2013-4521	06/11/2013 07/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEVIN COLQUITT Standly & Hamilton, LLP	K050646, K051986, K052390, ETC
2013-4522	06/11/2013 07/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEVIN N COLQUITT Standly & Hamilton, LLP	K042598, K043227, K043560, ETC
2013-4523	06/11/2013 07/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEVIN N COLQUITT Standly & Hamilton, LLP	K030597, K032269, K032269, ETC
2013-4524	06/11/2013 07/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEVIN N COLQUITT Standly & Hamilton, LLP	K082072, K082300, K082624, ETC
2013-4525	06/11/2013 07/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEVIN N COLQUITT Standly & Hamilton, LLP	K072083, K072423, K072832, ETC
2013-4526	06/11/2013 07/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEVIN N COLQUITT Standly & Hamilton, LLP	K083573, K083843, K090877, ETC
2013-4527	06/11/2013 07/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEVIN N COLQUITT Standly & Hamilton, LLP	K092812, K100676, K101423, ETC
2013-4528	06/11/2013 07/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEVIN N COLQUITT Standly & Hamilton, LLP	K111039, K120689
2013-4529	06/11/2013 07/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEVIN N COLQUITT Standly & Hamilton, LLP	K011978, K013248, K020872, ETC
2013-4530	06/11/2013 07/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEVIN N COLQUITT Standly & Hamilton, LLP	K961413, K982347, K983853, ETC
2013-4531	06/11/2013 07/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEVIN N COLQUITT Standly & Hamilton, LLP	K990392, K001945, K002361, ETC

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2013-4532	06/11/2013 07/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANDREW HACK MILLENNIUM MANAGEMENT LLC	AEGERION PHARMACEUTICALS INC - JUXTAPID (LOMITAPIDE) EIRS, 483S, UNTITLED LTRS 1/13 TO PRESENT
2013-4533	06/11/2013 07/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANDREW HACK MILLENNIUM MANAGEMENT LLC	NPS PHARMACEUTICALS INC - GATTEX (TEDUGLUTIDE) INJ EIRS, 483S, UNTITLED LTRS 1/13 TO PRESENT
2013-4534	06/11/2013 07/10/2013	FDA/OFVM/CFSAN/OCD/EOS/	ALISON YOUNG USA TODAY	CRAZE - CAERS
2013-4535	06/11/2013 07/10/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SE-FO/NOL-DO/NOL-CB/	ALISON YOUNG USA TODAY	RIGER; LABORATORIOS RIGER NATURAL SAI, JALISCO, MX - ENTRY 112-4819729-0 IMPORT REFUSAL RPT; RIGER NATURAL - CALZADE DE TIALPAN ENTRY 112-1341824-2 IMPORT REFUSAL RPT; RIGER NATURAL SAI - CARR NACIONAL ENTRY 112-7520250-0 IMPORT REFUSAL RPT
2013-4536	06/11/2013 07/10/2013	FDA/OC/OES/DFOI/	SPILLER JR, ROBERT M	THE DATE OF LAST RPTS SUMMARIZING ALL JUDGMENTS DECREES & COURT ORDERS WHICH HAVE BEEN RENDERED UNDER THIS ACT 21 USC 705 (A); LINK OR LOCATION OF THE LAST PUBLISHED RPT #13; EXPLAIN THE DECISION BY THE SECRETARY TO DISCONTINUE PUBLICATION OF THES STATUTORILY-REQUIRED PRTS 1/1/08 TO 6/7/13
2013-4537	06/11/2013 07/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	RYAN J O'NEIL DUANE MORRIS LLP	STRYKER CORP - CERVICORE INTERVIEWTEBRAL DISC P090011 COMM, PRESENTATIIONS, ANALYSES, ETC 7/04 TO 2/12
2013-4538	06/11/2013 07/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN PFAEHLER, ESQ DENTONS US LLP	STRYKER CORP - FLEXICORE INTERVERTABRAL DISC P070011 COMM, PRESENTATIONS, ANALYSES, ETC
2013-4539	06/11/2013 07/10/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORO/NE-FO/NWE-DO/NWE-CB/ OC/ORO/OE/ OC/ORO/OE/	Doe J	OFF - LABEL LDENTAL IMPLANT DVC - INVESTIGATION RECS
2013-4540	06/11/2013 07/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BEVAN #182723, JOHN D	AMBEIN, AMBIEN CR (ZOLPIDEM TARTRATE); CARBRITAL (PENTOBARBITAT, CARBROMAL); DALMANE (FLUAZEPAM HCL), ETC -AERS LAST 10 YRS
2013-4541	06/11/2013	FDA/OGROP/ORO/SE-FO/ATL-	WILLIAM REYNOLDS	SPINAL SOLUTIONS LLC - EIR 2011

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	07/10/2013	DO/ATL-CB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	FIRST I INVESTIGASTIONS	
2013-4542	06/11/2013 07/10/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	MOSES LEBOVITS DANIELS FINE ISRAEL ET AL	ATRICURE INC - ATRICURE ATRICLIP LAS EXCLUSION SYS WITH PRELOADED GILLINOV-COSGROVE CLIP APRVL, SUBMISSIONS, MODIFICATIONS, ETC
2013-4543	06/11/2013 07/10/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	KEVIN STRANGE WELLS FARGO SECURITIES	ST JUDE MEDICAL - WARNING LTR UPDATES 1/10/13
2013-4544	06/11/2013 07/10/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	JUAN SANEHCZ TULSA CHANNEL 8	SWAN BOTHERS DAIRY, CLAREMORE, OK - RECS
2013-4545	06/11/2013 08/07/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	SARA A STRICKLAND MORELLI RATNER PC	BAXTER HEALTHCARE CORP, GRIFOLS THERAPEUTICS INC, GRIFOLS USA CORP, ETC - HEPATITIS C VIRUS INTRAVENOUS IMMUNOGLOBULIN (IVIG) REC 2000 TO PRESENT
2013-4546	06/11/2013 07/10/2013	OC/ORA/ OC/ORA/	WJHL-TV	COMPOUNDING PHARMACIES IN TENNESSEE 5/30/11 PRESENT
2013-4547	06/11/2013 07/10/2013	FDA/OC/OES/DDM/	SAMANTHA HERBERT GOODWIN PROCTER LLP	DKT FDA-2013-N-0243
2013-4548	06/12/2013 07/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	R. SCOTT CAMPBELL SHIVER HAMILTON	SYMBIOS MEDICAL PRODUCTS LLC - DISPOSABLE INFUSION PUMP KIT GO PUMP RAPID RECOVERY SYS K072921
2013-4549	06/12/2013 07/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ARTHUR HILSCHER MANNKIND CORP	PULMOZYME DORMASE ALFA BLA 103532 - SBA
2013-4550	06/12/2013 07/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	Daan De Coster University College London and Cochrane Collaboration	TRIALS TO SUPPORT UNSUCCESSFUL LICENSING APPLICATIONS FOR BECLOMESTASONE INHALERS IN COPD
2013-4551	06/12/2013 07/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Andrea J Mesaros Fresenius-Kabi USA	Form 483, EIR and responses resulting from the 2011 FDA inspection of Gador, S.A. Pharmaceutical Ingredients Division Calle 10 No. 103 Parque Industrial Pilar Pilar B1630CFA Bs. As., Argentina
2013-4552	06/12/2013 07/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mahidhar Chinta Micro Labs USA, Inc	NDA 017443, ANDA 076856 - SBA

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2013-4553	06/12/2013 07/11/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Richard C. Mason, Esq. COZEN O'CONNOR PC	ARENESP, AMGEN, AMERISOURCEBERGEN CORP - INVESTIGATION RECS
2013-4554	06/12/2013 07/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kimberlee Washburn Kimberlee Washburn	K083009
2013-4555	06/12/2013 07/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mahidhar Chinta Micro Labs USA, Inc	NDA 018147 - SBA
2013-4556	06/12/2013 07/11/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the firm's responses for inspections performed from January 1, 2011 to March 20, 2013 for: JHP Pharmaceuticals, Rochester, MI
2013-4557	06/12/2013 07/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Florence Bourgeois Boston Children's Hospital Informatics Program	RITALIN, RITALIN SR, CYLERT ETC - STATISTICAL REVIEWS OF INITIAL APPROVAL PACKAGE OR NEXT AVAILABLE REVIEW; BIPHETAMINE - LABEL
2013-4558	06/12/2013 07/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mahidhar Chinta Micro Labs USA, Inc	NDA 017473 - SBA
2013-4559	06/12/2013 07/11/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Kevin Engholdt Infinitum Health, LLC	EUROPHARMA CO, INC - RESPONSES TO WARNING LETTER (04/24/2013 - 06/14/2013)
2013-4560	06/12/2013 07/11/2013	FDA/OFVM/CFSAN/OCD/EOS/	BORODIN, DMITY	GLUTINATE (GLUTIOUS) INFO
2013-4561	06/12/2013 07/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K962396
2013-4562	06/12/2013 07/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Timothy Bassett Pura Vida Investments	TACFIDERA, JAKAFI - AERS

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		FDA/OMPT/CDER/ORP/DIDP/		
2013-4563	06/12/2013 07/11/2013	FDA/OMPT/CTP/OD/	Teresa Nazario KYW-TV	ELECTRONIC CIGARETTES - AERS
2013-4564	06/12/2013 07/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	Alastair Monk Cupron Inc	K061242
2013-4565	06/12/2013 07/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	BTran Tran & Associates	P040047
2013-4566	06/12/2013 07/11/2013	FDA/OC/OES/DDM/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Oren Milgram Novalere FP, Inc.	NONPRESCRIPTION DRUGS ADVISORY COMMITTEE - ANNOUNCEMENT OF MEETING (06/01/2013 - 06/12/2013)
2013-4567	06/12/2013 07/11/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	ANNETTE PAUL AURORA BAY CARE MEDICAL CENTER	TRANSCRIPT FECAL MICROBIOTA FOR TRANSPLANTATION MTG 5/2/13
2013-4568	06/12/2013 07/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PATRICK P. MEVS MARTIN CLEARWATER & BELL	TEMODAR - CLNCL TRIALS
2013-4569	06/12/2013 07/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	W.E. CHALKLEY THOMSON REUTERS	PFIZER PHARMS - ACCURETIC (HYDROCHLOROTHIAZIDE; QUINAPRIL HYDROCHLORIDE) NDA 020-125 LBLG
2013-4570	06/12/2013 08/16/2013	FDA/OGROP/ORACE-FO/CIN- DO/CIN-CB/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OGROP/ORACE-FO/DET- DO/DET-CB/	EDWIN H. CLARK CLARK LAW OFFICE	INDIVIDUAL RECS
2013-4571	06/12/2013 07/11/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORACE-FO/NOL- DO/NOL-CB/	SETH M. HYATT BARRETT JOHNSTON LLC	STANDARD CANDY CO INC - INVESTIGATION
2013-4572	06/12/2013 07/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CRAIG TRAUTMAN INTAGRAS INC	DRUG LISTINGS NOT POSTED ON NLM

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		FDA/OMPT/CDER/ORP/DIDP/		
2013-4573	06/12/2013 07/11/2013	FDA/OC/OES/DDM/	CATHERINE M. DICKENSON BRYAN CAVE LLP	DKT FDA-2007-P-0190 CERTIFIED COPY
2013-4574	06/12/2013 07/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	JAY L.T. BREAKSTONE PARKER & WAICHMAN ATTYS	MEDTRONIC - INFUSE BONE GRAFT RHBMP-2; LT CAGE INFUSE BONE GRAFT LUMBAR TAPERED FUSION DVC CORR
2013-4575	06/13/2013 07/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	AUDREY SWEARINGEN EMERGO GROUP INC	ZIMMER - NOBEL REPLACE IMPLANT SYS ZFX ABUTMENT K120873
2013-4576	06/13/2013 07/12/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAAN DE COSTER UNIV COLLEGE LONDON & COCHRANE COLLABORATION	BECLOMETASONE INHALERS - TRIALS
2013-4577	06/13/2013 07/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORAP/PA-FO/SAN-DO/SAN-CB/	ANDREW HACK MILLENNIUM MANAGEMENT LLC	KYPROLIS (CARFLIZOMBI INJ) - AERS; ONYX PHARMACEUTICALS INC - EIRS, 483S, UNTITLED LTRS 6/12 TO PRESENT
2013-4578	06/13/2013 07/12/2013	FDA/OC/OES/DFOI/	Perez, Patricia L	MINOR DELETIONS
2013-4579	06/13/2013 07/12/2013	FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECS
2013-4580	06/13/2013 07/12/2013	FDA/OC/OES/DFOI/	ELISSA FLYNN-POPPEY MINTZ LEVIN ET AL	ARIAD PHARMACEUTICALS INC - ICLUSIG, PONATINIB RECS 3/1/12 TO 6/11/13
2013-4581	06/13/2013 08/12/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ROSIERE, SHAUN	LIST OF COMPANIES THAT HAVE APPLIED FOR NDA'S, ANDAS LAST 90 DAYS; NUMBER OF NDA, ANDA APPLICATIONS PER YR 2000 TO PRESENT
2013-4582	06/13/2013 07/12/2013	FDA/OC/OES/DFOI/	Robert King FDA NEWS	FOIA DISCLOSURE LOG (06/03/2013 - 06/07/2013)
2013-4583	06/13/2013	FDA/OMPT/CDER/ORP/DIDP/	david petrocine	SHENZHEN HEPALINK PHARMACEUTICAL CO, CHINA - EIR, 483 (01/01/2011 - 08/01/2011)

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	07/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Aceto Corporation	
2013-4584	06/13/2013 07/12/2013	FDA/OFVM/CFSAN/OCD/EOS/	John O'Loughlin Weil, Gotshal & Manges, LLP	TOPO CHICO MINERAL WATER - COMPLAINTS, FDA ACTIONS (01/01/2013 - 06/11/2013)
2013-4585	06/13/2013 07/12/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Regena Rosati Cornerstone Research	DRUGS WITH BLACK BOX WARNINGS - NAMES, DATES, INDICATIONS ETC
2013-4586	06/14/2013 07/15/2013	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	Scott Talbot Novel Laboratories	OHM LABORATORIES, NEW JERSEY - 483 (12/01/2012 - 12/31/2012)
2013-4587	06/14/2013 07/18/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Daniel Simpson LIFESOUTH COMMUNITY BLOOD CENTERS INC	BK120067
2013-4588	06/14/2013 07/15/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/ OC/ORA/ OC/ORA/	Monique V. Robinson SEECA Medical, Inc.	TESTING RESULTS
2013-4589	06/14/2013 07/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Edward E. Lisberg, MD Asthma and Allergy Center of Chicago, SC	K87379317, K83203719
2013-4590	06/14/2013 07/15/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/ORO/DIOP/	Mark Prinz Registrar Corp	RED LIST, ACTIVE IMPORT ALERT - LIST OF COMPANIES
2013-4591	06/14/2013 07/15/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	IFRAN A. LATEEF KNOBBE MARTENS OLSON & BEAR	COVIDIENS - OXIMAX PULSE OXIMETER MODEL N-600X K123581
2013-4592	06/14/2013 07/15/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	FOI Services, Inc.	REDACTED 510KS 5/13
2013-4593	06/14/2013 07/15/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	MUJIB U. QIDWAI GRIFOLS BIOLOGICALS INC	BAXTER PLASMA, ANGELES, CA - EIR 10/10 TO 10/12

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2013-4594	06/14/2013 07/15/2013	FDA/OGROP/ORO/ORO/DIOP/ OC/ORO/ OC/ORO/	DONALD BLUE GLOBAL TRADE INTELLIGENCE INC	ALL IMPORTS FROM 5/20/13 TO 6/15/13
2013-4595	06/14/2013 07/15/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	COLLEEN M. HEISEY JONES DAY	BETHKIS (TOBRAMYCIN INHALATION SOLUTION) NDA 20-1820 - LBLG RVW, MEDICAL RVW, CHEMISTRY RVW
2013-4596	06/14/2013 07/15/2013	FDA/OC/OES/DFOI/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 165504 5/14/13
2013-4597	06/14/2013 07/15/2013	FDA/OC/OES/DFOI/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 165500 5/20/13
2013-4598	06/14/2013 07/15/2013	FDA/OGROP/ORO/NE-FO/NWE- DO/NWE-CB/	JENNIFER SMITH CIVIL & ENVIRONMENTAL CONSULTANTS INC	OXUS ENVIRONMENTAL, PITTSFIELD, ME - INVESTIGATIONS
2013-4599	06/14/2013 07/15/2013	FDA/OGROP/ORO/SE-FO/ATL- DO/ATL-CB/	JOHNATHAN CARLSON WNCN NEWS	GATE GOURMET #302 - INSP 11/29/12
2013-4600	06/17/2013 07/16/2013	OC/CVM/OCD/	MCKENZIE CATO Hyman, Phelps & McNamara P.C.	BACKGROUND LEVELS OF DIOXIN AND DIOXIN-LIKE COMPOUNDS IN ANIMAL FEED - FIELD ASSIGNMENTS FOLLOW-UP RECS
2013-4601	06/17/2013 07/16/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SW-FO/DAL- DO/DAL-CB/ FDA/OGROP/ORO/SW- FO/SWID/SWID-CB/	CHRISTINE RAMETTE SURETY CLAIMS INC	AZTECA CANDIES INC - ENTRY #BKM-0028627-8 INVOICES, NOTICES OF ACTION, PACKING LISTS, ETC
2013-4602	06/17/2013 07/16/2013	FDA/OO/OHR/	RICHARD S LUNDIN NICKELSPORN & LUNDIN PC	INDIVIDUAL RECS
2013-4603	06/17/2013 07/16/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JONATHAN B NACE PAULSON & NACE	ABBOTT LABS - HUMIRA POST-APRVL SAFETY STUDIES; TREXALL, RHEUMATREX (METHOTREXATE) AERS 1998 TO 2012, ETC
2013-4604	06/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	TOSHIO MURATA	OCULUS OPTIKGERATE GMBH - PENTACAM SHEIMPFLUG CAMERA K030719

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	07/16/2013	FDA/OC/OES/DFOI/	NIDEK INC	
2013-4605	06/17/2013 07/16/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SARAH BUDUSON WEWS - NewsChannel5	PRADAXA - AERS 10/10 TO 6/15/13
2013-4606	06/17/2013 07/16/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DEBRA HATHAWAY THINC PHARMA	AMITIZA (LUBIPROSTONE) NDA 21-908/S010,S011 - RVWS, CORR
2013-4607	06/17/2013 07/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	LORI PFOHL TELEFLEX MEDICAL	KIMBERLY-CLARK - KIMVENT MICROCUFF SUBGLOTTIC SUCTIONING TUBE K120985
2013-4608	06/17/2013 07/16/2013	FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA REQUEST LOG 06/10/2013 - 06/14/2013
2013-4609	06/17/2013 07/16/2013	FDA/OMPT/CTP/OD/	Mark Zdechlik MINNESOTA PUBLIC RADIO NEWS	ELECTRONIC CIGARETTES - AERS DATABASE
2013-4610	06/17/2013 07/16/2013	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	Doe J	CONSUMER COMPLAINT
2013-4611	06/17/2013 07/16/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jocelyn Polito X-GEN PHARMACEUTICALS INC	CHONGQING PHARMA RESEARCH INSTITUTE CO, LTD, CHONGGGQING, CHINA - EIR,483 (07/26/2010 - 07/30/2010)
2013-4612	06/17/2013 07/16/2013	FDA/OC/OES/DDM/	John Chan UNIVERSITY OF CALIFORNIA, SAN FRANCISCO	ONCOLOGY DRUG ADVISORY COMMITTEE MEETING MINUTES, TRANSCRIPTS (01/01/1982 - 01/01/1998)
2013-4613	06/17/2013 07/16/2013	FDA/OGROP/ORR/CE-FO/CIN-DO/CIN-CB/	John Walsh James Alexander Corporation	P&G CHEMICALS, CINCINNATI, OH - EIR, 483 (06/14/2010 - 06/14/2013)
2013-4614	06/17/2013 07/16/2013	FDA/OC/OES/DFOI/	COOPER 328257, JACK	SUBOXONE, ROXY, PERCOCET - RECS
2013-4615	06/17/2013 07/16/2013	OC/ORR/ OC/ORR/ FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/	DUFFY, TAMMY	CMPLNT 131636
2013-4616	06/17/2013	OC/ORR/	Yingchao Xiao	AF4-0581272-4/2/1

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	07/16/2013	OC/OR/ FDA/OGROP/OR/SW-FO/SWID/SWID-CB/ FDA/OGROP/OR/SW-FO/DAL-DO/DAL-CB/	Lee & Xiao	
2013-4617	06/17/2013 07/16/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Sinem Tan MN Pharmaceuticals-Mustafa Nevzat Ilac	MUSTAFA NEVZAT ILAC SANAYII A.S., INSTANBUL - EIR 04/20/12 - 05/03/12
2013-4618	06/17/2013 07/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	RODNEY VAN DE HOEF VANDEHOEF, Rodney A	PRO LASER III, LIDAR - OUTPUT, MILLITATT RATING, ADVERSE EVENTS
2013-4619	06/17/2013 07/16/2013	FDA/OGROP/OR/CE-FO/MIN-DO/MIN-CB/	Curtis Walcker VRP Manufacturing, LLC	HILLESTAD PHARMACEUTICALS US, INC - 483, CORR (07/01/2012 - 06/11/2013)
2013-4620	06/17/2013 07/16/2013	FDA/OGROP/OR/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/OR/PA-FO/SEA-DO/SEA-CB/ FDA/OGROP/OR/SE-FO/FLA-DO/FLA-CB/ FDA/OGROP/OR/SW-FO/DAL-DO/DAL-CB/	DAGES, Joe. THOMPSON, Jackie. Keller and Heckman LLP	WARNING LETTER RESPONSES, ENFORCEMENT ACTION RECS
2013-4621	06/17/2013 07/16/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Eriko Yagi E. Yagi	SKYE PHARMA - 483, WARNING LETTER (10/01/2001 - 10/01/2006)
2013-4622	06/17/2013 07/16/2013	FDA/OGROP/OR/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Eriko Yagi E. Yagi	ALZA - 483, WARNING LETTER (05/01/1993 - 11/01/2001)
2013-4623	06/17/2013 07/16/2013	FDA/OC/OES/DDM/	ROSS RENDELMAN HOGAN LOVELLS LLP	DKT FDA-2013-P-0058, FDA-2013-P-0119, ETC.
2013-4624	06/18/2013 07/17/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	PCAS FINLAND OY, TURKU, FINLAND - EIRS, 483S, CO RESP 2/08/13

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-4625	06/18/2013 07/17/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	WALTER E CHALKLEY THOMSON REUTERS	BAXTER PHARMACEUTICALS SOLUTIONS LLC, BLOOMINGTON, IN - EIRS, 483S, CO RESP 03/12/13
2013-4626	06/18/2013 07/17/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	WALTER E CHALKLEY THOMSON REUTERS	AMBI PHARMACEUTICALS INC, BROOKSVILLE, FL - EIRS, 483S, CO RESP 03/30/12
2013-4627	06/18/2013 07/17/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	WALTER E CHALKLEY THOMSON REUTERS	AMAG PHARMACEUTICALS INC, LEXINGTON, MA - EIRS, 483S, CO RESP 02/07/13
2013-4628	06/18/2013 07/17/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	ACTAVIS ELIZABETH LLC, ELIZABETH, NJ - EIRS, 483S, CO RESP 02/15/13
2013-4629	06/18/2013 07/17/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	WALTER E CHALKLEY THOMSON REUTERS	WHITNEY LABS LP, ORMOND BEACH, FL - EIRS, 483S, CO RESP 01/26/12
2013-4630	06/18/2013 07/17/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	WALTER E CHALKLEY THOMSON REUTERS	TITAN MEDICAL ENTERPRISES INC (DBA US APOTHECARY LABS), SANTA FE SPRINGS, CA - EIRS, 483S, CO RESP 01/15/13
2013-4631	06/18/2013 07/17/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	WALTER E CHALKLEY THOMSON REUTERS	TG UNITED PHARMACEUTICALS INC, BROOKSVILLE, FL - EIRS, 483S, CO RESP 03/30/12
2013-4632	06/18/2013 07/17/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	AMERICAN NATIONAL RED CROSS, COLUMBUS, OH - EIRS. 483S, CO RESP 03/15/13
2013-4633	06/18/2013 07/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	NOVARTIS PHARMA BPO, HUNINGUE, FRANCE - EIRS, 483S, CO RESP 01/31/12
2013-4634	06/18/2013 07/17/2013	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	WALTER E CHALKLEY THOMSON REUTERS	MEDIMMUNE LLC, GAITHERSBURG, MD - EIRS, 483S, CO RESP 03/20/13
2013-4635	06/18/2013 07/17/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	MCKESSON MEDICAL SURGICAL, SWEDESSBORO, NJ - EIRS, 483S, CO RESP 12/08/11
2013-4636	06/18/2013 07/17/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	WALTER E CHALKLEY THOMSON REUTERS	ELI LILLY & CO, INDIANAPOLIS, IN - EIRS, 483S, CO RESP 02/14/13
2013-4637	06/18/2013 07/17/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	WALTER E CHALKLEY THOMSON REUTERS	KREMSERS URBAN PHARMACEUTICALS INC, SEYMOUR, IN - EIRS, 483S, CO RESP 10/31/12
2013-4638	06/18/2013	FDA/OGROP/ORA/CE-FO/BLT-	WASLTER E CHALKLEY	INOVA HEALTH CARE SERVICES, INOVA BLOOD DONOR

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	07/17/2013	DO/BLT-CB/	THOMSON REUTERS	SERVICES, STERLING, VA - EIRS, 483S, CO RESP 02/13/12
2013-4639	06/18/2013 07/17/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	WALTER E CHALKLEY THOMSON REUTERS	ELBA INC (ELBA LABORATORIES), TROY, MI - EIRS, 483S, CO RESP 09/27/12
2013-4640	06/18/2013 07/17/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	DPT LAKEWOOD LLC, LAKEWOOD, NJ - EIRS, 483S, CO RESP 09/27/12
2013-4641	06/18/2013 07/17/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	CSL PLASMA INC, BELOIT, WI - EIRS, 483S, CO RESP 02/20/13
2013-4642	06/18/2013 08/26/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	COREPHARMA LLC, MIDDLESEX, NJ - EIRS, 483S, CO RESP 06/11/12
2013-4643	06/18/2013 07/17/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	WALTER E CHALKLEY THOMSON REUTERS	CARDINAL HEALTH 414 LLC, TAMPA, FL - EIRS, 483S, CO RESP 03/19/13
2013-4644	06/18/2013 07/17/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	BROWN MD, RAYMOND, PHILADELPHIA, PA - EIRS, 483S, CO RESP 01/29/13
2013-4645	06/18/2013 07/17/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	WALTER E CHALKLEY THOMSON REUTERS	BOEHRINGER INGELHEIM PHARMACEUTICALS INC, DANBURY, CT - EIRS, 483S, CO RESP 01/30/13
2013-4646	06/18/2013 07/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sandy Lee B&H Consulting Services, Inc.	WOCKHARDT LIMITED, AURANGABAD, INDIA - EIR (03/01/2013 - 06/13/2013)
2013-4647	06/18/2013 07/17/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Adam Bobkin MILBERG LLP	MARC HERMELIN, K-V PHARM, ETHEX CORP - VARIOUS RECS
2013-4648	06/18/2013 07/17/2013	FDA/OC/OES/DFOI/	Desmond Jenson Tobacco Control Legal Consortium	2012-4834, 2012-8511, 2013-2393
2013-4649	06/18/2013 07/17/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Naoto Fujikawa Takeda Pharmaceutical Company Limited	NEW MOLECULAR ENTITIES APPROVED AS DRUGS BETWEEN 1/1/1985 AND 12/31/2012
2013-4650	06/18/2013 07/17/2013	OC/CVM/OCD/	Judith Hill INTERTEK CANTOX	AMMONIUM FORMATE - FOOD ADDITIVE PETITIONS
2013-4651	06/18/2013 07/17/2013	OC/ORACE-FO/ORM/ OC/ORACE-FO/ORM/	b. burgess BURGESS, BERNIE	LIST OF INSPECTIONS CONDUCTED BY LOS-DO FY 2007

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2013-4652	06/18/2013 07/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	D. Jonathan Corbin D Jonathan Corbin	IND RECS FOR ANY DRUG CONTAINING 3-BROMOPYRUVATE OR CHEMICAL ANALOGS
2013-4653	06/18/2013 07/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Dr J-I. Schafer Electro Medical Geratebau GmbH	K862106
2013-4654	06/18/2013 07/17/2013	FDA/OMPT/OSMP/OOPD/	Stanley Satz Advanced Imaging Projects, Inc.	FERUMOXYTOL - OOPD DESIGNATION RECS
2013-4655	06/18/2013 07/17/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	b. burgess BURGESS, BERNIE	FACTS 808885 - ORA FINANCIAL DOCUMENTS
2013-4656	06/18/2013 07/17/2013	OC/CVM/OCD/	Judith Hill Internek Cantox	POLYSORBATE 80 - FOOD ADDITIVE PETITIONS
2013-4657	06/18/2013 07/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John Bradley UNIVERSITY OF CALIFORNIA SAN DIEGO	NDA 050720, 050725, 050726
2013-4658	06/18/2013 07/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Linda Kariya Nihon Kohden Corporation	K123581
2013-4659	06/18/2013 07/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ashley Yeager The Simon Law Firm	INTRAVENOUS ADMINISTRATION OF BYNTYL - AERS
2013-4660	06/18/2013 07/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sandy Lee B&H Consulting Services, Inc.	WOCKHARDT LIMITED, INDIA - 483 (03/01/2013 - 06/14/2013)
2013-4661	06/18/2013 07/17/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	JoNel Aleccia MSNBC.COM	TOWNSEND FARMS, FAIRVIEW, OR - EIR, 483, WARNING LETTER (05/01/2013 - 06/14/2013)
2013-4662	06/18/2013 07/17/2013	FDA/OMPT/CTP/OD/	Doe J	INDIVIDUAL RECS
2013-4663	06/18/2013 07/31/2013	OC/ORA/ OC/ORA/	Mark Prinz Registrar Corp	FDA PRIOR NOTICE INFORMATION SUBMITTED TO FDA (01/01/2013 - 01/31/2013)
2013-4664	06/18/2013	FDA/OMPT/CTP/OD/	Chris Murphy	PLOOM MODEL ONE - FDA CLASSIFICATION RECS

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	07/17/2013		Valor Equity Partners	
2013-4665	06/18/2013 07/17/2013	FDA/OGROP/ORR/SW-FO/DEN-DO/DEN-CB/	Jody Roberts Mind Research Network	UNIVERSITY OF NEW MEXICO HEALTH SCIENCES CENTER - 483 (01/01/2013 - 06/17/2013)
2013-4666	06/18/2013 07/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Wendy Linthicum American Fluoroseal Corporation (now Saint Gobain PPL)	K933228
2013-4667	06/18/2013 07/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Wendy Linthicum American Fluoroseal Corporation (now Saint Gobain PPL)	K870865
2013-4668	06/18/2013 07/17/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Leanne Usa WOCKHARDT USA INC	ANDA 88-312
2013-4669	06/18/2013 07/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Wendy Linthicum American Fluoroseal Corporation (now part of Saint Gobain)	MAF 1143
2013-4670	06/18/2013 07/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Wendy Linthicum American Fluoroseal Corporation (now part of Saint Gobain)	MAF 1506
2013-4671	06/18/2013 07/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Walters AtriCure, Inc.	K090202, K120857
2013-4672	06/18/2013 07/17/2013	OC/CVM/OCD/	Sarah Dumas UNIVERSITY OF ILLINOIS	NADA 055-030 FOIA SUMMARY
2013-4673	06/19/2013 07/18/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Mahidhar Chinta Micro Labs USA, Inc	ANDA 091619 - SBA
2013-4674	06/19/2013 07/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	Gary Syring Quality & Regulatory Associates, LLC	K970951
2013-4675	06/19/2013 07/18/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Gary Syring Quality & Regulatory Associates, LLC	K884937
2013-4676	06/19/2013 07/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	Gary Syring SYRING, GARY J	K033978

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2013-4677	06/19/2013 07/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Constance M Williams Williams, Constance M	LUPRON - AERS
2013-4678	06/19/2013 07/18/2013	OC/CVM/OCD/	John Russell The Indianapolis Star	ANIMAL DRUG APPROVALS 01/01/1993 - 12/31/2008
2013-4679	06/19/2013 07/18/2013	FDA/OMPT/OSMP/OOPD/	Timothy Cote Cote Orphan Consulting	EPOETIN ALFA - ORPHAN PRODUCT DESIGNATION RECS
2013-4680	06/19/2013 07/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Laura Strickler CBS EVENING NEWS	NEXIUM, ABILIFY, CRESTOR ETC - DRUG MASTER FILE
2013-4681	06/19/2013 07/18/2013	FDA/OC/OES/DDM/	SAMANTHA HERBERT GOODWIN PROCTER LLP	DKT FDA-2009-M-0101
2013-4682	06/19/2013 07/18/2013	FDA/OC/OES/DDM/	ROSS RENDELMAN HOGAN LOVELLS LLP	DKT FDA-2013-P-0058, FDA-2013-P-0119, ETC.
2013-4683	06/19/2013 07/18/2013	FDA/OC/OCC/	DANA A. PRIVU EPSTEIN BECKER & GREEN PC	HOME BREW LAB TESTS
2013-4684	06/19/2013 07/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KAREN COLLINS HARDISON COCHRAN	MIRENA IUD - LGLG 2000 TO 2013
2013-4685	06/19/2013 07/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	STEPHEN C. SCHULTE WINSTON & STRAWN LLP	BRAIN LAB AG - NOVALIS SHAPED BEAM SURGERY SYS 510K
2013-4686	06/19/2013 07/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	IAN McALLISTER KREINDLER & KREINDLER	SMITH & NEPHEW - R3 CONSTRAINED LINER K111635 6/9/11
2013-4687	06/19/2013 07/18/2013	FDA/OO/OFBA/OAGS/	KREINDLER & KREINDLER	BILDERBERG CONFERENCE - CORR 2008 TO 2013
2013-4688	06/19/2013 07/18/2013	FDA/OC/OES/DFOI/	CORBIN, D JONATHAN .	1305533; 1305537
2013-4689	06/19/2013 07/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CAREN MARTINI YES PHARMACEUTICAL	PFIZER - ADVIL CONGESTION RELIEF SAFETY RTP

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-4690	06/19/2013 07/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	McGEE B10590, CLAUDE	ANTERIOR LUMBAR DISK & FUSION - APRVL
2013-4691	06/19/2013 07/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHELLEY WHITE FIGARI & DAVENPORT	AVASTIN (BEVACIZUMAB) - EFFICACY
2013-4692	06/19/2013 07/18/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	STEPHEN C. SCHULTE WINSTON & STRAWN LLP	VARIAN MEDICAL SYS - 4D INTEGRATED TREATMENT CONSOLE - RECALL 10/16/09
2013-4693	06/19/2013 07/18/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OO/OFBA/OAGS/	MINDY GOLDSTEIN, Esq. EMORY SCHOOL OF LAW	FDA FOOD PROCESSING SECTOR STUDY FINAL RPT 11/11
2013-4694	06/19/2013 07/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	INTERMUNE PHARMS - ACTIMMUNE (INTERFERON GAMMA-1B) BLA 10-3836 APRVL, LBLG
2013-4695	06/20/2013 07/19/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	A LAYNE STACKHOUSE JONES WARD PLC	MIRENA (LEVONORGESTREL-RELEASING) INTRAUTERINE DVC - CLNCL TRIALS, RPTS, CORR, ETC
2013-4696	06/20/2013 07/19/2013	OC/ORA/ORM/ OC/ORA/ORM/	ROBERT KING FDANEWS	LIST OF 483S FOR PHARMACEUTICAL, BIOLOGICS & MEDICAL DVC MFG BOTH IN THE US & OUTSIDE THE US 5/1-31/13
2013-4697	06/20/2013 07/19/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	KRISTI O SMEDLEY WASHINGTON INFORMATION SOURCE	HUVEPHARMA INC, ST LOUIS, MO - EIRS, 483S 1/2/13 TO PRESENT
2013-4698	06/20/2013 07/19/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	BRENDA M GARTZ ELI LILLY & CO	MANKIND CORP, DUANBURY, CT - EIRS 2009 TO PRESENT
2013-4699	06/20/2013 07/19/2013	FDA/OC/OES/ FDA/OC/OL/	ABRAHAM PAYTON AMERICAN BRIDGE 21ST	REP DAVID JOYCE & FDA COMMISSIONER, DEPUTY COMMISSIONER, ASSOCAITE COMMISSIONER, ETC 1/3/13 TO PRESENT; FRANCIS J FRANK SASINOWSKI & FDA

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		FDA/OC/OPP/OP/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/OIP/ OC/ORO/ OC/ORO/	CENTURY	COMMISSIONER, DEPUTY COMMISSIONER, ASSOCIATE COMMISSIONER, CORR ETC
2013-4700	06/20/2013 07/19/2013	FDA/OGROP/ORO/SE-FO/FLA- DO/FLA-CB/	SHELLY REILLY AARP	CRYSTAL CARE INTERNATIONAL INC, LUTZ, FL - WARNING LTR 5/22/09 COMPLIANCE WITH REGULATIONS
2013-4701	06/20/2013 07/19/2013	FDA/OGROP/ORO/SW-FO/KAN- DO/KAN-CB/ OC/ORO/ OC/ORO/	BRAD HODGES FREMONT FARMS LLC	FREMONT FRAMS LLC -SPL 800442 - ANALYTICAL RPT 5/31/13
2013-4702	06/20/2013 07/19/2013	FDA/OFVM/CFSAN/OCD/EOS/	JASON A DEAN Hulsey Oliver & Mahar, LLP	JARCHEM INDUSTRIES INC - FOOD FACILITY REGISTRATION NO 10526878760
2013-4703	06/21/2013 07/22/2013	FDA/OGROP/ORO/CE-FO/DET- DO/DET-CB/ FDA/OGROP/ORO/CE-FO/MIN- DO/MIN-CB/ FDA/OGROP/ORO/CE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORO/SW-FO/KAN- DO/KAN-CB/	Sonali Gunawardhana Wiley ReinLLP	KERRY INGREDIENTS AND FLAVORINGS - EIR, 483, CORR (02/01/2013 - 06/14/2013)
2013-4704	06/21/2013 07/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Elizabeth Bohn Bohn, Elizabeth	VIVIAN - APPROVAL RECS
2013-4705	06/21/2013 07/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K121474
2013-4706	06/21/2013 07/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K100723
2013-4707	06/21/2013 07/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K103470
2013-4708	06/21/2013 07/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K120179

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2013-4709	06/21/2013 07/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K100386
2013-4710	06/21/2013 07/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kevin Minnich B. Braun Medical Inc.	K110901
2013-4711	06/21/2013 07/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kellin Chatfield DLA Piper LLP (US)	K925008
2013-4712	06/21/2013 07/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	510K REDACTED AND RELEASED IN MAY 2013
2013-4713	06/21/2013 07/22/2013	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2013-2539
2013-4714	06/21/2013 07/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Allison Scott Esaote, S.p.A.	K070903 K083882 K101605 ETC
2013-4715	06/21/2013 07/22/2013	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2013-3716
2013-4716	06/21/2013 07/22/2013	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2013-3522
2013-4717	06/21/2013 07/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Justin M McFadden STOEL RIVES LLP	DMF 21221
2013-4718	06/21/2013 07/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lisa Suchar self-employed	ADASUVE - SBA
2013-4719	06/21/2013 07/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Theresa Deisher Sound Choice Pharmaceutical Institute	MMRII - APPROVAL LETTERS
2013-4720	06/21/2013	FDA/OMPT/CDER/ORP/DIDP/	Merlaine Bissainthe	AMBIEN - AERS

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	07/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Merlaine Bissainthe, Attorney at Law	
2013-4721	06/21/2013 07/22/2013	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	b. burgess BURGESS, BERNIE	110674 - EIR, ENDORSEMENT
2013-4722	06/21/2013 07/22/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Tammy Nash OptumRx	OPTUM RX, OVERLAND PARK, KS - EIR (04/02/2012 - 06/18/2013)
2013-4723	06/21/2013 07/22/2013	FDA/OMPT/OSMP/OOPD/	Anne Madej Genentech, Inc.	EXEMESTANE - ORPHAN PRODUCT DESIGNATION
2013-4724	06/21/2013 07/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Eric Thostesen JANSSEN ORTHO LLC	CENEXI - EIR (07/01/2012 - 06/19/2013)
2013-4725	06/21/2013 07/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Majid Iqbal Motherisk	BUPROPION, ESCITALOPRAM - AERS
2013-4726	06/21/2013 07/22/2013	OC/CVM/OCD/	Becky Armfield NOVARTIS ANIMAL HEALTH US INC	RACTOPAMINE HYDROCHLORIDE TYPE B LIQUID FEED ANALYTICAL METHOD
2013-4727	06/21/2013 07/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	XELLIA PHARMACEUTICALS, COPENHAGEN, DENMARK - 483, EIR SUMMARIES
2013-4728	06/21/2013 07/22/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Paul Knoepfler UC DAVIS	INTELLICELL BIOSCIENCES INC - 483 (03/01/2013 - 06/19/2013)
2013-4729	06/21/2013 07/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	XELLIA PHARMACEUTICALS, COPENHAGEN, DENMARK - EIR
2013-4730	06/21/2013 07/22/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Michael E Rettig, R.N. B.S.N. Michael E Rettig, R.N. B.S.N. Legal Nurse Consultant	AXIOBIONICS, LLC, ANN ARBOR, MI - RECALL, WARNING LETTER RECS (01/01/2011 - 06/20/2013)
2013-4731	06/21/2013	FDA/OC/OES/DDM/	Jacki Thompson	FDA-2009-D-0430

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	07/22/2013	FDA/OFVM/CFSAN/OCD/EOS/	Keller and Heckman LLP	
2013-4732	06/21/2013 07/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	LISINOPRIL - TESTING RECS
2013-4733	06/21/2013 07/22/2013	OC/CVM/OCD/	Mike Smith Truth in Food/Custom Publications LLC	MILK SAMPLING FIELD ASSIGNMENT RESULTS (11/01/2011 - 06/20/2013)
2013-4734	06/21/2013 07/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Shalin Jani Aerie Pharmaceuticals, Inc.	NDA 019779 SBA
2013-4735	06/21/2013 07/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Phylis C Dryden DRYDEN, FORREST	AFINITOR - AERS SUMMARY
2013-4736	06/21/2013 08/29/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Rachel Johnson FOI Services, Inc.	BK100056
2013-4737	06/21/2013 07/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 21610 ABUK IMPURITIES
2013-4738	06/21/2013 07/22/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/ OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/OIP/	REBECCA CASE LERNERS LLP	STRYKER - REJUVENATE MODULAR-NECK STEMS PRE-MARKET APRVL, MONOGRAPHS, PROD INSERTS, ETC
2013-4739	06/21/2013 07/22/2013	OC/CVM/OCD/	STEPHEN J TELKEN SCHOEN WALTON TELKEN & FOSTER LLC	INDIVIDUAL RECS
2013-4740	06/21/2013 07/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	J KENNETH KRUVANT J KENNETH KRUVANT LAW	ADVANCED ORTHOPEDIC SOLUTIOS - ES TROCHANTERIC NAIL CMLPLNTS LAST TEN YRS; INDIVIDUAL RECS

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			OFCS	
2013-4741	06/21/2013 07/22/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	FRAN SILVERMAN TRUTH IN ADVERTISING.ORG	VEVMA NUTRITION CO, SCOTTSDALE, AZ - EIR, 483, CO RESP 11/12
2013-4742	06/21/2013 07/22/2013	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	EVAN BASLER LIFE SOUTH COMMUNITY BLOOD CENTERS	PUGET SOUND BLOOD CENTER, SEATTLE, WA - EIR, 483 1/14/13-2/15/13
2013-4743	06/24/2013 07/23/2013	FDA/OO/OFBA/OAGS/	Prakash Behrani Platinum Systems, Inc.	HHSF223200950034P - MOST RECENT PROPOSAL
2013-4744	06/24/2013 07/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jeffrey Meyerson The Meyerson Law Firm, PLC	K090949
2013-4745	06/24/2013 07/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Davey Leu Mello Biotech	IND 69896
2013-4746	06/24/2013 07/23/2013	FDA/OFVM/CFSAN/OCD/EOS/	Kristi Wolff Wolff, Kristi	SPHAERANTHUS INDICUS - NEW DIETARY INGREDIENT RECS
2013-4747	06/24/2013 07/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Quan Zhao, Md Phoenix Childrens Hospital	RITUXIMAD - AERS
2013-4748	06/24/2013 07/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tamilselvi.S Quest Lifesciences Pvt Ltd	QUEST LIFESCIENCES PVT LTD, CHENNAI, INDIA - EIR 12/26/2011 TO 12/30/2011
2013-4749	06/24/2013 07/23/2013	FDA/OFVM/CFSAN/OCD/EOS/	Joshua Valero Capstone Law, APC	KNUDSEN - NUTRIENT CONTENT CLAIMS (CERTIFIED) (06/20/2004 - 06/20/2013)
2013-4750	06/24/2013 07/23/2013	FDA/OFVM/CFSAN/OCD/EOS/	Joshua Valero Capstone Law, APC	SMUCKER - NUTRIENT CONTENT CLAIMS (CERTIFIED) (6/20/2009 - 06/20/2013)
2013-4751	06/24/2013 07/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Scott A. Hodes Scott A. Hodes, Attorney at Law	ICLUSIG - ISR
2013-4752	06/24/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2013-3787 - REQUEST LETTER

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	07/23/2013		MERCK & CO., INC.	
2013-4753	06/24/2013 07/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3744 - REQUEST LETTER
2013-4754	06/24/2013 07/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3639 - REQUEST LETTER
2013-4755	06/24/2013 07/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3633 - REQUEST LETTER
2013-4756	06/24/2013 07/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3868 - REQUEST LETTER
2013-4757	06/24/2013 07/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3525 - REQUEST LETTER
2013-4758	06/24/2013 07/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3458 - REQUEST LETTER
2013-4759	06/24/2013 07/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3459 & 2013-3460 - REQUEST LETTER
2013-4760	06/24/2013 07/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3615 - REQUEST LETTER
2013-4761	06/24/2013 07/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3462 - REQUEST LETTER
2013-4762	06/24/2013 07/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3630 - REQUEST LETTER
2013-4763	06/24/2013 07/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3996 - REQUEST LETTER
2013-4764	06/24/2013 07/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3723 - REQUEST LETTER
2013-4765	06/24/2013 07/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4099 - REQUEST LETTER
2013-4766	06/24/2013 07/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3461 - REQUEST LETTER ONLY
2013-4767	06/24/2013 07/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3889 - REQUEST LETTER ONLY
2013-4768	06/24/2013 07/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4020 - REQUEST LETTER ONLY

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2013-4769	06/24/2013 07/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3678 - REQUEST LETTER
2013-4770	06/24/2013 07/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3499 - REQUEST LETTER
2013-4771	06/24/2013 07/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3602 - REQUEST LETTER
2013-4772	06/24/2013 07/24/2013	FDA/OO/OHR/ FDA/OC/OES/	Stacylyn Dewey ROPES & GRAY LLP	INDIVIDUAL RECS
2013-4773	06/24/2013 07/23/2013	FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/	Lynn Keefe Lynn Keefe	BRACCO DIAGNOSTICS - 483 (01/01/2008 - 06/19/2013)
2013-4774	06/24/2013 07/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	Vivianne Noetzel Vivianne Noetzel	K102947, K120711, K130361
2013-4775	06/24/2013 07/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	Saleem Musallam Excite Medical corp.	K103248
2013-4776	06/24/2013 07/23/2013	FDA/OC/OES/DDM/	LAUREN FAMEGGIA Hyman, Phelps and McNamara	OTC VOL 210421, 210014, ETC.
2013-4777	06/24/2013 07/23/2013	FDA/OC/OES/DDM/	LAUREN FAMEGGIA Hyman, Phelps and McNamara	OTC VOL 210013
2013-4778	06/24/2013 07/23/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	R.O. DEAN COMPLIANCE SYSTEMS INTERNATIONAL LLC	SMITH & NEPHEW - OSTEORAPTOR K082215
2013-4779	06/24/2013 07/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	R.O. DEAN COMPLIANCE SYSTEMS INTERNATIONAL LLC	ARTHREX - INTERFERENCE SCREW K062466
2013-4780	06/24/2013 07/23/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	R.O. DEAN COMPLIANCE SYSTEMS INTERNATIONAL LLC	SMITH & NEPHEW - BIORAPTOR 2.3 PK SUTURE ANCHOR 071586
2013-4781	06/24/2013 07/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	R.O. DEAN COMPLIANCE SYSTEMS INTERNATIONAL LLC	PROMEDICAL PRODUCTS CO LTD, LIYANG, CHINA - EIR, 483
2013-4782	06/24/2013 07/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	R.O. DEAN COMPLIANCE SYSTEMS INTERNATIONAL LLC	PARCUS - KNOTLESS PEEK CF PUSH IN SUTURE ANCHORS K113730
2013-4783	06/24/2013 07/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	R.O. DEAN COMPLIANCE SYSTEMS	SMITH & NEPHEW - BIOSURE PK INTERFERENCE SCREW K083635

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			INTERNATIONAL LLC	
2013-4784	06/24/2013 07/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	R.O. DEAN COMPLIANCE SYSTEMS INTERNATIONAL LLC	SMITH & NEPHEW - TWINFIX ULTRA HA SUTURE ANCHOR K093844
2013-4785	06/24/2013 07/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	JANET COOPER WESTMED INC.	CIRCUIT BREATHING W CONNECTOR ADAPTER Y PIECE K904538
2013-4786	06/24/2013 07/23/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	STEPHEN T. FOWLER WESTMED INC.	AMERICAN MEDICAL SYS INC - SUGICAL MESH DVC FOR PELVIC FLOOR REPAIR K023516
2013-4787	06/24/2013 07/23/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	A. LUKE SMITH, Esq. FARUQI & FARUQI LLP	ANDA 77-575
2013-4788	06/24/2013 07/23/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	A. LUKE SMITH, Esq. FARUQI & FARUQI LLP	ANDA 91-226
2013-4789	06/24/2013 07/23/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	A. LUKE SMITH, Esq. FARUQI & FARUQI LLP	ANDA 77-830
2013-4790	06/24/2013 07/23/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	A. LUKE SMITH, Esq. FARUQI & FARUQI LLP	ANDA 78-773
2013-4791	06/24/2013 07/23/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	A. LUKE SMITH, Esq. FARUQI & FARUQI LLP	ANDA 90-548
2013-4792	06/24/2013 07/23/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BETH ZIEMBA CELL THERAPEUTICS INC	TOSEDOSTAT - FAERS
2013-4793	06/24/2013	FDA/OFVM/CFSAN/OCD/EOS/	GEORGE G. MISKO	4/9/2013 CONFERENCE IN NEW ORLEANS, LA - AUDIO OF POWERPOINT PRESENTATION "RISK ASSESSMENT OF

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	07/23/2013		Keller and Heckman LLP	CYCLIC SILOXANES OCTAMETHYLCYCLOTETRAILOXANE"
2013-4794	06/24/2013 07/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	STEPHEN T. FOWLER REED SMITH LLP	AMERICAN MEDICAL SYS INC K011251 - REVIEWER NOTES, MTG MINS
2013-4795	06/24/2013 07/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	CHRISTINE S. RICHARD INDAGO GROUP	INTUITIVE - SURGICAL DA VINCI ROBOT MAUDE DATA
2013-4796	06/25/2013 07/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nancy Kotlowski Baxter Baker Sldle Conn & Jones, LLP	HUMIRA - AERS
2013-4797	06/25/2013 07/24/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	soma das The Economic Times, Times of India	RANBAXY - 483 (04/04/2012 - 06/12/2013)
2013-4798	06/25/2013 07/24/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Laura Strickler CBS NEWS	RANBAXY 483 (01/01/2013 - 06/24/2013)
2013-4799	06/25/2013 07/24/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Barbara J. Lipshutz Jacobs & Burleigh LLP	CORAD HEALTHCARE, INC - REGISTRATION STATUS, DRUGS MANUFACTURED OR DISTRIBUTED, 483 ETC
2013-4800	06/25/2013 07/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ayesha Adil The Weinberg Group	ANDA 78912
2013-4801	06/25/2013 07/24/2013	FDA/OGROP/ORACE-FO/SEA-DO/SEA-CB/	Brad Averill Green Valley Group, LLC, dba	WILDTIME FOODS, EUGENE, OR - EIR MARCH 2013

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			Wildtime Foods	
2013-4802	06/25/2013 07/24/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Rachel Johnson FOI Services, Inc.	MAQUET - COMPLIANCE CORR, INVESTIGATION
2013-4803	06/25/2013 07/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	soma das The Economic Times,Times of India	RANBAXY, MOHALI, INDIA - 483 (02/01/2012 - 06/06/2013)
2013-4804	06/25/2013 07/24/2013	FDA/OFVM/CFSAN/OCD/EOS/	Francis Thevenet AIDGUM/AIPG	TRAGACANTH GUM PUBLICATIONS
2013-4805	06/25/2013 07/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tim Henkel VenatoRx Pharmaceuticals, Inc.	NDA 050706
2013-4806	06/25/2013 07/24/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Muna Shikaki Al Arabiya	RANBAXY - 483 (01/01/2013 - 06/24/2013)
2013-4807	06/25/2013 07/24/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Natasha Singer THE NEW YORK TIMES	GNC, ANDERSON, SC, LEETSDALE, PA (05/01/2013 - 06/24/2013) - INSPECTION RECS, REQUEST TO DETAIL DMAA CONTAINING PRODUCTS
2013-4808	06/25/2013 07/24/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Josh Scheinblum KGAN	RANBAXY - 483 (01/01/2013 - 06/24/2013)
2013-4809	06/25/2013 07/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Andrew Kolodny MD Physicians for Responsible Opioid	EMAILS TO OR FROM DOUGLAS THROCKMORTON RE HYDROCODONE

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Prescribing	
2013-4810	06/25/2013 07/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gary McGarity Gary J McGarity, PharmD	ACULAR OPHTHALMIC SOLUTION OR KETOROLAC ORAL OR INJECTABLE - NEUROTOXICITY
2013-4811	06/25/2013 07/24/2013	FDA/OMPT/CTP/OD/	Desmond Jenson Tobacco Control Legal Consortium	GRANDFATHERED TOBACCO PRODUCT DETERMINATION FOR GF1200548
2013-4812	06/25/2013 07/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dr. Remington L. Nevin Johns Hopkins Bloomberg School of Public Health	AERS 8504150
2013-4813	06/25/2013 07/24/2013	FDA/OFVM/CFSAN/OCD/EOS/ OC/CVM/OCD/	Kyle Herink Kemin Industries, Inc.	AMMONIUM FORMATE - FAP
2013-4814	06/25/2013 07/24/2013	FDA/OFVM/CFSAN/OCD/EOS/	Jessica Swanson Innovative Science Solutions	SUCRALOSE - AERS
2013-4815	06/25/2013 07/24/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	Lara N. Simmons Northpoint Services - Medline Industries, Inc.	NORTHPOINT SERVICES, WAUKEGAN, IL - EIR 10/01/2011 - 11/01/2011
2013-4816	06/25/2013 07/24/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORACE-FO/NYK-DO/NYK-DCB/	Manfred Steiner Ratio Health USA inc	FDA CORR WITH HAROLD M HOFFMAN
2013-4817	06/25/2013 07/24/2013	FDA/OFVM/CFSAN/OCD/EOS/	Thenell & Associates LLC 20130620 THENELL & ASSOCIATES LLC	BIOTECHNOLOGY NOTIFICATION FILE 000125
2013-4818	06/25/2013 07/24/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 5/13-17/13
2013-4819	06/25/2013 07/24/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 5/20-24/13
2013-4820	06/25/2013 07/24/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Doe J	BEAFEATERS - CMLPNTS
2013-4821	06/25/2013 07/24/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 5/27-31/13

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2013-4822	06/25/2013 07/24/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 6/03-07/13
2013-4823	06/25/2013 07/24/2013	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESRS 5/13-17/13
2013-4824	06/25/2013 07/24/2013	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 5/20-24/13
2013-4825	06/25/2013 07/24/2013	FDA/OFVM/CFSAN/OCD/EOS/	KATHYRN L CONIGLIO Keller and Heckman LLP	MISSISSIPPI RIVER CORP - RECYCLED PULP LTR OF NO OBJECTION CORR, SAFETY ASSESSMENTS, TOXICOLOGY RVWS, ETC
2013-4826	06/25/2013 07/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARY B SZALKOWSKI PRISMA CORP	INDAPAMIDE - AERS
2013-4827	06/25/2013 07/24/2013	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	FOI DAILY LOG 5/27-31/13
2013-4828	06/25/2013 07/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARY B SZALKOWSKI PRISMA CORP	INDAPAMIDE - ISRS 9112795, 9135479, 9157753; PERINDOPRIL - ISRS 893672, 9028946, 9055527
2013-4829	06/25/2013 07/24/2013	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 6/3-7/13
2013-4830	06/25/2013 07/24/2013	FDA/OC/OES/DFOI/	CORLEY #58854-006, JOHNNIE	LEGISLATIVE HISTORY ON FEDERAL STATUTE 18 USC 2118 ROBBERY OR BURGLARY OF CONTROLLED SUBSTANCES 1984
2013-4831	06/25/2013 07/24/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 5/13-17/13
2013-4832	06/25/2013 07/24/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 5/20-24/13
2013-4833	06/25/2013 07/24/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOIA REQUESTS 5/27-31/13
2013-4834	06/25/2013 07/24/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOIA REQUESTS 6/3-7/13
2013-4835	06/25/2013 07/24/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOIA REQUESTS 5/13-17/13

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2013-4836	06/25/2013 07/24/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSEDFOIA REQUESTS 5/20-24/13
2013-4837	06/25/2013 07/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	COOK, DELLANA	ACCUTANE - AERS
2013-4838	06/25/2013 07/24/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSEDL FOIA REQUETS 5/27-31/13
2013-4839	06/25/2013 07/24/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 6/3/7/13
2013-4840	06/25/2013 07/24/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 5/13-17/13
2013-4841	06/25/2013 07/24/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 5/20-24/13
2013-4842	06/25/2013 07/24/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 5/27-31/13
2013-4843	06/25/2013 07/24/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 6/3-7/13
2013-4844	06/25/2013 07/24/2013	FDA/OGROP/ORACE-FO/MIN- DO/MIN-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	BRISTOL-MYERS SQUIBB CO INC - EIRS, 483S, CO RESP 02/07/13
2013-4845	06/25/2013 07/24/2013	FDA/OC/OCC/	JENNIFER HSIEH DEERFIELD INSTITUTE	THE MEDICINES CO, FOLEY HOAG - ORITAVANCIN MTG MINS, AGENDA, INTINERARY, ETC 6/13/13
2013-4846	06/25/2013 07/24/2013	FDA/OGROP/ORACE-FO/MIN- DO/MIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	3M COMPANY IRB, ST PAUL, MN - EIRS, 483S, CO RESP 10/10/12
2013-4847	06/25/2013 07/24/2013	OC/CVM/OCD/	SILVIA ULM BURDOCK GROUP	PROTEINASE, ENDOPEPTIDASE, PROTEOLYTIC ENZYME - REGULATORY STATUS, CONSUMPTION, USES AND SAFETY RECS

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2013-4848	06/25/2013 07/24/2013	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	ALLOSOURCE, CHICAGO, IL - EIRS, 483S, CO RESP 03/12/12
2013-4849	06/25/2013 07/24/2013	OC/CVM/OCD/	SILVIA ULM BURDOCK GROUP	AMYLOGLUCOSIDASE, GLUZYME, DIAZYME, DISTILLASE, OPTIDEX - REGULATORY STATUS, CONSUMPTION, USES AND SAFETY RECS
2013-4850	06/25/2013 07/24/2013	FDA/OGROP/ORASE-FO/FLADO/FLA-CB/	WALTER E CHALKLEY THOMSON REUTERS	BELCHER PHARMACEUTICALS, LARGO, FL - EIRS, 483S, CO RESP 01/07/13
2013-4851	06/25/2013 07/24/2013	FDA/OGROP/ORACE-FO/BLTDO/BLT-CB/	WALTER E CHALKLEY THOMSON REUTERS	BIOMAT USA INC, DANVILLE, VA - EIRS, 483S, CO RESP 05/12/12
2013-4852	06/25/2013 09/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	WALTER E CHALKLEY THOMSON REUTERS	GLAXOSMITHKLINE, RIXENSART, BELGIUM - EIRS, 483S, CO RESP 10/05/12
2013-4853	06/25/2013 07/24/2013	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	ELORAC INC, VERNON HILLS, IL - EIRS, 483S, CO RESP 01/30/12
2013-4854	06/25/2013 07/24/2013	FDA/OGROP/ORACE-FO/BLTDO/BLT-CB/	WATER E CHALKLEY THOMSON REUTERS	BOEHRINGER INGELHEIM CHEMICALS INC, PETERSBURG, VA - EIRS, 483S, CO RESP 04/04/12
2013-4855	06/25/2013 07/24/2013	FDA/OGROP/ORAPA-FO/SEADO/SEA-CB/	WALTER E CHALKLEY THOMSON REUTERS	GRIFOLS BIOMAT USA INC, POCATELLO, ID - EIRS, 483S, CO RESP 04/24/12
2013-4856	06/25/2013 08/01/2013	FDA/OGROP/ORAPA-FO/SANDO/SAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	JAZZ PHARMACEUTICALS INC, PALO ALTO, CA - EIRS, 483S, CO RESP 05/30/12
2013-4857	06/25/2013 07/24/2013	FDA/OGROP/ORASE-FO/FLADO/FLA-CB/	WALTER E CHALKLEY THOMSON REUTERS	MCR AMERICAN PHARMACEUTICALS INC, BROOKSVILLE, FL - 03/30/12
2013-4858	06/25/2013 07/24/2013	FDA/OGROP/ORACE-FO/BLTDO/BLT-CB/	WALTER E CHALKLEY THOMSON REUTERS	NIEL T CONSTANTINE - EIRS, 483S, CO RESP 08/20/12
2013-4859	06/25/2013 08/09/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	SHABLEAU, RAMONA.	DR PAUL J SARATA, CHICAGO, IL - AERS 9/2/11
2013-4860	06/25/2013 07/24/2013	OC/CVM/OCD/	SILVIA ULM BURDOCK GROUP	AMYLASE FROM ASPERGILLUS ORYZAE - REGULATORY STATUS, CONSUMPTION, USES AND SAFETY RECS
2013-4861	06/25/2013 07/24/2013	OC/CVM/OCD/	SILVIA KIM BURDOCK GROUP	CELLULASE FROM TRICHODERMA REESEI - REGULATORY STATUS, CONSUMPTION, USES AND SAFETY RECS
2013-4862	06/25/2013	FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY	PFIZER IRELAND PHARMS, DUBLIN 22, IRELAND - EIR, 483,

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	09/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	THOMSON REUTERS	CO RESP 6/28/12
2013-4863	06/25/2013 07/24/2013	FDA/OGROP/ORR/SW-FO/DAL- DO/DAL-CB/	WALTER E CHALKLEY THOMSON REUTERS	QUADRANT CHEMICAL CORP, GARLAND, TX - EIR, 483, CO RESP 1/4/12
2013-4864	06/25/2013 07/24/2013	FDA/OGROP/ORR/CE-FO/NWJ- DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	RARITAN PHARMACEUTICALS INC, EAST BRUNSWICK, NJ - EIR, 483, CO RESP 8/21/12
2013-4865	06/25/2013 07/24/2013	FDA/OGROP/ORR/SW-FO/DAL- DO/DAL-CB/	WALTER E CHALKLEY THOMSON REUTERS	HEALTHCARE MEDICAL & RESPIRATORY CARE INC, HOT SPRINGS, AR - EIR, 483, CO RESP 6/20/12
2013-4866	06/25/2013 07/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, INDIA - EIR, 483, CO RESP 6/13/12
2013-4867	06/25/2013 07/24/2013	FDA/OGROP/ORR/SE-FO/FLA- DO/FLA-CB/	WALTER E CHALKLEY THOMSON REUTERS	TG UNITED LABS LLC, BROOKSVILLE, FL - EIR, 483, CO RESP 3/30/12
2013-4868	06/25/2013 07/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	TOMASZ ZIELINSKI MD, KATOWICE, POLAND - EIR, 483, CO RESP 8/3/12
2013-4869	06/25/2013 07/24/2013	FDA/OGROP/ORR/CE-FO/CHI- DO/CHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	DR LEONARD VALENTINO, CHICAGO, IL - EIR, 483, CO RESP 8/16/12
2013-4870	06/25/2013 07/24/2013	FDA/OGROP/ORR/CE-FO/NWJ- DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	VALIDUS PHARMACEUTICALS INC, PARSIPPANY, NJ - EIR, 483, CO RESP 7/10/12
2013-4871	06/25/2013 07/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/ORR/OCI/ OC/ORR/OCI/	Doe J	LTR OF 9/27/07 FROM DSI, RESP OF 11/29/07; EMAIL OF 9/26/11 FROM OSI
2013-4872	06/25/2013 07/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WOODS 10-D-2776, LEON	PIROXICAIN - AER

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2013-4873	06/26/2013 07/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	LIPOID, GERMANY - EIR 2011
2013-4874	06/26/2013 07/25/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECS
2013-4875	06/26/2013 07/25/2013	FDA/OGROP/ORACE-FO/PHI- DO/PHI-CB/	Catherine Templeton for Henry H. Ottens Manufacturing Compan Henry H. Ottens Manufacturing Company, Inc.	HENRY H OTTENS MANUFACTURING COMPANY, PHILADELPHIA, PA - EIR REDACTED (05/01/2012 - 06/20/2013)
2013-4876	06/26/2013 07/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	LIPOID, GERMANY - EIR SUMMARY 2011
2013-4877	06/26/2013 07/25/2013	OC/ORACE/ORM/ OC/ORACE/ORM/	David Mangione Govzilla, Inc.	LIST OF INSPECTIONS (05/19/2013 - 06/21/2013)
2013-4878	06/26/2013 07/25/2013	FDA/OGROP/ORACE-FO/ATL- DO/ATL-CB/ FDA/OGROP/ORACE-FO/FLA- DO/FLA-CB/	Tony L. Bennett ENCO Pharmaceutical Development, Inc.	ENCO PHARMACEUTICALS DEVELOPMENT, CARY, NC; JACKSONVILLE, FL - PUBLIC RECS (01/01/2005 - 06/21/2013)
2013-4879	06/26/2013 07/25/2013	OC/CVM/OCD/	Bert Baker Zoetis Inc.	NADA 120-299 FOIA SUMMARY
2013-4880	06/26/2013 07/25/2013	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	BLA 125166 - FOIA REQUESTS
2013-4881	06/26/2013 07/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	BLA 125166
2013-4882	06/26/2013 07/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Douglas Fulton Crystal Bay Consulting	K080145, K083352
2013-4883	06/26/2013 07/25/2013	FDA/OC/OES/DDM/	Freddy Mejia Ansell Healthcare Products LLC	DKT 75N-0183

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2013-4884	06/26/2013 07/25/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 6/3-7/13
2013-4885	06/26/2013 07/25/2013	FDA/OFVM/CFSAN/OCD/EOS/	PAULINA DO EXPONENT	GRAS 000037
2013-4886	06/26/2013 07/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	STEPHEN BEEKMAN ALCON LABORATORIES INC	EXCELVISION, CEDEX, FRANCE - 483 2012
2013-4887	06/26/2013 07/25/2013	FDA/OO/OHR/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	LORRAINE PHILIPPS AMABILE & ERMAN PC	INDIVIDUAL RECS
2013-4888	06/26/2013 07/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DODGE, ALLENE M	VIVOTROL (NALTRXENE ER INJECTABLE SUSPENSION) NDA 21-897/S015 - SBA
2013-4889	06/26/2013 07/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	AYA ABOUNASR UNIV OF CALIFORNIA SAN FRANCISCO	CLEMASTINE FUMARATE NDA 73-283 - TOXICITY TESTS, AERS, MEDICAL RVWS, ETC
2013-4890	06/26/2013 07/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	AYA ABOUNASR UNIV OF CALIFORNIA SAN FRANCISCO	TAVIST TABS NDA 17-661 - AERS, TOXICITY TESTS, MEDICAL RVWS, ETC
2013-4891	06/26/2013 07/25/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 6/3-7/13
2013-4892	06/26/2013 07/25/2013	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 6/3-7/13
2013-4893	06/26/2013 07/25/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 6/3-7/13
2013-4894	06/26/2013 07/25/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 6/3-7/13
2013-4895	06/26/2013 07/25/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 5/27-31/13

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2013-4896	06/26/2013 07/25/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 5/27-31/13
2013-4897	06/26/2013 07/25/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 5/27-31/13
2013-4898	06/26/2013 07/25/2013	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 5/27-31/13
2013-4899	06/26/2013 07/25/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 5/27-31/13
2013-4900	06/26/2013 07/25/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRMAP CanReg, Inc.	FOI DAILY LOG 5/20-24/13
2013-4901	06/26/2013 07/25/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 5/20-24/13
2013-4902	06/26/2013 07/25/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 5/20-24/13
2013-4903	06/26/2013 07/25/2013	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 5/20-24/13
2013-4904	06/26/2013 07/25/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 5/20-24/13
2013-4905	06/26/2013 07/25/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	STEPHEN T. FOWLER REED SMITH LLP	AMERICAN MEDICAL SYS INC - K 70065 REVIEWER DECISION NOTES
2013-4906	06/26/2013 07/25/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	STEPHEN T. FOWLER REED SMITH LLP	AMERICAN MEDICAL SYS INC - K080185 REVIEWER DECISION NOTES
2013-4907	06/26/2013 07/25/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	STEPHEN T. FOWLER REED SMITH LLP	AMERICAN MEDICAL SYS INC - K040623 REVIEWER DECISION NOTES
2013-4908	06/26/2013 07/25/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	STEPHEN T. FOWLER REED SMITH LLP	AMERICAN MEDICAL SYS INC - K040537 REVIEWER DECISION NOTES
2013-4909	06/26/2013 07/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KATHRYN A. PRYOR, Esq. SIMON GREENSTONE ET AL	IBUPROFEN - AER 2/12 TO 6/13

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2013-4910	06/26/2013 07/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	KILPATRICK, PETER	DJO LLC - EMPI PHOENIX K124016
2013-4911	06/26/2013 07/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FRIEDMAN, ROBERT.	CHILDRENS MOTRIN SUSPENSION LIQUID - FAERS 1969 TO 2013
2013-4912	06/26/2013 07/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MICHAEL J. GLIDDEN, Esq. PEREZ AND MORRIS LLC	KENALOG (TRIAMCINOLONE ACETONIDE) EFFICACY
2013-4913	06/26/2013 07/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	OLE ALEKSANDER BERG CHITINOR	DMF 19244; 19245; 19246
2013-4914	06/26/2013 07/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ABOUNASR, AYA	CLEMASTINE FUMARATE - NDA, AER, MEDICAL RVWS
2013-4915	06/26/2013 07/25/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SE-FO/NOL- DO/NOL-CB/ FDA/OC/OES/DFOI/	TURNER, ERWIN LLOYD	CMPLNT 121322
2013-4916	06/26/2013 07/25/2013	FDA/OGROP/ORO/CE-FO/PHI- DO/PHI-CB/	KATHY CONACHER DRAGER MEDICAL INC	DRAEGER MEDICAL INC - EIR 6/29-7/9/09
2013-4917	06/26/2013 07/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	DAN RICE DAVID HEALTH SOLUTIONS	K952163, FEI 3009507304 8/12/96
2013-4918	06/26/2013 07/25/2013	FDA/OGROP/ORO/SE-FO/ATL- DO/ATL-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	AARON S. JOPHLIN BELL LEGAL GROUP LLC	DR. GREGORY GARDZIOLA, SOUTH CAROLINA - INFO

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-4919	06/26/2013 07/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	VICTORIA CHERRIMAN BODYWISE LTD	BODYWISE LTD - ALMONDSBURY, BRISTOL NATRACARE TAMPON K954942
2013-4920	06/26/2013 07/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	STEPHEN T. FOWLER REED SMITH LLP	AMERICAN MEDICAL SYS INC K033636 - REVIEWER DECISION NOTES
2013-4921	06/26/2013 07/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MATTHEW K. SCHWENCKE SEARCY DENNEY ET AL	NITROFURANTOIN; MACRODANTIN; MACROBID - WARINGS, LBLG, EFFICACY 2001 TO 2008
2013-4922	06/26/2013 07/25/2013	FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/ FDA/OMPT/CDRH/OCER/DFOI/	DANIEL W. ERNSBERGER BEHREND & ERNSBERGER PC	SMITH & NEPHEW - VISIONAIRE KNEE REPLACEMENT AER
2013-4923	06/27/2013 07/26/2013	FDA/OFVM/CFSAN/OCD/EOS/	Todd Rogers Clipper Corporation	KAIRUM CO, LIMITED, FUJIAN, CHINA - INSPECTION RECS (01/23/2010 - 06/26/2013)
2013-4924	06/27/2013 07/26/2013	FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/	Ethan Lovell JANUS CAPITAL GROUP INC	QUALITEST/VINTAGE PHARMACEUTICALS, HUNTSVILLE, AL - EIR (01/01/2010 - 09/30/2013)
2013-4925	06/27/2013 07/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Victoria Cherriman Bodywise (UK) Ltd	K954942 - REGISTRATION CONFIRMATION
2013-4926	06/27/2013 07/26/2013	OC/CVM/OCD/	Nancy Agan Nancy Agan	LANTUS - AERS
2013-4927	06/27/2013 07/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dr. Melvyn Harris Dr. Melvyn Harris	ULTRAM, ULTRACET - RECS RE WARNING CHANGE
2013-4928	06/27/2013 07/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K102512
2013-4929	06/27/2013 07/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Arlene D Ast Ast , Arlene D	DARVOCET - STUDY OF CARDIAC TOXICITY, REMOVAL FROM MARKET
2013-4930	06/27/2013 07/26/2013	FDA/OFVM/CFSAN/OCD/EOS/	Jim Huang Bemis Company, Inc.	FCN 123, 349, 413 ETC - CHEMISTRY MEMORANDA
2013-4931	06/27/2013	FDA/OMPT/CDER/GRP/DIDP/	Dawn Spark	NDA 019926 - SBA

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	07/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ProStrakan Limited	
2013-4932	06/27/2013 07/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Carter Gould JMP Securities	ADCETRIS - AERS
2013-4933	06/27/2013 07/26/2013	FDA/OMPT/CTP/OD/	Stacy Jones The Star-Ledger	ELECTRONIC CIGARETTES, E-LIQUIDS, ACCESSORIES - AERS
2013-4934	06/27/2013 07/26/2013	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	NV SUMATRA - NEW TOBACCO PRODUCT SUBMISSIONS
2013-4935	06/27/2013 07/26/2013	FDA/OFVM/CFSAN/OCD/EOS/	Elaine Meloan AIB International	RESCISSION LETTER FROM CFSAN TO CLAUSEN ELY OR CORN REFINERS ASSOCIATION (01/28/2010 - 06/21/2013)
2013-4936	06/27/2013 07/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Chris Patullo Long Pharmaceuticals, LLC	TRIAMCINOLONE ACETONIDE, 0.1% PASTE - APPROVAL LETTERS, ADMIN RECS, BIOEQUIVALENCE REVIEWS, ETC
2013-4937	06/27/2013 07/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	Frederick Nielson Nellis AFB Family Medicine Residency	METHYLSULFONYLMETHANE - AERS
2013-4938	06/27/2013 07/26/2013	FDA/OMPT/CTP/OD/	John Shoemaker Visium	FOUR NSE ORDERS DISCLOSED JUNE 25, 2013 FROM CTP
2013-4939	06/27/2013 07/26/2013	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	TOBACCO PRODUCT AERS
2013-4940	06/27/2013 07/26/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/	Farah Awan AUROBINDO PHARMA USA INC	TESTING RESULTS
2013-4941	06/27/2013 07/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Boston Scientific 510(k) #K121048 Anna Christensen Consulting	K121048
2013-4942	06/27/2013	FDA/OMPT/CDER/ORP/DIDP/	Seongsoo Park	ACTIGALL - EXPIRATION DATE CHANGE

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	07/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAEWOONG AMERICA INC	
2013-4943	06/27/2013 07/26/2013	FDA/OC/OES/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Mark McCarty Medical Device Daily	INTERNAL RECS RE ALVARO PASCUAL-LEONE AND 2/10/12 MEETING OF NEUROLOGICAL DEVICES ADVISORY COMMITTEE
2013-4944	06/27/2013 07/26/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 5/13-17/13
2013-4945	06/27/2013 07/26/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 5/13-17/13
2013-4946	06/27/2013 07/26/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 5/13-17/13
2013-4947	06/27/2013 07/26/2013	FDA/OC/OES/DFOI/	GLADYS SB TONKIN WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 5/13-17/13
2013-4948	06/27/2013 07/26/2013	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 5/13-17/13
2013-4949	06/27/2013 07/26/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 6/3-7/13
2013-4950	06/27/2013 07/26/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 5/27-31/13
2013-4951	06/27/2013 07/26/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 5/20-24/13
2013-4952	06/27/2013 07/26/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 5/13-17/13
2013-4953	06/27/2013 07/26/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 6/3-7/13
2013-4954	06/27/2013 07/26/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 5/27-31/13
2013-4955	06/27/2013 07/26/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 5/20-24/13
2013-4956	06/27/2013	FDA/OC/OES/DFOI/	LAUREN S BARR	FOI DAILY LOG 5/13-17/13

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	07/26/2013		JH BARR & ASSOCIATES LLC	
2013-4957	06/27/2013 07/26/2013	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TORREY COPE SIDLEY AUSTIN LLP	AKORN INC - PHENYLEPHRIN EHCL OPHTHALMIC SOL USP WARNING LTR COMM 3/29/07 TO PRESENT
2013-4958	06/27/2013 07/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PAULSON & NACE	ABBOTT LABS - HUMIRA POST-APRVL SAFETY STUDIES; TREXALL, RHEUMATREX (METHOTREXATE) AERS 1998 TO 2012, ETC
2013-4959	06/27/2013 07/26/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OFVM/CFSSAN/OCD/EOS/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	NICHOLAS PARALISI DIETRICH LAW FIRM PC	RICH PRODUCTS -STAIN O121 OUTBREAK INVESTIGATION, RECALL, RECS
2013-4960	06/27/2013 08/19/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	JENNIFER LAWRENCE ESQ LAWRENCE FIRM	INTUITIVE SURGICAL INC - DA VINCI SURGICAL SYS K130726, K122532, K123840, ETC
2013-4961	06/27/2013 07/26/2013	FDA/OO/OHR/	Doe J	PERSONNEL RECS
2013-4962	06/27/2013 07/26/2013	FDA/OC/OES/DDM/ FDA/OMPT/CTP/OD/	MARILYNN WHITNEY COVINGTON & BURLING LLP	DKT 2011N-0867
2013-4963	06/27/2013 07/26/2013	FDA/OO/OFBA/OAGS/	ZAHRA SHAH Singhal & Company, Inc.	#HHSF2232008300141
2013-4964	06/27/2013 07/26/2013	FDA/OO/OFBA/OAGS/	NATHAN A BEAVER FOLEY & LARDNER LLP	GRANT DEVELOPMENT OF BIO-RELEVANT IN-VITRO ASSAY TO DETERMINE LABILE IRON IN THE PARENTERAL IRON COMPLEX PRODUCT - INDIVIDUALS WHO SUBMITTED GRANT REQUESTS, APPL
2013-4965	06/27/2013	FDA/OMPT/CDER/GRP/DIDP/	DAVID HOFFMEISTER	ADVAIR NDA 21-077/S050 - SBA

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	07/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WILSON SONSINI ET AL	
2013-4966	06/27/2013 07/26/2013	FDA/OFVM/CFSAN/OCD/EOS/	MAREN R CAVE SWIFT CURRIE MCGHEE & HIERS	SALMONELLA SEROTYPE TENNESSEE - SURVEILLANCE DATA 2011
2013-4967	06/27/2013 07/26/2013	FDA/OC/OES/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	CHRISTA C COTTRELL KIRKLAND & ELLIS LLP	PLASMA PROTEIN THERAPEUTICS ASSN - PLASMA- DERIVED PROTEIN THERAPIES (PDPT) RECS, CORR 1998 TO 2010
2013-4968	06/27/2013 08/12/2013	FDA/OFVM/CFSAN/OCD/EOS/	MITZI NG CLARK Keller and Heckman LLP	FCN 1266
2013-4969	06/27/2013 08/12/2013	FDA/OMPT/CTP/OD/ FDA/OMPT/CTP/OD/ FDA/OC/OES/DFOI/ FDA/OMPT/CTP/OD/	JOEL KURTZBERG CAHILL GORDON & REINDEL	EXPERIMENTAL STUDY OF GRAPHIC CIGARETTE WARNING LABELS - DRAFTS, ANALYSIS, COMM, ETC
2013-4970	06/27/2013 07/26/2013	FDA/OGROP/ORR/SE-FO/NOL- DO/NOL-CB/	RANDALL S HAYNES MORRIS HAYNES & HORNSBY	LIFESOUTH COMMUNITY BLOOD CENTERS INC - INSP EXHIBITS 11/11
2013-4971	06/27/2013 07/26/2013	FDA/OGROP/ORR/SE-FO/NOL- DO/NOL-CB/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	RANDALL S HAYNES MORRIS HAYNES & HORNSBY	EAST ALABAMA MEDICAL CENTER, LIFESOUTH COMMUNITY BLOOD CENTERS INC - EIRS, 483S, CORR, ETC
2013-4972	06/27/2013 07/26/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	RICHARD A BASLER MED-VISORY CONSULTING INC	SMITH MEDICAL - MEDFUSION 400 INFUSION PUMP K111386
2013-4973	06/27/2013 07/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	ANKE WEISBRICH SENTEC AG	DVC MASTER FILE MAF 1176
2013-4974	06/27/2013 07/26/2013	OC/ORR/ OC/ORR/ FDA/OGROP/ORR/SE-FO/FLA- DO/FLA-CB/	SAMANTHA MYERS ROANOKE CLAIMS SERVICES	EXPRESS FREIGHT INTL - ENTRY #AL600480928 NOTICES FOR REQUEST OF INFORMATION, NOTICES OF ACTION, CBP REDELIVER NOTICES, ETC
2013-4975	06/27/2013 07/26/2013	OC/ORR/ORM/ OC/ORR/ORM/	GAIL LESSICK LACHMAN CONSULTANT SERVICES INC	DRUG COMPANIES, MEDICAL DVC MFRS, BIORESEARCH MONITORING (BIMO), ETC - DOMESTIC AND FOREIGN INSPS, 483S 5/1-31/13
2013-4976	06/28/2013 07/29/2013	FDA/OC/OES/DDM/	GEORGE O'BRIEN HOGAN LOVELLS LLP	DKT FDA-2013-P-0058, FDA-2013-P-0119, ETC.
2013-4977	06/28/2013	FDA/OMPT/CDER/ORP/DIDP/	Michael Higgins	HUMALOG, NOVOLOG, EXUBERA - AERS

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	07/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Highline Research Advisors	
2013-4978	06/28/2013 07/29/2013	FDA/OMPT/CTP/OD/	Desmond Jenson Tobacco Control Legal Consortium	GRANDFATHERED TOBACCO PRODUCT DETERMINATION FOR GF1200548
2013-4979	06/28/2013 07/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Timothy Bassett Pura Vida Investments	DIMETHYL FUMARATE - 9284739 9292048 9304601 ETC
2013-4980	06/28/2013 07/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORAP/PA-FO/SEA-DO/SEA-CB/	bob taylor bob taylor	CHURCH OF JESUS CHRIST OF LATTER-DAY SAINTS DRY PACK CANNING FACILITY, BREMERTON, WA - INSPECTION REPORTS (06/01/2008 - 06/01/2011)
2013-4981	06/28/2013 07/29/2013	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2012-6315
2013-4982	06/28/2013 07/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	LATANIA BLACK MEDTRONIC	REGENERATION TECHNOLOGIES INC - STERLING CANCELLOUS CHIPS; CUBES K051615
2013-4983	06/28/2013 07/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	LATANIA BLACK MEDTRONIC	REGENERATION TECHNOLOGIES INC - BIOSET XC K060180
2013-4984	06/28/2013 07/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	LATANIA BLACK MEDTRONIC	REGENERATION TECHNOLOGIES INC - STERLING INTERFERENCE SCREW HT K052405
2013-4985	06/28/2013 07/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	LATANIA BLACK MEDTRONIC	REGENERATION TECHNOLOGIES INC - BIOSET XC K060180
2013-4986	06/28/2013 07/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	LATANIA BLACK MEDTRONIC	REGNERATION TECHNOLOGIES INC - STERLING CANCELLOS CHIPS; CUBES K051615
2013-4987	06/28/2013 07/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	LATANIA BLACK MEDTRONIC	REGENERATION TECHNOLOGIES INC - STERLING INTERFERENCE SCREW HT K052405
2013-4988	06/28/2013 07/29/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	MUJIB GRIFOLS BIOLOGICALS INC	CSL BEHRING, BERN SWITZERLAND - 483, EIR 1/10 TO 12/12
2013-4989	06/28/2013 07/29/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/ORP/DIDP/	JANNA dePORT NC INTEGRATIVE MEDICAL	HCG - AER

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SOCIETY	
2013-4990	06/28/2013 07/29/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JENNIFER HSIEH DEERFIELD INSTITUTE	SEATTLE GENETICS - ADCETRIS (BRENTUXIMAB VEDOTIN) AER
2013-4991	06/28/2013 07/29/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	WEINBERG, SANFORD .	CMLPNT 131562
2013-4992	06/28/2013 07/29/2013	FDA/OFVM/CFSAN/OCD/EOS/	JANNA dePORTER CENTER FOR SCIENCE IN THE PUBLIC INTEREST	RHM RESEARCH ENGLAND - MYCOP (MYCELIUM FUSARIUM GRAMINEARUM) FAP
2013-4993	06/28/2013 07/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	LATANIA BLACK MEDTRONIC	REGENERATION TECHNOLOGIES INC - STERLING INTERFERENCE SCREW ST K050767
2013-4994	06/28/2013 07/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	LATANIA BLACK MEDTRONIC	REGENERATION TECHNOLOGIES INC - STERLING INTERFERENCE SCREW ST K050767
2013-4995	06/28/2013 07/29/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	K. MICHELLE VASSALLO LINCARE INC	NEW ENGLAND LIFE CARE, SOUTH PORTLAND, ME - 483, EIR, WARNING LTR 1/98 TO PRESENT
2013-4996	06/28/2013 07/29/2013	FDA/OC/OES/DDM/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LOCKE 2540578 2 LEFT, EDWARD	BRISTOL MYERS SQUIBB - COUMADIN BLACK BOX WARNING
2013-4997	06/28/2013 07/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	ANTHONY PAVEL MORGAN LEWIS	IRVINE SCIENTIFIC SALES CO INC - CONTINUOUS SINGLE CULTURE COMPLETE K121572
2013-4998	06/28/2013 07/29/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	WASHINGTON, PAMELA	CMLPNT 128812
2013-4999	06/28/2013 07/29/2013	FDA/OFVM/CFSAN/OCD/EOS/	ROBERT K REIMANN JAMES E FREEMYER PC	E COLI OUTBREAK 9/09 TO PRESENT
2013-5000	06/28/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	ROOPAL P. LUHANA	SMITH & NEPHEW INC - R3 ACETABULAR SYS CMLPNTS, INVESTIGATIONS, RECALLS

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	07/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	CHAFFIN LUHANA LLP	
2013-5001	06/28/2013 07/29/2013	FDA/OGROP/ORR/SE-FO/NOL-DO/NOL-CB/ FDA/OC/OES/DFOI/ FDA/OGROP/ORR/SE-FO/NOL-DO/NOL-CB/	TURNER, ERWIN LLOYD	CMPLNT 121322
2013-5002	06/28/2013 07/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANDERSON 605229, PERCY	MORBIC MELOXICAM; DIURETIC HYDROCHLOROTHIAZIDE - AER
2013-5003	06/28/2013 07/29/2013	FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/	GILL, DAVID A	NATURA PET PRODUCTS - SALMONELLA INFO
2013-5004	06/28/2013 07/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	CITALOPRAM - AER
2013-5005	06/28/2013 07/29/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELWOOD, JOHNNA	ZOFRAN - AER
2013-5006	07/01/2013 07/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	James Simmons Alamo Bone and Joint Clinic	K071833
2013-5007	07/01/2013 07/30/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Brian Brockway VivaQuant, LLC	K103764 ,K081444, K092947 ETC
2013-5008	07/01/2013 07/30/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Barbara B. Perkins not applicable	K872369 - PREDICATE DEVICE
2013-5009	07/01/2013 07/30/2013	FDA/OGROP/ORR/PA-FO/SEA-DO/SEA-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Brent Ardaugh Framingham Heart Study	HEART-AID MODEL 60 EXTERNAL DEFIBRILLATOR - RECALL RECS
2013-5010	07/01/2013 07/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	Stephanie A. Richards Manning Curtis Bradshaw & Bednar	K020086
2013-5011	07/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson	K102258

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	07/30/2013		FOI Services, Inc.	
2013-5012	07/01/2013 07/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K101561
2013-5013	07/01/2013 07/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K021989
2013-5014	07/01/2013 07/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	Robert Miller Flared Medical LLC	K941299
2013-5015	07/01/2013 07/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	510K number K123169 OralID, Forward Science LLC Gross, Richard	K123169
2013-5016	07/01/2013 07/30/2013	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	ELECTRONIC CIGARETTES - AERS
2013-5017	07/01/2013 07/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	Ariel Dora Stern NATIONAL BUREAU OF ECONOMIC RESEARCH	NONAPPROVED PMA DATA
2013-5018	07/01/2013 07/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Florence Bourgeois Boston Children's Hospital Informatics Program	CYLERT, ADDERALL, DEXEDRINE ETC - PIVOTAL EFFICACY AND SAFETY CLINICAL TRIAL DATA
2013-5019	07/01/2013 07/30/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORASW-FO/KAN- DO/KAN-CB/ FDA/OGROP/ORASW-FO/SAN- DO/SAN-CB/	RUDY ORTIZ WAWONA PACKING COMPANY LLC	PESTICIDE RESIDUE SAMPLE NUMBER 800343
2013-5020	07/01/2013 07/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	Deanna Hunt Self	K073111
2013-5021	07/01/2013 07/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	David Changaris Ceela Naturals	SALICYLIC ACID - CURRENTLY LISTED MANUFACTURERS
2013-5022	07/01/2013 07/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Patricia Kime Gannett Government Media, Inc	ISR 8274421

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-5023	07/01/2013 07/30/2013	FDA/OFVM/CFSAN/OCD/EOS/	Monica Engebretson Cruelty Free International	COSMETICS SAFETY TESTS
2013-5024	07/01/2013 07/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Virginia Baker NA	ARICEPT, NAMENDA - AERS
2013-5025	07/01/2013 07/30/2013	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	Mike Conley The McDowell News	BAXTER INTERNATIONAL, MARION, NC - RESPONSE TO WARNING LETTER
2013-5026	07/01/2013 07/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mondira Bhattacharya AbbVie, Inc.	915 COMPREHENSIVE REVIEW OF ANDROGEL 1.62%
2013-5027	07/01/2013 07/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Amy Gonzales AMGEN INC.	MUSTAFA NEVZAT PHARMACEUTICALS, ISTANBUL, TURKEY - EIR 05/02/2012 - 05/30/2013
2013-5028	07/01/2013 07/30/2013	FDA/OGROP/ORR/NE-FO/NYK-DO/NYK-DCB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OCC/ OC/ORR/OCI/ OC/ORR/OCI/	PAULA RAMER KAYE SCHOLER LLP	RANBAXY USA INC, RANBAXY LABORATORIES LTD (RANBAXY) - MINS OF MEETINGS, NOTES, WARNING LTRS, ETC
2013-5029	07/01/2013 07/30/2013	FDA/OGROP/OIP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PAULA RAMER KAYE SCHOLER LLP	RANBAXY USA INC, RANBAXY LABORATORIES LTD (RANBAXY) - WORLD HEALTH ORGANISATION COMM, RPT, ETC 2004
2013-5030	07/01/2013 07/30/2013	FDA/OC/OES/DFOI/	PAULA RAMER KAYE SCHOLER LLP	RANBAXY USA INC, RANBAXY LABORATORIES LTD (RANBAXY) - INVESTIGATIONS 1/05 TO PRESENT

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2013-5031	07/01/2013 07/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OCC/ OC/ORO/OCI/ OC/ORO/OCI/	PAULA RAMER KAYE SCHOLER LLP	RANBAXY USA INC, RANBAXY LABORATORIES LTD (RANBAXY) - INVESTIGATION CORR
2013-5032	07/01/2013 07/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OCC/ OC/ORO/OCI/ OC/ORO/OCI/	PAULA RAMER KAYE SCHOLER LLP	RANBAXY USA INC, RANBAXY LABORATORIES LTD (RANBAXY) DAIICHI SANKYO COMPANY LTD NEGOTIATIONS , RPTS INTERNAL, EXTERNAL
2013-5033	07/01/2013 07/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PAULA RAMER KAYE SCHOLER LLP	RANBAXY USA INC, RANBAXY LOBORATORIES LTD (RANBAXY) - DINESH THAKUR OR RAJINDER KUMAR, RPTS, EMAIL, ETC 2004
2013-5034	07/01/2013 07/30/2013	FDA/OGROP/ORO/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PAULA RAMER KAYE SCHOLER LLP	RANBAXY USA INC, RANBAXY LABORATORIES LTD (RANBAXY) - DEWAS FACILITIES EIRS, 483S1/28/08-2/12/08, OHM LABS, GLOVERSVILLE FACILITY 7/13/09-8/12/09, ETC
2013-5035	07/01/2013 07/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OCC/ OC/ORO/OCI/ OC/ORO/OCI/	PAULA RAMER KAYE SCHOLER LLP	RANBAXY USA INC, RANBAXY LABORATORIES LTD (RANBAXY) - DINESH THAKUR, RAJINDER COMM, AUDIT RPT, ETC 2004
2013-5036	07/01/2013	FDA/OMPT/CDRH/OCER/DFOI/		INDIVIDUAL RECS

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	07/30/2013		PLATSKY, HENRY	
2013-5037	07/01/2013 07/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	BENJAMIN LL ENGLAND BENJAMIN L ENGLAND & ASSOCIATES LLC	SILVERLON - CONTAC WOUND DRESSING K991463; SILVERLONE DIRECT PRESSURE WOUND CLOSURE STRIP K984204; SILVERLON DIRECT PRESSURE WOUND DRESSING K984207, ETC
2013-5038	07/01/2013 07/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOANNE S HAWANA ARENT FOX LLP	ORA VERSES INJ OR PHENTWOLAMINE MESYLATE - ISRS 8247773, 7897322
2013-5039	07/01/2013 07/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ALESHIRE 278999, DAVID .	ROXISCT 30 MG; SOBOXEN - AERS
2013-5040	07/01/2013 07/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OCC/	PAULA RAMER KAYE SCHOLER LLP	RANBAXY USA INC, RANBAXY LABORATORIES LTD (RANBAXY) - DAIICHI SANKYO COMPANY LTD CORR, INTERVIEWS, MEETINGS, ETC 2004
2013-5041	07/01/2013 07/30/2013	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	DOUGLAS N BLUE ZETETIC	SIMILAC, ENFAMIL INFANT FORMULA ENTRY NUMBER DP4- 062812-8 PHOTOGRAPHS, OASIS COMPUTER DATA BASE SCREEN SHOTS
2013-5042	07/01/2013 07/30/2013	FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/	J KENT LOWRY ARMSTRONG TEASDALE LLP	NATURAL PET PRODUCTS INC - SALMONELLA INVESTIGATION RPTS, ADMINISTRATIVE SANCTIONS 3/19/13 TO PRESENT
2013-5043	07/01/2013 07/30/2013	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	COLEN GRACE DONOFRIO BABST/CALLAND	GILES CHEMICAL (PREMIER CHEMICALS LLC), WAYNESVILLE, NC - EIRS 8/2/12
2013-5044	07/01/2013 07/30/2013	FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/ OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SW- FO/SWID/SWID-CB/ FDA/OGROP/ORA/SW- FO/SWID/SWID-CB/	CHRISTINE RAMETTE SURETY CLAIMS INC	ENTRY NUMBER BPX-0001405-6
2013-5045	07/02/2013 07/31/2013	FDA/OMPT/CDRH/OCER/DFOI/	Scott Nadeau Covidien llc	K926118 - SUMMARY LETTER

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2013-5046	07/02/2013 07/31/2013	FDA/OMPT/OSMP/OOPD/	Lauren A. Farruggia Hyman, Phelps & McNamara P.C.	PROCYSBI - ORPHAN DRUG DESIGNATION FILE
2013-5047	07/02/2013 07/31/2013	FDA/OC/OES/DFOI/	Megan Pickel BEVERIDGE & DIAMOND	CFSAN FOIA REQUESTS 06/07/2013 TO 07/01/2013
2013-5048	07/02/2013 07/31/2013	FDA/OMPT/CDRH/OCER/DFOI/	Alexis McKenzie Key Tech	BAXA CORPORATION EXACTA-MIX 2400 510K SUMMARY
2013-5049	07/02/2013 07/31/2013	FDA/OMPT/CDRH/OCER/DFOI/	Robert Wick Tosoh Bioscience, Inc.	K12129 - 510K SUMMARY
2013-5050	07/02/2013 07/31/2013	FDA/OFVM/CFSAN/OCD/EOS/ OC/CVM/OCD/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	ENSURE - AERS
2013-5051	07/02/2013 07/31/2013	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	SLIM FAST - AERS
2013-5052	07/02/2013 07/31/2013	FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/	Doe J	DAVOL BARD MESH PERFIX PLUS LARGE MONAFILAMENT KNITTED POLYPROPYLENE - RECALL RECS (09/01/2003 - 06/28/2013)
2013-5053	07/02/2013 07/31/2013	FDA/OMPT/CDRH/OCER/DFOI/	Stephanie A. Richards Manning Curtis Bradshaw & Bednar	DYNAMIC COMPRESSION SHAPE MEMORY ALLOY STAPLE - IDE
2013-5054	07/02/2013 07/31/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORASW-FO/KAN- DO/KAN-CB/ FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/	Pete Kennedy Pete Kennedy	DAIRY OF THE OZARKS, LLC - CORR, EMAIL, AGREEMENTS ETC (06/01/2013 - 05/15/2013)
2013-5055	07/02/2013 07/31/2013	FDA/OMPT/CDRH/OCER/DFOI/	Scott Nadeau Covidien llc	K802286 - 510K SUMMARY
2013-5056	07/02/2013 07/31/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Hong Luo HARVARD BUSINESS SCHOOL	NDA, ANDA APPROVALS 01/01/1980 - 06/01/2013
2013-5057	07/02/2013 07/31/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Lori Franson Lori Franson, Individual	ZYPREXA RELPREV

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-5058	07/02/2013 07/31/2013	FDA/OGROP/ORR/SW-FO/DEN-DO/DEN-CB/	Vince Calhoun UNIVERSITY OF NEW MEXICO	UNM HEALTH SCIENCE CENTER IRB - EIR (05/01/2013 - 08/01/2013)
2013-5059	07/02/2013 07/31/2013	FDA/OC/OES/DFOI/	ELENA HOWELL HOGAN LOVELLS LLP	2013-3989
2013-5060	07/02/2013 07/31/2013	FDA/OMPT/CDRH/OCER/DFOI/	ELLEN RELKIN ESQ WEITZ & LUXEMBERG PC	BIOMET INC - RECAP FEMORAL RESURFACING SYS MDRS, MEMOS, CLNCL TRIALS, ETC
2013-5061	07/02/2013 07/31/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OCC/ FDA/OC/OES/DDM/	LOUISE N HOWE GOODWIN PROCTER LLP	CARDIOVASCULAR INTRAVASCULAR FILTERS - RECLASSIFICATION FROM CLASS III TO CLASS II
2013-5062	07/02/2013 07/31/2013	FDA/OC/OES/DFOI/	CARLA R SCARMAZZI King & Spalding LLP	INTUITIVE SURGICAL, SUNNYVALE, CA - 483S 1/103 TO PRESENT
2013-5063	07/02/2013 07/31/2013	FDA/OC/OES/DFOI/	BRODY MULLINS WALL STREET JOURNAL	2011-6067, 2011-7185, 2011-7361, ETC
2013-5064	07/02/2013 07/31/2013	FDA/OC/OES/DFOI/	BRODY MULLINS WALL STREET JOURNAL	2009-1630, 2009-1631, 2009-1645, ETC
2013-5065	07/02/2013 07/31/2013	FDA/OC/OES/DFOI/	BRODY MULLINS WALL STREET JOURNAL	2012-7775, 2012-5883, 2012-7797, ETC
2013-5066	07/02/2013 07/31/2013	FDA/OC/OES/DDM/	WILLIAM C WHITE II PARKMAN & WHITE LLC	GUIDANCE FOR INDUSTRY TESTING FOR SALMONELLA SPECIES IN HUMAN FOODS AND DIRECT-HUMAN-CONTACT ANIMAL FOODS
2013-5067	07/02/2013 07/31/2013	OC/CVM/OCD/	KRISTI O SMEDLEY PHD WASHINGTON INFORMATION SOURCE	NEW AAFCO FEED INGREDIENT DEFINITION FOR DEOILED DISTILLERS PRODS
2013-5068	07/02/2013 07/31/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KAREN COLLINS HARDISON COCHRAN	MIRENA - MDRS 1/08 TO PRESENT
2013-5069	07/02/2013 09/17/2013	OC/ORR/ OC/ORR/	JAMES, AL	INDIVIDUAL RECS 4/13 TO 6/13
2013-5070	07/02/2013 07/31/2013	FDA/OC/OES/DFOI/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	2013-2551, 2013-2466, 2013-2321, ETC
2013-5071	07/02/2013	FDA/OMPT/CDER/GRP/DIDP/	AYA ABOUNASR	CLEMASTINE FUMARATE TABS ANDA 73-283, ANDA 73-458;

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	07/31/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	UNIV OF CALIFORNIA	TAVIST-1 NDA 17-661, NDA 20-925 APRVL RECS, AERS 1997 TO PRESENT
2013-5072	07/02/2013 07/31/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	2013-4343
2013-5073	07/03/2013 08/01/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	Caroline Unger Central Texas Regional Blood and Tissue Center	BACTERIN INTERNATIONAL, INC - 483, RESPONSE TO 483, RESPONSE TO WARNING LETTER, ETC (07/16/2012 - 07/01/2013)
2013-5074	07/03/2013 08/01/2013	FDA/OMPT/CTP/OD/	Anna Edney BLOOMBERG NEWS	COMPANIES AND PRODUCTS ISSUED A NON SUBSTANTIALLY EQUIVALENT ORDER FROM CTP; SUBSTANTIALLY EQUIVALENT AND NOT SUBSTANTIALLY EQUIVALENT ORDERS
2013-5075	07/03/2013 08/01/2013	FDA/OMPT/OSMP/OOPD/	Sharon Sakai Adamas Pharmaceuticals, Inc.	APOMORPHINE - ORPHAN DRUG DESIGNATION
2013-5076	07/03/2013 08/01/2013	OC/ORA/ORM/ OC/ORA/ORM/	Mark Prinz Registrar Corp	FOREIGN FOOD FACILITIES ISSUED FORM 483 05/13/2013 - 06/30/2013
2013-5077	07/03/2013 08/01/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Victor Martinez Victor Martinez	FOOD BANK OF THE RIO GRANDE VALLEY, INC, PHARR, TEXAS - INSPECTIONS, TESTING, COMMUNICATIONS
2013-5078	07/03/2013 08/01/2013	OC/CVM/OCD/	Paul K. Mignon Mignon, Paul K	ANADA 200-168 AMENDMENTS
2013-5079	07/03/2013 08/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	Scott Nadeau Covidien llc	K810216 - SUMMARY LETTER
2013-5080	07/03/2013 08/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	Carrie Gray Phillips Law Group PLLC	ST JUDE MEDICAL - ADVERSE EVENT RECS
2013-5081	07/03/2013 08/01/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	510K REDACTED AND RELEASED JUNE 2013
2013-5082	07/03/2013 08/01/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Marion McNeilly Annie's Marlborough Ltd	442-0762268-7 35898052 - TEST RESULTS
2013-5083	07/03/2013 08/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shalin Jani Aerie Pharmaceuticals Inc.	IOPIDINE - SBA
2013-5084	07/03/2013	FDA/OMPT/CDER/GRP/DIDP/	Ashley Yeager	ISR 6749253, 6776928, 6809862 ETC

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	08/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	The Simon Law Firm	
2013-5085	07/03/2013 08/01/2013	FDA/OC/OES/DFOI/ FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/ OC/ORA/OCI/ OC/ORA/OCI/	Heather M. McKinney Renaud Cook Drury Mesaros, PA	TRIAD GROUP, H&P INDUSTRIES, EDGE PARK MEDICAL SUPPLIES ETC - INVESTIGATION RECS
2013-5086	07/03/2013 08/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	C. Gansen GANSEN LAW GROUP	ADVATE - CASE REPORTS
2013-5087	07/03/2013 08/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	b. burgess BURGESS, BERNIE	CDER OSI RECORDS RE C1639 BETWEEN 12/7/2006 AND 1/15/2007
2013-5088	07/03/2013 08/01/2013	FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA LOG 6/24/2013 TO 6/28/2013
2013-5089	07/03/2013 08/01/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Julie Quick BioLife Plasma Services L.P.	QUALTEX LABORATORY, NORCROSS, GA - EIR (01/01/2009 - 07/01/2013)
2013-5090	07/03/2013 08/01/2013	FDA/OC/OES/	Anna Edney BLOOMBERG NEWS	EMAIL, CORR BETWEEN MARGARET HAMBURG AND LEONA BRENNER-GATI
2013-5091	07/03/2013 08/01/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	JESSICA QUIASON 1199 SEIU	BRIGHAM & WOMENS HOSPITAL, MCLEAN HOSPITAL, MASSACHUSETTS GENERAL HOSPITAL, ETC - INFORMED CONSENT ISSUES COMM
2013-5092	07/03/2013 08/01/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Doe J	INDIVIDUAL RECS

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2013-5093	07/03/2013 08/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELLIOT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	KYPROLIS (CARFILZOMIB) - FAERS 1/12 TO PRESENT
2013-5094	07/03/2013 08/01/2013	FDA/OC/OES/DDM/	SAMANTHA HERBERT GOODWIN PROCTER LLP	DKT FDA-2013-N-0234
2013-5095	07/03/2013 08/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	RICHARD A. MONTAGNA, Ph.D. RHEONIX	LUMINEX MOLECULAR DIAGNOSTICS, ONTARIO, CANADA - XTAG GASTROINTESTINAL PATHOGEN PANEL (GPP) K121894
2013-5096	07/03/2013 08/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	MINA KIMES BLOOMBERG NEWS	CYBER SECURITY INCIDENTS IMPACTING MEDICAL DVC MFRS, HOSPITALS, USERS, ETC LAST 24 MONTHS
2013-5097	07/03/2013 08/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	MINA KIMES BLOOMBERG NEWS	CYBER SECURITY VULNERABILITIES COMM LAST 24 MONTHS
2013-5098	07/03/2013 08/01/2013	OC/ORO/ORM/ OC/ORO/ORM/	ROBERT KING FDA NEWS	MEDICAL DVC MANUFACTURING, CLINICAL TRIAL FACILITIES - 483 6/1-30/13
2013-5099	07/03/2013 08/01/2013	FDA/OC/OES/DFOI/	BURTON, JOHN M	CASE # PH 044016
2013-5100	07/03/2013 08/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	PLX PHARMA - ASPIRIN NDA 203-697 LBLG
2013-5101	07/03/2013 08/01/2013	FDA/OGROP/ORO/PA-FO/SEA-DO/SEA-CB/	JAMES A. PERKINS LARSON BERG ET AL	INDIVIDUAL RECS
2013-5102	07/03/2013 08/13/2013	FDA/OMPT/CTP/OD/	AZIM CHOWDHURY Keller and Heckman LLP	LORILLARD TOBACCO CO - NEWPORT NON MENTHOL GOLD BOX 100 SUSTAINABLE EQUIVALENCE RPTS
2013-5103	07/03/2013 08/15/2013	FDA/OFVM/CFSAN/OCD/EOS/	PAULINA DO EXPONENT	SAINT GOBAIN ADVANCED CERAMICS CORP - BORON NITRIDE FCN 289; COLOR MATRIX GROUP - SODIUM BOROHYDRIDE FCN 1224; TOTAL LUBRIFIANTS - CALCIUM BORATE FCN 1189
2013-5104	07/03/2013 08/01/2013	FDA/OC/OES/DFOI/	BRODY MULLINS WALL STREET JOURNAL	2011-4942; 2011-5064, 2011-9169 ETC
2013-5105	07/03/2013 08/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	RICHARD A. MONTAGNA, Ph.D. RHEONIX	BIOFIRE DIAGNOSTICS, SALT LAKE CITY, UT - FILM ARRAY BLOOD CULTURE IDENTIFICATION (BCID) PANEL K130914
2013-5106	07/03/2013 08/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	RICHARD A. MONTAGNA, Ph.D. RHEONIX	LUMINEX MOLECULAR DIAGNOSTICS, TORONTO, ONTARIO - X TAG GASTROINTESTINAL PATHOGEN PANEL (GPP)

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				K121454
2013-5107	07/03/2013 08/01/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	EXPANDED ACCESS TO INVESTIGATIONAL DRUGS REQUESTS 6/1/12
2013-5108	07/03/2013 08/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	NICKI M. McDONALD BLASKE AND BLASKE PLC	VASCUTEK LTD - GELWEAVE DVC PROTHESIS RECS
2013-5109	07/03/2013 08/01/2013	FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/ FDA/OGROP/ORAPA-FO/SEA- DO/SEA-CB/	K. MICHELLE VASSALLO LINCARE INC	ADVENTIST MEDICAL EQUIPMENT, PORTLAND, OR - 483, EIR, WARNING LTR 1/98 TO PRESENT
2013-5110	07/03/2013 08/15/2013	FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/ OC/OR/ OC/OR/ OC/OR/ OC/OR/	MATTHEW C. MOEHLMAN LABATON SUCHAROW	YUM BRANDS INC - CHEMICAL CONTAMINANTS IN POULTRY SUPPLIED TO THE CHINESE BUSINESS SEGMENT OF KFC
2013-5111	07/05/2013 08/02/2013	FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/	WALTER E CHALKELY THOMSON REUTERS	EXEMPLAR LABORATORIES LLC, FALL RIVER, MA - EIRS, 483S, CO RESP 1/13/12
2013-5112	07/05/2013 08/02/2013	FDA/OGROP/ORACE-FO/DET- DO/DET-CB/	WALTER E CHALKLEY THOMSON REUTERS	ELI LILLY & CO, INDIANAPOLIS, IN - EIRS, 483S, CO RESP 12/14/12
2013-5113	07/05/2013 08/02/2013	FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	EISAI INC, WOODCLIFF LAKE, NJ - EIRS, 483S, CO RESP 1/17/13
2013-5114	07/05/2013 08/02/2013	FDA/OGROP/ORAPA-FO/SAN- DO/SAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	DYNAVAX TECHNOLOGIES CORP, BERKELEY, CA - EIRS, 483S, CO RESP 10/17/12
2013-5115	07/05/2013 08/02/2013	FDA/OGROP/ORAPA-FO/SAN- DO/SAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	CHILDREN'S HOSPITAL RESEARCH CENTER OAKLAND, OAKLAND, CA - EIRS, 483S, CO RESP 1/09/13
2013-5116	07/05/2013 08/02/2013	FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/	WALTER E CHALKLEY THOMSON REUTERS	BIOGEN IDEC INC, CAMBRIDGE, MA - EIRS, 483S, CO RESP 3/15/13
2013-5117	07/05/2013 08/02/2013	FDA/OGROP/ORACE-FO/DET- DO/DET-CB/	WALTER E CHALKLEY THOMSON REUTERS	BIO-BLOOD COMPONENTS INC, GARY, IN - EIRS, 483S, CO RESP 1/14/13
2013-5118	07/05/2013	FDA/OGROP/ORAPA-FO/SEA-	WALTER E CHALKLEY	BENAROYA RESEARCH INSTITUTE, SEATTLE, WA - EIRS,

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	08/02/2013	DO/SEA-CB/	THOMSON REUTERS	483S, CO RESP 1/29/13
2013-5119	07/05/2013 08/02/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	AKORN INC, SOMERSET, NJ - EIRS, 483S, CO RESP 2/01/13
2013-5120	07/05/2013 08/02/2013	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	WALTER E CHALKLEY THOMSON REUTERS	VETERANS ADMINISTRATION MEDICAL CENTER, BOISE, ID - EIRS, 483S CO RESP 1/24/13
2013-5121	07/05/2013 08/02/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	WALTER E CHALKLEY THOMSON REUTERS	ROBERT J SHULMAN, HOUSTON, TX - EIRS, 483S, CO RESP 5/09/12
2013-5122	07/05/2013 08/02/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	DIANE J NUGENT MD, ORANGE, CA - EIRS, 483S, CO RESP 6/22/12
2013-5123	07/05/2013 09/05/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	WALTER E CHALKLEY THOMSON REUTERS	NOVARTIS VACCINES & DIAGNOSTICS GMBH & CO, KG, MARBURG, GERMANY - EIRS, 483S, CO RESP 7/17/12
2013-5124	07/05/2013 10/08/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	WALTER E CHALKLEY THOMSON REUTERS	LAS CRUCES BIOLOGICALS LLC, LAS CURCES, NM - EIRS, 483S, CO RESP 2/13/13
2013-5125	07/05/2013 08/02/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	WALTER E CHALKLEY THOMSON REUTERS	MICHAEL T JARRATT MD, AUSTIN, TX - EIRS, 483S, CO RESP 6/21/12
2013-5126	07/05/2013 10/08/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	WALTER E CHALKLEY THOMSON REUTERS	INNOVASIC INC, SALT LAKE CITY, UT - EIRS, 483S, CO RESP 4/27/12
2013-5127	07/05/2013 08/02/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	WALTER E CHALKLEY THOMSON REUTERS	IBA MOLECULAR, STERLING, VA - EIRS, 483S, CO RESP 2/01/13
2013-5128	07/05/2013 08/02/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	GE HEALTHCARE, MEDICAL DIAGNOSTICS, PRINCETON, NJ - EIRS, 483S, CO RESP 8/20/12
2013-5129	07/05/2013 08/02/2013	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	WALTER E CHALKLEY THOMSON REUTERS	CUMBERLAND PHARMACEUTICALS INC, NASHVILLE, TN - EIRS, 483S, CO RESP 4/04/12
2013-5130	07/05/2013 08/02/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	WALTER E CHALKLEY THOMSON REUTERS	CAPRICORN PHARMA INC, FREDERICK, MD - EIR, 483S, CO RESP 3/04/13
2013-5131	07/05/2013 08/02/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	WALTER E CHALKLEY THOMSON REUTERS	BIO-CONCEPT LABORATORIES INC, SALEM, NH - EIRS, 483S, CO RESP 1/10/13
2013-5132	07/05/2013 08/02/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	WALTER E CHALKLEY THOMSON REUTERS	AVIOQ INC, RESEARCH TRAIANGLE PARK, NC - EIRS, 483S, CO RESP 2/08/13

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2013-5133	07/05/2013 08/02/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	AUROBINDO PHARMA LTD, UNIT VI, HYDERABAD, INDIA - EIRS, 843S, CO RESP 9/21/12
2013-5134	07/05/2013 08/02/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	ASTRAZENECA, MACCLESFIELD, CHESHIRE, UK - EIRS, 483S, CO RESP 3/16/12
2013-5135	07/05/2013 08/02/2013	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	AKORN INC, DECATUR, IL - EIRS, 483S, CO RESP 10/26/11
2013-5136	07/08/2013 08/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Cliff Katz KELLEY DRYE & WARREN LLP	CELECOBIX - DATE OF FIRST SUBSTANTIALLY COMPLETE GENERIC DRUG APPLICATION
2013-5137	07/08/2013 08/05/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Christine Livoti BIOPHARM INSIGHT	COMPLETE RESPONSE LETTERS - TOTAL NUMBER ISSUED PER YEAR FOR NDA, BLA (01/01/2008 - 12/31/2012)
2013-5138	07/08/2013 08/05/2013	OC/ORACE/ORM/ OC/ORACE/ORM/ FDA/OC/OES/DFOI/ OC/ORACE/OE/ OC/ORACE/OE/	Querida Anderson BIOPHARM INSIGHT	BIOPHARM, GENERIC, PHARMACEUTICALS ETC - LIST OF INSPECTIONS (04/01/2013 - 06/30/2013)
2013-5139	07/08/2013 08/05/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOIA REQUESTS CLOSED 06/01/13 TO 6/30/13
2013-5140	07/08/2013 08/05/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 6/1-30/2013
2013-5141	07/08/2013 08/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Paul E. Greenberg Analysis Group, Inc.	FDA INVESTIGATING REPORTS OF POSSIBLE INCREASED RISK OF PANCREATITIS ETC - RESEARCH PROVIDED TO FDA; ANALYSES OF AERS; FDA SAFETY STUDIES ETC

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2013-5142	07/08/2013 08/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jennifer Fuson American Association for Justice	ESSURE - ADVERSE EVENT REPORTS
2013-5143	07/08/2013 08/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Thomas Carney Forsyth Medical Center	ZOLEDRONIC ACID, IBANDRONATE SODIUM - AERS
2013-5144	07/08/2013 08/05/2013	FDA/OC/OES/DDM/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Robin Primeau MURRAY LAW FIRM	ENDOCRINOLOGIC AND METABOLIC DRUGS ADVISORY COMMITTEE RECS
2013-5145	07/08/2013 08/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Eva von Schaper BLOOMBERG NEWS	RANBAXY LABORATORIES. MOHALI, INDIA - INSPECTION RECS
2013-5146	07/08/2013 08/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Paul E. Greenberg Analysis Group, Inc.	FDA SURVEILLANCE OF ADVERSE DRUG EFFECTS - ALL RECS
2013-5147	07/08/2013 08/05/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ziad Gellad, MD MPH Gellad, Ziad	MIRENA IUD - AERS
2013-5148	07/08/2013 08/05/2013	FDA/OFVM/CFSAN/OCD/EOS/	John Lauerman BLOOMBERG NEWS	TA-65 - AERS
2013-5149	07/08/2013 08/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	Linda Kariya Nihon Kohden Corporation	K964122
2013-5150	07/08/2013 08/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jeffery A. Pecoraro Home	COMPLAINT 130596 - RECS RE CDRH FOLLOW UP
2013-5151	07/08/2013 08/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Shin Kang WELLS FARGO	TECFIDERA, KALYDECO, STRIBILD - AERS

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-5152	07/08/2013 08/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	William Slevin Post Medical	K072667
2013-5153	07/08/2013 08/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ken Greenberg Ghost Tree Capital	JUXTAPID, LOMITAPIDE, KYNAMRO, ETC - AERS
2013-5154	07/08/2013 08/05/2013	FDA/OFVM/CFSAN/OCD/EOS/	joseph pereira emerson college	DIETARY SUPPLEMENTS - HOSPITAL EMERGENCY ROOM ADMISSIONS AND DEATHS IN NEW ENGLAND
2013-5155	07/08/2013 08/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jennifer Quinlan Power Rogers & Smith, P.C.	DESMOPRESSIN - AERS
2013-5156	07/08/2013 08/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Susan Todd West-Ward Pharmaceutical Corp.	CIPLA, LTD, MUMBAI, INDIA - 483
2013-5157	07/08/2013 08/05/2013	FDA/OMPT/CTP/OD/	Mark Greenwold Campaign for Tobacco Free Kids	ALL RECS RE RISK ASSESSMENT MODEL USED BY FDA IN EVALUATING THE TOXICITY OF PRODUCTS UNDER THE TECHNICAL PROJECT LEAD MEMORANDA RE SE REPORTS SE0003730 SE0003731
2013-5158	07/08/2013 08/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	Post Medical Post Medical	K111085
2013-5159	07/08/2013 08/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Nalini Singh University of Kansas, School of Pharmacy	ANDA 040479
2013-5160	07/08/2013 08/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rishi Sinha Stryker Inc.	K122160
2013-5161	07/08/2013 08/05/2013	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	James Peluso Avid Radiopharmaceuticals, Inc.	DR COLEMAN, DUKE UNIVERSITY PET FACILITY - EIR (11/01/2010 - 11/30/2010)
2013-5162	07/08/2013 08/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sharon Sakai Adamas Pharmaceuticals	NDA 19385

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-5163	07/08/2013 08/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sharon Sakai Adamas Pharmaceuticals	NDA 19334
2013-5164	07/08/2013 08/05/2013	FDA/OC/OES/DDM/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mathieu CHARVERIAT THERANEXUS	PREGABALIN (LYRICA), DULOXETIN (CYMBALTA), AMITRIPTYLIN (as LAROXYL) ETC - SAFETY LABELING CHANGES, SBA, ADVISORY COMMITTEE MINUTES ETC
2013-5165	07/08/2013 08/05/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Dr. Rudy Zimmer Dr. Rudy Zimmer	DUKORAL - BLA
2013-5166	07/08/2013 08/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bao Le ARIAD Pharmaceuticals, Inc.	ICLUSIG - AERS
2013-5167	07/08/2013 08/05/2013	FDA/OGROP/ORAC/CE-FO/CIN- DO/CIN-CB/	Scott Carlson AVON PRODUCTS, INC.	OHIO ALUMINUM CHEMICALS, LLC, HAMILTON, OH - 483, EIR (01/01/2009 - 07/05/2013)
2013-5168	07/08/2013 08/05/2013	FDA/OGROP/ORAC/CE-FO/MIN- DO/MIN-CB/	Nicole Norfleet STAR TRIBUNE	HMONGTOWN MARKETPLACE, HMONG VILLAGE, ST PAUL, MN - COMPLAINTS
2013-5169	07/08/2013 08/05/2013	FDA/OFVM/CFSAN/OCD/EOS/	Jim Huang Bemis Company, Inc.	THRESHOLD OF REGULATION RECORD 08-001 RE USE OF POLYURETHANE ADHESIVE IN FOOD PACKAGING FOR MICROWAVE COOKING
2013-5170	07/08/2013 08/05/2013	FDA/OFVM/CFSAN/OCD/EOS/	Amy Stewart Amy Stewart	ANGOSTURA BARK, EXTRACT ON GRAS LIST
2013-5171	07/08/2013 08/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mark Conkling, Practice Manager Meadowlark Family Healthcare	PRAMIPEXOLE - STUDIES
2013-5172	07/08/2013 08/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mark Conkling Meadowlark Family Healthcare	PRAMIPAXOLE DIHYDROCHLORIDE FOR DEPRESSION - STUDIES
2013-5173	07/08/2013	FDA/OMPT/CTP/OD/	Rachel Johnson	TOBACCO FILLER MATERIAL

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	08/05/2013	FDA/OO/OFBA/OAGS/	FOI Services, Inc.	
2013-5174	07/08/2013 08/05/2013	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	TOBACCO SUBSTANTIAL EQUIVALENCE
2013-5175	07/08/2013 08/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELLIOT FAVUS MD FAVUS INSTITUTIONAL RESEARCH LLC	JUXTAPID (LOMITAPIDE) - AERS
2013-5176	07/08/2013 08/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	MERCK CONSUMER CARE - OXYTROL (OXYBUTYNIN) NDA 202-211 LBLG
2013-5177	07/08/2013 08/05/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	ROBERT KING FDA NEWS	FAREVA RICHMOND, INC; PHARMACEUTICS INTRNTIONAL; UNITED THERAPEUTICS CORP - 483S 5/1-31/13
2013-5178	07/08/2013 08/05/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	FOREST PHARMACEUTICALS INC, CINCINNATI, OH - EIR, 483, CO RESP 11/5/12
2013-5179	07/08/2013 08/05/2013	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	ROBERT KING FDA NEWS	AKOM INC; AVA INC; RICHARD WOLF MEDICAL INSTRUMENTS CORP, ETC - 483S 5/1-31/13
2013-5180	07/08/2013 08/05/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	WALTER E CHALKLEY THOMSON REUTERS	GADAL LABORATORIES INC, MIAMI, FL - EIR, 483, CO RESP 1/23/13
2013-5181	07/08/2013 08/05/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OC/OES/DFOI/	ROBERT KING FDA NEWS	PETNET SOLUTIONS INC; SCM TRUE AIR TECHNOLOGIES LLC; TRANSDERMAL CAP INC, ETC - 483S 5/1-31/13
2013-5182	07/08/2013 08/05/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	WALTER E CHALKLEY THOMSON REUTERS	JAEB CENTER FOR HEALTH RESEARCH IRB, TAMPA, FL - EIR, 483, CO RESP 1/30/13
2013-5183	07/08/2013 08/05/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	ROBERT KING FDA NEWS	ORIGINAL CREAM CO; KALCHEM INTERNATIONAL INC; TULSA DENTAL PRODUCTS LLC (TULSUA DENTAL SPECIALTIES), ETC - 483S 5/1-31/13
2013-5184	07/08/2013 08/05/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	ROBERT KING FDA NEWS	NEW VISTAS INC; TMJ MEDICAL LLC, SUMMIT MEDICAL PRODUCTS INC, ETC - 483S 5/1-31/13
2013-5185	07/08/2013	FDA/OGROP/ORASE-FO/FLA-	WALTER E CHALKLEY	LIFESOUTH COMMUNITY BLOOD CENTERS, CHIEFLAND, FL

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	08/05/2013	DO/FLA-CB/ FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	THOMSON REUTERS	- EIR, 483, CO RESP 1/31/13
2013-5186	07/08/2013 08/05/2013	FDA/OGROP/ORR/CE-FO/DET-DO/DET-CB/	ROBERT KING FDA NEWS	BAXTER PHARMACEUTICAL SOLUTIONS INC; CRACO PHARMACEUTICAL LABORATORIES LTD; FLOTEC INC - 483S 5/1-31/13
2013-5187	07/08/2013 08/05/2013	FDA/OGROP/ORR/SE-FO/SJN-DO/SJN-CB/	WALTER E CHALKLEY THOMSON REUTERS	MSD INTERNATIONAL GMBH PUERTO RICO BRANCH LLC, ARECIBO, PR - EIR, 483, CO RESP 1/24/13
2013-5188	07/08/2013 08/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ROBERT KING FDA NEWS	ARCH PHARMALABS LTD; ESTEVE QUIMICA S A; SHILPA MEDICARE LTD, ETC - 483S 5/1-31/13
2013-5189	07/08/2013 08/05/2013	FDA/OGROP/ORR/CE-FO/PHI-DO/PHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	NOVUM PHARMACEUTICAL RESEARCH SERVICES, PITTSBURGH, PA - EIR, 483, CO RESP 2/19/13
2013-5190	07/08/2013 08/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	ROBERT KING FDA NEWS	ULRICH GMBH & CO KG; CSR ELETRONICA; ITALIA MEDICA SRL, ETC - 483S 5/1-31/13
2013-5191	07/08/2013 08/05/2013	FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/	ROBERT KING FDA NEWS	ERGOSAFE PRODUCTS LLC; SUNBEAM PRODUCTS INC; BAYER HEALTH CARE LLC - 483S 5/1-31/13
2013-5192	07/08/2013 08/05/2013	FDA/OGROP/ORR/NE-FO/NYK-DO/NYK-DCB/	WALTER E CHALKLEY THOMSON REUTERS	MICHAEL E PICHICHERO MD, ROCHESTER, NY - EIR, 483, CO RESP 6/29/12
2013-5193	07/08/2013 08/05/2013	FDA/OGROP/ORR/NE-FO/NWE-DO/NWE-CB/	ROBERT KING FDA NEWS	HAEMONETICS CORP; JENSEN INDUSTRIES INC; HUESTIS MACHINE CORP, ETC - 483S 5/1-31/13
2013-5194	07/08/2013 08/05/2013	FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	RELIABLE BIOPHARMACEUTICAL CORP, OVERLAND, MO - EIR, 483,CO RESP 1/25/13
2013-5195	07/08/2013 08/05/2013	FDA/OGROP/ORR/CE-FO/NWJ-DO/NWJ-CB/	ROBERT KING FDA NEWS	LAXMI DENTAL LAB USA INC; VITAIRE CORP; ALMARK TOOL & MANUFACTURING COMPANY INC, ETC - 483S 5/1-31/13
2013-5196	07/08/2013 08/05/2013	FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/	WALTER E CHALKLEY THOMSON REUTERS	ALFRED J RODRIGUEZ MD, PA, PLANO, TX - EIR, 483, CO RESP 2/7/13
2013-5197	07/08/2013 08/05/2013	FDA/OGROP/ORR/SE-FO/NOL-DO/NOL-CB/	ROBERT KING FDA NEWS	BIOMEDICAL RESEARCH FOUNDATION OF NORTHWEST LOUISIANA; TOTAL PHARMACY SERVICES INC; QUALITEST PHARMS - 483S 5/1-31/13
2013-5198	07/08/2013 08/05/2013	FDA/OGROP/ORR/NE-FO/NYK-DO/NYK-DCB/	ROBERT KING FDA NEWS	CENTRAL RADIOPHARMACEUTICAL SERVICES INC; NORTH SHORE LIJ/RESEARCH INSTITUTE; A & Z PHARMACEUTICALS INC, ETC - 483S 5/1-31/13
2013-5199	07/08/2013	FDA/OGROP/ORR/CE-FO/PHI-DO/PHI-CB/	ROBERT KING	NORTHTEC LLC; HOME INFUSION SYSTEMS INC; DT DAVIS ENTERPRISES LTD, ETC - 483S 5/1-31/13

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	08/05/2013		FDA NEWS	
2013-5200	07/08/2013 08/05/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	ROBERT KING FDA NEWS	NOVARTIS VACCINE & DIAGNOSTICS INC; BAYER HEALTHCARE PHARMACEUTICALS INC; INTELAMETRIX INC, ETC - 483S 5/1-31/13
2013-5201	07/08/2013 08/05/2013	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	ROBERT KING FDA NEWS	ST JUDE MEDICAL PUETRO RICO LLC; BECTON DICKINSON CARIBE LTD; ZIMMER MANUFACTURING BV - 483S 5/1-13/13
2013-5202	07/08/2013 08/05/2013	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	ROBERT KING FDA NEWS	BIOTRONICK INC; PARKS MEDICAL ELECTRONICS INC; JUBLIANT HOLLISTERSTIER, LLC, ETC - 483S 5/1-31/13
2013-5203	07/08/2013 08/05/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	ROBERT KING FDA NEWS	AMOCOR FLEXIBLES COMMERCE; DISCUS DENTAL LLCL; UNICARE BIOMEDICAL INC, ETC - 483S 5/1-13/13
2013-5204	07/08/2013 08/05/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	SHELLY D SENDERS MD, SOUTH EUCLID, OH - EIR, 483, CO RESP 7/17/12
2013-5205	07/08/2013 08/05/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	ROBERT KING FDA NEWS	CORERX INC; HOIZON PHARMACEUTICALS INC; ATLANTIC PRO NUTRIENWTS INC (XYMOGEN), ETC 483S 5/1-31/13
2013-5206	07/08/2013 08/05/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	UPSHER SMITH LABORATORIES INC, MAPLE GROVE, MN - EIR, 483, CO RESP 3/1/13
2013-5207	07/08/2013 08/05/2013	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	WALTER E CHALKLEY THOMSON REUTERS	BAXTER HEALTHCARE CORP, JAYUYA, PR - EIR, 483, CO RESP 3/13/13-4/19/13
2013-5208	07/08/2013 08/05/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	WALTER E CHALKLEY THOMSON REUTERS	BAXTER HEALTHCARE CORP, MARION, NC - EIR, 483, CO RESP 11/7-16/12
2013-5209	07/08/2013 08/05/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	WALTER E CHALKLEY THOMSON REUTERS	BOSTON SPINE GROUP, NEWTON, MA - EIR, 483, CO RESP 11/15/11-12/7/11
2013-5210	07/08/2013 08/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	CONTRACT PHARMACEUTICAL SERVICES OF AUSTRALIA PTY LTD, NORTH RYDE,NSW, AUSTRALIA - EIR, 483, CO RESP 10/30/12-11/1/12
2013-5211	07/08/2013 08/05/2013	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	HOSPIRA, LAKE FOREST, IL - EIR, 483, CO RESP 10/3-10/12
2013-5212	07/08/2013 08/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	NOVARTIS INTERNATIONAL AG, BASEL, SWITZERLAND - EIR, 483, CO RESP 10/15-23/12
2013-5213	07/08/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	WALTER E CHALKLEY	NOVARTIS CONSUMER HEALTH, LINCOLN, NE - EIR, 483, CO RESP 6/13/11-7/8/11

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	08/05/2013		THOMSON REUTERS	
2013-5214	07/08/2013 08/05/2013	FDA/OGROP/ORR/SE-FO/SJN-DO/SJN-CB/	WALTER E CHALKLEY THOMSON REUTERS	AGROPHARMA LABORATORIES INC, SALINAS, PR - EIR, 483, CO RESP 3/20/13
2013-5215	07/08/2013 08/05/2013	FDA/OGROP/ORR/CE-FO/MIN-DO/MIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	AERO COMPRESSED GASES INC, MILWAUKEE, WI - EIR, 483, CO RESP 2/5/13
2013-5216	07/08/2013 08/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	RPG LIFE SCIENCES LTD 463, MUMBAI, MAHARASHTRA, INDIA - EIR, 483, CO RESP 11/20-24/12
2013-5217	07/08/2013 09/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OC/OES/DFOI/	WALTER E CHALKLEY THOMSON REUTERS	KEDRION SPA, BOLOGNANA, ITALIA - EIR, 483, CO RESP 4/18/12
2013-5218	07/08/2013 08/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	ACE JAPAN CO LTD, HIGASHINE, JAPAN - EIR, 483, CO RESP 10/26/12
2013-5219	07/08/2013 08/05/2013	FDA/OC/OES/DDM/	PETER S. HARRIS PREMIER DUE DILIGENCE	DKT & DKT LOG OF 1995N-0259
2013-5220	07/09/2013 08/06/2013	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	ROBERT KING FDA NEWS	CARDIOGENESIS CORP - 483S 5/1-31/13
2013-5221	07/09/2013 08/06/2013	FDA/OFVM/CFSAN/OCD/EOS/	CHRISTINE FORGUES MORGAN LEWIS & BOCKIUS LLP	ROCK STAR ENERGY DRINK - CAERS 10/12 TO PRESENT
2013-5222	07/09/2013 08/06/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	CHASTINE 12B2563, JAMES	IPRATROPIUM, EICOSAPENTAENOIC, BECHOMETHASOME, ETC - RECS
2013-5223	07/09/2013 08/06/2013	FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/	PATRICIA L REGENYE Celgene Corporation	EVAN HERSH, ARIZONA CANCER CTR, TUCSON, AZ - 483S 6/00 TO PRESENT

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2013-5224	07/09/2013 08/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MICHAEL R COHEN RPH MS SCD INSTITUTE FOR SAFE MEDICATION PRACTICES	MEDWATCH RPTS CODED AS MEDICATION ERRORS 6/1-30/13
2013-5225	07/09/2013 08/06/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	MARISOL FERNANDEZ GRIFOLS BIOLOGICALS INC	BAXTER HEALTHCARE CORP, MARION, NC - EIRS, 483S 1/12 TO 5/13
2013-5226	07/09/2013 08/06/2013	FDA/OC/OES/DFOI/	DONALD HENTON COVIDIEN	2012-200 - DELETED RECS
2013-5227	07/09/2013 08/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	AMY MITCHELL GLAXO SMITH KLINE	GLAXOSMITHKLINE, PARMA - QUALITY ASSURANCE PROFILE (QAP)
2013-5228	07/09/2013 08/06/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CATHERINE GILFEDDER REPRIEVE	ANIP ACQUISITION CO - WARNING LTR, CO RESP, REGLAN CORR 9/11 TO PRESENT, ETC
2013-5229	07/09/2013 08/06/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	CATHERINE GILFEDDER REPRIEVE	BIOSANTE PHARMACEUTICALS INC - VIOLATIONS, INVESTIGATIONS
2013-5230	07/09/2013 08/06/2013	FDA/OMPT/OSMP/OOPD/	STANLEY SATZ PHD Advanced Imaging Projects, Inc.	LEUCOVORIN - STABILITY DATA, APRVL LTR, CORR, ETC
2013-5231	07/09/2013 08/06/2013	FDA/OC/OES/DFOI/	CODY MONROE ASE Direct Inc.	FDA GOVERNMENT PURCHASE CARD HOLDERS NAMES AND PHONE NUMBERS LAST 2 YRS
2013-5232	07/09/2013 08/06/2013	FDA/OO/OFBA/OAGS/	ALEXANDER CAMPBELL 32BJ SEIU	BUDGET SERVICES & SUPPLIES LLC - CONTRACT #HHSF223201310006C
2013-5233	07/09/2013 08/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	ZOLEDRONIC - AERS
2013-5234	07/09/2013 08/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	TAKEDA LABS - SOLUTAB PHARMACOLOGY RECS, EIRS 1/06 TO PRESENT

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-5235	07/09/2013 08/06/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	Doe J	INDIVIDUAL RECS
2013-5236	07/09/2013 08/06/2013	FDA/OC/OES/ FDA/OFVM/CFSAN/OCD/EOS/	TOM NASH MUCKROCK NEWS	COCA COLA CO, PEPSI CO - USE OF 4-METHYLIMIDAZOLE CORR 2009 TO PRESENT
2013-5237	07/09/2013 08/06/2013	FDA/OFVM/CFSAN/OCD/EOS/	TOM NASH MUCKROCK NEWS	USE OF 4-METHYLIMIDAZOLE IN SODA - RPTS, MEMOS 2009 TO PRESENT
2013-5238	07/09/2013 08/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	MICHAEL ZIMKOWSKI UNIV OF COLORADO AT DENVER	PARIETEX MONOFILAMENT POLYESTER MESH K090858
2013-5239	07/09/2013 08/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	MICHAEL ZIMKOWSKI UNIV OF COLORADO AT DENVER	COMPOSIX L/P MESH WITH ECHO PS POSITIONING SYS K102788
2013-5240	07/09/2013 08/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	STEPHANIE PHILBIN GOODWIN PROCTER LLP	ACRYSOFT UV ABSORBING INTRAOCULAR LENSES P930014, META-MV PACING SYS P880038 - SS&E
2013-5241	07/09/2013 08/06/2013	FDA/OC/OES/DDM/	ROBERT F CHURCH HOGAN LOVELLS US LLP	DKT 1975N-0336
2013-5242	07/09/2013 08/06/2013	FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	MICHAEL MASUDA NOLAND HAMERLY ETIENNE & HOSS	ROBERT A HOHBERG, HOHBERG POULTRY RANCHES, ONTARIO, CA; FONTANA, CA - APRVLS, INVESTIGATIONS, VIOLATIONS, ETC 1994 TO PRESENT
2013-5243	07/09/2013 08/06/2013	FDA/OC/OES/DFOI/ FDA/OGROP/ORO/CE-FO/NWJ-DO/NWJ-CB/	FRULLO JR, RAYMOND L	ARM & HAMMER TOOTHPASTE - INSP RESULTS LAST TEN YRS
2013-5244	07/09/2013 08/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PAMELA SHEPPARD TARO PHARMACEUTICALS USA INC	MERZ PHARMS - NAFTIN (NAFTIFINE HCL) NDA 204-286 SBA, MOR, LBLG, ETC
2013-5245	07/09/2013 08/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Margaret Sestrom PFIZER	XOLAIR - SBA
2013-5246	07/09/2013 08/06/2013	FDA/OGROP/ORO/PA-FO/SEA-DO/SEA-CB/	Doe J	INDIVIDUAL RECS

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		FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDRH/OCER/DFOI/		
2013-5247	07/09/2013 08/06/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mahidhar Chinta Micro Labs USA, Inc	NDA 020336 - SBA
2013-5248	07/09/2013 08/06/2013	FDA/OGROP/ORANE-FO/NYK- DO/NYK-DCB/ FDA/OMPT/CDRH/OCER/DFOI/	Doe J	INDIVIDUAL RECS
2013-5249	07/09/2013 08/06/2013	FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA REQUEST LOG 07/01/2013 - 07/05/2013
2013-5250	07/09/2013 08/06/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NINGBO SMART PHARMACEUTICAL COMPANY, CHINA - INVESTIGATOR DIARY
2013-5251	07/09/2013 08/06/2013	FDA/OGROP/ORANE-FO/NYK- DO/NYK-DCB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORACE-FO/MIN- DO/MIN-CB/ FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/	DEBORAH M FIELD MORRIS & MORRIS	INDIVIDUAL RECS
2013-5252	07/09/2013 08/27/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Rachel Johnson FOI Services, Inc.	BK120067
2013-5253	07/09/2013 08/06/2013	FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/ FDA/OMPT/CDRH/OCER/DFOI/	MATTHEW T JONES MCFARLANE & DOLAN LAW OFCS	ST JUDE MEDICAL - EON MINI-3788 (PG) RECALL RECS
2013-5254	07/09/2013 08/06/2013	FDA/OC/OES/DDM/	Mark Oremus MCMASTER UNIVERSITY	PERIPHERAL AND CENTRAL NERVOUS SYSTEM DRUGS ADVISORY COMMITTEE - RECS RE 7/7/89 MTG
2013-5255	07/09/2013 08/06/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bob Ciesla Personal Consumer Information	ISR 6555078 6647694 6867721 ETC
2013-5256	07/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Tim Lohnes	K092309

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	08/06/2013		Orchid Design	
2013-5257	07/09/2013 08/06/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachelle Lyon JANUS CAPITAL GROUP INC	ZYTIGA, XTANDI - AERS
2013-5258	07/09/2013 08/06/2013	FDA/OC/OES/DFOI/	Carol L. Price Carol L. Price	DAVINCI ROBOTIC SURGICAL DEVICE - RECS RE DEFECT
2013-5259	07/09/2013 08/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	BTran Tran & Associates	K973806
2013-5260	07/09/2013 08/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	BTran Tran & Associates	K926508
2013-5261	07/09/2013 08/06/2013	FDA/OO/OFBA/OAGS/	Marcy Welkie MPF Federal, LLC	HHSF223200830014I
2013-5262	07/09/2013 08/06/2013	FDA/OFVM/CFSAN/OCD/EOS/	Dojin Ryu University of Idaho	OCCURENCE OF OCHRATOXIN IN FOODS AND AGRICULTURAL COMMODITIES
2013-5263	07/09/2013 08/06/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Nicole Norfleet STAR TRIBUNE	HMONGTOWN MARKETPLACE, HMONG VILLAGE, ST PAUL, MN - COMPLAINTS
2013-5264	07/09/2013 08/06/2013	FDA/OC/OES/DFOI/	Yingchao Xiao Lee & Xiao	IMPORTER, EXORTER
2013-5265	07/09/2013 08/06/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	b.burgess BURGESS, BERNIE	CONVERSATION BY DAN-MY CHU DS1 1/24/07 RE C1639
2013-5266	07/09/2013 08/06/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Christopher J. Gansen Gansen Law Group, P.C.	HEMOFIL M - AERS
2013-5267	07/09/2013 08/06/2013	FDA/OO/OFBA/OAGS/	Tyson Bellamy FEFA LLC	HHSF223201210142C
2013-5268	07/10/2013 08/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	ROBERT O DEAN COMPLIANCE SYSTEMS INTERNATIONAL LLC	GRI MEDICAL & ELECTRONIC TECHNOLOG CO LTD, JIAXING, ZHEJIANG, CHINA - EIRS, 483S, ACTION PLAN MOST CURRENT

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2013-5269	07/10/2013 08/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	MARA CALER ALERE DAN DIEGO INC	BECKMAN COULTER INC - ACCESS TNL TEST K121214
2013-5270	07/10/2013 08/07/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	REID BECK BECK & AMSDEN PLLC	ABILIFY - AERS
2013-5271	07/10/2013 08/07/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	HATTON 1519223, ROLAND	MIRAPOX - ISRS 4100477, 4124388, 5856767, ETC
2013-5272	07/10/2013 08/07/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	LESLIE LOCHMAN CAPE RADIOLOGY GROUP	MERCERVILLE RADIOLOGY ASSOCIATES PA - WARNING LTR CLOSE OUT LTR 5/19/97
2013-5273	07/10/2013 08/07/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OC/OES/DFOI/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	VINCENT TONG BURESH KAPLAN FELLER AT EL	MMI, CUPERTINO, CA - EIR, ATTACHMENTS, EXHIBITS 4/16/12-5/8/12
2013-5274	07/10/2013 08/07/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	DONALD N BLUE ZETETIC INC	FIBREBOARD BOXES STE HAIR CARE PRODS ENTRY NUMBER EHP-007191-6 (SHAMPOO, CONDITIONER) - PHOTOGRAPHS, OASIS SCREEN SHOTS
2013-5275	07/10/2013 08/07/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANOKHI J KAPASI DEGGE GROUP LTD	ISR 3170570, 3567433, 3764906, ETC
2013-5276	07/10/2013 08/07/2013	FDA/OO/OHR/	PAUL VACLAVIK	PER CORE V USPS HHS-FDA-MP-11-463297, HHS-CDRH-DE-11-511106, HHS FDA-MP-11-493192, ETC APPLICANT QUALIFICATIONS
2013-5277	07/10/2013 08/07/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORASW-FO/SWID/SWID-CB/	SAMANWTHA MYERS ROANOKE CLAIMS SERVICES	ENTRY NUMBER DC101014389 - LIST FDA NOTICE OF ACTION, BILLS OF LANDING COMMERCIAL INVOICES, ETC

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2013-5278	07/10/2013 08/07/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/	PATRICK J CAULFIELD GRUNFELD DESIDERIO LEBOWITZ ET AL	OLEIFICIO MONTALBANO SPA (MONTALBANO AGRICOLA ALIMENTARE TOSCANA SPA); COSTA D'ORO SPA - OLIVE OIL NONEXEMPT RECS
2013-5279	07/11/2013 08/08/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/NE-FO/NWE-DO/NWE-CB/	JOHN P KROMER CONNORS & VILARDO LLP	LEWISTON COMMERCIAL WAREHOUSE - LEGIONNAIRES DISEASE INVESTIGATION RECS, TEST RESULTS, EMAILS, ETC
2013-5280	07/11/2013 08/08/2013	FDA/OC/OES/DFOI/	CHRISTINA RAFFAELE AVALON RISK MANAGEMENT INC	ENTRY #60510811122 - NOTICE OF FDA ACTION #1
2013-5281	07/11/2013 08/08/2013	FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/	CYNTHIA L MAZZUTO RN LYTAL REITER CLARK ET AL	INDIVIDUAL RECS
2013-5282	07/11/2013 08/08/2013	FDA/OC/OES/ FDA/OGROP/OIP/	DAVID G MORGAN REUTERS	PLANNED EXPANSION OF FDA INSP CAPACITY IN CHINA
2013-5283	07/11/2013 08/08/2013	FDA/OC/OES/DDM/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OCC/	CONNOR G SHEEHAN DUNN SHEEHAN LLP	GLAXOSMITHKLINE LLC - LAMICTAL AERS, CLNCL TRIALS, RISK ASSESSMENTS, ETC
2013-5284	07/11/2013 08/08/2013	OC/ORO/ OC/ORO/ OC/ORO/ORM/ OC/ORO/ORM/ OC/ORO/OE/ OC/ORO/OE/	ERICA JORGENSEN WSB-TV Special Projects	INSPS IN GEORGIA 7/1/08 TO 7/1/13
2013-5285	07/11/2013 08/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORO/ORO/DIOP/ FDA/OC/OCC/ OC/ORO/ OC/ORO/	JON M SANDS FEDERAL PUBLIC DEFENDER ARIZONA	SODIUM THIOPENTAL, PENTOBARBITAL SODIUM, PROPOFOL, ETC - IMPORTATION RECS 2/1/11 TO PRESENT

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2013-5286	07/11/2013 08/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOSEPH KICEINA ABBOTT POINT OF CARE INC	HEMOCHRON JR APTT K940401, K923761; HEMOCHRON JR GENERATION II K974799, ETC
2013-5287	07/11/2013 08/08/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RYE, SHANIAN	MEDICATIONS APPROVED TO TREAT MENTAL ILLNEESES IN ILLINOIS

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2013-5288	07/11/2013 08/08/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	THANKUR, CHANDAR	CR BARD INC - WARNING LTR SJN-08-06 7/22/08, #03-ATL-26 9/16/03 CLOSEOUT RECS
2013-5289	07/11/2013 08/08/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	THANKUR, CHANDAR	LIFECCELL CORP - WARNING LTR #09-NWJ-01 10/1008, 5/5/011
2013-5290	07/11/2013 08/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	SANDY MASTROIANNI ITC	DMI BLOOD GAS ANALYZER & CARTRIDGE K924758
2013-5291	07/11/2013 08/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	SANDY MASTROIANNI ITC	IRMA SL BLOOD ANALYSIS SYS CR CARTRIDGE K030035
2013-5292	07/11/2013 08/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	SANDY MASTROIANNI ITC	IRMA BLOOD ANALYSIS SYS LACTATE CARTRIDGE K013938
2013-5293	07/11/2013 08/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	SANDY MASTROIANNI ITC	IRMA SL BLOOD ANALYSIS SYS GL CARTRIDGE K011586
2013-5294	07/11/2013 08/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	SANDY MASTROIANNI ITC	IRMA BLOOD ANALYSIS SYS K981270
2013-5295	07/11/2013 08/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	SANDY MASTROIANNI ITC	IRMA BLOOD ANALYSIS SYS WITH OPTIONAL MULTI-USE CARTRIDGE K980523
2013-5296	07/11/2013 08/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	SANDY MASTROIANNI ITC	IRMA BLOOD ANALYSIS SYS K974396
2013-5297	07/11/2013 08/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	SANDY MASTROIANNI ITC	IRMA BLOOD ANALYSIS SYS K945240
2013-5298	07/12/2013 08/09/2013	FDA/OC/OES/DFOI/	Carol L. Price Carol L. Price	DAVINCI ROBOTIC SURGICAL DEVICE - REPORTS OF PROBLEMS
2013-5299	07/12/2013 09/05/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	C. Gansen GANSEN LAW GROUP	HEMOFIL - AERS
2013-5300	07/12/2013 08/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NINGBO SMART, NINGBO, CHINA - EIR, 483, CORR
2013-5301	07/12/2013 08/09/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	George Martens Carbunny LLC	BIOLOGICAL DEVIATION REPORTS SUBMITTED BY OHIO STATE UNIVERSITY MEDICAL CENTER
2013-5302	07/12/2013 08/09/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Melissa McCaughey DePuy Synthes Spine	DEPUY MITEK, DEPUY ORTHO - EIR 08/03/2012 - 07/01/2013

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2013-5303	07/12/2013 08/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John Franolic VersaPharm Inc.	ANDA 202459 - SBA
2013-5304	07/12/2013 08/09/2013	FDA/OFVM/CFSAN/OCD/EOS/	Todd McInerney Magrabar Chemical Corporation	ENZYME TECHNICAL ASSOCIATION - SUBMISSIONS ON ANTIFOAMS AND FLOCCULANTS
2013-5305	07/12/2013 08/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Daniel Lin ELI LILLY & CO	NDA 018450) filed by Abbvie in September 1981
2013-5306	07/12/2013 08/09/2013	FDA/OGROP/ORR/PA-FO/SEA-DO/SEA-CB/	David Luke Palmer Natural Products	PALMER NATURAL PRODUCTS - TRANSCRIPT OF CALL WITH SEATTLE DISTRICT 06/18/2013
2013-5307	07/12/2013 08/09/2013	FDA/OGROP/ORR/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORR/CE-FO/NWJ-DO/NWJ-CB/	Rachel Johnson FOI Services, Inc.	APPLIED NUTRITION CORPORATION - EIR, 483, CORR ETC
2013-5308	07/12/2013 08/09/2013	FDA/OMPT/CTP/OD/	Desmond Jenson Tobacco Control Legal Consortium	GRANDFATHERED TOBACCO PRODUCT STATUS DETERMINATION - CORR, SUMMARIES, ETC (06/22/2009 - 07/09/2013)
2013-5309	07/12/2013 08/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kaori Asakawa Experien Group LLC	K961385 - TRANSFER OF OWNERSHIP LETTER
2013-5310	07/12/2013 08/09/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Bao Tran Tran Associates	K983658, K090169, K090598 ETC
2013-5311	07/12/2013 08/09/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Sergey Zavyalov, Sergey	K980745, K033448
2013-5312	07/12/2013 08/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	James Heaney Heaney, James	REGISTERED ACTIVE INGREDIENT PRODUCERS FOR CAS# 8001-54-5; FEGISTERED INNERT INGREDIENT PRODUCERS FOR CAS# 8001-54-5
2013-5313	07/12/2013 08/09/2013	FDA/OC/OES/DFOI/	Liz Szabo USA TODAY	PREVIOUSLY FILED FOIA
2013-5314	07/12/2013 08/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Cora Sim Ellipse Technologies, Inc.	K930836
2013-5315	07/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	Cora Sim	K910483

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	08/09/2013		Ellipse Technologies, Inc.	
2013-5316	07/12/2013 08/09/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Michael Garff Fresh Medical Laboratories	K032350, K874181
2013-5317	07/12/2013 08/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Cora Sim Ellipse Technologies, Inc.	K031875
2013-5318	07/12/2013 08/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mahidhar Chinta Micro Labs USA, Inc	LINEZOLID - SBA
2013-5319	07/12/2013 08/09/2013	FDA/OGROP/ORAP/PA-FO/LOS- DO/LOS-CB/	Matthew J Dodds CITIGROUP	ST JUDE SYLMAR, CA FACILITY - ALL RECS (03/01/2013 - 07/11/2013)
2013-5320	07/12/2013 08/09/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANOKHI J KAPASI DEGGE GROUP LTD	ISRS - 3018238-7, 3118880-9, 3019234-6, ETC
2013-5321	07/12/2013 08/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	ANOKI J KAPASI DEGGE GROUP LTD	ISRS - 4828879-X, 4711307-2, 4616001-4, ETC
2013-5322	07/12/2013 08/09/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANOKHI J KAPASI DEGGE GROUP LTD	ISRS - 321823-0, 3143443-9, 3158856-9, ETC
2013-5323	07/12/2013 08/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Xin Pan Weiss Asset Management	STRIDES ARCOLAB - 483 (06/01/2013 - 07/10/2013)
2013-5324	07/12/2013	FDA/OGROP/ORAP/PA-FO/LOS-	Eric White	PURETEK CORPORATION, SAN FERNANDO, CA - 483

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	08/09/2013	DO/LOS-CB/	MISSION PHARMACAL COMPANY/PRESIDENT	(07/01/2010 - 07/31/2013)
2013-5325	07/12/2013 08/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Laura Strickler CBS NEWS	RANBAXY FOREIGN FACILITIES - INSPECTION RECS, NOTES, 483 ETC (01/01/2011 - 01/01/2013)
2013-5326	07/12/2013 08/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Thomas M. Burton THE WALL STREET JOURNAL	CLINICAL INSPECTION SUMMARY BY OFFICE OF SCIENTIFIC INVESTIGATIONS RE CLINICAL TRIALS
2013-5327	07/12/2013 08/09/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OC/OES/DFOI/	Ricky Swan Swan, Ricky L	SWAN BROS DAIRY INC, CLAREMORE, OK - EIR, LAB REPORTS
2013-5328	07/12/2013 08/09/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANOKHI J KAPASI DEGGE GROUP LTD	ISRS - 3594674-5, 3911077-1, 3977207-0, ETC
2013-5329	07/12/2013 08/09/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANOKI J KAPASI DEGGE GROUP LTD	ISRS - 438568-8, 4584792-7, 4389882-X, ETC
2013-5330	07/12/2013 08/09/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANOKHI J KAPASI DEGGE GROUP LTD	ISRS - 6135920-3, 5317709-8, 5317711-6, ETC
2013-5331	07/12/2013 08/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jeannie Lin Route One Investment Company	AGILA SPECIALTIES - 483 (06/17/2013 - 07/10/2013)

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2013-5332	07/12/2013 08/09/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANOKHI J KAPASI DEGGE GROUP LTD	ISRS - 6905200-4, 7033816-6, 7777191-8, ETC
2013-5333	07/12/2013 08/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	PAULL CAMPBELL VASCULAR SOLUTIONS INC	VASCULAR SOLUTIONS INC, ZERUSA LTD - GUARDIAN HEMOSTATIS VALVE K052381, K073620
2013-5334	07/12/2013 08/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	PAM PUMMILL SYBRON DENTAL SPECIALTIES	SONENDO INC, LAGUNA HILLS, CA - ENDOTHERAPY SYS K130025
2013-5335	07/12/2013 08/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	NAYAN RAVAL SILARX PHARMACEUTICALS INC	SILARX PHARMACEUTICALS INC, SPRING VALLEY, NY - QAP
2013-5336	07/12/2013 08/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SAMO, SALIH	ISRS 3477397, 4103405, 4139030, ETC
2013-5337	07/12/2013 08/09/2013	FDA/OGROP/ORPA/PA-FO/LOS- DO/LOS-CB/	STEVEN E FORMAKER FREEDMAN & TAITELMAN LLP	WISDOM PROTEINS INC, SAN DIEGO, CA - CMLPNTS, INVESTIGATION, CONSENT AGREEMENTS 1/11 TO PRESENT
2013-5338	07/12/2013 08/09/2013	OC/ORPA/ OC/ORPA/ FDA/OGROP/ORPA/SW-FO/DAL- DO/DAL-CB/ FDA/OC/OES/DFOI/	TAYLOR, DOREEN A	COMPLIANCE RPT 130314
2013-5339	07/12/2013 08/09/2013	FDA/OGROP/ORPA/PA-FO/LOS- DO/LOS-CB/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Robert Pyrtle Pyrtle, Robert	SCANTIBODIES BIOLOGICS, INC, EL CAJON, CA - EIR (01/01/2013 - 07/10/2013)
2013-5340	07/12/2013 08/09/2013		PETER HARRIS PREMIER DUE DILIGENCE	DKT 1995N-0259
2013-5341	07/12/2013 08/09/2013		HILLARY RUBIN KENYON & KENYON LLP	DKT 1995S-0316

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2013-5342	07/12/2013 08/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Christopher Smith Symmetry Medical Inc.	K012105
2013-5343	07/12/2013 08/09/2013	FDA/OFVM/CFSAN/OCD/EOS/	Anahad OConnor NEW YORK TIMES	MEAL REPLACEMENT PRODUCTS - AERS
2013-5344	07/12/2013 08/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	A1481259 STUDY TO ASSESS PDE5
2013-5345	07/12/2013 08/09/2013	FDA/OMPT/CTP/OD/ FDA/OO/OFBA/OFO/OFM/BTAMS /	Michael Felberbaum THE ASSOCIATED PRESS	CTP - BUDGETS, USER FEES
2013-5346	07/12/2013 08/14/2013	FDA/OGROP/ORACE-FO/DET- DO/DET-CB/	Diane Lehman wilson UNIVERSITY OF MICHIGAN MEDICAL SCHOOL	UNIVERSITY OF MICHIGAN - EIR 02/10/2010 - 02/10/2012
2013-5347	07/12/2013 08/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dheeresh Pathak Dheeresh Pathak	AGILA SPECIALTIES - 483 (01/01/2013 - 07/10/2013)
2013-5348	07/12/2013 08/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	David Lin BIOLOGICS CONSULTING GROUP	SKYLA - APPROVAL RECS
2013-5349	07/12/2013 08/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Neal Wadhera Partner Fund Management	STRIDES ARCOLAB - 483 06/15/2013 - 07/10/2013
2013-5350	07/12/2013 08/09/2013	FDA/OC/OES/DFOI/	Michael Felberbaum THE ASSOCIATED PRESS	CTP FOIA REQUESTS
2013-5351	07/15/2013 08/12/2013	FDA/OGROP/ORASE-FO/FLA- DO/FLA-CB/	Mariela Ochoa Swiss Caps, USA, Inc.	SWISS CAPS USA - EIR REDACTED 11/08/2010 TO 11/17/2010
2013-5352	07/15/2013 08/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kristen Bunnell, PharmD RHODE ISLAND HOSPITAL	LEVETIRACETAM - AERS

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2013-5353	07/15/2013 08/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Chris Hutts Cantrell Drug Company	OUTSOURCE HUMAN DRUG COMPOUNDER BUSINESS CLASSIFICATION
2013-5354	07/15/2013 08/12/2013	FDA/OFVM/CFSAN/OCD/EOS/	ryan houser Vemma	VERVE - CAERS
2013-5355	07/15/2013 08/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	joe enos enos, joe	LORAZAPM - AERS, VIOLATIONS
2013-5356	07/15/2013 08/12/2013	OC/CVM/OCD/	Becky Armfield NOVARTIS ANIMAL HEALTH US INC	NADA 141-345
2013-5357	07/15/2013 08/12/2013	OC/ORO/ OC/ORO/ FDA/OC/OES/DFOI/ FDA/OGROP/ORO/ORO/DIOP/	Denise Malan Investigative Reporters and Editors	OASIS DATA
2013-5358	07/15/2013 08/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	A. Luke Smith FARUQI & FARUQI LLP	ANDA 077571 ROUTING SHEET
2013-5359	07/15/2013 08/21/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Barry Gene Hicks Fresenius-Kabi USA	BK120067
2013-5360	07/15/2013 08/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	A. Luke Smith FARUQI & FARUQI LLP	ANDA 077571 FINAL APPROVAL LETTER
2013-5361	07/15/2013 08/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection report from November 2012 for: Boehringer-Ingelheim Pharma GmbH & Co. KG, Ingelheim am Rhein, Germany
2013-5362	07/15/2013 08/12/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Irene Libin Steven H. Schafer & Associates	DA VINCI SURGICAL SYSTEM

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2013-5363	07/15/2013 08/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Cathy Burgess ALSTON & BIRD LLP	STRIDES ARCOLAB - 483 (06/01/2013 - 07/12/2013)
2013-5364	07/15/2013 08/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	Carl Jenkins WOOD BURDITT GROUP	K820673 K833261 K881422
2013-5365	07/15/2013 08/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	Casey A. Metzger STRYKER INSTRUMENTS	K002348 - REVIEWER NOTES
2013-5366	07/15/2013 08/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kelly McNamara INTUITIVE SURGICAL	K110639
2013-5367	07/15/2013 08/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	SCF-001 AC NDA 20231 S/046
2013-5368	07/15/2013 08/12/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Donald L. Bredle, PhD University of Wisconsin - Eau Claire	REGULATORY OVERVIEW OF HYDROXYETHYL STARCH SOLUTIONS - RECS
2013-5369	07/15/2013 08/12/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Marc Weiner, M.D. UTHSCSA	RIFAMPIN - PRECLINICAL TOXICOLOGY AND SAFETY DATA
2013-5370	07/15/2013 08/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	Alain Jordan Aleva Neurotherapeutics SA	P840001
2013-5371	07/15/2013 08/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	Joyce Greene Joyce Greene Research	MICRONUCLEUS FORMATION MEETING - TRANSCRIPT (07/31/2000 - 08/10/2000)
2013-5372	07/15/2013 08/12/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dr. Sue Feldman Community Health Alliance	ADVERSE DRUG REDACTIONS IN VIRGINIA HOSPITALS (01/01/2012 - 07/13/2013)
2013-5373	07/15/2013	FDA/OGROP/ORO/SE-FO/ATL-	ROBERT KING	MEDI FARE DRUG & HOME HEALTH CARE, BLACKSBURG,

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	08/12/2013	DO/ATL-CB/	FDA NEWS	SC; BIO MERIEUX INC, DURHAM, NC - 483 6/13
2013-5374	07/15/2013 08/12/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	ROBERT KING FDA NEWS	ZIMMER TRABECULAR METAL TECHNOLOGY INC, PARSIPPANY, NJ; DELVA TOOL & MACHINE CRP, CINNAMINSON, NJ; ADVANCED PRECISION INC, SPARTA, NJ - 483 6/13
2013-5375	07/15/2013 08/12/2013	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	ROBERT KING FDA NEWS	MAIN STREET FAMILY PHARMACY LLC, NEWBERN, TN; OWEN BIOSCIENCES INC, BATON ROUGE, LA; LEISURE PRODUCTS, INC, KINGSPORT, TN - 483 6/13
2013-5376	07/15/2013 08/12/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	ROBERT KING FDA NEWS	CARESTREAM HEALTH INC, ROCHESTER, NY; LNK INT'L INC, HAUPPAUGE, NY; AMERICARE COMPOUNDING LLC, GARDEN CITY SOUTH, NY - 483 6/13
2013-5377	07/15/2013 08/12/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	ROBERT KING FDA NEWS	TEVA PHARMACEUTICALS USA INC, SELLERSVILLE, PA; GLOBUS MEDICAL INC, AUDUBON, PA - 483 6/13
2013-5378	07/15/2013 08/12/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	ROBERT KING FDA NEWS	MOTION ANALYSIS CORP, SANTA ROSA, CA; MORGAN MEDESIGN INC, SANTA ROSA, CA; DOCXS BIOMEDICAL PRODUCTS LLC, UKIAH, CA - 483 6/13
2013-5379	07/15/2013 08/12/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	ROBERT KING FDA NEWS	AD TECH MEDICAL INSTRUMENT CORP, RACINE WI; PMT CORP, CHANHASSEN, MN; BELL INTL LABS INC, MINNEAPLOIS, MN - 483 6/13
2013-5380	07/15/2013 08/12/2013	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	ROBERT KING FDA NEWS	UNITED CONTACT LENS INC, ARLINGTON, WA - 483 6/13
2013-5381	07/15/2013 08/12/2013	OC/ORA/ OC/ORA/ FDA/OMPT/CDRH/OCER/DFOI/	ROBERT KING FDA NEWS	PT PANASONIC HEALTHCARE, INDONESIA - 483 6/13
2013-5382	07/15/2013 08/12/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	ROBERT KING FDA NEWS	SANQUIN PLASMA PRODUCTS, AMSTERDAM, NETHERLANDS - 483 6/13
2013-5383	07/15/2013 08/12/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	ROBERT KING FDA NEWS	AFTON SCIENTIFIC LLC, CHARLOTTESVILLE, VA; PRAXIR DISTRIBUTION MID ATLANTIC LLC, JESSUP, MD - 483 6/13
2013-5384	07/15/2013 08/12/2013	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	ROBERT KING FDA NEWS	7 MILE SOLUTIONS INC, MAXANT TECHNOLOGIES, NILES IL; PARO ROBOTS US INC, SCHAUMBURG, IL - 483 6/13
2013-5385	07/15/2013 08/12/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	ROBERT KING FDA NEWS	OHIO ALUMINUM CO, WEST CHESTER, OH; GFS CHEMICALS INC, COLUMBUS, OH - 483 6/30
2013-5386	07/15/2013 08/12/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	ROBERT KING FDA NEWS	GENESYS ORTHOPEDIC SYS LLC, AUSTIN, TX; WILDCAT MEDICAL EQUIPMENT INC, TULSA, OK; GENESIS BIOSYSTEMS INC, LEWISVILLE, TX - 483 6/13
2013-5387	07/15/2013 08/12/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	ROBERT KING FDA NEWS	PETNET SOLUTIONS INC, ALBUQUERQUE, NM, COLORADO MEDICAL SYCLOTRON LLC, DENVER, CO; VICON MOTION SYS INC, CENTENNIAL CO - 483 6/13

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2013-5388	07/15/2013 08/12/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	ROBERT KING FDA NEWS	SYMBIOS MEDICAL PRODUCTS LLC, INDIANAPOLIS, IN; SERVAPURE CO, BAY CITY, MI; ZIMMER INC, WARSAW, IN - 483 6/13
2013-5389	07/15/2013 08/12/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	ROBERT KING FDA NEWS	SYSTEMS ONE LLC, STUART, FL; NOVALIS MEDICAL LLC, TAMPA, FL; TOBY ORTHOPAEDICS INC, CORAL GABLES, FL - 483 6/13
2013-5390	07/15/2013 08/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ROBERT KING FDA NEWS	PHARMAZEUTISCHE FABRIK, DR RECKEWEG & CO GMBH, BENSHEIM, GERMANY; SYNTRION GMBH, CAWL, GERMANY; PRODUCTS CHIMIQUES AUXILIARIES ET DE SYNTHESE SA, LIMAY, FRANCE - 483 6/13
2013-5391	07/15/2013 08/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	ROBERT KING FDA NEWS	LAERDAL MEDICAL CO LTD, SUZHOU, CHINA; CHANGZHOU DSB MEDICAL CO LTD, CHANGZHOU CITY, CHINA - 483 6/13
2013-5392	07/15/2013 08/12/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	ROBERT KING FDA NEWS	MATHESON TRI GAS, WAVERLY, NE - 483 6/13
2013-5393	07/15/2013 08/12/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	ROBERT KING FDA NEWS	TEVA PARENTERAL MEDICINES INC, IRVINE, CA; KC PHARMACEUTICALS INC, POMONA, CA; PRIMA PHARM INC, SAN DIEGO, CA - 483 6/13
2013-5394	07/15/2013 08/12/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	ROBERTKING FDA NEWS	TOWER LABS LTD, CENTERBROOK, CT; BRISTOL MYERS SQUIBB, DEVENS, MA; PRECISION DERMATOLOGY INC, CUMBERLAND, RI - 483 6/13
2013-5395	07/15/2013 08/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ALESHIRE 278999, DAVID .	AER - TROFRANIL ETC
2013-5396	07/15/2013 08/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BENJAMIN P. LEWIS MITSUBISHI TANABE PHARMA DEVELOPMENT OF AMERICA INC	NALFURAFINE HCI - IND
2013-5397	07/15/2013 08/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	Dennis Raisch UNIVERSITY OF NEW MEXICO	MEDWATCH REPORTS
2013-5398	07/16/2013 08/13/2013	FDA/OMPT/CTP/OD/ FDA/OC/OCC/	Desmond Jenson Tobacco Control Legal Consortium	RECORDS RE LETTER FROM REYNOLDS AMERICAN SERVICES COMPANY, MANAGING COUNSEL MITCHELL NEUHAUSER TO LAWRENCE DEYTON AND ELIZABETH

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				DICKINSON SENT 1/15/13
2013-5399	07/16/2013 08/13/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Angela Stagg IMPULSE DYNAMICS	LONESTAR, AMARILLO, TX - CORRECTION AND PREVENTATIVE ACTIONS
2013-5400	07/16/2013 08/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Robin Yurk, MD, MPH Mutiple Site-National & International Multi-disciplinary	INDIVIDUAL RECS
2013-5401	07/16/2013 08/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Laura Strickler CBS NEWS	WOCKHARDT - LOGS, CORR, 483 ETC (01/01/2011 - 07/01/2013)
2013-5402	07/16/2013 08/13/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Cindy Ingold, Quality Director American Red Cross Blood Services - Missouri Illinois Region	AMERICAN RED CROSS BLOOD SERVICES NORTH COUNTY CENTER, FLORISSANT, MO - EIR (12/04/2012 - 12/12/2012)
2013-5403	07/16/2013 08/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Christopher T. Frenz MOUNT SINAI SCHOOL OF MEDICINE	K843135
2013-5404	07/16/2013 08/13/2013	FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA REQUEST LOG 7/08/2013 TO 7/12/2013
2013-5405	07/16/2013 08/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lauren C. Stipp Stipp, Lauren C	LIST OF EMERGENCY IND APPROVED BY FDA SINCE 2011 FOR SYNACTHEN
2013-5406	07/16/2013 08/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Christopher T. Frenz MOUNT SINAI SCHOOL OF MEDICINE	K931654
2013-5407	07/16/2013 08/13/2013	FDA/OC/OES/DFOI/	Megan Pickel Beveridge & Diamond, PC	2013-4475
2013-5408	07/16/2013 08/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Christopher T. Frenz MOUNT SINAI SCHOOL OF MEDICINE	I K923260
2013-5409	07/16/2013 08/13/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	James Barton Herbalife International of America, Inc.	MANHATTAN DRUG COMPANY, HILLSIDE, NJ - EIR, WARNING LETTER (01/01/2011 - 07/15/2013)
2013-5410	07/16/2013	FDA/OMPT/CDER/GRP/DIDP/	James Barton	NINGBO ZHENHAI HAIDE BIOCHEM - WARNING LETTER, EIR

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	08/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Herbalife International of America, Inc.	
2013-5411	07/16/2013 08/13/2013	FDA/OC/OES/DFOI/	Joe Neel NPR National Public Radio	FOIA REQUEST LOG 01/01/2012 - 07/15/2013
2013-5412	07/16/2013 08/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Christopher T. Frenz MOUNT SINAI SCHOOL OF MEDICINE	K925565
2013-5413	07/16/2013 08/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Mia Ware COVIDIEN	K120657
2013-5414	07/16/2013 08/13/2013	FDA/OC/OES/DFOI/	Megan Pickel Beveridge & Diamond, PC	2013-4817
2013-5415	07/16/2013 08/13/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	James Barton Herbalife International of America, Inc.	PHARMACHEM LABORATORIES, KEARNY, NJ - EIR, WARNING LETTER (01/01/2010 - 07/15/2013)
2013-5416	07/16/2013 08/13/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	James Barton Herbalife International of America, Inc.	TOWER LABORATORIES, CENTERBROOK, CT - EIR, WARNING LETTER (01/01/2010 - 07/15/2013)
2013-5417	07/16/2013 08/13/2013	OC/CVM/OCD/ FDA/OC/OCC/	THOMAS CLUDERAY ENVIRONMENTAL WORKING GROUP	EWG - SUPERBUGS INVADE AMERICAN SUPERMARKETS RPT CORR BTWN FDA AND REPRESENTATIVES OF THE POULTRY, LIVESTOCK OR ANIMAL FEED AND PHARMACEUTICAL INDUSTRIES
2013-5418	07/16/2013 08/13/2013	FDA/OC/OES/DFOI/ FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	BOB O'MALLEY Segal McCambridge Singer & Mahoney	MORTON GROVE PHARMS - CARBAXEFED RECS 1/00 TO PRESENT
2013-5419	07/16/2013 08/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DEENA B KLABER GIBSON DUNN & CRUTCHER LLP	GE HEALTHCARE - OMNISCAN NDA 20-123, NDA 22-066 MEMO TO FILE 5/15/07
2013-5420	07/16/2013	FDA/OC/OES/DFOI/	LOUIS KOORY ESQ	SALMONELLA OUTBREAK - INVESTIGATION RECS

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	08/13/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OC/OES/DFOI/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ OC/ORA/ORO/DFS/ OC/ORA/ORO/DFS/	MISSION LAW CENTER	
2013-5421	07/16/2013 09/06/2013	FDA/OMPT/CTP/OD/ FDA/OO/OFBA/OAGS/	MARILYNN WHITNEY COVINGTON & BURLING LLP	RESEARCH TRIANGLE INSTITUTE - TOBACCO MENTHOL STUDIES HHSF223201000044C COMM, DATA ANALYSIS
2013-5422	07/16/2013 08/13/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	MARK MCLEAN MEYERSON LAW FIRM PC	APP PHARMACEUTICALS LLC - HEPARIN PRODUCTION MTG MINS, CORR, TRANS, ETC
2013-5423	07/16/2013 08/13/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OC/OCC/	RASHIDA RICHARDSON CENTER FOR HIV LAW & POLICY	DR BERNARD BRANSON - CORR, CMLPTS 2008 TO 2012; ORASURE TECHNOLOGIES INC - ORAQUICK RAPID HIV TESTS CORR, RECS 2008 TO 2012
2013-5424	07/16/2013 08/13/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	FRIEDMAN, ROBERT	CHILDREN'S TYLENOL SUSPENSION LIQUID - FAERS 1969 TO 2013
2013-5425	07/16/2013 08/13/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	JUSTIN DIMARTINO RETROPHIN INC	NOVARTIS PHARMACEUTICAL CORP - SYNTOCINON (OXYTOCIN NASAL SOL) NDA 12-285 VOLUNTARY WITHDRAWAL 8/7/97
2013-5426	07/16/2013 08/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	TUCHIN, STACEY	GC AMERICA - G-AENIAL UNIVERSAL FLO MATERIAL SAFETY DATA SHEET (MSDS)
2013-5427	07/16/2013 08/13/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	MARTINEZ #1652478, ENRIQUE	UNISOM, TULENEX, PROMESCENT, ETC - RECS

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2013-5428	07/16/2013 08/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	THOMAS J OSTROWSKI Draeger Medical Systems Inc	PHILIPS - INTELLIVUE CLINICAL INFORMATION PORTFOLIO K100272
2013-5429	07/16/2013 08/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARIANNE C LEBLANC SUGARMAN AND SUGARMAN PC	VERTEX PHARMACEUTICALS INC - INCIVEK CLNCL TRIALS, AERS, CORR, ETC
2013-5430	07/16/2013 08/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MAHENDER KORAPATI APPCO PHARMACEUTICALS CORP	SHIONOGI INC - ROBINUL (GLYCOPYRROLATE TABS) NDA 12-827 LBLG
2013-5431	07/16/2013 08/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BILL ESPSTEIN ESQ GARMO & GARMO LLP	MAXITROL (NEOMYCIN, POLYMYXIN B, DEXAMETHASONE OPHTHALMIC SUSPENSION) - AERS
2013-5432	07/16/2013 08/13/2013	FDA/OC/OL/	Jason Cherkis The Huffington Post	FDA CORR WITH REP LOUIE GOHMERT (01/03/2005 - 07/15/2013)
2013-5433	07/16/2013 08/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	BILL EPSTEIN ESQ GARMO & GARMO LLP	TOBRADEX (TOBRAMYCIN AND DEXAMETHASONE OPHTHALMIC SUSPENSION) - AERS
2013-5434	07/16/2013 08/13/2013	OC/CVM/OCD/	Jeanna Wheeler Seattle Institute for Biomedical and Clinical Research	NADA 115-732
2013-5435	07/16/2013 08/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Martin Leitritz University Eye Hospital	XATALAN APPROVAL RECS
2013-5436	07/16/2013 08/13/2013	FDA/OC/OES/DDM/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Jason L. Schwartz PRINCETON UNIVERSITY	HEPTAVAX-B - DOCKET, BLA, ADVISORY COMMITTEE MEETINGS ETC
2013-5437	07/16/2013 08/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Eli G. Phillips, Jr. University of the Incarnate Word, Feik School of Pharmacy	PRILOSEC - ORIGINAL APPROVAL LETTER 9/14/1989

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2013-5438	07/16/2013 08/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Eli G. Phillips Jr University of the Incarnate Word, Feik School of Pharmacy	AMOXIL - ORIGINAL APPROVAL LETTER 10/21/1980
2013-5439	07/16/2013 08/13/2013	OC/CVM/OCD/	Kathy Hee Kathy Hee	VIVASTEM LLC, STEMPHASE - COMMUNICATIONS WITH FDA (01/01/2011 - 07/16/2013)
2013-5440	07/16/2013 08/13/2013	FDA/OC/OES/DDM/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Jason L. Schwartz PRINCETON UNIVERSITY	RECOMBIVAX HB - BLA, ADVISORY COMMITTEE MEETINGS
2013-5441	07/16/2013 08/13/2013	OC/ORO/ OC/ORO/ FDA/OC/OES/	Jason Cherkis The Huffington Post/Jason Cherkis	VA GOV BOB MCDONNELL - CORR WITIH FDA (01/01/2010 - 07/15/2013)
2013-5442	07/16/2013 08/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ALEXANDER G PILLER LATHAM & WATKINS LLP	PADDOCK LLC - PHOSLO GELCAPS ANDA 91-312 QUALITY OVERALL SUMMARY, PHARMACEUTICAL DEVELOPMENT RPT
2013-5443	07/16/2013 08/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ALEXANDER G PILLER LATHAM & WATKINS LLP	INVAGEN PHARMACEUTICALS INC - PHOSLO GELCAPS ANDA 203-135 QUALITY OVERALL SUMMARY, PHARMACEUTICAL DEVELOPMENT RPT
2013-5444	07/16/2013 08/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	THOMAS J OSTROWSKI Draeger Medical Systems Inc	IMDSOFT - METAVISION CIS K012349
2013-5445	07/16/2013 08/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	THOMAS J OSTROWSKI Draeger Medical Systems Inc	PICIS - WEIGHT BASED DOSE CONVERTER K121542
2013-5446	07/16/2013 08/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	THOMAS J OSTROWSKI Draeger Medical Systems Inc	CERNER CARE - AWARE IBUS K093134
2013-5447	07/17/2013 08/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LALITHA SUBRAMANIAN DR REDDY'S LABORATORIES INC	CAROLINA MEDICAL - TRIAMCINOLONE ACETONIDE ANDA 89-595 SBA
2013-5448	07/17/2013 08/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LALITHA SUBRAMANIAN DR REDDY'S LABORATORIES INC	CAROLINA MEDCL - TRIAMCINOLONE ACETONIDE ANDA 89-595 SBA

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2013-5449	07/17/2013 08/14/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LALITHA SUBRAMANIAN DR REDDY'S LABORATORIES INC	PERRIGO NEW YORK - TRIAMCINOLONE ACETONIDE ANDA 87-385 SBA
2013-5450	07/17/2013 08/14/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LALITHA SUBRAMANIAN DR REDDY'S LABORATORIES INC	PERRIGO NEW YORK - TRIAMCINOLONE ACETONIDE ANDA 87-357 SBA
2013-5451	07/17/2013 08/14/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LALITHA SUBRAMANIAN DR REDDY'S LABORATORIES INC	PERRIGO NEW YORK - TRIAMCINOLONE ACETONIDE ANDA 87-356 SBA
2013-5452	07/17/2013 08/14/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LALITHA SUBRAMANIAN DR REDDY'S LABORATORIES INC	FOUGERA PHARMS - TRIAMCINOLONE ACETONIDE ANDA 85-692 SBA
2013-5453	07/17/2013 08/14/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LALITHA SUBRAMANIAN DR REDDY'S LABORATORIES INC	TARO - NYSTATIN & TRIAMCINOLONE ACETONIDE ANDA 62-364 SBA
2013-5454	07/17/2013 08/14/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LALITHA SUBRAMANIAN DR REDDY'S LABORATORIES INC	TARO - NYSTATIN & WTRIAMCINOLONE ACETONIDE ANDA 63-305 SBA 3/29/93
2013-5455	07/17/2013 08/14/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LALITHA SUBRAMANIAN DR REDDY'S LABORATORIES INC	TARO - NYSTATIN ANDA 64-022 SBA
2013-5456	07/17/2013 08/14/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LALITHA SUBRAMANIAN DR REDDY'S LABORATORIES	FOUGERA PHARMS - NYSTATIN ANDA 62-124 SBA

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	INC	
2013-5457	07/17/2013 08/14/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	DAVID SCOTT BLUE ZETETIC	BOXES FOR HAIR SHAMPOO & CONDITIONERS 8, 21 PALLETS ENTRY NUMBER EHP00774480 - PHOTOGRAPHS, OASIS COMPUTER DATA BASE SCREEN SHOTS
2013-5458	07/17/2013 08/14/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	DONALD N BLUE ZETETIC INC	SEXY HAIR CONCEPTS ENTRY #3HP00774480 - RECS
2013-5459	07/17/2013 08/14/2013	FDA/OC/OES/	MOTEN, LAVEETA D	LISTING OF DATES IN HOURS, MINS THAT LAVEETA D MOTEN WAS LOGGED ON TO THE HHS, FDA, OMS, CFSAN COMPUTER SYS AFTER 4:30 PM MONDAY THROUGH FRIDAY ON LEGAL HOLIDAYS, & ON WEEKENDS 1/1/11-8/14/11
2013-5460	07/17/2013 08/14/2013	FDA/OC/OES/ FDA/OC/OES/DFOI/	MOTEN, LAVEETA D	LISTING OF ALL DATES IN HOURS , MINS LAVEETA D MOTEN WAS LOGGED ON TO THE HHS, FDA, OMS, CFSAN COMPUTER SYS AFTER 4:30 PM MONDAY THROUGH FRIDAY, ON LEGAL HOLIDAYS & ON WEEKENDS 12/5/11 TO 6/30/12
2013-5461	07/17/2013 08/14/2013	FDA/OC/OES/ FDA/OC/OES/DFOI/	MOTEN, LAVEETA D	LISTING OF ALL DATES HOURS & MINS THAT LAVETTA D MOTEN WAS LOGGED ON TO THE HHS, FDA, OMS, CFSAN COMPUTER SYS AFTER 4:30 PM MONDAY THROUGH FRIDAY, ON LEGALL HOLIDAYS & WEEKENDS 7/1/10-12/31/10
2013-5462	07/17/2013 08/14/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	ANDREW HACK MILLENNIUM MANAGEMENT LLC	MANNKIND CORP, VALENCIA, CA, PARAMUS, NJ, DANBURY, CT - EIRS, 483S, UNTITLED LTRS 1/12 TO PRESENT
2013-5463	07/17/2013 08/14/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANDREW HACK MILLENNIUM MANAGEMENT LLC	DR JANET WOODCOCK OFFICE OF STRATEGIC PROGRAMS, OFFICE OF HEALTH & CONSITUENT AFFAIRS, PARENT PROJECT MUSCULAR DYSTROPHY - MEETING 7/9/13
2013-5464	07/17/2013 08/14/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELENA HOWELL HOGAN LOVELLS US LLP	APRVD DRUG PRODS LISTED BY ACTIVE INGREDIENT
2013-5465	07/17/2013 08/14/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MICHELLE WILSON VIRTUAL REGULATORY SOLUTIONS	MENADIONE - NDA 02-139 NON-CLNCL, CLINICAL SAFETY RECS SBA

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2013-5466	07/17/2013 08/14/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	SMITHKLINE BEECHMAN (CORK) LTD DBA GLAXOSMITHKLINE -AVANDAMET (METFORMIN HCL ROSIGILTAZONE MALEATE) NDA 21-410/032, APRVL PKG 1/25/13
2013-5467	07/17/2013 08/14/2013	FDA/OC/OES/DDM/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEMP LITTLE KEMP LITTLE LLP	ALLERGAN INC - LATISSE CLNCL INVESTIGATIONS, STUDIES, OPHTHALMIC DRUGS A/C 12/5/08
2013-5468	07/17/2013 08/14/2013	FDA/OC/OCC/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	BAYER, RANGE RICHARD D	DECLARATION OF MARY T CARDEN - TABS 55-63, EXHIBITS 274, 275
2013-5469	07/17/2013 08/14/2013	FDA/OFVM/CFSAN/OCD/EOS/	JOHN H COX INTERNATIONAL ASSOCIATION OF COLOR MANUFACTURERS	FRUIT JUICE OR VEGETABLE JUICE - OPINIONS 6/25/08; GNT USA INC - SPIRULINA CONCENTRATE PETITION
2013-5470	07/17/2013 08/14/2013	OC/CVM/OCD/	KRISTI O SMEDLEY WASHINGTON INFORMATION SOURCE	ZILPATEROL HCL (ZILMAX) TYPE C MEDICATED FEED NADA 141-258 - ANALYTICAL METHODS
2013-5471	07/17/2013 08/14/2013	FDA/OMPT/CTP/OD/	NATALIE N SANDERS LATHAM & WATKINS LLP	FOUR NEW TOBACCO PRODS - COMM RELATING TO THE NON SUBSTANTITALLY EQUIALENT DETERMINATIONS WITHOUT LIMITATIONS, COMM TO APRVL OR DENIAL OF THE SUBSTANTIAL EQUIVALENCE SUBMISSIONS
2013-5472	07/17/2013 08/14/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORANE-FO/NYK- DO/NYK-DCB/ FDA/OGROP/ORASE-FO/ATL- DO/ATL-CB/ FDA/OGROP/ORASE-FO/NOL- DO/NOL-CB/ OC/ORAO/O/D/S/ OC/ORAO/O/D/S/ FDA/OGROP/ORAPA-FO/SAN- DO/SAN-CB/	NICHOLAS J PAROLISI LITCHFIELD CAVO LLP	E COLI 0121 MUTISTATE OUTBREAK - LINE LISTS, CORR, EMAILS, ETC 12/20/12 TO 4/15/13
2013-5473	07/17/2013	FDA/OFVM/CFSAN/OCD/EOS/		SOY & SOY PRODS EFFECTS

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	08/14/2013		CASSELLS B-8317 T-20, KEITH M	
2013-5474	07/17/2013 08/14/2013	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	Russ Garrison Garrison, Russell	VERATHON INC, BOTHELL, WA - EIR (10/01/2012 - 07/01/2013)
2013-5475	07/18/2013 08/15/2013		MATT SMITH MATT SMITH	DKT 1995N-0259
2013-5476	07/18/2013 08/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shara Ambrosecchia G&W LABORATORIES INC	NDA 019048 - SBA
2013-5477	07/18/2013 08/15/2013	OC/ORPA/ OC/ORPA/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Michael Atkins Atkins Intellectual Property, PLLC	BQL-0015477-1/1/5; BQL-0015477-1/1/9; BQL-0017148-6/1/5; ETC
2013-5478	07/18/2013 08/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Nicole Larch Sandberg, Phoenix and vonGontard	BENTYL, DICYCOLMINE HYDROCHLORIDE - MEDWATCH RPTS
2013-5479	07/18/2013 08/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michael R. Liepman, M.D. Western Michigan University School of Medicine, Department of Psychiatry, Research Division	SUMMARY OF DATA SUPPORTING BLACK BOX HEPATOXICITY WARNING ON ORAL NALREXONE
2013-5480	07/18/2013 08/15/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	T. Christian Miller PROPUBLICA	JOHNSON & JOHNSON, HORSHAM, PA - INSPECTION RECS APRIL 2011
2013-5481	07/18/2013 08/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Beau Bassett Pura Vida Investments	9284733 9292050 9299545 ETC
2013-5482	07/18/2013 08/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ivan Poullaos, for Watson Laboratories, Inc. WINSTON & STRAWN LLP	MYLAN TECHNOLOGIES, MYLAN PHARMACEUTICALS, INC, MYLAN INC - 180 DAY MARKET EXCLUSIVITY FOR GENERIC VERSION OF LIDODERM
2013-5483	07/18/2013 08/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michele Sinoway Lachman Consultants	ANDA 203263 - SBA

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2013-5484	07/18/2013 08/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K040395
2013-5485	07/18/2013 08/15/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michele Sinoway Lachman Consultants	NDA 50718 S002
2013-5486	07/18/2013 08/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Garth Conrad Medtronic Spinal & Biologics	MEDTRONIC SOFAMOR DANEK GMBH, DEGGENDORG, GERMANY - EIR (03/01/2011 - 07/30/2010)
2013-5487	07/18/2013 08/15/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Scott hodes Scott A. Hodes, Attorney at Law	SPRYCEL, TASIGNA, GLEEVEC - AERS
2013-5488	07/18/2013 08/15/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	James Barton Herbalife International of America, Inc.	NINGBO ZHENHAI HAIDE BIOCHEM, CHINA - 483 (01/01/2012 - 07/15/2013)
2013-5489	07/18/2013 08/15/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michele Sinoway Lachman Consultants	NDA 50718 - SBA
2013-5490	07/18/2013 08/15/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Richard Lee RICHARD LEE COBB & HALL	HUMIRA - AERS
2013-5491	07/18/2013 08/15/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Richard Lee RICHARD LEE COBB & HALL	STELARA - AERS
2013-5492	07/18/2013 08/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Greg Clark Clark, Greg B	K837494

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2013-5493	07/18/2013 08/15/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Richard Lee RICHARD LEE COBB & HALL	EMBREL - AERS
2013-5494	07/18/2013 08/15/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mahidhar Chinta Micro Labs USA, Inc	EDECIN - SBA
2013-5495	07/18/2013 08/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K093397
2013-5496	07/18/2013 08/15/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	HUMIRA - STABILITY/TEMPERATURE EXCURSION INFORMATION
2013-5497	07/18/2013 08/15/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Rachael Tanner Rachael Tanner	K050783
2013-5498	07/18/2013 08/15/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	NDA 202379 S005
2013-5499	07/18/2013 08/15/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nancy Kotlowski Baxter Baker Sidle Conn & Jones, LLP	HUMIRA - AERS
2013-5500	07/18/2013 08/15/2013	FDA/OO/OHR/ FDA/OFVM/CFSAN/OCD/EOS/	Cheryl Stevens Stevens, Cheryl L	INDIVIDUAL RECS
2013-5501	07/18/2013 08/15/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Shara Ambrosecchia G&W LABORATORIES INC	NDA 019117, S012 - SBA
2013-5502	07/18/2013 08/15/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Shara Ambrosecchia G&W LABORATORIES INC	ANDA 072494 - SBA

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-5503	07/18/2013 08/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shara Ambrosecchia G&W LABORATORIES INC	ANDA 063305 - SBA
2013-5504	07/18/2013 08/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shara Ambrosecchia G&W LABORATORIES INC	ANDA 062364
2013-5505	07/18/2013 08/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Bret Andrte EyeReg Consulting, Inc.	K980818
2013-5506	07/18/2013 08/15/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Marilee Kartje Teva Pharmaceuticals	GENZYME, ALLSTON, MA - RESPONSE TO 483 (10/01/2009 - 10/31/2010)
2013-5507	07/18/2013 08/15/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Dunlap Alpert Medical School of Brown University	MIRENA IUD - CLINICAL TRIAL DATA; BURLEX - POSTMARKET STUDY; MIRENA PERFORATION AND MIGRATION RATES ETC
2013-5508	07/18/2013 08/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michael Higgins Highline Research Advisors	EXUBERA, HUMALOG, NOVOLOG - AERS
2013-5509	07/18/2013 08/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	INVESTIGATION RECS
2013-5510	07/18/2013 08/15/2013	FDA/OFVM/CFSAN/OCD/EOS/	Stephen Gardner The Center for Science in the Public Interest	BAYER DIETARY SUPPLEMENTS - AERS
2013-5511	07/18/2013 08/15/2013	FDA/OC/OES/DDM/	Freddy Mejia Ansell Healthcare Products LLC	DKT 75N-0183
2013-5512	07/18/2013 08/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	BIOPHOSPHONATES - MEDICATION GUIDES

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2013-5513	07/18/2013 09/10/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Rachel Johnson FOI Services, Inc.	BAYER, BERKELEY, CA - EIR 8/11
2013-5514	07/18/2013 08/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	IBANDRONATE - MEDICATION GUIDE
2013-5515	07/18/2013 08/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Pamela miller Pamela Miller	INDIVIDUAL RECS
2013-5516	07/18/2013 08/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Antonei B. Csoka, Ph.D. HOWARD UNIVERSITY	SSRI, SNRI MEDICATIONS - SEXUAL AERS
2013-5517	07/18/2013 08/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dr. Remington Lee Nevin Johns Hopkins Bloomberg School of Public Health	OTSG CORR WITH FDA RE WITHDRAWAL OF NDA 019578
2013-5518	07/18/2013 08/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Ben Joseph Rice Voelker	CORR BTWN FDA/MEDSUN AND INTUITIVE SURGICAL RE SMALL SAMPLE SURVERY OF DA VINCI SURGICAL SYSTEM (01/01/2013 - 07/17/2013)
2013-5519	07/18/2013 08/15/2013	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	David Mangione Govzilla, Inc.	CSL BEHRING LLC, BRADLEY, IL - EIR, 483 (05/30/2013 - 05/30/2013)
2013-5520	07/18/2013 08/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	JANICE M. HOGAN HOGAN LOVELLS US LLP	BLUESHINE - GOLD SERIES LASER DVC K110375
2013-5521	07/18/2013 08/15/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	JANICE . HOGAN HOGAN LOVELLS US LLP	CUTERA - GENESIS PLUS LASER SYS K103626
2013-5522	07/18/2013 08/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	JAICE M. HOGAN HOGAN LOVELLS US LLP	PINPOINTE - FOOTLASER DVC K093547
2013-5523	07/18/2013 08/15/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	LEWIS T. STONEBURNER CANTOR STONEBURNER ET AL	PENISULA KIDNEY ASSOCIATES PC, HAMPTON, VA; VASCULAR ACCESS CENTER, HAMPTON, VA - MEDCOMP OR BARD QUINTON CATHETER MEDWATCH RPT 9/7/10
2013-5524	07/18/2013 08/15/2013	FDA/OFVM/CFSAN/OCD/EOS/	SEAN HIGGINS, Esq. ANDREWS & THORNTON	JACK 3D, OXY ELITE PRO, NUTREX LIPO 6 BLACK PRODUCTS, ETC - CAERS 12/17/12 TO PRESENT

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2013-5525	07/18/2013 08/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SEAN HIGGNINS, Esq. ANDREWS & THORNTON	FORTHANE - NDA, APRVL
2013-5526	07/18/2013 08/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	BRUCE SHERMAN, RN Vistakon	VISTAKON - MW5020993
2013-5527	07/18/2013 08/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	BRUCE SHERMAN, RN Vistakon	VISTAKON - MW5023889
2013-5528	07/18/2013 08/15/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	WALTER E. CHALKLEY THOMSON REUTERS	MARKSANS PHARMACEUTICALS LTD, COMMACK, NY - EIR, 483, CO RESP 1/26/12
2013-5529	07/18/2013 08/15/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	WALTER E. CHALKLEY THOMSON REUTERS	OTSUKA AMERICA PHARMACEUTICAL INC, ROCKVILLE, MD - EIR, 483, CO RESP 7/20/12
2013-5530	07/18/2013 08/15/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	WALTER E. CHALKLEY THOMSON REUTERS	PHARMALUCENCE INC, BILLERICA, MA - CO RESP, EIR, 483 3/13/12
2013-5531	07/18/2013 08/15/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	WALTER E. CHALKLEY THOMSON REUTERS	LANNETT CO INC, PHILADELPHIA, PA - CO RESP, EIR, 483 8/17/12
2013-5532	07/18/2013 08/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	US GENERICS PROGRAM, BARRANQUILLA, COLOMBIA - CO RESP, EIR, 483 6/22/12
2013-5533	07/18/2013 08/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	US GENERICS PROGRAM, BARRANQUILLA, COLOMBIA - CO RESP, EIR, 483 6/22/09
2013-5534	07/18/2013 08/15/2013	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	WALTER E. CHALKLEY THOMSON REUTERS	FRESENIUS KABI USA LLC, SCHAUMBURG, IL - EIR, 483, CO RESP 5/4/12
2013-5535	07/18/2013 08/15/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	WALTER E. CHALKLEY THOMSON REUTERS	B BRAUN MEDICAL INC, IRVINE, CA - EIR, 483, CO RESP 3/8/12
2013-5536	07/18/2013 08/15/2013	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	WALTER E. CHALKLEY THOMSON REUTERS	APRIA HEALTHCARE INC, FIFE, WA - EIR, 483, CO RESP 2/7/12
2013-5537	07/18/2013 08/15/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	WALTER E. CHALKLEY THOMSON REUTERS	AMPHASTAR PHARMACEUTICALS INC, RANCHO CUCAMONGA, CA - EIR, 483, CO RESP 6/28/12

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2013-5538	07/18/2013 08/15/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	WALTER E. CHALKLEY THOMSON REUTERS	AMAG PHARMACEUTICALS INC, CAMBRIDGE, MA - CO RESP, EIR, 483 5/24/12
2013-5539	07/18/2013 08/15/2013	FDA/OC/OL/	JONES, THOMAS H	SENATOR MARY PRYOR - CORR
2013-5540	07/18/2013 08/15/2013	FDA/OFVM/CFSAN/OCD/EOS/	MITCHELL A CHESSEMAN, Ph.D. STEPTOE & JOHNSON	FCN 1072
2013-5541	07/18/2013 08/15/2013	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	LIZ SZABO USA TODAY	STAINISLAW BURZYNSKI, RASHID BUTTAR, JOSEPH MERCOLA - WARNING LTRS
2013-5542	07/18/2013 08/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	MICHAEL R. McCARTHY PARSONS BEHLE & LATIMER	SYNTHES - VARIABLE ANGLE FOREFOOT MIDFOOT SYS K100776
2013-5543	07/18/2013 08/15/2013	FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JORDAN HILL COHEN MILSTEIN HAUSFELD & TOLL	IMPAX LABORATORIES INC & FDA - MEMOS, INSPECTOR NOTES, EMAILS, ETC
2013-5544	07/18/2013 08/16/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/ORO/DIOP/	DONALD BLUE GLOBAL TRADE INTELLIGENCE INC	IMPORTS FROM 6/16/13 TO 7/13/15
2013-5545	07/19/2013 08/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	MASSIMO CALAFIORE FACET-LINK INC	LIMACORPORATE SPA - DELTA TT ACETABULAR SYS K112898
2013-5546	07/19/2013 08/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	MASSIMO SALAFIORE FACET-LINK INC	EXACTECH INC - NOVATION EMPIRE ACETABULAR AUGENTS WITH INTEGRIP DVC K101761
2013-5547	07/19/2013 09/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	SANDRA LITAO, DASMARINAS, PHILLIPPINES - EIR, 483, CO RESP 7/6/12

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/		
2013-5548	07/19/2013 09/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	WALTER E CHALKLEY THOMSON REUTERS	UERM MEMORIAL MEDI, QUEZON, PHILLIPPINES - EIR, 483, CO RESP 6/29/12
2013-5549	07/19/2013 08/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	ROCHE DIAGNOSTICS GMBH, PENZBERG, GERMANY - EIR, 483, CO RESP 10/16/12
2013-5550	07/19/2013 08/16/2013	FDA/OGROP/ORAP/PA-FO/SEA- DO/SEA-CB/	WALTER E CHALKLEY THOMSON REUTERS	LINCARE INC, PORT ANGELES, WA - EIR, 483, CO RESP 4/16/12
2013-5551	07/19/2013 08/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	LABORATORIOS GRIFOLS SA, BARCELONA, SPAIN - EIR, 483, CO RESP 7/11/12
2013-5552	07/19/2013 08/16/2013	FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/	WALTER E CHALKLEY THOMSON REUTERS	EXEMPLAR PHARMACEUTICALS LLC, FALL RIVER, MA - EIR, 483, CO RESP 2/15/13
2013-5553	07/19/2013 08/16/2013	FDA/OGROP/ORASW-FO/DEN- DO/DEN-CB/	WALTER E CHALKLEY THOMSON REUTERS	EXEMPLA INC (DBA EXEMPLA LUTHERAN MEDICAL CENTER), WHEAT RIDGE, CO - EIR, 483, CO RESP 1/14/13
2013-5554	07/19/2013 08/16/2013	FDA/OGROP/ORACE-FO/MIN- DO/MIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	JANET K TILLISCH MD, FARGO, ND - EIR, 483, CO RESP 4/9/13
2013-5555	07/19/2013 08/16/2013	FDA/OGROP/ORACE-FO/CIN- DO/CIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	XANODYNE PHARMACEUTICALS INC, NEWPORT, KY - EIR, 483, CO RESP 3/30/12
2013-5556	07/19/2013 08/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	WOCKHARDT LTD, AURANGABAD, INDIA - EIR, 483, CO RESP 1/27/12
2013-5557	07/19/2013 08/16/2013	FDA/OGROP/ORASE-FO/SJN- DO/SJN-CB/	WALTER E CHALKLEY THOMSON REUTERS	ORTHO BIOLOGICS LLC, MANATI, PR - EIR, 483, CO RESP 2/14/13

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2013-5558	07/19/2013 08/16/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	OHM LABORATORIES INC, NEW BRUNSWICK, NJ - EIR, 483, CO RESP 12/18/12
2013-5559	07/19/2013 08/16/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	WALTER E CHALKLEY THOMSON REUTERS	NEW YORK BLOOD CENTER INC, NEW YORK, NY - EIR, 483, CO RESP 1/15/13
2013-5560	07/19/2013 08/16/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	WALTER E CHALKLEY THOMSON REUTERS	NEPHRON PHARMACEUTICALS CORP, ORLANDO, FL - EIR, 483, CO RESP 8/17/12
2013-5561	07/19/2013 08/16/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	NATIONWIDE CHILDREN'S HOSPITAL IRB, COLUMBUS, OH - EIR, 483, CO RESP 1/25/13
2013-5562	07/19/2013 08/16/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	MEDI PHYSICS INC (DBA GE HEALTH CARE INC), SOUTH PLAINFIELD, NJ - EIR, 483, CO RESP 1/9/13
2013-5563	07/19/2013 08/16/2013	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	MEDEFIL INC, GLENDALE HEIGHTS, IL - EIR, 483, CO RESP 5/25/12
2013-5564	07/19/2013 08/16/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	ST LUKE'S HOSPITAL BLOOD BANK, KANSAS CITY, MO - EIR, 483, CO RESP 3/13/13
2013-5565	07/19/2013 08/16/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	SGS LIFE SCIENCE SERVICES, WEST CHESTER, PA - EIR, 483, CO RESP 3/6/13
2013-5566	07/19/2013 08/16/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	QUALIMAX LLC, RIDGEFIELD, NJ - EIR, 483, CO RESP 3/6/13
2013-5567	07/19/2013 08/16/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Liz Szabo USA TODAY	BURZYNSKI - ADVERSE EVENTS
2013-5568	07/19/2013 08/16/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	PLASMACARE INC, CLEVELAND, OH - EIR, 483, CO RESP 1/31/13
2013-5569	07/19/2013 08/16/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Liz Szabo USA TODAY	BURZYNSKI RESEARCH INSTITUTE, HOUSTON, TX - INSPECTION REPORTS, CORR (01/01/2001 - 07/17/2013)
2013-5570	07/19/2013 08/16/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	WALTER E CHALKLEY THOMSON REUTERS	TISHCON CORP, SALISBURY, MD - EIR, 483, CO RESP 1/30/13

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2013-5571	07/19/2013 08/16/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Claus Fuxen Siegfried AG	SIEGFRIED MALTA LTD, MALTA - QAP
2013-5572	07/19/2013 08/16/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/ FDA/OFVM/CFSAN/OCD/EOS/	Boris Friedman Kline & Company	ABBOTT NUTRITION, TIPP CITY, OH - EIR (01/01/2013 - 07/19/2013)
2013-5573	07/19/2013 08/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Anna Edney BLOOMBERG NEWS	INTUITIVE SURGICAL ROBOTS - RESULTS FROM SURGEON SURGEY
2013-5574	07/19/2013 08/16/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Madhav Kamat Ursam Pharma LLC	08P-0591/CP1 - SBA
2013-5575	07/19/2013 08/16/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Peter Anderson Ashcraft& Gerel	K011071, K070430, P98002
2013-5576	07/19/2013 08/16/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	WALTER E CHALKLEY THOMSON REUTERS	STERIS ISOMEDIX SERVICES, NORTHBOROUGH, MA - EIR, 483, CO RESP 1/4/13
2013-5577	07/19/2013 08/16/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	WALTER E CHALKLEY THOMSON REUTERS	UNIV OF CALIFORNIA, SAN DIEGO, CA - EIR, 483, CO RESP 1/15/13
2013-5578	07/19/2013 08/16/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	WALTER E CHALKLEY THOMSON REUTERS	WAYNE CONCEPT MANUFACTURING CO INC, FORT WAYNE, IN - EIR, 483, CO RESP 1/10/13
2013-5579	07/19/2013 08/16/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	WALTER E CHALKLEY THOMSON REUTERS	VISTAPHARM INC, LARGO, FL - EIR, 483, CO RESP 6/15/12
2013-5580	07/19/2013 08/16/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	WALTER E CHALKLEY THOMSON REUTERS	VERTEX PHARMACEUTICALS INC, CAMBRIDGE, MA - EIR, 483, CO RESP 8/2/12
2013-5581	07/19/2013 08/16/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	SANDOZ GMBH, LANGKAMFEN, AUSTRIA - EIR, 483, CO RESP 3/16/12
2013-5582	07/19/2013 08/16/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	WALTER E CHALKLEY THOMSON REUTERS	PFIZER INC, PEARL RIVER, NY - EIR, 483, CO RESP 10/24/12
2013-5583	07/19/2013 08/16/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	WALTER E CHALKLEY THOMSON REUTERS	ALBANY MEDICAL CENTER HOSPITAL BLOOD BANK, ALBANY, NY - EIR, 483, CO RESP 1/14/13

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2013-5584	07/19/2013 08/16/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	NEXTWAVE PHARMS - QUILLIVANT XR (METHYLPHENIDATE HCL) NDA 202-100/S001 APRVL LTR
2013-5585	07/19/2013 08/16/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Neal Wadhwa Partner Fund Management	AGILA, INDIA - 483 (07/01/2003 - 07/19/2013)
2013-5586	07/19/2013 08/16/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Carol Wasteney The Mentholatum Company	TOPICAL SKIN BLEACHING DRUG PRODUCTS CONTAINING 2% AND 4% HYDROQUINONE
2013-5587	07/19/2013 08/16/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ira Matthew Mains Offutt Nord Burchett, PLLC	KETOROLAC TROMETHAMINE 30 MG/ML CONCENTRATION - APPROVED PACKAGE INSERTS
2013-5588	07/19/2013 08/16/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lauren Miller Miller, Lauren	FRUCTOSIN - ALL RECS
2013-5589	07/19/2013 08/16/2013	OC/ORO/ORM/ OC/ORO/ORM/	David Mangione Govzilla, Inc.	LIST OF INSPECTIONS 06/22/2013 - 07/17/2013
2013-5590	07/19/2013 08/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K082423
2013-5591	07/19/2013 08/16/2013	FDA/OGROP/ORO/NE-FO/NWE- DO/NWE-CB/	Mary A. Matthew, Vice President Regulatory Affairs ZIOPHARM Oncology	ZIOPHARM - COMPLAINTS
2013-5592	07/22/2013 08/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Adrienne E. Faerber, PhD Dartmouth Inst. Cent. For Med. Media.	NDA 125288 - CHECKLIST
2013-5593	07/22/2013	FDA/OFVM/CFSAN/OCD/EOS/	John Blackwell	ANATABLOC - AERS

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	08/19/2013		RICHMOND TIMES-DISPATCH	
2013-5594	07/22/2013 08/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K090915
2013-5595	07/22/2013 08/19/2013	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2008-2174
2013-5596	07/22/2013 08/19/2013	FDA/OC/OES/DFOI/	CHRISTOPHER SZECHENYI ONE POINT INVESTIGATIONS	OMONTYS - AERS
2013-5597	07/22/2013 08/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/CVM/OCD/	BEN ELGIN BLOOMBERG NEWS	RACTOPAMINE - AERS 1/1/03 TO 7/13/13
2013-5598	07/22/2013 08/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/CVM/OCD/	BEN ELGIN BLOOMBERG NEWS	ZILPATEROL - AERS 1/1/03 TO 7/17/13
2013-5599	07/22/2013 08/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/CVM/OCD/	BEN ELGIN BLOOMBERG NEWS	CARBADOX - AERS 1/1/03 TO 7/17/13
2013-5600	07/22/2013 08/19/2013	FDA/OC/OES/ FDA/OC/OES/DFOI/	BRODY MULLINS WALL STREET JOURNAL	INTUITIVE SURGICAL - COVER LTRS FOR COMPANIES THAT FILED FOIA REQUESTS 2013
2013-5601	07/22/2013 08/19/2013	FDA/OC/OES/ FDA/OC/OES/DFOI/	BRODY MULLINS WALL STREET JOURNAL	INTUTIVE SURGICAL - 2012-2367, 2012-2875, 2012-4606, ETC COVER LTRS
2013-5602	07/22/2013 08/19/2013	FDA/OC/OES/DFOI/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 165500 - ADDITONAL RECS
2013-5603	07/22/2013 08/19/2013	FDA/OC/OES/DFOI/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 165504 - ADDITIONAL RECS
2013-5604	07/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	NYROBIA FREEMAN	ARTHREX INC, NAPLES, FL - MIXING & DELIVERY SYS

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	08/19/2013		CONMED LINVATEC CORP	K121124
2013-5605	07/22/2013 08/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	JACQUELINE J CHAN K&L GATES	NEBA HEALTH LLC - NEUROPSYCHIATRIC COMPACT EEG SYS ASSESMENT AID SUBMISSIONS, PETITIONS, CORR, ETC 7/15/13
2013-5606	07/22/2013 08/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DENIS VANNESS VANNESS & VANNESS PA	AMBIEN (ZOLPIDEN TARTRATE) - AERS
2013-5607	07/22/2013 08/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	TORRENT PHARMS, KALAMAZOO, MI - ZOLPIDEM TARTARATE AERS
2013-5608	07/22/2013 08/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRIDE#320426, PHILIP	MARIJUANA, PSYCHADELIC MSHROOMS, METH, ETC - AERS
2013-5609	07/22/2013 08/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MEREDITH N REINHARDT DRINKER BIDDLE REATH LLP	EIL LILLY & CO - ZPREXA LTRS 1/12/07, 2/20/07, 3/28/07, ETC
2013-5610	07/22/2013 08/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	CELGENE CORP - FOCALIN (DEXMETHYLPHENIDATE HCL) NDA 21-278/001 APRVL LTR LBLG 1/03/02
2013-5611	07/22/2013 03/13/2014	FDA/OFVM/CFSAN/OCD/EOS/	ANNE SHEROD LEAVITT PARTNERS	LUBRIIZO CORP - FCN 148
2013-5612	07/22/2013 08/19/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 6/24-28/13
2013-5613	07/22/2013 08/19/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 6/24-28/13

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2013-5614	07/22/2013 08/19/2013	FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 6/24-28/13
2013-5615	07/22/2013 08/19/2013	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 6/24-28/13
2013-5616	07/22/2013 08/19/2013	FDA/OC/OES/DFOI/	KENNETH TEID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 6/24-28/13
2013-5617	07/22/2013 08/19/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 6/17-21/13
2013-5618	07/22/2013 08/19/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 6/17-21/13
2013-5619	07/22/2013 08/19/2013	FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 6/17-21/13
2013-5620	07/22/2013 08/19/2013	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 6/17-21/13
2013-5621	07/22/2013 08/19/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORO/PA-FO/SEA- DO/SEA-CB/	DEMENT-MYERS, PATRICIA A	CMPLNT 131784
2013-5622	07/22/2013 08/19/2013	FDA/OFVM/CFSAN/OCD/EOS/	PAULINA DO EXPONENT, INC.	ADEKA CORP - FCN 719
2013-5623	07/22/2013 08/19/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/NE-FO/NWE- DO/NWE-CB/	ANNE KERR B & A BROKERS INC	OCEAN PREMIUM INC - AHS-0146103-4 LAB RPTS
2013-5624	07/22/2013 08/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LESTER GIBBS ACTELION CLINICAL RESEARCH INC	TEMODAR (TEMOZOLOMIDE) CAPS NDA 21-029/S008 SUMMARY, ASSESSMENT
2013-5625	07/22/2013	FDA/OC/OES/DFOI/		FOI DAILY LOG 7/1-5/13

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	08/19/2013		FOI Services, Inc.	
2013-5626	07/22/2013 08/19/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 6/24-28/13
2013-5627	07/22/2013 08/19/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 6/17-21/13
2013-5628	07/22/2013 08/19/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 6/10-14/13
2013-5629	07/22/2013 08/19/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 7/1-5/13
2013-5630	07/22/2013 08/19/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 7/1-5/13
2013-5631	07/22/2013 08/19/2013	FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 7/1-5/13
2013-5632	07/22/2013 08/19/2013	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 7/1-5/13
2013-5633	07/22/2013 08/19/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 7/1-5/13
2013-5634	07/23/2013 08/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John Franolic VERSAPHARM INCORPORATED	ANDA 040771 - SBA
2013-5635	07/23/2013 08/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	8334428 8341524 8344995 ETC
2013-5636	07/23/2013 08/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORACE-FO/DET- DO/DET-CB/	David Mangione Govzilla, Inc.	COOK PHARMACIA LLC, BLOOMINGTON, IN - EIR, 483 (06/17/2013 - 06/17/2013)

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2013-5637	07/23/2013 08/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K960009
2013-5638	07/23/2013 08/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K946109
2013-5639	07/23/2013 08/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michael R. Liepman, M.D. Western Michigan University School of Medicine, Department of Psychiatry, Research Division	REVIA, NALTREXONE HYDROCHLORIDE - AERS
2013-5640	07/23/2013 08/20/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Kevin Lee Kevin Lee	K081307
2013-5641	07/23/2013 08/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jason Kantor CREDIT SUISSE	ADCETRIS - AERS
2013-5642	07/23/2013 08/20/2013	FDA/OGROP/ORACE-FO/CHI- DO/CHI-CB/ FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Alex Nussbaum HEALTHCOR MANAGEMENT LP	AKORN - 483 (07/01/2010 - 07/19/2013)
2013-5643	07/23/2013 08/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	CASE NUMBER 8563296
2013-5644	07/23/2013 08/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tom DeLong UNIVAR USA INC	RHODIA POLIAMIDE E ESPECIALIDADES, SAO PAULO, BRAZIL - EIR (03/01/2012 - 10/02/2012)
2013-5645	07/23/2013 08/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	8360804 8430873 8444923 ETC

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2013-5646	07/23/2013 08/20/2013	OC/CVM/OCD/	Stephanie Markey Dechra Development LLC	NADA 140474 - ORIGINAL FOIA SUMMARY
2013-5647	07/23/2013 08/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	8340068 8429241 8447180 ETC
2013-5648	07/23/2013 08/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	8322581 8358217 8431576 ETC
2013-5649	07/23/2013 08/20/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	David L. Shulman Law Office of David L. Shulman PLLC	GO FRESH, MINNEAPOLIS, MN - ALL RECS RE FDA, MN DEPT OF AGRICULTURE INSPECTION
2013-5650	07/23/2013 08/20/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	David Mangione Govzilla, Inc.	GENENTECH, OCEANSIDE, CA - EIR, 483 (05/23/2013 - 05/23/2013)
2013-5651	07/23/2013 09/06/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Jonathan Klein Sullivan & Associates, LLC	DEPUY HIP IMPLANTS - AERS, WARNING LETTERS, COMPLIANCE ACTIONS ETC
2013-5652	07/23/2013 08/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K932293
2013-5653	07/23/2013 08/20/2013	FDA/OO/OFBA/OAGS/	Rose Santos FOIA Group, Inc.	HHSF22301003T, HHSF22301004T - TASK ORDERS, MODIFICATIONS
2013-5654	07/23/2013 08/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michelle Elizabeth Legiec Eagle Pharmaceuticals, Inc.	CIPLA LIMITED, INDIA - INSPECTION RECS (04/01/2013 - 06/30/2013)
2013-5655	07/23/2013 08/20/2013	FDA/OO/OFBA/OAGS/	Nafisah Ula AFL-CIO	CONTRACTS BETWEEN FDA AND BARWOOD TAXI (01/01/2000 - 07/19/2013)
2013-5656	07/23/2013 08/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Adrienne E. Faerber, PhD Dartmouth Inst. Cent. For Med. Media.	ARCAPTA NEOHALE, BENLYSTA, HORIZANT ETC - MINUTES FROM PRE-NDA MEETINGS

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2013-5657	07/23/2013 08/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Adrienne E. Faerber, PhD Dartmouth Inst. Cent. For Med. Media.	EYLEA, ARCAPTA NEOHALER, GADAVIST ETC - ACTION CHECKLISTS
2013-5658	07/23/2013 08/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Ed Takken Self	NEBA COMACT EEG SYSTEM - DE NOVO APPLICATION
2013-5659	07/23/2013 08/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Adrienne E Faerber Dartmouth Inst. Cent. For Med. Media.	XANAX - MEDICAL REVIEW FROM ORIGINAL APPROVAL
2013-5660	07/23/2013 08/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Adrienne E. Faerber, PhD Dartmouth Inst. Cent. For Med. Media.	ARICEPT - P 56, 57 OF STATISTICAL REVIEW
2013-5661	07/23/2013 08/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jun Wu Astellas Scientific and Medical Affairs	GILOTRIF - SAFETY AND EFFICACY DATA
2013-5662	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 6/16-14/13
2013-5663	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/	WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 6/10-14/13
2013-5664	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/	GLADYS B. TONKIN WASHINGTON INFORMATION SOURCE	DAILY LOG 6/10-14/13
2013-5665	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DAVID McFARLAND FDA REVIEW/FDA WEBVIEW	DAILY CLOSED LOG 6/10-14/13
2013-5666	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DAVID McFARLAND FDA REVIEW/FDA WEBVIEW	DAILY LOG 6/17-21/13
2013-5667	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DAVID McFARLAND FDA REVIEW/FDA WEBVIEW	DAILY CLOSED LOG 6/24-28/13
2013-5668	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DAVID McFARLAND FDA REVIEW/FDA WEBVIEW	DAILY CLOSED LOG 7/1-5/13

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2013-5669	07/23/2013 08/20/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Anna Edney BLOOMBERG NEWS	MERCK - 483, WARNING LETTER RE SUGAMMADEX STUDY (01/01/2011 - 07/16/2013)
2013-5670	07/23/2013 08/20/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Anna Edney BLOOMBERG NEWS	INTUITIVE SURGICAL, SUNNYVALE, CA - WARNING LETTER (06/01/2013 - 07/19/2013)
2013-5671	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 6/10-14/13
2013-5672	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 6/17-21/13
2013-5673	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 6/24-28/12
2013-5674	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 7/1-5/13
2013-5675	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/	WOLTERS KLUWER LAW & BUSINESS	DAILY CLOSED LOG 6/10-14/13
2013-5676	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY CLOSED LOG 6/17-21/13
2013-5677	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY CLOSED LOG 6/24-28/13
2013-5678	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY CLOSED LOG 7/1-5/13
2013-5679	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY CLOSED LOG 6/10-14/13
2013-5680	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY CLOSED LOG 6/17-21/13
2013-5681	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 6/10-14/13
2013-5682	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY CLOSED LOG 6/24-28/13
2013-5683	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY CLOSED LOG 7/1-5/13

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2013-5684	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 6/24-28/13
2013-5685	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 6/17-21/13
2013-5686	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 6/10-14/13
2013-5687	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY CLOSED LOG 6/17-21/13
2013-5688	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY CLOSED LOG 6/24-28/13
2013-5689	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY CLOSED LOG 6/10-14/13
2013-5690	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY CLOSED LOG 7/1-5/13
2013-5691	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 7/1-5/13
2013-5692	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 6/10-14/13
2013-5693	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 6/17-21/13
2013-5694	07/24/2013 08/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	MANISH AHUJA BIO TEX INC	K121498
2013-5695	07/24/2013 09/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	MANISH AHUJA BIO TEX INC	K110943
2013-5696	07/24/2013 08/21/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	BOEHRINGER-INGELHEIM, AUSTRIA - EIR 4/13
2013-5697	07/24/2013 08/21/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	BOEHRINGER-INGELHEIM, AUSTRIA - 483 4/13

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2013-5698	07/24/2013 08/21/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN C THORNTON ANDREWS & THORNTON	APOTEX INC- LATANOPROST OPHTHALMIC SOL ANDA 77-697 SUPPL, AMENDMENTS, COMM, ETC
2013-5699	07/24/2013 08/21/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN C THORNTON ANDREWS & THORNTON	ALCON - LATANOPROST OPHTHALMIC SOL ANDA 91-449 SUPPL, AMENDMENTS, COMM, ETC
2013-5700	07/24/2013 08/21/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN C THORNTON ANDREWS & THORNTON	LUITPOLD PHARMACEUTICALS INC (AMERICAN REGENT INC) - LATANOPROST OPHTHALMIC SOL ANDA 200-925 SUPPL, AMENDMENTS, COMM, ETC
2013-5701	07/24/2013 08/21/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN C THORNTON ANDREWS & THORNTON	MYLAN PHARMACEUTICALS INC - LATANOPROST OPHTHALMIC SOL ANDA 201-786 SUPPL, AMENDMENTS, COMM, ETC
2013-5702	07/24/2013 08/21/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	JOHN C THORNTON ANDREWS & THORNTON	DR REEDY'S LABS LTD - LATANOPROST OPHTHALMIC SOL ANDA 202-077 SUPPL, AMENDMENTS, COMM, ETC
2013-5703	07/24/2013 08/21/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN C THORNTON ANDREWS & THORNTON	BAUSCH & LOMB PHARMACEUTICALS INC - LATANOPROST OPHTHALMIC SOL ANDA 201-006 SUPPL, AMENDMENTS, COMM, ETC
2013-5704	07/24/2013 08/21/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SCALIA, TONI	CLOZARIL - AERS
2013-5705	07/24/2013 08/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	FARHAD GHANI OPTIMA HEALTH SOLUTIONS INTERNATIONAL CORP	K060043 - CLEARANCE LTR

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2013-5706	07/24/2013 08/21/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ OC/CVM/OCD/	SHEDD, PATTI	SPL 787480, 787481 - TEST RESULTS
2013-5707	07/24/2013 08/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	NEISWONGER, LAURA	ATENOLO - AERS 2012 TO PRESENT
2013-5708	07/24/2013 08/21/2013	FDA/OFVM/CFSAN/OCD/EOS/	DIANNE L CHAMBERS HOGAN LOVELLS US LLP	MCCORMICK POLSKA SA - EIR
2013-5709	07/24/2013 08/21/2013	FDA/OC/OES/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/ORA/OCI/ OC/ORA/OCI/ FDA/OC/OES/DFOI/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	PAULA RAMER KAYE SCHOLER LLP	2007-2093, 2007-3834, 2007-7689, ETC
2013-5710	07/24/2013 09/13/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	CATHERINE A HAY MASSBIOLOGICS	MASSBIOLOGICS (MASSACHUSETTS PUBLIC HEALTH BIOLOGIC LABS) - PERTUSSIS IMMUNE GLOBULIN INTRAVENOUS BB-IND-4465 RECS
2013-5711	07/24/2013 08/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OCC/ OC/ORA/ OC/ORA/	ANGELA J MASON COCHRAN FIRM-DOTHAN PC	MAIN STREET FAMILY PHARMACY, NEWBERN, TN - INVESTIGATIONS; INDIVIDUAL RECS
2013-5712	07/24/2013 08/21/2013	FDA/OFVM/CFSAN/OCD/EOS/	FARINA ASLAM Keller and Heckman LLP	TESTING FOR ORGANIC AND INORGANIC ARSENIC IN RICE AND RICE PRODS 1991 TO PRESENT

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2013-5713	07/24/2013 08/21/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	COLCORD, JARD S	PEREGRINE PHARMS - BAVITUXIMAB (DOCETAXEL) FINALIZED END OF PHASE TWO MEETING MINS, CALANDER DATE
2013-5714	07/24/2013 08/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	ANNMARIE BROWN-JIMENEZ JOSEPH M LICHTENSTEIN PC	KARL STORZ ENDOSCOPIC DVC - RPT 10/22/07
2013-5715	07/24/2013 08/21/2013	FDA/OC/OES/DFOI/	ELLIOT FAVUS MD FAVUS INSTITUTIONAL RESEARCH LLC	PINNACLE MEDICARE SERVICES - IMPELLA CLNCL DATA, RECS
2013-5716	07/24/2013 08/21/2013	FDA/OC/OES/DFOI/	RISHAR, JOHN	ADDRESSES, NAMES, PHONE NUMBERS OF MFRS OF PERScription MEDICINES SEIZED ON 6/27/13
2013-5717	07/24/2013 08/21/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORO/CE-FO/DET-DO/DET-CB/ FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	CHRISTOPHER VAN GUNDY ROLL LAW GROUP PC	IMPORT ALERT 22-04 - ANALYSIS, TEST RESULTS, CORR, ETC
2013-5718	07/24/2013 08/21/2013	FDA/OGROP/ORO/SE-FO/NOL-DO/NOL-CB/	BREZA, ANDREW	MELALEUCA INC - RESP TO WARNING LTR 97-NSV-08
2013-5719	07/24/2013 08/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	MANISH AHUJA BIOTEX INC	K093995
2013-5720	07/24/2013 08/21/2013	FDA/OC/OES/DFOI/	Veronica Moten N.A.	LIST OF EEO COMPLAINTS
2013-5721	07/24/2013 08/21/2013	FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Liz Szabo USA TODAY	CORR BTWEEN FDA AND BURZYNSKI RESEARCH INSTITTUE, BURZYNSKI CLINIC, DR BURZYNSKI (06/01/2012 - 07/17/2013)

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2013-5722	07/24/2013 08/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	MANISH AHUJA BIOTEX INC	K061248
2013-5723	07/24/2013 08/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	MANISH AHUJA BIOTEX INC	K121479
2013-5724	07/24/2013 08/21/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	REBECCA K WOOD SIDLEY AUSTIN LLP	GE HEALTHCARE - OMNISCAN DRUG SAFETY OVERSIGHT BOARD MTG MINS 4/9/07
2013-5725	07/24/2013 08/21/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	REBECCA K WOOD SIDLEY AUSTIN LLP	GE HEALTHCARE - OMNISCAN NDA 20-123/S066 CORR, TELECONFERENCE MINS, ETC 5/1/06 TO 9/30/07
2013-5726	07/24/2013 08/21/2013	OC/CVM/OCD/	KRISTY O SMEDLEY PHD Center for Regulatory Services, Inc.	RHOSOPSEUDOMONAS IN BROILER CHICKEN - DAF 02374
2013-5727	07/24/2013 08/21/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OC/OES/DFOI/	JOHN C FISH JAMES DARK & BRILL ATTY AT LAW	PHILIP E MUCCIO, AXIOBIONICS - WEARABLE THERAPY INVESTIGATIONS, VIOLATION, COMPLIANCE RECS, ETC
2013-5728	07/24/2013 08/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	RACHEL ROMAN ESQ ZEVAN & DAVIDSON LAW FIRM LLC	THORATEC - PARACORPoreal VENTRICULAR ASSIST DVC (PVAD) APRVL RECS, LBLG
2013-5729	07/24/2013 08/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	PAMELA KOVOCHICH CRIVELLO.CARLSON	OLYMPUS - EVIS EXERA II GASTROINTESTINAL VIDEOSCOPE AND EVIS EXERA II COLONVIDEOSCOPE
2013-5730	07/24/2013 08/21/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mahidhar Chinta Micro Labs USA, Inc	ANDA 076278 - SBA
2013-5731	07/24/2013 08/21/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ketaki Gokhale BLOOMBERG NEWS	BIOCON LTD, BANGALORE, INDIA - 483 (07/24/2011 - 07/24/2013)
2013-5732	07/24/2013 08/21/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Doe J	INDIVIDUAL RECS

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		FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/		
2013-5733	07/24/2013 08/21/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	David Antoon David Antoon	INTUITIVE SURGICAL INC - DIGITAL MARKETING MATERIAL
2013-5734	07/24/2013 08/21/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mahidhar Chinta Micro Labs USA, Inc	ANDA 040103 - SBA
2013-5735	07/24/2013 08/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	Tara Burrell InSitu Technologies, Inc	K961507
2013-5736	07/24/2013 08/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	Tara Burrell InSitu Technologies, Inc.	K012752
2013-5737	07/24/2013 08/21/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dennis W. Raisch UNIVERSITY OF NEW MEXICO	BRENTUXIMAB - MEDWATCH FORMS
2013-5738	07/24/2013 08/21/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dennis W. Raisch UNIVERSITY OF NEW MEXICO	BRENTUXIMAB AND PML - MEDWATCH FORMS
2013-5739	07/24/2013 08/21/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sunil Patel Livwel Therapeutics Inc.	SANWA KAGAKI KENKYUSHO CO LTD, JAPAN - IND, INVESTIGATIONAL BROCHURE, INTERNAL NOTES ETC
2013-5740	07/24/2013 08/21/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Cathy Shachaf Orlucent	K062092
2013-5741	07/24/2013 08/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kaori Asakawa Experien Group, LLC.	K961382, K961383
2013-5742	07/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Philip Fish	K070210

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	08/21/2013		Philip Fish	
2013-5743	07/24/2013 08/21/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mahidhar Chinta Micro Labs USA, Inc	NDA 204150 - SBA
2013-5744	07/24/2013 08/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	Gerard Bencen CONSUMER	K131524, K131009
2013-5745	07/25/2013 08/22/2013	OC/ORR/ORM/ OC/ORR/ORM/	David Mangione Govzilla, Inc.	LIST OF INSPECTIONS - 01/01/2008 TO 07/19/2013
2013-5746	07/25/2013 08/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Dan Schreiber Applied Electrodynamics	K833928, K883911
2013-5747	07/25/2013 08/22/2013	FDA/OFVM/CFSAN/OCD/EOS/	Kenneth Grant Compliance Engineering, Inc.	FCN 852
2013-5748	07/25/2013 08/22/2013	FDA/OGROP/ORR/CE-FO/CIN-DO/CIN-CB/	Joy Flynn flynn, joy	CELSUS LABORATORIES, INC, CINCINNATI, OH - EIR (01/01/2008 - 07/22/2013)
2013-5749	07/25/2013 08/22/2013	OC/ORR/ OC/ORR/ FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/	b. burgess BURGESS, BERNIE	ORR FINANCIAL RECORD FOR FACTS 808885
2013-5750	07/25/2013 08/22/2013	FDA/OGROP/ORR/PA-FO/SAN-DO/SAN-CB/	David Antoon David Antoon	INTUITIVE SURGICAL, INC - WARNING LETTER, DOCUMENTATION (07/01/2013 - 07/18/2013)
2013-5751	07/25/2013 08/22/2013	FDA/OGROP/ORR/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joshua Kolsky Cohen Milstein Sellers & Toll PLLC	IMPAX LABORATORIES, HAYWARD, CA - EIR, 483 (01/01/2010 - 07/01/2013)
2013-5752	07/25/2013 09/03/2013	FDA/OGROP/ORR/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joshua Kolsky Cohen Milstein Sellers & Toll PLLC	IMPAX LABORATORIES, HAYWARD, CA - INSPECTION CORR (01/01/2010 - 07/01/2013)
2013-5753	07/25/2013	FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16)	NDA 020505/S-042, 020844/S-036

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	08/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MERCK & CO., INC.	
2013-5754	07/25/2013 08/22/2013	FDA/OC/OES/DFOI/	Robert King FDA NEWS	FOIA REQUEST LOG 07/15/2013 - 07/19/2013
2013-5755	07/25/2013 08/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Alexandra Gatten FORDHAM UNIVERSITY	WORKSHOP ON BATTERY POWERED MEDICAL DEVICES - LIST OF REGISTERED PARTICIPANTS (03/01/2013 - 07/30/2013)
2013-5756	07/25/2013 08/22/2013	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	Anita Duncan Reata Pharmaceuticals, Inc.	SCOTT ANTONIA MD, ALBERTO CHIAPPORI, MD, TAWEE TANVETYANON - 483, RESPONSE, CORR
2013-5757	07/25/2013 08/22/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Brian Brockway VivaQuant, LLC	K093288, K072558, K063222
2013-5758	07/25/2013 08/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	George Shamsoun METHAPHARM	PROVOCHOLINE, METHACHOLINE, METHACHOLINE CHLORIDE - AERS
2013-5759	07/25/2013 08/22/2013	FDA/OFVM/CFSAN/OCD/EOS/	Eric Lim Meng How Crystal Aesthetics	BACTOLAC - REGISTRATION INFORMATION (CERTIFIED)
2013-5760	07/25/2013 08/22/2013	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	TALC IN COSMETICS (CERTIFIED)
2013-5761	07/25/2013 08/22/2013	FDA/OFVM/CFSAN/OCD/EOS/	Christopher Barnett Chris Barnett	ENERGY DRINKS - FDA GUIDELINES
2013-5762	07/25/2013 08/22/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	CAPT Blane Wilson, USN, RET Wilson, USN, RET , CAPT Blane	IGG/IVIG - AERS
2013-5763	07/25/2013 08/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shin Kang WELLS FARGO	TECFIDERA - AERS
2013-5764	07/25/2013 08/22/2013	FDA/OC/OES/DDM/	Robin Primeau MURRAY LAW FIRM	ENDO AND METABOLIC DRUGS ADVISORY COMMITTEE, DRUG SAFETY MANAGEMENT ADVISORY COMMITTEE - PRESENTATION SLIDES, BRIEFING DOCUMENT, ETC (CERTIFIED)
2013-5765	07/25/2013 08/22/2013	FDA/OC/OES/DDM/	Robin Primeau MURRAY LAW FIRM	FDA BRIEFING DOCUMENT - AVANDIA NDA 21071

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2013-5766	07/25/2013 08/22/2013	FDA/OMPT/CTP/OD/	Ben Fenner Fredericks Peebles & Morgan LLP	CTP REVIEW, DETERMINATIONS RE NSE (03/22/2011 - 07/23/2013)
2013-5767	07/25/2013 08/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Christopher Brennan WESTLAW COURT EXPRESS	ANDA 203257
2013-5768	07/25/2013 08/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Patrick Winn Ra Medical Systems, Inc.	K101599
2013-5769	07/25/2013 08/22/2013	FDA/OO/OHR/ FDA/OO/OHR/ OC/ORO/ OC/ORO/	Roger Farmer NATIONAL TREASURY EMPLOYEES UNION	FLEXIBLE WORKPLACE AGREEMENT
2013-5770	07/25/2013 08/22/2013	FDA/OGROP/ORO/CE-FO/CHI-DO/CHI-CB/	Jane Bentley Alcon Laboratories, Inc.	ALCON LABS, DES PLAINES, IL - EIR (05/06/2013 - 07/19/2013)
2013-5771	07/25/2013 08/22/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	A. Thomas Doyle Surgical Specialties Corporation	K113004
2013-5772	07/25/2013 08/22/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DDM/	Desmond Jenson Tobacco Control Legal Consortium	FDA-2013-P-0435 - COMMENTS TO DOCKET
2013-5773	07/25/2013 08/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John Franolic VersaPharm Inc.	NDA 050689 - SBA
2013-5774	07/25/2013 08/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOSEPH WALKER THE WALL STREET JOURNAL	TECFIDERA - AERS
2013-5775	07/25/2013 08/22/2013	FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/	JOSEPH WALKER WALL STREET JOURNAL	INTUITIVE SURGICAL INC - WARNING LETTER
2013-5776	07/25/2013 08/22/2013	FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	Jon M. Pellett Barr Murman & Tonelli	MERRILL REUTER, MD, ADVANCED ORTHOPAEDICS - WARNING LETTERS, SANCTIONS, RESPONSES (9/01/2007 - 12/31/2012)
2013-5777	07/25/2013 08/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michael Basara Epien Medical, Inc.	K903163, K894247

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2013-5778	07/25/2013 08/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mahidhar Chinta Micro Labs USA, Inc	WELLBUTRIN - SBA
2013-5779	07/25/2013 08/22/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mahidhar Chinta Micro Labs USA, Inc	NDA 019906 - SBA
2013-5780	07/25/2013 08/22/2013	FDA/OMPT/CTP/OD/	Matt Mezvinsky RIDGEBACK CAPITAL MANAGEMENT LLC	MITCH ZELLER CONFERENCE CALL RE MENTHOL CIGARETTES - TRANSCRIPT (07/23/2013 - 07/24/2013)
2013-5781	07/25/2013 08/22/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA REQUEST LOG (06/17/2013 - 06/21/2013)
2013-5782	07/25/2013 08/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jameel Husain Fresenius Kabi USA, LLC	SANDOZ GMBH, AUSTRIA - MOST RECENT EIR
2013-5783	07/25/2013 08/22/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Doe J	INDIVIDUAL RECS
2013-5784	07/25/2013 08/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mahidhar Chinta Micro Labs USA, Inc	ANDA 075679 - SBA
2013-5785	07/25/2013 08/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Peter Lando IPNav	CDER MEETING RE THALIDOMIDE - TRANSCRIPT (09/04/1997 - 09/05/1997)
2013-5786	07/25/2013 08/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	EIR, 483 and all related correspondence for the 3/11/2009 and 3/12/2010 inspections of Sandoz Industrial Products, S.A., Barcelona, Spain

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2013-5787	07/25/2013 08/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORO/ORM/ OC/ORO/ORM/	Sandra O'Kelley Merial Limited	LIST OF HUMAN DRUG BIMO INSPECTIONS 01/01/2010 - 07/22/2013
2013-5788	07/25/2013 08/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	EIR, 483 and all related correspondence for the 5/16/2011 inspection of Laboratoire Unither, ZI de la Guerie, F-50211 COUTANCES Cedex France
2013-5789	07/25/2013 08/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	EIR, 483 and all related correspondence for the 8/4/2011 inspection of Asahi Glass Co., Ltd. Chiba Plant, 10 Goi-kaigan, Ichihara City, Chiba 290-8566, Japan
2013-5790	07/25/2013 08/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jameel Husain Fresenius Kabi USA, LLC	EIR for NV Organon, MSD, 5340 BH Oss, Netherlands (Issued May 31, 2013)
2013-5791	07/25/2013 08/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	EIR, 483 and all related correspondence for the 3/11/2009 and 3/12/2010 inspections of ZaCh System S.p.A. Via Dovaro 36045 Lonigo Vicenza, ITALY
2013-5792	07/25/2013 08/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Robin Primeau MURRAY LAW FIRM	DRUG SAFETY COMMUNICATION - UPDATE TO ONGOING SAFETY REVIEW OF ACTOS ETC (CERTIFIED)
2013-5793	07/25/2013 08/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Robin Primeau MURRAY LAW FIRM	DUETACT, ACTOSPLUS - APPROVAL LETTERS, CHEMISTRY REVIEWS, MEDICAL REVIEWS ETC (CERTIFIED)
2013-5794	07/25/2013 08/22/2013	FDA/OC/OES/DDM/	Robin Primeau MURRAY LAW FIRM	ENDO AND METABOLIC DRUGS ADVISORY COMMITTEE - 3/26/99, 4/22/99 TRANSCRIPT (CERTIFIED)
2013-5795	07/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Nalini Sundaram	RAVEN BIOLOGICAL - PRE-AMENDMENT DEVICE

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	08/22/2013		SNS Biosystems Inc	EVALUATION APPROVAL DOCUMENTATION
2013-5796	07/25/2013 08/22/2013	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	ACTIVE REGISTERED BRAND STYLES ISSUED UNDER SECTION 905 OF THE FSPTCA; IDENTITY OF PRODUCTS ISSUED ORDER OF ANNUAL REGISTRATION, MANUFACTURER
2013-5797	07/25/2013 08/22/2013	FDA/OC/OES/DDM/	Nick Gardner The International Food Additives Council	DKT FDA-2013-F-0700, FDA-2013-P-0472
2013-5798	07/25/2013 08/22/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/	Hiromi Price Eisai Inc.	ESAI, INC - PREDICT SCORE (01/01/2010 - 06/30/2013)
2013-5799	07/25/2013 08/22/2013	OC/ORO/ORM/ OC/ORO/ORM/	b. burgess BURGESS, BERNIE	LIST OF BIMO INSPECTIONS, PRE-APPROVAL INSPECTIONS CONUDCTED BY LOS-DO IN 2007
2013-5800	07/25/2013 08/22/2013	FDA/OC/OES/ FDA/OGROP/OIP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OCC/	RYAN LYNCH POLICY AND REGULATORY REPORT - FT GROUP	CORR BETWEEN FDA AND DOJ RE PHARMACEUTICALS IN CHINA
2013-5801	07/25/2013 08/22/2013	FDA/OGROP/ORO/SW-FO/KAN-DO/KAN-CB/	Scott Panagiotis Scott Panagiotis	LLOYD, INC, SHENANDOANH, IA - 483 04/16/2013
2013-5802	07/25/2013 08/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Paul Greenberg Analysis Group, Inc.	FDA SURVEILLANCE OF ADVERSE DRUG EFFECTS BY B. TIMOTHY HUMMER
2013-5803	07/25/2013 08/22/2013	FDA/OGROP/ORO/CE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/ORO/OCI/ OC/ORO/OCI/	Laura Strickler CBS NEWS	RANBAXY - PICTURES, IMAGES, VIDEOS OF FACILITIES TAKEN DURING INSPECTIONS OR RAIDS (01/01/2007 - 01/01/2013)
2013-5804	07/25/2013	FDA/OMPT/CDER/GRP/DIDP/	MAHYAR ETMINAN PHARM D	CIPROFLOXACIN, LEVOFLOXACIN, MOXIFLOXACIN - AER

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	08/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BC CHILDRENS HOSPITAL AND BC WOMENS HOSPITAL & HEALTH CENTRE	1990 TO PRESENT
2013-5805	07/25/2013 08/22/2013	FDA/OMPT/CTP/OD/	NATALIE N. SANDERS LATHAM & WATKINS LLP	NEWPORT - NON MENTHOL GOLD BOX 100 STN SE0003730, EA; NEWPORT - NON MENTHOL GOLD BOX STN SE0003731, EA
2013-5806	07/25/2013 08/22/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	BRETT PARK CONWAY HOMER & CHIN- CAPLAN PC	INDIVIDUAL RECS
2013-5807	07/25/2013 08/22/2013	FDA/OFVM/CFSAN/OCD/EOS/	FATIMA ASLAM Keller and Heckman LLP	FAP 3A4798
2013-5808	07/25/2013 08/22/2013	FDA/OC/OES/DDM/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CARLA SCARMAZZI King & Spalding LLP	DKT 2007D-0369; CYCLOSPORINE OPHTHALMIC EMULSION CORR, BIOAVAIL, BIOEQV TESTING, ETC
2013-5809	07/25/2013 08/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MOTT, VIRGINIA LEE	TEVA PHARMACEUTICALS - NAPROXEN AER
2013-5810	07/25/2013 08/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	ZACHARY K. GIAMPA, Esq LAW OFFICE OF RICHARD L GIAMPA	INDIVIDUAL RECS
2013-5811	07/25/2013 08/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	MARYANNE PLAYER CSL BEHRING	THROMBATE III (ANTITHROMBIN III) SBA
2013-5812	07/26/2013 08/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	Sun Choi ADVANCED STERILIZATION PRODUCTS	K102469
2013-5813	07/26/2013 08/23/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kimberly Ha BIOPHARM INSIGHT	TECFIDERA - MEDWATCH REPORTS

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		FDA/OMPT/CDER/ORP/DIDP/		
2013-5814	07/26/2013 08/23/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OGROP/ORACE-FO/DET- DO/DET-CB/	Steven R. Reed LANSING STATE JOURNAL	RECALL B-1675-12
2013-5815	07/26/2013 08/23/2013	FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/	Rachel Johnson FOI Services, Inc.	ALLERGAN, IRVINE, CA - EIR 2002
2013-5816	07/26/2013 08/23/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Becky Ditty Stryker IMT	K050973
2013-5817	07/26/2013 08/23/2013	FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/	Rachel Johnson FOI Services, Inc.	ALLERGAN, IRVINE, CA - 483, EIR
2013-5818	07/26/2013 08/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4072
2013-5819	07/26/2013 08/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-9324
2013-5820	07/26/2013 08/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-566
2013-5821	07/26/2013 08/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4874
2013-5822	07/26/2013 08/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3586
2013-5823	07/26/2013 08/23/2013	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2009-1512
2013-5824	07/26/2013 08/23/2013	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2008-8317
2013-5825	07/26/2013 08/23/2013	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2004-25710
2013-5826	07/26/2013 08/23/2013	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2004-25710
2013-5827	07/26/2013 08/23/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2004-15710
2013-5828	07/26/2013 08/23/2013	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2008-6750

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2013-5829	07/26/2013 08/23/2013	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2012-7961
2013-5830	07/26/2013 08/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4306 - REQUEST LETTER ONLY
2013-5831	07/26/2013 08/23/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	BLA 125433
2013-5832	07/26/2013 08/23/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Paul Greenberg Analysis Group, Inc.	FDA INVESTIGATING REPORTS OF POSSIBLE INCREASED RISK OF PANCREATITIS AND PRE-CANCEROUS FINDINGS OF THE PANCREAS FROM INCRETIN MIMETIC DRUGS FOR TYPE 2 DIABETES - MATERIALS SUBMITTED BY PETER BUTLER
2013-5833	07/26/2013 08/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	Benjamin Fleischman Decade Capital Management LLC	FDA HOSPITAL SURVEY, MEDSUN REPORT RE INTUITIVE SURGICAL
2013-5834	07/26/2013 08/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4719 - REQUEST LETTER ONLY
2013-5835	07/26/2013 08/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4570 - REQUEST LETTER
2013-5836	07/26/2013 08/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4568 - REQUEST LETTER
2013-5837	07/26/2013 08/23/2013	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2011-8979
2013-5838	07/26/2013 08/23/2013	FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/	Jane Bentley Alcon Laboratories, Inc.	ALCON LABS, HOUSTON, TX - EIR 05/13/2013 - 07/19/2013
2013-5839	07/26/2013 08/23/2013	FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/	Jane Bentley ALCON LABORATORIES	ALCON LABS, IRVINE, CA - EIR 07/01/2013 - 07/19/2013
2013-5840	07/26/2013 08/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4480 - REQUEST LETTER
2013-5841	07/26/2013 08/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOYCE MARSH HOLMES WEDDLE & BARCOTT	PRODISC-1 TOTALL DISC REPLACEMENT P050010 - AMENDMENTS, POST-MARKET STUDIES, MDRS, ETC 8/14/11
2013-5842	07/26/2013 08/23/2013	FDA/OGROP/ORR/PA-FO/SEA-DO/SEA-CB/ FDA/OMPT/CDER/ORP/DIDP/	BRAD SCHONHOFT	SAREPTA THERAPEUTICS, BOTHELL, WA - POTENTIAL SURROGATE ENDPOINTS MINS, EIRS, DISCUSSIONS 9/20/12 TO 7/24/13

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-5843	07/26/2013 08/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KATHRYN A PRYOR SIMON GREENSTONE ET AL	MOTRIN, ADVIL, ETC - AERS
2013-5844	07/26/2013 08/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PRENDERGAST, JOYCE E	CHANTIX (VERENICLINE) - AERS 3/1/13-7/18/13
2013-5845	07/26/2013 08/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FRIEDMAN, ROBERT	CHILDREN'S ADVIL SUSPENSION LIQUID ALL FLAVORS - AERS1969 TO 2013
2013-5846	07/26/2013 08/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CUCHETTI, RON	SHELF LIFE EXTENSION PROGRAM (SLEP) - DRUGS TESTED, STORAGE CONDITONS PRIOR TO TESTING, LENGTH OF TIME IN STORAGE, ETC
2013-5847	07/26/2013 08/23/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	JILLIAN NASH ALLTECH INC	RIDLEY FEED INGREDIENTS, MEDNODOTA, IL - 483S PAST 10 YRS
2013-5848	07/26/2013 08/23/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ OC/CVM/OCD/	SHARON MOZZI HANOVER INSURANCE GROUP	PETRA PET INC - BEEFEATER SWEET POTATO SNACKS TEST RESULTS
2013-5849	07/26/2013 08/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachael Tanner Rachael Tanner	K030136, K080704
2013-5850	07/26/2013 08/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kaori Asakawa EXPERIEN GROUP LLC	K052840
2013-5851	07/26/2013 08/23/2013	FDA/OC/OES/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OES/	NANDINI GOPINADH ALLIANCE FOR NATURAL HEALTH USA	DIETARY SUPPL - AERS, ENFORCEMENT ACTIONS 1/1/08 TO 12/21/12
2013-5852	07/26/2013	OC/CVM/OCD/	KRISTI O SMEDLEY	NOVOZYMES - GENETICALLY MODIFIED YEAST FOR USE

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	08/23/2013		WASHINGTON INFORMATION SOURCE	IN ETHANOL PRODS - SUMISSIONS, COMM
2013-5853	07/26/2013 08/23/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/MIN-DO/MIN-CB/	PARKER, RENEE C	BORDEN CHESSE - CMLPNT #132973
2013-5854	07/26/2013 08/23/2013	FDA/OC/OES/DDM/	ERIN HUGHES ERIN HUGHES	DKT FDA-2013-P-0148
2013-5855	07/26/2013 08/23/2013	FDA/OC/OES/DDM/	CARLA SCARMAZZI KING & SPALDING	DKT FDA-2007-D-0369, 1998D-0388
2013-5856	07/26/2013 08/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	Lauren A. Farruggia Hyman, Phelps & McNamara P.C.	P890003 S254
2013-5857	07/26/2013 08/23/2013	FDA/OGROP/ORO/CE-FO/BLT-DO/BLT-CB/	Karen Marshall Tarsa Therapeutics, Inc.	PHARMACEUTICALS INTERNATIONAL INC - 482, 483, RESPONSES ETC (01/26/2011 - 07/26/2013)
2013-5858	07/26/2013 08/23/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michelle Elizabeth Legiec Eagle Pharmaceuticals, Inc.	CIPLA LIMITED, INDIA - EIR, ANDA 200540 (04/01/2013 - 07/01/2013) /01/2013 - 7/01/2013)
2013-5859	07/26/2013 08/23/2013	FDA/OGROP/ORO/CE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORO/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORO/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORO/CE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORO/SE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORO/SW-FO/DEN-DO/DEN-CB/	Rachel Johnson FOI Services, Inc.	TOBACCO MANUFACTURERS - 483, EIR 7/1/12 TO 6/30/13
2013-5860	07/29/2013 08/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jonathan J. Darrow HARVARD MEDICAL SCHOOL	SMG 4820.3 - 1992, 2013

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DEACONESS HOSPITAL	
2013-5861	07/29/2013 08/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Diana Lac Genentech	CMX001 - FAST TRACK APPLICATION AND CORRESPONDENCE
2013-5862	07/29/2013 08/26/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	VAERS 494348
2013-5863	07/29/2013 08/26/2013	FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/	Barbara Kowinsky KOWINSKY, BARBARA	BOCCHE LABORATORIES, SANTA CLARITA, CA - EIR (01/01/2012 - 07/25/2013)
2013-5864	07/29/2013 08/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Thomas C. Stover Swiftwater Group LLC	TORECAN - PRESCRIBING INFORMATION, SBA REVIEWS
2013-5865	07/29/2013 08/26/2013	FDA/OGROP/ORO/SE-FO/SJN- DO/SJN-CB/	Rachel Johnson FOI Services, Inc.	LIFESCAN, AGUADILLA, PR - EIR, 483
2013-5866	07/29/2013 08/26/2013	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	TOBACCO MARKET ORDERS
2013-5867	07/29/2013 08/26/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Albert Lee AGILENT TECHNOLOGIES	ROCHE, AFFYMETRIX AMPLICHIP CYP450 - APPLICATION
2013-5868	07/29/2013 08/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Grace Bartoo Decus Biomedical	K120282
2013-5869	07/29/2013 08/26/2013	FDA/OGROP/ORO/PA-FO/SAN- DO/SAN-CB/	Rachel Johnson FOI Services, Inc.	LIFESCAN, MILPITAS, CA - EIR, 483
2013-5870	07/29/2013 08/26/2013	FDA/OMPT/CTP/OD/	Yitzchak Jacoboviz Capstone Law APC	CTP CORR WITH OMB RE MENTHOL CIGARETTES; : 03/31/2011 - 07/26/2013; RECORDS OF MEETINGS OR CALLS WITH OMB AND CTP RE MENTHOL CIGARETTES; RECS RE MENTHOL CIGARETTES AND OMB ETC
2013-5871	07/29/2013 08/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	LIFESCAN, IVERNESS, UK - EIR, 483
2013-5872	07/29/2013 08/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mara Jes Sanz CHEMO GROUP	NDA 021162 - AVAILABILITY OF RECORDS TO PUBLIC

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2013-5873	07/29/2013 08/26/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Tonya White-Salters White-Salters Consulting, LLC	BIORELIANCE, ROCKVILLE, MD - EIR, 483 (01/01/2010 - 06/20/2013)
2013-5874	07/29/2013 08/26/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OC/OES/DFOI/	Lynn T. Shepler, MD JD LTS & Associates /LYNN SHEPLER, MD JD	BAXTER - FORM 1571, 1572
2013-5875	07/29/2013 08/26/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Robin M Berger, MD Robin Berger MD PC	ISOTRETINOIN - EFFICACY OF IPLEDGE PROGRAM
2013-5876	07/29/2013 08/26/2013	FDA/OGROP/ORARO/DIOP/ FDA/OMPT/CDRH/OCER/DFOI/	Kenneth Tice Accogent LLC	COMMUNICATION AND POWER INDUSTRIES - IMPORTER IDENTIFICATION, DELISTING
2013-5877	07/29/2013 08/26/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Christine Rosenbaum Rosenbaum, Christine	SAMPLE RESULTS
2013-5878	07/29/2013 08/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	BTran Tran Associates	K093585, K963228
2013-5879	07/29/2013 08/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	P880047
2013-5880	07/29/2013 08/26/2013	FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA REQUEST LOG 7/22/2013 - 7/26/2013
2013-5881	07/29/2013 08/26/2013	FDA/OFVM/CFSAN/OCD/EOS/	KRISTI O. SMEDLEY, Ph.D. WASHINGTON INFORMATION SOURCE	FAP 6A3903
2013-5882	07/29/2013 08/26/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	TRAVIS SCHAFTENAAR MANULIFE ASSET MANAGEMENT	ANGIODYNAMICS - 483 RESP 9/24/12
2013-5883	07/29/2013 08/26/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	BRENDA LIGORSKY CARROLL KELLY ET AL	IMPLANON - AER
2013-5884	07/29/2013 08/26/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	JEROME P. PRATHER GARMER & PRATHER PLLC	MERCK & CO - VIOXX

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-5885	07/29/2013 08/26/2013	FDA/OMPT/CTP/OD/	ANNE D. SPIGGLE Patton Boggs LLP	NEWPORT MENTHOL GOLD BOX - STN SE0003731 EQUIV
2013-5886	07/29/2013 08/26/2013	FDA/OMPT/CTP/OD/	ANNE D. SPIGGLE Patton Boggs LLP	NEWPORT NON MENTHOL GOLD BOX 100 - STN SE0003730 EQUIV
2013-5887	07/29/2013 08/26/2013	FDA/OC/OES/DDM/	MICHELLE MORIN COVINGTON & BURLING LLP	CITIZEN PETITION OF DR J BARTHELOW CLASSEN 6/26/03 TO 8/5/02
2013-5888	07/29/2013 08/26/2013	FDA/OFVM/CFSAN/OCD/EOS/	JOAN SYLVAM BAUGHAN Keller and Heckman LLP	FCN 1231
2013-5889	07/30/2013 08/27/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	Christina Wolff Otsuka America Pharmaceutical Inc.	ARIFULLA KHAN, MD - EIR, 483, CLOSE OUT LETTER (01/30/2012 - 03/28/2012)
2013-5890	07/30/2013 08/27/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 50795 S 2, 10
2013-5891	07/30/2013 08/27/2013	FDA/OC/OES/DDM/ FDA/OFVM/CFSAN/OCD/EOS/	Theodore Maya Ahdoot & Wolfson, PC	REFERRALS, REQUESTS FOR GUIDANCE FROM US DISTRICT COURTS RE LABELING OF FOOD PRODUCTS LAST TEN YEARS
2013-5892	07/30/2013 08/27/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michael Linenberger, MD Michael Linenberger	FILGRASTIM - AERS
2013-5893	07/30/2013 08/27/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	Lajoya Sanfor/Jackson Sanford/Thomas, LaJoya	INDIVIDUAL RECS
2013-5894	07/30/2013 08/27/2013	FDA/OMPT/CDRH/OCER/DFOI/	Priya Jambhekar Alliqua Inc	K040019
2013-5895	07/30/2013 08/27/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHEA N SHAVER REILLY POZNER LLP	PROZAC (FLUOXETINE HCL) NDA 18-936, NDA 20-974 - AERS, MOR, APRVL LTRS, LBLG 12/29/87 TO 7/6/00, ETC
2013-5896	07/30/2013	FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	DAMARYS DE CASTILLO	OVAL SARNDIES ENTRY #BXH-0006701-2; GROUND GREEN PEPPERS BXH-0006963-8/1/2, BXH-0006946-3/1/2 -

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	08/27/2013		GOYA DE PUERTO RICO INC	RECS
2013-5897	07/30/2013 08/27/2013	FDA/OMPT/CDRH/OCER/DFOI/	ZARAH LEVIN-FRAGASS ESQ LANIER LAW FIRM	DR PETER S FINAMORE, WINTHROP UNIV HSOPTIAL, BOSTON SCIENTIFIC CORP - TRANSVAGINAL SURGICAL MESH CMLPNTS, MDRS, CORR, ETC
2013-5898	07/30/2013 08/27/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Christina Wolff Otsuka America Pharmaceutical Inc.	AHMAD HATIM SULAIMAN - EIR, 483, CLOSE OUT LETTER (04/09/2012 - 04/13/2012)
2013-5899	07/30/2013 08/27/2013	FDA/OGROP/ORACE-FO/PHI- DO/PHI-CB/	Joan Stitt (UG2CD-16); phone 267-305-7723 MERCK & CO., INC.	MERCK AND CO, WEST POINT, PA - INSPECTOR NOTES (01/15/2013 - 02/06/2013)
2013-5900	07/30/2013 08/27/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DAVID McFARLAND FDA REVIEW/FDA WEBVIEW	DAILY CLOSED LOG 7/15-19/13
2013-5901	07/30/2013 08/27/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DAVID McFARLAND FDA REVIEW/FDA WEBVIEW	DAILY CLOSED LOG 7/8-12/13
2013-5902	07/30/2013 08/27/2013	FDA/OC/OES/DFOI/	GLADYS B. TONKIN WASHINGTON INFORMATION SOURCE	DAILY LOG 7/8-12/13
2013-5903	07/30/2013 08/27/2013	FDA/OC/OES/DFOI/	GLADYS B. TONKIN WASHINGTON INFORMATION SOURCE	DAILY LOG 7/15-19/13
2013-5904	07/30/2013 08/27/2013	FDA/OC/OES/DFOI/	SANDY FRIEDMAN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 7/8-12/13
2013-5905	07/30/2013 08/27/2013	FDA/OC/OES/DFOI/	DEBI L. COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 7/15-19/13
2013-5906	07/30/2013 08/27/2013	FDA/OC/OES/DFOI/	SANDY FRIEDMAN WOLTERS KLUWER LAW & BUSINESS	DAILY CLOSED LOG 7/15-19/13
2013-5907	07/30/2013 08/27/2013	FDA/OC/OES/DFOI/	DEBI L. COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 7/8-12/13
2013-5908	07/30/2013 08/27/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 7/8-12/13
2013-5909	07/30/2013	FDA/OC/OES/DFOI/	BARBARA JONES	DAILY LOG 7/15-19/13

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	08/27/2013		DOMINION GROUP INC	
2013-5910	07/30/2013 08/27/2013	OC/ORO/ OC/ORO/	Doe J	MAIN STREET FAMILY PHARMACY, BLACK CENTER - METHYLPREDNISOLONE ACETATE (MPA) TEST RESULT, INVESTIGATION, PI, ETC
2013-5911	07/30/2013 08/27/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY CLOSED LOG 7/15-19/13
2013-5912	07/30/2013 08/27/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY CLOSED LOG 7/8-12/13
2013-5913	07/30/2013 08/27/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 7/15-19/13
2013-5914	07/30/2013 08/27/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 7/8-12/13
2013-5915	07/30/2013 08/27/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 7/15-19/13
2013-5916	07/30/2013 08/27/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 7/8-12/13
2013-5917	07/30/2013 08/27/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	CLOSED DAILY LOG 7/15-19/13
2013-5918	07/30/2013 08/27/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	CLOSED DAILY LOG 7/15-19/13
2013-5919	07/30/2013 08/27/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 7/15-19/13
2013-5920	07/30/2013 08/27/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 7/8-12/13
2013-5921	07/30/2013 08/27/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 7/8-12/13
2013-5922	07/30/2013 08/27/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 7/15-19/13
2013-5923	07/30/2013 08/27/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 7/15-19/13
2013-5924	07/30/2013 08/27/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 7/8-12/13

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2013-5925	07/31/2013 08/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	LUBOCK, PAUL	K111705
2013-5926	07/31/2013 08/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	MATT CLAUSEN MEDLINE INDUSTRIES INC	CHESTER PACKAGING LLC K841871
2013-5927	07/31/2013 09/12/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	CHLOE BOWER SYN GEN	CYTOMEDIX INC - ANGEL CONCENTRATED PLATELET RICH PLASMA BK110046
2013-5928	07/31/2013 08/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOYCE MARSH HOLMES WEDDLE & BARCOTT	PRODISC 1 TOTAL DISC REPLACEMENT - AER, PMA STUDY
2013-5929	07/31/2013 08/28/2013	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	PETER A. QUINTER GRAY ROBINSON ATTY	ENTRY NO JN8-00208975
2013-5930	07/31/2013 09/03/2013	FDA/OO/OHR/	ALEXIS N. TSOTAKOS, Esq. THE LAW OFFICES OF GARY M GILBERT & ASSOCIATES PC	INDIVIDUAL RECS
2013-5931	07/31/2013 08/28/2013	FDA/OC/OES/DFOI/	PATRICK A. ELWARD BINGHAM GREENBAUM ET AL	BAUSCH & LOMB INC - 2006 FUSARIUM KERATITIS OUTBREAK
2013-5932	07/31/2013 10/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KYLE ROCKERSHOUSEN WALSH KNIPPEN ET AL	VERSCD (MIDAZOLAM) PCKG
2013-5933	07/31/2013 08/28/2013	FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/	KRISTEN S. MOYERS WRIGHT LINDSEY & JENNINGS	KIMBERLY CLARK - KOTEX NEW BALANCE SECURITY TAMPON RECALL
2013-5934	07/31/2013 08/28/2013	FDA/OC/OES/DDM/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	MICHELLE L. MORIN COVINGTON & BURLING LLP	VACCINES & DIABETES MTG W/DR BART CLASSEN 1/30/95
2013-5935	07/31/2013 08/28/2013	OC/CVM/OCD/ FDA/OC/OES/ FDA/OC/OCC/	HANNAH CONNOR Humane Society of the United States	RACTOPAMINE - APRVL
2013-5936	07/31/2013 08/28/2013	FDA/OO/OFBA/OAGS/	NIKA GRACI PLANNED PARENTHOOD	SITE VISITS REVIEWS CONDUCTED AT OFFICE OF POPULATION AFFAIRS 2010, 2011, 2012

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2013-5937	08/01/2013 08/29/2013	FDA/OC/OES/DFOI/	Robert Blinn Pura Vida Funds	ST JUDE MEDICAL - 483 (08/01/2012 - 07/29/2013)
2013-5938	08/01/2013 08/29/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Angela Fu UNIVERSITY OF MARYLAND	K032986, K061079, K070211
2013-5939	08/01/2013 08/29/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Karen L. Richards Singulex, Inc.	K093758
2013-5940	08/01/2013 08/29/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Reza Davani Janet Jenner & Suggs LLC	K080238 K082052 K091057 ETC
2013-5941	08/01/2013 08/29/2013	FDA/OC/OES/DDM/	John Pribble The Medicines Company	DKT. 98-P-0086/CP1
2013-5942	08/01/2013 08/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	Mike O'Hara EPC	K123731
2013-5943	08/01/2013 08/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	Karen L. Richards Singulex, Inc.	K111452
2013-5944	08/01/2013 08/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sean Higgins ANDREWS & THORNTON	ANDA 202077
2013-5945	08/01/2013 08/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tom Namsavanh IntelGenx Corp.	NDA 017525
2013-5946	08/01/2013 08/29/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Joan Stitt (UG2CD-16); Phone - 267-305-7723 MERCK & CO., INC.	MERCK AND CO, DURHAM, NC - INVESTIGATOR NOTES (08/20/2012 - 08/31/2012)
2013-5947	08/01/2013 08/29/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mark Little Mark Little	COMMERCIAL IND SUBMISSIONS
2013-5948	08/01/2013	FDA/OMPT/CDER/ORP/DIDP/	Adrienne E Faerber	NDA 022083 S 16

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	08/29/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dartmouth Inst. Cent. For Med. Media.	
2013-5949	08/01/2013 08/29/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	F William Danby Danby and Margesson Dermatology	NIZORAL, SPORANOX - AERS
2013-5950	08/01/2013 08/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	Becky Ditty Stryker IMT	K111642
2013-5951	08/01/2013 08/29/2013	FDA/OGROP/ORA/PA-FO/SEA- DO/SEA-CB/	Susan Zolnier Zolnier, Susan	CHARLES RIVER CLINICAL SERVICES, TACOMA, WA - EIR, 483 (01/01/2010 - 12/31/2011)
2013-5952	08/01/2013 08/29/2013	FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/	William B Smith, MD New Orleans Center for Clinical Research	NEW ORLEANS CENTER FOR CLINICAL RESEARCH - EIR (09/01/1988 - 09/30/1988)
2013-5953	08/01/2013 08/29/2013	FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/	Lori Hays Merz North America, Inc.	MERZ AESTHETICS, FRANKSVILLE, WI - EIR (3/12/2013 - 04/19/2013)
2013-5954	08/01/2013 08/29/2013	FDA/OGROP/ORA/SW-FO/DEN- DO/DEN-CB/	Phil Boehm Bimbo Bakeries USA	BIMBO BAKERIES, DENVER, CO - EIR 2/12/13
2013-5955	08/01/2013 08/29/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sean Higgins ANDREWS & THORNTON	ANDA 201786
2013-5956	08/01/2013 08/29/2013	FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	ORR, PATRICK	VITEK INC - IMPLANT RECS, CORR
2013-5957	08/01/2013 08/29/2013	FDA/OC/OES/DFOI/	BLAZE, D'LANIE	MONITORING INCOMING SEAFOOD FROM JAPAN FOR RADIOACTIVITY - RECS
2013-5958	08/01/2013 08/29/2013	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/ FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	DENNIS L WEBB WEBB & SCARMOZZINO ATTY	GOLDCOAST SALADS - BLUE CRAB SPREAD CONTAMINATION INVESTIGATION 1/13
2013-5959	08/01/2013 08/29/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TIMOTHY M O'BRIEN LEVIN PAPANTONIO THOMAS ET AL	MERCK - FOSAMAX NDA 20-560 CMLPNTS, RPTS, CORR, ETC

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2013-5960	08/01/2013 08/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JACKIE HERNDON ZAREMBA BROWNELL & BROWN PLLC	ARAVA (LEFLUNOMIDE) - RECS (CERTIFIED)
2013-5961	08/01/2013 08/29/2013	FDA/OC/OES/DDM/	BRIAN BOXER WACHLER BOXER WACHLER VISION INSTITUTE	OPHTHALMIC DVCS PANEL MTG - TRANS 1995 & 1996
2013-5962	08/01/2013 08/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	EUROFINS LANCASTER LAB, WATERFORD, IRELAND - 483 3/13
2013-5963	08/01/2013 08/29/2013	FDA/OC/OES/DFOI/ FDA/OGROP/ORACE-FO/CHI- DO/CHI-CB/	Christina Wolff OTSUKA AMERICA PHARMACEUTICAL INC	MARK LERMAN - EIR, 483, CLOSE OUT (02/27/2012 - 04/04/2012)
2013-5964	08/01/2013 08/29/2013	FDA/OFVM/CFSAN/OCD/EOS/	A. Philip Leber A Philip Leber Consulting	FCN 176
2013-5965	08/01/2013 08/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Margaret Sestrom PFIZER	MEDROL - CMC REVIEW
2013-5966	08/01/2013 08/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Robin Richardson Robin Richardson	CELSTONE SOLUSPAN INJECTIONI - AERS, INSERT
2013-5967	08/01/2013 08/29/2013	FDA/OGROP/ORASE-FO/ATL- DO/ATL-CB/	David M. Pike David M. Pike	LIQUID PACKAGING RESOURCES, INC, ATLANTA, GA - PLANT REVIEW AUDIT INFORMATION (01/01/2008 - 12/31/2009)
2013-5968	08/01/2013 08/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	Pamela Heitz, Medtronic Neuro Regulatory Operations Medtronic Neuromodulation	13TH SYNCHROMED ANNUAL REPORT FOR 03/14/2000 TO 03/13/2001; P860004/R022
2013-5969	08/01/2013 10/28/2013	FDA/OFVM/CFSAN/OCD/EOS/	Merle Zimmermann AMERICAN HERBAL PRODUCTS ASSOCIATION	DIETARY SUPPLEMENT - AERS (08/01/2010 - 12/31/2010)
2013-5970	08/01/2013 08/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	EUROFINS LANCASTER LAB, WATERFORD, IRELAND - EIR 3/13

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2013-5971	08/01/2013 08/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	SHIRLEY ROBERSON OMRON HEALTHCARE INC	LECHNOLOGIES RESEARCH INC - ELECTROCARDIOGRAPH K052767
2013-5972	08/01/2013 08/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	SHIRLEY ROBERSON OMRON HEALTHCARE INC	MICROLIFE - BLOOD PRESSURE MONITOR K013485, K080337, K073198, ETC
2013-5973	08/01/2013 08/29/2013	FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/	Francis, Ana M	2012-5775
2013-5974	08/02/2013 08/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16); 267-305-7723 MERCK & CO., INC.	CLOSED FOIA REQUESTS 7/1-31/2013
2013-5975	08/02/2013 08/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16); 267-305-7723 MERCK & CO., INC.	FOI DAILY LOG 7/1-31/2013
2013-5976	08/02/2013 08/30/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	Kellie M. Collins Golden and Walters	LANHAM CATTLE FARM, MIDDLESBURG, KY - INVESTIGATION RECS (12/17/2012 - 07/31/2014)
2013-5977	08/02/2013 08/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Stacy Woepfel B. Braun Medical Inc.	NDA 019627 S060
2013-5978	08/02/2013 08/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	Richard Gross Gross, Richard E	K090169
2013-5979	08/02/2013 08/30/2013	FDA/OFVM/CFSAN/OCD/EOS/	Jorge Flores P.A Alberto Soler	GRAS DETERMINATION OF COCA LEAF (DECOCAINIZED)
2013-5980	08/02/2013 08/30/2013	FDA/OFVM/CFSAN/OCD/EOS/	Jorge Flores P.A Alberto Soler	FEMA 2329/CAS: 977073-62-3/EINECS: 283-877-4/21 - DATE OF APPROVAL
2013-5981	08/02/2013 08/30/2013	FDA/OFVM/CFSAN/OCD/EOS/	Jorge Flores P.A Alberto Soler	1958 GRAS LIST EXEMPT SUBSTANCE
2013-5982	08/02/2013 08/30/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	Gary Waugaman Lakeside Organic Gardens LLC	NEW YORK STATE E COLI SPINACH AND SPRING MIX OUTBREAK - INVESTIGATION REPORT 10/01/2012 - 12/31/2012
2013-5983	08/02/2013 08/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	Sandra Witt sandra witt	KNEE REPLACEMENT ADVERSE EVENTS
2013-5984	08/02/2013	FDA/OMPT/CDER/GRP/DIDP/	Bonnie Williams	ANDA 202631

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	08/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	
2013-5985	08/02/2013 08/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bonnie Williams FOI Services, Inc.	ANDA 201951
2013-5986	08/02/2013 08/30/2013	FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Paul Knoepfler Paul Knoepfler/UC Davis School of Medicine	CELLTEX - REPORTS, CORR, INVESTIGATIONS (01/01/2013 - 12/31/2013)
2013-5987	08/02/2013 08/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Vidhu Thaker Boston Childrens Hospital	ACCUTANE - AERS
2013-5988	08/02/2013 08/30/2013	FDA/OGROP/ORASW-FO/SAN- DO/SAN-CB/	Rao Maddula ARIAD PHARMACEUTICALS INC	AMPAC FINE CHEMICALS - 483, EIR (10/01/2009 - 10/04/2010)
2013-5989	08/02/2013 08/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sue Corbett THE RESEARCH INVESTMENT, INC.	PERIOD SAFETY UPDATE REPORT EPOS 12, SOLID 1000185514
2013-5990	08/02/2013 08/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	CAMPTOSAR - AERS
2013-5991	08/02/2013 08/30/2013	FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/ FDA/OGROP/ORASW-FO/DEN- DO/DEN-CB/	Michele Aguirre Clinical Research Advantage	JOHN F SPEER, ARLINGTON, TX - INSPECTION RECS (01/01/1986 - 12/30/1986)
2013-5992	08/02/2013 08/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anne Madej Genentech	NDA 202088
2013-5993	08/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson	510K RELEASED UNDER FOIA JULY 2013

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	08/30/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	
2013-5994	08/02/2013 08/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lucie Begert GUERBET LLC	MALLINCKRODT SODIUM CHLORIDE INJECTION 0.9% MODULE 5 CLINICAL, MODULE 2.5 CLINICAL OVERVIEW, MODULE 2.7 CLINICAL SUMMARY
2013-5995	08/02/2013 08/30/2013	FDA/OFVM/CFSAN/OCD/EOS/	Merle Zimmermann AMERICAN HERBAL PRODUCTS ASSOCIATION	DIETARY SUPPLEMENT AERS (09/01/2012 - 06/30/2013)
2013-5996	08/02/2013 09/26/2013	FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORASE-FO/FLA- DO/FLA-CB/ FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/ FDA/OGROP/ORASW-FO/DEN- DO/DEN-CB/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Surgery Center of the Rockies Boulter, Suzanne	SURGICAL TISSUE NETWORK, MUSCULOSKELETAL TRANSPLANT FOUNDATION, DOROTEA, ETC - AERS, INSPECTIONS (01/01/2012 - 07/31/2013)
2013-5997	08/02/2013 08/30/2013	FDA/OC/OES/DFOI/	MOTEN, LAVEETA D	COMPUTER USAGE FROM 7/1/10 TO 12/31/10
2013-5998	08/02/2013 08/30/2013	FDA/OC/OES/DFOI/	MOTEN, LAVEETA D	COMPUTER USAGE FROM 1/1/11 TO 7/14/11
2013-5999	08/02/2013 08/30/2013	FDA/OC/OES/DFOI/	MOTEN, LaVEETA D	COMPUTER USAGE FROM 12/5/11 TO 6/30/12
2013-6000	08/02/2013 08/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M. GARTZ ELI LILLY & CO	SHAANXI HANJIANG PHARMACEUTICAL GROUP CO, LTD, HANZHONG, CHINA - EIR 11/21/08, 10/14/10
2013-6001	08/02/2013 08/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FRIEDMAN, ROBERT	VIOXX - FAERS 1969 TO 2013
2013-6002	08/02/2013 08/30/2013	OC/ORACE/ORM/ OC/ORACE/ORM/	ROBERT KING FDA NEWS	ALL 483 NOTICES RECIEVED FOR FACILITIES 7/13
2013-6003	08/02/2013	FDA/OC/OES/DFOI/	BRODY MULLINS	2012-5582

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2013-6012	08/05/2013 09/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	MELISSA YEAGER KSHB-TV	ESSURE - MTG MINS , CORR, PMA APRVL 1/1/96 TO 7/31/13
2013-6013	08/05/2013 09/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	MELISSA YEAGER KSHB-TV	AVAILMED SA DE CV, TIJUANA, MEXICO - EIRS, WARNING LTRS 1/1/00 TO 7/31/13
2013-6014	08/05/2013 09/03/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JULIA P DURAN GOODWIN PROCTER LLP	INJECTAFER (FERRIC CARBOXYMALTOSE INJ) - NDA 203-565 - SBA
2013-6015	08/05/2013 09/03/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN E NIZNIK PORZIO BROMBERG & NEWMAN PC	INJECTAFER (FERRIC CARBOXYMALTOSE INJ) - NDA 203-565 - SBA
2013-6016	08/05/2013 09/03/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELENA HOWELL HOGAN LOVELLS US LLP	INJECTAFER (FERRIC CARBOXYMALTOSE) NDA 203-565 - SBA
2013-6017	08/05/2013 09/03/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	JOSH SULTAN CBS 2 NEWS CHICAGO	VEVMA, SCOTTSDALE, AZ - EIRS, CO RESP 10/1/12 TO 1/1/13
2013-6018	08/05/2013 09/03/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	TRAVIS SCHAFTENAAR MANULIFE ASSET MANAGEMENT	ANGIODYNAMICS - 483S 9/24/12
2013-6019	08/05/2013 09/03/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	BOBBIE J COLES-BROWN CARACO PHARMACEUTICAL LABS LTD	SUN PHARMACEUTICAL INDUSTRIES INC - ACKNOWLEDGEMENT RECEIPT LTR 7/21/11
2013-6020	08/05/2013 09/03/2013	FDA/OMPT/CTP/OD/	EDWARD B GERARD ROBBINS ARROYO LLP	STAR SCIENTIFIC INC - DEVELOPMENT, PROMOTIONS, SALES
2013-6021	08/05/2013 09/27/2013	FDA/OFVM/CFSAN/OCD/EOS/	LI ZHANG BASF Corp.	OMNOVA SOLUTIONS INC - FCN 244
2013-6022	08/05/2013 09/03/2013	FDA/OC/OES/ FDA/OFVM/CFSAN/OCD/EOS/	WILLIAM DOFFERMYRE WILLIAMS & CONNOLLY LLP	BEEF PRODUCTS INC - LEAN FINELY TEXTURED BEEF, FAT REDUCED BEEF, BONELESS LEAN BEEF TRIMMINGS CORR BETWEEN BPI EMPLOYEES, OLSSON FRANK & WEEDA PC, CMLPNTS, ETC
2013-6023	08/05/2013	OC/CVM/OCD/	Finola McConaghy	NADA 131-310

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	09/03/2013		Ceva Animal Health	
2013-6024	08/05/2013 09/03/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tina Lee Tris Pharma, Inc.	ADDERRAL XR CAPSULE 5, 10, 15, 20, 25, 30 MG
2013-6025	08/05/2013 09/03/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tina Lee TRIS PHARMA INC	ADDERRALL IR TABLETS 5, 7.5, 10, 12.5, 15, 20, 30 MG
2013-6026	08/05/2013 09/03/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bonnie Williams FOI Services, Inc.	ANDA 202542
2013-6027	08/05/2013 09/03/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Adrienne E. Faerber, PhD Dartmouth Inst. Cent. For Med. Media.	NDA 203188 - UNREDACTED MEDICAL AND STATISTICAL REVIEW
2013-6028	08/05/2013 09/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jack Rogers Polymer Technology Systems, Inc.	K090405, K130295
2013-6029	08/05/2013 09/03/2013	FDA/OMPT/CTP/OD/	Stanton A. Glantz, PhD UNIVERSITY OF CALIFORNIA SAN FRANCISCO	STN SE0003730
2013-6030	08/05/2013 09/03/2013	FDA/OMPT/CTP/OD/	Stanton A. Glantz, PhD UNIVERSITY OF CALIFORNIA SAN FRANCISCO	STN SE0003731
2013-6031	08/05/2013 09/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	Betty M Johnson Technolas Perfect Vision GmbH	K102727
2013-6032	08/05/2013 09/03/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Betty M Johnson Technolas Perfect Vision GmbH	K113479
2013-6033	08/05/2013 09/03/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OGROP/ORACE-FO/DET- DO/DET-CB/ FDA/OGROP/ORACE-FO/MIN-	Thambiah Sundaram Sundaram, Thambiah	K050591, K032914, K971432 ETC

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		DO/MIN-CB/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/ FDA/OC/OES/DFOI/		
2013-6034	08/05/2013 09/03/2013	FDA/OMPT/CTP/OD/	Allison O'Donnell Campaign for Tobacco Free Kids	NEWPORT NON-MENTHOL GOLD BOX 100, NEWPORT NON-MENTHOL GOLD BOX - FDA PREPARED RECS RE DESIGNATION AS SUBSTANTIALLY EQUIVALENT TO GRANDFATHERED PREDICATE PRODUCTS
2013-6035	08/05/2013 09/03/2013	FDA/OC/OES/DDM/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OC/OES/ FDA/OC/OL/	Patrick Terpstra Cox Media Group	COMMENTS TO FDA RE POLICY BANNING BLOOD 01/13/2013 - 08/02/2013
2013-6036	08/05/2013 09/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jose Schwank Starq	K950621
2013-6037	08/05/2013 09/03/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	David Dick UNIVERSITY OF IOWA	MOLECULAR IMAGING PROGRAM, STANFORD, CA - EIR (06/01/2007 - 12/12/2011)
2013-6038	08/05/2013 09/03/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Craig Miles CR MILES, PC	APPROVED PHASE I TRIAL FOR TREATMENT OF HYPERTROPHIC SCAR DEFECT
2013-6039	08/05/2013 09/03/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Sandy O'Kelley Merial Limited	NU-ERA FARMS, STILLWATER, OK - EIR 12/21/2012 - 02/28/2013

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2013-6040	08/06/2013 09/04/2013	FDA/OFVM/CFSAN/OCD/EOS/	JONATHAN W EMORD EMORD & ASSOCIATES, P.C.	BRASSICA PROTECTION PRODUCTS - GLUCORAPHANIN IN BEVERAGES, GRAS NOTIFICATION
2013-6041	08/06/2013 09/04/2013	FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	HYDROXYCUT, SMARTBURN, CREATINE 6000, ETC - CAERS 5/13 TO PRESENT
2013-6042	08/06/2013 09/04/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	K MICHELLE VASSALLO LINCARE INC	ANTHEM HEALTH SERVICES INC, NY - EIRS, 483S, WARNING LTRS 1/05 TO PRESENT
2013-6043	08/06/2013 09/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	EMILY K STRUNK AKIN GUMP ET AL	US PHARMACOPEIA CONVENTION, NATIONAL FORMULARY (USP-NF) - ELEMENTAL IMPURITIES STANDARDS, CORR
2013-6044	08/06/2013 09/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	EMILY K STRUNK AKIN GUMP ET AL	US PHARMACOPEIA, NATIONAL FORMULARY (USP-NF) - CORR, MEMORANDA OF UNDERSTANDING (MOU), EI STANDARDS, ETC
2013-6045	08/06/2013 09/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LA TOYA SUTTON MANATT PHELPS & PHILLIPS LLP	PEDICULICIDES - CORR, LACK OF EFFICACY RECS
2013-6046	08/06/2013 09/04/2013	FDA/OC/OES/DDM/	LA TOYA SUTTON MANATT PHELPS & PHILLIPS LLP	DKT 2010P-0312
2013-6047	08/06/2013 09/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	BOSTON SCIENTIFIC CORP - LITE PELVIC FLOOR REPAIR KIT K103426
2013-6048	08/06/2013 09/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	BOSTON SCIENTIFIC CORP - PINNACLE LITE PELVIC FLOOR REPAIR KIT, POSTERIOR UPHOLD LITE K122459
2013-6049	08/06/2013 09/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	LAVENIA FORD CARDINAL HEALTH	KIMBERLY-CLARK - PEDIATRIC/CHILD FACEMASK K113340
2013-6050	08/06/2013 09/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	LAVENIA FORD CARDINAL HEALTH	KIMBERLY-CLARK - PEDIATRIC/CHILD FACEMASK K103150
2013-6051	08/06/2013 09/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sarah Biwer DHL Global Forwarding	DRUG ESTABLISHMENT LIST 01/01/2013 - 12/31/2013

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2013-6052	08/06/2013 09/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Andrea McKeever South University School of Pharmacy	CABERGOLINE THERAPY - AERS
2013-6053	08/06/2013 09/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	Patrick J. Higgins Powers & Santola, LLP	KARL STORZ GMBH & CO ETC - REGISTRATIONS, 510K NOTIFICATIONS, MEDICAL DEVICE LISTINGS ETC
2013-6054	08/06/2013 09/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ed Dougherty Dougherty Modin Holloway & Kardis	ISONIAZID - BOX WARNING, PACKAGE INSERTS, PRECAUTIONS ETC
2013-6055	08/06/2013 09/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lia Obata Dowd DOWD & DOWD PC	MIRENA - AERS, APPLICATIONS, WARNINGS ETC
2013-6056	08/06/2013 09/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Melanie Daub Melanie Daub	STRATTERA - FAERS
2013-6057	08/06/2013 09/04/2013	FDA/OGROP/ORAC/FO-NWJ- DO/NWJ-CB/	Joy flynn flynn, joy	SPECTRUM CHEMICAL AND LABORATORY PRODUCTS, NEW BRUNSWICK, NJ - EIR MOST RECENT
2013-6058	08/06/2013 09/23/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Sarah Strand Sarah Strand - University of Arizona Department of Sociology	ASO4 - TESTING, SAFETY, APPROVAL FOR USE AS VACCINE ADJUVANT
2013-6059	08/06/2013 09/23/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Sarah Strand Sarah Strand - University of Arizona Department of Sociology	AMORPHOUS ALUMINUM HYDROXYPHOSPHATE SULFATE - TESTING, SAFETY, APPROVAL AS VACCINE ADJUVANT
2013-6060	08/06/2013 09/23/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Sarah Strand Sarah Strand - University of Arizona Department of Sociology	TESTING, SAFETY, APPROVAL OF THIMEROSAL/MERTHIOLATE
2013-6061	08/06/2013 09/04/2013	FDA/OGROP/ORAC/SW-FO/KAN- DO/KAN-CB/	Linda Bowen SANOFI	JOST CHEMICAL COMPANY, BRECKENRIDGE HILLS, MO - EIR (05/01/2012 - 05/31/2012)
2013-6062	08/06/2013 09/04/2013	FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA REQUEST LOG (07/29/2013 - 08/02/2013)
2013-6063	08/07/2013	FDA/OMPT/CDRH/OCER/DFOI/		SUROS SURGICAL SYSTEMS INC, INDIANAPOLIS, IN - ATEC

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	09/05/2013	FDA/OC/OES/DFOI/	KRUSE, JANICE	BREAST BIOPSY SYS K042290
2013-6064	08/07/2013 09/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	KRUSE, JANICE	RUBICOR MEDICAL INC, REDWOOD CITY, CA - MAGIC BREAST BIOPSY DVC K053151
2013-6065	08/07/2013 09/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	KRUSE, JANICE	RUBICOR MEDICAL INC, REDWOOD CITY, CA - BREAST BIOPSY DVC K071048
2013-6066	08/07/2013 09/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	JULIANNE SHERMAN CITIZENS COMMISSION ON HUMAN RIGHTS INTERNATIONAL	NEUROPSYCHIATRIC EEG BASED ASSESMENT AID (NEBA) SYS - ADHD NAMES, DISCLOSURE NOTICES, CLNCL STUDY 7/15/13
2013-6067	08/07/2013 09/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FRIEDMAN, ROBERT	AUGMENTIN SUSPENSION, AUGMENTIN-DUO SUSPENSION - FAERS 1969 TO 2013
2013-6068	08/07/2013 09/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MICHAEL R COHEN INSTITUTE FOR SAFE MEDICATION PRACTICES	MEDWATCH RPTS CODED AS MEDICATION ERRORS 7/1-31/13
2013-6069	08/07/2013 09/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RUSSELL #02B2141, DENNIS A	LITHIUM - AERS 2002 TO PRESENT
2013-6070	08/07/2013 09/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOYCE E PRENDERGAST	CHANTIX (VERENICLINE) - ISRS 6554745, 6912111, 6977379, ETC
2013-6071	08/07/2013 09/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/CVM/OCD/	CHARLES CELESTE EAS Consulting Group, LLC	CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG) CO LTD, SHIJIAZHUANG, CHINA - EIRS 7/23-26/12
2013-6072	08/07/2013 09/05/2013	FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/	CHASTITY RODRIGUEZ INTERNATIONAL SIGHT RESTORATION INC	LABORATORY CORPORATION OF AMERICA (LABCORP), TAMPA, FL - 483S, WARNING LTRS LAST 10 YRS
2013-6073	08/07/2013 09/05/2013	FDA/OGROP/ORO/PA-FO/SEA-DO/SEA-CB/	BRENDAN J FLAHERTY PRITZKER OLSEN	TOWNSEND FARMS INC - ORGANIC ANTIOXIDANT BLEND HEPATITIS A OUTBREAK FOODBORNE PATHOGEN

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		FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/		TESTING, EIRS, RPTS, ETC 2013
2013-6074	08/07/2013 09/05/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	2013-5606
2013-6075	08/07/2013 09/05/2013	FDA/OC/OES/DFOI/	ELENA HOWELL HOGAN LOVELLS LLP	2013-4749, 2013-4750
2013-6076	08/07/2013 09/05/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	ED PETRUS Nobel Laboratories, LLS	LOG OF CDER FOIA REQUESTS PENDING
2013-6077	08/07/2013 09/05/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARTIN RUBENSTEIN HOWARD M FILE ESQ PC	INDIVIDUAL RECS (CERTIFIED)
2013-6078	08/07/2013 09/05/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	BRETT PARK CONWAY HOMER & CHIN- CAPLAN PC	INDIVIDUAL RECS (CERTIFIED)
2013-6079	08/08/2013 09/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Falgun K Shah Reliance Mutual fund	RANBAXY LABORATORIES, PUNJAB, INDIA - 483 (11/01/2012 - 03/01/2013)
2013-6080	08/08/2013 09/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	Katrina Fiedler CONVATEC	K013814 UNREDACTED
2013-6081	08/08/2013 09/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	Katrina Fiedler CONVATEC	K080383 UNREDACTED
2013-6082	08/08/2013 09/06/2013	FDA/OC/OES/DFOI/	Jason A Dean Hulsey Oliver & Mahar, LLP	2013-4772 CERTIFIED
2013-6083	08/08/2013 09/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Stephen Dame DAME, STEPHEN	CELEXA - AERS
2013-6084	08/08/2013 09/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jeannie Lin Route One Investment Company	WOCKHARDT LIMITED, CHIKALTHANA, INDIA - 483 (07/15/2013 - 08/06/2013)

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-6085	08/08/2013 09/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	Katrina Fiedler CONVATEC	K063271 UNREDACTED
2013-6086	08/08/2013 09/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Richard Beasley Beasley, Richard	ALDARA - SIDE EFFECTS, DEATHS
2013-6087	08/08/2013 09/06/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	claudia calla dentilab del peru	IUD TCU-380A - 1993 STUDY
2013-6088	08/08/2013 09/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jessica Vickers Jessica Vickers	CITALOPRAM/QT PROLONGATION UPDATE - STUDIES USED
2013-6089	08/08/2013 09/06/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	Linda Bowen SANOFI	PHARMACIA & UPJOHN, KALAMAZOO, MI - EIR (06/01/2013 - 06/30/2013)
2013-6090	08/08/2013 09/06/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	Doe J	INDIVIDUAL RECS
2013-6091	08/08/2013 09/06/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	Robert Rothermund Robert Rothermund	TEVA PHARMACEUTICALS, CINCINNATI, OH - CORRESPONDENCE RE ROBERT ROTHERMUND, PAIGE DURKEE (04/02/2012 - 10/28/2013)
2013-6092	08/08/2013 09/06/2013	FDA/OFVM/CFSAN/OCD/EOS/	HARRY N. FINKBONE, DABT akzonobel	FCN 845 - UNDERLYING RISK ASSESSMENT FOR VCH (100-30-4) ETC
2013-6093	08/08/2013 09/06/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/ FDA/OC/OES/DFOI/ FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	Doe J	COMPLAINT FOLLOW UP
2013-6094	08/08/2013 09/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Thomas G. Kemmy Law Office of Thomas G. Kemmy	INFORMATION FOR HEALTHCARE PROFESSIONALS: FLUOROQUINOLONE ANTIMICROBIAL DRUGS (CERTIFIED)

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-6095	08/08/2013 09/06/2013	FDA/OC/OES/DDM/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	DKT 83P-0404 CITIZEN PETITION (CERTIFIED)
2013-6096	08/08/2013 09/06/2013	FDA/OFVM/CFSAN/OCD/EOS/	HARRY N. FINKBONE, DABT akzonobel	FCN 244 - RISK ASSESSMENT 4-VINYLCYCLOHEXANE ETC
2013-6097	08/08/2013 09/06/2013	FDA/OC/OES/DDM/	Jaime Vassallo, LexisNexis CourtLink Document Retrieval	CITIZEN PETITION, RESPONSES RE CANCER WARNING ON COSMETIC TALC (CERTIFIED)
2013-6098	08/08/2013 09/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kevin Whetstone Sunovion Pharmaceuticals Inc.	XOPENEX HFDA - APPROVAL PACKAGE
2013-6099	08/08/2013 09/06/2013	FDA/OC/OES/DDM/	Katherine Giannamore The Law Office of Katherine Giannamore, P.A.	DKT 80N-0146
2013-6100	08/08/2013 10/30/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Patrick Haffey Patrick Haffey	ACTHIB - MANUFACTURING INFORMATION, CONTRACT MANUFACTURING (08/05/2008 - 08/06/2013)
2013-6101	08/08/2013 09/06/2013	FDA/OC/OES/DDM/ FDA/OFVM/CFSAN/OCD/EOS/	HARRY N. FINKBONE, DABT akzonobel	DKT 1994F-0153 - RISK ASSESSMENT FOR 1,3-BUTADIENE
2013-6102	08/08/2013 09/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Rakesh Nayudu Espirito Santo Investment Bank	WOCKHARDT - EIR, 483 MOST RECENT (01/01/2013 - 08/06/2013)
2013-6103	08/08/2013 09/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	b. burgess BURGESS, BERNIE	LIST OF CDER DSI GCP 1 CLINICAL INVESTIGATOR INSPECTIONS IN 2007 BY LOS-DO; LIST OF CDER DSI GCP2 CLINICAL INVESTIGATOR INSPECTIONS IN 2007 BY LOS-DO
2013-6104	08/08/2013 09/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	b. burgess BURGESS, BERNIE	CDER DSI COMPLAINT 1006

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/ FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/		
2013-6105	08/08/2013 09/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Nicole Larch Sandberg, Phoenix and vonGontard	CASE REPORTS 6774803 6776928 6826076 ETC
2013-6106	08/08/2013 09/06/2013	FDA/OFVM/CFSAN/OCD/EOS/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	6/6/85 RE ASBESTOS IN TALC FROM QRAC TO W GARY FLAMM (CERTIFIED)
2013-6107	08/08/2013 09/06/2013	FDA/OC/OES/DDM/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	11/17/94 CITIZEN PETITION SEEKING CARCINOGENIC LABELING ON COSMETIC TALC PRODUCTS (CERTIFIED)
2013-6108	08/08/2013 09/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	Maria Tomasch KNXV-TV	ESSURE - COMPLAINTS, INVESTIGATIONS LAST TEN YEARS
2013-6109	08/08/2013 09/06/2013	FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/ OC/ORA/ OC/ORA/	Kim Aylesworth Aylesworth, Kim	GERBER, FORT SMITH, AR - ENVIRONMENTAL SALMONELLA SURVEILLANCE RESULTS (07/29/2013 - 08/06/2013)
2013-6110	08/08/2013 09/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Chirag Talati Espirito Santo Securities	RANBAXY, NOIDA - 483 12/21/12; 12/14/12; RANBAXY, VILLAGE TOANSA - 483 12/12/12 ETC
2013-6111	08/08/2013 09/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	Katrina Fiedler CONVATEC	K091034 UNREDACTED
2013-6112	08/08/2013 09/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	Katrina Fiedler CONVATEC	K090254 UNREDACTED
2013-6113	08/08/2013 09/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	Dennis McLaughlin PHILIPS MEDIZIN SYSTEME	K120579
2013-6114	08/08/2013 09/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	Tara Burrell InSitu Technologies, Inc	K050814
2013-6115	08/08/2013 09/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Caroline Palomeque JMP Securities	UCERIS - AERS

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-6116	08/08/2013 09/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shalin Jani Aerie Pharmaceuticals Inc.	NDA 204251 - SBA
2013-6117	08/08/2013 09/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	Katrina Fiedler CONVATEC	K123481 UNREDACTED
2013-6118	08/08/2013 09/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	Katrina Fiedler CONVATEC	K121275 UNREDACTED
2013-6119	08/08/2013 09/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	Katrina Fiedler CONVATEC	K112342 UNREDACTED
2013-6120	08/08/2013 09/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	Susan Quick Philips Healthcare (Cleveland), Inc.	K113394
2013-6121	08/08/2013 09/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Caroline Palomeque JMP Securities	XTANDI - AERS
2013-6122	08/08/2013 09/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Heather Behanna JMP Securities	CINRYZE, BERINERT - AERS
2013-6123	08/08/2013 09/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELLIOT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	NUEDEXTA (DEXTROMETHORPHAN HBR & QUINIDINE) - AERS 1/12 TO PRESENT
2013-6124	08/08/2013 09/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELLIOT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	BELVIQ (LORCASCRINE HYDROCHLORIDE) - AERS 1/12 TO PRESENT
2013-6125	08/08/2013	FDA/OMPT/CDER/GRP/DIDP/	ELLIOT FAVUS, MD	CRZALUTAMIDE - AERS 1/12 TO PRESENT

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	09/06/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FAVUS INSTITUTIONAL RESEARCH LLC	
2013-6126	08/08/2013 09/06/2013	FDA/OGROP/ORANE-FO/NYK- DO/NYK-DCB/	Eric Thostenes Janssen	LUITPOLD PHARMACEUTICALS, SHIRLEY, NY - 483 (03/01/2012 - 08/05/2013)
2013-6127	08/08/2013 09/06/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELIOTT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	OCRIPLASMIN - AERS 10/12 TO PRESENT
2013-6128	08/08/2013 09/06/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELLIOT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	PEMALIDOMIDE - AERS 1/13 TO PRESENT
2013-6129	08/08/2013 09/06/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELIOTT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	TECFIDERA (DIMETHYL FUMARATE) - AERS 3/13 TO PRESENT
2013-6130	08/08/2013 09/06/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELIOTT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	KADCYLA (TRASTUZUMAB EMTANSINE) - AERS 2/13 TO PRESENT
2013-6131	08/08/2013 09/06/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELIOTT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	AMPYRA FAERS 1/12 TO PRESENT
2013-6132	08/08/2013 09/06/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELLIOT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	ICLUSIG - AER 1/13 TO PRESENT
2013-6133	08/08/2013 09/06/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELLIOT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	ADCETRIS (BRENTUXIMAB VEDOTIN) AER 2/13 TO PRESENT

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2013-6134	08/08/2013 09/06/2013	FDA/OC/OES/DFOI/	ELLIOTT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	FOIA LOG 1/13 TO PRESENT
2013-6135	08/08/2013 09/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	ANDRENE HERON ROCHE DIAGNOSTICS	BAYER - 400 SYS K002738; RAPIPOINT 405 SYS K020616
2013-6136	08/08/2013 09/06/2013	FDA/OC/OES/DFOI/	ANDREW HACK, MD MILLENNIUM MANAGEMENT LLC	FOIA LOG 4/13 TO PRESENT
2013-6137	08/08/2013 09/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JULIE T. CLIFFORD INEOS OLEFINS AND POLYMERS USA	DMF 1362
2013-6138	08/08/2013 10/28/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORR/SW-FO/DAL- DO/DAL-CB/ FDA/OGROP/ORR/PA-FO/SEA- DO/SEA-CB/	TAPAN OZA QUELLER FISHER ET AL	USPS LABS LLC - JACK3D CORR
2013-6139	08/08/2013 09/06/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	PAUL J. WILSON INTERCELL USA INC	IXIARO - CLNCL ASSESSMENT, SUMMARY BASES FOR REGULATORY ACTION (UNREDACTED)
2013-6140	08/08/2013 09/06/2013	FDA/OGROP/ORR/CE-FO/MIN- DO/MIN-CB/	NOELLE SECHREST NESTLE NUTRITION	GERBER - EAU CLAIRE EIR 9/17-21/12; GATEWAY 6/5-8/12
2013-6141	08/08/2013 09/06/2013	FDA/OFVM/CFSAN/OCD/EOS/	THOMAS HASKINS GARDERE WYNNE SEWELL LLP	IRRADIATION PROCESS CORR 2006 TO PRESENT
2013-6142	08/09/2013 09/09/2013	FDA/OC/OES/DFOI/	BRODY MULLINS WALL STREET JOURNAL	2012-9102
2013-6143	08/09/2013 09/09/2013	FDA/OC/OES/DFOI/	BRODY MULLINS WALL STREET JOURNAL	2012-9102 - RESP LTR
2013-6144	08/09/2013 09/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GHORMLEY 138287 WTSP, ANTHONY T	LAMICTAL 25 MG - AERS
2013-6145	08/09/2013 09/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GHORMLEY 138287 WTSP, ANTHONY T	BUSE BARR - AERS

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2013-6146	08/09/2013 09/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	RENEE HAZELWOOD COCHLEAR AMERICAS	COCHLEAR LTD, LANE COVE, AUSTRALIA - EIR 4/8-11/13
2013-6147	08/09/2013 09/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	KRUSE, JANICE	BARD PERIPHERAL VASCULAR INC, TEMPE, AZ - FINESSE ULTRA BREAST BIOPSY SYS K093068
2013-6148	08/09/2013 09/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	SIBERY, MATTHEW	CIRCULATORY SYS DVC PANEL 4/7/97; CLNCL CHEMISTRY & CLNCL TOXICOLOGY DVCS PANEL 3/20/97; DENTAL PRODS PANEL 2/12/97, ETC - CONFILICT WAIVERS FOR PARTICIPANTS
2013-6149	08/09/2013 09/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELLIOT FAVUS FAVUS INSTITUTIONAL RESEARCH LLC	EXPAREL (BUPIVACAINE LIPOSOME INJ SUSPENSION) - AERS
2013-6150	08/09/2013 09/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	CHANDRAN TIRUVATTAR DR REDDY'S LABORATORIES INC	ACS DOBFAR INFO SA - ZOLEDRONIC ACID NDA 203-231 SBA
2013-6151	08/09/2013 09/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PAMELA SHEPPARD TARO PHARMACEUTICALS U.S.A., INC	G & W LABS - METRONIDAZOLE CREAM NDA 77-549, GALDERMA LABS LP - METROCREAM (MEETRONIDAZOLE) NDA 20-531 SBA
2013-6152	08/09/2013 09/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELENA HOWELL HOGAN LOVELLS US LLP	APOTEX INC - CANDESARTAN CILEXETIL ORAL TABS ANDA 202-079 APRVL LTR 8/2/13
2013-6153	08/09/2013 09/09/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	HECKADON, RONALD G	MAMMOGRAPHY FACILITY INSP - 55337, 55130, 55104, ETC RESULTS, VIOLATIONS 3/15/13-8/1/13
2013-6154	08/09/2013 09/09/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Doe J	STACKER 2 DIET PILLS - CMLPNTS 2/1/12 TO 8/5/13
2013-6155	08/09/2013 09/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bonnie Williams FOI Services, Inc.	BLA 103000 S 5050

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2013-6156	08/09/2013 09/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Scott Marmer Theranos, Inc.	K093910
2013-6157	08/09/2013 09/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Bonnie Williams FOI Services, Inc.	K123700
2013-6158	08/09/2013 09/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Scott Marmer Theranos, Inc.	K031359
2013-6159	08/09/2013 09/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	David Karshmer Avisa Pharma, Inc.	K041148
2013-6160	08/09/2013 09/09/2013	FDA/OC/OES/DDM/	GLORIA GASKINS KLEINFELD KAPLAN & BECKER	DKT 1994P-0077, 1997P-0386, ETC.
2013-6161	08/09/2013 09/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Scott Marmer Theranos, Inc.	K103041
2013-6162	08/09/2013 09/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Bonnie Williams FOI Services, Inc.	K130079
2013-6163	08/09/2013 09/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Bonnie Williams FOI Services, Inc.	K112820
2013-6164	08/09/2013 09/09/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	BRETT PARK CONWAY HOMER & CHIN- CAPLAN PC	INDIVIDUAL RECS (CERTIFIED)
2013-6165	08/09/2013 09/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Bonnie Williams FOI Services, Inc.	K094030
2013-6166	08/09/2013 09/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Elisa Murillo Pearson, Randall & Schumacher, P.A.	P860004
2013-6167	08/09/2013 09/09/2013	FDA/OC/OES/DDM/	TODD MACK WESTLAW COURT EXPRESS	DKT 1988P-0369, 2001P-0122, ETC.
2013-6168	08/09/2013 09/09/2013	FDA/OGROP/ORANE-FO/NYK- DO/NYK-DCB/ FDA/OMPT/CDRH/OCER/DFOI/	Dan Goldsmith X-Laser	LASERWORLD AG, LASERWORLD USA - ACTIONS, WARNING LETTERS, ETC (01/01/2008 - 08/07/2013)
2013-6169	08/09/2013 09/09/2013	FDA/OC/OES/DFOI/	ROBERT P CHARROW GREENBERG TRAURIG LLP	MEDTRONIC XOMED INC - LASER-SHIELD II ENDOTRACHEAL TUBE

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2013-6170	08/09/2013 10/11/2013	OC/ORO/ OC/ORO/ OC/ORO/ORO/DFS/ OC/ORO/ORO/DFS/ FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/ OC/ORO/	BLAZE, D'LANIE	FUKUSHIMA DAI' ICHI NUCLEAR PLANT - ACTIVE & INACTIVE MULTIPLE AGREEMENTS, E-MAIL CORR, TESTS, ETC
2013-6171	08/09/2013 09/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PHYLLIS B. KENT KENT ASSOCIATES INC	DR MARTIN ZAIAC - INSP MEMO TO FILE 8/812
2013-6172	08/09/2013 09/09/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	TED A. NOVICK GAINES NOVICH ET AL	MAUDE RPT 2520313-2011-0018 MEDRAD AVANTA FLUID MGMT INJECTION SYS ANGIOGRAPHIC INJECTOR
2013-6173	08/12/2013 09/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Caroline Palomeque JMP Securities	TACFIDERA - AERS
2013-6174	08/12/2013 09/10/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	Bill Anderson Bill Anderson	CEDAR GROVE CHEESE INC, PLAIN, WI - INSPECTION REPORTS SINCE 2000; TEST RESULTS
2013-6175	08/12/2013 09/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Gillham Joan Gillham	NDA 017456 - APPROVAL, DISCONTINUATION DATES
2013-6176	08/12/2013 09/10/2013	FDA/OFVM/CFSAN/OCD/EOS/	A. Philip Leber A. Philip Leber Consulting	FCN 1183
2013-6177	08/12/2013 09/10/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	Jack Beidleman Idahoan Foods, LLC	IDAHOAN FOODS, LEWISVILLE, ID - INSPECTOR NOTES 08/01/2013
2013-6178	08/12/2013 09/12/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	John Carey FOI Services, Inc.	ORIGINAL LICENSING FILES FOR VACCINE PRODUCTS UNDER THE BIOLOGICS CONTROL 1902
2013-6179	08/12/2013 09/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Scott Marmer Theranos, Inc.	K093972
2013-6180	08/12/2013	FDA/OMPT/CDER/GRP/DIDP/	Thomas Quail	N-ACETYLCYSTEINE - AERS

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	09/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Quail, Thomas	
2013-6181	08/12/2013 09/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Phillip Guerra AirwayTec	K760488
2013-6182	08/12/2013 09/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	alexander m m shepherd MD PhD UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO	GLYCOPYRROLATE - AERS
2013-6183	08/12/2013 09/10/2013	FDA/OC/OES/DFOI/	Megan Pickel Beveridge & Diamond, PC	CFSAN FOIA REQUESTS 07/01/2013 TO PRESENT
2013-6184	08/12/2013 09/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	shin kang WELLS FARGO	VIROPHARMA, NETHERLANDS, BELGIUM - 483, WARNING LETTER, EIR (01/01/2013 - 08/09/2013)
2013-6185	08/12/2013 09/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tom Namsavanh IntelGenx Corp.	ANDA 076762
2013-6186	08/12/2013 09/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Haram Kang UNIVERSITY OF ILLINOIS AT CHICAGO	TICAGRELOR - AERS
2013-6187	08/12/2013 09/10/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Shirley Roberson OMRON HEALTHCARE INC	K122458
2013-6188	08/12/2013 09/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Sew-Wah Tay Libra Medical	K111576
2013-6189	08/12/2013 09/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Frederic mMorneau Duchesnay Inc.	NDA021876
2013-6190	08/12/2013 09/10/2013	FDA/OGROP/ORO/PA-FO/SAN- DO/SAN-CB/	Doe J	SAN FRANCISCO HERB AND NATURAL FOOD CO, FREEMONT, CA - INVESTIGATION RECS 06/01/2012 - 09/30/2012

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2013-6191	08/12/2013 09/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Andrew Vaino Retrophin Inc.	NDA 009854
2013-6192	08/12/2013 09/10/2013	FDA/OC/OES/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CTP/OD/	Eric Tucker THE ASSOCIATED PRESS	STAR SCIENTIFIC - REPORTS, APPLICATIONS, UPDATED ETC
2013-6193	08/12/2013 09/10/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	ROBERT KING FDA NEWS	SHOWLINE AUTOMOTIVE PRODUCTS INC, US SOAPS MFG CO, RALEIGH, NC - 483 7/13
2013-6194	08/12/2013 09/10/2013	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	ROBERT KING FDA NEWS	BELL MOORE LABORATORIES INC, HAMPSTEAD, MD - 483 7/13
2013-6195	08/12/2013 09/10/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	ROBERT KING FDA NEWS	AVATAR CORP, UNIVERSITY PARK,IL ; HYDROX CHEMICAL CO, ELGIN, IL - 483 7/13
2013-6196	08/12/2013 09/10/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	ROBERT KING FDA NEWS	SELECTIVE MED COMPONENTS INC, MOUNT VERNON, OH - 483 7/13
2013-6197	08/12/2013 09/10/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	ROBERT KING FDA NEWS	HUMCO HOLDING GROUP INC, TEXARKANA, TX; ESTILL MEDICAL TECHNOLOGIES INC, DALLAS, TX - 483 7/13
2013-6198	08/12/2013 09/10/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	ROBERT KING FDA NEWS	LOS ALAMOS NATIONAL LABORATORY, LOS ALAMOS, NM - 483 7/13
2013-6199	08/12/2013 09/10/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	ROBERT KING FDA NEWS	BEACON HILL MEDICAL PHARMACY PC, SOUTHFIELD, MI; COOK BIOTECH INC, WEST LAFAYETTE, IN - 483 7/13
2013-6200	08/12/2013 09/10/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	ROBERT KING FDA NEWS	BAUSCH & LOMB, TAMPA, FL; LIFESAVING SYSTEMS CORP, APOLLO BEACH, FL; LENSTEC INC, ST PETERSBURG, FL - 483 7/13
2013-6201	08/12/2013 09/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ROBERT KING FDA NEWS	BRISTOL MYERS SQUIBB, ANAGNI, ITALY; SANOFI AVENTIS DEUTSCHLAND GMBH, FRANKFURT AM MAIN, GERMANY; ACS DOBFAR SPA, MILAN, ITALY - 483 7/13
2013-6202	08/12/2013 09/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	ROBERT KING FDA NEWS	SANOFI AVENTIS DEUTSCHLAND GMBH, FRANKFURT AM MAIN, GERMANY; UNIDUS CORP, CHUNGBUK, SOUTH KOREA; BRAHMS GMBH, HENNINGSDORF, GERMANY - 483 7/13
2013-6203	08/12/2013 09/10/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	ROBERT KING FDA NEWS	ESSEX CYROGENICS OF MISSOURI, KANSAN CITY, MO; DENTAL DESIGNS LABORATORY, LINCOLN, NE; GLOBAL MEDICAL HOLDINGS LLC, ADEL, IO - 483 7/13

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2013-6204	08/12/2013 09/10/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	ROBERT KING FDA NEWS	BIOELECTRIC RESEARCH CORP, PASADENA, CA; KDL PRECISION MOLDING, PACOIMA, CA; DEN MAT HOLDINGS LLC, LOMPOC, CA - 483 7/13
2013-6205	08/12/2013 09/10/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	ROBERT KING FDA NEWS	AMRI BURLINGTON INC, BURLINGTON, MA; SIRTEX WILMINGTON LLC, WILMINGTON, MA; NOVA BIOMEDICAL CORP, BILLERICA, MA - 483 7/13
2013-6206	08/12/2013 09/10/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	ROBERT KING FDA NEWS	ASHLAND SPECIALITY INGREDIENTS, CHATHAM, NJ; PERMA PURE LLC, TOMS RIVER, NJ - 483 7/13
2013-6207	08/12/2013 09/10/2013	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	ROBERT KING FDA NEWS	AIONEX INC, GOODLETTSVILLE, TN; VIRTUAL SUN LLC, JEMISON, AL - 483 7/13
2013-6208	08/12/2013 09/10/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	ROBERT KING FDA NEWS	ADVANCE PHARMACEUTICAL INC, HOLTSVILLE, NY; AMNEAL PHARMACEUTICALS, BROOKHAVEN, NY; PINE PHARMACY & HOME CARE PRODUCTS CTR INC, WILLIAMSVILLE, NY - 483 7/13
2013-6209	08/12/2013 09/10/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	ROBERT KING FDA NEWS	PIRAMAL CRITICAL CARE INC, BETHLEHEM, PA; DRAEGER MEDICAL SYSTEMS INC, TELFORD, PA; DRAEGER MEDICAL INC, TELFORD, PA - 483 1/13
2013-6210	08/12/2013 09/10/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	ROBERT KING FDA NEWS	FORMULATION TECHNOLOGY INC, OAKDALE, CA; BIO RAD LABORATORIES INC, HERCULES, CA; TOPCON MEDICAL LASER SYSTEMS INC, SANTA CLARA, CA - 483 7/13
2013-6211	08/12/2013 09/10/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	ROBERT KING FDA NEWS	NEO METRICS INC, PLYMOUTH, MN; INCONTROL MEDICAL LLC, BROOKFIELD, WI - 483 7/13
2013-6212	08/12/2013 09/10/2013	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	ROBERT KING FDA NEWS	UNIV OF WASHINGTON PET RADIOCHEMISTRY LABORATORY, SEATTLE, WA; KIRKMAN GROUP INC, LAKE OSWEGO, OR; ENDOGASTRIC SOLUTIONS INC, REDMOND, WA - 483 7/13
2013-6213	08/12/2013 09/10/2013	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	ROBERT KING FDA NEWS	GASCO INDUSTRIAL, GURABO, PR; PFIZER PHARMACEUTICALS, VEGA BAJA, PR - 483 7/13
2013-6214	08/13/2013 09/11/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Danielle Stampley Labaton Sucharow LLP	INTUITIVE SURGICAL - EIR, WARNING LETTERS, 483 ETC (01/01/2011 - 08/12/2013)
2013-6215	08/13/2013 09/11/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Danielle Stampley Labaton Sucharow LLP	INTUITIVE SURGICAL - APPROVAL RECS, INSPECTION RECS
2013-6216	08/13/2013 09/11/2013	OC/ORA/ OC/ORA/	JOSHUA GAYNOR CBS NEWS	SPECIALTY COMPOUNDING, LLC, CEDAR PARK, TX - 483
2013-6217	08/13/2013	FDA/OMPT/CDER/ERP/DIDP/	John Robinson	WOCKHARDT LIMITED, MAHARASHTA, INDIA - 483

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	09/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BluePoint Laboratories	(07/01/2013 - 08/12/2013)
2013-6218	08/13/2013 09/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Hllary Healy Hilary Healy	XOLAIR - AERS
2013-6219	08/13/2013 09/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	William Sietsema Sietsema, William	NDA 21743 S0003
2013-6220	08/13/2013 09/11/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Doe J	INDIVIDUAL RECS
2013-6221	08/13/2013 09/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Soma Das The Economic Times, The Times of India	USV LTD, MUMBAI, INDIA - 483 06/01/2012 - 08/12/2013
2013-6222	08/13/2013 09/11/2013	OC/ORA/ORM/ OC/ORA/ORM/	Mark Prinz Registrar Corp	FOREIGN FOOD FACILITIES THAT RECEIVED 483 FROM INSPECTION 07/01/2013 - 07/31/2013
2013-6223	08/13/2013 09/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	David Karshmer Avisa Pharma, Inc.	K011668, K130524
2013-6224	08/13/2013 09/11/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/CVM/OCD/ FDA/OFVM/CFSAN/OCD/EOS/	Anthony L. Osborn Goosmann Law Firm, PLC	CHONDROITIN SULFATE, TRYPSIN - PRODUCTION, MANUFACTURE, DISTRIBUTION ETC
2013-6225	08/13/2013	FDA/OC/OES/DFOI/	Desmond Jenson	CTP FOIA REQUEST LOG 06/22/2009 - 08/12/2013

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	09/11/2013		Tobacco Control Legal Consortium	
2013-6226	08/13/2013 09/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mahidhar Chinta Micro Labs USA, Inc	CHLORDIAZEPOXIDE, AMITRIPTYLINE HYDROCHLORIDE - SBA
2013-6227	08/13/2013 09/11/2013	FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA REQUEST LOG 08/05/2013 - 08/09/2013
2013-6228	08/13/2013 09/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Thaddeus Ritch EOHSI - Rutgers RWJMS	FDA DRUG SAFETY COMMUNICATION RE ANTIMALARIAL DRUG MEFLUQUINE HYDROCHLORIDE - NOTES, PROCEDURES, DATA REVIEWED ETC
2013-6229	08/13/2013 09/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHRISTOPHER BRENNAN WESTLAW COURT EXPRESS	JANUVIA (SITAGLIPTIN) NDA 21-995 - MEDICAL, SCIENTIFIC SAFETY RVWS, CORR, MINS, ETC
2013-6230	08/13/2013 09/11/2013	FDA/OC/OES/DDM/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DDM/	CHRISTOPHER BRENNAN WESTLAW COURT EXPRESS	FDA BIOEQU HEARING - TRANS, EXHIBIT 4 9/29/86-10/1/86
2013-6231	08/13/2013 09/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	RONALD G VAN VALEN NOVARTIS PHARMACEUTICAL CORP	FUJIREBIO DIAGNOSTICS INC, MALVERN, PA - ARCHITECT SIROLIMUS ASSAY; K070822
2013-6232	08/13/2013 09/11/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	MITCHELL, ERIC	ONE LAMBDA INC, CANOGA PARK, CA - HLA FUSION SOFTWARE BK120014
2013-6233	08/13/2013 09/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	LOFGREN, TRACY	CONMED CORP, UTICA, NY - INTRAVASCULAR CATHETER SECUREMENT K935389 ACCEPTANCE LTR, RPT
2013-6234	08/13/2013 09/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	INDIVIDUAL RECS
2013-6235	08/13/2013 09/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	Marion Tong MPT Consulting Marion Tong	K080451, K040763, K002680
2013-6236	08/13/2013	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/		ETHICON - US/MN-SUTURE ABSORBABLE, NON ABSORBABLE ENTRY AV3-0040036-1

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	09/11/2013		Doe J	
2013-6237	08/13/2013 09/11/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	JAVIER COLLAZO RespCare	VENTUS MEDICAL INC - PROVENT PROFESSIONAL SLEEP APNEA THERAPY K090398
2013-6238	08/13/2013 09/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PHYLLIS B KENT KENT ASSOCIATES INC	DR MARTIN ZAIAC - MEMO 8/8/12
2013-6239	08/13/2013 09/11/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Andrea C. Williams Andrea C. Williams	STUDIES SHOWING EFFICACY OF ULTHERA MACHINE ON SAGGING/WRINKLES NECK SKIN
2013-6240	08/13/2013 09/11/2013	OC/ORA/ OC/ORA/	SARAH SORSHER PUBLIC CITIZEN (HEALTH RESEARCH GROUP)	SPECIALTY COMPOUNDING LLC - 483 MINOR DELETIONS
2013-6241	08/13/2013 09/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DON J MIZERK HUSCH BLACKWELL LLP	TEVA PHARMS, ACTAVIS ELIZABETH, BARR LABS INC - AMPHETAMINE ASPARTERTE, AMPHETEMINE SULFATE, DEXTROAMPHETAMIN SACCHARATE ANDA 77-4488, ANDA 77302, ANDA 76536, ETC APRVL LTR 4/29/13, 6/22/12, 2/12/13
2013-6242	08/13/2013 09/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID M HOFFMEISTER WILSON SONSINI ET AL	RANBAXY LABORATORIES LTD, MOHALI, INDIA - ESOMEPRAZXOLE MAGESIUM ANDA 77-830 APRVL LTR 2/5/08, 483 1/1/12, 8/9/13
2013-6243	08/13/2013 09/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHRISTOPHER BRENNAN WESTLAW COURT EXPRESS	JANUMET (SITAGLIPHTIN (METFORMIN) NDA 22-044 - MEDICAL, SCIENTIFIC RVWS, CORR, MINS, ETC
2013-6244	08/13/2013 09/11/2013	FDA/OFVM/CFSAN/OCD/EOS/	EDWARD B GERARD ROBBINS ARROYO LLP	STAR SCIENTIFIC - ANATABLOC DEVELOPMENT, PROMOTION, REGULATION/SALE
2013-6245	08/13/2013 09/11/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORO/ORO/DIOP/	DONALD BLUE GLOBAL TRADE INTELLIGENCE INC	ENTRY 20130809-1 7/16/13-8/15/13
2013-6246	08/13/2013 09/11/2013	FDA/OC/OES/DFOI/	ANAIS VAILLANT MUCKROCK NEWS	AIRLINE DRINKING WATER INSP (PREVIOUSLY RELEASED)
2013-6247	08/13/2013 09/11/2013	FDA/OMPT/CTP/OD/	MARILYNN WHITNEY COVINGTON & BURLING LLP	MENTHOL VERSUS NONMENTHOL CIGARETTES - RPTS, ANALYSES, RESULTS, ETC 7/24/13

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2013-6248	08/13/2013 09/11/2013	FDA/OMPT/OSMP/OOPD/	ALAN CASH Terra Biological LLC	ORBAN BIOTECH LLC, BROOKLINE, MA - ORENCIA (ABATACEPT) ORPHAN DRUG APPL 5/30/13
2013-6249	08/13/2013 09/11/2013	FDA/OMPT/OSMP/OOPD/	ALAN CASH Terra Biological LLC	PENTWECH PHARMACEUTICALS INC, BUFFALO GROVE, IL - APOMORPHINE ORPHAN DRUG APPL 7/17/95
2013-6250	08/13/2013 09/11/2013	FDA/OFVM/CFSAN/OCD/EOS/	FRIEDMAN, ROBERT	KRAFT, WISHBONE, HIDDEN VALLEY SALAD DRESSING, ETC - CAERS 1969 TO 2013
2013-6251	08/13/2013 09/17/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDRH/OCER/DFOI/	FRANK S WILTON AMERICAN ASSOCIATION OF TISSUE BANKS	RECOMMENDATION OF THE TISSUE REFERENCE GROUP (TRG) - STAKEHOLDER SUBMISSIONS 2013
2013-6252	08/13/2013 09/11/2013	FDA/OC/OES/DFOI/	Margaret Sestrom PFIZER	483 for Dr. Malhotra B2061028 9002/018 Site 1055 Malhotra QR 72431
2013-6253	08/13/2013 09/11/2013	FDA/OC/OES/DFOI/	shin kang WELLS FARGO	pre-approval inspection form 483 and company response to the form 483 for Biomarin Pharmaceutical
2013-6254	08/14/2013 09/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 203565
2013-6255	08/14/2013 09/12/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Daniel Machian Los Angeles Department of Coroner	BREAST IMPLANT MCGHAN 168 300CC SN 11252169 LOT 1031234
2013-6256	08/14/2013 09/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rick Miller ProtoMED Inc	K103136
2013-6257	08/14/2013 09/12/2013	FDA/OFVM/CFSAN/OCD/EOS/	Kevin Fries COSMETIC INGREDIENT REVIEW	PAFA DATABASE
2013-6258	08/14/2013 09/12/2013	FDA/OC/OES/DFOI/	Daniel Machian Los Angeles Dept of Coroner	ALLERGAN, Style 68MP 390cc, Lot 1838586
2013-6259	08/14/2013 09/12/2013	FDA/OFVM/CFSAN/OCD/EOS/	Duane Stanford BLOOMBERG NEWS	HERBALIFE, ENSURE, SLIM-FAST - AERS
2013-6260	08/14/2013 09/12/2013	FDA/OC/OES/DFOI/	Jason A Dean Hulsey Oliver & Mahar, LLP	2013-4472 (CERTIFIED)
2013-6261	08/14/2013 09/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Eric D. tindal Nidey Erdahl Tindal & Fisher, PLC	ACORDA THERAPEUTICS WARNING LETTER - COMPANY RESPONSE ETC (07/01/2013 - 08/13/2013)

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2013-6262	08/14/2013 09/12/2013	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2013-4703
2013-6263	08/14/2013 09/12/2013	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2013-1338
2013-6264	08/14/2013 09/12/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SW-FO/KAN-DO/KAN-CB/	Fenella Cochrane Parnell Corporate Services US Inc	TEST RESULTS
2013-6265	08/14/2013 09/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	Indeep Aulak Response Point of Care, Inc.	K121214
2013-6266	08/14/2013 09/12/2013	FDA/OC/OES/DFOI/	Andrea Ferrenz Celltex Therapeutics Corporation	CELLTEX THERAPEUTICS CORPORATION - FOIA REQUESTS (03/18/2011 - 08/30/2013), 2012-5692, 2012-8891, 2013-2838
2013-6267	08/14/2013 09/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jamie Ridner COOK INCORPORATED	LATECBA DEVICE - IDE, SAFETY AND EFFECTIVENESS DATA
2013-6268	08/14/2013 09/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	Brian Hewko Brian Hewko	510K CLEARED FOR BONE WEDGE OR RECONSTRUCTION DEVICE MADE FROM PEEK BASED MATERIALS
2013-6269	08/14/2013 09/12/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/NE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	George Perham Dickinson Brands	ANALYTICAL RESULTS
2013-6270	08/14/2013 09/12/2013	OC/ORO/OE/ OC/ORO/OE/	Jeremy Graston Jeremy Graston	ARCHIVED RECALL DATA BEFORE 2004
2013-6271	08/14/2013 09/12/2013	FDA/OC/OES/DFOI/	Bennie Lee Cheatham, Jr Bennie Lee Cheatham, Jr.	PRESCRIPTION INFORMATION
2013-6272	08/14/2013 09/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS Consulting Group, LLC	BACTROBAN NASAL OINTMENT NDA 50-703 APRVL LTR, LBLG, MED RVW
2013-6273	08/14/2013	FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/	HENRY KIANG, Ph.D.	FEI 3000323451 5/16-23/12

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	09/12/2013		PHARMOUT	
2013-6274	08/14/2013 09/12/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	PATRICK ORR PATRICK ORR BARRISTER & SOLICITOR	VITEK INC - IMPLANT DOCS
2013-6275	08/14/2013 09/30/2013	FDA/OC/OES/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	FORD, RAHMAN A	AUTOLOGOUS (HOMOLOGOUS) STEM CELLS - POLICIES, PROCEDURES, CLNCL USE, ETC
2013-6276	08/14/2013 09/12/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	COLLEEN GRACE DONOFRIO BABST CALLAD CLEMENTS ET AL	GILES CHEMICAL, WAYNESVILLE, NC - EIR 8/12
2013-6277	08/14/2013 09/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	LESTER MAYERS, MD Pace University	IMPACT CONCUSSION ASSESSMENT PROGRAM 3/12
2013-6278	08/14/2013 09/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	ADAM M. DLUGACZ HPM&B ATTYS AT LAW	ST JUDE MEDICAL 6F ANGIO SEAL VASCULAR CLOSURE DVC 2000 TO 2013
2013-6279	08/14/2013 09/12/2013	FDA/OFVM/CFSAN/OCD/EOS/	MARILYNN WHITNEY COVINGTON & BURLING LLP	LTRS TO MICHAEL M LANDA 6/3/13
2013-6280	08/15/2013 09/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Albin Pearson Albin Pearson	REGEAR LIFE SCIENCES REBOUND - CLEARANCE RECS
2013-6281	08/15/2013 09/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	James Chen CREDIT SUISSE	TECFIDERA - AERS
2013-6282	08/15/2013 09/13/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Deborah Guercio THE BROOKLYN HOSPITAL CENTER	MORRELL M AVRAM - INSPECTION RECS 1/28/04
2013-6283	08/15/2013 09/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sean Higgins ANDREWS & THORNTON	MITOMYCIN - AERS
2013-6284	08/15/2013 01/13/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Mary Gustafson PPTA	LETTER FROM FDA TO PPTA 8/5/13
2013-6285	08/15/2013 09/13/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	Gretchen Ramos Ramos, Gretchen A	POMEGRANATE SEED RECALL - INVESTIGATIVE RECS
2013-6286	08/15/2013	FDA/OMPT/CDER/GRP/DIDP/	Michael Prudhomme	ZESTRIL - AERS FROM PHASE 1 AND 2 STUDIES

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	09/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Naval Aerospace Medicine Institute	
2013-6287	08/15/2013 09/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Anita Zacherl for OsteoMed OSTEOMED CORP	K924138
2013-6288	08/15/2013 09/13/2013	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	JET CIGARETTES - REGISTRATION, PRODUCT LISTING, INGREDIENTS ETC
2013-6289	08/15/2013 09/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Christopher B. Swanson ADVANCED STERILIZATION PRODUCTS	K123768
2013-6290	08/15/2013 09/13/2013	FDA/OC/OES/DDM/	Larry Biegelsen Wells Fargo Securities, LLC	DRAFT GUIDANCE RE CYCLOSPORINE - COMMENTS 06/20/2013 - 08/20/2013
2013-6291	08/15/2013 09/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Peter Mattesson HOTSWAP STOCKHOLM AB	K030289
2013-6292	08/15/2013 09/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Peter Mattesson HOTSWAP STOCKHOLM AB	K984053
2013-6293	08/15/2013 09/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Peter Mattesson HOTSWAP STOCKHOLM AB	K914735
2013-6294	08/15/2013 09/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Peter Mattesson HOTSWAP STOCKHOLM AB	K962928
2013-6295	08/15/2013 09/13/2013	FDA/OGROP/ORR/SE-FO/NOL-DO/NOL-CB/	Joanna McCracken Hall Booth Smith, P.C.	MAIN STREET FAMILY PHARMACY, NEWBERN, TN - INSPECTION RECS (03/15/2013 - 08/14/2013)
2013-6296	08/15/2013 09/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachelle Lyon JANUS CAPITAL GROUP INC	TECFIDERA - AERS
2013-6297	08/15/2013 09/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michael Manapol Law Offices of Brian D. Witzer, Inc.	ANDA 065156
2013-6298	08/15/2013 09/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Joseph E. Schwarz Natus Medical Incorporated	K111737
2013-6299	08/15/2013	FDA/OGROP/ORR/CE-FO/PHI-DO/PHI-CB/	Jon Mulberg	ANIMUS CORPORATION - EIR ATTACHMENT 5 3/25/2013 - 4/12/2013

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	09/13/2013		Animas Corporation	
2013-6300	08/15/2013 09/13/2013	FDA/OFVM/CFSAN/OCD/EOS/	ALISON YOUNG USA TODAY	WOW (REUMOFAN) - CAERS 151929, 151974, 153108. ETC
2013-6301	08/15/2013 09/13/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	JENNIFER ZACHARY COVINGTON & BURLING LLP	LLOYD LLC - 483 4/16/13
2013-6302	08/15/2013 09/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	FRANK E PISCITELLI JR PISCITELLI LAW FIRM	BOSTON SCIENTIFIC - GREENFIELD VENA CAVA FILTER MDRS
2013-6303	08/15/2013 09/13/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	ROBYN S MAGUIRE NUTTER MCCLENNEN & FISH LLP	DEPUY ORTHOPAEDICS INC - PINNACLE HIP IMPLANTS, METAL-ON-METAL PROSTHETIC HIP IMPLANTS RECS; WALLACE GREGORY SAWYER PHD, MARTIN K MCDERMOTT PHD, JOHN A TICHY PHD CORR, ETC
2013-6304	08/15/2013 09/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CRAIG TRAUTMAN INTAGRAS INC	DRUG LISTINGS NOT POSTED ON THE NATIONAL LIBRARY OF MEDICINE (NLM) WEBSITE, ESTABLISHMENT REGISTRATIONS, LABELER CODES
2013-6305	08/15/2013 09/13/2013	FDA/OC/OES/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OCC/	KEN CUMMINS CAPITOL GROUP	HEATHER BRESCH, MYLAN PHARMACEUTICALS INC - VISITATION LOGS FOR OFFICE OF THE COMMISSIONER, GENERAL COUNSEL, OFFICE OF GENERIC DRUGS, ETC 1/11 TO PRESENT
2013-6306	08/15/2013 09/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	MANDY J KAMYKOWSKI GREENSFELDER HEMKER & GALE PC	CYNOSURE SMART LIPO - MDRS
2013-6307	08/15/2013 09/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MANDY J KAMYKOWSKI GREENSFELDER HEMKER & GALE PC	SODIUM BICARBONATE - AERS
2013-6308	08/15/2013 09/13/2013	FDA/OC/OES/DDM/	DANYSH, KURT	PROZAC - CITIZNES COMMISSION ON HUMAN RIGHTS CITIZEN PETITION 10/11/90; PUBLIC CITIZEN HEALTH RESEARCH GROUP CITIZEN PETITION 5/91, ETC
2013-6309	08/15/2013 09/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DANYSH, KURT	PAXIL, ZOLOFT, CELEXA, ETC - AERS

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2013-6310	08/15/2013 09/13/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	STEVEN ELDER CAMPBELL TOBACCO REHANDLING COMPANY INC	CELTAB INC, MADISON, IN - EIR
2013-6311	08/15/2013 09/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SPENCER #13716219, NATHAN	ABILIFY, SEROQUEL - SAFETY STANDARDS, PUBLIC HEALTH ADVISORY, HEARINGS, ETC
2013-6312	08/15/2013 09/13/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	THOMPSON, RAY	AGFA HEALTHCARE CORP, CARLSTADT, NJ 3/11-29/13; BIO-MED USA INC, PATERSON, NJ 1/9-23/13; GENESIS BPS LLC, HACKENSACK, NJ 2/4-11/13, ETC - 483S
2013-6313	08/15/2013 09/13/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	THOMPSON, RAY	BALASSA LABORATORIES INC, PORT ORANGE, FL 2/13-19/13; CARIBE NATURAL LLC, MIAMI, FL 3/5-18/13; INSIGHT INSTRUMENTS INC, STUART, FL, ETC - 483S
2013-6314	08/15/2013 09/13/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	THOMPSON, RAY	CONTINENTAL MANUFACTURING CHEMIST INC, MADRID, IA 3/6-15/13; CENTRAL ADMIXTURE PHARMACY SERVICES INC, KANSAS CITY, MO 2/19-27/13; MEGA SUN INC, ST LOUIS, MO 2/28/13-3/6/13, ETC - 483S
2013-6315	08/15/2013 09/13/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	THOMPSON, RAY	AMERICAN ANTIBIOTICS INC, BALTIMORE, MD 3/5-28/13; MATH RESOLUTION LLC, COLUMBIA, MD 1/7-25/13; TRINITY STERILE INC, SALISBURY, MD 2/12-13/13, ETC - 483S
2013-6316	08/15/2013 09/13/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	THOMPSON, RAY	SPEED LABORATORY INC, BUFORD, GA 1/2-8/13; AMBIOPHARM INC, NORTH AUGUSTA, SC 3/26-28/13; STEWART COMPOUNDING PHARMACY, FAYETTEVILLE, NC 3/18-25/13, ETC - 483S
2013-6317	08/15/2013 09/13/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	THOMPSON, RAY	CATALENT PHARMA SOLUTIONS LLC, WINCHESTER, KY 1/28/13-2/5/13; PI PHARMA INC, CAMPTON, KY 1/29/13-2/22/13; ORTHOHELIX SURGICAL DESIGNS INC, MEDINA, OH 1/15-31/13, ETC - 483S
2013-6318	08/15/2013 09/13/2013	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	THOMPSON, RAY	ALMA LASERS INC, BUFFALO GROVE, IL 1/17-29/13; ENDOPLUS INC, BUFFALO GROVE, IL 2/21-26/13; HYDRITE CHEMICALS, UNIVERSITY PARK, IL 3/7-18/13, ETC - 483S
2013-6319	08/15/2013 09/13/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	THOMPSON, RAY	BIOMEDIX INC, BLOOMINGTON, IN 2/5/13-3/4/13; ASPEN SURGICAL PRODUCTS INC, CALEDONIA, MI 2/4-15/13; CAYMAN CHEMICAL COMPANY INC, ANN ARBOR, MI 2/21-28/13, ETC - 483S
2013-6320	08/15/2013 09/13/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	THOMPSON, RAY	COOPER SURGICAL INC, TRUMBULL, CT 12/17/12-1/16/13; BFS PHARMA INC, RANDOLPH, MA 12/10/12-1/17/13; BIOGEN IDEC INC, CAMBRIDGE, MA 3/4-15/13, ETC - 483S
2013-6321	08/15/2013 09/13/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	THOMPSON, RAY	LEE AND COMPANY, FORT SMITH, AR 2/19-21/13; ALOE VERA OF AMERICA INC, DALLAS, TX 12/14/12-1/11/13; MID-CONTINENT PACKAGING INC, ENID, OK 1/17-24/13, ETC -

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				483S
2013-6322	08/15/2013 09/13/2013	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	THOMPSON, RAY	BEZWECKEN INC, WILSONVILLE, OR 11/27/12-1/7/13; GENESIS NORTHWEST INC, PORTLAND, OR 1/2-18/13; ENDOGASTRIC SOLUTIONS INC, REDMOND, WA 1/16-25/13, ETC - 483S
2013-6323	08/15/2013 09/13/2013	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	THOMPSON, RAY	AGROPHARMA LABORATORIES INC, SALINAS, PR 2/25/13-3/20/13; CARDINAL HEALTH PR 218 INC, ANASCO, PR 1/22-29/13; JANSSEN ORTHO LLC, GURABO, PR 1/17/13-2/22/13, ETC - 483S
2013-6324	08/15/2013 09/13/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	THOMPSON, RAY	ADVANCE PHARMACEUTICAL INC, HOLTSVILLE, NY 1/3-11/13; AMRI RENSSELAER INC, RENSSELAER, NY 1/23-30/13; HYPERBARIC TECHNOLOGIES INC, AMSTERDAM, NY 2/11-20/13, ETC - 483S
2013-6325	08/15/2013 09/13/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	THOMPSON, RAY	ALLERGAN INC, IRVINE, CA 3/12-21/13; AMRON INTERNATIONAL, VISTA, CA 2/13-19/13; OPMX LLC, SAN DIEGO, CA 1/16/13-2/20/13, ETC - 483S
2013-6326	08/15/2013 09/13/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	THOMPSON, RAY	SPRAY-TEK INC, BETHLEHEM, PA 3/13-18/13; TROY MANUFACTURING INC, HAZLE TOWNSHIP, PA 2/6-12/13 - 483S
2013-6327	08/15/2013 09/13/2013	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	THOMPSON, RAY	EXXON MOBIL CHEMICAL CO, BATON ROUGE, LA 3/9-21/13; DOW CHEMICAL CO, PLAQUEMINE, LA 2/7-13/13; PETNET SOLUTIONS INC, COVINGTON, LA 1/14-17/13, ETC - 483S
2013-6328	08/15/2013 09/13/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	THOMPSON, RAY	ARIZANT HEALTHCARE INC, EDEN PRAIRIE, MN 3/14-28/13; ESCALON MEDICAL CORP, NEW BERLIN, WI 2/27/13-3/7/13; STEARNS PACKAGING CORP, MADISON, WI 3/11-20/13, ETC - 483S
2013-6329	08/15/2013 09/13/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	THOMPSON, RAY	AMGEN INC, BOULDER, CO 3/18-29/13; NOVARAD CORP, AMERICAN FORK, UT 3/4-11/13; BIOVISION TECHNOLOGIES LLC, GOLDEN, CO 2/11-20/13, ETC - 483S
2013-6330	08/15/2013 09/13/2013	FDA/OC/OES/DFOI/	JACQUELINE B KORT COOLEY LLP	2013-1699, 2013-2674, 2013-3623
2013-6331	08/15/2013 09/13/2013	FDA/OC/OES/DFOI/	JACQUELINE B KORT COOLEY LLP	2013-5596
2013-6332	08/16/2013 09/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	MELISSA EGAN Waters Corporation	DE NOVO - ORTHOPHOSPHATE TEST SYS K122282
2013-6333	08/16/2013 09/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	MELISSA EGAN Waters Corporation	THERMO SCIENTIFIC QMS TACROLIMUS IMMUNOASSAY, TACROLIMUS CALIBRATORS K123343
2013-6334	08/16/2013 09/16/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	MICRA BIOTECHNOLOGIES INC, RIVER EDGE, NJ - EIR, 483, CO 3/04/13

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2013-6335	08/16/2013 09/16/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	LINCARE INC, OTTAWA, KS - EIR, 483, CO RESP 01/16/13
2013-6336	08/16/2013 09/16/2013	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	FERRO PFANSTIEHL INC, WAUKEGAN, IL - EIR, 483, CO 02/11/13
2013-6337	08/16/2013 09/16/2013	FDA/OGROP/ORASE-FO/ATLDO/ATL-CB/	WALTER E CHALKLEY THOMSON REUTERS	CHARLES RIVER ENDOSAFE, CHARLESTON, SC - EIR, 483, CO RESP 01/15/13
2013-6338	08/16/2013 09/16/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	BIRCHWOOD LABORATORIES INC, EDEN PRAIRIE, MN - EIR, 483, CO RESP 01/07/13
2013-6339	08/16/2013 09/16/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	WALTER E CHALKLEY THOMSON REUTERS	AMRI RENSSLAER INC, RENSSLAER, NY - EIR, 483, CO RESP 01/30/13
2013-6340	08/16/2013 09/16/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	WALTER E CHALKLEY THOMSON REUTERS	AMPHASTAR PHARMACEUTICALS INC, RANCHO CUCAMONGA, CA - EIR, 483, CO RESP 02/06/13
2013-6341	08/16/2013 09/16/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	WALTER E CHALKLEY THOMSON REUTERS	JT INDUSTRIES, LOS ANGELES, CA - EIR, 483, CO RESP 01/18/13
2013-6342	08/16/2013 09/16/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	WALTER E CHALKLEY THOMSON REUTERS	AMES GOLDSMITH CORP, GLENS FALLS, NY - EIR, 483, CO RESP 01/10/13
2013-6343	08/16/2013 09/16/2013	FDA/OGROP/ORACE-FO/PHIDO/PHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	DERCHER ENTERPRISES INC (GORDON LABS), UPPER DARBY, PA - EIR, 483, CO RESP 01/18/13
2013-6344	08/16/2013 09/16/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	CHROMAC RESEARCH INC, SOMERSET, NJ - EIR, 483, CO RESP 01-31/13
2013-6345	08/16/2013 10/09/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	WALTER E CHALKLEY THOMSON REUTERS	CAYMAN CHEMICAL CO INC, ANN ARBOR, MI - EIR, 483, CO RESP 02/28/13
2013-6346	08/16/2013 09/16/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	APRIA HEALTHCARE INC (KNOLL PATIENT SUPPLY), TOPEKA, KS - EIR, 483, CO RESP 01/09/13
2013-6347	08/16/2013 09/16/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	WALTER E CHALKLEY THOMSON REUTERS	THE MENTHOLATUM CO, ORCHARD PARK, NY - EIR, 483, CO RESP 02/20/13
2013-6348	08/16/2013 09/16/2013	FDA/OGROP/ORASE-FO/ATLDO/ATL-CB/	WALTER E CHALKLEY THOMSON REUTERS	SPEED LABORATORY INC, BUFORD, GA - EIR, 483, CO RESP 01/08/13
2013-6349	08/16/2013 09/16/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ADELE GILPIN ARNOLD & PORTER	TARCEVA (ERLOTINIB HCL) NDA 02-1743 - SBA

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2013-6350	08/16/2013 09/16/2013	OC/ORO/ OC/ORO/	DR ROBERT L LYTLE DDS	WARNING LTR MIN 11-14 03/03/11 - NOT REMOVING FROM AGENCY'S WEBSITE RECS
2013-6351	08/16/2013 09/16/2013	FDA/OFVM/CFSAN/OCD/EOS/	MIWTCHELL S FUERST FUERST ITTLEMAN DAVID & JOSEPH PL	DRAFT GUIDANCE FOR INDUSTRY: REQUENTLY ASKED QUESTIONS ABOUT MEDICAL FOODS - DIABETWES MELLITUS TPE 1 & 2 COMMS, QUESTIONS, RECS, ETC
2013-6352	08/19/2013 09/17/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Eric Arnali, Inc.	K002679, K030531, K952794 ETC
2013-6353	08/19/2013 09/17/2013	FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/	Joyce Edwards Edwards, Joyce	RTI BIOLOGICS, INC, ALACHUA, FL - 483 (01/01/2011 - 08/15/2013)
2013-6354	08/19/2013 09/17/2013	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	FCN 1169
2013-6355	08/19/2013 09/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jan Cunningham Dechra Ltd Dechra Ltd	NDA# 020803
2013-6356	08/19/2013 09/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jan Cunningham Dechra Ltd Dechra Ltd	NDA 020583, 020841, 200738 ETC
2013-6357	08/19/2013 09/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jan Cunningham Dechra Ltd Dechra Ltd	HYALURONATE SODIUM - AERS
2013-6358	08/19/2013 09/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Stryker Endoscopy STRYKER ENDOSCOPY	K111154
2013-6359	08/19/2013 09/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Eric Joseph JMP Securities	ICLUSIG - AERS
2013-6360	08/19/2013 09/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kimberly Smith B. Braun Medical Inc.	K130416
2013-6361	08/19/2013 09/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Freddy Mejia Ansell Healthcare Products LLC	NDA 019028, ANDA 073695

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-6362	08/19/2013 09/17/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Shandin Duffer Baker Sterchi Cowden & Rice, LLC	NEVADA HEART AND VASCULAR CENTER, LAS VEGAS, NV - INVESTIGATION RECS 01/01/2011 - 01/01/2013
2013-6363	08/19/2013 09/17/2013	FDA/OC/OES/DDM/	Janet B. Arrowsmith Arrowsmith Consulting LLC	CLOZAPINE - ADVISORY COMMITTEE TRANSCRIPT AND BACKGROUND MATERIALS
2013-6364	08/19/2013 09/17/2013	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORA/ OC/ORA/ FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/ FDA/OC/OCTC/OCM/OEO/ FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ OC/ORA/ OC/ORA/ FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	Kathryn Dore JONES DAY	INDIVIDUAL RECS
2013-6365	08/19/2013 09/17/2013	FDA/OC/OES/DDM/	Adrian Chew Pinsent Masons LLP	PULMONARY ALLERGY DRUGS ADVISORY COMMITTEE - TRANSCRIPTS 01/01/1992 - 12/02/1996
2013-6366	08/19/2013 09/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Michael Russin Diabetes Sentry Products, Inc.	P810044 S005
2013-6367	08/19/2013 09/17/2013	OC/CVM/OCD/	John Russell The Indianapolis Star	CVM INVESTIGATION LOG RE RX DRUGS 01/01/1990 - 08/15/2013 ;
2013-6368	08/19/2013 09/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joakim Aske Aske, Joakim	WOCKHARDT LIMITED - 483, RESPONSES 01/01/2000 - 08/16/2013
2013-6369	08/19/2013 09/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ketaki Gokhale BLOOMBERG NEWS	WOCKHARDT LTD - 483 08/16/2011 - 08/16/2013

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-6370	08/19/2013 09/17/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Myron Holubiak Myron Holubiak	TRINAM - PHASE II AND PHASE III MEETINGS
2013-6371	08/19/2013 09/17/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CTP/OD/	Eric Tucker THE ASSOCIATED PRESS	STAR SCIENTIFIC - AERS
2013-6372	08/19/2013 09/17/2013	OC/ORA/ORM/ OC/ORA/ORM/	David Mangione Govzilla, Inc.	LIST OF 483S 07/18/2013 - 08/16/2013
2013-6373	08/19/2013 09/17/2013	FDA/OFVM/CFSAN/OCD/EOS/	Sean Higgins ANDREWS & THORNTON	DMAA - AERS
2013-6374	08/19/2013 09/17/2013	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	DEFOAMING AGENTS FOR POTATOES - OPINION LETTERS, SUBMISSIONS, REVIEWS ETC
2013-6375	08/19/2013 09/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Tuvia Rotberg Levisohn Berger, LLP	K011488
2013-6376	08/19/2013 09/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Donald L. Bredle, PhD University of Wisconsin - Eau Claire	HESPAN, HEXTEND, VOLUVEN - AERS
2013-6377	08/19/2013 09/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Dong Liang TEXAS SOUTHERN UNIVERSITY/ SCHOOL OF PHARMACY	K123050, K123844
2013-6378	08/19/2013 10/22/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/ FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	Blake Goodner BRIDGER BIOMED INC	GILEAD SCIENCES, FOSTER CITY, CA - 483, RESPONSE, WARNING LETTERS 01/03/2012 - 08/16/2013
2013-6379	08/19/2013 09/17/2013	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	Peter Waldran BAYER HEALTHCARE	LUITPOLD PHARMACEUTICALS, SHIRLEY, NY - EIR, 483, WARNING LETTER
2013-6380	08/19/2013 09/17/2013	FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/	Blake Goodner BRIDGER CAPITAL LLC	TORNIER NV, EDINA, MN - 483, RESPONSE, WARNING LETTER 01/03/2012 - 08/16/2013
2013-6381	08/19/2013 09/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kevin Liu UMI INTERNATIONAL	K113198
2013-6382	08/19/2013 09/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Melissa Brady Brady, Melissa	INNOVATIVE DENTAL LABORATORY SERVICES, INC, BUFFALO, NY - REGISTRATION

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2013-6383	08/19/2013 09/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bao Le ARIAD PHARMACEUTICALS INC	ICLUSIG - AERS
2013-6384	08/19/2013 09/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) 267-305-7723 MERCK & CO., INC.	2012-3406
2013-6385	08/19/2013 09/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) 267-305-7723 MERCK & CO., INC.	2013-5440 REQUEST LETTER
2013-6386	08/19/2013 09/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Katherine Giannamore The Law Office of Katherine Giannamore, P.A.	K862875
2013-6387	08/19/2013 09/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) 267-305-7723 MERCK & CO., INC.	2013-5436 REQUEST LETTER
2013-6388	08/19/2013 09/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) 267-305-7723 MERCK & CO., INC.	2013-5275 - REQUEST LETTER ONLY
2013-6389	08/19/2013 09/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) 267-305-7723 MERCK & CO., INC.	2013-5783 - REQUEST LETTER ONLY
2013-6390	08/19/2013 09/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) 267-305-7723 MERCK & CO., INC.	2013-5624 - REQUEST LETTER ONLY
2013-6391	08/19/2013 09/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) 267-305-7723 MERCK & CO., INC.	2013-5669 - REQUEST LETTER
2013-6392	08/19/2013 09/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) 267-305-7723 MERCK & CO., INC.	2013-5790 - REQUEST LETTER
2013-6393	08/19/2013 09/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) 267-305-7723 MERCK & CO., INC.	2013-5176 - REQUEST LETTER
2013-6394	08/19/2013 09/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) 267-305-7723	2013-5883 - REQUEST LETTER

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			MERCK & CO., INC.	
2013-6395	08/19/2013 09/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) 267-305-7723 MERCK & CO., INC.	2013-5187 - REQUEST LETTER
2013-6396	08/19/2013 09/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	DR. AIFREDO FALCONE, PISA, ITALY - EIR, 483S CO RESP 07/18/12
2013-6397	08/19/2013 09/17/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	WALTER E CHALKLEY THOMSON REUTERS	QUALTEX LABS, SAN ANTONIO, TX - EIR, 483, CO RESOP 02/19/13
2013-6398	08/19/2013 09/17/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	PADDOCK LABORATORIES LLC, MINNEAPOLIS, MN - EIR, 483, CO RESP 02/06/13
2013-6399	08/19/2013 09/17/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	NORTH AMERICAN SCIENCE ASSOCIATES INC, NORTHWOOD, OH - EIR, 483, CO RESP 01/18/13
2013-6400	08/19/2013 09/17/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	MOBIUS THERAPEUTICS LLC, SAINT LOUIS, MO - EIR, 483, CO RESP 01/17/13
2013-6401	08/19/2013 09/17/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	WILLIAM J REHEAD MD, MILWAUKEE, WI - EIR, 483S, CO RESP 05/03/12
2013-6402	08/19/2013 09/17/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	KNOX COMMUNITY HOSPITAL IRB, MOUNT VERNON, OH - EIR, 483, CO RESP 03/20/12
2013-6403	08/19/2013 09/17/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	WALTER E CHALKLEY THOMSON REUTERS	JAMES R DEXTER MD, REDLANDS, CA - EIR, 483, CO RESP 08/08/12
2013-6404	08/19/2013 09/17/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	FOREST RESEARCH INSTITUTE INC, JERSEY CITY, NJ - EIR, 483, CO RESP 02/14/12
2013-6405	08/19/2013 09/17/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	WALTER E CHALKLEY THOMSON REUTERS	COVENANT HEALTH CARE IRB, SAGINAW, MI - EIR, 483, CO RESP 05/02/12
2013-6406	08/19/2013 09/17/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	CELGENE CORP, SUMMIT, NJ - EIR, 483, CO RESP 09/12/12
2013-6407	08/19/2013 09/17/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	WALTER E CHALKLEY THOMSON REUTERS	EMD SERONO INC, ROCKLAND, MA - EIR, 483, CO RESP 08/21/12
2013-6408	08/19/2013 09/17/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	BELLIN HEALTH CORPATE IRB, GREEN BAY, WI - EIR, 483, CO RESP 07-25/12

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2013-6409	08/19/2013 09/17/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	KVK TECH INC, NEWTOWN, PA - EIR, 483, CO RESP 09/17/12
2013-6410	08/19/2013 09/17/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	WALTER E CHALKLEY THOMSON REUTERS	MCKESSON, SCOTTSDALE, AZ - EIR, 483, CO RESP 06/21/12
2013-6411	08/19/2013 09/17/2013	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	WALTER E CHALKLEY THOMSON REUTERS	NATUREPLEX LLC, OLIVE BRANCH, MS - EIR, 483, CO RESP 08/28/12
2013-6412	08/19/2013 09/17/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	WALTER E CHALKLEY THOMSON REUTERS	ISO-TEX DIAGNOTIS, INC, FRIENDSWOOD, TX - EIR, 483, CO RESP 09/07/12
2013-6413	08/19/2013 11/12/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	WALTER E CHALKLEY THOMSON REUTERS	TOLMAR INC, FORT COLLINS, CO - EIR, 483, CO RESP 09/07/12
2013-6414	08/19/2013 09/17/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	WALTER E CHALKLEY THOMSON REUTERS	VERSAPHARM INC, MARIETTA, GA - EIR, 483, CO RESP 06/08/12
2013-6415	08/19/2013 09/17/2013	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	SAGFENT PHARMACEUTICALS INC, SCHAUMBURG, IL - EIR, 483, CO RESP 05/11/12
2013-6416	08/19/2013 09/17/2013	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	WALTER E CHALKLEY THOMSON REUTERS	HAWTHORN PHARMACEUTICALS INC, MADISON, MS - EIR, 483, CO RESP 02/15/12
2013-6417	08/19/2013 09/17/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	EKR HOLDINGS INC, BEDMINSTER, NJ - EIR, 483, CO RESP 04/16/12
2013-6418	08/19/2013 09/17/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	WALTER E CHALKLEY THOMSON REUTERS	ZACHARY K SEGAL MD, MIAMI, FL - EIR, 483S, CO RESP 03/02/12
2013-6419	08/19/2013 09/17/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	WALTER E CHALKLEY THOMSON REUTERS	ALVARO H SKUPIN MD, MIAMI, FL - EIR, 483, CO RESP 08/29/12
2013-6420	08/19/2013 09/17/2013	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	WALTER E CHALKLEY THOMSON REUTERS	ALABAMA ORGAN CENTER, MOBILE, AL - EIR, 483, CO RESP 03/05/13
2013-6421	08/20/2013 09/18/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	ELLIOT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	2013-5780, 5772, 5398, 5350, 4938, 4244
2013-6422	08/20/2013 09/18/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	ELLIOT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	2013-5988, 4423, 4084
2013-6423	08/20/2013 09/18/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	ELLIOT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	2013-3708, 4460

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		FDA/OC/OES/DFOI/		
2013-6424	08/20/2013 09/18/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	ELLIOT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	2013-5780, 5772, 5398, 5350, 4938, 4244
2013-6425	08/20/2013 09/18/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	ELLIOT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	2013-4979, 5813
2013-6426	08/20/2013 09/18/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	ELLIOT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	2013-3907
2013-6427	08/20/2013 09/18/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	ELLIOT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	2013-3606, 3607, 4045, 4081
2013-6428	08/20/2013 09/18/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	ELLIOT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	2013-5761, 5481, 4056, 3984, 3969
2013-6429	08/20/2013 09/18/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	ELLIOT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	2013-3846
2013-6430	08/20/2013 09/18/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	ELLIOT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	2013-5642, 5585, 5349, 5347, 5331, 5323
2013-6431	08/20/2013 09/18/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELAINE S. WALLER, PharmD, MBA SEATTLE GENETICS INC	ADCETRIS (BRENTUXIMAB VEDOTIN) - ISRS 8813991, 8816974, 8486800 ETC
2013-6432	08/20/2013 09/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID M. HOFFMEISTER WILSON SOSINI GOODRICH & ROSATI	RANBAXY - ESOMEPRAZOLE MAGNESIUM ANDA 77-830 APRVL, 483 1/12/12 TO 8/9/13
2013-6433	08/20/2013 09/18/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FRIEDMAN., ROBERT	CALPOL SIX PLUS,CALPOL PAED SUSPENSION; CALPOL S/FREE SUSPENSION - FAERS 1969 TO PRESENT

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-6434	08/20/2013 09/18/2013	OC/ORO/ OC/ORO/ FDA/OMPT/CDRH/OCER/DFOI/	DIANE K. SHAW SHAW AND ASSOCIATES	DEPUY - AML HIP REPLACEMENT STEM DVC CMLPNTS, PAST EIGHT YRS
2013-6435	08/20/2013 09/18/2013	FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/	GAITHER, CHARLES .	MODERN HEALTH LABORATORIES INC, CULVER CITY, CA - EIR
2013-6436	08/20/2013 09/18/2013	FDA/OGROP/ORO/SE-FO/ATL- DO/ATL-CB/	COLLEEN GRACE DONOFRIO BABST CALLAD CLEMENTS ET AL	GILES CHEMICAL, WAYNESVILLE, NC - CORR, EIR 8/1-2/12
2013-6437	08/20/2013 09/18/2013	FDA/OC/OES/DDM/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ROBIN WINCHESTER Kessler Topaz Meltzer & Check, LLP	DCK FDA-2006-P-0007 - RECS; VIROPHARMA INC - SUPPLEMENTAL NDA 50-606/S028 MTG MINS, TRANS, CORR
2013-6438	08/20/2013 09/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELENA HOWELL HOGAN LOVELLS LLP	AGLIA SPECIALITIES PRIVATE LTD, INDIA - 483, EIR 2012 TO 2013
2013-6439	08/20/2013 09/18/2013	FDA/OC/OES/DDM/	CARLA SCARMAZZI KING & SPALDING	DKT FDA-2007-D-0362
2013-6440	08/20/2013 09/18/2013	FDA/OFVM/CFSAN/OCD/EOS/	JEFFREY H. SCHULTZ DRISCOLL FIRM PC	SIMPLY THICK LLC - RECALL, LBLG, WARNINGS 5/11 AND 12/11
2013-6441	08/20/2013 09/18/2013	FDA/OMPT/CTP/OD/	MARC J SCHEINESON ASLTON & BIRD LLP	SUBSTANTIAL EQUIVALENCE (SE) PROVISIONAL RPT RESP LTRS, ADVICE/INFORMATION LTRS, WITHDRAWAL LTRS, ETC 3/11
2013-6442	08/20/2013 09/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JAYA AYYAGARI DR REDDY'S LABORATORIES INC	PHARMACIA AND UPJOHN -DEPO - TESTOSTERONE (TESTOSTERONE CYPIONATE) ANDA 85-635 SBA
2013-6443	08/20/2013 09/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JAYA AYYAGARI DR REDDY'S LABORATORIES INC	PHARMACIA (METHYLPREDNISOLONE ACETATE) NDA 11- 757 SBA
2013-6444	08/20/2013	FDA/OMPT/CDER/GRP/DIDP/	JAYA AYYAGARI	PHARMACIA (DEPO PROVERA) NDA 20-246

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	09/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DR REDDY'S LABORATORIES INC	
2013-6445	08/20/2013 09/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JAYA AYYAGARI DR REDDY'S LABORATORIES INC	MERCK SHARP DOHME (CELESTONESOLUSPAN) NDA 14-602 SBA
2013-6446	08/20/2013 09/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANURAG PATEL, Ph.D. DR REDDY'S LABORATORIES INC	WARNER CHILCOTT US - ESTRACE ANDA 86-069 SBA
2013-6447	08/21/2013 09/19/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) 267-305-7723 MERCK & CO., INC.	2013-5222 - REQUEST LETTER
2013-6448	08/21/2013 09/19/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) 267-305-7723 MERCK & CO., INC.	2013-5255 - REQUEST LETTER
2013-6449	08/21/2013 09/19/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) 267-305-7723 MERCK & CO., INC.	2013-5336 - REQUEST LETTER
2013-6450	08/21/2013 09/19/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) 267-305-7723 MERCK & CO., INC.	2013-5320, 2013-5322, 13-5328 ETC REQUEST LETTER ONLY
2013-6451	08/21/2013 09/19/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) 267-305-7723 MERCK & CO., INC.	2013-5084 - REQUEST LETTER
2013-6452	08/21/2013 09/19/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) 267-305-7723 MERCK & CO., INC.	2013-5397 - REQUEST LETTER
2013-6453	08/21/2013 09/19/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) 267-305-7723 MERCK & CO., INC.	2013-5515 - REQUEST LETTER
2013-6454	08/21/2013 09/19/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) 267-305-7723 MERCK & CO., INC.	2013-5884 - REQUEST LETTER
2013-6455	08/21/2013	FDA/OMPT/CDER/ORP/DIDP/		INDIVIDUAL RECS

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	09/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	
2013-6456	08/21/2013 09/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mahidhar Chinta Micro Labs USA, Inc	ANDA 090168 SBA
2013-6457	08/21/2013 09/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Mathew Pexa LAKE REGION MEDICAL	K102588
2013-6458	08/21/2013 09/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mahidhar Chinta Micro Labs USA, Inc	SBA ANDA:090294
2013-6459	08/21/2013 09/19/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Robert Behrer Koster Keunen, Inc.	COMPLAINT 128467
2013-6460	08/21/2013 09/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Janica Alvarez Janica Alvarez	K950531, K020518, K081932
2013-6461	08/21/2013 09/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	BLA 103705 S 5209
2013-6462	08/21/2013 09/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ethan Hoffmann Sage Therapeutics	PHASE 4 COMMITMENTS FOR DEXMEDETOMIDINE
2013-6463	08/21/2013 09/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	NDA 200603 S 010, 011
2013-6464	08/21/2013 09/19/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	James McNally Velocity Diagnostics	K021317
2013-6465	08/21/2013 09/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 203263

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-6466	08/21/2013 09/19/2013	OC/CVM/OCD/	Sandy O'Kelley Merial Limited	AGRI-MECTIN PLUS CLURSULON - FOIA SUMMARY
2013-6467	08/21/2013 09/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Corinne Regnier BAXTER HEALTHCARE CORPORATION	K832285
2013-6468	08/21/2013 09/19/2013	FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA REQUEST LOG 8/12/2013 - 8/16/2013
2013-6469	08/21/2013 09/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sandy Chon Johns Hopkins University School of Medicine - Center for TB Research	APPROVAL LETTER HABITROL
2013-6470	08/21/2013 09/19/2013	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	METHODOLOGY FOR QUANTITATIVE RISK ASSESSMENT FOR GRANDFATHERED TOBACCO PRODUCTS
2013-6471	08/21/2013 09/19/2013	OC/CVM/OCD/	P.J. Huffstutter THOMSON REUTERS	ZILPATEROL - AERS
2013-6472	08/21/2013 09/19/2013	FDA/OGROP/ORAC/CE-FO/BLT-DO/BLT-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	PARI RESPIRATORY EQUIPMENT, INC, MIDLOTHIAN, VA - EIR 2008 TO PRESENT
2013-6473	08/21/2013 09/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Susan Eagle VANDERBILT UNIVERSITY	K110266
2013-6474	08/21/2013 09/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	ANDA 80439 S 000
2013-6475	08/21/2013 09/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GENE. E. MYERS, M.D. F.A.C.C. FLORIDA CARDIAC AND VASCULAR CONSULTANTS	PROTONIX (PANTOPRAZOLE) - AERS
2013-6476	08/21/2013 09/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	BOEHRINGER-INGELHEIM PHARM GMBH AND CO KG - 483

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2013-6477	08/21/2013 09/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	BLA 103705 S 5230
2013-6478	08/21/2013 09/19/2013	FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/	Chris Patullo Long Pharmaceuticals, LLC	FLEMING & CO PHARMACEUTICALS - EXHIBITS 7, 8, 12, 13, 14, 26
2013-6479	08/21/2013 09/19/2013	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/ FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WAYNE SADOWSKI NOVARTIS PHARMACEUTICALS CORP	BRISTOL-MYERS SQUIBB, PRINCETON, NJ 12/28/11-1/27/12; PPD DEVELOPMENT, MORRISVILLE, NC 3/12-16/12; WILLIAM KUFUS, SARATOGA, NY 2/9-24/12, ETC - EIRS, 483S, CORR, ETC
2013-6480	08/21/2013 09/19/2013	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	WAYNE SADOWSKI NOVARTIS PHARMACEUTICALS CORP	NOVARTIS PHARMACEUTICALS CORP (NPC), EAST HANOVER, NJ - EIR, 483, CORR, ETC 6/3-5/13
2013-6481	08/21/2013 09/19/2013	FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/	WAYNE SADOWSKI NOVARTIS PHARMACEUTICALS CORP	DR BRUCE ITELD MD, LOUISIANA HEART CENTER, SLIDELL, LA - EIR, 483, CORR, ETC 4/9-19/13
2013-6482	08/21/2013 09/19/2013	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	WAYNE SADOWSKI NOVARTIS PHARMACEUTICALS CORP	DR DAVID MARGOLIN, FRESNO, CA 3/6-20/13; DR JOSHUA SHUA-HAIM, MANCHESTER, NJ 3/5-29/13 - EIR, 483, CORR, ETC
2013-6483	08/21/2013 09/19/2013	FDA/OFVM/CFSAN/OCD/EOS/	FRAN SILVERMAN TRUTH IN ADVERTISING INC	VERMA NUTRITION CO - VERVE, VERVE BOLD, VERVE ZERO SUGAR, ETC CAERS
2013-6484	08/21/2013 09/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	ANNA MCCUTCHEN RYMED TECHNOLOGIES INC	VITAPATCH CATHETER SECUREMENT K896046
2013-6485	08/21/2013 09/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	JAMIE YIEH ABBOTT POINT OF CARE INC	I-STAT CELITE ACT CARTRIDGE K992571; I-STAT KAOLIN ACT CARTRIDGE K023582
2013-6486	08/21/2013 09/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	STEPHEN T FOWLER REED SMITH LLP	AMERICAN MEDICAL SYSTEMS INC - K100807 REVIEWER NOTES, TELECONFERENCE MINS
2013-6487	08/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	STEPHEN T FOWLER	AMERICAN MEDICAL SYSTEMS INC - K082677 REVIEWER DECISION NOTES, TELECONFERENCE MINS

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	09/19/2013		REED SMITH LLP	
2013-6488	08/21/2013 09/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	STEPHEN T FOWLER REED SMITH LLP	AMERICAN MEDICAL SYSTEMS INC - K082730 REVIEWER DECISION NOTES, TELECONFERENCE MINS
2013-6489	08/21/2013 09/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	STEPHEN T FOWLER REED SMITH LLP	AMERICAN SYSTEMS INC - K071902 REVIEWER DECISION NOTES, TELECONFERENCE MINS
2013-6490	08/21/2013 09/19/2013	FDA/OC/OES/DFOI/	BRODY MULLINS WALL STREET JOURNAL	2012-9101
2013-6491	08/21/2013 09/19/2013	FDA/OC/OES/DFOI/	BRODY MULLINS WALL STREET JOURNAL	2012-9103
2013-6492	08/21/2013 09/19/2013	FDA/OC/OES/DFOI/	BRODY MULLINS WALL STREET JOURNAL	2009-1632
2013-6493	08/21/2013 09/19/2013	FDA/OC/OES/DFOI/	BRODY MULLINS WALL STREET JOURNAL	2013-118
2013-6494	08/21/2013 09/19/2013	FDA/OC/OES/DFOI/	BRODY MULLINS WALL STREET JOURNAL	2013-1273
2013-6495	08/21/2013 09/19/2013	FDA/OC/OES/DFOI/	BRODY MULLINS WALL STREET JOURNAL	2012-5882
2013-6496	08/21/2013 09/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	NANCY GALLO HOME DIALYSIS PLUS (HD+)	NIPRO SET-SLIMLINE BLOOD TUBING SET WITH TRANSDUCER PROTECTORS AND PRIMING SET K112628
2013-6497	08/21/2013 09/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	NANCY GALLO HOME DIALYSIS PLUS (HD+)	NXSTAGE - BLOOD TUBING SET WITH PRE-ATTACHED DIALYZER K113023
2013-6498	08/21/2013 09/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	LIANE LAROCHELLE DEKA RESEARCH & DEVELOPMENT CORP	INFOPIA CO LTD - GLUNEO BLOOD GLUCOSE MONITORING SYS, PROFESSIONAL BLOOD GLUCOSE MONITORING SYS K130181
2013-6499	08/21/2013 09/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	LIANE LAROCHELLE DEKA RESEARCH & DEVELOPMENT CORP	FRESENIUS MEDICAL CARE NORTH AMERICA - 2008K @HOME HEMODIALYSIS MACHINE K124035
2013-6500	08/21/2013 09/19/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	PATRICIA L REGENYE Celgene Corporation	CHARLES BIRBARA, CLIN PHARMACOLOGY STUDY GROUP, WORCESTER, MA - EIR, 483, CORR 3/12 TO PRESENT
2013-6501	08/21/2013 09/19/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	PATRICIA L REGENYE Celgene Corporation	VINCENT HANSEN, CA ASSOC NORTHERN UTAH, OGDEN, UT - 483S 12/08 TO PRESENT
2013-6502	08/21/2013 09/19/2013	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	PATRICIA L REGENYE Celgene Corporation	JEFFREY SOSMAN, VANDERBILT UNIV MEDICAL CENTER, NASHVILLE, TN - 483S 9/10 TO PRESENT
2013-6503	08/21/2013	FDA/OGROP/ORASE-FO/FLA-	PATRICIA L REGENYE	STEPHEN BOOKBINDER, OCALA RHEUMATOLOGY

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	09/19/2013	DO/FLA-CB/ FDA/OC/OES/DFOI/	Celgene Corporation	RESEARCH CENTER, OCALA, FL - 483S 5/09 TO PRESENT
2013-6504	08/22/2013 09/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Charles F. Owen Willowcroft Pharm Inc	CROMOLYN SODIUM - DMF
2013-6505	08/22/2013 09/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jameel Husain Fresenius Kabi USA, LLC	DSM FINE CHEMICALS, LINZ, AUSTRIA - EIR
2013-6506	08/22/2013 09/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	IAVI IAVI	ITR LABORATORIES, CA NADA - EIR, 483, RESPONSE 01/01/2008 - 12/31/2008
2013-6507	08/22/2013 09/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Vikram Deswal East Bridge Capital Management Limited	WOCKHARDT, INDIA - 483 (07/15/2013 - 08/15/2013)
2013-6508	08/22/2013 09/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Cathy Shachaf Orlucent	K014018
2013-6509	08/22/2013 09/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Peter Costello Gawi, LLC	ARCTIC EASE PMA
2013-6510	08/22/2013 09/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mahidhar Chinta Micro Labs USA, Inc	NDA 021485
2013-6511	08/22/2013 09/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K130315
2013-6512	08/22/2013 09/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	William Sietsema Sietsema, William	NDA 021660
2013-6513	08/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Thomas P. Stewart	SHARPS AWAY VERTICAL DROP LID-3 GALLON 510K

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	09/20/2013		Industrial Water Solutions, Inc.	
2013-6514	08/22/2013 09/20/2013	FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	INTUITIVE SURGICAL - RECS RE PRESS RELEASE, WARNING LETTER, MEDSUN ETC
2013-6515	08/22/2013 09/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	A LUKE SMITH FARUQI & FARUQI LLP	ANDA 203-399 - ROUTING SHEET
2013-6516	08/22/2013 09/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	A LUKE SMITH FARUQI & FARUQI LLP	ANDA 203-399 APRVL LTR
2013-6517	08/22/2013 09/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	ANDRENE HERON ROCHE DIAGNOSTICS OPERATIONS	INPECCO-ABBOTT - ANALYZER K121012
2013-6518	08/22/2013 09/20/2013	FDA/OGROP/ORO/SE-FO/NOL-DO/NOL-CB/ FDA/OMPT/CDRH/OCER/DFOI/	LOREN LARKIN SAC CAPITAL ADVISORS LP	WRIGHT MEDICAL - AUGMENT NON-APPROVABLE LTR 8/13
2013-6519	08/22/2013 09/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	REO TANSHEMA MD HOSPITAL FOR SICK CHILDREN	VALPROIC ACID; VALPROATE; SODIUM VALPROATE - WARNING LTRS, SAFETY RECS, ALERTS SINCE 2/78
2013-6520	08/22/2013 09/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SABRINA BOODHAN HOSPITAL FOR SICK CHILDREN	CEFRIAXONE, HEMOLYTIC ANEMIA - AERS
2013-6521	08/22/2013 09/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Doe J	EPINEPHRINE BITATRATE - NDA 16-126 APRV PKG
2013-6522	08/22/2013 09/20/2013	FDA/OGROP/ORO/CE-FO/PHI-DO/PHI-CB/	SIDHARTHA SINGH BRIAR MEADS CAPITAL LLC	PROTICA INC, WHITEHALL, PA - EIRS, 483S 8/27/12, 3/26/13

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2013-6523	08/22/2013 09/20/2013	FDA/OGROP/ORPA-FO/SEA-DO/SEA-CB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Doe J	QQTECH RED LASER POINTER PEN - SPL 694073 LAB RPT FINDINGS
2013-6524	08/22/2013 09/20/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DE MATOS, JUSTIN A	M.G.L.A. CONTROLLED SUBSTANCES - REGULATIONS, ESTABLISHMENT, SCHEDULING, ETC
2013-6525	08/22/2013 09/20/2013	FDA/OC/OES/DDM/	BRODER, JILL	LIST OF CHRONOLOGICAL PETITIONS 1/97 TO 8/13
2013-6526	08/22/2013 09/20/2013	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORA/ OC/ORA/	Doe J	SIMPLY THICK LLC - THICKENING GEL PRODS RECALL, AERS, WARNINGS, ETC
2013-6527	08/22/2013 09/20/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORPA-FO/LOS-DO/LOS-CB/	HEALTHER GALE OLSSON FRANK WEEDA TERMAN MATZ PC	CADMIUM CHOCOLATE - SPL 814896 SAFETY ASSESSMENT ATTACHMENTS, EXHIBITS
2013-6528	08/22/2013 09/20/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Doe J	INDIVIDUAL RECS 09/15/07 TO PRESENT (CERTIFIED)
2013-6529	08/22/2013 09/20/2013	FDA/OFVM/CFSAN/OCD/EOS/	EMILY K STUNK AKIN GUMP ET AL	AMERICAN FROZON FOOD INSTITUTE, ETC - NUTRIENT DATABASES SUBMISSIONS 1998, 1999
2013-6530	08/22/2013 09/20/2013	FDA/OFVM/CFSAN/OCD/EOS/	K&L GATES	FCN 295
2013-6531	08/22/2013 09/20/2013	OC/ORA/ OC/ORA/	ROGER FARMER NATIONAL TREASURY EMPLOYEES UNION	SWR EMPLOYEES - EPISODIC, RECURRING FWAPS, COMPLIANCE OFFICERS
2013-6532	08/22/2013 09/20/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	MELANIE COURTOT TERRY FOX LABORATORY BCCRC	ANAPHYLAXIS;GUILLAIN BARRE SYNDROME - VAERS
2013-6533	08/22/2013 09/20/2013	FDA/OFVM/CFSAN/OCD/EOS/	MARILYNN WHITNEY COVINGTON BURLING LLP	FAP 3A4801
2013-6534	08/22/2013	FDA/OC/OES/DDM/	MARILYN WHITNEY	DKT FDA-2013-P-0148

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	09/20/2013		COVINGTON & BURLING LLP	
2013-6535	08/22/2013 09/20/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/	DOUGLAS N. BLUE, II ZETETIC INC	3MUS REDDOT ELECTRODE; 3M MICROPORE TAPE; 3M STERI STRIP ETC ENTRY NO AV3-0039844-1
2013-6536	08/22/2013 09/20/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/	DOUGLAS N. BLUE, II ZETETIC INC	NAIL POLISH; SHAMPOO - ENTRY NO M76-2038381-2
2013-6537	08/22/2013 09/20/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORO/CE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORO/SE-FO/NOL-DO/NOL-CB/	Doe J	CANNED MACKEREL ENTRY UPS-8050920-4, UPS-8052031-8 TEST RESULTS
2013-6538	08/22/2013 09/20/2013	FDA/OC/OES/DDM/	LAUREN FARRUGGIA Hyman, Phelps and McNamara	DKT FDA-2013-P-0148
2013-6539	08/22/2013 09/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	KRAUSER DMD, JACK	K961387
2013-6540	08/22/2013 09/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	KRAUSER DMD, JACK	K961386
2013-6541	08/22/2013 09/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	KRAUSER DMD, JACK	K961384
2013-6542	08/22/2013 09/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	KRAUSER DMD, JACK	K961383
2013-6543	08/22/2013 09/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	KRAUSER DMD, JACK	K961382
2013-6544	08/22/2013 09/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	KRAUSER DMD, JACK	K961381
2013-6545	08/23/2013 09/23/2013	FDA/OGROP/ORO/CE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Kimberly Viergever RIETZ LAW FIRM LLC	STRYKER REJUVENATE, ABG II MODULAR NECK HIP STEM - RECALL RECS
2013-6546	08/23/2013 09/23/2013	FDA/OGROP/ORO/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORO/CE-FO/DET-DO/DET-CB/	Alyssa Pagel Pagel, Alyssa	CONAGRA FOODS - EIR 01/01/2012 - 08/22/2013

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		FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/		
2013-6547	08/23/2013 09/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	Lance Caughfield Kelsoe, Khoury, Rogers, Caughfield & Clark, PC	K830004 SUMMARY
2013-6548	08/23/2013 09/23/2013	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	GRANDFATHERED TOBACCO STATUS DETERMINATION
2013-6549	08/23/2013 09/23/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Brian Sims Indiana Botanic Gardens, Inc.	ASI MARKETING LLC - 483, EIR 07/01/2010 - 06/30/2011
2013-6550	08/23/2013 09/23/2013	FDA/OFVM/CFSAN/OCD/EOS/	John Hilgren ECOLAB INC.	FCN 692
2013-6551	08/23/2013 09/23/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORA/ORO/DIOP/ FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Priya Dosanjh REPRIEVE	PENTOBARBITAL SODIUM POWDER IMPORTS 01/01/2013 - 08/21/2013
2013-6552	08/23/2013 09/23/2013	OC/CVM/OCD/	Chris Ramezanpour BIODIMENSIONS RENEWABLE OILS	CVM LETTER OF NO OBJECTION TO THE NC DEPT OF AGRICULTURE FOR RAPESEED MEAL TO BE USED AS A FEEDSTUFF FOR SPECIFIC LIVESTOCK SPECIES
2013-6553	08/23/2013 09/23/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	b. burgess BURGESS, BERNIE	FDA FUNDING RECS FOR INSPECTION 3004927371 JANUARY 2005
2013-6554	08/23/2013 09/23/2013	FDA/OFVM/CFSAN/OCD/EOS/	John Hilgren ECOLAB INC	8B4076
2013-6555	08/23/2013 09/23/2013	OC/ORA/ORM/ OC/ORA/ORM/	Merle Zimmermann AMERICAN HERBAL PRODUCTS ASSOCIATION	LIST OF GMP INSPECTIONS FOR COMPLIANCE WITH 21 CFR Part 111 05/01/2012 - 07/31/2013

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2013-6556	08/23/2013 09/23/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Sandy O'Kelley Merial Limited	SUSAN BAKER DVM, WEST PALM BEACH, FL; BILL CAMPAIGNE DVM, SEGUIN, TX, CALVERT LABORATORIES, SCOTT TOWNSHIP, PA ETC - EIR
2013-6557	08/23/2013 09/23/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OES/DFOI/	Jeffrey Gardner Jeffrey Gardner	HERBALIFE PRODUCTS - AERS 01/01/2008 - 08/21/2013
2013-6558	08/23/2013 09/23/2013	FDA/OFVM/CFSAN/OCD/EOS/	Katherine Peralta Northwestern University	ENERGY DRINKS - AERS
2013-6559	08/23/2013 09/23/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Dana Hayden Siegfried USA, LLC RA Manager Siegfried USA, LLC	MINUTES OF MEETING BETWEEN SIEGFRIED USA LLC AND NEW JERSEY DISTRICT OFFICE
2013-6560	08/23/2013 09/23/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Martha Raskin, Paralegal Rivkin Radler LLP	NDA 019839 - APPROVAL RECS
2013-6561	08/23/2013 09/23/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OC/OES/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lynn Shepler LTS & Associates /LYNN SHEPLER, MD JD	CORR BETWEEN FDA AND CDC RE LYME DISEASE OR BORRELLA BURGDORFERI 01/01/1977 - 08/19/2013
2013-6562	08/23/2013 09/23/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	CHANTELS BAKERY Denise Pender	CHANTELS BAKERY, STERLING,VA - RECS RE 7/3/13 INSPECTION, PHOTOS
2013-6563	08/23/2013 09/24/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORA/ OC/ORA/ FDA/OGROP/ORAPA-FO/SAN-	CINDI BRADEN Hickey Law Firm	TREN XTREME, AMERICAN CELLULAR LABS, MAURICE SANDOVAL, ETC - LAB RESULTS, WARNING LTRS, INVESTIGATION RECS, ETC

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		DO/SAN-CB/ OC/ORA/OCI/ OC/ORA/OCI/		
2013-6564	08/23/2013 09/23/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	John Zhao Ameri-Asian Trading Dev., Inc.	SAMPLE SLIDES
2013-6565	08/23/2013 09/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michele Sinoway LACHMAN CONSULTANT SERVICES, INC.	OGD MONTHLY STATISTICAL REPORT JULY 2013
2013-6566	08/23/2013 09/23/2013	FDA/OFVM/CFSAN/OCD/EOS/	JOHN VENADOS Herbalife International of America, Inc.	HERBALIFE PRODS - CAERS 1/10 TO PRESENT
2013-6567	08/23/2013 09/23/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	WANSING, HALEY	PIP AMERICA, PIP USA - BREAST IMPLANTS MODELS 99202, 97254 RECS PRIOR TO 2000
2013-6568	08/23/2013 09/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	S MICHAEL SHARP PHD REGULATORY CONSULTING LTD	SIS WOUND DRESSING K973170
2013-6569	08/23/2013 09/23/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ OC/CVM/OCD/ FDA/OFVM/CFSAN/OCD/EOS/	HEATHER GALE OLSSON FRANK & WEEDA	STATE GARDEN INC, CHELSEA, MA - RECS 10/12 TO 1/13
2013-6570	08/23/2013 09/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ROBERT E KILEY DANAHER LAGNESE PC	ZYLOPRIM (ALLOPURINOL) - WARNINGS, LBLG, AERS, ETC 5/10
2013-6571	08/23/2013 09/23/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHRISTOPHER HENDEL CONSUMER REPORTS	BELVIQ (LORCASERIN) - AERS
2013-6572	08/23/2013 09/23/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHRISTOPHER HENDEL CONSUMER REPORTS	QSYMIA (PHENTERMINE, TOPIRAMATE) - AERS

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2013-6573	08/23/2013 09/23/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FRIEDMAN, ROBERT	ERYTHROPEL SUSPENSION, ERYTHROPEL FORTE SF SUSPENSION - AERS 1969 TO 2013
2013-6574	08/23/2013 09/23/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DETOMA X0415531, GARY	LUNESTA - AERS
2013-6575	08/23/2013 09/23/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	DOTTIKON EXCLUSIVE SYNTHESIS AG, DOTTIKON, SWITZERLAND - EIR 9/28/12
2013-6576	08/23/2013 09/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	S MICHAEL SHARP PHD REGULATORY CONSULTING LTD	BRIDGE EXTRACELLULAR COLLAGEN MATRIX WOUND DRESSING K122502
2013-6577	08/23/2013 09/23/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	S MICHAEL SHARP PHD REGULATORY CONSULTING LTD	LTM WOUND DRESSING K082103
2013-6578	08/23/2013 09/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	Matt Strassner Powers Equity Holdings	K800839
2013-6579	08/23/2013 09/23/2013	FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/	Grady Ormond PHARMASYS	UNIVERSITY OF MIAMI CANCER RESEARCH CENTER - 483
2013-6580	08/23/2013 09/23/2013	FDA/OC/OES/DDM/	CARLA SCARMAZZI KING & SPALDING	DKT 2007-D-0369
2013-6581	08/23/2013 09/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	Reza Davani Janet Jenner & Suggs LLC	MASIMO CORPORATION, IRVINE, CA - FEB 2011 INSPECTION RECS; K111403, K120070
2013-6582	08/23/2013 09/23/2013	FDA/OGROP/ORO/NE-FO/NWE-DO/NWE-CB/	DANIEL R. SULLIVAN GENTRY LOCKE ET AL	NEW ENGLAN COMPOUNDING CENTER - 483 10/26/12 (CERTIFIED)
2013-6583	08/23/2013 09/23/2013	FDA/OC/OES/DFOI/	ANDREW HACK, MD PhD MILLENNIUM MANAGEMENT LLC	2013-4021, 4384, 4419, 4421, 4469, 4957 ETC
2013-6584	08/23/2013 09/23/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID G. ADAMS VENABLE LLP	EPINEPHRINE BITARTRATE NDA 16-126 - APRVL

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		FDA/OMPT/CDER/ORP/DIDP/		
2013-6585	08/23/2013 09/23/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	PHARMACIA & UPJOHN - ZYVOX NDA 21-131/001; 21-121/015; 21-131/016
2013-6586	08/26/2013 09/24/2013	FDA/OC/OES/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORA/OCI/ OC/ORA/OCI/	Mark Skertic Mark Skertic	CORR BETWEEN FDA AND RAJENDRA KUMAR RE RANBAXY 04/01/2004 - 06/01/2013
2013-6587	08/26/2013 09/24/2013	FDA/OC/OES/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORA/OCI/ OC/ORA/OCI/	Mark Skertic Mark Skertic	CORR BETWEEN FDA AND JAYADEEP DESHMUKH RE RANBAXY 04/01/2004 - 06/01/2013
2013-6588	08/26/2013 09/24/2013	FDA/OC/OES/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORA/OCI/ OC/ORA/OCI/	Mark Skertic Mark Skertic	CORR BETWEEN FDA AND DINESH THAKUR RE RANBAXY 04/01/2004 - 06/01/2013
2013-6589	08/26/2013 10/04/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Shalin Jani Aerie Pharmaceuticals, Inc.	CAYMAN CHEMICAL COMPANY, ANN ARBOR, MI; BIO-CONCEPT LABORATORIES, SALEM, NH; -CATALENT PHARMA SOLUTIONS, PHILADELPHIA, PA ETC - EIR LAST FIVE YEARS
2013-6590	08/26/2013 09/24/2013	FDA/OC/OES/ FDA/OMPT/CBER/OCOD/DDOM/	LYNN SHEPLER LTS & Associates /LYNN	LYME DISEASE RECS RE BORRELIOSIS BURGDORFERI, ALLEN C STEERE, GARY WORMSER ETC 01/01/1985 - 08/19/2013

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		ALFB/	SHEPLER, MD JD	
2013-6591	08/26/2013 09/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Deborah Lavoie Grayeski M SQUARED ASSOCIATES INC	LISTING OIF ALL PRIOR ORTHOPEDIC APPLICATIONS CITING SECTION 216 OF FDAMA AND AGENCY DISPOSITION
2013-6592	08/26/2013 09/24/2013	FDA/OFVM/CFSAN/OCD/EOS/	Susan G. Etheridge, Esq. Susan G. Etheridge, P.A.	MITRAGYNA SPECIOSA - CLINICAL OR PRECLINICAL STUDIES
2013-6593	08/26/2013 09/24/2013	FDA/OC/OES/DFOI/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Reza Davani Janet Jenner & Suggs LLC	MASIMO CORPORATION, IRVINE, CA - INSPECTION RECS; K111403; K120070 ETC
2013-6594	08/26/2013 09/24/2013	FDA/OC/OES/ FDA/OFVM/CFSAN/OCD/EOS/	Gabriela Steier CENTER FOR FOOD SAFETY	ALL RECS RE PRESENCE AND DEVELOPMENT OF GE ORANGES
2013-6595	08/26/2013 09/24/2013	FDA/OC/OES/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Lynn Shepler LTS & Associates /LYNN SHEPLER, MD JD	LYME DISEASE RECS RE BORRELIOSIS BURGENDORFERI, ALLEN C STEERE, GARY WORMSER ETC 08/01/1977 - 01/01/1985
2013-6596	08/26/2013 09/24/2013	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORAP/ OC/ORAP/ OC/ORAP/ORO/DFS/ OC/ORAP/ORO/DFS/ FDA/OGROP/ORAP/ORO/DIOP/ FDA/OC/OES/DFOI/ OC/ORAP/ OC/ORAP/	Thomas Uebel Thomas Uebel	FOOD FROM TAIWAN - QUANTITY OF DEHP AND MALEIC ACID FOUND, ANALYTIC METHODS, DETECTION LIMIT, ETC
2013-6597	08/26/2013 09/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Stephen Telfer E Ink Corporation	FLUOROQUINOLONE ANTIBIOTICS - AERS BY STATE 01/01/1987 - 01/01/2013
2013-6598	08/26/2013 09/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Neil Camera Laser Therapeutics, Inc.	K030622
2013-6599	08/26/2013 09/24/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	LYNN SHEPLER LTS & Associates /LYNN SHEPLER, MD JD	UNCOMPLETED FORMS THAT A FIRM WOULD COMPLETE FOR APPLICATION FOR VACCINE
2013-6600	08/26/2013 09/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John Oliver McKinley Resources, Inc.	LIST OF REGISTERED FOREIGN MANUFACTURERS OF ACTIVE PHARMACEUTICAL INGREDIENTS 01/01/2013 -

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		08/23/2013
2013-6601	08/26/2013 09/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John Oliver McKinley Resources, Inc.	LIST OF ALL REGISTERED FOREIGN MANUFACTURERS OF HYDROCORTISONE
2013-6602	08/26/2013 09/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John Oliver McKinley Resources, Inc.	LIST OF ALL REGISTERED FOREIGN MANUFACTURERS OF MICONAZOLE NITRATE 01/01/2013 - 08/23/2013
2013-6603	08/26/2013 09/24/2013	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	FCN 970
2013-6604	08/26/2013 09/24/2013	FDA/OFVM/CFSAN/OCD/EOS/	JoNel Aleccia, health reporter MSNBC.COM	TAYLOR FARMS DE MEXICO - 483 07/01/2013 - 08/23/2013
2013-6605	08/26/2013 09/24/2013	FDA/OO/OHR/	Michele Sinoway LACHMAN CONSULTANT SERVICES, INC.	GDUFA HIRES FOR FY13
2013-6606	08/26/2013 09/24/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Liz Pretzinger Rawls McNelis + Mitchell	INDIVIDUAL RECS
2013-6607	08/26/2013 09/24/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Harold Roy, CEO, Heeren Bros Inc HEEREN BROS INC	SAMPLE RESULTS
2013-6608	08/26/2013 09/24/2013	FDA/OGROP/ORACE-FO/KAN-DO/KAN-CB/	sidney a lewis sidney a. lewis	LEGACY PHARMACEUTICAL PACKAGING, EARTH CITY, MO - 483, RESPONSE 04/01/2012 - 08/15/2013
2013-6609	08/26/2013 09/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 201635
2013-6610	08/26/2013 04/01/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANNA MENEDJIAN The Sizemore Law Firm	JOHNSON & JOHNSON, INC MCNEIL CONSUMER HEALTHCARE CHILDRENS' MOTRIN - RECALL, LABELING, AERS ETC

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		FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/		
2013-6611	08/26/2013 09/24/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Rachel Johnson FOI Services, Inc.	NEUROSCIENCE - WARNING LETTER RECS
2013-6612	08/26/2013 09/24/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Pamela Vetter ALLOSOURCE	REQUEST FOR RECOMMENDATION SENT TO TISSUE REFERENCE GROUP RE FY 2013 UPDATE
2013-6613	08/26/2013 09/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	BOTOX - AERS
2013-6614	08/26/2013 09/24/2013	FDA/OO/OIM/OPILS/FDAHO/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Peter Sachs Collopy UNIVERSITY OF PENNSYLVANIA	MYRON STOLAROFF, LSD RESEARCH, Mescaline ETC BY AMPEX CORPORATION 01/01/1956 - 12/31/1967
2013-6615	08/26/2013 09/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John Strouse JOHNS HOPKINS UNIVERSITY	CEFTRIAXONE - MEDWATCH RPTS
2013-6616	08/26/2013 09/24/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OO/OFBA/OAGS/	Alon Peled THE HEBREW UNIVERSITY OF JERUSALEM	FDA-NTIS AGREEMENT TO PUBLISH FOOD CODE 2009 DATABASE
2013-6617	08/26/2013 09/24/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	ANNA MCCUTCHEN RYMED TECHNOLOGIES INC	VITAPATCH - K895920
2013-6618	08/26/2013 09/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	JAN MARIE EBERTH UNIV OF SOUTH CAROLINA/COLLEGE OF EPIDEMIOLOGY & BIOSTATISTICS	MAMMOGRAPHY FACILITIES IN THE US - (CERTIFIED) NAME, INSP DATE, FACILITY, ETC 7/1/13
2013-6619	08/26/2013 09/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	MELISSA EGAN WATERS CORP	VITEK MS K124067 - DENOVO CLASSIFICATION
2013-6620	08/26/2013 09/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	DAWN HAAKE NUVASIVE INC	NUVASIVE INC, MEMPHIS, TN - EIR 11/11

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2013-6621	08/26/2013 09/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DON J MIZERK HUSCH BLACKWELL LLP	PAR PHARMACEUTICAL INC - DONEPZIL HCL ANDA 202-542 APRVL LTR 7/24/13; MACLEODS PHARMACEUTICALS LTD - DONEPEZIL HCL ANDA 202-631 APRVL LTR 7/24/13; DR REDDY;S LABORATORIES INC - DONEPEZIL HCL ANDA 202-723 APRVL LTR 7/24/13
2013-6622	08/26/2013 09/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RUTH S TURNER FRESENIUS MEDICAL CARE	ABBOTT LABS (FMC) - INPERSOL/DELFLEX SAFE LOCK NDA 18-379 SAFETY RPTS, LBLG, CORR, ETC
2013-6623	08/26/2013 10/10/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	XIAO, CHRIS	REGENERXX STEM CELL THERAPY - INVESTIGATION, RESP
2013-6624	08/26/2013 09/24/2013	FDA/OO/OFBA/OAGS/	LAUREN R SILVIS SIDLEY AUSTIN LLP	NATIONAL RESEARCH COUNCIL - HHSF22301031T
2013-6625	08/26/2013 09/24/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/ FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	GARY C COOPER GARY C COOPER LAW OFC	PEI TEN FOOD CO LTD, TAOYUAN COUNTY, TAIWAN - IMPORT ALERT 99-19 ENTRY 9EH-0001727-9, 93H-0001693-3, 9EH-0001194-2 INTER-AGENCY OR INTRA-AGENCY MEMO, LTRS
2013-6626	08/26/2013 09/24/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/	Doe J	IMDICA INC - ENTRY #E8400752652 NOTICES FOR REQUEST OF INFORMATION (CF28), NOTICES OF ACTION PROPOSED (CF29), CBP REDELIVER NOTICES (CF-4647), ETC
2013-6627	08/26/2013 09/24/2013	FDA/OC/OES/DFOI/	Paul Wehling General Mills, Inc.	FDA BYLINES RELIABILITY REQUIREMENTS OF AOAC AND FOOD CODEX METHODS OF ANALYSIS ETC
2013-6628	08/27/2013 09/25/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Mary Faith Harty Harty, Mary Faith	RECS RE MISMATCHED LISTINGS OF TISSUE BANKS AT THE UNIVERSITY OF MIAMI
2013-6629	08/27/2013 09/25/2013	FDA/OGROP/ORO/SE-FO/NOL-DO/NOL-CB/	Mary Majer Wright Medical Technology, Inc.	DAVID KENT DEBOER, NASHVILLE, TN - EIR, 483 (01/31/2013 - 08/26/2013)
2013-6630	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2011-3989
2013-6631	08/27/2013 09/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Patrick Smith Franklin Law Group	APRIL 1984 DRUG BULLETIN SOURCE ADR HIGHLIGHT NO 83-12

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2013-6632	08/27/2013 09/25/2013	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	Alexandra Ajmo LIFE EXTENSION	XYMOGEN, ORLANDO, FL - EIR (08/26/2011 - 08/26/2013)
2013-6633	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	KATHRYN E WHITE EPSTEIN BECKER & GREEN PC	2012-6877
2013-6634	08/27/2013 09/25/2013	OC/ORR/ OC/ORR/ FDA/OGROP/ORR/ORO/DIOP/	MOLINE, MAGGIE	ECLOSION KFT - EPFX BIOFEEDBACK DVCS INVESTIGATION, RESEARCH RECS
2013-6635	08/27/2013 09/25/2013	OC/CVM/OCD/	KHUSHI K DESAI Earthjustice	AQUABOUNTY TECHNOLOGIES - AQUADVANTAGE GENETICALLY ENGINEERED (GE) SALMON APRVL RECS, BIOLOGICAL ASSESSMENT, CORR, ETC
2013-6636	08/27/2013 09/25/2013	FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORR/SW-FO/SWID/SWID-CB/	BENJAMIN L ENGLAND ESQ BENJAMIN L ENGLAND & ASSOCIATES LLC	ENTRY #DC1-0108151-1 - INSP, DETETIONS, REFUSAL OF ENTRY, ETC
2013-6637	08/27/2013 09/25/2013	FDA/OFVM/CFSAN/OCD/EOS/	CATHERINE R NIELSEN Keller and Heckman LLP	BRIK PAK INC - HYDROGEN PEROXIDE SOL FCN, RVW MEMO
2013-6638	08/27/2013 09/25/2013	OC/CVM/OCD/	TIM SCHWAB Food & Water Watch	AQUABOUNTY TECHNOLOGIES - AQUADVANTAGE GENETICALLY ENGINEERED SALMON NOAA RECS, CORR
2013-6639	08/27/2013 09/25/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORR/CE-FO/PHI-DO/PHI-CB/	SHELLY S JOCK RALPH C JONES LAW OFCS	MDRS 8010047-2013-00141M 9610773-2013-00043
2013-6640	08/27/2013 09/25/2013	FDA/OGROP/ORR/NE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORR/CE-FO/PHI-DO/PHI-CB/	SHELLY S JOCK RALPH C JONES LAW OFCS	OLYMPUS - SURGMASTER ELECTROSURGICAL UNIT (UES-40) RECALL NUMBER S-1277-2013 RECS
2013-6641	08/27/2013 09/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FINNEY H-19359, STANLEY	METAZIPINE 2001-2004; TRILOPTAL 2003-2007; LAMACTIL 2009-2013 - AERS
2013-6642	08/27/2013 09/25/2013	FDA/OC/OES/DDM/	DOREEN FRANK ENVISAGE CONSULTING LLC	DKT 1978N-0021D, 1980N-0036
2013-6643	08/27/2013 09/25/2013	FDA/OGROP/ORR/NE-FO/NYK-DO/NYK-DCB/	RAMIL M FERNANDO BIOSCREEN TESTING SERVICES INC	AMA LABORATORIES INC, NEW YORK, NY - EIRS, 483S, WARNING LTRS, ETC LAST 5 YRS

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2013-6644	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 7/29/13-8/2/13
2013-6645	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 8/5-9/13
2013-6646	08/27/2013 09/25/2013	OC/ORO/ORM/ OC/ORO/ORM/	GAIL LESSICK LACHMAN CONSULTANT SERVICES INC	DRUG COMPANIES, MEDICAL DVC MFRS, BIORESEARCH MONITORING (BIMO), ETC - DOMESTIC AND FOREIGN INSPS, 483S 6/1-30/13
2013-6647	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	DOMINION GROUP INC	DAILY LOG 7/22-26/13
2013-6648	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 7/22-26/13
2013-6649	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 7/22-26/13
2013-6650	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	7/29/13-8/2/13
2013-6651	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 8/5-9/13
2013-6652	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 7/29/13-8/2/13
2013-6653	08/27/2013 09/25/2013	FDA/OGROP/ORO/SW-FO/DEN- DO/DEN-CB/	GERARD RYAN BSC APTIV SOLUTIONS	DR LORA BARKE, DR TERESE I KASKE; RADIOLOGY IMAGING ASSOCIATES, ENGLEWOOD, CO; INVISION SALLY JOSE, GREENWOOD, CO - 483 2010
2013-6654	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 8/5-9/13
2013-6655	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 7/29/13-8/2/13
2013-6656	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 8/5-9/13
2013-6657	08/27/2013 09/25/2013	FDA/OGROP/ORO/PA-FO/SEA- DO/SEA-CB/	KELLI WASSGREN FRYE ELECTRONICS	FRYE ELECTRONICS, TIGARD, OR - EIR MOST RECENT
2013-6658	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 7/22-26/13

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2013-6659	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	GLADYS TONKIN WASHINGTON INFORMATION SOURCE	DAILY LOG 7/29/13-8/2/13
2013-6660	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	GLADYS TONKIN WASHINGTON INFORMATION SOURCE	DAILY LOG 8/5-9/13
2013-6661	08/27/2013 09/25/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	BAYER, RANGE RICHARD D	ALLOGENIC WHOLE BLOOD AND APHRESIS RED BLOOD CELL DONORS - POST-DONATION FATALITY RPTS FY 2006 AND FY 2008
2013-6662	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 7/29/13-8/2/13
2013-6663	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 8/5-9/13
2013-6664	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 7/22-26/13
2013-6665	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 7/22-26/13
2013-6666	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 7/29/13-8/2/13
2013-6667	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 8/5-9/13
2013-6668	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	DEBRA COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 7/22-26/13
2013-6669	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	SANDY FRIEDMAN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 7/22-26/13
2013-6670	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	SANDY FRIEDMAN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 8/5-9/13
2013-6671	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	SANDY FRIEDMAN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 7/29-8/2/13
2013-6672	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	DEBRA L. COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 8/5-9/13

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2013-6673	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	DEBRA COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 7/29/13-8/2/13
2013-6674	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	GLADYS TONKIN WASHINGTON INFORMATION SOURCE	DAILY LOG 7/22-26/13
2013-6675	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	LAUREN BARR JH BARR & ASSOCIATES LLC	DAILY LOG 8/5-9/13
2013-6676	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	LAUREN BARR JH BARR & ASSOCIATES LLC	DAILY CLOSED LOG 7/29/13-8/2/13
2013-6677	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	LAUREN BARR JH BARR & ASSOCIATES LLC	DAILY LOG 7/29/13-8/2/13
2013-6678	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	LAUREN BARR JH BARR & ASSOCIATES LLC	DAILY CLOSED OG 8/5/9/13
2013-6679	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	LAUREN BARR JH BARR & ASSOCIATES LLC	DAILY CLOSED LOG 7/22-26/13
2013-6680	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	LAUREN BARR JH BARR & ASSOCIATES LLC	DAILY LOG 7/22-26/13
2013-6681	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DAVID MacFARLAND FDA REVIEW/FDA WEBVIEW	DAILY CLOSED LOG 7/22-26/13
2013-6682	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DAVID MacFARLAND FDA REVIEW/FDA WEBVIEW	DAILY CLOSED LOG 8/5-9/13
2013-6683	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DAVID MacFARLAND FDA REVIEW/FDA WEBVIEW	DAILY LOG 7/29/13-8/2/13
2013-6684	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DAVID MacFARLAND FDA REVIEW/FDA WEBVIEW	DAILY LOG 7/29/13-8/2/13
2013-6685	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DAVID MacFARLAND FDA REVIEW/FDA WEBVIEW	DAILY LOG 7/29/13-8/2/13
2013-6686	08/27/2013 09/25/2013	FDA/OC/OES/DDM/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	DKT 78N-0021
2013-6687	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2011-8110

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2013-6688	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2011-4173
2013-6689	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	Robert King FDA NEWS	FOIA REQUEST LOG 08/19/2013 - 08/23/2013
2013-6690	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2011-5035
2013-6691	08/28/2013 09/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Elizabeth Nunez CNN	CIPROFLOXACIN - AERS
2013-6692	08/28/2013 09/26/2013	FDA/OMPT/OSMP/OOPD/	H. Greg Thomas codaDOSE, Inc	EPANED ORPHAN DRUG DESIGNATION REQUEST FOR TREATMENT OF HYPERTENSION IN PEDIATRIC PATIENTS
2013-6693	08/28/2013 09/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Van Langley Sandwick ORA, Inc	NDA 020613 S000
2013-6694	08/28/2013 09/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Janell Colley Tornier Inc.	K920666, K933361, K951740 ETC
2013-6695	08/28/2013 09/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Daniel O'Brien The Law Office of Daniel O'Brien	INCIVEK - ADVERSE EVENT, EXHIBITS, ETC
2013-6696	08/28/2013 09/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dominick DiPaolo DiPaolo, Dominick	WOCKHARDT LIMITED, INDIA - EIR 03/18/2013 - 07/18/2013
2013-6697	08/28/2013 09/26/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	shin kang WELLS FARGO	VIROPHARMA/SANQUIN - 483, EIR, REPSONSE 08/01/2013 - 08/26/2013
2013-6698	08/28/2013 09/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelina Slayton INC RESEARCH CONSULTING & SUBMISSIONS	NDA 21036 S 008

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2013-6699	08/28/2013 09/26/2013	OC/ORO/ OC/ORO/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	MICHAEL CHASEY 483, EIR JULY 1, 2009 TO PRESENT
2013-6700	08/28/2013 09/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Elizabeth Nunez CNN	MOXIFLOXACIN - AERS
2013-6701	08/28/2013 09/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DANIEL J CUSHING PHD NURON BIOTECH	BLA 103628/5191, 103628/5189
2013-6702	08/28/2013 09/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DANIEL J CUSHING PHD NURON BIOTECH	BLA 103780/5121
2013-6703	08/28/2013 09/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Steve Pardue Elevate Oral Care	K101346
2013-6704	08/28/2013 09/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Guy C Ruble Eli Lilly and Company, Inc.	NDA 022334/S-016
2013-6705	08/28/2013 09/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sandy Lee B&H Consulting Services, Inc.	WOCKHARDT LIMITED, INDIA - 483 07/01/2013 - 07/31/2013
2013-6706	08/28/2013 09/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FRATTI, JOHN	LEVAQUIN - AERS 1997 TO PRESENT
2013-6707	08/28/2013 09/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FRIEDMAN, ROBERT	TRADOREC XL 100, 200, 300 TABS - AERS 1969 TO PRESENT

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2013-6708	08/28/2013 09/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	GABRIEL LEOR COMBINED INNOVATIONS	HEALTHMATE INTERNATIONAL LLC, HI-DOW INERNTIONAL LLC - JQ-5C TECHNOLOGY DVC SPECIFICATIONS RELATED TO 510 APRVL, FDA FACILITY
2013-6709	08/28/2013 09/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN M ENGEL ENGEL NOVITT, LLP	ANTIBACTERIAL FLUOROQUINOLONE - LABEL CHANGES T0 WARNING OF RISK FOR POSSIBILITY PERMANET NERVE DAMAGE
2013-6710	08/28/2013 09/26/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	GRAIG ROUSH ROCHLINE INDUSTRIES	GUY & O'NEILL INC, FREDONIA, WI - EIRS, 483S, COMM 12/12
2013-6711	08/28/2013 09/26/2013	FDA/OC/OES/DFOI/	HILLS, SARAH	NIH, PHS, OLAW, ETC - CUMMULATIVE PERSONNEL SALARY PER YEAR
2013-6712	08/28/2013 09/26/2013	FDA/OFVM/CFSAN/OCD/EOS/	WIMBUSH #SB-3584, RICHARD M	MONO & DIALYCERIDES FROM PORK INGREDIENTS; LIST OF PORT INGREDIENTS
2013-6713	08/28/2013 09/26/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	REEL, CHARLES	MEDICAL DEVICE KING, PHARMALOGICAL INC - BOTOX SPL RPT INVESTIGATION 5/19/13
2013-6714	08/28/2013 09/26/2013	FDA/OC/OES/DDM/	SHARON DAVIS CROMWELL MOORING	DKT FDA-2013-P-0148
2013-6715	08/28/2013 09/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anita Fauchier, Executive Director, Regulatory Affairs Cempra Pharmaceuticals (Anita Fauchier)	WOCKHARDT, INDIA - 483 07/22/2013 - 07/31/2013
2013-6716	08/28/2013 09/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joakim Aske not applicable	WOCKHARDT - 483 06/01/2013 - 08/27/2013
2013-6717	08/28/2013 09/26/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Doe J	INDIVIDUAL RECS
2013-6718	08/28/2013 09/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Louis Marcoux ZELTIQ Aesthetics, Inc.	TRADE COMPLAINT RECS
2013-6719	08/28/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Susan Zolnier	MANNKIND CORPORATION, DANBURY, CT - EIR 11/12/2009 - 12/04/2009

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	09/26/2013		Zolnier, Susan	
2013-6720	08/28/2013 09/26/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Mary Emily Monroe McDowell Knight Roedder & Sledge, LLC	SUNFLOWER MEDICAL - REGISTRATION AND LISTING, GMP RECS, ADVERSE EVENTS
2013-6721	08/28/2013 09/26/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Anna Edney BLOOMBERG NEWS	RTI SURGICAL, MUSCULOSKELETAL TRANSPLANT FOUNDATION, SHIRE ETC - AERS
2013-6722	08/28/2013 09/26/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Kevin Meder MC Biopharma/Kevin Meder	K061855
2013-6723	08/29/2013 09/27/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	LA TOYA SUTTON MANATT PHELPS & PHILLIPS LLP	NIX LICE TREATMENT, RID, LICE SHIELD, ETC - LACK OF EFFICACY RPTS
2013-6724	08/29/2013 09/27/2013	FDA/OMPT/CDRH/OCER/DFOI/	ALEX C DAVIS JONES WARD PLC	ZIMMER - TRILOGY AB HIP DVC P040048 PRE-MARKET APRVL WITHDRAWAL
2013-6725	08/29/2013 09/27/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	B KRISTIAN RAMUSSEN CORY WATSON ET AL	FDA DRUG SAFETY COMMUNICATION: IMPORTANT SAFETY LABEL CHANGES TO CHOLESTEROL-LOWERING STATIN DRUGS 2/28/12; CLNCL TRIAL META-ANALYSES AND EPIDEMIOLOGICAL DATA
2013-6726	08/29/2013 09/27/2013	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/ FDA/OMPT/CDRH/OCER/DFOI/	MARK FORD ESQ FORD & FINNERTY LLC	ZEPPESSIS REPROCESSING LLC - MEDICAL SUCTION APPARATUS, MEDICAL MANIFOLDS/FILTERS, WARNING LTRS, ETC CORR 1/1/13
2013-6727	08/29/2013 09/27/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	ANDREA L NORDLUND AMERICAN RED CROSS GREAT LAKES REGION	AMERICAN RED CROSS, LANSING, MI 3/3-20/08, 4/5-27/10; FLINT, MI 10/10/12, ETC - EIRS
2013-6728	08/29/2013 09/27/2013	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	INDIVIDUAL RECS
2013-6729	08/29/2013 09/27/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	K MICHELLE VASSALLO LINCARE INC	BREWER MEDICAL SERVICES INC, AL - EIRS, 483S, WARNING LTRS, 1/05 TO PRESENT
2013-6730	08/29/2013 09/27/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	K MICHELLE VASSALLO LINCARE INC	BLUE RIDGE RESPIRATORY AND MEDICAL EQUIPMENT SERVICES LLC, VA - EIRS, 483S, WARNING LTRS 1/05 TO PRESENT
2013-6731	08/29/2013 12/16/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	CORBETT, SUZANNE	FOOD VENDORS, ASHFIELD, MA - VOLUNTARY NATIONAL RETAIL FOOD REGULATORY PROGRAM STANDARDS RECS

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2013-6732	08/29/2013 09/27/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	WALTTLER E CHALKLEY THOMSON REUTERS	VISTAPHARM INC, LARGO, FL - EIR, 483, CO RESP 6/15/12
2013-6733	08/29/2013 09/27/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	WALTTLER E CHALKLEY THOMSON REUTERS	STERI-PHARMA LLC, SYRACUSE, NY - EIR, 483, CO RESP 9/20/12
2013-6734	08/29/2013 09/27/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	WALTTLER E CHALKLEY THOMSON REUTERS	PERRIGO HOLLAND INC, HOLLAND, MI - EIR, 483, CO RESP 8/24/12
2013-6735	08/29/2013 09/27/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTTLER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	LEK PHARMACEUTICALS, LIUBLJANA, SLOVENIA - EIR, 483, CO RESP 4/6/12
2013-6736	08/29/2013 09/27/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	WALTTLER E CHALKLEY THOMSON REUTERS	GILEAD SCIENCES INC, FOSTER CITY, CA - EIR, 483, CO RESP 6/26/12
2013-6737	08/29/2013 11/20/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	WALTTLER E CHALKLEY THOMSON REUTERS	CODY LABORATORIES INC, CODY, WY - EIR, 483, CO RESP 10/12/12
2013-6738	08/29/2013 09/27/2013	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	WALTTLER E CHALKLEY THOMSON REUTERS	ELORAC INC, VERNON HILLS, IL - EIR, 483, CO RESP 1/20/12
2013-6739	08/29/2013 09/27/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTTLER E CHALKLEY THOMSON REUTERS	JQC (HUAYIN) PHARMACEUTICAL CO LTD, HUAYIN CITY, CHINA - EIR, 483, CO RESP 1/24/13
2013-6740	08/29/2013 09/27/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTTLER E CHALKLEY THOMSON REUTERS	CELGENE CORP, SUMMIT, NJ - EIR, 483, CO RESP 7/30/12
2013-6741	08/29/2013 09/27/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	WALTTLER E CHALKLEY THOMSON REUTERS	MID-CONTINENT PACKAGING INC, ENID, OK - EIR, 483, CO RESP 1/24/13
2013-6742	08/29/2013 09/27/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	WALTTLER E CHALKLEY THOMSON REUTERS	NGL NE LLP (SHORELINE COMPRESSED GAS), NORTH HAVEN, CT - EIR, 483, CO RESP 1/9/13
2013-6743	08/29/2013 09/27/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	WALTTLER E CHALKLEY THOMSON REUTERS	NORTH ATLANTIC MEDICAL SERVICE, LEOMINSTER, MA - EIR, 483, CO RESP 1/29/13
2013-6744	08/29/2013 09/27/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	WALTTLER E CHALKLEY THOMSON REUTERS	OHIO VALLEY MEDICAL GAS & SUPPLY, EVANSVILLE, IN - EIR, 483, CO RESP 1/31/13
2013-6745	08/29/2013 09/27/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	WALTTLER E CHALKLEY THOMSON REUTERS	PETNET SOLUTIONS INC, CHARLOTTESVILLE, VA - EIR, 483, CO RESP 2/19/13
2013-6746	08/29/2013	FDA/OGROP/ORACE-FO/PHI-	WALTTLER E CHALKLEY	POWDERSIZE INC, QUAKERTOWN, PA - EIR, 483, CO RESP

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	09/27/2013	DO/PHI-CB/	THOMSON REUTERS	2/26/13
2013-6747	08/29/2013 09/27/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTNER E CHALKLEY THOMSON REUTERS	SONAR PRODUCTS INC, CARLSTADT, NJ - EIR, 483, CO RESP 2/15/13
2013-6748	08/29/2013 09/27/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2011-6515
2013-6749	08/29/2013 09/27/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2011-8048
2013-6750	08/29/2013 09/27/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2011-6452
2013-6751	08/29/2013 09/27/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2011-7753
2013-6752	08/29/2013 09/27/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2011-8026
2013-6753	08/29/2013 09/27/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2011-7611
2013-6754	08/29/2013 09/27/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2011-6474
2013-6755	08/29/2013 09/27/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2013-186
2013-6756	08/29/2013 09/27/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2013-205
2013-6757	08/30/2013 09/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	Gwen Majors Majors, Gwen	K11277
2013-6758	08/30/2013 09/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CARTER GOULD GOULD, CARTER	GATTEX - AERS

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2013-6759	08/30/2013 09/30/2013	FDA/OFVM/CFSAN/OCD/EOS/	Dr. Erick DeWolf KANSAS STATE UNIVERSITY	LEVELS OF MYCOTOXIN DEOXYNIVALENOL IN WHEAT GRAIN AND FOOD PRODUCTS LAST TEN YEARS
2013-6760	08/30/2013 09/30/2013	FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Mary Emily Monroe McDowell Knight Roedder & Sledge, LLC	RAY'S INC - REGISTRATION AND LISTING, INSPECTION RECS, ADVERSE EVENTS
2013-6761	08/30/2013 09/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mark Prinz Registrar Corp	ELECTRONIC LIST OF DRUG DATA SUBMITTED TO FDA 06/01/2009 - 05/31/2013
2013-6762	08/30/2013 09/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ali Bonakdar VIRGINIA COMMONWEALTH UNIVERSITY	ADVERSE EVENTS BY STATE
2013-6763	08/30/2013 09/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tannista Banerjee AUBURN UNIVERSITY	IRB ASSOCIATE WITH NEW MOLECULAR ENTITIES APPROVED 07/01/1993 - 12/31/2005
2013-6764	08/30/2013 09/30/2013	OC/ORR/ OC/ORR/ FDA/OGROP/ORR/NE-FO/NWE-DO/NWE-CB/	Mary Hancock Registrar Corp	182-0271232-1/1/1
2013-6765	08/30/2013 09/30/2013	OC/ORR/ OC/ORR/ FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/	Doe J	INDIVIDUAL RECS
2013-6766	08/30/2013 09/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Elizabeth Nunez CNN	LEVOFLOXACIN - AERS
2013-6767	08/30/2013 09/30/2013	FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Mary Emily Monroe McDowell Knight Roedder & Sledge, LLC	SIZEWISE RENTALS - REGISTRATION AND LISTING, INSPECTION RECS, ADVERSE EVENTS
2013-6768	08/30/2013 09/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rivelino Montenegro Medovent GmbH	K002098

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2013-6769	08/30/2013 09/30/2013	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	FCN 1177
2013-6770	08/30/2013 09/30/2013	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	FCN 1212
2013-6771	08/30/2013 09/30/2013	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	FCN 1213
2013-6772	08/30/2013 09/30/2013	OC/CVM/OCD/	Chad Miller U.S. citizen	RACTOPAMINE, TYLOSIN - FDA SUPPORT FOR DEC 2009 STATEMENT RE ENVIRONMENTAL IMPACT ASSESSMENT
2013-6773	08/30/2013 09/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tina Lee Tris Pharma Inc.	NDA 020844 - APPROVAL PACKAGE
2013-6774	08/30/2013 09/30/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/	Allison J. Leonard Patino & Associates, P.A.	LANMAN KEMP & BARCLAY & CO - REVIEW OF LABELS FLORIDA WATER
2013-6775	08/30/2013 09/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tina Lee Tris Pharma Inc.	NDA 017851 APPROVAL PACKAGE
2013-6776	08/30/2013 09/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	Lawrence Biegelsen WELLS FARGO	CARDIOMEMS - RESPONSE TO WARNING LETTER
2013-6777	08/30/2013 09/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tina Lee Tris Pharma Inc.	NDA 018029
2013-6778	08/30/2013 09/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Fred Saulo Wilson Sonsini Goodrich & Rosati	ANDA 78-340 TENTATIVE APPROVAL LETTER
2013-6779	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2013-249
2013-6780	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723	2013-274

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			MERCK & CO., INC.	
2013-6781	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2013-775
2013-6782	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2013-770
2013-6783	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2013-263
2013-6784	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2013-266
2013-6785	08/30/2013 12/26/2013	FDA/OFVM/CFSAN/OCD/EOS/	FOI Services, Inc.	FCN 939
2013-6786	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2013-761
2013-6787	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2013-759
2013-6788	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2013-277
2013-6789	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2013-741
2013-6790	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2013-738
2013-6791	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2013-368
2013-6792	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2013-733

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2013-6793	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2013-727
2013-6794	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2013-726
2013-6795	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2013-724
2013-6796	08/30/2013 09/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	Michael Wurst STUDENT	K120188, K014108, K123217 ETC
2013-6797	08/30/2013 09/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	Evelyn Gittinger Gamma Medica, Inc.	MQSA CERTIFIED FACILITY LIST BY FACILITY TYPE
2013-6798	08/30/2013 09/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Paul Wagner Allianz	MTG MINUTES BETWEEN SAREPTA THERAPEUTICS AND FDA DIVISION OF NEUROLOGY PRODUCTS RE ETEPLIRSEN
2013-6799	08/30/2013 09/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nancy Dougherty SANOFI	4350738, 4360507, 6059993 ETC
2013-6800	08/30/2013 09/30/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	McGuff Pharmaceuticals, Inc Kington Capital Management	MCGUFF PHARMACEUTICALS, SANTA ANA, CA - 483, EIR 09/01/2011 - 08/28/2013
2013-6801	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2012-8566
2013-6802	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2012-8185
2013-6803	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2012-7928
2013-6804	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2012-7753

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2013-6805	08/30/2013 09/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	Michael Lalonde Deshum Medical LLC	K121374
2013-6806	08/30/2013 09/30/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Alan Katz BLOOMBERG	LIST OF DRUGS APPROVED WITH BLACK BOX WARNINGS, LIST OF DRUGS WITH BLACK BOX WARNING ADDED AFTER FIRST APPROVAL, LIST OF WORDING CHANGES ETC
2013-6807	08/30/2013 09/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tina Lee Tris Pharma Inc.	NDA 010187
2013-6808	08/30/2013 09/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K131870
2013-6809	08/30/2013 09/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Shara Ambrosecchia G&W Laboratories Inc.	NDA 020700 - SBA
2013-6810	08/30/2013 09/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	Stephen Inglese Quality Solutions and Support, LLC	K121920;
2013-6811	08/30/2013 09/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	Stephen Inglese Quality Solutions and Support, LLC	K113097
2013-6812	08/30/2013 09/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	Stephen Inglese Quality Solutions and Support, LLC	K122950
2013-6813	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2012-7667
2013-6814	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2013-369
2013-6815	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2013-489
2013-6816	08/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723	2012-7577

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	09/30/2013		MERCK & CO., INC.	
2013-6817	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2012-7094
2013-6818	08/30/2013 09/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	PATHEON UK LIMITED, SWINDON, UK - EIR, 483, CO RESP 7/20/12
2013-6819	08/30/2013 09/30/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	GE HEALTHCARE AS, OSLO, NORWAY - EIR, 483, CO RESP 12/13/12
2013-6820	08/30/2013 09/30/2013	FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/	WALTER E CHALKLEY THOMSON REUTERS	MEDISCA INC, IRVING, TX - EIR, 483, CO RESP 1/26/12
2013-6821	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2012-6211
2013-6822	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2013-512
2013-6823	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2012-6008
2013-6824	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2012-5215
2013-6825	08/30/2013 09/30/2013	FDA/OGROP/ORR/CE-FO/PHI-DO/PHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	GLAXO SMITH KLINE, COLLEGEVILLE, PA - EIR, 483, CO RESP 9/19/12
2013-6826	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2012-4825
2013-6827	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2012-2779

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2013-6828	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2012-1491
2013-6829	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2013-589
2013-6830	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2013-721
2013-6831	08/30/2013 09/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	WOCKHARDT LTD, AURANGABAD, INDIA - EIR, 483, CO RESP 3/18-22/13
2013-6832	08/30/2013 09/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	SENTISS PHARMA PVT LTD, KHERA NIHLA VILLAGE, TEHSIL NALAGARH, INDIA 3/25/13, 4/3/13
2013-6833	08/30/2013 09/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	POSH CHEMICALS PVT LTD, HYDERABAD, INDIA - EIE, 483, CO RESP 3/3-8/13
2013-6834	08/30/2013 09/30/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	LIFESERVE BLOOD CTR, DES MOINES, IA - EIR, 483, CO RESP 6/13-27/13
2013-6835	08/30/2013 09/30/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	RELIABLE BIOPHARMACEUTICAL CORP, OVERLAND, MO - EIR, 483, CO RESP 4/27/12
2013-6836	08/30/2013 09/30/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	WALTER E CHALKLEY THOMSON REUTERS	RHODES PHARMACEUTICALS LP, COVENTRY, RI - EIR, 483, CO RESP 3/21/12
2013-6837	08/30/2013 09/30/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	WALTER E CHALKLEY THOMSON REUTERS	THOMAS R WALTERS MD, AUSTIN, TX - EIR, 483, CO RESP 4/19/12
2013-6838	08/30/2013 09/30/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	TRI MED SUPPLES INC, PLYMOUTH MTG, PA - EIR, 483, CO RESP 4/6/12
2013-6839	08/30/2013 09/30/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	WALTER E CHALKLEY THOMSON REUTERS	UPM PHARMACEUTICALS, BALTIMORE, MD - EIR, 483, CO RESP 11/13/12
2013-6840	08/30/2013	FDA/OGROP/ORAPA-FO/SAN-	WALTER E CHALKLEY	WESTWOOD LABORATORIES, AZUSA, CA - EIR, 483, CO

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	09/30/2013	DO/SAN-CB/ FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	THOMSON REUTERS	RESP 4/11/12
2013-6841	08/30/2013 09/30/2013	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	WALTER E CHALKLEY THOMSON REUTERS	WYETH PHARMACEUTICAL CO, GUAYAMA, PR - EIR, 483, CO RESP 7/11/12
2013-6842	08/30/2013 09/30/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	WALTER E CHALKLEY THOMSON REUTERS	ALLAY PHARMACEUTICALS LLC, HIALEAH, FL - EIR, 483, CO RESP 10/12/12
2013-6843	08/30/2013 09/30/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	WALTER E CHALKLEY THOMSON REUTERS	PERNIX MANUFACTURING LLC, HOUSTON, TX - EIR, 483, CO RESP 1/12/12
2013-6844	08/30/2013 09/30/2013	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	STERIS ISOMEDIX SERVICES, LIBERTYVILLE, IL - EIR, 483, CO RESP 1/29/13
2013-6845	08/30/2013 09/30/2013	FDA/OGROP/ORAP/PA-FO/SEADO/SEA-CB/	WALTER E CHALKLEY THOMSON REUTERS	KENNETH E KRELL MD, IDAHO FALLS, ID - EIR, 483, CO RESP 7/27/13
2013-6846	08/30/2013 09/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	INTAS PHARMACEUTICALS LTD, AHMEDABAD CITY, INDIA - EIR, 483, CO RESP 5/19/12
2013-6847	08/30/2013 09/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WATER E CHALKLEY THOMSON REUTERS	DISHMAN PHARMACEUTICALS & CHEMICALS LTD - AHMEDABAD GUJARAT, INDIA 3/17/12
2013-6848	08/30/2013 09/30/2013	FDA/OGROP/ORACE-FO/CINDO/CIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	CBA RESEARCH INC, LEXINGTON, KY - EIR, 483, CO RESP 10/19/12
2013-6849	08/30/2013 09/30/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	WALTER E CHALKLEY THOMSON REUTERS	BANNER PHARMACAPS INC, HIGH POINT, NC - EIR, 483, CO RESP 6/6/12
2013-6850	08/30/2013 09/30/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	WALTER E CHALKLEY THOMSON REUTERS	ALAUNUS PHARMACEUTICAL LLC, FRAMINGHAM, MA - EIR, 483, CO RESP 11/16/12
2013-6851	08/30/2013 09/30/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	WALTER E CHALKLEY THOMSON REUTERS	CAPE MEDICAL SUPPLY INC, SANDWICH, MA - EIR, 483, CO RESP 5/11/12
2013-6852	08/30/2013 09/30/2013	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	WALTER E CHALKLEY THOMSON REUTERS	GTX INC, MEMPHIS, TN - EIR, 483, CO RESP 7/19/12
2013-6853	08/30/2013 09/30/2013	FDA/OGROP/ORACE-FO/PHIDO/PHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	BIOCLINICA INC, NEWTOWN, PA - EIR, 483, CO RESP 3/7/12

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2013-6854	08/30/2013 09/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	FRESENIUS KABI AG, BAD HOMBURG, GERMANY - EIR, 483, CO RESP 1/14-18/13
2013-6855	08/30/2013 09/30/2013	FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	WALTER E CHALKLEY THOMSON REUTERS	HOSPITAL ESPANOL AUXILIO MUTUO DE PUERTO RICO INC IRB, SAN JUAN, PR - EIR, 483, CO RESP 1/28/13
2013-6856	09/03/2013 10/17/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OCC/ OC/ORA/OCI/ OC/ORA/OCI/	Mona McCombs McCombs, Mona	PROTOCOL FOR TRANSPORTING ADULTERATED FOOD
2013-6857	09/03/2013 10/17/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Alan Katz BLOOMBERG	LIST OF DRUGS VOLUNTARILY WITHDRAWN BY SPONSOR, LIST OF DRUGS WITHDRAWN FOR SAFETY REASONS
2013-6858	09/03/2013 10/17/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Christie Frayser Christie Frayser	ORTHO DIAGNOSTIC SYSTEMS, INC, RARITAN, NJ - LOT NUMBER RHL 265B, RHL 265K, RHL232A - MEDWATCH ALERTS, PROCESSING, POWDER SUBSTANCE ETC
2013-6859	09/03/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dennis W. Raisch UNIVERSITY OF NEW MEXICO	RITUXIMAB - AERS
2013-6860	09/03/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Gina Pera Gina Pera	ANDA 202608 - BIOEQUIVALENCE STUDIES
2013-6861	09/03/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Anita Fauchier Cempra Pharmaceuticals (Anita Fauchier)	WOCKHARDT, INDIA - RESPONSE TO 483
2013-6862	09/03/2013 10/17/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	Brenda Sweet TUCKER ELLIS LLP	JOHNSON & JOHNSON, HORSHAM, PA - EIR, 483 4/14/11, 10/2/09, ETC

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2013-6863	09/03/2013 10/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joyce Daubert Joyce Daubert	DICLEGIS - EFFICACY STUDIES
2013-6864	09/03/2013 10/17/2013	FDA/OGROP/ORR/SE-FO/NOL-DO/NOL-CB/	Jonathan Rudner Ampro Industries, Inc.	KEYSTONE LABORATORIES, INC - WARNING LETTERS 01/01/2009 - 12/31/2011
2013-6865	09/03/2013 10/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tina Lee Tris Pharma, Inc.	NDA 011552
2013-6866	09/03/2013 10/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tina Lee Tris Pharma Inc.	NDA 019478
2013-6867	09/03/2013 10/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tina Lee Tris Pharma Inc.	NDA 020198
2013-6868	09/03/2013 10/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tina Lee Tris Pharma Inc.	NDA 018482
2013-6869	09/03/2013 10/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tina Lee Tris Pharma Inc.	NDA 019684
2013-6870	09/03/2013 10/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tina Lee Tris Pharma Inc.	NDA 018333
2013-6871	09/03/2013 10/17/2013	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	RECS RE FOUR TOBACCO PRODUCTS DETERMINED NSE
2013-6872	09/03/2013	FDA/OC/OES/DDM/	Joyce Daubert	BENDECTIN - ADVISORY COMMITTEE

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	10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joyce Daubert	
2013-6873	09/03/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Vanessa Perez EXPONENT, INC.	CARBINOXAMINE CONTAINING DRUGS - DEATH REPORTS
2013-6874	09/03/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kara Plauger UPMC St. Margaret Hospital	FLUOROQUINOLONES - AERS
2013-6875	09/03/2013 10/17/2013	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	FCN 939
2013-6876	09/03/2013 10/17/2013	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	John Walsh James Alexander Corporation	WELCH, HOLME, AND CLARK COMPANY, NEWARK, NJ - EIR, 483, RECALL 08/29/2011 - 08/29/2013
2013-6877	09/03/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michael Manapol Law Offices of Brian D. Witzer, Inc.	ANDA 065156
2013-6878	09/03/2013 10/17/2013	FDA/OGROP/ORA/PA-FO/SEA- DO/SEA-CB/	John Walsh James Alexander Corporation	TOKYO CHEMICAL INDUSTRY COMPANY, LTD, PORTLAND, OR - EIR, 483 RECALLS 08/29/2010 - 08/29/2013
2013-6879	09/03/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michele Sinoway Lachman Consultants	ANDA 91052
2013-6880	09/03/2013 10/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Julie Schoell Stryker IMT	K111970
2013-6881	09/03/2013 10/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Oliver Clemens Materialise NV	K130126, K131129
2013-6882	09/03/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Christine Gassner GASSNER, VIRGINIA	MYSOLINE/PRIMIDONE - AERS 01/01/2011 - 09/01/2013

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-6883	09/03/2013 10/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Korey L Tichenor Smiles and Laughs Co.	STATISTICS COLLECTED BY FDA RE MQSA
2013-6884	09/03/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tina Lee Tris Pharma Inc.	NDA 019183
2013-6885	09/03/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOSEPH WALKER Walker, Joseph	TECFIDERA - ISR
2013-6886	09/03/2013 10/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Randy Veliky LEXINGTON CLINIC	K121920
2013-6887	09/03/2013 10/17/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Randy Veliky Lexington Intl LLC	K113097
2013-6888	09/03/2013 10/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Randy Veliky Lexington Intl LLC	K122950
2013-6889	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	FOI DAILY LOG 8/1/13-31/2013
2013-6890	09/03/2013 10/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	William H. Delp Delp, William H	MEDICAL DEVICES CLEARED TO BE MARKETED UNDER 868.5470
2013-6891	09/03/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dr Stephen Garner Mathys & Squire LLP	SUGEN, INC - IND SU6668
2013-6892	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	CLOSED FOIA REQUESTS ON CD 8/1-31/2013
2013-6893	09/03/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Faryal Hasan Hyman, Phelps & McNamara, P.C.	OFFICE OF GENERIC DRUGS STATISTICAL REPORT FOR JULY AND AUGUST 2013
2013-6894	09/03/2013	FDA/OMPT/CDER/GRP/DIDP/	Tina Lee	NDA 020142

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	10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tris Pharma Inc.	
2013-6895	09/03/2013 10/17/2013	FDA/OC/OES/DDM/	Ben Traywick Traywick Law Offices	JOINT MEETING OF THE ENDOCRINOLOGIC AND METABOLIC DRUGS ADVISORY COMMITTEE - TRANSCRIPT
2013-6896	09/03/2013 10/17/2013	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	TOBACCO SUBSTANTIAL EQUIVALENCE ORDERS
2013-6897	09/03/2013 10/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K130793
2013-6898	09/03/2013 10/17/2013	FDA/OMPT/CTP/OD/ FDA/OC/OEXA/OMA/	Rachel Johnson FOI Services, Inc.	RECS RE CTP PRESS RELEASE
2013-6899	09/03/2013 10/17/2013	FDA/OGROP/ORAC/CE-FO/CHI-DO/CHI-CB/	Rachel Johnson FOI Services, Inc.	F&F FOODS, CHICAGO, IL - EIR
2013-6900	09/03/2013 10/17/2013	OC/ORAC/ OC/ORAC/ FDA/OGROP/ORAC/CE-FO/MIN-DO/MIN-CB/	David M Longseth Longseth, David M	SAMPLE RESULTS
2013-6901	09/03/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NANJING KING-FRIEND BIOCHEMICAL, CHINA - EIR, 483, ETC
2013-6902	09/03/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tina Lee Tris Pharma, Inc.	NDA 204242
2013-6903	09/03/2013 10/17/2013	FDA/OFVM/CFSAN/OCD/EOS/	James H. Botkin BOTKINCHEMIE	FAP Octadecanoic acid 2-(2-hydroxyethyl) octadecylaminoethyl ester (CAS Reg. No. 52497-24-2), (octadecylimino) diethylene distearate (CAS Reg. No. 94945-28-5), and octadecyl bis(hydroxyethyl)amine (CAS Reg. No. 10213-78-2)
2013-6904	09/03/2013 10/17/2013	FDA/OC/OES/DDM/	Myra Wooley MASSACHUSETTS COLLEGE OF PHARMACY	1997 report by CDER titled "Retrospective review of ecotoxicity data submitted in environmental assessments for public display." (Docket No. 96N-0057)
2013-6905	09/03/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	DOXYCYCLINE INJ ANDA 50-442 - APRVL LTR, LBLG, MEDICAL RVW, ETC

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2013-6906	09/03/2013 10/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	DOXORUBINCIN LIPOSOME ANDA 50-718 - APRVL LTR, LBLG, MEDICAL RVW, ETC
2013-6907	09/03/2013 10/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	VISTARIL (HYDROXYUZINE PALMOATE) NDA 11-459 - APRVL LTR, LBLG, MEDICAL RVW, ETC
2013-6908	09/03/2013 10/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	DOXYCYCLINE INJ ANDA 62-475 - APRVL LTR, LBLG, MEDICAL RVWS, ETC
2013-6909	09/03/2013 10/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JAYA AYYAGARI DR REDDY'S LABORATORIES INC	DR REDDY'S LABS LTD - ATORVASTATIN CALCIUM ORAL ANDA 091-650 - SBA
2013-6910	09/03/2013 10/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JAYA AYYAGARI DR REDDY'S LABORATORIES INC	DR REDDY'S LABS LTD - ATORVASTATIN CALCIUM ANDA 203-257 SBA
2013-6911	09/03/2013 10/17/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	YAW DAKO COUNTRY PURE FOODS	GREGORY PACKAGING, NEWARK, NJ - EIR MOST RECENT
2013-6912	09/03/2013 10/17/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	YAW DAKO COUNTRY PURE FOODS	CITRUS SYSTEMS INC, HOPKINS, MN - EIR MOST RECENT
2013-6913	09/03/2013 10/17/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	YAW DAKO COUNTRY PURE FOODS	M&B JUICE, TAMPA, FL - EIR MOST RECENT
2013-6914	09/03/2013 10/17/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	YAW DAKO COUNTRY PURE FOODS	KING JUICE CO, MILWAUKEE, WI - EIR MOST RECENT
2013-6915	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	DAVID E OUTWATER OUTWATER & PINCKES LLP	ALCOA CIRCLE, CORONA, CA - POLYETHYLENE, PET BOTTLES & CONTAINERS SALES, LAB RPTS, WARNING LTRS, ETC 1/1/06 TO P RESENT
2013-6916	09/03/2013	FDA/OMPT/CDER/ORP/DIDP/	PAMELA SHEPPARD	AQUA PHARMS - CORDRAN LOTION TOPICAL NDA 13-790

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	10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TARO PHARMACEUTICALS USA INC	SBA
2013-6917	09/03/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	RACHEL JOHNSON FOI Services, Inc.	OLMESARTAN - ISRS 6585297, 7454426, 7457740, ETC
2013-6918	09/03/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	DANA HAYDEN Siegfried USA, LLC	PROPARACAINE HCL DMF 26989 - LIST OF CURRENT CUSTOMERS
2013-6919	09/03/2013 10/17/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	Doe J	GENERAL MILLS CEREAL LLC, GOLDEN VALLEY, MN - RAISIN NUT BRAN CEREAL CMLPLNTS
2013-6920	09/03/2013 10/17/2013	FDA/OFVM/CFSAN/OCD/EOS/	CARRIE L TEETER Keller and Heckman LLP	FCN 772
2013-6921	09/03/2013 10/17/2013	FDA/OMPT/CTP/OD/	MARILYNN WHITNEY COVINGTON & BURLING LLP	TOBACCO PRODS - EIGHT NOT SUBSTANTIALY EQUIVALENT (NSE) ORDERS, APPL, RVW, ETC
2013-6922	09/03/2013 11/21/2013	FDA/OFVM/CFSAN/OCD/EOS/	HEALTHER GALE OLSSON FRANK & WEEDA	REGULATROY & OR ENFORCEM3ENT IN MEASURES PERTAINING TO USSE OF THE WORD FRESH IN FOOD LBLG - CORR RECS 9/08 TO PRESENT
2013-6923	09/03/2013 10/17/2013	FDA/OC/OES/DDM/ FDA/OFVM/CFSAN/OCD/EOS/	SYLVIA WU CENTER FOR FOOD SAFETY	DKT 2006P-0101/CP1
2013-6924	09/03/2013 10/17/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MICHAEL PFEIL MERZ PHARMACEUTICALS GMBH	NOVARTIS VACCINES & DIAGNOSTICS INC USA 5/10/13; JANSSEN BIOLOGICS BV, NETHERLANDS; LONZA AG, SWITZERLAND 9/18/13 EIRS

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2013-6925	09/03/2013 10/17/2013	OC/CVM/OCD/	CYNDY BURINDA PHOENIX REGULATORY ASSOCIATES LTD	DIAMOND V - TRANSITION COW STUDIES CORR
2013-6926	09/03/2013 10/17/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/	JENNIFER O'BRIAN AbbVie, Inc.	ABBVIE INC - IMPORTS, PREDICT SCORES 1/1/13-7/15/13
2013-6927	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2013-258
2013-6928	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2013-262
2013-6929	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2012-8579
2013-6930	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2012-8580
2013-6931	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2012-8643
2013-6932	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2012-8721
2013-6933	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2012-8730
2013-6934	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2012-8782
2013-6935	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2012-8567
2013-6936	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723	2012-8988

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			MERCK & CO., INC.	
2013-6937	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723	2012-8992
			MERCK & CO., INC.	
2013-6938	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723	2012-8993
			MERCK & CO., INC.	
2013-6939	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723	2012-8996
			MERCK & CO., INC.	
2013-6940	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723	2012-9094
			MERCK & CO., INC.	
2013-6941	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2013-2420
			MERCK & CO., INC.	
2013-6942	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2013-2421
			MERCK & CO., INC.	
2013-6943	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2013-1523
			MERCK & CO., INC.	
2013-6944	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2013-1542
			MERCK & CO., INC.	
2013-6945	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2013-1596
			MERCK & CO., INC.	
2013-6946	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2013-1951
			MERCK & CO., INC.	
2013-6947	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2013-1887
			MERCK & CO., INC.	
2013-6948	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2013-1915
			MERCK & CO., INC.	
2013-6949	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2013-2423
			MERCK & CO., INC.	
2013-6950	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2013-1186
			MERCK & CO., INC.	
2013-6951	09/03/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2013-1188

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	10/17/2013		MERCK & CO., INC.	
2013-6952	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1924
2013-6953	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1271
2013-6954	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2022
2013-6955	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2051
2013-6956	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1395
2013-6957	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2068
2013-6958	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1426
2013-6959	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2093
2013-6960	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2397
2013-6961	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1432
2013-6962	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1451
2013-6963	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2110
2013-6964	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1479
2013-6965	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1921
2013-6966	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2305
2013-6967	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2427

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2013-6968	09/04/2013 10/02/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Paul Wagner Allianz	MTG MINUTES FROM 7/23/13 AND ANY PRE-MEETING AND POST-MEETING CORR BETWEEN FDA AND SAREPTA RE ETEPLIRSEN FOR TREATMENT OF DUCHENE'S MUSCULAR DYSTROPHY 01/01/2013 - 08/28/2013
2013-6969	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2221
2013-6970	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1700
2013-6971	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1701
2013-6972	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1702
2013-6973	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1805
2013-6974	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1835
2013-6975	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1836
2013-6976	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1884
2013-6977	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1704
2013-6978	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1719
2013-6979	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1765
2013-6980	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1741
2013-6981	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1754
2013-6982	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1761
2013-6983	09/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2013-1789

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	10/02/2013		MERCK & CO., INC.	
2013-6984	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1792
2013-6985	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2013-742
2013-6986	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-756
2013-6987	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-789
2013-6988	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-794
2013-6989	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-792
2013-6990	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-802
2013-6991	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-799
2013-6992	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-800
2013-6993	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-803
2013-6994	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-811
2013-6995	09/04/2013 10/02/2013	FDA/OGROP/OR/SE-FO/FLA-DO/FLA-CB/	DOUGLAS N BLUE II ZETETIC INC	SMITHS MEDICAL CATHETERS ENTRY #109-0875029-1 - RECS
2013-6996	09/04/2013 10/02/2013	FDA/OC/OL/	THOMAS H JONES 339 GROUP LLC	SEN MITCH MCCONNELL - FEDERAL FUNDING LEGISLATION, REGULATIONS, RECOMMENDATIONS, ETC CORR, RESP
2013-6997	09/04/2013 10/02/2013	FDA/OGROP/OR/PA-FO/SAN-DO/SAN-CB/	SETH J MANFREDI GORDON & REES LLP	NEXT SEAFOOD INC, HAYWARD, CA - EIRS, TEST RESULTS, LTRS, ETC 2/22/08-12/31/08
2013-6998	09/04/2013 10/02/2013	FDA/OGROP/OR/PA-FO/SAN-DO/SAN-CB/	WILLIAM S NORTON MOTLEY RICE LLC	HOSPIRA INC, MORGAN HILL, CA - INSP 4/21-22/09 RECS
2013-6999	09/04/2013	FDA/OC/OES/DFOI/	ELENA HOWELL	2013-6529

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	10/02/2013		HOGAN LOVELLS LLP	
2013-7000	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	ELENA HOWELL HOGAN LOVELLS LLP	2013-6250
2013-7001	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	DANYSH, KURT	MEDICAL DICTIONARY FOR REGULATORY ACTIVITIES (MEDDRA)
2013-7002	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	DANYSH, KURT	ISRS 4638251-3, 4655315-9, 5074682-8, ETC
2013-7003	09/04/2013 10/02/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	TAMIKA L BELL BIOSCREEN TESTING SERVICES INC	BEAUTY-FILL, PISCATAWAY, NJ - EIRS, 483S, WARNING LTRS LAST 5 YRS
2013-7004	09/04/2013 10/02/2013	OC/ORACE/ORM/ OC/ORACE/ORM/	ROBERT KING FDA NEWS	PHARMACEUTICAL, BIOLOGICS, MEDICAL DVC MFG, CLNCL TRIAL FACILITIES IN AND OUTSIDE THE US - 483S 8/1-31/13
2013-7005	09/04/2013 10/02/2013	FDA/OFVM/CFSAN/OCD/EOS/	WILLIAM A OLSON PHD WASHINGTON INFORMATION SOURCE	LYONDELL BASELL INDUSTRIES - ETHYLENE/PROPYLENE COPOLYMERS FCN 1051
2013-7006	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-809
2013-7007	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-812
2013-7008	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-833
2013-7009	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-876
2013-7010	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-974
2013-7011	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1381
2013-7012	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1201
2013-7013	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1029
2013-7014	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1061

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2013-7015	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2212
2013-7016	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4627
2013-7017	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4636
2013-7018	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4862
2013-7019	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4864
2013-7020	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-5178
2013-7021	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2929
2013-7022	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2947
2013-7023	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2963
2013-7024	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3050
2013-7025	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3296
2013-7026	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4349
2013-7027	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2568
2013-7028	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2515
2013-7029	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2498
2013-7030	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2485
2013-7031	09/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2013-2484

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	10/02/2013		MERCK & CO., INC.	
2013-7032	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4342
2013-7033	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2483
2013-7034	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4068
2013-7035	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4065
2013-7036	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4202
2013-7037	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3340
2013-7038	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2753
2013-7039	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2602
2013-7040	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3483
2013-7041	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4586
2013-7042	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	John Walsh James Alexander Corporation	NATUREX - EIR, 483, RECALL 07/01/2011 - 09/03/2013
2013-7043	09/04/2013 10/02/2013	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	Richard O. Wood the Wood Burditt group	ORGAN RECOVERY SYSTEMS, INC, ITASCA, IL - EIR, 483, 482 ETC 1/1/11 TO PRESENT
2013-7044	09/05/2013 10/03/2013	FDA/OC/OES/DDM/	COVINGTON & BURLING LLP	DKT FDA-1996-N-0050
2013-7045	09/05/2013 10/03/2013	FDA/OC/OES/DDM/	LAUREN FARRUGGIA Hyman, Phelps & McNamara, P.C.	DKT FDA-2013-P-0283
2013-7046	09/05/2013 10/03/2013	OC/ORACE-FO/LOS-DO/LOS-CB/	TERRY SHAIN MEDICAL WASTE SERVICES	FDA MANDATED DESTRUCTION ACTIVITY LOS ANGELES, CA 1/12 TO 3/31/13

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2013-7047	09/05/2013 10/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	ANDREA N. WALLEN DELPHINUS MEDICAL TECHNOLOGIES INC	IVU IMAGING CORP - SOFIA ATUS IMAGING DVC K080555
2013-7048	09/05/2013 10/03/2013	OC/ORA/OCI/ OC/ORA/OCI/	FRANK C. DAVIS MELODY CHRISTIAN ACADEMY	INDIVIDUAL RECS
2013-7049	09/05/2013 10/03/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HEALY, HILARY	XOLAIR - AER
2013-7050	09/05/2013 10/03/2013	FDA/OFVM/CFSAN/OCD/EOS/	ERIC F. GREENBERG ERIC F GREENBERG PC	FCN 815
2013-7051	09/05/2013 10/03/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORA/ OC/ORA/	NADIA A. PATEL BONNER KIERNAN TREBACH ET AL	NEW ENGLAND COMPOUNDING CTR, FRAMINGHAM, MA - METHYLPREDNISOLONE ACETATE INVESTIGATION, INSP, RECS
2013-7052	09/05/2013 10/03/2013	FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SUSAN E. SATKOWSKI LAVIN O'NEIL RICCI CEDRONE & DISIPIO	AVANTIX LABORATORIES; TDM PHARMACEUTICAL RESEARCH LLC - 482, 483, EIR, BIOEQUIV
2013-7053	09/05/2013 10/25/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/ORO/DIOP/	BENJAMIN L. ENGLAND, Esq. BENJAMIN L ENGLAND & ASSOCIATES LLC	FDA REGULATED ARTICLES 1/08 TO PRESENT
2013-7054	09/05/2013 10/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	THOMAS TRIMNAL STERLING MEDICAL LLC..	HYSTEROSALPINGOGRAPHY & SONOHSTYEROGRAPHY CATHETER SET K092969
2013-7055	09/06/2013 10/04/2013	FDA/OC/OES/DDM/	JOANNA MCCALL NATIONAL CORPORATE RESEARCH	DKT FDA-1996-N-0050
2013-7056	09/06/2013 10/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K051671
2013-7057	09/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	Leann Christman	K090449

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	10/04/2013		Medos Medizintechnik AG	
2013-7058	09/06/2013 10/04/2013	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	Richard O. Wood the Wood Burditt group	UNIVERSITY OF FLORIDA, CERHB, FLORIDA BIOLOGIX, ALACHUA, FL - - 482, 483 EIR ETC
2013-7059	09/06/2013 10/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jeanmarie Sales MEDTRONIC	K123633
2013-7060	09/06/2013 10/04/2013	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	Jason A Dean Hulsey Oliver & Mahar, LLP	AMERICAN CUSTOM BLENDERS, LLC, JEFFERSON, GA - 01/01/2011 - 09/03/2013
2013-7061	09/06/2013 10/04/2013	FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA DISCLOSURE LOG (08/26/2013 - 08/30/2013)
2013-7062	09/06/2013 10/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	Mark Skertic Mark Skertic	RANBAXY PHARMACEUTICALS - PREVIOUSLY RELEASED RECORDS 04/01/2004 - 06/01/2013
2013-7063	09/06/2013 10/04/2013	FDA/OGROP/ORR/NE-FO/NYK-DO/NYK-DCB/	John Walsh James Alexander Corporation	SCHOTT GLASS, ELMSFORD, NY - EIR, 483, RECALL (08/01/2011 - 09/03/2013)
2013-7064	09/06/2013 10/04/2013	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	John Walsh James Alexander Corporation	POREX TECHNOLOGIES, FAIRBURN, GA - 483, EIR, RECALL 06/01/2011 - 09/03/2013;
2013-7065	09/06/2013 10/04/2013	FDA/OGROP/ORR/CE-FO/MIN-DO/MIN-CB/	John Walsh James Alexander Corporation	TEEL PLASTICS, INC, BARABOO, WI - 483, EIR, RECALL 08/01/2011 - 09/03/2013
2013-7066	09/06/2013 10/04/2013	FDA/OGROP/ORR/CE-FO/BLT-DO/BLT-CB/	John Walsh James Alexander Corporation	KLOCKNER PENTAPLAST OF AMERICA, INC, GORDONSVILLE, VA - 483, EIR, RECALL 08/01/2011 - 09/03/2013
2013-7067	09/06/2013 10/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	Tina Wu APTIV SOLUTIONS	K120218 K113655 K113222 ETC
2013-7068	09/06/2013 10/04/2013	FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/	Daria Church Clariant Corporation	FCN 809
2013-7069	09/06/2013 10/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tina Lee Tris Pharma Inc.	NDA 020450
2013-7070	09/06/2013 10/04/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ORP/DIDP/	Jonathan J. Darrow BRIGHAM AND WOMEN'S HOSPITAL	RECS THAT SUMMARIZE NOVEL NEW DRUGS APPROVED IN EACH CALENDAR 01/01/1979 - 12/31/2010

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2013-7071	09/06/2013 10/04/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OES/DDM/ FDA/OFVM/CFSAN/OCD/EOS/	Beth Briczinski NATIONAL MILK PRODUCERS FEDERATION	FDA-2013-N-0888 - PETITION
2013-7072	09/06/2013 10/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORA/ OC/ORA/ OC/ORA/ OC/ORA/	Mark Wolfe Tom Rhodes Law Firm, P.C.	SPECIALTY COMPOUNDING RECALL OF CALCIUM GLUCONATE
2013-7073	09/06/2013 10/04/2013	FDA/OMPT/OSMP/OOPD/	Orphan Designation Request for Qutenza LCC Consulting, LLC	QUTENZA - ORPHAN PRODUCT DESIGNATION
2013-7074	09/06/2013 10/04/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/ FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/ FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/	Mary Clare Jalonick THE ASSOCIATED PRESS	TAYLOR FARMS DE MEXICO - 483, INVESTIGATION RECS 09/01/2003 - 09/03/2013
2013-7075	09/06/2013 10/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	RON JEFFREY CAS MEDICAL SYSTEMS INC	NONIN MEDICAL INC - K102715
2013-7076	09/06/2013 10/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	XIN MENG III SOLUTION LABORARY	SYNAPSE 3D LUNG & ABDOMEN ANAYLIS - K130542; MIPLATFORM MEDICAL IMAGING SUITE - K131424
2013-7077	09/06/2013 10/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JAYA AYYAGARI DR REDDY'S LABORATORIES INC	ATORVASTATIN CALCIUM TABS - ANDA 91-650, 203-257 BIOEQV RVWS, MODULE 3.2P.1 COMPOSITION SECTION
2013-7078	09/06/2013	FDA/OFVM/CFSAN/OCD/EOS/	HEALTHIER M HAUGHEY	RED BULL, MONSTER, ROCK STAR, ETC - CAERS 2010 TO

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	10/04/2013		ROCKY MOUNTAIN POISON AND DRUG CENTER	PRESENT
2013-7079	09/06/2013 10/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CAUDLE #20711-058, BRANDON LEE	TRUVADA - PI
2013-7080	09/06/2013 10/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Barbara Kowinsky KOWINSKY, BARBARA	BASF Grenzach GmbH - EIR JULY 2011
2013-7081	09/06/2013 10/04/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	John Walsh James Alexander Corporation	ATLANTIC SCALE COMPANY, NUTLEY, NJ - EIR, 483, RECALL (04/01/2011 - 09/03/2013) ;
2013-7082	09/06/2013 10/04/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	John Walsh James Alexander Corporation	BRANDT BOX & PAPAER CO, COLUMBIA, NJ - EIR, 483, RECALL 08/01/2011 - 09/03/2013
2013-7083	09/06/2013 10/04/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	John Walsh James Alexander Corporation	ACCU-GLASS LLC, ST LOUIS, MO - EIR, 483, RECALL 08/01/2011 - 09/03/2013
2013-7084	09/06/2013 10/04/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	John Walsh James Alexander Corporation	FRUTAROM USA, INC, NORTH BERGEN, NJ - EIR, 483, RECALL 06/01/2011 - 09/03/2013
2013-7085	09/06/2013 10/04/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	John Walsh James Alexander Corporation	GERRESHEIMER GLASS INC, VINELAND, NJ - EIR, 483, RECALL 07/01/2011 - 09/03/2013
2013-7086	09/06/2013 10/04/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	John Walsh James Alexander Corporation	MID-YORK PRESS, INC, SHERBURNE, NY - EIR, 483, RECALL 07/01/2011 - 09/03/2013
2013-7087	09/06/2013 10/04/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	John Walsh James Alexander Corporation	STERIPRO LABS, ITASCA, IL - EIR, 483, RECALL 08/01/2011 - 09/03/2013
2013-7088	09/09/2013 10/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 22047 S 11
2013-7089	09/09/2013 10/07/2013	OC/CVM/OCD/	Sandy O'Kelley Merial Limited	AGRI-MECTIN PLUS CLORSULON - FOIA SUMMARY
2013-7090	09/09/2013 10/07/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	John Walsh James Alexander Corporation	TECTUBES USA, VINELAND, NJ - EIR, 483, RECALL
2013-7091	09/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson	510K REDACTED AND RELEASED IN AUGUST 2013 NOT SENT TO FOI SERVICES

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	10/07/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	FOI Services, Inc.	
2013-7092	09/09/2013 10/07/2013	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	John Walsh James Alexander Corporation	STERIGENICS, WILLOWBROOK, IL - EIR, 483, RECALL
2013-7093	09/09/2013 10/07/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Remel, Inc. Fresenius Kabi USA, LLC	REMEL, INC, LENEXA, KS - 483, RESPONSE 01/01/2010 - 09/03/2013
2013-7094	09/09/2013 10/07/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	John Walsh James Alexander Corporation	INHANCE TECHNOLOGIES, ALLENTOWN, PA - EIR, 483, RECALL 06/01/2011 - 09/03/2013
2013-7095	09/09/2013 10/07/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	John Brown J Brown Enterprises	K052925, K991430
2013-7096	09/09/2013 10/07/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anna Azvolinsky Anna Azvolinsky	ANDA 077425
2013-7097	09/09/2013 10/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Sun Choi ADVANCED STERILIZATION PRODUCTS	K111391, K111375, K111377
2013-7098	09/09/2013 10/07/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Eric Young Kessler Topaz Meltzer Check LLP	ST JUDE MEDICAL - EIR 6/8/2009 TO 7/8/2009, ATTACHMENT 5
2013-7099	09/09/2013 10/07/2013	FDA/OC/OES/DDM/	Alan Katz BLOOMBERG NEWS	ANTI-INFECTIVE DRUGS ADVISORY COMMITTEE MEETINGS RE MDR-TB - MINUTES 06/01/2009 - 11/29/2012
2013-7100	09/09/2013 10/07/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ OC/CVM/OCD/	Doe J	INDIVIDUAL RECS
2013-7101	09/09/2013 10/07/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Jonathan Siegel Kingdon Capital Management	SANQUIN PLASMA PRODUCTS, AMSTERDAM, NETHERLANDS - 483, EIR 05/15/2013 - 09/04/2013
2013-7102	09/09/2013 10/07/2013	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	4MEI IN SOFT DRINKS - FOIA REQUESTS
2013-7103	09/09/2013 10/07/2013	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	4MEI IN SOFT DRINKS AND CARAMEL COLOR - CORR
2013-7104	09/09/2013 10/07/2013	FDA/OC/OES/DDM/	Alberto Soler Alberto Soler	42 FR 14308

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2013-7105	09/09/2013 10/07/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	LALILAB4055 LALILAB, INC.	Entry # 523-1008810-0 ANALYTICAL WORKSHEETS
2013-7106	09/09/2013 10/07/2013	FDA/OC/OES/DDM/	Lon Schneider MD Lon Schneider MD	PERIPHERAL AND CNS DRUGS ADVISORY COMMITTEE MEETINGS - AGENDAS, ROSTERS, MINUTES ETC 01/01/1989 - 01/01/1999
2013-7107	09/09/2013 10/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Vikas Narang GPC Medical Limited	K070761;
2013-7108	09/09/2013 10/07/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Chiedozie Ayika Heywood Hospital	FDA Drug Safety Communication: FDA requires label changes to warn of risk for possibly permanent nerve damage from antibacterial fluoroquinolone drugs taken by mouth or by injection - AERS REPORTING
2013-7109	09/09/2013 10/07/2013	OC/ORO/ OC/ORO/	Derrick Gingery THE PINK SHEET	FORM 483 FOR QUALITY AND STERILITY TESTING LABORATORIES RE COMPOUNDING PHARMACIES 01/01/2013 - 09/04/2013
2013-7110	09/09/2013 10/07/2013	FDA/OC/OES/DDM/	Jorge Flores P.A Alberto Soler	35 FR 18623 Dec. 12, 1970; 36 FR 12093 June 25, 1971; 37 FR 25705 Dec. 2, 1972 ETC
2013-7111	09/09/2013 10/07/2013	FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Peter T. Anderson, Esq. Ashcraft & Gerel	MEDTRONIC MINIMED PARADIGM INSULIN INFUSION SET - RECALL RECS
2013-7112	09/09/2013 10/07/2013	FDA/OGROP/ORO/PA-FO/SEA-DO/SEA-CB/	Peter Waldran BAYER HEALTHCARE	JUBILANT-HOLLISTERSTIER, SPOKANE, WA - EIR, 483, WARNING LETTER 09/01/2005 - 09/01/2013
2013-7113	09/09/2013 10/07/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOSEPH WALKER Walker, Joseph	COMPLAINTS MADE TO DSI RE CLINICAL TRIAL RECRUITMENT OR CLINICAL TRIAL MARKETING
2013-7114	09/09/2013 10/07/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Meghan Lewallen MELLINO ROBENALT LLC	SCOPOLAMINE - MEDWATCH FORMS; PADER; PSUR
2013-7115	09/09/2013 10/07/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Peter R. Breggin, MD Center for the Study of Empathic Therapy	METOCLOPRAMIDE - SRS SPONTANEOUS REPORTING SYSTEM SUMMARY DATA

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2013-7116	09/09/2013 11/29/2013	FDA/OMPT/CTP/OD/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	GRANDFATHERED TOBACCO PRODUCTS
2013-7117	09/09/2013 10/07/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/CVM/OCD/	Amy Babcock Hudson Highlands Veterinary Medical Group	INDIVIDUAL RECS
2013-7118	09/09/2013 10/07/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lorraine Barde Lorraine Barde	ALPRAZOLAM - AERS, STUDIES
2013-7119	09/09/2013 10/07/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Lalit Ortho Care	DATA OF TECHNOLOGICAL CHARACTERISTICS AND BIOMECHANIAL TESTING/BENCH TESTING OF PREDICATE DEVICES
2013-7120	09/09/2013 10/07/2013	FDA/OC/OES/DFOI/	Jessica Kelly South Carolina Attorney General's Office	YASMIN - AERS
2013-7121	09/09/2013 10/07/2013	FDA/OC/OES/DFOI/	Jessica Kelly South Carolina Attorney General's Office	YAZ - AERS
2013-7122	09/09/2013 10/07/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Hollie Lawrence Regions Hospital	LIDODERM PATCH - AERS
2013-7123	09/09/2013 10/07/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jennifer Janisch CBS NEWS	ALL ADVERSE EVENTS REPORTED TO THE FDA BY DEPARTMENT OF DEFENSE EMPLOYEES, TO INCLUDE TRICARE EMPLOYEES, MILITARY DOCTORS, MILITARY PHARMACISTS, AND ANY OTHER DEPARTMENT OF DEFENSE EMPLOYEE FOR THE DRUG MEFLOQUINE
2013-7124	09/09/2013 10/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Leann Christman Medos Medizintechnik AG	K090450
2013-7125	09/09/2013 10/07/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Wendy Taylor TAYLOR, WENDY	K090850, K082575, K081979 ETC
2013-7126	09/09/2013 10/07/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	John Walsh James Alexander Corporation	NICOSIN EXTRUSION, BRAZIL, IN - EIR, 483, RECALL 09/05/2010 - 09/05/2013

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2013-7127	09/09/2013 10/07/2013	FDA/OFVM/CFSAN/OCD/EOS/	Mitchell Cheeseman Steptoe & Johnson LLP	FAP 5A4459, 5A4460
2013-7128	09/09/2013 10/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Gary J Syring Gary Syring	K112102, K120450
2013-7129	09/09/2013 10/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K102469
2013-7130	09/09/2013 10/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Dolly Pena NA	ESSURE - CLINICAL STUDIES
2013-7131	09/09/2013 10/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ingrid Hoos Horizon Pharma, Inc.	NDA 022304
2013-7132	09/09/2013 10/07/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/	Eun Bang, Eun	K122389
2013-7133	09/09/2013 10/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Lillie Thomas ORTHOFIX INC.	K130932
2013-7134	09/09/2013 10/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Lillie Thomas ORTHOFIX INC.	P850007/S005
2013-7135	09/09/2013 10/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Lillie Thomas ORTHOFIX INC.	P850007/S004
2013-7136	09/09/2013 10/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Peter Sun Sol Enterprises	K092240
2013-7137	09/09/2013 10/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 202515
2013-7138	09/09/2013 10/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michele Sinoway LACHMAN CONSULTANT SERVICES INC	ANDA 090431

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2013-7139	09/09/2013 10/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Jane Bentley ALCON LABORATORIES INC	ALCON LABORATORIES, CORK, IRELAND - EIR 02/21/2011 - 02/24/2011
2013-7140	09/09/2013 10/07/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	TCheney TC Consulting	HENRY FRAZER, PHARMD, MONTGOMERY, AL - 483 09/24/2012 - 10/03/2102
2013-7141	09/09/2013 10/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Leann Christman Medos Medizintechnik AG	HILITE 7000, 7000 LT 510K
2013-7142	09/09/2013 10/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	Beverly Ann Sakuda THE QUEEN'S MEDICAL CENTER	OXYELITE PRO - AERS
2013-7143	09/09/2013 10/07/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Shin Kang WELLS FARGO	BIOMARIN - 483, REPONSE, EIR 01/01/2013 - 09/05/2013
2013-7144	09/09/2013 10/07/2013	OC/CVM/OCD/ FDA/OC/OES/	Lewis Bollard Humane Society of the United States	ZIMLAX - CORR, SUSPENSION, STUDIES ETC
2013-7145	09/09/2013 10/07/2013	FDA/OC/OES/DDM/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sara Green MERRIMACK PHARMACEUTICALS INC	FDA STAFF MANUAL GUIDE 4850.7
2013-7146	09/09/2013 10/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	SHENZHEN ANT HI-TECH INDUSTRIAL CO., LTD - APPROVAL RECS FOR HIGH PRESSURE SYRINGES
2013-7147	09/09/2013 10/07/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/ORO/DIOP/	DEVA SUNDARARAJAN GLOBAL TRADE INTELLIGENCE INC	IMPORT RECS 7/1/13 TO PRESENT
2013-7148	09/09/2013 10/07/2013	FDA/OFVM/CFSAN/OCD/EOS/	ANDREA STOUT HEEKIN & HEEKIN	MT HEALTHY HATCHERIES - SALMONELLA CONTAMINATION INVESTIGATION RECS 4/11
2013-7149	09/09/2013 10/07/2013	FDA/OC/OES/DFOI/	DANYSH, KURT	INDIVIDUAL RECS

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2013-7150	09/09/2013 10/07/2013	OC/CVM/OCD/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CTP/OD/ FDA/OC/OCC/	JANICE M HOGAN HOGAN LOVELLS LLP	LIST OF SPECIAL GOVERNMENT EMPLOYEES WHO COULD SERVE AS TEMPORARY VOTING MEMBERS FOR FDA A/C MTGS
2013-7151	09/09/2013 10/07/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KAITLYN N DAY WARNER NORCROSS & JUDD LLP	XELLIA PHARMS - BACITRACIN CORR
2013-7152	09/09/2013 10/07/2013	FDA/OFVM/CFSAN/OCD/EOS/	DON M OBERT COWAN LIEBOWITZ & LATMAN PC	LIN'S WAHA USA INTERNATIONAL CORP - ENTRY #U79-1682226-6 LAB RPTS, EIRS, 483S, ETC
2013-7153	09/09/2013 10/07/2013	FDA/OFVM/CFSAN/OCD/EOS/	DON M OBERT COWAN LIEBOWITZ & LATMAN PC	LIN'S ENTERPRISE (USA) INC - ENTRY #ES3-2070142-9 LAB RPTS, EIRS, 483S, ETC
2013-7154	09/09/2013 10/07/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	MICHELE L BUENAFE MORGAN LEWIS & BOCKIUS LLP	LED INTELLECTUAL PROPERTIES LLC - LIGHTSTIM K120775, K101190
2013-7155	09/09/2013 10/07/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CINIMERA, KRISTA	OTSUKA PHARMACEUTICAL DEVELOPMENT & COMMERCIALIZATION INC - TOLVAPTAN COMPLETE RESP LTR 8/29/13
2013-7156	09/09/2013 10/07/2013	FDA/OC/OES/DFOI/	CHRISTOPHER VAN GUNDY ROLL LAW GROUP PC	DETROIT RECS - MINOR DELETIONS
2013-7157	09/09/2013 10/07/2013	FDA/OC/OES/DFOI/	CHRISTOPHER VAN GUNDY ROLL LAW GROUP PC	LOS ANGELES RECS - MINOR DELETIONS
2013-7158	09/09/2013 10/07/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SW-FO/DAL-	SAMANTHA MYERS ROANOKE CLAIMS SERVICES	MARROKO VALLEY LLC - ENTRY #BYX00637516, #BYX00633887 NOTICES FOR REQUEST OF INFORMATION (CF28), FDA NOTICE OF ACTION, CBP REDELIER NOTICES (CF4647), ETC

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		DO/DAL-CB/ FDA/OGROP/ORASW- FO/SWID/SWID-CB/		
2013-7159	09/09/2013 10/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Lillie Thomas ORTHOFIX INC.	K972768
2013-7160	09/09/2013 10/07/2013	FDA/OO/OFBA/OAGS/	Maria Herbert MCH Consulting Services	TOBACCO TRIBAL COMPLIANCE OUTREACH AND COMMUNICATIONS FDA-13-223-SOL-00071; THIRD PARTY AUDIT RECALL 12-223-SOL-00100
2013-7161	09/09/2013 10/07/2013	FDA/OGROP/ORAS/SE-FO/FLA- DO/FLA-CB/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Robert King FDA NEWS	BELCHER PHARMACEUTICALS, LARGO, FL - 483
2013-7162	09/09/2013 10/07/2013	OC/ORAS/ OC/ORAS/ FDA/OGROP/ORAS/SE-FO/FLA- DO/FLA-CB/	Robyn M. Buckley York Williams, LLP	CONSUMER COMPLAINT 115081
2013-7163	09/09/2013 10/07/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ingrid Hoos Horizon Pharma, Inc.	NDA 200533
2013-7164	09/09/2013 10/07/2013	FDA/OO/OFBA/OAGS/	Michelle Seissler FEFA LLC	HHSF223201110113A
2013-7165	09/09/2013 10/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Marie Thibault LAZARD CAPITAL MARKETS	CARDIOMEMS' CHAMPION HF MONITORING SYSTEM - ADDITIONAL DATA SUBMISSION
2013-7166	09/09/2013 10/07/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Rachel Johnson FOI Services, Inc.	VACCINE LICENSE NUMBER 3
2013-7167	09/09/2013 10/07/2013	FDA/OC/OES/DDM/	Richard B. Smith, Ph.D. Richard B. Smith, Ph.D.	OPHTHALMIC DEVICES PANEL - TRANSCRIPTS 01/01/1995 - 12/31/1996
2013-7168	09/09/2013 10/07/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Kerry Thacker Kerry Thacker	IND 15376
2013-7169	09/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Dr Andrew Naylor	HDE H010005

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	10/07/2013		Newcastle University	
2013-7170	09/09/2013 12/05/2013	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	FAP 5B3894, 8B4071
2013-7171	09/09/2013 10/07/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Ortav Yehudai Great Point Partners, LLC	OSIRIS THERAPEUTICS, COLUMBIA, MD - 483, WARNING LETTER, UNTITLED LETTER
2013-7172	09/09/2013 10/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Lillie Thomas ORTHOFIX INC.	K030197
2013-7173	09/09/2013 10/07/2013	FDA/OC/OES/DFOI/	Adriene Azariance Huntington Memorial Hospital Inpatient Pharmacy	PHARMEDIUM SERVICES, LLC - INSPECTION RECS
2013-7174	09/09/2013 10/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Lillie Thomas ORTHOFIX INC.	K011965
2013-7175	09/09/2013 10/07/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/OSMP/OOPD/ FDA/OMPT/OSMP/OCP/	Amy Tseng TissueTech, Inc.	TISSUE REFERENCE GROUP RECOMMENDATION DOCUMENTS
2013-7176	09/09/2013 10/07/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Greg Allison Greg Allison	ANDA 091189
2013-7177	09/09/2013 10/07/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Megan Healey Megan Healey	NEW ENGLAND CORD BANK - INSPECTION RECS 01/01/2013 - 09/08/2013
2013-7178	09/09/2013 10/07/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Megan Healey Megan Healey	VIACORD - INSPECTION RECS 01/01/2013 - 09/08/2013
2013-7179	09/09/2013 10/07/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Megan Healey Megan Healey	CORD BLOOD REGISTRY - INSPECTION RECS 01/01/2013 - 09/08/2013
2013-7180	09/09/2013 10/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Susan Quick Philips Healthcare Inc (Cleveland)	K083421
2013-7181	09/09/2013 10/07/2013	FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA REQUEST LOG 9/2/2013 TO 9/6/2013
2013-7182	09/09/2013 10/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Susan Quick Philips Healthcare Inc (Cleveland)	K121434
2013-7183	09/09/2013 10/07/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Steve Unwin Steve Unwin	JAMES C FREEMAN, MD - RESPONSE TO 483

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2013-7184	09/09/2013 10/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Joseph Dohm TEL-Atomic Inc	THE SCIENCE SOURCE - ANNUAL REPORTS FOR RADIATION EMITTING PRODUCTS 06/30/2012 - 09/07/2013
2013-7185	09/10/2013 10/08/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	ROBERT KING FDA NEWS	BIOGEN IDEC, RESEARCH TRIANGLE PARK, NC - 483S 8/1-31/13
2013-7186	09/10/2013 10/08/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	ROBERT KING FDA NEWS	KAWKNAD MANUFACTURING INDUSTRIES INC, ALEXANDRIA, VA; BARR LABORATORIES INC (TEVA), FOREST, VA; TETRACORE INC, ROCKVILLE, MD, ETC - 483S 8/1-31/13
2013-7187	09/10/2013 10/08/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	ROBERT KING FDA NEWS	RSB SPINE LLC, CLEVELAND, OH - 483S 8/1-31/13
2013-7188	09/10/2013 10/08/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	ROBERT KING FDA NEWS	ARJOHUNTLEIGH INC, SAN ANTONIO, TX; RETRACTABLE TECHNOLOGIES INC, LITTLE ELM, TX; OTOTRONIX LLC, SPRING, TX, ETC - 483S 8/1-31/13
2013-7189	09/10/2013 10/08/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	ROBERT KING FDA NEWS	CME AMERICA LLC, GOLDEN, CO; PROVIDENCE GLOBAL MEDICAL INC, SALT LAKE CITY, UT; CORGENIX INC, BROOMFIELD, CO, ETC - 483S 8/1-31/13
2013-7190	09/10/2013 10/08/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	ROBERT KING FDA NEWS	TANGENT MEDICAL TECHNOLOGIES, INC, ANN ARBOR, MI; KING SYSTEMS CORP, NOBLESVILLE, IN; KREMERS URBAN PHARMACEUTICALS INC, SEYMOUR, IN, ETC - 483S 8/1-31/13
2013-7191	09/10/2013 10/08/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	ROBERT KING FDA NEWS	GAMBRO RENAL PRODUCTS INC, DAYTONA BEACH, FL; BIOMET 3I LLC, PALM BEACH GARDENS, FL; FIBER OPTIC CABLES INC, LARGO, FL, ETC - 483S 8/1-31/13
2013-7192	09/10/2013 10/08/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ROBERT KING FDA NEWS	MAYNE PHARMA INTERNATIONAL PTY LTD, SALISBURY SOUTH AUSTRALIA; LABORATORIOS JALOMA SA DE CV, GUADALAJARA, MEXICO; MERK SA DE CV, NAUCALPAN DE JUAREZ, MEXICO, ETC - 483S 8/1-31/13
2013-7193	09/10/2013 10/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	ROBERT KING FDA NEWS	MP BIOMEDICALS ASIA PACIFIC PTD LTD, SINGAPORE; PHILIPS & NEUSOFT MEDICAL SYSTEMS CO LTD, SHENYANG, CHINA; CHEEN HOUNG ENTERPRISE CO LTD, TAIPEI, TAIWAN, ETC - 483S 8/1-31/13
2013-7194	09/10/2013 10/08/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	ROBERT KING FDA NEWS	HOSPIRA INC, MCPHERSON, KS; WEXFORD LABS INC, KIRKWOOD, MO; CERTIFIED SAFETY MFG INC, KANSAS CITY, MO - 483S 8/1-31/13
2013-7195	09/10/2013 10/08/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	ROBERT KING FDA NEWS	SHIRE HUMAN GENETIC THERAPIES INC, CAMBRIDGE, MA; PHARMAGEN LABORATORIES INC, STAMFORD, CT; IMAGE DIAGNOSTICS INC, FITCHBURG, MA, ETC - 483S 8/1-31/13
2013-7196	09/10/2013 10/08/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	ROBERT KING FDA NEWS	PHARMACY CREATIONS, RANDOLPH, NJ; NOVEL LABORATORIES INC, SOMERSET, NJ; PROSEC

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				PROTECTION SYSTEMS INC, LAKEWOOD, NJ - 483S 8/1-31/13
2013-7197	09/10/2013 10/08/2013	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	ROBERT KING FDA NEWS	KEYSTONE LABORATORIES INC, MEMPHIS, TN; GENERAL HEARING INSTRUMENTS INC, HARAHAN, LA - 483S 8/1-31/13
2013-7198	09/10/2013 10/08/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	ROBERT KING FDA NEWS	ULTRALAB LABORATORIES INC, HIGHLAND, NY; ESTEE LAUDER IN (LEN RON MFG), MELVILLE, NY; ALTAIRE PHARMACEUTICALS INC, AQUEBOGUE, NY, ETC - 483S 8/1-31/13
2013-7199	09/10/2013 10/08/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	ROBERT KING FDA NEWS	LANNETT COMPANY INC, PHILADELPHIA, PA; SIGMA PHARM LABORATORIES LLC, BENSLEM, PA - 483S 8/1-31/13
2013-7200	09/10/2013 10/08/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	ROBERT KING FDA NEWS	AMPAC FINE CHEMICALS LLC, RANCHO CORDOVA, CA - 483S 8/1-31/13
2013-7201	09/10/2013 10/08/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	ROBERT KING FDA NEWS	GREENWAY RESEARCH LAB, BURNSVILLE, MN; FONTAROME CHEMICAL INC, ST FRANCIS, WI; FONTAROME CHEMICAL INC, ST FRANCIS, WI; CONTINENTAL MEDICAL LABS INC, WATERFORD, WI - 483S 8/1-31/13
2013-7202	09/10/2013 10/08/2013	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	ROBERT KING FDA NEWS	KIRKMAN GROUP INC, LAKE OSWEGO, OR - 483S 8/1-31/13
2013-7203	09/10/2013 10/08/2013	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	ROBERT KING FDA NEWS	PFIZER PHARMACEUTICALS INC, BARCELONETA, PR - 483S 8/1-31/13
2013-7204	09/10/2013 10/08/2013	FDA/OMPT/CDRH/OCER/DFOI/OC/ORA/OC/ORA/	ROBERT KING FDA NEWS	LAERDAL MEDICAL A/S, STAVANGER, NORWAY 8/1-31/13
2013-7205	09/10/2013 10/08/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	ROBERT KING FDA NEWS	SANITOR CORP, HUNTINGTON BEACH, CA; ALLIANCE MEDICAL PRODUCTS INC, IRVINE, CA; CAPCO CUSTOM PACKAGING INC, SANTA FE SPRINGS, CA, ETC - 483S 8/1-31/13
2013-7206	09/10/2013 10/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Parul Chansoria STRYKER ENDOSCOPY	K954465
2013-7207	09/10/2013 10/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Hiroaki Wakamoto JNC CORPORATION	K131619
2013-7208	09/10/2013 10/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Chris Smith Symmetry Medical Manufacturing, Inc.	K113776
2013-7209	09/10/2013	FDA/OC/OES/	Brett Norman	Letters from state legislators to Commissioner Margaret Hamburg

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	10/08/2013	FDA/OMPT/CTP/OD/	POLITICO	regarding potential regulation of menthol cigarettes
2013-7210	09/10/2013 10/08/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Marc Eisen Freelance writer & editor Marc Eisen	QUINCY BIOSCIENCE, MADISON, WI - WARNING LETTER RECS
2013-7211	09/10/2013 10/08/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Patty Dold Dold, Patty	LIST OF DIALYSIS CLINICS IN US USING FESENIUM DIALYSATE GRANYFLO AND/OR NATURALYTE 07/01/2003 - 12/30/2012
2013-7212	09/10/2013 10/08/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Joy Flynn flynn, joy	WEST PHARMACEUTICALS, JERSEY SHORE, PA - EIR 11/03/2011 - 09/09/2013
2013-7213	09/10/2013 10/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Request for 510k STRYKER ENDOSCOPY	K083707
2013-7214	09/10/2013 10/08/2013	FDA/OFVM/CFSAN/OCD/EOS/	Larry Feinberg KnipBio	FAP 7C0283
2013-7215	09/10/2013 10/08/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Donna Cowan VeroScience LLC	PATHEON PHARMACEUTICALS INC, CINCINNATI, OH - EIR 01/01/2011 - 09/09/2013
2013-7216	09/10/2013 10/08/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dheeresh Pathak Dheeresh Pathak	WOCKHARDT, INDIA - 483 07/01/2013 - 09/10/2013
2013-7217	09/10/2013 10/08/2013	FDA/OC/OES/DFOI/	HERBST, JACQUELINE	COMMISSIONED CORP INVESTIGATION CRITERIA
2013-7218	09/10/2013 10/08/2013	FDA/OC/OES/DFOI/	HERBST, JACQUELINE	INDIVIDUAL RECS
2013-7219	09/10/2013 10/08/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GERRIE OLOVER DAVA PHARMACEUTICALS INC	DOXEPIN ANDA 71-673; 71-674; 71-675; 71-676; 71-685; 71-686 APRVL 1/5/88
2013-7220	09/10/2013 10/08/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HOLLAND, CHRIS	MARQIBO KIT (VINCRISTINE SULFATE) NDA 02-497 APRVL 8/9/12 - RVW
2013-7221	09/10/2013 10/08/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS Consulting Group, LLC	BLOXIVERZ (NEOSTIGMAINE METHYL SULPHATE) NDA 04-078 - APRVL, LBLG, MEDICAL RVW, PHARMACOLOGY RVW, CHEMISTRY RVW

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-7222	09/10/2013 10/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MICHAEL R. COHEN INSTITUTE FOR SAFE MEDICATION PRACTICES	REDACTED MEDWATCH RPTS 8/13
2013-7223	09/10/2013 10/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	JUDY ZHU HANGZHOU CONOD MEDICAL CO LTD	K030813
2013-7224	09/10/2013 10/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	RACHEL ROBERTS INDAGO GROUP	SURGICAL MESH FOR POP/SUI REPAIR - MDR RPTS 2000 TO PRESENT
2013-7225	09/10/2013 10/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TAMI DALBERG INDENA USA INC	SICOR DE MEXICO SA DE CV, MEXICO - 483 7/13
2013-7226	09/10/2013 10/08/2013	FDA/OC/OES/DDM/	MARK B. GOLDSTEIN POMERANTZ HUFFORD ET AL	TRANSCRIPT OF MTG OF BLOOD ADVISORY COMMITTEE 12/2/93
2013-7227	09/10/2013 10/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PAMELA SCHANEEN SHIONOGI INC	OSPHENA (OSPHEMIFENE) PHARMACOLOGY RVW UNREDACTED 4/25/12
2013-7228	09/10/2013 10/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WILLIAM J. DUBANEVICH PARKER & WAICHMAN ATTYS	MERCK & CO - GLUCAGON LIKE PEPTIDE THERAPIES INVESTIGATIONS
2013-7229	09/11/2013 10/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARILYNN WHITNEY COVINGTON BURLING LLP	ANDA 77-425 - AMENDMENT COVER LTRS 4/13/12, 8/1/12, 8/8/12, 8/15/12, 9/28/12, 6/11/13 & 7/30/13
2013-7230	09/11/2013 10/09/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	WALTER G CRUMP GUY KORNBLUM & ASSOCIATES	NEXT SEAFOOD - RPTS, CORR, INVESTIGATION RECS, ETC
2013-7231	09/11/2013 10/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	JENNIFER HSIEH DEERFIELD INSTITUTE	RESULTS OF THE MEDSUN SURVEY REGARDING THE DA VINCI SURGICAL SYS
2013-7232	09/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	ELIZABETH FELT WAKEMAN	SURGICAL MESH - EMAIL NOTIFICATIONS OR MAILINGS

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	10/09/2013		ZUKOWSKI ROGERS FLOOD & MCARDLE LAW OFCS	SENT TO PHYSICIANS 1/08 AND 1/09
2013-7233	09/11/2013 10/09/2013	FDA/OFVM/CFSAN/OCD/EOS/	FRIEDMAN, ROBERT	LEAN CUISINE, NUTRISYSTEM, HEALTHY CHOICE, ETC - CAERS 1969 TO 2013
2013-7234	09/11/2013 10/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	HUNTINGTON, DAVID G	EDAP TMS SA CORP - ABLATHERM HIFU DVC MTG RECS 6/3/13
2013-7235	09/11/2013 10/09/2013	OC/ORO/ORM/ OC/ORO/ORM/	SASHA L PERKINS THOMSON REUTERS	DRUG MFRS, LABLERS, REPACKERS, ETC - FOREIGN AND DOMESTIC INSPS 3/1/13 TO PRESENT
2013-7236	09/11/2013 10/09/2013	FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/	WALTER E CHALKLEY THOMSON REUTERS	CURTIS HORN MD, SAN ANTONIO, TX - EIR, 483, CO RESP 2/13/12
2013-7237	09/11/2013 10/09/2013	FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	GENESIS PHARMACEUTICALS INC, HENDERSON, NV - EIR, 483, CO RESP 9/13/12
2013-7238	09/11/2013 10/09/2013	FDA/OGROP/ORO/CE-FO/CIN-DO/CIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	DAVID J PORTMAN MD, COLUMBUS,OH - EIR, 483, CO RESP 10/26/12
2013-7239	09/11/2013 10/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	CENEXI LABORATORIES THISSEN SA, BRAINE L'ALLEUD, BELGIUM - EIR, 483,CO RESP 7/17/12
2013-7240	09/11/2013 10/09/2013	FDA/OGROP/ORO/CE-FO/BLT-DO/BLT-CB/	WALTER E CHALKLEY THOMSON REUTERS	BIORELIANCE CORP, ROCKVILLE, MD - EIR, 483, CO RESP 7/3/12
2013-7241	09/11/2013 10/09/2013	FDA/OGROP/ORO/CE-FO/PHI-DO/PHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	AUXILIUM PHARMACEUTICALS INC, HORSHAM, PA - EIR, 483, CO RESP 7/6/12
2013-7242	09/11/2013 10/09/2013	FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/	WALTER E CHALKLEY THOMSON REUTERS	WILLIAM M KUFS MD, SARATOGA SPRINGS, NY - EIR, 483, CO RESP 2/9/12
2013-7243	09/11/2013 10/09/2013	FDA/OGROP/ORO/NE-FO/NWE-DO/NWE-CB/	WALTER E CHALKLEY THOMSON REUTERS	VERTEX PHARMACEUTICALS INC, CAMBRIDGE, MA - EIR, 483, CO RESP 1/13/12
2013-7244	09/11/2013 10/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	UNICHEM LABORATORIES LTD, GOA, INDIA - EIR, 483, CO RESP 4/6/12
2013-7245	09/11/2013 10/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	TAKEDA PHARMACEUTICAL CO LTD, OSAKA, JAPAN - EIR, 483, CO RESP 8/2/12

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-7246	09/11/2013 10/09/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	WALTER E CHALKLEY THOMSON REUTERS	STERIS ISOMEDIX SERVICES INC, SANDY, UT - EIR, 483, CO RESP 3/21/12
2013-7247	09/11/2013 10/09/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	SANOVI-AVENTIS US LLC, ST LOUIS, MO - EIR, 483, CO RESP 3/14/12
2013-7248	09/11/2013 10/09/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	WALTER E CHALKLEY THOMSON REUTERS	ROBIN KROLL MD, SEATTLE, WA - EIR, 483, CO RESP 12/20/12
2013-7249	09/11/2013 10/09/2013	FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	WALTER E CHALKLEY THOMSON REUTERS	PFIZER PHARMACEUTICALS LLC, VEGA BAJA, PR - EIR, 483, CO RESP 8/10/12
2013-7250	09/11/2013 10/09/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	OAKWOOD LABORATORIES LLC, SOLON, OH - EIR, 483, CO RESP 9/20/12
2013-7251	09/11/2013 10/09/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	NESHER PHARMACEUTICALS (USA) LLC, BRIDGETON, MO - EIR, 483S, CO RESP 12/6/12
2013-7252	09/11/2013 10/09/2013	FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	WALTER E CHALKLEY THOMSON REUTERS	ABBVIE BIOTECHNOLOGY LTD, BARCELONETA, PR - EIR, 483, CO RESP 7/2/12
2013-7253	09/11/2013 10/09/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	DAKOTA LABORATORIES LLC, MITCHELL, SD - EIR, 483, CO RESP 4/5/12
2013-7254	09/11/2013 10/09/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	DAKOTA LABORATORIES LLC, MITCHELL, SD - EIR, 483, CO RESP 8/31/11
2013-7255	09/11/2013 10/09/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/ FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	DAKOTA LABORATORIES LLC, ST LOUIS, MO - EIR, 483, CO RESP 6/22-24/10
2013-7256	09/11/2013 10/09/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	WALTER E CHALKLEY THOMSON REUTERS	STEWART PHARMACEUTICALS INC (STEWART COMPOUNDING PHARMACY), FAYETTEVILLE, NC - EIR, 483, CO RESP 3/18-25/13
2013-7257	09/11/2013 10/09/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	HENRY A FRAZER PHARM D, MONTGOMERY, AL - EIR, 483, CO RESP 9/24/12-10/3/12
2013-7258	09/12/2013 12/30/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	Peter Waldran BAYER HEALTHCARE	NELSON LABS, SALT LAKE CITY, UT - EIR, 483, RESPONES 09/09/2008 - 09/09/2013
2013-7259	09/12/2013	FDA/OGROP/ORA/SE-FO/ATL-	Peter Waldran	AAI PHARMA, WILMINGTON, NC - EIR, 483, RESPONSE

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	10/10/2013	DO/ATL-CB/	BAYER HEALTHCARE	09/09/2008 - 09/09/2013
2013-7260	09/12/2013 10/10/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Peter Waldran Berkeley Healthcare	IRVINE PHARMACEUTICAL, IRVINE, CA - EIR, 483, RESPONSE 09/09/2008 - 09/09/2013
2013-7261	09/12/2013 10/10/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Peter Waldran BAYER HEALTHCARE	EUROFINS LANCASTER LABORATORIES, LANCASTER, PA - EIR, 483, RESPONSE 09/09/2008 - 09/09/2013
2013-7262	09/12/2013 10/10/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Peter Waldran BAYER HEALTHCARE	COVIDIEN, AUGUSTA, GA - EIR, 483, RESPONSE 09/09/2008 - 09/09/2013
2013-7263	09/12/2013 10/10/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	Peter Waldran BAYER HEALTHCARE	COVIDIENT, DELAND, FLA - EIR, 483, RESPONSE 09/09/2008 - 09/09/2013
2013-7264	09/12/2013 10/10/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Peter Waldran BAYER HEALTHCARE	TERUMO MEDICAL CORPORATION, PHOENIX, AZ -EIR, 483, RESPONSE 09/09/2008 - 09/09/2013
2013-7265	09/12/2013 10/10/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Peter Waldran BAYER HEALTHCARE	BD MEDICAL SYSTEMS, FRANKLIN LAKES, NJ - EIR, 483, RESPONSE 09/09/2008 - 09/09/2013
2013-7266	09/12/2013 12/30/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	Peter Waldran BAYER HEALTHCARE	BD MEDICAL, SANDY, UT - EIR, 483, RESPONSE 09/08/2008 - 09/08/2013
2013-7267	09/12/2013 10/10/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	John Walsh James Alexander Corporation	PENTA MANUFACTURING COMPANY, LIVINGSTON, NJ - EIR, 483, RESPONSE 09/09/2010 - 09/09/2013
2013-7268	09/12/2013 10/10/2013	OC/CVM/OCD/	David L Fisher Freeport-McMoRan Sales Company	INADA 010-046-Hoo6 - MANUFACTURING CHEMISTRY SECTION
2013-7269	09/12/2013 10/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	William R. Myers Myers, William R	ESSURE - POST APPROVAL STUDIES
2013-7270	09/12/2013 10/10/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Robert Mahler Ansell Healthcare Products LLC	K100635
2013-7271	09/12/2013 10/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K120012
2013-7272	09/12/2013 10/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K071079
2013-7273	09/12/2013 10/10/2013	FDA/OFVM/CFSAN/OCD/EOS/	Mitchell A. Cheeseman Cheeseman, Mitch	FCN 62
2013-7274	09/12/2013 10/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	DANIEL MARTOS Martos, Arden	K954707
2013-7275	09/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	DANIEL MARTOS	K050907

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	10/10/2013		Martos, Arden	
2013-7276	09/12/2013 10/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	DANIEL MARTOS DANIEL MARTOS	K933433
2013-7277	09/12/2013 10/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Salyton INC RESEARCH CONSULTING & SUBMISSIONS	SBA 20589 S019
2013-7278	09/12/2013 10/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	SBA 20589 S17
2013-7279	09/12/2013 10/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	NDA 201292 S 001
2013-7280	09/12/2013 10/10/2013	FDA/OC/OES/DDM/	Katherine Giannamore The Law Office of Katherine Giannamore, P.A.	DKT. 80N-0146
2013-7281	09/12/2013 10/10/2013	FDA/OFVM/CFSAN/OCD/EOS/	Mitchell A. Cheeseman Cheeseman, Mitch	FCN 185
2013-7282	09/12/2013 10/10/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michelle Daniels Daniels, Michelle	LISTING OF DESI PRODUCTS CURRENTLY ON THE MARKET
2013-7283	09/12/2013 10/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sheena M. Posey Norris The National Academies (Institute of Medicine)	NDA 022244 - ACTION LETTER

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2013-7284	09/12/2013 10/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	BLA 103000 S5050
2013-7285	09/12/2013 10/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Michelle Zwernemann Infinite Biomedical Technologies, LLC	K032833
2013-7286	09/12/2013 10/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kyan Mulligan none	DR REDDY QUENTIAPINE FUMARATE - AERS
2013-7287	09/12/2013 10/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John Franolic VersaPharm Inc.	ANDA 078854
2013-7288	09/12/2013 10/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	MANISH AHUJA BIO TEX INC	K112094
2013-7289	09/12/2013 10/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	MANISH AHUJA BIO TEX INC	K990278
2013-7290	09/12/2013 10/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	MANISH AHUJA BIO TEX INC	K032054
2013-7291	09/12/2013 10/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	MANISH AHUJA BIO TEX INC	K060808
2013-7292	09/12/2013 10/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	MANISH AHUJA BIO TEX INC	K924348
2013-7293	09/12/2013 10/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	MANISH AHUJA BIO TEX INC	K971247
2013-7294	09/12/2013 10/10/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	JABONES PARDO SA MADRID, SPAIN - EIRS, 483S, CO RESP 03/11-14/113
2013-7295	09/12/2013	FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY	IBI-ISTITUTO BIOCHIMICO ITALIANO GIOVANNI LORENZINI SPA, APRILLA, ITALY - EIRS, 483S, CO RESP 10/05/12

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	10/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	THOMSON REUTERS	
2013-7296	09/12/2013 10/10/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	CATALENT PHARMA SOLUTIONS LLC, SOMERSET, NJ - EIRS, 483S, CO RESP 12/19/12
2013-7297	09/12/2013 10/10/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	WALTER E CHALKLEY THOMSON REUTERS	AMGEN INC, THOUSAND OAKS, CA - EIRS, 483S, CO RESP 12/12/12
2013-7298	09/12/2013 10/10/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	SA ANALYTICAL LLC, MUNDELEIN, IL - EIRS, 483S, CO RESP 01/16/13
2013-7299	09/12/2013 10/10/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	WALTER E CHALKLEY THOMSON REUTERS	LOWELL ROGER, EVANSVILLE, IN - EIRS, 483S, CO RESP 01/03/13
2013-7300	09/12/2013 10/10/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	INTERSTATE BLOOD BANK INC, PHILADELPHIA, PA - EIRS, 483S, CO RESP 03/12/13
2013-7301	09/12/2013 10/10/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	HOXWORTH BLOOD CENTER, FORT MITCHELL, KY - EIRS, 483S, CO RESP 01/07/13
2013-7302	09/12/2013 10/10/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	WALTR E CHALKLEY THOMSON REUTERS	CARTER BLOOD CARE - CEDAR HILL DONATION CENTER, CEDAR HILL, TX - EIRS, 483S, CO RESP 02/02/13
2013-7303	09/12/2013 10/10/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	WALTER E CHALKLEY THOMSON REUTERS	GRIFOLS THERAPEUTICS INC, MELVILLE, NY - EIRS, 483S, CO RESP 09/02/12
2013-7304	09/12/2013 10/10/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	AULTMAN HOSPITAL, CANTON, OH - EIRS, 483S, CO RESP 02/08/13
2013-7305	09/12/2013 10/10/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	RARITAN PHARMACEUTICALS INC, EAST BRUNSWICK, NJ - EIRS, 483S, CO RESP 09/19/12
2013-7306	09/12/2013 10/10/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	WALTER E CHALKLEY THOMSON REUTERS	MONOSOL RX LLC, PORTAGE, IN - EIRS, 483S, CO RESP 09/13/12
2013-7307	09/12/2013 10/10/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	WALTER E CHAKLEY THOMSON REUTERS	LTS LOHMANN THERAPY SYSTEMS CORP, WEST CALDWELL, NJ - EIRS, 483S, CO RESP 09/11/12
2013-7308	09/12/2013 10/10/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	WALTER E CHALKLEY THOMSON REUTERS	BETHESDA MEMORIAL HOSPITAL IRB, BOYNTON BEACH, FL - EIRS, 483S, CO RESP 09/07/12
2013-7309	09/12/2013 10/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	YONSUNG FINE CHEMICALS CO LTD, GYEONGGI-DO, SOUTH KOREA - EIRS, 483S, CO RESP 10/25/12

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-7310	09/12/2013 10/10/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	APTUIT (SCIENTIFIC OPERATIONS) LLC, HARRISONVILLE, MO - EIRS, 483S, CO RESP 11/14/12
2013-7311	09/12/2013 10/10/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	WALTER E CHALKLEY THOMSON REUTERS	BOSTON ANALYTICAL LINC, SALEM, NH - EIRS, 483S, CO RESP 11/09/12
2013-7312	09/12/2013 10/10/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	WALTER E CHALKLEY THOMSON REUTERS	MARK B FARIES MD, SANTA MONICA, CA - EIRS, 483S, CO RESP 11/30/12
2013-7313	09/12/2013 10/10/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	WALTER E CHALKLEY THOMSON REUTERS	SIGHTLIFE, SEATTLE, WA - EIRS, 483S, CO RESP 12/17/12
2013-7314	09/12/2013 10/10/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	WALTER E CHALKLEY THOMSON REUTERS	ATLANTA BLOOD SERVICES, MARIETTA, GA - EIRS, 483S, CO RESP 03/20/13
2013-7315	09/12/2013 10/10/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	MERICON INDUSTRIES INC, PEORIA, IL - EIRS, 483S, CO RESP 04/27/12
2013-7316	09/12/2013 10/10/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	LAMBDA RESEARCH INC, CINCINNATI, OH - EIRS, 483S, CO RESP 04/27/12
2013-7317	09/12/2013 10/10/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	JACOBUS PHARMACEUTICAL COMPANY, INC, PLAINSBORO, NJ - EIRS, 483S, CO RESP 04/16/12
2013-7318	09/12/2013 10/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	RICHARD KAPLAN GENERAL SLEEP CORP	ADVANCED BRAIN MONITORING INC, CARLSBAD, CA - K120450
2013-7319	09/12/2013 10/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	DEBORAH LAVOIE GRAYSESKI M SQUARED ASSOCIATES INC	IMPLEMENTATION OF SECTION 216 & THE REQUIREMENTS TO FULFILL SIMILARITY OF A PROD IN TO THE APRVD PRODIN CONTEXT OF EVOKING SECTION 216
2013-7320	09/12/2013 10/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	OXCARBAZEPINE ORAL SUSPENSION 300 MG/5ML ANDA 202-961 - APRVL LTR, LBLG, MEDICAL OFFICERS RVWS, ETC
2013-7321	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	JASON SMATHERS MUCKROCK NEWS	DIVESTITURE OF PROHIBITED HOLDINGS
2013-7322	09/12/2013 10/10/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	NATALIA DERIN QUELLER FISHER ET AL	USPS LABS LLC - 483S, RESP, ATTACHMENTS, EXHIBITS, ETC 02/21/12
2013-7323	09/12/2013 10/10/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDER/GRP/DIDP/	MACKIE A BARCH PHARMAGEN LABS	PHARMAGEN LABS - CMLPNT

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2013-7324	09/12/2013 10/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	COLEEN KLASMEIER SIDLEY AUSTIN LLP	PRESCRIPTION DRUG PROMOTION - TALK PAPER 7/18/91; PFIZER INC - LTR 7/13/82; BRISTO-MYERS SQUIB - REGULATORY LTR 1/25/91
2013-7325	09/12/2013 10/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WENDY R FLEISHMAN LIEFF CABRASER ET AL	BAYER CORP - ENTERIC COATED ASPRIN RPTS, INVESTIGATIONS, STATEMENTS, ETC
2013-7326	09/12/2013 10/10/2013	FDA/OGROP/ORAP/PA-FO/SEA- DO/SEA-CB/	HEALTHIER GALE OLSSON FRANK & WEEDA	METAGENICS INC - WARNING LTR 8/13/13
2013-7327	09/12/2013 11/04/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Rachel Johnson FOI Services, Inc.	BK120012
2013-7328	09/12/2013 10/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelina Slayton INC RESEARCH CONSULTING & SUBMISSIONS	SBA 20589 S015
2013-7329	09/12/2013 10/10/2013	FDA/OGROP/ORAP/PA-FO/SAN- DO/SAN-CB/	Anna Edney BLOOMBERG NEWS	INTUITIVE, SUNNYVALE, CA - 483 01/10/2000 - 09/11/2013
2013-7330	09/12/2013 10/10/2013	FDA/OGROP/ORAP/SE-FO/FLA- DO/FLA-CB/	ROSSMERI MONTALVO ALTUS RESEARCH	SAMUEL LN LEDERMAN MD - EIR, INTERNAL CORR, DETERMINATIONS
2013-7331	09/12/2013 10/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelina Slayton INC RESEARCH CONSULTING & SUBMISSIONS	NDA 202379
2013-7332	09/12/2013 10/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELIZABETH BARBEHENN PUBLIC CITIZEN (HEALTH RESEARCH GROUP)	FETZIMA (LEVOMILNACIPRAN) NDA 204-168 APRVL PKG
2013-7333	09/12/2013 10/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Anna Edney BLOOMBERG NEWS	INTUITIVE SURGICAL - HOSPITAL AERS 01/01/2000 - 09/11/2013

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2013-7334	09/12/2013 10/10/2013	OC/CVM/OCD/	Janice Cacioli LUITPOLD PHARMACEUTICALS, INC.	FOIA SUMMARIES NADA 012-198, NADA 012-204
2013-7335	09/12/2013 10/10/2013	FDA/OO/OIM/OPILS/FDAHO/	Katherine Michelle Hardy none	FDA Oral History Interview, Merrill - Part I ABOUT FDA
2013-7336	09/12/2013 10/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jane Bentley Alcon Laboratories, Inc.	ALCON CUSI SA, BARCELONA, SPAIN - EIR 09/05/2011 - 09/09/2011
2013-7337	09/12/2013 10/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jane Bentley Alcon Laboratories, Inc.	CIBA VISION, BATAM, INDONESIA - EIR 05/02/2011 - 05/05/2011
2013-7338	09/12/2013 10/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Jane Bentley Alcon Laboratories, Inc.	ALCON GRESHABER, SWITZERLAND - EIR 04/11/2011 - 04/14/2011
2013-7339	09/12/2013 10/10/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Jane Bentley Alcon Labs, Inc.	ALCON LABS, HUNTINGTON, WV - EIR 09/23/2011 - 05/31/2011
2013-7340	09/12/2013 10/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jane Bentley Alcon Laboratories, Inc.	CIBA VISION, GROSSWALLASTADT, GERMANY - EIR 06/27/2011 - 08/31/2011
2013-7341	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCRAMP CanReg, Inc.	DAILY LOG 8/19-23/13
2013-7342	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCRAMP CanReg, Inc.	DAILY LOG 8/12-16/13
2013-7343	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 8/12-16/13
2013-7344	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY CLOSED LOG 8/19-23/13
2013-7345	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 8/12-16/13
2013-7346	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	DRBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 8/19-23/13

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2013-7347	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY CLOSED LOG 8/19-23/13
2013-7348	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY CLOSED LOG 8/12-16/13
2013-7349	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 8/19-23/13
2013-7350	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 8/19-23/13
2013-7351	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 8/12-16/13
2013-7352	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 8/12-16/13
2013-7353	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	DAVID MacFARLAND FDA REVIEW/FDA WEBVIEW	DAILY CLOSED LOG 8/12-16/13
2013-7354	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	DAVID MacFARLAND FDA REVIEW/FDA WEBVIEW	DAILY LOG 8/19-23/13
2013-7355	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 8/19-23/13
2013-7356	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 8/12-16/13
2013-7357	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 8/19-23/13
2013-7358	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 8/12-16/13
2013-7359	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	GLADYS B. TONKIN WASHINGTON INFORMATION SOURCE	DAILY LOG 8/19-23/13
2013-7360	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	GLADYS B. TONKIN WASHINGTON INFORMATION SOURCE	DAILY LOG 8/12-16/13
2013-7361	09/12/2013	FDA/OFVM/CFSAN/OCD/EOS/	Joan Stitt (UG2CD-16)	2013-6078 - REQUEST LETTER

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	10/10/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OC/OES/DFOI/	MERCK & CO., INC.	
2013-7362	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-6445 - REQUEST LETTER ONLY
2013-7363	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-6700 - REQUEST LETTER ONLY
2013-7364	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY CLOSED LOG 8/12-16/13
2013-7365	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-6606 - REQUEST LETTER ONLY
2013-7366	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-6077 - REQUEST LETTER ONLY
2013-7367	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-6229 - REQUEST LETTER ONLY
2013-7368	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY CLOSED LOG 8/19-23/13
2013-7369	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY CLOSED LOG 8/19-23/13
2013-7370	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 8/12-16/13
2013-7371	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-6243 - REQUEST LETTER
2013-7372	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-5959 - REQUEST LETTER
2013-7373	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-6455 - REQUEST LETTER
2013-7374	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-6001 - REQUEST LETTER
2013-7375	09/13/2013 10/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	Peter Waldran BAYER HEALTHCARE	BAXTER BIODOME, MARSA, MALTA - EIR, 483, RESPONSES 09/09/2008 - 09/09/2013
2013-7376	09/13/2013 10/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	Peter Waldran BAYER HEALTHCARE	MEDIMOP MEDICAL PRODUCTS, RAANANA, ISRAEL - EIR, 483, RESPONSES 09/09/2008 - 09/09/2013

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2013-7377	09/13/2013 10/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	Peter Waldran BAYER HEALTHCARE	BIOFARMITALIA, ITALY - EIR, 483, RESPONSES 09/09/2008 - 09/09/2013
2013-7378	09/13/2013 10/11/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	John Walsh James Alexander Corporation	EMD MILLIPORE CORPORATION, GIBBSTOWN, NJ - EIR, 483, RECALL 09/09/2009 - 09/09/2013
2013-7379	09/13/2013 10/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Peter Waldran BAYER HEALTHCARE	VETTER PHARMA FERTIGUNG, RAVENSBURG, GERMANY - EIR, 483, RESPONSES 09/09/2008 - 09/09/2013
2013-7380	09/13/2013 10/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Peter Waldran BAYER HEALTHCARE	VETTER PHARMA FERTIGUNG, LANGENARGEN, GERMANY - EIR, 483, RESPONSE 09/09/2008 - 09/09/2013
2013-7381	09/13/2013 10/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	Shannon McOsker Shannon McOsker	ESSURE - CLINICAL STUDIES
2013-7382	09/13/2013 10/11/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	John Walsh James Alexander Corporation	AMRESKO, SOLON, OH - EIR, 483, RECALL 09/01/2010 - 09/10/2013
2013-7383	09/13/2013 10/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Robert Mahler Ansell Healthcare Products LLC	NDA 17768
2013-7384	09/13/2013 10/11/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	John Walsh James Alexander Corporation	APPLIED PLASTICS, OAK CREEK, WI - EIR, 483, RECALL 09/01/2010 - 09/10/2013
2013-7385	09/13/2013 10/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ilya Kister NEW YORK UNIVERSITY MEDICAL CENTER	AZATHIOPRINE - AERS
2013-7386	09/13/2013 10/11/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jacqueline Coleman Coleman, Jacqueline	ESTRACE VAGINAL CREAM CLINICAL TRIALS INFORMATION 01/01/1984 - 09/10/2013

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-7387	09/13/2013 10/11/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	DAVID M, PIKE David M. Pike	LIQUID PACKAGING RESOURCES, ATLANTA, GA - 483 01/01/2010 - 09/10/2013
2013-7388	09/13/2013 10/11/2013	FDA/OC/OES/DDM/ FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	DKT 2013-N-0778
2013-7389	09/13/2013 10/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Elliot Wilbur WILBUR, ELLIOT	OFFICE OF GENERIC DRUGS STATISTICAL REPORT - MOST RECENT
2013-7390	09/13/2013 10/11/2013	FDA/OFVM/CFSAN/OCD/EOS/	A Philip Leber A Philip Leber Consulting	FCN 1251
2013-7391	09/13/2013 10/11/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/ORO/DIOP/ OC/ORA/ORM/ OC/ORA/ORM/ OC/ORA/ORM/ OC/ORA/ORM/	Patrick Woodall Food & Water Watch	FDA FISH, FISHERY, AND SEAFOOD IMPORT INSPECTION, LABORATORY TESTING AND TOTAL IMPORT LINES OF ENTRY FOR FDA PRODUCT CODE 16
2013-7392	09/13/2013 10/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Caj Boatright ARNOLD & ITKIN LLP	ZOLOFT - RECS RE BIRTH DEFECTS AND PREGNANCY
2013-7393	09/13/2013 10/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	TAKEDA, SINGEN, GERMANY - EIR, 483 1/1/07 TO PRESENT
2013-7394	09/13/2013 10/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	BLA 125320 007
2013-7395	09/13/2013 10/11/2013	OC/ORA/ OC/ORA/ OC/ORA/ORM/	Rend Al-Mondhiry COUNCIL FOR RESPONSIBLE NUTRITION	LIST OF FACILITIES RE DIETARY SUPPLEMENT OR COMPONENT OF DIETARY SUPPLEMENT

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		OC/ORR/ORM/ FDA/OFVM/CFSAN/OCD/EOS/		
2013-7396	09/13/2013 10/11/2013	OC/ORR/ OC/ORR/ FDA/OGROP/ORR/SW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORR/PA-FO/SEA-DO/SEA-CB/	Gitte Laasby MILWAUKEE JOURNAL SENTINEL	CHOBANI - LAB TEST RESULTS SUBMITTED TO FDA
2013-7397	09/13/2013 10/11/2013	FDA/OC/OES/DFOI/	Christopher Brennan WESTLAW COURT EXPRESS	JANUVIA, JANUMET - FOIA REQUESTS AND RECORDS
2013-7398	09/13/2013 10/11/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Golnaz Moeini STRYKER CORP	K091515
2013-7399	09/13/2013 10/11/2013	FDA/OGROP/ORR/CE-FO/NWJ-DO/NWJ-CB/	Carolyn Wolski Michael Foods, Inc.	MICHAEL FOODS, INC, ELIZABETH, NJ - RECS RE OUTBREAK REPORT : 05/15/2010 - 08/15/2010
2013-7400	09/13/2013 10/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/	shin kang WELLS FARGO	GILEAD SCIENCES - 483, EIR 01/01/2013 - 09/12/2013
2013-7401	09/13/2013 10/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	B. Eugene Guthery, M. D. INNOVATIVE PHARMACEUTICALS, LLC	NDA 022055
2013-7402	09/13/2013 10/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	B. Eugene Guthery, M. D. INNOVATIVE PHARMACEUTICALS, LLC	IND 66095
2013-7403	09/13/2013 10/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jennifer Newberger Hyman, Phelps & McNamara P.C.	CORR BETWEEN FDA AND MANUFACTURERS OR DISTRIBUTORS OF PERSONAL SOUND AMPLIFICATION PRODUCTS RE SALE OF THOSE PRODUCTS 06/01/2012 - 09/13/2013
2013-7404	09/13/2013 10/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	B. Eugene Guthery, M D. Innovative Pharmaceuticals,LLC	IND FOR XF-73

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-7405	09/13/2013 10/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	DEPUY - HIP IMPLANTS MDRS
2013-7406	09/13/2013 10/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	AMY GAITHER LATHAM & WATKINS LLP	KARMELSONIX - WIM PC MODEL 1010 K071955
2013-7407	09/13/2013 10/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	PAUL SVILANS JOHNSON WINTER ET AL	BORN BRANDS - BABY WEDGE MTGS, WARNINGS
2013-7408	09/13/2013 10/11/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	David Green CIBA VISION Corporation	CIBA VISION CORPORATION, DULUTH, GA - EIR 09/01/2012 - 09/01/2013
2013-7409	09/13/2013 10/11/2013	FDA/OFVM/CFSAN/OCD/EOS/	LISA Y. LEFFERTS CENTER FOR SCIENCE IN THE PUBLIC INTEREST	CAFFEINE ADDED TO FOOD AND DRINKS - GRAS, CORR
2013-7410	09/13/2013 10/11/2013	FDA/OC/OES/DFOI/	GARDNER, JEFFREY	PERSONALIZED PROTEIN POWDER
2013-7411	09/13/2013 10/11/2013	FDA/OC/OES/DFOI/	DAWN M. CHITTY TORRENT PHARMA INC	POTIGA (EZOGABINE) NDA 22-345
2013-7412	09/13/2013 10/11/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	PAUL B. CALLAHAN CHARLES RIVER LABS	CHARLES RIVER LABORATORIES INC, SPENCERVILLE, OH - EIR 10/30/12-11/15/12
2013-7413	09/13/2013 10/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID M. HOFFMEISTER WISLON SONSINI ET AL	COPAXONE NDA 20-622/S083, S085; ADRENALIN NDA 20-800/S023 - SBA
2013-7414	09/13/2013 10/11/2013	FDA/OC/OES/DDM/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	B. KRISTIAN W. RASMUSSEN CORY WATSON ET AL	NEXIUM (ESOMEPRAZOLE) - APRVL, RVWS, CORR, WARNINGS
2013-7415	09/13/2013 10/11/2013	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	DIANNE L. CHAMBERS HOGAN LOVELLS LLP	McCORMICK & COMPANY, HUNT VALLEY, MD - EIR MOST RECENT
2013-7416	09/13/2013 10/11/2013	FDA/OFVM/CFSAN/OCD/EOS/	EMILY K. STRUNK AKIN GUMP ET AL	PROCESADORA DE PRODUCTOS MARINOS DELIFISH SA, PUERTO MONTT, CHILE - LAB RPTS, ANALYTICAL W/S, EIR, ETC
2013-7417	09/13/2013 10/11/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	PATRICK KELLY CONWAY HOMER & CHIN-	INDIVIDUAL RECS

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			CAPLAN PC	
2013-7418	09/13/2013 10/11/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	PATRICK KELLY CONWAY HOMER & CHIN- CAPLAN PC	INDIVIDUAL RECS
2013-7419	09/13/2013 10/11/2013	FDA/OC/OES/DFOI/	Doe J	USE OF EMPLOYEE EDUCATION & TRAINING
2013-7420	09/13/2013 10/11/2013	OC/ORO/ORM/ OC/ORO/ORM/	KIM C. CAPONE PORZIO LIFE SCIENCES	PDMA 2008 TO PRESENT
2013-7421	09/13/2013 10/11/2013	FDA/OGROP/ORO/SE-FO/FLA- DO/FLA-CB/	FORD, LISA	ROSEMONT FARMS, PLANT CITY, FL - INSP
2013-7422	09/13/2013 10/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	CARLO CASULO, MD ASCEND CAPITAL LLC	AMPIO - AMPION TYPE B PRE-BLA MTG MINS 10/29/13, LTR 9/6/13
2013-7423	09/13/2013 10/11/2013	FDA/OC/OES/DFOI/	GARDNER, JEFFREY	2012-2202, 2012-2938, 2012-6232, ETC
2013-7424	09/16/2013 10/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Anne Mitchell Anne Mitchell	CPT1300384 - CORR
2013-7425	09/16/2013 10/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Astrid Marx Heraeus Medical GmbH	K112470
2013-7426	09/16/2013 10/15/2013	FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/	Sylvia Hinds Hinds, Sylvia L	ALLIANCE MEDICAL PRODUCTS, INVINE, CA - EIR, 483 09/01/2011 - 09/13/2013
2013-7427	09/16/2013 10/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Seth Miller Cubist Pharmaceuticals	NDA 050706
2013-7428	09/16/2013 10/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Golnaz Moeini STRYKER CORP	K101077
2013-7429	09/16/2013 10/15/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Steven Yu Ryuh Biomedical Research Foundation	NDA 020505 - OLD LABEL INFO

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-7430	09/16/2013 10/15/2013	FDA/OFVM/CFSAN/OCD/EOS/	Danny Robbins Atlanta Journal-Constitution	DIETARY SUPPLEMENTS CONTAINING DMAA - AERS
2013-7431	09/16/2013 10/15/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K122356
2013-7432	09/16/2013 10/15/2013	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2013-1209
2013-7433	09/16/2013 10/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	NDA 22334 S 016
2013-7434	09/16/2013 10/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ilya Kister NEW YORK UNIVERSITY MEDICAL CENTER	GLATIRAMER - AERS
2013-7435	09/16/2013 10/15/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Carol L. Price Carol L. Price	DAVINCI ROBOTIC SURGICAL DEVICE - COMPLAINTS RE DEVICE AT CITY OF HOPE HOSPITAL, DUARTE, CA 01/01/2000 - 09/10/2013
2013-7436	09/16/2013 10/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K121678
2013-7437	09/16/2013 10/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	George Hwang EOS Pharmaceutical Corp.	NORVIR 80 MG/ML ORAL SOLUTION - APPROVAL LETTER, LABELING, CMC ETC
2013-7438	09/16/2013 10/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	AnnaMarie Daniels AnnaMarie Daniels	K081465 K123338 K131475 ETC
2013-7439	09/16/2013 10/15/2013	FDA/OC/OES/DDM/	Lael J Pickett Lael J Pickett	ORTHOPEDICS AND REHABILITATION DEVICES ADVISORY PANEL - TRANSCRIPT 11/20/1996 - 11/20/1996
2013-7440	09/16/2013 10/15/2013	FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/ FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/	JOSEPH R. WARNHOFF PERFORMANCE PRODUCTS, INC.	PERFORMANCE PRODUCTS, INC, ST LOUIS, MO - INTERNAL REPORTS RE INSPECTIONS 01/01/2011 - 08/01/2013

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2013-7441	09/16/2013 10/15/2013	FDA/OC/OES/DFOI/	Robert FDANEWS	FOIA DISCLOSURE LOG 09/09/2013 - 09/13/2013
2013-7442	09/16/2013 10/15/2013	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	Jeff Peterson Ater Wynne LLP	YOCREAM INTERNATIONAL, INC, PORTLAND, OIR - INSPECTION RECS, ENFORCEMENT ACTIONS, CONTRACT INSPECTIONS ETC 01/01/2007 - 09/13/2013
2013-7443	09/16/2013 10/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Hummad Tasneem University of Memphis	K052155
2013-7444	09/16/2013 10/15/2013	OC/ORAP/ORM/ OC/ORAP/ORM/	David Mangione Govzilla, Inc.	LIST OF INSPECTIONS 08/1713 - 09/15/2013
2013-7445	09/16/2013 10/15/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	INDIVIDUAL RECS
2013-7446	09/16/2013 10/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	VLK BAJNATH ARTHREX INC	MW#5031363 - FACILITY NAME, TELEPHONE NUMBER
2013-7447	09/16/2013 10/15/2013	FDA/OGROP/OIP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WILLIAM J DUBANEVICH PARKER & WAICHMAN ATTYS	AMYLLIN PHARMACEUTICALS LLC, ELI LILLY & CO, MERCK SHARP & DOHME CORP, ETC - GLP-1 BASED DIABETES THERAPIES CORR, AERS 1/1/00 TO 9/11/13
2013-7448	09/16/2013 10/15/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	WILLIAM A GARVIN BUCHANAN INGERSOLL & ROONEY PC	BOCA PHARMACAL INC, QUALITEST PHARMS - 483S WARNING LTRS 1/12 TO PRESENT

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		FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/		
2013-7449	09/16/2013 10/15/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	paul hopper Nucleus Therapeutics	MEDCLONE - PHASE 1 IND
2013-7450	09/16/2013 10/15/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORR/NE-FO/NYK-DO/NYK-DCB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/ OC/ORR/ OC/ORR/ OC/ORR/OCI/ OC/ORR/OCI/	Bruce Ricigliano VP of Operations American Lifestyle American Lifestyle	VICEREX - INVESTIGATION RECS (04/29/2013 - 05/08/2013)
2013-7451	09/17/2013 10/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	b. burgess BURGESS, BERNIE	response/memo sent by leslie ball or other dsi personnel in response to I3938 OIG/HHS
2013-7452	09/17/2013 10/30/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORR/SW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORR/PA-FO/SEA-DO/SEA-CB/ FDA/OGROP/ORR/SW-FO/DEN-DO/DEN-CB/	Jason Ahlmann Zija International, Inc.	ZIJA INTERNATIONAL INC - INVESTIGATION RECS (01/16/2005 - 09/16/2013)
2013-7453	09/17/2013 10/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	Most recent QAP for Novartis in Emeryville, CA
2013-7454	09/17/2013 10/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	Most recent QAP for Novartis in Emeryville, CA

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2013-7455	09/17/2013 10/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	QAP information 2007-present for Novartis, Emeryville, CA
2013-7456	09/17/2013 10/30/2013	FDA/OO/OFBA/OAGS/ FDA/OMPT/CTP/OD/	Kenneth A. Horton Managed Care of Western New York, d/b/a Probe Services	13-223-SOL-00173
2013-7457	09/17/2013 10/30/2013	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	CAP 3C0198
2013-7458	09/17/2013 10/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joseph P. Reo Merck Consumer Care	DITROPAN IMMEDIATE RELEASE TABLET 5 MG - HUMAN CLINICAL TRIALS, PHARMACOLOGY 06/01/1975 - 07/30/1975
2013-7459	09/17/2013 10/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K113700
2013-7460	09/17/2013 10/30/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDRH/OCER/DFOI/	LYNN SHEPLER Self	C6 TESTING DATA SEX DIFFERENCES RE LYME DISEASE 09/01/2003 - 09/16/2013
2013-7461	09/17/2013 10/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA22406 S1, S2, S3
2013-7462	09/17/2013 10/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	ANDA 76477
2013-7463	09/17/2013 10/30/2013	FDA/OFVM/CFSAN/OCD/EOS/	Philip Leber A. Philip Leber Consulting	FCN1282
2013-7464	09/17/2013 10/30/2013	FDA/OFVM/CFSAN/OCD/EOS/	Philip Leber A. Philip Leber Consulting	FCN1237
2013-7465	09/17/2013 10/30/2013	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORA/	CARLA R SCARMAZZI King & Spalding LLP	CHOBANI GREEK YOGURT - CMLPNTS 8/2/13 TO PRESENT

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		OC/ORAI/		
2013-7466	09/17/2013 10/30/2013	FDA/OGROP/ORI/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORI/PA-FO/SAN-DO/SAN-CB/	HEWLETT, IRIS	SAN MATEO MEDICAL CENTER RADIOLOGY DEPT, SAN MATEO, CA - QUALITY CONTROL EVALUATIONS, ANNUAL INSPS, TEST RESULTS, ETC 2001 TO 7/13
2013-7467	09/17/2013 10/30/2013	OC/CVM/OCD/ OC/CVM/OCD/	KRISTI O SMEDLEY PHD WASHINGTON INFORMATION SOURCE	METAL METHIOMINE HYDROXY ANALOGUE - SUBMISSION, CORR
2013-7468	09/17/2013 10/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ROWENA DODARO ALKERMES GAINESVILLE L LLC	VIVITROL - ISRS 8738905, 8583821
2013-7469	09/17/2013 10/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CAUDLE #20711-058, BRANDON LEE	TRUVADA, PREZISTA, NORVIR - PI
2013-7470	09/17/2013 10/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SAMUEL F COLIN MD FIRST MANHATTAN CO	VICTOZA (LIRAGLUTIDE) - AERS 2/10 TO PRESENT
2013-7471	09/17/2013 10/30/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDRH/OCER/DFOI/	LYNN SHEPLER Self	ISPOT LYME TEST - DATA SUBMITTED 09/01/2010 - 09/17/2013
2013-7472	09/17/2013 10/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jeannie Lin Route One Investment Company	AGILA SPECIALTIES - WARNING LETTER 06/27/2013 - 09/16/2013
2013-7473	09/17/2013 10/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nirav Jhaveri Jhaveri, Nirav	AGILA INJECTIBLES - WARNING LETTER 09/15/2013 - 09/16/2013
2013-7474	09/17/2013 10/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ted Keller Sigma Capital Management	STRIDES ARCOLABL INJECTIBLE (AGILA SPECIALTIES) - WARNING LETTER, 483 05/31/2013 - 09/30/2013

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-7475	09/17/2013 10/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	Natalie Mink KARL STORZ Endoscopy America, Inc.	KARL STORZ GMBH & CO KG, TUTTLINGEN, GERMANY - EIR 10/15/12
2013-7476	09/17/2013 10/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dr. Ulrike Domack EXDRA GmbH	NDA004782-S141 - BIOEQUIVALENCE STUDY; NDA004782- S142 - BIOEQUIVALENCE STUDY
2013-7477	09/17/2013 11/12/2013	FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	Buddy Keeley Seafood Supply Company	DALLAS DISTRICT SEAFOOD INSPECTION RECS 01/01/2011 - 09/01/2013
2013-7478	09/17/2013 10/30/2013	OC/CVM/OCD/	Kelly Perfield Elanco Animal Health - Kelly Perfield	N-140872-R-0265
2013-7479	09/17/2013 10/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID GORTLER, PHARMD, FCCP GEORGETOWN UNIVERSITY SCHOOL OF MEDICINE	MEDWATCH RECS RE ZOLOFT
2013-7480	09/17/2013 10/30/2013	FDA/OC/OES/DFOI/	Chirag Talati Espirito Santo Securities	RANBAXY - 483, EIR SINCE MARCH 2013
2013-7481	09/17/2013 10/30/2013	FDA/OC/OES/DFOI/	Esther Farber Labaton Sucharow, LLP	2011-5064, 2012-2367, 2012-4606 ETC
2013-7482	09/17/2013 10/30/2013	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2013-2536
2013-7483	09/18/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jennifer Panagoulas GENZYME	Form 483 issued to Dragana Obradovic, MD Military Medical Academy, Belgrade, Serbia
2013-7484	09/18/2013 10/17/2013	FDA/OC/OES/DFOI/	Jennifer Panagoulas GENZYME	Form 483 issued to Tomasz Zielinski, MD, Diagnomed Clinical Research UI Lesnego Potoku, 40-414 Katowice Poland
2013-7485	09/18/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jennifer Panagoulas GENZYME	Form 481 issued to Karl Baum, MD, Heningsdorf, Germany

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		FDA/OMPT/CDER/ORP/DIDP/		
2013-7486	09/18/2013 10/17/2013	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	Information for 3 tobacco studies
2013-7487	09/18/2013 10/17/2013	FDA/OFVM/CFSAN/OCD/EOS/	Kim Carson EXPONENT	DECAFFEINATED TEAT - LABELING POLICY 01/01/1980 - 01/01/1990
2013-7488	09/18/2013 10/17/2013	FDA/OFVM/CFSAN/OCD/EOS/	Kim Carson EXPONENT	DECAFFEINATED COFFEE - LABELING POLICY 01/01/1980 - 01/01/1990
2013-7489	09/18/2013 10/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Cathy Burgess ALSTON & BIRD LLP	STRIDES ARCOLAB - WARNING LETTER 06/01/2013 - 09/17/2013
2013-7490	09/18/2013 10/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	John Fesko Fesko, John D	P10020, P110012, P110030
2013-7491	09/18/2013 10/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Paul Nemeth iCeutica Operations, LLC	ZACH SYSTEMS, SA, AVRILLE CEDEX, FRANCE - INSPECTION REPORT 01/01/2006 - 06/30/2013
2013-7492	09/18/2013 10/17/2013	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	Tina Ball Barnhardt Manufacturing Company	BARNHARDT MANUFACTURING COMPANY, CHARLOTTE, NC - EIR 12/12/2011 - 12/14/2011
2013-7493	09/18/2013 10/17/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OCC/ FDA/OC/OES/ FDA/OFVM/CFSAN/OCD/EOS/	John Hnatio FoodQuestTQ LLC	FOODQUEST TQ LLC - 351 EMAILS RE MEMORANDUM 05/20/2013 - 08/21/2013
2013-7494	09/18/2013 10/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	NDA Approval summary (SBA) for TROKENDI XR, NDA 201635 Tian, Wendy	NDA 201635 - SBA
2013-7495	09/18/2013 10/17/2013	FDA/OFVM/CFSAN/OCD/EOS/	Joe Hain Bryant Christie Inc.	CALCIUM STEAROLYN-2-LACTYLATE - SAFETY AND CHEMISTRY DATA
2013-7496	09/18/2013 10/17/2013	FDA/OMPT/CTP/OD/	Brady Dennis THE WASHINGTON POST	LIST OF LISTENING SESSION MEETINGS THAT CTP HAS HAD WITH ANY REPRESENTATIVES OF THE E-CIGARETTE INDUSTRY 09/01/2012 - 09/17/2013
2013-7497	09/18/2013 10/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Paul Nemeth iCeutica Operations, LLC	OLON SPA, RODANO, ITALY - INSPECTION REPORTS FOR DRUG QUALITY ASSURANCE 01/02/2006 - 06/28/2013

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-7498	09/18/2013 10/17/2013	FDA/OC/OES/DFOI/	Heather Corwin-Smith or Sherry Anne Lear Law Offices of Sherry Anne Lear	IRENDA COPORATION - WARNING LETTER (CERTIFIED) 04/15/2013 - 04/15/2013
2013-7499	09/18/2013 10/17/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Tim Farber Astellas Pharm Global Development, Inc.	GENENTECH, SAN FRANCISCO, CA - EIR 08/01/2012 - 08/01/2013
2013-7500	09/18/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Chirag Talati Espirito Santo Securities	WOCKHARDT - EIR, 483 01/01/2011 - 09/18/2013
2013-7501	09/18/2013 10/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	DR. RAJIV VARMA SAFE OBSTETRIC SYSTEMS LTD	MILEX PRODUCTS INC - INFLAT O BALL K904026
2013-7502	09/18/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Meghan C. Lewallen Mellino Robenalt, LLC	SCOPOLAMINE - ADVERSE EVENT REPORT
2013-7503	09/18/2013 10/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	DR RAJIV VARMA SAFE OBSTETRIC SYSTEMS LTD	BIOTEQUE AMERICA INC - INFLATABLE PESSARY K092981
2013-7504	09/18/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID DAVIS PUBLIC CITIZEN	ARICEPT (DONEPEZIL) NDA 20-690/S2-037; 21-720/S-010; 22-568/S-007
2013-7505	09/18/2013 10/17/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	MERYL NASS MD MOUNT DESEA ISLAND HOSPITAL	ANTHRAX VACCINE - SAFETY INFORMATION FROM TRIALS 2002 TO 2007; VAERS
2013-7506	09/18/2013 10/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	DOBSON, DONALD MARK .	AGREEMENT BETWEEN FDA, MEDTRONIC & WARSAW ORTHOPEDIC CO
2013-7507	09/18/2013 10/17/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDRH/OCER/DFOI/	NICOLE STARK ESQ	SEPRAFILM RECALL
2013-7508	09/18/2013 10/17/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ OC/ORA/	SAMANTHA MYERS ROANOKE CLAIMS SERVICES	SUPER PAN BAKERY INC - ENTRY NO ESD00450715

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		OC/ORAI/		
2013-7509	09/18/2013 10/17/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GADDIE, DEBORAH	RESTATSIS - AERS
2013-7510	09/18/2013 10/17/2013	FDA/OC/OES/DFOI/	Jeannie Lin Route One Investment Company	WOCKHARDT, INDIA - 483 07/01/2013 - 08/16/2013
2013-7511	09/19/2013 10/18/2013	FDA/OMPT/OSMP/OOPD/	Deborah Casso EpiSource	Orphan drug application and any resulting correspondence for Kcentra (Proper name: Prothrombin Complex Concentrate, Human)
2013-7512	09/19/2013 10/18/2013	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	SABILA SRL - CORR WITH FDA RE WARNING LETTER 7/1/13
2013-7513	09/19/2013 10/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	Spring Miranda Philips Medical Systems (Cleveland), Inc.	K131576
2013-7514	09/19/2013 10/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Alan Katz BLOOMBERG NEWS	NDA 050733-035 LABELING
2013-7515	09/19/2013 10/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joshua A. Klarfeld ULMER & BERNE LLP	SSRI - AERS, CATEGORIZATION RECS, ETC
2013-7516	09/19/2013 10/18/2013	FDA/OC/OES/DFOI/	ZITTKOWAKI	POPULATION GROWTH - INVENTORY, CATALOG, SUMMARIES 2009 TO PRESENT
2013-7517	09/19/2013 10/18/2013	FDA/OC/OES/DFOI/	KLEN REID WASHINGTON INFORMATION SOURCE	PRINTOUT OF ALL CLOSED FOIA FOR EIRS & 483S 1/13 TO PRESENT
2013-7518	09/19/2013 10/18/2013	FDA/OFVM/CFSAN/OCD/EOS/	MARILYNN WHITNEY COVINGTON & BURLING LLP	LIVING ESSENTIALS - 5 HOUR ENRGY; PEPSI CO INC - AMP ENERGY; CELSIUS HOLDINGS INC, GLIF SHOT GEL ETC - CORR 2/13/13 TO PRESENT
2013-7519	09/19/2013 10/18/2013	FDA/OFVM/CFSAN/OCD/EOS/	MARILYNN WHITNEY COVINGTON & BURLING LLP	COCA-COLA CO - NOS DRINK & VITAMIN WATER ENERGY CONTAINING ADDED CAFFEINE LTRS 8/1/13, 6/3/13
2013-7520	09/19/2013	FDA/OMPT/CDER/ORP/DIDP/	LESLIE SANDS	ASTELLAS PHARMA US INC - ASTAGRAF XL (TACROLIMUS)

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	10/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LUPIN PHARMACEUTICALS INC	ER CAPS) NDA 204-096 SBA
2013-7521	09/19/2013 10/18/2013	FDA/OGROP/ORAP/FO/LOS- DO/LOS-CB/	LINDSAY A ABRAHAM WESTERN INSTITUTIONAL REVIEW BOARD	SCANTIBODIES BIOLOGICS INC, EL CAJON, CA; SCANTIBODIES LABORATORY INC, SANTEE, CA - EIRS, 483S, 482S, ETC 3/13 TO 5/13
2013-7522	09/19/2013 10/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	BARRY MEIER NEW YORK TIMES	BSD-2000 INTERNAL DISPUTE RESOLUTION MTG MEMOS, RPTS, RECS
2013-7523	09/19/2013 10/18/2013	FDA/OC/OES/DFOI/	AIMEE JOHNSON FULBRIGHT & JAWORSKI LLP	NEVADA PUBLIC RECORDS DECLARATION - RECS (CERTIFIED)
2013-7524	09/19/2013 10/18/2013	FDA/OC/OES/DFOI/	DEBORAH K DODGE HALL ANSLEY RODGERS ET AL	LETTERMAN FEED - CMPNT 115361
2013-7525	09/19/2013 10/18/2013	FDA/OFVM/CFSAN/OCD/EOS/	SUSAN B CASPER PROPER COURSE INC	US INFANT FORMULA - LIST OF FIRMS NOT IN CHINA
2013-7526	09/20/2013 10/21/2013	FDA/OMPT/CTP/OD/	Kyle Rozema Cornell University	QUANTITIES OF MENTHOL IN EACH CIGARETTE - PUBLISHED LIST
2013-7527	09/20/2013 10/21/2013	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2013-6279
2013-7528	09/20/2013 10/21/2013	FDA/OGROP/ORAP/CE-FO/NWJ- DO/NWJ-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	David Kim Partner Fund Management	RANBAXY LABORATORIES LIMITED, INDIA, NEW JERSEY - 483 01/03/2012 - 09/19/2013
2013-7529	09/20/2013 10/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Karen Schultz The Dominion Group	ANDA 202580
2013-7530	09/20/2013 10/21/2013	FDA/OGROP/ORAP/NE-FO/NYK- DO/NYK-DCB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MCKENZIE E CATO Hyman, Phelps & McNamara P.C.	ACTIN BIOMED, ARCHER BIOSCIENCES, FORESIGHT BIOTHERAPEUTICS - RPTS, SUMMARIES, INVESTIGATION RECS, ETC 2009 TO PRESENT

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2013-7531	09/20/2013 10/21/2013	FDA/OC/OES/DFOI/ FDA/OGROP/ORASW-FO/KAN- DO/KAN-CB/	MARY STIPANCIC PHARMA MEDICA RESEARCH INC	GATEWAY MEDICAL RESEARCH (CETERO/PRACS), ST CHARLES, MO - 483, CO RESP 1/03 TO 4/13
2013-7532	09/20/2013 10/21/2013	FDA/OFVM/CFSAN/OCD/EOS/	VINCENT RABOTEAU Center For Food Safety	REMOVAL OF POLLEN FROM HONEY, FILTRATION, ULTRA- FILTRATION & DEFINITION OF HONEY, ETC - RECS
2013-7533	09/20/2013 10/21/2013	FDA/OMPT/CTP/OD/	MARK E GREENWOLD CAMPAIGN FOR TOBACCO- FREE KIDS	DISTRIBUTOR, RETAILER, MFR OF TOBACCO PRODS - CORR, RECS
2013-7534	09/20/2013 10/21/2013	FDA/OC/OES/DDM/ FDA/OMPT/CTP/OD/	MARK E GREENWOLD CAMPAIGN FOR TOBACCO- FREE KIDS	DKT 2012N-0212
2013-7535	09/20/2013 10/21/2013	FDA/OGROP/ORASE-FO/ATL- DO/ATL-CB/ OC/ORA/ OC/ORA/	HUFFMAN, RAY	CMPLNT 131441
2013-7536	09/20/2013 10/21/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	JANIS WILSON GRIFOLS INC	SOURCE PLASMA LICENSED FACILITIES - IND STUDY PROTOCOLS FOR IMMUNIZATION PROGRAMS THAT STUDIED THE SAFETY OF DONORS WHO RECEIVED VACCINE INJECTIONS
2013-7537	09/20/2013 10/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	LAVENIA FORD CARDINAL HEALTH	BONOS R PMMA BONE CEMENT - K123225
2013-7538	09/20/2013 10/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	LAVENIA FORD CARDINAL HEALTH	DEPUY - CMW1, CMW2, CMW3 BONE CEMENT K053003
2013-7539	09/20/2013 10/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	LAVENIA FORD CARDINAL HEALTH	DEPUY - CMW 1 GENTAMICIN BONE CEMENT K053002
2013-7540	09/20/2013 10/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	LAVENIA FORD CARDINAL HEALTH	BONOS R GENTA PMMA BONE CEMENT - K123081
2013-7541	09/20/2013 10/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	DAVID DAVIS HOVERTECH INTERNATIONAL	DT DAVIS ENTERPRISES LTD (HOVERTECH INTERNATIONAL) - HOVERTRANS TRANSFORMER MODEL HTT-650P K102236
2013-7542	09/23/2013 10/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Maria Merchant Somnarus Inc	K121319, K113862
2013-7543	09/23/2013 10/22/2013	FDA/OGROP/ORACE-FO/DET- DO/DET-CB/	Tonya Hatton Grifols Plasmacare	GRIFOLS PLASMACARE, TERRE HAUTE, IN - 482, EIR (01/01/2011 - 12/31/2011)
2013-7544	09/23/2013 10/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Marco Manduchi Thema s.r.l.	K121418

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2013-7545	09/23/2013 10/22/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Rebecca Dandeker MORGAN, LEWIS & BOCKIUS	PFIZER, ROCHESTER, MI - EIR 11/13/2012 - 12/13/2012
2013-7546	09/23/2013 10/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rebecca Dandeker MORGAN LEWIS & BOCKIUS LLP	FORMOSA LABORATORIES, TAOYUAN, TAIWAN - 483 05/07/2012 - 05/10/2012
2013-7547	09/23/2013 10/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rebecca Dandeker MORGAN, LEWIS & BOCKIUS	FORMOSA LABORATORIES, TAOYUAN, TAIWAN - EIR (05/07/2012 - 05/10/2012)
2013-7548	09/23/2013 10/22/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Travis Siverson BIRCHWOOD LABORATORIES INC	OH SO CLEAN, INC, SAN FRANCISCO, CA - RESPONSES, CORRECTIVE ACTION, ETC 09/01/2010 - 07/19/2012
2013-7549	09/23/2013 10/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Deborah Sontag THE NEW YORK TIMES	BUPRENORPHINE ADDICTION PRODUCTS - AERS 03/11/2013 - 09/20/2013
2013-7550	09/23/2013 10/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Karen Denny TECHLAB, Inc.	K032222
2013-7551	09/23/2013 10/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Timothy A. Kolaya Greenberg Traurig, P.A.	ANDA 077656, ANDA 077658
2013-7552	09/23/2013 10/22/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Rebecca Dandeker MORGAN, LEWIS & BOCKIUS	PFIZER, INC, ROCHESTER, MN - EIR 06/11/2012 - 06/15/2012
2013-7553	09/23/2013 10/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	alex russell Asta Fluidic Technologies, Inc.	K990641, K892241, K071652
2013-7554	09/23/2013 10/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Ben Joseph Rice Voelker	FDA, MEDSUUN, INTUTIVE SURGICAL - CORR RE SMALL SAMPLE SURVEY OF DA VINCI SURGICAL SYSTEM 05/01/2013 - 09/20/2013
2013-7555	09/23/2013 10/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Thomas Hwang HARVARD UNIVERSITY	PMA WTIH APPROVED PEDIATRIC SUBPOPULATIONS FOR 2012 01/01/2012 - 12/31/2012
2013-7556	09/23/2013 10/22/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	KEN REID WASHINGTON INFORMATION	GLUTATHIONE CORP, ELMSFORD, NY - 483, CO RESP WARNING LTR, ETC 9/12 TO 10/12

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2013-7557	09/23/2013 10/22/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	KEN REID WASHINGTON INFORMATION SOURCE	ACCLARENT, MENLO PARK, CA - 483, CO RESP, WARNING LTR, ETC 1/13 TO 2/13
2013-7558	09/23/2013 10/22/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	KEN REID WASHINGTON INFORMATION SOURCE	MEGA SUN INC, ST LOUIS, MO - 483, CO RESP, WARNING LTR, ETC 2/13 TO 3/13
2013-7559	09/23/2013 10/22/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KEN REID WASHINGTON INFORMATION SOURCE	AGNESIAN HEALTHCARE, FOND DU LAC, WI - 483, CO RESP, WARNING LTR, ETC 11/12
2013-7560	09/23/2013 10/22/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	KEN REID WASHINGTON INFORMATION SOURCE	BIOCOMPATIBLES INC, OXFORD, CT - 483, CO RESP, WARNING LTR, ETC 2/13 TO 4/13
2013-7561	09/23/2013 10/22/2013	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	KEN REID WASHINGTON INFORMATION SOURCE	OLYMPIA WOMEN'S HEALTH, OLYMPIA, WA - 483, CO RESP, WARNING LTR, ETC 2/13 TO 3/13
2013-7562	09/23/2013 10/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KEN REID WASHINGTON INFORMATION SOURCE	HOSPIRA HEALTHCARE INDIA, ARIPERUMBURDUR, INDIA - 483, CO RESP, WARNING LTR, ETC 10/12
2013-7563	09/23/2013 10/22/2013	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	KEN REID WASHINGTON INFORMATION SOURCE	PUGET SOUND BLOOD CENTER, SEATTLE, WA - 1/13 TO 2/13
2013-7564	09/23/2013 10/22/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	KEN RIED WASHINGTON INFORMATION SOURCE	FINEMOST CORP, CERRITOS, CA - 483, CO RESP, WARNING LTR 9/12
2013-7565	09/23/2013 10/22/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	KEN REID WASHINGTON INFORMATION SOURCE	ALEXION PHARMACEUTICALS, CHESHIRE, CT - 483, CO RESP, WARNING LTR, ETC 7/12 TO 8/12
2013-7566	09/23/2013 10/22/2013	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	KEN REID WASHINGTON INFORMATION SOURCE	MICHAEL RING MD, SPOKANE, WA - 483, CO RESP. WARNING LTR, ETC 7/12 TO 8/12
2013-7567	09/23/2013	FDA/OGROP/ORACE-FO/CIN-	KEN REID	AMRESKO, SOLON, OH - 483, CO RESP WARNING LTR, ETC

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	10/22/2013	DO/CIN-CB/	WASHINGTON INFORMATION SOURCE	10/12 TO 12/12
2013-7568	09/23/2013 10/22/2013	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	KEN REID WASHINGTON INFORMATION SOURCE	AIONEX, GOODLETTSVILLE, TN - 483, CO RESP WARNING LTR, ETC 11/12
2013-7569	09/23/2013 10/22/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	KEN REID WASHINGTON INFORMATION SOURCE	ACELL INC, COLUMBIA, MD - 483, CO RESP, WARNING LTR, ETC 11/12 TO 12/12
2013-7570	09/23/2013 10/22/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	KEN REID WASHINGTON INFORMATION SOURCE	AUTOMATED OPHTHALMICS, COLUMBIA, MD - 483, CO RESP, WARNING LTR, ETC 2/13 TO 3/13
2013-7571	09/23/2013 10/22/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	KEN REID WASHINGTON INFORMATION SOURCE	EDWARDS LIFESCIENCES, DRAPER, UT - 483, CO RESP, WARNING LTR, ETC 1/13 TO 2/13
2013-7572	09/23/2013 10/22/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	KEN RIED WASHINGTON INFORMATION SOURCE	ELECTROMEDICAL PRODUCTS INTERNATIONAL INC, MINERAL WELLS, TX - 483, CO RESP, WARNING LTR, ETC 1/13 TO 2/13
2013-7573	09/23/2013 10/22/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	KEN REID WASHINGTON INFORMATION SOURCE	K S CHOI CORP, LOS ANGELES, CA - 483, CO RESP, WARNING LTR, ETC 12/12 TO 2/13
2013-7574	09/23/2013 10/22/2013	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	KEN REID WASHINGTON INFORMATION SOURCE	RIVERPOINT MEDICAL, PORTLAND, OR - 483, CO RESP, WARNING LTR, ETC 1/13 TO 2/13
2013-7575	09/23/2013 10/22/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	KEN REID WASHINGTON INFORMATION SOURCE	VALLEY HEALTH WINCHESTER MEDICAL CENTR IRB, WINCHESTER, VA - 483, CO RESP WARNING LTR, ETC 1/13 TO 2/13
2013-7576	09/23/2013 10/22/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	KEN REID WASHINGTON INFORMATION SOURCE	CISPHARMA, CRANBURY, NJ - 483, CO RESP, WARNING LTR, ETC 3/12 TO 4/12
2013-7577	09/23/2013 10/22/2013	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	KEN REID WASHINGTON INFORMATION SOURCE	ALMA LASERS INC, BUFFALO GROVE, IL - 483, CO RESP, WARNING LTR, ETC 1/13
2013-7578	09/23/2013 10/22/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	KEN REID WASHINGTON INFORMATION SOURCE	ALPHA MEDICAL INSTRUMENTS, MISSION VIEJO, CA - 483, CO RESP, WARNING LTR, ETC 12/12 TO 1/13
2013-7579	09/23/2013 10/22/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	KEN REID WASHINGTON INFORMATION	TRANSONIC SYSTEMS INC, ITHACA, NY - 483, CO RESP, WARNING LTR, ETC 2/13 TO 3/13

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2013-7580	09/23/2013 10/22/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	KEN REID WASHINGTON INFORMATION SOURCE	BIOMEDIX INC, BLOOMINGTON, IN - 483, CO RESP, WARNING LTR 2/13 TO 3/13
2013-7581	09/23/2013 10/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	shin kang WELLS FARGO	KALYDECO, JAKAFI, TECFIDERA, ETC - AERS 07/01/2013 - 09/30/2013
2013-7582	09/23/2013 10/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Neil Malhotra Malhotra, Neil	CM-AT - EFFICACY, ADVERSE EVENTS 09/01/2010 - 09/23/2013
2013-7583	09/23/2013 10/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	HUES, TOLEDO .	COAPT SYSTEMS - NOVELLE GEL CLNCL TRIALS, AER
2013-7584	09/23/2013 10/22/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANDREW HACK, MD, PhD. MILLENNIUM MANAGEMENT LLC	NPS PHARMACEUTICALS - GATTEX FAERS, EIR, 483, UNTITLED LTRS
2013-7585	09/23/2013 10/22/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANDREW HACK, MD, PhD. MILLENNIUM MANAGEMENT LLC	AEGERION PHARMACEUTICALS INC - JUXTAPID (LOMITAPIDE) AER, EIR, 483, UNTITLED LTRS
2013-7586	09/23/2013 10/22/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	ANDREW HACK, MD, PhD. MILLENNIUM MANAGEMENT LLC	ISIS PHARMACEUTICALS INC - 483, EIR, UNTITLED LTRS 1/13 TO PRESENT
2013-7587	09/23/2013 10/22/2013	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	ANDREW HACK, MD, PhD. MILLENNIUM MANAGEMENT LLC	SEATTLE GENETICS INC - EIR, 483, UNTITLED LTRS 4/13 TO PRESENT
2013-7588	09/23/2013	FDA/OGROP/ORAPA-FO/LOS-	DAVID LOHMAN	THERAPEUTICS INC - EIR, 483, UNTITLED LTRS 1/10 TO

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	10/22/2013	DO/LOS-CB/	MILLENNIUM MANAGEMENT LLC	PRESENT
2013-7589	09/23/2013 10/22/2013	FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA REQUEST LOG 09/16/2013 - 09/20/2013
2013-7590	09/23/2013 10/22/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID LOHMAN MILLENNIUM MANAGEMENT LLC	DEPOMED - GRALISE (GABAPENTIN) FAERS, UNTITLED LTRS 1/11 TO PRESENT
2013-7591	09/23/2013 10/22/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	JENNIFER HSIEH DEERFIELD INSTITUTE	BIOGEN IDEC INC - 483
2013-7592	09/23/2013 10/22/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	BRENDA M. GARTZ ELI LILLY & CO	DYAX CORP, CAMBRIDGE, MA - 483 7/11
2013-7593	09/23/2013 10/22/2013	OC/ORPA/ OC/ORPA/	KYRIAKIDIS., JOANNA	AMERIDOSE LLC, WESTBOROUGH, MA - EIR
2013-7594	09/23/2013 10/22/2013	OC/ORPA/OCI/ OC/ORPA/OCI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Doe J	INDIVIDUAL RECS
2013-7595	09/23/2013 10/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	RITALIN - AER
2013-7596	09/23/2013 10/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	MEDWATCH RPT
2013-7597	09/23/2013 10/22/2013	FDA/OO/OFBA/OAGS/	DAVID S. NALVEN HAGANS BERMAN ET AL	ASTELLAS PHARMA INC - PROGRAF (TACROLIMUS) DOCS

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2013-7598	09/23/2013 10/22/2013	FDA/OFVM/CFSAN/OCD/EOS/	FRANCIS, ANA	LTR FROM UNITED TO FDA
2013-7599	09/23/2013 10/22/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	MICHAEL S. HEYL HOGAN LOVELLS LLP	IVERA MEDICAL CORP - INVESTIGATIONS
2013-7600	09/23/2013 10/22/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	APRIL M. BIGGS THOMAS THOMAS & HAFFER	GPR CO, ROYERSFORD, PA - INVESTIGATIONS, CORR
2013-7601	09/23/2013 10/22/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	PATRICK KELLY CONWAY HOMER & CHIN-CAPLAN PC	INDIVIDUAL RECS
2013-7602	09/23/2013 10/22/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	JENNIFER A. HYLEMON MORRISON MAHONEY LLP	ENDO WRIST HOT SHEARS - RECALL
2013-7603	09/23/2013 10/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WARREN WILLIAMS FOREST RESEARCH INSTITUTE	AMITIZA (LUBIPROSTONE) NDA 21-908/S-011 APRVL
2013-7604	09/23/2013 10/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	SANDY MASTROIANNI ITC	PRO TIME - MICROCOAGULATION SYS K961835
2013-7605	09/23/2013 10/22/2013	FDA/OC/OES/DFOI/	SKERTIC, MARK	2006-9732, 2008-7899, 2012-6322 ETC
2013-7606	09/24/2013 10/23/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	KEN REID WASHINGTON INFORMATION SOURCE	HAIR LABS INC, NASHVILLE, TN - 483, CO RESP, WARNING LTR, ETC 4/13
2013-7607	09/24/2013 10/23/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	KEN REID WASHINGTON INFORMATION SOURCE	CONAIR CORP, STAMFORD, CT - 483, CO RESP, WARNING LTR, ETC 5/13
2013-7608	09/24/2013 10/23/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	KEN REID WASHINGTON INFORMATION SOURCE	LIFESERVE BLOOD CENTER, DES MOINES, IA - 483, CO RESP, WARNING LTR, ETC 6/13
2013-7609	09/24/2013 10/23/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	KEN REID WASHINGTON INFORMATION SOURCE	LUMIQUICK DIAGNOSTICS INC, SANTA CLARA, CA - 483, CO RSP, WARNING LTR, ETC 11/12 TO 12/12

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2013-7610	09/24/2013 10/23/2013	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	KEN REID WASHINGTON INFORMATION SOURCE	ZEPPESSIS REPROCESSING LLC, GARDEN CITY, ID - 483, CO RESP, WARNING LTR, ETC 4/13
2013-7611	09/24/2013 10/23/2013	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	KEN REID WASHINGTON INFORMATION SOURCE	PETER SCHIFF ENTERPRISES, COOKEVILLE, TN - 483, CO RESP, WARNING LTR, ETC 3/13 TO 4/13
2013-7612	09/24/2013 10/23/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	KEN REID WASHINGTON INFORMATION SOURCE	AMRESKO, SOLON, OH - EIR, RESP, CORR 10/12 TO 12/12
2013-7613	09/24/2013 10/23/2013	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	KEN REID WASHINGTON INFORMATION SOURCE	AIONEX, GOODLETTSVILLE, TN - EIR, RESP, CORR 11/12
2013-7614	09/24/2013 10/23/2013	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	KEN REID WASHINGTON INFORMATION SOURCE	RIVERPOINT MEDICAL, PORTLAND, OR - EIR, RESP, CORR 1/13 TO 2/13
2013-7615	09/24/2013 10/23/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	KEN REID WASHINGTON INFORMATION SOURCE	K S CHOI CORP, LOS ANGELES, CA - EIR, RESP, CORR 12/12 TO 2/13
2013-7616	09/24/2013 10/23/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	KEN REID WASHINGTON INFORMATION SOURCE	FINEMOST CORP, CERRITOS, CA - EIR, RESP, CORR 9/12
2013-7617	09/24/2013 10/23/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	KEN REID WASHINGTON INFORMATION SOURCE	GYRUS ACMI, STAMFORD, CT - EIR, RESP, CORR 7/12 TO 8/12
2013-7618	09/24/2013 10/23/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	KEN REID WASHINGTON INFORMATION SOURCE	GLUTATHIONE CORP, ELMSFORD, NY - EIR, RESP, CORR 9/12 TO 10/12
2013-7619	09/24/2013 10/23/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	KEN REID WASHINGTON INFORMATION SOURCE	ALEXION PHARMS, CHESHIRE, CT - EIR, RESP, CORR 7/12 TO 8/12
2013-7620	09/24/2013 10/23/2013	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	KEN REID WASHINGTON INFORMATION SOURCE	MICHAEL RING MD, SPOKANE, WA - EIR, RESP, CORR 7/12 TO 8/12
2013-7621	09/24/2013 10/23/2013	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	KEN REID WASHINGTON INFORMATION SOURCE	PARKS MEDICAL ELECTRONIC, ALOHA, OR - 483, CO RESP, WARNING LTR, ETC 7/12 TO 8/12
2013-7622	09/24/2013	FDA/OGROP/ORACE-FO/CHI-	KEN RIED	LIFEWATCH SERVICES, ROSEMEONT, IL - 483, CO RESP,

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	10/23/2013	DO/CHI-CB/	WASHINGTON INFORMATION SOURCE	WARNING LTR, ETC 8/12 TO 9/12
2013-7623	09/24/2013 10/23/2013	FDA/OGROP/ORPA/FO/SEA-DO/SEA-CB/	KEN REID WASHINGTON INFORMATION SOURCE	BACTERIN INTERNATIONAL, BELGRADE, MT - 483, CO RESP, WARNING LTR, ETC 7/12
2013-7624	09/24/2013 10/23/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	KEN REID WASHINGTON INFORMATION SOURCE	ABBEY COLOR, PHILADELPHIA, PA - 483, CO RESP, WARNING LTR, ETC 3/12
2013-7625	09/24/2013 10/23/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	KEN REID WASHINGTON INFORMATION SOURCE	SOVEREIGN PHARM, FORT WORTH, TX - 483, CO RESP, WARNING LTR, ETC 1/12 TO 2/12
2013-7626	09/24/2013 10/23/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	KEN RIED WASHINGTON INFORMATION SOURCE	JANET K TILLISCH MD, FARGO, ND - 483, CO RESP, WARNING LTR, ETC 4/13
2013-7627	09/24/2013 10/23/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEN REID WASHINGTON INFORMATION SOURCE	WOCKHARDT LTD, AURANGABAD, INDIA - 483, CO RESP, WARNING LTR, ETC 3/13
2013-7628	09/24/2013 10/23/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	KEN REID WASHINGTON INFORMATION SOURCE	INTUITIVE SURGICAL INC, SUNNYVALE, CA - 483, CO RESP, WARNING LTR, ETC 4/13 TO 5/13
2013-7629	09/24/2013 10/23/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	KEN REID WASHINGTON INFORMATION SOURCE	STEWART COMPUNDING PHARMACY, FAYETTEVILLE, NC - 483, CO RESP, WARNING LTR, ETC 3/13
2013-7630	09/24/2013 10/23/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	KEN REID WASHINGTON INFORMATION SOURCE	ANSAR GROUP, PHILADELPHIA, PA - 483, CO RESP, WARNING LTR, ETC 5/12 TO 6/12
2013-7631	09/24/2013 10/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	DAVID E OUTWATER ESQ OUTWATER & PINCKES LLP	APOGEE - POLYETHYLENE AND PET BOTTLES AND CONTAINERS INVESTIGATIONS, TESTING, LAB RPTS, ETC
2013-7632	09/24/2013 10/23/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SHERRY L CONDIE X-GEN PHARMACEUTICALS INC	INDOCO REMEDIES LTD, GOA, INDIA - DRUG PROD DOSAGE FORMS, INSPECTIONAL STATUS, INSPS LAST 3 YRS
2013-7633	09/24/2013 10/23/2013	FDA/OC/OCC/	Lytle, Robert	LAWS, RULES, REGULATIONS ETC WHICH FDA USES TO SUPPORT THE CLAIM THAT THE FDA DOES NOT

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				RECOGNIZE PRIVATE MEMBERSHIP ASSOCIATIONS
2013-7634	09/24/2013 10/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	STUTE, HANK	PARAGON VISION SCIENCES - CPT1200119
2013-7635	09/24/2013 10/23/2013	FDA/OC/OES/DFOI/	A SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 167755, 165500, 165504
2013-7636	09/24/2013 10/23/2013	FDA/OO/OFBA/OAGS/	TARASUK, JOHN	ROBERT WOTKOWSKI, KEYSTONE PROPERTY RESOURCES INC; MAURICE ELECTRIC - CONTRACT RECS
2013-7637	09/24/2013 10/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	KRISTIN DAVENPORT GOODWIN PROCTER LLP	PARKER HANNIFIN CORP - INDEGO EXOSKELETON RECS
2013-7638	09/24/2013 10/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	CARLO CASULO MD ASCEND CAPITAL LLC	INSULET CORP - OMNIPOD MDRS 1/13 TO PRESENT
2013-7639	09/24/2013 10/23/2013	FDA/OGROP/ORASW-FO/DEN- DO/DEN-CB/	MARTI GROS ACTITECH	INNOVATIVE FLEXPAC, SPRINGVILLE, UT - REGISTRATION TYPE, STATUS, AUDIT RPTS
2013-7640	09/24/2013 10/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	JAMIE YIEH ABBOTT POINT OF CARE INC	TAS PT ONE TEST CARD K955843; COAG-1 PT TEST CARD K882456; COAG-1 PT-NC TEST CARD K904325, ETC
2013-7641	09/24/2013 10/23/2013	OC/CVM/OCD/ FDA/OGROP/ORASW-FO/KAN- DO/KAN-CB/	JILLIAN NASH ALLTECH INC	DIAMOND V, CEDAR RAPIDS, IA - CORR 7/13 TO 8/13
2013-7642	09/24/2013 10/23/2013	OC/CVM/OCD/ FDA/OGROP/ORASW-FO/KAN- DO/KAN-CB/	JILLIAN NASH ALLTECH INC	PURINA ANIMAL NUTRITION LLC, ST LOUIS, MO - 483S, CORR LAST TEN YRS
2013-7643	09/24/2013 10/23/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	JANIS SWABY REXAM HEALTHCARE	REXAM - ACKNOWLEDGEMENT LTRS FOR TYPE III DMFS
2013-7644	09/25/2013 10/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Tomas Friend KIPA AB	PMA P000039
2013-7645	09/25/2013 10/24/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Karl Gallegos, MD Karl Gallegos	MINOCYCLINE - FAERS
2013-7646	09/25/2013 10/24/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Curtis Hogue DISCOVERY CAPITAL	REGADENOSCAN - FAERS

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MANAGEMENT	
2013-7647	09/25/2013 10/24/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Kelli Dryer STRYKER SUSTAINABILITY SOLUTIONS	K101797
2013-7648	09/25/2013 10/24/2013	FDA/OFVM/CFSAN/OCD/EOS/ ICRS, LLC	Janet Blaschke	PAFA DATABASED DATA 09/01/1980 - 08/30/2013
2013-7649	09/25/2013 10/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dr. Coco Chen Chen, Coco	BRILACIDIN - PHASE 1 AND PHASE 2 CLINICAL STUDY RESULTS
2013-7650	09/25/2013 10/24/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Alex Greene Bionova Medical	K060046
2013-7651	09/25/2013 10/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	I Friedman N/A	INTERMUNE - AERS
2013-7652	09/25/2013 10/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Chandrika Vira FITZPATRICK CELLA HARPER & SCINTO	K971819
2013-7653	09/25/2013 10/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Willene Brondum Insys Therapeutics, Inc.	NDA 204242 - SBA
2013-7654	09/25/2013 10/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Irina Rivkind CANTOR FITZGERALD	LINZESS - FAERS
2013-7655	09/25/2013 10/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FDA form 483 for USV Limited India Drug Regulations	USV LIMITED, INDIA - 483 01/01/2013 - 09/24/2013

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-7656	09/25/2013 10/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K100831
2013-7657	09/25/2013 10/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K112394
2013-7658	09/25/2013 10/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Karen Denny TECHLAB, Inc.	K023599
2013-7659	09/25/2013 10/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/OSMP/OOPD/	John Callahan Hapten Pharmaceuticals, LLC	CEPTARIS - APPROVAL RECS 01/01/2004 - 09/01/2013
2013-7660	09/25/2013 10/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Elana Markovitz Orthospace Ltd	K121216
2013-7661	09/25/2013 10/24/2013	FDA/OMPT/CDRH/OCER/DFOI/ OC/ORO/ OC/ORO/	Aram Sethian Quad Capital	ICU MEDICAL, INC - CONSUMER COMPLAINTS 01/01/2007 - 09/24/2013
2013-7662	09/25/2013 10/24/2013	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/	Thomas Evans Soltec ventures	ALDRICH CHEMICAL CO - IMPORT RECS FOR SEA SNAIL
2013-7663	09/25/2013 10/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kelly A. Blessing-Maire Blessing-Maire, Kelly A	VICTOZA - AERS
2013-7664	09/25/2013 10/24/2013	FDA/OC/OES/DFOI/	Shuo Yang UNIVERSITY OF BRITISH COLUMBIA	FOIA REQUEST LOG 01/01/2004 - 08/31/2013
2013-7665	09/25/2013 10/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Coco Chen Chen, Coco	KEVETRIN - PHAES I CLINICAL TRIALS, ADVERSE EVENTS

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2013-7666	09/25/2013 10/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nathaniel August Mangrove Partners	TAKEDA - CORR WITH FDA RE OMONTYS, PEGINESATIDE
2013-7667	09/25/2013 10/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Ketaki Gokhale BLOOMBERG NEWS	SUN PHARMACEUTICAL INDUSTRIES LTD, CARACO PHARMACEUTICAL LABORATORIES (09/23/2011 - 09/24/2013)
2013-7668	09/25/2013 10/24/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	Joshua Clark Davis DUKE UNIVERSITY	OHSAWA FOUNDATION, NY, NY - INSPECTION RECS 01/01/1960 - 01/01/1970
2013-7669	09/25/2013 10/24/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Joshua Clark Davis DUKE UNIVERSITY	NEW AGE NATURAL FOODS STORE, SAN FRANCISCO, CA - INSPECTION RECS 01/01/1964 - 12/31/1973
2013-7670	09/25/2013 10/24/2013	FDA/OFVM/CFSAN/OCD/EOS/	Thomas Mullarkey MORNINGSTAR COSULTING INC	MONSTER ENERGY DRINKS - AERS
2013-7671	09/25/2013 10/24/2013	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	Rachel Johnson FOI Services, Inc.	LORILLARD TOBACCO, DANVILLE, VA - INSPECTOR DIARIES
2013-7672	09/25/2013 10/24/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Denise Bennington Ascension Technology Corporation	ASCENSION TECHNOLOGY CORPORATION, SHELBURNE, VT - INVESTIGATION STATUS
2013-7673	09/25/2013 10/24/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Thomas Leusner Prirista	SHIRE, LEXINGTON, MA - BIOLOGICS PRODUCT DEVIATION REPORTS 09/01/2012 - 09/23/2013
2013-7674	09/25/2013 10/24/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Brian Lemasters Brian Lemasters	INSPIRE-MD - ADVERSE EVENTS, 483 1/01/2010 - 09/22/2013
2013-7675	09/25/2013 10/24/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	John Strelecki STRELECKI, SAMUEL J	IRONWOOD CANCER AND RESEARCH CENTER, DR MIKHAIL SHTIVELBAND 03/01/2012 - 12/31/2012

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2013-7676	09/25/2013 10/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joy V. Rousso Shapiro Capital Management	MALLINKRODT PHARMACEUTICALS MNK-395 - NDA
2013-7677	09/25/2013 10/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CJ Sylvester Catapult. Ltd.	JETREA - AERS
2013-7678	09/25/2013 10/24/2013	FDA/OGROP/ORR/NE-FO/NWE-DO/NWE-CB/	Joshua Clark Davis DUKE UNIVERSITY	EREWON TRADING CO - INSPECTION RECS 01/01/1966 - 12/31/1973
2013-7679	09/25/2013 10/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tommy Noh Wilson Sonsini Goodrich & Rosati, P.C.	MECHLORETHAMINE HYDROCHLORIDE - APPROVAL HISTORY
2013-7680	09/25/2013 10/24/2013	FDA/OC/OES/DFOI/	Stace Sirmans UNIVERSITY OF FLORIDA	FOIA REQUEST LOG 01/01/2008 - 08/01/2013
2013-7681	09/25/2013 10/24/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Timothy B Bassett Pura Vida Investments	JUXTAPED, KYNAMRO - AERS
2013-7682	09/25/2013 10/24/2013	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	Rachel Johnson FOI Services, Inc.	AMERICAN SNUFF - EXHIBITS 10/3/2011
2013-7683	09/25/2013 10/24/2013	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORR/ OC/ORR/	HEATHER GALE OLSSON FRANK WEEDA TERMAN MATZ PC	CADMIUM IN CHOCOLATE - SAFETY ASSESSMENT MEMO & RPT 9/18/13
2013-7684	09/25/2013 10/24/2013	FDA/OMPT/CTP/OD/ FDA/OC/OEXA/OMA/	CAROLLO, RUSSELL	SERVICES, COUNSEL, ADVICE PROVIDED BY GOOGLE - CORR, FOIA REQUESTS, TRAVEL RECS, ETC
2013-7685	09/25/2013 10/24/2013	FDA/OC/OES/DFOI/	PRICE, GRETA S	INDIVIDUAL RECS
2013-7686	09/25/2013 10/24/2013	FDA/OFVM/CFSAN/OCD/EOS/	CARRIE TEETER Keller and Heckman LLP	NIPPON STEEL & SUMITOMO METAL CORP - FCN 1253
2013-7687	09/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	MIKE SHEPARD	FLOWMEDICA INC - BENEPHIT BIFURCATED INFUSION

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	10/24/2013		RENE MEDICAL	CATHETER, BENEPHIT 5FR INTRODUCER SHEATH SYS K050205
2013-7688	09/25/2013 10/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	MIKE SHEPARD RENE MEDICAL	FLOWMEDICA INC - BENEPHIT INFUSION SYS K082163
2013-7689	09/25/2013 10/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	JAMES MAGUIRE DAVID ROSEN & ASSOCIATES PC	MAQUET CADRIOPULMONARY AG - QUADROX ID DIFFUSION MEMBRANE OXYGENATOR K112360 RECS 1/11 TO 12/11
2013-7690	09/25/2013 10/24/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDRH/OCER/DFOI/	JAMES MAGUIRE DAVID ROSEN & ASSOCIATES PC	MAQUET CARDIOPULMONARY AG, MAQUET CARDIOVASCULAR LLC - EIRS. 483S. WARNING LTRS, ETC
2013-7691	09/25/2013 10/24/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDRH/OCER/DFOI/	JAMES MAGUIRE DAVID ROSEN & ASSOCIATES PC	MAQUET CARDIOPULMOMARY AG - QUADROX ID DIFFUSION MEMBRANE OXYGENATOR RECALL RECS,CORR, RVWS, ETC
2013-7692	09/25/2013 10/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	JAMES MAGUIRE DAVID ROSEN & ASSOCIATES PC	MAQUET CARDIOPULMONARY AG - QUADROX ID DIFFUSION MEMBRANE OXYGENATOR K101153
2013-7693	09/25/2013 10/24/2013	FDA/OFVM/CFSAN/OCD/EOS/	MICHELLE L BRISCOE BROOKS RAND LABS	RICE DATA EXCEL FORMAT
2013-7694	09/25/2013 02/21/2014	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	HILL, MELISSA D	INDIVIDUAL RECS
2013-7695	09/25/2013 10/24/2013	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	KEN REID WASHINGTON INFORMATION SOURCE	OLYMPIA WOMENS HEALTH, OLYMPIA, WA - EIR, CO RESP 2/13 TO 3/13
2013-7696	09/25/2013 10/24/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	KEN REID WASHINGTON INFORMATION SOURCE	BIOMERIEUX, DURHAM, NC - EIRS, RESP, CORR 1/12 TO 3/12
2013-7697	09/25/2013 10/24/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	KEN REID WASHINGTON INFORMATION SOURCE	CELLTEX THERAPEUTICS, SUGARLAND, TX - EIRS, RESP, CORR 4/12
2013-7698	09/25/2013 10/24/2013	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	KEN REID WASHINGTON INFORMATION SOURCE	PUGET SOUND BLOOD CENTER, SEATTLE, WA - 1/13 TO 2/13
2013-7699	09/25/2013 10/24/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	KEN REID WASHINGTON INFORMATION SOURCE	WESTONE LABORATORIES, COLORADO SPRINGS, CO - EIR, CO RESP 7/12
2013-7700	09/25/2013	FDA/OGROP/ORASE-FO/FLA-	KEN REID	NEXERA MEDICAL, FORT LAUDERDALE, FL - EIR, CO RESP

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	10/24/2013	DO/FLA-CB/	WASHINGTON INFORMATION SOURCE	7/12
2013-7701	09/25/2013 10/24/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	KEN REID WASHINGTON INFORMATION SOURCE	COCOKEFIR LLC, MEDINA, MN - EIR, CO RESP 5/12
2013-7702	09/25/2013 10/24/2013	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	KEN REID WASHINGTON INFORMATION SOURCE	TISSUE BANK INT'L, MEMPHIS, TN - 483, CO RESP, WARNING LTR 6/12
2013-7703	09/25/2013 10/24/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	KEN REID WASHINGTON INFORMATION SOURCE	LAKEWOOD LLC, LAKEWOOD, NJ - EIRS, RESP, CORR 2/12 TO 3/12
2013-7704	09/25/2013 10/24/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	KEN REID WASHINGTON INFORMATION SOURCE	MIR-COM PRODUCTS, CENTRAL CITY, PA - EIR, RESP, CORR 6/12
2013-7705	09/25/2013 10/24/2013	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	KEN REID WASHINGTON INFORMATION SOURCE	MARTIN S BALIN MD, CHICAGO, IL - EIR, RESP, CORR 6/12 TO 8/12
2013-7706	09/25/2013 10/24/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	KEN REID WASHINGTON INFORMATION SOURCE	COCOKEFIR LLC, MEDINA, MN - 483, CO RESP, WARNING LTR 5/12
2013-7707	09/25/2013 10/24/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	KEN REID WASHINGTON INFORMATION SOURCE	NEXERA MEDICAL, FORT LAUDERDALE, FL - 483, CO RESP, WARNING LTR 7/12
2013-7708	09/25/2013 10/24/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	KEN REID WASHINGTON INFORMATION SOURCE	WESTONE LABORATORIES, COLORADO SPRINGS, CO - 483, CO RESP, WARNING LTR 7/12
2013-7709	09/25/2013 10/24/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	KEN REID WASHINGTON INFORMATION SOURCE	PERFORMANCE PRODUCTS, ST LOUIS, MO - 483, CO RESP, WARNING LTR 7/12
2013-7710	09/25/2013 10/24/2013	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	KEN REID WASHINGTON INFORMATION SOURCE	MARTIN A BALIN MD, CHICAGO, IL - 483, CO RESP, WARNING LTR 6/12 TO 8/12
2013-7711	09/25/2013 10/24/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	KEN REID WASHINGTON INFORMATION SOURCE	GYRUS ACMI, STAMFORD, CT - 483, CO RESP, WARNING LTR 7/12 TO 8/12
2013-7712	09/25/2013 10/24/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	KEN REID WASHINGTON INFORMATION	STATRX USA, GAINESVILLE, GA - 483, CO RESP, WARNING LTR 2/12

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2013-7713	09/25/2013 10/24/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	KEN REID WASHINGTON INFORMATION SOURCE	I SHAY COSMETICS, GARDEN, CA - 483, CO RESP, WARNING LTR 2/12
2013-7714	09/25/2013 10/24/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	KEN REID WASHINGTON INFORMATION SOURCE	BIOCOMPATIBLES INC, OXFORD, CT - EIR, CO RESP 2/13 TO 4/13
2013-7715	09/25/2013 10/24/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	KEN REID WASHINGTON INFORMATION SOURCE	AGNESIAN HEALTHCARE, FOND DU LAC, WI - EIR, CO RESP 11/12
2013-7716	09/25/2013 10/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Makoto Kaino Japan Asia Clinical Research Product Creation Unit, Eisai Co., Ltd	CLINICAL INVESTIGATORS - 483 (01/01/2008 - 09/25/2013)
2013-7717	09/25/2013 10/24/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	brandi kopp Brandi Kopp	JUICE PLUS COMPLETE - TEST RESULTS (06/24/2013 - 09/24/2013)
2013-7718	09/25/2013 10/24/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	KEN REID WASHINGTON INFORMATION SOURCE	MEGA SUN INC, ST LOUIS, MO - EIR, CO RESP 2/12 TO 3/12
2013-7719	09/25/2013 10/24/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Sara Neily The Doyle Firm	STRYKER TRIDENT HIP SYSTEM - RECALL RECS, WARNING LETTER (01/01/2006 - 09/24/2013)
2013-7720	09/25/2013 10/24/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Rachel Johnson FOI Services, Inc.	AMERICAN SNUFF, WINSTON-SALEM, NC - INVESTIGATOR DIARIES
2013-7721	09/25/2013 10/24/2013	FDA/OC/OES/ FDA/OMPT/CTP/OD/ FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	E CIGARETTE REGULATIONS - CORR
2013-7722	09/25/2013 10/24/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Rachel Johnson FOI Services, Inc.	LORRILARD TOBACCO, DANVILLE, VA - EXHIBITS FOR 7/26/2012 INSPECTION
2013-7723	09/25/2013 10/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Elyse Ball University of Akron Research Foundation	P960052
2013-7724	09/25/2013	OC/CVM/OCD/	Sandy O'Kelley	MERIAL LIMITED - RECS RE G-002819-G-0002-AD, G-002893-G-0002-AD, G-002819 G-002893

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	10/24/2013		Merial Limited	
2013-7725	09/25/2013 10/24/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	KEN REID WASHINGTON INFORMATION SOURCE	ACCLARENT, MENLO PARK, CA - EIR, CO RESP 1/13 TO 2/13
2013-7726	09/25/2013 10/24/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	KEN REID WASHINGTON INFORMATION SOURCE	PERFORMANCE PRODUCTS, ST LOUIS, MO - EIR, RESP,CORR 7/12
2013-7727	09/25/2013 10/24/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	KEN REID WASHINGTON INFORMATION SOURCE	VALLEY HEALTH WINCHESTER MEDICAL CTR IRB, WINCHESTER, VA - EIR, CO RESP 1/13 TO 2/13
2013-7728	09/25/2013 10/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Zeeshan Raza Raza, Zeeshan	HEPAHOPE - CLINICAL HOLD RECS 01/01/2000 - 09/24/2013
2013-7729	09/25/2013 10/24/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	KEN REID WASHINGTON INFORMATION SOURCE	STATRX USA, GAINESVILLE, GA - EIR, RESP, CORR 2/12
2013-7730	09/25/2013 10/24/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	KEN REID WASHINGTON INFORMATION SOURCE	INNOVACYN INC, RIALTO, CA - 483, CO RESP, WARNING LTR 11/11 TO 12/11
2013-7731	09/25/2013 10/24/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	KEN REID WASHINGTON INFORMATION SOURCE	COMAPNY INTUITIVE SURGICAL INC, SUNNYVALE, CA - EIR, RESP, CORR 4/13 TO 5/13
2013-7732	09/25/2013 10/24/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	KEN REID WASHINGTON INFORMATION SOURCE	SPINE FRONTER, BEVERLY, MA - 483, CO RESP, WARNING LTR 5/12 TO 7/12
2013-7733	09/25/2013 10/24/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	KEN REID WASHINGTON INFORMATION SOURCE	I SHAY COSMETICS, GARDENA, CA - EIR, RESP, CORR 2/12
2013-7734	09/25/2013 10/24/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	KEN REID WASHINGTON INFORMATION SOURCE	LAKEWOOD LLC, LAKEWOOD, NJ - 483, CO RESP, WARNING LTR 2/12 TO 3/12
2013-7735	09/25/2013 10/24/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	KEN REID WASHINGTON INFORMATION SOURCE	SCM TRUE AIR TECHNOLOGIES, LOUISVILLE, KY - EIR, RESP, CORR 5/13
2013-7736	09/25/2013 10/24/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	KEN REID WASHINGTON INFORMATION SOURCE	MIR COM PRODUCTS, CENTRAL CITY, PA - 483, CO RESP, WARNING LTR 6/12

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2013-7737	09/25/2013 10/24/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	KEN REID WASHINGTON INFORMATION SOURCE	CELL TEX THERAPEUTICS, SUGARLAND, TX - 483, CO RESP, WARNING LTR 4/12
2013-7738	09/25/2013 10/24/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	KEN REID WASHINGTON INFORMATION SOURCE	BIOMERIEUX, DURHAM, NC - 483, CO RESP, WARNING LTR 1/12 TO 3/12
2013-7739	09/26/2013 10/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sheila Gray WKEF/WRGT TV	MIRENA IUD - AERS
2013-7740	09/26/2013 10/25/2013	OC/CVM/OCD/	Becky Armfield NOVARTIS ANIMAL HEALTH US INC	NADA 141-406 FOIA SUMMARY
2013-7741	09/26/2013 10/25/2013	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	Franco Medeiros PROCTER & GAMBLE	GLAXOSMITHKLINE, MEMPHIS, TN - INSPECTION RECS 09/01/1990 - 09/25/2013
2013-7742	09/26/2013 10/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sheena M. Posey Norris The National Academies (Institute of Medicine)	NDA 050786 - ACTION LETTER
2013-7743	09/26/2013 10/25/2013	FDA/OC/OES/DFOI/	Kari Twaite BEVERIDGE & DIAMOND PC	FOIA REQUESTS FILED WITH CFSAN 08/01/2012 - 09/25/2013
2013-7744	09/26/2013 10/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Brooke Hazan KENYON & KENYON LLP	IND 21487 - CLINICAL STUDY
2013-7745	09/26/2013 10/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Intertox< Inc. Intertox, Inc.	K914776
2013-7746	09/26/2013 10/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Manish Ahuja BioTex Inc.	K944463
2013-7747	09/26/2013 10/25/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	b. burgess BURGESS, BERNIE	EI ENDORSEMENT FOR FEI 3004927371
2013-7748	09/26/2013 10/25/2013	FDA/OFVM/CFSAN/OCD/EOS/	Lauren Farruggia Hyman, Phelps & McNamara P.C.	ZARBEE - COMMUNICATIONS WITH FDA RE LABEL CLAIMS
2013-7749	09/26/2013	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson	FAP 1041

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	10/25/2013		FOI Services, Inc.	
2013-7750	09/26/2013 10/25/2013	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	FAP 1041
2013-7751	09/26/2013 10/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 18680 - FINAL LABELING AND PATIENT INSERT; NDA 18680 S 60- MATERIALS SENT OR RECEIVED BY FDA
2013-7752	09/26/2013 10/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Michelle Garcia Garcia, Michelle	ESSURE - ADVERSE EVENTS
2013-7753	09/26/2013 10/25/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/	DIANNE L CHAMBERS HOGAN LOVELLS US LLP	C PACIFIC FOODS - CANNED MUSHROOM SLICED 6 CANS RECALL F-17590-2013 ANALYTICAL RECS, TEST RESULTS
2013-7754	09/26/2013 10/25/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/SAN- DO/SAN-CB/	DIANNE L CHAMBERS HOGAN LOVELLS LLP	CROWN PACIFIC INTERNTIONAL LLC - HAWAII FRESH SWEET BASIL F-1873-2013 ANALYTICAL RECS, TEST RESULTS
2013-7755	09/26/2013 10/25/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/	DIANNE L CHAMBERS HOGAN LOVELLS LLP	BAO GONG DA INC - AMERICAN GINSENG F-153-2013 ANALYTICAL RECS, TEST RESULTS
2013-7756	09/26/2013 10/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEVIN E MINNICH B BRAUN MEDICAL INC	B BRAUN MEDICAL INC - INFUSOMAT SPACE PUMP INFUSION SYS SOFTWARE J K103572; PERFUSOR SPACE SYRINGE PUMP SOFTWARE J K122452 REVIEWER'S NOTES
2013-7757	09/26/2013 10/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	ERIC D FADER DAY PITNEY LLP	ADVVERSE EVENT KEYS 3053543, 3906483, 2531355
2013-7758	09/26/2013 10/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	JAMIE YIEH ABBOTT POINT OF CARE INC	OPTIC MEDICAL SYSTEMS - K131126
2013-7759	09/26/2013 10/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SHEA N SHAVER REILLY POZNER LLP	EFFEXOR (VENLAFAXINE HCL) NDA 20-151 - CORR, APRVL LTRS, AERS, ETC
2013-7760	09/26/2013 10/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JODY L GREEN DENVER HEALTH ROCKY MOUNTAIN POISON & DRUG	ISR 7382479, 7814351, 8067430, ETC - COUGH & COLD PREPARATIONS

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		FDA/OMPT/CDER/GRP/DIDP/	CENTER	
2013-7761	09/26/2013 10/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	S ALBERT EDWARDS S ALBERT EDWARDS, PHARM D	PRESCRIPTION DRUG WRAP -UP (DESI-2) - RONDEX, CARBAXAFED LTR
2013-7762	09/26/2013 10/25/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN CREWDSON PROJECT ON GOVERNMENT OVERSIGHT	PRADAXA - AERS 12/31/12 TO PRESENT
2013-7763	09/26/2013 10/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FRIEDMAN, ROBERT	BUCCASTEM 3MG TABS - AERS 1969 TO PRESENT
2013-7764	09/26/2013 10/25/2013	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	KIM C CAPONE PORZIO LIFE SCIENCES	CARACO PHARMACEUTICAL LABORATORIES LTD, CRANBURY, NJ - EIRS, 483S 6/28/11
2013-7765	09/26/2013 10/25/2013	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/ OC/ORA/ OC/ORA/ OC/ORA/ OC/ORA/	SAK, DAN	BACK CENTER, MELBOURNE, FL - MULTI-DOSE CONTAINER OF MPA PICTURE
2013-7766	09/26/2013 10/25/2013	FDA/OFVM/CFSAN/OCD/EOS/	WILBUR JOHNSON JR COSMETIC INGREDIENT REVIEW	PENTAERYTHRYL TETRA-DL-T-BUTYL HYDROXYHYDROCINAMATE - CHEMICAL & PHYSICAL PROPERTIES, METABOLISM BIOAVL, DERMAL PENETRATION, ETC
2013-7767	09/26/2013 10/25/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	PAUL T LANDIS FAIN ANDERSON VANDERHOEF PLLC	KINGPIN TATTOO INC - ONE TATTO INK RECALL F-2112- 2012 RPTS, FINAL CONCLUSIONS
2013-7768	09/26/2013 10/25/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/PA-FO/SEA- DO/SEA-CB/	JACQUELINE J CHAN K&L GATES	METAGENIC INC, GIG HARBOR, WA - WARNING LTR SEA 13-27 CORR, NOTES, DOCUMENTATION, ETC 8/12/13
2013-7769	09/27/2013 10/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Michelle Garcia Garcia, Michelle	ESSURE - FIVE YEAR POST APPROVAL STUDY
2013-7770	09/27/2013	FDA/OMPT/CDER/GRP/DIDP/	b. burgess	COMPLAINTS FILED IN CDER DATABASE AFTER 1639

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	10/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BURGESS, BERNIE	
2013-7771	09/27/2013 10/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Luis Rolfo Luis Rolfo	CUTOFF LEVELS FOR PSYCHEMEDICS MARIJUANA HAIR DRUG TEST
2013-7772	09/27/2013 10/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Peter Mattesson Hotswaqp Stockholm AB	K881183
2013-7773	09/27/2013 10/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Byron J Wyche Capstone Investment Advisors	NUMBER OF FACILITIES APPROVED FOR DIGITAL MAMMOGRAPHY SCREENING BY YEAR; NUMBER OF DIGITAL MAMMOGRAPHY MACHINES APPROVED FOR SERVICE BY YEAR; NUMBER OF FACILITIES APPROVED FOR TOMOSYNTHESIS 3D DIGITAL MAMMOGRAPHY BY YEAR ETC
2013-7774	09/27/2013 10/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joel Bamford Cochrane Skin Group	ADVERSE EVENT SUMMARIES - VARIOUS DRUGS
2013-7775	09/27/2013 10/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Amanda Dykeman N/A	ESSURE - FIVE YEAR POST STUDY
2013-7776	09/27/2013 10/28/2013	FDA/OMPT/OSMP/OOPD/	Joshua A. Malamud Hyman, Phelps & McNamara P.C.	NYMALIZE - ORPHAN DRUG DESIGNATION
2013-7777	09/27/2013 10/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	NSQ1 Integrated Plasmonics	K914469, K913105, K990688 ETC
2013-7778	09/27/2013 10/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K101200
2013-7779	09/27/2013 10/28/2013	OC/CVM/OCD/	PJ Huffstutter Thomson Reuters/Reuters News	ZILPATEROL - AERS
2013-7780	09/27/2013 10/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K101250
2013-7781	09/27/2013 10/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K103025
2013-7782	09/27/2013 10/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nicholas Croce none	IND 15376

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		FDA/OMPT/CBER/OCOD/DDOM/ ALFB/		
2013-7783	09/27/2013 10/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K103088
2013-7784	09/27/2013 10/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K123864
2013-7785	09/27/2013 10/28/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Heidi Fezatte Elorac Inc.	Oxylone Topical fluorometholone NDA
2013-7786	09/27/2013 10/28/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Edward Zane Chilton Investment Company	QSYMIA - AERS
2013-7787	09/27/2013 10/28/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	jeffrey gardner Jeffrey Gardner	IPI-145 - AERS
2013-7788	09/27/2013 10/28/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Joshua Jennings COWEN AND COMPANY	P950022/S042
2013-7789	09/27/2013 10/28/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	jeffrey gardner Jeffrey Gardner	PRO044, PRO045, PRO053 - AERS
2013-7790	09/27/2013 10/28/2013	FDA/OGROP/ORR/SE-FO/FLA- DO/FLA-CB/ FDA/OMPT/CTP/OD/	Dan Lieberman ABC NEWS	VAPOR SHARK, VAPOR HOG; E-CIGARETTE - COMPLAINTS 09/01/2013 - 09/26/2013
2013-7791	09/27/2013 10/28/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ OC/ORR/ OC/ORR/	Ashley Marucci Eccleston and Wolf, PC	NECC - METHYLPREDNISOLONE ACETATE 80 Mg/ml Lot 05212012@68
2013-7792	09/27/2013	FDA/OMPT/CDER/ERP/DIDP/	Angelia Slayton	NYCOMED, SINGEN, GERMANY - EIR 6/2/09

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	10/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	INC RESEARCH CONSULTING & SUBMISSIONS	
2013-7793	09/27/2013 10/28/2013	FDA/OGROP/ORACE-FO/PHI- DO/PHI-CB/	Rebekah Cafrelli Rebekah Cafrelli	HERSHEY MEDICAL CENTER BLOOD BANK - REPORTS SUBMITTED TO FDA 07/11/2013 - 08/15/2013
2013-7794	09/27/2013 10/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Angela Lynch Angela Lynch	STOP/ESSURE - TRIAL RECS
2013-7795	09/30/2013 10/29/2013	FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/	John H. Reed Reed, John H	ROYAL RAYMOND FIFE, SAN DIEGO, CA - INVESTIGATION RECS 01/01/1910 - 12/31/2012
2013-7796	09/30/2013 10/29/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Isabella Biedenharn Isabella Biedenharn	YASMIN - AERS
2013-7797	09/30/2013 10/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	Dora Fong KARL STORZ ENDOSCOPY AMERICA INC	K124031
2013-7798	09/30/2013 10/29/2013	FDA/OC/OES/DDM/	Sarah L. Scott Goodell DeVries Leech & Dann LLP	FDA COMMITTEE MEETING FOR PEDIATRIC IBUPROFEN - MEETING MINUTES 01/01/1994 - 06/20/1995
2013-7799	09/30/2013 10/29/2013	FDA/OGROP/ORACE-FO/DET- DO/DET-CB/	Rebecca Dandeker MORGAN, LEWIS & BOCKIUS	ALBEMARLE CORPORATION, SOUTH HAVEN, MI - EIR SUMMARY (01/01/2012 - 01/31/2012)
2013-7800	09/30/2013 10/29/2013	FDA/OC/OES/DDM/	Sarah L. Scott Goodell DeVries Leech & Dann LLP	FDA OTC DRUG ADVISORY COMMITTEE - MTG MINUTES WITH DR ERIC PAUL BASS 01/01/1990 - 12/31/1996
2013-7801	09/30/2013 10/29/2013	FDA/OGROP/ORACE-FO/MIN- DO/MIN-CB/	Rachelle Lyon Janus Capital Group Attn: Rachelle Lyon	SENSIENT TECHNOLOGIES CORP - 483, RESPONSE 09/01/2011 - 09/27/2013
2013-7802	09/30/2013 10/29/2013	FDA/OGROP/ORAPA-FO/SEA- DO/SEA-CB/	Curtis Walcker VRP Manufacturing, LLC	METAGENICS - RESPONSE TO WARNING LETTERS
2013-7803	09/30/2013 10/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	Heather Neely Neely, Heather	K131345
2013-7804	09/30/2013 10/29/2013	FDA/OGROP/ORACE-FO/DET- DO/DET-CB/	Rebecca Dandeker MORGAN, LEWIS & BOCKIUS	ALBERMARLE CORPORATION, SOUTH HAVEN, MI - EIR SUMMARY 02/12/2013 - 02/15/2013
2013-7805	09/30/2013 10/29/2013	FDA/OGROP/ORACE-FO/DET- DO/DET-CB/	Rebecca Dandeker MORGAN, LEWIS & BOCKIUS	ALBEMARLE CORPORATION, SOUTH HAVEN, MI - EIR 02/12/2013 - 02/15/2013
2013-7806	09/30/2013	FDA/OGROP/ORACE-FO/DET-	Rebecca Dandeker	ALBERMARLE CORPORATION, SOUTH HAVEN, MI - EIR

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	10/29/2013	DO/DET-CB/	MORGAN, LEWIS & BOCKIUS	01/01/2012 - 01/31/2012
2013-7807	09/30/2013 10/29/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Mary E. Lynn The Windward Company	WIL RESEARCH LABORATORIES, ASHLAND, OH - EIR 03/06/2013 - 03/21/2013
2013-7808	09/30/2013 10/29/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Soma Das The Economic Times, The Times of India	OHM LABS, US - 483 06/29/2012 - 09/01/2013
2013-7809	09/30/2013 10/29/2013	OC/ORACE/OCI/ OC/ORACE/OCI/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Doe J	INDIVIDUAL RECS
2013-7810	09/30/2013 10/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	Randall Taradash Taradash Law Office	HOSPIRA PLUMB PUMP - MAUDE REPORTS 09/28/2004 - 09/28/2013
2013-7811	09/30/2013 10/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	Randall Taradash Taradash Law Office	ABBOTT PLUMB PUMP - MAUDE REPORTS 10/28/2004 - 09/28/2013
2013-7812	09/30/2013 10/29/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Matthew Hodgson Matthew Hodgson	C FORDHAM VON REYN, MD - WARNING LETTER FOLLOW UP
2013-7813	09/30/2013 10/29/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	KEN REID WASHINGTON INFORMATION SOURCE	JANET K TILISCH MD, FARGO, ND - EIR, CO RESP, CORR 4/13
2013-7814	09/30/2013 10/29/2013	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	KEN REID WASHINGTON INFORMATION SOURCE	PETER SCHIFFENT ENTERPRISES, COOKEVILLE, TN - EIR, CO RESP, CORR 3/13 TO 4/113
2013-7815	09/30/2013 10/29/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	KEN REID WASHINGTON INFORMATION SOURCE	LUMIQUICK DIAGNOSTICS INC, SANTA CLARA, CA - EIR, CO RESP, CORR 11/12 TO 12/12
2013-7816	09/30/2013 10/29/2013	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	KEN REID WASHINGTON INFORMATION SOURCE	ZEPPESSIS REPROCESSING LLC, GARDEN CITY, ID - EIR, CO RESP, CORR 4/13
2013-7817	09/30/2013 10/29/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	KEN REID WASHINGTON INFORMATION SOURCE	AUTOMATED OPHTHALMIC, COLUMBIA, MD - EIR, CO RESP, CORR 2/13 TO 3/13
2013-7818	09/30/2013 10/29/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	KEN REID WASHINGTON INFORMATION SOURCE	BIOMEDIX INC, BLOOMINGTON, IN - EIR, CO RESP, CORR 2/13 TO 3/13

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2013-7819	09/30/2013 10/29/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	KEN REID WASHINGTON INFORMATION SOURCE	ACELL INC, COLUMBIA, MD - EIR, CO RESP, CORR 11/12 TO 12/12
2013-7820	09/30/2013 10/29/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	KEN REID WASHINGTON INFORMATION SOURCE	ELECTROMEDICAL PRODUCTS INTERNATIONAL INC, MINERAL WELLS, TX - EIR, CO RESP, CORR 1/13 TO 2/13
2013-7821	09/30/2013 10/29/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	KEN REID WASHINGTON INFORMATION SOURCE	SOVEREIGN PHARMS, FORT WORTH, TX - EIR, CO RESP, CORR 1/12 TO 2/12
2013-7822	09/30/2013 10/29/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	KEN REID WASHINGTON INFORMATION SOURCE	CISPHARMA, CRANBURY, NJ - EIR, CO RESP CORR 3/12 TO 4/12
2013-7823	09/30/2013 10/29/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	KEN REID WASHINGTON INFORMATION SOURCE	TRANSONIC SYSTEMS INC, ITHACA, NY - EIR, CO RESP, CORR 2/13 TO 3/13
2013-7824	09/30/2013 10/29/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	KEN REID WASHINGTON INFORMATION SOURCE	CONAIR CORP, STAMFORD, CT - EIR, CO RESP, CORR 5/13
2013-7825	09/30/2013 10/29/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	KEN REID WASHINGTON INFORMATION SOURCE	SPINE FRONTIER, BEVERLY, MA - EIR, CO RESP, CORR 5/12 TO 7/12
2013-7826	09/30/2013 10/29/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	KEN REID WASHINGTON INFORMATION SOURCE	STEWART COMPOUNDING PHARMACY, FAYETTEVILLE, NC - EIR, CO RESP, CORR 3/13
2013-7827	09/30/2013 10/29/2013	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	KEN REID WASHINGTON INFORMATION SOURCE	HAIR LABS INC, NASHVILLE, TN - EIR, CO RESP, CORR 4/13
2013-7828	09/30/2013 10/29/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	KEN REID WASHINGTON INFORMATION SOURCE	SCM TRUE AIR TECHNOLOGIES, LOUISVILLE, KY - 483, CO RESP, WARNING LTR, ETC 5/13
2013-7829	09/30/2013 10/29/2013	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	KEN REID WASHINGTON INFORMATION SOURCE	BACTERIN INTERNATONAL, BELGRADE, MT - EIR, CO RESP, CORR 7/12
2013-7830	09/30/2013 10/29/2013	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	KEN REID WASHINGTON INFORMATION SOURCE	TISSUE BANK INTERNATIONAL / NATIONAL EYE BANK CENTER, MEMPHIS, TN - EIR, CO RESP, CORR 6/11
2013-7831	09/30/2013	FDA/OGROP/ORACE-FO/CHI-	KEN REID	LIFEWATCH SERVICES, ROSEMONT, IL - EIR, CO RESP,

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	10/29/2013	DO/CHI-CB/	WASHINGTON INFORMATION SOURCE	CORR 8/12 TO 9/12
2013-7832	09/30/2013 10/29/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	KEN REID WASHINGTON INFORMATION SOURCE	ABBEY COLOR, PHILADELPHIA, PA - EIR, CO RESP, CORR 3/12
2013-7833	09/30/2013 10/29/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	KEN REID WASHINGTON INFORMATION SOURCE	ANSAR GROUP, PHILADELPHIA, PA - EIR, CO RESP, CORR 5/12 TO 6/12
2013-7834	09/30/2013 10/29/2013	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	KEN REID WASHINGTON INFORMATION SOURCE	PARKS MEDICAL ELECTRONICS, ALOHA, OR - EIR, CO RESP, CORR 7/12 TO 8/12
2013-7835	09/30/2013 10/29/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	KEN REID WASHINGTON INFORMATION SOURCE	EDWARDS LIFESCIENCES, DRAPER, UT - EIR, CO RESP, CORR 1/13 TO 2/13
2013-7836	09/30/2013 10/29/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	KEN REID WASHINGTON INFORMATION SOURCE	LIFESERVE BLOOD CENTER, DES MOINES, IA - EIR, CO RESP, CORR 6/13
2013-7837	09/30/2013 10/29/2013	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	KEN REID WASHINGTON INFORMATION SOURCE	ALMA LASERS INC, BUFFALO, GROVE, IL - EIR, CO RESP, CORR 1/13
2013-7838	09/30/2013 10/29/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	KEN REID WASHINGTON INFORMATION SOURCE	INNOVACYN INC, RIALTO, CA - EIR, CO RESP, CORR 11/11 TO 12/11
2013-7839	09/30/2013 10/29/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ OC/ORA/ OC/ORA/ FDA/OC/OCTC/OCM/OEO/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEN REID WASHINGTON INFORMATION SOURCE	CUSTOM COMPOUNDING CENTERS, LOS ALAMITOS, CA - EIR, CO RESP, CORR 11/12 TO 12/12
2013-7840	09/30/2013 10/29/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	KEN REID WASHINGTON INFORMATION SOURCE	ALPHA MEDICAL INSTRUMENTS, MISSION VIEJO, CA - EIR, CO RESP, CORR 12/12/ TO 1/13

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2013-7841	09/30/2013 10/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEN REID WASHINGTON INFORMATION SOURCE	WOCKHARDT LTD, AURANGABAD, INDIA - EIR, CO RESP, CORR 3/13
2013-7842	09/30/2013 10/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	KRIS J KONTIS MEDICAL CHEMICAL CORP	ADVANCED STERILIZATION PRODUTS INC - CIDEX OPA SOL K002401
2013-7843	09/30/2013 10/29/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	KRIS J KONTIS MEDICAL CHEMICAL CORP	MINNTECH CORP - RAPICIDE OPA-28 K120306
2013-7844	09/30/2013 10/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	KRIS J KONTIS MEDICAL CHEMICAL CORP	SERIM RESEARCH CORP - RAPICIDE OPA-28 TEST STRIPS K120652
2013-7845	09/30/2013 10/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	KRIS J KONTIS MEDICAL CHEMICAL CORP	SERIM RESEARCH CORP - CIDEX OPA SOL TEST STRIPS K992341
2013-7846	09/30/2013 10/29/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	KRIS J KONTIS MEDICAL CHEMICAL CORP	ADVANCED STERILIZATION PRODUCTS INC - CIDEX OPA CONCENTRATE K032959
2013-7847	09/30/2013 10/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	KRIS J KONTIS MEDICAL CHEMICAL CORP	ALBERT BROWNE LTD - BROWNE CIDEX OPA INDICATOR K991709
2013-7848	09/30/2013 10/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	KRIS J KONTIS MEDICAL CHEMICAL CORP	ADVANCED STERILIZATION PRODUCTS INC - CIDEX OPA SOL K991487
2013-7849	09/30/2013 10/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	KRIS J KONTIS MEDICAL CHEMICAL CORP	ADVANCED STERILIZATION PRODUCTS INC - CIDEX OPA SOL K001381
2013-7850	09/30/2013 10/29/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDRH/OCER/DFOI/	MELISSA A. JONES LAW OFFICES OF RICHARD N SHAPIRO	TRIDENT - PSL ACETABULAR SHELLS; PSL HA SOLID BACK - PMA, 510K
2013-7851	09/30/2013 10/29/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDRH/OCER/DFOI/	MELISSA A. JONES LAW OFFICES OF RICHARD N SHAPIRO	TRIDENT - ACETABULAR SHELLS K001448
2013-7852	09/30/2013 10/29/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDRH/OCER/DFOI/	MELISSA A. JONES LAW OFFICES OF RICHARD N SHAPIRO	HOWMEDICA OSTEONICS CORP - ABC/TRIDENT SYSTEMS PMA
2013-7853	09/30/2013 10/29/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	EVA STEINICK HemoCue AB	ROCHE - IMFORM; K121679; ABBOT - FREE STYLE PRECISIONS PRO K130094; NOVA - STATATRIP K063821
2013-7854	09/30/2013 10/29/2013	FDA/OC/OES/DDM/	KRISTIO O SMEDLEY WASHINGTON INFORMATION	DKT 1995-S-0039 - 75 DAY NOTICE

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			SOURCE	
2013-7855	09/30/2013 10/29/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	DONALD N. BLUE ZETETIC INC	ETHICON - US/NM SUTURE ABSORBABLE & NON ABSORBABLE ENTRY #AV3-0040036-1
2013-7856	09/30/2013 10/29/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	DONALD N. BLUE ZETETIC INC	ETHICON - ETHIBOND EXCEL SUTURE ENTRY NO UPS-8151908-7
2013-7857	09/30/2013 10/29/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	DONAL N. BLUE ZETETIC INC	ETHICON - NON ABSORBABLE SUTURES & ABSORBABLE SUTURES ENTRY NO AV3-0039869-0
2013-7858	09/30/2013 10/29/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	K. MICHELLE VASSALLO LINCARE INC	CLARK RESPIRATORY & MEDICAL SUPPLY, HIGHLAND, NY - 483, EIR, WARNING LTR 1/98 TO PRESENT
2013-7859	09/30/2013 10/29/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	K. MICHELLE VASSALLO LINCARE INC	OXY MED INC, MIDDLETON, OH - 483, EIR, WARNING LTR 1/98 TO PRESENT
2013-7860	09/30/2013 10/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MICHELE SINOWAY, PhD LACHMAN CONSULTANT SERVICES, INC.	USV LIMITED, MUMBAI, INDIA - 483 7/6/13
2013-7861	09/30/2013 10/29/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Jerome Lew Walt Disney Studios	OSTEOGENICS BIOMEDICAL - DATE OF SUBMISSION, FEI
2013-7862	09/30/2013 10/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	COLLEEN M. HEISEY JONES DAY	DR REDDYS LABS - AZACITIDINE ANDA 201-537 APRVL
2013-7863	09/30/2013 10/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JAYA AYYAGARI DR REDDY'S LABORATORIES INC	SUN PHARMA GLOBAL - DOXORUBICIN HCL (LIPOSOMAL) ANDA 203-263 SBA
2013-7864	09/30/2013 10/29/2013	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	MAGGIE IHA-PETERSEN FLEGENHEIMER INTERNATIONAL INC	ENTRY NO MU8-0029278-9
2013-7865	09/30/2013 10/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	NEMEL, RANDY	GABAPENTIN - AER
2013-7866	09/30/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR	DAILY CLOSED LOG 8/26-30/13

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	10/29/2013		JH BARR & ASSOCIATES LLC	
2013-7867	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY CLOSED LOG 9/2-6/13
2013-7868	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 8/26-30/13
2013-7869	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 9/2-6/13
2013-7870	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY CLOSED LOG 8/26-30/13
2013-7871	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 8/26-30/13
2013-7872	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 9/2-6/13
2013-7873	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY CLOSED LOG 9/2-6/13
2013-7874	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 9/2-6/13
2013-7875	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 8/26-30/13
2013-7876	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 9/2-6/13
2013-7877	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 8/26-30/13
2013-7878	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	GLADYS B. TONKIN WASHINGTON INFORMATION SOURCE	DAILY LOG 9/2-6/13
2013-7879	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	GLADYS B. TONKIN WASHINGTON INFORMATION SOURCE	DAILY LOG 8/26-30/13
2013-7880	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 8/26-30/13
2013-7881	09/30/2013	FDA/OC/OES/DFOI/		DAILY LOG 9/2-6/13

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	10/29/2013		FOI Services, Inc.	
2013-7882	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 8/26-30/13
2013-7883	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 9/2-6/13
2013-7884	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 9/2-6/13
2013-7885	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	DEBRA L. COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 8/26-30/13
2013-7886	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	SANDY FRIEDMAN WOLTERS KLUWER LAW & BUSINESS	DAILY CLOSED LOG 8/26-30/13
2013-7887	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	DEBI L. COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY CLOSED LOG 9/2-6/13
2013-7888	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	DAVID McFARLAND FDA REVIEW/FDA WEBVIEW	DAILY CLOSED LOG 8/26-30/13
2013-7889	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	DAVID McFARLAND FDA REVIEW/FDA WEBVIEW	DAILY CLOSED LOG 9/2-6/13
2013-7890	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	2013-2471, 3021, 3532
2013-7891	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	2013-721, 930, 737
2013-7892	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	2013-142, 8434, 8069
2013-7893	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	2012-7797, 2191, 2975
2013-7894	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	DEERFIELD INSTITUTE	BIOGEN IDEC - 483 3/15/13
2013-7895	10/17/2013	FDA/OMPT/OSMP/OOPD/	SABINE VUKELICH	REGENERON - RILONACEPT ORPHAN DRUG ASSESMENT

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	11/15/2013		XOMA	
2013-7896	10/17/2013 11/15/2013	FDA/OMPT/OSMP/OOPD/	SABINE VUKELICH XOMA	NOVARTIS - CANAKIUMAB ORPHAN DRUG ASSESMENT
2013-7897	10/17/2013 11/15/2013	FDA/OMPT/OSMP/OOPD/	SABINE VUKELICH XOMA	ALLERGAN - OZURDEX ORPHAN DRUG ASSESMENT
2013-7898	10/17/2013 11/15/2013	FDA/OMPT/OSMP/OOPD/	SABINE VUKELICH XOMA	AMGEN - ANAKINRA ORPHAN DRUG ASSESMENT
2013-7899	10/17/2013 12/11/2013	FDA/OMPT/CTP/OD/	ANNE D SPIGGLE PATTON BOGGS, L.L.P.	HBI INTERNATIONAL -ELEMENTS AFICIANDADO KS SLIM ROLLING PAPER & PAPER TIPS SUBSTANTIAL EQUIVALANCE RPT, AMMENDMENTS, COMM, ETC 9/26/13
2013-7900	10/17/2013 11/27/2013	FDA/OMPT/CTP/OD/	ANNE D SPIGGLE PATTON BOGGS, L.L.P.	REPUBLIC TOBACCO IP - TOP REGULAR 100MM FILTERED CIGARETTE TUBES SUBSTANIAL EQUIVALENCE RPT, AMMENDMENTS, COMM, ETC 9/26/13
2013-7901	10/17/2013 12/10/2013	FDA/OMPT/CTP/OD/	ANNE D SPIGGLE PATTON BOGGS, L.L.P.	HBI INTERNATIONAL - ELEMENTS AFICIONADO 1, 1/4 ROLLING PAPER & PAPER TIPS SUSTANTIALY EQUIVALENT RPT, AMENDMENTS, COMM, ETC 9/26/134
2013-7902	10/17/2013 11/27/2013	FDA/OMPT/CTP/OD/	ANNE D SPIGGLE PATTON BOGGS, L.L.P.	REPUBLIC TOBACCO IP - TOPS GOLD 100MM FILTERED CIGARETTE TUBES SUBSTANTIAL EQUVALENCE RPT, AMENDMENTS, COMM, ETC 9/26/2013
2013-7903	10/17/2013 11/15/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	JOON HWANG B & D DENTAL CORP	B&D DENTAL CORP - DENTAL SHADE RESIN MATERIAL K110131
2013-7904	10/17/2013 11/15/2013	FDA/OC/OES/DDM/	KRISTI O SMEDLEY WASHINGTON INFORMATION SOURCE	DKT 1995S-0039
2013-7905	10/17/2013 11/15/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	A LAYNE STACKHOUSE JONES WARD PLC	NORPLANT; (LEVONORGESTREL) IMPLANTS APRVL RECS, RPTS, CORR, ETC
2013-7906	10/17/2013 11/15/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	LUCREZIA HINMAN COUNTY LINE PHARMACEUTICALS LLC	LIDEX (FLUOCINONIDE) OINTMENT NDA 16-909 - APRVL LTR 09/22/71
2013-7907	10/17/2013 11/15/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SUZIE KESCHAMRUS AVANIR PHARMACEUTICALS INC	NUJEDXTA (DEXTROMETHORPHAN HYDROBROMID 20 MG, QUINDINE SULFATE 10MG) NDA 21-879 - RPTS 10/29/10 TO PRESENT

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		FDA/OMPT/CDER/ORP/DIDP/		
2013-7908	10/17/2013 11/15/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SHARICK NAQI WINSTON & STRAWN	NOVARTIS - CLNCL TRIAL STUDY CZOL-44600411 CONSENT FORM
2013-7909	10/17/2013 11/15/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RAPHAEL LEWIS NORTH RUN CAPITAL LP	LEVOTHYROXINE SODIUM ANDA SINCE 1/10
2013-7910	10/17/2013 11/15/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	RAPHAEL LEWIS NORTH RUN CAPITAL LP	JEROME STEVENS PHARMACEUTICALS INC - 483 SINCE 1/12
2013-7911	10/17/2013 11/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOSEPH P MCGINN ESDAILE BARRETT JACOBS & MONE	ARTHROCARE CORP, STEWARD HEALTH CARE ANDOVER SURGERY CENTER - DIAMONDVAC 90 AERS
2013-7912	10/17/2013 11/15/2013	FDA/OC/OES/DDM/	WILLIAM J. SKINNER MUSCATATUCK PUBLISHERS INC	DKT 95S-0162
2013-7913	10/17/2013 11/20/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/OIP/	MARILYNN WHITNEY COVINGTON BURLING LLP	WORLD HEALTH ORGANIZATION - CORR 1/13 TO PRESENT
2013-7914	10/17/2013 11/15/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID P. JORDAN THOMSON REUTERS	VALACYCLOVIR HCI 51660-0905-30; 51660-0904-30 - NDC
2013-7915	10/17/2013 11/15/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	WALTER E CHALKLEY THOMSON REUTERS	MOMENTA PHARMACEUTICALS INC, CAMBRIDGE, MA - EIR, 483, CO RESP 06/08/12
2013-7916	10/17/2013 11/15/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	LIBRA TECHNICAL CENTER LLC, METUCHEN, NJ - EIR, 483, CO RESP 05/11/12
2013-7917	10/17/2013 11/15/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	WALTER E CHALKLEY THOMSON REUTERS	KATH KHEMICALS LLC, STERLING HEIGHTS, MI - EIR, 483, CO RESP 11/01/12

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2013-7918	10/17/2013 11/15/2013	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	WALTER E CHALKLEY THOMSON REUTERS	JONATHAN K WISE, METAIRIE, LA - EIR, 483, CO RESP 03/14/12
2013-7919	10/17/2013 11/15/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	WALTER E CHALKLEY THOMSON REUTERS	ALLERQUEST LLC, PLAINVILLE, CT - EIR, 483, CO RESP 05/18/12
2013-7920	10/17/2013 11/15/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	WALTER E CHALKLEY THOMSON REUTERS	BAYSHORE MEDICAL CENTER INC IRB, PASADENA, TX - EIR, 483, CO RESP 04/23/12
2013-7921	10/17/2013 11/15/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	WALTER E CHALKELEY THOMSON REUTERS	BIOLOGICAL RESEARCH SOLUTIONS INC, ROCHESTER HILLS, MI - EIR, 483, CO RESP 05/24/12
2013-7922	10/17/2013 11/15/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	WALTER E CHALKLEY THOMSON REUTERS	CANGENE BIOPHARMA INC, BALTIMORE, MD - EIR, 483, CO RESP 09/01/12
2013-7923	10/17/2013 11/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	CIPLA, LTD, BANGALORE, KARNATAKA, INDIA - EIR, 483, CO RESP 06/28/12
2013-7924	10/17/2013 11/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CLAUDINE Q. HOMOLASH SHELLER LAW OFCS	NEPHRON PAHRMACEUTICALS CORP - ASTHMANEFRIN INHALATION SOLUTION NDC; NEPHRON PHARMACEUTICALS CORP - OVER THE COUNTER PRIMATENE MIST CFC INHALER & EZ BREATHE ATOMIZER MEDWATCH
2013-7925	10/17/2013 11/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	R.O. DEAN COMPLIANCE SYSTEMS INTERNATIONAL LLC	NIPRO PUREFLUX H K122343
2013-7926	10/17/2013 11/15/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	R.O. DEAN COMPLIANCE SYSTEMS INTERNATIONAL LLC	BAXTER - XENIUM DIALYZER K062079
2013-7927	10/17/2013 11/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	R.O. DEAN COMPLIANCE SYSTEMS INTERNATIONAL LLC	FRESENIUS - OPTIFLUX DIALYZER K082414
2013-7928	10/17/2013 11/15/2013	OC/CVM/OCD/	TIM SCHWAB Food and Water Watch	AQU ADVANTAGE SALMON MTG 9/19-20/10
2013-7929	10/17/2013 11/15/2013	FDA/OC/OES/DFOI/	SABRINA C CUNNINGHAM HARE WYNN NEWELL & NEWTON LLP	SERRATIA MARCESENS BATERMIA OUTBREAK IN ALABAMA HOSPITALS 2011
2013-7930	10/17/2013 11/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MCNAIR III #508652, JOE	ZOLOFT; RISPERDAL - AER

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2013-7931	10/17/2013 11/15/2013	FDA/OFVM/CFSAN/OCD/EOS/	SHELY GARG SANDLER TRAVIS & ROSENBERG PA	LIST OF ANY & ALL FOOD FACILITIES THAT HAVE DESIGNATED TOYOTA TSUSHO AMERICA INC AS US AGENT, REGISTRATION NO, MAILING ADDRESS, TEEPHONE NO, ETC
2013-7932	10/17/2013 11/15/2013	FDA/OC/OES/DFOI/	TUCKER 1495137, EDWARD	MEDICAL RECS
2013-7933	10/17/2013 11/15/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CAUDLE, BRANDON	PRESTIVA - PACKAGE INSERT
2013-7934	10/17/2013 11/15/2013	OC/ORR/ORM/ OC/ORR/ORM/	WISEMAN, TODD	LIST OF ALL 483S 2013
2013-7935	10/17/2013 11/15/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BLAIN, NOELLE	DECADRON (DEXAMETNASONE) AER
2013-7936	10/17/2013 11/15/2013	FDA/OC/OES/DFOI/	MARK VANDEHAAR WILLKIE FARR & GALLAGHER LLP	SAC CAPITAL ADVISORS LLP; SIGMA CAPITAL MANAGEMENT LLC - WALL STREET JOURNAL ARTICLE ENTITLED OPEN-GOVERNMENT LAWS FUEL HEDGE-FUND PROFITS RESP TO FOI REQUEST
2013-7937	10/17/2013 11/15/2013	FDA/OGROP/ORR/CE-FO/DET- DO/DET-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORR/CE-FO/NWJ- DO/NWJ-CB/	GUISTO, MARYANN	STRYKER - TRIDENT HEMISPHERICAL ACETABULAR SHELL W/X3 POLYETHYLENE - RECALL 1996 TO 2013
2013-7938	10/17/2013 11/15/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORR/SE-FO/SJN- DO/SJN-CB/ FDA/OGROP/ORR/NE-FO/NYK-	ALYSON OLIVER, Esq. OLIVER LAW GROUP	COOPER VISION - AVAIRA TORIC & SPHERE SOFT CONTACT LENSES APRVLS

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		DO/NYK-DCB/		
2013-7939	10/17/2013 11/15/2013	OC/CVM/OCD/	CRISTINA STELLA CENTER FOR FOOD SAFETY	ZOETIS INC - ROXARONE; CARBARSONE; NITARSONE; FLEMING LABS INC ARSANILIC ACID - APRVL, WITHDRAWAL
2013-7940	10/17/2013 11/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	AARON L. EMBREY ANDRUS HOOD & WAGSTAFF PC	PROXY BIOMEDICAL LTD - POLYFORM SYNTHETIC MESH K051245
2013-7941	10/17/2013 11/15/2013	FDA/OC/OES/DFOI/	QUYNH C. SPERRAZZA FAEGRE BAKER DANIELS	SIMPLY THICK - DOCS 6/11 TO PRESENT
2013-7942	10/17/2013 11/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	JONATHAN W. EMORD EMORD & ASSOCIATES, P.C.	CYNOSURE - SMART LIPO AER, Cmplnts
2013-7943	10/17/2013 11/15/2013	FDA/OMPT/CTP/OD/	NATALIE N. SANDERS LATHAM & WATKINS LLP	HBI INT'L ELEMENTS AFICIONADO KS SLIM; AFICIONADO 1 & 1/4; REPUBLIC TOBACCO LP TOP GOLD 100MM; REGULAR 100MM - BIOEQUIV
2013-7944	10/17/2013 11/15/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID HILZENRATH PROJECT ON GOVERNMENT OVERSIGHT	BOEHRINGER INGELHEIM PHARMACEUTICALS INC - PRADAXA (DABIGATRAN ETEXILATE MESYLATE) UNREDACTED
2013-7945	10/18/2013 11/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEN REID WASHINGTON INFORMATION SOURCE	CHUNGDO PHARMACEUTICAL CO LTD, HUPEONG-DONG, CHUNCHEON, SOUTH KOREA - EIR, CO RESP, CORR 03/13
2013-7946	10/18/2013 11/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEN REID WASHINGTON INFORMATION SOURCE	JABONES PARDO SA, MADRID, SPAIN - EIR, CO RESP, CORR 03/13
2013-7947	10/18/2013 11/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEN REID WASHINGTON INFORMATION SOURCE	PROMED EXPORTS PRIVATE LTD, HIMACHAL PRADESH, INDIA - EIR, CO RESP, CORR 03/13 TO 04/13
2013-7948	10/18/2013 11/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEN REID WASHINGTON INFORMATION SOURCE	POSH CHEMICALS PRIVATE LTD, HYDERABAD, INDIA - EIR, CO RESP, CORR 03/13
2013-7949	10/18/2013	FDA/OMPT/CDER/ORP/DIDP/	KEN REID	RPG LIFE SCIENCES LTD, NAVI MUMBAI, MAHARASHTRA, INDIA - EIR, CO RESP, CORR 01/13

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	11/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WASHINGTON INFORMATION SOURCE	
2013-7950	10/18/2013 11/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	ASAHI KASAI MEDICAL, OITA-SHI, JAPAN - EIR, CO RESP, CO 03/13
2013-7951	10/18/2013 11/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	GS MEDICAL PACKAGING INC, MISSISSAUGA, CANADA - EIR, RESP, CORR 01/13
2013-7952	10/18/2013 11/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	EBEWE PHARMA, UNTERACH AM ATTERSEE, AUSTRIA - EIR, CO RESP, CORR 10/12
2013-7953	10/18/2013 11/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEN REID WASHINGTON INFORMATION SOURCE	CONTRACT PHARMACEUTICAL SERVICES OF AUSTRALIA, NORTH RYDE, AUSTRALIA - EIR, CO RESP, CORR 10/12 TO 11/12
2013-7954	10/18/2013 11/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	RPG LIFE SCIENCES LTD, ANKLESHWAR, GUJARAT, INDIA - EIR, CO RESP, CORR 11/12
2013-7955	10/18/2013 11/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEN REID WASHINGTON INFORMATION SOURCE	SHANGHAI HUHUI DAILY USE CHEMICAL PRODUCTS, SHANGAI, CHINA - EIR, CO RESP, CORR 02/12
2013-7956	10/18/2013 11/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	DMC MEDICAL TECHNOLOGY & MFG, HEYUAN CITY, CHINA - EIR, CO RESP, CORR 04/12
2013-7957	10/18/2013 11/18/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	KEN REID WASHINGTON INFORMATION SOURCE	SANOFI PASTEUR, MARCY I'ETOLE, FRANCE - EIR, CO RESP, CORR 03/12 TO 04/12
2013-7958	10/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID	HUBEI WEILKANG PROTECTIVE PRODUCTS CO LTD, XIANTO CITY, HUBEI, CHINA - EIR, CO RESP, CORR 04/13

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	11/18/2013		WASHINGTON INFORMATION SOURCE	
2013-7959	10/18/2013 11/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	HUBEI WEIKANG PROTECTIVE PRODUCTS CO LTD, XIANTO CITY, HUBEI, CHINA - 483 CO RESP, WARNING LTR, ETC 04/13
2013-7960	10/18/2013 11/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	LEISEGANG FEINMECHANIK-OPTIK, BERLIN, GERMANY - EIR, CO RESP, CORR 04/12
2013-7961	10/18/2013 11/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEN REID WASHINGTON INFORMATION SOURCE	A NELSON & CO LTD, LONDON, ENGLAND, UK - EIR, CO RESP, CORR 11/11
2013-7962	10/18/2013 11/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	PRINCE MEDICAL, ERCUIS, FRANCE - EIR, CO RESP, CO 03/12
2013-7963	10/18/2013 11/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEN REID WASHINGTON INFORMATION SOURCE	CHUNGDO PHARMACEUTICAL CO LTD, HUPEONG-DONG, CHUNCHEON, SOUTH KOREA - 483, CO RESP, WARNING LTR, ETC 03/13
2013-7964	10/18/2013 11/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEN REID WASHINGTON INFORMATION SOURCE	NOVO NORDISK, BAGSVAERD, DENMARK - EIR, CO RESP, CORR 12/12
2013-7965	10/18/2013 11/18/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	KEN REID WASHINGTON INFORMATION SOURCE	SANOBI PASTEUR LTD, TORONTO, ONTARIO, CANADA - EIR, CO RESP, CORR 04/12
2013-7966	10/18/2013 11/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KURT DL-4879	ISRS 4638251-3, 4655315-9, 5074682-8, ETC
2013-7967	10/18/2013 11/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KURT DL-4879	MEDDRA MEDICAL DICTIONARY FOR REGULATORY ACTIVITIES - CURRENT
2013-7968	10/18/2013	FDA/OMPT/CDER/ORP/DIDP/		INDIVIDUAL RECS

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	11/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	
2013-7969	10/18/2013 11/18/2013	FDA/OC/OES/DFOI/	JOSHUA KINCANNON KEEFE BARTELS CLARK ATTY AT LAW	STRYKER ORTHOPAEDICS - MODULAR HIP K071082
2013-7970	10/18/2013 11/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	HIMANSHU SUD RDZR LLC	AMMONUL INJ - NATURE & IDENITY OF PARTICULATES
2013-7971	10/18/2013 11/18/2013	FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/	ROBERT KALKSTEIN VITERION CORP	CARDIOCOM LLC - SEIZURES, INJUNCTIONS, WARNING LTRS, ETC LAST 12 MONTHS
2013-7972	10/18/2013 11/18/2013	FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/	JOHN C FISH JAMES DARK & BRILL ATTY AT LAW	AXIOBIONICS - INVESTIGATION RECS
2013-7973	10/18/2013 12/05/2013	FDA/OC/OES/DFOI/	WILLIS TAYLOR NAPIER GAULT MOORE PLC	UNIV OF LOUISVILLE HOSPITAL OR UNIV MEDICAL CENTER INC - CMPLNT 5026922
2013-7974	10/18/2013 11/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tom Detzel PROPUBLICA	NDA 202155 - 483
2013-7975	10/18/2013 11/18/2013	FDA/OC/OES/DFOI/ FDA/OGROP/OIP/	Elisa Wouk Almino NEW YORK UNIVERSITY	Trans-Pacific Partnership and FDA
2013-7976	10/18/2013 11/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tom Detzel PROPUBLICA	NDA 22406, NDA 202439 - 483
2013-7977	10/18/2013 11/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tom Detzel PROPUBLICA	NDA 22512 - 483
2013-7978	10/18/2013 11/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tom Detzel PROPUBLICA	NDA 22512 - 483

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2013-7979	10/18/2013 11/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tom Detzel PROPUBLICA	PMR 1797-1 QUARTERLY REPORTS
2013-7980	10/18/2013 11/18/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Darragh Mcnicholas NYU- Journalism School	REGULATORY PROCEDURES FOR LICENSURE OF GENERIC MEDICATIONS, BIOEQUIVALENCE TO BRAND NAMES
2013-7981	10/18/2013 11/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K052233
2013-7982	10/18/2013 11/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K052233
2013-7983	10/18/2013 11/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K052233
2013-7984	10/18/2013 11/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Manoj Garg DSP Merrill Lynch	CIPLA LTD - 483 04/30/2013 - 09/29/2013
2013-7985	10/18/2013 11/18/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	NSQ6 Integrated Plasmonics	K103544
2013-7986	10/18/2013 11/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	Tim L. Orchid Orthopedics	K092309
2013-7987	10/18/2013 11/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	NSQ2 Integrated Plasmonics	K063276
2013-7988	10/18/2013 11/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	NSQ3 Integrated Plasmonics	K070068
2013-7989	10/18/2013 11/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	NSQ4 Integrated Plasmonics	K070929
2013-7990	10/18/2013 11/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	Dr. Diane Sudduth EMERGO GROUP INC	K130821

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2013-7991	10/18/2013 11/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	NSQ5 Integrated Plasmonics	K090405
2013-7992	10/18/2013 11/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	NSQ7 Integrated Plasmonics	K103175
2013-7993	10/18/2013 11/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca Dandeker Morgan, Lewis & Bockius LLP	PIRAMAL HEALTHCARE LIMITED, PRADESH, INDIA - EIR SUMMARY 01/31/2012 - 02/02/2012
2013-7994	10/18/2013 11/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca Dandeker Morgan, Lewis & Bockius LLP	PIRAMAL HEALTHCARE LIMITED, PRADESH, INDIA - EIR 01/31/2012 - 02/02/2012
2013-7995	10/18/2013 11/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	Connor Landgraf Eko Devices	K131287
2013-7996	10/18/2013 11/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mark S Godfrey Brown University Internal Medicine	DISULFIRAM - AERS 09/07/2000 - 09/30/2013
2013-7997	10/18/2013 11/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca Dandeker Morgan, Lewis & Bockius LLP	MALLADI DRUGS AND PHARMACEUTICALS, LTD, TAMIL NADU, INDIA - EIR SUMMARY 09/10/2012 - 09/14/2012
2013-7998	10/18/2013 11/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kathy Osgerby Taylor Wessing LLP	HERCEPTIN, TRASTUZUMAB - RECS RE PHARMACOKINETICS, HALF-LIFE 01/01/2000 - 12/31/2001
2013-7999	10/18/2013 11/18/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOIA REQUESTS CLOSED 9/1-30/2013
2013-8000	10/18/2013 11/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DR. AHMET TUTUNCU PATARA PHARMACEUTICALS	INHALED CROMOLYN SODIUM (INTAL MDI NDA 018887, DPI CAPSULE NDA 016990, INHALATION SOLUTION NDA 018596); ORAL CROMOLYN SODIUM (GASTROCROM ORAL CONCENTRATE NDA 020479, ORAL CAPSULE NDA 019188) - SBA
2013-8001	10/18/2013	FDA/OGROP/ORO/PA-FO/SAN-	David Mangione	GENENTECH, VACAVILLE, CA - EIR, 483 08/26/2013 -

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	11/18/2013	DO/SAN-CB/	Govzilla, Inc.	09/06/2013
2013-8002	10/18/2013 11/18/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 9/1-30/2013
2013-8003	10/18/2013 11/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca Dandeker Morgan, Lewis & Bockius LLP	MALLADI DRUGS AND PHARMACEUTICALS, LTD, TAMIL NADU, INDIA - EIR 09/10/2012 - 09/14/2012
2013-8004	10/18/2013 11/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca Dandeker Morgan, Lewis & Bockius LLP	MALLADI DRUGS AND PHARMACEUTICALS, LTD, TAMIL NADU, INDIA - 483 09/10/2012 - 09/14/2012
2013-8005	10/18/2013 11/18/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Alexander T. Zachos, J.D. Acella Pharmaceuticals, LLC	ACELLA PHARMACEUTICALS, LLC, ALPHARETTA, GA - EIR 03/19/2012 - 03/22/2012
2013-8006	10/18/2013 11/18/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	NSQ8 Integrated Plasmonics	K033847, K022661, K020235, ETC
2013-8007	10/18/2013 11/18/2013	FDA/OMPT/CTP/OD/	Desmond Jenson Tobacco Control Legal Consortium	ALL TOBACCO PRODUCTS LISTED BY MANUFACTURER UNDER 21 U.S.C. 387e(i)
2013-8008	10/18/2013 11/18/2013	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	Rebecca Dandeker Morgan, Lewis & Bockius LLP	FERRO PFANSTIEHL LABORATORIES, WAUKEGAN, IL - EIR 02/04/2013 - 02/11/2013
2013-8009	10/18/2013 11/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Brittney Bullock KANNER & WHITELEY LLC	LIDODERM - NDC
2013-8010	10/18/2013 11/18/2013	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	Rebecca Dandeker Morgan, Lewis & Bockius LLP	FERRO PFANSTIEHL LABORATORIES, WAUKEGAN, IL - EIR SUMMARY 02/04/2013 - 02/11/2013
2013-8011	10/18/2013 11/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 21529 S7
2013-8012	10/18/2013 11/18/2013	FDA/OGROP/ORACE-FO/NWJDO/NWJ-CB/	John Walsh James Alexander Corporation	ACROS ORGANICS, MORRIS PLAINS, NJ - EIR, 483, RECALLS 10/01/2009 - 09/30/2013
2013-8013	10/18/2013	FDA/OC/OES/DDM/	Matthew Frontini	DISCUSSION RE SAFETY AND EFFECTIVENESS OF

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	11/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gilbert's LLP	COPAXONE - TRANSCRIPT 09/19/1996 - 09/19/1996
2013-8014	10/18/2013 11/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	NYSTATIN ANDA 62-124 - APRVL , LBLG, MEDICAL RVW, PHARMACOLOGY RVW
2013-8015	10/18/2013 11/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	NYSTATIN ANDA 64-022 - APRVL, LBLG, CHEMISTRY RVW, MEDICAL RVW, PHARMACOLOGY RVW
2013-8016	10/18/2013 11/18/2013	FDA/OFVM/CFSAN/OCD/EOS/	CHARLES CELESTE EAS CONSULTING GROUP LLC	FCN 349
2013-8017	10/18/2013 11/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	NYSTATIN ANDA 65-203 - APRVL LTR, LBLG, MEDICAL RVW, CHEMISTRY RVW, PHARMACOLOGY RVW
2013-8018	10/18/2013 11/18/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	WEST, ROBIN	CC-125053
2013-8019	10/18/2013 11/18/2013	OC/ORARM/ OC/ORARM/	ROBERT KING FDA NEWS	ALL MEDICAL DVC & CLNCL TRIAL FACILITIES - 483S 9/13
2013-8020	10/18/2013 11/18/2013	OC/ORAM/ OC/ORAM/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	SAMANTHA MYERS ROANOKE CLAIMS SERVICES	GRAVITY DEFYER INC - ENTRY NO ASQ00263852
2013-8021	10/18/2013 11/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	INETTA WALKER ESTECH	K090385, K060721, K093679, K101961, K925914 UNREDACTED
2013-8022	10/18/2013 11/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TARA RYAN ESTECH	ALCON LABORATORIES INC - OTC 100022, 100035, 100036

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		FDA/OC/OES/DDM/		
2013-8023	10/18/2013 11/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	RUBEN F. SALINAS AMNISURE INTERNATIONAL LLC	HOLOGIC INC - ADEZA FETAL FIBRONECTIN EIK PMA P920048; RAPID FFN FOR THE TLIQ SYS PMA P920048/S006; AZEDA BIOMEDICAL - FETAL FIBRONECTIN EIK PMA P920048/S001 ETC
2013-8024	10/18/2013 11/18/2013	FDA/OC/OES/DDM/ FDA/OGROP/ORPA/FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	SARAH HODGSON METZGER LAW GROUP	MCGHAN MEDICAL - BREAST IMPLANTS PMA
2013-8025	10/18/2013 11/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	PATRICIA L. KELLY ESDAILE BARRETT & ESDAILE	RED LASER POINTER STAGE LASER LIGHT PEN - AER, INVESTIGATIONS, CMLPLNTS
2013-8026	10/18/2013 11/18/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	BRETT PARK CONWAY HOMER & CHIN-CAPLAN PC	INDIVIDUAL RECS
2013-8027	10/18/2013 11/18/2013	OC/ORPA/ OC/ORPA/	THOMAS R. HARRINGTON NELSON LEVINE DE LUCA EL AL	MEDICAL CTR PHARMACY, MIDLAND, TX - INVESTIGATIONS
2013-8028	10/18/2013 11/18/2013	OC/ORPA/ OC/ORPA/	THOMAS R. HARRINGTON NELSON LEVINE DE LUCA EL AL	KV PHARMACEUTICAL, ST LOUIS, MO - INVESTIGATION
2013-8029	10/18/2013 11/18/2013	OC/ORPA/ OC/ORPA/	THOMAS R. HARRINGTON NELSON LEVINE DE LUCA EL AL	NECC - METHYLPREDNISOLONE ACETATE MENINGITIS INFECTION
2013-8030	10/18/2013 11/18/2013	OC/ORPA/ OC/ORPA/ FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	THOMAS R. HARRINGTON NELSON LEVINE DE LUCA EL AL	MAIN STREET PHARMACY, SAVANNAH, TN - INVESTIGATIONS
2013-8031	10/18/2013 11/18/2013	OC/ORPA/ OC/ORPA/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	THOMAS R. HARRINGTON NELSON LEVINE DE LUCA EL AL	CUSTOM RX COMPOUNDING PHARMACY, RICHFIELD, MN - INVESTIGATION
2013-8032	10/18/2013 11/18/2013	OC/ORPA/ OC/ORPA/	THOMAS R. HARRINGTON NELSON LEVINE DE LUCA EL AL	AMBULATORY SURGERY CTR, STOCKTON, CA - INVESTIGATION

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2013-8033	10/18/2013 11/18/2013	OC/ORA/ OC/ORA/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	THOMAS R. HARRINGTON NELSON LEVINE DE LUCA EL AL	MED 4 HOME, KANSAS CITY, MO - INVESTIGATION
2013-8034	10/18/2013 11/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DANIEL J. DRISCOLL ISAAC WILES ET AL	PHYSICIAN RECORDS FOR DIVISION OF ANESTHESIA & ANALGESICS 1/03 TO PRESENT, APRVD DRUGS 1/03 TO PRESENT
2013-8035	10/18/2013 11/18/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	CHRISTINE M. BURNS DISCOVERY LABORATORIES INC	DISCOVERY LABORATORIES INC, WARRINGTON, PA - FEI 3004898726; DISCOVERY LABORATORIES INC, TOTOWA, NJ - FEI 3004014226
2013-8036	10/18/2013 11/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	BARRY J. STANIFORD NIPRO Diagnostics	MW 5031360
2013-8037	10/18/2013 11/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	BARRY J. STANIFORD NIPRO Diagnostics	MW 5031456
2013-8038	10/18/2013 11/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	BARRY J. STANIFORD NIPRO Diagnostics	MW 5031392
2013-8039	10/18/2013 11/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	ROBERT P. CHARROW GREENBERG TRAUIG LLP	MALLINCKRODT CRITICAL CARE LASER FLEX TRACHEAL TUBE 510K
2013-8040	10/18/2013 11/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	NYROBIA FREEMAN CONMED LINVATEC CORP	APEX - KISCHNER WIRES & STEINMANN PINS K121004
2013-8041	10/18/2013 11/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	MAURA M. McINTYRE UNGARETTI & HARRIS	ADHEZION BIOMEDICAL LLC K130474, K083354, K082993
2013-8042	10/18/2013 11/18/2013	FDA/OC/OES/ FDA/OC/OES/DDM/ FDA/OFVM/CFSSAN/OCD/EOS/ FDA/OGROP/OIP/	TOM NELTNER NATURAL RESOURCES DEFENSE COUNCIL	GRN 1,35,36 ETC
2013-8043	10/21/2013 11/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ketaki Gokhale Bloomberg News	CIPLA LTD - 483 10/03/2011 - 10/01/2013

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-8044	10/21/2013 12/31/2013	FDA/OFVM/CFSAN/OCD/EOS/	Sarah Hodgson METZGER LAW GROUP	GIB, LLC DBA BRAZILIAN BLOWOUT - CORR, RESEARCH, TESTING 01/01/2000 - 10/01/2013
2013-8045	10/21/2013 11/19/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	William Hulbert ClearView Diagnostics In.	K030223, K041380, K070803 ETC
2013-8046	10/21/2013 11/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Alexander Hess Ruberry, Stalmack & Garvey, LLC	CELEXA, CITALOPRAM - ISR
2013-8047	10/21/2013 11/19/2013	FDA/OMPT/OSMP/OOPD/	Chelli Miller Chelli Miller	ICODEXTRIN - ORPHAN APPLICATION
2013-8048	10/21/2013 11/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bhagwan S chaudhary IndiaNivesh Research Group	ANDA DIOVAN, NEXIUM
2013-8049	10/21/2013 11/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Lillie Thomas ORTHOFIX INC.	K022695
2013-8050	10/21/2013 11/19/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Paul Cascone The Argen Corporation	K111935, K111935, K111935 ETC
2013-8051	10/21/2013 11/19/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	Bhagwan S chaudhary IndiaNivesh Research Group	OHM LABORATORIES, INC, GLOVERSVILLE, NY - EIR, 483 01/01/2012 - 10/01/2013
2013-8052	10/21/2013 11/19/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	Bruce E. Johnson Schwabe North America	CANTON LABORATORIES PVT LTD, GUJJURAT, INDIA - EIR MOST RECENT Date Range: 10/02/2011 - 10/02/2013; FOOD FACILITY REGISTRATION
2013-8053	10/21/2013 11/19/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	Bruce E. Johnson Schwabe North America	CANTON CHEM, INC, CLARKSVILLE, MD - EIR MOST RECENT, FOOD FACILITY REGISTRATION
2013-8054	10/21/2013 11/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lisa Beck BAXTER HEALTHCARE	IPSENT BIOPHARM LTD, UK - EIR, 483 09/01/2012 - 09/30/2013

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2013-8055	10/21/2013 11/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Christopher Glorioso WNBC TV	CONCEPTUS, INC, BAYER, INC, ESSURE - PMA ANNUAL REPORTS, CLINICAL TRIALS, POST APPROVAL STUDIES, ETC
2013-8056	10/21/2013 11/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Bo Tran Bao Tran	K081724
2013-8057	10/21/2013 11/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sunny Hirpara Navitus Health Solution	BUPHENYL - APPROVAL PACKAGE
2013-8058	10/21/2013 11/19/2013	OC/ORA/ORM/ OC/ORA/ORM/ OC/ORA/OE/ OC/ORA/OE/	Querida Anderson BIOPHARM INSIGHT	BIOTECH, GENERICS, PHARMACEUTICAL COMPANIES, ETC - LIST OF INSPECTIONS
2013-8059	10/21/2013 11/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Marcia van de Boogaard Global Quality Alliance, LLC	SYNCO BIOPARTNERS - UNTITLED LETTERES, 483, EIR 01/01/2011 - 10/02/2013
2013-8060	10/21/2013 11/19/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Marietta Forcht FORCHT, M	INDIVIDUAL RECS
2013-8061	10/21/2013 11/19/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Giselle Campanaro bioCSL	VAERS RECS
2013-8062	10/21/2013 11/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mahidhar Chinta Micro Labs USA, Inc	DILTIAZEM HYDROCHLORIDE - SBA
2013-8063	10/21/2013 11/19/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	William Slevin NORTH AMERICAN RESCUE LLC	TACTICAL MEDICAL SOLUTIONS, ANDERSON, SC - 483 10/01/2012 - 10/01/2013
2013-8064	10/21/2013 11/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michelle Peahota THOMAS JEFFERSON UNIVERSITY HOSPITAL, INC.	TIGECYCLINE MORTALITY DATA

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2013-8065	10/21/2013 11/19/2013	OC/CVM/OCD/ FDA/OFVM/CFSAN/OCD/EOS/	Cristina Stella CENTER FOR FOOD SAFETY	Any and all documents related to correspondence between FDA and the sponsors of the four arsenic-based animal drugs: roxarsone, sponsored by Zoetis, Inc.; carbarsone, sponsored by Zoetis, Inc.; nitarosone, sponsored by Zoetis, Inc.; and arsanilic acid, sponsored by Fleming Labs, Inc.
2013-8066	10/21/2013 11/19/2013	FDA/OC/OES/DFOI/	Robert King FDA NEWS	Disclosure FOI request log date range 9/30/2013 to 10/4/2013
2013-8067	10/21/2013 11/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Peter Sun Sol Enterprises	K062003
2013-8068	10/21/2013 11/19/2013	FDA/OC/OES/DFOI/	Robert King FDANEWS	Disclosure FOI request log date range 9/23/2013 to 9/27/2013
2013-8069	10/21/2013 11/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Peter Sun Sol Enterprises	K101267
2013-8070	10/21/2013 11/19/2013	FDA/OC/OES/DFOI/	Sheila Kumar Columbia University Graduate School of Journalism	FOIA REQUEST LOGS
2013-8071	10/21/2013 11/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jay Cecil Valence Life Sciences	QSYMIA - AERS
2013-8072	10/21/2013 11/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEN REID WASHINGTON INFORMATION SOURCE	INTERNATIONAL LABS, CALGARY, CANADA - EIR, CO RESP, CORR 2/12
2013-8073	10/21/2013 11/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEN REID WASHINGTON INFORMATION SOURCE	WYETH LEDERLE, CATANIA, ITALY - EIR, CO RESP, CORR 7/12
2013-8074	10/21/2013 11/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEN REID WASHINGTON INFORMATION SOURCE	PEKING MEDICINE MANUFACTORY, TSUEN WAN, HONG KONG - EIR, CO RESP, CORR 4/12 TO 5/12
2013-8075	10/21/2013 11/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	GEXFIX SA, CAROUGE, SWITZERLAND - EIR, CO RESP, CORR 1/13

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2013-8076	10/21/2013 11/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	WONJLIN MULSAN CO, NAMDONG-GU, SOUTH KOREA - 483S, CO RESP, WARNING LTR, ETC 4/13
2013-8077	10/21/2013 11/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEN REID WASHINGTON INFORMATION SOURCE	JABONES PARDO SA, MADRID, SPAIN - 483, CO RESP, WARNING LTR, ETC 3/13
2013-8078	10/21/2013 11/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	SOLEETCH CORP, TAIPEI, TAIWAN - 483, CO RESP, WARNING LTR, ETC 05/13
2013-8079	10/21/2013 11/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEN REID WASHINGTON INFORMATION SOURCE	JUBILANT HOLLISTER STIER, KIRKLAND, QUEBEC, CANADA - EIR, CO RESP, CORR 03/12
2013-8080	10/21/2013 11/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEN REID WASHINGTON INFORMATION SOURCE	POSH CHEMICALS PRIVATE LTD, HYDERABAD, INDIA - 483, CO RESP, WARNING LTR, ETC 03/12
2013-8081	10/21/2013 11/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEN REID WASHINGTON INFORMATION SOURCE	PROMED EXPORTS PRIVATE LTD, HIMACHAL PRADESH, INDIA - 483, CO RESP, WARNING LTR, ETC 03/13 TO 04/13
2013-8082	10/21/2013 11/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	WEBER MEDICAL GMBH, LAUFENFORD, GERMANY - 483, CO RESP, WARNING LTR, ETC 01/13
2013-8083	10/21/2013 11/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEN REID WASHINGTON INFORMATION SOURCE	RPG LIFE SCIENCES LTD, ANKLESHWAR, GUJARAT, INDIA - 483, CO RESP, WARNING LTR, ETC 11/12
2013-8084	10/21/2013 11/19/2013	FDA/OGROP/ORP/SE-FO/ATL-DO/ATL-CB/	LOREN LARKIN SAC CAPITAL ADVISORS LP	PREMIER INC - OIG RELATING TO GROUP PURCHASING ORGANIZATION (GPO) BUSINESS MODEL & EQUITY OWNERSHIP STRUCTURE PAST 2 YRS
2013-8085	10/21/2013 11/19/2013	FDA/OGROP/ORP/SW-FO/DAL-DO/DAL-CB/	K MICHELLE VASSALLO LINCARE INC	NPATIENT SUPPORT SERVICES INC OR MIDSOUTH DISTRIBUTION INC, TX, AR - EIRS, 483S, WARNING LTRS, ETC 1/98 TO PRESENT

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2013-8086	10/21/2013 11/19/2013	FDA/OFVM/CFSAN/OCD/EOS/	CHARLES CELESTE EAS Consulting Group, LLC	FCN 961
2013-8087	10/21/2013 11/19/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OFVM/CFSAN/OCD/EOS/OC/ORA/OCI/ OC/ORA/OCI/	ALFRED C CONSTANTS III CONSTANTS LAW OFFICES LLC	ARCON OR ARCON VITAMINS, PATERSON, NJ; TRIARCO OR TRIARCO INDUSTRIES, PATERSON, NJ; NULL'S WHOLE FOODS, ETC - GARY NULL'S ULTIMATE POWER MEAR & GARY NULL'S ULTIMATE POWER MIX RECS 2009 TO PRESENT
2013-8088	10/21/2013 11/19/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ OC/ORA/OCI/ OC/ORA/OCI/	CHRISTINE A SAMMARCO ANTIN EHRlich & EPSTEIN LLP	TRIARCO INDUSTRIES; ARCHON VITAMIN CORP, GARY NULL & ASSOCIATES INC - GARY NULL'S ULTIMATE POWER MEAL & ULTIMATE POWER MIX EIRS, Cmplnts, VIOLATIONS, ETC
2013-8089	10/21/2013 11/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	MICHAEL S HEYL HOGAN LOVELLS LLP	IVERA MEDICAL CORP - THREE TRADE Cmplnts 06/27/11, 07/22/11, 06/25/13
2013-8090	10/21/2013 11/19/2013	FDA/OC/OES/DFOI/	STEWART #674116, TERRY	CODE OF FEDERAL REGULATIONS - TABLE OF CONTENTS
2013-8091	10/21/2013 11/19/2013	FDA/OFVM/CFSAN/OCD/EOS/	CHARLES CELESTE EAS Consulting Group, LLC	FCN 918
2013-8092	10/21/2013 11/19/2013	FDA/OFVM/CFSAN/OCD/EOS/	CHARLES CELESTE EAS CONSULTING GROUP LLC	FCN 844
2013-8093	10/21/2013 11/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEN REID WASHINGTON INFORMATION SOURCE	RPG LIFE SCIENCES LTD, MAKARASHTRA, INDIA - 483S, CO RESP, WARNING LTR, ETC 1/13
2013-8094	10/21/2013 11/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEN REID WASHINGTON INFORMATION SOURCE	ASADA MILLING CO, GUNNA, JAPAN - 483S, CO RESP, WARNING LTR, ETC 10/12
2013-8095	10/21/2013	FDA/OMPT/CDER/ORP/DIDP/	KEN REID	ASADA MILLING CO, GUNMA, JAPAN - EIR, RESP, CORR

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	11/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WASHINGTON INFORMATION SOURCE	10/12
2013-8096	10/21/2013 11/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	SPES MEDICA, BATTIPAGLIA, ITALY - EIR, RESP, CORR 10/12
2013-8097	10/21/2013 11/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	ENRAF-NONIUS BV, ROTTERDAM, METHERLANDS - 483, CO RESP, WARNING LTR, ETC 3/13
2013-8098	10/21/2013 11/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	ENRAF-NONIUS BV, ROTTERDAM, NETHERLANDS - EIR, RESP, CORR 3/13
2013-8099	10/21/2013 11/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	SOLEETECH CORP, TAIPEI, TAIWAN ROC - EIR, RESP, CORR 5/13
2013-8100	10/21/2013 11/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	UNISIS CORP, TOKYO, JAPAN - EIR, RESP, CORR 5/12
2013-8101	10/21/2013 11/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEN REID WASHINGTON INFORMATION SOURCE	HAMELN PHARMS, HAMELN, GERMANY - 483, CO RESP, WARNING LTR, ETC 6/12
2013-8102	10/21/2013 11/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	UNISIS CORP, TOKYO, JAPAN - 483, CO RESP, WARNING LTR, ETC 5/12
2013-8103	10/21/2013 11/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	SPES MEDICA, BATTIPAGLIA, ITALY - 483, CO RESP, WARNING LTR, ETC 10/12
2013-8104	10/21/2013 11/19/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	SANOFI PASTEUR, MARCY I'ETIOLE, FRANCE - 483, CO RESP, WARNING LTR, ETC 3/12 TO 4/12
2013-8105	10/21/2013 11/19/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	SANOFI PASTEUR LTD, TORONTO, CANADA - 483, CO RESP, WARNING LTR, ETC 4/12
2013-8106	10/21/2013 11/19/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/ORP/DIDP/	KEN REID WASHINGTON INFORMATION	FERCY PERSONAL CARE PRODUCTS, ZHEJIANG, CHINA - 483, CO RESP, WARNING LTR, ETC 3/12

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2013-8107	10/21/2013 11/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEN REID WASHINGTON INFORMATION SOURCE	INTERNATIONAL LABS, CALGARY, CANADA - 483, CO RESP, WARNING LTR, ETC 2/12
2013-8108	10/21/2013 11/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEN REID WASHINGTON INFORMATION SOURCE	TAIWAN THREE MAST PHARMACEUTICALCO, TAINAN CITY, TAIWAN - 483, CO RESP, WARNING LTR, ETC 4/12
2013-8109	10/21/2013 11/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	OSACHI CO LTD, NAGANO, JAPAN - 483, CO RESP. WARNING LTR, ETC 8/12
2013-8110	10/21/2013 11/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	MERIDIAN AG, THUN, SWITZERLAND - 483, CO RESP, WARNING LTR, ETC 6/12
2013-8111	10/21/2013 11/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEN REID WASHINGTON INFORMATION SOURCE	NOVO NORDISK, BAGSVAERD, DENMARK - 483, CO RESP, WARNING LTR, ETC 12/12
2013-8112	10/21/2013 11/19/2013	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	WALTER E. CHALKLEY THOMSON REUTERS	JM MURRAY CTR INC, CORTLAND, NY - EIR, 483, CO RESP 9/13/12
2013-8113	10/21/2013 11/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEN REID WASHINGTON INFORMATION SOURCE	BEANNE CHEMICAL CO, TAICHUNG CITY, TAIWAN - 483, CO RESP, WARNING LTR, ETC 5/12
2013-8114	10/21/2013 11/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	CENTRAL SURGICAL COMPANY LTD, LONDON, ENGLAND, UK - 483, CO RESP, WARNING LTR, ETC 8/12
2013-8115	10/21/2013 11/19/2013	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	WALTER E. CHALKLEY THOMSON REUTERS	HALOCARBON PRODUCTS CORP, BEECH ISLAND, SC - EIR, 483, CO RESP 11/2/12
2013-8116	10/21/2013 11/19/2013	FDA/OFVM/CFSAN/OCD/EOS/	KEN REID WASHINGTON INFORMATION	FERCY PERSONAL CARE PRODUCTS, ZHEJIANG, CHINA - EIR, RESP, CORR 3/12

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2013-8117	10/21/2013 11/19/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	WALTER E. CHALKLEY THOMSON REUTERS	DOUGLAS LORENZ, HENDERSON, NV - EIR, 483, CO RESP 4/25/12
2013-8118	10/21/2013 11/19/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	WALTER E. CHALKLEY THOMSON REUTERS	ST JOSEPH MERCY OAKLAND HEALTH SYS, IRB, PONTIAC, MI - EIR, 483, CO RESP 4/17-22/13
2013-8119	10/21/2013 11/19/2013	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	WALTER E. CHALKLEY THOMSON REUTERS	LIFE SOUTH COMMUNITY BLOOD CENTERS INC, MADISON, AL - EIR, 483, CO RESP 1/31/13
2013-8120	10/21/2013 11/19/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	WALTER E. CHALKLEY THOMSON REUTERS	RICHARD C JOSIASSEN PhD, CONSHOHOCKEN, PA - EIR, 483, CO RESP 5/2/12
2013-8121	10/21/2013 11/19/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	WALTER CHALKLEY THOMSON REUTERS	L. PERRIGO CO, ALLEGAN, MI - EIR, 483, CO RESP 5/8/12
2013-8122	10/21/2013 11/19/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	WALTER E. CHALKLEY THOMSON REUTERS	LINCARE INC, GALAX, VA - EIR, 483, CO RESP 5/24/12
2013-8123	10/21/2013 11/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	FARMHISPANIA SA, MONTMELO, SPAIN - EIR, 483, CO RESP 12/12/12
2013-8124	10/21/2013 11/19/2013	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	WALTER E. CHALKLEY THOMSON REUTERS	ROY LESTER SCHNEIDER HOSPITAL, ST THOMAS, VI - EIR, 483, CO RESP 2/15/12
2013-8125	10/21/2013 11/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	YUKI GOSEI KOGYO CO LTD, IWAKI-SHI, JAPAN - EIR, 483, CO RESP 6/22/12
2013-8126	10/21/2013 11/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	VIRCHOW LABORATORIES LTD, HYDERABAD, INDIA - EIR, 483, CO RESP 10/16/12
2013-8127	10/21/2013 11/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	NORDION CANADA INC, KANATA, CANADA - EIR, 483, CO RESP 4/4/12
2013-8128	10/21/2013 11/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	ALCHEM INTL LTD, BALLABGARH, FARIDABAD HARYANA, INDIA - EIR, 483, CO RESP 7/11/12

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2013-8129	10/21/2013 11/19/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	WALTER E. CHALKLEY THOMSON REUTERS	ONE BLOOD INC, VERO BEACH, FL - EIR, 483, CO RESP 5/11/12
2013-8130	10/21/2013 11/19/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	WALTER E. CHALKLEY THOMSON REUTERS	PLASMA CARE INC, BIRMINGHAM, AL - EIR, 483, CO RESP 3/30/12
2013-8131	10/21/2013 11/19/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	WALTER E. CHALKLEY THOMSON REUTERS	PROJECT INC, ST LOUIS, MO - EIR, 483, CO RESP 7/2/12
2013-8132	10/21/2013 11/19/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	WALTER E. CHALKLEY THOMSON REUTERS	SHIRE HUMAN GENETICS THERAPIES INC, CAMBRIDGE, MA - EIR, 483, CO RESP 1/11/12
2013-8133	10/21/2013 11/19/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	WALTER E. CHALKLEY THOMSON REUTERS	SUNIL PATEL, ABILENE, TX - EIR, 483, CO RESP 9/21/12
2013-8134	10/21/2013 11/19/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	WALTER E. CHALKLEY THOMSON REUTERS	AIDAREX PHARMACEUTICALS LLC, CORONA, CA - EIR, 483, CO RESP 2/22/12
2013-8135	10/21/2013 11/19/2013	FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	WALTER E. CHALKLEY THOMSON REUTERS	TAPI PUERTO RICO INC, HUMACAO, PR - EIR, 483, CO RESP 6/29/12
2013-8136	10/21/2013 11/19/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	WALTER E. CHALKLEY THOMSON REUTERS	TRIS PHARMA INC, MONMOUTH JUNCTION, NJ - EIR, 483, CO RESP 6/15/12
2013-8137	10/21/2013 11/19/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	WALTER E. CHALKLEY THOMSON REUTERS	UNIV OF CONNECTICUT HEALTH CTR/IRB FARMINGTON, CT - EIR, 483, CO RESP
2013-8138	10/21/2013 11/19/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	WALTER E. CHALKLEY THOMSON REUTERS	WELDING & THERAPY SERVICE INC, PRINCETON, IN - EIR, 483, CO RESP 7/27/12
2013-8139	10/21/2013 11/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	WOCKHARDT LTD, AURANGABAD, INDIA - EIR, 483, CO RESP 6/15/12
2013-8140	10/21/2013 11/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	ZYDUS BSV PHARMA PRIVATE LTD, AHMEDABAD, INDIA - EIR, 483, CO RESP 10/4/12
2013-8141	10/21/2013 11/19/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	WALTER E. CHALKLEY THOMSON REUTERS	BLOOD CTR, THIBODAU, LA - EIR, 483, CO RESP 1/16/13
2013-8142	10/21/2013	FDA/OGROP/ORA/CE-FO/PHI-	WALTER E. CHALKLEY	MUTUAL PHARMACEUTICAL COMPANY INC, PHILADELPHIA,

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	11/19/2013	DO/PHI-CB/	THOMSON REUTERS	PA - EIR, 483, CO RESP 1/27/12
2013-8143	10/21/2013 12/16/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	WALTER E. CHALKLEY THOMSON REUTERS	MERIDIAN MEDICAL TECHNOLOGIES A PFIZER CO, BRENTWOOD, MO - EIR, 483, CO RESP 2/13/12
2013-8144	10/21/2013 11/19/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	WALTER E. CHALKLEY THOMSON REUTERS	MARCUS RESEARCH LAB, INC, SAINT LOUIS, MO - EIR, 483, CO RESP 7/6/12
2013-8145	10/21/2013 11/19/2013	OC/ORASW-FO/KAN-DO/KAN-CB/ OC/ORASW-FO/KAN-DO/KAN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	THOMAS R. HARRINGTON NELSON LEVINE DE LUCA EL AL	APOTHECURE, SAVANNAH, TN - INVESTIGATIONS
2013-8146	10/21/2013 11/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	NYROBIA FREEMAN CONMED LINVATEC CORP	TRILLIANT - SURGICAL K WIRES K121008
2013-8147	10/21/2013 11/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	NYROBIA FREEMAN CONMED LINVATEC CORP	TELEFLEX MEDICAL - KMEDIC INTERNAL/EXTERNAL FIXATION DVC K070561
2013-8148	10/22/2013 11/20/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Prathuyusha Devireddy EASTERN MICHIGAN UNIVERSITY	INSPECTION DATA
2013-8149	10/22/2013 11/27/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Garrett Booth Vanderbilt University Medical Center/Jim Ayers Inst for Precancer Detection & Diagnosis	ONSET OF SYMPTOMS TO TIME OF DEATH FOR ANAPHYLASIX
2013-8150	10/22/2013 11/20/2013	FDA/OC/OES/DDM/ FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Molshree Gupta METZGER LAW GROUP	MCGHAN MEDICAL BREAST IMPLANTS - APPROVAL RECS ETC
2013-8151	10/22/2013 11/20/2013	FDA/OC/OES/DFOI/	Darshan Mehta ET Now	OHM LABS - 483 12/18/12
2013-8152	10/22/2013	FDA/OMPT/CDER/GRP/DIDP/	Nathaniel August	OMONTYS - CASE REPORTS

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	11/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mangrove Partners	
2013-8153	10/22/2013 11/20/2013	OC/CVM/OCD/	Robert Whelan Whelan, Robert P	AFOXOLANER, NEXGARD - SAFETY, EFFICACY DATA
2013-8154	10/22/2013 11/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	T. Christian Miller PROPUBLICA	Slwann J. Postmarketing Safety Review McNeil Product Recall of Certain OTC Children's and Infants Products, January 11, 2011
2013-8155	10/22/2013 11/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Liana Nabi Comprehensive Pharmacy Services	IM ZYPREXA AND PARENTERAL BENZODIAZEPINES INTERACTION - CHANGES IN PACKAGE INSERT 01/01/2004 - 01/01/2006
2013-8156	10/22/2013 11/20/2013	FDA/OGROP/ORAN/NE-FO/NWE-DO/NWE-CB/	John Walsh James Alexander Corporation	ALPHA AESAR, WARD HILL, MA - EIR, 483, RECALL 09/01/2009 - 10/04/2013
2013-8157	10/22/2013 11/21/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Christine Bariahtaris Infotrieve, Inc.	Skin test method for evaluation of subject sensitivity to standardized allergenic extracts and for assignment of allergy units to reference preparations using the ID50EAL method
2013-8158	10/22/2013 11/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rebecca Dandeker MORGAN, LEWIS & BOCKIUS	FORMOSA LABORATORIES, TAOYUAN, TAIWAN - EIR 05/07/2012 - 05/10/2012
2013-8159	10/22/2013 11/20/2013	FDA/OGROP/ORAN/SE-FO/NOL-DO/NOL-CB/	John Walsh James Alexander Corporation	EXXON MOBILE CHEMICAL CO, BATON ROUGE, LA - EIR, 483, RECALL 11/01/2009 - 10/04/2013
2013-8160	10/22/2013 11/20/2013	FDA/OFVM/CFSAN/OCD/EOS/	Adam Orr personal	SUCRALOSE - SAFETY DATA FOR APPROVAL
2013-8161	10/22/2013 11/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	None SIMONETTI, E	K970133
2013-8162	10/22/2013 11/20/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K121598, K123845
2013-8163	10/22/2013 11/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelina Slayton INC RESEARCH CONSULTING & SUBMISSIONS	BLA 103705 S 5231

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2013-8164	10/22/2013 11/20/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Christian Levesque Conrad & Scherer	Stryker ABG II modular-neck hip stem and/or the Rejuvenate Hip System
2013-8165	10/22/2013 11/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dan Stanton in-Pharmatechnologist.com	MSN LABS, HYDREBAD, INDIA - 483 09/01/2013 - 10/08/2013
2013-8166	10/22/2013 11/20/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Leslie Paul PERRIGO CO	OHM LABORATORIES, GLOVERSVILLE, NY - EIR 12/01/2012 - 10/09/2013
2013-8167	10/22/2013 11/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bao Le ARIAD Pharmaceuticals Inc.	ICLUSIG - AERS
2013-8168	10/22/2013 11/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Brandon Stempo B. Braun Medical Inc.	Summary Basis of Approval documents for Clinolipid, NDA 204508
2013-8169	10/22/2013 11/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Olivier Berlage Tweedy, Browne Company LLC	INVOKANA - AERS
2013-8170	10/22/2013 11/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Michael Singer BRAINSCOPE COMPANY INC	K080377
2013-8171	10/22/2013 11/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Donald Switzer Bonezzi Switzer Polito & Hupp Co, LPA	Succinylcholine - AERS
2013-8172	10/22/2013 11/20/2013	FDA/OO/OFBA/OAGS/	Richard Corretjer Quotient, Inc.	HHSF223201000054I
2013-8173	10/22/2013 11/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	W E CHALKLEY THOMSON REUTERS	NOVARTIS PHARMS - EXTAVIA (INTERFERON BETA 1-B) BLA 125-290 APRVL LTR 06/22/11

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2013-8174	10/22/2013 11/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	W E CHALKLEY THOMSON REUTERS	QUESTCOR PHARMA - HP ACTHAR GEL (REPOSITORY CORTICOTROPIN) NDA 22-432 APRVL LTR 07/05/12
2013-8175	10/22/2013 11/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	AMAURY SANCHEZ NOVEN PHARMACEUTICALS INC	WATSON LABS INC - LIDOCAINE 5% PATCH ANDA 200-675 SBA
2013-8176	10/22/2013 12/11/2013	FDA/OMPT/CTP/OD/	NATALIE N SANDERS LATHAM & WATKINS LLP	STN SE00032897 OCB ORGANIC HEMP SINGLE WIDE; STN SE0003298 OCB ORGANIC HEMP KING SIZE SLIM; STN DE0003299 OCB ORGANIC HEMP 12/4 SIZE - SUBSTANTIAL EQUIVALENCE RPTS, EA
2013-8177	10/22/2013 11/20/2013	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	BETTY BEHRENS REGAN ZAMBRI LONG & BERTRAM PLLC	THERMO PAC, STONE MOUNTAIN, GA - EIR
2013-8178	10/22/2013 11/20/2013	FDA/OFVM/CFSAN/OCD/EOS/	JANNA DEPORTER CENTER FOR SCIENCE IN THE PUBLIC INTEREST	REBAUDIOSIDE A - TOXICOLOGY EVALUATIONS, MEMOS, LTRS, ETC
2013-8179	10/22/2013 11/20/2013	FDA/OMPT/CTP/OD/	NATALLIE N SANDERS LATHAM & WATKINS LLP	STN SE0001697 HBI INTERNATIONAL ELEMENTS AFICIONADO KS SLIM; STN SE0001698 HBI INTERNATIONAL ELEMENTS AFICIONADO 11/4; STN SE0003199 REPUBLIC TABACCO LP TOP GOLD 100M, ETC - SUBSTANTIAL EQUIVALENCE RPTS, EA
2013-8180	10/22/2013 11/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	DAVID J BALINT BALIANT & ASSOCIATES PLLC	COVIDIEN UNITED STATES SURGICAL CORP, NORTH HAVEN, CT - PRO TACK FIXATION DVC 510K
2013-8181	10/22/2013 11/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	ANDREW M BEATO STEIN MITCHELL & MUSE LLP	CDRH & BILIARY STENT DVS MFR MTG - POWERPOINT PRESENTATION ATTENDANCE LIST 03/12/07
2013-8182	10/22/2013 11/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARY B SZALKOWSKI PRISMA CORP	INDAPAMIDE, PERINDOPRIL - AERS
2013-8183	10/22/2013 11/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID M HOFFMEISTER WILSON SONSINI ET AL	COPAXONE (GLATIRAMER ACETETE NDA 20-622 - REQUESTS & AMENDMENTS FOR PEDIATRUC STUDIES

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		FDA/OMPT/CDER/ORP/DIDP/		
2013-8184	10/22/2013 11/20/2013	FDA/OC/OES/	DAVID C BABAIAAN QUORUM REVIEW IRB	IRB REGISTRATION - NAME, MAILING ADDRESS, PHONE NUMBER, ETC
2013-8185	10/22/2013 11/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BORIS PEAKER PHD OPPENHEIMER & CO INC	SEATTLE GENETICS - ADCETRIS (BRENTUXIMAB) AERS, COMM
2013-8186	10/22/2013 11/20/2013	FDA/OFVM/CFSAN/OCD/EOS/	ROBERT E LYTLE SZAFERMAN LAKIND BLUMSTEIN ET AL	DR IRVING SELIKOFF, ARTHUR LANGER PHD, CONTRIBUTIONS OF FIBERS FROM TALC TO HUMAN LUNG BURDEN - PRESENTATION 1968
2013-8187	10/22/2013 11/20/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	DIANNE L CHAMBERS HOGAN LOVELLS LLP	NEW DREAM TEAM INC - FRESH BASIL (SWEET HAWAIIAN AND THAI) RECALL #F-1883-2013 RECS
2013-8188	10/22/2013 11/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Martinez, Lucy	MDS PHARMA SERVICES, SAINT- LAURENT (MONTREAL) QUEBEC CANADA, TORONTO, ONTARIO, CANADA - WARNING LTRS OBSTRUCTED RECS 07/07-09/03, 03/06-24/06
2013-8189	10/22/2013 11/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	CATHERINE R NIELSEN Keller and Heckman LLP	MONOETHANOLAMIE - TOXICITY RECS, CHEMISTRY & TOXICOLOGY RVWS, MEMO, ETC
2013-8190	10/22/2013 11/20/2013	OC/ORA/OCI/ OC/ORA/OCI/	ROBERTA MASCIA JOHNS EASTERN COMPANY INC	INDIVIDUAL RECS
2013-8191	10/22/2013 11/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	LEONARD NASS COMPRESSION THERAPY CONCEPTS	MDR RPT #MV5029732
2013-8192	10/22/2013 11/20/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	EDWIN E RODRIGUEZ MEDEFIL INC	EIR RPTS & REGULATORY MINS 12/01/09 TO 02/10, 12/08/10 TO 01/31/11, 04/20/11, ETC
2013-8193	10/22/2013 11/20/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	ANTHONY DELLIGATTI SKINNER LAW FIRM	ULTRALITE ENTERPRISES INC - UVB NARROWBAND TREATMENT MDRS, INVESTIGATION RECS
2013-8194	10/22/2013	FDA/OMPT/CDER/ORP/DIDP/	ELENA HOWELL	DATSCAN (IOFLUPANE, IOFLUPANE I-123) NDA 22-454 - EIGHT FACTOR ANALYSIS, SCHEDULING RECS, CORR, ETC

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	11/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Hogan Lovells, ILP	
2013-8195	10/22/2013 11/20/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	CHASTITY RODRIGUEZ INTERNATIONAL SIGHT RESTORATION INC	RESTORE SIGHT INTERNATIONAL EYE BANK, LAS VEGAS, NV; SOUTH DAKOTA LIONS EYE & TISSUE BANK, SIOUX FALLS, SD; WESTERN TEXAN LIONS EYE BANK, SAN ANGELO, TX - 483S, WARNING LTRS LAST 10 YRS
2013-8196	10/22/2013 11/20/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GOINS 302385, MICHAEL	PRIOSEC (OMEPRAZOLE), COGENTIN (BENZTROPINE), PEANUT BUTTER, ETC - AERS, CAERS
2013-8197	10/22/2013 11/20/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	MANUELL A ROMERO MANUEL A ROMERO PC	GOYA'S FOODS INC - CMLPNT 125436
2013-8198	10/22/2013 11/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FRIEDMAN, ROBERT	TIXYLIX NIGHT COUGH LIQUID - AERS 1969 TO 2013
2013-8199	10/22/2013 11/20/2013	FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	KIM C CAPONE PORZIO LIFE SCIENCES	LANZA & SONS INC, BAYAMON, PR - EIRS, 483S
2013-8200	10/22/2013 11/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SPENCER AR4467, NATHAN	ABILIFY, SEROQUEL, HALDOL, ETC - AERS, TESTING, POLICIES, ETC 2000-2008
2013-8201	10/22/2013 11/20/2013	FDA/OMPT/OSMP/OOPD/	PAUL KETTERIDGE PD REGULATORY CONSULTING LLC	ABRAXANE (PACLITAXEL PROTEIN-BOUND PARTICLES NDA 21-660 - APPL, RVWS, DESIGNATION LTR, ETC
2013-8202	10/22/2013 11/20/2013	FDA/OC/OES/DFOI/	HASANATI D15084, JACHI	PRIVACY ACT, FOIA SYSTEM OF RECORDS - LIST
2013-8203	10/22/2013 11/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	THOMAS, JOHN ROD	EIKO LTD - ARC MASTER METAL LAMP REQUIREMENTS FOR MANUFACTURE, INSTALLATION, USAGE
2013-8204	10/22/2013	FDA/OC/OES/DDM/	KRISTI O SMEDLEY PHD	DKT 1995S-0039 - RPTS 539, 540, 541, ETC

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	11/20/2013		WASHINGTON INFORMATION SOURCE	
2013-8205	10/22/2013 11/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	LIANE LAROCHELLE DEKA RESEARCH & DEVELOPMENT CORP	INSULET CORP - OMNIPOD INSULIN MANAGEMENT SYS K131294
2013-8206	10/22/2013 11/20/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORPA-FO/SEA-DO/SEA-CB/	ROBERT PLOTZ TRAVELERS INDEMNITY CO	TESTING OATMEAL FOR MOLD - RECS
2013-8207	10/22/2013 11/20/2013	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	KIM C CAPONE PORZIO LIFE SCIENCES	NESTLE HEALTH SCIENCES-PAMLAB INC, COVINGTON, LA - EIR, 483 8/15/13
2013-8208	10/22/2013 11/20/2013	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	KIM C CAPONE PORZIO LIFE SCIENCES	LEE MEDICAL INTERNATIONAL INC, HARAHAN, LA - EIR, 483 8/14/13
2013-8209	10/22/2013 11/20/2013	FDA/OC/OL/	JASON SMATHERS MUCKROCK NEWS	GOVERNMENT SHUTDOWN - CONGRESSIONAL CORR 9/13 TO 10/13
2013-8210	10/22/2013 11/20/2013	FDA/OC/OES/DFOI/	JASON SMATHERS MUCKROCK NEWS	FOIA REQUESTS FY 2013
2013-8211	10/22/2013 11/20/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	LUCIRE, YOLANDE	RISPERDAL (RISPERIDONE) NDA 20-272 - SAFETY UPDATE
2013-8212	10/22/2013 11/20/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	DACOSTA, ELEANOR	NBTY INC (NATURE'S BOUNTY), NY - EIRS
2013-8213	10/23/2013 11/21/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	T. Christian Miller PROPUBLICA	FDA Division of Medication Error Prevention and Analysis (DMEPA) analysis of pediatric acetaminophen overdose for the Office of Postmarketing Drug Risk Assessment (OPDRA)
2013-8214	10/23/2013 11/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	Loren Larkin SAC CAPITAL MANAGEMENT LLC	CORR RE DISPUTE RESOLUTION PANEL - BIOMIMETIC THERAPEUTICS, WRIGHT MEDICAL
2013-8215	10/23/2013 11/21/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORASW-FO/DAL-	Steve Rogers Zoetis Inc.	DEBORAH EDWARDS PETTY, LARGO, FL - 482 6/22/11; CURTIS DAME, KALAMAZOO, MI - 482 6/30/11; JUDY ZINN, TULSA, OK - 483 6/7/2011

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		DO/DAL-CB/		
2013-8216	10/23/2013 11/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Cara Weyker Horizon Pharma Inc.	AENOVA FRANCE, SAS, FRANCE - EIR 05/27/2013 - 10/04/2013
2013-8217	10/23/2013 11/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Maria Luz Pascual RFS Pharma LLC	248 AERS
2013-8218	10/23/2013 11/21/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Mary Emily Monroe McDowell Knight Roedder & Sledge, LLC	SUNFLOWER MEDICAL - AERS, REIGSTRATION AND LISTING, CAPA ETC
2013-8219	10/23/2013 11/21/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Mary Emily Monroe McDowell Knight Roedder & Sledge, LLC	SIZEWISE RENTALS - AERS, REIGSTRATION AND LISTING, CAPA ETC
2013-8220	10/23/2013 11/21/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Mary Emily Monroe McDowell Knight Roedder & Sledge, LLC	AMERICAN NATIONAL MANUFACTURING - AERS, REIGSTRATION AND LISTING, CAPA ETC
2013-8221	10/23/2013 11/21/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Mary Emily Monroe McDowell Knight Roedder & Sledge, LLC	RAY'S INC, DBA WHEELCHAIRS OF KANSAS - AERS, REIGSTRATION AND LISTING, CAPA ETC
2013-8222	10/23/2013 11/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Irina Rivkind CANTOR FITZGERALD	AMITIZA - AERS
2013-8223	10/23/2013 11/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michele Sinoway LACHMAN CONSULTANT SERVICES, INC.	OGD Monthly Statistical Report for September 2013 issued by Martin Shimer, Chief, Regulatory Support Branch through Peter Rickman, Director, Division of Labeling and Program Support
2013-8224	10/23/2013 11/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Elena Howell HOGAN LOVELLS US LLP	NDA 022454 - RECS RE CONTROLS

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2013-8225	10/23/2013 11/21/2013	FDA/OC/OES/ FDA/OFVM/CFSAN/OCD/EOS/	Wiggin and Dana LLP WIGGIN AND DANA	FDA CORR WITH NATIONAL CONSUMERS LEAGUE RE BREAD ETC
2013-8226	10/23/2013 11/21/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Scott M. Perry Perry Charnoff PLLC	Complete Prescribing Information for Zyprexa (Olanzapine)
2013-8227	10/23/2013 11/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	COMPLAINT FOLLOW UP RECS
2013-8228	10/23/2013 11/21/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	BLA 103705 S 5311
2013-8229	10/23/2013 11/21/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joshua A. Klarfeld ULMER & BERNE LLP	PAXIL, PROZAC, ZOLOFT, ETC - AERS
2013-8230	10/23/2013 11/21/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jill Escher Escher Fund for Autism	Colprosterone (manufacturer unknown) Deladroxate 110 (Squibb) Deladroxate 130 (Squibb) Deladroxate 150 (Squibb) Delalutin 142 (Squibb) Norlutin Acetate (Parke Davis) Provera (Upjohn) Provest (Upjohn) Delestrogen (Squibb)- Distribution recs 1950-1979
2013-8231	10/23/2013 11/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	David Windish Newtyn Management	WRIGHT MEDICAL - APPEAL OF NOT APPROVAL LETTER RE AUGMENT BONE GRAFT
2013-8232	10/23/2013 11/21/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	David Windish Newtyn Management	WRIGHT MEDICAL - NOT APPROVABLE LETTER
2013-8233	10/23/2013 11/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	Alex Greene Austin Medical Ventures	K090926
2013-8234	10/23/2013 11/21/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	BLA 103705 S 5312
2013-8235	10/23/2013 11/21/2013	FDA/OMPT/CTP/OD/	Sandra Song Medill School of Journalism, Northwestern University	FDA CORR WITH TOBACCO INDUSTRY

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2013-8236	10/23/2013 11/21/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDRH/OCER/DFOI/	DEVONA, DENNIS R	ENDOCRAFT LLC - OWNER/PERATOR NO 9035069; REGISTERED ESTABLISHMENT NAME/OWNER/OPERATOR; REGISTERED ESTABLISHMENT NO 1225968
2013-8237	10/23/2013 11/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	ADELE GILPIN ARNOLD & PORTER	COLLAGEN BONE HEALING PROTECTIVE SHEET - K052041
2013-8238	10/23/2013 11/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID LONERGAN EIRGEN PHARMA LTD	NOVEL LABS INC - MISOPROSTOL ANDA 91-667 RVW SUMMARY
2013-8239	10/23/2013 11/21/2013	OC/ORA/ OC/ORA/ OC/ORA/ OC/ORA/	SULLIVAN, DENISE	FINAL CONFLICT PREVENTION & RESOLUTION STAFF RPT ON EMPLOYEE ISSUES
2013-8240	10/23/2013 11/21/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	BETTY BEHRENS REGAN ZAMBRI LONG & BERTRAM PLLC	THERMO PAC, STONE MOUNTAIN, GA - EIR ATTACHMENTS
2013-8241	10/23/2013 11/21/2013	FDA/OC/OES/DFOI/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/ORA/OCI/ OC/ORA/OCI/	OWEN P MCGOWAN MCGOWAN & ASSOCIATES ATTY	OPTIMUM HEALTH DISTRIBUTING - TREN 2 EXTREME OR SSL TREN 2 HARDCORE CMLPNTS, MFR INSERTS, FLYERS, ETC
2013-8242	10/23/2013 11/21/2013	FDA/OC/OES/DFOI/	GARCIA M1813, NICKOLAS	CLASS ACTION CIVIL LAW SUIT ON MENTAL HEALTH & PSYCHOTROPIC DRUGS & MEDICATION - ATTORNEY ADDRESSES, NAMES, ADDRESS OF THE COURTS
2013-8243	10/23/2013 11/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BORIS PEAKER PHD OPPENHEIMER & CO INC	GENZYME CORP - RENAGEL (SEVELAMER HCL), RENVELA (SEVELAMER CARBONATE) CORR
2013-8244	10/23/2013 11/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	MAURA MARTIN NORDEN SIDLEY AUSTIN LLP	BTL INDUSTRIES - CORR, CMLPNTS, RECS
2013-8245	10/23/2013	FDA/OO/OFBA/OAGS/	DANIEL L GORDON	KINGDOMWARE TECHNOLOGIES & SDV SECURITY LLC -

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	11/21/2013		GEORGE WASHINGTON UNIVERSITY	GAO DKT B-405568.3, B-405568.4
2013-8246	10/23/2013 11/21/2013	FDA/OC/OL/	ABRAHAM PAYTON AMERICAN BRIDGE 21ST CENTURY	REP BILL CASSIDY - CORR 1/3/09 TO PRESENT; REP STEVE DAINES - CORR 1/13/13 TO PRESENT; REP SHELLEY CAPITO - CORR 1/3/01 TO PRESENT, ETC
2013-8247	10/23/2013 11/21/2013	FDA/OC/OES/DDM/ FDA/OMPT/CDRH/OCER/DFOI/	STALLWORTH, JOANA M	UV-X SYS FOR CORNEAL COLLAGEN CROSS-LINKING IN EYES WITH CORNEAL ECTASIA OR PROGRESSIVE KERATOCONUS STDIES CONDUCTED IN NATIONAL SITES (EMERY UNIV WITH PI R DOYLE STULTING) - SS&E, OFFICERS IN CHARGE OF OVERSIGHT, NAMES OF INVESTIGATORS, ETC 2009 TO PRESENT
2013-8248	10/23/2013 11/21/2013	OC/ORO/ OC/ORO/	BRIANNA SMITH WSPA-TV	GREENVILLE, SC REGIONAL POST - LIST OF FURLOUGHED EMPLOYEES, JOB DESCRIPTIONS, COMPANIES NEGLECTED FOR INSPS BECAUSE OF FURLOUGHS, ETC
2013-8249	10/23/2013 11/21/2013	FDA/OMPT/CTP/OD/	SUZANNA D JENSEN Kleinfeld, Kaplan and Becker, LLP	LORILLAD TOBACCO CO - SE RPTS SE0003730, SE0003731
2013-8250	10/23/2013 11/21/2013	FDA/OC/OES/DFOI/	EDISON, LEWIS	INDIVIDUAL RECS
2013-8251	10/23/2013 11/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	LIANE LAROCHELLE DEKA RESEARCH & DEVELOPMENT CORP	FRESENIUS MEDICAL CARE - FRESENIUS LIBERTY CYCLER K123630
2013-8252	10/23/2013 11/21/2013	FDA/OGROP/ORO/CE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDRH/OCER/DFOI/	ALEKSEY FEYGIN BASICHAS & ASSOCIATES PC	STRYKER HOWMEDICAL OSTEOONICS - SHELL RESTORATION ADM LT48, REJUVENATE MODULAR STEM SZ, INSERT REST ADM X3 28/48, ETC RECALL RECS
2013-8253	10/23/2013 11/21/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	EVA MARIE CARNEY RICHARDS KIBBE & ORBE LLP	WYETH - BAZEDOXIFEN COMPLETE RESP LTR 12/24/07; GTX - TOREMIFENE COMPLETE RESP LTR 11/2/09; PFIZER - LASOFOXIFENE NDA 22-242 COMPLETE RESP LTR 1/16/09, ETC
2013-8254	10/23/2013 11/21/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PEARL TONG-NGORK SYRACUSE ORTHOPEDIC SPECIALISTS	NEUROTROPIN IND 108584 - RECS
2013-8255	10/24/2013 11/22/2013	FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/	Genevive Blanchette ALGORITHMHE PHARMA INC	COVANCE, INC QPS LLC - 483 03/01/2013 - 10/01/2013
2013-8256	10/24/2013 11/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	BLA 103705 S 5332

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-8257	10/24/2013 11/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	BLA 103705 S 5344
2013-8258	10/24/2013 11/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection report, 483 and the firm's response for the February 17, 2012 inspection for: Dr. Kiat Ruxrungham, Bangkok, Thailand
2013-8259	10/24/2013 11/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Renee Murphy Alphatec Spine, Inc.	K130646
2013-8260	10/24/2013 11/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dr. Shelley Amuh Amuh, Shelley	MEFLOQUINE - AERS
2013-8261	10/24/2013 11/22/2013	FDA/OC/OES/DFOI/	Desmond Jenson Tobacco Control Legal Consortium	CTP FOIA REQUEST LOG
2013-8262	10/24/2013 11/22/2013	FDA/OFVM/CFSAN/OCD/EOS/	Kathy Moss FedEx Trade Networks Transport & Brokerage, Inc.	FEDEX TRADE NETWORKS TRANSPORT & BROKERAGE - LIST OF COMPANIES DESIGNATING AGENT FOR FOOD FACILITY
2013-8263	10/24/2013 11/22/2013	FDA/OGROP/ORO/CE-FO/NWJ- DO/NWJ-CB/	P Sunthakar Revogenex Inc.	CATALENT PHARMA SOLUTIONS, SOMERSET, NJ - 483 10/02/2012 - 10/11/2013
2013-8264	10/24/2013 11/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Greg Bruno Greg Bruno	XTANDI, ACTHAR GEL, SOVAPEVIR ETC - AERS
2013-8265	10/24/2013 11/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Sindura Penubarthi Masimo Corporation	K112820
2013-8266	10/24/2013 11/22/2013	FDA/OGROP/ORO/SW-FO/DAL- DO/DAL-CB/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Paul Knoepfler UC DAVIS SCHOOL OF MEDICINE	CELLTEX - INSPECTIONS, CORR WITH FDA; EXPORTATION RECS 05/01/2013 - 12/31/2013
2013-8267	10/24/2013	FDA/OMPT/CDER/GRP/DIDP/	Rebecca Dandeker	Jiangsu Yunyang Group Pharmaceutical Co. Ltd., Jiangsu,

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	11/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MORGAN, LEWIS & BOCKIUS	China - 483
2013-8268	10/24/2013 11/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca Dandeker MORGAN, LEWIS & BOCKIUS	Jiangsu Yunyang Group Pharmaceutical Co. Ltd., Jiangsu, China - EIR SUMMARY
2013-8269	10/24/2013 11/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Stacy Hawkins Stacy Hawkins	K121165
2013-8270	10/24/2013 11/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Sindura Penubarthi Masimo Corporation	K131111
2013-8271	10/24/2013 11/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Junan Guo AMRI	GLAND PHARMA LIMITED, INDIA - 483 07/01/2012 - 10/11/2013
2013-8272	10/24/2013 11/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca Dandeker MORGAN, LEWIS & BOCKIUS	Jiangsu Yunyang Group Pharmaceutical Co. Ltd., No., Jiangsu, China - EIR
2013-8273	10/24/2013 11/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Sindura Penubarthi Masimo Corporation	K094030
2013-8274	10/24/2013 11/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michelle Masson TRILLIUM HEALTH CARE PRODUCTS INC	DEAD SEA BROMINE COMPANY LTD, ISRAEL - EIR 10/01/2010 - 10/10/2013
2013-8275	10/24/2013 11/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	Nicole DeVirgiliis Chelsea Therapeutics, Inc.	NDA 203202
2013-8276	10/24/2013 11/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Sindura Penubarthi Masimo Corporation	K123700

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2013-8277	10/24/2013 11/22/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Sindura Penubarthi Masimo Corporation	K123581
2013-8278	10/24/2013 11/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	InnoPharma,Inc Innopharma,Inc	NDA 12142 - APPROVAL RECS
2013-8279	10/24/2013 11/22/2013	FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/	Soma Das The Economic Times, The Times of India	OHM LABS, NJ - EIR 12/12
2013-8280	10/24/2013 11/22/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Jennifer Brooks Microbiotix, Inc.	K895920
2013-8281	10/24/2013 11/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachae Tanner Univerisity of Washington	K970685
2013-8282	10/24/2013 11/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Michelle Collins Motion View Software LLC	K122065
2013-8283	10/24/2013 11/22/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Alex Greene Austin Medical	K101861
2013-8284	10/24/2013 11/22/2013	FDA/OO/OHR/	BRIAN S. PEARSON IHC FINANCIAL GROUP	RELELASABLE EMPLOYEE RECORDS
2013-8285	10/24/2013 11/22/2013	FDA/OFVM/CFSAN/OCD/EOS/	FRIEDMAN, ROBERT. .	FRENCHS, MRS DASH, ANNIES NATURALS - CAERS 1969 TO PRESENT
2013-8286	10/24/2013 11/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FRIEDMAN, ROBERT. .	PHILLIPS MILK OF MAGNESIA - AERS 1969 TO PRESENT
2013-8287	10/24/2013 11/22/2013	FDA/OFVM/CFSAN/OCD/EOS/	FRIEDMAN, ROBERT. .	TYSON, TGI FRIDAYS, GORTONS - CAERS 1969 TO PRESENT
2013-8288	10/24/2013 11/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	S. MICHAEL SHARP, PhD. REGULATORY CONSULTING LTD	POSSIS MEDICAL - PERMA PASS VASCULAR GRAFT K984183
2013-8289	10/24/2013 11/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	S. MICHAEL SHARP, Ph.D REGULATORY CONSULTING LTD	IMPRA EPTV VASCULAR GRAFT K791810
2013-8290	10/24/2013 11/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WILLIAM KIDDELL TEVA BRANDED PHARMACEUTICAL PRODUCTS	NASACORT ALLERGY (TRIAMCINOLONE ACETONIDE) NDA 20-468 S/035

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2013-8291	10/24/2013 11/22/2013	FDA/OFVM/CFSAN/OCD/EOS/	LAURA ANDERSON ARKEMA INC	FCN 874
2013-8292	10/24/2013 11/22/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	KIM HENDERSON SANOFI PASTEUR	NOVARTIS VACCINES & DIAGNOSTICS LTD, SPEKE LIVERPOOL, UK - 483
2013-8293	10/24/2013 11/22/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	KIM HENDERSON SANOFI PASTEUR	MEDIMMUNE, SPEKE LIVERPOOL, UK - 483
2013-8294	10/24/2013 11/22/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OGROP/ORACE-FO/PHI- DO/PHI-CB/	KIM HENDERSON SANOFI PASTEUR	MERCK & CO, WEST POINT, PA - 483
2013-8295	10/24/2013 11/22/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	KIM HENDERSON SANOFI PASTEUR	GLAXO SMITH KLINE, DRESDEN, GERMANY - 483
2013-8296	10/24/2013 11/22/2013	OC/ORACE/OCI/ OC/ORACE/OCI/	JACK GILLUM ASSOCIATED PRESS	ARMED RESPONSE TEAM, SPECIAL RESPONSE TEAM EMAILS, CONTRACTS, POLICIES, ETC
2013-8297	10/24/2013 11/22/2013	FDA/OFVM/CFSAN/OCD/EOS/	JOAN SORRENTINO FREEHILL HOGAN & MAHARR LLP	NSF SINGAPORE, SINGAPORE; PT KEMILAU BINTANG TIMUR, MAKASAR, SULAWESI SELTAN, INDONESIA - INVESTIGATIONS
2013-8298	10/24/2013 11/22/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DDM/	JOSEPH H. SAUNDERS SAUNDERS & WALKER PA	BIOMET - METAL ON METAL (MOM) PETITION 8/5/09
2013-8299	10/24/2013 11/22/2013	FDA/OC/OES/ FDA/OC/OES/DDM/ FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KIMBERLY LAMBERT ADAMS LEVIN PAPANTONIO ET AL	REBIF (INTERFERON BETA 1A) AERS, CORR, CMLPLNTS, INQUIRIES, ETC
2013-8300	10/24/2013 11/22/2013	FDA/OC/OES/ FDA/OC/OES/DDM/ FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	B. KRISTIAN W. RASMUSSEN CORY WATSON ET AL	EISAI INC - ACIPHEX (RABEPRAZOLE SODIUM) RECS

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2013-8301	10/24/2013 11/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PAMELA SHEPPARD TARO PHARMACEUTICALS USA INC	GALDERMA LABS LP MIRVASO (BRIMONIDINE TARTRATE) SBA, MEDICAL RVW, CHEMISTRY RVW
2013-8302	10/24/2013 11/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID M. HOFFMEISTER WILSON SOSINI GOODRICH & ROSATI	OTREXUP (METHOTREXATE) NDA 204-824 - APRVL RECS
2013-8303	10/24/2013 11/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	VINCENT 02A2314, DAMON	NDAS 2013 TO 2014
2013-8304	10/24/2013 11/22/2013	FDA/OC/OES/DDM/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	NINA G. SHAPIRSHTEYN ALEXANDER LAW GROUP LLP	ETHICON - PROXIMATE PPH PROCEDURE SET PPH03 APRVL, LBLG
2013-8305	10/24/2013 11/22/2013	FDA/OGROP/ORA/CE-FO/CIN- DO/CIN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	NINA G. SHAPIRSHTEYN ALEXANDER LAW GROUP LLP	ETHICON - PROXIMATE PPH PROCEDURE SET PPH03 MDRS, INVESTIGATIONS, LBLG
2013-8306	10/24/2013 11/22/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	BRETT PARK CONWAY HOMER & CHIN- CAPLAN PC	INDIVIDUAL RECS
2013-8307	10/24/2013 11/22/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	BRETT PARK CONWAY HOMER & CHIN- CAPLAN PC	INDIVIDUAL RECS
2013-8308	10/25/2013 11/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	MEDINVENTS NV, HASSELT, BELGIUM - 483, CO RESP, WARNING LTR, ETC 01/13
2013-8309	10/25/2013 11/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	RUBIMED AG, HERGISWILL, SWITZERLAND - EIR, CO RESP, CORR 01/13
2013-8310	10/25/2013 11/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION	TYTEX SLOVAKIA SRO, HUMENNE, SLOVAK REPUBLIC - EIR, CO RESP, CORR 01/13

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			SOURCE	
2013-8311	10/25/2013 11/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	KOOJOO TRADING CO, GMPO-CITY, GEYONGKI-DO, SOUTH KOREA - EIR, CO RESP, CORR 03/13
2013-8312	10/25/2013 11/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	KOOJOO TRADING CO, GMPO-CITY GEYONGKI-DO, SOUTH KOREA - 483, CO RESP, WARNING LTR, ETC 04/13
2013-8313	10/25/2013 11/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	GS MEDICAL PACKAGING INC, MISSISSAUGA, CANADA - 483, CO RESP, WARNING LTR, ETC 01/13
2013-8314	10/25/2013 11/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FEEL TECH, CHEONAN-SI, SOUTH KOREA - 483, CO RESP, WARNING LTR, ETC 11/12
2013-8315	10/25/2013 11/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	CARE CIAGNOSTIC GMBH, MOELLERSDORF, AUSTRIA - 483, CO RESP, WARNING LTR, ETC 12/12
2013-8316	10/25/2013 11/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	WYETH LEDERLE, CATANIA, ITALY - 483, CO RESP, WARNING LTR, ETC 07/12
2013-8317	10/25/2013 11/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	GRI MEDICAL & ELECTRONIC TECHNOLOGY CO LTD, JIAXING, ZHEJIANG, CHINA - 483, CO RESP, WARNING LTR, ETC 12/12
2013-8318	10/25/2013 11/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEN REID WASHINGTON INFORMATION SOURCE	CONTRACT PHARMACEUTICAL SERVICES OF AUSTRALIA, NORTH RYDE, AUSTRALIA - 483, CO RESP, WARNING LTR, ETC 10/12 TO 11/12
2013-8319	10/25/2013 11/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEN REID WASHINGTON INFORMATION SOURCE	EBEWE PHARMA, UNTERACH AM ATTRRSEE, AUSTRIA - 483, CO RESP, WARNING LTR, ETC 10/12
2013-8320	10/25/2013 11/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	GEXFIX SA, CAROUGE, SWITZERLAND - 483, CO RESP, WARNING LTR, ETC 01/13

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2013-8321	10/25/2013 11/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	GRI MEDICAL & ELECTRONIC TECHNOLOGY CO LTD, JIAXING, ZHEJIANG, CHINA - EIR, CO RESP, CORR 12/12
2013-8322	10/25/2013 11/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	CARE DIAGNOSTICA GMBH, MOELLERSDORF, AUSTRIA - EIR, CO RESP, CORR 12/12
2013-8323	10/25/2013 11/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	SAFECROSS FIRST AID, TORONTO, ONTARIO, CANADA - EIR, CO RESP CORR 01/13
2013-8324	10/25/2013 11/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FEEL TECH, CHEONAN-SI, SOUTH KOREA - EIR, CO RESP, CORR 11/12
2013-8325	10/25/2013 11/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	WEBER MEDICAL GMBH, LAUENFOERDE, GERMANY - EIR, CO RESP, CORR 01/13
2013-8326	10/25/2013 11/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	SUPEREX CANADA, TORONTO, ONTARIO, CANADA - EIR, CO RESP, CORR 01/13
2013-8327	10/25/2013 11/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEN REID WASHINGTON INFORMATION SOURCE	JUBILANT HOLLISTER STIER, KIRKLAND, QUEBEC, CANADA - 483, CO RESP, WARNING LTR, ETC 03/12
2013-8328	10/25/2013 11/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEN REID WASHINGTON INFORMATION SOURCE	P A BENJAMIN MANUFACTURING, KINGSTON, JAMAICA - 483, CO RESP, WARNING LTR, ETC 05/12
2013-8329	10/25/2013 11/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEN REID WASHINGTON INFORMATION SOURCE	P A BENJAMIN MANUFACTURING, KINGSTON, JAMAICA - EIR, CO RESP, CORR 05/12
2013-8330	10/25/2013 11/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	WONJIN MULSAN CO LTD, NAMDONG-GU, INCHEON, SOUTH KOREA - EIR, CO RESP, CORR 03/13
2013-8331	10/25/2013 11/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEN REID WASHINGTON INFORMATION SOURCE	HOSPIRA HEALTHCARE INDIA - SRIPERUMBURDUR, INDIA - EIR, CO RESP, CORR 10/12

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2013-8332	10/25/2013 11/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	ASAHI KASAI MEDICAL, OITA-SHI, JAPAN - 483, CO RESP, WARNING LTR, ETC 03/13
2013-8333	10/25/2013 11/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	RICK YARBOROUGH NBC4	POST-APRVL STUDY (PAS) 1 UNDER ESSURE SYS PHASE II & PIVOTAL TRIALS - 5 YR FOLLOW-UP
2013-8334	10/25/2013 11/25/2013	FDA/OO/OFBA/OAGS/	MICHAEL MORISY MUCKROCK NEWS	CONTRACTS HHSM500201100128G, ETC
2013-8335	10/25/2013 08/15/2014	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OMPT/CDRH/OCER/DFOI/	Doe J	MONTEFIORE MEDICAL CENTER, ALBERT EINSTEIN COLLEGE; YASHLVA UNIV - SCIENTIFIC EXPERIMENTATION MEDICAL RECS 1947 TO 1971
2013-8336	10/25/2013 11/25/2013	OC/ORA/OCI/ OC/ORA/OCI/	JACK GILLUM ASSOCIATED PRESS	SWAT SPECIAL RESPONSE TEAM, ARMED RESPONSE TEAM, SRT - EMAILS, CONTRACTS WITH PRIVATE SECURITY CO, DIGITAL COPIES OF ANY DATABASE SPREADSHEET, ETC PAST FIVE YRS
2013-8337	10/28/2013 11/26/2013	FDA/OC/OES/DFOI/	Narayan Lakshman The Hindu	RANBAXY LABORATORIES, RANBAXY USA - VARIOUS RECS
2013-8338	10/28/2013 11/26/2013	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORA/ OC/ORA/ FDA/OGROP/ORA/ORO/DIOP/	DANNY DONGMIN NA Danny Dongmin Na	JAPANESE SEAFOOD IMPORTED; INSPECTION RESULTS 01/14/2012 - 10/13/2013
2013-8339	10/28/2013 11/26/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Alexandria Johnson Northwestern University (Student)	CELEBREX - FOIA REQUESTS, APPROVALS
2013-8340	10/28/2013 11/26/2013	FDA/OFVM/CFSAN/OCD/EOS/	Kevin I. Goldberg Goldberg, Finnegan & Mester, LLC	MONSTER ENERGY DRINK, RED BULL, FIVE HOUR ENERGY ETC - AERS ETC 10/23/2012 - 10/13/2013
2013-8341	10/28/2013 11/26/2013	OC/ORA/OE/ OC/ORA/OE/	George Ball UNIVERSITY OF MINNESOTA	PRODUCT RECALL DATA
2013-8342	10/28/2013 11/26/2013	FDA/OC/OES/DFOI/	Kelsey Ott Medill School, Northwestern University	FOIA LOG 09/03/2013 - 11/14/2013
2013-8343	10/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Angie Fimalino	POST APPROVAL DATA - ESSURE 01/01/2002 - 10/01/2013

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	11/26/2013		Angie Fimalino	
2013-8344	10/28/2013 11/26/2013	FDA/OC/OES/DFOI/	Kimberly Streff Hinkhouse Williams Walsh	ZIMMER DUROM ACETABULAR CUP - RECS
2013-8345	10/28/2013 11/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Neel Tanna Yost Capital	AGILA - INSPECTIONS, APPROVAL RECS JAN 2013 TO PRESENT
2013-8346	10/28/2013 11/26/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	Fenella Cochrane Parnell Corporate Services US Inc	ANADA 200-310, ANADA 200-541 - SAMPE RESULTS
2013-8347	10/28/2013 11/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tommy Noh Wilson Sonsini Goodrich & Rosati	MECHLORETHAMINE HYDROCHLORIDE - APPROVAL HISTORY
2013-8348	10/28/2013 11/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Biren Gondaliya cataway inc	NDA 019111; ANDA 091632
2013-8349	10/28/2013 11/26/2013	FDA/OC/OES/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OPP/OP/ FDA/OC/OL/	Amanda Nordstrom PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS	COSMETICS, COSMETIC INGREDIENTS REGULATION - INTERNAL AND EXTERNAL CORR JAN 2010 TO PRESENT
2013-8350	10/28/2013 11/26/2013	OC/ORA/ OC/ORA/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	R. Courtney Hughes Hughes Law Firm	MAIN STREET FAMILY PHARMACY - TEST RESULTS, REPORTS ETC Date Range: 12/01/2012 - 10/15/2013
2013-8351	10/28/2013 11/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	David Farias Donna B Michelson PA	MCNEIL CONSUMER PRODUCTS CO - WARNING LETTERS 1990-1996

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		OC/ORAI/ OC/ORAI/		
2013-8352	10/28/2013 11/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Randy Gonzales CardiAQ Valve Technologies	Edwards Lifesciences: Filing to FDA for Sapien Transcatheter Valve P1 10021
2013-8353	10/28/2013 11/26/2013	FDA/OC/OES/DFOI/	Alberto G. Rossi University of Maryland - College Park	FOIA REQUEST LOG
2013-8354	10/28/2013 11/26/2013	FDA/OFVM/CFSAN/OCD/EOS/	Christopher Go Velocimedia, Inc	FOOD FACILITY REGISTRATIONS 01/01/2012 - 10/16/2013
2013-8355	10/28/2013 11/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Juliana Wrexler BIOPHARM INSIGHT	ICLUSIG - AERS
2013-8356	10/28/2013 11/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca Ryan Martha Jefferson Hospital	CHLOROTHIAZIDE - APPROVAL RESEARCH RECS
2013-8357	10/28/2013 11/26/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Tyler R. Smith Knox Ricksen LLP	ORTHOPEDIC ALLIANCE, LLC, MARIETTA, CA - INSPECTION REPORT, 510K, PARTNERSHIP RECS ETC
2013-8358	10/28/2013 11/26/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Tyler R. Smith Knox Ricksen LLP	ORTHOPEDIC ALLIANCE, MARIETTA, GA - INSPECTION REPORT, 510K, PARTNERSHIP ETC
2013-8359	10/28/2013 11/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lauren Farruggia Hyman, Phelps & McNamara P.C.	NASACORT ALLERGY 24 HOUR - APPROVED OTC LABELING FOR S 035
2013-8360	10/28/2013 11/26/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	John T. Sullivan McElroy Deutsch Mulvaney & Carpenter	PLAINVIEW COOPERATIVE RECALL RECS 01/01/2009 - 01/01/2011
2013-8361	10/28/2013 11/26/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	John T. Sullivan McElroy Deutsch Mulvaney & Carpenter	TRANS-PACKER SERVICES, NEW YORK, NY - NOTICES, INSPECTION REPORTS, TEST RESULTS 01/01/2007 - 01/01/2010
2013-8362	10/28/2013 11/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Laura L Boll Medovations Inc.	K122417

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2013-8363	10/28/2013 11/26/2013	FDA/OC/OES/DDM/	Robin Myers Primeau MURRAY LAW FIRM	JOINT MEETING OF ENDO AND METABOLIC DRUGS AC, DRUG SAFETY MANAGEMENT AC - TRANSCRIPT 7/30/07, QUESTIONS, ROSTER ETC (CERTIFIED)
2013-8364	10/28/2013 11/26/2013	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	TOBACCO PRODUCTS DETERMINED NSE 9/26/2013 - CORR, DOCUMENTATION, SUMMARIES
2013-8365	10/28/2013 11/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Brian M. Overstreet ADVERSEEVENTS INC	6887734, 6887753, 6887755 - CASE REPORTS
2013-8366	10/28/2013 11/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	REVIEWS, COMMENTS, CONSULTATIONS BY OMPI OR DBRUP RE MEDICATION GUIDE FOR IBANDRONATE SODIUM 2010-2012
2013-8367	10/28/2013 11/26/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	510K RELEASED SEPTEMBER 2013
2013-8368	10/28/2013 11/26/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Jack Encarnacao BOSTON HERALD	GENZYME - 483 01/01/2009 - 10/17/2013
2013-8369	10/28/2013 11/26/2013	FDA/OFVM/CFSAN/OCD/EOS/	Mitchell A. Cheeseman, Ph.D. Cheeseman, Mitch	FCN 993
2013-8370	10/28/2013 11/26/2013	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2013-7442
2013-8371	10/28/2013 11/26/2013	FDA/OFVM/CFSAN/OCD/EOS/	Mitchell A. Cheeseman, Ph.D. Cheeseman, Mitch	FCN 1247
2013-8372	10/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Sheila Ramerman	K111026

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	11/26/2013		SJR Associates	
2013-8373	10/28/2013 11/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K923898
2013-8374	10/28/2013 11/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K994152
2013-8375	10/28/2013 11/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K000634
2013-8376	10/28/2013 11/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K934166
2013-8377	10/28/2013 11/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Joanne Conde XODUS MEDICAL	K132224
2013-8378	10/28/2013 11/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anne Daub VISIUM ASSET MANAGEMENT LLC	KYPROLIS - AER
2013-8379	10/28/2013 11/26/2013	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/ FDA/OMPT/CDRH/OCER/DFOI/	CHRISTINE E SANCHEZ Needle & Ellenberg, P.A.	HOLLYWOOD DIAGNOSTICS CENTER INC, HOLLYWOOD, FL - RECS 1/1/94 TO 10/4/13
2013-8380	10/28/2013 11/26/2013	FDA/OC/OES/DFOI/	JOANNA JESPERSON GLEASON FLYNN EMIG & FOGLEMAN	INDIVIDUAL RECS
2013-8381	10/28/2013 11/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	MERIDIAN AG, THUN, SWITZERLAND - EIR, RESP, CORR 6/12
2013-8382	10/28/2013 11/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	OSACHI CO LTD, NAGANO, JAPAN - EIR, RESP, CORR 8/12
2013-8383	10/28/2013 11/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEN REID WASHINGTON INFORMATION SOURCE	TAIWAN THREE MAST PHARMACEUTICAL CO, TAINAN CITY, TAIWAN - EIR, RESP, CORR 4/12
2013-8384	10/28/2013 11/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEN REID WASHINGTON INFORMATION SOURCE	BEANNE CHEMICAL CO, TAICHUNG CITY, TAIWAN - EIR, RESP, CORR 5/12

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-8385	10/28/2013 11/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	CENTRAL SURGICAL CO LTD, LONDON, ENGLAND, UK - EIR, RESP, CORR 8/12
2013-8386	10/28/2013 11/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	AC COSSOR & SON SURGICAL LTD, HARLOW, UK - 483, CO RESP, WARNING LTR, ETC 8/12
2013-8387	10/28/2013 11/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	AC COSSOR & SON SURGICAL LTD, HARLOW, UK - EIR, RESP, CORR 8/12
2013-8388	10/28/2013 11/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KEN REID WASHINGTON INFORMATION SOURCE	PEKING MEDICINE MANUFACTORY, TSUEN WAN, HONG KONG - 483, CO RESP, WARNING LTR, ETC 4/12 TO 5/12
2013-8389	10/28/2013 11/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KEN REID WASHINGTON INFORMATION SOURCE	A NELSON & CO LTD, LONDON, UK - 483, CO RESP, WARNING LTR, ETC 11/11
2013-8390	10/28/2013 11/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	LEISEGANG FEINMECHANIK-OPTIK, BERLIN, GERMANY - 483, CO RESP, WARNING LTR, ETC 4/12
2013-8391	10/28/2013 11/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	DMC MEDICAL TECHNOLOGY & MFG, HEYUAN CITY, CHINA - 483, CO RESP, WARNING LTR, ETC 4/12
2013-8392	10/28/2013 11/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	PRINCE MEDICAL, ERCUIS, FRANCE - 483, CO RESP, WARNING LTR, ETC 3/12
2013-8393	10/28/2013 11/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	INTEGRA NEUROSCIENCES LTD, HAMPSHIRE, ENGLAND, UK - 483, CO RESP, WARNING LTR, ETC 6/12
2013-8394	10/28/2013 11/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	TYTEX SLOVAKIA SRO, HUMENNE, SLOVAK REPUBLIC - 483, CO RESP, WARNING LTR, ETC 1/13
2013-8395	10/28/2013 11/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	NATUS EUROPE, PLANEGG, GERMANY -483, CO RESP, WARNING LTR, ETC 11/12

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2013-8396	10/28/2013 11/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEN REID WASHINGTON INFORMATION SOURCE	SHANGHAI HUHUI DAILY USE CHEMICAL PRODUCTS, SHANHAI, CHINA - 483, CO RESP, WARNING LTR, ETC 2/12
2013-8397	10/28/2013 11/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	NATUS EUROPE, PLANEGG, GERMANY - EIR, RESP, CORR 11/12
2013-8398	10/28/2013 11/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEN REID WASHINGTON INFORMATION SOURCE	BOEHRINGER INGELHEIM PHARMACEUTICALS, INGELHEIM AM RHEIN, GERMANY - EIR, RESP, CORR 11/12
2013-8399	10/28/2013 11/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	RUBIMED AG, HERGISWILL, SWITZERLAND - 483, CO RESP, WARNING LTR, ETC 1/13
2013-8400	10/28/2013 11/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	SUPEREX CANADA, TORONTO, ONTARIO, CANADA - 483, CO RESP, WARNING LTR, ETC 1/13
2013-8401	10/28/2013 11/26/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/ OC/ORA/ OC/ORA/	KEN REID WASHINGTON INFORMATION SOURCE	EMAIL ADDRESSES OF PHARMACEUTICAL AND MEDICAL DVC MFR QUALITY AND REGULATORY PERSONNEL
2013-8402	10/28/2013 11/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	LUCKY BOARD MANUFACTURING, PANCHIAO, TAIPEI, TAIWAN - 483, CO RESP, WARNING LTR, ETC 3/13
2013-8403	10/28/2013 11/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	INTEGRA NEUROSCIENCES LTD, HAMPSHIRE, ENGLAND, UK - EIR, RESP, CORR 6/12
2013-8404	10/28/2013 11/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEN REID WASHINGTON INFORMATION SOURCE	HAMELN PHARMS, HAMELN, GERMANY - EIR, RESP, CORR 6/12

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-8405	10/28/2013 11/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	LUCKY BOARD MANUFACTURING, PANCHIAO, TAIPEI, TAIWAN - EIR, RESP, CORR 3/13
2013-8406	10/28/2013 11/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	MEDINVENTS NV, HASSELT, BELGIUM - EIR, RESP,CORR 1/13
2013-8407	10/28/2013 11/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARIE-CLAUDE MALBOEUF LA PRESSE	MEDWATCH COUNTERFEIT DRUG RPTS
2013-8408	10/29/2013 11/27/2013	FDA/OC/OES/DDM/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jerry Hu Jerry Hu	VASCEPA - RECS RE ADVISORY COMMITTEE 10/31/2012 - 10/31/2013
2013-8409	10/29/2013 11/27/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Blake Goodner BRIDGER BIOMED INC	MALLINCKRODT PLC, ST LOUIS, MO - 483, WARNING LETTERS, RESPONSES 01/03/2012 - 10/17/2013
2013-8410	10/29/2013 11/27/2013	FDA/OC/OES/DDM/	Robin Myers Primeau MURRAY LAW FIRM	ENDO AND METABOLIC DRUGS AC - TRANSCRIPT 03/01/1999 - 05/01/1999 (CERTIFIED)
2013-8411	10/29/2013 11/27/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K022465
2013-8412	10/29/2013 11/27/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Natalie Morrison BIOPHARM INSIGHT	GLAXOSMITHKLINE PANAMA - INSPECTION RECS
2013-8413	10/29/2013 11/27/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 20468 S 35
2013-8414	10/29/2013 11/27/2013	FDA/OC/OES/DDM/	Robin Myers Primeau MURRAY LAW FIRM	FDA briefing information, Avandia Tablets, for the July 13-14, 2010 Joint meeting of the Endo and Metabolic Drugs Advisory Committee and Drug Safety and Risk Management Advisory Committee" meeting; transcript of the July 13, 2010 joint meeting of the Endo and Metabolic Drugs Advisory Committee and Drug

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				Safety and Risk Management Advisory Committee meeting; summary of the minutes, meeting roster, agenda, slides from any and all presenters, and questions to the committees from the July 13-14, 2010 meeting; and the briefing document on Cardiovascular Safety of Rosiglitazone provided by GlaxoSmithKline for that joint meeting.
2013-8415	10/29/2013 11/27/2013	OC/CVM/OCD/	Dr W Robert Dodemaide ECO LLC doing business as ECO Animal Health	1) Method for assaying Tiamulin in Type C Feed; 2) Method for assaying Lincomycin in Type C Feed
2013-8416	10/29/2013 11/27/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Blake Goodner BRIDGER BIOMED INC	MINDRAY - 483, WARNING LETTERS, RESPONSES 01/03/2012 - 10/11/2013
2013-8417	10/29/2013 11/27/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Monica Reckless Salix Pharmaceuticals, Inc.	NDA 17351
2013-8418	10/29/2013 11/27/2013	FDA/OC/OES/DDM/	Lisa Mandrusiak Oblon, Spivak, McClelland, Maier & Neustadt, L.L.P.	78N-0038
2013-8419	10/29/2013 11/27/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Blake Goodner BRIDGER BIOMED INC	ALLERGAN, IRELAND - 483, WARNING LETTER, RESPONSES 01/03/2012 - 10/17/2013
2013-8420	10/29/2013 11/27/2013	FDA/OC/OES/DDM/	Robin Myers Primeau MURRAY LAW FIRM	The FDA briefing document submitted by the Division of Metabolism and Endocrine Products and Office of Surveillance and Epidemiology for the July 30, 2007 joint meeting of the Endo and Metabolic Drugs Advisory Committee and Drug Safety Management committee meeting; and the FDA briefing document entitled "Cardiovascular Safety of Rosiglitazone" provided by GlaxoSmithKline for that meeting (certified)
2013-8421	10/29/2013 11/27/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Ellen Mae Cabana Solta Medical, Inc.	K082609, K123237, K120257

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2013-8422	10/29/2013 11/27/2013	FDA/OGROP/ORR/SE-FO/NOL-DO/NOL-CB/	Blake Goodner BRIDGER BIOMED INC	WRIGHT MEIDCAL, ARLINGTON, TN - 483, WARNING LETTER, RESPONSES 01/03/2012 - 10/17/2013
2013-8423	10/29/2013 11/27/2013	FDA/OGROP/ORR/PA-FO/SAN-DO/SAN-CB/	Blake Goodner BRIDGER BIOMED INC	INTUITIVE SURGICAL, SUNNYVALE, CA - 483, WARNING LETTER, RESPONSES 01/03/2012 - 10/17/2013
2013-8424	10/29/2013 11/27/2013	FDA/OFVM/CFSAN/OCD/EOS/	Joshua H. Eggnatz Eggnatz, Joshua	REDLINE, REDLINE ENERGY SUPPLEMENT, REDLINE ENERGY DRINK ETC - CORR, EMAIL, COMPLAINTS ETC 01/01/2003 - 10/17/2013
2013-8425	10/29/2013 11/27/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Blake Goodner BRIDGER BIOMED INC	RESMED, AUSTRALIA - 483, WARNING LETTER, RESPONSES 01/03/2012 - 10/17/2013
2013-8426	10/29/2013 11/27/2013	FDA/OGROP/ORR/CE-FO/NWJ-DO/NWJ-CB/	Gregory Gogo Gregory Gogo, Esq.	CISPHARMA, INC, CRANBURY, NJ - 483 12/26/2010 - 01/31/2011
2013-8427	10/29/2013 11/27/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	LAERDAL MEDICAL, CHINA - EIR JUNE 2013
2013-8428	10/29/2013 11/27/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	LAERDAL MEDICAL, NORWAY - EIR AUGUST 2013
2013-8429	10/29/2013 11/27/2013	FDA/OMPT/CDRH/OCER/DFOI/	Lauren Sweeney WKMG-TV	ESSURE SYSTEM - ANNUAL REPORTS, 5 YEAR FOLLOW UP, POST APPROVAL STUDY
2013-8430	10/29/2013 12/17/2013	FDA/OFVM/CFSAN/OCD/EOS/	Jim Lukanich ChemCal, Inc.	FCN 31, FAP 7A4539
2013-8431	10/29/2013 11/27/2013	FDA/OMPT/CDRH/OCER/DFOI/	EndoLok 510(k) submission by Syntheon LLC Artann Laboratories	K080317
2013-8432	10/29/2013 11/27/2013	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	SIMPLY THICK - CAERS
2013-8433	10/29/2013 11/27/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Monty L. Patterson Monty L. Patterson	MIFEPREX - AERS

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-8434	10/29/2013 11/27/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Edward Brown Edward Brown	PROPECIA - AERS
2013-8435	10/29/2013 11/27/2013	FDA/OMPT/CDRH/OCER/DFOI/	Michael Magnani Saranas, Inc.	K050395, K052319, K080825 ETC
2013-8436	10/29/2013 12/05/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OGROP/ORAP/FO/SEA- DO/SEA-CB/	Milton Dtsopoulos Datsopoulos, MacDonald & Lind, P.C.	BIOLIFE PLASMA SERVICES, MISSOULA, MT - CORR, CASE REPORTS, INSPECTION RECS 01/01/2005 - 10/18/2013
2013-8437	10/29/2013 11/27/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Monty L. Patterson Abortion Pill Risks	MIFEPREX - AERS
2013-8438	10/29/2013 11/27/2013	FDA/OFVM/CFSAN/OCD/EOS/	Tara Conley INTERTEK CANTOX	Brookdale Dental Center of NewYork University. 1973. Letter from Dr. JR Stern to Dr. B La Du summarizing the results of testing acute testing with forms of Malic Acid. Food and Agriculture Organization of the United Nations/World Health Organization (FAO/WHO) etc
2013-8439	10/29/2013 11/27/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jessica Heck UNIVERSITY OF WISCONSIN HOSPITAL AND CLINICS	RITUXIMAB, BENDAMUSTINE, ALLOPURINOL - MEDWATCH SAFETY SUMMARY
2013-8440	10/29/2013 11/27/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jon Kluff Atika Capital	GATTEX - AERS
2013-8441	10/29/2013 11/27/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kenneth A Gandy Gandy, Kenneth A	K061880
2013-8442	10/29/2013 11/27/2013	FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA REQUEST LOG 10/14/2013 - 10/18/2013
2013-8443	10/29/2013 11/27/2013	FDA/OO/OFBA/OAGS/	Dean Ledbetter New Paradigm Management	RESCUE SOCIAL CHANGE - CONTRACT, RFP 11/19/2012 - 11/21/2012
2013-8444	10/29/2013	FDA/OMPT/CDER/GRP/DIDP/	shin kang	GILENYA, AUBAGIO, AVONEX - AERS

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	11/27/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WELLS FARGO	
2013-8445	10/29/2013 11/27/2013	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2013-6302
2013-8446	10/29/2013 11/27/2013	OC/ORR/ORM/ OC/ORR/ORM/	David Mangione Govzilla, Inc.	LIST OF 483, EIR, INSPECTIONS 09/16/2013 - 10/19/2013
2013-8447	10/29/2013 11/27/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	UMER RAFFAT ISI GROUP	COPAXONE - APPROVAL REVIEW RECS
2013-8448	10/29/2013 11/27/2013	OC/ORR/ORM/ OC/ORR/ORM/	Mark Prinz Registrar Corp	LIST OF FOREIGN FOOD FACILITIES THAT RECEIVED 483 07/01/2013 - 09/30/2013
2013-8449	10/29/2013 11/27/2013	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2013-6055
2013-8450	10/29/2013 11/27/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jerry Hu Jerry Hu	AMARIN CORP - DAY 74 LETTER RE ANCHOR INDICATION FOR VASCEPA
2013-8451	10/29/2013 11/27/2013	FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA REQUEST LOG 10/21/2013 - 10/25/2013
2013-8452	10/29/2013 11/27/2013	FDA/OC/OES/DFOI/	Prakash Behrani Platinum Systems, Inc.	HHSF223200950034P - PROPOSAL
2013-8453	10/29/2013 11/27/2013	FDA/OC/OES/DFOI/ FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	Thomas Smith BLOOMBERG	BIOGEN - INSPECTION RECS 06/01/2013 - 10/28/2013
2013-8454	10/29/2013 11/27/2013	OC/CVM/OCD/ OC/ORR/ OC/ORR/	CORNELIUS FROLIK DAYTON DAILY NEWS	JERKY PET TREATS - CMLPNTS, AER
2013-8455	10/29/2013 11/27/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MALDONADO 11R0696, MANUEL	TATTOO WRECKING BALM - AER; BETTER BUSINESS BUREAU ADDRESSES

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/		
2013-8456	10/29/2013 11/27/2013	FDA/OMPT/CDRH/OCER/DFOI/	MICHELE L. BUENAFE MORGAN LEWIS COUNSELORS AT LAW	SIEMENS MEDICAL SOLUTIONS USA INC - MODULAR ANGIOGRAPHIC SYS K123529
2013-8457	10/29/2013 11/27/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	TYLER R. SMITH Knox Ricksen LLP	ORTHOPAEDIC ALLIANCE LLC - U2 TOTAL KNEE SYS K082424 WARNING LTR, ETC
2013-8458	10/29/2013 11/27/2013	FDA/OMPT/CDRH/OCER/DFOI/	GIORDANO, ANN	SORIN GROUP CANADA INC - MITROFLOW AORTIC PERICARDIAL HEART VALVES - RECALL 2/05 TO PRESENT
2013-8459	10/29/2013 11/27/2013	OC/CVM/OCD/	KRISTI O. SMEDLEY, Ph.D. WASHINGTON INFORMATION SOURCE	FLY LARVA FOR ANIMAL & AQUACULTURE FEED - CORR
2013-8460	10/29/2013 11/27/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PAUL P. GAFFNEY CURRAN FIRM	PLAVIX (CLOPIDOGREL BISULFATE) APRVL
2013-8461	10/29/2013 11/27/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	OFLAXACIN, AMOXICILLIN, ZITHROMAX - MEDWATCH RPTS
2013-8462	10/29/2013 11/27/2013	FDA/OGROP/ORA/CE-FO/BLT- DO/BLT-CB/	WILLIAM M. TIANO TIANO O'DELL	PANERA BREAD, BARBOURSVILLE, WV; MARSHALL UNIV CAFETERIA, HUNTINGTON, WV - FOOD POISONING 4/22/12 TO PRESENT
2013-8463	10/29/2013 11/27/2013	FDA/OC/OES/DFOI/	WOOD, ROBERT .	HAIR RESTORATION
2013-8464	10/29/2013 11/27/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JAMES R. JOHNSON HOGAN LOVELLS LLP	TRIAMCINOLONE HEXACETONIDE - APRVL
2013-8465	10/29/2013 11/27/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JAMES R. JOHNSON HOGAN LOVELLS US LLP	TRIAMCINOLONE - APRVL
2013-8466	10/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	DAVE ELIAS	ESSURE PERMANENT BRITH CONTROL - CMLNPTS

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	11/27/2013	FDA/OMPT/CDRH/OCER/DFOI/	NBC 2 WBBH	
2013-8467	10/29/2013 11/27/2013	FDA/OMPT/CDRH/OCER/DFOI/	BEN OMAR ARRINGTON PROCENT TECHNOLOGIES LLC	PIKE LBAS INC - VASOSOL ORGAN PERFUSION SOLUTION MEDTRONIC PORTABLE BYPASS SYS IDE GO30132/S010
2013-8468	10/29/2013 11/27/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PAM WHITFIELD HOTZE HEALTH AND WELLNESS CENTER	PROTOCOL FOR ALA (ALPHA LIPOIC ACID)
2013-8469	10/29/2013 11/27/2013	FDA/OMPT/CDRH/OCER/DFOI/	DEBORAH A. ROWE SUTTER LAW FIRM	FRESENIUS MEDICAL CARE NORTH AMERICA - NATURALYTE GRANUFLO ACID CONCENTRATE & LIQUID ACID CONCENTRATE
2013-8470	10/29/2013 11/27/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	BRETT PARK CONWAY HOMER & CHIN- CAPLAN PC	INDIVIDUAL RECS
2013-8471	10/29/2013 11/27/2013	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	INDIVIDUAL RECS
2013-8472	10/29/2013 11/27/2013	FDA/OC/OES/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OCC/	JAYDEE HANSON SMITH, EUGENE .	NANOTECHNOLOGY DERIVED MATERIALS USED IN FOOD - DOCS SINCE 2003
2013-8473	10/29/2013 11/27/2013	FDA/OC/OES/DFOI/	SUSAN M. SUTTER Elsevier Business Intelligence	2012-2342 RECONSIDERATION
2013-8474	10/29/2013 11/27/2013	FDA/OMPT/CDRH/OCER/DFOI/	DEBORAH A. ROWE SUTTER LAW FIRM	FRESENIUS MEDICAL CARE NORTH AMERICA - NATURALYTE LIQUID ACID CONCENTRATE PRODUCTS SENT TO VW
2013-8475	10/29/2013 11/27/2013	FDA/OMPT/CDRH/OCER/DFOI/	DEBORAH A. ROWE SUTTER LAW FIRM	FRESENIUS MEDICAL CARE NORTH AMERICA - NATURLYTE GRANUFLO ACID CONCENTRATE - PRODUCTS SENT TO VW
2013-8476	10/29/2013 11/27/2013	FDA/OGROP/ORO/PA-FO/SEA- DO/SEA-CB/	JOE CADOTTE TIMES NEWS	CHOBANI YOGART, TWIN FALLS ID - INSP 9/5/13
2013-8477	10/29/2013 11/27/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SIDNEY M. WOLFE, MD PUBLIC CITIZEN	CV OF DR LYNN DRAKE DERMATOLOGIC & OPHTHAMOLOGIC ADVISORY COMMITTEE - UNREDACTED
2013-8478	10/29/2013 11/27/2013	FDA/OC/OES/DFOI/	CAITLIN HOWELL IOVATE HEALTH SCIENCES INTERNATIONAL INC	OXY ELITE - AER

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2013-8479	10/29/2013 11/27/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BIREN GONDALIYA cataway inc	PENNWALT - TUSSIONEX NDA 019111; TRIS PHARMA INC - HYDROCODONE POLISIREX & CHLORPHENIRAMINE POLISTIREX ANDA 091632 SBA
2013-8480	10/29/2013 11/27/2013	FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECS
2013-8481	10/29/2013 11/27/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANTON AMANN, PhD ROXANE LABORATORIES INC	SALIX PHARMACEUTICALS INC - XIFAXAN RIFAXIMIN NDA 021361 TOXICITY
2013-8482	10/30/2013 11/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JoAnna Riggs Riggs, JoAnna	NUMBER OF PEOPLE FURLOUGHED FROM CDER ORP DIVISIONS
2013-8483	10/30/2013 11/29/2013	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	Dillon Cho Cho, Dillon	YS HEALTH CORP - WARNING LETTER FOLLOW UP 12/01/2012 - 10/18/2013
2013-8484	10/30/2013 11/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Paul Blackburn Cubist Pharmaceuticals	PRA INTERNATIONAL, NETHERLANDS - EIR, 483, RESPONSE 1/29/09
2013-8485	10/30/2013 11/29/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	John Walsh James Alexander Corporation	CORCO CHEMICAL CO, FAIRLESS HILLS, PA - EIR, 483, RECALL 11/01/2009 - 10/21/2013
2013-8486	10/30/2013 11/29/2013	OC/ORACE/ORM/ OC/ORACE/ORM/	Mark Prinz Registrar Corp	FOREIGN FOOD FACILITIES THAT RECEIVED EIR 10/1/11 TO 12/31/12
2013-8487	10/30/2013 11/29/2013	FDA/OC/OES/DFOI/	Ketaki Gokhale BLOOMBERG NEWS	RANBAXY - 483 10/21/2011 - 10/21/2013
2013-8488	10/30/2013 11/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Summary Basis of Approval Appco Pharmaceuticals Corporation	NDA 018063
2013-8489	10/30/2013 11/29/2013	OC/ORACE/OCI/ OC/ORACE/OCI/	Doe J	INDIVIDUAL RECS
2013-8490	10/30/2013	FDA/OGROP/ORACE-FO/CIN-	John Walsh	EQUISTAR CHEMICALS LP, CINCINNATI, OH - EIR, 483,

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	11/29/2013	DO/CIN-CB/	James Alexander Corporation	RECALLS 11/01/2009 - 10/21/2013
2013-8491	10/30/2013 11/29/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	John Walsh James Alexander Corporation	ARKEMA, BLOOMING PRAIRIE, MN - EIR, 483, RECALL
2013-8492	10/30/2013 11/29/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Oren Milgram Novalere FP, Inc.	NDA 020468 S-035
2013-8493	10/30/2013 11/29/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Ilan Landesman Biop Medical	K042894, K033783
2013-8494	10/30/2013 11/29/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jeanna Wheeler Seattle Institute for Biomedical and Clinical Research	NCT00838890, NCT00886782 - FOIA STATEMENT SUMMARIES
2013-8495	10/30/2013 11/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	Thomas Hirte Boston Scientific Endoscopy	K111495
2013-8496	10/30/2013 11/29/2013	FDA/OC/OES/DFOI/	T. Christian Miller PROPUBLICA	2006-14446
2013-8497	10/30/2013 11/29/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Rachel Johnson FOI Services, Inc.	OSIRIS, COLUMBIA, MD - EIR, 483 1/1/13 TO PRESENT
2013-8498	10/30/2013 11/29/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Rachel Johnson FOI Services, Inc.	OSIRIS, COLUMBIA, MD - INVESTIGATOR DIARIES 1/1/13
2013-8499	10/30/2013 11/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	Mike Wolford, Mike	K112671
2013-8500	10/30/2013 11/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	Mike Wolford, Mike	K112671
2013-8501	10/30/2013 11/29/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jared Levine Harvard Extension School	NDA 020121 - APPROVAL RECS, PACKAGE INSERT, CARTON, ETC
2013-8502	10/30/2013 11/29/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Michael Rabin Advanced Healthcare Technologies	CAPILLUS LLC, MIAMI, FL - 483 05/16/2013 - 05/16/2013
2013-8503	10/30/2013 11/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	Michael Johnson Michael Johnson (CR BARD)	K120440

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2013-8504	10/30/2013 11/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kristofer Halvorson Kristofer Halvorson	K122520
2013-8505	10/30/2013 11/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Marc Elia BRIDGER CAPITAL LLC	ADCENTRIS - AERS
2013-8506	10/30/2013 11/29/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Wendy T. Crow Wesley Medical Center	INDIVIDUAL RECS
2013-8507	10/30/2013 11/29/2013	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	XYREM - FOIA REQUESTS
2013-8508	10/30/2013 11/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joseph Sum FIRST MANHATTAN CO	XTANDI - AERS
2013-8509	10/30/2013 11/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	DRUG SAFETY OVERSIGHT BOARD - MEETING MINUTES
2013-8510	10/30/2013 11/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jill Clark STRYKER SUSTAINABILITY SOLUTIONS	K123444
2013-8511	10/30/2013 11/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joshua Malamud Hyman, Phelps & McNamara P.C.	OTREXUP - SBA
2013-8512	10/30/2013 11/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GINGER ALLEN KTVT-TV	KRATOM - AERS
2013-8513	10/30/2013 11/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nathaniel August Mangrove Partners	OMONTYS - AERS

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2013-8514	10/30/2013 12/05/2013	FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/ OC/ORO/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORO/ OC/ORO/	JoNel Aleccia, health reporter MSNBC.COM	INTENTIONAL ADULTERATION EMAILS 07/01/2012 - 10/22/2013
2013-8515	10/30/2013 11/29/2013	FDA/OGROP/ORO/PA-FO/SEA-DO/SEA-CB/	Erin K Individual Erin K	METAGENICS - WARNING LETTER RESPONSE 08/13/2013 - 10/31/2013
2013-8516	10/30/2013 11/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 22496
2013-8517	10/30/2013 11/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	Lihi Liviatan Medi-tate Ltd.	K130651
2013-8518	10/30/2013 11/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	Karen L. Richards Singulex, Inc.	K111452
2013-8519	10/30/2013 11/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	Nancy Skocypec B. Braun Medical Inc.	K130857 - REVIEWER NOTES
2013-8520	10/30/2013 11/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Damon Daulerio Neos Therapeutics, Inc.	ANDA 077302
2013-8521	10/30/2013 11/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jochen Neuhaus Mint Medical GmbH	K111642
2013-8522	10/30/2013 11/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	ROBERT KING FDANEWS	CSO SRI, SCANDICCI, ITALY; GN RESOUND CHINA, XIAMEN, CHINA; PLEXUS ELECTRONCI ASSEMBLY, BAYAN LEPAS, MALAYSIA, ETC - 483S 9/1-30/13
2013-8523	10/30/2013 11/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ROBERT KING FDA NEWS	NOVO NARDISA A/S, BAGSVAERD, DENMARK; SHANGHAI HENGRUI PHARMS, SHANGHAI, CHINA; USV LTD, DABHEL,

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		DAMAN, INDIA, ETC - 483S 9/1-30/13
2013-8524	10/30/2013 11/29/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	ROBERT KING FDA NEWS	THE COMPOUNDING SHOP INC, ST PETERSBURG, FL; LEX INC, MEDLEY, FL; BARO-THERAPIES INC, MIRAMAR BEACH, FL, ETC - 483S 9/1-30/13
2013-8525	10/30/2013 11/29/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	ROBERT KING FDA NEWS	OXUS AMERICA INC, ROCHESTER HILLS, MI - 483S 9/1-30/13
2013-8526	10/30/2013 11/29/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	ROBERT KING FDANEWS	CONMED ELECTROSURGERY, CENTENNIAL, CO - 483S 9/1-30/13
2013-8527	10/30/2013 11/29/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	ROBERT KING FDA NEWS	SPECIALTY COMPOUNDING LLC, CEDAR PARK, TX; KIMBERLY CLARK CORPORATION SAN ANTONIO OPERATIONS, SAN ANTONIO, TX; CHASE MEDICAL, RICHARDSON, TX - 483 9/1-30/13
2013-8528	10/30/2013 11/29/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	ROBERT KING FDA NEWS	SALITILLO CORP, MILLERSBURG, OH; LUCERO MEDICAL LLC, INDEPENDENCE, OH - 483S 9/1-30/13
2013-8529	10/30/2013 11/29/2013	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	ROBERT KING FDA NEWS	PHARMACEUTICS INTERNATIONAL INC, COCKEYSVILLE, MD; MERCK SHARP & DOHME CORP, (SUBSIDIARY OF MERK & CO INC), ELKTON, VA; TERUMO MEDICAL CORP, ELKTON, MD, ETC - 483S 9/1-30/13
2013-8530	10/30/2013 11/29/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	ROBERT KING FDA NEWS	EISAI INC, RESEARCH TRIANGLE PARK, NC; DEB USA INC, STANLEY, NC; HYPERBRANCH MEDICAL TECHNOLOGY INC, DURHAM, NC - 483S 9/1-30/13
2013-8531	10/30/2013 11/29/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	ELENA HOWELL HOGAN LOVELLS US LLP	CASTLE CHEESE INC, SLIPPERY ROCK, PA - EIRS, 483S, CORR 11/14/12-12/11/12
2013-8532	10/30/2013 11/29/2013	FDA/OC/OES/DFOI/	ELENA HOWELL HOGAN LOVELLS US LLP	2013-7748
2013-8533	10/30/2013 11/29/2013	FDA/OC/OES/DFOI/	ELENA HOWELL HOGAN LOVELLS US LLP	2013-3989
2013-8534	10/30/2013 11/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	STEPHANIE FULLARD POREX CORP	BAXTER HEALTHCARE CORP - DVC MASTER FILE (MAF) 1107 (VOL 1,2,4 (PARTS A, B, C) PMA LTR 2001
2013-8535	10/30/2013 11/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	Garcia, Michelle	MDR 2951250-2013-0017
2013-8536	10/30/2013 11/29/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	ANGELINI LABOPHARM LIMITED PARTNERSHIP - OLEPTRO (TRAZODONE HCL) NDA 22-411/005/006 APRVL LTR, LBLG

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2013-8537	10/30/2013 11/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KISHEN MEHTA ADAGE CAPITAL MANAGEMENT LP	OCRIPLASMIN (JETREA) - AERS
2013-8538	10/30/2013 11/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARY ANDERSON SHIRE INC	DESFERAL NDA 16-267/011/008/000 - APRVL, EFFICACY (MARK IV) 6/4/79, 03/04/77, 04/01/68
2013-8539	10/30/2013 11/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FRIEDMAN, ROBERT	IMODOUM A-D (LOPERAMIDE HCL) LIQUID - AERS 1969 TO PRESENT
2013-8540	10/30/2013 11/29/2013	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/ FDA/OC/OES/DFOI/ FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	ETRISH MCGRADY PRITZKER OLSEN	2013-2083 - DELETED RECS, 28 EXHIBITS
2013-8541	10/31/2013 12/02/2013	FDA/OGROP/ORR/CE-FO/BLT-DO/BLT-CB/	Teri Brown Sentara Healthcare	SENTARA VIRGINIA BEACH GENERAL IRB - 483 10/06/2006 - 10/06/2006
2013-8542	10/31/2013 12/02/2013	FDA/OGROP/ORR/CE-FO/DET-DO/DET-CB/	Gael Tisack TERUMO CARDIOVASCULAR SYSTEMS CORP	TERUMO CARDIOVASCULAR SYSTEMS CORPORATION, ANN ARBOR, MI - EIR 01/01/2010 - 12/31/2012
2013-8543	10/31/2013 12/02/2013	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2013-3698
2013-8544	10/31/2013 12/02/2013	FDA/OC/OES/DFOI/	Thomy Tonia Institute of Social and Preventive Medicine	ERYTHROPOIESIS STIMULATING AGENTS - STUDIES, TRIAL RECS, CSR, ETC
2013-8545	10/31/2013 12/02/2013	FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/	Dawn Antosh University Hospitals MacDonald Clinical Research Unit	DR JAMES LIU, SAN DIEGO, CA - 483, RESPONSE 01/01/1983 - 01/01/1988
2013-8546	10/31/2013 12/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K123096
2013-8547	10/31/2013 12/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K120040

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2013-8548	10/31/2013 12/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K110189
2013-8549	10/31/2013 12/02/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Yvonne Chung Bain & Co.	COMPOUNDING PHARMACIES - AERS
2013-8550	10/31/2013 12/02/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Farah Ali SPI PHARMA INC	SPI PHARMA - EIR SEPT 2012 REDACTED
2013-8551	10/31/2013 12/02/2013	FDA/OMPT/CTP/OD/	Stacy Ehrlich KLEINFELD KAPLAN AND BECKER	REVIEWER GUIDE TO TRAIN STAFF RE SE REVIEW PROCESS; SOP ON CTP POLICIES AND PROCEDURES FOR MTGS
2013-8552	10/31/2013 12/02/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Arrastia, Capote & Phang Arrastia, Capote & Phang, LLP	KOVA LABORATORIES, MARGATE, FL - 483 1/1/13
2013-8553	10/31/2013 12/02/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Amelia McGannon Orbis Biosciences	ANDA 088703
2013-8554	10/31/2013 12/02/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	John Walsh James Alexander Corporation	SCHOTT NORTH AMERICA, INC, LEBANON, PA - EIR AUGUST 2010 TO PRESENT
2013-8555	10/31/2013 12/02/2013	OC/ORACE/ OC/ORACE/ FDA/OGROP/ORAPAF-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAPAF-FO/SAN-DO/SAN-CB/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Matthew Haberkorn Haberkorn & Associates	SALMONELLA NEWPORT VIRUS, INFECTION IN CALIFORNIA
2013-8556	10/31/2013 12/02/2013	FDA/OFVM/CFSAN/OCD/EOS/	Wendy Crossland CROSSLAND, WENDY	RED BULL - AERS
2013-8557	10/31/2013	FDA/OMPT/CDRH/OCER/DFOI/	Avital Merl	K103825, K100504

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	12/02/2013	FDA/OC/OES/DFOI/	Becton Dickinson & Company	
2013-8558	10/31/2013 12/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	Avital Merl Becton Dickinson & Company	K103825, K100504
2013-8559	10/31/2013 12/02/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Avital Merl Becton Dickinson & Company	K093364, K090245
2013-8560	10/31/2013 12/02/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	Edward W Skepnek Valnet Inc.	LOS ALAMOS - EIR 07/15/2013 - 08/15/2013
2013-8561	10/31/2013 12/02/2013	FDA/OGROP/ORASW-FO/SAN-DO/SAN-CB/	Fusion Legal Fusion Legal	ALLURE LABS, INC, HAYWARD, CA - COMPLAINTS, INVESTIGATIONS, CORR
2013-8562	10/31/2013 12/02/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Elizabeth Wolk Beveridge & diamond, P.C.	PROVISIONAL PEER REVIEWED TOXICITY VALUES FOR SULFOLANE - COMMENTS, CORR, EMAIL
2013-8563	10/31/2013 12/02/2013	FDA/OGROP/ORASW-FO/SAN-DO/SAN-CB/	Fusion Legal Fusion Legal	DERMAQUEST INTERNATIONAL, HAYWARD, CA - COMPLAINTS, INVESTIGATIONS, COMM 01/01/2011 - 12/31/2012
2013-8564	10/31/2013 12/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	Avital Merl BECTON DICKINSON	K131294, K122953
2013-8565	10/31/2013 12/02/2013	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	TOBACCO PRODUCTS - AERS
2013-8566	10/31/2013 12/02/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Dustin Block IPD Analytics, LLC	ANDA 091424 - EFFECTIVE APPROVAL LETTER
2013-8567	10/31/2013 12/02/2013	FDA/OFVM/CFSAN/OCD/EOS/	Lynn P. Tordo Thor Specialties, Inc.	FCN 104
2013-8568	10/31/2013 12/02/2013	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	ELECTRONIC CIGARETTE - AERS
2013-8569	10/31/2013 12/02/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Jared Abrams Abrams, Jared	INVOKANA - AERS
2013-8570	10/31/2013 12/02/2013	FDA/OMPT/CTP/OD/	Suzanne Jensen Kleinfeld, Kaplan & Becker, LLP	ALL SE REPORTS SUBJECT OF SE ORDER OR NSE ORDER JUNE 1, 2013

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2013-8571	10/31/2013 12/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	Seirra Scientific 510k submission K031169 Artann Laboratories	K031169
2013-8572	10/31/2013 12/02/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Daniel Eugene Maddox MAYO CLINIC	OMALIZUMAB - AERS
2013-8573	10/31/2013 12/02/2013	OC/CVM/OCD/ FDA/OC/OES/ OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/	KELSEY RINEHART ANIMAL LEGAL DEFENSE FUND	FOSTER FARMS, LIVINGSTON, CA; FRESNO, CA - SALMONELLA HEIDELBERG OUTBREAK RECS, USE OF ANTIBIOTICS AND MEDICATED FEEDS, INSPS, ETC
2013-8574	10/31/2013 12/02/2013	FDA/OC/OES/DFOI/	 CRISTO, MARYANN	STRYKER - TRIDENT HEMISPHERICAL ACETABULAR SHELL WITH X3 POLYETHYLENE RECS, STUDIES
2013-8575	10/31/2013 12/02/2013	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/ OC/ORO/ OC/ORO/ORM/ OC/ORO/ORM/	RICHARD LARDNER ASSOCIATED PRESS	CHINESE FOOD FACILITIES INSP RECS 2008 TO PRESENT
2013-8576	10/31/2013 12/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	VERN WILLIAMS ZEPPESSIS REPROCESSING	STRYKER - NEPTUNE WASTE MANAGEMENT SYS K012991
2013-8577	10/31/2013 12/02/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ERIN E WARREN VENABLE LLP	PHENAZOPRIDINE HCI - MFRS, PROD NAMES 1/08 TO PRESENT
2013-8578	10/31/2013 12/02/2013	FDA/OGROP/ORO/CE-FO/NWJ-DO/NWJ-CB/	DOUGLAS N BLUE II ZETETIC INC	OHM LABORATORIES INC, NEW BRUNSWICK, NJ - EIR 12/18/12
2013-8579	10/31/2013 12/02/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	UNYIME OGUTA HILL TOP RESEARCH	HILL TOP RESEARCH, WINNIPEG, MANITOBA, CANADA - EIR 12/4-8/06
2013-8580	10/31/2013 12/02/2013	FDA/OGROP/ORO/NE-FO/NWE-DO/NWE-CB/	PAUL B CALLAHAN CHARLES RIVER LABS	TOXIKON CORP, BEDFORD, MA - 483 2013

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2013-8581	10/31/2013 12/02/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	PAUL B CALLAHAN CHARLES RIVER LABS	STILLMEADOW INC, SUGAR LAND, TX - 483 2013
2013-8582	10/31/2013 12/02/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	DAVID WILKS MICRO-DISTRIBUTING	BRANAN MEDICAL CORP - ORATECT ORAL FLUID DRUG SCREEN DVCS K103227
2013-8583	10/31/2013 12/02/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELLIOT FAVUS FAVUS INSTITUTIONAL RESEARCH LLC	OCIPLASMIN - AERS 8/13 TO PRESENT
2013-8584	10/31/2013 12/02/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	HARALD KIRSEBOM TPR-GROUP APS	OHM LABORATORIES INC, NEW BRUNSWICK, NJ - EIR 12/12
2013-8585	10/31/2013 12/02/2013	OC/ORA/ OC/ORA/ FDA/OMPT/CDRH/OCER/DFOI/	ROBERT KING FDANEWS	BIENNE AIR, BIENNE, SWITZERLAND; 3SHAPE POLAND SP, ZOO, SZCZECIN, POLAND; AMICO PATIENT CARE EQUIPMENT, RICHMOND HILL, CANADA - 483S 9/1-3/13
2013-8586	10/31/2013 12/02/2013	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	ROBERT KING FDA NEWS	MYLAN LLC, CAGUAS, PR - 483 9/1-30/13
2013-8587	10/31/2013 12/02/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	ROBERT KING FDA NEWS	NATRIUM PRODUCTS INC, CORTLAND, NY - 483S 9/1-30/13
2013-8588	10/31/2013 12/02/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	ROBERT KING FDA NEWS	U-SYSTEMS INC, SUNNYVALE, CA; NUVOLASE INC, CHICO, CA; ALLERGAN INC, VACAVILLE, CA, ETC - 483S 9/1-30/13
2013-8589	10/31/2013 12/02/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	ROBERT KING FDA NEWS	PURDY-PAK INC (DBA TITE-PAK & PPI), EAST NORRITON, PA; DELAVAU LLC, PHILADELPHIA, PA - 483S 9/1-30/13
2013-8590	10/31/2013 12/02/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	ROBERT KING FDA NEWS	CAMBRIDGE MAJOR LABORATORIES INC, GERMANTOWN, WI; NATIONAL PACKAGING SERVICES CORP, GREEN BAY, WI; LIFE TECHNOLOGIES CORP, BROWN DEER, WI, ETC - 483S 9/1-30/13
2013-8591	10/31/2013 12/02/2013	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	ROBERT KING FDA NEWS	TELEFLEX MEDICAL, ARLINGTON HEIGHTS, IL - 483S 9/1-30/13
2013-8592	10/31/2013 12/02/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	ROBERT KING FDA NEWS	ALLIED HEALTHCARE PRODUCTS INC, ST LOUIS, MO - 483S 9/1-31/13
2013-8593	10/31/2013 12/02/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	ROBERT KING FDA NEWS	PATEINTSAFE SOLUTIONS INC, SAN DIEGO, CA; LAELEDE INC, RANCHO DOMINGUEZ, CA; FUSION PHARMACEUTICALS LLC, CAMARILLO, CA, ETC - 483S 9/1-31/13
2013-8594	10/31/2013 12/02/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	ROBERT KING FDA NEWS	SDI DIAGNOSTICS INC, EASTON, MA; MEDTRONIC NAVIGATION INC, LITTLETON, MA; NURSE ALARM SYSTEMS INC, VERNON, CT, ETC - 483S 9/1-31/13

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2013-8595	10/31/2013 12/02/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	ROBERT KING FDA NEWS	LAUREATE BIOPHARMACEUTICALS SERVICES INC, PRINCETON, NJ; ORIGIO INC, MOUNT LAUREL, NJ; MINDRAY DS USA INC (DBA MINDRAY NORTH AMERICA), MAHWAH, NJ - 483S 9/1-30/13
2013-8596	10/31/2013 12/02/2013	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	ROBERT KING FDA NEWS	DR REDDY'S LABORATORIES LOUISIANA LLC, SHREVEPORT, LA; GYRUS ENT LLC (SUBSIDIARY OF GYRUS ACMI INC), BARTLETT, TN - 483S 9/1-30/13
2013-8597	10/31/2013 12/02/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	ROBERT KING FDA NEWS	SANOPI PASTEUR LTD, CANNAUGHT CAMPUS, NORTH YORK, CA - 483S 9/1-30/13
2013-8598	11/01/2013 12/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Elia Abi-Jaoude UNIVERSITY OF TORONTO	PAXIL STUDY 329 - FDA REVIEWS, BRIEFINGS, CORR ETC
2013-8599	11/01/2013 12/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	FOIA Request for Mimics 510(k) Submission #K073468 Prevue Medical	K073468
2013-8600	11/01/2013 12/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	Tina Mayer BECTON DICKINSON	K102512
2013-8601	11/01/2013 12/03/2013	FDA/OFVM/CFSAN/OCD/EOS/	Wendy Crossland CROSSLAND, WENDY	MONSTER ENERGY DRINK - AERS
2013-8602	11/01/2013 12/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	Tina Mayer BECTON DICKINSON	K120395
2013-8603	11/01/2013 12/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	Tina Mayer BECTON DICKINSON	K132142
2013-8604	11/01/2013 12/03/2013	FDA/OFVM/CFSAN/OCD/EOS/	Wendy Crossland CROSSLAND, WENDY	ROCKSTAR ENERGY DRINK - AERS
2013-8605	11/01/2013 12/03/2013	OC/ORAOE/ OC/ORAOE/	nina fuentes de tienda Utrecht University	RECALL DATA - DRUGS AND BIOLOGICS
2013-8606	11/01/2013 12/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	MONTELUKAST - AERS
2013-8607	11/01/2013 12/03/2013	FDA/OMPT/CTP/OD/ FDA/OC/OES/DFOI/	Stacy Ehrlich KLEINFELD KAPLAN AND BECKER	NSE ORDERS 01/01/2013 - 10/25/2013

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2013-8608	11/01/2013 12/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	Stephanie Fullard Porex Corporation	MAF-1107 UNREDACTED
2013-8609	11/01/2013 12/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Audra Dorazio Isis Pharmaceuticals, Inc.	STAFF MANUAL GUIDE 4850.7
2013-8610	11/01/2013 12/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rick Yarborough WRC NBC Washington	ESSURE SYSTEM PHASE II AND PIVOTAL TRIALS - 5 YEAR FOLLOW UP
2013-8611	11/01/2013 12/03/2013	OC/CVM/OCD/	Sandra O'Kelley Merial Limited	AGRI-MECTIN PLUS CLORSULON - FOIA SUMMARY
2013-8612	11/01/2013 12/03/2013	FDA/OC/OES/DFOI/	Kari L. Twaite BEVERIDGE & DIAMOND PC	CFSAN FOIA REQUESTS 09/25/2013 - 10/25/2013
2013-8613	11/01/2013 12/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	Paulette L. Shinabery Shinabery, Paulette L	SURGICAL SPECIALTIES CORP - LETTER REMOVING APPROVAL FOR NON ABSORBABLE POLYPROPYLENE BARBED CONTOUR THREADS USED IN PLASTIC SURGERY; LETTER TO PHYSICIANS
2013-8614	11/01/2013 12/03/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Dean Irwin Ra Medical Systems, Inc.	PHOTOMEDEX, CARLSBAD, CA - 483 08/01/2013 - 10/24/2013
2013-8615	11/01/2013 12/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Daniel Rushing INDIANA UNIVERSITY	REGORAFENIB - AERS
2013-8616	11/01/2013 12/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	William Lewis AccelaPHARM, LLC	GATTEX - AERS
2013-8617	11/01/2013 12/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	William Lewis AccelaPHARM, LLC	JUXTAPID - AERS
2013-8618	11/01/2013 12/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	N. Epstein Azimuth Therapy Ltd.	K855063
2013-8619	11/01/2013 12/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Malia Segar Cote Orphan Consulting	NDA 22432

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-8620	11/01/2013 12/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	Carl Jenkins WOOD BURDITT GROUP	K03302217; K00236419; K95020321; ETC
2013-8621	11/01/2013 12/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	N. Epstein Azimuth Therapy Ltd.	K910648
2013-8622	11/01/2013 12/03/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	William Stahovec Catalyst Pharmaceutical Partners	JACOBUS PHARMACEUTICAL CO, INC, PLAINSBORO, NJ - EIR 03/01/2012 - 12/31/2012
2013-8623	11/01/2013 12/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	K. L. Parthasarathy-MD. PARTHASARATHY, K L	BESIVANCE - AERS 01/01/2012 - 10/15/2013
2013-8624	11/01/2013 12/03/2013	FDA/OO/OHR/	Doe J	INDIVIDUAL RECS
2013-8625	11/01/2013 12/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	N. Epstein Azimuth Therapy Ltd.	K060870
2013-8626	11/01/2013 12/03/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Kelley Webb Rawls McNelis + Mitchell	INDIVIDUAL RECS
2013-8627	11/01/2013 12/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	David Martin Timeline Productions	CHANTIX - SAFETY REPORTS
2013-8628	11/01/2013 12/03/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Ream Zeitoun Catalent Pharma Solutions	ASSOCIATES OF CAPE CODE, EAST FALMOUTH, MA - 483 06/01/2013 - 06/30/2013
2013-8629	11/01/2013 12/03/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	William Stahovec Catalyst Pharmaceutical Partners	JACOBUS PHARMACEUTICALS CO, PLAINSBORO, NJ - EIR 01/01/2011 - 11/28/2011
2013-8630	11/01/2013 12/03/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Charles J. Sapienza LCR Hqallcrest	K112256, K932129, K122555 ETC
2013-8631	11/01/2013 12/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Barbara Shatkin Barbara Shatkin	CIPROFLAXIN - AERS
2013-8632	11/01/2013	FDA/OGROP/ORA/CE-FO/NWJ-	Mark Charest	JACOBUS PHARMACEUTICAL COMPANY, INC - 483,

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	12/03/2013	DO/NWJ-CB/	CHAREST, MARK	WARNING LETTER, RESPONSES 01/01/2011 - 10/29/2013
2013-8633	11/01/2013 12/03/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MANDY J KANYUKOWSKI GREENSFELDER HEMKER & GALE PC	LIDOCAINE - AERS
2013-8634	11/01/2013 12/03/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MANDY J KANYKOWKI GREENSFELDER HEMKER & GALE PC	SODIUM BICARBONATE - ISRS 7723955, 7839262, 7839275, ETC
2013-8635	11/01/2013 12/03/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CANDLE, BRANDON LEE	STRIBILD - PI
2013-8636	11/01/2013 12/03/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CANDLE, BRANDON LEE	NORVIR - PI
2013-8637	11/01/2013 12/03/2013	FDA/OFVM/CFSAN/OCD/EOS/	CHARLES CELESTE EAS CONSULTING GROUP LLC	FAP 9A4692
2013-8638	11/01/2013 12/03/2013	FDA/OFVM/CFSAN/OCD/EOS/	CHARLES CELESTE EAS CONSULTING GROUP LLC	FAP 0A4724
2013-8639	11/01/2013 12/03/2013	FDA/OFVM/CFSAN/OCD/EOS/	CHARLES CELESTE EAS CONSULTING GROUP LLC	FAP 7A4532
2013-8640	11/01/2013 12/03/2013	FDA/OFVM/CFSAN/OCD/EOS/	ALISON YOUNG USA TODAY	CRAZE SUPPL - CAERS
2013-8641	11/01/2013 12/03/2013	FDA/OFVM/CFSAN/OCD/EOS/	ALISON YOUNG USA TODAY	DETONATE SUPPL - CAERS 1/12 TO PRESENT
2013-8642	11/01/2013 12/03/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	ALISON YOUNG USA TODAY	DENDROBIUM, DENDROBIN, DENDROBEX - CAERS 1/12 TO PRESENT
2013-8643	11/01/2013	FDA/OGROP/ORO/CE-FO/NWJ-	ALISON YOUNG	GASPARI NUTRITON - EIRS, 4583S, CORR 1/09 TO

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	12/03/2013	DO/NWJ-CB/	USA TODAY	PRESENT
2013-8644	11/01/2013 12/03/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	ALISON YOUNG USA TODAY	DRIVEN SPORTS SUPPL - EIRS, 483S, CO RESP, CORR 1/09 TO PRESENT
2013-8645	11/01/2013 12/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	J. DONALD HENSON, SR Henson, J. Donald	RESP TO HOLZERLAND MEMO 10/29/13
2013-8646	11/01/2013 12/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	DEBORAH A ROWE SUTTER LAW FIRM	FRESENIUS MEDICAL LCARE NORTH AMERICA - NATURALYE GRANUFLO (POWDER) ACID CONCENTRATE; NATURALYTE LIQUID ACID CONCENTRATE - LOCATION, DATE, NAMES, ETC
2013-8647	11/01/2013 12/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	Keane, Barbara	METRONIC - INFUSION PUMP RPT
2013-8648	11/01/2013 12/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	MONICA KING KIMBERLY-CLARK HEALTHCARE	OXBAND WOUND DRESSING - K043063
2013-8649	11/01/2013 12/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	QOL MEDICAL LLC - SUCRAID (SACROSIDASE) NDA 20-772/005/006/007 APRVL PKG
2013-8650	11/01/2013 12/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	A LAYNE STACKHOUSE JONES WARD PLC	NORPLANT SYS IN PLASTIC CONTAINERS - NDA 20-088 - LBLG
2013-8651	11/01/2013 12/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KATZ & DOUGHERTY LLC	INDIVIDUAL RECS
2013-8652	11/01/2013 12/03/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Teresa Briggs, Quality Manager Nestle Nutrition, Gerber	GERBER - EIR 10/24/2012 - 12/31/2012
2013-8653	11/01/2013 12/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DDM/	Lisa Mandrusiak Oblon, Spivak, McClelland, Maier & Neustadt, L.L.P.	PHOTOCHEMISTRY AND PHOTOBIOLOGY OF SUNSCREEN - PUBLIC MEETING TRANSCRIPTS 09/19/1996 - 09/20/1996
2013-8654	11/01/2013 12/03/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Grady Ormond PHARMASYS	UNIVERSITY OF MIAMI - WARNING LETTER, 483 01/01/2010 - 12/31/2011

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2013-8655	11/01/2013 12/03/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sean McMahon Kennedy Capital Management	AMAG PHARMACEUTICAL - FDA LETTER RE EXTENSION FOR FERAHEME SUPPLEMENTAL NDA 01/01/2013 - 10/28/2013
2013-8656	11/01/2013 12/03/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michele Sinoway LACHMAN CONSULTANT SERVICES, INC.	MONTHLY, QUARTERLY OGD WORKLOAD ACTIVITY 09/15/2013 - 10/08/2013
2013-8657	11/01/2013 12/03/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Weiheng(Kevin) Kong HEC Pharm USA Inc	ANDA 202058
2013-8658	11/01/2013 12/03/2013	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Loren Larkin LARKIN, LOREN	BIOGEN ELOCTATE - CORR WITH FDA
2013-8659	11/01/2013 12/03/2013	FDA/OC/OES/DDM/ FDA/OC/OES/DFOI/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/ OC/CVM/OCD/	Harry Tempkins Newman & Tempkins, P.A.	12-P-0313-1
2013-8660	11/01/2013 12/03/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KASTANES, JOHN	AICURIS - PRITELIVIR SAFETY RECS
2013-8661	11/01/2013 12/03/2013	FDA/OGROP/ORR/CE-FO/MIN-DO/MIN-CB/	Jennifer Franklin Gerber Products Company dba Nestle Nutrition - Eau Claire	NESTLE GATEWAY, EAU CLAIRE, WI - EIR 04/26/2011 - 04/28/2011

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2013-8662	11/01/2013 12/03/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ryan Smith Smith, Ryan	JUXTAPID - AERS
2013-8663	11/01/2013 12/03/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MATTHEW PERRONE ASSOCIATED PRESS	ZOGENIX INC, SANDIEGO, CA - ZOHYDRO NDA 202-880 COMM, MEMOS, APRVL, ETC 10/24/12 TO 10/24/13
2013-8664	11/01/2013 12/03/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	TERRI L. HOPPER DURDEN ENTERPRISES	DURDEN ENTERPRISES, AUBURN, GA - EIR 09/09/2009 - 09/15/2009
2013-8665	11/01/2013 12/03/2013	FDA/OC/OES/DFOI/	ALICEA, SIMONE	LIST OF FOI REQUESTS RELATED TO GENETIC ENGINEERING MODIFICATION PAST YR
2013-8666	11/01/2013 12/03/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Pavle Sedic LELO Inc.	K021356
2013-8667	11/01/2013 12/03/2013	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	TOBACCO NSE RECS
2013-8668	11/01/2013 12/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	Mike Wolford Wolford, Mike	K123234
2013-8669	11/01/2013 12/03/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	Zhanna Yuabova Boehringer Ingelheim Pharmaceuticals Inc.	QUINTILES INC, KANSAS CITY, MO - EIR 11/19/2003 - 11/19/2006
2013-8670	11/01/2013 12/03/2013	OC/ORA/ OC/ORA/	Yolanda Vazquez European Imports Inc	9WX-0200577-6 LINE 0049 - LAB RESULTS
2013-8671	11/01/2013 12/03/2013	FDA/OC/OES/DFOI/	LEE #B60072, ALBERT	BENZENE - AERS
2013-8672	11/01/2013 12/03/2013	FDA/OC/OES/DFOI/	BANKS CELL 217, YUJUAN	ROBERT DEAN, LOS ANGELES, CA - MISCONDUCT, PERJURY, TAMPERING, ETC
2013-8673	11/01/2013 12/03/2013	FDA/OFVM/CFSAN/OCD/EOS/	GARY J BURIN TECHNOLOGY SCIENCES GROUP INC	FCN 1293
2013-8674	11/01/2013 12/03/2013	FDA/OC/OES/ FDA/OC/OES/DDM/	B KRISTIAN RASMUSSEN CORY WATSON ET AL	TAKEDA PHARMACEUTICALS USA INC (TAKEDA PHARMACEUTICALS AMERICA INC) - DEXILANT RPTS, MINS, TRANS, ETC

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		FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/ORO/ OC/ORO/		
2013-8675	11/01/2013 12/03/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/BLT-DO/BLT-CB/ OC/ORO/OCI/ OC/ORO/OCI/	REEL, CHARLES	PHARMALOGICAL INC -MDK/MEDICAL DEVICE KING; BOTOX INVESTIGATION RECS 5/29/13
2013-8676	11/01/2013 12/03/2013	FDA/OC/OES/DFOI/	Dr Reena Harjai APCER Pharma Solutions, Inc	KINEVAC - FOIA REQUEST 01/01/1976 - 12/31/2002
2013-8677	11/04/2013 12/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Benjamin Hunter Pharmacy Technician Certification Board	NEXIUM, TOPROL - FAERS QUARTERLY DATA FILES
2013-8678	11/04/2013 12/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dennis Raisch UNIVERSITY OF NEW MEXICO	TBO-FILGRASTIM - AERS
2013-8679	11/04/2013 12/04/2013	FDA/OGROP/ORO/CE-FO/MIN-DO/MIN-CB/	Chris Koscick GOJO Industries, Inc.	ROCKLINE INDUSTRIES, SHEBOYGAN, WI - EIR 01/30/2013 - 02/06/2013
2013-8680	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	Baker Hostetler Baker Hostetler	2013-6594
2013-8681	11/04/2013 12/04/2013	FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/	Leslie Nicholson American Red Cross - Donor Management Center	AMERICAN RED CROSS DONOR MANAGEMENT CENTER, TULSA, OK - EIR 02/04/2013 - 03/01/2013
2013-8682	11/04/2013 12/04/2013	FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/	Vince Ochotorena BLOOD SYSTEMS, INC.	QUALTEX LABORATORIES, SOUTH TEXAS BLOOD AND TISSUE CENTER - EIR, 483, WARNING LETTER 01/01/2010 - 10/30/2013
2013-8683	11/04/2013	FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/	Leonard Krause	MAGNI GROUP, INC - WARNING LETTER CORR 07/15/2013 - 10/30/2013

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	12/04/2013		Compliance Specialists LLC	
2013-8684	11/04/2013 12/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	gerald cagle gerald cagle	VIZAMYL - APPROVAL RECS
2013-8685	11/04/2013 12/04/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Farah Ali SPI PHARMA INC	CMIC CMO USA, CRANBURY, NJ - 483 NOVEMBER 2011
2013-8686	11/04/2013 12/04/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Leslie Nicholson American Red Cross - Donor and Client Support Center	AMERICAN RED CROSS DONOR AND CLIENT SUPPORT CENTER, PHILADELPHIA, PA - EIR 09/05/2012 - 10/26/2012
2013-8687	11/04/2013 12/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Samantha Al-Faruque Sibley Memorial Hospital	TRANEXAMIC ACID INJECTION - AERS
2013-8688	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORACE/ OC/ORACE/ FDA/OGROP/ORAPPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ OC/ORACE/ OC/ORACE/ OC/ORACE/ OC/ORACE/	Sam May MAY, SAMUEL	AMGEN EPOGEN, ARANESP - 483, WARNING LETTER, RECALLS ETC 09/22/2007 - 10/28/2013
2013-8689	11/04/2013 12/04/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Ryan Smith Smith, Ryan	SENSIENT TECHNOLOGIES CORP, MILWAUKEE, WI - 483 09/01/2011 - 10/29/2013
2013-8690	11/04/2013	FDA/OO/OFBA/OAGS/	Philip Ewbank	Scimetrika \$40 million Indefinite Delivery/Indefinite Quantity single-award contract by the FDA

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	12/04/2013		AIM Inc.	
2013-8691	11/04/2013 12/04/2013	OC/OROA/ OC/OROA/	Yolanda Vazquez European Imports Inc	ENTRY 9WX-0200577-6 LINE 006
2013-8692	11/04/2013 12/04/2013	FDA/OGROP/OROA/SE-FO/ATL-DO/ATL-CB/	Leslie Nicholson American Red Cross - Donor and Client Support Center	AMERICAN RED CROSS - DONOR AND CLIENT SUPPORT CENTER, CHARLOTTE, NC - EIR 08/26/2012 - 11/16/2012
2013-8693	11/04/2013 12/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sandra Bartlett INTERNATIONAL CONSORTIUM OF INVESTIGATIVE JOURNALISTS	DROSPIRENONE - AERS
2013-8694	11/04/2013 12/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	Anna Edney BLOOMBERG NEWS	INTUITIVE SURGICAL ROBOTIC DA VINCI DEVICE - SURGEON SURVEY RESULTS 01/01/2012 - 10/30/2013
2013-8695	11/04/2013 12/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	Connor Landgraf Eko Devices	K130409
2013-8696	11/04/2013 12/04/2013	FDA/OC/OES/DDM/	Jason L. Schwartz PRINCETON UNIVERSITY	Meeting transcripts, summary minutes, and agendas from selected meetings of the Vaccines and Related Biological Products Advisory Committee and the Blood Products Advisory Committee
2013-8697	11/04/2013 12/04/2013	FDA/OGROP/OROA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/OROA/PA-FO/SAN-DO/SAN-CB/	Paul Knoepfler UC DAVIS SCHOOL OF MEDICINE	CELL SURGICAL NETWORK IN CA, DR ELLIOT B LANDER, DR MARK BERMAN - INSPECTIONAL CORR 01/01/2013 - 10/28/2013
2013-8698	11/04/2013 12/04/2013	OC/OROA/ OC/OROA/ FDA/OGROP/OROA/ORO/DIOP/	Ryan Clancey Ware Manufacturing Inc.	CONTAINERS HELD FOR EXAMINATION 01/01/2013 - 10/29/2013
2013-8699	11/04/2013 12/11/2013	OC/OROA/ OC/OROA/ FDA/OGROP/OROA/ORO/DIOP/ FDA/OGROP/OROA/ORO/DIOP/	Thomas Bernhardt, UNIDO United Nations Industrial Development Organization (UNIDO)	OASIS BORDER REJECTION DATA 01/01/2011 - 12/31/2013
2013-8700	11/04/2013 12/04/2013	OC/OROA/ OC/OROA/ FDA/OGROP/OROA/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/OROA/SW-FO/SWID/SWID-CB/	Eleanor DaCosta United States Pharmacopeial Convention (USP)	IMPORT REFUSALS 228-6015638-3/1/1/B, 228-6015638-3/1/1/C - LAB RESULTS
2013-8701	11/04/2013	FDA/OC/OES/DFOI/	kelly wallace	INDIVIDUAL RECS

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	12/04/2013		wallace, kelly	
2013-8702	11/04/2013 12/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Yamil Hernandez Cerium Pharmaceuticals, Inc.	NDA 17861
2013-8703	11/04/2013 12/04/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	James McNair Freelance writer & editor Marc Eisen	MINDRAY, MAHWAH, NJ - 48306/01/2012- 11/29/2012
2013-8704	11/04/2013 12/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	Tyler Thornhill Tyler Thornhill	INTUITIVE SURGICAL - COMM WITH FDA RE 510K
2013-8705	11/04/2013 12/04/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	Leonard Krause Compliance Specialists LLC	SIMILASAN CORPORATION - CORR RE WARNING LETTER 05/05/2003 - 10/30/2013
2013-8706	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16); joan_stitt@merck.com MERCK & CO., INC.	FOI DAILY LOG 10/1-31/2013
2013-8707	11/04/2013 12/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John Shoemaker Visium	COMETRIQ - AERS
2013-8708	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	CLOSED FOIA REQUESTS OCT 2013
2013-8709	11/04/2013 12/04/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/ORO/DIOP/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Eleanor DaCosta United States Pharmacopeial Convention (USP)	IMPORT ALERT 16-47 - LAB RESULTS
2013-8710	11/04/2013 12/04/2013	FDA/OMPT/CTP/OD/	Stacy Ehrlich KLEINFELD KAPLAN AND BECKER	NSE CORR 10/01/2013 - 10/31/2013
2013-8711	11/04/2013 12/04/2013	OC/CVM/OCD/	Rachel Johnson FOI Services, Inc.	Assay Method B00925 for Tylosin
2013-8712	11/04/2013 12/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	Barry Constantine CONSTANTINE, BARRY E	K955506
2013-8713	11/04/2013	FDA/OMPT/CDER/ORP/DIDP/	Tom Detzel	CLINICAL, SPONSOR, CRO SITES XARELTO, PRADAXA, ELIQUIS - 483 09/25/2008 - 04/30/2012

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	12/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/ FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/ FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/ FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/ FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/ FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/ FDA/OC/OES/DFOI/	PROPUBLICA	
2013-8714	11/04/2013 12/04/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/ORO/DIOP/	Eleanor DaCosta United States Pharmacopeial Convention (USP)	IMPORT ALERT 16-128 - LAB DATA
2013-8715	11/04/2013 12/04/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/ORO/DIOP/ FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Eleanor DaCosta United States Pharmacopeial Convention (USP)	IMPORT ALERT 22-04 7/24/2013 - LAB RESULTS
2013-8716	11/04/2013 12/04/2013	OC/CVM/OCD/	Rachel Johnson FOI Services, Inc.	Assay method B05965 for Tylosin
2013-8717	11/04/2013 12/04/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/ORO/DIOP/ FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	Eleanor DaCosta United States Pharmacopeial Convention (USP)	IMPORT ALERT 09-01 - 6/20/13 - LAB RESULTS
2013-8718	11/04/2013	FDA/OGROP/ORA/CE-FO/NWJ-	Adam Feuerstein	JACOBUS PHARMACEUTICALS, PLAINSBORO, NJ - 483

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	12/04/2013	DO/NWJ-CB/	THESTREET.COM	01/01/2011 - 11/01/2013
2013-8719	11/04/2013 12/04/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/ FDA/OGROP/ORO/CE-FO/CHI-DO/CHI-CB/ FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORO/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	Eleanor DaCosta United States Pharmacopeial Convention (USP)	IMPORT ALERT 36-01 10/22/2013 - LAB RESULTS
2013-8720	11/04/2013 12/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tom Burton THE WALL STREET JOURNAL	ICLUSIG - AERS
2013-8721	11/04/2013 12/04/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/	Eleanor DaCosta United States Pharmacopeial Convention (USP)	IMPORT REFUSAL 112-0350231-7/1/1 - LAB RESULTS
2013-8722	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	Deep Krothapalli DEEP KROTHAPALLI	Date Range: 05/05/2010 - 07/05/2010; I would like to request FDA- CDRH all 483s issued during this time period. If the cost of providing these documents will exceed \$250, please call us first for authorization of the charges.;
2013-8723	11/04/2013 12/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K132612
2013-8724	11/04/2013 12/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joyce Godshall TEVA PHARMACEUTICAL USA	NDA 203585 CASE REPORTS
2013-8725	11/04/2013 12/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	TERBUTALINE - PACKAGE INSERT 01/20/2000 - 04/03/2000

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2013-8726	11/04/2013 12/06/2013	FDA/OC/OES/DFOI/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ OC/ORA/ OC/ORA/	Katherine M. Hunt Murray & Murray Co., L.P.A.	SUBWAY RESTAURANTS AND REGIONAL CENTERS - WARNING LETTERS, UNTITLED LETTERS, INSPECTIONS ETC 10/31/2010 - 10/31/2013
2013-8727	11/04/2013 12/04/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Kevin M. Barth Ballenger, Barth, Hoefer & Lewis, LLP	NATIONAL FOOD AND BEVERAGE, DALLAS, TX - INSPECTION LINES, WARNING LETTERS, RESPONSE LETTERS ETC 01/01/2008 - 10/31/2013
2013-8728	11/04/2013 12/04/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORASW-FO/SWID/SWID-CB/ FDA/OGROP/ORASW-FO/SWID/SWID-CB/ FDA/OGROP/ORASW-FO/SWID/SWID-CB/	Eleanor DaCosta United States Pharmacopeial Convention (USP)	IMPORT ALERT 16-04 - LAB RESULTS
2013-8729	11/04/2013 12/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	Dana Deyette OptiScan Biomedical	K060660
2013-8730	11/04/2013 12/04/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Gavin Anderson Azaya Therapeutics, Inc.	ANDA 2013263
2013-8731	11/04/2013 12/04/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	William Lewis AccelaPHARM, LLC	PROCYSBI - AERS
2013-8732	11/04/2013 12/04/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	William Lewis AccelaPHARM, LLC	RAVICTI - AERS
2013-8733	11/04/2013 12/04/2013	FDA/OC/OES/DDM/	Henry Talbot N/A	DR RONALD J DOUGHERTY - HYDROCODONE PETITION 01/01/1999 - 01/31/1999
2013-8734	11/04/2013 12/04/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORASW-FO/SWID/SWID-CB/	Eleanor DaCosta United States Pharmacopeial Convention (USP)	IMPORT ALERT 28-07 12/02/2012 - LAB RESULTS
2013-8735	11/04/2013	FDA/OMPT/CBER/OCOD/DDOM/	Shana Griffith	FINAL MEMO FOR BLOOD FATALITIES FOR FY 2008

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	12/04/2013	ALFB/	Artesia General Hospital	
2013-8736	11/04/2013 12/04/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/NE-FO/NYK- DO/NYK-DCB/	Eleanor DaCosta United States Pharmacopeial Convention (USP)	PRAN TURMERIC - RECALL LAB RESULTS
2013-8737	11/04/2013 12/04/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SE-FO/NOL- DO/NOL-CB/	ALFOCAN, S. A. ALFOCAN, S. A.	ENTRY REPORTS AND LAB RESULTS
2013-8738	11/04/2013 12/04/2013	FDA/OMPT/OSMP/OOPD/	Leeanne Bruin UNCW Center for Marine Science	KALYDECO, CAYSTON - ORPHAN DRUG DESIGNATION RECS
2013-8739	11/04/2013 12/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Robyn J. De Vos Crooks, Low & Connell, S.C.	MANNITOL INJECTION 25%; 12.5grams/50ml, VERSED INJECTION - PACKAGE INSERT (CERTIFIED)
2013-8740	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 9/23-27/13
2013-8741	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	JH BARR JH BARR & ASSOCIATES LLC	DAILY LOG 9/30/13-10/4/13
2013-8742	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	LAUREN S, BARR JH BARR & ASSOCIATES LLC	DAILY LOG 9/30/13-10/4/13
2013-8743	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 9/16-20/13
2013-8744	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY CLOSED LOG 9/30/13-10/4/13
2013-8745	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY CLOSED LOG 9/13-20/13
2013-8746	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY CLOSED LOG 9/23-27/13
2013-8747	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY CLOSED LOG 10/7-11/13
2013-8748	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 9/09/13-9/13/13
2013-8749	11/04/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR	DAILY CLOSED LOG 9/9-13/13

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	12/04/2013		JH BARR & ASSOCIATES LLC	
2013-8750	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	GLADYS B. TONKIN WASHINGTON INFORMATION SOURCE	DAILY LOG 930/13-10/4/13
2013-8751	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	GLADYS B. TONKIN WASHINGTON INFORMATION SOURCE	DAILY LOG 9/23-27/13
2013-8752	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	GLADYS B. TONKIN WASHINGTON INFORMATION SOURCE	DAILY LOG 9/16-20/13
2013-8753	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	GLADYS B. TONKIN WASHINGTON INFORMATION SOURCE	DAILY LOG 9/9-13/13
2013-8754	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 9/9-13/13
2013-8755	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 9/16-20/13
2013-8756	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 9/30/13-10/4/13
2013-8757	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 9/23-27/13
2013-8758	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP WASHINGTON INFORMATION SOURCE	DAILY LOG 9/9-13/13
2013-8759	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP WASHINGTON INFORMATION SOURCE	DAILY CLOSED LOG 9/16-20/13
2013-8760	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP WASHINGTON INFORMATION SOURCE	DAILY LOG 9/16-20/13
2013-8761	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP WASHINGTON INFORMATION SOURCE	DAILY LOG 9/23-27/13

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2013-8762	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY CLOSED LOG 9/30/13-10/4/13
2013-8763	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY CLOSED LOG 9/23-27/13
2013-8764	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAIL LOG 9/30/13-10/4/13
2013-8765	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY CLOSED LOG 10/7-11/13
2013-8766	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY CLOSED LOG 9/9-13/13
2013-8767	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 9/30/13-10/4/13
2013-8768	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 9/9-13/13
2013-8769	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 9/16-20/13
2013-8770	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 9/23-27/13
2013-8771	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	DAVID McFARLAND FDA REVIEW/FDA WEBVIEW	DAILY CLOSED LOG 9/9-13/13
2013-8772	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	DAVID McFARLAND FDA REVIEW/FDA WEBVIEW	DAILY CLOSED LOG 10/7-11/13
2013-8773	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	DAVID MacFARLAND FDA REVIEW/FDA WEBVIEW	DAILY CLOSED LOG 9/30/13-10/4/13
2013-8774	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	DAVID MacFARLAND FDA REVIEW/FDA WEBVIEW	DAILY CLOSED LOG 9/23-27/13
2013-8775	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	DAVID McFARLAND FDA REVIEW/FDA WEBVIEW	DAILY CLOSED LOG 9/16-20/13
2013-8776	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 9/9-13/13
2013-8777	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 9/16-20/13
2013-8778	11/04/2013	FDA/OC/OES/DFOI/		DAILY LOG 9/13-10/4/13

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	12/04/2013		FOI Services, Inc.	
2013-8779	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 9/23-27/13
2013-8780	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 9/16-20/13
2013-8781	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 10/7-11/13
2013-8782	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 9/23-27/13
2013-8783	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 9/30-10/4/13
2013-8784	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 9/9-13/13
2013-8785	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	SANDY FRIEDMAN WOLTERS KLUWER LAW & BUSINESS	CLOSED DAILY LOG 9/30/14-10/4/13
2013-8786	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED DAILY LOG 9/23-27/13
2013-8787	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY CLOSED LOG 9/16-20/13
2013-8788	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	DEBRA L. COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 9/9-13/13
2013-8789	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	DEBRA L. COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 9/16-20/13
2013-8790	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	DEBRA L. COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 9/23-27/13
2013-8791	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	DEBRA L. COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY CLOSED 9/30-10/4/13
2013-8792	11/04/2013	FDA/OC/OES/DFOI/	SANDY FRIEDMAN	DAILY CLOSED LOG 10/7-11/13

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	12/04/2013		WOLTERS KLUWER LAW & BUSINESS	
2013-8793	11/04/2013 12/04/2013	FDA/OC/OES/DFOI/	SANDY FRIEDMAN WOLTERS KLUWER LAW & BUSINESS	DAILY CLOSED LOG 9/9-13/13
2013-8794	11/05/2013 12/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michele Sinoway LACHMAN CONSULTANT SERVICES, INC.	OGD MONTHLY REPORT OCTOBER 2013
2013-8795	11/05/2013 12/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	INDIVIDUAL RECS
2013-8796	11/05/2013 12/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Helena Champion Drug Quality Assurance, LLC	ELOCTATE - 483 01/01/2013 - 10/28/2013
2013-8797	11/05/2013 12/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Helena Champion Drug Quality Assurance, LLC	SWEDISH ORPHAN BIOVITRUM AB, STOCKHOLM, SWEVEN - 483 01/01/2013 - 10/28/2013
2013-8798	11/05/2013 12/05/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALL RECS 01/01/2009 - 12/31/2010
2013-8799	11/05/2013 12/05/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	510K REDACTED OCTOBER 2013
2013-8800	11/05/2013 12/05/2013	FDA/OGROP/ORO/SE-FO/NOL-DO/NOL-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	SESSIONS CO, ENTERPRISE, AL - RECALL RECS 01/01/2009 - 12/31/2010
2013-8801	11/05/2013 12/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tal Elmatad Tal Elmatad	ORANGE BOOK DATA - ARCHIVED 01/01/2002 - 12/31/2013

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2013-8802	11/05/2013 12/05/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/NE-FO/NYK- DO/NYK-DCB/	Eleanor DaCosta United States Pharmacopeial Convention (USP)	IMPORT REFUSAL KM6-0044921-9/5/1 GARLIC POWDER - LAB RESULTS
2013-8803	11/05/2013 12/05/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/NE-FO/NYK- DO/NYK-DCB/	Eleanor DaCosta United States Pharmacopeial Convention (USP)	IMPORT REFUSAL 399-0919683-2/1/1/C, 399-0919683-2/1/1/D OLIVE REFINED VEG OIL,SINGLE INGREDIENT - LAB RESULTS
2013-8804	11/05/2013 12/05/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SE-FO/ATL- DO/ATL-CB/	Eleanor DaCosta United States Pharmacopeial Convention (USP)	IMPORT REFUSAL EE3-1203575-5/1/1 GARLIC POWDER - LAB RESULTS
2013-8805	11/05/2013 12/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	Loren Larkin SAC CAPITAL ADVISORS LP	FDA CORR WITH DANAHER RE CLEAR ALIGNER DENTAL PRODUCTS 11/01/2011 - 11/01/2013
2013-8806	11/05/2013 01/02/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SW-FO/KAN- DO/KAN-CB/	Jim Doyle St. Louis Post-Dispatch	MERIDIAN MEDICAL TECHNOLOGIES - 483, WARNING LETTER 01/01/2010 - 11/01/2013
2013-8807	11/05/2013 12/05/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/SAN- DO/SAN-CB/	Eleanor DaCosta United States Pharmacopeial Convention (USP)	IMPORT REFUSAL BGL-0416132-9/1/1 HOT GARLIC POWDER - LAB RESULTS
2013-8808	11/05/2013 12/05/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/NE-FO/NYK- DO/NYK-DCB/	Eleanor DaCosta United States Pharmacopeial Convention (USP)	IMPORT REFUSAL 497-1002162-5/2/1 GARLIC GROUND CRACKED - LAB RESULTS
2013-8809	11/05/2013 12/05/2013	OC/CVM/OCD/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sierra Timmons Student	HYDROCHLOROTHIAZIDE - ORIGINAL ANIMAL STUDIES
2013-8810	11/05/2013 12/05/2013	OC/ORO/ OC/ORO/	Susan Thixton Association for Truth in Pet Food	RECS FROM NY STATE DEPARTMENT OF AGRICULTURE AND MARKETS RE TESTING OF CHINESE DOG JERKY TREATS 01/01/2013 - 02/28/2013

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		OC/CVM/OCD/ FDA/OGROP/ORANE-FO/NYK- DO/NYK-DCB/		
2013-8811	11/05/2013 12/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Juliana Wexler BioPharm Insight	PMR, MPC RECS RE POMALYST, ICLUSIG, KYPROLIS ETC
2013-8812	11/05/2013 12/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jennifer Brennan COVIDIEN	K102168
2013-8813	11/05/2013 12/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jennifer Brennan COVIDIEN	K091808
2013-8814	11/05/2013 12/05/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Jennifer Brennan COVIDIEN	K990144
2013-8815	11/05/2013 12/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jennifer Brennan COVIDIEN	K091808, K102168
2013-8816	11/05/2013 12/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	william j crumb jr willim j crumb jr	INTUNIV - THOROUGH QT STUDY RESULTS
2013-8817	11/05/2013 12/05/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Peter T. Anderson, Esq. ASHCRAFT & GEREL, LLP	FRESENIUS MEDICAL CARE 2008K DIALYSIS MACHINE - 510K
2013-8818	11/05/2013 12/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	Peter T. Anderson, Esq. Ashcraft& Gerel	FRESENIUS 2008T DIALYSIS MACHINES - 510K
2013-8819	11/05/2013 12/05/2013	OC/ORAN/ OC/ORAN/ FDA/OGROP/ORAN/SE-FO/NOL- DO/NOL-CB/	Doe J	INDIVIDUAL RECS
2013-8820	11/05/2013 12/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michael P. Manapol Law Offices of Brian D. Witzer, Inc.	DILANTIN - WARNING RECS 01/01/2001 - 12/14/2011
2013-8821	11/05/2013 12/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	AUTUMN L. BORTON PFIZER INC	INSTITUTE MASSONE SA, ARGENTINA - 483, EIR, CO RESP SINCE 11/12

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2013-8822	11/05/2013 12/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	AUTUMN L. BORTON PFIZER INC.	SICOR DE MEXICO SA DE CV, MEXICO - 483, EIR, CO RESP SINCE 7/26/13
2013-8823	11/05/2013 12/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	AUTUMN L. BORTON PFIZER INC.	DR REDDYS DE MEXICO, MEXICO - 483, EIR, CO RESP SINCE 3/30/12
2013-8824	11/05/2013 12/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	AUTUMN L. BORTON PFIZER INC.	ORGANO SINTESIS SA, MEXICO - EIR, 483, CO RESP SINCE 10/25/12
2013-8825	11/05/2013 12/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	AUTUMN L. BORTON PFIZER INC.	LABORATORIES LIMONT SA, MEXICO - EIR, 483, CO RESP 10/19/12
2013-8826	11/05/2013 12/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	AUTUMN L. BORTON PFIZER INC.	SIPRA LABS, INDIA - 483, EIR, CO RESP 9/22/11
2013-8827	11/05/2013 12/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN J. MALLOY MALLOY & ASSOCIATES INC	TESTOSTERONE TEST SYS K120009; LIASION 25 OH VITAMIN D TOTAL ASSAY K112725
2013-8828	11/05/2013 12/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	KEPPRA; IMDUR; LISINOPRIL - AER
2013-8829	11/05/2013 12/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RYAN, BRENDAN	SPECIAL PROTOCOL ASSESSMENT (SPA)
2013-8830	11/05/2013	FDA/OMPT/CDRH/OCER/DFOI/		TRANSTRACHEAL SYS INC K981080, K970018

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	12/05/2013		SPOFFORD, BRYAN	
2013-8831	11/05/2013 12/05/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	CAMACHO, JESSICA	CMLPNT 127509; 128637; 130162 ETC
2013-8832	11/05/2013 12/05/2013	FDA/OC/OES/DFOI/	CAITLIN HOWELL IOVATE HEALTH SCIENCES INTERNATIONAL INC	OXY ELITE; USP LABS OXYELITE; USP OXYELITE - RECS 6/12 TO PRESENT
2013-8833	11/05/2013 12/05/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORO/PA-FO/SEA-DO/SEA-CB/	DAVID E. PERRY Charles Taylor Adjusting	CHOBANI INC - GREEK YOGART RECALL, INVESTIGATIONS
2013-8834	11/05/2013 12/05/2013	FDA/OC/OES/DFOI/	JASON SMATHERS MUCKROCK NEWS	DIVESTITURE OF PROHIBITED HOLDINGS MEMO - FORM LTR
2013-8835	11/05/2013 12/05/2013	FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/	MATTHEW PERRONE ASSOCIATED PRESS	CORR BETWEEN FDA & ZOGENIX INC, SAN DIEGO, CA 10/24/12 TO 10/24/13
2013-8836	11/05/2013 12/05/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KIM HENDERSON SANOFI PASTEUR	GLAXO SMITH KLINE BIOLOGICALS, WAVRE, BELGIUM - 483
2013-8837	11/05/2013 12/20/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORO/PA-FO/SEA-DO/SEA-CB/	CARLA R. SCARMAZZI KING & SPALDING	CHOBANI INC - RECALL
2013-8838	11/05/2013 12/05/2013	FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/	K MICHELLE VASSALLO KING & SPALDING	HOME HEALTH PAVILLION, NEWBURGH, NY - 483, EIR, WARNING LTR 1/98 TO PRESENT
2013-8839	11/05/2013 12/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LESLIE SANDS LUPIN PHARMACEUTICALS INC	EISAI INC - ARICEPT (DONEPEZIL HYDROCHLORIDE) NDA 20-690

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-8840	11/05/2013 12/05/2013	FDA/OC/OES/DFOI/	REBECCA FIELD EMERSON MITTS LAW LLC	DIRECT VET MARKETING INC - WARNING LTR SINCE 1/09
2013-8841	11/05/2013 12/05/2013	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	K. MICHELLE VASSALLO LINCARE INC	EDDIE TESTS HOME MEDICAL, RINGGOLD, GA - EIRS, WARNING LTRS, 483 1/98 TO PRESENT
2013-8842	11/05/2013 12/05/2013	FDA/OMPT/CTP/OD/	NATALIE N. SANDERS LATHAM & WATKINS LLP	SUBSTANTIAL EQUIVALENCE RPTS FOR ALL FIVE TOBACCO PRODUCTS
2013-8843	11/05/2013 12/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORR/CE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORR/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/ FDA/OC/OES/DFOI/	JOHN CREWDSON PROJECT ON GOVERNMENT OVERSIGHT	EIRS, 483S
2013-8844	11/05/2013 12/17/2013	FDA/OC/OES/ FDA/OMPT/CTP/OD/ FDA/OC/OCC/ FDA/OC/OL/	ASHLEY W. CRAIG VENABLE LLP	E CIGARETTES - AERS, CONGRESSIONAL CORR, SAFETY RECS, ETC
2013-8845	11/05/2013 12/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	BENJAMIN L. ENGLAND, Esq. BENJAMIN L ENGLAND & ASSOCIATES LLC	K124044; K061466
2013-8846	11/05/2013 12/05/2013	FDA/OC/OES/DFOI/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	IOVATE, SMARTBURN, HYDROXYCUT, ETC - AER
2013-8847	11/05/2013 12/05/2013	FDA/OFVM/CFSSAN/OCD/EOS/ OC/ORR/	DIANNE L. CHAMBERS HOGAN LOVELLS LLP	CAERS

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		OC/OR/ FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/		
2013-8848	11/06/2013 12/06/2013	FDA/OFVM/CFSAN/OCD/EOS/	JORI BALDWIN IMPROV'EAT	JULIAN BAKERY, PALEO INC, PHILIPPINES - FOOD FACILITY REGISTRATION
2013-8849	11/06/2013 12/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHANNON TURNER GLAXO SMITH KLINE	BARNARD CASTLE - QUALITY ASSURANCE PROFILE (QAP)
2013-8850	11/06/2013 12/06/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DANA THOMPSON FULBRIGHT & JAWORSKI LLP	DERMA SCIENCES INC, PRINCETON, NJ - MEDIHONEY MDRS, CORR, 510K, ETC 1/07 TO PRESENT, ETC
2013-8851	11/06/2013 12/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TONIA THOMY Institute of Social and Preventive Medicine	ERYTHROPOIESIS-STIMULATING AGENTS - RECS
2013-8852	11/06/2013 12/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARK L WINDHAM SMITH SEGURA & RAPHAEL LLP	INVIVO BIOEQUIVALENCE STUDY FOR CONJUGATED ESTROGENS TABS - FDA DRAFT GUIDANCE 6/16/89
2013-8853	11/06/2013 12/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kasia Petchel Optimer Pharmaceuticals, Inc.	DIFICID - AERS
2013-8854	11/06/2013 12/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	Karin Desjardins COVIDIEN	K993933
2013-8855	11/06/2013 12/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Patricia O'Donnell Ironwood Pharmaceuticals	LINZESS - AERS

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-8856	11/06/2013 12/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Cynthia Kusba CONSUMER	CORTROSYN TM - AERS
2013-8857	11/06/2013 12/06/2013	FDA/OC/OES/DFOI/	Bill Arden Wisconsin Analysts, Inc.	FOIA LOG 01/01/2013 - 11/05/2013
2013-8858	11/06/2013 12/06/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Aaron Craig MicroHealth	K100066, K120314, K112370
2013-8859	11/06/2013 12/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dennis Raisch UNIVERSITY OF NEW MEXICO	ICLUSIG - AERS
2013-8860	11/06/2013 12/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lisa Katz Lisa Katz	DOXYCYCLINE - AERS
2013-8861	11/06/2013 12/06/2013	FDA/OC/OES/DFOI/	Doe J	BARD - KUGEL MESH RECALL RECS
2013-8862	11/06/2013 02/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jonathan Demchick Morgan Stanley	INTUITIVE SURGICAL - COMM WITH FDA RE NEW PRODUCT APPROVALS 11/04/2011 - 12/31/2013
2013-8863	11/06/2013 12/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Alyssa F. Ossenkop Ossenkop, Alyssa F	MIRVASO - AERS
2013-8864	11/06/2013 12/06/2013	FDA/OGROP/ORAC/CE-FO/NWJ-DO/NWJ-CB/	William Stahovec Catalyst Pharmaceutical Partners, Inc.	JACOBUS PHARMACEUTICAL, PLAINSBORO, NJ - EIR, 483 01/05/2003 - 12/31/2011
2013-8865	11/06/2013 12/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K081136
2013-8866	11/06/2013 12/06/2013	FDA/OC/OES/DDM/ FDA/OC/OES/DFOI/	ANNESLEY H DEGARIS CORY WATSON ET AL	HOWMEDICA OSTEONICS CORP, STRYKER ORTHOPEDICS - STRYKER REJUVENATE MODULAR HIP IMPLANT MINS, TRANS, RPTS, ETC

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		FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDRH/OCER/DFOI/		
2013-8867	11/06/2013 12/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	Renee Murphy Alphatec Spine	K110216
2013-8868	11/06/2013 12/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	JETREA - AERS
2013-8869	11/06/2013 12/06/2013	FDA/OMPT/CTP/OD/	Katherine Peralta MEDILL NEWS SERVICE	ECIGARETTES - AERS LAST THREE YEARS
2013-8870	11/06/2013 12/06/2013	FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA REQUEST LOG 10/28/2013 - 11/01/2013
2013-8871	11/06/2013 12/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	AGILA - MOST RECENT INSPECTION RECS
2013-8872	11/06/2013 12/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	Julie Hall Butler, Vines & Babb, PLLC	ANGIO-SEAL STS PLUS VASCULAR CLOSURE DEVICE - ADVERSE EVENTS
2013-8873	11/06/2013 12/06/2013	FDA/OFVM/CFSAN/OCD/EOS/	Rend Al-Mondhiry COUNCIL FOR RESPONSIBLE NUTRITION	DIETARY SUPPLEMENT REGISTRATION DATA
2013-8874	11/06/2013 12/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	EDWARDS, S ALBERT	AVELOX (MOXIFLOXACIN HCL) TABS, NOROXIN (NORFLOXACIN) TABS, FLOXIN (OFLOXACIN) TABS, ETC - LBLG CHANGE
2013-8875	11/06/2013 12/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	Full 510(k) for K953673 TIDI Products, LLC	K953673
2013-8876	11/06/2013 12/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	submit report of 510(k) Number K781831 and K801199 Besmed Health Business Corp.	K781831, K801199
2013-8877	11/06/2013 12/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELIZABETH BARBEHENN PHD PUBLIC CITIZEN	VIZAMYL (FLUTEMETAMOL F-18) NDA 203-137 APRVL RECS

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-8878	11/06/2013 12/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELIZABETH BARBEHENN PHD PUBLIC CITIZEN	BRISDELLE (PAROXETINE MESYLATE) NDA 204-516 - APRVL RECS
2013-8879	11/06/2013 12/06/2013	FDA/OC/OES/DFOI/	SCZGELSKI, DOUGLAS	FDA HIRING PREFERENCE TO PEOPLE WHO HAVE SERVED IN THE PEACE CORPS
2013-8880	11/06/2013 12/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FRIEDMAN, ROBERT	NOXAFIL ORAL SUSPENSION - AERS 1969 TO 2013
2013-8881	11/06/2013 12/06/2013	FDA/OFVM/CFSAN/OCD/EOS/	FRIEDMAN, ROBERT	COROMEGA CHILD BRAIN & BODY DHA PACKETS - CAERS 1969 TO 2013
2013-8882	11/06/2013 12/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	MICHELE L BUENAFE MORGAN LEWIS & BOCKIUS LLP	CDRH UNTITLED LTRS, CORR CONCERNING VIOLATIVE MEDICAL DVC ADVERTISING, MARKETING, LBLG, ETC 1/12 TO 6/12
2013-8883	11/06/2013 12/06/2013	OC/ORA/ OC/ORA/ OC/ORA/ORM/ OC/ORA/ORM/	GAIL LESSICK LACHMAN CONSULTANT SERVICES, INC.	DRUG COMPANIES, MEDICAL DVC MFRS, BLOOD ESTABLISHMENTS, ETC - DOMESTIC AND FOREIGN INSPS 7/1-31/13
2013-8884	11/06/2013 12/06/2013	OC/ORA/ OC/ORA/ FDA/OFVM/CFSAN/OCD/EOS/ OC/ORA/ OC/ORA/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Liz Weiss U.S. News & World Report Travel	VESSEL INSPECTION REPORT INFORMATION ON HEALTH QUALITY 01/01/2008 - 10/28/2013
2013-8885	11/06/2013 12/06/2013	FDA/OC/OES/DDM/	MARK L WINDHAM SMITH SEGURA & RAPHAEL LLP	DKT 1985P-0097
2013-8886	11/06/2013 12/06/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	Steve Rogers Zoetis Inc.	BASI PRECLINICAL SERVICES, BIOANALYTICAL SERVICES, MT VERNON, IN - EIR, 483 01/01/2006 - 11/06/2013
2013-8887	11/06/2013 12/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	W E CHALKLEY THOMSON REUTERS	INTELENCE (ETRAVIRINE) NDA 22-187/S001 - APRVL RECS

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-8888	11/06/2013 12/06/2013	FDA/OO/OHR/	EDWARDS, S ALBERT	CDER - NUMBER OF FTES WORKING IN THE OFFICE OF DRUG SAFETY (ODS), NUMBER OF VACANT FTES NOT CURRENTLY STAFFED IN THE ODS, ETC
2013-8889	11/06/2013 12/06/2013	OC/ORO/ORM/ OC/ORO/ORM/	ROBERT KING FDA NEWS	PHARMACEUTICAL, BIOLOGICS, MEDICAL DVC MFG, CLNCL TRIAL FACILITIES INSIE & OUTSIDE THE US - 483S 10/1-31/13
2013-8890	11/06/2013 12/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHANNON TURNER GLAXO SMITH KLINE	GLAXOSMITHKLINE, BARNARD CASTLE, COUNTY DURHAM - EIR 4/13 TO 5/13
2013-8891	11/06/2013 12/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANDREW ALLEN RECKITT BENCKISER HEALTHCARE INTERNATIONAL LTD	BOEHRINGER INGELHEIM PHARMA GMBH & CO KG, INGELHEIM AM REHIN, GERMANY - EIR
2013-8892	11/06/2013 12/06/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	Mohit Bhat Kline & company Inc.	ROCHE DIAGNOSTICS, INDIANAPOLIS, IN AND PONCE, PR; NIPRO, FT LAUDERDALE, FL - EIR LAST FIVE YEARS
2013-8893	11/07/2013 12/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Christine Done, Regulatory Affairs Specialist Merit Medical Systems, Inc.	K062126 - SUBSTANTIAL EQUIVALENCE LETTER
2013-8894	11/07/2013 12/09/2013	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	Nate Morabito WJHL-TV	NORTHEAST TENNESSEE, SOUTHWEST VIRGINIA BLOOD BANK INSPECTIONS 01/01/2011 - 11/06/2013
2013-8895	11/07/2013 12/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K092398
2013-8896	11/07/2013 12/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ravi Pamnani STANFORD UNIVERSITY	CORTIFOAM APPROVAL RECS
2013-8897	11/07/2013 12/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ravi Pamnani STANFORD UNIVERSITY	ROWASA APPROVAL RECS

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2013-8898	11/07/2013 12/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Steven Tish DSM CAPITAL	TECFIDERA - AERS
2013-8899	11/07/2013 12/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Priya Karani BARCLAYS	JUXTAPID - AERS
2013-8900	11/07/2013 12/09/2013	OC/ORA/ OC/ORA/ OC/ORA/ OC/ORA/	Cathy Burgess ALSTON & BIRD	PHARMEDIUM - EIR 01/01/2013 - 11/06/2013
2013-8901	11/07/2013 12/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lawrence Blackmon Lawrence Blackmon	WOCKHARDT LTD - WARNING LETTER RECS 01/01/2013 - 11/06/2013
2013-8902	11/07/2013 12/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Faryal Hasan Hyman, Phelps & McNamara P.C.	ANDA 076133 APPROVAL LETTER
2013-8903	11/07/2013 12/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Derek Miles Larry Franklin Law Group, PSC	VACUUM, FORCEPS - ADVERSE EVENTS 2008
2013-8904	11/07/2013 12/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rayna E. Kessler LOPEZ MCHUGH LLP	BENICAR, BENICAR HCT, AZOR - NDA, COMMUNICATIONS, INTERNAL RECS ETC
2013-8905	11/07/2013 12/09/2013	FDA/OMPT/OSMP/OOPD/	Peter Mione CutisPharma, Inc.	EPANED - ORPHAN DESIGNATION RECS
2013-8906	11/07/2013 12/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Laura K. Chico Robert W. Baird & Co.	KYPROLIS - AERS

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		FDA/OMPT/CDER/ORP/DIDP/		
2013-8907	11/07/2013 12/09/2013	OC/CVM/OCD/	James Strickland WSB-TV	SPINOSAD - CVM ADE COMPREHENSIVE CLINICAL DATA REPORT
2013-8908	11/07/2013 12/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Amy Moore Sprout Pharmaceuticals	VIAGRA - AERS
2013-8909	11/07/2013 12/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	David Niedrig UniversityHospital Zurich	RIVAROXABAN - AERS
2013-8910	11/07/2013 12/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Laura K. Chico Robert W. Baird & Co.	ICLUSIG - AERS
2013-8911	11/07/2013 12/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	LIMIN ZHENG FISH & RICHARDSON PC	NANOSTRING TECHNOLOGIES INC - BREAST CANCER PROGNOSTIC GENE SIGNATURE ASSAY K130010
2013-8912	11/07/2013 12/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SUZANNE D JENSEN Kleinfeld, Kaplan Becker, LLP	DRUG ABUSE WARNING NETWORK (DAWN) - SOURCE RECS, CALCULATIONS, TABLES, ETC 2004 TO 2008
2013-8913	11/07/2013 12/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	NATALIE M MACKIEL WOLF POPPER LLP	AMARIN CORP - VASCEPA (ICOSPAENT EWTHYL) NDA 202-057/S005 PROTOCOL ASSESSMENT AGREEMENT, COMM, MEMOS, ETC
2013-8914	11/07/2013 12/09/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OC/OES/DFOI/	WNTERS 411079, BRANDON	WISCONSIN RESOURCE CENTER - BRAIN TAMPERING ALTERING CONTROLLING TECHNOLOGIES RECS
2013-8915	11/07/2013 12/09/2013	FDA/OC/OES/DFOI/	SIN, SARAH	DRUG RECALLS - FOIA REQUESTS 10/12 TO 10/13
2013-8916	11/07/2013 12/09/2013	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	AMALIA COVALLO AITA DIAGONAL AL GRUPO TACA	LAB RESULTS
2013-8917	11/08/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Tracy Johnson-Hall	ARIZONA FIRMS RECALL RECORDS 01/01/2009 - 12/31/2010

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	12/10/2013		Tracy Johnson-Hall	
2013-8918	11/08/2013 12/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	AGILA SPECIALTIES, INDIA - EIR SUMMARIES
2013-8919	11/08/2013 12/10/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	CALIFORNIA FIRMS RECALL RECS 01/01/2008 - 12/31/2011
2013-8920	11/08/2013 12/10/2013	FDA/OGROP/ORA/SW-FO/DEN- DO/DEN-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	COLORADO FIRMS RECALL RECS 01/01/2008 - 12/31/2010
2013-8921	11/08/2013 12/10/2013	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	CONNECTICUT FIRMS RECALL RECS 01/01/2009 - 12/31/2010
2013-8922	11/08/2013 12/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	John Chapman Stem Cell Partners LLC	K121005
2013-8923	11/08/2013 12/10/2013	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	FLORIDA FIRMS RECALL RECS 11/01/2008 - 12/31/2011
2013-8924	11/08/2013 12/10/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SEA- DO/SEA-CB/	Doe J	SAMPLE RESULTS
2013-8925	11/08/2013 12/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Prashanth jayaram prashanth jayaram - cig	KYRPOLIS, ADCENTRIS, NIVOLUMAB, ETC - AERS
2013-8926	11/08/2013 12/10/2013	FDA/OMPT/OSMP/OOPD/	Orphan Designation Request for Gralise LCC Consulting, LLC	GRALISE - ORPHAN DRUG DESIGNATION 01/01/2008 - 01/01/2013
2013-8927	11/08/2013 12/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Brian Steck Mangrove Partners	AGILA SPECIALTIES PRIVATE LIMITED - 483 11/07/2008 - 11/07/2013
2013-8928	11/08/2013	FDA/OMPT/CDER/GRP/DIDP/	Junan Guo	THERAPURE BIOPHARMA, CANADA - 483, UNTITLED

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	12/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/CVM/OCD/	AMRI	LETTER 04/01/2012 - 11/01/2013
2013-8929	11/08/2013 12/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	William birdsall Birdsall, William	RELIANT HEART, HOUSTON, TX - IDE RECS
2013-8930	11/08/2013 12/10/2013	FDA/OC/OES/DDM/	Janet Arrowsmith Arrowsmith Consulting LLC	CLOZARIL - ADVISORY COMMITTEE RECS 02/01/1984 - 04/30/1984
2013-8931	11/08/2013 12/10/2013	FDA/OC/OES/DDM/	Janet Arrowsmith Arrowsmith Consulting LLC	CLOZARIL - PSYCHOPHARMACOLOGICAL ADVISORY COMMITTEE RECS 02/01/1984 - 04/30/1984
2013-8932	11/08/2013 12/10/2013	FDA/OC/OES/DFOI/	Laurice Koury Laurice Skin Care & Cosmetics	COMPLAINT RECS
2013-8933	11/08/2013 12/10/2013	FDA/OC/OES/DFOI/	Relian Heart Inc. Birdsall, William	RELIANT HEART DEVICE
2013-8934	11/08/2013 12/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Junan Guo AMRI	ARCH PHARMALABS LTD, INDIA; VITALIFE LABORATORIES, INDIA - 483 10/01/2009 - 02/28/2010
2013-8935	11/08/2013 12/18/2013	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	ARKANSAS FIRM RECALL RECS 01/01/2008 - 12/31/2011
2013-8936	11/08/2013 12/10/2013	FDA/OC/OES/DFOI/	SHERRY, EDWARD J	ECOSMART - AERS
2013-8937	11/08/2013 12/10/2013	OC/ORO/ OC/ORO/	MARIA K PULZETTI FEDERAL COMMUNITY DEFENDER OFFICE FOR EASTERN DISTRICT OF PA	EAGLE ANALYTICAL SERVICES, HOUSTON, TX - EIRS, 483S, WARNING LTRS, ETC 1/11 TO PRESENT
2013-8938	11/08/2013 12/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WARREN WILLIAMS FOREST RESEARCH INSTITUTE	TEFLARO (CEFTAROLINE) MEDWATCH RPTS
2013-8939	11/08/2013	FDA/OFVM/CFSAN/OCD/EOS/	DR. GIBBERT SCHLEIER	FCN 1181

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	12/10/2013		BASF SE	
2013-8940	11/08/2013 12/10/2013	FDA/OFVM/CFSAN/OCD/EOS/	JEREMY JOHNSON Traditional Medicines	HAIN CELESTIAL GROUP INC - SLEEPYTIME THROAT TAMER RECS
2013-8941	11/08/2013 12/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	RISPERDAL - AER
2013-8942	11/08/2013 12/10/2013	FDA/OC/OES/DDM/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OL/	RAYNA E. KESSLER LOPEZ MCHUGH LLP	DAIICHI SANKYO - BENICAR, BENICAR HCT, AZOR (OLMESARTAN) NDA, DEAR DOCTOR LTRS, TRANS, ETC
2013-8943	11/08/2013 12/10/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/	Doe J	INDIVIDUAL RECS
2013-8944	11/08/2013 12/10/2013	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/ORM/ OC/ORO/ORM/	RICHARD LARDNER ASSOCIATED PRESS	REGULATED HUMAN FOOD PRODUCTION PROCESSING PLANTS & HUMAN FOOD DISTRIBUTION FACILITIES IN CHINA - 483S 2008 TO PRESENT
2013-8945	11/08/2013 12/10/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/	CHARLES S ROWLEY ROWLEY LAW PA	CMPLNT 133879
2013-8946	11/08/2013 12/10/2013	FDA/OFVM/CFSAN/OCD/EOS/	MONG THU NGO BASF CORP	SPRAGUE-DAWLEY RATS, CD-1 MICE - PIGMENT RED 181 STUDIES 1982
2013-8947	11/12/2013 12/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K132297
2013-8948	11/12/2013 12/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	KYPROLIS - FAER
2013-8949	11/12/2013 12/11/2013	FDA/OC/OES/DFOI/	Alexander G. Barney The Karmel Law Firm	HILL-ROM, BATESVILLE, IN - ALL RECS 03/01/2011 - 11/08/2013

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2013-8950	11/12/2013 12/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John Movassaghi John Movassaghi	CHANTIX - AERS
2013-8951	11/12/2013 12/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	Sally Bowden Biegler GmbH	K050123
2013-8952	11/12/2013 12/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	William Lewis AccelaPHARM, LLC	ICLUSIG - AERS
2013-8953	11/12/2013 12/11/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Symbio, LLC Symbio, LLC	DOW PHARMACEUTICAL SCIENCES, PETALUMA, CA - EIR LAST THREE YEARS
2013-8954	11/12/2013 12/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	William Lewis AccelaPHARM, LLC	OMONTYS - AERS
2013-8955	11/12/2013 01/27/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Reed Smith LLP REED SMITH LLP	BENEFIX - TEST METHODS, SPECIFICATIONS, TEST RESULTS ETC
2013-8956	11/12/2013 12/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	ICLUSIG - AERS
2013-8957	11/12/2013 12/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nathaniel August August, Nathaniel	OMONTYS - CASE REPORTS
2013-8958	11/12/2013 12/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Elliot Grysen Elliot Grysen	METHADONE - AERS

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		FDA/OMPT/CDER/ORP/DIDP/		
2013-8959	11/12/2013 12/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sandra Bartlett INTERNATIONAL CONSORTIUM OF INVESTIGATIVE JOURNALISTS	SCHERING, BERLEX, BAYER - DDMAC LETTERS
2013-8960	11/12/2013 12/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rich Laguna iRhythm Technologies, Inc.	K122184
2013-8961	11/12/2013 12/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	Margaret P. Kerns LRGHealthcare	BAXTER HEALTHCARE CORPORATION - WARNING LETTER UPDATES, STATUS RECS 04/01/2013 - 11/08/2013
2013-8962	11/12/2013 12/11/2013	FDA/OGROP/ORACE-FO/CIN- DO/CIN-CB/	David Bregar D D Bregar	BREMNER FOODS, PRINCETON, KY - INSPECTION RECS, LAB RESULTS 08/01/2013 - 10/31/2013
2013-8963	11/13/2013 12/12/2013	FDA/OGROP/ORACE-FO/CIN- DO/CIN-CB/	Blake Goodner BRIDGER BIOMED INC	ORTHOHELIX, MEDINA, OH - 483, RESPONSES, WARNING LETTERS 01/03/2012 - 11/11/2013
2013-8964	11/13/2013 12/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	b. burgess BURGESS, BERNIE	DSI RESPONSE TO OIG/HHS RE: I3938
2013-8965	11/13/2013 12/12/2013	FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN MAINE 01/01/2008 - 12/31/2011
2013-8966	11/13/2013 12/12/2013	FDA/OGROP/ORACE-FO/BLT- DO/BLT-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN MARYLAND 01/01/2008 - 12/31/2011
2013-8967	11/13/2013 12/27/2013	FDA/OGROP/ORACE-FO/DET- DO/DET-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN MICHIGAN 01/01/2008 - 12/31/2011
2013-8968	11/13/2013 12/12/2013	FDA/OC/OES/DDM/	Sarah L. Scott Goodell DeVries Leech & Dann LLP	JOINT MTG OF THE ARTHRITIS ADVISORY COMMITTEE AND DRUG SAFETY AND RISK ASSESSMENT COMMITTEE - TRANSCRIPT 10/09/1996 - 10/09/1996
2013-8969	11/13/2013 12/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sandra Bartlett INTERNATIONAL CONSORTIUM OF INVESTIGATIVE JOURNALISTS	BAYER WHITE PAPER SUBMITTED TO FDA RE YASMIN 01/07/2004 - 12/31/2004
2013-8970	11/13/2013 12/12/2013	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	CTP GUIDANCE TO TRAIN STAFF RE SE DETERMINATIONS - CORR, RESEARCH, BACKGROUND, ETC
2013-8971	11/13/2013 12/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Beth Glasgow GOJO Industries, Inc.	FDA MTG RE CITIZEN PETITION AND/OR TIME AND EXTENT APPLICATION TO SUPPORT HYDROGEN PEROXIDE

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		INCLUSION IN THE TENTATIVE FINAL MONOGRAPH FOR HEALTHCARE ANTISEPTIC PRODUCTS
2013-8972	11/13/2013 12/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jared Levine Harvard Extension School	NDA 020468 S035 SUPPLEMENT APPROVAL LETTER
2013-8973	11/13/2013 12/12/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Shaohong (Sherry) Zhang Shire Human Genetic Therapies, Inc	SHIRE HUMAN GENETIC THERAPY, BELMONT, MA - EIR 06/02/2011 - 06/02/2011
2013-8974	11/13/2013 12/12/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Shaohong (Sherry) Zhang Shire Human Genetic Therapies, Inc	SHIRE HUMAN GENETIC THERAPIES, INC, BELMONT, MA - EIR 06/02/2011 - 06/02/2011
2013-8975	11/13/2013 12/12/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS IN LOUISIANA
2013-8976	11/13/2013 12/12/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS IN ILLINOIS 01/01/2008 - 12/31/2011
2013-8977	11/13/2013 12/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PROFESSOR DAVID GORTLER GEORGETOWN UNIVERSITY SCHOOL OF MEDICINE	LEXAPRO - CASE REPORTS
2013-8978	11/13/2013 12/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	ANDA 202881
2013-8979	11/13/2013 12/12/2013	OC/ORA/ OC/ORA/ OC/ORA/OE/ OC/ORA/OE/	Kevin M. Barth Ballenger, Barth, Hoefer & Lewis, LLP	ON THE BORDER SAUCE - RECALL RECS 01/01/2009 - 11/11/2013
2013-8980	11/13/2013 12/12/2013	FDA/OC/OES/DFOI/	Ben Mouton Mouton, Benjamin	LIGACLIP MCA - MAUDE REPORTS, WARNING LETTERS, RECALLS 11/01/2013 - 11/11/2013
2013-8981	11/13/2013 12/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PROFESSOR DAVID GORTLER GEORGETOWN UNIVERSITY SCHOOL OF MEDICINE	CITALOPRAM - CASE REPORTS

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2013-8982	11/13/2013 12/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joshua A. Klarfeld ULMER & BERNE LLP	PAXIL - SBA
2013-8983	11/13/2013 12/18/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Reed Smith LLP REED SMITH LLP	RIXUBIS - TEST METHODS, SPECIFICATIONS, RESULTS ETC
2013-8984	11/13/2013 12/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	ANDA 65068
2013-8985	11/13/2013 12/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	ANDA 63014
2013-8986	11/13/2013 12/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	20 MMU PENICILLIN G SODIUM - NDA/ANDA
2013-8987	11/13/2013 12/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Juan Carlos Mondragon Quintana Harvard Kennedy School	FOREIGN DRUG PRODUCTS APPROVED 01/01/1990 - 10/31/2013
2013-8988	11/13/2013 12/12/2013	FDA/OGROP/ORAC/CE-FO/NWJ- DO/NWJ-CB/	William Stahovec Catalyst Pharmaceutical Partners	JACOBUS PHARMACEUTICAL CO, PLAINSBORO, NJ - EIR 01/01/2013 - 11/11/2103
2013-8989	11/13/2013 12/12/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORAC/ OC/ORAC/	Samuel May May, Sam J	BIOLOGICAL PRODUCT DEVIATIONS, ANNUAL, AND DISTRIBUTION REPORTS 11/08/2002 - 11/10/2008
2013-8990	11/13/2013	FDA/OC/OES/DFOI/	Robert King	FOIA REQUEST LOG 11/04/2013 - 11/08/2013

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	12/12/2013		FDANEWS	
2013-8991	11/13/2013 12/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rich Laguna iRhythm Technologies Inc.	K130294
2013-8992	11/13/2013 12/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michael Rice Marathon Pharmaceuticals, LLC	WOCKHARDT LTD - 483 07/01/2013 - 11/01/2013
2013-8993	11/13/2013 12/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kiran Kumar Gande Appco Pharmaceuticals Corporation	NDA 012649 - INSERT
2013-8994	11/13/2013 05/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Thomas Carpenter Nielsen BioSciences, Inc.	CANDIN - APPROVAL LETTERS, SUMMARY BASIS FOR REGULATORY ACTION, APPROVAL HISTORY ETC 01/01/1994 - 12/31/1996
2013-8995	11/13/2013 12/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mukteeshwar Gande Riconpharma, LLC	ANDA 087203
2013-8996	11/13/2013 12/27/2013	FDA/OGROP/ORR/CE-FO/DET-DO/DET-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCTS RECALLS FOR INDIANA FIRMS 01/01/2009 - 12/31/2011
2013-8997	11/13/2013 12/12/2013	FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCTS RECALLS FOR IOWA FIRMS 01/01/2009 - 12/31/2011
2013-8998	11/13/2013 12/12/2013	FDA/OGROP/ORR/PA-FO/SEA-DO/SEA-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCTS RECALLS FOR IDAHO FIRMS 01/01/2009 - 12/31/2011
2013-8999	11/13/2013 12/12/2013	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	Tracy Johnson-Hall COLLEGE OF WILLIAM AND MARY	PRODUCTS RECALLS FOR GEORGIA FIRMS 01/01/2009 - 12/31/2011
2013-9000	11/13/2013 12/12/2013	FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/ FDA/OGROP/ORR/CE-FO/CIN-DO/CIN-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCTS RECALLS FOR KANSAS FIRMS 01/01/2009 - 12/31/2010

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2013-9001	11/13/2013 12/12/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCTS RECALLS FOR HAWAII FIRMS 01/01/2008 - 12/31/2009
2013-9002	11/13/2013 12/12/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCTS RECALLS FOR INDIANA FIRMS 01/01/2009 - 12/31/2010
2013-9003	11/13/2013 12/12/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCTS RECALLS FOR MASSACHUSETTS FIRMS 01/01/2008 - 12/31/2011
2013-9004	11/13/2013 12/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jared Levine Harvard Extension School	NDA 020468/S-035 SUPPLEMENTAL APPROVAL LETTER
2013-9005	11/12/2013 12/11/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OFVM/CFSAN/OCD/EOS/	William Stewart William Stewart	JUST LIKE SUGAR - RECS 2004-2005
2013-9006	11/12/2013 12/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	Leo Basta NorthStar Biomedical Associates	K911577
2013-9007	11/12/2013 12/11/2013	FDA/OC/OES/DFOI/	MATTHEW MAHAFFIE BUCHANAN INGERSOLL & ROONEY PC	DKT 1976N-0377, SKT 1998P-1041, DKT 2013D-0880, ETC
2013-9008	11/12/2013 12/11/2013	FDA/OC/OES/DFOI/	CHRIS CELESTE EAS CONSULTING GROUP LLC	OTC VOL 100022, 100035, 100036
2013-9009	11/12/2013 12/11/2013	FDA/OC/OES/DFOI/	DAVID LENNETT NATURAL RESOURCES DEFENSE COUNCIL	DKT 2011N-0146-0024
2013-9010	11/12/2013 12/11/2013	FDA/OC/OES/DFOI/	CARLA DECARMAZZI KING & SPALDING	DKT 1978N-0272
2013-9011	11/12/2013 12/11/2013	FDA/OC/OES/DFOI/	SEAN WITZLING CITIZENS FOR HEALTH	DKT 2013P-0291
2013-9012	11/12/2013 12/11/2013	FDA/OC/OES/DFOI/	MARILYNN WHITNEY COVINGTON & BURLING LLP	DKT 1992P-0487
2013-9013	11/12/2013 12/11/2013	FDA/OC/OES/DFOI/	KLEINFELD KAPLAN AND BECKER	DKT 2008P-0407, DKT 2008P-0460
2013-9014	11/12/2013 12/11/2013	FDA/OC/OES/DFOI/	COLETTE MCCRONE VENABLE LLP	FERTILITY & MATERNAL HEALTH DRUGS A/C; JOINT A/C MTG BTWN FERTILITY & MATERNAL HEALTH DRUGS A/C

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2013-9015	11/12/2013 12/11/2013	FDA/OC/OES/DFOI/	MARILYNN WHITNEY COVINGTON & BURLING LLP	DKT 1975P-0006
2013-9016	11/12/2013 12/11/2013	FDA/OC/OES/DFOI/	MARILYNN WHITNEY COVINGTON & BURLING LLP	DKT 2012D-1145-0006
2013-9017	11/12/2013 12/11/2013	FDA/OC/OES/DFOI/	CARLA DECARMAZZI KING & SPALDING	DKT 2007D-0369
2013-9018	11/12/2013 12/11/2013	FDA/OC/OES/DFOI/	MARILYNN WHITNEY COVINGTON & BURLING LLP	DKT 2004N-0279
2013-9019	11/12/2013 12/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	Devin Craven Rheonix. Inc.	K032194
2013-9020	11/12/2013 12/11/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	JEFF GERRH PROPUBLICA	DKT 1977N-0094
2013-9021	11/12/2013 12/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	Devin Craven Rheonix, Inc.	K102911
2013-9022	11/12/2013 12/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Matthew Berry Non	LOMITAPIDE - CORR RE AERS, DROP OUT RATES, PATIENT REGISTRIES ETC 12/01/2012 - 11/11/2013
2013-9023	11/12/2013 12/11/2013	FDA/OC/OES/DFOI/	HEATHER GALE OLSSON FRANK & WEEDA	DKT 20013P-1293
2013-9024	11/12/2013 12/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	Blake Goodner BRIDGER BIOMED INC	TORNIER, MONTBONNOT, FRANCE - 483, RESPONSE 01/03/2012 - 11/11/2013
2013-9025	11/12/2013 12/11/2013	FDA/OC/OES/DFOI/	Jason DeYoung Jason DeYoung	FOOD FACILITY REGISTRATION DATA - OHIO, INDIANA, MICHIGAN
2013-9026	11/13/2013 12/12/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-7596 REQUEST LETTER
2013-9027	11/13/2013 12/12/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-7447 - REQUEST LETTER
2013-9028	11/13/2013 12/12/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	William Savage BRIGHAM AND WOMEN'S HOSPITAL	TRANSFUSION RELATED FATALITIES DUE TO ANAPHYLAXIS
2013-9029	11/13/2013 12/12/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Eli Chen Nanophthalmos	K101861

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2013-9030	11/13/2013 12/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	Eli Chen Nanophthalmos	K123464
2013-9031	11/13/2013 12/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K021837
2013-9032	11/13/2013 12/12/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-7228 - REQUEST LETTER
2013-9033	11/13/2013 12/12/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-7397 - REQUEST LETTER
2013-9034	11/13/2013 12/12/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-7445 - REQUEST LETTER
2013-9035	11/13/2013 12/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	Devin Craven Rheonix, Inc.	K111409
2013-9036	11/13/2013 12/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sandra Bartlett INTERNATIONAL CONSORTIUM OF INVESTIGATIVE JOURNALISTS	YASMIN - IMS, SERS DATABASE REVIEWS TO CALCULATE THROMBOEMBOLIC EVENT RATE
2013-9037	11/13/2013 12/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	Devin Craven Rheonix, Inc.	K121710
2013-9038	11/13/2013 12/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	Devin Craven Rheonix, Inc.	K122062
2013-9039	11/13/2013 12/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	Devin Craven Rheonix, Inc.	K130268
2013-9040	11/13/2013 12/12/2013	FDA/OC/OES/DDM/	Anthony LaViola Boca Pharmacal, LLC	00P-1641/CP1
2013-9041	11/13/2013 12/12/2013	FDA/OFVM/CFSAN/OCD/EOS/	Laura cardenas Cardenas, Laura N	YOLI.COM -SAFETY, APPROVAL 10/01/2012 - 11/12/2013
2013-9042	11/13/2013 12/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Brooke Hazan KENYON & KENYON LLP	NDA 21487 - SAFETY REVIEW
2013-9043	11/13/2013 12/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sandra Bartlett INTERNATIONAL CONSORTIUM OF INVESTIGATIVE JOURNALISTS	MINUTES OF TELECONFERENCE WITH SCHERING/BERLEX/BAYER RE SAFETY OF YASMIN 01/01/2000 - 12/21/2006

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2013-9044	11/13/2013 12/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Brooke Hazan KENYON & KENYON LLP	NDA 21627 - CLINICAL PHARMACOLOGY BIOPHARMACEUTICS REVIEW
2013-9045	11/13/2013 12/12/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Chris Ritter Ritter, Chris	ORTHOSCAN HD WITH FLAT DETECTOR-OR - APPROVAL, COMPLIANCE RECS 01/01/2000 - 11/12/2013
2013-9046	11/13/2013 12/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Brian Overstreet ADVERSEEVENTS INC	ZIRGAN - AERS
2013-9047	11/13/2013 12/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Brian Overstreet ADVERSEEVENTS INC	VPRIV - AERS
2013-9048	11/13/2013 12/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Patrick Knowles Patrick Knowles	SAREPTA THERAPEUTICS - CORR, ARTICLES, NOTES RE ETEPLIRSEN 05/01/2013 - 11/12/2013
2013-9049	11/13/2013 12/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CAUDLE, BRANDON	VIREAOL - PI
2013-9050	11/13/2013 12/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CAUDLE, BRANDON	COMPLERA - PI
2013-9051	11/13/2013 12/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CAUDLE, BRANDON	TRIZIVIR - PI

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2013-9052	11/13/2013 12/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CAUDLE, BRANDON	EMTRIVA - PI
2013-9053	11/13/2013 12/12/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANDREW HACK, MD, Ph.D. MILLENNIUM MANAGEMENT LLC	JUXTAPID (LOMITAPIDE) FAERS; AEGERION PHARMACEUTICALS INC - 483, EIR, UNTITLED LTRS 8/1/13 TO PRESENT
2013-9054	11/13/2013 12/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	ANDREW HACK MD, Ph.D. MILLENNIUM MANAGEMENT LLC	ONYX PHAMACEUTICALS INC; AMGEN INC - 483, EIR, UNTITLED LTRS 5/1/13 TO PRESENT; KYPROLIS (CARFILZOMIB) FAERS
2013-9055	11/13/2013 12/12/2013	OC/CVM/OCD/	KRISTI O. SMEDLEY, Ph.D. Center for Regulatory Services, Inc.	FAP 2226
2013-9056	11/13/2013 12/12/2013	FDA/OFVM/CFSAN/OCD/EOS/	VISAGINE VIJAYAKULASINGAM IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 169605, 167755, 165504, 165500
2013-9057	11/13/2013 12/12/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANDREW HACH, MD, Ph.D. MILLENNIUM MANAGEMENT LLC	SEATTLE GENETICS INC - 483, EIR , UNTITLED LTRS, 2/1/13 TO PRESENT; ADCETRIS (BRETUXIMAB VEDOTIN) FAERS
2013-9058	11/13/2013 12/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	S. ALBERT EDWARDS S ALBERT EDWARDS, PHARM D	LEVAQUIN - LBLG VERSION 3 & 8
2013-9059	11/13/2013 12/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PETER S. REICHERTZ SHEPPARD MULLIN ET AL	GENERAMEDIX - NULECIT ANDA 78-215 BIOEQUIV, CHEMISTRY RVW 10/1/09 TO PRESENT

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2013-9060	11/13/2013 12/12/2013	FDA/OC/OES/DFOI/	ZACK SAMPSON MUCKROCK NEWS	SHUTDOWN DOCUMENTS
2013-9061	11/13/2013 12/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	BARRY STANIFORD NIPRO Diagnostics	MW 5032320
2013-9062	11/13/2013 12/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	BARRY STANIFORD NIPRO Diagnostics	MW 5032049
2013-9063	11/13/2013 12/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	BARRY STANIFORD NIPRO Diagnostics	MW 5032347
2013-9064	11/13/2013 12/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	SHARI L. MYSZKA 3M ESPE Dental Products	PULPDENT CORP - FLOURIDE VARNISH K093620
2013-9065	11/13/2013 12/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	SHARI MYSZKA 3M ESPE Dental Products	PULPDENT CORP - ACTIV VARNISH K112946
2013-9066	11/13/2013 12/12/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	SHARI L. MYSZKA 3M ESPE Dental Products	DENTAL TECHNOLOGIES INC - ALPHA PRO WHITE VARNISH K124025
2013-9067	11/13/2013 12/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	SHARI L. MYSZKA 3M ESPE Dental Products	ELEVATE ORAL CARE - SMARTCOAT NAF VARNISH K131376
2013-9068	11/13/2013 12/12/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DENNIS C. GUCCIARDO HOGAN LOVELLS LLP	DEPUY ORTHOPEDICS INC - K011533, K031495, K031803 ETC
2013-9069	11/13/2013 12/12/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DENNIS C. GUCCIARDO Hogan Lovells, ILP	DEPUY ORTHOPEDICS INC - K983014, K033273, K043058
2013-9070	11/13/2013 12/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ARTHUR Y. TSIEN OFW LAW	REMODULIN (TREPASTINIL) NDA 21-272/S020 APRVL
2013-9071	11/13/2013 12/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SEIDMAN, ROBERT	HP ACTHAR NDA N008372 SBA

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2013-9072	11/13/2013 12/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	LEAH R. CAPITINI ANDRUS HOOD & WAGSTAFF PC	BOSTON SCIENTIFIC CORP - BLUE SUI SLING K121754
2013-9073	11/13/2013 12/12/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	K. MICHELLE VASSALLO LINCARE INC	HOME HEALTH PAVILLION, NEWBURGH, NY - 483, EIR, WARNING LTR 1/98 TO PRESENT
2013-9074	11/13/2013 12/12/2013	FDA/OC/OES/DFOI/	GEORGE A. STAMBOULIDIS BAKER & HOSTETLER, LLP	MINOR DELETIONS
2013-9075	11/13/2013 12/12/2013	FDA/OC/OES/DFOI/	KATHRYN E. WHITE ESPTEIN BECKER ET AL	MINOR DELETIONS
2013-9076	11/13/2013 12/12/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/OIP/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	SEAN MEENAN WINSTON & STRAWN LLP	LIBERT VEGETABLE OIL - INVESTIGATIONS 2008 TO 2010
2013-9077	11/13/2013 12/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SAMMY ALMASHAT, MD PUBLIC CITIZEN	KETOCONAZOLE - SAFETY & EFFICACY
2013-9078	11/14/2013 12/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K031328
2013-9079	11/14/2013 12/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K080668
2013-9080	11/14/2013 12/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K130366
2013-9081	11/14/2013 12/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K101431
2013-9082	11/14/2013 12/13/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K022236
2013-9083	11/14/2013 12/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K102511
2013-9084	11/14/2013 12/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Brian Overstreet ADVERSEEVENTS INC	LATUDA - AERS
2013-9085	11/14/2013	FDA/OMPT/CDER/GRP/DIDP/	Brian Overstreet	ONFI - AERS

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2013-9086	11/14/2013 12/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Brian Overstreet ADVERSEEVENTS INC	ZEMAIRA - AERS
2013-9087	11/14/2013 12/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Brian Overstreet ADVERSEEVENTS INC	ISOPTO CARPINE - AERS
2013-9088	11/14/2013 12/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Brian Overstreet ADVERSEEVENTS INC	EDARBYCLOR, INTERMEZZO, EYLEA - AERS
2013-9089	11/14/2013 12/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Brian Overstreet ADVERSEEVENTS INC	XIAFLEX - AERS
2013-9090	11/14/2013 12/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Brian Overstreet ADVERSEEVENTS INC	LASTACRAFT - AERS
2013-9091	11/14/2013 12/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Brian Overstreet ADVERSEEVENTS INC	GLASSIA - AERS
2013-9092	11/14/2013	FDA/OMPT/CDER/ORP/DIDP/	Brian Overstreet	STAXYN - AERS

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2013-9093	11/14/2013 12/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Brian Overstreet ADVERSEEVENTS INC	JAKAFI - AERS
2013-9094	11/14/2013 12/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Brian Overstreet ADVERSEEVENTS INC	ERIVEDGE - AERS
2013-9095	11/14/2013 12/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Brian Overstreet ADVERSEEVENTS INC	XTANDI - AERS
2013-9096	11/14/2013 12/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Brian Overstreet ADVERSEEVENTS INC	SIRTURO, ELIQUIS, SIGNIFOR - AERS
2013-9097	11/14/2013 12/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Brian Overstreet ADVERSEEVENTS INC	ADCIRCA - AERS
2013-9098	11/14/2013 12/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Brian Overstreet ADVERSEEVENTS INC	ARCALYST - AERS
2013-9099	11/14/2013 12/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Brian Overstreet ADVERSEEVENTS INC	BIDIL - AERS
2013-9100	11/14/2013 12/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Brian Overstreet ADVERSEEVENTS INC	EGRIFTA - AERS

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2013-9101	11/14/2013 12/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tyler Carter Waycross Partners	SAREPTA THERAPEUTICS - MTG MINUTES 11/8/13
2013-9102	11/14/2013 12/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Brian Overstreet ADVERSEEVENTS INC	PERJETA - AERS
2013-9103	11/14/2013 12/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Brian Overstreet ADVERSEEVENTS INC	KYPROLIS - AERS
2013-9104	11/14/2013 12/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Brian Overstreet ADVERSEEVENTS INC	LOESTRIN FE - AERS
2013-9105	11/14/2013 12/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Brian Overstreet ADVERSEEVENTS INC	APTOM, GAZYVA, ADEMPAS ETC
2013-9106	11/14/2013 12/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Brian Overstreet ADVERSEEVENTS INC	INLYTA - AERS
2013-9107	11/14/2013 12/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Brian Overstreet ADVERSEEVENTS INC	EPIDUO - AERS
2013-9108	11/14/2013	FDA/OMPT/CDER/ORP/DIDP/	Brian Overstreet	QNASI - AERS

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2013-9109	11/14/2013 12/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Brian Overstreet ADVERSEEVENTS INC	ULFESIA - AERS
2013-9110	11/14/2013 12/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Brian Overstreet ADVERSEEVENTS INC	ZYMAXID - AERS
2013-9111	11/14/2013 12/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Brian Overstreet ADVERSEEVENTS INC	BOSULIF - AERS
2013-9112	11/14/2013 12/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	David Dortch QIAGEN Inc.	QIAGEN - EIR 01/01/2013 - 11/12/2013
2013-9113	11/14/2013 12/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Brian Overstreet ADVERSEEVENTS INC	XYNTHA - AERS
2013-9114	11/14/2013 12/13/2013	FDA/OFVM/CFSAN/OCD/EOS/	Scott Thenell THENELL & ASSOCIATES LLC	MON 87769 Biotechnology Notification File No. 117
2013-9115	11/14/2013 12/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Brian Overstreet ADVERSEEVENTS INC	7533182, 7533186, 7533200, ETC - CASE REPORTS
2013-9116	11/14/2013 12/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K093659
2013-9117	11/14/2013 12/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Glen Kelley INTELLIJECT LLC	NDA 019430 - MANUFACTURING CHANGES

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2013-9118	11/14/2013 12/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Adrienne E Faerber, PhD Dartmouth Inst. Cent. For Med. Media.	Annual Report on Postmarketing Requirements and Commitments from Eisai Inc for Belviq (lorcaserin, NDA 22529) submitted to FDA on August 20, 2013; Annual Report on Postmarketing Requirements and Commitments from Vivus Inc for Qsmia (phentermine/topiramate, NDA 22580) submitted to FDA on September 16, 2013
2013-9119	11/14/2013 12/13/2013	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	Melody Petersen THE ORANGE COUNTY REGISTER	UNIVERSITY OF CALIFORNIA IRVINE - 483 01/01/2009 - 11/30/2013
2013-9120	11/14/2013 12/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Raquel Mura Reckitt Benckiser Inc.	TADAFIL, CIALIS - AERS SUMMARY
2013-9121	11/14/2013 12/13/2013	FDA/OFVM/CFSAN/OCD/EOS/	Scott Thenell THENELL & ASSOCIATES LLC	MON 87705 (MON-8775-6) Biotechnology Notification File No. 121
2013-9122	11/14/2013 12/13/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	510K Changzhou Holymed Products Co., Ltd	K050207, K021692
2013-9123	11/14/2013 12/13/2013	OC/ORAP/ OC/ORAP/ FDA/OGROP/ORAP/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORAP/SW-FO/SWID/SWID-CB/	SAMANTHA MYERS ROANOKE CLAIMS SERVICES	QUALITY PRODUCE - ENTRY #FS300471133 NOTICES FOR REQUEST OF INFORMATION (CF28), NOTICE OF ACTION, CBP REDELIVER NOTICES (CF4647), ETC
2013-9124	11/14/2013 12/13/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	BRETT PARK CONWAY HOMER & CHIN-CAPLAN PC	INDIVIDUAL RECS
2013-9125	11/14/2013 12/13/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Michelle D. Johnson JOHNSON, MICHELLE R	VAERS DATA - FLU VACCINE IN MARYLAND 01/01/2009 - 10/01/2013
2013-9126	11/14/2013 12/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Matthew McKeever Matt McKeever	SAREPTA THERAPEUTICS - PREMEETING COMMENTS, MEETING MINUTES 04/01/2013 - 11/08/2013
2013-9127	11/14/2013	FDA/OMPT/CBER/OCOD/DDOM/	Michelle D. Johnson	VAERS DATA - FLU VACCINE VIRGINIA, DC 01/01/2009 -

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	12/13/2013	ALFB/	JOHNSON, MICHELLE R	10/31/2013
2013-9128	11/14/2013 12/13/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Foley Hoag LLP on behalf of karmadata, Inc. karmadata, Inc.	Submitted Investigational New Drug Applications (Form 1571) and Statements of Investigator (Form 1572) to the FDA on File from January 1, 2007 to Present
2013-9129	11/14/2013 12/13/2013	FDA/OGROP/ORASW-FO/DEN- DO/DEN-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN S BAKER IV LIGHTFOOT FRANKLIN & WHITE LLC	WWW.THEHCDROPS.COM, THE HCG DROPS LLC - HOMEOPATHIC HCG RECS
2013-9130	11/14/2013 12/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SEBASTIAN SALAS-VEGA LONDON SCHOOL OF ECONOMICS AND POLITICAL SCIENCE	ABILIFY, PRADAXA, PRISTIQ, ETC - EFFICACY TRIALS 2000 TO 2010
2013-9131	11/14/2013 12/13/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DDM/ FDA/OMPT/CDRH/OCER/DFOI/	PAUL STOKELY ROSENBLATT BUTLER SNOW ET AL	DKT 1978N-2650
2013-9132	11/14/2013 12/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHANNA WONG BIOCARE MEDICAL	K120663
2013-9133	11/14/2013 12/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANUSHA KAMBHAMPATY RETROPHIN INC	JOHNSON AND JOHNSON, ORTHO-MCNEIL-JANSSEN PHARMS DIVISION/SK BIOPHARMACEUTICALS - CARISBAMATE RECS
2013-9134	11/14/2013 12/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CAUDLE, BRANDON	RETROVIR - PI
2013-9135	11/14/2013 12/13/2013	OC/ORASOCI/ OC/ORASOCI/	Doe J	INDIVIDUAL RECS
2013-9136	11/14/2013 12/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MICHAEL R COHEN RPH MS SCD INSTITUTE FOR SAFE	MEDWATCH RPTS CODED AS MEDICATION ERRORS 10/1- 31/13

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MEDICATION PRACTICES	
2013-9137	11/14/2013 12/13/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	JIM YOUNG GENERAL PHYSIOTHERAPY, INC.	GENERAL PHYSIOTHERAPY INC, ST LOUIS, MO - EIR MOST RECENT
2013-9138	11/14/2013 12/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Althea Burton PATH	K080040
2013-9139	11/14/2013 12/13/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALL DATA FOR OHIO FIRMS 01/01/2008 - 12/31/2011
2013-9140	11/14/2013 12/13/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALL DATA FOR NEW YORK FIRMS 01/01/2008 - 12/31/2011
2013-9141	11/14/2013 12/13/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALL DATA FOR NORTH CAROLINA FIRMS 01/01/2009 - 12/31/2011
2013-9142	11/14/2013 12/13/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALL DATA FOR OREGON FIRMS 01/01/2008 - 12/31/2011
2013-9143	11/14/2013 03/21/2014	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALL DATA FOR PENNSYLVANIA FIRMS 01/01/2008 - 12/31/2011
2013-9144	11/14/2013 12/13/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALL DATA FOR RHODE ISLAND FIRMS 01/01/2009 - 12/31/2011
2013-9145	11/14/2013 12/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	SUSAN HAMET DAVA PHARMACEUTICALS INC	CHARTWELL PHARMS, CONGERS, NY - QUALITY ASSURANCE PROFILE (QAP), CO RESP, EIR 9/19/12
2013-9146	11/14/2013 12/13/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	GARRETT S BOOTH MD MS VANDERBILT UNIVERISTY MEDICAL CENTER	BLOOD PRODUCT TRANSFUSION FATALITES - RECS 2005 TO PRESENT
2013-9147	11/14/2013 12/13/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	AMANDA NERONE HEARTLAND LIONS EYE BANKS	INDIANA LIONS EYE AND TISSUE TRANSPLANT BANK, INDIANAPOLIS,IN - EIR, 483, RECALLS LAST 2 YRS
2013-9148	11/14/2013 12/13/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	AMANDA NERONE HEARTLAND LIONS EYE BANKS	VRL LABS, CENTENNIAL, CO - EIR, 483, RECALLS LAST 2 YRS
2013-9149	11/14/2013 12/13/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	AMANDA NERONE HEARTLAND LIONS EYE BANKS	LABS INC, CENTENNIAL, CO - EIR, 483, RECALLS LAST 2 YRS

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2013-9150	11/14/2013 12/13/2013	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	AMANDA NERONE HEARTLAND LIONS EYE BANKS	LIFESOURCE, ROSEMONT, IL - EIR, 483, RECALLS LAST 2 YRS
2013-9151	11/14/2013 12/13/2013	FDA/OGROP/ORASW-FO/KANDOKAN-CB/	AMANDA NERONE HEARTLAND LIONS EYE BANKS	MIDWEST TRANSPLANT NETWORK, WESTWOOD, KS - EIR, 483, RECALLS LAST 2 YRS
2013-9152	11/14/2013 12/13/2013	FDA/OGROP/ORAPAF-FO/SEADO/SEA-CB/	AMANDA NERONE HEARTLAND LIONS EYE BANKS	SIGHTLIFE, SEATTLE, WA - EIR, 483, RECALLS LAST 2 YRS
2013-9153	11/14/2013 12/13/2013	FDA/OGROP/ORASW-FO/KANDOKAN-CB/	AMANDA NERONE HEARTLAND LIONS EYE BANKS	MID-AMERICA TRANSPLANT SERVICES, ST LOUIS, MO - EIR, 483, RECALLS LAST 2 YRS
2013-9154	11/14/2013 12/13/2013	FDA/OGROP/ORASW-FO/KANDOKAN-CB/	AMANDA NERONE HEARTLAND LIONS EYE BANKS	IOWA LIONS EYE BANK, CORALVILLE, IA - EIR, 483, RECALLS LAST 2 YRS
2013-9155	11/14/2013 12/13/2013	FDA/OGROP/ORASW-FO/KANDOKAN-CB/	AMANDA NERONE HEARTLAND LIONS EYE BANKS	MIDWEST TRANSPLANT NETWORK, KANSAS CITY, KS - EIR, 483, RECALLS LAST 2 YRS
2013-9156	11/14/2013 12/13/2013	FDA/OFVM/CFSAN/OCD/EOS/	JEREMY JOHNSON Traditional Medicinals, Inc.	GOLDEN TEMPLE OF OREGON LLC, EASY WEST TEA COMPANY LLC (YOGI TEA) - NOTIFICATION LTRS 1995 TO PRESENT
2013-9157	11/14/2013 12/13/2013	FDA/OFVM/CFSAN/OCD/EOS/	JEREMY JOHNSON Traditional Medicinals, Inc.	TADIN INC, TADIN HERB AND TEA CO (TADIN AND/OR LIFESTYLE AWARENESS) - NOTIFICATION LTRS 208 TO PRESENT
2013-9158	11/15/2013 12/16/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN MINNESOTA 01/01/2008 - 12/31/2011
2013-9159	11/15/2013 12/16/2013	FDA/OGROP/ORAPAF-FO/SEADO/SEA-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN WASHINGTON 01/01/2008 - 12/31/2011
2013-9160	11/15/2013 12/16/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN VIRGINIA 01/01/2009 - 12/31/2010
2013-9161	11/15/2013 12/16/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN VERMONT 01/01/2009 - 12/31/2011
2013-9162	11/15/2013 12/16/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN UTAH 01/01/2009 - 12/31/2011
2013-9163	11/15/2013 12/16/2013	FDA/OGROP/ORAPAF-FO/SANDOSAN-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN NEVADA 01/01/2009 - 12/31/2011
2013-9164	11/15/2013 01/07/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN NEW JERSEY 01/01/2008 - 12/31/2011
2013-9165	11/15/2013 12/16/2013	FDA/OGROP/ORASW-FO/KANDOKAN-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN NEBRASKA 01/01/2008 - 12/31/2011

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2013-9166	11/15/2013 12/16/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN NEW HAMPSHIRE 01/01/2009 - 12/31/2010
2013-9167	11/15/2013 12/24/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN TEXAS 01/01/2008 - 12/31/2011
2013-9168	11/15/2013 12/16/2013	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN MONTANA 01/01/2008 - 12/31/2010
2013-9169	11/15/2013 12/16/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN WISCONSIN 01/01/2008 - 12/31/2011
2013-9170	11/15/2013 12/16/2013	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN TENNESSEE 01/01/2008 - 12/31/2011
2013-9171	11/15/2013 12/16/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN MISSOURI 01/01/2008 - 12/31/2011
2013-9172	11/15/2013 12/16/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN SOUTH CAROLINA 01/01/2009 - 12/31/2010
2013-9173	11/15/2013 12/16/2013	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN MISSISSIPPI 01/01/2009 - 12/31/2011
2013-9174	11/15/2013 12/24/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN OKLAHOMA 01/01/2009 - 12/31/2010
2013-9175	11/15/2013 12/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Martha Raskin Rivkin Radler LLP	NDA 019839 - CMC, STABILITY
2013-9176	11/15/2013 12/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jessica Swanson Innovative Science Solutions	BLA 101995
2013-9177	11/15/2013 12/16/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	RALPH G. PATINO, Esq. Patino & Associates, P.A.	LAMHAM KEMP & BARCLAY, WESTWOOD, NJ - INVESTIGATION RECS,FLORIDA WATER APRVL, RECS, CORR. ETC
2013-9178	11/15/2013 12/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	ANGELA BUCKNER NIXON PEABODY LLP	CONTACT SURGICAL INC - NUMERIS GUIDED COAGULATION SYS W/VISITRAX MODELS CSK 121, 122, 123, 125 K090202
2013-9179	11/15/2013 12/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DOMINIQUE F. GALLACHER RICHARDS KIBBE & ORBE LLP	QUESTCOR PHARMACEUTICALS INC - ACTHAR GEL NDA 22-432

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2013-9180	11/15/2013 12/16/2013	FDA/OMPT/CTP/OD/	CHRISTOPHER HENDEL CONSUMER REPORTS	E CIGARETTES - AER THRU 11/13
2013-9181	11/15/2013 12/16/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	SARA A. STRICKLAND, Esq. MORELLI RATNER PC	IVIG BLLOD PRODUCT W/HEPATITIS - CASE 6288271, 6305352
2013-9182	11/15/2013 12/16/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	PRESTON J. DUGAS, III McDONALD LAW FIRM	BARD PERIPHERAL VASCULAR INC - MDRS, ENFORCEMENT RPTS, MARKETING MATERIALS, ETC
2013-9183	11/15/2013 04/29/2014	FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	PRESTON J. DUGAS, III McDONALD LAW FIRM	INTUITIVE SURGICAL INC - MDRS, ENFORCEMENT RTPS, MARKETING MATERIALS, ETC
2013-9184	11/15/2013 01/09/2014	FDA/OC/OES/DDM/ FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	ANNA C. SWEENEY SADAKA ASSOCIATES LLC	MERCK - ZOSTAVAX 483, EIR, CO RESP, WARNING LTR 1/17, 2/15, 4/28/08
2013-9185	11/15/2013 12/16/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CEPEDA 12R0035, JUNIOR LORENZO	EMBREL (ETANERCEPT) - CAERS, INGREDIENTS
2013-9186	11/15/2013 12/16/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WARD, JEANIE	POLYETHYLENE GLYCOL 3350 - AER
2013-9187	11/18/2013 12/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Althea Burton PATH	K063223
2013-9188	11/18/2013 12/17/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Lisa Van Buskirk Lisa Van Buskirk	K060305
2013-9189	11/18/2013 12/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Christopher W. Spofford MicroAire Surgical Instruments LLC	K081848
2013-9190	11/18/2013 12/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michelle Garcia Garcia, Michelle	P020014

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2013-9191	11/18/2013 12/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ryan Smith Janus Capital Group Attn: Rachelle Lyon	TECFIDERA/BG-12
2013-9192	11/18/2013 12/17/2013	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SW-FO/KAN-DO/KAN-CB/	Kurt Buckman Pinnacle Foods Group LLC	SAMPLE RESULTS
2013-9193	11/18/2013 03/17/2014	FDA/OFVM/CFSAN/OCD/EOS/	Janet Shepard Liberty Specialty Chemicals	FCN RE RED PIGMENT 122
2013-9194	11/18/2013 12/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Justin Durel Aubuchon, Ranieri & Panzeri, P.C. - attn:JMD	NDA 021168 S 12
2013-9195	11/18/2013 12/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Andrew Himself, Andrew	VIOXX - AERS
2013-9196	11/18/2013 12/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John Hamilton John Hamilton at Duke University	AZT - EXPANDED CRITERIA
2013-9197	11/18/2013 12/17/2013	FDA/OC/OES/DFOI/	Alberto Rossi UNIVERSITY OF MARYLAND	FOIA LOGS
2013-9198	11/18/2013 12/17/2013	FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	Allison Latos WSOC	AMERICAN RED CROSS, CHARLOTTE, NC - INSPECTION RECS 01/01/2010 - 11/14/2013
2013-9199	11/18/2013 12/17/2013	OC/CVM/OCD/	Cristina Stella & Jeff Pierce Center for Food Safety & Animal Legal Defense Fund	TRENBOLONE ACETATE - COMMUNICATIONS WITH EPA, ADVERSE EVENTS, ENVIRONMENTAL IMPACT ETC
2013-9200	11/18/2013	FDA/OMPT/CDER/ORP/DIDP/	Robyn Harrington	IMBRUVICA - REVIEW RECS

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	12/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Harrington, Robyn	
2013-9201	11/18/2013 12/17/2013	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	Ritu Baral CANACCORD GENUITY	BIOGEN IDEC, RESEARCH TRIANGLE PARK, NC - 483 08/01/2013 - 11/30/2013
2013-9202	11/18/2013 12/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kyle Rood UNIVERSITY OF MISSOURI	NDA 11429
2013-9203	11/18/2013 12/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K060309
2013-9204	11/18/2013 12/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Christopher W. Spofford MicroAire Surgical Instruments LLC	K092284
2013-9205	11/18/2013 12/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Adrienne E Faerber Dartmouth Inst. Cent. For Med. Media.	NDA 021928 S 19, 20, 21
2013-9206	11/18/2013 12/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Michelle Garcia Garcia, Michelle	P020014 - SUPPLEMENTS
2013-9207	11/18/2013 12/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Barry Sands RQMIS Inc.	K102329
2013-9208	11/18/2013 12/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOSEPH WALKER Walker, Joseph	MEETING MINUTES RE SERAPTA
2013-9209	11/18/2013 12/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOSEPH WALKER Walker, Joseph	JUXTAPID - AERS
2013-9210	11/18/2013 12/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOSEPH WALKER Walker, Joseph	JUXTAPID - AERS

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2013-9211	11/18/2013 12/17/2013	FDA/OGROP/ORPA/FO/SEA-DO/SEA-CB/	Linda L. Brothers Airgas USA LLC	AIRGAS USA LLC, TACOMA, WA - EIR, INSPECTOR NOTES 10/09/2012 - 11/09/2012
2013-9212	11/18/2013 12/17/2013	FDA/OC/OES/DFOI/	Daniel Jacobs Kora LLC	RANBAXY - MANUFACTURING, CORR, MEMOS, ETC 01/01/2007 - 11/16/2013
2013-9213	11/18/2013 12/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Christopher W. Spofford MicroAire Surgical Instruments LLC	K120328
2013-9214	11/18/2013 12/17/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Ritu Baral CANACCORD GENUITY	BIOGEN IDEC, CAMBRIDGE, MA - 483 08/01/2013 - 11/30/2013
2013-9215	11/18/2013 12/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ritu Baral CANACCORD GENUITY	BIOGEN IDEC, HILLEROD, DENMARK - 483 08/01/2013 - 11/30/2013
2013-9216	11/18/2013 12/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Christopher W. Spofford MicroAire Surgical Instruments LLC	K121005
2013-9217	11/18/2013 12/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ravi Pamnani STANFORD UNIVERSITY	ZETONNA - APPLICATION RECS
2013-9218	11/18/2013 12/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Valter Rnnholm LM-Instruments Oy	LM INSTRUMENTS - DOCUMENT E356922
2013-9219	11/18/2013 12/17/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Vivian Campanile Vivian Campanile	DAVAO PHARMACEUTICALS & ULTRA TAB LABS, HIGHLAND, NY - VIOLATIONS
2013-9220	11/18/2013 12/17/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DENNIS C GUCCIARDO Hogan Lovells, ILP	DEPUY - SUMMIT ACETABULAR SYS K983014; PINNACLE ACETABULAR CUP SYS, ESL MARATHON PLYETHYLENE LINERS & ULTIMA UNIPOLAR FEMORAL LHEADS - K033273; PINNACLE CONSTRAINED ACETABULAR LINERS - K043058, ETC
2013-9221	11/18/2013 12/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DR REDDY'S LABORATORIES INC	ABBVIE - ANDROGEL NDA 22-309/001 SBA
2013-9222	11/18/2013 12/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FRIEDMAN, ROBERT	NUROFEN - FOR CHILDREN SUSPENSION AERS 1969 TO PRESENT

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		FDA/OMPT/CDER/ORP/DIDP/		
2013-9223	11/18/2013 12/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OC/OES/DFOI/	KATHLYN QUERUBIN COOLEY LLP	HEPLISAV - FOI REQUESTS, RESP, RECS
2013-9224	11/18/2013 12/17/2013	FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORA/ OC/ORA/	L CULLEN MOORE RYMER MOORE JACKSON ETA	SPECIALTY COMPOUNDING LLC, AUSTIN, TX - EIRS 8/13/13-9/13/13
2013-9225	11/18/2013 12/17/2013	FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORA/ OC/ORA/	RAYMOND L SOLANO SPECIALTY COMPOUNDING	CORPUS CHRISTI MEDICAL CENTER -21 BAGS OF CALCIUM GLUCONATE SPL 824947/; SPECIALTY COMPOUNDING LLC, CEDAR PARK, TX - 7 VIALS OF CALCIUM GLUCONATE SPL 825575; SPECIATY COMPOUNDING LLC, CEDAR PARK, TX - 2 CONTAINERS FROM CALCIUM SACCHRATE USP TETRAHYDRATE BULK SPL 792773, ETC TEST RESULTS
2013-9226	11/18/2013 12/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	AUTUMN L BORTON PFIZER INC	XELLIA, COPENAGHEN, DENMARK - EIR 10/12
2013-9227	11/18/2013 12/17/2013	OC/CVM/OCD/	JEANNIE PERRON COVINGTON BURLING LLP	NORTH CAROLINA DEPARTMENT OF AGRICULTURE OR NORTH CAROLINA STATE ANIMAL FEED REGULATOR - HIGH ERUCID ACID RAPESEED MEAL LTR 1/10 TO PRESENT
2013-9228	11/18/2013 12/17/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	PATRICK KELLY CONWAY HOMER & CHIN- CAPLAN PC	INDIVIDUAL RECS (CERTIFIED)
2013-9229	11/18/2013	FDA/OFVM/CFSAN/OCD/EOS/	CAITLIN HOWELL	USP LABS LLC - OXYELITE RESP TO WARNING LTR,

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	01/23/2014	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS; OXYELITE PRO DIETARY SUPPLEMENTS CO RESP; RECALL CORR
2013-9230	11/18/2013 12/17/2013	FDA/OC/OES/DFOI/	The Walters Law Firm, LLC The Walters Law Firm, The Walters Law Firm	GONAL F ADVERSE EVENT REPORTS
2013-9231	11/18/2013 12/17/2013	FDA/OC/OL/	JONES, THOMAS H	CORR FROM SENATOR MIKE ENZI
2013-9232	11/18/2013 12/17/2013	FDA/OC/OL/	JONES, THOMAS H	CORR FROM CONGRESSMAN WILLIAM CASSIDY
2013-9233	11/18/2013 12/17/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Peiser, Harold	ION LABS INC, CLEARWATER, FL - 483, EIR, WARNING LTR
2013-9234	11/19/2013 12/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Patrick Knowles Patrick Knowles	SAREPTA THERAPEUTICS - RECS RE NATURAL HISTORY DATA IN DUCHENNE MUSCULAR DYSTROPHY 07/01/2013 - 11/12/2013
2013-9235	11/19/2013 12/18/2013	FDA/OGROP/OIP/	EtoTakanori ??????? (http://echo-news.net)	CORR BETWEEN FDA AND JAPANESE MHLW RE RANBAXY 01/01/2013 - 11/18/2013
2013-9236	11/19/2013 01/22/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OGROP/ORA/ORO/DIOP/ FDA/OC/OCC/ FDA/OC/OES/	Marcelo Rochabrun The Daily Princetonian	BEXSERO - IND, EMAIL, INVESTIGATION ETC

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		FDA/OC/OEXA/OMA/		
2013-9237	11/19/2013 12/18/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ OC/CVM/OCD/	Kellie Collins Golden & Walters, PLLC	SMITH BROTHERS FARM, CABELLSVILLE, KY - RECALL 12/09/2009
2013-9238	11/19/2013 12/18/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Heather Behanna jmp	JAKAFI - AERS
2013-9239	11/19/2013 12/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K131355
2013-9240	11/19/2013 12/18/2013	OC/CVM/OCD/ OC/ORACE/ OC/ORACE/ FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORACE-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORACE-FO/DAL-DO/DAL-CB/	Dennis Ventura Tressler LLP	FIRST COMMUNICATIONS BETWEEN FDA AND NESTLE PURINA, WAGGIN TRAIN RE JERKY TREATS
2013-9241	11/19/2013 12/18/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORACE-FO/DEN-DO/DEN-CB/	Nicole Chambers The Potts Law Firm, LLP	MINNESOTA DAIRY FARMS - INSPECTION RECS 2000 TO PRESENT
2013-9242	11/19/2013 12/18/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Jack Wang University of Tokyo	REMICADE - AER
2013-9243	11/19/2013 12/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	Lindsey Folio ZOLL MEDICAL CORPORATION	P060040/S023
2013-9244	11/19/2013 12/18/2013	FDA/OFVM/CFSAN/OCD/EOS/	Mark Pohl Health Science Funding, LLC	PAN AMERICAN LABS, LLC - RESPONSE TO WARNING LETTER 11/20/2009 - 12/31/2009
2013-9245	11/19/2013 12/18/2013	FDA/OGROP/ORACE-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORACE-FO/SAN-DO/SAN-CB/	Blake Goodner BRIDGER BIOMED INC	GILEAD SCIENCES, FOSTER CITY - 483, RESPONSE, WARNING LETTER 09/01/2013 - 11/18/2013
2013-9246	11/19/2013	FDA/OMPT/CDER/ERP/DIDP/	Ilya Kister	LEFUNOMIDE, TERIFLUNOMIDE - AERS

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	12/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	NYU	
2013-9247	11/19/2013 12/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	NDA 20468 S 035
2013-9248	11/19/2013 12/18/2013	FDA/OFVM/CFSAN/OCD/EOS/	Mark Pohl Health Science Funding, LLC	EFFICAS, INC - WARNING LETER RESPONSE 09/28/2007 - 10/31/2007
2013-9249	11/19/2013 12/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Paul Long Watson Laboratories, Inc.	NDA 021211 - SBA
2013-9250	11/19/2013 12/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Adrienne E Faerber, PhD Dartmouth Inst. Cent. For Med. Media.	NDA 20762 SUPPLEMENTS
2013-9251	11/19/2013 12/18/2013	FDA/OC/OES/DFOI/	Robert King FDA NEWS	FOIA REQUEST LOG 11/11/2013 - 11/15/2013
2013-9252	11/19/2013 12/18/2013	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	RENEGADE, TIMBER WOLF ETC - SE REPORTS, CORR ETC
2013-9253	11/19/2013 12/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	William S. Denney William S. Denney	CLINICAL SUTY REPORT SYNOPSES RE DRUG INTERACTION STUDIES 01/01/2012 - 12/31/2012
2013-9254	11/19/2013 12/18/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Richard W. Gonnello Faruqi & Faruqi, LLP	DYNAVAX TECHNOLOGIES HEPLISAV - RECS RE SAFETY, MANUFACTURE, CLINICAL HOLD ETC
2013-9255	11/19/2013 12/18/2013	FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECS
2013-9256	11/19/2013 12/18/2013	FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/ FDA/OMPT/CDRH/OCER/DFOI/	DAVE DIAMOND GOLDBERG & OSBORNE	SMITH & NEPHEW - TWINFIX RECALL RECS, STATUS RPTS, CORRECTIVE ACTION, ETC
2013-9257	11/19/2013	FDA/OFVM/CFSAN/OCD/EOS/	VISAGINE VJAYAKULASINGAM	HYDROXYCUT, SMARTBURN, RAPID SLIM, ETC - CAERS 8/2/13 TO PRESENT

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	12/18/2013		IOVATE HEALTH SCIENCES INTERNATIONAL INC	
2013-9258	11/19/2013 12/18/2013	FDA/OFVM/CFSAN/OCD/EOS/	PHILIP LING CANADIAN TELEVISION (CTV) NEWS	XL FOODS INC - E COLI OUTBREAK LAB RESULTS, AUDTIS, TRACEBACKS, ETC 7/1/12 TO PRESENT
2013-9259	11/19/2013 12/18/2013	FDA/OC/OES/ FDA/OFVM/CFSAN/OCD/EOS/	LEAH M NICHOLLS PUBLIC JUSTICE	CORR BTWN HOGAN LOVELLS US LLP, LAUREN COLTON, MICHAEL KIDNEY & FDA RELATING TO BOTTLED WATER OR FLUORIDE
2013-9260	11/19/2013 12/18/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	ELENA HOWELL HOGAN LOVELLS US LLP	2013-8913
2013-9261	11/19/2013 12/18/2013	FDA/OGROP/ORR/SE-FO/NOL-DO/NOL-CB/	DOUGLAS N BLUE II ZETETIC INC	JOHNSON & JOHNSON AND CIBA VISION - CONTACT LENSES IMPORT REFUSAL RECS
2013-9262	11/19/2013 12/18/2013	FDA/OGROP/ORR/SE-FO/NOL-DO/NOL-CB/	DOUGLAS N BLUE II ZETETIC INC	JOHNSON & JOHNSON, CIBA VISION - CONTACT LENSES IMPORT REFUSAL RECS
2013-9263	11/19/2013 12/18/2013	FDA/OGROP/ORR/SE-FO/NOL-DO/NOL-CB/	DOUGLAS N BLUE II ZETETIC INC	JOHNSON & JOHNSON, CIBA VISION - CONTACT LENSES IMPORT REFUSAL RECS
2013-9264	11/19/2013 12/18/2013	FDA/OMPT/CTP/OD/	SUZANNE D JENSEN Kleinfeld, Kaplan and Becker, LLP	ENVIRONMENTAL ASSESSMENTS (EA) SE0003730, SE0003731, SE0001697, ETC
2013-9265	11/19/2013 12/18/2013	OC/CVM/OCD/	EDDIE JOLLY INDEPENDENT TURTLE FARMERS OF LOUISIANA	TURTLE BAN 1975 - ANNUAL RVW MINS
2013-9266	11/19/2013 02/07/2014	FDA/OFVM/CFSAN/OCD/EOS/	NIELS OLDE RIEKERINK POLYSCOPE POLYMERS BV	STYRENE-MALEIC ANHYDRIDE COPOLYMERS - RECS
2013-9267	11/20/2013 12/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Michael Auld ETHICON ENDO-SURGERY, INC.	K113706
2013-9268	11/20/2013 12/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jan Eberth UNIVERSITY OF SOUTH CAROLINA	CERTIFIED MAMMOGRAPHY FACILITIES DATA 07/01/2009 - 07/01/2013
2013-9269	11/20/2013 12/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dustin Block IPD Analytics, LLC	ANDA 202580 for - EFFECTIVE APPROVAL LETTERS
2013-9270	11/20/2013 12/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Charles Simpson DENTSPLY INTL	K123514
2013-9271	11/20/2013	FDA/OGROP/ORR/CE-FO/MIN-	Michele Fojut	DANISCO USA INC, MADISON, WI - EIR 04/30/2013 -

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	12/19/2013	DO/MIN-CB/	DANISCO USA Inc	08/26/2013
2013-9272	11/20/2013 12/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Chris Spofford MicroAire Surgical Instruments LLC	K101713
2013-9273	11/20/2013 12/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ted Keller Sigma Capital Management	KYPROLIS - AERS
2013-9274	11/20/2013 12/31/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Julie Wood Singulex, Inc.	BK110039, BK110038
2013-9275	11/20/2013 12/19/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Robert D. Wilson Wilson & Wilson Co., L.P.A.	K082993, K130474, K123936
2013-9276	11/20/2013 12/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Adam Thompson PROPUBLICA	NUEDEXTA - AERS
2013-9277	11/20/2013 12/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RAGHURAM PANNALA SCIEGEN PHARMACEUTICALS INC	ANDA 200828 - CONTAINER LABEL, PACKAGING
2013-9278	11/20/2013 12/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Chris Spofford MicroAire Surgical Instruments LLC	K121703
2013-9279	11/20/2013 12/19/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Danielle Isham Echoing Hills Village, INC	MEDICINES WITH TARDIVE DYSKINESIA AS ADVERSE EVENT
2013-9280	11/20/2013 12/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Chris Spofford MicroAire Surgical Instruments LLC	K120902
2013-9281	11/20/2013 12/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	VIASYS HEALTHCARE, HOECHBERG, GERMANY - 483, REPSONSE APRIL - JULY 2010
2013-9282	11/20/2013 12/19/2013	FDA/OC/OES/DDM/ FDA/OMPT/CDER/ORP/DIDP/	ANNEMIEKE TENNIS KANNER & WHITELEY LLC	SHIRE PHARMACEUTICALS GROUP - ADDERALL XR CITIZEN PETITION DKT FDA-2005-P-012

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2013-9283	11/20/2013 12/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANNEMIEKE TENNIS KANNER & WHITELEY LLC	BARR LABORATORIES INC - ANDA 76-536; IMPAX LABORATORIES INC - ANDA 78-852 APRVL FOR COMMERCIAL MANUFACTURE & SALE
2013-9284	11/20/2013 12/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	ERICA LORING BIOFILM INC	ANSELL HEALTHCARE PRODUCTS LLC - LIFESTYLES LUXE PREMIUM PERSONAL LUBRICANT K122477
2013-9285	11/20/2013 12/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	ERICA LORING BIOFILM INC	ONE, BOSTON, MA - PERSONAL LUBRICANT K110690
2013-9286	11/20/2013 12/19/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	KARYL HASKELL COVIDIEN	COVIDIEN - SUPER DIMENSION EIR 10/8/12
2013-9287	11/20/2013 12/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WILLIAM CHALKLEY THOMSON REUTERS	GENENTECH - XOLAIR (OMALIZUMAB) BLA 103976 APRVL LTR
2013-9288	11/20/2013 12/19/2013	FDA/OC/OES/DFOI/	FLUKER 03338084, EDDIE	NATIONAL ORGANIC PROGRAM PROCEDURES TO CERTIFY SOIL
2013-9289	11/21/2013 12/20/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-7935 REQUEST LETTER
2013-9290	11/21/2013 12/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jayesh Mehta Jayesh Mehta	THALIDOMIDE - STUDY DATA
2013-9291	11/21/2013 12/20/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jayesh Mehta MD Jayesh Mehta	BART BARLOGIE - INVESTIGATIONS 01/01/2005 - 11/01/2013
2013-9292	11/21/2013 12/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Brant S Mittler M.D. J.D. Brant S Mittler PC	K963596

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2013-9293	11/21/2013 12/20/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Brant S Mittler M.D. J.D. Brant S Mittler PC	K945067
2013-9294	11/21/2013 12/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Brant S. Mittler M.D. J.D. Brant S Mittler PC	K955057
2013-9295	11/21/2013 12/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Brant S. Mittler M.D. J.D. Brant S Mittler PC	K913729
2013-9296	11/21/2013 12/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Elvia Contreras Lopez Nobles Medica Technology II, Inc.	K972911
2013-9297	11/21/2013 12/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Adrienne E. Faerber, PhD Dartmouth Inst. Cent. For Med. Media.	NDA 019908 Supplement 22 Ambien CR (zolpidem) NDA 021774 Supplement 3 Lipitor (atorvastatin) NDA 020702 Supplement 33 Lipitor (atorvastatin) NDA 020702 Supplement 47
2013-9298	11/21/2013 12/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dustin Block IPD Analytics, LLC	ANDA 202731 - EFFECTIVE APPROVAL LETTER
2013-9299	11/21/2013 12/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Chris Nidel Gelbins of America	LEVAQUIN, AVELOX - CLINICAL DATA, ADVERSE EVENTS, COMMUNICATIONS ETC
2013-9300	11/21/2013 12/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mark Karvosky Cresheim Capital	KYPROLIS - AERS
2013-9301	11/21/2013 12/20/2013	FDA/OC/OES/DFOI/	Steven R. Seaward NCTR	INVESTIGATION RECS
2013-9302	11/21/2013 12/20/2013	FDA/OC/OES/DFOI/ FDA/OGROP/ORO/SW-FO/DEN-DO/DEN-CB/	Gina L. Meyer GEHC Surgery	INSPECTION RECS
2013-9303	11/21/2013 12/20/2013	OC/CVM/OCD/	KRISTI O SMEDLEY Center for Regulatory Services, Inc.	ZOETIS (PFIZER), MUMBAI, INDIA - EIRS, 483S MOST RECENT
2013-9304	11/21/2013	OC/CVM/OCD/	KRISTI O SMEDLEY	ZOETIS - TYPE A MEDICATED CATTLE FEED ANADA 200-548 (ACTOGAIN 45 - RACTOPAMINE HCL) FOI SUMMARY

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	12/20/2013		Center for Regulatory Services,Inc.	
2013-9305	11/21/2013 12/20/2013	OC/CVM/OCD/	KRISTI O SMEDLEY Center for Regulatory Services,Inc.	ZOETIS - TYPE A MEDICATED FEED FOR SWINE ANADA 200-542 (ENGAIN 9 & 45 - RACTOPAMINE HCL) FOI SUMMARY
2013-9306	11/21/2013 12/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	ERICA LORING BIOFILM INC	TRIGG LABORATORIES INC, VALENCIA, CA - WET PLATINUM PERSONAL LUBRICANT K130012
2013-9307	11/21/2013 12/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOON HWANG B&D DENTAL TECHNOLOGIES	B&D DENTAL CORP - DENTAL SHADE RESIN K122269
2013-9308	11/21/2013 12/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	STEVEN A SIMON STEVEN A SIMONS LAW OFC	INSATIABLE SUN, WOODLAND HILLS, CA - MDRS
2013-9309	11/21/2013 12/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	AARON TVEDT PIVOTAL HEALTH SOLUTIONS	CTBOX CERVICAL/LUMBAR TRACTION DVC - K063353
2013-9310	11/21/2013 12/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	MEIKE OETTING DRAGER MEDICAL GMBH	ARIZANT HEALTHCARE INC - 3M SPOTON TEMPERATURE MONITORING SYS K120412
2013-9311	11/21/2013 12/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GILLION FS-0850, TRAVIS	ELI LILLY & CO - ISRS US201309002639; ELI LILLY CO & GLOBAL PATIENT SAFETY - ISRS US201309002640
2013-9312	11/21/2013 12/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DANYSH DL-4879	ELI LILLY & CO - ISRS US201309002639; EILI LILLY & CO & GLOBAL PATIENT SAFETY - ISRS US201309002640
2013-9313	11/21/2013 12/20/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	michael gibson michael gibson	HOSPIRA, MCPHERSON, KS - 483 MOST RECENT 10/01/2013 - 11/20/2013
2013-9314	11/21/2013 12/20/2013	OC/ORAS/ OC/ORAS/ FDA/OGROP/ORASORO/DIOP/	Mark Prinz Registrar Corp	COMPANIES ON RED LIST OF ACTIVE IMPORT ALERT
2013-9315	11/21/2013 12/20/2013	OC/ORAS/ORM/ OC/ORAS/ORM/	David Mangione Govzilla, Inc.	LIST OF INSPECTIONS 1/1/00 TO 11/20/13
2013-9316	11/21/2013 12/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Zhenya Senyak MPNforum Magazine	Phase 2 study of SAR302503 in patients with myelofibrosis NCT01420770; Phase 2 study of SAR302503 in myelofibrosis patients previously treated with ruxolitinib. NCT01523171
2013-9317	11/21/2013	FDA/OMPT/CDER/ORP/DIDP/	KLATE EYNOLDS	4Q2012 -ISRS 7498878, 7814351, 8067430, ETC

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	12/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ROCKY MOUNTAIN POISON DRUG CTR	
2013-9318	11/21/2013 12/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Adrienne E. Faerber, PhD Dartmouth Inst. Cent. For Med. Media.	NDA 020489 S 25 Androgel 1% (testosterone); NDA 021015 S 11 Testoderm Patch (testosterone); NDA 019762 Initial Approval Testopel pellets (testosterone) NDA 080911 Initial Approval
2013-9319	11/21/2013 12/20/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	CHONGWU ZHONG SHANDONG FENGHUA FOOD CO.,LTD	SHANDONG - IMPORT RECS
2013-9320	11/21/2013 12/20/2013	FDA/OC/OES/DFOI/ OC/CVM/OCD/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Polly Murdoch Murdoch, Polly L	RACTOPAMINE IN LIVESTOCK FEED 10/20/2012 - 12/01/2013
2013-9321	11/21/2013 12/20/2013	OC/ORA/ OC/ORA/	Charles M Barr None - Private Individual	PREVACID - CONSUMER COMPLAINTS 11/02/2012 - 11/20/2013
2013-9322	11/21/2013 12/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KNITTER, MICHAEL JOHN	ASTRAZENCA PHARMACEUTICAL LP - PROPOFOL/DIPRIVAN TRIAL #08591L-0068
2013-9323	11/21/2013 12/20/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Abhishek Gurnani Amin Talati LLC	QUINCY BIOSCIENCE MANUFACTURING INC, MADISON, WI - CORR, 483, WARNING LETTER ETC 01/01/2006 - 11/20/2013
2013-9324	11/21/2013 01/24/2014	FDA/OC/OES/DFOI/	David Mangione Govzilla, Inc.	483 RELEASED SINCE 3/14/13
2013-9325	11/21/2013 12/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mahidhar Chinta Micro Labs USA, Inc	NDA 018333 - SBA

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-9326	11/21/2013 12/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Nathaniel August Mangrove Partners	OMONTYS - CASE REPORTS
2013-9327	11/21/2013 12/20/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	WOODS 358-884, ROBERT	UNIVERSAL NUTRITION, NEW BRUNSWICK, NJ - CMLPTS
2013-9328	11/21/2013 12/20/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANDREW HACK MILLENNIUM MANAGEMENT LLC	PROCYSBI (CYSTEAMINE GASTRORESISTANT HAD CAPS) AERS; RAPTOR PHARMS, NOVATO, CA - EIRS, 483S, UNTITLED LTRS 1/13 TO PRESENT
2013-9329	11/21/2013 12/20/2013	FDA/OMPT/CTP/OD/	MARILYNN WHITNEY COVINGTON BURLING LLP	EIGHT TOBACCO PRODS - NOT SUBSTANTIALLY EQUIVALENT (NSE) ORDERS SE0001762, SE0003525, SE0003526, , ETC
2013-9330	11/21/2013 12/20/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/ OC/CVM/OCD/ FDA/OFVM/CFSAN/OCD/EOS/	BARRETT, DONNIE R	CHS INC, HUTCHINSON, KS - ULTRA-SOY TEXTURED VEGETABLE PROTEIN MINCED SC (SF) RECS
2013-9331	11/21/2013 12/20/2013	FDA/OFVM/CFSAN/OCD/EOS/	LI ZHANG BASF - The Chemical Company	DOW CHEMICAL CO - FCN 106 7/00-12/00
2013-9332	11/21/2013 12/20/2013	FDA/OC/OES/DFOI/	MCKENZIE CATO Hyman, Phelps & McNamara P.C.	2013-7689, 2013-7690, 2013-7692, ETC
2013-9333	11/21/2013 12/20/2013	FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	MATTHEW W CLARK BOYLE SHAUGHNESSY & CAMPO PC	BRIGHAM & WOMEN'S HOSPITAL, BOSTON, MA - CARMEN CARTAGENA RPTS, CMLPTS, PHOTOGRAPHS, ETC; LANMAN & KEMP BARCLAY & CO INC - FLORIDA WATER RPTS, COMPLNTS, PHOTOGRAPHS, ETC
2013-9334	11/21/2013 12/20/2013	FDA/OC/OES/DFOI/	ELLIOT FAVUS FAVUS INSTITUTIONAL RESEARCH LLC	FOI DAILY LOG 4/20/13 TO PRESENT
2013-9335	11/21/2013 12/20/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	BRETT PARK CONWAY HOMER & CHIN-CAPLAN PC	INDIVIDUAL RECS 9/10/08 to PRESENT (CERTIFIED)
2013-9336	11/21/2013	FDA/OMPT/CDER/GRP/DIDP/	David Hermelin	ANDA 080778, ANDA 084629, ANDA 084921 ETC

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	12/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Xeragenx LLC	
2013-9337	11/21/2013 12/20/2013	FDA/OGROP/ORR/SW-FO/DAL- DO/DAL-CB/	Jennifer Brooks Microbiotix, Inc.	TEXAS LIVER INSTITUTE, ALAMO MEDICAL RESEARCH, SAN ANTONIO, TX - 483 01/01/2003 - 11/21/2013
2013-9338	11/21/2013 12/20/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-8294 - REQUEST LETTER
2013-9339	11/21/2013 12/20/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-8061 - REQUEST LETTER
2013-9340	11/21/2013 12/20/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-8434 - REQUEST LETTER
2013-9341	11/21/2013 12/20/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-8506 - REQUEST LETTER
2013-9342	11/21/2013 12/20/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-7966 - REQUEST LETTER
2013-9343	11/21/2013 12/20/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-7968 - REQUEST LETTER
2013-9344	11/21/2013 12/20/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-8529 - REQUEST LETTER
2013-9345	11/22/2013 12/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michael R. Rudnick, MD Penn Presbyterian Medical Center - Michael Rudnick MD	POLYETHYLENE GLYCOL 3550 PRODUCTS - AERS
2013-9346	11/22/2013 12/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	Joseph Zwischenberger, M.D. UNIVERSITY OF KENTUCKY	G960257 - IDE, REPORTS
2013-9347	11/22/2013 12/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dustin Block IPD Analytics, LLC	ANDA 078908 - EFFECTIVE APPROVAL LETTER
2013-9348	11/22/2013 12/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Raffi Ara Chalian personal	ETC 1002 - AERS

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2013-9349	11/22/2013 12/23/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Leo Sternlicht RIDGEBACK CAPITAL MANAGEMENT LLC	JAKAFI, GILENYA, TECFIDERA, ETC - AERS
2013-9350	11/22/2013 12/23/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JoAnna Riggs Riggs, JoAnna	DETERMINATION OF WHAT EMPLOYEES WERE FURLOUGHED FROM DIDP
2013-9351	11/22/2013 12/23/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	JUXTAPID - AERS
2013-9352	11/22/2013 12/23/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	GATTEX - AERS
2013-9353	11/22/2013 12/23/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	XTANDI - AERS
2013-9354	11/22/2013 12/23/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	ADCENTRIS - AERS
2013-9355	11/22/2013 12/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	Julie K. Tibbets, Esq. ALSTON & BIRD	ARTERX SURGICAL SEALANT - REVIEW AND PMA RECS 01/01/2005 - 11/21/2013
2013-9356	11/22/2013 12/23/2013	FDA/OGROP/ORACE-FO/BLT- DO/BLT-CB/ FDA/OGROP/ORACE-FO/CHI- DO/CHI-CB/ FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORACE-FO/NYK- DO/NYK-DCB/	Seth Payer UFCW INTERNATIONAL UNION, CLC	GOYA FOODS FACILITIES, SECAUCUS, NJ, PEDRICKTOWN, NJ, ANGOLA, NY ETC - 483 01/01/2011 - 11/21/2013

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		FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/		
2013-9357	11/22/2013 12/23/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Curtis Hogue DISCOVERY CAPITAL MANAGEMENT	ONYX, KYPROLIS - AERS
2013-9358	11/22/2013 12/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	Julie K. Tibbets, Esq. ALSTON & BIRD	ARISTA AH ABSORBABLE HEMOSTAT - REVIEW, APPROVAL RECS
2013-9359	11/22/2013 12/23/2013	OC/ORA/ OC/ORA/ FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	NICHOLAS J PAROLISI JR LITCHFIELD CAVO LLP	HORIZON MILLING - RICH PRODUCTS E COLI TEST RESULTS, INVESTIGATION RECS, CORR, ETC 10/13
2013-9360	11/22/2013 12/23/2013	FDA/OMPT/CTP/OD/	RHODETTA WALTON Commonwealth Brands, Inc.	TIMBER WOLF LONG CUT WINTERGREEN STN SE0001762, RENEGADE LING CUT STRAIGHT STN SE0003525, RENEGADE LONG CUT WINTERGREEN STN SE0003526, ETC - SUBSTANTIAL EQUIVALENCE RPTS
2013-9361	11/22/2013 12/23/2013	FDA/OMPT/CTP/OD/	NATALIE SANDERS LATHAM & WATKINS LLP	SUBSTANTIAL EQUIVALENCE EXEMPTION (SEE) REQUESTS SUBMITTED TO THE CENTER FOR TOBACCO PRODUCTS
2013-9362	11/22/2013 12/23/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	HOLLY J BAYNE BAYNE & ASSOCIATES	ASEPTIC SOLUTIONS USA LLC, CORONA, CA; ARIZONA PRODUCTION AND PACKAGING, TEMPE, AZ; NUTRAVAIL LLC, CHANTILLY, CA, ETC - CORR, TRANS, EIRS, ETC
2013-9363	11/22/2013 12/23/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rowena Dodaro Alkermes Gainesville LLC	FAERS CASE NUMBERS SOURCE DOCUMENTATION 8789691 8799464 8839325 ETC

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2013-9364	11/22/2013 12/23/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	David J Martin Meyers, Rodbell & Rosenbaum, P.A.	VIRBRIO CONTROL REPORTS FOR VA, DE; PROGRAM EVALUATION REPORTS FOR VA, DE; OYSTER GROWING REPORTS FOR VA, DE ETC 01/01/2010 - 11/21/2013
2013-9365	11/22/2013 12/23/2013	OC/ORACE/ OC/ORACE/	NICOLE G ANDREWS SERPE JONES ANDREWS COLLANDER BELL	SPECIALTY COMPOUNDING - CALCIUM GLUCONATE TESTING, MEMOS, RPTS, ETC 1/11 TO PRESENT
2013-9366	11/22/2013 12/23/2013	FDA/OFVM/CFSAN/OCD/EOS/ DO/FLA-CB/	RICHARD LARDNER ASSOCIATED PRESS	YANTAI NORTH ANDRE JUICE CO LTD 9/26/13; YUET HEUNG YUEN SAUCE FOOD CO LTD 9/25/13; DAJI FOODSTUFF FACTORY 2/1/13, ETC - 483S
2013-9367	11/22/2013 12/23/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ROBERT KING FDA NEWS	EPAX NORWAY AS, AALESUND, NORWAY; HETERO LABS LTD, RANGAREDDY, INDIA; RA CHEM PHARMA LTD, HYDERABAD, INDIA, ETC - 483S 10/1-31/13
2013-9368	11/22/2013 12/23/2013	FDA/OGROP/ORACE-FO/FLA-DO/FLA-CB/	ROBERT KING FDA NEWS	NATURE'S RITE LLC, SARASOTA, FL; REFINE USA LLC, JACKSONVILLE, FL; STATCORP MEDICAL, JACKSONVILLE, FL , ETC - 483S 10/1-31/13
2013-9369	11/22/2013 12/23/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	ROBERT KING FDA NEWS	BRISTOL-MYERS SQUIBB COMPANY INC, MOUNT VERNON, IN - 483S 10/1-31/13
2013-9370	11/22/2013 12/23/2013	FDA/OGROP/ORACE-FO/DEN-DO/DEN-CB/	ROBERT KING FDA NEWS	WILEY CHEMISTS INC, SANTA FE, NM; SANODZ INC, BROOMFIELD, CO; NSPIRE HEALTH INC, LONGMONT, CO, ETC - 483S 10/1-31/13
2013-9371	11/22/2013 12/23/2013	FDA/OGROP/ORACE-FO/DAL-DO/DAL-CB/	ROBERT KING FDA NEWS	BASF CORP, BISHOP, TX; MINDWAYS SOFTWARE INC, AUSTIN, TX - 483S 10/1-31/13
2013-9372	11/22/2013 12/23/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	ROBERT KING FDA NEWS	CARDIOX CORP, COLUMBUS, OH - 483S 10/1-31/13
2013-9373	11/22/2013 12/23/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	ROBERT KING FDA NEWS	HEALTHY SPIRIT LLC, BALTIMORE, MD - 483S 10/1-31/13
2013-9374	11/22/2013 12/23/2013	FDA/OGROP/ORACE-FO/ATL-DO/ATL-CB/	ROBERT KING FDA NEWS	BLUE RIDGE PHARMACY AND COMPOUNDING CENTER, RALEIGH, NC - 483S 10/1-31/13
2013-9375	11/22/2013	FDA/OGROP/ORACE-FO/SEA-DO/SEA-CB/	ROBERT KING	WYEAST MEDICAL CORP, CLACKAMAS, OR - 483S 10/1-31/13

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	12/23/2013		FDA NEWS	
2013-9376	11/22/2013 12/23/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	ROBERT KING FDA NEWS	MILLIPORE (UK) LTD, LIVINGSTON, GREAT BRITAIN - 483S 10/1-31/13
2013-9377	11/22/2013 12/23/2013	FDA/OGROP/ORASE-FO/SJN- DO/SJN-CB/	ROBERT KING FDA NEWS	BIO LAB-ST JOSEPH CORP, BAYAMON, PR - 483S 10/1- 31/13
2013-9378	11/22/2013 12/23/2013	FDA/OGROP/ORACE-FO/CHI- DO/CHI-CB/	ROBERT KING FDA NEWS	M D TECHNOLOGIES INC, ELIZABETH, IL - 483S 10/1-31/13
2013-9379	11/22/2013 12/23/2013	FDA/OGROP/ORACE-FO/PHI- DO/PHI-CB/	ROBERT KING FDA NEWS	DRUMMOND SCIENTIFIC CO, BROOMALL, PA - 483S 10/1- 31/13
2013-9380	11/22/2013 12/23/2013	FDA/OGROP/ORANE-FO/NYK- DO/NYK-DCB/	ROBERT KING FDA NEWS	CEROVENE INC. VALLEY COTTAGE, NY; GLOTTAL ENTERPRISES INC, SYRACUSE, NY; DDC TECHNOLOGIES INC, OCEANSIDE, NY, ETC - 483S 10/1-31/13
2013-9381	11/22/2013 12/23/2013	FDA/OGROP/ORASE-FO/NOL- DO/NOL-CB/	ROBERT KING FDA NEWS	DELTA PHARMA INC, RIPLEY, MS - 483S 10/1-31/13
2013-9382	11/22/2013 12/23/2013	FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/	ROBERT KING FDANEWS	AUROLIFE PHARMA LLC, DAYTON, NJ; WEST-WARD PHARMACEUTICAL CORP, CHERRY HILL, NJ; MAQUET CARDIOVASCULAR LLC, WAYNE, NJ - 483S 10/1-31/13
2013-9383	11/22/2013 12/23/2013	FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/	ROBERT KING FDA NEWS	BIOGEN IDEC INC, CAMBRIDGE, MA; TEDOR PHARMA INC, CUMBERLAND, RI; PHARMASOL CORP, SOUTH EASTON, MA, ETC - 483S 10/1-31/13
2013-9384	11/22/2013 12/23/2013	FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/	ROBERT KING FDA NEWS	MASIMO CORP, IRVINE, CA - 483S 10/1-31/13
2013-9385	11/22/2013 12/23/2013	FDA/OGROP/ORASW-FO/KAN- DO/KAN-CB/	ROBERT KING FDA NEWS	MERIDIAN MEDICAL TECHNOLOGIES INC, ST LOUIS, MO; HOT SHOTS NUCLEAR MEDICINE, DAVENPORT, IA; HANDI- CRAFT CO, ST LOUIS, MO, ETC - 483S 10/1-31/13
2013-9386	11/22/2013 12/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	ROBERT KING FDA NEWS	SHIMA LABORATORIES CO LTD, ITABASHI-KU TOKYO, JAPAN; SHANGHAI KINDLY ENTERPRISE DEVELOPMENT GROUP CO LTD, SHANGHAISHI, CHINA; ZHONGSHAN TRANSTEK MEDICAL ELECTRONICS CO LTD, ZHONGSHAN, CHIN - 483S 10-1-31/13
2013-9387	11/22/2013 12/23/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	MYTRES F CREAM (NYSTATIN AND TRIAMCINOLONE ACETONIDE) ANDA 62-597 - APRVL LTR, LBLG, RVWS, ETC
2013-9388	11/22/2013 12/23/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	TRIAMCINOLONE OINTMENT ANDA 89-796 - APRVL LTR, LBLG, RVWS, ETC

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-9389	11/22/2013 12/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	NYSTATIN AND TRIAMCINOLONE OINTMENT ANDA 63-305 - APRVL LTR, LBLG, RVWS, ETC
2013-9390	11/22/2013 12/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	DERMACOMB CREAM (NYSTATIN AND TRIAMCINOLONE) ANDA 62-364 - APRVL LTR, LBLG, RVWS, ETC
2013-9391	11/22/2013 12/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	YONEJI MZUNO NIDEK CO LTD	OCULUS OPTIKGERAETE GMBH - CORVIS ST K113066
2013-9392	11/22/2013 12/23/2013	FDA/OC/OES/DFOI/	MICHAEL THOMAS WELLS FARGO FUNDS MANAGEMENT GROUP	NUMBER OF DRUG THERAPIES APRVD LAST 10 YRS
2013-9393	11/25/2013 12/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kiran Kumar Gande Appco Pharmaceuticals Corporation	NDA 18644 - SBA
2013-9394	11/25/2013 12/24/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	Blake Goodner Bridger Corporation	MALLINCKRODT, ST LOUIS, MO - 483, RESPONSE, WARNING LETTERS 01/01/2012 - 11/22/2013
2013-9395	11/25/2013 12/24/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Blake Goodner Bridger Corporation	MALLINCKRODT, RALEIGH, NC - 483, RESPONSE, WARNING LETTER 01/01/2012 - 11/22/2013
2013-9396	11/25/2013 12/24/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	Blake Goodner Bridger Corporation	MALLINCKRODT, HOBART, NY - 483, RESPONSE, WARNING LETTER 01/01/2012 - 11/22/2013
2013-9397	11/25/2013 12/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ayesha Adil The Weinberg Group	ANDA 077007
2013-9398	11/25/2013 12/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Richard Klemm ORBIMED ADVISORS LLC	JETREA - AERS
2013-9399	11/25/2013	FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson	POMALYST - FAERS

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	12/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	
2013-9400	11/25/2013 12/24/2013	FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 10/21-25/13
2013-9401	11/25/2013 12/24/2013	FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 10/28/13-11/1/13
2013-9402	11/25/2013 12/24/2013	FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 11/4-8/13
2013-9403	11/25/2013 12/24/2013	FDA/OC/OES/DFOI/	DEBRA COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 11/4-8/13
2013-9404	11/25/2013 12/24/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 10/28/13-11/01/13
2013-9405	11/25/2013 12/24/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 11/4/8/13
2013-9406	11/25/2013 12/24/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 11/4-8/13
2013-9407	11/25/2013 12/24/2013	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 11/4-8/13
2013-9408	11/25/2013 12/24/2013	FDA/OC/OES/DFOI/	GLADYS B TONKIN Center for Regulatory Services,Inc.	FOI DAILY LOG 10/21-25/13
2013-9409	11/25/2013 12/24/2013	FDA/OC/OES/DFOI/	GLADYS B TONKINS Center for Regulatory Services,Inc.	FOI DAILY LOG 10/28/13-11/1/13
2013-9410	11/25/2013 12/24/2013	FDA/OC/OES/DFOI/	GLADYS B TONKINS Center for Regulatory Services,Inc.	FOI DAILY LOG 11/4-8/13
2013-9411	11/25/2013 12/24/2013	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 10/21-25/13
2013-9412	11/25/2013 12/24/2013	FDA/OC/OES/DFOI/	KLEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 10/28/13-11/1/13

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2013-9413	11/25/2013 12/24/2013	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOIF DAILY LOG 11/4-8/13
2013-9414	11/25/2013 12/24/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 10/21-25/13
2013-9415	11/25/2013 12/24/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 10/28/13-11/1/13
2013-9416	11/25/2013 12/24/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 11/4-8/13
2013-9417	11/25/2013 12/24/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 11/4-8/13
2013-9418	11/25/2013 12/24/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 10/21-25/13
2013-9419	11/25/2013 12/24/2013	FDA/OC/OES/DFOI/	LAUREN S SBARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 10/28/13-11/1/13
2013-9420	11/25/2013 12/24/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 11/4-8/13
2013-9421	11/25/2013 12/24/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 10/21-25/13
2013-9422	11/25/2013 12/24/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 10/28/13-11/1/13
2013-9423	11/25/2013 12/24/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 11/4-8/13
2013-9424	11/25/2013 12/24/2013	FDA/OO/OFBA/OAGS/	MAURA NORDEN SIDLEY AUSTIN LLP	CONTRACT #HHSF22301031T
2013-9425	11/25/2013 12/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Peter R. Breggin, MD Center for the Study of Empathic Therapy	LEXAPRO - AERS
2013-9426	11/25/2013 12/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	ADCENTRIS - AERS

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2013-9427	11/25/2013 12/24/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Edward W Skepnek Valnet Inc.	ALLERGY LABORATORIES, OKLAHOMA CITY, OK - EIR 03/15/2013 - 05/15/2013
2013-9428	11/25/2013 12/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Peter R. Breggin, MD Center for the Study of Empathic Therapy	LEXAPRO - NDA SUMMARY
2013-9429	11/25/2013 12/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Karen Denny Techulon, Inc.	KYNAMRO - NDA APPROVAL SUMMARY
2013-9430	11/25/2013 12/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	XTANDI - AERS
2013-9431	11/25/2013 12/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Mark Michalski Butterfly Networks Inc	K092756, K102153, K090505 ETC
2013-9432	11/25/2013 12/24/2013	FDA/OC/OES/DFOI/	CanReg, Inc.	DAILY CLOSED LOG 10/14-18/13
2013-9433	11/25/2013 12/24/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 10/14-18/13
2013-9434	11/25/2013 12/24/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY CLOSED LOG 10/28/13-11/1/13
2013-9435	11/25/2013 12/24/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY CLOSED LOG 10/21-25/13
2013-9436	11/25/2013 12/24/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED DAILY LOG 10/28/13-11/1/13
2013-9437	11/25/2013 12/24/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED DAILY LOG 10/14-18/13
2013-9438	11/25/2013 12/24/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED DAILY LOG 10/21-25/13
2013-9439	11/25/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR	CLOSED DAILY LOG 11/4-8/13

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	12/24/2013		JH BARR & ASSOCIATES LLC	
2013-9440	11/25/2013 12/24/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY CLOSED LOG 10/28/13-11/1/13
2013-9441	11/25/2013 12/24/2013	FDA/OC/OES/DFOI/	LAUREN S, BARR JH BARR & ASSOCIATES LLC	CLOSED DAILY LOG 10/21/13-25/13
2013-9442	11/25/2013 12/24/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 10/14-18/13
2013-9443	11/25/2013 12/24/2013	FDA/OC/OES/DFOI/	JH BARR & ASSOCIATES LLC	DAILY CLOSED LOG 10/14-18/13
2013-9444	11/25/2013 12/24/2013	FDA/OC/OES/DFOI/	DAVID McFARLAND FDA REVIEW/FDA WEBVIEW	DAILY CLOSED LOG 10/14-18/13
2013-9445	11/25/2013 12/24/2013	FDA/OC/OES/DFOI/	DAVID McFARLAND FDA REVIEW/FDA WEBVIEW	DAILY CLOSED LOG 10/21-25/13
2013-9446	11/25/2013 12/24/2013	FDA/OC/OES/DFOI/	DAVID McFARLAND FDA REVIEW/FDA WEBVIEW	DAILY CLOSED LOG 10/28/13-11/1/13
2013-9447	11/25/2013 12/24/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 10/21-25/13
2013-9448	11/25/2013 12/24/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 10/14-18/13
2013-9449	11/25/2013 12/24/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 10/14-18/13
2013-9450	11/25/2013 12/24/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 10/21-25/13
2013-9451	11/25/2013 12/24/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 10/28/13-11/1/13
2013-9452	11/25/2013 12/24/2013	FDA/OC/OES/DFOI/	DOMINION GROUP INC	DAILY LOG 10/14-18/13
2013-9453	11/25/2013 12/24/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY CLOSED LOG 10/14-18/13
2013-9454	11/25/2013 12/24/2013	FDA/OC/OES/DFOI/	Center for Regulatory Services, Inc.	DAILY LOG 10/14-18/13
2013-9455	11/25/2013	FDA/OC/OES/DFOI/		DAILY LOG 10/14-18/13

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	12/24/2013		WASHINGTON INFORMATION SOURCE	
2013-9456	11/26/2013 12/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Cathy Rosenbaum BETHESDA NORTH HOSPITAL	OFIRMEV - SAFETY REPORTS
2013-9457	11/26/2013 12/26/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Lisa Robertson Rawls McNelis + Mitchell	INDIVIDUAL RECS
2013-9458	11/26/2013 12/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	J. Miles Morgan Hendrickson & Long, PLLC	ICY HOT, EXTRA STRENGTH ICY HOT, ETC - REPORTS, INVESTIGATIONS, ADVERSE EVENTS ETC
2013-9459	11/26/2013 12/26/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	Rachel Johnson FOI Services, Inc.	ALLERGAN, IRVINE, CA - INVESTIGATOR DIARIES
2013-9460	11/26/2013 12/26/2013	FDA/OGROP/ORA/CE-FO/CIN- DO/CIN-CB/	Rachel Johnson FOI Services, Inc.	NATIONAL BIOLOGICAL, BEACHWOOD, OH - INVESTIGATORY DIARIES
2013-9461	11/26/2013 12/26/2013	FDA/OGROP/ORA/CE-FO/CHI- DO/CHI-CB/	Hayley Lewis Depomed, Inc	WOCKHARDT CONTRACT MANUFACTURING, MORTON GROVE, IL - EIR, 483 03/24/2010 - 03/08/2012
2013-9462	11/26/2013 12/26/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Kelley Webb Rawls McNelis + Mitchell	INDIVIDUAL RECS
2013-9463	11/26/2013 12/26/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Stefano Magarotto IneSalus Corp	NUC - 510K EXAMPLE
2013-9464	11/26/2013 12/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	JEROME LEW JEROME LEW	CPT 1200691
2013-9465	11/26/2013 12/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	William Lewis AccelaPHARM, LLC	KYPROLIS - AERS
2013-9466	11/26/2013 12/26/2013	FDA/OGROP/ORA/CE-FO/CIN- DO/CIN-CB/	Rachel Johnson FOI Services, Inc.	Inspection information for National Biological, Beachwood, OH

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2013-9467	11/26/2013 12/26/2013	FDA/OGROP/ORPA/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Michael Kosnar NBC NEWS	ADVANCED BIONICS CORP, VALENCIA, CA - 483, WARNING LETTER, RECALL RECS 01/01/2010 - 11/22/2013
2013-9468	11/26/2013 12/26/2013	FDA/OFVM/CFSAN/OCD/EOS/	Mark Prinz Registrar Corp	Constanza Agroindustrial, S.R.L. Av.27 De Febrero No. 1515 Santo Domingo Dominican Republic; Franchi Fish S.A. Calle 302 y Avenida 4 de Novembre Manta Ecuador; Choudhury & Company (Bangladesh) Ltd. 34/a Kalurghat Heavy Industrial Area Chittagong Bangladesh etc - 483
2013-9469	11/26/2013 12/26/2013	FDA/OGROP/ORPA/PA-FO/LOS-DO/LOS-CB/	Rachel Johnson FOI Services, Inc.	Inspection information for Allergan, Irvine, CA
2013-9470	11/26/2013 12/26/2013	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	Information regarding tobacco substantial equivalence orders
2013-9471	11/26/2013 12/26/2013	FDA/OC/OES/DFOI/	TERESA M KELLEY SEMMES BOWEN & SEMMES	SATEESH APTE, IMMUNOSCIENCE INC, PLEASANTON AND DUBLIN, CA - CMLPNTS 2008 TO PRESENT
2013-9472	11/26/2013 12/26/2013	FDA/OGROP/ORPA/PA-FO/SEA-DO/SEA-CB/ OC/CVM/OCD/	MEGAN E GARRETT SMITH HARTVIGSEN PLLC	RANGEN INC - INVESTIGATIVE RPTS, WARRANTS, CMLPNTS, ETC 1/13 TO PRESENT
2013-9473	11/26/2013 12/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	DAVID ZUCKERMAN DPM CLEARLYBEAUTIFULNAILS	CPT1300261
2013-9474	11/26/2013 12/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID LOHREY CEDAR PHARMACEUTICALS	EVERYLIFE - CORR, CONTACT INFO, CURRENT ADDRESS
2013-9475	11/26/2013 12/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	EDWARDS, S ALBERT	LEVAQUIN (FLUOROQUINOLONES) - DPV11 RVW 5/10
2013-9476	11/26/2013 12/26/2013	FDA/OGROP/ORPA/SE-FO/ATL-DO/ATL-CB/	CARL IOOS TOP TOBACCO LP	TOP TOBACCO LP, WACCAMAW, NC - EIR, 482 6/5/13, CORPORATE ORGANIZATIONAL CHART, ETC
2013-9477	11/26/2013 12/26/2013	FDA/OMPT/CTP/OD/	NATALIE N SANDERS LATHAM & WATKINS LLP	CENTER FOR TOBACCO PRODUCTS REVIEWERS GUIDE 2012
2013-9478	11/26/2013 02/25/2014	FDA/OFVM/CFSAN/OCD/EOS/	KRISTIN R HOSSENZADEH PETER G ANGELOS LAW OFC	COLGATE-PALMOLIVE CO - PRESENCE OF ASBESTOS OR ASBESTIFORM MINERALS IN TALC OBTAINED FROM MINES IN MT OR NC RECS
2013-9479	11/26/2013 12/26/2013	FDA/OFVM/CFSAN/OCD/EOS/	JOANNA R DRAKE VERTO LEGAL SOLUTIONS LLC	FDA ADVISORY OPINION 10/6/1959 - AUTOLYZED YEAST EXTRACT GRAS

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2013-9480	11/26/2013 12/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	RON LETOURNEAU RG MEDICAL DIAGNOSTICS	ARC THERMAL WRAP - MARKETING RECS
2013-9481	11/26/2013 12/26/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	RICHARD W GONNELLO ESQ FARUQI & FARUQI LLP	DYNAVAX TECHNOLOGIES CORP - EIRS, 483S 2007 TO PRESENT
2013-9482	11/26/2013 01/13/2014	OC/ORPA/ OC/ORPA/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	KIMBERLY CURTH WSMV TV	OL' ROY DOG FOOD - RECALLS, CMLPNTS, WARNING LTRS, ETC 2008 TO PRESENT
2013-9483	11/26/2013 12/26/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	KRISTI O SMEDLEY PHD Center for Regulatory Services,Inc.	BIMEDA INC, LE SUEUR, MN - EIR, 483 MOST RECENT
2013-9484	11/26/2013 12/26/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	KRISTIN O SMEDLEY PHD Center for Regulatory Services,Inc.	PHARMACIA AND UPJOHN, KALAMAZOO, MI - EIR, 483 MOST RECENT
2013-9485	11/26/2013 12/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	MONICA KING KIMBERLY-CLARK HEALTHCARE	NATROX TOPICAL OXYGEN DELIVERY SYS K112634
2013-9486	11/26/2013 12/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	MONICA KING KIMBERLY-CLARK HEALTHCARE	EPIFLO SYS K120764
2013-9487	11/26/2013 12/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	MONICA KING KIMBERLY-CLARK HEALTHCARE	TRANSCU 02 K090681
2013-9488	11/26/2013 12/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	ERICA LORING BIOFILM INC	SSL AMERICAS INC - DUREX PLAY TEMPTATIONS ASSORTED LUUBRICANTS K060098
2013-9489	11/26/2013 12/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Megan Taylor National Institute on Drug Abuse, NIH	FDA Form 1572 from IND 117902
2013-9490	11/26/2013 12/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	ERICA LORING BIOFILM INC	DAAVLIN DISTRIBUTING CO - DERMAL WITH DIGITAL TIMER K073587
2013-9491	11/27/2013 12/27/2013	OC/ORPA/ OC/ORPA/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Doe J	CMLPNT 131187
2013-9492	11/27/2013	FDA/OMPT/CDER/ORP/DIDP/	BOB TREMMEL	5 FLOUROURACIL; XELODA; DIHYDROPYRIMIDINE

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	12/27/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WELLSTAT THERAPEUTIC CORP	DEHYDROGENASE DEFICIENCY - AER
2013-9493	11/27/2013 12/27/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HALL 01699310, GERALD	AMBIEN - AER
2013-9494	11/27/2013 12/27/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID MARTIN Timeline Productions	CHANTIX (VARENICLINE) - AER 1/06 TO 11/4/08
2013-9495	11/27/2013 12/27/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Enrique Seoane-Vazquez MASSACHUSETTS COLLEGE OF PHARMACY	Request for Scripts (programming) used to produce the online version of Drugs@FDA
2013-9496	11/27/2013 12/27/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	David P. Summers David P. Summers	IND 61026
2013-9497	11/27/2013 12/27/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Timothy B Bassett Pura Vida Investments	JUXTAPID - ISR
2013-9498	11/27/2013 01/24/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Madeline McNair CTV News	GARDISIL - REPORTS, MEMOS, EMAILS ETC
2013-9499	11/27/2013 12/27/2013	FDA/OMPT/CDRH/OCER/DFOI/	Sam D Kestenbaum HARPER'S MAGAZINE	23ANDME - EMAIL, RECORDINGS, MINUTES ETC
2013-9500	11/27/2013 12/27/2013	FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA REQUEST LOG 11/18/2013 - 11/22/2013
2013-9501	11/27/2013 12/27/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PATRICK KELLY CONWAY HOMER & CHIN- CAPLAN PC	INDIVIDUAL RECS

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		FDA/OMPT/CBER/OCOD/DDOM/ALFB/		
2013-9502	11/27/2013 12/27/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Meaghan Meyer Maplehurst Bakeries, LLC	GRANNY'S KITCHEN LLC, FRANKFORT, NY - INSPECTIONS, CONSUMER COMPLAINTS 01/01/2013 - 11/25/2013
2013-9503	11/27/2013 12/27/2013	FDA/OMPT/CTP/OD/	Allison ODonnell Campaign for Tobacco Free Kids	SE0001762, SE0003525, SE0003526 ETC
2013-9504	11/27/2013 12/27/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	FERRIC PYROPHOSPHATE DRUGS APPROVED
2013-9505	11/27/2013 12/27/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	David Prince Prince, David M	CHANTIX - AERS
2013-9506	11/27/2013 12/27/2013	FDA/OMPT/CDRH/OCER/DFOI/	Trishia Dwyer GE Healthcare	K130277
2013-9507	11/27/2013 12/27/2013	FDA/OMPT/CDRH/OCER/DFOI/	Robert W. Steins Product Make	K802146, K883917, K931908 ETC
2013-9508	11/27/2013 12/27/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Robert W. Steins Product Make	K802146, K883917, K931908, ETC
2013-9509	11/27/2013 12/27/2013	FDA/OMPT/CDRH/OCER/DFOI/	HONSUN (NANTONG) CO., LTD. HONSUN (NANTONG) CO., LTD.	K092245
2013-9510	11/27/2013 12/27/2013	FDA/OC/OES/DFOI/	Kari Twaite Beveridge & Diamond, PC	CFSAN FOIA REQUESTS 10/25/2013 - 11/26/2013
2013-9511	11/27/2013 12/27/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	EDWARD A. TENTHOFF PIPER JAFFRAY & CO	ADCETRIS (BRENTUXIMAB VEBOTIN) FAERS; SEATTLE GENETIC INC 483, EIR, UNTITLED LTRS 2/13 TO PRESENT
2013-9512	11/27/2013 12/27/2013	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OES/	WILLIAM P. TRAYLOR, III YEAROUT & TRAYLOR PC	INDIVIDUAL RECS
2013-9513	11/27/2013	FDA/OC/OES/DFOI/	KRISTEN S. MOYERS	MINOR DELETIONS

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	12/27/2013		WRIGHT LINDSEY & JENNINGS	
2013-9514	11/27/2013 12/27/2013	FDA/OMPT/CDRH/OCER/DFOI/	SETH A. MAILHOT MICHAEL BEST & FREIDRICH	MARKER TEST DIAGNOSTICS INC - RUMA MARKER SYS 513 REDACTED
2013-9515	11/27/2013 12/27/2013	FDA/OFVM/CFSAN/OCD/EOS/	LYTTON SMITH KARR TUTTLE CAMPBELL LAW OFFICES	CDC INVESTIGATION ON SKIN INFECTIONS 10/11 TO PRESENT
2013-9516	11/27/2013 12/27/2013	FDA/OGROP/ORANE-FO/NYK- DO/NYK-DCB/	RYAN MICHAEL FOURNIER, Esq. BENJAMIN L ENGLAND & ASSOCIATES LLC	ENTRY BQL-0034317-6
2013-9517	11/27/2013 12/27/2013	FDA/OC/OES/	KEITH JACKSON RILEY & JACKSON PC	INDIVIDUAL RECS
2013-9518	11/27/2013 12/27/2013	FDA/OC/OES/	VICKI LANKFORD CORY WATSON ET AL	INDIVIDUAL RECS
2013-9519	11/27/2013 12/27/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	THOMAS M. BURTON WALL STREET JOURNAL	ICLUSIG - AER
2013-9520	11/27/2013 12/27/2013	OC/ORAO/OCI/ OC/ORAO/OCI/	ALISON YOUNG USA TODAY	DIETARY SUPPLEMENT ISSUES 1/07 TO PRESENT
2013-9521	11/29/2013 12/30/2013	FDA/OGROP/ORACE-FO/CHI- DO/CHI-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Sarah Fitzgerald LIL' DRUG STORE PRODUCTS INC	SASMAR, INC - RECS RE CONCEIVE PLUS 01/01/2012 - 11/22/2013
2013-9522	11/29/2013 12/30/2013	FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Danielle Eisner Law Offices of Ronald A. Marron, APLC	STANDARD HOMEOPATHIC COMPANY; HYLAND'S INC; STANDARD HOMEOPATHIC LABORATORIES - COMMUNICATIONS WITH FDA
2013-9523	11/29/2013	FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/	Sarah Fitzgerald	LACLEDE - LUVENA RECS 01/01/2009 - 11/22/2013

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	12/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/OSMP/OCP/	LIL' DRUG STORE PRODUCTS INC	
2013-9524	11/29/2013 12/30/2013	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	Abbott, D. D., and J. W. E. Harrison. Methyl Salicylate: Studies of osseous changes in the rat, reproduction in the rat and mouse, and liver and kidney effects in the dog
2013-9525	11/29/2013 12/30/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Rohit Vanjani OPPENHEIMER	LANNETT COMPANY INC - 483 07/01/2013 - 10/04/2013
2013-9526	11/29/2013 12/30/2013	FDA/OFVM/CFSAN/OCD/EOS/	Matthew Latch none	LIVING ESSENTIALS 5 HOUR ENERGY- CORR WITH FDA RE 21 CFR 0 101.93(a)(l)
2013-9527	11/29/2013 12/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Galaxy Bio. Inc/NAL pharma Inc. Galaxy Bio Inc	Sun Pharma Global's Doxorubicin Hydrochloride Liposomal Injection ANDA documents
2013-9528	11/29/2013 12/30/2013	FDA/OFVM/CFSAN/OCD/EOS/	Sue Mucklow Wells fargo Insurance Services	SIMPLY THICK - ADVERSE EVENTS, MEDWATCH REPORTS 01/01/2010 - 01/01/2013
2013-9529	11/29/2013 12/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jerold Hodge Jerold Hodge	ACUTANE - ORIGINAL DAILY DOSAGE AMOUNTS
2013-9530	11/29/2013 12/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Yigal Nochomovitz Morgan Stanley	ADCETRICS, KYPROLIS - AERS
2013-9531	11/29/2013 12/30/2013	FDA/OFVM/CFSAN/OCD/EOS/	Dr. John Hnatio FoodQuestTQ LLC	LIST OF COMPANIES USING SOFTWARE THAT DUPLICATES FOODQUESTTQ
2013-9532	11/29/2013 12/30/2013	FDA/OGROP/ORACE-FO/LOS-DO/LOS-CB/	Ronald Campbell ORANGE COUNTY REGISTER	BAXTER HEALTHCARE, IRVINE, CA - 483, CORR 01/01/2011 - 10/31/2013
2013-9533	11/29/2013 12/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	Anthony Blumfield Radnostics	K042697
2013-9534	11/29/2013	FDA/OC/OES/DFOI/	Debbie J. Locklear, Paralegal	DA VINCI ROBOT - ALL RECS

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	01/15/2014		Gloria Seidule, PA	
2013-9535	11/29/2013 12/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	Anthony Blumfield Radnostics	K091529
2013-9536	11/29/2013 12/30/2013	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	Larry Hagerman HAGERMAN, LARRY M	HYROX CHEMICAL, ELGIN, IL - 483 07/23/2013 - 07/23/2013
2013-9537	11/29/2013 12/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Terri Borud Borud, Terri	KARIVA - PRODUCT INSERT 01/01/2008 - 03/30/2009
2013-9538	11/29/2013 12/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Molly Redden MOTHER JONES	LEVONORGESTREL - AERS, MEDWATCH REPORTS
2013-9539	12/02/2013 12/31/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FRIEDMAN, ROBERT	ROTARIX (ROTAVIRUS VACCINE LIVE ORAL) - AERS 1969 TO PRESENT
2013-9540	12/02/2013 12/31/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FRIEDMAN, ROBERT	SUPRALIP 160 MG TABS - AERS 1969 TO PRESENT
2013-9541	12/02/2013 12/31/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DIANA M FELICI ONYX PHARMACEUTICALS	KYPROLIS (CARFILZOMIB) - AERS
2013-9542	12/02/2013 12/31/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TORREY COPE SIDLEY AUSTIN LLP	UNTITLED LTRS - AMBISOME (LIPOSOMAL AMPHOTERCIN B) NDA 50-740 3/19/97; XENICAL (ORLISTAT CAPS) NDA 20-766 8/21/97; INTEGRILIN (INTRIFIBAN) NDA 20-718 9/25/97, ETC PROMOTIONAL MATERIALS
2013-9543	12/02/2013 12/31/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GREEN, COTTRELL	ULCERATIVE COLITIS - AERS; HIV - PAMPHLET, BROCHURE, BOOKLET; PREDNISONE 20 MG, ASACOL 400 MG, BENTYL 10 MG, ETC AERS

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2013-9544	12/02/2013 12/31/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	CHASTITY JOY RODRIGUEZ INTERNATIONAL SIGHT RESTORATION INC	LIONS EYE BANK OF PUERTO RICO INC, SAN JUAN, PR; LIONS EYE BANK OF LONG ISLAND, VALLEY STREAM, NY - 483S, WARNING LTRS LAST 10 YRS
2013-9545	12/02/2013 12/31/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	KRISTINA SASICH GASS WEBER MULLINS LLC	RICH PRODUCTS CORPORATION (RICH PRODUCTS PLANT), WAYCROSS, GA - EIRS, ASSESMENT, CORRECTIVE ACTIONS, ETC 1/11 TO PRESENT
2013-9546	12/02/2013 12/31/2013	OC/OR/ OC/OR/ FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Doe J	SMUCKERS - JIF PEANUT BUTTER RPT
2013-9547	12/02/2013 12/31/2013	FDA/OC/OES/DFOI/	Doe J	JOSEPH SHEEY, JAMES CHARLES - INVESTIGATOR MISCONDUCT, FALSE RPTS, PERJURY, ETC
2013-9548	12/02/2013 12/31/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Eun Jin Bang Eun Jin Bang	REMICADE - SAFETY AND EFFICACY RECS
2013-9549	12/02/2013 12/31/2013	OC/CVM/OCD/	TIM SCHWAB Food & Water Watch	VETERINARY MEDICINE A/C (VMAC) 1/1/13 TO11/22/13 - RECEIPTS ON EXPENDITURES, LABOR COSTS, CMLPLNTS WITH CONFLICT OF INTEREST POLICIES, ETC
2013-9550	12/02/2013 12/31/2013	FDA/OMPT/CTP/OD/	Bradley Saran Bradley Saran	VAPORIZED TOBACCO PRODUCTS - HEALTH EFFEECTS
2013-9551	12/02/2013 12/31/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Molly Redden MOTHER JONES	LEVONORGESTREL - AGENCY REVIEW OF RELATIONSHIP BETWEEN EFFICACY AND PATIENT WEIGHT
2013-9552	12/02/2013 12/31/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bethany Farmer INFOTRIEVE	NDA 20186, Review and evaluation of pharmacology and toxicology data; NDA 18240, Review and evaluation of pharmacology and toxicology data, NDA 18240, Review and evaluation of pharmacology and toxicology data, ETC
2013-9553	12/02/2013 12/31/2013	FDA/OC/OES/DFOI/	Andrew Witzke A.T. Kearney	Recall and market withdrawals (voluntary and mandated) performed and reported by the FDA
2013-9554	12/02/2013 12/31/2013	OC/OR/ OC/OR/	JOSHUA AXELROD NATIONAL PRESS BUILDING	MARYLAND CONGRESSIONAL DELEGATION - REP ANDY HARRIS, REP DUTCH RUPERSSBERGER, REP JOHN SARBANES, ETC CORR 1/09 TO PRESENT

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		FDA/OC/OL/		
2013-9555	12/02/2013 12/31/2013	FDA/OC/OES/	ALICE DREGER NORTHWESTERN UNIV FEINBERG SCHOOL OF MEDICINE	WRITTEN & ORAL COMM BETWEEN ROBERT SKIP NELSON & FDA ETHICS & INTEGRITY STAFF 1/09 TO 10/13
2013-9556	12/02/2013 12/31/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jorge Alemany JANUS DEVELOPMENTS	Marimastat IND
2013-9557	12/02/2013 12/31/2013	FDA/OMPT/CDRH/OCER/DFOI/	Raj Sardesai Raj Sardesai	K100011
2013-9558	12/02/2013 12/31/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Colleen O'Hara Law Office of Colleen O'Hara	LEXAPRO, PROZAC, DIAZEPAM ETC - AERS
2013-9559	12/02/2013 12/31/2013	FDA/OMPT/CDRH/OCER/DFOI/	Yu-Ju Chiang Chung Yuan Christian University	K113780
2013-9560	12/02/2013 12/31/2013	FDA/OFVM/CFSAN/OCD/EOS/	Joseph Lenthall Mewburn Ellis LLP	GRN000041
2013-9561	12/02/2013 12/31/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Andrew Kiss Boston Children's Hospital Informatics Program	TENEX - APPROVAL PACKAGE FOR TREATMENT OF HYPERTNESION
2013-9562	12/02/2013 12/31/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Steven Yu Ryuh Biomedical Research Foundation	NDA 050582
2013-9563	12/02/2013 12/31/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ghada Khouri Support group for victims of cancer quackery, Lebanon	NABIL HABIB, VIANOVA LABS - CORR WITH FDA 01/01/1999 - 12/01/2013
2013-9564	12/02/2013 12/31/2013	FDA/OMPT/CDRH/OCER/DFOI/	Pavle Sedic LELO Inc.	K994079
2013-9565	12/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	Pavle Sedic	K983045

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	12/31/2013		LELO Inc.	
2013-9566	12/02/2013 12/31/2013	FDA/OMPT/CTP/OD/	MARK E GREENWOLD CAMPAIGN FOR TOBACCO-FREE KIDS	TOBACCO PROD MFR - SE0001762, SE0003525, SE0003526, ETC
2013-9567	12/02/2013 12/31/2013	FDA/OFVM/CFSAN/OCD/EOS/	WILLIAM A OLSON Center for Regulatory Services, Inc.	ETOYO SEIKRAN KAISHA LTD - SILICON DIOXIDE FCN 549
2013-9568	12/02/2013 12/31/2013	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORA/ OC/ORA/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	KRISTINA SASICH GASS WEBER MULLINS LLC	RICH PRODUCT CORP - FARM RICH, MARKET DAY, SCHWAN'S E COLI OUTBREAK RECALLS W/S, RESULTS. TESTING, ETC 3/13 TO 4/13
2013-9569	12/02/2013 12/31/2013	FDA/OC/OES/DFOI/	OGLESBY #194567, JOHN	LIST OF FOUR BASIC FOOD GROUPS & THE CALORIE CONTENT
2013-9570	12/02/2013 12/31/2013	FDA/OMPT/CTP/OD/	Lt. Rick Qualls Clovis Fire Department	ROLL YOUR OWN CIGARETTES - SELF EXTINGUISH RECS
2013-9571	12/03/2013 01/02/2014	FDA/OMPT/CDRH/OCER/DFOI/	Nancy MacDonald Health Policy Associates, Inc.	K863939
2013-9572	12/03/2013 01/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 11/1-30/2013
2013-9573	12/03/2013 01/02/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	Redacted 510(k)s for November 2013
2013-9574	12/03/2013 01/02/2014	FDA/OMPT/CDRH/OCER/DFOI/	Barry Callahan RJL SYSTEMS	K122388
2013-9575	12/03/2013 01/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kiran Kumar Gande Appco Pharmaceutical Corporation	NDA 018604 - SBA
2013-9576	12/03/2013 01/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dustin Block IPD Analytics, LLC	NDA 021560 - EFFECTIVE APPROVAL LETTER
2013-9577	12/03/2013 01/02/2014	FDA/OC/OES/DFOI/	Robert King FDANEWS	DISCLOSURE FOI REQUEST LOG 11/25/2013 - 11/29/2013
2013-9578	12/03/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	CLOSED FOIA REQUESTS 11/1-30/2013

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	01/02/2014		MERCK & CO., INC.	
2013-9579	12/03/2013 01/02/2014	FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/	Irma Barr CEPHEID	CEPHEID, SUNNYVALE, CA - EIR 01/16/2012 - 12/02/2013
2013-9580	12/03/2013 01/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DR. REENA HARJAI APCER Pharma Solutions, Inc	KINEVAC (SINCALIDE) - AER
2013-9581	12/03/2013 01/02/2014	FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	DIMITRI SIRAKOFF DO, SANTA ANA, CA - EIR, 483, CO RESP 1/09/13-2/6/13
2013-9582	12/03/2013 01/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	ALEXION PHARM- SOLARIS (ECULIZUMAB) BLA 125166/172 APRVL 9/23/11
2013-9583	12/03/2013 01/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	ZIMENG JIN, BEJING, CHINA - EIR, 483, CO RESP 4/18/12
2013-9584	12/03/2013 01/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	WELLINGTON LABORATORIES INC, GUELPH, CANADA - EIR, 483, CO RESP 7/19/12
2013-9585	12/03/2013 01/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	JANSSEM BIOLOGICS, RINGASKIDDY, IRELAND - EIR, 483, CO RESP 6/18/12
2013-9586	12/03/2013 01/02/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	WALTER E. CHALKLEY THOMSON REUTERS	FENWAL A FRESENIUS KABI CO, BAD HOMBURG, GERMANY - EIR, 483, CO RESP 4/9-25/13
2013-9587	12/03/2013	FDA/OGROP/ORO/CE-FO/PHI-	WALTER E. CHALKLEY	PROMETHEAN LIFESCIENCES INC, PITTSBURGH, PA - EIR,

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	01/02/2014	DO/PHI-CB/	THOMSON REUTERS	483, CO RESP 1/11/13
2013-9588	12/03/2013 01/02/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	TARAPUR, BOISAR DISTRICT THANE, MAHARASHTRA, INDIA FEI 3009688205; TALGHAR THANE DISTRICT, MAHARASHTRA, INDIA FEI 3006418686 - EIR, 483, CO RESP 10/25-30/12, 11/1-5/12
2013-9589	12/03/2013 01/02/2014	FDA/OGROP/ORAN/NE-FO/NYK- DO/NYK-DCB/	WALTER E. CHALKLEY THOMSON REUTERS	MERCY MEDICAL CTR, ROCKVILLE CENTRE, NY - EIR, 483, CO RESP 3/11/13
2013-9590	12/03/2013 01/02/2014	FDA/OGROP/ORAN/NE-FO/NWE- DO/NWE-CB/	WALTER E. CHALKLEY THOMSON REUTERS	PRECISION DERMATOLOGY INC, CUMBERLAND, RI - EIR, 483, CO RESP 4/17/12
2013-9591	12/03/2013 01/02/2014	FDA/OGROP/ORAN/SW-FO/KAN- DO/KAN-CB/	WALTER E. CHALKLEY THOMSON REUTERS	QA LABORATORIES, KANSAS CITY, MO - EIR, 483, CO RESP 5/11/12
2013-9592	12/03/2013 01/02/2014	FDA/OGROP/ORAN/CE-FO/DET- DO/DET-CB/	WALTER E. CHALKLEY THOMSON REUTERS	PFIZER INC, ROCHESTER, MI - EIR, 483, CO RESP 6/15/12
2013-9593	12/03/2013 01/02/2014	FDA/OGROP/ORAN/SW-FO/KAN- DO/KAN-CB/	WALTER E. CHALKLEY THOMSON REUTERS	MEDTRONIC INC, WEST DES MOINES, IA - EIR, 483, CO RESP 11/6/12
2013-9594	12/03/2013 01/02/2014	FDA/OGROP/ORAN/PA-FO/SEA- DO/SEA-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORAN/PA-FO/SEA- DO/SEA-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	GENENTECH INC, HILLSBORO, OR - EIR, 483, CO RESP 6/27/12
2013-9595	12/03/2013 01/02/2014	FDA/OGROP/ORAN/NE-FO/NWE- DO/NWE-CB/	WALTER E. CHALKLEY THOMSON REUTERS	WILLIAM McGEE, SPRINGFIELD, MA - EIR, 483, CO RESP 1/13/12
2013-9596	12/03/2013 01/02/2014	FDA/OGROP/ORAN/SW-FO/DEN- DO/DEN-CB/	WALTER E. CHALKLEY THOMSON REUTERS	USL PHARMA INC, DENVER, CO - EIR, 483, CO RESP 9/25/12
2013-9597	12/03/2013	FDA/OMPT/CDER/GRP/DIDP/	WALTER E. CHALKLEY	TEMMLER PHARMA GMBH & CO KG, MARBURG, GERMANY

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	01/02/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	THOMSON REUTERS	- EIR, 483, CO RESP 6/22/12
2013-9598	12/03/2013 01/02/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	SUN PHARMACEUTICALS INDUSTRIES LTD, HALOL, INDIA - EIR, 483, CO RESP 9/28/12
2013-9599	12/03/2013 01/02/2014	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	WALTER E. CHALKLEY THOMSON REUTERS	STEFAN SCHNEIDER, MD , LONG BEACH, CA - EIR, 483, CO RESP 1/26/12
2013-9600	12/03/2013 01/02/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	SMITH KLINE BEECHAM LTD, WORTHING, UK - EIR, 483, CO RESP 10/19/12
2013-9601	12/03/2013 01/02/2014	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	WALTER E. CHALKLEY THOMSON REUTERS	ROSARIO HIDALGO MD, TAMPA, FL - EIR, 483, CO RESP 12/4/12
2013-9602	12/03/2013 01/02/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	AGILA SPECIALTIES PRIVATE LTD, BANGALORE, INDIA - EIR, 483, CO RESP 6/17-27/13
2013-9603	12/03/2013 01/02/2014	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	WALTER E. CHALKLEY THOMSON REUTERS	AKORN INC, DECATUR, IL - EIR, 483, CO RESP 5/25/12
2013-9604	12/03/2013 01/02/2014	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	WALTER E. CHALKLEY THOMSON REUTERS	BRISTOL MYERS SQUIBB CO INC, EAST SYRACUSE, NY - EIR, 483, CO RESP 2/7/13
2013-9605	12/03/2013 01/02/2014	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	WALTER E. CHALKLEY THOMSON REUTERS	OMID NASSIM MD ALIA CLINICAL RESEARCH INC, HUNTINGTON PARK, CA - EIR, 483, CO RESP 10/12/12-12/5/12
2013-9606	12/03/2013 01/02/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	WALTER E. CHALKLEY THOMSON REUTERS	SANQUIN PLASMA PRODUCTS & CAF DCF, AMSTERDAM, NETHERLANDS - EIR, 483, CO RESP 5/13
2013-9607	12/03/2013 01/02/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KRISTI O. SMEDLEY, Ph.D. Center for Regulatory Services, Inc.	FREY TOX GMBH, HERZBERG, GERMANY - EIR, 483 MOST RECENT

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-9608	12/04/2013 01/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	Gael Tisack TERUMO CARDIOVASCULAR SYSTEMS CORP	K001520
2013-9609	12/04/2013 01/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Diana Felici ONYX PHARMACEUTICALS	KYPROLIS - MEDWATCH
2013-9610	12/04/2013 01/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	7260352, 8092214, 6561702 ETC
2013-9611	12/04/2013 01/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Heather Knobbe Gentry Locke Rakes & Moore, LLP	2006 Limited FDA Survey of Compounded Drug Products: http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/pharmacycompounding/ucm204237.htm ; The Special Risks of Pharmacy Compounding- May 31, 2007: http://www.drugs.com/fda-consumer/the-special-risks-of-pharmacy-compounding-74.html ; FDA and Pharmacy Compounding- video, uploaded to Youtube Oct. 26, 2010: http://www.youtube.com/watch?v=kif_rmtlQb0
2013-9612	12/04/2013 01/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kenneth Daly BURG SIMPSON ET AL	NDA 18-081; NDA 18-082; NDA 18-723; ETC
2013-9613	12/04/2013 01/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Xin Pan Weiss Asset Management	AGILA SPECIALTIES PRIVATE LIMITED - INSPECTION RECS 01/01/2013 - 12/03/2013
2013-9614	12/04/2013 01/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Eileen Flowers Jefferies LLC	ICLUSIG - AERS
2013-9615	12/04/2013 01/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jill Clark STRYKER SUSTAINABILITY SOLUTIONS	K130744
2013-9616	12/04/2013	FDA/OMPT/CDER/GRP/DIDP/	Haley Reddington	PRADAXA, VICTOZA, LIPITOR - AERS

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2013-9617	12/04/2013 01/03/2014	FDA/OC/OES/DFOI/	Rolland Gauthier FALCON RESEARCH	PATIENT ASSISTANCE PROGRAMS - INVESTIGATIONS
2013-9618	12/04/2013 01/03/2014	FDA/OFVM/CFSAN/OCD/EOS/	JAIME R BARCUS Golden & Walters, PLLC	TACO BELL RESTAURANTS - FOOD BORNE ILLNESSES STUDIES 4/10 TO 6/10
2013-9619	12/04/2013 01/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	PERIACTIN (CYPROHEPTADINE) - AERS, STUDIES
2013-9620	12/04/2013 01/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DANYSH #DL-4879, KURT M	ELI LILLY & CO - PROZAC (FLUOXETINE HCL) ISR CORR
2013-9621	12/04/2013 01/03/2014	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	K MICHELLE VASSALLO LINCARE INC	DEFELICECARE INC, WV - EIRS, 483S, WARNING LTRS 1/98 TO PRESENT
2013-9622	12/04/2013 01/03/2014	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JONATHAN D PAVLOVCAK HILL WALLACK LLP	INVAGEN PHARMS - AMLODIPINE BESYLATE TABS RECALL RECS
2013-9623	12/04/2013 01/03/2014	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	PETER J GALLAGHER PORZIO BROMBERG & NEWMAN PC	BRENDAN MURPHY, RIVER'S EDGE PHARMACEUTICALS LLC, KYLEMORE PHARMACEUTICALS LLC - WARNING LTRS, 483S, CONSENT DEVREES, ETC 1/09 TO PRESENT
2013-9624	12/04/2013 01/03/2014	FDA/OC/OES/DFOI/	HOPE, FRANK	JOB ANNOUNCEMENT WRITE-EDITOR - SELECTED APPLICANTS REFERENCE CHECKS, JOB EVALUATIONS, NOTES, ETC
2013-9625	12/04/2013 01/03/2014	FDA/OC/OES/DDM/	RACHANOW, GERALD	DKT 2003N-0539
2013-9626	12/04/2013 01/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	EDWARDS, S ALBERT	APRVD DRUGS OR INVESTIGATIONAL DRUG PRODS WITH AN INDICATIOIN OR RESEARCH TO TREAT OCULOPHARYNGEAL MUSCULAR DYSTROPHY

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-9627	12/04/2013 01/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Riikka Kaihovaara Yleisradio / Finnish Broadcasting Media	LYRICA - AERS
2013-9628	12/04/2013 01/03/2014	FDA/OFVM/CFSAN/OCD/EOS/	Crystal N. Skelton KELLEY DRYE & WARREN LLP	NOODLE PRODUCTS - RULEMAKING RECORDS
2013-9629	12/04/2013 01/03/2014	OC/ORR/ORM/ OC/ORR/ORM/	ROBERT KING FDA NEWS	PHARMACEUTICAL, BIOLOGICS, MEDICAL DVC MFG, CLNCL TRIAL FACILITIES IN AND OUTSIDE THE US - 483S 11/1-31/3
2013-9630	12/04/2013 01/03/2014	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	CHESTER, VICKI	PHOTOMEDEX INC, CARLSBAD, CA - 483S 9/13 TO 12/13
2013-9631	12/04/2013 01/03/2014	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CAMPANILE, VIVIAN	IPCA LABORATORIES LTD, MUMBAI, INDIA - INSP RECS
2013-9632	12/04/2013 01/03/2014	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	JOAN FRIEND AMERICAN RED CROSS CENTRAL PLAINS BLOOD SERVICES REGION	AMERICAN RED CROSS BLOOD SERVICES CENTRAL PLAINS REGION, WICHITA, KS - EIR 7/22-26/13
2013-9633	12/04/2013 01/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	STEPHANIE PHILBIN GOODWIN PROCTER LLP	ACRYSOF UV ABSORBING INTRAOCULAR LENSES P930014; ACRYSOF NATURAL SINGLE-PIECE POSTERIOR CHAMBER INTRAOCULAR LENSES P930014/S009, ETC
2013-9634	12/05/2013 01/06/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Melissa Young Medafor, Inc.	K103641
2013-9635	12/05/2013 01/06/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Eileen Flowers Jefferies LLC	KYPROLIS - AERS
2013-9636	12/05/2013 01/06/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	A.C. Thompson PROPUBLICA	NUEDEXTA - AERS
2013-9637	12/05/2013	FDA/OMPT/CDER/GRP/DIDP/	Eileen Flowers	POMALYST - AERS

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	01/06/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jefferies LLC	
2013-9638	12/05/2013 01/06/2014	FDA/OMPT/CDRH/OCER/DFOI/	Karen L. Richards Singulex, Inc.	K121214
2013-9639	12/05/2013 01/13/2014	FDA/OFVM/CFSAN/OCD/EOS/	WILLIAM A OLSON Center for Regulatory Services,Inc.	IMPERIAL CHEMICAL INDUSTRIES LTD - OLEFIN POLYMERS FAP 7B2170
2013-9640	12/05/2013 01/06/2014	FDA/OFVM/CFSAN/OCD/EOS/	WILLILAM A OLSON Center for Regulatory Services,Inc.	SUN OIL CO - OLEFIN POLYMERS FAP 5B16-2, FAP 5B1603
2013-9641	12/05/2013 01/06/2014	FDA/OFVM/CFSAN/OCD/EOS/	WILLIAM A OLSON Center for Regulatory Services,Inc.	SANDOZ COLORS & CHEMICALS - OLEFIN POLYMERS FAP 382851
2013-9642	12/05/2013 01/06/2014	FDA/OFVM/CFSAN/OCD/EOS/	WILLIAM A OLSON Center for Regulatory Services,Inc.	SANDOZ COLORS & CHEMICALS - OLEFIN POLYMERS FAP 9B3431
2013-9643	12/05/2013 01/06/2014	FDA/OC/OES/DFOI/	S ALBERT EDWARDS S ALBERT EDWARDS, PHARM D	RPT TO CONGRESS - MOST RECENT
2013-9644	12/05/2013 01/06/2014	FDA/OMPT/CDRH/OCER/DFOI/	MARK MCLEAN MEYERSON LAW FIRM PC	NUVASIVE INC - XL TDR CLNCL TRIAL
2013-9645	12/05/2013 01/06/2014	FDA/OMPT/CDRH/OCER/DFOI/	JUDY F GORDON CLINREG CONSULTING SERVICES INC	CARL ZEISS SURGICAL - STERILE SURGICAL DRAPE K800552
2013-9646	12/05/2013 01/06/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Matt Cine/Jeremy Cain GIDEON COOPER & ESSARY	LIST OF FDA EMPLOYEES AT THE AMERICAN SOCIETY OF HEALTH-SYSTEMPHARMACISTS - COST, MATERIALS 12/4-8/11, 6/9/13/12, 12/2/6/12
2013-9647	12/05/2013 01/06/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OMPT/CDRH/OCER/DFOI/	BETHANY KENNEDY EMORD & ASSOCIATES, P.C.	DR MARTIN P GALLAGER (MEDICALL WELLNESS ASSOCIATES), JEANNEWTTE, PA - ALLEGED USE OF OZONE AND /OR OZONE LAST FIVE YRS
2013-9648	12/05/2013 01/06/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	ERICA DOMINGO FOLKMAAN LAW OFC	DKT CAM-L-2659-12 - BOBBY CHEZ INVESTIGATIONS, VIOLATIONS ; ROBERT SLIWOWSKI, LINDA SLIWOWSKI, CATHERINE SHUKDINAS - CORR ; BOBBY CHEZ - CRAB CAKES NUTRITION LBLG, ETC 2005 TO PRESENT
2013-9649	12/05/2013 01/06/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	PATRICK KELLY CONWAY HOMER & CHIN-CAPLAN PC	INDIVIDUAL RECS (CERTIFIED)
2013-9650	12/05/2013	FDA/OC/OL/	SPENCER THOMAS	UNITED STATES HOUSE OF REPRESENTATIVES -

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	01/06/2014	OC/ORO/ OC/ORO/ FDA/OC/OL/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GIDEON COOPER & ESSARY	COMMITTEE ON ENERGY & COMMERCE FUNGAL MENINGITIS OUTBREAK RECS 11/14/12, LTR 11/16/12, 2/1/13 LTR, ETC
2013-9651	12/05/2013 01/06/2014	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 11/18-22/13
2013-9652	12/05/2013 01/06/2014	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 11/18-22/13
2013-9653	12/05/2013 01/06/2014	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 11/11-15/13
2013-9654	12/05/2013 01/06/2014	OC/ORO/ OC/ORO/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARK BOGETICH PUBLIC AFFAIRS INC	JEFFREY E STONE - REGISTRATION, CMLPNTS, AUDITS ETC; TEMECULA PHARMACY - REGISTRATION, CMLPNTS AUDITS, ETC 11/1/94 TO 11/1/99; TEMECULA COMPOUNDING PHARMACY - REGISTRATION, CMLPNTS, AUDITS, ETC 12/6/99 TO 12/1/02
2013-9655	12/05/2013 01/06/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARY B SZALKOWSKI PRISMA CORP	PERINDOPRIL - AERS 11/1-30/13
2013-9656	12/05/2013 01/06/2014	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 11/11-15/13
2013-9657	12/05/2013 01/06/2014	FDA/OC/OES/DFOI/	ERIKA MALADY FIRST RECORDS RETRIEVAL	DERMAQUEST INC - EIRS, 483S, RPTS, ETC
2013-9658	12/05/2013 01/06/2014	FDA/OC/OES/DFOI/	DEBRA L. COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 11/18-22/13
2013-9659	12/05/2013 01/06/2014	FDA/OC/OES/DFOI/	SANDY FRIEDMAN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 11/11-15/13
2013-9660	12/05/2013	FDA/OC/OES/DFOI/	DEBRA L. COHEN	DAILY LOG 11/11-15/13

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	01/06/2014		WOLTERS KLUWER LAW & BUSINESS	
2013-9661	12/05/2013 01/06/2014	FDA/OC/OES/DFOI/	SANDY FRIEDMAN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 11/18-22/13
2013-9662	12/05/2013 01/06/2014	FDA/OC/OES/DFOI/	LISA TARRISON SCHRAMP CanReg, Inc.	DAILY LOG 11/11-15/13
2013-9663	12/05/2013 01/06/2014	FDA/OC/OES/DFOI/	LISA TARRISON SCHRAMP CanReg, Inc.	DAILY LOG 11/18-22/13
2013-9664	12/05/2013 01/06/2014	FDA/OC/OES/DFOI/	LISA TARRISON SCHRAMP CanReg, Inc.	DAILY LOG 11/11-15/13
2013-9665	12/05/2013 01/06/2014	FDA/OC/OES/DFOI/	LISA TARRISON SCHRAMP CanReg, Inc.	DAILY LOG 11/18-22/13
2013-9666	12/05/2013 01/06/2014	FDA/OC/OES/DFOI/	DAVID McFARLAND FDA REVIEW/FDA WEBVIEW	DAILY LOG 11/11-15/13
2013-9667	12/05/2013 01/06/2014	FDA/OC/OES/DFOI/	DAVID McFARLAND FDA REVIEW/FDA WEBVIEW	DAILY LOG 11/18-22/13
2013-9668	12/05/2013 01/06/2014	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 11/11-15/13
2013-9669	12/05/2013 01/06/2014	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	DAILY LOG 11/18-22/13
2013-9670	12/05/2013 01/06/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 11/18-22/13
2013-9671	12/05/2013 01/06/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 11/11-15/13
2013-9672	12/05/2013 01/06/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 11/18-22/13
2013-9673	12/05/2013 01/06/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 11/11-15/13
2013-9674	12/05/2013 01/06/2014	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 11/11-15/13
2013-9675	12/05/2013	FDA/OC/OES/DFOI/	BARBARA JONES	DAILY LOG 11/18-22/13

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	01/06/2014		DOMINION GROUP INC	
2013-9676	12/05/2013 01/06/2014	FDA/OC/OES/DFOI/	Center for Regulatory Services, Inc.	DAILY LOG 11/11-15/13
2013-9677	12/05/2013 01/06/2014	FDA/OC/OES/DFOI/	GLADYS B TONKIN Center for Regulatory Services, Inc.	DAILY LOG 11/18-22/13
2013-9678	12/06/2013 01/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	Colin Lecher Popular Science	23ANDME - RECS RE WARNING LETTER
2013-9679	12/06/2013 01/07/2014	FDA/OFVM/CFSAN/OCD/EOS/	Crystal Skelton KELLEY DRYE & WARREN LLP	CHOW MEIN NOODLES - COMPLIANCE PROGRAM GUIDANCE RECS
2013-9680	12/06/2013 01/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Peter Mione CutisPharma, Inc.	EPANED - REVIEW RECS
2013-9681	12/06/2013 01/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kasia Petchel Optimer Pharmaceuticals, Inc.	8817836, 9496582
2013-9682	12/06/2013 01/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dawn Chitty TORRENT PHARMA INC	NDA 21526
2013-9683	12/06/2013 01/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dawn Chitty TORRENT PHARMA INC	ANDA 201046
2013-9684	12/06/2013 01/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Audrey Zaweski Peconic Regulatory Consulting LLC	PEPTIDO GMBH, BEXBACH, GERMANY - 483 04/06/2012 - 04/06/2012
2013-9685	12/06/2013 01/14/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/	JoNel Aleccia, health reporter MSNBC.COM	RECS RE REVIEW, DETENTION AND REFUSAL OF SHIPMENTS OF JERKY-TYPE PET PRODUCTS 01/01/2013 - 12/04/2013
2013-9686	12/06/2013	OC/ORO/ORM/	Michele Sinoway	LIST OF INSPECTIONS NOVEMBER 2013

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	01/07/2014	OC/ORR/ORM/	LACHMAN CONSULTANT SERVICES, INC.	
2013-9687	12/06/2013 01/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	Brian Gall PRECEPT MEDICAL PRODUCTS INC	FDA, Office of Device Evaluation, Center for Devices and Radiological Health: Interim guidance for substantiating liquid-proof or impervious claim using ASTM ES-21 and ASTM ES-22 standard test methods. FDA, March 19, 1995
2013-9688	12/06/2013 01/07/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Audrey Zaweski Peconic Regulatory Consulting LLC	PEPTIDO GMBH, BEXBACH, GERMANY - EIR 04/06/2012 - 04/06/2012
2013-9689	12/06/2013 01/07/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 19123 S34 -TENTATIVE APPROVAL LETTER
2013-9690	12/06/2013 01/07/2014	FDA/OC/OCC/ FDA/OC/OES/ FDA/OFVM/CFSAN/OCD/EOS/	Connor Sheets International Business Times	PAPA JOHN'S PIZZA, APPLEBEE'S, CHEESECAKE FACATORY ETC - COMMUNICATION WITH FDA RE MENU LABELING LEGISLATION
2013-9691	12/06/2013 01/07/2014	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	Mohit Bhat Kline & company Inc.	ROCHE DIAGNOSTICS OPERATIONS, INC, INDIANAPOLIS, IN - EIR EXHIBITS 01/01/2011 - 12/31/2011
2013-9692	12/06/2013 01/30/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Rachel Johnson FOI Services, Inc.	BK130030
2013-9693	12/06/2013 01/07/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	Joseph Tyler PharmSupply	HOLLISTER-STIER, SPOKANE, WA - 483 04/15/2013 - 05/10/2013
2013-9694	12/06/2013 01/07/2014	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Wei Tang Wei Tang	NOVEL INGREDIENT SERVICE, LLC, WEST CALDWELL, NJ - 483 RESPONSE 02/15/2012 - 12/25/2012
2013-9695	12/06/2013 01/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jeff Mayes seca	K091369
2013-9696	12/06/2013 01/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jeff Mayes seca	K070999
2013-9697	12/06/2013 01/07/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Carolyn Horn JMP Securities	PROCYSBI - AERS

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-9698	12/06/2013 01/07/2014	FDA/OC/OES/DFOI/	Pallavi Ail The Financial Express	LIST OF INDIAN COMPANIES INSPECTED 01/01/2011 - 12/05/2013
2013-9699	12/06/2013 01/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jeff Mayes seca	K830292
2013-9700	12/06/2013 01/07/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Raja Agnihotram Fresenius Kabi USA, LLC	NDA 204223
2013-9701	12/06/2013 01/07/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Xin Pan Weiss Asset Management	AGILA SPECIALTIES, STRIDES ARCOLAB - 483 01/01/2008 - 03/31/2013
2013-9702	12/06/2013 01/07/2014	FDA/OC/OEXA/OMA/	Leo Sternlicht RIDGEBACK CAPITAL MANAGEMENT LLC	Transcript of the press briefing that FDA commissioner Margaret Hamburg attended on December 2, 2013; video
2013-9703	12/06/2013 01/07/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/	Doe J	INDIVIDUAL RECS
2013-9704	12/06/2013 01/07/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Vincent P. Andolina AuroMedics Pharma LLC	ANDA 079001 LABELING
2013-9705	12/06/2013 01/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	Nicole Dove Summit Medical Inc	K122313
2013-9706	12/06/2013 01/07/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	John Franolic VersaPharm Inc.	NDA 013790
2013-9707	12/06/2013 01/07/2014	FDA/OFVM/CFSAN/OCD/EOS/	Mitchell Jones THE UNIVERSITY OF VERMONT	MERCURY CONCENTRATION DATA FOR HERRING ON PER FISH BASIS
2013-9708	12/06/2013	FDA/OGROP/ORO/CE-FO/PHI-		PET ARMOR CO, YARDLEY, PA - RECS

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	01/07/2014	DO/PHI-CB/	Doe J	
2013-9709	12/06/2013 01/07/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Darshan Mehta ET Now	GLENMARK GENERICS INDORE - 483 10/25/13
2013-9710	12/06/2013 01/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	Camille Thornton MACE Concepts, LLC	K112627
2013-9711	12/06/2013 01/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	Malka Berndt Accellent, Inc.	K000135, K983867, K001098 ETC
2013-9712	12/06/2013 01/07/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	BOYLE, LEO J	INDIVIDUAL RECS
2013-9713	12/06/2013 01/07/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GULLION FS-0850, TRAVIS	ELI LILLY & CO - PROZAC (FLUOXETINE HCL) ISR RECS
2013-9714	12/06/2013 01/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	LEWIS WARD LW WARD AND ASSOCIATES	NOVITAS MEDICAL LLC - COMPRESSION SYS K121001
2013-9715	12/06/2013 01/07/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	RICHARD A WRIGHT CORY WATSON ET AL	ANTIPSYCHOTIC MEDICATION APRVD FOR USE FOR CHILDREN - AERS, WARNINGS, DRUG INTERACTIONS, ETC 1/00 TO PRESENT
2013-9716	12/06/2013 01/07/2014	FDA/OC/OES/DFOI/	MARILYNN WHITNEY COVINGTON & BURLING LLP	MINOR DELETIONS
2013-9717	12/06/2013 01/07/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	R CLIFTON MERRELL GREENBERG TRAUIG LLP	ALIGN, ALIGN TO URETHRAL SUPPORT SYS K093405; ALIGN URETHRAL SUPPORT SYS K070073
2013-9718	12/06/2013 01/07/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	R CLIFTON MERRELL GREENBERG TRAUIG LLP	PHILIPS SUMIKA, CHEVRON PHILIPS - MARLEX POLYPROPYLENE RESIN IN MEDICAL DVCS, APRVL, 510K CLEARANCE, ETC
2013-9719	12/06/2013 01/07/2014	OC/ORACE/ OC/ORACE/	THOMAS R HARRINGTON NELSON LEVINE DE LUCA EL AL	K-V PHARM - METHYLPREDNISOLONE EIRS, 483S, CORR, ETC

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		FDA/OGROP/ORR/SE-FO/NOL-DO/NOL-CB/		
2013-9720	12/06/2013 02/07/2014	OC/ORR/ OC/ORR/	THOMAS R HARRINGTON NELSON LEVINE DE LUCA EL AL	APOTHECURE, DALLAS, TX - EIRS, 483S
2013-9721	12/06/2013 01/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KATE C BEARDSLEY BEARDSLEY LAW LLC	ANTARES PHARMA - OTREXUP (METHOTREXATE) INJ NDA 204-824 APRVL RECS
2013-9722	12/06/2013 01/07/2014	FDA/OFVM/CFSAN/OCD/EOS/	SILVIA ULM BURDOCK GROUP	QUILLAJA SAPONARIA - FOOD MASTER FILE
2013-9723	12/06/2013 01/07/2014	FDA/OFVM/CFSAN/OCD/EOS/	SILVIA ULM BURDOCK GROUP	YUCCA SCHIDIGERA - FOOD MASTER FILE
2013-9724	12/06/2013 01/07/2014	FDA/OC/OES/DFOI/	MARILYNN WHITNEY COVINGTON & BURLING LLP	DKT 1998P-0683
2013-9725	12/06/2013 01/07/2014	FDA/OC/OES/DFOI/	MARILYNN WHITNEY COVINGTON & BURLING LLP	DKT 1998P-0683 VOL 1
2013-9726	12/09/2013 01/08/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mark Mathieu PAREXEL	CDER Drug Review and Approval Statistics;
2013-9727	12/09/2013 01/08/2014	OC/CVM/OCD/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Yumna Shabaik UNIVERSITY OF SOUTHERN CALIFORNIA	The action of Cremophor EL and polyoxyethylene sorbitan monooleate (PSM) on the blood pressure of animals etc
2013-9728	12/09/2013 01/08/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dr Sarah Bull Ricardo-AEA	ENTROPIN - ESTEROM IND NONCLINICAL SAFETY ASSESSMENT DATA ETC
2013-9729	12/09/2013 01/08/2014	FDA/OGROP/ORR/NE-FO/NYK-DO/NYK-DCB/	Felicia Muhammad MUHAMMAD, A	INDIVIDUAL RECS
2013-9730	12/09/2013 01/08/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joyce Godshall Teva Pharmaceutical Inc.	QUARTETTE, QNASL - LISTING OF CASE REPORTS 09/01/2013 - 11/30/2013

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2013-9731	12/09/2013 01/08/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Paul E. Greenberg Analysis Group, Inc.	VICTOZA, JANUVIA, BYETTA - OFFICE OF SAFETY AND EPIDEMIOLOGY REVIEWS, AERS
2013-9732	12/09/2013 01/08/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Paul E. Greenberg Analysis Group, Inc.	Materials submitted by Dr. Peter Butler and colleagues, which prompted the FDA's March 14, 2013 Drug Safety Communication entitled "FDA investigating reports of possible increased risk of pancreatitis and pre-cancerous findings of the pancreas from incretin mimetic drugs for type 2 diabetes."
2013-9733	12/09/2013 01/08/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joshua A. Klarfeld ULMER & BERNE LLP	PAXIL, CELEXA, LEXAPRO - FOIA LOG; OSE MEMO, MEETING MINUTES, CORR RE SAFETY ISSUES ASSOCIATED WITH SSRI
2013-9734	12/09/2013 01/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	John Beasley MedTech Review, LLC	PMA NUMBER FOR PECO MEDICAL, INC CATHETER, URETHRAL ETC
2013-9735	12/09/2013 01/08/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Paul E. Greenberg Analysis Group, Inc.	Any analyses or reports that FDA has completed since March 2013 as part of its investigation into "reports of possible increased risk of pancreatitis and pre-cancerous findings of the pancreas from incretin mimetic drugs for type 2 diabetes."
2013-9736	12/09/2013 01/08/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Ron Ferguson LED Technologies	K101190
2013-9737	12/09/2013 01/08/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	David Mangione Govzilla, Inc.	MERCK & CO, INC, LANSDALE, PA, AMBLER, PA - EIR, 483 (09/24/2013 - 10/08/2013)
2013-9738	12/09/2013 01/08/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	MCNEIL PPC, INC, LITIZ, PA - 483, RESPONSE 7/22/11
2013-9739	12/09/2013 01/08/2014	FDA/OFVM/CFSAN/OCD/EOS/	Arlene Morales BURDOCK GROUP	TANNIC ACID - RECS RE REGULATORY STATUS, CONSUMPTION, USES ETC
2013-9740	12/09/2013 01/08/2014	FDA/OC/OES/DFOI/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Paul Nobrega Central Solutions, Inc.	DERMARITE INDUSTRIES, PATERSON, NJ - 483, WARNING LETTER (01/03/2008 - 12/05/2013)
2013-9741	12/09/2013	FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson	Post-approval toxicology studies for NDA 202515

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	01/08/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	
2013-9742	12/09/2013 01/08/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	William Lewis AccelaPHARM, LLC	ADCETRIS - AERS
2013-9743	12/11/2013 01/10/2014	FDA/OFVM/CFSAN/OCD/EOS/	Mark Smith CBS NEWS	USPLABS - LETTER TO FDA RE SUPPLEMENT 11/04/2013 - 12/06/2013
2013-9744	12/11/2013 01/10/2014	OC/CVM/OCD/	Michelle Staso staso, michelle	INDIVIDUAL RECS
2013-9745	12/11/2013 01/10/2014	FDA/OFVM/CFSAN/OCD/EOS/	Arlene Morales BURDOCK GROUP	GALLNUT EXTRACT REGULATORY STATUS, CONSUMPTION, USES ETC
2013-9746	12/11/2013 01/10/2014	FDA/OFVM/CFSAN/OCD/EOS/	Arlene Morales BURDOCK GROUP	GALLIC ACID - REGULATORY STATUS, CONSUMPTION, USES ETC
2013-9747	12/11/2013 01/10/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jonathan J. Darrow BRIGHAM AND WOMEN'S HOSPITAL	DRUGS DESIGNATED FOR PRIORITY REVIEW 01/01/1988 - 12/31/1997
2013-9748	12/11/2013 01/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jane M. Hastedt G.C. Hanford Manufacturing Company	SANDOZ GMBH, AUSTRIA - 483, EIR (10/03/2012 - 10/12/2012)
2013-9749	12/11/2013 01/10/2014	FDA/OGROP/ORO/CE-FO/CHI-DO/CHI-CB/	Paul Nobrega Central Solutions, Inc.	WEINMAN PRODUCTS, GURNEE, IL - 483, WARNING LETTER 01/05/2008 - 12/05/2013
2013-9750	12/11/2013 01/10/2014	FDA/OGROP/ORO/SW-FO/KAN-DO/KAN-CB/	Paul Nobrega Central Solutions, Inc.	CUSTOM SOLUTIONS, INC, BLUE SPRINGS, MO - 483, WARNING LETTER 01/05/2008 - 12/05/2013
2013-9751	12/11/2013 01/10/2014	FDA/OGROP/ORO/SW-FO/KAN-DO/KAN-CB/	Paul Nobrega Central Solutions, Inc.	ORIGINAL JUAN, KANSAS CITY, KS - 483, WARNING LETTER 01/05/2008 - 12/04/2013
2013-9752	12/11/2013 01/10/2014	FDA/OGROP/ORO/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORO/SE-FO/FLA-	Lucas E. Gilmroe Bernstein Litowitz Berger & Grosmann LLP	INVACARE CORPORATION - 483, WARNING LETTER, PERMANENT INJUNCTION ETC

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		DO/FLA-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OCC/ FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/ FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/		
2013-9753	12/11/2013 01/10/2014	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/ORO/DIOP/	Brian Soo Hoo Soo Hoo Customs Broker	UNILEVER PHILLIPINES - FEI NUMBERS
2013-9754	12/11/2013 01/10/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jonathan J. Darrow BRIGHAM AND WOMEN'S HOSPITAL	NME, BIOLOGICS APPROVED UNDER FAST TRACK 01/01/1995 - 12/31/1999
2013-9755	12/11/2013 01/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	David von Wiegandt Branstetter, Stranch and Jennings, PLLC	METAXALONE - APPROVAL PACKAGE
2013-9756	12/11/2013 01/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Keith Hochhalter Hochhalter, Keith	COMPLAINT RECS
2013-9757	12/11/2013 01/10/2014	FDA/OFVM/CFSAN/OCD/EOS/	Merle Zimmermann AMERICAN HERBAL PRODUCTS ASSOCIATION	DIETARY SUPPLEMENT - MEDWATCH FORMS 01/01/2011 - 06/30/2011
2013-9758	12/11/2013 01/10/2014	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Doe J	SAMPLE RESULTS
2013-9759	12/11/2013 01/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	armando lauritano LAURITANO, G	ADVENTRIS - AERS

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-9760	12/11/2013 01/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Larissa Adam Larissa Adam	K132636
2013-9761	12/11/2013 01/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Gary Pekoe Arkios BioDevelopment International	K002886
2013-9762	12/11/2013 01/10/2014	FDA/OFVM/CFSAN/OCD/EOS/	Merle Zimmermann AMERICAN HERBAL PRODUCTS ASSOCIATION	DIETARY SUPPLEMENT - MEDWATCH FORMS 07/01/2013 - 11/30/2013
2013-9763	12/11/2013 01/10/2014	FDA/OFVM/CFSAN/OCD/EOS/	Merle Zimmermann AMERICAN HERBAL PRODUCTS ASSOCIATION	DIETARY SUPPLEMENT - MEDWATCH FORMS (07/01/2011 - 12/31/2011)
2013-9764	12/11/2013 01/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Benjamin Holmes SonoStik	K123759, K112347, K073241 ETC
2013-9765	12/11/2013 01/22/2014	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Jason B. Werner Werner, Jason B	SEVENTH WAVE LABORATORIES, CHESTERFIELD, MO - EIR 08/01/2013 - 12/09/2013 ;
2013-9766	12/11/2013 01/10/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Abhishek K. Gurnani Amin Talati & Upadhye, LLC	K982425
2013-9767	12/11/2013 01/10/2014	FDA/OFVM/CFSAN/OCD/EOS/	Merle Zimmermann AMERICAN HERBAL PRODUCTS ASSOCIATION	DIETARY SUPPLEMENTS - MEDWATCH FORMS 01/01/2012 - 08/31/2013
2013-9768	12/11/2013 01/10/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sasha Damouni BLOOMBERG NEWS	SEATTLE GENETICS ADCENTRIS TOXICITY REPORTS 02/01/2013 - 12/09/2013
2013-9769	12/11/2013 01/10/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kiran Kumar Gande Appco Pharmaceutical Corporation	NDA 019668 - SBA
2013-9770	12/11/2013 01/10/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kiran Kumar Gande Appco Pharmaceutical Corporation	NDA 020657 - SBA

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		FDA/OMPT/CDER/ORP/DIDP/		
2013-9771	12/11/2013 01/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Peter R. Breggin Center for the Study of Empathic Therapy	EFFEXOR - AERS
2013-9772	12/11/2013 01/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	John Roberts BECTON, DICKINSON AND COMPANY	K131549
2013-9773	12/11/2013 01/10/2014	FDA/OGROP/ORO/ORO/DIOP/	DEVA SUNDARARAJAN GLOBAL TRADE INTELLIGENCE INC	IMPORT 20131204-1, 7/15/13 - MANIFEST
2013-9774	12/11/2013 01/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	RONALD L. FERGUSON LED Technologies	LED INTELLECTUAL PROPERTIES LLC - LIGHT FOR WRINKLES K101190 USER MANUAL, PREDICATE CHART, OUTER LABEL
2013-9775	12/11/2013 01/23/2014	OC/ORO/ OC/ORO/	JOHN MARK ZINI GIDEON COOPER & ESSARY	DELTA PHARMA INC, RIPLEY, MS - 483S, EIRS, WARNING LTRS. ETC
2013-9776	12/11/2013 01/10/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	MOHIT BHAT Kline & company Inc.	MINOR DELETIONS
2013-9777	12/11/2013 01/10/2014	FDA/OC/OES/DFOI/	ELIOTT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	2013-9328
2013-9778	12/11/2013 01/10/2014	FDA/OC/OES/DFOI/	WILLIAM McCONAGHA SIDLEY AUSTIN LLP	2013-66
2013-9779	12/12/2013 01/13/2014	FDA/OGROP/ORO/CE-FO/PHI- DO/PHI-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection report for the May 21, 2013 inspection for: Teva Pharmaceuticals USA, Inc., Sellersville, PA
2013-9780	12/12/2013 01/13/2014	FDA/OGROP/ORO/CE-FO/PHI- DO/PHI-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection report for the July 22, 2011 inspection for: McNeil PPC, Inc., Litiz, PA
2013-9781	12/12/2013 01/13/2014	FDA/OGROP/ORO/CE-FO/PHI- DO/PHI-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable 483 and the firm's response for the May 21, 2013 inspection for: Teva Pharmaceuticals USA, Inc., Sellersville, PA
2013-9782	12/12/2013 01/13/2014	FDA/OGROP/ORO/SE-FO/ATL- DO/ATL-CB/ FDA/OC/OES/DFOI/	Dennis Straub Thermo Pac, LLC	THERMO PAC, STONE MOUNTAIN, GA - EIR, EXHIBITS UNREDACTED 5/23/11 TO 6/03/11
2013-9783	12/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	James Doulgeris	K102334

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	01/13/2014		MOFFITT CANCER CENTER	
2013-9784	12/12/2013 01/13/2014	FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA REQUEST LOG 12/02/2013 - 12/06/2013
2013-9785	12/12/2013 01/13/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Thuc Quyen Nguyen Georgetown University Hospital	SUMATRIPTAN - AERS
2013-9786	12/12/2013 01/13/2014	OC/CVM/OCD/	James Strickland WSB-TV	SPINOSAD, MILBEMYCIN OXIME FOR DOGS - CVM ADE REPORTS 01/13/2011 - 12/10/2013
2013-9787	12/12/2013 01/13/2014	FDA/OGROP/ORR/SE-FO/NOL-DO/NOL-CB/	Allison Kay Moody Farris Bobango Branran PLC, Attn: Allison Moody	LEISURE PRODUCTS, INC, KINGSPORT, TN - INSPECTIONS ETC 12/10/2009 - 12/10/2013
2013-9788	12/12/2013 01/13/2014	FDA/OC/OL/	Robert Blaskiewicz PRIVATE CITIZEN	REP JOE BARTON - CORR WITH FDA RE BURZYNSKI 01/01/1995 - 12/31/1999
2013-9789	12/12/2013 01/13/2014	FDA/OGROP/ORR/SE-FO/NOL-DO/NOL-CB/	Renee Smith SARAH CANNON RESEARCH INSTITUTE	SARAH CANNON RESEARCH INSTITUTE SERVICES DIVISION, NASHVILLE, TN - EIR, NOTIFICATION LETTER, CLOSE OUT INFORMATION (11/28/2011 - 12/09/2011)
2013-9790	12/12/2013 01/13/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tal Elmatad Tal Elmatad	ADNA DATA 01 /01/1990 - 12/31/2013
2013-9791	12/12/2013 01/13/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dr Yolande Lucire Dr Yolande Lucire & Associates	RISPERDAL RECS 01/11/1993 - 12/28/2013
2013-9792	12/12/2013 01/13/2014	OC/ORR/ OC/ORR/ FDA/OGROP/ORR/NE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORR/NE-FO/NYK-DO/NYK-DCB/	Doe J	LAB RESULTS
2013-9793	12/12/2013 01/13/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ted Keller Sigma Capital Management	ADCETRIS - AERS

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-9794	12/12/2013 01/13/2014	FDA/OMPT/CDRH/OCER/DFOI/	James Doulgeris MOFFITT CANCER CENTER	K131810, K131785
2013-9795	12/12/2013 01/13/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ayesha Adil The Weinberg Group	NDA 020622
2013-9796	12/12/2013 01/13/2014	FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	DERMARITE INDUSTRIES LLC, PATERSON, NJ - EIR, 483, CO RESP 5/10/12
2013-9797	12/12/2013 01/13/2014	FDA/OGROP/ORACE-FO/PHI- DO/PHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	JAMES F PINGANK JR MD, PITTSBURGH, PA - EIR, 483, CO RESP 12/6/12
2013-9798	12/12/2013 01/13/2014	FDA/OGROP/ORACE-FO/BLT- DO/BLT-CB/	WALTER E CHALKLEY THOMSON REUTERS	MARK A RINGOLD, MD (NEW RIVER VALLEY RESEARCH), CHRISTIANBURG, VA - EIR, 483, CO RESP 1/17/12
2013-9799	12/12/2013 01/13/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/CVM/OCD/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	ABBOTT GMBH & CO KG, LUDWIGSHAFEN, GERMANY - EIR, 483, CO RESP 10/25/12
2013-9800	12/12/2013 01/13/2014	FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	AKORN INC, SOMERSET, NJ - EIR, 483, CO RESP 5/11/12
2013-9801	12/12/2013 01/13/2014	FDA/OGROP/ORANE-FO/NYK- DO/NYK-DCB/	WALTER E CHALKLEY THOMSON REUTERS	BIOMEDICAL RESEARCH ALLIANCE OF NEW YORK IRB, NEW HYDE PARK, NY - EIR, 483, CO RESP 2/14/12
2013-9802	12/12/2013 01/13/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	CALYX CHEMICALS & PHARMS, THANE, INDIA - EIR, 483, CO RESP 3/22/12
2013-9803	12/12/2013 01/13/2014	FDA/OGROP/ORACE-FO/PHI- DO/PHI-CB/	WALTER E CHALKELEY THOMSON REUTERS	DENNIS J HURWIWITZ MD (HU7RWITZ CENTER IOR PLASTIC SURGERY), PITTSBURGH, PA - EIR, 483, CO RESP 3/13 TO 4/2/13
2013-9804	12/12/2013 01/13/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	WOCKHARDT LTD (BANDRA KURLA COMPLEX), MUMBAI, MAHRASHTRA, INDA - EIR, 483, CO RESP 7/22-31/13

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2013-9805	12/12/2013 01/13/2014	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	WALTER E CHAKLEY THOMSON REUTERS	BLU CARIBE INC, DORADO, PR - EIR, 483, CO RESP 10/22/12
2013-9806	12/12/2013 01/13/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	AMERICAN NATIONAL RED CROSS, COLUMBUS, OH - EIR, 483, CO RESP 2/29/12
2013-9807	12/12/2013 02/28/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	WALTER E CHALKLEY THOMSON REUTERS	ACTAVIS, SALT LAKE CITY, UT - EIR, 483, CO RESP 6/8/12
2013-9808	12/12/2013 01/13/2014	FDA/OMPT/CDRH/OCER/DFOI/	Andie Lin Qualtech Consulting Corporation	K122248
2013-9809	12/12/2013 01/13/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	WALTER E CHAKLEY THOMSON REUTERS	JOHN E LOWE MD, OGDEN, UT - EIR, 483, CO RESP 5/11/12
2013-9810	12/12/2013 01/13/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	WALTER E CHALKLEY THOMSON REUTERS	KP PHARMACEUTICAL TECH, BLOOMINGTON, IN - EIR, 483, CO RESP 12/17/12
2013-9811	12/12/2013 01/13/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	JANSSEN BIOTECH INC, MALVERN, PA - EIR, 483, CO RESP 6/15/12
2013-9812	12/12/2013 01/13/2014	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	WALTER E CHALKLEY THOMSON REUTERS	ALLERGY LABORATORIES, INC, OKLAHOMA CITY, OK - EIR, 483, CO RESP 4/16-26/13
2013-9813	12/12/2013 01/13/2014	FDA/OMPT/CDRH/OCER/DFOI/	LATANIA BLACK MEDTRONIC	NUVASIVE - SURGICAL MESH SYS K081377
2013-9814	12/12/2013 01/13/2014	FDA/OMPT/CDRH/OCER/DFOI/	LEWIS WARD L W WARD & ASSOCIATES INC	CLOUD-BASED LINAC QA - INVESTIGATION
2013-9815	12/12/2013 01/13/2014	FDA/OC/OES/DFOI/	Joshua A. Klarfeld ULMER & BERNE LLP	INDIVIDUAL RECS
2013-9816	12/12/2013 01/13/2014	FDA/OFVM/CFSAN/OCD/EOS/	D. Todd Smith The University of Virginia School of Nursing	DMAA - CASE STUIES AND REFERENCE ARTICLES 01/01/2007 - 12/10/2013
2013-9817	12/12/2013 01/13/2014	FDA/OC/OES/	Rachel Johnson FOI Services, Inc.	TOBACCO USER FEES
2013-9818	12/12/2013 01/13/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Hormoz Moaven Deallus Consulting	AVERAGE OR MEDIAN TIME TO RECEIVE FDA FAST TRACK APPROVAL RE NEUROSCIENCE DRUGS 01/01/2003 - 12/10/2013
2013-9819	12/12/2013 01/13/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Monty L. Patterson Monty L. Patterson	MIFEPREX CASE REPORTS

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2013-9820	12/12/2013 01/13/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kiran Kumar Gande Appco Pharmaceutical Corporation	NDA 020584 - SBA
2013-9821	12/12/2013 01/13/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kiran Kumar Gande Appco Pharmaceutical Corporation	ANDA 062644 - SBA
2013-9822	12/12/2013 01/13/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kiran Kumar Gande Appco Pharmaceutical Corporation	NDA 020897 - SBA
2013-9823	12/12/2013 01/13/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kiran Kumar Gande Appco Pharmaceutical Corporation	ANDA 074222 - SBA
2013-9824	12/12/2013 01/13/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kiran Kumar Gande Appco Pharmaceutical Corporation	NDA 019112 - SBA
2013-9825	12/12/2013 01/13/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kiran Kumar Gande Appco Pharmaceutical Corporation	NDA 019898 - SBA
2013-9826	12/12/2013 01/13/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kiran Kumar Gande Appco Pharmaceutical Corporation	NDA 050775 - SBA
2013-9827	12/12/2013 01/13/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mahidhar Chinta Micro Labs USA, Inc	ANDA 076361 - SBA

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		FDA/OMPT/CDER/ORP/DIDP/		
2013-9828	12/12/2013 01/13/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mahidhar Chinta Micro Labs USA, Inc	ANDA 070213 - SBA
2013-9829	12/12/2013 01/13/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mahidhar Chinta Micro Labs USA, Inc	ANDA 076919 - SBA
2013-9830	12/12/2013 01/13/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mahidhar Chinta Micro Labs USA, Inc	ANDA 075272 - SBA
2013-9831	12/12/2013 01/13/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gary Hackworth GARY HACKWORTH	AUBAGIO - AERS
2013-9832	12/12/2013 01/13/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MICHAEL R COHEN INSTITUTE FOR SAFE MEDICATION PRACTICES	MEDWATCH RPTS CODED AS MEDICATION ERRORS 11/1-30/13
2013-9833	12/12/2013 01/13/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	EDEN, REVEREND LLOYD	AUREDMYCIN; CHLOROMYCETIN; DIHYDROSTREPTOMYCIN, ETC - AERS
2013-9834	12/12/2013 01/13/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELLIOT FAVUS FAVUS INSTITUTIONAL RESEARCH LLC	PROCYSBI (CYSWTEAMINE BITARTRATE) - AERS 1/12 TO PRESENT
2013-9835	12/12/2013 01/13/2014	FDA/OGROP/ORP/PA-FO/SEA-DO/SEA-CB/	SONY ALEER NUTSCH CLEMENTS BROWN & MCNICHOLS PA	HINRICHS TRADING (HINRICHS TRADING CO), CRAIGMONT, ID - RPTS, RESP, CONTACT RECS 5/11-13/13
2013-9836	12/12/2013	FDA/OGROP/ORP/CE-FO/NWJ-DO/NWJ-CB/	ALEX TIMIAN	JOEL S ROSS (JOEL S GROSS), MEMORY ENHANCEMENT CENTER OF NEW JERSEY (MEMORY ENHANCEMENT

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	01/13/2014		MINTZ GROUP	CENTER OF AMERICA) - AUDITS, INVESTIGATIONS, CMLPTS
2013-9837	12/12/2013 01/13/2014	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	JOHN-MARK ZINI GIDEON COOPER & ESSARY	EDWARDS PHARMACEUTICAL INC, RIPLEY, MS - EIRS, 483S, WARNING LTRS, ETC
2013-9838	12/12/2013 01/13/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	DEAN F SWANSON JAMES S SORRELS OFC	KINPIN TATTOO SUPPLY INC - ONE INK EIRS, INTERVIEWS, COMM 12/3/04; PAPILLON SUPPLY & MANUFACTURING INC - TRIBAL BLACK OR DEEP BLUE INKS EIRS, MEMOS, EMAILS
2013-9839	12/12/2013 01/13/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	MELISSA W SHISLER WILSON ELSEER MOSKOWITZ EDELMAN & DICKER LLP	RICH PRODUCTS CORP - E COLI MULTISTATE OUTBREAK CAERS, RPTS, MEMOS, ETC 12/30/12S TO 4/15/13
2013-9840	12/12/2013 01/13/2014	OC/ORARM/ OC/ORARM/	THOMPSON, RAY	LIST OF ALL SITES FDA CONDUCTED GMP, GLP, GCP INSP 4/1/13-10/30/13
2013-9841	12/12/2013 01/13/2014	FDA/OFVM/CFSAN/OCD/EOS/	CARRIE P MORGAN OLSSON FRANK WEEDA TERMAN BODE MATZ	MEETING BETWEEN METAGENICS & CFSAN 12/9/13
2013-9842	12/12/2013 01/13/2014	FDA/OO/OHR/	S ALBERT EDWARDS S ALBERT EDWARDS, PHARM D	CDER EMPLOYEES
2013-9843	12/12/2013 01/13/2014	FDA/OO/OHR/ OC/ORAM/ OC/ORAM/ FDA/OGROP/ORARORO/DIOP/ FDA/OO/OHR/ FDA/OMPT/CDRH/OCER/DFOI/	MOLINE, MAGGIE	CAPT DOMENIC J VENEZIANO. CHRISTOPHER T SMITH; CAROLE JONES, ETC - JOB TITLES, DUTIES, QUALIFICATIONS, ETC
2013-9844	12/12/2013 01/13/2014	OC/ORAM/ OC/ORAM/	LARA WEISS GOLDBERG & GILLE LAW OFCS	FRANKS COMPOUNDING LAB, OCALA, FL - DYE BRILLIANT BLUE GRAND TRIAMCINOCLONE RECS
2013-9845	12/13/2013 01/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	David Davis BECKMAN COULTER INC	ACUMENT TECHNOLOGIES, LTD - EIR, 483 08/29/2013 - 11/30/2013
2013-9846	12/13/2013 01/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	George Ball UNIVERSITY OF MINNESOTA	MEDICAL DEVICE RECALLS - DISTRICT COMPLETE DATE, FIRM AWARENESS DATE
2013-9847	12/13/2013 01/14/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nancy Rogers Nancy Rogers, c/o CRMC	TIGECYCLINE DRUG SAFETY COMMUNICATION 9/27/13 - META-ANALYSIS

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-9848	12/13/2013 01/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	David Davis BECKMAN COULTER INC	STRATEC BIOMEDICAL SYSTEMS AG - EIR, 483 06/06/2013 - 08/31/2013
2013-9849	12/13/2013 01/14/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Paula Katz Paula Katz	4897884, 8426838 - REPORTS
2013-9850	12/13/2013 01/14/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OC/OES/DFOI/	Arnali, Inc. Arnali, Inc.	K042792
2013-9851	12/13/2013 01/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	K092981 SAFE OBSTETRIC SYSTEMS LTD	K092981
2013-9852	12/13/2013 01/14/2014	FDA/OC/OES/DDM/	Janet Arrowsmith Arrowsmith Consulting LLC	PSYCHOPHARMACOLOGIC DRUGS ADVISORY COMMITTEE - TRANSCRIPT, BACKGROUND MATERIALS
2013-9853	12/13/2013 01/14/2014	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/ FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	Amela Cenanovic Lewis Brisbois Bisgaard & Smith	Hepatitis A Outbreak associated with pomagranate seeds and /or frozen berry blend
2013-9854	12/13/2013 01/14/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Philip Kim, Philip H	ZOLOFT - AERS
2013-9855	12/13/2013 01/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	Dr R Varma SAFE OBSTETRIC SYSTEMS LTD	K904774
2013-9856	12/13/2013 01/14/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Dr R Varma SAFE OBSTETRIC SYSTEMS LTD	K904026
2013-9857	12/13/2013	FDA/OMPT/CDER/GRP/DIDP/	Mahidhar Chinta	ANDA 075237 - SBA

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	01/14/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Micro Labs USA, Inc	
2013-9858	12/13/2013 01/14/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	William C. Tubbs Promedior, Inc.	PIRFENIDONE NDA
2013-9859	12/13/2013 01/14/2014	FDA/OMPT/CTP/OD/	MELISSA WHITTINGHAM COVINGTON BURLING LLP	22 REFUSAL TO ACCEPT LTRS FOR EXEMPTION REQUESTS - APPL, CORR 6/13 TO 7/13
2013-9860	12/13/2013 01/14/2014	FDA/OMPT/CTP/OD/ FDA/OMPT/CTP/OD/	MELISSA WHITTINGHAM COVINGTON BURLING LLP	FOUR NOT SUBSTANTIALLY EQUIVALENT ORDERS 8/13; FIVE NOT SUBSTANTIALLY EQUIVALENT ORDERS 10/13 - APPL, CORR RVWS
2013-9861	12/13/2013 01/14/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	SANDY MASTROIANNI ITC	HEMOCHRON JR CITRATE APTT CUVETTE - K014008
2013-9862	12/13/2013 01/14/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	SIG RA C NARDI RHEIN83 SRL	K950260
2013-9863	12/13/2013 01/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	MONICA KING KIMBERLY-CLARK HEALTHCARE	NIMBUS ELECTROSURGICAL RADIOFREQUENCY MULTITNED EXPANDABLE ELECTRODE - K121773
2013-9864	12/13/2013 01/14/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELAINE S WALLER SEATTLE GENETICS INC	ADCETRIS (BRENWTUXIMAB VEDOTIN) - AERS 3/1/13- 11/30/13
2013-9865	12/13/2013 01/14/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FRIEDMAN, ROBERT	SALOFALK ENEMAS - AERS 1969 TO 2013
2013-9866	12/13/2013 01/14/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	FRIEDMAN, ROBERT	EXOREX LOTION; MEDERMA FOR SCAR REDUCTION; ALCIS DAILY RELIEF PAIN RELIEF CREAM, ETC - AERS
2013-9867	12/13/2013 01/14/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SW-FO/DAL-	BENJAMIN L ENGLAND BENJAMIN L ENGLAND & ASSOCIATES LLC	MARTINEZ DRY PEPPERS INC - FDA & CUSTOMS RECS ENTRY DV1-0117625-8, CUSTOM NO 2010-2305-0-00510- 01, 2014-2304-3-00005-01, NOTES, INTER-AGENCY MEMOS, PHOTOS, ETC

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		DO/DAL-CB/ FDA/OGROP/ORASW- FO/SWID/SWID-CB/		
2013-9868	12/13/2013 01/14/2014	FDA/OC/OES/DFOI/	JAMES E WALKER LITIGATION MAMAGEMENT COUNSEL	MULTI-STATE OUT BREAK OF SALMONELLA ENTERITIDIS LINKED TO RESTAURANT CHAIN A - COMM, TEST RESULTS, INVOICES, ETC 10/11
2013-9869	12/13/2013 01/14/2014	FDA/OC/OES/DFOI/	GAYLE DOUGLAS HENINGER GARRISON DAVIS LLC	INDIVIDUAL RECS
2013-9870	12/13/2013 01/14/2014	FDA/OC/OES/ FDA/OC/OES/DFOI/	SEAWARD, STEVEN	MONEY PAID OUT FOR EEO CASES FY2010, FY2011
2013-9871	12/13/2013 01/14/2014	FDA/OGROP/ORASW- DO/SAN-CB/	Doe J	BAXTER BIOSCIENCE, HAYWARD, CA - CLEAN STEAM GENERATOR CONWTAMINATION RECS 10/12/12, 10/16/12
2013-9872	12/13/2013 01/14/2014	FDA/OGROP/ORASW- DO/SEA-CB/	BOB O'BRYANT SALMOLUX SEA PASSION	JENSENS OLD FASHIONED SMOKEHOUSE INC, SEATTLE, WA - LISTERIA MONOCYTOGENES ISOLATES HISTORY
2013-9873	12/16/2013 01/15/2014	FDA/OMPT/OSMP/OOPD/	Rachel Johnson FOI Services, Inc.	Orphan Drug Application for Secukinumab
2013-9874	12/16/2013 01/15/2014	FDA/OMPT/OSMP/OOPD/	Rachel Johnson FOI Services, Inc.	Orphan Drug Application for Gevokizumab
2013-9875	12/16/2013 01/15/2014	FDA/OMPT/OSMP/OOPD/	Rachel Johnson FOI Services, Inc.	Orphan Drug Application for Sirolimus
2013-9876	12/16/2013 01/15/2014	FDA/OMPT/OSMP/OOPD/	Rachel Johnson FOI Services, Inc.	Orphan Drug Application for Infliximab
2013-9877	12/16/2013 01/15/2014	FDA/OMPT/OSMP/OOPD/	Rachel Johnson FOI Services, Inc.	Orphan Drug Application for AI-RSA
2013-9878	12/16/2013 01/15/2014	FDA/OMPT/OSMP/OOPD/	Rachel Johnson FOI Services, Inc.	Orphan Drug Application for Ozurdex
2013-9879	12/16/2013 01/15/2014	FDA/OMPT/OSMP/OOPD/	Rachel Johnson FOI Services, Inc.	Orphan Drug Application for Durezol
2013-9880	12/16/2013 01/15/2014	FDA/OMPT/OSMP/OOPD/	Rachel Johnson FOI Services, Inc.	Orphan Drug Application for Retisert
2013-9881	12/16/2013 01/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kenneth Orce Jr Orce Global Intelligence	Clinical Drug Trials of Bapineuzumab and Policies Concerning the Confidentiality of, and Access to, Clinical Drug Trial Information

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-9882	12/16/2013 01/15/2014	FDA/OGROP/ORR/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Esther Farber Labaton Sucharow LLP	INTUITIVE SURGICAL, INC RECALL Z-0436-2014
2013-9883	12/16/2013 01/15/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sarah Krebs SFL Regulatory Affairs & Scientific Communication GmbH	SANDIMMUNE, NEORAL - PRECLINICAL AND CLINICAL SAFETY EFFICACY AND SAFETY DATA
2013-9884	12/16/2013 01/15/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Himanish Mandava EASTERN MICHIGAN UNIVERSITY	OFFICE OF PRESCRIPTION DRUG PROMOTION LETTERS, DIVISION OF DRUG MARKETING, ADVERTISING, AND COMMUNICATIONS - NUMBER OF EMPLOYEES, BUDGET 01/01/1997 - 12/31/2013
2013-9885	12/16/2013 01/15/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	EIR for Abbott, Olst, Netherlands
2013-9886	12/16/2013 01/15/2014	FDA/OGROP/ORR/SE-FO/SJN-DO/SJN-CB/	Rachel Johnson FOI Services, Inc.	EIR for AMO Puerto Rico, in Anasco, Puerto Rico
2013-9887	12/16/2013 01/15/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORR/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORR/CE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORR/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORR/PA-FO/SEA-DO/SEA-CB/	John David Hart, Celina Davila THE LAW OFFICES OF JOHN DAVID HART	OXYELITE PRO - CORR, NOTICES, NEW DIETARY INGREDIENTS ETC 12/13/2011 - 12/13/2013
2013-9888	12/16/2013 01/15/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Chirag Talati Espirito Santo Securities	INDOCO REMEDIES - 483, EIR 01/01/2013 - 12/17/2013

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2013-9889	12/16/2013 01/15/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Rebecca Dandeker MORGAN, LEWIS & BOCKIUS	AVANTOR PERFORMANCE MATERIALS, INC, PARIS, KY - 483 08/01/2012 - 08/31/2012
2013-9890	12/16/2013 01/15/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Rebecca Dandeker MORGAN, LEWIS & BOCKIUS	AVANTOR PERFORMANCE MATERIALS, PARIS, KY - EIR 12/01/2010 - 12/31/2010
2013-9891	12/16/2013 01/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	Lisa Burns Church & Dwight Co., Inc.	K123436
2013-9892	12/16/2013 01/15/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OC/OES/DFOI/	Sarah Strand UNIVERSITY OF ARIZONA	GARDISIL - FAST TRACK REVIEW RECS
2013-9893	12/16/2013 01/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	INTRAVENOUS CATHETER RECS 02/17/2012 - 12/12/2013
2013-9894	12/16/2013 01/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	Lisa Burns Church & Dwight Co., Inc.	K123567
2013-9895	12/16/2013 01/15/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Rebecca Dandeker MORGAN, LEWIS & BOCKIUS	AVANTOR PERFORMANCE MATERIALS, PARIS, KY - EIR SUMMARY 12/01/2010 - 12/31/2010
2013-9896	12/16/2013 01/15/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Rebecca Dandeker MORGAN, LEWIS & BOCKIUS	AVANTOR PERFORMANCE MATERIALS, PARIS, KY - 843 12/01/2010 - 12/31/2010
2013-9897	12/16/2013 01/15/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Rebecca Dandeker MORGAN, LEWIS & BOCKIUS	AVANTOR PERFORMANCE MATERIALS, PARIS, KY - EIR 08/01/2012 - 08/31/2012
2013-9898	12/16/2013 01/15/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Rebecca Dandeker MORGAN, LEWIS & BOCKIUS	AVANTOR PERFORMANCE MATERIALS, PARIS, KY - EIR SUMMARY 08/01/2012 - 08/31/2012
2013-9899	12/16/2013 01/15/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Sarah Strand Sarah Strand - University of Arizona Department of Sociology	List of the FDA VRBPAC committee members 2005-2007, full names by year or term
2013-9900	12/16/2013 01/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOANNE S HAWANA ARENT FOX LLP	SEPTOCAINE INJ, ARTICAINE HCL - ISRS 8604633, 8784250, 8828682M ETC
2013-9901	12/16/2013 01/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	BETHANY KENNEDY EMORD & ASSOCIATES, P.C.	REPROCESSED SINGLE-USE MEDICAL DVCS THAT RECEIVED MARKETING CLEARANCE - SS&E
2013-9902	12/16/2013 01/15/2014	FDA/OC/OES/DFOI/	ADAM M SLATER MAZIE SLATER KATZ ET AL	INTUITIVE SURGICAL INC - DA VINCI SURGICAL SYS APRVL RECS, RECALLS, WARNINGS, ETC
2013-9903	12/16/2013 01/15/2014	FDA/OC/OES/DFOI/	ANDREW HACK MILLENNIUM MANAGEMENT LLC	FOI LOGS FOR CDER, CBER, CDRH 7/15/13 TO PRESENT

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2013-9904	12/17/2013 01/16/2014	FDA/OC/OES/DFOI/	Courtney Costello Creative Services, Inc.	JONATHAN BERNSTEIN, HEMOPHELIA TREATMENT CENTER OF LOS VEGAS
2013-9905	12/17/2013 01/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	William Hoos Hoos Consulting	AVASTIN - HEMOPTYSIS REPORTS
2013-9906	12/17/2013 01/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	Medtronic Sofamor Danek, Lee Grant MEDTRONIC SOFAMOR DANEK	K111626, K083714
2013-9907	12/17/2013 01/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	Medtronic Sofamor Danek, Lee Grant MEDTRONIC SOFAMOR DANEK	K110348, K092234
2013-9908	12/17/2013 01/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	Medtronic Sofamor Danek, Lee Grant MEDTRONIC SOFAMOR DANEK	K111801
2013-9909	12/17/2013 01/16/2014	FDA/OC/OES/DFOI/	MaryBeth Conner FALCON RESEARCH	2013-8173, 2013-8174
2013-9910	12/17/2013 01/16/2014	FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/	Melissa Pong Dohmen Safety	DOHMEN SAFETY, EMERYVILLE, CA - EIR 12/06/2013 - 12/13/2013
2013-9911	12/17/2013 01/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	Medtronic Sofamor Danek, Lee Grant MEDTRONIC SOFAMOR DANEK	K102677
2013-9912	12/17/2013 01/16/2014	FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	Danielle Eisner Law Offices of Ronald A. Marron, APLC	STANDARD HOMEOPATHIC COMPANY, INC, LOS ANGELES, CA - EIR 10/19/2011 - 12/14/2011
2013-9913	12/17/2013 01/16/2014	FDA/OGROP/ORO/NE-FO/NWE-DO/NWE-CB/	Thomas McGrath AMRI BURLINGTON	PHARMALUCENCE INC, BEDFORD, MA, BILLERICA, MA - 483 04/27/2009 - 12/16/2013
2013-9914	12/17/2013 01/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	Medtronic Sofamor Danek, Lee Grant MEDTRONIC SOFAMOR DANEK	K131405
2013-9915	12/17/2013 01/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	Medtronic Sofamor Danek, Lee Grant MEDTRONIC SOFAMOR DANEK	K122742, K123045, K130868 ETC
2013-9916	12/17/2013 01/16/2014	FDA/OGROP/ORO/SW-FO/KAN-DO/KAN-CB/	Gloria J Thesenvitz Nova-Tech, Inc.	NOVA-TECH, INC, GRAND ISLAND, NE - EIR 05/01/2013 - 12/12/2013

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2013-9917	12/17/2013 01/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	Duncan Badertscher Best Sanitizers Inc	K102996
2013-9918	12/17/2013 01/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bao Le ARIAD Pharmaceuticals Inc.,	ICLUSIG - AERS
2013-9919	12/17/2013 01/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	Medtronic Sofamor Danek, Lee MEDTRONIC SOFAMOR DANEK	K091278
2013-9920	12/17/2013 01/16/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Duncan Badertscher Best Sanitizers Inc.	K123768
2013-9921	12/17/2013 01/16/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Medtronic Sofamor Danek, Lee Grant MEDTRONIC SOFAMOR DANEK	K031511
2013-9922	12/17/2013 01/16/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Stephanie Wood Stephanie Wood	INDIVIDUAL RECS
2013-9923	12/17/2013 01/16/2014	OC/ORA/ OC/ORA/ FDA/OGROP/ORACE-FO/DIOP/ FDA/OGROP/ORACE-FO/NOL-DO/NOL-CB/	Daniela Zeilinger Hans Riegelein & Sohn GmbH & Co KG	IMPORT ALERT 9920 - LOT NUMBERS
2013-9924	12/17/2013 01/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	Medtronic Sofamor Danek, Lee Grant MEDTRONIC SOFAMOR DANEK	K130887, K123909
2013-9925	12/17/2013 01/16/2014	FDA/OGROP/ORACE-FO/DAL-DO/DAL-CB/	CHARLES CELESTE EAS CONSULTING GROUP LLC	CELANESE CORPOATION HEADQUARTERS, IRVING, TX - EIRS, 483S
2013-9926	12/17/2013 01/16/2014	FDA/OGROP/ORACE-FO/DAL-DO/DAL-CB/	CHARLES CELESTE EAS CONSULTING GROUP LLC	BP NORTH AMERICA CORPORATE OFFICE & HEADQUARTERS, HOUSTON, TX - EIRS,483S
2013-9927	12/17/2013 01/16/2014	FDA/OGROP/ORACE-FO/DAL-DO/DAL-CB/	CHARLES CHRIS EAS CONSULTING GROUP LLC	LYONDELLBASELL TOWER, HOUSTON, TX - EIRS, 483S
2013-9928	12/17/2013 01/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	COPAXONE - NDA 20-622
2013-9929	12/17/2013	FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE	FERRING PHARMS - EUFLEXXA (SODIUM HYLAURONATE)

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	01/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	EAS CONSULTING GROUP LLC	APRVL LTR, LBLG, MOR RVWS, ETC
2013-9930	12/17/2013 01/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	CHARLES CELESTE EAS CONSULTING GROUP LLC	KENALOG-10 - NDA 12-041 APRVL LTR, LBLG, MOR, ETC
2013-9931	12/17/2013 01/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	CHARLES CELESTE EAS CONSULTING GROUP LLC	KENALOG-40 - NDA 19-901 APRVL LTR, LBLG, MOR, ETC
2013-9932	12/17/2013 01/16/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OFVM/CFSAN/OCD/EOS/	CHARLES CELESTE EAS CONSULTING GROUP LLC	FCN 57
2013-9933	12/17/2013 01/16/2014	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	PATRICIA L REGENYE Celgene Corporation	ARA DKIRANIAN, SAN DIEGO ARTHRITIS, SAN DIEGO, CA - 483S 7/11 TO 12/13
2013-9934	12/17/2013 01/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ROBERT L BUCK ROBERT LOYE BUCK	TERBUTALINE SULFATE ANDA 75-877, 77-152 - SBA
2013-9935	12/17/2013 01/16/2014	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	PATRICIA L REGENYE Celgene Corporation	JOHN DIPERSIO, WASHINGTON UNIV SCH MED, ST LOUIS, MO - 483S 6/03 TO 12/13
2013-9936	12/17/2013 01/16/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	PATTI WALLER MARLER CLARK ATTYS	OXYELITE PRO - HEPATITIS OUTBREAK INVESTIGATON

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		FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAP/PA-FO/SEA-DO/SEA-CB/		
2013-9937	12/17/2013 01/16/2014	OC/ORAP/ORM/ OC/ORAP/ORM/	SASHA L. PERKINS THOMSON REUTERS	FOEIGN & DOMESTIC DRUG INSPECTIONS 7/13 TO PRESENT
2013-9938	12/17/2013 01/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MAURA M. NORDEN SIDLEY AUSTIN LLP	ZYRTEC (CETIRIZINE HCI) INVESTIGATION 1/98 TO 12/31/05
2013-9939	12/17/2013 01/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	MONICA KING KIMBERLY-CLARK HEALTHCARE	STRYKER VENOM ELECTRODES & CANNULAE K123178
2013-9940	12/17/2013 01/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	LESTER, JOHN	AMNIOFIX INJECTABLE & MIMEDX EPIFIX
2013-9941	12/17/2013 01/16/2014	FDA/OGROP/ORAP/SE-FO/FLA-DO/FLA-CB/ FDA/OMPT/CDRH/OCER/DFOI/	G. STANFORD PIERCE ADVANCED ORTHOGONAL EQUIPMENT INC	ATLAS ADJUSTING INSTRUMENT 510K
2013-9942	12/17/2013 01/16/2014	FDA/OGROP/ORAP/SW-FO/DAL-DO/DAL-CB/	PATRICIA L. REGENYE Celgene Corporation	MUZAFFAR QUILBASH, UNIV OF TEXAS MD ANDERSON CANCER CTR, HOUSTON, TX - 483 10/11 TO PRESENT
2013-9943	12/17/2013 01/16/2014	FDA/OGROP/ORAP/SW-FO/DEN-DO/DEN-CB/	PATRICIA L. REGENYE Celgene Corporation	VINVENT HANSEN, CA ASSOC NORTHERN UTAH, OGDEN, UT - 483 12/08 TO PRESENT
2013-9944	12/17/2013 01/16/2014	FDA/OGROP/ORAP/SE-FO/NOL-DO/NOL-CB/	PATRICIA L REGENYE Celgene Corporation	DAVID SPIGEL, SARAH CANNON CANCER CENTER, NASHVILLE, TN - 483S 10/11 TO 12/13
2013-9945	12/17/2013 01/16/2014	FDA/OGROP/ORAP/CE-FO/MIN-DO/MIN-CB/	PATRICIA L. REGENYE Celgene Corporation	PAUL RITCH, FROEDTERT MEM LUTHERAN HOSP E, MILWAUKEE, WI - 483 6/04 TO PRESENT
2013-9946	12/17/2013 01/16/2014	FDA/OGROP/ORAP/SW-FO/DAL-DO/DAL-CB/	PATRICIA L REGENYE Celgene Corporation	DOWLING (DOW) STOUGH, STOUGH CLNC BURKE PHARMS RES; HOT SPRINGS, AR - EIRS, 483S 6/09 TO 12/13
2013-9947	12/17/2013 01/16/2014	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	PATRICIA L REGENYE Celgene Corporation	LYDIE HAZAN, IMPACT CLINICAL TRIALS, LOS ANGELES, CA - 483S 10/06 TO 12/13
2013-9948	12/17/2013	FDA/OGROP/ORAP/CE-FO/BLT-DO/BLT-CB/	PATRICIA L. REGENYE	VICTOR PRIEGO, CTR FOR CANCER & BLOOD DISORDERS PC, BETHESDA, MD - 483 10/12 TO PRESENT

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	01/16/2014		Celgene Corporation	
2013-9949	12/17/2013 01/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	YVES POULIN Celgene Corporation	CTR DERMATOLOGIQUE DU QUEBEC METROPOLITAIN, QUEBEC, CANADA - EIRS 4/06 TO 12/13
2013-9950	12/17/2013 01/16/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	PATRICIA L REGENYE Celgene Corporation	ALEKSANDER SKOTNICKI, SZPITAL UNWERSYTECKI W KRAKOWIE - 483S 1/13 TO 12/13
2013-9951	12/17/2013 01/16/2014	FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/	PATRICIA L REGENYE Celgene Corporation	AMBROSE TSANG, HACIENDA DIALYSIS CENTER, DOWNEY, CA - 483S 6/09 TO 12/13
2013-9952	12/18/2013 01/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	Medtronic Sofamor Danek, Lee Grant MEDTRONIC SOFAMOR DANEK	K111891, K070573, K072253 ETC
2013-9953	12/18/2013 01/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	Medtronic Sofamor Danek, Lee Grant MEDTRONIC SOFAMOR DANEK	K080646, K113593
2013-9954	12/18/2013 01/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	Medtronic Sofamor Danek, Lee Grant MEDTRONIC SOFAMOR DANEK	K113732, K110204
2013-9955	12/18/2013 02/20/2014	FDA/OMPT/CDRH/OCER/DFOI/	Medtronic Sofamor Danek, Lee Grant MEDTRONIC SOFAMOR DANEK	K121658, K122901, K130932
2013-9956	12/18/2013 01/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	Medtronic Sofamor Danek, Lee Grant MEDTRONIC SOFAMOR DANEK	K130874, K122845
2013-9957	12/18/2013 01/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	Medtronic Sofamor Danek, Lee Grant MEDTRONIC SOFAMOR DANEK	K131431
2013-9958	12/18/2013 01/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	Medtronic Sofamor Danek, Lee Grant MEDTRONIC SOFAMOR DANEK	MEDICREA - 510K
2013-9959	12/18/2013 01/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	Medtronic Sofamor Danek, Lee Grant MEDTRONIC SOFAMOR DANEK	MAZOR - 510K
2013-9960	12/18/2013 01/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	Medtronic Sofamor Danek, Lee Grant MEDTRONIC SOFAMOR DANEK	K052398

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2013-9961	12/18/2013 01/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	Medtronic Sofamor Danek MEDTRONIC SOFAMOR DANEK	LDR SPINE USA - 510K
2013-9962	12/18/2013 01/17/2014	FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA REQUEST LOG 12/09/2013 - 12/13/2013
2013-9963	12/18/2013 01/17/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Medtronic Sofamor Danek, Lee Grant MEDTRONIC SOFAMOR DANEK	K102293, K124058, K131449 ETC
2013-9964	12/18/2013 01/17/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Mary Gustafson PLASMA PROTEIN THERAPEUTICS ASSOCIATION	PREFERRED BLOOD PRODUCTS - REFERENCE NUMBER 91-0425 ETC
2013-9965	12/18/2013 01/17/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Medtronic Sofamor Danek, Lee Grant MEDTRONIC SOFAMOR DANEK	K100070, K042544
2013-9966	12/18/2013 01/17/2014	FDA/OGROP/ORACE-FO/CHI- DO/CHI-CB/ FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Brian H. Brick Napoli Bern Ripka Shkolnik LLP	AKORN, INC - CORR WITH FDA RE BACITRACIN ETC 01/01/2008 - 12/16/2013
2013-9967	12/18/2013 01/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	James Doulgeris MOFFITT CANCER CENTER	K132859, K123932
2013-9968	12/18/2013 01/17/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORASW-FO/DEN- DO/DEN-CB/ FDA/OGROP/ORASW- FO/SWID/SWID-CB/	Keith R. Scranton Franklin D. Azar & Associates, P.C.	JIMMY JOHN'S INVESTIGATION
2013-9969	12/18/2013 01/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	Dora Fong KARL STORZ ENDOSCOPY AMERICA INC	K080612
2013-9970	12/18/2013 01/17/2014	FDA/OGROP/ORASE-FO/ATL- DO/ATL-CB/	ROBERT KING FDA NEWS	MEDTEC, HILLSSBOROUGH, NC; STERIMED, CARTERSVILLE, GA - 483S 11/1-30/13
2013-9971	12/18/2013 01/17/2014	FDA/OGROP/ORACE-FO/BLT- DO/BLT-CB/	ROBERT KING FDA NEWS	ELECTRONIC DEVELOPMENT LABS INC, DANVILLE, VA; CONTOUR HEALER, VIRGINIA BEACH, VA - 483S 11/1-30/13
2013-9972	12/18/2013	FDA/OGROP/ORACE-FO/CIN-	ROBERT KING	CLINICAL APOTHECARIES, MEDINA, OH; KETTERING

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	01/17/2014	DO/CIN-CB/	FDA NEWS	MEDICAL CENTER, KETTERING, OH - 483S 11/1-30/13
2013-9973	12/18/2013 01/17/2014	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	ROBERT KING FDA NEWS	CANTRELL DRUG CO, LITTLE ROCK, AK; SPECTRUM LABS, IRVING, TX; THERMOTEK INC, FLOWER MOUND, TX, ETC - 483S 11/1/30/13
2013-9974	12/18/2013 01/17/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	ROBERT KING FDA NEWS	FREELAND SYSTEMS LLC, WESTMINSTER, CO; ULTRADENT PRODUCTS INC, SOUTH JORDAN, UT; ROCKY MOUNTAIN RESEARCH INC, SALT LAKE CITY, UT - 483S 11/1/30/13
2013-9975	12/18/2013 01/17/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	ROBERT KING FDA NEWS	SPECIALTY MEDICINE COMPOUNDING PHARMACY PC, SOUTH LYON, MI; SIGMA-TAU PHARMASOURCE INC, INDIANAPOLIS, IN; ACCRA PAC, KIK CUSTOM PRODUTS, ELKHART, IN, ETC - 483S 11/1-30/13
2013-9976	12/18/2013 01/17/2014	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	ROBERT KING FDA NEWS	SUN & SKIN CARE RESEARCH INC, COCOA, FL; AMAZING SOUR SOP INC, MARGATE, FL; IQ FORMULATIONS LLC, SUNRISE, FL, ETC - 483S 11/1-30/13
2013-9977	12/18/2013 01/17/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ROBERT KING FDA NEWS	SHIRATORI PHARMACEUTICAL CO LTD, CHIBA CITY, JAPAN; TAYCA CORP, OKAYAMA-SHI, OKAYAMA, JAPAN; FARCHEMIA SRL, TREVIGLIO, ITALY, ETC - 483S 11/1-30/13
2013-9978	12/18/2013 01/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	ROBERT KING FDA NEWS	ZHONGSHAN A & E INDUSTRIES CO LTD, GUANGDONG, CHINA; SYNETHES TUTTLINGEN GMBH, TUTTLINGEN, GERMANY; CHONGOING ALTRUN BIOLOGICAL TECHNOLOGY DEV, CHONGQING, CHINA, ETC - 483S 11/1-30/13
2013-9979	12/18/2013 01/17/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	ROBERT KING FDA NEWS	GENERAL PHYSIOTHERAPY INC, EARTH CITY, MO; STANLEY SECURITY SOLUTIONS INC, LINCOLN, NB; MILLENIA PRODUCTIONS LLC, WICHITA, KS, ETC 483S 11/1-30/13
2013-9980	12/18/2013 01/17/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	ROBERT KING FDA NEWS	AJINOMOTO ALTHEA INC, SAN DIEGO, CA; DEXCOM INC, SAN DIEGO, CA; ADVANCED MEDICAL INNOVATIONS, CHATSWORTH, CA - 483S 11/1-30/13
2013-9981	12/18/2013 01/17/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	ROBERT KING FDA NEWS	MEM INC, MADISON, CT; CODMAN & SHURTLEFF INC, RAYNHAM, MA; ARROW INTERNATIONAL INC, TELEFLEX MEDICAL INC, EVERTT, MA, ETC - 483S 11/1-30/13
2013-9982	12/18/2013 01/17/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	ROBERT KING FDA NEWS	AMMEAL PHARMACEUTICALS, LLC, PATERSON, NJ; EMCURE PHARMACEUTICALS USA, EAST BRUNSWICK, NJ; NEPHROS INC, RIVER EDGE, NJ
2013-9983	12/18/2013 01/17/2014	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	ROBERT KING FDA NEWS	AMPLION CLINICAL COMMUNICATIONS INC, NASHVILLE, TN; ADVANCED BREATH DIAGNOSTICS, BRENTWOOD, TN - 483S 11/1-30/13

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2013-9984	12/18/2013 01/17/2014	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	ROBERT KING FDA NEWS	JEROME STEVENS PHARMACEUTICALS INC, BOHEMIA, NY; EPIMED INTERNATIONAL INC, JOHNSTOWN, NY; ELLIQUENCE LLC, BALDWIN, NY, ETC - 483S 11/1/30/13
2013-9985	12/18/2013 01/17/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	ROBERT KING FDA NEWS	CIMA TECHNOLOGY INC, PITTSBURGH, PA - 483S 11/1-30/13
2013-9986	12/18/2013 01/17/2014	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	ROBERT KING FDA NEWS	CAREFUSION 2200 INC, VERNON HILLS, IL; BISCO INC, SCHAUMBERG, IL; ROCKFORD SPECIALTIES, LOVES PARK IL, ETC - 483S 11/1-30/13
2013-9987	12/18/2013 01/17/2014	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	ROBERT KING FDA NEWS	ST JUDE MEDICAL PUERTO RICO LLC, ARECIBO, PR - 483S 10/1-31/13
2013-9988	12/18/2013 01/17/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Adrienne E Faerber, PhD Dartmouth Inst. Cent. For Med. Media.	NDA 022037
2013-9989	12/18/2013 01/17/2014	FDA/OC/OES/DFOI/	Kelli Dryer STRYKER SUSTAINABILITY SOLUTIONS	RECALL Z-0615-06 - STATUS OF RECALL
2013-9990	12/18/2013 01/17/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	MCNEIL PPC, INC, LITIZ, PA - 483, RESPONSE JUNE 3, 2010
2013-9991	12/18/2013 01/17/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	MCNEIL PPC, INC, LITIZ, PA - EIR JUNE 3, 2010
2013-9992	12/18/2013 01/17/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Colleen O'Hara Law Office of Colleen O'Hara	8541629; 8605324; 8537218 ETC
2013-9993	12/18/2013 01/17/2014	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	ROBERT KING FDA NEWS	ORCHID ORTHOPEDIC SOLUTIONS OREGON, INC, OREGON CITY, OR -483S 11/1-30/13
2013-9994	12/18/2013 01/17/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	ROBERT KING FDANEWS	BAXTER MANUFACTURING SPA, RIETI, ITALY 483S 11/1-30/13
2013-9995	12/18/2013 01/17/2014	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	ROBERT KING FDA NEWS	WISCONSIN PHARMACAL CO, INC LLC, JACSKSON, WI; BOSTON SCIENTIFIC CRM CORP, ST PAUL, MN - 483S 11/1-30/13
2013-9996	12/18/2013 01/17/2014	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	ROBERT KING FDANEWS	LEITERS CAMBRIAN PARK DRUGS INC, LEITERS PHARMACY, SAN JOSE, CA; CARDINAL HEALTH LLC 414,

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		OC/ORO/ OC/ORO/		LAS VEGAS NV; EVERGLO NATURAL VETERINARY SERVICES INC, SEA RANCH, CA, ETC - 483S 11/1-30/13
2013-9997	12/19/2013 01/21/2014	FDA/OC/OES/DDM/ FDA/OFVM/CFSAN/OCD/EOS/ OC/CVM/OCD/	JOANNA R. DRAKE VERTO LEGAL SOLUTIONS LLC	DKT DAF 06281
2013-9998	12/19/2013 01/21/2014	FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/	JESSICA SPEER MCGIVNEY & KLUGER PC	MIRA HEALTH PRODUCTS - SMPL 776374, 817219, 817591, CMLPNT 130948 2012 TO 2013
2013-9999	12/19/2013 01/21/2014	FDA/OFVM/CFSAN/OCD/EOS/	FRIEDMAN, ROBERT	CAERS FOR FAST FOOD RESTAURANTS 1969 TO PRESENT
2013-10000	12/19/2013 01/21/2014	FDA/OC/OES/DDM/ FDA/OFVM/CFSAN/OCD/EOS/	CHRISTOPHER C. DeMERLIS COLORCON	MARS INC - SPIRULINA BLUE DKT FDA-2011-C-0878
2013-10001	12/19/2013 01/21/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	MONICA KING, MBA KIMBERLY-CLARK HEALTHCARE	URGENT PC NEUROMODULATION SYS K071822
2013-10002	12/19/2013 01/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER CHALKLEY THOMSON REUTERS	BIOGEN IDEC - TYSABRI (NATALIZUMAB) BLA 125104/570 APRVL 10/7/11
2013-10003	12/19/2013 01/21/2014	FDA/OGROP/ORO/PA-FO/SEA-DO/SEA-CB/ FDA/OMPT/CDRH/OCER/DFOI/	KATHLEEN J. LOVE MCGINN, CARPENTER, MONTROYA & LOVE, P.A.	BIOTRONIK INC - OSWEGO, OR - EIR
2013-10004	12/19/2013 01/21/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORO/CE-FO/DET-DO/DET-CB/	STEPHEN H. MEYER THE LAW OFFICE OF NICK STEIN	CRONOBACTER SAKAZAKII - MARCH 2011
2013-10005	12/19/2013 01/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	JAMES KELLER COOPERSURGICAL INC	K1216677, K954099
2013-10006	12/19/2013 01/21/2014	FDA/OGROP/ORO/SE-FO/NOL-DO/NOL-CB/	KRISTINA SASICH GASS WEBER MULLINS LLC	HOIZON MILLINGS PLANT, CHATTANOOGA, TN - INVESTIGATIONS 1/11 TO PRESENT
2013-10007	12/19/2013 01/21/2014	FDA/OC/OES/DFOI/	SHANE ALLEN NBC 5 KXAS-TV	LSG SKY CHEFS - WARNING LTRS 1/10 TO 11/26/13
2013-10008	12/19/2013 01/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	WINTERS 411079, BRANDON	INFORMATION REGARDING WISCONSIN RESOURCE CENTER
2013-10009	12/19/2013 01/21/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/	ELENA HOWELL HOGAN LOVELLS LLP	2013-9259 REQUEST LTR
2013-10010	12/19/2013	FDA/OMPT/CBER/OCOD/DDOM/	ERIC SUBA	MERCK; GLAXO SMITH - RECS REFERRING TO

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	01/21/2014	ALFB/	KAISER PERMANENTE MEDICAL CENTER	TECHNOLOGY TRANSFERS FROM THE FED GOV'T FOR THE DEVELOPMENT OF HPV VIRUS
2013-10011	12/20/2013 01/22/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michael S. Sawaya Altaire Pharmaceuticals, Inc.	ANDA 203257
2013-10012	12/20/2013 01/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jack Douglas Self	ODE REVIEWER QUESTIONS SENT TO SPONSORS IN RESPONSE TO IDE, 510K, PMA, SUPPLEMENT ETC
2013-10013	12/20/2013 01/22/2014	FDA/OC/OES/	HumanTouch, LLC HumanTouch, LLC	EMPLOYEE AND CONTRACTOR INFORMATION
2013-10014	12/20/2013 01/22/2014	FDA/OMPT/OSMP/OOPD/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	AFATINIB - FDA REVIEWS
2013-10015	12/20/2013 01/22/2014	FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/	Rachel Johnson FOI Services, Inc.	ALLERGAN, IRVINE, CA - EIR, 483 01/01/2012 TO PRESENT
2013-10016	12/20/2013 01/22/2014	FDA/OMPT/OSMP/OOPD/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	CRIZOTINIB - FDA REVIEWS
2013-10017	12/20/2013 01/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	Medtronic Sofamor Danek, Lee Grant MEDTRONIC SOFAMOR DANEK	P11009
2013-10018	12/20/2013 01/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	Medtronic Sofamor Danek, Lee Grant MEDTRONIC SOFAMOR DANEK	P070001
2013-10019	12/20/2013 01/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	Alex Greene Bionova Medical	K852750
2013-10020	12/20/2013 01/22/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Robert Dennis Steed Robert Dennis Steed	K061110
2013-10021	12/20/2013 01/22/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Meagan Day Helmsing Leach Herlong Newman and Rouse	KLONOPIN - AERS
2013-10022	12/20/2013 01/22/2014	FDA/OMPT/OSMP/OOPD/	Amy Speros Latham & Wakins LLP	TREANDA - OPD REVIEW RECS
2013-10023	12/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson	K102649

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	01/22/2014		FOI Services, Inc.	
2013-10024	12/20/2013 01/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K072021
2013-10025	12/20/2013 01/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	Lillie Thomas ORTHOFIX INC.	K941048
2013-10026	12/20/2013 01/22/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Robert Wolfangel CERTUS INTERNATIONAL INC	NDA 020570
2013-10027	12/20/2013 01/22/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	James Doulgeris MOFFITT CANCER CENTER	K101471
2013-10028	12/20/2013 01/22/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Brett Rhodes Inter Med / Vista Dental Products	K123215, K970114, K033033 ETC
2013-10029	12/20/2013 01/22/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Diana Felici ONYX PHARMACEUTICALS	KYPROLIS - ISR
2013-10030	12/20/2013 01/22/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/CVM/OCD/	SENISE HAMMANG BIOPHARMA COMPLIANCE SERVICES, LLD	EXCELL GMBH, BAVARIA, GERMANY - EIRS, 483S MOST RECENT
2013-10031	12/20/2013 01/22/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DENISE HAMMANG BIOPHARMA COMPLIANCE SERVICES, LLD	ONOTEC HARMA PRODUKTION GMBH, SAXONY-ANHALT, GERMANY - EIRS, 483S MOST RECENT
2013-10032	12/20/2013 01/22/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DENISE HAMMANG BIOPHARMA COMPLIANCE SERVICES, LLD	IDT BIOLOGIKA GMBH, SAXONY-ANHALT, GERMANY - EIRS, 483S MOST RECENT

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2013-10033	12/20/2013 01/22/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RAJAN S EMBRAN JUBILANT CADISTA PHARMACEUTICALS INC	KREMERS URBAN PHARMA - ISOSORBIDE MONONITRATE ER TABS ANDA 75-155; BIAXIN - CLARITHROMYCIN TABS NDA 50-662; SADOZ - PERPHENAZINE TABS ANDA 89-686, ETC SBA
2013-10034	12/20/2013 01/22/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	STEPHEN M BENARDO LAW OFFICES OF STEPHEN M BENARDO	FORCES OF NATURE INC, FORCES OF NATURE B CURED, CURE HEALING, ETC - VIOLATIONS 2010, 2011
2013-10035	12/20/2013 01/22/2014	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ OC/ORA/ OC/ORA/	BENJAMIN L ENGLAND BENJAMIN L ENGLAND & ASSOCIATES LLC	UNICORN PACIFIC CORP - ENTRY 739-6192351-0 LAB RPT, W/S, LABEL RVWS, ETC
2013-10036	12/20/2013 01/22/2014	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/ OC/ORA/ OC/ORA/	KATHLEEN J LOVE MCGINN, CARPENTER, MONTROYA & LOVE, P.A.	BIOTRONIK INC, OSWEGO, OR - EIRS, OPENING & CLOSING SUMMARY, BRIEF LTRS 2002 TO PRESENT
2013-10037	12/20/2013 01/22/2014	FDA/OC/OES/ FDA/OC/OCC/	FATIMA ASLAM Keller and Heckman LLP	POSSIBLE FOOD RELATED LITIGATION MTG - MINS, RECS 12/9-13/13
2013-10038	12/20/2013 01/22/2014	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	SANDRA W CUNEO CUNEO GILBERT ET AL	23ANDME INC, MOUNTAINVIEW, CA - SALIVA COLLECTION KIT, & PERSONAL GENOME SERVICES (PGS) MARKETING CLEARANCE, CLNCL STUDIES, TEST, ETC
2013-10039	12/23/2013 01/23/2014	FDA/OFVM/CFSAN/OCD/EOS/	Tracy Gibbons Clifford Law Offices	CONSOLIDATED GRAIN AND BARGE CO, MT CARROLL, IL - FOOD FACILITY REGISTRATION MODULE 2010-2013
2013-10040	12/23/2013 01/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lisa Hartling UNIVERSITY OF ALBERTA	ACETAMINOPHEN - AERS
2013-10041	12/23/2013 01/23/2014	FDA/OC/OCC/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	11166-01 WOOD BURDITT GROUP	US V. 285 CASES - CONSENT DECREES

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2013-10042	12/23/2013 01/23/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Yitzchak Jacobovitz Capstone Investment Advisors	DRUGS MANUFACTURED IN PUERTO RICO, INSPECTION REPORTS
2013-10043	12/23/2013 01/23/2014	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORR/SW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORR/SW-FO/DEN-DO/DEN-CB/	Dave Milton Coker, Schickel, Sorenson & Posgay, P.A.	SANDOZ RECALL RECS 2/01/2009 - 12/18/2013
2013-10044	12/23/2013 01/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K132512
2013-10045	12/23/2013 01/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K133314
2013-10046	12/23/2013 01/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Christine Livoti BioPharm Insight (part of the Financial Times Group)	SOVALDI - MEDWATCH REPORTS
2013-10047	12/23/2013 01/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Christine Livoti BioPharm Insight (part of the Financial Times Group)	MEDIVIR - MEDWATCH REPORTS
2013-10048	12/23/2013 01/23/2014	OC/CVM/OCD/	Kimberly Kindy THE WASHINGTON POST	NARMS DATABASE
2013-10049	12/23/2013 01/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	John Sawin Sawin Law Firm, Ltd.	P970051
2013-10050	12/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	Elias A. Rivera	K111405

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	01/23/2014		Tengion Inc.	
2013-10051	12/23/2013 01/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ted Keller Sigma Capital Management	SOLIRIS - AERS
2013-10052	12/23/2013 01/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Erin Delaney Erin Delaney	ASACOL, ASACOL HD - AERS
2013-10053	12/23/2013 01/23/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	DR JAYSON L PARKER UNIV OF TORONTO MISSISSAUGA	ABBOTT - MULTI LINK ULTRA/MULTI LINK ZETA CORONARY STENT P970020/S017,S021,S023,S024; R4 VASCULAR INC - MODIFIED VECTOR CATHETER K131329, ETC
2013-10054	12/23/2013 01/23/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	PAUL B CALLAHAN CHARLES RIVER LABS	SNBL USA FACILITY, EVERETT, WA - 483 11/18/13
2013-10055	12/23/2013 01/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	W E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	MERZ PHARMA - ZEOMIN (INCOBOTULINUMTOXIN A) BLA 125360/S007 SBA, MEDICAL RVW
2013-10056	12/23/2013 01/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KANAN SOLANKI PHARM D NOVEN PHARMACEUTICALS INC	ORTHO CYCLEN (NORGESTIMTE/ETHINYL ESTRADIOL) TABS NDA 19-653/S000 - PHARMACOLOGY/ TOXICOLOGY RVWS
2013-10057	12/23/2013 01/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	VIK BAJNATH ARTHREX INC	MW50333085
2013-10058	12/23/2013 01/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SILVIA MAMBER MD VALEANT CANADA LP	TRAZODONE - AERS 12/1/11 TO 12/1/13
2013-10059	12/23/2013 01/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SILVIA MAMBER MD VALEANT CANADA LP	TRIAZOLAM - AERS 12/1/11 TO 12/1/13

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2013-10060	12/23/2013 01/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SILVIA MAMBER MD VALEANT CANADA LP	TEMAZEPAM - AERS 12/1/11 TO 12/1/13
2013-10061	12/23/2013 01/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SILVIA MAMBER MD VALEANT CANADA LP	ZALEPLONE - AERS 12/1/11 TO 12/1/13
2013-10062	12/23/2013 01/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SILVIA MAMBER MD VALEANT CANADA LP	ESZOPICLONE - AERS 12/1/11 TO 12/1/13
2013-10063	12/23/2013 01/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SILVIA MAMBER MD VALEANT CANADA LP	ZOLPIDEM - AERS 12/1/11 TO 12/1/13
2013-10064	12/23/2013 01/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SILVIA MAMBER MD VALEANT CANADA LP	LORAZEPAM - AERS 12/1/11 TO 12/1/13
2013-10065	12/23/2013 01/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SILVIA MAMBER MD VALEANT CANADA LP	CLONAZEPAM - AERS 12/1/11 TO 12/1/13
2013-10066	12/23/2013 01/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SILVIA MAMBER MD VALEANT CANADA LP	FLURAZEPAM - AERS 12/1/11 TO 12/1/13
2013-10067	12/23/2013 01/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SILVIA MAMBER MD VALEANT CANADA LP	NITRAZEPAM - AERS 12/1/11 TO 12/1/13
2013-10068	12/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Marge Walls-Walker	P100010 S015

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	01/24/2014		Cook Medical	
2013-10069	12/24/2013	OC/ORO/	M Walter Levine	ENTRY 739-6192351-0 - SAMPLE RESULTS
	01/24/2014	OC/ORO/ FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/	Diversified Holistics Ltd	
2013-10070	12/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Marge Walls-Walker	PMA 100010
	01/24/2014		Cook Medical	
2013-10071	12/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kevin Walls	SMT SWISS MICROTECHNOLOGY AG - EIR 12/3/12
	01/24/2014		Regulatory Insight, Inc.	
2013-10072	12/24/2013	FDA/OGROP/ORO/CE-FO/BLT-DO/BLT-CB/	Rachel Johnson	TEVA - EIRs, 483 LAST TWO YEARS
	01/24/2014	FDA/OGROP/ORO/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORO/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORO/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORO/CE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORO/SE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORO/SW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORO/SW-FO/KAN-DO/KAN-CB/	FOI Services, Inc.	
2013-10073	12/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Elias A. Rivera	K040897
	01/24/2014		Tengion, Inc.	
2013-10074	12/24/2013	FDA/OMPT/CDER/ORP/DIDP/	Robert Bexton	HOSPIRA, INC, IRUNGATTUKOTTAI, INDIA - 483 12/10/2013 - 12/10/2013
	01/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Aristotle Capital Management	

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2013-10075	12/24/2013 01/24/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michael L. VanErp Johnson & Wyngaarden, P.C.	LAMICTAL - REMS PACKAGE INSERT 08/01/2009 - 08/31/2009
2013-10076	12/24/2013 01/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	Justin Scanlan Simple Science, LLC	K113693
2013-10077	12/24/2013 01/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	Brian Romot OPTIMA NEUROSCIENCE	K132306 SUMMARY
2013-10078	12/24/2013 01/24/2014	FDA/OC/OES/DFOI/	Shea Shaver Reilly Pozner, LLP	2013-7479
2013-10079	12/24/2013 01/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	Warren Craycroft Intersection Medical Inc	K042113
2013-10080	12/24/2013 01/24/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jill Conner Teva Pharmaceuticals	LOVENOX, ENOXAPARIN - AERS
2013-10081	12/24/2013 01/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	Shea Shaver Reilly Pozner, LLP	K974098
2013-10082	12/24/2013 01/24/2014	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	PLASMA BIOLOGICAL SERVICES INC, ELGIN, IL - EIRS, 483S, CO RESP 2/21/13
2013-10083	12/24/2013 01/24/2014	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	WALTER E CHALKLEY THOMSON REUTERS	IU HEALTH GOSHEN HOSPITAL IRB, GOSHEN, IN - EIRS, 483S, CO RESP 11/6/12
2013-10084	12/24/2013 01/24/2014	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	WALSTER E CHALKLEY THOMSON REUTERS	LIFEGAS LLC, YPSILANTI, MI - EIRS, 483S, CO RESP 9/14/12
2013-10085	12/24/2013 01/24/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	NOVARTIS PHARMA AG, BASEL, SWITZERLAND - EIRS, 483S, CO RESP 7/26/12
2013-10086	12/24/2013 01/24/2014	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	WALTER E CHALKLEY THOMSON REUTERS	OHM PHARMA INC, MINERAL WELLS, TX - EIRS, 483S, CO RESP 11/30/12
2013-10087	12/24/2013 01/24/2014	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	QUANTEX LABORATORIES INC, EDISON, NJ - EIRS, 483S, CO RESP 12/28/12

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2013-10088	12/24/2013 01/24/2014	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	ACCUGEN LABORATORIES INC, WILLOWBROOK, IL - EIRS, 483S, CO RESP 11/8/12
2013-10089	12/24/2013 01/24/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	WALTER E CHALKLEY THOMSON REUTERS	TEVA PARENTERAL MEDICINES INC, IRVINE, CA - EIRS, 483S, CO RESP 4/24/12
2013-10090	12/24/2013 01/24/2014	FDA/OGROP/ORACE-FO/PHIDO/PHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	VIDA CECILIA ALMARIO PASSERO MD, PITTSBURGH, PA - EIRS, 483S, CO RESP 10/12/12
2013-10091	12/24/2013 01/24/2014	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	NYU HOSPITAL CENTER, NEW YORK, NY - EIRS, 483S, CO RESP 3/25/13
2013-10092	12/24/2013 01/24/2014	FDA/OGROP/ORASE-FO/FLADO/FLA-CB/	WALTER E CHALKLEY THOMSON REUTERS	BAUSCH & LOMB INC, TAMPA, FL - EIRS, 483S, CO RESP 3/21/12
2013-10093	12/24/2013 01/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	DR REDDY'S LABORATORIES LTD, HYDERABAD, AP, INDIA - EIRS, 483S, CO RESP 4/16/12
2013-10094	12/24/2013 01/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	HAUPT PHARMA BERLIN, GMBH, BERLIN, GERMANY - EIRS, 483S, CO RESP 4/19/12
2013-10095	12/24/2013 01/24/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	WALTER E CHALKLEY THOMSON REUTERS	ST VINCENT HOSPITAL & HEALTH CARE CENTER IRB, INDIANPOLIS, IN - EIRS, 483S, CO RESP 8/12-26/13
2013-10096	12/24/2013 01/24/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	WALTER E CHALKLEY THOMSON REUTERS	GENZYME CORP, FRAMINGHAM, MA - EIRS, 483S, CO RESP 7/13/12
2013-10097	12/24/2013 01/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	KARINA MEIJER MD, GRONINGEN, NETHERLAND - EIRS, 483S, CO RESP 9/7/12
2013-10098	12/24/2013 01/24/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E. CHALKLEY THOMSON REUTERS	AMERIDERM LABS, PATERSON, NJ - EIR, 483, CO RESP 2/13/13
2013-10099	12/24/2013 01/29/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	WALTER E. CHALKLEY THOMSON REUTERS	JHP PHARMACEUTICALS LLC, ROCHESTER, MI - EIR, 483, CO RESP 12/28/12
2013-10100	12/24/2013 01/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	MYLAN LABS LTD, AURANGABAD, INDIA - EIR, 483, CO RESP 3/9/12

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2013-10101	12/24/2013 01/24/2014	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	WALTER E. CHALKLEY THOMSON REUTERS	PFIZER INC, GROTON, CT - EIR, 483, CO RESP 2/24/12
2013-10102	12/24/2013 01/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	WALTER E. CHALKLEY THOMSON REUTERS	ROCHE DIAGNOSTICS GMBH, MANNHEIM, GERMANY - EIR, 483, CO RESP 4/26/12
2013-10103	12/24/2013 01/24/2014	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	SANOFI US, BRIDGEWATER, NJ - EIR, 483, CO RESP 5/17/12
2013-10104	12/24/2013 01/24/2014	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	WALTER E. CHALKLEY THOMSON REUTERS	UNIVERSITY OF WASHINGTON HUMAN SUBJECTS DIVISION, SEATTLE, WA - EIR, 483, CO RESP 8/10/12
2013-10105	12/24/2013 01/24/2014	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	WALTER E. CHALKLEY THOMSON REUTERS	WAYNE CHEMICALS INC, FORT WAYNE, IN - EIR, 483, CO RESP 10/30/12
2013-10106	12/24/2013 01/24/2014	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	WALTER E. CHALKLEY THOMSON REUTERS	PLASMA CARE INC, INDIANAPOLIS, IN - EIR, 483, CO RESP 2/26/13
2013-10107	12/24/2013 01/24/2014	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	WALTER E. CHALKLEY THOMSON REUTERS	ELORAC INC, VERNON HILLS, IL - EIR, 483, CO RESP 11/14/12
2013-10108	12/24/2013 01/24/2014	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	WALTER E. CHALKLEY THOMSON REUTERS	CARDINAL HEALTH, ROSEVILLE, MN - EIR, 483, CO RESP 9/26/12
2013-10109	12/24/2013 01/24/2014	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	JUBILANT HOLLISTER STIER LLC, SPOKANE, WA - EIR, 483, CO RESP 5/10/13
2013-10110	12/24/2013 01/24/2014	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	WALTER E. CHALKLEY THOMSON REUTERS	FELDMAN JEREMY, PHOENIX, AZ - EIR, 483, CO RESP 6/6/12
2013-10111	12/24/2013 01/24/2014	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	GEORGE C VELMAHOS MD PhD, BOSTON, MA - EIR, 483, CO RESP 7/25/13
2013-10112	12/27/2013 01/28/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Rachel Johnson FOI Services, Inc.	MIMEDX - CORR WITH FDA RE UNTITLED LETTER
2013-10113	12/27/2013 01/28/2014	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	Debbie Metzger Metzger, Debbie A	CRAVE BROTHERS FARMSTEAD CHEESE, WATERLOO, WI - REPORTS, NOTES, CORR ETC 01/01/2013 - 12/20/2013
2013-10114	12/27/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson	MARQUET, RASTATT, GERMANY - COMPLIANCE CORR

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	01/28/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	
2013-10115	12/27/2013 01/28/2014	FDA/OMPT/CDRH/OCER/DFOI/	Justi Scanlan Simple Science, LLC	K090206
2013-10116	12/27/2013 01/28/2014	FDA/OFVM/CFSAN/OCD/EOS/	Susan Matthees GENERAL MILLS	PARTIALLY HYDROGENATED OILS - STUDIES
2013-10117	12/27/2013 03/07/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mary Gustafson PPTA	HYDROXYETHYL STARCH SOLUTIONS - DIFFERENCES BETWEEN SAFETY ALERTS 06/11/2013 - 11/15/2013
2013-10118	12/27/2013 01/28/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ted Keller Sigma Capital Management	INSYS THERAPEUTICS - MARKETING MATERIALS FOR SUBSYS 01/01/2010 - 12/31/2013
2013-10119	12/27/2013 01/28/2014	FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/	Mark Ratkowski HOSPIRA INC	WEST-WARD PHARMACEUTICAL CORPORATION, CHERRY HILL, NJ - EIR 10/09/2013 - 10/22/2013
2013-10120	12/27/2013 01/28/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Donald O'Keefe Da Yu Enterprises, LLC	NEW COMMERCIAL BIOLOGICS IND RECEIVED BY CDER EACH YEAR 2004 TO 2012
2013-10121	12/27/2013 01/28/2014	FDA/OGROP/ORASW-FO/KAN- DO/KAN-CB/	D. John Sauer Clark & Sauer, LLC	MERIDIAN MEDICAL TECHNOLOGIES, ST LOUIS, MO - 483, EIR 01/01/2010 - 12/31/2013
2013-10122	12/27/2013 01/28/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Amy Taylor INFOTRIEVE	NDA 18240
2013-10123	12/27/2013 01/28/2014	FDA/OGROP/ORAPA-FO/SEA- DO/SEA-CB/	David E Perry Charles Taylor Adjusting	CHOBANI INC - RECALL RECS 07/01/2013 - 12/20/2013
2013-10124	12/27/2013 01/28/2014	FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/	Mark Ratkowski HOSPIRA INC	WEST-WARD PHARMACEUTICAL, CHERRY HILL, NJ - EIR, 483 06/10/2013 - 06/14/2013
2013-10125	12/27/2013 01/28/2014	FDA/OC/OES/DFOI/	Kari Twaite BEVERIDGE & DIAMOND PC	CFSAN FOIA REQUESTS 11/26/2013 - 12/20/2013

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2013-10126	12/27/2013 01/28/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Mark Ratkowski HOSPIRA INC	WEST-WARD PHARMACEUTICALS, CHERRY HILL, NJ - 483 10/09/2013 - 12/22/2013
2013-10127	12/27/2013 01/28/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Malia Segar Cote Orphan Consulting	NDA 22432 - NOT APPROVABLE LETTER
2013-10128	12/27/2013 01/28/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Malia Segar Cote Orphan Consulting	Acthar Gel NDA 8372
2013-10129	12/27/2013 01/28/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Malia Segar Cote Orphan Consulting	NDA 22-432 S 8-372/S-039
2013-10130	12/27/2013 01/28/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	carolina soto Miami Children's hospital	LAMICTAL IR - AERS
2013-10131	12/26/2013 01/27/2014	FDA/OMPT/CDRH/OCER/DFOI/	Benjamin Winters Gilliland & Hayes, LLC	MEDRAD AVANTA FLUID MANAGEMENT INJECTION SYSTEM - REPORTS OF AIR EMBOLISM (CERTIFIED)
2013-10132	12/26/2013 01/27/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Robert Fortner Slate	HERCEPTIN - REVIEW RECS
2013-10133	12/26/2013 01/27/2014	OC/CVM/OCD/	Belinda S Thompson DVM Animal Health Diagnostic Center - Dr. Belinda Thompson	FENBENDAZOLE ANIMAL SAFETY
2013-10134	12/26/2013 01/27/2014	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	F-0184-0187-2014 - HHE
2013-10135	12/26/2013 01/27/2014	FDA/OC/OES/ FDA/OC/OES/DDM/ FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/	Jason W. Sapsin Fox Rothschild, LLP	HP ACTHAR GEL, QUESTCOR PHARMACEUTICALS - COMMENTS, SUBMISSIONS, INQUIRIES 12/23/2013 - 01/01/2008

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2013-10136	12/26/2013 01/27/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mark Pregenzer Ronald Reagan UCLA Medical Center	MERREM PI STABILITY CHANGES
2013-10137	12/27/2013 01/28/2014	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	Jayme Donnelly Alaffia - Agbanga Karite	STRAHL & PITSCH, BABYLON, NY - LAST TWO 483
2013-10138	12/27/2013 01/28/2014	FDA/OMPT/CDRH/OCER/DFOI/	JEROME LEW Self	HDE H040004
2013-10139	12/27/2013 01/28/2014	FDA/OMPT/CDRH/OCER/DFOI/	John Sawin Sawin Law Firm, Ltd.	COCHLEAR LIMITED - EIR 1/1/11 TO 12/31/12
2013-10140	12/27/2013 01/28/2014	OC/ORA/OCI/ OC/ORA/OCI/	Doe J	INDIVIDUAL RECS
2013-10141	12/27/2013 01/28/2014	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OMPT/CDRH/OCER/DFOI/	David Armstrong BLOOMBERG NEWS	DR SAMIN K SHARMA - INSPECTIONS, ENFORCEMENT ACTIONS, REVIEWS ETC 01/01/2000 - 01/01/2014
2013-10142	12/27/2013 01/28/2014	FDA/OMPT/OSMP/OOPD/	Hannah Barnhorn Beckfield College	DOMPERIDONE - ORPHAN APPLICATION RECS 05/30/2011 - 12/26/2013
2013-10143	12/27/2013 01/28/2014	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Elyse Behling CONSUMER	GIMBAL BROTHERS, SOUTH SAN FRANCISCO, CA - 483, EIR, WARNING LETTERS ETC
2013-10144	12/27/2013 01/28/2014	FDA/OO/OHR/	Doe J	HHS-FDA-MP-14-984787
2013-10145	12/27/2013 01/28/2014	FDA/OO/OHR/	Doe J	HHS-FDA-MP-14-984787
2013-10146	12/30/2013 01/29/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Nissim Shaked Nissim Shaked	K063346
2013-10147	12/30/2013 01/29/2014	FDA/OMPT/CDRH/OCER/DFOI/	Nissim shaked Nissim Shaked	K023799
2013-10148	12/30/2013 01/29/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Deborah Bebernes Deborah L Bebernes	HYLAND'S TEETHING TABLETS - AERS

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2013-10149	12/30/2013 01/29/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	kate Willson WILLAMETTE WEEK	GEEVEC, ICLUSIG - AERS, FOIA REQUESTS, ETC
2013-10150	12/30/2013 01/29/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Reem Mohamed FDB Health (First Data Bank)	STRUCTURED PRODUCT LABELING FOR BULK INGREDIENTS FOR HUMAN PRESCRIPTION COMPOUNDING
2013-10151	12/30/2013 01/29/2014	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	Jayne Donnelly Alaffia - Agbanga Karite	CARRUBBA AROMATICS BOTANICAL EXTRACTS, MILFORD, CT - 483
2013-10152	12/30/2013 01/29/2014	FDA/OGROP/ORA/PA-FO/SEA- DO/SEA-CB/	Jayne Donnelly Alaffia - Agbanga Karite	LIBERTY NATURAL PRODUCTS, OREGON CITY, OR - 483
2013-10153	12/30/2013 01/29/2014	FDA/OGROP/ORA/CE-FO/CHI- DO/CHI-CB/	Jayne Donnelly Alaffia - Agbanga Karite	VANTAGE OLEOCHEMICALS, CHICAGO, IL - 483
2013-10154	12/30/2013 01/29/2014	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	Viviana P. Varela SEDGWICK LLP	DE LA PEDRAJA RADIOLOGY ASSOCIATES, INC - INSPECTIONS
2013-10155	12/30/2013 01/29/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jenny Boucher, PharmD Lehigh Valley Health Network	FLUOROQUINOLONES - PERIPHERAL NEUROPATHY
2013-10156	12/31/2013 01/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Steve Lawson Steve Lawson	ANTIBIOTIC DRUGS - ISR SUMMARY
2013-10157	12/31/2013 01/30/2014	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORA/OCI/ OC/ORA/OCI/ FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/	Doe J	STIMEREX ES - INVESTIGATION RECS 09/01/2013 - 01/01/2014
2013-10158	12/31/2013	FDA/OGROP/ORA/SW-FO/DAL-	Jayne Donnelly	DOW CHEMICALS, FREEPORT, TX - LAST TWO 483

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	01/30/2014	DO/DAL-CB/	Alaffia - Agbanga Karite	
2013-10159	12/31/2013 01/30/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	Steven R. Andrews Law Offices of Steven R. Andrews	AMR/TFC For Cause-MAP00098/FDA 148916, Radiology Associates of Tallahassee 6/13/11
2013-10160	12/31/2013 01/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Aneta Riki Leavitt Eastern Michigan University School of Health Sciences	BISPHOSPHONATE DRUGS - MEDWATCH FORMS
2013-10161	12/31/2013 01/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rob Devaney (MXO) MX Orthopedics	K120493
2013-10162	12/31/2013 01/30/2014	FDA/OC/OES/DFOI/	Robert King FDANEWS	Disclosure FOI request log date range 12/23/2013 to 12/27/2013
2013-10163	12/31/2013 01/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nicholas Mancini Hanson Curran LLP	FENTORA - PUBLIC HEALTH ADVISORY (CERTIFIED); INFORMATION FOR HEALTHCARE PROFESSIONALS (CERTIFIED), ETC
2013-10164	12/31/2013 01/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rob Devaney (MXO) MX Orthopedics	K930834
2013-10165	12/31/2013 01/30/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Rob Devaney (MXO) MX Orthopedics	K050636
2013-10166	12/31/2013 01/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rafe Lewis NORTH RUN CAPITAL LP	HOSPIRA, IRUNGATTUKOTTAI, INDIA - 483 12/01/2013 - 12/27/2013
2013-10167	12/31/2013 01/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	Donald Barry MEDICA CORPORATION	K031560
2014-1	01/02/2014 01/31/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Darshan Mehta ET Now	INDOCO REMEDIES, GOA, INDIA - 483 08/30/2013 - 08/31/2013
2014-2	01/02/2014 01/31/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jack P Douglas Self	DEVICE REPORT ANALYSIS RECS 12/15/2010 - 12/31/2013
2014-3	01/02/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jeff Hover	K874573

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	01/31/2014		Jeff Hover	
2014-4	01/02/2014 01/31/2014	FDA/OFVM/CFSAN/OCD/EOS/	JIM FALLER, Ph.D. Valley Chemical Solutions, Inc.	AMMONIUM CARBONATE 21 CFR 184-1137 - APRVL
2014-5	01/02/2014 01/31/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PATTERSON 530597, JOHNNY	METHOTREXATE; PLAQUENIL (HYDROXYCHLOROQUINE SULFATE) - AER
2014-6	01/02/2014 01/31/2014	FDA/OMPT/CDRH/OCER/DFOI/	COURTLAND IMEL CEUTICAL LABORATORIES INC	SOLTA MEDICAL INC - THERMAGE CPT SYS K132431; K090580, PELLEVE MEDICAL INC - GLIDESAFE TREATMENT SYS K102698
2014-7	01/02/2014 01/31/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DON J. MIZERK HUSCH BLACKWELL LLP	ACTAVIS ELIZABETH - LUVOX CR (FLUVOXAMINE MALEATE) ANDA 91-482 FINAL APRVL LTR 11/18/13
2014-8	01/02/2014 01/31/2014	FDA/OMPT/CDRH/OCER/DFOI/	MR. LIM KOI-YONG PLEASURE LATEX PRODUCTS SDN BHD	PLEASURE LATEX PRODUCTS - K023333
2014-9	01/02/2014 01/31/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HOWELL, DAVID	DEPAKOTE; TEGRETOL - AER
2014-10	01/02/2014 01/31/2014	OC/CVM/OCD/	KRISTI O. SMEDLEY, Ph.D. Center for Regulatory Services, Inc.	PULSE FIBER, PULSE FLOUR, PULSE PROTEIN, PULSE STARCH -SUBMISSIONS TO SUPPORT DEFINITIONS 12/4/13
2014-11	01/02/2014 01/31/2014	FDA/OFVM/CFSAN/OCD/EOS/	ROBERT S. McQUATE, Ph.D. GRAS ASSOCIATES LLC	FCN 70
2014-12	01/02/2014 01/31/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	MELISSA A. PICKETT BEASLEY ALLEN ET AL	AUXILIUM - TESTIM SBA, NDA, AER
2014-13	01/02/2014 01/31/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MELISSA A. PICKETT BEASLEY ALLEN ET AL	ACTAVIS - ANDRODERM SBA, NDA, AER

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		FDA/OC/OES/DFOI/		
2014-14	01/02/2014 01/31/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MELISSA A. PICKETT BEASLEY ALLEN ET AL	LILY - AXIRON SBA, NDA, AER
2014-15	01/02/2014 01/31/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MELISSA A. PICKETT BEASLEY ALLEN ET AL	ENDO PHARMACEUTICALS - FORTESTA SBA, NDA, AER
2014-16	01/02/2014 01/31/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MELISSA A. PICKETT BEASLEY ALLEN ET AL	ABBVIE - ANDROGEL SBA, NDA, AER
2014-17	01/02/2014 01/31/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OL/	MICHAEL JACOBSON, Ph.D. CENTER FOR SCIENCE IN THE PUBLIC INTEREST	JOLT, ROCKSTAR, MONSTER ENERGY DRINK DEATHS 1/09 TO PRESENT
2014-18	01/02/2014 01/31/2014	FDA/OFVM/CFSAN/OCD/EOS/	JANNA dePORTER CENTER FOR SCIENCE IN THE PUBLIC INTEREST	CORR REGARDING VITAMINS IN DIET COKE PLUS
2014-19	01/02/2014 01/31/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DON J. MIZERK HUSCH BLACKWELL LLP	PAR PHARMA - DEXILANT (DEXLANSOPRAZOLE ER CAPS) NDA 202-294 APRVL
2014-20	01/02/2014 01/31/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CLARK SULLIVAN TROUTMAN SANDERS LLP	DEFICIENCY LTRS ISSUED BY OGD
2014-21	01/02/2014 01/31/2014	FDA/OMPT/CDRH/OCER/DFOI/	JOHN F. MAHON, Jr. WILLIAMS VENKER ET AL	INTUITIVE SURGICAL - DA VINCI SURGICAL ROBOT TRAINING PROTOCOL 1/11 TO 3/12
2014-22	01/02/2014 01/31/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	KRISTIN HIGBEE SUMMIT MEDICAL PRODUCTS	PALM PUMP K002434; AMBIT INTERMITTENT AMBULATORY INFUSION PUMP K033425; AMBIT CONTINUOUS

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			INC	AMBULATORY INFUSION PUMP KO33325
2014-23	01/02/2014 01/31/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CODY M. GREENES LEVENSTEN LAW FIRM	ANDROGEL - AER, CLNCL TRIAL 12/09
2014-24	01/02/2014 01/31/2014	FDA/OMPT/CDRH/OCER/DFOI/	MARK McLEAN MEYERSON LAW FIRM PC	NUVASIVE INC - XL TDR MEDICAL DVC APRVL, MDRS, CORR
2014-25	01/02/2014 01/31/2014	FDA/OFVM/CFSAN/OCD/EOS/	FRIEDMAN, ROBERT	TACO BELL CILANTRO DRESSING; SONIC RANCH DRESSING; STARBUCKS CAESAR DRESSING ETC - CAERS 1969 TO 2013
2014-26	01/02/2014 01/31/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ZOIA PLOSCARU NOSTRUM LABORATORIES INC	MYLAN - LEVOTHYROXINE SODIUM TABLETS USP ANDA 76-187 CMC, BIOEQUV
2014-27	01/02/2014 01/31/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHANDRAN TIRUVATTAR DR REDDYS LABORATORIES INC	FOUGERA - LIDOCAINE ANDA 80-198 SBA
2014-28	01/02/2014 01/31/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	CLOSED FOIA REQUESTS 12/1-31/2013
2014-29	01/02/2014 01/31/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 12/1-31/2013
2014-30	01/02/2014 01/31/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	CLOSED FOIA REQUESTS 2013
2014-31	01/03/2014 02/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Shelburne Ellipse Technologies Inc	K130556
2014-32	01/03/2014 02/03/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Jon Kirk Smith Smithers Pharma Services LLC	SMITHERS PHARMA SERVICES LL - EIR 1/14/2013
2014-33	01/03/2014 02/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Andrea Demakas ADVERSEEVENTS INC	ICLUSIG - AERS
2014-34	01/03/2014 02/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jesse Newman THE WALL STREET JOURNAL	ZILPATEROL - TESTING, STUDY, APPROVAL ETC

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2014-35	01/03/2014 02/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Andrea Demakas ADVERSEEVENTS INC	ENBREL - AERS
2014-36	01/03/2014 02/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Andrea Demakas ADVERSEEVENTS INC	HUMIRA (ADALIMUMAB), TYSABRI (NATALIZUMAB), REMICADE (INFLIXIMAB), ETC - FAERS
2014-37	01/03/2014 02/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Paul Smith; Corporate Quality Assurance Auditor Fresenius Kabi USA	TEVA PHARMACHEMIE, HAARLEM, NETHERLANDS - EIR, 483 01/04/2012 - 01/01/2014
2014-38	01/03/2014 02/03/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Jack T Krauser JACK T KRAUSER	K961381, K961382, K961383 ETC
2014-39	01/03/2014 02/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rhonda Woodard Wolf, Tiedeken & Woodard, P.C.	P090018 - ANNUAL REPORTS, PEDIODIC POST- APPROVAL STUDY REPORTS 03/17/2010 - 01/02/2014
2014-40	01/03/2014 02/03/2014	OC/CVM/OCD/	Jesse Newman THE WALL STREET JOURNAL	RACTOPAMINE - TESTING, STUDY, APPROVAL ETC
2014-41	01/03/2014 02/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Raghuram Pannala Pannala, Raghu ram	ANDA 078612, ANDA 202101 - LABEL, INSERT
2014-42	01/03/2014 02/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	Postmarket surveillance information for Johnson & Johnson
2014-43	01/03/2014 02/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	Postmarket surveillance info for Osteotechnology
2014-44	01/03/2014 02/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	Postmarket surveillance info for Zimmer
2014-45	01/03/2014 02/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	Postmarket surveillance info for Stryker

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2014-46	01/03/2014 02/03/2014	OC/CVM/OCD/	Rachel Johnson FOI Services, Inc.	2006-P-2010 - REFERENCE RECS
2014-47	01/03/2014 02/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	Postmarket surveillance info for Implantology
2014-48	01/03/2014 02/03/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	mark cuker williams cuker berezofsky	EXTREME LASERCOMB - APPROVAL RECS
2014-49	01/03/2014 02/03/2014	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Scott Kendall THERMOFISHER SCIENTIFIC	THERMOFISHER - EIR 1/19/2012 - 02/07/2012
2014-50	01/03/2014 02/03/2014	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Evelyn Jaume - Paralegal Mase Lara Eversole	TAYLOR FARMS FLORIDA - INSPECTION RECS, COMPLAINT RECS 08/07/2012 - 08/08/2012
2014-51	01/03/2014 02/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Meagan Day Helmsing Leach Herlong Newman and Rouse	KLONOPIN - AERS
2014-52	01/03/2014 02/03/2014	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Dr. Vinay Bhatt Bhatt, Vinay	NESHER PHARMACEUTICALS - EIR 10/28/2013 - 11/08/2013
2014-53	01/06/2014 02/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DENISE HAMMANG BIOPHARMA COMPLIANCE SERVICES LLC	EXCELLA GMBH, BAVARIA, GERMANY - EIR 5/13
2014-54	01/06/2014 02/04/2014	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORA/ OC/ORA/	ROBERT M SMITH PLAUCHE & CARR LLP	VIBRIO VULNIFICUS - DEATHS REPORTED 2008 TO 2013
2014-55	01/06/2014 02/04/2014	OC/CVM/OCD/	ELENA HOWELL Hogan Lovells, ILP	DKT 2006-P-0010
2014-56	01/06/2014 02/10/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OC/OCC/ FDA/OC/OES/ FDA/OC/OEXA/OMA/	MARSO, ANDY	NOVARTIS - BEXSERO AGENCY EMAILS
2014-57	01/06/2014	FDA/OMPT/CDER/ORP/DIDP/	Jennifer Burke	ASTRAZENECA - SEROQUEL, RISPERDAL CORR WITH DDMAC

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	02/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DRINKER BIDDLE & REATH	
2014-58	01/06/2014 02/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jennifer Burke DRINKER BIDDLE & REATH	ELI LILLY - ZYPREXA, RISPERDAL CORR WITH DDMAC
2014-59	01/06/2014 02/04/2014	FDA/OC/OES/DDM/	WILLIAM J SKINNER RPH ESQ MUSCATATUCK PUBLISHERS INC	DKT 1995S-0039
2014-60	01/06/2014 02/04/2014	FDA/OC/OES/DDM/	WILLIAM J SKINNER MUSCATATUCK PUBLISHERS INC	DKT 1995S-0163
2014-61	01/06/2014 02/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bob Szurgot SAGENT PHARMACEUTICALS INC	DIPRIVAN - AERS
2014-62	01/06/2014 02/04/2014	FDA/OFVM/CFSAN/OCD/EOS/	Rend Al-Mondhiry COUNCIL FOR RESPONSIBLE NUTRITION	DIETARY SUPPLEMENT DATA
2014-63	01/06/2014 02/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jeanine Dermer Dermer, Jeanine K	ARMOUR - AERS
2014-64	01/06/2014 02/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jeanine Dermer Dermer, Jeanine K	SYNTHROID - AERS
2014-65	01/06/2014 02/04/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	510K RELEASED NOVEMBER 2013
2014-66	01/06/2014 02/04/2014	FDA/OMPT/CDRH/OCER/DFOI/	Xiancheng Shao Neusoft Medical Systems Co.,Ltd.	K050559
2014-67	01/06/2014 02/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Philip Blair Abledoc	SIMVASTATIN - AERS

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2014-68	01/06/2014 02/04/2014	FDA/OGROP/ORPA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	PETER LOFTUS WALL STREET JOURNAL	23ANDME INC, MOUNTAIN VIEW, CA - CORR 1/07 TO PRESENT
2014-69	01/06/2014 02/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Philip Blair Abledoc	VYTORIN - AERS
2014-70	01/06/2014 02/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Philip Blair Abledoc	ADVICOR - AERS
2014-71	01/06/2014 02/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Philip Blair Abledoc	LOVASTATIN - AERS
2014-72	01/06/2014 02/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DR. REENA HARJAI APCER Pharma Solutions, Inc	KINEVAC (SINCALIDE) - AER 1/76 TO 12/02
2014-73	01/06/2014 02/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Philip Blair Abledoc	PRAVASTATIN - AERS
2014-74	01/06/2014 02/04/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CTP/OD/	CHARLES CELESTE EAS CONSULTING GROUP LLC	BP INTERNATIONAL HEADQUARTERS, LONDON, UK - EIRS, 483S
2014-75	01/06/2014 02/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lauren Farruggia Hyman, Phelps & McNamara P.C.	ANDA 078271 - APPROVAL LETTER
2014-76	01/06/2014 02/04/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	POSTMARKET SURVEILLANCE STUDIES FOR STRYKER

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2014-77	01/06/2014 02/04/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	THOMAS LAUGHLIN SCOTT & SCOTT	EDWARDS LIFESCIENCES CORP - SAPIEN TRANSCATHETER HEART VALVE MODEL 9000TFX APRVL, INVESTIGATIONS
2014-78	01/06/2014 02/04/2014	FDA/OC/OES/DDM/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WILLIAM B. FEDERMAN FEDERMAN & SHERWOOD	SAREPTA THERAPEUTICS INC - ETEPLIRSEN STUDIES, TESTING, MINS, ETC
2014-79	01/06/2014 02/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BOB TREMMEL, PHARM D WELLSTAT THERAPEUTIC CORP	FLUOROURACIL - ISRS 8557831, 8089162, 7849706, ETC
2014-80	01/06/2014 02/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PATRICIA L. REGENYE Celgene Corporation	GUSTAVO LUGO-ZAMUDIO, HOSPITAL JUAREZ DE AV INSTITUTO POLITECNICO NACIONAL, MEXICO CITY, MEXICO - 483S 7/08 TO PRESENT
2014-81	01/06/2014 02/04/2014	OC/ORAO/OCI/ OC/ORAO/OCI/	JOSEPH J. VOCCOLA, Esq. JOSEPH J VOCCOLA AND ASSOCIATES	INDIVIDUAL RECS
2014-82	01/06/2014 02/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELLIOT FAVUS MD FAVUS INSTITUTIONAL RESEARCH LLC	CYSTEAMINE BITARTRATE - AERS
2014-83	01/06/2014 02/04/2014	OC/ORAO/ORM/ OC/ORAO/ORM/	ROBERT KING FDA NEWS	LIST OF 483S ISSUED BY DISTRICT 12/13
2014-84	01/06/2014 02/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KOOPMAN 91058, ADAM	MODAFAMIL - RECS
2014-85	01/07/2014	FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson	DRUG SAFETY OVERSIGHT BOARD - JAN 2013 MEETING MATERIALS

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	02/05/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FOI Services, Inc.	
2014-86	01/07/2014 02/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	COURTLANT IMEL CEUTICAL LABORATORIES INC	PRIMAEVA MEDICAL INC - PRIMAEVA MEDICAL SYS K082145
2014-87	01/07/2014 02/05/2014	FDA/OGROP/ORR/SE-FO/ATL- DO/ATL-CB/	Hanna Raskin The Post & Courier	JELLY BALLS, LLC - CORR, INSPECTIONS, COMPLAINTS ETC 01/01/2012 - 01/01/2014
2014-88	01/07/2014 02/05/2014	FDA/OGROP/ORR/PA-FO/SAN- DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	JASON EVANS CASEY GERRY SCHENK ET AL	23ANDME INC, MOUNTAIN VIEW, CA - EMAILS, NOTES, MINS, ETC
2014-89	01/07/2014 02/05/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MICHAEL R COHEN INSTITUTE FOR SAFE MEDICATION PRACTICES	MEDWATCH RPTS CODES AS MEDICATION ERRORS 12/1- 31/13
2014-90	01/07/2014 02/05/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID M HOFFMEISTER WILSON SONSINI ET AL	OTREXUP (METHOTREXATE) INJ NDA 204-824 APRVL PKG
2014-91	01/07/2014 02/05/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DOBEK, DOLORES	VENAPAMIL ER 180 MG - AERS
2014-92	01/07/2014 02/05/2014	FDA/OFVM/CFSAN/OCD/EOS/	Dr. John Hnatio FoodQuestTQ LLC	DOCUMENTS, EMAILS, COMMUNICATIONS FROM FDA/HHS EMPLOYEES RE FOODQUEST 03/01/2013 - 01/06/2014
2014-93	01/07/2014 02/05/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORR/SW-FO/DAL- DO/DAL-CB/	PATRICIA A MALONE COMMUNITY BLOOD CENTER	FORT WORTH EYE BANK, FT WORTH, TX - EIR MOST RECENT
2014-94	01/07/2014 02/05/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Katherine Groff New England Anti Vivisection Society	ANNUAL BUDGET INFORMATION FOR NON ANIMAL TEST MODELS FOR DRUGS AND MEDICAL DEVICES 01/01/2008 - 12/20/2013

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		FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/		
2014-95	01/07/2014 02/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ROBERT L GREEN ALLEN SUMMERS SIMPSON AT EL	GENENTECH INC, SAN FRANCISCO, CA -(PULMOZME) RHDNASE STABILITY TESTS
2014-96	01/07/2014 02/05/2014	FDA/OFVM/CFSAN/OCD/EOS/	Paul Fowler UNILEVER	COLOURANT MATERIALS - SAFETY DATA
2014-97	01/07/2014 02/05/2014	FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA REQUEST LOG 12/30/2013 - 01/03/2014
2014-98	01/07/2014 02/05/2014	FDA/OGROP/ORACE-FO/CIN- DO/CIN-CB/	Lynn Lundy West Pharmaceutical Services, Inc.	STERIGENICS, WESTERVILLE, OH - EIR 10/31/2011 - 12/31/2011
2014-99	01/07/2014 02/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Larry Perez SKYTRON	MDR 3354118
2014-100	01/07/2014 02/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TENECIA SULLIVAN SALAMANDRA LLC	METHYLTHONINIUM - ISRS 5791235, 6779107, 8538705, ETC
2014-101	01/07/2014 02/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Larry Perez Skytron, A Division of the KMW Group, Inc.	MDR 3261044
2014-102	01/07/2014 02/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mahidhar Chinta Micro Labs USA, Inc	NDA 020193 - SBA
2014-103	01/07/2014 02/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	THOMPSON, RAY	WOCKHARDT LTD, WALUJ, INDIA 3/13-22/13; WOCKHARDT LTD, SOLAN, NALAGARH, HIMCHAL PRADESH, INDIA; WOCLCHARD LTD AURANGABAD MAHARASHTRA, INDIA 7/22-31/13 EIRS 9/9/13/13
2014-104	01/07/2014 02/05/2014	FDA/OC/OES/DFOI/	JACQUELINE PROSCIA WILSON SOSINI GOODRICH & ROSATI	DKT 2013P-1641
2014-105	01/07/2014 02/05/2014	FDA/OC/OES/DFOI/	AFIF GHANNOUM ARMS PHARM	OTC V 210013-210015, 130167; DKT 1981N-0033, C13, C15

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2014-106	01/07/2014 02/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	EISIMINEER T-04210, WESLEY R	KLONOPIN (CLONAZEPAM) AERS 11/97 TO PRESENT
2014-107	01/07/2014 02/05/2014	FDA/OC/OES/DFOI/	JAMIE OWENS WILSON SOSINI GOODRICH & ROSATI	DKT 2013P-1128
2014-108	01/07/2014 02/05/2014	FDA/OC/OES/DFOI/	DEBORAH ZAGER VENABLE LLP	DKT 1986P-0367
2014-109	01/07/2014 02/05/2014	FDA/OC/OES/DFOI/	EMILY SHERMAN SIDLEY AUSTIN LLP	DKT 2001D-0213
2014-110	01/07/2014 02/05/2014	FDA/OGROP/ORAN/NE-FO/NWE-DO/NWE-CB/	Richard W. Gonnello Faruqi & Faruqi, LLP	COLEY PHARMACEUTICALS, WELLESLEY, MA - INSPECTION RECS SINCE 2007
2014-111	01/07/2014 02/05/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Richard W. Gonnello Faruqi & Faruqi, LLP	RHEIN BIOTECH - INSPECTION RECS SINCE 2007
2014-112	01/07/2014 02/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Carol Jarrett Teva Pharmagovigilance	QNASI - AERS
2014-113	01/07/2014 02/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Carol Jarrett Teva Pharmacovigilance	QUARTETTE - AERS
2014-114	01/07/2014 02/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Carol Jarrett Teva Pharmacovigilance	SYNRIBO - AERS

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-115	01/07/2014 02/05/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shin Kang WELLS FARGO	KALYDECO, TECFIDERA, SOVALDI, ETC - AERS
2014-116	01/07/2014 02/05/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Anupama Ravi,MD Mayo Clinic - Anupama Ravi, MD	Levofloxacin-Related Eosinophilia Levofloxacin-Related Eosinophilic Cardiac Disease
2014-117	01/07/2014 02/05/2014	FDA/OC/OES/DFOI/	DAISY SOO ROPES & GRAY LLP	DKT 1998N-1265
2014-118	01/07/2014 02/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Larry Perez Skytron, A Dvision of the KMW Group, Inc.	MDR MW5033082
2014-119	01/07/2014 02/05/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHARON WARBINGTON MIKART INC	ORTHO MCNEIL PHARM - PARAFLEX (CHLORZOAZONE 250 MG) TABS NDA 11-300 APRVL, LBLG 12/12/58 TO 9/25/97
2014-120	01/07/2014 02/05/2014	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	RANIL LM FERNANDO BIOSCREEN TESTING SERVICES INC	MICRO QUALITY LABS INC, BURBANK, CA - EIRS, 483S, WARNING LTRS LAST FIVE YRS
2014-121	01/07/2014 02/05/2014	FDA/OC/OES/DFOI/	DAISY JOO ROPES & GRAY LLP	DKT 1998N-1265
2014-122	01/07/2014 02/05/2014	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	ANDREW P MCDEVITT WALKUP MELODIA ET AL	LA TAPATIA LLC, SOUTH SAN FRANCISCO, CA - EIRS, CORR, VIOLATION RECS 5/15/12, 5/23/12, ETC
2014-123	01/07/2014 02/05/2014	FDA/OC/OES/DFOI/	TIM POWELL CUNEO GILBERT ET AL	DKT 2010N-0274
2014-124	01/07/2014 02/05/2014	FDA/OFVM/CFSAN/OCD/EOS/	TUNNELL, SHARON	SHAKLEE 180 LEAN & HEALTHY KIT - CAERS
2014-125	01/07/2014 02/05/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	EDWARD JOHN ALLERA BUCHANAN INGERSOLL & ROONEY PC	TELEPHONE CONFERENCE BTWN CENTER FOR BIOLOGICS EVALUATION & RESEARCH & THERAPEUTICS INC - MINS 10/13
2014-126	01/07/2014 02/05/2014	FDA/OC/OES/DFOI/	AMIE N VANELLA FAEGRE BAKER DANIELS	SIMPLY THICK OR SIMPLY THICK LLC - FOIA REQUEST LTRS 10/13 TO PRESENT

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2014-127	01/07/2014 02/05/2014	FDA/OC/OES/DFOI/	GAYLE DOUGLAS HENINGER GARRISON DAVIS LLC	INDIVIDUAL RECS
2014-128	01/08/2014 02/06/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Raghuram P SCIEGEN PHARMACEUTICALS INC	ANDA 090165, 202102 - LABEL, PACKAGE INSERT
2014-129	01/08/2014 02/06/2014	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2013-2533
2014-130	01/08/2014 02/06/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K133029
2014-131	01/08/2014 02/06/2014	FDA/OMPT/CDRH/OCER/DFOI/	Wenyng Zhu USC - University of Southern California	K012761
2014-132	01/08/2014 02/06/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Judith Baigis GEORGETOWN UNIVERSITY	CALCITONIN SALMON NASAL SPRAY - AERS
2014-133	01/08/2014 02/06/2014	FDA/OGROP/ORAPA-FO/SAN- DO/SAN-CB/	Kate Hege Beeson, Tayer & Bodine	TAYLOR FARMS PACIFIC - INSPECTION, ENFORCEMENT RECS
2014-134	01/08/2014 02/06/2014	FDA/OGROP/ORACE-FO/DET- DO/DET-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Gregory A Hall Law Office of Gregory A Hall	BIOMET COMPREHENSIVE SHOULDER PROSTHESIS - 510K, EIR, 483 ETC
2014-135	01/08/2014 02/06/2014	FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/	Jackie Garcia BASF Corporation	BASF - REDACTED EIR 10/21/2013 - 10/25/2013
2014-136	01/08/2014 02/06/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ OC/ORA/ OC/ORA/	DIONNE SEARCEY THE WALL STREET JOURNAL	Record layouts (column names, and descriptions where available) for all databases containing information about facilities that handle (i.e., test, store, or otherwise process) umbilical cord blood stem cells, including historical facility inspections.
2014-137	01/08/2014 02/06/2014	OC/ORA/ OC/ORA/ FDA/OGROP/ORACE-FO/BLT- DO/BLT-CB/ FDA/OGROP/ORACE-FO/DET-	Doe J	INDIVIDUAL RECS

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		DO/DET-CB/		
2014-138	01/08/2014 02/06/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Zhenya Senyak MPNforum Magazine	SAR302503 - PHASE III CLINICAL TRIAL RECS ETC
2014-139	01/08/2014 02/06/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Postow Joan Postow	FORTEO - AERS
2014-140	01/08/2014 02/06/2014	FDA/OC/OES/DFOI/	Malia Segar Cote Orphan Consulting	ACATHAR GEL
2014-141	01/08/2014 02/06/2014	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	INDIVIDUAL RECS
2014-142	01/08/2014 02/06/2014	FDA/OGROP/ORR/SE-FO/SJN-DO/SJN-CB/ FDA/OGROP/ORR/SE-FO/SJN-DO/SJN-CB/	GARNIER, CARLOS M CALDERON	INDIVIDUAL RECS
2014-143	01/08/2014 02/06/2014	FDA/OMPT/CDRH/OCER/DFOI/	MATTHEW A ZEPNICK The Edelsteins, Faegenburg & Brown, LLP	TRANS1 - AXIAL LIF 2L ANTERIOR SPINAL FIXATION MDRS
2014-144	01/08/2014 02/06/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MATTHEW E KONOSKY UBS GLOBAL ASSET MANAGEMENT	BOEHRINGER-INGELHEIM, RHEIN, GERMANY - 483S 1/1/10 TO 1/1/14
2014-145	01/08/2014 02/06/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JENNIFER HSIEH DEERFIELD INSTITUTE	AEGERION PHARMS - JUXTAPID (LOMITAPIDE MEDYLATE) AERS 3/6/13 TO PRESENT
2014-146	01/08/2014 02/06/2014	FDA/OMPT/CDRH/OCER/DFOI/	Liam Mullins National University of Ireland, Galway	K123696, K123803, K133282
2014-147	01/08/2014 02/06/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	MATTHEW J FOCHT GLEASON FLYNN EMIG & FOGLEMAN	BIOMET 3I - FULL OSSEOTITE CERTAIN TEMPERED IMPLANTS CMLPNTS, INVESTIGATIONS
2014-148	01/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	MARK CHEN	AUTO SUTURE MICRO SURGICLIP APPLIER K001450;

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	02/06/2014		NANOVA INC	HEMO-LOK SM8 K003337; WECK HEMO-LOK AUTOMATIC LIGATING CLIP APPLIER K021808
2014-149	01/08/2014 02/06/2014	FDA/OMPT/CDRH/OCER/DFOI/	MARK CHEN NANOVA INC	NYLON LIGATING CLIP K801124; PROLENE POLYPROPYLENE LIGATING CLIP K811935; PDS ABSORBABLE LIGATING CLIP K812323
2014-150	01/08/2014 02/06/2014	FDA/OMPT/CDRH/OCER/DFOI/	MARK CHEN NANOVA INC	AUTO SUTURE R CLIP K771112; LIGACLIP MULTIPLE LIGATING CLIPS K771413; HEMOCLIP SURGICAL OCCLUDING CLIP K800079
2014-151	01/08/2014 02/06/2014	FDA/OMPT/CDRH/OCER/DFOI/	MARK CHEN NANOVA INC	HEM-O-LOK KL CLIP K030311; HEM-O-LOK LIGATION CLIP K062914; HEM-O-LOK MODEL 523935 K982944
2014-152	01/08/2014 02/06/2014	FDA/OFVM/CFSAN/OCD/EOS/	Bob Thompson Capitol Plastic Products LLC	CAPITOL PLASTIC PRODUCTS, LLC - BIOTERRORISM REGISTRATION
2014-153	01/08/2014 02/06/2014	FDA/OMPT/CDRH/OCER/DFOI/	MARK CHEN NANOVA INC	MULTICLIP DISP LIGATING CLIP DVC K820999; AUTO SUTURE POLY SURGICLIP HEMOSTATIC K831457
2014-154	01/09/2014 02/07/2014	FDA/OC/OL/ FDA/OC/OL/	Scott Hodes Scott A. Hodes, Attorney at Law	REP ALLYSON SCHWARTZ - CORR WITH FDA 01/01/2005 - 01/08/2014
2014-155	01/09/2014 02/07/2014	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2013-1902
2014-156	01/09/2014 02/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	Ditza Auerbach BreatheVision Ltd.	K120087
2014-157	01/09/2014 02/07/2014	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	Tobacco substantial equivalence information
2014-158	01/09/2014 02/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nate Jones WAGSTAFF & CARTMELL LLP	LETTER TO BRIAN A FEAGINS, MD FROM CDER DSI (CERTIFIED)
2014-159	01/09/2014 02/07/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2013-8530
2014-160	01/09/2014 02/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Joe Krzywicki Joe Krzywicki	Company Name, Phone number, Website, Email, and contact person for all Active Generic Manufacturing Pharmaceutical Companies and Medical Equipment Manufacturing Companies in the United States
2014-161	01/09/2014	FDA/OGROP/ORACE-FO/CHI-	David Savidge	ALMA LASER, BUFFALO GROVE, IL - 483, RESPONSE

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	02/07/2014	DO/CHI-CB/	G&M Health, LLC	01/21/2013 - 06/14/2013
2014-162	01/09/2014 02/07/2014	FDA/OFVM/CFSAN/OCD/EOS/	Joshua A. Jendza BASF Corp.	FAP 2258 SAFETY DATA
2014-163	01/09/2014 02/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kenneth Daly BURG SIMPSON ET AL	NDA18723, 18081, 18-082 - THREE DOCUMENTS
2014-164	01/09/2014 02/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jonathan Reeves MAKO Surigcal Corp	K122160
2014-165	01/09/2014 02/07/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-9195 - REQUEST LETTER ONLY
2014-166	01/09/2014 02/07/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-9249 - REQUEST LETTER ONLY
2014-167	01/09/2014 02/07/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-9498 - REQUEST LETTER ONLY
2014-168	01/09/2014 02/07/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-9043 - REQUEST LETTER ONLY
2014-169	01/09/2014 02/07/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-9457 - REQUEST LETTER ONLY
2014-170	01/09/2014 02/07/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-8959 - REQUEST LETTER ONLY
2014-171	01/09/2014 02/07/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-8880 - REQUEST LETTER ONLY
2014-172	01/09/2014 02/07/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-9184 - REQUEST LETTER ONLY
2014-173	01/09/2014 02/07/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-8874 - REQUEST LETTER ONLY
2014-174	01/09/2014 02/07/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-8795 - REQUEST LETTER ONLY
2014-175	01/09/2014 02/07/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-8828 - REQUEST LETTER ONLY
2014-176	01/09/2014 02/07/2014	FDA/OO/OFBA/OAGS/	John Woodley Trusted Technologies LLC	HHSF223201310004I - EMAILS

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2014-177	01/09/2014 02/07/2014	FDA/OFVM/CFSAN/OCD/EOS/	FRIEDMAN, ROBERT	HERSHY'S, NESTLE, SORBEE, ETC - CAERS
2014-178	01/09/2014 02/07/2014	FDA/OFVM/CFSAN/OCD/EOS/	VISAGINE VIJAYAKULASINGAM IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS - 169396, 169605, 169701
2014-179	01/09/2014 02/07/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	BRETT PARK CONWAY HOMER & CHIN- CAPLAN PC	INDIVIDUAL RECS
2014-180	01/09/2014 02/07/2014	FDA/OFVM/CFSAN/OCD/EOS/	JANNA dePORTER CENTER FOR SCIENCE IN THE PUBLIC INTEREST	INTERNATIONAL TECHNICAL CARAMEL ASSN (ITCA), GROCERY MFRS ASSN (GMA), SRI CONSULTING, ETC - USE OF CARAMEL COLORING IN FOOD TRANS, MINS, EMAILS, ETC
2014-181	01/09/2014 02/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anna Edney BLOOMBERG NEWS	CDER COMPLETE REPSONSE APPEALS - NAME OF PARTY, REASONS, OUTCOME 01/01/1993 - 12/31/2013
2014-182	01/09/2014 02/07/2014	FDA/OC/OES/DFOI/	Doe J	EMPLOYEE RECS
2014-183	01/09/2014 02/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C. TOWNSEND GRADIENT TECHNOLOGIES LLC	GRADIENT - QUADRABLOC TENS MODEL K102278
2014-184	01/09/2014 02/07/2014	FDA/OMPT/OSMP/OOPD/	Elinore Mercer Cote Orphan Consulting	OZURDEX - DESIGNATION RECS
2014-185	01/09/2014 02/07/2014	FDA/OMPT/OSMP/OOPD/	Elinore Mercer Cote Orphan Consulting	RETISERT - DESIGNATION RECS
2014-186	01/09/2014 02/07/2014	FDA/OMPT/OSMP/OOPD/	Elinore Mercer Cote Orphan Consulting	DUREZOL - DESIGNATION RECS
2014-187	01/09/2014 02/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ted Keller Sigma Capital Management	SOVALDI - AERS
2014-188	01/09/2014 02/07/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORO/PA-FO/SAN- DO/SAN-CB/	Mohit Bhat Kline & company Inc.	ABBOTT IRELAND DIABETES CARE, ABBOTT DIABETES CARE LIMITED, I-SENS WONJU FACTORY ETC - EIR 01/01/2009 - 01/09/2014
2014-189	01/09/2014 02/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C. TOWNSEND GRADIENT TECHNOLOGIES LLC	K950435 UNREDACTED, REVIEWERS NOTES

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2014-190	01/09/2014 02/07/2014	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Brenda Van Goethem Nature's Way Product	HARMONY FOODS CORPORATION, SANTA CRUZ, CA - EIR, 483, WARNING LETTER
2014-191	01/10/2014 02/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	ELENA CAVALIERE SOUTHMEDIC INC	K130379
2014-192	01/10/2014 02/10/2014	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORA/ OC/ORA/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	BENJAMIN L ENGLAND ESQ BENJAMIN L ENGLAND & ASSOCIATES LLC	IMPEX GROUP - ENTRY #923-0084621-6 RECS
2014-193	01/10/2014 02/10/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	FRAYSER, CHRISTIE E	RHOGAM, IMMUNOGLOBIN (D) - POLICIES, REQUIREMENTS FOR TRANSFUSIONS TO PREGNANT WOMEN
2014-194	01/10/2014 02/10/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	PATRICK KELLY CONWAY HOMER & CHIN- CAPLAN PC	INDIVIDUAL RECS
2014-195	01/10/2014 02/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	HELDER A SOUSA DATASCOPE CORP	GETINGE AB - P850023/S001,S002,S003, ETC
2014-196	01/10/2014 02/10/2014	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	MARTIN SINGER NEW WAVE SURGICAL CORP	NEW WAVE SURGICAL CORP, POMPANO BEACH, FL - EIR 7/10
2014-197	01/10/2014 02/10/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDRH/OCER/DFOI/	CLAUDIA NARDI RHEIN83 SRL	RHEIN 83 SRL, BOLOGNA, ITALY - EIR, 483 7/19-22/06
2014-198	01/10/2014 02/10/2014	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	ROBERT KING FDA NEWS	AUTOMATED OPHTHALMICS INC, ELKRIDGE, MD - 483S 12/1-31/13
2014-199	01/10/2014 02/10/2014	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	ROBERT KING FDA NEWS	DIXON INVESTMENTS, ORCHARD HILL, GA - 483S 12/1-31/13
2014-200	01/10/2014 02/10/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	ROBERT KING FDANEWS	AKRON COATING & ADHESIVES INC, AKRON, OH; GOJO INDUSTRIES, CUYAHOGA FALLS, OH; GIBSON LABORATORIES, LEXINGTON, KY - 483S 12/1-31/13
2014-201	01/10/2014 02/10/2014	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	ROBERT KING FDANEWS	DERMAMEDICS LLC, OKLAHOMA CITY, OK; SEATEX ;TD, ROSENBER, TX; ALEX ORTHOPEDIC INC, GRAND PRAIRIE, TX, ETC - 483S 12/1-31/13
2014-202	01/10/2014 02/10/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	ROBERT KING FDA NEWS	FMC CORP, GREEN RIVER, WY - 483S 12/1-31/13
2014-203	01/10/2014	FDA/OGROP/ORACE-FO/DET-	ROBERT KING	ANALYTICAL CONTROL SYSTEMS INC, FISHERS, IN; ELI

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	02/10/2014	DO/DET-CB/	FDA NEWS	LILLY & CO, INDIANAPOLIS, IN; MATERIALISE USA LLC, PLYMOUTH, MI, ETC - 483S 12/1-31/13
2014-204	01/10/2014 02/10/2014	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	ROBERT KING FDANEWS	SMARTSCIENCE LABORATORIES INC, TAMPA,FL; BIOSCULPTURE TECHNOLOGY INC, WEST PALM BEACH, FL; SALT CHAMBER LLC, BOCA RATON, FL, ETC - 483S 12/1-31/13
2014-205	01/10/2014 02/10/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ROBERT KING FDA NEWS	HERBAMED AG, BUHLER, SWITZERLAND; HOSPIRA HEALTHCARE INDIA PVT LTD, SRIPERUMBUDUR, KANCHEEPURAM, INDIA; ATUL LTD, VALSAD, INDIA - 483S 12/1-31/13
2014-206	01/10/2014 02/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	ROBERT KING FDA NEWS	ROMINGER MEDIZINTECHNIK GMBH, SEITINGEN-OBERFLACHT, GERMANY; PETERS SURGICAL, BOBIGNY, FRANCE; GALEMED XIAMEN CO LTD, XIAMEN, CHINA, ETC - 483S 12/1-31/13
2014-207	01/10/2014 02/10/2014	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	ROBERT KING FDA NEWS	SIGMA-ALDRICH MFG LLC, ST LOUIS, MO; UNIV OF IOWA PHARMS (UIP), IOWA CITY, IA - 483S 12/1-31/13
2014-208	01/10/2014 02/10/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	ROBERT KING FDA NEWS	PURETEK CORP,SAN FERNANDO, CA; STASON PHARMS, IRVINE, CA; ANCHEN PHARMS, IRVINE, CA, ETC - 483S 12/1-31/13
2014-209	01/10/2014 02/10/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	ROBERT KING FDA NEWS	IBA MOLECULAR NORTH AMERICA INC, HAVERHILL, ME; BRAINTREE LABORATORIES INC, HOLBROOK, MA; NUCLEA DIAGNOSTIC LABORATORIES LLC, ETC - 483S 12/1-31/13
2014-210	01/10/2014 02/10/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	ROBERT KING FDANEWS	CMIC CMO USA CORP, CRANBURY, NJ; GRANT INDUSTRIES INC, ELMWOOD PARK, NJ; AUSTARPHARMA LLC, EDISON, NJ - 483S 12/1-31/13
2014-211	01/10/2014 02/10/2014	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	ROBERT KING FDANEWS	PHARMA PAC LLC, DE KALB, MS; AMCOL HEALTH & BEAUTY SOLUTIONS, LAFAYETTE, LA - 483S 12/1-31/13
2014-212	01/10/2014 02/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Merge CAD Elucid Bioimaging Inc.	K092954
2014-213	01/10/2014 02/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Dan Schreiber Applied Electrodynamics	K833928, K883911
2014-214	01/10/2014 02/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Amanda Williams Gustafson Gluek	P040033
2014-215	01/10/2014 02/10/2014	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	ROBERT KING FDANEWS	UNITED GUARDIAN INC, HAUPPAUGE, NY; ADVANCE PHARMACEUTICAL INC, HOLTSMILLE, NY; FOUGERA PHARMS, HICKSVILLE, NY, ETC - 483S 12/1-31/13
2014-216	01/10/2014 02/10/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sherrie McNamara Fleet Laboratories	RECTAL SODIUM PHOSPHATE - AERS

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2014-217	01/10/2014 02/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Susan Eisner Eisner, Susan	LEXAPRO ETC - AERS
2014-218	01/10/2014 02/10/2014	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	ROBERT KING FDA NEWS	PRAXAIR DISTRIBUTION INC, HILLSIDE, IL; ALIGN SPINE LLC, CRYSTAL LAKE, IL; SMART MEDICAL TECHNOLOGY INC, DARIEN, IL, ETC - 483S 12/1-31/13
2014-219	01/10/2014 02/10/2014	FDA/OGROP/ORASE-FO/SJNDO/SJN-CB/	ROBERT KING FDA NEWS	OMEGA & DELTA CO INC, CAROLINA, PR; BRISAS DE CARIBE CORP, BAYAMON, PR; LANTHEUS MI RADIPHARMACEUTICALS INC, SAN JUAN, PR - 483S 12/1-31/13
2014-220	01/10/2014 02/10/2014	FDA/OGROP/ORAPA-FO/SEADO/SEA-CB/	ROBERT KING FDA NEWS	RIVERPOINT MEDICAL LLC, PORTLAND, OR; SHASTA TECHNOOGIES, SHERWOOD, OR, SEMLER TECHNOLOGIES INC, MILWAUKIE, OR, ETC - 483S 12/1-31/13
2014-221	01/10/2014 02/10/2014	FDA/OGROP/ORACE-FO/MINDO/MIN-CB/	ROBERT KING FDA NEWS	BROOKFIELD PRESCRIPTION CENTER INC (MD CUSTOM RX), BROOKFEILD, WI - 483S 12/1-31/13
2014-222	01/10/2014 02/10/2014	FDA/OGROP/ORAPA-FO/SANDO/SAN-CB/	ROBERT KING FDANEWS	PHOENIX DEVENTURES, MORGAN HILL, CA; GOLD STANDARD DIAGNOSTICS, DAVIS, CA; PREXION INC, SAN MATEO, CA - 483S 12/1-31/13
2014-223	01/10/2014 02/10/2014	OC/ORAC/ OC/ORAC/ FDA/OMPT/CDRH/OCER/DFOI/	ROBERT KING FDA NEWS	RUDISCHHAUSER SURGICAL INSTRUMENTS MFG, TUTTLINGEN, GERMANY; COOERVISION MFG, EASTLEIGH, UK; IMS INTERNAZIONALE MEDICO SCIENTIFICA SRL, SASSO, MARCON, ITALY - 483S 12/1-31/13
2014-224	01/13/2014 02/11/2014	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	SE0003526
2014-225	01/13/2014 02/11/2014	FDA/OFVM/CFSAN/OCD/EOS/	Liz Sonnenberg akzonobel	FCN 87
2014-226	01/13/2014 02/11/2014	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	SE0003525
2014-227	01/13/2014 02/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	Peter Manilla Manilla, Peter	K121287
2014-228	01/13/2014 02/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	Dr. Yossi Muncher Dr. Yossi Muncher	K123280, K131688
2014-229	01/13/2014 02/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Martin R. Prince, MD, PhD Weill Cornell Medical Center	6229095 6298529 6533700 ETC

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2014-230	01/13/2014 02/11/2014	FDA/OGROP/ORAC/CE-FO/NWJ- DO/NWJ-CB/	Frank Hannon Alva-Amco Pharmacal Companies, Inc.	FRUTAROM, NORTH BERGEN, NJ - EIR 07/01/2011 - 12/31/2013
2014-231	01/13/2014 02/11/2014	FDA/OGROP/ORAC/NE-FO/NYK- DO/NYK-DCB/	John Walsh James Alexander Corporation	US LAMINATING, BOHEMIA, NY - EIR, 483, RECALL 01/01/2011 - 01/10/2014
2014-232	01/13/2014 02/11/2014	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	SE0004386
2014-233	01/13/2014 02/11/2014	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	TOBACCO STUDIES
2014-234	01/13/2014 02/11/2014	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	SE0004388
2014-235	01/13/2014 02/11/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Julia Morteo Cubist Pharmaceuticals	NDA 21775 - SBA
2014-236	01/13/2014 03/11/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Ingrid Mehlhorn SIEMENS HEALTHCARE DIAGNOSTICS INC	BK110070
2014-237	01/13/2014 02/11/2014	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	SE0004387
2014-238	01/13/2014 02/11/2014	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	SE0001762
2014-239	01/13/2014 02/11/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Jennifer Levitz WALL STREET JOURNAL	K050404, K990144, K002489 ETC
2014-240	01/13/2014 02/11/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	EIR, 483 for MedImmune in Nijmegen, Netherlands 6/21/13
2014-241	01/13/2014	FDA/OMPT/CDER/GRP/DIDP/	Steven Yu	ANDA 078605, ANDA 078723, ANDA 090955

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	02/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ryuh Biomedical Research Foundation	
2014-242	01/13/2014 02/11/2014	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	SE0003529
2014-243	01/13/2014 02/11/2014	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	SE0003528
2014-244	01/13/2014 02/11/2014	FDA/OC/OES/DFOI/	GLADYS B TONKIN Center for Regulatory Services,Inc.	FOI DAILY LOG 12/2-6/13
2014-245	01/13/2014 02/11/2014	FDA/OC/OES/DFOI/	GLADYS B TONKIN Center for Regulatory Services,Inc.	FOI DAILY LOG 12/23-27/13
2014-246	01/13/2014 02/11/2014	FDA/OC/OES/DFOI/	GLADYS B TONKIN Center for Regulatory Services,Inc.	FOI DAILY LOG 12/16-20/13
2014-247	01/13/2014 02/11/2014	FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 12/2-6/13
2014-248	01/13/2014 02/11/2014	FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 12/23-27/13
2014-249	01/13/2014 02/11/2014	FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 12/16-20/13
2014-250	01/13/2014 02/11/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 12/2-6/13
2014-251	01/13/2014 02/11/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 12/23-27/13
2014-252	01/13/2014 02/11/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 12/16-20/13
2014-253	01/13/2014 02/11/2014	FDA/OC/OES/DFOI/	DOMINION GROUP INC	FOI DAILY LOG 12/2-6/13
2014-254	01/13/2014 02/11/2014	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 12/23-27/13
2014-255	01/13/2014 02/11/2014	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 12/16-20/13

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2014-256	01/13/2014 02/11/2014	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 12/16-20/13
2014-257	01/13/2014 02/11/2014	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 12/23-27/13
2014-258	01/13/2014 02/11/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 12/23-27/13
2014-259	01/13/2014 02/11/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 12/23-27/13
2014-260	01/13/2014 02/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	Q VANBENSCHOTEN INTERTEK TESTING SERVICES NA INC	QMEDIC - K121552 COMM 5/1/13 TO 6/20/13
2014-261	01/13/2014 02/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	SANDY MASTROIANNI ITC	DIRECTDRAW SUPERSERUM-MINI - K935081
2014-262	01/13/2014 02/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DOTT GIUSEPPE G MIGLIO MIPHARM SPA	MIPHARM SPA, MILANO, ITALY - QAP
2014-263	01/13/2014 02/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SUZANNE D JENSEN KLEINFELD KAPLAN & BECKER	SOVALDI (SOFOSBUVIR) TABS - RVWS, APRVL
2014-264	01/13/2014 02/11/2014	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	WONDA SOMERVILLE AMERICAN RED CROSS SOUTHERN CALIFORNIA REGION	RED CROSS SOUTHERN CALIFORNIA REGION BLOOD SERVICES, PASADENA DONOR, CENTER, POMONA FACILITY, WEST LOS ANGELES, ETC - EIRS
2014-265	01/13/2014 02/11/2014	FDA/OC/OES/DFOI/	CanReg, Inc.	DAILY LOG 12/19-13/13
2014-266	01/13/2014 02/11/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 12/2-6/13
2014-267	01/13/2014 02/11/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 12/16-20/13
2014-268	01/13/2014 02/11/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	J DAVID STANDEFFER STANDEFFER & HARBIN LL,P	INVACARE - POWER WHEELCHAIR RECALLS, INCIDENT RPT, EVALUATIONS & ANALYSIS, ETC

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2014-269	01/13/2014 02/11/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 11/25-29/13
2014-270	01/13/2014 02/11/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 12/23-27/13
2014-271	01/13/2014 02/11/2014	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 12/9-13/13
2014-272	01/13/2014 02/11/2014	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 12/2-6/13
2014-273	01/13/2014 02/11/2014	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 11/25-29/13
2014-274	01/13/2014 02/11/2014	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY CLOSED LOG 12/23-27/13
2014-275	01/13/2014 02/11/2014	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 12/16-20/13
2014-276	01/13/2014 02/11/2014	FDA/OFVM/CFSAN/OCD/EOS/	MITZI NG CLARK Keller and Heckman LLP	FCN 239
2014-277	01/13/2014 02/11/2014	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	DAILY LOG 11/25-29/13
2014-278	01/13/2014 02/11/2014	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	DAILY LOG 12/2-6/13
2014-279	01/13/2014 02/11/2014	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	DAILY LOG 12/9-13/13
2014-280	01/13/2014 02/11/2014	FDA/OC/OES/DFOI/	SHELLY GARG SANDLER, TRAVIS & ROSENBERG, P.A.	TOWNSEND FARMS - ORGANIC ANTIOXIDANT BLEND PROD HEPATITIS A OUTBREAK, RPT, LABS, MFG, ETC 1/13 TO PRESENT
2014-281	01/13/2014 02/11/2014	OC/CVM/OCD/	MICHAEL HAYES MONTGOMERY MCCracken WALKER ET AL	ELANCO ANIMAL HEALTH (ELI LILLY & CO) - OPTAFLEXX (RACTOPAMINE HCL) NADA 141-221 AERS
2014-282	01/13/2014 02/11/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 12/9-13/13

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2014-283	01/13/2014 02/11/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 11/25-29/13
2014-284	01/13/2014 02/11/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 12/23-27/13
2014-285	01/13/2014 02/11/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 12/23-27/13
2014-286	01/13/2014 02/11/2014	FDA/OC/OES/DFOI/	DAVID MacFARLAND FDA REVIEW/FDA WEBVIEW	DAILY CLOSED LOG 12/16-20/13
2014-287	01/13/2014 02/11/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY CLOSED LOG 11/25-29/13
2014-288	01/13/2014 02/11/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 12/23-27/13
2014-289	01/13/2014 02/11/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 12/9-13/13
2014-290	01/13/2014 02/11/2014	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 12/9-13/13
2014-291	01/13/2014 02/11/2014	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 11/25-29/13
2014-292	01/13/2014 02/11/2014	FDA/OC/OES/DFOI/	GLADYS B. TONKIN Center for Regulatory Services, Inc.	DAILY LOG 11/25-29/13
2014-293	01/13/2014 02/11/2014	FDA/OC/OES/DFOI/	GLADYS B. TONKIN Center for Regulatory Services, Inc.	DAILY CLOSED LOG 12/9-13/13
2014-294	01/13/2014 02/11/2014	FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA REQUEST LOG 01/06/2014 - 01/10/2014
2014-295	01/14/2014 02/12/2014	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Nate Jones WAGSTAFF & CARTMELL LLP	DR BRIAN A FEAGINS - 483, CORR 01/03/2001 - 12/31/2003 (CERTIFIED)
2014-296	01/14/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Jennifer Moore	LANHAM FARM, CASEY COUNTY, KENTUCKY - EIR EXHIBITS, ATTACHMENTS 01/01/2013 - 01/01/2014

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	02/12/2014		Regard Law Group	
2014-297	01/14/2014 02/12/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Robert Fortner Slate	HERCEPTIN - RECORDS FROM 2006 MEDICAL REVIEW
2014-298	01/14/2014 02/12/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Williard Shanken MD Williard J Shanken MD	ADHD MEDICATION - AERS
2014-299	01/14/2014 02/12/2014	FDA/OFVM/CFSAN/OCD/EOS/	Brian MacFarland Brian MacFarland	LIFEVANTAGE - MARKETING REVIEW FOR PROTANDIM 06/06/2013 - 01/10/2014
2014-300	01/14/2014 02/12/2014	FDA/OC/OCC/	Dinesh S Thakur Dinesh S Thakur	LETTER FROM CARMEN SHEPARD TO RALPH TYLER AND KEITH WEBBER RE RANBAXY 03/01/2011 - 04/01/2011
2014-301	01/14/2014 03/20/2014	FDA/OGROP/ORR/SW-FO/DEN- DO/DEN-CB/	Sam May MAY, SAMUEL	AMGEN, COLORADO - EIR, 483, CORR 01/01/2005 - 12/31/2014
2014-302	01/14/2014 02/12/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michele Sinoway LACHMAN CONSULTANT SERVICES, INC.	ANDA 079046 - SBA
2014-303	01/14/2014 02/12/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michele Sinoway LACHMAN CONSULTANT SERVICES, INC.	ANDA 200822 - SBA
2014-304	01/14/2014 02/12/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michele Sinoway LACHMAN CONSULTANT SERVICES, INC.	ANDA 079087 - SBA
2014-305	01/14/2014 02/12/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Adrienne E Faerber, PhD Dartmouth Inst. Cent. For Med. Media.	SEROQUEL XR (QUETIAPINE) 022047 S 6, 7, 8 ETC
2014-306	01/14/2014	FDA/OFVM/CFSAN/OCD/EOS/	Joshua A. Malamud	FW BRYCE, IAN MOORES - FOOD FACILITY REGISTRATION

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	02/12/2014		Hyman, Phelps & McNamara P.C.	AGENT
2014-307	01/14/2014 02/12/2014	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	SE TOBACCO ORDERS
2014-308	01/14/2014 02/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kofi Aninakwa Sirona Dental Systems, Inc.	K122065
2014-309	01/14/2014 02/12/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michele Sinoway LACHMAN CONSULTANT SERVICES, INC.	NDA 202880
2014-310	01/14/2014 02/12/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 61621
2014-311	01/14/2014 02/12/2014	FDA/OMPT/CTP/OD/	Lynn Walsh Scripps	PROPOSED RULES RE E-CIGARETTE DEFINITION
2014-312	01/14/2014 02/12/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Darshan Mehta ET Now	RANBAXY TOANSA, PUNJAB, INDIA - 483 01/11/2014
2014-313	01/14/2014 02/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	Mary Ann Greenawalt Creating Compliance	K081060
2014-314	01/14/2014 02/12/2014	FDA/OFVM/CFSAN/OCD/EOS/	Valentina Potienko Europharma US	New Dietary Ingredient (NDI) Notification
2014-315	01/14/2014 02/12/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	Closed FOIA REQUESTS 11/25-29/13
2014-316	01/14/2014 02/12/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 12/02-06/13
2014-317	01/14/2014 02/12/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESRS 12/09-13/13
2014-318	01/14/2014 02/12/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 12/16-20/13
2014-319	01/14/2014 02/12/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW &	CLOSED FOIA REQUESTS 11/25-29/13

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			BUSINESS	
2014-320	01/14/2014 02/12/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 12/2-6/13
2014-321	01/14/2014 02/12/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 12/9-13/13
2014-322	01/14/2014 02/12/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 12/16-20/13
2014-323	01/14/2014 02/12/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 11/25-29/13
2014-324	01/14/2014 02/12/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 12/2-6/13
2014-325	01/14/2014 02/12/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 12/9-13/13
2014-326	01/14/2014 02/12/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHAMP CanReg, Inc.	CLOSED FOIA REQUESTS 12/16-20/13
2014-327	01/14/2014 02/12/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 11/25-29/13
2014-328	01/14/2014 02/12/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 12/03-06/13
2014-329	01/14/2014 02/12/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 12/09-13/13
2014-330	01/14/2014 02/12/2014	FDA/OC/OES/DFOI/	LLAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 12/16-20/13
2014-331	01/14/2014 02/12/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	LEXAPRO - CMLNPTS
2014-332	01/14/2014 02/12/2014	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 11/25-29/13
2014-333	01/14/2014 02/12/2014	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 12/2-6/13

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2014-334	01/14/2014 02/12/2014	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 12/9-13/13
2014-335	01/14/2014 02/12/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	VICTORIA SCOTT Hemispherx Biopharma, Inc	ANIMAL RULE - PROD APRVL, HUMAN DATA, ANIMAL DATA, ETC
2014-336	01/14/2014 02/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	TWEED HANUSEK ABBOTT DIABETES CARE INC	FREESTYLE LITE TEST STRIP, OMNIPOD METER - RPTS
2014-337	01/14/2014 02/12/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	A C THOMPSON PROPUBLICA	NUDEXTA (DEXTROMETHORPHAN AND QUINIDINE) - ISRS 7958308, 7997614, 8022468, ETC
2014-338	01/14/2014 02/12/2014	FDA/OC/OES/DFOI/ FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	ANDREW G KIMBALL DICKIE MCCAMEY & CHILCOTE	BOSTON SALADS AND PROVISIONS COMPANY INC - READY-TO-EAT CHICKEN SALAD & SEAFOOD SALAD RECALL RECS, STUDIES, TEST RESULTS, ETC
2014-339	01/14/2014 04/10/2014	FDA/OFVM/CFSAN/OCD/EOS/	CARRIE L TEETER Keller and Heckman LLP	CIBA-GEIGY CORP - OXIDIZED BIS(HYDROGENATED TALLOW ALKYL)AMINES FAP 3B4410
2014-340	01/14/2014 02/12/2014	FDA/OFVM/CFSAN/OCD/EOS/	CARRIE L TEETER Keller and Heckman LLP	CIBA SPECIALTY CHEMICALS CORP - FCN 53
2014-341	01/14/2014 02/12/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	S ALBERT EDWARDS, PHARM D	ORTHO-MCNEIL-JANSEN PHARMS - LEVAQUIN SAFTEY LBLG
2014-342	01/14/2014 02/12/2014	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	GARY GEMME HARVEST FARM	KALE - PESTICIDE RESIDUE TEST RESULTS
2014-343	01/14/2014 02/12/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LAKSHMAN, NARAYAN	RANBAXY, PUNJAB, INDIA - 483, RECS
2014-344	01/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	JENNIFER LEVITZ	SMITH & NEPHEW INC - TRUCLEAR MORCELLATOR SYS

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	02/12/2014	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	WALL STREET JOURNAL	K110038; ETHICON INC - GYNECARE LAPAROSCOPIC MORCELLATOR K993801; COOK UROLOGICAL INC - COOK TISSUE MORCELLATOR, ETC
2014-345	01/14/2014 02/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	CARROLL L MARTIN UNITED STATES ENDOSCOPY GROUP INC	K132776
2014-346	01/14/2014 02/12/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DR REENA HARJAI APCER Pharma Solutions, Inc	TREANDA (BENDAMUSTINE HCL) INJ NDA 22-249/S015 SBA
2014-347	01/14/2014 02/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	LORI A FITTON Navilyst Medical, Inc	MEDRAD INC - MEDRAD STELLANT CT INJECTOR SYS WITH P3T CARDIAC K082905
2014-348	01/14/2014 02/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	LORI A FITTON Navilyst Medical, Inc	SULZER CARBOMEDICS INC - ANNULOFLIES ANNUOPLASTY SYS K023185
2014-349	01/14/2014 02/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	LORI A FITTON Navilyst Medical, Inc	MALLINCKRODT INC - OPTIVANTAGE DH INJECTOR SYS WITH ENHANCED COMMUNICATION K063503
2014-350	01/14/2014 02/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	LORI A FITTON Navilyst Medical, Inc	NEMOTO KYORINDO CO LTD - CONTRAST DELIVERY SYS DUAL SHOT ALPHA K062168
2014-351	01/14/2014 02/12/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	LORI A FITTON Navilyst Medical, Inc	NEMOTO KYORINDO CO LTD - CONTRAST MEDIUM AUTOMATIC INJECTOR K091734
2014-352	01/14/2014 02/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	LORI A FITTON Navilyst Medical, Inc	MEDRAD INC - MEDRAD STELLANT CT INJECTOR SYS WITH P3T K072886
2014-353	01/14/2014 02/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	LORI A FITTON Navilyst Medical, Inc	MEDRAD INC - MEDRAD AVANTA FLUID MANAGEMENT INJ SYS K050456
2014-354	01/14/2014 02/12/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tushar Maloo Kora Capital LLC	RANBAXY, PUNJAB, INDIA - 483 (01/01/2011 - 01/14/2014)
2014-355	01/14/2014 02/12/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rupali mukherjee The times of India	RANBAXY TOANSA - 483 01/01/2011 - 01/14/2014

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2014-356	01/14/2014 02/12/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sumeet Chatterjee THOMSON REUTERS	RANBAXY, TOANSA PUNJAB INDIA - 483 12/02/2013 - 01/14/2014
2014-357	01/14/2014 02/12/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ketaki Gokhale BLOOMBERG NEWS	WOCKHARDT LTD, INDIA - 483, EIR 08/01/2013 - 01/14/2014
2014-358	01/14/2014 02/12/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dheeresh Pathak Pathak, Dheeresh	INDOCO REMEDIES, INDIA - 483 01/02/2013 - 01/14/2014
2014-359	01/14/2014 02/12/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ketaki Gokhale BLOOMBERG NEWS	RANBAXY - 483, EIR 10/01/2013 - 01/14/2014
2014-360	01/14/2014 04/14/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Geoffrey R. Chambers Geoffrey R. Chambers	BREAKTHROUGH THERAPY DESIGNATION 01/02/2013 - 01/14/2014
2014-361	01/14/2014 02/12/2014	FDA/OGROP/ORAP/PA-FO/SAN- DO/SAN-CB/	Robert J. Bingle Bingle, Robert J	ABBOTT DIABETES CARE - COMPLAINTS RE FREESTYLE LITE BLOOD GLUCOSE TEST STRIPS
2014-362	01/15/2014 02/13/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Matthew P. Teague Beasley, Allen, Crow, Methvin, Portis & Miles, P.C	ANDROGEL, ADRODERM, AXIRON ETC - READILY AVAILABLE RECS
2014-363	01/15/2014 02/13/2014	FDA/OC/OES/DFOI/	Jaime Vassallo LEXISNEXIS COURTLINK INC	2012-7291
2014-364	01/15/2014 02/13/2014	OC/CVM/OCD/	Chad Risley Berg+Schmidt America, LLC	CONJUGATED LINOLEIC ACID DATA

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2014-365	01/15/2014 02/13/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	sue sladen SGS Life Science Services	BLUE STREAM LABORATORIES, CAMBRIDGE, MA - 483 01/01/2011 - 01/01/2014
2014-366	01/15/2014 02/13/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Richard Mannarino Marulli, Lindenbaum & Tomaszewski, LLP	CERTIFIED DRUG RECS
2014-367	01/15/2014 02/13/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Richard Mannarino Marulli, Lindenbaum & Tomaszewski, LLP	IMURAN - CERTIFIED RECS
2014-368	01/15/2014 02/13/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Richard Mannarino Marulli, Lindenbaum & Tomaszewski, LLP	PLAQUENIL - CERTIFIED RECS
2014-369	01/15/2014 03/05/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDRH/OCER/DFOI/	Elizabeth Stump Precision for Medicine	VIOLATIONS OF INFORMED CONSENT PROVISIONS RE USE OF RESIDUAL HUMAN TISSUE SPECIMENS - UNTITLED LETTERS
2014-370	01/15/2014 02/13/2014	FDA/OMPT/CDRH/OCER/DFOI/	Evelyn De La Vega Bausch and Lomb Inc	P980040 S039
2014-371	01/15/2014 02/13/2014	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	TOBACCO ESTABLISHMENT REGISTRATION AND PRODUCT LISTINGS 2013
2014-372	01/15/2014 02/13/2014	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Stephanie Batliner BAYER HEALTHCARE LLC	BAYER HEALTHCARE ANIMAL HEALTH, ST JOSEPH, MO - EIR 08/02/2013 - 01/14/2014
2014-373	01/15/2014 02/13/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rich Laguna iRhythm Technologies, Inc.	K131045
2014-374	01/15/2014 02/13/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Cecile Schilis-Gallego Columbia Journalism School	YAZ, YASMIN, OCELLA ETC - ISR 09/01/2012 - 12/31/2012
2014-375	01/15/2014 02/13/2014	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Robert J. Bingle Bingle, Robert J	ABBOTT DIABETES CARE, INC - EIR, 483, CAPA ETC AUGUST 2009 TO PRESENT
2014-376	01/15/2014 02/13/2014	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OC/OES/DFOI/	Robert J. Bingle Bingle, Robert J	ABBOTT DIABETES CARE, INC FREESTYLE LITE BLOOD GLUCOSE TEST STRIPS - TESTING RECS AUGUST 2009 TO PRESENT

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/		
2014-377	01/15/2014 02/13/2014	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Robert J. Bingle Bingle, Robert J	ABBOTT DIABETES CARE INC FREESTYLE LITE BLOOD GLUCOSE TEST STRIPS - CONSUMER COMPLAINTS AUGUST 2009 TO PRESENT
2014-378	01/15/2014 02/13/2014	FDA/OC/OES/DDM/	Robert J. Bingle Bingle, Robert J	ABBOTT DIABETES CARE INC FREESTYLE LITE BLOOD GLUCOSE TEST STRIPS - ADVISORY COMMITTEE RECS AUGUST 2009 TO PRESENT
2014-379	01/15/2014 02/13/2014	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Robert J. Bingle Bingle, Robert J	ABBOTT DIABETES CARE INC FREESTYLE LITE BLOOD GLUCOSE TEST STRIPS USED WITH OMNIPOD INSULIN MANAGEMENT SYSTEM - CONSUMER COMPLAINTS AUGUST 2009 TO PRESENT
2014-380	01/15/2014 02/13/2014	FDA/OC/OES/DDM/	Robert J. Bingle Bingle, Robert J	ABBOTT DIABETES CARE INC FREESTYLE LITE BLOOD GLUCOSE TEST STRIPS BUILT INTO OMNIPOD INSULIN MANAGEMENT SYSTEM -ADVISORY COMMITTEE RECS AUGUST 2009 TO PRESENT
2014-381	01/15/2014 02/13/2014	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Robert J. Bingle Bingle, Robert J	ABBOTT DIABETES CARE INC FREESTYLE LITE BLOOD GLUCOSE TEST STRIPS BUILT INTO OMNIPOD INSULIN MANAGEMENT SYSTEM - CONSUMER COMPLAINTS AUGUST 2009 TO PRESENT
2014-382	01/15/2014 02/13/2014	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Robert J. Bingle Bingle, Robert J	ABBOTT DIABETES CARE INC FREESTYLE LITE BLOOD GLUCOSE TEST STRIPS BUILT ONTO OMNIPOD - EIR, 483, CAPA ETC 2009 TO PRESENT
2014-383	01/15/2014 02/13/2014	FDA/OC/OES/DFOI/ OC/ORA/OE/ OC/ORA/OE/	Josh Long, Legal Editor Virgo Publishing / Natural Products Insider	LIST OF DIETARY SUPPLEMENT FIRMS INSPECTED FY 2013

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2014-384	01/15/2014 02/13/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ARCURI, KAREN	ISRS 8927903, 8814255, 8809302 ETC
2014-385	01/15/2014 02/13/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CORNELSON HELTON MD, SHARLA	ALLERGAN - BOTOX AER 4/12 TO PRESENT
2014-386	01/15/2014 02/13/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/NE-FO/NWE- DO/NWE-CB/	Doe J	SPL 80503 - KALE, TEST RESULTS
2014-387	01/15/2014 02/13/2014	FDA/OC/OES/DFOI/ FDA/OO/OHR/ OC/ORO/ OC/ORO/	MASON, KEITH	INDIVIDUAL RECS
2014-388	01/15/2014 03/10/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/SEA- DO/SEA-CB/	VINCENT RODRIGUEZ AMCO INSURANCE CO	CMPLNT 135420
2014-389	01/15/2014 02/13/2014	FDA/OC/OES/DFOI/	NICHOLAS A. KAMPARS DAVIS WRIGHT TREMAINE LLP	HEPATITIS OUTBREAK - TOWNSEND FARMS CA, HI, NV ETC
2014-390	01/15/2014 02/13/2014	FDA/OC/OES/DFOI/ OC/CVM/OCD/	PHONG L. TRAN ROBBINS GELLER ET AL	DOG JERKY TREATS - NESTLE PURINA PETCARE CO, CHINA INVESTIGATIONS
2014-391	01/15/2014 02/13/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/ FDA/OGROP/ORO/NE-FO/NYK- DO/NYK-DCB/ FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORO/SE-FO/FLA- DO/FLA-CB/	THOMAS C. GRAHAM SIEGEL YUEN ET AL	OCEAN PIONEER FOOD SDN BHD, MALAYSIA - SHRIMP TESTING, CMPLNTS, INVESTIGATIONS RECS, ETC 2011 TO 2013
2014-392	01/15/2014 02/13/2014	FDA/OC/OES/DFOI/	MARGO E. BROEHL MARGO E BROEHL ATTORNEY	CORR BETWEEN CMS AND CO DEPT OF HEALTH CARE POLICY & FINANCING RE APRVL OF STANDARDS FOR

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			AT LAW	MEDICAL DVCS
2014-393	01/16/2014 02/14/2014	FDA/OC/OES/DFOI/ FDA/OGROP/ORPA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	Pam Williams Williams, Pam	HOSPIRA - 483, WARNING LETTER 03/02/2013 - 01/02/2014
2014-394	01/16/2014 02/14/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Peter Mu Mu, Peter	NDA 21743 S018
2014-395	01/16/2014 02/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	Michael Malton personal	APTERYX INC XRAYVISION SOFTWARE 510K RECS
2014-396	01/16/2014 02/14/2014	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	WALTER E CHALKLEY THOMSON REUTERS	BARR LABORATORIES INC, (TEVA), FOREST, VA - EIRS, 483S, CO RESP 8/12-23/13
2014-397	01/16/2014 02/14/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	WALTER E CHALKLEY THOMSON REUTERS	BAXTER PHARMACEUTICAL SOLUTIONS LLC, BLOOMINGTON, IN - EIRS, 483S, CO RESP 5/20-24/13
2014-398	01/16/2014 02/14/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	WALTER E CHALKLEY THOMSON REUTERS	CARACO PHARMACEUTICAL LABORATORIES LTD, DETROIT, MI - EIRS, 483S, CO RESP 5/21-30/13
2014-399	01/16/2014 02/14/2014	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	CARDINAL HEALTH, GLENDALE HEIGHTS, IL - EIRS, 483S, CO RESP 11/14/13
2014-400	01/16/2014 02/14/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	WALTER E CHALKLEY THOMSON REUTERS	ELI LILLY & CO, INDIANAPOLIS, IN - EIRS, 483S, CO RESP 4/19/13
2014-401	01/16/2014 02/14/2014	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	GENZYME (SANOFI CO), LYNNWOOD, WA - EIRS, 483S, CO RESP 5/20-24/13
2014-402	01/16/2014	FDA/OGROP/ORASE-FO/FLA-	WALTER E CHALKLEY	IVAX PHARMACEUTICALS INC, DORAL, FL - EIRS, 483S, CO

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	02/14/2014	DO/FLA-CB/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	THOMSON REUTERS	RESP 6/6/13
2014-403	01/16/2014 02/14/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	YUNG SHIN PHARMACEUTICAL INDUSTRY CO LTD, TACHIA, TAIWAN - EIRS, 483S, CO RESP 4/30/12
2014-404	01/16/2014 02/14/2014	FDA/OGROP/ORACE-FO/CHI- DO/CHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	FRESENIUS KABI USA LLC, MELROSE PARK, IL - EIRS, 483S, CO RESP 11/20/12
2014-405	01/16/2014 02/14/2014	FDA/OGROP/ORASE-FO/SJN- DO/SJN-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	VWR ADVANCED INSTRUMENTS LLC, MANATI, PR - EIRS, 483S, CO RESP 4/3/12
2014-406	01/16/2014 02/14/2014	FDA/OGROP/ORACE-FO/CIN- DO/CIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	TEVA WOMENS HEALTH INC, CINCINNATI, OH - EIRS, 483S, CO RESP 6/4/12
2014-407	01/16/2014 02/14/2014	FDA/OGROP/ORASE-FO/ATL- DO/ATL-CB/	WALTER E CHALKLEY THOMSON REUTERS	SYNTHON PHARMACEUTICALS INC, RESEARCH TRIANGLE PARK, NC - EIRS, 483S, CO RESP 5/18/12
2014-408	01/16/2014 02/14/2014	FDA/OGROP/ORASW-FO/KAN- DO/KAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	SIGMA-ALDRICH MFG, LLC, SAINT LOUIS, MO - EIRS, 483S, CO RESP 6/18/12
2014-409	01/16/2014 02/14/2014	FDA/OGROP/ORACE-FO/DET- DO/DET-CB/	WALTER E CHALKLEY THOMSON REUTERS	PHARMACIA & UPJOHN LLC, KALAMAZOO, MI - EIRS, 483S, CO RESP 8/29/12
2014-410	01/16/2014 02/14/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	OTSUKA PHARMACEUTICAL CO LTD, TOKUSHIMA, JAPAN - EIRS, 483S, CO RESP 8/2/12
2014-411	01/16/2014 02/14/2014	FDA/OGROP/ORACE-FO/BLT- DO/BLT-CB/	WALTER E CHALKLEY THOMSON REUTERS	MYLAN PHARMACEUTICALS INC, MORGANTOWN, WV - EIRS, 483S, CO RESP 2/2/12
2014-412	01/16/2014 02/14/2014	FDA/OGROP/ORAPA-FO/SEA- DO/SEA-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	LINCARE INC, NEWPORT, OR - EIRS, 483S, CO RESP 6/1/12
2014-413	01/16/2014 02/14/2014	FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	BRACCO DIAGNOSTICS INC, EAST PRINCETON, NJ - EIRS, 483S, CO RESP 7/11/13
2014-414	01/16/2014 02/14/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	MERCK SHARP & DOHME LTD, SINGAPORE - EIRS, 483S, CO RESP 6/29/09-7/3/09

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2014-415	01/16/2014 02/14/2014	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ OC/ORA/ OC/ORA/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	FVS HOLDINGS (GREEN VALLEY DRUGS), HENDERSON, NV - EIRS, 483S, CO RESP 3/11-15/13
2014-416	01/16/2014 02/14/2014	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	WALTER E CHALKLEY THOMSON REUTERS	SREEDHAR SAMUDRALA MD, FRANKLIN, TN - EIRS, 483S, CO RESP 3/12-28/13
2014-417	01/16/2014 02/14/2014	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	WALTER E CHALKLEY THOMSON REUTERS	LONZA BIOLOGICS INC, PORTSMOUTH, NH - EIRS, 483S, CO RESP 9/30/13
2014-418	01/16/2014 02/14/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	SANDOZ CANADA INC, BOUCHERVILLE, CANADA - EIRS, 483S, CO RESP 10/22/13
2014-419	01/16/2014 03/06/2014	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	AMPAC FINE CHEMICALS LLC, RANCHO CORDOVA, CA - EIRS, 483S, CO RESP 8/12-15/13
2014-420	01/16/2014 02/14/2014	OC/ORA/ OC/ORA/	DAVID P SHELDON DAVID P SHELDON LAW OFCS	SUMMARY RPT FOR PREMIUM PAY APRVD FOR NWE-DO EMPLOYEES 1/08 TO PRESENT; INDIVIDUAL RECS
2014-421	01/16/2014 02/14/2014	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	JONATHAN R MACBRIDE CHARTWELL LAW OFCS LLP	ROYAL FOOD DISTRIBUTORS, HIGHTSTOWN, NJ - EIR 6/17/12, MEMO 7/12/12
2014-422	01/16/2014 02/14/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	CHRIS SZECHENYI ON POINT INVESTIGATIONS	OVASCIENCE - AUGMENT UNTITLED LTR, RECS
2014-423	01/16/2014 02/14/2014	FDA/OFVM/CFSAN/OCD/EOS/	LAURA ANDERSON ARKEMA INC	FCN 1255
2014-424	01/16/2014 02/14/2014	FDA/OFVM/CFSAN/OCD/EOS/	LAURA ANDERSON ARKEMA INC	FCN 1293
2014-425	01/16/2014 02/14/2014	FDA/OFVM/CFSAN/OCD/EOS/	Sontakay, Suresh	FCN 180
2014-426	01/16/2014 02/14/2014	OC/ORA/ OC/ORA/	SAMANTHA MYERS ROANOKE CLAIMS SERVICES	HANTHAR WINN LLC - ENTRY #KV425066088, #KV425056618 NOTICES FOR REQUEST OF INFORMATION (CF28, FDA NOTICE OF ACTION, CBP REDELIVER NOTICES (CF4647), ETC
2014-427	01/16/2014 02/14/2014	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	SUSAN CARUSO DANIEL J. HANNON & ASSOCS	NEW YORK GOURMET SALADS INC, BROOKLYN, NY 0 483S, NOTES PRIOR TO AND INCLUDING 4/10

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			INC	
2014-428	01/16/2014 02/14/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WILLIAM E GANNON JR MD CAPITAL CITY TECHNICAL CONSULTING	XELODA - ISRS 9496249, 8558257, 8504558, ETC
2014-429	01/16/2014 02/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	Wei-Lun Chen Joy Medical Devices Corp.	K032268, K110949
2014-430	01/16/2014 02/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	Wei-Lun Chen Joy Medical Devices Corp.	K110949, K110949
2014-431	01/16/2014 02/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	Lise Terkelsen Tonica Elektronik A/S	K122288
2014-432	01/16/2014 03/04/2014	OC/ORA/ OC/ORA/	Mark Prinz Registrar Corp	PRIOR NOTICE DATA 02/01/2013 - 02/28/2013
2014-433	01/16/2014 02/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	Amanda Babcock Stryker Sustainability Solutions	K121381
2014-434	01/16/2014 02/14/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Himani Chandna Gurtoo Hindustan Times Newspaper	RANBAXY TOANSA, PUNJAB, INDIA - MOST RECENT 483; WARNING LETTER, 483, IMPORT ALERT ETC 01/01/2008 - 01/15/2014
2014-435	01/16/2014 02/14/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Beulah Okonkwo Okonkwo, Beulah M	ANTI-DEPRESSANTS AVAILABLE 1983, 1984
2014-436	01/16/2014 02/14/2014	FDA/OMPT/OSMP/OCP/	Gerald Steel Gerald Steel PE	RFD130072, RFD130073, RFD 130074 - DESIGNATION RECS
2014-437	01/16/2014 02/14/2014	FDA/OMPT/OSMP/OCP/ FDA/OC/OCC/	Gerald Steel Gerald Steel PE	RFD130072, RFD130073, RFD130074 - EMAIL, CONTACT INFO ETC
2014-438	01/16/2014 02/14/2014	FDA/OC/OES/DDM/ FDA/OFVM/CFSSAN/OCD/EOS/	Steve Glickman Steve Glickman	Guidance on Labeling of Foods That Need Refrigeration by Consumers -Reference docs, comments, updates etc
2014-439	01/16/2014 02/14/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Chris Spofford MICROAIRE SURGICAL INSTRUMENTS	BK110040, BK080004
2014-440	01/16/2014	FDA/OGROP/ORACE-FO/DET- DO/DET-CB/	Senait Fisseha, MD, JD, FACLM	UNIVERSITY OF MICHIGAN CENTER FOR REPRODUCTIVE MEDICINE - EIR 09/01/2013 - 09/30/2013

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	02/14/2014		University of Michigan Center for Reproductive Medicine	
2014-441	01/17/2014 02/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	NDA 22465 S 010
2014-442	01/17/2014 02/18/2014	FDA/OMPT/CDRH/OCER/DFOI/	Joseph W. Moss, Jr. Erwin Bishop Capitano & Moss, PA	K090609
2014-443	01/17/2014 02/18/2014	FDA/OMPT/CDRH/OCER/DFOI/	Joseph W. Moss, Jr. Erwin Bishop Capitano & Moss, PA	K063026
2014-444	01/17/2014 02/18/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Kenneth Nip Eksigent LLC	K003543
2014-445	01/17/2014 02/18/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Robert Hoy Rensselaer Polytechnic Institute	K012751
2014-446	01/17/2014 02/18/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Benjamin Burgin Salix Pharmaceuticals, Inc.	NEXGEN PHARMA, IRVINE, CA - 483 MARCH 2013
2014-447	01/17/2014 02/18/2014	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Robert Lehmann M.D. Lehmann Eye Center	LEHMAN EYE CENTER, NACOGDOCHES, TX - 483 01/01/1998 - 06/01/1998
2014-448	01/17/2014 02/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/OSMP/OOPD/	Matt Medlin CATO RESEARCH	REVLIMID - ORPHAN DRUG RECS
2014-449	01/17/2014 02/18/2014	OC/ORA/ OC/ORA/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Doe J	INDIVIDUAL RECS
2014-450	01/17/2014 02/18/2014	OC/ORA/OCI/ OC/ORA/OCI/	John Woodley Trusted Technologies LLC	TRUSTED TECHNOLOGIES - IG REPORT
2014-451	01/17/2014 02/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Cecile Schilis-Gallego Columbia Journalism School	BAYER - COMMUNICATIONS WITH FDA RE YASMIN, YAZ
2014-452	01/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	Sandy Lee	GEN-PROBE LIFE SCIENCES LTD, SCOTLAND - WARNING

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	02/18/2014	OC/CVM/OCD/	B&H Consulting Services, Inc.	LETTER, 483 MOST RECENT
2014-453	01/17/2014 02/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Soma Das The Economic Times, The Times of India	RANBAXY TOANSA - 483 01/08/2014 - 01/13/2014
2014-454	01/17/2014 02/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Soma Das The Economic Times, The Times of India	FDA LETTER TO DAIICHI RE RANBAXY 01/15/2008 - 05/15/2009
2014-455	01/17/2014 02/18/2014	OC/ORO/ORM/ OC/ORO/ORM/	David Mangione Govzilla, Inc.	LISTING OF 483, INSPECTIONS ETC 01/01/2013 - 01/16/2014
2014-456	01/17/2014 02/18/2014	FDA/OMPT/CDRH/OCER/DFOI/	Cesar DelAguila DelAguila, Cesar	K120126
2014-457	01/17/2014 02/18/2014	FDA/OMPT/CDRH/OCER/DFOI/	Mark Barbieri Barbieri, Mark H	K122458
2014-458	01/17/2014 02/18/2014	FDA/OMPT/CDRH/OCER/DFOI/	Mark Barbieri Barbieri, Mark H	K132148
2014-459	01/17/2014 02/18/2014	FDA/OC/OES/DFOI/	SUSAN CARUSO DANIEL J. HANNON & ASSOCS INC	NEW YORK GOURMET SALADS, BROOKLYN, NY - 483
2014-460	01/17/2014 02/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	AVELOX - AER
2014-461	01/17/2014 02/18/2014	FDA/OC/OES/DFOI/	ROGER M. WHITE GEORGIA STATE UNIV COLLEGE OF BUSINESS	FORM 450 FILINGS OF EMPLOYEES & CONSULTANTS 1998 TO 2013
2014-462	01/17/2014 02/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	W.E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	JANSSEN PHARMS - TOPAMAX SPRINKLE (TOPIRAMATE) NDA 20-505/S046; 20-844/S038 APRVL
2014-463	01/17/2014 02/18/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	KRISTEN R. DAVENPORT GOODWIN PROCTER LLP	MIMEDX GROUP CO (SURGICAL BIOLOGICS) - UNTITLED LTR 8/28/13 CORR
2014-464	01/17/2014	FDA/OGROP/ORO/CE-FO/DET-	ELLEN RELKIN, Esq.	ZIMMER INC - ML TAPER HIP PROSTHESIS W/KINECTIV

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	02/18/2014	DO/DET-CB/ FDA/OMPT/CDRH/OCER/DFOI/	WEITZ & LUXEMBERG PC	TECHNOLOGY & CLS BREVIUS HIP STEM W/KINECTIV TECHNOLOGY MDRS, MEMOS, CLNCL STUDIES, ETC
2014-465	01/17/2014 02/18/2014	FDA/OC/OES/DFOI/	TIMOTHY V. MAHAR, JR. HELLENKAMP LAW FIRM	STARBUCKS COFFEE CO, SOMERVILLE, MA - CMLPLNT 4/23/10
2014-466	01/17/2014 02/18/2014	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DIANNE L. CHAMBERS HOGAN LOVELLS LLP	2013-10116
2014-467	01/17/2014 02/18/2014	FDA/OC/OES/	NORMAN M. GOLDFARB JOURNAL OF CLINICAL RESEARCH BEST PRACTICES	GCPQUESTIONS@OC.FDA.GOV - QUESTIONS & ANSWERS
2014-468	01/17/2014 02/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KATHRYN GRACE JORDAN PATIENT PROGRESS	OPIOID RECLASSIFICATION PRESS RELEASE 10/24/13
2014-469	01/17/2014 02/18/2014	FDA/OC/OES/DDM/	DAN LITVIN GARWIN GERSTEIN & FISHER LLP	ASTELLAS PHARMA US INC - PROGRAF (TACROLIMUS) DKT 1975N-0051
2014-470	01/17/2014 02/18/2014	FDA/OC/OES/DFOI/	BRADLEY R. BURTON BURTON LAW FIRM	INDIVIDUAL RECS
2014-471	01/17/2014 02/18/2014	FDA/OC/OES/DFOI/	GAYLE DOUGLAS HENINGER GARRISON DAVIS LLC	INDIVIDUAL RECS
2014-472	01/17/2014 02/18/2014	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	ERIN E. OBERG WILSON ELSE ET AL	NATURES NECTAR APPLE JUICE FROM CONCENTRATE; CRANBERRY APPLE JUICE COCTAIL RECALL F1245-2012; F1246-2012
2014-473	01/17/2014 02/18/2014	FDA/OC/OES/DFOI/	DOUG L. PHEIFER BOWMAN AND BROOKE LLP	BOLTHOUSE FARMS INC, WASHINGTON COUNTY, GA - CARROT JUICE BOTULISM INVESTIGATION
2014-474	01/17/2014 02/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WARD, JEANIE	ISRS 8816191, 8820937, 8821554
2014-475	01/21/2014 02/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	Elizabeth Stump Precision for Medicine	K123567, K123436
2014-476	01/21/2014 02/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K131649
2014-477	01/21/2014	FDA/OMPT/CBER/OCOD/DDOM/	Richard Mannarino	PREDNISONE - LABELING (CERTIFIED)

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	02/19/2014	ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Marulli, Lindenbaum & Tomaszewski, LLP	
2014-478	01/21/2014 02/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Adam Sheka University of Wisconsin School of Medicine and Public Health	LOPERAMIDE - NARRATIVE CASE REPORTS 6699430 7844310 7960652
2014-479	01/21/2014 02/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	NDA 203214 S 002
2014-480	01/21/2014 02/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K131649
2014-481	01/21/2014 02/19/2014	FDA/OC/OES/DFOI/	Robert King FDA NEWS	FOIA REQUEST LOG 1/13/2014 TO 1/17/2014
2014-482	01/21/2014 02/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Adrienne Faerber (new phone: 608.345.5380) Dartmouth Inst. Cent. For Med. Media.	NDA 202379 S 5
2014-483	01/21/2014 02/19/2014	FDA/OC/OES/DFOI/	Dean Gresham PAYNE MITCHELL LAW GROUP	INTUITIVE DA VINCI SURGICAL SYSTEM - ALL RECS 01/01/2010 - 01/17/2014
2014-484	01/21/2014 02/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	Martie Manno Angino & Rovner, P.C.	DA VINCI SURGICAL ROBOT DEVICE - TRAINING AND CREDENTIAL RECOMMENDATIONS 01/01/2013 - 01/20/2014
2014-485	01/21/2014 02/19/2014	FDA/OGROP/ORACE-FO/CHI- DO/CHI-CB/ FDA/OGROP/ORASW-FO/KAN- DO/KAN-CB/	Amanda Nerone Saving Sight	AMERICAN RED CROSS NATIONAL TESTING LABORATORY, ST LOUIS, MO - EIR, 483 01/01/2012 - 01/01/2014; AURORA AREA BLOOD BANK, AURORA, IL - EIR, 483 01/01/2012 - 01/01/2014
2014-486	01/21/2014 02/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joshua Gaynor CBS NEWS	RANBAXY - 483 01/01/2014 - 01/20/2014
2014-487	01/22/2014	FDA/OFVM/CFSAN/OCD/EOS/	Kim Carson	FCN 1224, FCN 1189

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	02/20/2014		EXPONENT, INC.	
2014-488	01/22/2014 02/20/2014	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Rachel Johnson FOI Services, Inc.	HOSPIRA, MCPHERSON, KS - MOST RECENT EIR
2014-489	01/22/2014 02/20/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tina Babos IPD ANALYTICS LLC	ANDA 091433 - FINAL APPROVAL LETTER
2014-490	01/22/2014 02/20/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Cathy Rosenbaum TriHealth - Bethesda North Hospital	OFIRMEV - ANNUAL AND PERIODIC REPORTS 12/06/2008 - 12/06/2013
2014-491	01/22/2014 02/20/2014	FDA/OMPT/CDRH/OCER/DFOI/	Lori Riley Lori Riley	ANIMAS VIBE - APPROVAL INFO
2014-492	01/22/2014 02/20/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Margaret Sestrom PFIZER	VENLAFAXINE 8282530, 8283301, 8286789 ETC
2014-493	01/22/2014 02/20/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Faryal Hasan Hyman, Phelps & McNamara P.C.	A list, by year, from 1984 to 2014, of all patents submitted to FDA for listing in FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations," including the date each patent was considered listed in such publication pursuant to 21 C.F.R. 314.53(d)(5) and the New Drug Application with respect to which such patent information was submitted.
2014-494	01/22/2014 02/20/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2047
2014-495	01/22/2014 02/20/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K132887
2014-496	01/22/2014 02/20/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Janaya Williams Aradigm Corporation	NDA 50718 - SBA
2014-497	01/22/2014 02/20/2014	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	Amanda Nerone Saving Sight	GIFT OF HOPE ORGAN AND TISSUE DONOR NETWORK, ITASCA, IL - 483, EIR 01/01/2012 - 01/01/2014
2014-498	01/22/2014 02/20/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Adrienne Faerber (new phone 608.345.5380)	HUMIA 125057 Supplements 114, 95, 62; Lyrica 021446 Supplements 18; Januvia 021995 Supplements (2, 3, 4, 6) and

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dartmouth Inst. Cent. For Med. Media.	(10, 11, 12, 14) - APPROVAL PACKAGES
2014-499	01/22/2014 02/20/2014	FDA/OMPT/CDRH/OCER/DFOI/	Wei-Lun Chen Joy Medical Devices Corp.	K091729
2014-500	01/22/2014 02/20/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Adrienne E Faerber new phone 608.345.5380 Dartmouth Inst. Cent. For Med. Media.	Prozac (fluoxetine) 018936; Prozac (fluoxetine) 018936 supplement 004; Prozac (fluoxetine) 018936 supplement 58 etc - APPROVAL RECS
2014-501	01/22/2014 02/20/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dheeresh Pathak Dheeresh Pathak	INDOCO REMEDIES, GOA, INDIA - 483 01/01/2005 - 12/22/2011
2014-502	01/22/2014 02/20/2014	FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/	Cathy Walker (for Scott De'Aeth) Aegerion Pharmaceuticals, Inc	EXOVA, SANTA FE SPRINGS, CA - EIR 01/01/2013 - 12/31/2013
2014-503	01/22/2014 02/20/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Katie Utehs KTVU-TV	NUVARING - AERS
2014-504	01/22/2014 02/20/2014	FDA/OMPT/CDRH/OCER/DFOI/	Karen Denny TECHLAB, Inc.	K121397
2014-505	01/22/2014 02/20/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Diane Duffey Habush Habush & Rottier S.C.	HOSPIRA LIDOCAINE HCI INJECTION , HOSPIRA 1% LIDOCAINE HCI INJECTION - AERS
2014-506	01/22/2014 05/09/2014	FDA/OFVM/CFSAN/OCD/EOS/	Katherine Blok Hoagland, Longo, Moran, Dunst & Doukas, LLP	ASBESTOS IN TALC
2014-507	01/22/2014 02/20/2014	FDA/OMPT/CDRH/OCER/DFOI/	Pavle Sedic LELO Inc.	K983045
2014-508	01/22/2014 02/20/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Brian Waldman ARENT FOX LLP	RENTSCHLER BIOTECHNOLOGIE GmbH - 483, EIR MOST RECENT

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-509	01/22/2014 02/20/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Charlotte Brennand Takeda Pharmaceuticals International Co.	PROFESSOR BRIGITTE DRENO, FRANCE - 483 4/2/98
2014-510	01/22/2014 02/20/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jennifer C. Smith-Parker BIOPHARM INSIGHT	OFIRMEV - MEDWATCH REPORTS
2014-511	01/22/2014 02/20/2014	FDA/OC/OES/DFOI/	Peter T. Anderson, Esq. ASHCRAFT & GEREL, LLP	FRESENIUS 2008 SERIES DIALYSIS MACHINES RECALL RECS 01/01/2010 - 01/17/2014
2014-512	01/22/2014 02/20/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ricki Linksman Linksman, Ricki	ZOMETA - AERS
2014-513	01/22/2014 03/19/2014	FDA/OC/OES/ FDA/OFVM/CFSAN/OCD/EOS/	Helena Bottemiller POLITICO	SAM KASS - EMAILS TO, FROM OR ABOUT 01/02/2013 - 01/20/2014
2014-514	01/23/2014 02/21/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/SEA- DO/SEA-CB/	Melanie Usher Usher, Melanie	INDIVIDUAL RECS
2014-515	01/23/2014 02/21/2014	FDA/OGROP/ORO/SE-FO/SJN- DO/SJN-CB/	Lily Tandjung Gilead Sciences Inc.	PFIZER, BARCELONETA, PR - 483 08/05/2013 - 08/20/2013
2014-516	01/23/2014 02/21/2014	FDA/OGROP/ORO/SE-FO/FLA- DO/FLA-CB/ FDA/OC/OES/DFOI/	Cindy Bolger Entin & Della Fera, P.A.	SOUTH FLORIDA BIOAVAILABILITY CLINIC, MIAMI, FL - INSPECTION REPORTS 01/01/2006 - 01/01/2008
2014-517	01/23/2014 02/21/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	AMY BURKHOLDER CBS NEWS	CELEXA - AERS
2014-518	01/23/2014 02/21/2014	FDA/OGROP/ORO/NE-FO/NYK- DO/NYK-DCB/	Biko Koenig Biko Koenig	BAKEWISE BRANDS, INC, MACEDON, NY - INSPECTION RECS 04/01/2011 - 07/01/2012
2014-519	01/23/2014 02/21/2014	FDA/OGROP/ORO/CE-FO/DET- DO/DET-CB/	Scott Hood General Mills, Inc.	G&G PEPPERS, GLASTON, IN - EIR, 483

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2014-520	01/23/2014 03/06/2014	FDA/OFVM/CFSAN/OCD/EOS/	Richard Taylor Taylor, Richard F.	CAP-7C0284
2014-521	01/23/2014 02/21/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Divya Seth Lampf, Lipkind Prupis and Petigrow	CORR BETWEEN FDA AND BEAUMONT HOSPITAL, ROYAL OAKS, MI RE OTHER SONIC GEL 01/01/2011 - 01/21/2014
2014-522	01/23/2014 02/21/2014	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Biko Koenig Biko Koenig	BAKEWISE BRANDS, INC, MACEDON, NY - INSPECTION RECS 01/01/2010 - 04/02/2013
2014-523	01/23/2014 02/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN C BROWNE Bernstein Litowitz Berger & Grosman LLP	ARIAD PHARMACEUTICALS INC - ICLUSIG (PONATINIB) IND APPL PROCESS, PRE-NDA PROCESS RECS
2014-524	01/23/2014 02/21/2014	FDA/OC/OES/DFOI/	ELENA HOWELL HOGAN LOVELLS US LLP	2013-9618
2014-525	01/23/2014 02/21/2014	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	CHERYL CANNON Needle & Ellenberg, P.A.	HOLLYWOOD DIAGNOSTICS CTR; NATIONAL NUCLEAR CTR, HOLLYWOOD, FL - EIRS 9/1./10 TO 10/1/10
2014-526	01/23/2014 02/21/2014	OC/ORACE/OCI/ OC/ORACE/OCI/	Doe J	INDIVIDUAL RECS
2014-527	01/23/2014 02/21/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	PATTI WALLER MARLER CLARK LLP, PS	GLASS ONION CATERING, RICHMOND, CA - READY TO EAT SALADS E COLI OUTBREAK INVESTIGATION RECS, LAB RESULTS, CORR, ETC 10/13 TO 11/13
2014-528	01/23/2014 02/21/2014	OC/ORACE/OCI/ OC/ORACE/OCI/ FDA/OO/OFBA/OAGS/	Doe J	INDIVIDUAL RECS
2014-529	01/23/2014 02/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PAMELA SHEPPARD TARO PHARMACEUTICALS USA INC	ACTAVIS MIDATLANTIC - IBUPROFEN ANDA 74-978 SBA, MOR, LBLG, ETC
2014-530	01/23/2014 02/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	PIERCE, G STANFORD	ATLAS ADJUSTING INSTRUMENT - K946258
2014-531	01/23/2014 02/21/2014	FDA/OC/OES/DDM/	Brown, Shawn	GENERAL HOSPITAL & PERSONAL USE DEVICES PANEL OPEN SESSION - TRANS, RECS 8/2/99
2014-532	01/23/2014 02/21/2014	OC/ORACE/ OC/ORACE/ FDA/OMPT/CDER/ORP/DIDP/	ANDREW S LEVINE DONOGHUE BARRETT ET AL	MARLBORO HOSPITAL, MARLBORO, MA - FILLINGS, FORMS, APPLS FOR REGISTRATION AS A COMPOUNDING PHARMACY, ETC

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2014-533	01/23/2014 02/21/2014	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	BENJAMIN L ENGLAND BENJAMIN L ENGLAND & ASSOCIATES LLC	HNC FOOD AMERICA - DESTRUCTION OF CRAWFISH CORR, RECS
2014-534	01/23/2014 02/21/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OC/OES/DFOI/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	BENJAMIN L ENGLAND BENJAMIN L ENGLAND & ASSOCIATES LLC	XIAMEN HAIDA CO LTD - ENTRY NUMBERS 112-0730373-2, ATM-1018779-6 RECS, CORR
2014-535	01/23/2014 02/21/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	HAMILTON, LEROY L	CDRH - OMB 0910-0138 FDA FORM 3429 CORR
2014-536	01/23/2014 03/24/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	KAREN A SHEPHERD PHD GE HEALTHCARE BIO-SCIENCES INC	SYNGEN INC - SYNGENX-1000 BOK120061
2014-537	01/23/2014 02/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TODD FEATHERS MUCKROCK NEWS	LAST 5 DRUGS DENIED FDA APRVL - RPT
2014-538	01/23/2014 02/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID LOHMAN MILLENNIUM MANAGEMENT LLC	AMAG PHARMS - FERAHEME (FERUMOXYTOL) AERS
2014-539	01/23/2014 02/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	DelAguila, Cesar	OVERTUBE BAROSENCE ENGOGASTRIC TUBE AND INTRODUCER BOUGIE K120126
2014-540	01/23/2014 02/21/2014	FDA/OC/OES/DFOI/	SMATHERS, JASON	FDA EMAILS CONTAINING THE WORD SMATHERS
2014-541	01/23/2014 02/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	RICK RUTHERFORD RUTHERFORD MEDDEV CONSULTING INC	HEINZ KURZ, DUSSLINGEN, GERMANY - EIR, 483, CORR 6/18-21/07
2014-542	01/23/2014 02/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	RICK RUTHERFORD RUTHERFORD MEDDEV CONSULTING INC	BUHLMANN LABORATORIES AG, SCHOENENBUCH, SWITZERLAND - EIR, 483, CORR 8/16-19/10
2014-543	01/23/2014	FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY	PARKE DAVIS - NEURONTIN (GABAPENTIN) NDA 20-

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	02/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	THOMSON REUTERS	235/S050, NDA 20-882/S0035, NDA 21-129/S033 APRVL RECS
2014-544	01/23/2014 02/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	PARKE DAVIS - NEURONTIN (GABAPENTIN) NDA 20-235/S043, NDA 20-882/S030, NDA 21-129/S029 APRVL RECS
2014-545	01/23/2014 02/21/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OCC/ FDA/OO/OFBA/OAGS/ FDA/OO/OHR/ OC/ORA/OCI/ OC/ORA/OCI/	JOHN H HNATIO ED PHD FoodQuestTQ LLC	FOODQUESTTQ - FOOD DEFENSE PLAN BUILDER, CARVER+SHOCK, FOOD DEFENCE MITIGATION STRATGIES DATABASE, ETC FDA DUPLCIATE SUMMARY TO DEVELOP, MARKET, EDUCATE USERS, ETC
2014-546	01/24/2014 02/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Madhusudana Reddy Subbireddy KVK Tech Inc.	LIMIT OF BENZOIC ACID IMPURITY IN RLD TENUATE FOR DIETHYLPROPION HYDROCHLORIDE TABLETS USP 25 ETC
2014-547	01/24/2014 02/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Yamil Hernandez Cerium Pharmaceuticals, Inc.	NDA 017861 - PACKAGE INSERT
2014-548	01/24/2014 02/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	Michael Capellan TriMed, Inc.	K0902890
2014-549	01/24/2014 02/24/2014	FDA/OC/OES/DFOI/ FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/ FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORA/CE-FO/PHI-	SHANE ALLEN NBC 5 KXAS-TV	LSG SKY CHEFS - EIR 1/12 TO 12/23/13

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		DO/PHI-CB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/		
2014-550	01/24/2014 02/24/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Elizabeth Jordan Capital Appeals Project	ALKALOIDS - 11 AERS
2014-551	01/24/2014 02/24/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lisa Girion LOS ANGELES TIMES	NDA 20553
2014-552	01/24/2014 02/24/2014	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	Alexandra Ajmo LIFE EXTENSION	NUTRITIONAL LABORATORIES INTERNATIONAL, MISSOULA, MT - EIR 01/01/2011 - 01/01/2014
2014-553	01/24/2014 02/24/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LEANNE USA WOCKHARDT USA INC	SUPERNUS PHARMS - TROKENDI XR (TOPIRAMATE) NDA 201635 CHEMISTRY RVW
2014-554	01/24/2014 02/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	MEGAN RUPCICH OMNITECH SYSTEMS INC	NOVASURE IMDEDANCE CONTROLLED ENDOMETRIAL ABLATION DVC SYS - P010013
2014-555	01/24/2014 02/24/2014	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	DEBBIE L. BUCKLES SHOOK HARDY & BACON LLP	APTUIT INC, KANSAS CITY, MO - INSP RECS 5/08 TO 1/11
2014-556	01/24/2014	FDA/OMPT/OSMP/OOPD/	SCOTT M. LASSMAN	TYVASO (TREPASTINIL INHALATIONAL) - ORPHAN DRUG

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	02/24/2014		KLEINFELD KAPLAN & BECKER	DESIGNATION APPL RVW
2014-557	01/24/2014 02/24/2014	FDA/OMPT/OSMP/OOPD/	SCOTT M. LASSMAN Kleinfeld Kaplan and Becker LLP	TYVASO (TREPASTINIL INHALATIONAL) NDA 22-387 - ORPHAN DRUG EXCLUSIVITY APRVL, RVWS
2014-558	01/24/2014 02/24/2014	FDA/OMPT/OSMP/OOPD/	SCOTT M. LASSMAN KLEINFELD KAPLAN & BECKER	ORENITRAM (TREPASTINIL) NDA 203-496 - ORPHAN DRUG EXCLUSIVITY APRVL, RVWS
2014-559	01/24/2014 02/24/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SCOTT M. LASSMAN KLEINFELD KAPLAN & BECKER	ORENITRAM (TREPASTINIL) NDA 203496 RVW, APRVL
2014-560	01/24/2014 02/24/2014	FDA/OMPT/OSMP/OOPD/	SCOTT M. LASSMAN KLEINFELD KAPLAN & BECKER	ORENITRAM (TREPASTINIL) NDA 203-496 - ORPHAN DRUG EXCLUSIVITY APRVL, RVWS
2014-561	01/24/2014 02/24/2014	FDA/OMPT/OSMP/OOPD/	SCOTT M. LASSMAN Kleinfeld, Kaplan Becker, LLP	REMODULIN (TREPASTINIL INJ) NDA 21-272 - ORPHAN DRUG EXCLUSIVITY APRVL, RVWS
2014-562	01/24/2014 02/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	STEPHANIE PHILBIN GOODWIN PROCTER LLP	MEDTRONIC CORE VALVE SYS - P130021
2014-563	01/24/2014 02/24/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	BENJAMIN L. ENGLAND, Esq. BENJAMIN L ENGLAND & ASSOCIATES LLC	GREENBRIER INTL INC - ENTRY NO UPS-8372655-7, LAB TESTING RPT
2014-564	01/24/2014 02/24/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	JOHN J. FOLEY SIMMONS BROWDER GIANARIS	COOK BIOTECH INC - SURGICAL MESH K980431, CMLPLNTS, MDRS
2014-565	01/24/2014 02/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	JOHN J. FOLEY SIMMONS BROWDER GIANARIS	COOK MEDCIAL INC - K992159 CMLPLNTS, MDRS
2014-566	01/24/2014 02/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	JOHN J. FOLEY SIMMONS BROWDER GIANARIS	COOK BIOTECH INC - ANTERIOR & POSTERIOR PELVIC FLOOR GRAFTS K13006 CMLPLNTS, MDRS
2014-567	01/24/2014 02/24/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	JOHN J. FOLEY SIMMONS BROWDER GIANARIS	SURGISIS - SURGISIS ES K062696 CMLPLNTS, AER
2014-568	01/24/2014 02/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	JOHN J. FOLEY SIMMONS BROWDER GIANARIS	COOK BIOTECH INC - SIS HERNIA REPAIR DVC K062697 CMLPLNTS, MDRS
2014-569	01/24/2014 02/24/2014	OC/ORO/ OC/ORO/	L. CULLEN MOORE RYMER MOORE JACKSON ETA	SPECIALTY COMPOUNDING LLC - INSP SMPL 824947, 792770, 825575 ETC
2014-570	01/27/2014 02/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Carol S. Kopf Carol S. Kopf	FLUORIDE - AERS

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2014-571	01/27/2014 02/25/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Doe J	INDIVIDUAL RECS
2014-572	01/27/2014 02/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Anthony Lenza Anthony Lenza	The official minutes from the Type C meeting with Provectus Biopharmaceuticals and FDA's Division of Oncology Products 2 on December 16, 2013
2014-573	01/27/2014 02/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	Emergo Group - Diane Sudduth Biovance	K032091
2014-574	01/27/2014 02/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jane Campbell Jane B. Campbell	ANDA 76350 - ORIGINAL APPROVAL LETTER
2014-575	01/27/2014 02/25/2014	FDA/OFVM/CFSAN/OCD/EOS/	Elizabeth Jordan Capital Appeals Project	EPHEDRA - AERS
2014-576	01/27/2014 02/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	Maneesh Gujrati Case Western Reserve University Biomedical Engineering Department	K870118
2014-577	01/27/2014 02/25/2014	OC/CVM/OCD/	Gregory Paul Morgan & Paul	NADA 140-989 - LABELS, MATERIAL SAFETY DATA SHEETS
2014-578	01/27/2014 02/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kiran Kumar Gande Appco Pharmaceuticals Corporation	NDA 009175 - SBA
2014-579	01/27/2014 02/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Matt Davidson Verrica Pharmaceuticals	CANTHARIDIN, CANTHARONE, CANTHACUR - AERS
2014-580	01/27/2014 02/25/2014	FDA/OFVM/CFSAN/OCD/EOS/	Jeff Sherman OL Products	confidentiality petition for a cosmetic trade secret ingredient that was successfully approved by the FDA in the last 12 years
2014-581	01/27/2014 02/25/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/	Robert Ross Robert Ross	Products made or marketed by Star Scientific, Inc. or Rock Creek Pharmaceuticals, Inc., including Anatabloc and CigRx

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2014-582	01/27/2014 02/25/2014	FDA/OGROP/ORO/CE-FO/CHI-DO/CHI-CB/	LeAnn Seidl-Kollmer Schwabe North America	PRIMROSE CANDY - EIR, 483 09/01/2010 - 01/01/2011
2014-583	01/27/2014 02/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	Dr. Diane Sudduth Biovance	K051255
2014-584	01/27/2014 02/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	Felicia Ruley Daval Inc.	K063671
2014-585	01/27/2014 02/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	Laura Boll Medovations Inc.	K091070
2014-586	01/27/2014 02/25/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ariel O Antezana NYU School of Medicine, Multiple Sclerosis Center	NATALIZUMAB - AERS
2014-587	01/27/2014 02/25/2014	FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECS
2014-588	01/27/2014 02/25/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kiran Kumar Gande Appco Pharmaceuticals Corporation	NDA 013217 - SBA
2014-589	01/27/2014 02/25/2014	FDA/OMPT/CTP/OD/	Stacy Ehrlich KLEINFELD KAPLAN AND BECKER	\Copies of all Requests for Exemption from Substantial Equivalence for tobacco products filed with the Center for Tobacco Products (CTP) to date and copies of all Refusal to Accept (RTA) letters for Exemption Requests for tobacco products issued by CTP to date

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2014-590	01/27/2014 02/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	Felicia Ruley Davol Inc.	K083467
2014-591	01/27/2014 02/25/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Chris Drane Chris Drane	Date Range: 12/18/2013 - 12/18/2013; Meeting minutes from Type C meeting with Provectus Biopharmaceuticals, Inc. (formerly Provectus Pharmaceuticals, Inc.
2014-592	01/27/2014 02/25/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kevin Balthaser Balthaser, Kevin J	Provectus Biopharmaceuticals, Inc. Type C meeting the FDA Division of Oncology Products 2 on December 16, 2013 Meeting Minutes.
2014-593	01/27/2014 02/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	Peter Dhaliwal Valley Cancer Medical Center	CORR BETWEEN CDRH AND SUN NUCLEAR CORPORATION RE CLASSIFICATION GUIDANCE, COMPLIANCE AND CLASSIFICATION APPROVAL PROCESS
2014-594	01/27/2014 02/25/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Anthony Stuckwisch Kremers Urban Pharmaceuticals Inc.	KREMERS URBAN PHARMACEUTICALS, SEYMOUR, IN - EIR
2014-595	01/27/2014 02/25/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Steven c Finley Hennefer Finley & Wood	SYMBIOS MEDICAL PRODUCTS LLC GOPUMPS - COMPLAINTS 03/01/2012 - 06/06/2013
2014-596	01/27/2014 02/25/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	Alex Thomason Thomason Law and Justice, PS	COCHLEAR NUCLEUS CI512 COCHLEAR IMPLANT - RECALL RECS
2014-597	01/27/2014 02/25/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Sonya Colberg TheStreetSweeper	UNILIFE - EIR, 483, CORR 01/01/2010 - 01/20/2014
2014-598	01/27/2014 02/25/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Michael Rabin Advanced Healthcare Technologies, Inc.	CAPILLUS LLC - WARNING LETTER CORR 09/20/2013 - 01/23/2014;
2014-599	01/27/2014 02/25/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Elena Prager The Wharton School, University of Pennsylvania	DRUG SHORTAGE RECS

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-600	01/27/2014 02/25/2014	FDA/OC/OES/DFOI/	KRISTI O SMEDLEY Center for Regulatory Services, Inc.	2013-4650
2014-601	01/27/2014 02/25/2014	FDA/OC/OES/DFOI/	KRISSTI O SMEDLEY Center for Regulatory Services, Inc.	2012-6460
2014-602	01/27/2014 02/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	WILLIAM A OLSON Center for Regulatory Services, Inc.	KASRL STORZ ENDOSCOPY-AMERICA INC - PHOTODYNAMIC DIAGNOSTIC D-LIGHT P050027
2014-603	01/27/2014 02/25/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	JOHN J FOLEY SIMMONS BROWDER GIANARIS	COOK BIOTECH INC - SURGISIS BIODESIGN TISSUE GRAFT K073391
2014-604	01/27/2014 02/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	JOHN J FOLEY SIMMONS BROWDER GIANARIS	(COOK BIOTECH INC; COOK MEDICAL INC, ETC) - STRATASIS URETHRAL SLING - K020654
2014-605	01/27/2014 02/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	JOHN J FOLEY SIMMONS BROWDER GIANARIS	COOK SBIOTECH INC; COOK MEDICAL INC, ETC - SURGISIS HERNIA REPAIR DVC K974540
2014-606	01/27/2014 02/25/2014	FDA/OMPT/CDRH/OCER/DFOI/ OC/ORAI/ OC/ORAI/	GONZALES, TODD	COMPLIANCE POLICY GUIDE (CPG) SEC 305.100 ACUPPUNTURE DVC & ACCESSORIES (CPG 7124.11) 6/15/76, 3/22/78, 10/1/80, ETC
2014-607	01/27/2014 02/25/2014	FDA/OFVM/CFSAN/OCD/EOS/	FRIEDMAN, ROBERT	BETTY CROCKER, STOUFFER'S, ORGAN, ETC - CAERS BOXED STARCHES 1969 TO PRESENT
2014-608	01/27/2014 02/25/2014	FDA/OFVM/CFSAN/OCD/EOS/	FRIEDMAN, ROBERT	POP-TARTS, NUTRI-GRAIN, PEDIASURE, ETC - CAERS 1969 TO PRESENT
2014-609	01/27/2014 02/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CARROLL, TRAVIS M	ROXICODONE 30 MG, OXYCONTIN 40 MG, XANAX 2 MG, ETC - AERS
2014-610	01/27/2014 02/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	STEVE RICHARDSON JHP Pharmaceuticals, LLC	DEXMEDETOMIDINE HCL INJ NDA 21-038 - FORMS 3542 & 3542A
2014-611	01/27/2014 02/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PALADINO #488269/590, BRIAN	NEURONTIN (GABAPENTIN) - AERS
2014-612	01/27/2014	FDA/OGROP/ORAI/CE-FO/NWJ-	MIKE RUSSELL	INTEGRATED ANALYTICAL LABORATORIES LLC,

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	02/25/2014	DO/NWJ-CB/	DELAVAL MANUFACTURING	RANDOLPH, NJ - EIRS, 483S PAST FIVE YRS
2014-613	01/27/2014 02/25/2014	FDA/OFVM/CFSAN/OCD/EOS/	CARRIE L TEETER Keller and Heckman LLP	FCN 897
2014-614	01/27/2014 02/25/2014	FDA/OC/OES/ FDA/OMPT/CTP/OD/	JORDEN, LYNN	CORR BWT FDA & MONICA WEHBY; MONICA WEHBY-GRAND; MONICA WEHBY-VOGT 1/90 TO PRESENT
2014-615	01/27/2014 02/25/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	INDIVIDUAL RECS
2014-616	01/27/2014 02/25/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	BRET SCHULTZ RT WHOLESALE, LLC	MONICA WENBY -VOGT - LTRS, RPTS, REQUESTS ETC 1/90 TO PRESENT
2014-617	01/27/2014 03/13/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	MARC D VITALE BROWNSTEIN VITALE & WEISS PC	INDIVIDUAL RECS
2014-618	01/27/2014 02/25/2014	FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA DISCLOSURE LOG 1/20/2014 - 1/24/2014
2014-619	01/27/2014 02/25/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Sarah MERCY MEDICAL CENTER	MCV4 VACCINE - AERS
2014-620	01/28/2014 02/26/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jason Russell HOGAN LOVELLS US LLP	K121590
2014-621	01/28/2014 02/26/2014	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	FCN 1020
2014-622	01/28/2014 02/26/2014	FDA/OC/OES/DFOI/	Kari L. Twaite BEVERIDGE & DIAMOND PC	CVM FOIA REQUESTS 12/20/13 TO PRESENT
2014-623	01/28/2014 02/26/2014	FDA/OFVM/CFSAN/OCD/EOS/	Jim Huang Bemis Company, Inc.	FCN 1041, 1265 - CHEMISTRY MEMORANDA
2014-624	01/28/2014 02/26/2014	FDA/OC/OES/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OO/OHR/	Doe J	INDIVIDUAL RECS
2014-625	01/28/2014 02/26/2014	FDA/OC/OES/DFOI/	Garret Locke Iowa Lions Eye Bank	FOIA REQUESTS - LAST THREE YEARS RE IOWA LIONS EYE BANK
2014-626	01/28/2014 02/26/2014	FDA/OMPT/CDRH/OCER/DFOI/	Laura Beil Men's Health magazine	INTUITIVE SURGICAL DA VINCI ROBOTIC SURGERY SYSTEM - MDR 01/01/2005 - 01/01/2014

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2014-627	01/28/2014 02/26/2014	FDA/OC/OES/DDM/	Chris Lahiff McDermott Will & Emery LLP	CONSUMERS UNION - CARAMEL COLORING AND 4-MEL PETITION 01/01/2014 - 01/31/2014
2014-628	01/28/2014 02/26/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nigel J McWilliam McWilliam, Nigel J	REGRANEX(R) - SBA
2014-629	01/28/2014 02/26/2014	FDA/OC/OES/DDM/ FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ OC/CVM/OCD/	Adam Diederich Front Range Equine Rescue	EQUINE OR HORSE SLAUGHTER, DRUG RESIDUE TESTING, PATRON FARMS, DKT FDA-2012-P-0299 01/01/2012 - 01/22/2014
2014-630	01/28/2014 02/26/2014	FDA/OMPT/CDRH/OCER/DFOI/	Peggy McLaughlin MPM ADVISORS	PRODUCT CODE PFP CREATION UNDER CFR 878.4025
2014-631	01/28/2014 02/26/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tushar Maloo Kora Capital LLC	RANBAXY - IMPORT ALERT, CONSENT DECREE, ALTERNNATIVE SITE FILINGS, PROCESS UPDATE ETC 01/01/2011 - 01/24/2014
2014-632	01/28/2014 02/26/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ted Keller Sigma Capital Management	SOVALDI - AERS 01/04/2012 - 01/26/2014
2014-633	01/28/2014 02/26/2014	OC/ORO/ OC/ORO/ OC/ORO/ORO/DFS/ OC/ORO/ORO/DFS/	Martell Winters Nelson Laboratories	STERILITY ANALYTICAL MANUAL
2014-634	01/28/2014 02/26/2014	FDA/OMPT/CDRH/OCER/DFOI/	Daniel Olivier Certified Compliance Solutions, Inc.	K092746
2014-635	01/28/2014 02/26/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	DOUGLAS P OH-KEITH D'AMORE LAW GROUP	BREG INC - BREG PAIN CARE 2000 PUMP, 20001 PUMP APRVL RECS, TRANS, PHOTOGRAPHIS, ETC
2014-636	01/28/2014 02/26/2014	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	MW5026684
2014-637	01/28/2014 02/26/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	MERCK - NOROXIN (NORFLOXACIN) NDA 19-384/S054 APRVL LTR

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2014-638	01/28/2014 02/26/2014	FDA/OMPT/CDRH/OCER/DFOI/	JOSEPH KICEINA ABBOTT POINT OF CARE INC	AVOXIMETER 4000 K951485; AVOXIMETER K932954, K92207
2014-639	01/28/2014 02/26/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JAMES R JOHNSON HOGAN LOVELLS US LLP	DIGOXIN - APRVL LTRS, MARKETING RECS ON OR BEFORE 9/29/97
2014-640	01/28/2014 02/26/2014	FDA/OC/OES/DFOI/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	ERIC S FREDERICKSON HARMAN LAW LLC	CATHERINE M SZYMAN, MEDTRONIC MINIMED, NORTHRIDGE, CA - WARNING LTR 9/19/13, CO RESP, 483, ETC
2014-641	01/28/2014 02/26/2014	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Doe J	EAT-RITE CMLPNT
2014-642	01/28/2014 02/26/2014	FDA/OMPT/CDRH/OCER/DFOI/	DAVID KERNAN NEUROSPECTRUM LLC	SPARTAN ORTHOPAEDIC WRIST BRACE K031576
2014-643	01/28/2014 02/26/2014	FDA/OMPT/CDRH/OCER/DFOI/	JANN WHALEY INGENERON INC	MEDI-KAHN USA INC - LIPOKIT WITH DISPOSABLE 50CC AFT SYRINGE K121703
2014-644	01/28/2014 02/26/2014	FDA/OMPT/CDRH/OCER/DFOI/	JANN WHALEY INGENERON INC	CYTORI THERAPEUTICS INC - PUREGRAFT 850/PURE SYS K113255
2014-645	01/28/2014 02/26/2014	FDA/OMPT/CDRH/OCER/DFOI/	JANN WHALEY INGENERON INC	SOUND SURGICAL TECHNOLOGIES LLC - ORIGINS LIPOHARVESTING SYS K120328
2014-646	01/28/2014 02/26/2014	FDA/OMPT/CDRH/OCER/DFOI/	JANN WHALEY INGENERON INC	HARVEST TECHNOLOGIES CORP - ADIPREP ADIPOSE TRANSFER SYS K121005
2014-647	01/29/2014 02/27/2014	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Michael Bouchon CHELSEA THERAPEUTICS INC	DR JOSEPH JANKOVIC, HOUSTON, TX - EIR 01/24/2012 - 02/02/2012
2014-648	01/29/2014 02/27/2014	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ OC/ORA/OE/ OC/ORA/OE/	Lizette Casas Casas, Lizette	HYDRAVAX CAPSULES - LAB RESULTS
2014-649	01/29/2014 02/27/2014	FDA/OMPT/CTP/OD/	Lynn Walsh E.W. Scripps Company	E-CIGARETTE APPLICATIONS SUBMITTED, CONSIDERED AND/OR DENIED 01/01/2009 - 01/28/2014
2014-650	01/29/2014	FDA/OMPT/CDER/ORP/DIDP/	tony ajoudani	LANTANOPROST - AERS

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	02/27/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ajoudani, tony	
2014-651	01/29/2014 02/27/2014	FDA/OMPT/CDRH/OCER/DFOI/	Laura Boll Medovations Inc.	K062222
2014-652	01/29/2014 02/27/2014	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Amy Stanton AMGEN INC.	AMGEN - EIR 06/04/2013 - 06/17/2013
2014-653	01/29/2014 02/27/2014	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	FCN 257
2014-654	01/29/2014 02/27/2014	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	FCN 418
2014-655	01/29/2014 02/27/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Alireza Ahmadvand Imperial College London	STATIN DRUGS - DEATH DATA
2014-656	01/29/2014 02/27/2014	FDA/OMPT/CDRH/OCER/DFOI/	John Whalen U. Southern California	K935160
2014-657	01/29/2014 02/27/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Laila Carolina Abu Esba King Faisal Specialist Hospital	ASTAGRAF - APPROVABLE LETTER
2014-658	01/29/2014 02/27/2014	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	Cathy Walker (for Scott De'Aeth) Aegerion Pharmaceuticals, Inc	SSCI, WEST LAFAYETTE, IN - EIR 01/02/2013 - 12/31/2013
2014-659	01/29/2014 02/27/2014	FDA/OMPT/CDRH/OCER/DFOI/	Warren B. Craycroft Intersection Medical Inc	K131509
2014-660	01/29/2014 02/27/2014	FDA/OMPT/CDRH/OCER/DFOI/	Warren B. Craycroft Intersection Medical Inc	K112830
2014-661	01/29/2014 02/27/2014	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Laurie Dubois Laurie Dubois	AGAVE CLINICAL RESEARCH, PREMIERE PHARMACEUTICAL RESEARCH, TEMPE, AZ - 482, 483 05/02/2013 - 01/28/2014
2014-662	01/29/2014 02/27/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Tom Zarembinski BioTime, Inc.	K053655, K121964

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2014-663	01/29/2014 02/27/2014	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Cathy Walker (for Scott De'Aeth) Aegerion Pharmaceuticals, Inc	ACCELERATION LABORATORY SERVICES, LEE'S SUMMIT, MO - EIR 01/01/2013 - 12/31/2013
2014-664	01/29/2014 02/27/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Simon Liem Freelance journalist/author	PURDUE PHARMA - LETTER TO FDA 3/19/13
2014-665	01/29/2014 02/27/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Nina Fuentes Utrecht University	DRUG AND BIOLOGIC WITHDRAWAL DATA 01/01/2004 - 10/31/2013
2014-666	01/29/2014 02/27/2014	FDA/OGROP/ORASORO/DIOP/OC/ORASOE/ OC/ORASOE/	Mark Prinz Registrar Corp	RED LIST COMPANIES
2014-667	01/29/2014 02/27/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Amy Stanton AMGEN INC.	PROLIA RECALL - HHA 09/15/2013 - 09/30/2013
2014-668	01/29/2014 02/27/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Amy Stanton AMGEN INC.	AMGEN EPO GLASS LAMELLAE RECALL - HHA
2014-669	01/29/2014 02/27/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michael Bouchon CHELSEA THERAPEUTICS INC	DR VOLODYMYR LEBEDYNETS, KHARIV, UKRAINE - EIR JAN 2012
2014-670	01/29/2014 02/27/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michael Bouchon CHELSEA THERAPEUTICS INC	PROF VALERY BITENSKYY, ODESSA, UKRAINE - EIR JAN 2012
2014-671	01/29/2014 02/27/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michael Bouchon CHELSEA THERAPEUTICS INC	PROF LYUDMYLA DZYAK - DNIPROPETROVSK, UKRAINE - EIR JAN 2012

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2014-672	01/29/2014 02/27/2014	FDA/OC/OES/DFOI/	WHITNEY AM7655, RAYMOND	BROCHURES
2014-673	01/29/2014 02/27/2014	FDA/OMPT/CDRH/OCER/DFOI/	SHANE ALLEN NBC 5 KXAS-TV	AUTOMATED EXTERNAL DEFIBRILLATOR - MDRS 2010 TO 2013
2014-674	01/29/2014 02/27/2014	FDA/OMPT/CDRH/OCER/DFOI/	COURTLAND IMEL CEUTICAL LABS	LUTRONIC CORP - INFINI RADIOFREQUENCY SYS K121481
2014-675	01/29/2014 02/27/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BARRY R. CONYBEARE CONYBEARE LAW OFFICE P C	INDIVIDUAL RECS
2014-676	01/29/2014 02/27/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	THOMPSON, RAY	ACTAVIS PHARMA MANUFACTURING PVT LTD, KANCHEEPURAM DISTRICT, TAMIL NADU, INDIA - 483 9/9-13/13
2014-677	01/29/2014 02/27/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	THOMPSON, RAY	AGILA SPECIALTIES PRIVATE LTD, BAGALORE, INDIA - 483 6/17/13 - 9/13/13
2014-678	01/29/2014 02/27/2014	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	THOMPSON, RAY	BECTON DICKENSON & CO, HUNT VALLEY, MD; TERUMO MEDICAL CORP, ELKTON, MD; MERCK SHARP & DOHME CORP, ELKTON, VA - 483
2014-679	01/29/2014 02/27/2014	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	THOMPSON, RAY	OMEGA TECH LABS LLC, GARDEN CITY, ID; JUBILANT HOLLISTERSTIER LLC, SPOKANE, WA; GENZYME A SONOFI CO, LYNNWOOD, WA - 483
2014-680	01/29/2014 02/27/2014	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	THOMPSON, RAY	QUALITEST PHARMACEUTICALS, HUNTSVILLE, AL; DR REDDYS LABS LOUISIANA LLC, SHREVEPORT, LA - 483
2014-681	01/29/2014 02/27/2014	FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	THOMPSON, RAY	AMGEN MANUFACTURING LTD INC, JUNCOS, PR; BAXTER HEALTHCARE CORP, JAYUYA, PR; BECTON DICKINSON CARIBE LTD, SAN LORENZO, PR - 483
2014-682	01/29/2014 02/27/2014	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	THOMPSON, RAY	BAUSCH & LOMB INC, TAMPA, FL; BAXTER CORP ENGLEWOOD DAYTONA BEACH, DAYTONA BEACH, FL; HORIZON PHARMACEUTICALS INC, RIVIERA BEACH, FL - 483
2014-683	01/29/2014	FDA/OGROP/ORA/SE-FO/ATL-		ACELLA PHARMACEUTICALS, ALPHARETTA, GA; CLINICAL

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	02/27/2014	DO/ATL-CB/	THOMPSON, RAY	SPECIALTIES COMPOUNDING PHARMACY, AUGUSTA, GA; OSMOTICA PHARMACEUTICAL CORP, MARIETTA, GA - 483
2014-684	01/29/2014 02/27/2014	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	THOMPSON, RAY	ABBOTT DIABETES CARE INC, ALAMEDA, CA; ALLURE LABS INC, HAYWARD, CA; BIO RAD LABORATORIES INC, HERCULES, CA - 483
2014-685	01/29/2014 02/27/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	THOMPSON, RAY	ACCUMETRICS INC, SAN DIEGO, CA; AMGEN INC, THOUSAND OAKS, CA; B BRAUN MEDICAL INC, IRVINE, CA - 483
2014-686	01/29/2014 02/27/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	THOMPSON, RAY	PHARMAGEN LABORATORIES INC. STAMFORD, CT; TOWER LABORATORIES LTD, CENTERBROOK, CT; BRISTOL MYERS SQUIBB, DEVENS, MA - 483
2014-687	01/29/2014 02/27/2014	FDA/OMPT/CDRH/OCER/DFOI/	LORI PFOHL TELEFLEX MEDICAL	FISHER & PAYKEL - RT019 INSPIRATORY EXPIRATORY FILER K050927
2014-688	01/29/2014 02/27/2014	FDA/OMPT/CDRH/OCER/DFOI/	LORI PFOHL TELEFLEX MEDICAL	FISHER & PAYKEL - RT020 EXPIRATORY FILER K002839
2014-689	01/29/2014 02/27/2014	FDA/OC/OES/DFOI/	TAO LI UNIVERSITY OF WARWICK	REQUESTS 10/1/07 TO 9/30/13
2014-690	01/29/2014 02/27/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	JOHN F. JOHNSON, III Esq. BENJAMIN L ENGLAND & ASSOCIATES LLC	EXAMINATION GOLOVES - K081089, K092327, K090568
2014-691	01/29/2014 02/27/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ROBERT A. NORGARD NORGARD & NORGARD	INTRAVENOUS MIDAZOLAM HCL- AER
2014-692	01/29/2014 02/27/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	JUSTIN HENGESBACH SEVEN RIVERS REGIONAL MEDICAL CTR	BACTERIA INT'L INC BIOLOGICS DIVISION, BELGRADE, MO; ORGANOGENESIS INC, CANTON, MA; RTI BIOLOGICS INC, ALACHUA, FL - EIR PAST 10 YRS
2014-693	01/29/2014 02/27/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	ANTHONY M. ELEFThERI LEWIS WAGNER LLP	CHAMBERLAIN FARMS INC, OWENSVILLE, IN - SALMONELLA RECALL, INSPS, RPTS, LTRS, ETC 2012
2014-694	01/29/2014 02/27/2014	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	SONYALEE R. NUTSCH CLEMENTS BROWN & MCNICHOLS PA	COLUMBIA GRAIN, CRAIGMONT, ID - INSP 5/13/11 TO 5/12/13
2014-695	01/29/2014 02/27/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHNATHAN W. EMORD EMORD & ASSOCIATES, P.C.	BLIS TECHNOLOGIES LTD - STREPTOCOCCUS SALIVARIUS IMPORT ALERT 66-41

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2014-696	01/29/2014 02/27/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/	DOUGLAS N. BLUE, II ZETETIC INC	ALL SHIPMENTS REGULATED BY FDA 1/13 TO 1/15/14
2014-697	01/29/2014 02/27/2014	FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORO/NE-FO/NWE-DO/NWE-CB/	Doe J	TRADER JOES, CHINO HILLS, CA - INDIAN FARE PUNJAB CHOLEY FOOD TAMPERING INVESTIGATION
2014-698	01/30/2014 02/28/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MAE CALE NATURAL RESOURCES DEFENSE COUNCIL	COLGATE-PALMOLIVE - TRICLOSAN NDA 20-231 ANNUAL RPTS, SAFETY AND EFFICACY RECS 7/12/97 TO 1/24/14
2014-699	01/30/2014 02/28/2014	FDA/OMPT/CDRH/OCER/DFOI/	GERARD RYAN PARKER WAICHMAN LLP	MEDTRONIC INC - INFUSE BONE GRAFT/LT-CAGE LUMBAR TAPERED FUSION DVC DEFINITION/AND INTENT OF THE WORD EXPERIENCED, CORR, ATTACHMENTS, ETC
2014-700	01/30/2014 02/28/2014	FDA/OC/OES/DFOI/	ANNE L WEISMANN Citizens for Responsibility and Ethics in Washington	TOTAL COST OF TRAVEL BY FDA EMPLOYEES 5/22/13 TO PRESENT
2014-701	01/30/2014 02/28/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	BRETT PARK CONWAY HOMER & CHIN-CAPLAN PC	INDIVIDUAL RECS
2014-702	01/30/2014 02/28/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DR SOMA RAJU HETERO USA INC	CARDIAZEM CD (DILTIAZEM HCL XR) NDA 20-062 - CHEMISTRY RVW, BIOEQV, CORR
2014-703	01/30/2014 02/28/2014	FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/	RAY THOMPSON THOMPSON, RAY	ABBE LABORATORIES INC, FARMINGDALE, NY 4/10-12/13; ADVANCE PAHRAMACEUTICAL INC, HOLTSMVILLE, NY 6/25/13-7/2/13; AMERICARE COMPOUNDING LLC, GARDEN CITY SOUTH, NY 6/3-19/13, ETC - 483S
2014-704	01/30/2014 02/28/2014	FDA/OGROP/ORO/CE-FO/PHI-DO/PHI-CB/	THOMPSON, RAY	ACCUPAC INC, MAINLAND, PA 7/16-19/13; DELAVAU LLC, PHILADELPHIA, PA 9/19-30/13; DRAEGER MEDICAL INC, TELFORD, PA 6/25/13-7/3/13, ETC - 483S
2014-705	01/30/2014	FDA/OGROP/ORO/SW-FO/DEN-DO/DEN-CB/		BAXTER CORPORATION ENGLEWOOD, ENGLEWOOD, CO 10/21-30/13; CONMED ELECTROSURGERY, CENTENNIAL,

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	02/28/2014		THOMPSON, RAY	CO 8/12/13-9/20/13; HOSPIRA BOULDER INC, BOULDER, CO 5/6-15/13, ETC - 483S
2014-706	01/30/2014 02/28/2014	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	THOMPSON, RAY	BASF CORP, BISHOP, TX 10/21-25/13; IDEV TECHNOLOGIES INC, WEBSTER, TX 4/18/13-5/3/13; HUMCO HOLDING GROUP INC, TEXARKANA, TX 7/15-24/13, ETC - 483S
2014-707	01/30/2014 02/28/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	THOMPSON, RAY	AAI PHARMA ANALYTICAL SERVICES, EDISON, NJ 4/3-9/13; BASF CORP, WASHINGTON, NJ 5/20-28/13; DATASCOPE CORP, DAYTON, NJ 8/28/13-10/17/13, ETC - 483S
2014-708	01/30/2014 02/28/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kiran Kumar Gande Appco Pharmaceuticals Corporation	ALBUTEROL TABLETS - RLD LABELING
2014-709	01/30/2014 02/28/2014	FDA/OMPT/CDRH/OCER/DFOI/	Veeraraghavan Sundar Veeraraghavan Sundar	K890519, K905522
2014-710	01/30/2014 02/28/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joseph Carrado Joseph Carrado	NDA 020503
2014-711	01/30/2014 02/28/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jasmanda Wu SANOFI	FINGOLIMOD - AERS 01/01/2013 - 12/31/2013
2014-712	01/30/2014 02/28/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jasmanda Wu SANOFI	DIMETHYL FUMARATE - AERS
2014-713	01/30/2014 02/28/2014	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	THOMPSON, RAY	BAYER HEALTH CARE LLC, SHAWNEE, KS 5/8-21/13; FOREST PHARMACEUTICALS INC, EARTH CITY, MO 11/12-26/13; PRISM MEDICAL USA INC, MARYLAND HEIGHTS, MO 4/24/13-5/2/13, ETC - 483S
2014-714	01/30/2014 02/28/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jasmanda Wu SANOFI	TERIFLUNOMIDE - AERS
2014-715	01/30/2014 02/28/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ashley Koczur THOMAS JEFFERSON	PRADAXA - AERS

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	UNIVERSITY	
2014-716	01/30/2014 02/28/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Teresa Tung Alpha Pharma Services LLC	ANDA 90-843 APPROVAL LETTER
2014-717	01/30/2014 02/28/2014	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	Karen Marshall TARSA THERAPEUTICS INC	QS Pharma, Boothwyn, PA - EIR, 483
2014-718	01/30/2014 02/28/2014	FDA/OMPT/CDRH/OCER/DFOI/	Javier Collazo RespCare	K120665
2014-719	01/30/2014 02/28/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Andrew Barlow ALKERMES INC	NDA 204242
2014-720	01/30/2014 02/28/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Scott Soracoe Macquarie	ANDA FILINGS RE DUONEB
2014-721	01/30/2014 02/28/2014	FDA/OC/OES/DFOI/	Thomas Kita Thomas Kita - Charlotte School of Law	EMPLOYEE MISCONDUCT RECORDS
2014-722	01/30/2014 02/28/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Cindy Schuster Schuster, Cindy	BYSTOLIC - AERS
2014-723	01/30/2014 02/28/2014	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	THOMPSON, RAY	COOK BIOTECH INC, W LAFAYETTE, IN 7/8-16/13; COOK INC, SPENCER, IN 7/22-30/13; ELI LILLY AND CO, INDIANAPOLIS, IN 4/15-19/13, ETC - 483S
2014-724	01/30/2014 02/28/2014	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	steve miller florida center	COMMUNICATIONS WITH FLORIDA DEPT OF HEALTH 11/30/2012 - 01/29/2014

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		OC/ORO/OCI/ OC/ORO/OCI/		
2014-725	01/30/2014 02/28/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lynn Walsh E.W. Scripps Company	CDER E-CIGARETTE APPLICATIONS 01/01/2009 - 01/29/2014
2014-726	01/30/2014 02/28/2014	FDA/OGROP/ORO/CE-FO/MIN-DO/MIN-CB/	THOMPSON, RAY	BECKMAN COULTER INC, CHASKA, MN 5/20/13-6/19/13; GE HEALTHCARE LLC, WAUKESHA, WI 6/17/13; BELL INTERNATIONAL LABORATORIES INC, MINNEAPOLIS, MN 6/12-26/13, ETC - 483S
2014-727	01/30/2014 02/28/2014	OC/ORO/ OC/ORO/ OC/ORO/OE/ OC/ORO/OE/	Jacob Harris THE NEW YORK TIMES	RECALL ENTERPRISE SYSTEM - DATA DICTIONARY
2014-728	01/30/2014 02/28/2014	OC/ORO/ OC/ORO/ OC/ORO/OE/ OC/ORO/OE/	Jacob Harris THE NEW YORK TIMES	RECALL ENTERPRISE SYTEM DATA
2014-729	01/30/2014 02/28/2014	FDA/OGROP/ORO/CE-FO/CIN-DO/CIN-CB/	THOMPSON, RAY	ALKERMES INC, WILMINGTON, OH 6/19-28/13; CARDIOX CORP, COLUMBUS, OH 10-28-30/13; GFS CHEMICALS INC, COLUMBUS, OH 6/25-27/13, ETC - 483S
2014-730	01/30/2014 02/28/2014	OC/ORO/ OC/ORO/ OC/ORO/OE/ OC/ORO/OE/	Jacob Harris THE NEW YORK TIMES	FOOD RECALL DATA
2014-731	01/30/2014 02/28/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nancy Parker Janssen Global Medical Safety	MEDWATCH REPORT
2014-732	01/30/2014 02/28/2014	FDA/OGROP/ORO/CE-FO/CHI-DO/CHI-CB/	THOMPSON, RAY	AKORN INC, DECATUR, IL 4/15/13-5/3/13; CAREFUSION 2200 INC, VERNON HILLS, IL 9/9/13-11/5/13; CIBA VISION CORP, DES PLAINES, IL 5/6-9/13, ETC - 483S
2014-733	01/30/2014 02/28/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MATTHEW W LAMB WARNER CHILCOTT	TEVA PHARMS - RISEDRONATE SODIUM ANDA 79-215 TENTATIVE APRVL LTR

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-734	01/30/2014 02/28/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANDREW E ROSENZWEIG QUINTAIROS PRIETO WOOD & BOYER PA	METHADONE - AERS
2014-735	01/30/2014 02/28/2014	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	NPS PHARMS, BEDMINSTER, NJ - EIRS, 483S, UNTITLED LTRS; GATTEX (TEDUGLUTIDE INJ) - AERS
2014-736	01/30/2014 02/28/2014	FDA/OGROP/ORA/PA-FO/SEA- DO/SEA-CB/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	SEATTLE GENETICS, BOTHELL, WA - EIRS, 483S, UNTITLED LTRS, ETC 11/1/13 TO PRESENT
2014-737	01/30/2014 02/28/2014	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	AEGERION PHARMACEUTICALS INC - EIRS, 483S, UNTITLED LTRS, ETC 11/1/13 TO PRESENT; JUXTAPID (LOMITAPIDE) - AERS 11/1/13 TO PRESENT
2014-738	01/30/2014 02/28/2014	FDA/OFVM/CFSAN/OCD/EOS/	COLEEN WALDENMAYER Keller and Heckman LLP	DOW AGROSCIENCES, MARTEK BIOSCIENCES CORP - EICOSAPENTAENOIC ACID (EPA), DOCOSAHEXAENOIC ACID (DHA) PETITIONS OR NOTIFICATIONS
2014-739	01/30/2014 02/28/2014	FDA/OFVM/CFSAN/OCD/EOS/	COLEEN WALDENMAYER Keller and Heckman LLP	BASF CORP - OMEGA-3-RICH FISH OILS - FAP, NEW DIETARY INGREDIENT NOTIFICATIONS
2014-740	01/30/2014 02/28/2014	FDA/OFVM/CFSAN/OCD/EOS/	COLEEN WALDENMAYER Keller and Heckman LLP	MONSANTO CO - STEARIDONIC ACID (SDA), OMEGA-3- RICH OILS THROUGH GENETIC MODIFICATION OF PLANT- SOURCED PRODS INSPS, CORR, APPLS, ETC
2014-741	01/30/2014 02/28/2014	FDA/OFVM/CFSAN/OCD/EOS/	COLEEN WALDENMAYER Keller and Heckman LLP	BASF CORP, AMARIN CORP - EICOSAPENTAENOIC ACID (EPA)-RICH FISH OIL PETITIONS OR NOTIFICATIONS
2014-742	01/30/2014 02/28/2014	FDA/OFVM/CFSAN/OCD/EOS/	COLEEN WALDENMAYER Keller and Heckman LLP	DUPONT, PIONEER, SOLAE LLC - EICOSAPENTAENOIC ACID (EPA), DOCOSAHEXAENOIC ACID (DHA)-RICH OILS PETITIONS AND NOTIFICATIONS
2014-743	01/31/2014 03/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	ZOLPIDEM ETC - DATA, STUDIES

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2014-744	01/31/2014 03/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K121819
2014-745	01/31/2014 03/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K112549
2014-746	01/31/2014 03/03/2014	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Rachel Johnson FOI Services, Inc.	QUANTUM HERBAL PRODUCTS - 483, WARNING LETTER RESPONSE ETC
2014-747	01/31/2014 03/03/2014	FDA/OFVM/CFSAN/OCD/EOS/	Michael Felberbaum THE ASSOCIATED PRESS	STAR SCIENTIFIC, INC - CORR AND RESPONSE TO WARNING LETTER 12/02/2013 - 02/28/2014
2014-748	01/31/2014 03/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	Veeraraghavan Sundar Veeraraghavan Sundar	K872265, K874854
2014-749	01/31/2014 03/03/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	MCNEIL CONSUMER PHARMACEUTICAL PRODUCTS, LANCASTER, PA - EIR AUGUST 2013
2014-750	01/31/2014 03/03/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	MCNEIL CONSUMER PHARMACEUTICAL PRODUCTS, LANCASTER, PA - 483 AUGUST 2013
2014-751	01/31/2014 03/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Courtney Thomas NPS PHARMACEUTICALS	NDA 16618, NDA 20344 - SBA
2014-752	01/31/2014 03/03/2014	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	FCN 231
2014-753	01/31/2014 03/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K113836
2014-754	01/31/2014 03/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	Korina Akhondzadeh KARA & Associates, Inc.	K123220
2014-755	01/31/2014 03/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	Korina Akhondzadeh KARA & Associates, Inc.	K102640
2014-756	01/31/2014 03/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	Korina Akhondzadeh KARA & ASSOCIATES INC	K102654
2014-757	01/31/2014 03/03/2014	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	FCN 336
2014-758	01/31/2014 03/03/2014	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	FCN 130

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2014-759	01/31/2014 03/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Travis W Cope Cope, Travis W	NYMOX PHARMACEUTICAL CORPORATION - CORR RE PHASE 3 3 BPH CLINICAL TRIALS 01/01/2010 - 01/30/2014
2014-760	01/31/2014 03/03/2014	FDA/OFVM/CFSAN/OCD/EOS/ OC/CVM/OCD/	Valerie Jean Valerie Jean	HGC IN FISH PRODUCTION RECS 01/01/1990 - 01/29/2014
2014-761	01/31/2014 03/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca L. Dandeker Morgan, Lewis & Bockius LLP	MALLADI DRUGS & PHARMACEUTICALS LTD, INDIA - 483, EIR 1/1/10 TO 12/30/13
2014-762	01/31/2014 03/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca L. Dandeker Morgan, Lewis & Bockius LLP	MALLADI DRUGS & PHARMACEUTICALS, INDIA - EIR SUMMARY 01/01/2010 - 12/30/2013
2014-763	01/31/2014 03/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca L. Dandeker Morgan, Lewis & Bockius LLP	Hangzhou Zhongmei Huadong, China - EIR, 483 1/1/10 to 12/30/13
2014-764	01/31/2014 03/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca L. Dandeker Morgan, Lewis & Bockius LLP	XELLIA PHARMACEUTICALS LTD, HUNGARY - EIR SUMMARIES 01/01/2010 - 12/30/2013
2014-765	01/31/2014 03/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca L. Dandeker Morgan, Lewis & Bockius LLP	XELLIA PHARMACEUTICALS LTD, HUNGARY - EIR, 483 01/01/2010 - 12/30/2013
2014-766	01/31/2014 03/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca L. Dandeker Morgan, Lewis & Bockius LLP	Hangzhou Zhongmei Huadong, China - EIR SUMMARIES 1/1/10 TO 12/30/13
2014-767	01/31/2014 03/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca L. Dandeker Morgan, Lewis & Bockius LLP	TEVA PHARMACEUTICAL WORKS PRIVATE LIMITED CO, HUNGARY - EIR, 483 01/01/2010 - 12/30/2013

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		FDA/OMPT/CDER/ORP/DIDP/		
2014-768	01/31/2014 03/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca L. Dandeker Morgan, Lewis & Bockius LLP	CADILA HEALTHCARE, INDA - EIR, 483 01/01/2010 - 12/30/2013
2014-769	01/31/2014 03/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca L. Dandeker Morgan, Lewis & Bockius LLP	DIPHARMA FRANCIS, ITALY - EIR, 483 01/01/2010 - 12/30/2013
2014-770	01/31/2014 03/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca L. Dandeker Morgan, Lewis & Bockius LLP	CADILA HEALTHCARE - EIR SUMMARIES 01/01/2010 - 12/30/2013
2014-771	01/31/2014 03/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca L. Dandeker Morgan, Lewis & Bockius LLP	SIFAVITOR, ITALY - EIR, 483 01/01/2010 - 12/30/2013
2014-772	01/31/2014 03/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca L. Dandeker Morgan, Lewis & Bockius LLP	NICHOLAS PIRAMAL, INDIA - EIR SUMMARY 01/01/2010 - 12/30/2013
2014-773	01/31/2014 03/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca L. Dandeker Morgan, Lewis & Bockius LLP	NICHOLAS PIRAMAL, INDIA - 483, EIR 01/01/2010 - 12/30/2013
2014-774	01/31/2014 03/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca L. Dandeker Morgan, Lewis & Bockius LLP	GUFIC BIOSCIENCES LTD, INDIA - EIR, 483 01/01/2010 - 12/30/2013
2014-775	01/31/2014 03/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca L. Dandeker Morgan, Lewis & Bockius LLP	TEVA PHARMACEUTICAL WORKS PRIVATE LIMITED, HUNGARY - EIR, 483 01/01/2010 - 12/30/2013

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2014-776	01/31/2014 03/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca L. Dandeker Morgan, Lewis & Bockius LLP	GUFIC BIOSCIENCES LTD, INDIA - EIR SUMMARY 01/01/2010 - 12/30/2013
2014-777	01/31/2014 03/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca L. Dandeker Morgan, Lewis & Bockius LLP	DIPHARMA FRANCIS, ITALY - EIR SUMMARIES 01/01/2010 - 12/30/2013
2014-778	01/31/2014 03/03/2014	FDA/OC/OES/DFOI/	Carmine J. Pearl, II Willis DePasquale	TOWNSEND FARMS OUTBREAK RECS 01/01/2012 - 01/31/2014
2014-779	01/31/2014 03/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca L. Dandeker Morgan, Lewis & Bockius LLP	SIMS, ITALY - EIR, 483 01/01/2010 - 12/30/2013
2014-780	01/31/2014 03/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca L. Dandeker Morgan, Lewis & Bockius LLP	SIFAVITOR, ITALY - 483, EIR 01/01/2010 - 12/30/2013
2014-781	01/31/2014 03/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca L. Dandeker Morgan, Lewis & Bockius LLP	SIMS, ITALY - EIR SUMMARY 01/01/2010 - 12/30/2013
2014-782	01/31/2014 03/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca L. Dandeker Morgan, Lewis & Bockius LLP	NORTH CHINA PHARMACEUTICALS - EIR, 483 01/01/2010 - 12/30/2013
2014-783	01/31/2014 03/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca L. Dandeker Morgan, Lewis & Bockius LLP	NORTH CHINA PHARMACEUTICAL - EIR SUMMARY 01/01/2010 - 12/30/2013
2014-784	01/31/2014 03/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	QMedic 510K Application (K121552) Medeia Inc	K121552

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2014-785	01/31/2014 03/03/2014	FDA/OC/OES/DFOI/	Karen Bzdyk Donna B Michelson PA	MCNEIL CONSUMER & SPECIALTY PHARMACEUTICALS, MCNEIL CONSUMER HEALTHCARE, MCNEIL PPC - VIOLATIONS, WARNIGN LETTERS ETC 01/01/1994 - 12/31/2003
2014-786	01/31/2014 03/03/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	LINH CHU DYNVAX TECHNOLOGIES	TOLOSA HUNT - HEPLISAV BLA 125-428 CAVERNOUS SINUS SYNDROME CASE STUDY DV2-HBV-16 EVALUATION
2014-787	01/31/2014 03/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	ANN MARIE DUFFY Mayer Brown LLP	NELLCOR N-50 POWERBASE; N-50 PULSE OXIMETER K901399 - APRVL RECS
2014-788	01/31/2014 03/03/2014	FDA/OC/OCC/ FDA/OC/OES/ FDA/OC/OES/DDM/ FDA/OFVM/CFSAN/OCD/EOS/	BRIDGET M. LEE Earthjustice	ENVIRONMENTAL WORKING GROUP (EWG) PETITION FOR REGULATORY ACTION FOR KERATIN HAIR STRAIGHTENING PRODUCTS 1/11 TO PRESENT
2014-789	01/31/2014 03/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	GERARD RYAN PARKER & WAICHMAN ATTYS	MEDTRONIC INC - INFUSE BOSE GRAFT LT CAGE LUMBAR TAPERED FUSION DVC - APRVL
2014-790	01/31/2014 03/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	TRACEY B. KIRSCH ELECTROMEDICAL PRODUCTS INTL	ELECTROMEDICAL PRODUCTS INC - ALPHA STIM CS K896948
2014-791	01/31/2014 03/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	MAURA NORDEN SIDLEY AUSTIN LLP	MENTOR - CPX 4 BREAST TISSUE EXPANDERS; CPX W/SUTURE TABS BREAST TISSUE EXPANDERS K130813
2014-792	01/31/2014 03/03/2014	OC/CVM/OCD/	ALVARO L. MEJER MEJER LAW PA	HEALTH HAZARD EVLAUATIONS RELATED TO GLASS IN ANIMAL FEED
2014-793	02/03/2014 03/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John Tomaszewski L'Oreal USA Products, Inc	NDA 19501
2014-794	02/03/2014 03/04/2014	FDA/OMPT/CDRH/OCER/DFOI/	lapyx Medical Inc. lapyx Medical Inc	K120888
2014-795	02/03/2014 03/04/2014	FDA/OMPT/CDRH/OCER/DFOI/	Thomas Flannery of lapyx Medical Inc lapyx Medical Inc	K102567
2014-796	02/03/2014 03/04/2014	FDA/OFVM/CFSAN/OCD/EOS/	Debbie Metzger Segal McCambridge Singer & Mahoney	ULTIMATE ORANGE, ULTIMATE PUNCH - AERS
2014-797	02/03/2014 03/04/2014	FDA/OMPT/CDRH/OCER/DFOI/	Carl Jenkins WOOD BURDITT GROUP	K132368, K131197, K130446 ETC

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2014-798	02/03/2014 03/04/2014	FDA/OMPT/CDRH/OCER/DFOI/	Mbithi Muthini Spine View, Inc.	K130820
2014-799	02/03/2014 03/04/2014	FDA/OMPT/CDRH/OCER/DFOI/	mbithi muthini Spine View, Inc.	K113447
2014-800	02/03/2014 03/04/2014	FDA/OMPT/CDRH/OCER/DFOI/	Mbithi Muthini Spine View, Inc.	K081917
2014-801	02/03/2014 03/04/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	510K REDACTED JANUARY 2014
2014-802	02/03/2014 03/04/2014	FDA/OMPT/OSMP/OOPD/	Matt Medlin CATO RESEARCH	IBRUTINIB - ORPHAN DESIGNATION REQUEST RECS 01/01/2012 - 12/03/2012
2014-803	02/03/2014 03/04/2014	FDA/OC/OES/DFOI/	David Mangione Govzilla, Inc.	FOIA REQUESTS MADE TO FDA LAST THREE MONTHS (11/01/2013 - 01/31/2014)
2014-804	02/03/2014 03/25/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Art Rankis Art Rankis	BK050058, BK070055
2014-805	02/03/2014 03/04/2014	FDA/OGROP/ORPA-FO/SAN- DO/SAN-CB/	Rachel Johnson FOI Services, Inc.	BAYER, BERKELEY, CA - EIR 09/10-20/2013
2014-806	02/03/2014 03/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Most Recent Labeling for Ativan (lorazepam) tablets APTIV SOLUTIONS	ATIVAN 1 MG TABLETS - MOST RECENT LABELING 01/02/2008 - 01/31/2014
2014-807	02/03/2014 03/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Most recent labeling for Zyloprim (allopurinol) tablets APTIV SOLUTIONS	ZYLOPRIM 100 AND 300 MG TABLETS - MOST RECENT LABELING
2014-808	02/03/2014 03/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Amy Kneifel APTIV SOLUTIONS	ISOSORBIDE MONONITRATE EXTENDED RELEASE TABLETS FROM KREMERS URBAN (01/01/2010 - 01/31/2014) - MOST RECENT LABELING
2014-809	02/03/2014 03/04/2014	FDA/OMPT/CTP/OD/	Lynn Walsh E.W. Scripps Company	E-CIGARETTES - AERS
2014-810	02/03/2014 04/10/2014	FDA/OGROP/ORPA-FO/SAN- DO/SAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	BIO-RAD LABORATORIES INC, HERCULES, CA - EIR, 483, CO RESP 7/10/13

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			(SCIENTIFIC) SAS	
2014-811	02/03/2014 03/04/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	WALTER E CHALKLEY THOMSON REUTERS	DR VELMAHOS GEORGE, MASS GENERAL HOSPITAL, BOSTON, MA - EIR, 483, CO RESP 7/11-25/13
2014-812	02/03/2014 03/04/2014	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	AGNES UBANI MD, WINDSOR MEDICAL CLINIC, TAMPA, FL - EIR, 483, CO RESP 5/29/13-6/6/13
2014-813	02/03/2014 03/04/2014	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	WALTER E CHALKLEY THOMSON REUTERS	OSIRIS THERAPEUTICS INC, COLUMBIA, MD - EIR, 483, CO RESP 5/23/13-6/4/13
2014-814	02/03/2014 03/04/2014	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	MERCY HOSPITAL & MEDICAL CENTER IRB, CHICAGO, IL - EIR, 483, CO RESP 5/6/13-6/13/13
2014-815	02/03/2014 03/04/2014	FDA/OGROP/ORACE-FO/CINDO/CIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	ELIAS I TRABOULSI MD, CLEVELAND,OH - EIR, 483, CO RESP 5/15/13
2014-816	02/03/2014 03/04/2014	FDA/OGROP/ORACE-FO/DETDO/DET-CB/	WALTER E CHALKLEY THOMSON REUTERS	HENRY FORD HEALTH SYSTEM IRB, DETROIT, MI - EIR, 483, CO RESP 5/15/13
2014-817	02/03/2014 03/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/CVM/OCD/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	ZHEJIANG JIUZHOU PHARMACEUTICAL CO LTD, TAIZHOU, ZHEJIANG PROV, CHINA - EIR, 483, CO RESP 10/24/13
2014-818	02/03/2014 04/02/2014	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	DR WETHOFF CONSTANCE, NEW YORK BLOOD CENTER, LONG ISLAND CITY, NY - EIR, 483, CO RESP 8/21/13-9/12/13
2014-819	02/03/2014 03/04/2014	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	RICHMOND UNIVERSITY MEDICAL CENTER, STATEN ISLAND, NY - EIR, 483, CO RESP 1/23/13
2014-820	02/03/2014 03/04/2014	FDA/OGROP/ORACE-FO/MINDO/MIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	CAMBRIDGE MAJOR LABORATORIES INC, GERMANTOWN, WI - EIR, 483, CO RESP 9/18/13
2014-821	02/03/2014 03/04/2014	FDA/OGROP/ORASW-FO/DALDO/DAL-CB/	WALTER E CHALKLEY THOMSON REUTERS	ERIC J LAWITZ MD, SAN ANTONIO, TX - EIR, 483, CO RESP 8/24/12
2014-822	02/03/2014 03/04/2014	FDA/OGROP/ORASE-FO/SJNDO/SJN-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	ST JUDE MEDICAL PUERTO RICO LLC, ARECIBO, PR - EIR, 483, CO RESP 5/7/13
2014-823	02/03/2014 03/04/2014	FDA/OGROP/ORASE-FO/SJNDO/SJN-CB/	WALTER E CHALKLEY THOMSON REUTERS	MSD INTERNATIONAL GMBH LLC, BARCELONETA, PR - EIR, 483, CO RESP 6/20/12

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			(SCIENTIFIC) SAS	
2014-824	02/03/2014 03/04/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	PHARMAFORCE INC, COLUMBUS, OH - EIR, 483, CO RESP 2/7/12
2014-825	02/03/2014 03/25/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	SANDOZ INC, BROOMFIELD, CO - EIR, 483, CO RESP 8/14/12
2014-826	02/03/2014 03/04/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	WALTER E CHALKLEY THOMSON REUTERS	SANOVI PASTEUR LTD, NORTH YORK, CANADA - EIR, 483, CO RESP 9/20/13
2014-827	02/03/2014 03/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	BANNER PHARMACAPS EUROPE BV, TILBURG, NETHERLANDS - EIR, 483, CO RESP 3/14/12
2014-828	02/03/2014 03/04/2014	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	ADVANCE PHARMACEUTICAL INC, HOLTSVILLE, NY - EIR, 483, CO RESP 7/2/13
2014-829	02/03/2014 03/04/2014	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	EISAI INC, RESEARCH TRIANGLE PARK, NC - EIR, 483, CO RESP 9/13/13
2014-830	02/03/2014 03/04/2014	FDA/OO/OFBA/OAGS/	JEFF STACHEWICZ FOIA GROUP INC	SMARTPAY CREDIT CARD PURCHASE PROGRAM
2014-831	02/03/2014 03/04/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	RONALD H BLUMBERG ESQ BLUMBERG LAW GROUP LLP	BAYER HEALTHCARE PHARMS - MIRENA INTRA UTERINE SYS CORR, SAFETY TESTING, MDRS, ETC 1/08 TO PRESENT
2014-832	02/03/2014 03/04/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SARAH NEWHALL ESQ NEW HAMPSHIRE PUBLIC DEFENDER	ISRS 5015389, 3436945, 5772469, ETC
2014-833	02/03/2014 03/04/2014	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	CARLOS MONDRIGUEZ TORRES BUFETE MONDRIGUEZ & MONDRIGUEZ	BRISTOL MYERS SQUIBB, HUMACAO, PR - 483S 5/3-6,24-25,28/10, 6/1,9,18,22,25/10
2014-834	02/03/2014	OC/CVM/OCD/	KRISTI O SMEDLEY PHD	BETAINE (HCL OR ANHYDROUS) AAFCO 90.7 - RECS

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	03/04/2014	FDA/OC/OES/DFOI/	Center for Regulatory Services, Inc.	
2014-835	02/03/2014 03/04/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CAROL VILLEGAS Labaton Sucharow LLP	ARIAD - ICLUSIG (PONATINIB) NDA 203-496/S008,S008 AERS, APRVL RECS, LBLG, ETC
2014-836	02/03/2014 03/04/2014	FDA/OFVM/CFSAN/OCD/EOS/	NANDAKUMARA D SARMA RPH PHD UNITED STATES PHARMACOPEIA	ARGININE, CAFFEINE, CREATINE, ETC - CAERS 1/08 TO 12/13
2014-837	02/03/2014 03/04/2014	FDA/OFVM/CFSAN/OCD/EOS/	NANDAKUMARA D SARMA RPH PHD UNITED STATES PHARMACOPEIA	JACK3D, YOK3D, MUSCLE ARMOR, ETC - CAERS 1/08 TO 12/13
2014-838	02/03/2014 03/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	MERCK - NOROXIN (NORFLOXACIN) NDA 19-384/S058 APRVL RECS
2014-839	02/03/2014 03/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	DAVA PHARMS - PROPYLTHIOURACIL NDA 06- 188/S020,S022
2014-840	02/04/2014 03/05/2014	FDA/OC/OCC/ FDA/OFVM/CFSAN/OCD/EOS/	Alan Suderman THE ASSOCIATED PRESS	STAR SCIENTIFIC, INC - COMMUNICATIONS BETWEEN FDA AND US ATTORNEY 01/04/2012 - 01/30/2014
2014-841	02/04/2014 03/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Bruno Edling AprioMed AB	K973565, K960065
2014-842	02/04/2014 03/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michele Sinoway LACHMAN CONSULTANT SERVICES, INC.	ANDA 200822 - BIOEQUIVALENCE SUMMARY
2014-843	02/04/2014 03/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca L. Dandeker Morgan, Lewis & Bockius LLP	SIMS, MALLADI, GUFIC ETC - EIR 01/01/2010 - 12/30/2013

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		OC/CVM/OCD/		
2014-844	02/04/2014 03/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/CVM/OCD/	Rebecca L. Dandeker Morgan, Lewis & Bockius LLP	SIMS, MALLADI, GUFIC ETC - 483, EIR SUMMARY (01/01/2010 - 12/30/2013)
2014-845	02/04/2014 03/05/2014	FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/	JOSEPH WALKER Walker, Joseph	ADVANCED NEUROMODULATION SYSTEMS, PLANO, TX - VIOLATION RECS 03/07/2009 - 01/31/2014
2014-846	02/04/2014 03/05/2014	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORR/SE-FO/NOL-DO/NOL-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	RECALLS BY FIRMS LOCATED IN ALABAMA - 01/01/2004 - 12/31/2012
2014-847	02/04/2014 03/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nicola Hartigan David A. Klein	PROSCAR - SBA
2014-848	02/04/2014 03/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Margaret Sestrom PFIZER	NDA 19872 - SBA
2014-849	02/04/2014 03/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Robert D. Wilson Wilson & Wilson Co., L.P.A.	K130474
2014-850	02/04/2014 03/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Robert D. Wilson Wilson & Wilson Co., L.P.A.	K123936
2014-851	02/04/2014 03/05/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Robert D. Wilson Wilson & Wilson Co., L.P.A.	K101276
2014-852	02/04/2014 03/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Robert D. Wilson Wilson & Wilson Co., L.P.A.	K100423
2014-853	02/04/2014 03/05/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Gary Syring SYRING, GARY J	K053609, K062134
2014-854	02/04/2014 03/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Daisy Pagan OMT LLC	K931548
2014-855	02/04/2014 03/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELLIOT FAVUS FAVUS INSTITUTIONAL	LINZESS (LINACLOTIDE) - AERS 1/12 TO PRESENT

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RESEARCH LLC	
2014-856	02/04/2014 03/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELLIOT FARVUS FAVUS INSTITUTIONAL RESEARCH LLC	ADCETRIS (BRENTUXIMAB VEDOTIN) - AERS 6/13 TO PRESENT
2014-857	02/04/2014 03/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELLIOT FAVUS FAVUS INSTITUTIONAL RESEARCH LLC	MANNKINC - AFREZZA (INHALED INSULIN) AERS 1/09 to PRESENT
2014-858	02/04/2014 03/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	ANN WATEHOUSE HILL-ROM	STRYKER CORP - K103536; INTERNATIONAL BIOPHYSICS CORP - K122480
2014-859	02/04/2014 03/05/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORACE-FO/MIN- DO/MIN-CB/	IVAR SORENSEN ACUITY MEDICAL INTL	SOUTHERN HILLS GENERAL HOSPITAL IRB, HOT SPRINGS, SD - TESMAC OPEN LABEL STUDY, AUDITS 2000 TO PRESENT
2014-860	02/04/2014 03/05/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	ADRIAN O VEGA WILL FERGUSON & ASSOCIATES	OLYMPUS AMERICA, SAN JOSE, CA - TRACHEAL INTUBATING FIBERSCOPE APRVL, TESTING PROTOCOLS, RESULTS, ETC
2014-861	02/04/2014 03/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	JAYSON L PARKER UNIV OF TORONTO MISSISSAUGA	ABBOTT - MULTI LINK UTRA/MULTI LINK ZETA CORONARY STENT P970020 APRVL, CLNCL RECS 10/2/97; R4 VASCULAR INC - MEODIFIED VECTOR CATHETER K131329; BOSTON SCIENTIFIC -SYMMETRY SMALL VESSEL BALLOON DILATION CATHETER K953502, ETC
2014-862	02/04/2014 03/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MAKOTO KAINO EISAI CO LTD	SEOUL NATIONAL UNIV HOSPITAL, SEOUL KOREA 4/2/12; SEOUL NATI UNIV HOSPITAL DEPT MED, SEOUL KOREA 5/23/11; ASAN MED CTR, SEOUL KOREA 4/9/12 - EIRS, 483S, ETC
2014-863	02/04/2014 03/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JAY E SIROIS CHRA CONSUMER HEALTHCARE PRODUCTS ASSOCIATION	TOPICAL ACNE NONPRESCRIPTION &/OR SALICYLIC ACID - AERS, FAFTEY RECS
2014-864	02/04/2014	FDA/OGROP/ORACE-FO/NOL-	PATRICIA LL REGENYE	EDWARD KIM, UNIV UROLOGY, KNOXVILLE, TN - 483S 6/05

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	03/05/2014	DO/NOL-CB/	Celgene Corporation	TO PRESENT
2014-865	02/04/2014 03/05/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/	DEVA SUNDARARAJAN GLOBAL TRADE INTELLIGENCE INC	IMPORT REFUSAL RECS 8/14/13 TO PRESENT
2014-866	02/04/2014 03/05/2014	FDA/OC/OES/DDM/ FDA/OFVM/CFSAN/OCD/EOS/	AMI V GADHIA CONSUMERS UNION	CARMEL COLOR IN FOODS & BEVERAGES - PETITION, APRVL, FR NOTICES 1/60 TO 12/79
2014-867	02/04/2014 03/05/2014	FDA/OO/OIM/OPILS/FDAHO/	JOSHUA CLARK DAVIS DUKE UNIVERSITY	OHSAWA FOUNDATION; NATURES CUPBOARD RESTAURANT GEORGE OHSAWA, IRMA PAULE (PAUL) - RECS
2014-868	02/04/2014 03/05/2014	FDA/OO/OIM/OPILS/FDAHO/ FDA/OO/OIM/OPILS/FDAHO/	JOSHUA CLARK DAVIS DUKE UNIVERSITY	EREWHON TRADING CO, AVELINE KUSHI, MICHIO KUSHI, KEIZO KUSHI, ETC - RECS
2014-869	02/04/2014 03/05/2014	FDA/OC/OES/DFOI/	MARDY, GAELLE A	LIST OF THE AMOUNT OF TIME FDA HAS RELEASED A WARNING DUE TO THE WRONG DOSAGE, ITEMS DEFECTED, RECALL OF A DRUG
2014-870	02/04/2014 03/05/2014	FDA/OO/OIM/OPILS/FDAHO/	JOSHUA CLARK DAVIS DUKE UNIVERSITY	MACROBIOTICS OR MACROBIOTIC DIET - RECS 1965 TO 1970
2014-871	02/04/2014 03/05/2014	FDA/OO/OFBA/OAGS/	JEFF STACHEWICZ FOIA GROUP INC	HHSF22301100381 - CONTRAST, WINNING PROPOSALS, BINDDER'S LIST, ETC
2014-872	02/04/2014 03/05/2014	FDA/OC/OES/DFOI/	KAREN BZDYK Donna B Michelson PA	2004-18120, 2010-6248, 2010-6251, ETC
2014-873	02/04/2014 03/05/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	BRETT PARK CONWAY, HOMER & CHIN- CAPLAN PC	INDIVIDUAL RECS (CERTIFIED)
2014-874	02/04/2014 03/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Pauliana Hall PCH integrated Regulatory Services, Inc.	NDA 019429
2014-875	02/04/2014 03/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	John Sokolowski Fluidnet Corp	K121613
2014-876	02/04/2014 03/05/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Pauliana Hall PCH integrated Regulatory Services, Inc.	NDA 020232
2014-877	02/04/2014	FDA/OMPT/CDER/ORP/DIDP/	Pauliana Hall	NDA 088616

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	03/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PCH integrated Regulatory Services, Inc.	
2014-878	02/04/2014 03/05/2014	FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA REQUEST LOG 01/27/2014 - 01/31/2014
2014-879	02/04/2014 03/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dr. Dhruvajyoti Pathak NOVARTIS PHARMACEUTICALS CO	3795530 4127070 5734751 ETC
2014-880	02/04/2014 03/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Pauliana Hall PCH integrated Regulatory Services, Inc.	NDA 017534
2014-881	02/04/2014 03/05/2014	OC/ORO/ORM/ OC/ORO/ORM/ OC/ORO/OE/ OC/ORO/OE/	Querida Anderson BIOPHARM INSIGHT	BIOTECH, GENERICS, PHARMACEUTICAL COMPANIES, CROs INSPECTED 10/01/13 TO 12/31/13
2014-882	02/04/2014 03/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jennifer C. Smith-Parker BIOPHARM INSIGHT	NDA 022575 - MEDWATCH REPORTS; NDA 205123 - MEDWATCH REPORTS
2014-883	02/05/2014 03/06/2014	FDA/OMPT/CDRH/OCER/DFOI/	Angela Erickson INSTITUTE FOR JUSTICE	TOMOGRAPHY CT SCANNER DATA 01/01/2001 - 12/31/2013
2014-884	02/05/2014 03/06/2014	FDA/OMPT/CDRH/OCER/DFOI/	Angela Erickson INSTITUTE FOR JUSTICE	MRI MACHINE DATA 01/01/2001 - 12/31/2013
2014-885	02/05/2014 03/06/2014	FDA/OGROP/ORO/CE-FO/CHI-DO/CHI-CB/	Robert Bexton Aristotle Capital Management	BAXTER, ROUND LAKE, IL - 483 12/01/2013 - 01/22/2014
2014-886	02/05/2014 03/06/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	Lewis Kaufman Lewis Kaufman	SUNLESS TANNING SPRAY - AERS
2014-887	02/05/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	LIST OF CLOSED FOIA REQUESTS 1/1/2014 TO 1/31/2014

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	03/06/2014	FDA/OC/OES/DFOI/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	MERCK & CO., INC.	
2014-888	02/05/2014 03/06/2014	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Steven Rogers Zoetis Inc.	VETERINARY RESOURCES, INC, AMES, IA - EIR 07/01/2008 - 01/31/2014
2014-889	02/05/2014 03/06/2014	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	Steve Rogers Zoetis Inc.	JOHNSON RESEARCH, LLC, PARMA, ID - EIR 07/01/2008 - 01/31/2014
2014-890	02/05/2014 03/06/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	Steve Rogers Zoetis Inc.	SOUTHWEST BIO-LABS INC, LAS CRUCES, NM - EIR 09/01/2011 - 01/31/2014
2014-891	02/05/2014 03/06/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Steve Rogers Zoetis Inc.	RICERCA BIOSCIENCES COMPANY, PAINESVILLE, OH - EIR 07/01/2011 - 01/31/2014
2014-892	02/05/2014 03/06/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Steve Rogers Zoetis Inc.	CHARLES RIVER LABORATORY, SPENCERVILLE, OH - EIR 09/01/2011 - 01/31/2014
2014-893	02/05/2014 03/06/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 1/1-31/2014
2014-894	02/05/2014 03/06/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	John Sokolowski Fluidnet Corp.	K123049
2014-895	02/05/2014 03/06/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Nikhilesh Singh TRANSCEPT PHARMACEUTICALS INC	VESANOID - AERS
2014-896	02/05/2014 03/06/2014	FDA/OFVM/CFSAN/OCD/EOS/	Mitchall A. Cheeseman Cheeseman, Mitch	FCN 1272
2014-897	02/05/2014 03/06/2014	FDA/OMPT/CDRH/OCER/DFOI/	Richard Roesner SurgiPros	K123234, K102146
2014-898	02/05/2014 03/06/2014	FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECS
2014-899	02/05/2014 03/06/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kelly Clendenny Sigma-Aldrich Corporation	K932615
2014-900	02/05/2014 03/06/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	J Gooch Gooch Law firm	ANDA 079221

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2014-901	02/05/2014 04/09/2014	FDA/OFVM/CFSAN/OCD/EOS/	Food Contact Notification N0 1045 Point Plastic Srl	FCN 1045
2014-902	02/05/2014 03/06/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Mark Zanecki Zanecki, Irene	ST JOSEPH MERCY OAKLAND TRINITY MICHIGAN - WARNING LETTER RECS 01/01/2013 - 02/04/2014
2014-903	02/05/2014 03/06/2014	FDA/OC/OES/DFOI/	Charlene F. Richardson Richardson, Charlene F	DIOVAN HISTORY
2014-904	02/05/2014 03/06/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JAMIE KELLER PIRAMAL CRITICAL CARE INC	BAXTER HEALTHCARE - SIPRANE (DESFLURANE) N020118 APRVL
2014-905	02/05/2014 03/06/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	VILLARREAL, SANDRA	KLONOPIN - AER
2014-906	02/05/2014 03/06/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOZWIAK T-81269, RICHARD	ZOLOFT; VICODIN - AER
2014-907	02/05/2014 03/06/2014	OC/ORACE/ORM/ OC/ORACE/ORM/	ROBERT KING FDA NEWS	ALL MEDICAL DVC & CLINICAL TRAIL FACILITIES - 483 1/2014
2014-908	02/05/2014 03/06/2014	FDA/OC/OES/DFOI/ FDA/OGROP/ORACE-FO/SAN-DO/SAN-CB/	SANDRA ROBINSON, Ph.D. MIDWEST CENTER FOR INVESTIGATIVE REPORTING	CORR BETWEEN FDA & FOSTER FARMS , LIVINGSTON, CA 2013 TO 2014
2014-909	02/05/2014 03/06/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GREG SCHUSTER MORELLI RATNER PC	TESTOSTERONE - AER
2014-910	02/05/2014 03/06/2014	FDA/OGROP/ORACE-FO/LOS-DO/LOS-CB/	SCOTT J. TEPPER LAW OFFICES OF GARFIELD & TEPPER	J DELUCA FISH CO, JOHN DELUCA, SEA STAR FOODS INC, WILMINGTON, CA, ETC - RECS 1/00 TO 1/05

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2014-911	02/05/2014 03/06/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORO/CE-FO/CHI-DO/CHI-CB/	WILL McKENNA HOUND & GATOS PET FOODS CORP	CMP LNT 3009682133
2014-912	02/05/2014 03/06/2014	FDA/OC/OES/DFOI/	JAUNITA BRUMITT KOREIN TILLERY	MISOURRI STATUTE 490.220
2014-913	02/05/2014 03/06/2014	FDA/OC/OES/DFOI/	CAROL VILLEGAS LABATON SUCHAROW	2013-4084, 4423, 4580, 5166, 6368, 9918
2014-914	02/05/2014 03/06/2014	FDA/OC/OES/DFOI/	Doe J	PERSONNEL RECS 8/12 TO 2/14
2014-915	02/05/2014 03/06/2014	FDA/OC/OES/DFOI/	Doe J	PERSONNEL RECS 8/12 TO 2/14
2014-916	02/05/2014 03/06/2014	FDA/OC/OES/DFOI/ FDA/OO/OHR/	Doe J	PERSONNEL RECS 8/12 TO 10/12
2014-917	02/05/2014 03/06/2014	FDA/OFVM/CFSAN/OCD/EOS/	VISAGINE VIJAYAKULASINGAM IOVATE HEALTH SCIENCES INTERNATIONAL INC	IOVATE, HYDROXYCUT, SMARTBURN ETC - AER 11/13 TO PRESENT
2014-918	02/05/2014 03/06/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LESLIE SANDS LUPIN PHARMACEUTICALS INC	HYPERION THERAPS INC - BUPHENYL (SODIUM PHENYLBUTYRATE) NDA 20-572 - SBA
2014-919	02/05/2014 03/06/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LESLIE SANDS LUPIN PHARMACEUTICALS INC	HYPERION THERAPS INC - BUPHENYL (SODIUM PHENYLBUTYRATE) NDA 20-573 - SBA
2014-920	02/05/2014 03/06/2014	FDA/OO/OFBA/OAGS/	KAITLIN DEVINE SUNLIGHT FOUNDATION	SMARTPAY TRANSACTONS ABOVE 5000.00 BEWTWEEN 2007 TO 2013
2014-921	02/06/2014 03/07/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Diana Halim AnGes, Inc.	SANOFI PHASE THREE STUDY RECS - TAMARIS
2014-922	02/06/2014 03/07/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Diana Halim AnGes, Inc.	SANOFI PHASE THREE STUDY RECS - TAMARIS
2014-923	02/06/2014	FDA/OMPT/CDER/ORP/DIDP/	Shreena Patel	ANDA 076135 - APPROVAL PACKAGE

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	03/07/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Amneal Pharmaceuticals	
2014-924	02/06/2014 03/07/2014	OC/ORA/ORM/ OC/ORA/ORM/	Jeremy Singer-Vine THE WALL STREET JOURNAL	MARCS DATA RE CORD BLOOD FACILITIES
2014-925	02/06/2014 03/07/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ayesha Adil The Weinberg Group	NDA 020622 S 089 - SBA
2014-926	02/06/2014 03/07/2014	FDA/OFVM/CFSAN/OCD/EOS/	Janet Blaschke International Cosmetics & Regulatory Specialists, LLC	PAFA DATABASE
2014-927	02/06/2014 03/07/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Cynthia Berringer Kadmon Pharmaceuticals, LLC	NDA 019194
2014-928	02/06/2014 03/07/2014	FDA/OC/OES/DFOI/	Sherry Purvis-Wynn personal	INDIVIDUAL RECS
2014-929	02/06/2014 03/07/2014	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	Mary Ann B. Kinard Facet Technologies, LLC	FACET TECHNOLOGIES, KENNESAW, GA - EIR 09/24/2013 - 01/30/2014
2014-930	02/06/2014 03/07/2014	FDA/OC/OES/DFOI/	Laura Hobbs for Jaime Vassallo CourtLink Document Retrieval	2011-7649
2014-931	02/06/2014 03/07/2014	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Thomas DesChamps Healthcare Value Capital	ALEXION PHARMACEUTICALS - CORR WITH FDA 01/01/2013 - 02/05/2014
2014-932	02/06/2014 03/07/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tammy Monteith Banner Pharmacaps, Inc. d.b.a. Patheon Pharmaceuticals, Inc.	NDA 020267
2014-933	02/06/2014	OC/ORA/	George Salmas	IMPORT ALERT 16-81

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	03/07/2014	OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/	The Food Lawyers	
2014-934	02/06/2014 03/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Laura Hobbs for Jaime Vassallo CourtLink Document Retrieval	ANDA 75877
2014-935	02/07/2014 03/10/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 1/20-25/14
2014-936	02/07/2014 03/10/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 1/13-18/14
2014-937	02/07/2014 03/10/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 1/6-11/14
2014-938	02/07/2014 03/10/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 12/30/13 TO 1/4/14
2014-939	02/07/2014 03/10/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 1/20-24/14
2014-940	02/07/2014 03/10/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 1/13-17/14
2014-941	02/07/2014 03/10/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUEST 1/6-10/14
2014-942	02/07/2014 03/10/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 12/30/13-1/4/14
2014-943	02/07/2014 03/10/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 1/20-24/13
2014-944	02/07/2014 03/10/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 1/13-17/13
2014-945	02/07/2014 03/10/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 12/30/13-1/3/14
2014-946	02/07/2014 03/10/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 1/6-10/14

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2014-947	02/07/2014 03/10/2014	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 1/20-24/14
2014-948	02/07/2014 03/10/2014	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 1/13-17/14
2014-949	02/07/2014 03/10/2014	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 1/6-10/14
2014-950	02/07/2014 03/10/2014	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 12/30/13-1/4/14
2014-951	02/07/2014 03/10/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 1/20-24/14
2014-952	02/07/2014 03/10/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 1/13-17/14
2014-953	02/07/2014 03/10/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 1/6-10/14
2014-954	02/07/2014 03/10/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 12/30/13-1/4/14
2014-955	02/07/2014 03/10/2014	FDA/OC/OES/DFOI/	BRIDGET K SMITHA Greenberg Traurig, P.A.	TARMAC PRODUCTS INC (AXARA PHARMS) - WARNING LTR 2/4/11 (CERTIFIED); ANDA 75-794 (CERTIFIED); DEPT OF JUSTICE PRESS RELEASE REGARDING ABBOTT LABS 5/7/12 (CERTIFIED)
2014-956	02/07/2014 03/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ROBERT A NORGDARD NORGARD & NORGDARD	MIDAZOLAM HCL - AERS
2014-957	02/07/2014 03/10/2014	FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECS
2014-958	02/07/2014 03/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORAP/PA-FO/SEA-DO/SEA-CB/ FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	ALICJA WOJEWNIA DICENTRA REGULATORY & SCIENTIFIC SOLUTIONS	VIMAX - DISTRIBUTOR NAME, LOT NUMBER TESTED, SPL PURCHASE LOCATION, ETC
2014-959	02/07/2014	FDA/OMPT/CDER/ORP/DIDP/	GREG SCHUSTER	ANDROGEL, AXIRON, TESTIM - AERS

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	03/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MORELLI ALTERS RATNER LAW FIRM	
2014-960	02/07/2014 03/10/2014	FDA/OFVM/CFSAN/OCD/EOS/	MELVIN F O'BRIEN DICKIE MCCAMEY & CHILCOTE	OPI PRODUCTS INC - NAIL LACQUERS, NAIL ENVY PRODS CMLNPTS, INVESTIGATION RECS
2014-961	02/07/2014 03/10/2014	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/ FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	SHAYNE HELLER LACHAPELLE HELLER LACHAPELLE	BETANCOURT SPORTS NUTRITION LLC - RIPPED JUICE EX2, RIPPED JUICE REV-PEA STATEMENTS OF NUTRITIONAL SUPPORT, CAERS, CORR, ETC
2014-962	02/07/2014 03/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FISTER, PAUL	CBA PHARMA INC (CBA INTERNATIONAL INC, APPLIED MEDICAL TECHNOLOGIES) - CBT-1 COMPLETE RESP LTR
2014-963	02/07/2014 03/10/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	MELISSA L KORFHAGE DINSMORE & SHOHL LLP	PARCELL LABORATORIES LLC, APHATEC HOLDINGS INC, NEW ENGLAND CRYOGENIC CENTER, ETC - PUREGEN OSTEOPROGENITOR CELL ALLOGRAFT (ELA CELLS) WARNING LTRS, 483S, UNTITLED LTRS, ETC
2014-964	02/07/2014 03/10/2014	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	MANUEL E VELASQUEZ BOLNER'S FIESTA PRODUCTS INC	BOLNER'S FIESTA PRODUCTS INC, SAN ANTONIO, TX - SPL 812122 TEST RESULTS
2014-965	02/07/2014 03/10/2014	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	MANUEL E VELASQUEZ BOLNER'S FIESTA PRODUCTS INC	BOLNER'S FIESTA PRODUCTS INC, SAN ANTONIO, TX - SPL 812121 TEST RESULTS
2014-966	02/07/2014 03/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GUY R BUCCI BUCCI BAILEY & JARVIS LC	MYLAN PHARMS - PHENYTOIN SODIUM CAPS AERS, APRVL RECS 1998 TO 2006
2014-967	02/07/2014 03/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	AMY MITCHELL GLAXO SMITH KLINE	GLAXOSMITHKLINE, CORK - QUALITY ASSURANCE PROFILE (QAP)

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-968	02/07/2014 03/10/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	GORDON HARNACK ORACLE CONSULTING GROUP	BIOMET MANUFACTURING CORP - BIOMET SLEEVE AND BUTTON SOFT TISSUE DVCS K071704
2014-969	02/07/2014 03/10/2014	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	Doe J	INDIVIDUAL RECS
2014-970	02/07/2014 03/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	BENJAMIN L ENGLAND ESQ BENJAMIN L ENGLAND & ASSOCIATES LLC	EXAMINATION GLOVES K111589, K123368
2014-971	02/07/2014 03/10/2014	FDA/OC/OES/DFOI/	SCHUDY, JEREMY	OFFICE OF THE INSPECTOR GENERAL (OIG) COMPLIANCE PROGRAM - VIOLATIONS, PENALTIES, YEARS OF PARTICIPATION, ETC LAST 24 MONTHS
2014-972	02/07/2014 03/10/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	HAMILTON, LEROY L PHD	FRANCES KELSEY AWARD RECIPIENTS - NAMES, DATES, REASON FOR THE AWARD
2014-973	02/07/2014 03/10/2014	FDA/OC/OES/DFOI/	KAREN BZDYK ESQ Donna B Michelson PA	WARNER-LAMBERT, PFIZER - SUDAFED FOIA REQUESTS
2014-974	02/07/2014 03/10/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	SEATTLE GENETICS - ADCETRIS (BRENTUXIMAB VEDOTIN) AERS
2014-975	02/07/2014 03/10/2014	FDA/OGROP/ORA/CE-FO/BLT- DO/BLT-CB/ FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	UNITED THERAPEUTICS CORP, SILVER SPRING, MD; RESEARCH TRIANGLE PARK, NC - EIRS, 483S, UNTITLED LTRS 1/13 TO PRESENT
2014-976	02/07/2014 03/10/2014	FDA/OGROP/ORA/CE-FO/CHI- DO/CHI-CB/ FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/ FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	AUXILIUM PHARMS, MALVERN, PA, CHESTERBROOK, PA; ACTIENT HOLDINGS, LAKE FOREST, IL; SLATE PHARMS, DURHAM, NC - EIRS, 483S, UNTITLED LTRS 4/13 TO PRESENT
2014-977	02/07/2014 03/10/2014	FDA/OFVM/CFSAN/OCD/EOS/	DAVIS #13-04439, THOMAS C	ASPARTAME - CAERS

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2014-978	02/10/2014 03/11/2014	OC/ORO/ OC/ORO/	George Ball UNIVERSITY OF MINNESOTA	ORA INSPECTORS IN DEVICE PLANTS - TOTAL NUMBER
2014-979	02/10/2014 03/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Julia Chan Cipher Pharmaceuticals Inc.	NDA 02237 - NDA APPROVAL LETTER, NDA SUPPLEMENTAL APPROVAL LETTER (CERTIFIED)
2014-980	02/10/2014 03/11/2014	FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/ FDA/OO/OHR/ FDA/OO/OHR/	Liran Eisenberg Amber IT Consulting	DANIEL FAM - TRAINING, WARNING LETTERS, BIO ETC
2014-981	02/10/2014 03/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Pauliana Hall PCH integrated Regulatory Services, Inc.	OCTIN, OCTINUM NDA APPROVAL PACKAGE
2014-982	02/10/2014 03/11/2014	FDA/OFVM/CFSAN/OCD/EOS/	Jennifer Hunt Spectronics Corporation	CASE NO 518-47-8 URANINE - TOXICOLOGY DATA
2014-983	02/10/2014 03/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Andrea Demakas ADVERSEEVENTS INC	GADAVIST (GADOBUTROL), PHOSLYRA (CALCIUM ACETATE), GENERESS FE (NORETHINDRONE; ETHINYL ESTRADIOL; FERROUS FUMARATE) ETC - AERS
2014-984	02/10/2014 03/11/2014	FDA/OC/OES/DFOI/	Bridget Smitha Greenberg Traurig c/o Bridget Smitha	CERTIFIED RECORDS
2014-985	02/10/2014 03/11/2014	FDA/OGROP/ORO/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORO/CE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORO/PA-FO/SEA-DO/SEA-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Genevive Blanchette ALGORITHM PHARMA INC	NOVUM, CLARENCE, NY; NOVUM, PITTSBURG, PA; QPS, LLC, HYDERABAD, INDIA ETC - 483 (01/01/2013 - 12/31/2013)

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2014-986	02/10/2014 03/11/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Cecile Schilis-Gallego Columbia Journalism School	BAYER YAZ - MARKETING RECS 03/01/2006 - 10/01/2011
2014-987	02/10/2014 03/11/2014	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Rebecca Dandeker Morgan, Lewis & Bockius LLP	HALO PHARMACEUTICAL, NJ - 483, EIR SUMMARY (07/01/2013 - 10/15/2013)
2014-988	02/10/2014 03/11/2014	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	PNC 561
2014-989	02/10/2014 03/11/2014	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Michelle Kern Hospira, Inc.	HOSPIRA, AUSTIN, TX - EIR 07/30/2012 - 08/24/12
2014-990	02/10/2014 03/11/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ellen Camos ANI Pharmaceuticals, Inc.	ANDA 71977
2014-991	02/10/2014 03/11/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ellen Camos ANI Pharmaceuticals, Inc.	ANDA 88921
2014-992	02/10/2014 03/11/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ellen Camos ANI Pharmaceuticals, Inc.	NDA 40111
2014-993	02/10/2014 03/11/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ellen Camos ANI Pharmaceuticals, Inc.	ANDA 061591
2014-994	02/10/2014 03/11/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ellen Camos ANI Pharmaceuticals, Inc.	ANDA 77641
2014-995	02/10/2014 03/11/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ellen Camos ANI Pharmaceuticals, Inc.	ANDA 80259

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-996	02/10/2014 03/11/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ellen Camos ANI Pharmaceuticals, Inc.	ANDA 088922
2014-997	02/10/2014 03/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	Beka Vite Vascular Solutions, Inc.	K052381, K073620
2014-998	02/10/2014 03/11/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Cecile Schilis-Gallego Columbia Journalism School	NATAZIA - AERS
2014-999	02/10/2014 03/11/2014	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Michelle Kern Hospira, Inc.	HOSPIRA, ROCKY MOUNT, NC - EIR (02/12/2013 - 02/06/2014)
2014-1000	02/10/2014 03/11/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ellen Camos ANI Pharmaceuticals, Inc.	ANDA 88682
2014-1001	02/10/2014 03/11/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shelley Schmidt Chiesi Pharmaceuticals Inc.	RENTSCHLER BIOTECHNOLOGIE GMBH & CO - EIR, 483 09/20/2013
2014-1002	02/10/2014 03/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	Greg Davis DAVIS, GREGORY	K130663
2014-1003	02/10/2014 03/11/2014	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Denise Murrell OPTI Medical	OPTI MEDICAL - EIR JUNE 2013
2014-1004	02/10/2014 03/11/2014	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	Chastity Rodriguez INTERNATIONAL SIGHT RESTORATION INC	KANSAS EYE BANK - WARNING LETER, 483 01/01/2004 - 02/05/2014
2014-1005	02/10/2014 03/11/2014	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Rebecca Dandeker Morgan, Lewis & Bockius LLP	HALO PHARMA - EIR 07/01/2013 - 10/15/2013
2014-1006	02/10/2014 03/11/2014	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ OC/ORA/OCI/ OC/ORA/OCI/	Rachel Walling TUCKER ELLIS LLP	DR JOHN HISERODT - INVESTIGATION RECS 01/01/1996 - 01/01/2000

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2014-1007	02/10/2014 03/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Andrea Demakas ADVERSEEVENTS INC	BRISDELLE (PAROXETINE MESYLATE), LO MINASTRIN FE (ETHINYL ESTRADIOL; NORETHINDRONE ACETATE) ETC - AERS
2014-1008	02/10/2014 03/11/2014	FDA/OFVM/CFSAN/OCD/EOS/	Courtland W. Creekmore, Esq. SCOTT COLE & ASSOCIATES, APC	Any and all data, studies, reports provided to Food and Drug Administration by Consumer Reports and/or Johns Hopkins Center for a Livable Future regarding the presence of 4-Methylimidazole in soft drinks
2014-1009	02/10/2014 03/11/2014	FDA/OFVM/CFSAN/OCD/EOS/	Judy Negley Valspar Corporation	FCN 1281
2014-1010	02/10/2014 03/11/2014	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	Michelle Kern Hospira, Inc.	HOSPIRA, ROCKY MOUNT, NC - EIR 09/30/2013 - 02/06/2014
2014-1011	02/10/2014 03/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	Andreas Stromberger Covidien Group Japan	K923436
2014-1012	02/10/2014 03/11/2014	FDA/OGROP/ORR/CE-FO/BLT-DO/BLT-CB/	Rachel Johnson FOI Services, Inc.	UNIVERSITY OF MARYLAND MEDICAL SCHOOL - EIR, 483
2014-1013	02/10/2014 03/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jay Cohen MD Jay Cohen MD	FLUOROQUINOLONE ANTIBIOTICS - AERS
2014-1014	02/10/2014 03/11/2014	FDA/OGROP/ORR/CE-FO/BLT-DO/BLT-CB/	Seth Payer UFCW INTERNATIONAL UNION, CLC	KEANY PRODUCE, LANDOVER, MD - INSPECTION RECS 01/01/2012 - 02/07/2014
2014-1015	02/10/2014 03/11/2014	FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/	Rachel Johnson FOI Services, Inc.	STILLMEADOW, SUGARLAND, TX - EIR, 483
2014-1016	02/10/2014 03/11/2014	FDA/OGROP/ORR/CE-FO/DET-DO/DET-CB/	DENNIS C GUCCIARDO HOGAN LOVELLS LLP	DEPUY ORTHOPEDICS INC, WARSAW, IN - EIR 5/10/11-6/7/11
2014-1017	02/10/2014 03/11/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 12/30/13-1/3/14
2014-1018	02/10/2014 03/11/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 12/30/13-1/3/14
2014-1019	02/10/2014 03/11/2014	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 12/30/13-1/3/14
2014-1020	02/10/2014	FDA/OC/OES/DFOI/	KEN REID	FOI DAILY LOG 1/20-24/14

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	03/11/2014		WASHINGTON INFORMATION SOURCE	
2014-1021	02/10/2014 03/11/2014	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 1-6-10/14
2014-1022	02/10/2014 03/11/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 1/20/13-1/24/14
2014-1023	02/10/2014 03/11/2014	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 12/30/13-1/3/14
2014-1024	02/10/2014 03/11/2014	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 1/20-24/14
2014-1025	02/10/2014 03/11/2014	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 1/6-10/14
2014-1026	02/10/2014 03/11/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 1/6-11/14
2014-1027	02/10/2014 03/11/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 1/20-25/14
2014-1028	02/10/2014 03/11/2014	FDA/OC/OES/DFOI/	GLADYS B TONKIN Center for Regulatory Services,Inc.	FOI DAILY LOG 1/20-24/14
2014-1029	02/10/2014 03/11/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 1/6-10/14
2014-1030	02/10/2014 03/11/2014	FDA/OC/OES/DFOI/	GLADYS B TONKIN Center for Regulatory Services,Inc.	FOI DAILY LOG 12/30/13-1/4/14
2014-1031	02/10/2014 03/11/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 1/13-17/14
2014-1032	02/10/2014 03/11/2014	FDA/OC/OES/DFOI/	GLADYS B TONKIN Center for Regulatory Services,Inc.	FOI DAILY LOG 1/6-10/14
2014-1033	02/10/2014 03/11/2014	FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 12/30/13-1/4/14
2014-1034	02/10/2014 03/11/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 1/13-17/14
2014-1035	02/10/2014	FDA/OC/OES/DFOI/	BARBARA JONES	FOI DAILY LOG 1/13-17/14

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	03/11/2014		DOMINION GROUP INC	
2014-1036	02/10/2014 03/11/2014	FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 1/20-24/14
2014-1037	02/10/2014 03/11/2014	FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 1/6-10/14
2014-1038	02/10/2014 03/11/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 1/13-17/14
2014-1039	02/10/2014 03/11/2014	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD Center for Regulatory Services, Inc.	FOI DAILY LOG 1/13-17/14
2014-1040	02/10/2014 03/11/2014	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 1/13-17/14
2014-1041	02/11/2014 03/12/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ellen Camos ANI Pharmaceuticals, Inc.	ANDA 62698
2014-1042	02/11/2014 03/12/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ellen Camos ANI Pharmaceuticals, Inc.	ANDA 077979
2014-1043	02/11/2014 03/12/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SW-FO/DAL- DO/DAL-CB/ FDA/OGROP/ORO/SW- FO/SWID/SWID-CB/	Luis Chavarria Supaso International LLC	U93-0076366-8
2014-1044	02/11/2014 03/28/2014	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	A copy of any and all research, studies, data, or science related to youth performed or collected by the Food & Drug Administration in developing The Real Cost campaign for the Tobacco-Free Kids program
2014-1045	02/11/2014 03/12/2014	FDA/OGROP/ORO/PA-FO/SAN- DO/SAN-CB/	Rachel Johnson FOI Services, Inc.	LIFESCAN, MILPITAS, CA - EIR, 483
2014-1046	02/11/2014	FDA/OMPT/CBER/OCOD/DDOM/	Susan McCormack	CURRENT LIST OF DRUGS AND BIOLOGICS WITH

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	03/12/2014	ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Susan McCormack	BREAKTHROUGH THERAPY DESIGNATION
2014-1047	02/11/2014 03/12/2014	FDA/OGROP/ORAN/NE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	EIR, 483 and the firm's response for the May 2, 2013 inspection for: Shire Human Genetic Therapies, Inc., Lexington, MA
2014-1048	02/11/2014 03/12/2014	FDA/OGROP/ORAN/NE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection report, 483 and the firm's response for the May 2, 2013 inspection for: Lonza, Hopkinton, MA.
2014-1049	02/11/2014 03/12/2014	FDA/OGROP/ORAN/NE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection report, 483 and the firm's response for the April 9, 2013 inspection for: Genzyme, Northborough, MA
2014-1050	02/11/2014 03/12/2014	FDA/OGROP/ORAN/NE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection report, 483 and the firm's response for the March 26, 2013 inspection for: Cubist Pharmaceuticals, Inc., Lexington, MA
2014-1051	02/11/2014 03/12/2014	FDA/OGROP/ORAN/NE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection report, 483 and the firm's response for the June 20, 2013 inspection for: Bristol Myers Squibb, Devens, MA
2014-1052	02/11/2014 03/12/2014	FDA/OGROP/ORAN/NE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection report, 483 and the firm's response for the March 15, 2013 inspection for: Biogen Idec, Inc., Cambridge, MA
2014-1053	02/11/2014 03/12/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Melissa Hibbs Hospital of the University of Pennsylvania	MULTIHANCE - AERS
2014-1054	02/11/2014 03/12/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ketaki Gokhale BLOOMBERG NEWS	LIST OF FINISHED PHARMACEUTICAL PRODUCUTS WITH RANBAXY API
2014-1055	02/11/2014 03/12/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	EFFEXOR XR - MEDWATCH FORMS

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2014-1056	02/11/2014 03/12/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Karen Schultz The Dominion Group	XARELTO - AERS
2014-1057	02/11/2014 03/12/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rob M Hagopian MEDICA CORPORATION	K031560
2014-1058	02/11/2014 03/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	Alexander Jacob Evanoff Northwestern Univeristy	K871358, K871358, K902936
2014-1059	02/11/2014 03/12/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tina M. Babos IPD ANALYTICS LLC	ANDA 202206 - APPROVAL LETTER
2014-1060	02/11/2014 03/12/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	William J. Gazonas William J. Gazonas	PROVECTUS PHARMACEUTICALS - MTG MINUTES 12/12/2013 - 12/31/2013
2014-1061	02/11/2014 03/12/2014	FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA REQUEST LOG 02/03/2014 - 02/07/2014
2014-1062	02/11/2014 03/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	Gregory Maschek MEDTRONIC, INC.	K123045
2014-1063	02/11/2014 03/12/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Evelyn Webster Pinsent Masons	INACTIVE INGREDIENT LIST 1996
2014-1064	02/11/2014 03/12/2014	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2012-7143
2014-1065	02/11/2014 03/12/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Theis Terwey NB Capital Research GmbH	TECFIDERA - AERS
2014-1066	02/11/2014 03/12/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/	Jasmanda Wu SANOFI	TERIFLUNOMIDE - AERS

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2014-1067	02/11/2014 03/12/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jasmanda Wu SANOFI	DIMETHYL FUMARATE - AERS
2014-1068	02/11/2014 03/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	Ryan Fitzpatrick Ryan Fitzpatrick	K130012
2014-1069	02/11/2014 03/12/2014	OC/CVM/OCD/	Jen French WSYX/WTTE (Sinclair Broadcasting)	SPINOSAD, MILBEMYCIN - AERS
2014-1070	02/11/2014 03/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	ACP Arrastia Capote & Phang	K062433
2014-1071	02/11/2014 03/12/2014	FDA/OFVM/CFSAN/OCD/EOS/	Dale Bauer Kemira Chemicals	OPINION LETTER RE SILOXANES AND SILICONES (02/08/1960 - 02/07/2014)
2014-1072	02/11/2014 03/12/2014	FDA/OGROP/ORR/SE-FO/ATL- DO/ATL-CB/	Margaret Groves, JD, CRA, CCRP DUKE UNIVERSITY	DUKE UNIVERSITY - EIR, CLOSEOUT LETTER (10/15/2013 - 01/31/2014)
2014-1073	02/11/2014 03/12/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Casey McDonald BIOPHARM INSIGHT	EYLEA, LUCENTIS - MEDWATCH RPTS
2014-1074	02/11/2014 03/12/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Adrienne E Faerber PhD (608) 345-5380 Dartmouth Inst. Cent. For Med. Media.	REMICADE 103772 S5113, 103772 S5301, 103772 S5077
2014-1075	02/11/2014 03/12/2014	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORR/ORM/ OC/ORR/ORM/	Mark Prinz Registrar Corp	LISTING OF FOREIGN FOOD FACILITIES (10/01/2013 - 01/31/2014)
2014-1076	02/11/2014 03/12/2014	FDA/OGROP/ORR/NE-FO/NYK- DO/NYK-DCB/	VANESSA C. JACKSON Bactolac Pharmaceutical, Inc.	ALASKA SPRINGS, WESTBURY, NY - EIR, 483 SINCE 1/10
2014-1077	02/11/2014 03/12/2014	FDA/OFVM/CFSAN/OCD/EOS/	JAMES MCGINLEY SONGWON INTERNATIONAL - AMERICAS INC	FCN 1270

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2014-1078	02/11/2014 03/12/2014	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	BENJAMIN L. STEWART BAILEY BEAUER PLLC	NAVARRO PECAN COMPANY; SOUTH GEORGIA PECAN COMPANY - CIVIL SUIT 13-CV-00734-P
2014-1079	02/11/2014 03/12/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	THOMPSON 1883463, THOMAS	HOSPICE INC - REGLAN WARNING LABEL 2006 TO 2009
2014-1080	02/11/2014 03/12/2014	FDA/OFVM/CFSAN/OCD/EOS/	FRIEDMAN, ROBERT	BETTY CROCKER; DUNCAN HINES - CAKE MIX CAERS 1996 TO 2014
2014-1081	02/11/2014 03/12/2014	FDA/OMPT/CTP/OD/	United Banking Systems 04991-004 Elliott Greenleaf & Siedzikowski, P.C.	CTP VS VICTOR TORRES - NOTICE OF SETTLEMENT AGREEMENT
2014-1082	02/11/2014 03/12/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORASW-FO/SWID/SWID-CB/	SAMANTHA MYERS ROANOKE CLAIMS SERVICES	MT EXPORT SERVICES LLC - ENTRY NO DV101433683
2014-1083	02/11/2014 03/12/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LAWRENCE F. TRACEY TRACEY LAW FIRM	CELEXA/CITALOPRAM - RAT STUDIES BY DR. BARRY ROSLOFF 1983 TO 1991
2014-1084	02/11/2014 03/12/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	COCHRAN, IRIS	BIOGEN - TECFIDERA 7/12 TO PRESENT
2014-1085	02/11/2014 03/12/2014	FDA/OC/OES/DFOI/	ANDREW HACK, MD, Ph.D. MILLENNIUM MANAGEMENT LLC	2013 - 5481, 5541, 5861 ETC
2014-1086	02/11/2014 03/12/2014	FDA/OFVM/CFSAN/OCD/EOS/	WILLIAM A. OLSON, Ph.D. Center for Regulatory Services, Inc.	FCN 549
2014-1087	02/11/2014 03/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	ANNE M. HULL HUTTON & HUTTON	EDWARDS LIFESCIENCES - VALVE SAPIEN RF 26MM - MAUDE RPT
2014-1088	02/11/2014 03/12/2014	FDA/OFVM/CFSAN/OCD/EOS/	ALISA BOUCHER BASF CORP	EASTMAN CHEMICAL CO - FCN 1056; FCN 770

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2014-1089	02/11/2014 03/12/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/	BOBBY SCHOCHET OLSSON FRANK & WEEDA	CANDY TREASURE, LEBANON, NJ - CHOCO TREASURE CHOCOLATE EGG PRODUCT FDA LTR
2014-1090	02/11/2014 03/12/2014	OC/ORACE/OCI/ OC/ORACE/OCI/	MICHAEL D. RESNICK ZUBER LAWLER & DEL DUCA	TSITALIA LLC SPECIALITY FOODS OF ALABAMA INC; SPECIALITY FOODS OF ARIZONA INC - INVESTIGATION 1/11 TO 12/31/12
2014-1091	02/11/2014 03/12/2014	FDA/OFVM/CFSAN/OCD/EOS/	FRIEDMAN, ROBERT	BETTER THAN MILK; SILK SOYMILK; SLIM FAST ETC - CAERS
2014-1092	02/11/2014 03/12/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WRIGHT 05449-010, JAMES	AMITRIPTYLINE; PROZAC; CELEXA; DEPRAKOTE; ZOLOFT; EFFEXOR - AER
2014-1093	02/11/2014 03/12/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/	PETER ALDHOUS MATTER	IMMUNOVATIVE THERAPIES LTD CARLSBAD, CA - 483, CO RESP, CMLPTS
2014-1094	02/11/2014 03/12/2014	FDA/OC/OES/DFOI/	DR. TAO LI UNIVERSITY OF WARWICK	ALL REQUESTS 1/99 TO 12/31/06; 9/31/13 TO 1/31/14
2014-1095	02/11/2014 03/12/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CASEY DOUGAL DOUGAL, CASEY	EXPIRED DRUG PATENTS 1/84 TO 2/28/14
2014-1096	02/11/2014 03/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	DelAguila, Cesar	BAROSENSE ENGOGASTRIC TUBE & INTRODUCER BOUGIE
2014-1097	02/12/2014 03/13/2014	FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN ARIZONA - RES RECORDS 01/01/2004 - 12/31/2012
2014-1098	02/12/2014 03/25/2014	FDA/OGROP/ORASW-FO/DEN- DO/DEN-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN COLORADO - RES RECORDS 01/01/2004 - 12/31/2012
2014-1099	02/12/2014 03/13/2014	FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN ARKANSAS - RES RECORDS 01/01/2004 - 12/31/2012
2014-1100	02/12/2014 03/13/2014	FDA/OGROP/ORASE-FO/ATL- DO/ATL-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN GEORGIA - RES RECORDS 01/01/2004 - 12/31/2012
2014-1101	02/12/2014 03/13/2014	FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN CONNECTICUT - RES RECORDS 01/01/2004 - 12/31/2012
2014-1102	02/12/2014	FDA/OGROP/ORAPA-FO/SEA-	Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN IDAHO - RES RECORDS

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	03/13/2014	DO/SEA-CB/	Tracy Johnson-Hall	01/01/2004 - 12/31/2012
2014-1103	02/12/2014 03/13/2014	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN FLORIDA - RES RECORDS 01/01/2004 - 12/31/2012
2014-1104	02/12/2014 03/13/2014	FDA/OGROP/ORR/CE-FO/CHI-DO/CHI-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN ILLINOIS - RES RECORDS 01/01/2004 - 12/31/2012
2014-1105	02/12/2014 03/13/2014	FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORR/PA-FO/SAN-DO/SAN-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN CALIFORNIA - RES RECORDS 01/01/2004 - 12/31/2012
2014-1106	02/12/2014 03/13/2014	FDA/OGROP/ORR/PA-FO/SAN-DO/SAN-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN HAWAII - RES RECORDS 01/01/2004 - 12/31/2012
2014-1107	02/12/2014 03/13/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Paul A. Orth, PharmD. Eli Lilly and Company, Inc.	Review documents for the supplemental approval for: treatment patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test first-line. This sNDA was approved on 5-14-2013;
2014-1108	02/12/2014 03/13/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	LYNN T SHEPLER LTSHEPLER	LYMERIX - PRE-IND MEETING RECS 01/01/1992 - 12/01/1994
2014-1109	02/12/2014 03/13/2014	FDA/OMPT/CDRH/OCER/DFOI/	Carla Astudillo NJ.com	ALARM FATIGUE - MAUDE REPORTS 02/10/2001 - 02/10/2014
2014-1110	02/12/2014 03/13/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	DAWN RIVERA RIVERA, DAWN	ST. JUDES PM2218 - APPROVAL STATUS
2014-1111	02/12/2014 03/13/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Adrienne E Faerber 608.345.5380 Dartmouth Inst. Cent. For Med. Media.	BLA 103772 S 2032
2014-1112	02/12/2014 03/13/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	OMONTYS - PHASE II CLINICAL TRIALS
2014-1113	02/12/2014 03/13/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CYNTHIA BERRINGER Kadmon Pharmaceuticals, LLC	NDA 019853

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2014-1114	02/12/2014 03/13/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CYNTHIA BERRINGER Kadmon Pharmaceuticals, LLC	REFUSE TO FILE LETTER OR ANY INFORMATION ON COPREXA
2014-1115	02/12/2014 03/13/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CYNTHIA BERRINGER Kadmon Pharmaceuticals, LLC	NDA 019854
2014-1116	02/12/2014 03/13/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Karen Denny TECHLAB, Inc.	K070660
2014-1117	02/12/2014 04/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORAP/PA-FO/LOS- DO/LOS-CB/	Bianca Garcia UNITE HERE	ZICAM - AERS
2014-1118	02/12/2014 03/13/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/OSMP/OOPD/	Ashley Joyner PILLSBURY WINTHROP SHAW PITTMAN LLP	RAPTOR PHARMACEUTICALS PROCYSBI - ORPHAN DRUG RECS, NDA; CORR
2014-1119	02/12/2014 03/13/2014	FDA/OC/OES/DFOI/	Doe J	NUVARING - AERS
2014-1120	02/12/2014 03/13/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dhruvesh Sanghvi BreathingStocks	SHILPA , RAICHUR - 483 02/02/2013 - 02/06/2014
2014-1121	02/12/2014 03/13/2014	FDA/OMPT/CDRH/OCER/DFOI/	RENEE HAZELWOOD COCHLEAR AMERICAS	OTICON MEDICAL AB - PONTO PLUS & PONTO PLUS POWER K132775
2014-1122	02/12/2014 03/13/2014	FDA/OMPT/CDRH/OCER/DFOI/	ELAINE H TESENG KING & SPALDING	INTUITIVE SURGICAL INC - DA VINCI; SI SURGEON SIDE CART Z-1686-2013; VISION SYS CART Z-1687-2013; DUAL CAMERA CONTROLLER 2-1688-2013, ETC HEALTH RISK ASSESSMENTS
2014-1123	02/12/2014	FDA/OMPT/CDER/ORP/DIDP/	ODDVEIG HELLAND	PENN PHARM (PENN PHARMA), TREDEGAR GWENT, UK - EIR 2012

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	03/13/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PHOTOCURE ASA	
2014-1124	02/12/2014 03/13/2014	FDA/OC/OES/DDM/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DONNA B MICHELSON Donna B Michelson PA	ISRS 3002177, 3008728, 3118616, ETC - FORMS 3500A, 1639, ETC; MCNEIL CONSUMER HEALTHCARE - ADVIL (IBUPROFEN) NDA 18-989 PETITIONS
2014-1125	02/12/2014 03/13/2014	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	WOODS 358-884, ROBERT	UNIVERSAL NUTRITION, NEW BRUNSWICK, NJ - FORMULATED & MANUFACTURED VITAMINS CMLPNTS
2014-1126	02/12/2014 03/13/2014	FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	AUTUMN L BORTON PFIZER	WYETH (PFIZER), CAGUAS, PR - EIR 8/11
2014-1127	02/12/2014 03/13/2014	FDA/OO/OFBA/OAGS/	VRITI JAIN DEMOCRATIC SENATORIAL CAMPAIGN COMMITTEE	AMY G STEPHENS - RVW RECS, DELIBERATIONS, TRAVEL EXPENSES, ETC
2014-1128	02/12/2014 03/13/2014	FDA/OO/OHR/	CHESTER CO JUSTICE CENTER	INDIVIDUAL RECS
2014-1129	02/12/2014 03/13/2014	FDA/OFVM/CFSAN/OCD/EOS/	JOSEPH E DIETRICH III DIETRICH LAW FIRM PC	RICH PRODUCTS - E COLI INVESTIGATION, RECALL STRAIN 0121, ETC 12/30/12 TO 4/15/13
2014-1130	02/12/2014 03/13/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DONNA B MICHELSON Donna B Michelson PA	ISRS 3002175, 3004521, 3030045, ETC - FORMS 3500A, 1639, ETC
2014-1131	02/12/2014 03/13/2014	FDA/OFVM/CFSAN/OCD/EOS/	KRISTINA SASICH GASS WEBER MULLINS LLC	RICH PRODUCTS CORP - INVESTIGATION, RECALL W/S, RESULTS, ETC 03/13, 4/13
2014-1132	02/12/2014 03/13/2014	FDA/OFVM/CFSAN/OCD/EOS/	PATTI WALLER MARLER CLARK ATTYS	RICH PRODUCTS CORP - FROZEN SNACK FOOD E COLI 0121 OMM, RPTS, RESULTS, ETC
2014-1133	02/12/2014 03/13/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	2014-368 (CERTIFIED)
2014-1134	02/12/2014 03/13/2014	FDA/OC/OES/DFOI/	CARTER 98B0249, LANCE	CATALOG OF PUBLICATIONS
2014-1135	02/12/2014	FDA/OFVM/CFSAN/OCD/EOS/	NICHOLAS J PAROLIST	RICH PRODUCTS CORP - MULTISTATE E COLI 0121 OUTBREAK CAERS, RPTS, E-MAILS, ETC 12/30/12-4/15/13

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	03/13/2014		LITCHFIELD CAVO LLP	
2014-1136	02/12/2014 03/13/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TODD FEATHERS MUCKROCK NEWS	LTRS OR FORMS OF COMM NOTIFYING COMPANIES THAT FDA APRVL HAS BEEN WITHDRAWN FROM A DRUG 1/13 TO PRESENT
2014-1137	02/12/2014 03/13/2014	OC/ORO/ORM/ OC/ORO/ORM/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SUH, DON	LIST OF ALL COSMETIC & PHARMACEUTICAL MFG FACILITIES IN CHINA, INDIA WHICH HAVE A GMP REGISTRY
2014-1138	02/12/2014 03/13/2014	FDA/OC/OES/DFOI/	AMIE N VANELLA FAEGRE BAKER DANIELS	SIMPLY THICK, SIMPLY THICK LLC - FOIA REQUESTS 12/31/13 TO PRESENT
2014-1139	02/13/2014 03/14/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Mark W. McGlothlin Apex Medical Technologies, Inc.	K100767, K070800, K072169
2014-1140	02/13/2014 03/14/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Avital Levertov - Elcam Medical ELCAM MEDICAL	K051667
2014-1141	02/13/2014 03/14/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mark Murray Aegerion Pharmaceuticals Inc	JUXTAPID - MEDWATCH FORMS
2014-1142	02/13/2014 03/14/2014	FDA/OC/OES/DFOI/	Jessica Prats Jessica Prats	PRESERVATIVES ON FRESH PRODUCE; PRESERVATIVES ON FRESH MEAT, ETC
2014-1143	02/13/2014 03/14/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mark Murray Aegerion Pharmaceuticals Inc	KYNAMRO - MEDWATCH REPORTS
2014-1144	02/13/2014 03/14/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mark Pohl Health Science Funding, LLC	ANDA 071334 - APPROVAL LETTER

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-1145	02/13/2014 03/14/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Christine Livoti BIOPHARM INSIGHT	ONGLYZA, KOMBIGLYZE XR - AERS
2014-1146	02/14/2014 03/17/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	John Bonasera Medrobotics	K033954
2014-1147	02/14/2014 03/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kristen Welsh AccessRec LLC	K051709
2014-1148	02/14/2014 03/17/2014	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2014-831
2014-1149	02/14/2014 03/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kathryn Stinson IMPAC Medical Systems, Inc.	K131891, K123291, K093527
2014-1150	02/14/2014 03/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kevin MacDonald Kevin MacDonald	K021813
2014-1151	02/14/2014 03/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kristen Welsh AccessRec LLC	K120302
2014-1152	02/14/2014 03/17/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Kristan Phillips MacroGenics	PARAXEL, BILLERICA, MA - 483 01/03/2011 - 02/03/2014
2014-1153	02/14/2014 03/17/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Anne Lennon Anne Lennon	RIMADYL - AERS
2014-1154	02/14/2014 03/17/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Brian Jacobus B Jacobus	PROVACTUS BIOPHARMACEUTICALS - TYPE C MEETING MINUTES
2014-1155	02/14/2014 03/17/2014	FDA/OO/OHR/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michael Anisfeld Globepharm	Number of Job Positions within FDA that require incumbents to be Pharmacists

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		FDA/OMPT/CDER/GRP/DIDP/ OC/ORO/ OC/ORO/ FDA/OO/OHR/		
2014-1156	02/14/2014 03/17/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OGROP/ORO/SE-FO/FLA- DO/FLA-CB/	Arthur Meisel Arthur Meisel, Esq.	UNIVERSITY OF MIAMI MILLER SCHOOL OF MEDICINE TISSUE BANK - BONE GRAFT RECS 01/01/2012 - 02/11/2014
2014-1157	02/14/2014 03/17/2014	FDA/OGROP/ORO/SW-FO/DEN- DO/DEN-CB/	John Murray Murray - Brown Laboratories	All Laboratory results, investigation results and actions taken associated with Bueno Chili Listeria
2014-1158	02/14/2014 03/17/2014	FDA/OMPT/CDRH/OCER/DFOI/ OC/ORO/OE/ OC/ORO/OE/	Emily Campbell University of the Sciences	RECALL DATA FOR 510K APPROVED MEDICAL DEVICES (01/01/2008 - 12/31/2013)
2014-1159	02/14/2014 03/17/2014	FDA/OGROP/ORO/PA-FO/SAN- DO/SAN-CB/	Faye R. Wright Boehringer Ingelheim	GENENTECH- 483 01/01/2013 - 02/13/2014
2014-1160	02/14/2014 03/17/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sherrie McNamara Fleet Laboratories	SODIUM PHOSPHATE CASE NARRATIVES
2014-1161	02/14/2014 03/17/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Peter Aldhous MATTER	IMMUNOVATIVE THERAPIES LTD - CLINICAL TRIAL RECS (03/12/2009 - 02/10/2014)
2014-1162	02/14/2014 03/17/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Brian A. Potoski Potoski, Brian A	MERREM I.V. - APPROVAL RECS
2014-1163	02/14/2014 03/17/2014	OC/ORO/ORM/ OC/ORO/ORM/ FDA/OC/OES/DFOI/ OC/ORO/OE/ OC/ORO/OE/	Merle Zimmermann (ext. 106) AMERICAN HERBAL PRODUCTS ASSOCIATION	LIST OF GMP INSPECTIONS UNDER 21 CFR Part 210-211 (01/01/2012 - 12/31/2013)

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2014-1164	02/14/2014 03/17/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Dr. Diane Bigham/ SPossehl RN Urologic Consultants P.C.	UROLOGIC CONSULTANTS PC, WYOMING, MI - EIR (01/01/2013 - 02/28/2013)
2014-1165	02/14/2014 03/17/2014	FDA/OFVM/CFSAN/OCD/EOS/	Steve Hentges AMERICAN CHEMISTRY COUNCIL	The Agency Review of a 90-day toxicity study on bisphenol A (CAS RN 80-05-7) in the Sprague-Dawley rat conducted at NCTR (C10034)
2014-1166	02/14/2014 03/17/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jameel Husain Fresenius Kabi USA, LLC	BASF, GERMANY - EIR 01/02/2012 - 02/12/2014
2014-1167	02/14/2014 03/17/2014	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Nichol Monaghan Novartis Consumer Health Inc.	NOVARTIS CUSTOMER HEALTH, INC, LINCOLN, NE - EIR 01/28/2013 - 02/14/2013
2014-1168	02/14/2014 03/17/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Whit Richardson Bangor Daily News	BROWNE TRADING CO, PORTLAND, ME - INSPECTION RECS 05/01/2013 - 02/12/2014
2014-1169	02/14/2014 03/17/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Barbara Young George King Biomedical, Inc.	BLOOD ESTABLISHMENTS THAT HAVE AMENDMENTS TO PLASMAPHERESE DONORS WITH HEMOPHELIA ETC
2014-1170	02/14/2014 03/17/2014	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Nichol Monaghan Novartis Consumer Health Inc.	NOVARTIS CONSUMER HEALTH, LINCOLN, NE - EIR 10/15/2013 - 10/21/2013
2014-1171	02/14/2014 03/17/2014	OC/ORASW-FO/ OC/ORASW-FO/ FDA/OC/OES/DFOI/ OC/ORASW-FO/ OC/ORASW-FO/	Merle Zimmermann (ext. 106) AMERICAN HERBAL PRODUCTS ASSOCIATION	LIST OF GMP INSPECTIONS UNDER 21 CFR PART 111 (01/01/2012 - 12/31/2013)
2014-1172	02/14/2014 03/17/2014	FDA/OC/OES/DFOI/	Irene O'Connor WFSB-TV	NUVARING - AERS
2014-1173	02/18/2014 03/18/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kerry King Intertox, Inc.	K130387
2014-1174	02/18/2014 03/18/2014	FDA/OMPT/CDRH/OCER/DFOI/	Matthew Nowland Becton Dickinson Diabetes Care	PMA P120010
2014-1175	02/18/2014 03/18/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Paul Shields Enteris Biopharma, Incorporated	NDA019010
2014-1176	02/18/2014	FDA/OMPT/CDER/GRP/DIDP/	Sandy Lee	METHENAMINE HIPPURATE - SBA

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	03/18/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	B&H Consulting Services, Inc.	
2014-1177	02/18/2014 03/18/2014	FDA/OMPT/CDRH/OCER/DFOI/	Scott Prier Panasonic Healthcare Corporation	MAUDE REPORT 2820316 RECS
2014-1178	02/18/2014 03/18/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sarah Lynch Schachter, Hendy & Johnson, P.S.C.	NDA 021463
2014-1179	02/18/2014 03/18/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sarah Lynch Schachter, Hendy & Johnson, P.S.C.	NDA 021454
2014-1180	02/18/2014 03/18/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sarah Lynch Schachter, Hendy & Johnson, P.S.C.	ANDA 080911
2014-1181	02/18/2014 03/18/2014	FDA/OFVM/CFSSAN/OCD/EOS/	Lauren Costantini LCC Consulting, LLC	ACCERA INC - WARNING LETTER RESPONSE 11/01/2013 - 02/13/2014
2014-1182	02/18/2014 03/18/2014	FDA/OMPT/CDRH/OCER/DFOI/	Matthew C. Ashby, Paralegal Coordinator Meyer Darragh Buckler Bebenek & Eck, PLLC	DRIVER MEDICAL SHOWER CHAIR/COMMODE - EVENT RECS 2438477-2013-00014
2014-1183	02/18/2014 03/18/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lara J. Say DOUGLAS & LONDON	MEDWATCH REPORT 2011-BP-28228BP
2014-1184	02/18/2014 03/18/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sarah Lynch Schachter, Hendy & Johnson, P.S.C.	ANDA 085635
2014-1185	02/18/2014 03/18/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sarah Lynch Schachter, Hendy & Johnson,	ANDA 086030

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	P.S.C.	
2014-1186	02/18/2014 03/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John M. Nardo MD John M. Nardo MD	LURADISONE - APPROVAL RECS
2014-1187	02/18/2014 03/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Paul Reinfelds Paul Reinfelds	ONCASPAR BLA. 103411 - APPROVAL LETTERS, SUMMARY OF APPROVAL
2014-1188	02/18/2014 03/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sarah Lynch Schachter, Hendy & Johnson, P.S.C.	NDA 022504
2014-1189	02/18/2014 03/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Deirdre Mooney, MD MPH Maine Medical Center	REGADENOSON - AERS
2014-1190	02/18/2014 03/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sarah Lynch Schachter, Hendy & Johnson, P.S.C.	NDA 20489 S3
2014-1191	02/18/2014 03/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sarah Lynch Schachter, Hendy & Johnson, P.S.C.	NDA 022309
2014-1192	02/18/2014 03/18/2014	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	COMPLAINT RECS
2014-1193	02/18/2014 03/18/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/NE-FO/NYK- DO/NYK-DCB/	Doe J	INDIVIDUAL RECS
2014-1194	02/18/2014	FDA/OMPT/CDER/ORP/DIDP/	Sarah Lynch	NDA 021015

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	03/18/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Schachter, Hendy & Johnson, P.S.C.	
2014-1195	02/18/2014 03/18/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Somer Baburek Somer Baburek	K101801
2014-1196	02/18/2014 03/18/2014	FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS IN CANADA
2014-1197	02/18/2014 03/18/2014	FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS IN INDIA 01/01/2004 - 12/31/2012
2014-1198	02/18/2014 03/18/2014	FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS IN GREECE 12/28/2012 - 12/28/2012
2014-1199	02/18/2014 03/18/2014	FDA/OGROP/ORACE-FO/DET- DO/DET-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN INDIANA 01/01/2004 - 12/31/2012
2014-1200	02/18/2014 03/18/2014	FDA/OGROP/ORACE-FO/KAN- DO/KAN-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN IOWA 01/01/2004 - 12/31/2012
2014-1201	02/18/2014 03/18/2014	FDA/OGROP/ORACE-FO/DET- DO/DET-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN MICHIGAN 01/01/2004 - 12/31/2012
2014-1202	02/18/2014 03/18/2014	FDA/OGROP/ORACE-FO/NWE- DO/NWE-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN MASSACHUSETTS 01/01/2004 - 12/31/2012
2014-1203	02/18/2014 03/18/2014	FDA/OGROP/ORACE-FO/BLT- DO/BLT-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN MARYLAND 01/01/2004 - 12/31/2012
2014-1204	02/18/2014 03/18/2014	FDA/OGROP/ORACE-FO/NWE- DO/NWE-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN MAINE 01/01/2004 - 12/31/2012
2014-1205	02/18/2014 03/18/2014	FDA/OGROP/ORACE-FO/NOL- DO/NOL-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN LOUISIANA 01/01/2004 - 12/31/2012
2014-1206	02/18/2014 03/28/2014	FDA/OGROP/ORACE-FO/DEN- DO/DEN-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN NEW MEXICO 01/01/2004 - 12/31/2012
2014-1207	02/18/2014 03/18/2014	FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORACE-FO/CHI- DO/CHI-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN NEW JERSEY 01/01/2004 - 12/31/2012

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		FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OC/OES/DFOI/		
2014-1208	02/18/2014 03/18/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN NEW HAMPSHIRE 01/01/2004 - 12/31/2012
2014-1209	02/18/2014 03/18/2014	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN NEW YORK 01/01/2004 - 12/31/2012
2014-1210	02/18/2014 03/18/2014	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN NEBRASKA 01/01/2004 - 12/31/2012
2014-1211	02/18/2014 03/18/2014	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN MISSOURI 01/01/2004 - 12/31/2012
2014-1212	02/18/2014 03/18/2014	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN MINNESOTA 01/01/2004 - 12/31/2012
2014-1213	02/18/2014 03/18/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN KENTUCKY 01/01/2004 - 12/31/2012
2014-1214	02/18/2014 03/18/2014	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN KANSAS 01/01/2004 - 12/31/2012
2014-1215	02/18/2014 03/18/2014	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN NORTH CAROLINA 01/01/2004 - 12/31/2012
2014-1216	02/18/2014 03/18/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN ONIO 01/01/2004 - 12/31/2012
2014-1217	02/18/2014 03/18/2014	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN OKLAHOMA 01/01/2004 - 12/31/2012
2014-1218	02/18/2014 03/18/2014	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN WISCONSIN 01/01/2004 - 12/31/2012
2014-1219	02/18/2014 03/18/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN WYOMING 01/01/2004 - 12/31/2012
2014-1220	02/18/2014 03/18/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN VERMONT 01/01/2004 - 12/31/2012
2014-1221	02/18/2014 03/18/2014	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN WASHINGTON 01/01/2004 - 12/31/2012
2014-1222	02/18/2014	FDA/OGROP/ORACE-FO/BLT-	Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN VIRGINIA 01/01/2004 -

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	03/18/2014	DO/BLT-CB/	Tracy Johnson-Hall	12/31/2012
2014-1223	02/18/2014 03/28/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN DENVER 01/01/2004 - 12/31/2012
2014-1224	02/18/2014 03/18/2014	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN TEXAS 01/01/2004 - 12/31/2012
2014-1225	02/18/2014 03/18/2014	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN TENNESSEE 01/01/2004 - 12/31/2012
2014-1226	02/18/2014 03/18/2014	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN SOUTH CAROLINA 01/01/2004 - 12/31/2012
2014-1227	02/18/2014 03/18/2014	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN WEST VIRGINIA 01/01/2004 - 12/31/2012
2014-1228	02/18/2014 04/03/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN PENNSYLVANIA 01/01/2004 - 12/31/2012
2014-1229	02/18/2014 03/18/2014	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN PUERTO RICO 01/01/2004 - 12/31/2012
2014-1230	02/18/2014 03/18/2014	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN OREGON 01/01/2004 - 12/31/2012
2014-1231	02/18/2014 03/18/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN RHODE ISLAND 01/01/2004 - 12/31/2012
2014-1232	02/18/2014 03/18/2014	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	PRODUCT RECALLS FOR FIRMS IN US VIRGIN ISLANDS 01/01/2004 - 12/31/2012
2014-1233	02/18/2014 03/18/2014	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Tracy Johnson-Hall Tracy Johnson-Hall	RECALLS FOR FIRMS IN NORTH DAKOTA 01/01/2004 - 12/31/2012
2014-1234	02/18/2014 03/18/2014	OC/CVM/OCD/	Doe J	INDIVIDUAL RECS
2014-1235	02/18/2014 03/18/2014	FDA/OMPT/CDRH/OCER/DFOI/	Ariel Dora Stern NATIONAL BUREAU OF ECONOMIC RESEARCH	IDE APPLICATIONS
2014-1236	02/18/2014 03/18/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Sean M. O'Connell Englewood Hospital, Vascular Surgery, Mt. Sinai School of Medicine	K032420
2014-1237	02/18/2014 03/18/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Gerald White Pacific Precision Products	Date Range: 01/04/2012 - 02/14/2014; Requesting Redacted copy of all information submitted by Pacific Precision Products Ref: K120566 and any relative form to the 510K process.. NOTE:

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				PPP is requesting there own information, I provide the redacted copy to the FDA on 9/5/13 and need a copy for our records and currently still hold the position of Quality Manager at PPP and the contact person on the 510K K120566 ;
2014-1238	02/18/2014 03/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BERKILD, BRENDA	TAMSULOSIN - AER
2014-1239	02/18/2014 03/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CRISSEP #1258732, KENNETH	THORAZINE, TOPAMAX, PROZAC, RITALIN, PAXIL - AER
2014-1240	02/18/2014 03/18/2014	FDA/OFVM/CFSAN/OCD/EOS/	MITZI NG CLARK Keller and Heckman, LLP	VINLY CHLORIDE-VINYL ACETATE COPOLYMERS (POLYVINYL CHLORIDE-ACETATE) - OPINION LTRS
2014-1241	02/18/2014 03/18/2014	FDA/OO/OHR/	CARTER, EDWARD	CHEMIST JOB VACANCY HHS-FDA-CVM-DE-1017014 - RATINGS, RANKINGS, EMAILS, ETC
2014-1242	02/18/2014 03/18/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	K. MICHELLE VASSALLO LINCARE INC	COMMUNITY OXYGEN, ME - 483, EIR, WARNING LTR 1/98 TO PRESENT
2014-1243	02/18/2014 03/18/2014	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	K. MICHELLE VASSALLO LINCARE INC	HEALTHCARE SUPPORT SERVICES INC, VA - EIR, 483, WARNING LTR 1/98 TO PRESENT
2014-1244	02/18/2014 03/18/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	K. MICHELLE VASSALLO LINCARE INC	KING HOME MEDICAL, MI - 483, EIR, WARNING LTR 1/98 TO PRESENT
2014-1245	02/18/2014 03/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN M. WILUSZ SUGARMAN AND SUGARMAN PC	LEVAQUIN - AER
2014-1246	02/18/2014 03/18/2014	FDA/OC/OES/DFOI/	SCHUDY, JEREMY	OIG DATA
2014-1247	02/18/2014 03/18/2014	FDA/OC/OES/DFOI/	DOMINIQUE F. GALLACHER RICHARDS KIBBE & ORBE LLP	QUESTCOR PHARMACEUTICALS INC, ANAHEIM HILLS, CA - ACTHAR GEL - CORR BETWEEN FDA & QUESTCOR
2014-1248	02/18/2014 03/18/2014	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	ROBERT KING FDA NEWS	MED IMMUNE VACCINES INC, SANTA CLARA, CA - 483 1/14
2014-1249	02/18/2014 03/18/2014	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	ROBERT KING FDA NEWS	ALTASOURCE LLC, ROSWELL, GA - 483 1/14

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2014-1250	02/18/2014 03/18/2014	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	ROBERT KING FDA NEWS	KERMA MEDICAL PRODCUTS INC, SUFFOLK, VA - 483 1/14
2014-1251	02/18/2014 03/18/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	ROBERT KING FDA NEWS	KUTOL PRODCUTS, SHARONVILLE, OH; IBA MOLECULAR NORTH AMERICA, OAKWOOD VILLAGE , OH; POLAR PRODUCTS INC, STOW, OH - 483 1/14
2014-1252	02/18/2014 03/18/2014	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	ROBERT KING FDA NEWS	ELECTRO MEDICAL INC, TULSA, OK - 483 1/14
2014-1253	02/18/2014 03/18/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	ROBERT KING FDA NEWS	FRESENIUS MEDICAL CARE, OGDEN, UT; NYTONE MEDICAL PRODUCTS INC, BLUFFDALE, UT; ZYNEX MEDICAL INC, LONE TREE, CO - 483 1/14
2014-1254	02/18/2014 03/18/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	ROBERT KING FDA NEWS	FERNDALE LABORATORIES INC, FERNDALE, MI; CENTURY PHARMACEUTICALS INC, INDIANAPOLIS, IN; DOW CORNING CORP, HEMLOCK, MI - 483 1/14
2014-1255	02/18/2014 03/18/2014	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	ROBERT KING FDA NEWS	AMERICAN INDUSTRIAL PLASTICS, DAYTONA BEACH, FL; KOUME LIPOPLASTY PRODUCTS INC, SUNRISE, FL; EXCITE MEDICAL CORP, TAMPA, FL - 483 1/14
2014-1256	02/18/2014 03/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ROBERT KING FDA NEWS	RANBAXY LABORATORIES LTD, PUNJAB, INDIA - 483 1/14
2014-1257	02/18/2014 03/18/2014	FDA/OMPT/CDRH/OCER/DFOI/	ROBERT KING FDA NEWS	PRECISION NEEDLE MANUFACTURING INC, GYUNGGI DO, SO KOREA; HEALTH LINE INTL CO LTD, FOSHAN, GUANGDONG, CHINA; MAQUET CARDIOPULMONARY AG, HIRRLINGEN, GERMANY - 483 1/14
2014-1258	02/18/2014 03/18/2014	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	ROBERT KING FDA NEWS	SURGICAL INSTRUMENT MANUFACTURERS INC, FENTON, MO; FIRESTONE OPTICS INC, KANSAS CITY MO; PROTEK MEDICAL PRODUCTS, CORALVILLE, IA - 483 1/14
2014-1259	02/18/2014 03/18/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ OC/ORA/ OC/ORA/	ROBERT KING FDA NEWS	ZIONS RX FORMULATIONS SERVICES LLC, MESA, AZ; UNITED CONSORTIUM INC, VALENCIA, CA; AAREN SCIENTIFIC INC, ONTARIO, CA - 483 1/14
2014-1260	02/18/2014 03/18/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-460 - REQUEST LETTER ONLY
2014-1261	02/18/2014 03/18/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	ROBERT KING FDA NEWS	ABA PGT INC, MANCHESTER, CT; CONAIR CORP, STAMFORD CT; INTEGRA BURLINGTON MA, BURLINGTON, MA - 483 1/14
2014-1262	02/18/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2014-474- REQUEST LETTER ONLY

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	03/18/2014		MERCK & CO., INC.	
2014-1263	02/18/2014 03/18/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-498 - REQUEST LETTER ONLY
2014-1264	02/18/2014 03/18/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-503 - REQUEST LETTER ONLY
2014-1265	02/18/2014 03/18/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-615 - REQUEST LETTER ONLY
2014-1266	02/18/2014 03/18/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-637 - REQUEST LETTER ONLY
2014-1267	02/18/2014 03/18/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-617 - REQUEST LETTER ONLY
2014-1268	02/18/2014 03/18/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-675 - REQUEST LETTER ONLY
2014-1269	02/18/2014 03/18/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	ROBERT KING FDA NEWS	TEMPTIME CORP, MORRIS PLAINS, NJ; FUJINON INC, WAYNE, NJ; SUNRISE PHARMACEUTICAL INC, RAHWAY, NJ - 483 1/14
2014-1270	02/18/2014 03/18/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-678 - REQUEST LETTER ONLY
2014-1271	02/18/2014 03/18/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-10160 - REQUEST LETTER ONLY
2014-1272	02/18/2014 03/18/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-9542 - REQUEST LETTER ONLY
2014-1273	02/18/2014 03/18/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-69 - REQUEST LETTER ONLY
2014-1274	02/18/2014 03/18/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-9548 - REQUEST LETTER ONLY
2014-1275	02/18/2014 03/18/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-9731 - REQUEST LETTER ONLY
2014-1276	02/18/2014 03/18/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-9737 - REQUEST LETTER ONLY
2014-1277	02/18/2014 03/18/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-9892 - REQUEST LETTER ONLY
2014-1278	02/18/2014 03/18/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-10010 - REQUEST LETTER ONLY

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2014-1279	02/18/2014 03/18/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-414 - REQUEST LETTER ONLY
2014-1280	02/18/2014 03/18/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-384 - REQUEST LETTER ONLY
2014-1281	02/18/2014 03/18/2014	FDA/OGROP/ORR/SE-FO/NOL-DO/NOL-CB/	ROBERT KING FDA NEWS	CHATTEM CHEMICALS INC, CHATTANOOGA, TN; BAXTER HEALTHCARE CORP, CLEVELAND, MS - 483 1/14
2014-1282	02/18/2014 03/18/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-67 - REQUEST LETTER ONLY
2014-1283	02/18/2014 03/18/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-36 - REQUEST LETTER ONLY
2014-1284	02/18/2014 03/18/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-6506
2014-1285	02/18/2014 03/18/2014	FDA/OGROP/ORR/NE-FO/NYK-DO/NYK-DCB/	ROBERT KING FDA NEWS	AMRI RENNELAER, RENNELEAR, NY; LNK INTERNATIONAL INC, HAUPPAUGE, NY - 483 1/14
2014-1286	02/18/2014 03/18/2014	FDA/OGROP/ORR/CE-FO/CHI-DO/CHI-CB/	ROBERT KING FDA NEWS	SAGE PRODUCTS INC, CARY, IL - 483 1/14
2014-1287	02/18/2014 03/18/2014	FDA/OGROP/ORR/SE-FO/SJN-DO/SJN-CB/	ROBERT KING FDA NEWS	MSD INTERNATIONAL GMBH, BARCELONETA, PR; COOPER VISION CARIBBEAN CORP, JUANA DIAZ, PR - 483 1/14
2014-1288	02/18/2014 03/18/2014	FDA/OGROP/ORR/PA-FO/SEA-DO/SEA-CB/	ROBERT KING FDA NEWS	PHYSIO CONTROL INC, REDMOND, WA; PRO TRAINERS CHOICE COMPANY INC, KINGSTON, WA; SONIVATE MEDICAL INC, BEVERTON, OR - 483 1/14
2014-1289	02/18/2014 03/18/2014	FDA/OGROP/ORR/CE-FO/MIN-DO/MIN-CB/	ROBERT KING FDA NEWS	FONTAROME CHEMICAL INC, ST FRANCIS, WI; AYRSHIRE ELECTRONICS MINNESOTA, OAKDALE, MN; ENCHANTMENT MEDICAL LLC, WAUWATOSA, WI - 483 1/14
2014-1290	02/19/2014 03/19/2014	FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/	Farah Ali SPI PHARMA INC	AJINOMOTO ALTHEA INC, SAN DIEGO, CA - 483 11/01/2013 - 11/29/2013
2014-1291	02/19/2014 03/28/2014	FDA/OGROP/ORR/CE-FO/DET-DO/DET-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ann Yeh Chirogate International Inc.	AZZA TALAAT - 483S 01/01/2008 - 02/14/2014
2014-1292	02/19/2014 03/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Heather A. Dorsey Morgan, Lewis & Bockius LLP	NDA 11153 S37 - SUPPLEMENTAL APPROVAL LETTER

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-1293	02/19/2014 03/19/2014	FDA/OGROP/ORAP/PA-FO/SAN-DO/SAN-CB/	Farah Ali SPI PHARMA INC	CATALENT HEALTH, LLC - 483 11/01/2013 - 11/29/2013
2014-1294	02/19/2014 03/19/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OGROP/ORAP/PA-FO/SEA-DO/SEA-CB/ FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Sarah Geisert General Mills, Inc.	GENERAL MILLS - EIR 02/11/2013 - 02/14/2014
2014-1295	02/19/2014 03/19/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Richard W. Gonnello Faruqi & Faruqi, LLP	AVECIA BIOTECHNOLOGY, MILFORD, MA - 01/01/2010 - 02/14/2014
2014-1296	02/19/2014 03/19/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	Farah Ali SPI PHARMA INC	SANDOZ INC - 483 10/01/2013 - 10/31/2013
2014-1297	02/19/2014 03/19/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Seongsoo Park DAEWOONG AMERICA INC	URSO, URSO FORTE - SHELF LIFE RECS
2014-1298	02/19/2014 03/19/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Leslie Edwards Waters, Kraus & Paul	ZIMMER DUROM CUP - HHE, COMPLAINTS, FIELD ACTIONS ETC 01/01/2006 - 12/31/2010
2014-1299	02/19/2014 03/19/2014	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	Marc Elia BRIDGER CAPITAL LLC	BAXTER, IRVINE, CA - WARNING LETTER, EIR, 483 01/01/2013 - 02/18/2014
2014-1300	02/19/2014 03/19/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dawn Chitty TORRENT PHARMA INC	ANDA 202498
2014-1301	02/19/2014 03/19/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	B&H Consulting Services, Inc. B&H Consulting Services, Inc.	ANDA 076411 - SBA
2014-1302	02/19/2014	FDA/OMPT/CDER/GRP/DIDP/	Jiye Ahn	NDA20471

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	03/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Qurient Co., Ltd	
2014-1303	02/19/2014 03/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dawn Chitty TORRENT PHARMA INC	ANDA 201791
2014-1304	02/19/2014 03/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	Ingrid Mehlhorn SIEMENS HEALTHCARE DIAGNOSTICS INC	K131203
2014-1305	02/19/2014 03/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lawrence Masten, PhD, DABT Lawrence Masten Consuting	NEURONTIN - AERS
2014-1306	02/19/2014 03/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	Gina To Sirius Engineering LLC	K123544
2014-1307	02/19/2014 03/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	Gina to Sirius Engineering LLC	K130911
2014-1308	02/19/2014 03/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	Scott Corchero Precision Solutions	K122829
2014-1309	02/19/2014 03/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	Scott Corchero Precision Solutions	K122386
2014-1310	02/19/2014 03/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	Reliable Test Kits, LLC Reliable Test Kits, LLC	K123703
2014-1311	02/19/2014 03/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	Reliable Test Kits, LLC Reliable Test Kits, LLC	K103574
2014-1312	02/19/2014 03/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	Scott Corchero Precision Solutions	K121091
2014-1313	02/19/2014 03/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	Scott Corchero Precision Solutions	K123120
2014-1314	02/19/2014 03/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Todd A. Hunter Jr. Hilliard Munoz & Gonzales LLP	INCIVEK - AERS

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		FDA/OMPT/CDER/ORP/DIDP/		
2014-1315	02/19/2014 03/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Marc Elia BRIDGER CAPITAL LLC	JUXAPID - AERS
2014-1316	02/19/2014 03/19/2014	FDA/OC/OES/DFOI/	ROBERT K LU ROBBINS GELLER ET AL	HP ACTHAR GEL, REPOSITORY CORTICOTROPIN INJ - APRVL RECS, INVESTIGATION, MEMOS, ETC; QUESTCOR PHARMACEUTICALS INC - CORR
2014-1317	02/19/2014 03/19/2014	OC/ORA/ OC/ORA/ FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	POE, BEVERLY K	THICKEND WATER SPL 835059 - RECS
2014-1318	02/19/2014 03/19/2014	FDA/OFVM/CFSAN/OCD/EOS/	JACQUELINE J CHAN K&L GATES	BASF AKTIENGESELLSCHAFT - FCN 726
2014-1319	02/19/2014 03/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SHOBHA REDDY CHAGAM DR REDDYS LABORATORIES INC	BIOMARIN - KUVAN (SAPROPTERIN DIHYDROCHLORIDE) NDA 205-065 SBA
2014-1320	02/19/2014 03/19/2014	FDA/OC/OES/DDM/	Holland, Bruce	DKT 2013P-1612
2014-1321	02/19/2014 03/19/2014	FDA/OFVM/CFSAN/OCD/EOS/	KEVIN S FRIES COSMETIC INGREDIENT REVIEW	VOLUNTARY COSMETIC REGISTRATION PROGRAM (VCRP) SPREADSHEET
2014-1322	02/19/2014 03/19/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	CHRIS SZECHENYI ON POINT INVESTIGATIONS	OVASCIENCE - AUGMENT LTRS 2012, 2013
2014-1323	02/19/2014 03/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	A LUKE SMITH ESQ RADICE LAW FIRM	ANDA 77-571 - ARPVL RECS
2014-1324	02/19/2014 03/19/2014	FDA/OC/OES/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/OIP/	TOM NELTNER NATURAL RESOURCES DEFENSE COUNCIL	CIBA SPECIALTY CHEMICAL CORP - SODIUM PERCHLORATE MONOHYDRATE THRESHOLD OF REGULATION SUBMISSION 05-006 COMMENTS, CORR
2014-1325	02/19/2014 03/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	CHRISTOPHER S RUSSOMANN RUSSOMANNO & BORRELLO	INDIVIDUAL RECS
2014-1326	02/19/2014	FDA/OGROP/ORASE-FO/NOL-	JAMES E SWAUGER PHD	AMERICAN SNUFF COMPANY LLC, CLARKSVILLE, TN - EIR,

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	03/20/2014	DO/NOL-CB/	RAI SERVICES CO	CORR, ENDORSEMENTS, ETC 1/10-11/12; 1/12-13/12
2014-1327	02/19/2014 03/19/2014	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	JAMES E SWAUGER PHD RAI SERVICES CO	RJ REYNOLDS TOBACCO CO, WINSTON-SALEM, NC - EIR, CORR, EXHIBITS, ETC 2/20/13-3/1/13; SANTA FE NATURAL TOBACCO COMPANY INC, OXFORD, NC - EIR, CORR, EXHIBITS, ETC 3/25/13-4/2/13
2014-1328	02/19/2014 03/19/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	K MICHELLE VASSALLO LINCARE INC	PALM DRUG INC (PALM DRUG MEDICAL SUPPLIES) - EIRS, 483S 1/198 TO PRESENT
2014-1329	02/19/2014 03/19/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	K MICHELLE VASSALLO LINCARE INC	UNITED PATIENT CARE, OH - EIRS, 483S 1/98 TO PRESENT
2014-1330	02/19/2014 03/19/2014	FDA/OC/OES/ OC/OR/ OC/OR/ OC/OR/OCI/ OC/OR/OCI/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	WALL STREET JOURNAL	RANBAXY LABS - INSP RECS
2014-1331	02/19/2014 03/19/2014	FDA/OFVM/CFSAN/OCD/EOS/	HARRIS, CHRIS	FULVIC ACID - NOTIFICATIONS
2014-1332	02/19/2014 03/19/2014	FDA/OC/OES/DFOI/	DOMINIQUE F GALLACHER RICHARDS KIBBE & ORBE LLP	QUESTCOR PHARMACEUTICALS INC - HP ACTHAR GEL (REPOSITORY CORTICOTROPIN INJ) RECS
2014-1333	02/19/2014 03/19/2014	OC/OR/ OC/OR/ OC/OR/ORO/DFS/ OC/OR/ORO/DFS/ OC/CVM/OCD/	JENNIFER FIALA VIN NEWS SERVICE	NEW YORK STATE DEPT OF AGRICULTURE AND MARKETS - JERKY PET TREATS ANTIBIOTICS TESTING ANALYTICAL METHODS 2012
2014-1334	02/19/2014 03/19/2014	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	ELLIOT FAVUS MD FAVUS INSTITUTIONAL RESEARCH LLC	EXUBERA (HUMAN INSULIN) - AERS 1/03 TO PRESENT

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2014-1335	02/19/2014 03/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	VIK BAJNATH ARTHREX INC	MW 5033046
2014-1336	02/19/2014 03/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KRISTI O SMEDLEY PHD Center for Regulatory Services, Inc.	SERUMWERK BERNBURG AG, BERNBURG, GERMANY - EIRS, 483S 11/1/11 TO PRESENT
2014-1337	02/19/2014 03/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	MCCOY, SHERYL	APOGEE ORTHOSOLUTIONS LLC - MONSTER SCREWW SYS K124027
2014-1338	02/19/2014 03/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	MCCOY, SHERYL	ACCUMED LLC - CANNULATED SCREW K123890
2014-1339	02/19/2014 03/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	MCCOY, SHERYL	ARTHREX INC - ARTHRES COMPRESSION FT SCREW K132217
2014-1340	02/19/2014 03/19/2014	FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	Denise Murrell OPTI Medical	OPTI MEDICAL - EIR JUNE 2013
2014-1341	02/19/2014 03/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Makoto Kaino Kaino, Makoto	CLINICAL INVESTIGATOR 483
2014-1342	02/19/2014 03/19/2014	FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA REQUEST LOG 02/10/2014 - 02/14/2014
2014-1343	02/19/2014 03/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	J.D. Webb The OrthoMedix Group, Inc.	INVESTIGATION RECS
2014-1344	02/19/2014 03/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sarfaraz K. Niazi Therapeutic Proteins International, LLC	BLA 125057
2014-1345	02/19/2014 03/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sarfaraz K. Nlazi Therapeutic Proteins International, LLC	BLA 980286
2014-1346	02/19/2014 03/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sarfaraz K. Niazi Therapeutic Proteins International, LLC	BLA 125031

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-1347	02/19/2014 03/19/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sarfaraz K. Nlazi Therapeutic Proteins International, LLC	BLA 961136
2014-1348	02/19/2014 03/19/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Kim Seidel Pennside Partners Ltd.	PNU-IMMUNE - CLINICAL REVIEW RECS
2014-1349	02/19/2014 03/19/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Nik Nikolov UNIVERSITY OF GEORGIA	IND APPLICATION DATA
2014-1350	02/19/2014 03/19/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	RISPERDAL - AERS
2014-1351	02/20/2014 03/20/2014	FDA/OMPT/CDRH/OCER/DFOI/	Peter A. Takes, Ph.D. Kypha, Inc.	K040579
2014-1352	02/20/2014 03/20/2014	FDA/OMPT/CDRH/OCER/DFOI/	Peter A. Takes, Ph.D. Kypha, Inc.	K110761
2014-1353	02/20/2014 03/20/2014	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	Nicole Oliynyk ARIAD Pharmaceuticals Inc.	XCELIENCE, TAMPA, FL - EIR 02/19/2012 - 02/19/2014
2014-1354	02/20/2014 03/20/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	patrick fries Patrick Fries	PROVACTUS PHARMACEUTICALS - MTG NOTES, CORR 01/05/2013 - 02/15/2014
2014-1355	02/20/2014 03/20/2014	FDA/OC/OES/DFOI/	DORCA BARES DORCA BARES	ADHD MEDICINE RECALLS
2014-1356	02/20/2014 03/20/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	MARINOL - EIGHT FACTOR ANALYSIS

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2014-1357	02/20/2014 03/20/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bao Le ARIAD Pharmaceuticals, Inc.	ICLUSIG - APPROVAL PACKAGE
2014-1358	02/20/2014 03/20/2014	OC/CVM/OCD/	Jan Perkins LLOYD, Inc.	NADA 092836 APPROVAL DATE
2014-1359	02/20/2014 03/20/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Adrienne E Faerber (New phone: 608.345.5380) Dartmouth Inst. Cent. For Med. Media.	NDA 016273
2014-1360	02/20/2014 03/20/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bao Le ARIAD Pharmaceuticals, Inc.	ICLUSIG - AERS
2014-1361	02/20/2014 03/20/2014	FDA/OFVM/CFSAN/OCD/EOS/	Eleanor DaCosta United States Pharmacopeial Convention (USP)	WESTERN COMMERCE - ADULTERATION OF AGAVE SYRUP WITH HIGH FRUCTOSE CORN SYRUP
2014-1362	02/20/2014 03/20/2014	FDA/OMPT/CDRH/OCER/DFOI/	Cynthia Rose Rose, Cynthia	Biomet Orthopedics Biomet Poly Patella Button 9 mm ht., patella button, model #: 11-150828 - ADVERSE EVENTS
2014-1363	02/20/2014 03/20/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Cynthia Rose Rose, Cynthia	XARELTO - AERS
2014-1364	02/20/2014 03/20/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dennis W. Raisch UNIVERSITY OF NEW MEXICO	BRENTUXIMAB - AERS
2014-1365	02/20/2014 03/20/2014	FDA/OMPT/CDRH/OCER/DFOI/	Leslie Hamilton Hamilton, Leslie D	MEDICAL CENTER PAIN MANAGEMENT - Form 2579 -Report of Assembly of a Diagnostic X-ray System for my the C-Arm
2014-1366	02/20/2014 03/20/2014	FDA/OGROP/ORR/SW-FO/DEN-DO/DEN-CB/	JOE KOHL SPEER LAWL FIRM	DEL ORO DAIRY, ANTHONY, NM - RECS 2005 TO PRESENT

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2014-1367	02/20/2014 03/20/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	JOE KOHL SPEER LAWL FIRM	ROCKVIEW DAIRY & HIGH LONESOME DAIRY, HOBBS, NM - RECS 2005 TO PRESENT
2014-1368	02/20/2014 03/20/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	JOE KOHL SPEER LAWL FIRM	DELNORTE DAIRY LLC; DAYBREAK DAIRY LLC (GORZEMAN DAIRY); MOUNTAIN VIEW DAIRY LLC, DONA ANA COUNTY, NM, ETC - RECS 2005 TO PRESENT
2014-1369	02/20/2014 03/20/2014	FDA/OMPT/CDRH/OCER/DFOI/	LUCY UNGER WILLIAMS VENKER ET AL	DAVINCISI SURGICAL SYS USER MANUAL (P/N550650); DA VINCI REPROCESSING INSTRUMENTS & ACESSORIES USER MANUAL (P/N550675); DA VINCI REPROCESSING INSTRUTIONS (P/N550875) 3/12
2014-1370	02/20/2014 03/20/2014	FDA/OMPT/CDRH/OCER/DFOI/	ANDREW J SCHOLZ GOLDBERG SEGALLA	MITAKA KOHI CO LTD - POINT-SETTER PNEUMATIC ARM PSMS2 WITH SCHEMATICS & OR DRAWINGS - 510K
2014-1371	02/20/2014 03/20/2014	FDA/OMPT/CDRH/OCER/DFOI/	SUSANNAH R CONN ROBBINS GELLER ET AL	MEDTRONIC INC - RECOMBINANT HUMAN BONE MORPHOGENETIC PROTEIN RHBMP-2 (INFUSE, AMPLIFY) - COMM, P000058 1/1/99, 7/2/02; COMM, AERS 7/2/02 TO PRESENT, COMM POST-APRVL STUDIES 7/2/02 TO PRESENT, ETC
2014-1372	02/20/2014 03/20/2014	FDA/OMPT/CDRH/OCER/DFOI/	TRACEY R KIRSCH Electromedical Products International Inc	AMERICAN IMEX ULTIMA XS - K880751, K895295, K912289
2014-1373	02/20/2014 03/20/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MICHAEL R COHEN INSTITUTE FOR SAFE MEDICATION PRACTICES	MEDWATCH RPTS CODED AS MEDICATION ERRORS 1/1-31/14
2014-1374	02/20/2014 03/20/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PATRICIA L REGENYE Celgene Corporation	ALFREDO FALCONE, A.O.U. PISANA ONCOLOGIE MEDICA 2S0, CHIARA, PISA, ITALY - 483S 11/12 TO PRESENT
2014-1375	02/20/2014 03/20/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	CAUDLE #20711-058, BRANDON LEE	TIVICAY (DOLTEGRAVIR) - PI
2014-1376	02/20/2014 03/20/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARY B SZALKOWSKI PRISMA CORP	PERGOLIDE (PERMAX), VALVULOPATHY - BASIS FOR WITHDRAWAL, AERS

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2014-1377	02/20/2014 03/20/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DOLORS APARICIO LABORATORIOS INIBAS SA	DESI 10598 - BENDECTIN PEER RVW RPT 1975
2014-1378	02/20/2014 03/20/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SUSANE G YESNICK DRINKER BIDDLE REATH LLP	EFFEXOR - LTRS, ATTACHMENTS RE: LBLG 9/25/02, 3/20/03, 8/8/03, ETC
2014-1379	02/20/2014 03/20/2014	FDA/OGROP/ORAC/CE-FO/NWJ-DO/NWJ-CB/	SUZANNE D JENSEN KLEINFELD KAPLAN & BECKER	ASCEND LABS, MONTVALE, NJ - EIRS, 483S INSP CLASSIFICATIONS 1/13 TO PRESENT
2014-1380	02/20/2014 03/20/2014	FDA/OGROP/ORAC/CE-FO/PHI-DO/PHI-CB/	AUTUMN L BORTON PFIZER	SHARP PACKAGING SOLUTIONS, ALLENTOWN, PA - 483S 1/9/10/13/15/14
2014-1381	02/20/2014 03/20/2014	FDA/OGROP/ORAC/SE-FO/FLA-DO/FLA-CB/	JOETTE GIOVINCO WTVT FOX 13	WARNING LTR TO DR MARK D SANCHEZ - WHAT PROMPTED THE INSP OR CMLNT
2014-1382	02/20/2014 03/20/2014	FDA/OGROP/ORAC/SW-FO/KAN-DO/KAN-CB/	HAGER, MITCH	CMLNT #135240
2014-1383	02/20/2014 03/20/2014	OC/ORAC/ORM/ OC/ORAC/ORM/	THOMPSON, RAY	LISTING OF SITES WHICH CONDUCTED GMP, GLP, OR GCP INSP 12/1/13-1/31/14
2014-1384	02/20/2014 03/20/2014	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORAC/ OC/ORAC/ FDA/OFVM/CFSAN/OCD/EOS/ OC/ORAC/ OC/ORAC/	W HOLT HARRELL HARRELL & HARRELL	PHUSION PROJECTS - ALCOHOLIC ENERGY DRINKS, FOUR LOKO TEST RESULTS 2009 TO PRESENT
2014-1385	02/20/2014 03/20/2014	FDA/OC/OES/DFOI/	KELLY, SHANNON B	COMPOUNDING OF DRUGS FOR USE IN ANIMALS POLICY RECS
2014-1386	02/20/2014 03/20/2014	FDA/OC/OES/DDM/	MEGAN L CLAYTON JOHNS HOPKINS BLOOMBERG SCHOL OF PUBLIC HEALTH	DKT FDA-201N-0921
2014-1387	02/20/2014 03/20/2014	OC/ORAC/OCI/ OC/ORAC/OCI/	KATHY S JOHNSON TWIN CITY NEWS	OPTIMUS INC (MARKY'S CAVIAR) - CAVIAR SMUGGLING INVESTIGATION RECS
2014-1388	02/20/2014 03/20/2014	FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECS

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2014-1389	02/20/2014 03/20/2014	FDA/OC/OES/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/OIP/	VIRGINIA ROBNETT COALITION FOR SENSIBLE SAFEGUARDS	PROPOSED FOREIGN SUPPLIER VERIFICATION PROGRAM RULE - COMM, MEETINGS, NOTES, ETC
2014-1390	02/20/2014 03/20/2014	FDA/OC/OES/DFOI/	SLADE, CHARLES	FEDERAL ANALYSIS OF 30 ANTIBIOTICS USED IN ANIMALS THAT CONTRIBUTE TO ANTIBACTERIAL RESISTANCE IN HUMANS
2014-1391	02/20/2014 03/20/2014	FDA/OMPT/CDRH/OCER/DFOI/	Pivi Mesiranta Mectalent Medical Services	K131699
2014-1392	02/20/2014 03/20/2014	FDA/OMPT/CDRH/OCER/DFOI/	Maritza Ward HealthTronics	K060279
2014-1393	02/20/2014 03/20/2014	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2013-7507
2014-1394	02/20/2014 03/20/2014	FDA/OC/OES/DDM/	Douglas Kelly Clark Hill PLC	2006P-0054/CCP1
2014-1395	02/20/2014 03/20/2014	FDA/OMPT/CDRH/OCER/DFOI/	Ned Feder PROJECT ON GOVERNMENT OVERSIGHT	PMA P000058
2014-1396	02/21/2014 03/21/2014	FDA/OC/OES/DFOI/	CROSBY T50417, COURTNEY	UNCLE BENS RICE - RECALL
2014-1397	02/21/2014 03/21/2014	FDA/OC/OES/DFOI/	NICOLAS 635504, ALBERT	REGLAN; ZOFRAM - WARNINGS 12/11 TO 6/12
2014-1398	02/21/2014 03/21/2014		HUGE, GARY	LIST OF US INSPECTED FACILITIES
2014-1399	02/21/2014 03/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SAMPSON 226369, DONALD HORACE	REMERON; BUSPAR; PROZAC; DEPAKOTE - AER
2014-1400	02/21/2014 03/21/2014	FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/	SHARI C. PEARCE VETERANS AFFAIRS MEDICAL CENTER	HOSPITAL BLOOD BANK - EIR, 483 2/13
2014-1401	02/21/2014 03/21/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	JASBIR SRA, MD, FACC, FHRS APN HEALTH LLC	BIOSENSE WEBSTER IND - CARTO XP V8 EP NAVIGATION SYS K042999
2014-1402	02/21/2014 03/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K121698

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2014-1403	02/21/2014 03/21/2014	FDA/OC/OL/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angel R. Cancela Arnold & Porter LLP	RESPONSE TO LETTER TO MARGARET HAMBURG RE DRUG LABELING CHANGES 01/22/2014 - 02/20/2014
2014-1404	02/21/2014 03/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	Leon Amariglio Lexington Medical, Inc.	K073122
2014-1405	02/21/2014 03/21/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-331 REQUEST LETTER
2014-1406	02/21/2014 03/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	Leon Amariglio Lexington Medical, Inc.	K073164
2014-1407	02/21/2014 03/21/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sumitra Ghatge Ghatge, Sumitra M	LILLY NUS CENTRE FOR CLINICAL PHARMACOLOGY, SINGAPORE -STUDY F3Z-EW-IOPY(a) REPORT
2014-1408	02/21/2014 03/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	Leon Amariglio Lexington Medical, Inc.	K072814
2014-1409	02/21/2014 03/21/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Melissa Spencer Transition Therapeutics Inc.	NDA 019010, NDA 019732 - PHARMACOLOGY REVIEW
2014-1410	02/21/2014 03/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	Deb COVIDIEN	K091934
2014-1411	02/21/2014 03/21/2014	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	Chastity Rodriguez Alchimia	AL.CHI.Mi.A SRL, CORAL GABLES, FL - WARNING LETTER, 483 LAST TEN YEARS
2014-1412	02/21/2014 03/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K944253
2014-1413	02/21/2014 03/21/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sarah Lynch Schachter, Hendy & Johnson, P.S.C.	AndroGel 1% NDA 021015, AndroGel 1.62% NDA 022309
2014-1414	02/21/2014 03/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	Gael Tisack Terumo Cardiovascular Group	Sorin Group Deutschland GmbH - 483 APRIL 2011

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2014-1415	02/21/2014 03/21/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/	Scott Fawcett Carroll Quality Consult, Inc.	Custom Veterinary Services, Inc., Miami, FL - 483, EIR, UNTITLED LETTER
2014-1416	02/21/2014 03/21/2014	FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/	Dallas Cole PUBLIC RECORD STRATEGIES	PACHECO - ENFORCEMENT RECS 02/01/1991 - 02/18/2014
2014-1417	02/21/2014 03/21/2014	FDA/OFVM/CFSAN/OCD/EOS/	Eleanor DaCosta United States Pharmacopeial Convention (USP)	MEMO DATED: August 1, 2000/ FROM: Alan Bailey, FDA Office of Food Additives Safety Staff TO: Mark Hept/ RE: Food Contact Notification 7390 and 7391/ CONTAINING: information on the carcinogenic unit risk for p-toluidine and an explanation for its derivation
2014-1418	02/21/2014 03/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Erin E. Keplinger Erin E. Keplinger	FDA's priority classification system in effect from about 1974 through at least 1979 (if not later) that classified drug products by chemical and therapeutic potential, using a number and a letter, respectively. It may be in Staff Manual Guide BD4820.3
2014-1419	02/21/2014 03/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	Min Lian, MD, PhD WASHINGTON UNIVERSITY SCHOOL OF MEDICINE	FDA-certified radiation therapy facilities from January 1, 2005 through the current. Expected information includes: address, facility name, certified year and expiration year, number of units, number of physicians.
2014-1420	02/21/2014 03/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	Min Lian, MD, PhD WASHINGTON UNIVERSITY SCHOOL OF MEDICINE	FDA-certified mammography facilities from January 1, 2005 through the current. Expected information includes: address, facility name, certified year and expiration year, mobile or non-mobile, number of units, number of physicians
2014-1421	02/21/2014 03/21/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Paula Peters SmokeSygnals	FECAL MICROBIOTA TRANSPLANT RECS
2014-1422	02/21/2014 03/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHRIS SZECHENYI ONE POINT INVESTIGATIONS	ACHILLION PHARMACEUTICALS - SOVAPREVIR CORR
2014-1423	02/21/2014 03/21/2014	FDA/OGROP/ORO/PA-FO/SEA-DO/SEA-CB/	SHERI O. COVINGTON K&L GATES	HEMCARE OF OREGON INC, WILSONVILLE, OR - EIR 11/27/12 TO 1/7/13
2014-1424	02/21/2014 03/21/2014	FDA/OGROP/ORO/SW-FO/KAN-DO/KAN-CB/	DAVID H. LUGINBILL AHLERS COONEY DORWEILER ET AL	MCF LIQUIDATION, ANKENY, IA - RECALL, CORR, CMLPNT, RPTS, ETC
2014-1425	02/21/2014	FDA/OMPT/CDER/ORP/DIDP/	DAVID M. HOFFMEISTER	DR REDDY'S - SUMATRIPTAN SUCCINATE ANDA 90-495 - APRVL

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	03/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WILSON SOSINI GOODRICH & ROSATI	
2014-1426	02/21/2014 03/21/2014	FDA/OC/OES/DFOI/	BRETT PARK CONWAY HOMER & CHIN- CAPLAN PC	INDIVIDUAL RECS
2014-1427	02/21/2014 03/21/2014	FDA/OC/OES/DFOI/	BRETT PARK CONWAY HOMER & CHIN- CAPLAN PC	INDIVIDUAL RECS
2014-1428	02/24/2014 03/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	David Mangione Govzilla, Inc.	BOEHRINGER INGELHEIM, VIENNA, AUSTRIA - 483 09/01/2007 - 01/31/2010
2014-1429	02/24/2014 03/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	Heejung Byun University of Maryland, College Park	Establishment Registration & Device Listing HISTORICAL DATA
2014-1430	02/24/2014 03/24/2014	FDA/OFVM/CFSAN/OCD/EOS/	Deepak Kumar Kumar, Deepak	WHEY PROTEIN ISOLATE - NUTRITIONAL DATA
2014-1431	02/24/2014 03/24/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Eureka Ross Central Texas Regional Blood and Tissue Center	Biological License Application (BLA) submission documents-US license #244- for the licensures that we obtained from FDA in December 1996 for manufacturing CRYOPRECIPITATE AHF and PLATELETS
2014-1432	02/24/2014 03/24/2014	FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/	Pankaj Macwan HERBALIFE INTERNATIONAL	TOWER LABORATORIES, CENTERBROOK, CT - 483 06/01/2013 - 01/31/2014
2014-1433	02/24/2014 03/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mikhail Matchenko Keck Graduate Institute	QUINALDINE BLUE - APPROVAL RECS
2014-1434	02/24/2014 03/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mikhail Martchenko Keck Graduate Institute	AMODIAQUINE - APPROVAL RECS
2014-1435	02/24/2014 03/24/2014	OC/ORA/ OC/ORA/ FDA/OGROP/ORASE-FO/FLA-	Doe J	INDIVIDUAL RECS

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		DO/FLA-CB/		
2014-1436	02/24/2014 03/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Christopher Hamma US Biotest, Inc.	NDA 20262 - SBA
2014-1437	02/24/2014 03/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	ANDA 202093
2014-1438	02/24/2014 03/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	ANDA 202286
2014-1439	02/24/2014 03/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K091939
2014-1440	02/24/2014 03/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jay Jennings Jay Jennings	epi-pen epinephrine auto injector - AERS
2014-1441	02/24/2014 03/24/2014	OC/ORO/ OC/ORO/	sue richmond law of compounding/ Sue Richmond	DIAMONDBACK DRUGS - 483, WARNING LETTER 01/01/2012 - 02/14/2014
2014-1442	02/24/2014 03/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lynn Keefe Lynn Keefe	MULTIHANCE - DEATHS
2014-1443	02/24/2014 03/24/2014	FDA/OFVM/CFSAN/OCD/EOS/	Marne Rasinen Ecolab	FCN 880, 1132, 1247
2014-1444	02/24/2014 03/24/2014	FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/	Scott Fawcett Carroll Quality Consult, Inc.	BOCA BIOLISTICS, COCONUT CREEK, FL - EIR 03/01/2013 - 03/31/2013
2014-1445	02/24/2014 03/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	DR GERT KUCHLER SOMNOMEDICS AMERICA INC	SOTERA WIRELESS INC - VISI MOBILE MONITORING SYS K130709
2014-1446	02/24/2014 03/24/2014	FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	MELANIE D HAMMOND FREEMAN MATHIS & GARY LLP	CHEMENCE INC, CHEMCENCE MEDICAL PRODUCTS INC, JAMES V QUINN MD - RECS

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2014-1447	02/24/2014 03/25/2014	FDA/OFVM/CFSAN/OCD/EOS/	TAKAYO NAGASAWA FUJISANKEI COMMUNICATIONS INTERNATIONAL	NOBUYOSHI KURAOKA, WAKE INTERNATIONAL CORP - SAFETY OF PUFFER FISH IMPORTED FROM JAPAN 1985 TO 1989 VIDEO
2014-1448	02/24/2014 03/24/2014	FDA/OFVM/CFSAN/OCD/EOS/	VISAGINE VIJAYAKULASINGAM IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 172926
2014-1449	02/24/2014 03/24/2014	FDA/OFVM/CFSAN/OCD/EOS/	JUANITA DEPTOWICZ SUNLESS INC	MYSTIC TAN - CAERS 172659
2014-1450	02/24/2014 03/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SHARON WARBINGTON MIKART INC	PARAFLEX - CONTAINER LBLG
2014-1451	02/24/2014 03/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DR REENA HARJAI APCER Pharma Solutions, Inc	KINEVAC (SINCALIDE) - AERS 1/103 TO 12/08
2014-1452	02/24/2014 03/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SARFARAZ K NIAZI Therapeutic Proteins International, LLC	ADAKIMUMAB BLA 125057
2014-1453	02/24/2014 03/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SARFARAZ K NIAZI Therapeutic Proteins International, LLC	PEG FILGRASTIM BLA 125031
2014-1454	02/24/2014 03/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SARFARAZ K NIAZI Therapeutic Proteins International, LLC	TRASTUZUMAB BLA 980369
2014-1455	02/24/2014 03/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SARFARAZ K NIAZI Therapeutic Proteins International, LLC	CETUXIMAB BLA 125084
2014-1456	02/24/2014 03/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SARFARAZ K NIAZI Therapeutic Proteins International,	INFLIXIMAB BLA 980012

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LLC	
2014-1457	02/24/2014 03/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SARFARAZ K NIAZI Therapeutic Proteins International, LLC	ETANERCEPT BLA 980286
2014-1458	02/24/2014 03/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SARFARAZ K NIAZI Therapeutic Proteins International, LLC	BEVACIZUMAB BLA 125085
2014-1459	02/24/2014 03/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SARFARAZ K NIAZI Therapeutic Proteins International, LLC	RITUXIMAB BLA 970244
2014-1460	02/24/2014 03/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SARFARAZ K NIAZI Therapeutic Proteins International, LLC	RITUXIMAB BLA 970260
2014-1461	02/24/2014 03/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SARFARAZ K NIAZI Therapeutic Proteins International, LLC	FILGRASTIM BLA 96-1136
2014-1462	02/24/2014 03/24/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	NATHAN M SHAW KNOBBE MARTENS OLSON & BEAR	COVIDIEN - N-200 PULSE OXIMETER K863784, K022819
2014-1463	02/24/2014 03/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	NATHAN M SHAW KNOBBE MARTENS OLSON & BEAR	COVIDIEN - N-395 PULSE OXIMETER K991823, K993637
2014-1464	02/24/2014 03/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	NATHAN M SHAW KNOBBE MARTENS OLSON & BEAR	COVIDIEN - N-100 PULSE OXIMETER K822909
2014-1465	02/24/2014 03/24/2014	FDA/OFVM/CFSAN/OCD/EOS/	FRIEDMAN, ROBERT	COLLEGE INN, HEALTHY CHOICE, BEAR CREEK SOUPS, ETC - CAERS 1969 TO 2014
2014-1466	02/24/2014	FDA/OFVM/CFSAN/OCD/EOS/		A1 STEAK SAUCE, ANNIE'S NATURAL, MRS DASH, ETC -

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	03/24/2014		FRIEDMAN, ROBERT	CAERS 1969 TO 2014
2014-1467	02/24/2014 03/24/2014	FDA/OFVM/CFSAN/OCD/EOS/	FRIEDMAN, ROBERT	SARA LEE, KRAFT COOL WHIP, MRS SMITH'S - CAERS 1969 TO 2014
2014-1468	02/25/2014 03/25/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Leigh Walsh SHIRE PHARMACEUTICALS INC	WARNING LETTER 320-13-015 - CORR RE RESPONSE TO OBSERVATIONS
2014-1469	02/25/2014 03/25/2014	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Kathy Simpson Celleration, Inc.	AROBELLA MEDICAL - EIR 06/01/2012 - 12/31/2012
2014-1470	02/25/2014 03/25/2014	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Kathy Simpson Celleration, Inc.	AROBELLA MEDICAL - 483, RESPONSES, INVESTIGATOR NOTES ETC 06/01/2012 - 12/31/2012
2014-1471	02/25/2014 03/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	Tameka R. White The Rudman Law Firm APC	STERIS 20 STERILANT CONCENTRATE RECS 01/01/2008 - 02/21/2014
2014-1472	02/25/2014 03/25/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	William Blake William Blake	OPANA - AERS
2014-1473	02/25/2014 03/25/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Cecile Schilis-Gallego Columbia Journalism School	Correspondence and promotional material for the oral contraceptive Natazia (Bayer)
2014-1474	02/25/2014 03/25/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Christine Livoti BIOPHARM INSIGHT	ONGLYZA, KOMBIGLYZE XR - MEDWATCH REPORTS
2014-1475	02/25/2014 03/25/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	Certificate of a Pharmaceutical Product for (1) Tecfidera delayed-release capsules, or (2) dimethyl fumarate as bulk active ingredient
2014-1476	02/25/2014 03/25/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	James F. Green, Esq. ASHCRAFT & GEREL, LLP	CERTIFIED RECS

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		FDA/OC/OES/DFOI/		
2014-1477	02/25/2014 03/25/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	A.Kiran Kumar RA Chem Pharma Ltd, Clinical Research & Biosciences Division	RA Chem Pharma Ltd, Clinical Research & Biosciences Division, Hyderabad - EIR ATTACHMENTS
2014-1478	02/25/2014 03/25/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	jesse m polansky md polansky	NCEP and other cardiac risk calculators in industry promotional and non-promotional usage
2014-1479	02/25/2014 03/25/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	jesse polansky md mph polansky	Supplemental new drug application approved for Zocor t by FDA on 6/11/08
2014-1480	02/25/2014 03/25/2014	FDA/OC/OES/	Barry Wides North White Oak Civic Association	FDA MOU 225-12-0025 signed by Commissioner Hamburg on 5/1/13 with an affiliate of Percontee/Global LifeSci
2014-1481	02/25/2014 03/25/2014	FDA/OC/OES/	Barry Wides North White Oak Civic Association	FDA MOU 225-12-0025 signed by Commissioner Hamburg on 5/1/13 with an affiliate of Percontee/Global LifeSci
2014-1482	02/25/2014 03/25/2014	FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/	James E. McCarthy McCarthy, James A.	ATRIUM MEDICAL CORPORATION, HUDSON, NH - 483 10/11/2012 - 02/28/2014
2014-1483	02/25/2014 03/25/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Monica Michelotti UNIVERSITY OF MICHIGAN	AVASTIN, LUCENTIS, EYLEA - AERS
2014-1484	02/25/2014 03/25/2014	FDA/OGROP/ORASE-FO/FLA- DO/FLA-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	Any and all information concerning the Pharmaceutical Development Group of Tampa, FL or Cheryl Blume, PhD
2014-1485	02/25/2014 03/25/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K071037
2014-1486	02/25/2014 03/25/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K072222

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2014-1487	02/25/2014 03/25/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K071619
2014-1488	02/25/2014 03/25/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K073088
2014-1489	02/25/2014 03/25/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Chandra S Joshi AnalyticsPlus	K100066
2014-1490	02/25/2014 03/25/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SW-FO/KAN-DO/KAN-CB/	Derrick Bautsita Big Heart Pet Brands	SAMPLE RESULTS
2014-1491	02/25/2014 03/25/2014	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Yamil Hernandez Cerium Pharmaceuticals, Inc.	NDA 020645
2014-1492	02/25/2014 03/25/2014	FDA/OC/OES/DFOI/ FDA/OC/OES/DDM/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OES/DFOI/	Kimberly Kindy THE WASHINGTON POST	FOIA for documents related to FAP 3A4798 and FDA-2013-P-0472, filed by Richard C. Theuer
2014-1493	02/25/2014 03/25/2014	FDA/OC/OES/DFOI/	Kimberly Kindy THE WASHINGTON POST	FOIA filed on Feb. 10, 2014 by the Natural Resources Defense Council. Subject stated in FOIA: "FOIA Request for Records Threshold of Regulation Submission No. 05-006 regarding sodium perchlorate monohydrate."
2014-1494	02/25/2014 03/25/2014	FDA/OC/OES/DFOI/	Robert King FDA NEWS	FOIA REQUEST LOT 02/17/2014 - 02/21/2014
2014-1495	02/25/2014 03/25/2014	FDA/OFVM/CFSAN/OCD/EOS/	AZIM CHOWDHURY Keller and Heckman LLP	PPG INDUSTRIES INC - FCN 1213
2014-1496	02/25/2014 03/25/2014	FDA/OFVM/CFSAN/OCD/EOS/	AZIM CHOWDHURY Keller and Heckman LLP	PPG INDUSTRIES INC - FCN 1177
2014-1497	02/25/2014 03/25/2014	FDA/OFVM/CFSAN/OCD/EOS/	AZIM CHOWDHURY Keller and Heckman LLP	FCN 1212
2014-1498	02/25/2014 03/25/2014	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	SARFARAZ K NIAZI Therapeutic Proteins International, LLC	FILGRASTIM BLA 96-1136; ETANERCEPT BLA 98-026; CETUXIMAB BLA 125-084, ETC

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2014-1499	02/25/2014 03/25/2014	FDA/OC/OCC/ FDA/OC/OES/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OPP/OP/	O'NEILL, JAMES T	DEPT OF DEFENSE - POLICY TOWARD LABORATORY DEVELOPED TESTS, HEALTH PROGRAM POLICY TOWARD REIMBURSEMENT TESTS, COMM, ETC 2005 TO PRESENT
2014-1500	02/25/2014 03/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELENA HOWELL HOGAN LOVELLS US LLP	CERTIFICATE OF A PHARMACEUTICAL PROD - TECIFERA (DIMETYHL FUMARATE) DELAYED-RELEASE CAPS OR DIMETHYL FUMARATE
2014-1501	02/25/2014 03/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KISHEN MEHTA ADAGE CAPITAL MANAGEMENT LP	KYPORLIS (CARFILZOMIB) - AERS 1/12 TO PRESENT
2014-1502	02/25/2014 03/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CLARK SULLIVAN TROUTMAN SANDERS LLP	US PATENT # 7,022,713 NDA 22-363 - FORMS 3542
2014-1503	02/25/2014 03/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANIL SACHEVA AGILA SPECIALTIES INC	IMMUNEX - THIOPLEX INJ USP 15 MG NDA 20-058 LBLG, PI
2014-1504	02/25/2014 03/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	STEFANIE GOBIN GERALD LB LEFCOURT PC	AMBIEN - LABEL CHANGE 2007, DOSAGE CHANGE 2013, LABEL CHANGE 2008
2014-1505	02/25/2014 03/25/2014	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	CRAIG ROUSH ROCHLINE INDUSTRIES	GO JO INDUSTRIES INC, AKRON, OH - EIRS, 483S, CORR 11/13
2014-1506	02/25/2014 03/25/2014	FDA/OC/OES/DFOI/	ELENA HOWELL HOGAN LOVELLS LLP	2014-608
2014-1507	02/25/2014 03/25/2014	FDA/OMPT/OSMP/OOPD/	ELIZABETH SMITHHART BUTLER SNOW LLP	WILLIAM M LEE MD, ACUTE LIVER FALURE STUDY GROUP - GRANT APPL, CORR, RPTS, ETC
2014-1508	02/25/2014 03/25/2014	FDA/OO/OFBA/OAGS/	S ALBERT EDWARDS PHARMD S ALBERT EDWARDS, PHARM D	SOURCES SOUGHT NOTICE - ELECTONIC MEDICAL RECS DATA
2014-1509	02/25/2014	OC/ORA/	GORDON HARNACK	BLANK COPY OF FORM 483

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	03/25/2014	OC/ORAI/	ORACLE CONSULTING GROUP	
2014-1510	02/25/2014 03/25/2014	OC/CVM/OCD/	ASHVIN ASHOK CENTER FOR DISEASE DYNAMICS, ECONOMICS & POLICY	RETAIL MEAT - ACESS TO NARMS RECS
2014-1511	02/25/2014 03/25/2014	FDA/OC/OES/DFOI/	PATRICK KELLY CONWAY HOMER & CHIN- CAPLAN PC	INDIVIDUAL RECS (CERTIFIED)
2014-1512	02/26/2014 03/26/2014	FDA/OGROP/ORAI/SE-FO/ATL- DO/ATL-CB/	Nancy Fulginiti Sandoz Inc.	SANDOZ, INC, WILSON, NC - EIR APRIL 2013
2014-1513	02/26/2014 03/26/2014	FDA/OMPT/CDRH/OCER/DFOI/	Cristina Zavaleta STANFORD UNIVERSITY	G130064
2014-1514	02/26/2014 03/26/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	DIRECT REPORTS, MEDWATCH REPORTS, ANY SOURCE DOCUMENTS 85801346 86594845 87135284 ETC
2014-1515	02/26/2014 03/26/2014	FDA/OMPT/CDRH/OCER/DFOI/	Hui Ouyang Cook Inc.	K862347
2014-1516	02/26/2014 03/26/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anna Edney BLOOMBERG NEWS	All adverse event reports related to atorvastatin, furosemide and metoprolol succinate from any companies brand or generic
2014-1517	02/26/2014 03/26/2014	FDA/OMPT/CDRH/OCER/DFOI/	David Asbury Innerspace Neuro Solutions	K083378
2014-1518	02/26/2014 03/26/2014	FDA/OMPT/CDRH/OCER/DFOI/	Patrick Cheng Children's National Medical Center, Sheikh Zayed Institute	K123445
2014-1519	02/26/2014 03/26/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Cynthia Wojtaszek Bristol Myers-Sqibb	NDA 202806 S002 - SBA
2014-1520	02/26/2014 03/26/2014	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	SE info for Sutra Bidis tobacco products
2014-1521	02/26/2014	FDA/OMPT/CDER/ORP/DIDP/	Marie Link	Number of REMS Drug Error Reports (by drug) - from 2008 through 2013

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	03/26/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	REMS Logic, LLC	
2014-1522	02/26/2014 03/26/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K073130
2014-1523	02/26/2014 03/26/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Elinore Mercer Cote Orphan Consulting	NDA 018662
2014-1524	02/26/2014 03/26/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/OSMP/OOPD/	Jonathan J. Darrow BRIGHAM AND WOMEN'S HOSPITAL	DEXFENFLURAMINE (NDA 020344) - ACCELERATED APPROVAL, ORPHAN DESIGNATION, PRIORITY REVIEW
2014-1525	02/26/2014 03/26/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jonathan J. Darrow BRIGHAM AND WOMEN'S HOSPITAL	IND EFFECTIVE AND SUBMISSION DATES
2014-1526	02/26/2014 03/26/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jonathan J. Darrow BRIGHAM AND WOMEN'S HOSPITAL	IND SUBMISSION AND EFFECTIVE DATES
2014-1527	02/26/2014 03/26/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jonathan J. Darrow BRIGHAM AND WOMEN'S HOSPITAL	IND EFFECTIVE AND SUBMISSION DATES
2014-1528	02/26/2014 03/26/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jonathan J. Darrow BRIGHAM AND WOMEN'S HOSPITAL	Orlaam (levomethadyl acetate hcl) (N020315) (1993); Trasylol (aprotinin) (N020304) (1993); Renormax (spirapril hcl) (N020240) (1994) - Seeking documents that indicate whether the following drugs benefitted from (1) accelerated approval, (2) an orphan designation, or (3) a fast-track (including subpart E) designation.

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		FDA/OMPT/OSMP/OOPD/		
2014-1529	02/26/2014 03/26/2014	FDA/OMPT/CDRH/OCER/DFOI/	Patrick Cheng Children's National Medical Center, Sheikh Zayed Institute	K070426, K130165, K131596
2014-1530	02/26/2014 03/26/2014	FDA/OGROP/ORO/ORO/DIOP/ OC/ORO/ OC/ORO/ FDA/OFVM/CFSAN/OCD/EOS/	Steven M. Melendez Vice Motherboard	Any import bulletins or other records relating to restrictions on the import and/or sale of kratom or kratom-containing supplements
2014-1531	02/26/2014 03/26/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dheeresh Pathak Dheeresh Pathak	NATCO PHARMAC LIMITED, INDIA - 483 01/01/2010 - 02/25/2014
2014-1532	02/26/2014 03/26/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Taylor Wofford Freelance journalist/author	Any and all e-mail or written correspondence between Dr. Bob A. Rappaport, Division Director, DAAAP, or any of his staff, and any representatives or employees of Zogenix, Inc 01/01/2010 - 02/25/2014
2014-1533	02/26/2014 03/26/2014	FDA/OMPT/CDRH/OCER/DFOI/	Veeraraghavan Sundar Veeraraghavan Sundar	K132984
2014-1534	02/26/2014 05/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K100468
2014-1535	02/26/2014 03/26/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/	GEORGE SALMAS The Food Lawyers	PETITION OT REMOVE EMPACADORA SAN LORENZO FROM IMPORT ALERT LIST
2014-1536	02/26/2014 03/26/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kofi Aninakwa Sirona Dental Systems, Inc.	K122467
2014-1537	02/26/2014 03/26/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joel Mindel MOUNT SINAI MEDICAL CENTER GREATER MIAMI SKIN & LASER CTR	Number of optic neuropathy reports per year for 2007, 2008, 2009 2010, 2011, 2012, and 2013 for each of the following drugs: amiodarone, Pacerone, Cardarone and Maltaq
2014-1538	02/26/2014 03/26/2014	FDA/OFVM/CFSAN/OCD/EOS/	JUANITA DEPTOWICZ SUNLESS INC	MYSTIC TAN - CAERS 172659
2014-1539	02/26/2014 03/26/2014	FDA/OC/OES/DFOI/	MICHELE L BUENAFE MORGAN LEWIS & BOCKIUS LLP	ROCHE DIAGNOSTICS CORP - SENSEWEAR ARMBAND C030022 513G SUBMISSION

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2014-1540	02/26/2014 03/26/2014	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	DAVID LEVINE R1 TECHNOLOGIES LLC	INHALATION PLASTICS (IPI MEDICAL) - RAYMOND MLECKO, STEVEN EICH, MICHAEL LANG, RICHARD HARRISON CORR 1/90 TO 12/02
2014-1541	02/26/2014 03/26/2014	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	VANESSA C JACKSON Bactolac Pharmaceutical, Inc.	NATURE'S VALUE INC, CORAM, NY - DIETARY SUPPLEMENT EIRS, 483S 1/10 TO PRESENT
2014-1542	02/26/2014 03/26/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	OLENA IZHAK UNIV OF HELSINIKI	YEARLY APRVD DRUG PRODS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS LIST; ORANGE BOOK 1970 TO PRESENT, ETC
2014-1543	02/26/2014 03/26/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Patrick Cheng Children's National Medical Center, Sheikh Zayed Institute	K000801, K061058, K062385, ETC
2014-1544	02/26/2014 03/26/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Theis Terwey NB Capital Research GmbH	CHENIX, CHENODIOL - APPROVAL RECS
2014-1545	02/26/2014 03/26/2014	FDA/OFVM/CFSAN/OCD/EOS/	BOOKER, BRIAN	HEALTH/PLUS/PRIME - REGISTERED FACILITY; GARCINIA CAMBOGIA - RECS
2014-1546	02/26/2014 03/26/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Jason Au-Yeung Indiana University School of Dentistry	MINDRAY NORTH AMERICA - INVESTIGATION RECS 11/01/2013 - 02/25/2014
2014-1547	02/26/2014 03/26/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SPELLMAN 95105-C2D2, JOHN E	NAME OF THE DRUG THAT CURES HEPATITIS C
2014-1548	02/26/2014 03/26/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jonathan J. Darrow BRIGHAM AND WOMEN'S HOSPITAL	IND EFFECTIVE DATE AND SUBMISSION DATES
2014-1549	02/26/2014 03/26/2014	FDA/OC/OES/DFOI/	Kari L. Twaite BEVERIDGE & DIAMOND PC	ALL FOIA REQUESTS FILED WITH CFSAN 01/27/2014 - 02/25/2014
2014-1550	02/26/2014 03/26/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K061871
2014-1551	02/26/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson	K080612

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	03/26/2014		FOI Services, Inc.	
2014-1552	02/26/2014 03/26/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K042961
2014-1553	02/26/2014 03/26/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K063345
2014-1554	02/26/2014 03/26/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	Information regarding demonstrating that an ANDA is bioequivalent to RESTASIS
2014-1555	02/26/2014 03/26/2014	FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/	MARTHA E MARRAPESE Keller and Heckman LLP	NO OBJECTION LTRS (NOL) FOR POST-CONSUMER RECYCLED PLASTICS FOR FOOD CONTACT ARTICLES - REQUEST FOR SUBMISSIONS AND CORRESPONDING AGENCY RVW MEMO
2014-1556	02/26/2014 03/26/2014	FDA/OMPT/CTP/OD/	NATALIE N SANDERS LATHAM & WATKINS LLP	JASH INTERNATIONAL - SUTRA BIDIS RED, MENTHOL, RED CONE, MENTHOL CONE TOBACCO PRODS FOUND TO BE NOT SUBSTANTIALLY EQUIVALENT (NSE)
2014-1557	02/26/2014 04/11/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OMPT/CDRH/OCER/DFOI/	LENNIE F BOLLINGER WORMINGTON LAW GROUP PLLC	STRYKER - NEPTUNE 1 SILVER WASTE MANAGEMENT SYS; NEPTUNE S ULTRA WASTE MANAGEMENT SYS - RECALL RECS, CORR, RPTS, ETC
2014-1558	02/27/2014 03/27/2014	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	Amanda Nerone Saving Sight	LIONS VISIONGIFT, PORTLAND, OR - 483, EIR 11/01/2011 - 11/01/2013
2014-1559	02/27/2014 03/27/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Rachel Johnson FOI Services, Inc.	483s for Parexel, Billerica, MA
2014-1560	02/27/2014 03/27/2014	FDA/OFVM/CFSAN/OCD/EOS/	Nathan A. Beaver FOLEY & LARDNER LLP	GRN 498
2014-1561	02/27/2014 03/27/2014	FDA/OC/OES/DDM/	Joseph Ciccone Church & Dwight Co., Inc.	DKT 80N-0042
2014-1562	02/27/2014 03/27/2014	FDA/OMPT/CDRH/OCER/DFOI/	Paul Danese FDABLE LLC	MAUDE REPORTS RE OTP, OTN, PAH ETC 01/01/2010 - 12/31/2013
2014-1563	02/27/2014 03/27/2014	OC/ORORM/ OC/ORORM/ FDA/OC/OES/DFOI/ OC/ORAOE/ OC/ORAOE/	Merle Zimmermann (ext. 106) AMERICAN HERBAL PRODUCTS ASSOCIATION	LIST OF INSPECTIONS FOR COMPLIANCE WITH 21 CFR Part 110
2014-1564	02/27/2014	FDA/OGROP/ORAPA-FO/LOS-	Peter Aldhous	DR MICHAEL BERGER, IMMUNOVATIVE THERAPIES,

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	03/27/2014	DO/LOS-CB/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OC/OES/	MATTER	BIOMEDIRB - INSPECTION RECS 04/27/2010 - 02/24/2014
2014-1565	02/27/2014 03/27/2014	FDA/OO/OIM/OPILS/FDAHO/	Michelle Minton The Competitive Enterprise Institute	PARTIALLY HYDROGENATED OIL - RECORDS OF ANTIQUITY
2014-1566	02/27/2014 03/27/2014	FDA/OC/OES/DFOI/	Logs-admin The Weinberg Group	FOIA DAILY LOG 01/02/2013 - 02/27/2014
2014-1567	02/28/2014 03/28/2014	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	CHASTITY JOY RODRIGUEZ INTERNATIONAL SIGHT RESTORATION INC	NUMEDS INC, ISANTI, MN - 483 2011 TO PRESENT
2014-1568	02/28/2014 03/28/2014	FDA/OMPT/CDRH/OCER/DFOI/	CHASTITY JOY RODRIGUEZ INTERNATIONAL SIGHT RESTORATION INC	AL CHI MI A SRL, PONTE S NICOLO ITALY - 483, WARNING LTRS LAST 3 YRS
2014-1569	02/28/2014 03/28/2014	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	CHASTITY JOY RODRIGUEZ INTERNATIONAL SIGHT RESTORATION INC	STRADIS HEALTHCARE, LAWRENCEVILLE, GA - 483 LAST 3 YRS
2014-1570	02/28/2014 03/28/2014	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	CHASTITY JOY RODRIGUEZ INTERNATIONAL SIGHT RESTORATION INC	ALCON RESEARCH LTD, FORT WORTH, TX - 483 2011 TO PRESENT
2014-1571	02/28/2014 03/28/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	CHASTITY JOY RODRIGUEZ INTERNATIONAL SIGHT RESTORATION INC	MIDMARK CORP, VERSAILLES, OH - 483 LAST 3 YRS
2014-1572	02/28/2014 03/28/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	CHASTITY JOY RODRIGUEZ INTERNATIONAL SIGHT RESTORATION INC	BAUSCH & LOMB INC, IRVINE, CA - 483 LAST 3 YRS
2014-1573	02/28/2014 03/28/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	CHASTITY JOY RODRIGUEZ INTERNATIONAL SIGHT RESTORATION INC	DUTCH OPHTHALMIC USA INC, EXETER, NH - 483 2011 TO PRESENT
2014-1574	02/28/2014 03/28/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	CHASTITY JOY RODRIGUEZ INTERNATIONAL SIGHT RESTORATION INC	FISHER SCIENTIFIC CO LLC, PITTSBURGH, PA - 483 LAST 3 YRS
2014-1575	02/28/2014 03/28/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	CHASTITY JOY RODRIGUEZ INTERNATIONAL SIGHT RESTORATION INC	HAI LABORATORIES INC, LEXINGTON, MA - 483 LAST 3 YRS
2014-1576	02/28/2014	FDA/OGROP/ORASW-FO/KAN-	CHASTITY JOY RODRIGUEZ	KANSAS EYE BANK & CORNEA RESEARCH CTR, WICHITA,

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	03/28/2014	DO/KAN-CB/	INTERNATIONAL SIGHT RESTORATION INC	KS - 483 LAST 3 YRS
2014-1577	02/28/2014 03/28/2014	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	CHASTITY JOY RODRIGUEZ INTERNATIONAL SIGHT RESTORATION INC	MIDINE INDUSTRIES INC, MUNDELEIN, IL - 483 2011 TO PRESENT
2014-1578	02/28/2014 03/28/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	CHASTITY JOY RODRIGUEZ INTERNATIONAL SIGHT RESTORATION INC	MORIA INC, DOYLESTOWN, PA - 483 LAST 3 YRS
2014-1579	02/28/2014 03/28/2014	FDA/OMPT/CDRH/OCER/DFOI/	S. MICHAEL SHARP, Ph.D. REGULATORY CONSULTING LTD	TXCELL LASER DELIVERY SYS - K121475
2014-1580	02/28/2014 03/28/2014	FDA/OMPT/CDRH/OCER/DFOI/	S. MICHAEL SHARP, Ph.D. REGULATORY CONSULTING LTD	PASCAL STREAMLINE 577 W/ACCESSORIES - K111108
2014-1581	02/28/2014 03/28/2014	FDA/OMPT/CDRH/OCER/DFOI/	S. MICHAEL SHARP, Ph.D. REGULATORY CONSULTING LTD	ELLEX 2RT - K122202
2014-1582	02/28/2014 03/28/2014	FDA/OC/OES/DFOI/	Anna Edney BLOOMBERG NEWS	483S FOR DRUG COMPANIES - INDIA, SAN FRANCISCO 02/29/2012 - 02/25/2014
2014-1583	02/28/2014 03/28/2014	FDA/OMPT/OSMP/OCP/ FDA/OC/OCC/	KATHLEEN M. BEAUCHAMP HALSCION INC	HALSCION - HYDROGEL SCAFFOLD APPEAL RFD120011 8/7/12
2014-1584	02/28/2014 03/28/2014	FDA/OMPT/CDRH/OCER/DFOI/	JEFFREY C. DALBEY KNIT-RITE INC	BOSSONG K123820; BELLAVAR K131496; JOBST K951234 ETC
2014-1585	02/28/2014 03/28/2014	FDA/OC/OES/DFOI/	GEMBARSKI 31086B, JOSEPH	BROCHURES
2014-1586	02/28/2014 03/28/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	UMBERGER, CHRIS	WELLBUTRIN XL; FLOMAX; SUBOXONE - AER
2014-1587	02/28/2014 03/28/2014	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	RANDALL YIP KGO Television/ ABC NEWS	GOURMET ROCKSTARS - INVESTIGATION
2014-1588	02/28/2014 05/08/2014	OC/ORA/ OC/ORA/	ANN MULLEN WXYZ TV	NUTRO BRANDS - 127 CMLNPTS 1/11 TO PRESENT
2014-1589	02/28/2014 03/28/2014	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/ORO/DIOP/	DONALD N. BLUE ZETETIC	ALL SHIPMENT DATA 1/13 TO 1/31/13
2014-1590	02/28/2014	OC/ORA/	DONALD N. BLUE	ALL SHIPMENT DATA 1/16/14 TO 2/26/14

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	03/28/2014	OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/	ZETETIC	
2014-1591	02/28/2014 03/28/2014	FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	MAUREEN JAROSCAK JAROSCAK, MAUREEN	JOHNATHAN FIELDING MD, LOS ANGELES COUNTY DEPT OF PUBLIC HEALTH - CORR TO FDA
2014-1592	02/28/2014 03/28/2014	FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	MAUREEN JAROSCAK JAROSCAK, MAUREEN	ALLERGAN - LAP BAND WARNING LTRS
2014-1593	02/28/2014 03/28/2014	OC/ORO/ORM/ OC/ORO/ORM/	ROBERT KING FDA NEWS	ALL PHARMACEUTICAL INSP, 483 - 1/2014
2014-1594	03/04/2014 04/01/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mikhail Martchenko Keck Graduate Institute	Camoquin, Flavoquine, Miaquin - approval recs
2014-1595	03/04/2014 04/01/2014	FDA/OMPT/CDRH/OCER/DFOI/	Scott Corchero Precision Solutions	K062074
2014-1596	03/04/2014 04/01/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mikhail Martchenko Keck Graduate Institute	VERNITEST - APPROVAL RECS
2014-1597	03/04/2014 04/01/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/OSMP/OOPD/	Jonathan J. Darrow BRIGHAM AND WOMEN'S HOSPITAL	NORMIFLO - ACCELERATED APPROVAL, ORPHAN DESIGNATION, FAST TRACK
2014-1598	03/04/2014 04/01/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jonathan J. Darrow BRIGHAM AND WOMEN'S HOSPITAL	IVERMECTIN (NDA N050742) - ACCELERATED APPROVAL, ORPHAN DESIGNATION, FAST TRACK
2014-1599	03/04/2014 04/01/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jonathan J. Darrow BRIGHAM AND WOMEN'S HOSPITAL	REMICADE - PRIORITY REVIEW, FAST TRACK

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2014-1600	03/04/2014 04/01/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jonathan J. Darrow BRIGHAM AND WOMEN'S HOSPITAL	Hismanal (astemizole); Omiflox (temafloxacin hcl); Manoplax (flosequinan) etc - accelerated approval, orphan designation, fast track
2014-1601	03/04/2014 04/01/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jonathan J. Darrow BRIGHAM AND WOMEN'S HOSPITAL	Permax (pergolide mesylate); Propulsid (cisapride monohydrate); Zagam (sparfloxacin) etc - accelerated approval, orphan designation, fast track etc
2014-1602	03/04/2014 04/01/2014	FDA/OMPT/CDRH/OCER/DFOI/	Michael G. Hodgkins Veron, Bice, Palermo & Wilson, LLC	Terumo Perfusion System 1 - MDR
2014-1603	03/04/2014 04/01/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Catherine Clapp Unilever	ANDA 088228, ANDA 089996 LABELING, APPROVAL RECS
2014-1604	03/04/2014 04/01/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Naltrexone Records Allodynamic Therapeutics, LLC	127607A N18932 Trexan/ReVia 50 mg tablets (DuPont Merck) 12/30/1994 Supplemental Approval New Indication - Treatment of Alcoholism): S10 Approval Letter, Final Labeling, Medical Officers Review, Correspondence ETC
2014-1605	03/04/2014 04/01/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Revia 1999 Labeling Revisions Allodynamic Therapeutics, LLC	N164792A N18932 Revia 50 mg tablets (Dupont Pharmaceuticals) 03/05/1999 Supplemental approval Labeling revisions: S13 & S14 Approval Leter N164792B N18932 Revia 50 mg tablets (Dupont Pharmaceuticals) 03/05/1999 Supplemental approval Labeling revisions: S14 Pharmacology/Toxicology N164792C N18932 Revia 50 mg tablets (Dupont Pharmaceuticals) ETC
2014-1606	03/04/2014 04/01/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	David L. Rosen FOLEY & LARDNER LLP	NDA 062663
2014-1607	03/04/2014 04/01/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jenloga Approval Allodynamic Therapeutics, LLC	5243864A N22331 - Jenloga 0.1 mg tablets (Addrenix) 09/29/2009 Approval (Hypertension) ETC

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-1608	03/04/2014 04/01/2014	FDA/OMPT/CDRH/OCER/DFOI/	David Hill Accendo Surgical	K111014
2014-1609	03/04/2014 04/01/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Jessica Swanson Innovative Science Solutions	MONOVISC - SBA
2014-1610	03/04/2014 04/01/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jonathan J. Darrow BRIGHAM AND WOMEN'S HOSPITAL	TAMIFLU, PLETAL, PANRETIN ETC - IND EFFECTIVE DATE, SUBMISSION DATE
2014-1611	03/04/2014 04/01/2014	FDA/OMPT/CDRH/OCER/DFOI/	David Hill Accendo Surgical	K093556
2014-1612	03/04/2014 04/01/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Richard W. Gonnello FARUQI & FARUQI LLP	CHELSEA THERAPEUTICS INTERNATIONAL LTD - SPA, INFORMATION LETTERS
2014-1613	03/04/2014 04/01/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Georgiann Keyport CANOPY MEDICAL INC	K080679
2014-1614	03/04/2014 04/01/2014	FDA/OMPT/CDRH/OCER/DFOI/	Georgiann Keyport CANOPY MEDICAL INC	K063061
2014-1615	03/04/2014 04/01/2014	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	Karen Yu Carlsbad Technology, Inc.	STASON PHARMACEUTICALS - 483 12/09/2013 - 12/18/2013
2014-1616	03/04/2014 04/01/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mikhail Martchenko Keck Graduate Institute	VAPORPAC - APPROVAL
2014-1617	03/04/2014 04/01/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michelle Elizabeth Legiec Eagle Pharmaceuticals, Inc.	TEVA, NETANYA, ISRAEL - 483, RESPONSE, EIR 01/01/2013 - 03/31/2013
2014-1618	03/04/2014	FDA/OMPT/CDRH/OCER/DFOI/	David Hill	K904473

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	04/01/2014		Accendo Surgical	
2014-1619	03/04/2014 04/01/2014	FDA/OMPT/CDRH/OCER/DFOI/	Michael Barton NORTH AMERICAN MEDICAL CORP	K111501
2014-1620	03/04/2014 04/01/2014	FDA/OMPT/CDRH/OCER/DFOI/	Georgiann Keyport CANOPY MEDICAL INC	K110005
2014-1621	03/04/2014 04/01/2014	FDA/OMPT/CDRH/OCER/DFOI/	Michael Griffiths Griffiths, Michael	K920948
2014-1622	03/04/2014 04/01/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bobby Torgoley Mallinckrodt LLC	ACTHAR GEL REPORT 12/09/2013 - 12/17/2013
2014-1623	03/04/2014 04/01/2014	FDA/OMPT/CDRH/OCER/DFOI/	JB Anderson Amerx Health Care Corporation	K970133, K971918, K002136 ETC
2014-1624	03/04/2014 04/01/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Suzanne O'Shea FAEGRE BAKER DANIELS	FORM 3542, 3542a BY INO THERAPEUTICS TO NDA 20845 FOR 6125846 8431163 8573209 8573210
2014-1625	03/04/2014 04/01/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dustin Block IPD Analytics, LLC	ANDA 201823, ANDA 201950 - EFFECTIVE APPROVAL LETTER
2014-1626	03/04/2014 04/01/2014	FDA/OMPT/CDRH/OCER/DFOI/	Linda Kariya Nihon Kohden America, Inc.	K083271
2014-1627	03/04/2014 04/01/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Courtney Bond RETROPHIN INC	ACTHAR GEL REPORT
2014-1628	03/04/2014 04/01/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jennifer Gottschling Cubist Pharmaceuticals, Inc.	ENTEREG - 2 AERS
2014-1629	03/04/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Brian Kim	UNILIFE CORPORATION, YORK, PA - 483 03/01/2013 - 08/01/2013

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	04/01/2014		Ghost Tree Capital, LLC	
2014-1630	03/04/2014 04/01/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OC/OES/DFOI/	Alexandra Ajmo LIFE EXTENSION	VESTA PHARMACEUTICALS, INDIANAPOLIS, IN - EIR 01/01/2012 - 01/31/2014
2014-1631	03/04/2014 04/01/2014	FDA/OMPT/CDRH/OCER/DFOI/	Enrique Plazarte Jarden CS	K110068
2014-1632	03/04/2014 04/01/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	MERCK SHARP & DOHME CORP, AMBLER, PA - EIR, 483, CO RESP 12/20/13
2014-1633	03/04/2014 04/01/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	ANCHEN PHARMACEUTICALS INC, IRVINE, CA - EIR, 483, CO RESP 12/20/13
2014-1634	03/04/2014 04/01/2014	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	CSL PLASMA INC, LAWRENCE, KS - EIR, 483, CO RESP 1/9/14
2014-1635	03/04/2014 04/01/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	FRESENIUS MEDICAL CARE, NORTH AMERICA, OGDEN, UT - EIR, 483, CO RESP 1/10/14
2014-1636	03/04/2014 05/13/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	NOVARTIS VACCINES & DIAGNOSTICS SRL, SOVICILLE, ITALY - EIR, 483, CO RESP 6/18/13
2014-1637	03/04/2014 04/01/2014	OC/ORAE/ OC/ORAE/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	CUSTOM COMPOUNDING CTR, LOS ALAMITOS, CA - EIR, 483, CO RESP 11//13 TO 12/13
2014-1638	03/04/2014 04/01/2014	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/ OC/ORAE/ OC/ORAE/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	MEDAUS INC, BIRMINGHAM, AL - EIR, 483, CO RESP 3/22/13
2014-1639	03/04/2014 04/01/2014	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	BRI INSTITUTIONAL REVIEW BOARD INC, HOUSTON, TX - EIR, 483, CO RESP 2/7/13
2014-1640	03/04/2014 04/01/2014	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	BELCHER PHARMACEUTICALS LLC, LARGO, FL - EIR, 483, CO RESP 1/7/13

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2014-1641	03/04/2014 04/01/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	MEDIMMUNE BV, NIJMEGEN, NETHERLANDS - EIR, 483, CO RESP 6/13-21/13
2014-1642	03/04/2014 04/01/2014	FDA/OGROP/ORASE-FO/ATL- DO/ATL-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	DEB USA INC, STANLEY, NC - EIR, 483, CO RESP 9/23-24/13
2014-1643	03/04/2014 04/01/2014	FDA/OGROP/ORACE-FO/CHI- DO/CHI-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	XTTRIUM LABORATORIES INC, MOUNT PROSPECT, IL - EIR, 483, CO RESP 12/5/13
2014-1644	03/04/2014 04/01/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	RPG IFE SCIENCES LTD, THANE, INDIA - EIR, 483, CO RESP 1/31/13
2014-1645	03/04/2014 04/01/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	INDOCO REMEDIES LTD, VERNA GOA, INDIA - EIR, 483, CO RESP 8/23/12
2014-1646	03/04/2014 04/01/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	USV LTD, MUMBAI, INDIA - EIR, 483, CO RESP 6/7-11/13
2014-1647	03/04/2014 04/01/2014	FDA/OGROP/ORAPA-FO/SAN- DO/SAN-CB/ FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	AMGEN INC, THOUSAND OAKS, CA - EIR, 483, CO RESP 6/4-17/13
2014-1648	03/04/2014 04/01/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	3M HEALTH CARE LTD, LOUGHBOROUGH, UK - EIR, 483, CO RESP 4/15/13
2014-1649	03/04/2014 04/01/2014	FDA/OC/OES/DFOI/	RANDI MICHELSON LAW OFFICE OF DONNA B	2010-5621

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			MICHELSON PA	
2014-1650	03/04/2014 04/01/2014	FDA/OFVM/CFSAN/OCD/EOS/ OC/CVM/OCD/	ELEANOR A. KOLTON GREENBERG TRAURIG LLP	DKT 1976F-0096
2014-1651	03/04/2014 04/01/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOSE MATHIEU ENG ASC PLASTUBE NORTH AMERICA	DMF 21501 - POLYFOIL TUBES; 21502 - MONOLAYER TUBES; 21503 CO EXTRUSION TUBES
2014-1652	03/04/2014 04/01/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	CLOSED FOIA REQUEUSTS 2/1-28/2014
2014-1653	03/05/2014 04/02/2014	FDA/OGROP/ORAP/PA-FO/SEA- DO/SEA-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	ARIFULLA KHAN MD, BELLEVUE, WA - EIRS, 483S, CO RESP 4/10/13
2014-1654	03/05/2014 04/02/2014	FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	ALCON RESEARCH LTD, FORT WORTH, TX - EIRS, 483S, CO RESP 5/8/13
2014-1655	03/05/2014 04/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	LONZA BIOLOGICS, WOKINGHAM, UK - EIRS, 483S, CO RESP 9/24/12
2014-1656	03/05/2014 04/02/2014	FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	MERCK & CO INC, SPRINGFIELD, NJ - EIRS, 483S, CO RESP 2/29/12
2014-1657	03/05/2014 04/02/2014	FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/ FDA/OC/OES/DFOI/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	AMERIDOSE LLC, WESTBOROUGH, MA - EIRS, 483, CO RESP 11/9/12
2014-1658	03/05/2014 04/02/2014	FDA/OGROP/ORASE-FO/FLA- DO/FLA-CB/ FDA/OC/OES/DFOI/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	BALASSA LABORATORIES INC, PORT ORANGE, FL - EIRS, 483S, CO RESP 2/19/13
2014-1659	03/05/2014 04/02/2014	FDA/OGROP/ORACE-FO/CIN- DO/CIN-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	SHAMROCK MEDICAL SOLUTIONS GROUP LLC, LEWIS CENTER, OH - EIRS, 483S, CO RESP 3/5/13
2014-1660	03/05/2014 04/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN MANTIA GLENROCK ASSET MANAGEMENT	QUESTOR PHARMS - ACTHAR RESEARCH RPT RECS

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2014-1661	03/05/2014 04/02/2014	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	DR REDDY'S LABORATORIES LOUISIANA LLC, SHREVEPORT, LA - EIRS, 483S, CO RESP 9/6/13
2014-1662	03/05/2014 04/02/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	AAIPHARMA ANALYTICAL SERVICES, EDISON, NJ - EIRS, 483S, CO RESP 4/9/13
2014-1663	03/05/2014 04/02/2014	FDA/OMPT/CDRH/OCER/DFOI/	ANGELA BOUSE TELEFLEX MEDICAL	ARBOR TECHNOLOGIES INC - ANESTHESIA CONDUCTION FILLER K902666
2014-1664	03/05/2014 04/02/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	AIR LIQUIDE ELETRONICS US, LP, MORRISVILLE, PA - EIRS, 483S, CO RESP 4/17/13
2014-1665	03/05/2014 04/02/2014	FDA/OMPT/CDRH/OCER/DFOI/	PEG GARLITZ REED SMITH LLP	INDIVIDUAL RECS
2014-1666	03/05/2014 04/02/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	AMGEN INC, BOULDER, CO - EIRS, 483S, CO RESP 3/29/13
2014-1667	03/05/2014 04/02/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	BAYER HEALTHCARE PHARMACEUTICALS INC, PINE BROOK, NJ - EIRS, 483S, CO RESP 7/11/13
2014-1668	03/05/2014 04/02/2014	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	A.I.G. TECHNOLOGIES INC, DEERFILED BEACH, FL - EIRS, 483S, CO RESP 11/20/12
2014-1669	03/05/2014 04/02/2014	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	ALLERGY LABORATORIES INC, OKLAHOMA CITY, OK - EIRS, 483S, CO RESP 6/27/12
2014-1670	03/05/2014 04/02/2014	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	WATSON LABORATORIES INC, CORONA, CA - EIRS, 483S, CO RESP 11/26/12
2014-1671	03/05/2014 05/07/2014	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	BAYER HEALTHCARE PHARMACEUTICALS INC, EMERYVILLE, CA - EIRS, 483S, CO RESP 5/23/13
2014-1672	03/05/2014 04/02/2014	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	MYLAN LLC, CAGUAS, PR - EIRS, 483S, CO RESP 6/7/12
2014-1673	03/05/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	WALTER E CHALKLEY	FRANCISCAN ST ELIZABETH HEALTH IRB, LAFAYETTE, IN - EIRS, 483S, CO RESP 2/13/13

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	04/02/2014		THOMSON REUTERS (SCIENTIFIC) SAS	
2014-1674	03/05/2014 04/02/2014	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	WALTER E CHAKLEY THOMSON REUTERS (SCIENTIFIC) SAS	SOVEREIGN PHARMACEUTICALS LLC, FORTH WORTH, TX - EIRS, 483S, CO RESP 6/21/13
2014-1675	03/05/2014 04/02/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	SANQUIN PLASA PRODUCTS, AMSTERDAM, NETHERLANDS - EIRS, 483S, CO RESP 6/4/13
2014-1676	03/05/2014 04/02/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	COREPHARMA LLC, MIDDESEX, NJ - EIRS, 483S, CO RESP 3/26/13
2014-1677	03/05/2014 04/02/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	CITIUS PHARMS, MAYNARD, MA - EIRS, 483S, CO RESP 3/14/13
2014-1678	03/05/2014 04/02/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	BEN VENUE LABORATORIES INC, BEDFORD, OH - EIRS, 483S, CO RESP 3/29/13
2014-1679	03/05/2014 04/02/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	CBSCHEM LTD, TEME, AZ - EIRS, 483S, CO RESP 4/24/13
2014-1680	03/05/2014 04/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	EDWARD B MULLIGAN COHEN & MALAD LLP	ELI LILLY & CO, ACRUX PHARMA PTY LTD - AXIRON NDA 22-504 CORR, MINS, TRANS, ETC
2014-1681	03/05/2014 04/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	FRESENIUS KABI ONCOLOGY LTD, NADIA, INDIA - EIRS, 483S, CO RESP 1/18/13
2014-1682	03/05/2014 04/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHRIS SZECHENYI ON POINT INVESTIGATIONS	ACHILLION PHARMS - SOVAPREVIR (ACH 1625) AERS

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-1683	03/05/2014 04/02/2014	FDA/OGROP/ORO/SE-FO/SJN-DO/SJN-CB/	JEFFREY D LONG CANADIAN FISH EXPORTERS INC	SALTED POLLOCK FILLETS - ENTRY XXX-01824854, XXX-0182483-9 EXXHIBITS, CONCLUSIONS
2014-1684	03/05/2014 04/02/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LANCE L SHEA BAKER & HOSTETLER, LLP	HYDROCORTISONE ACETATE NDA 17-351/S027 - APRVL LRECS
2014-1685	03/05/2014 04/02/2014	FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANNA EDNEY BLOOMBERG	483S, INDIA, SAN FRANCISCO
2014-1686	03/05/2014 04/02/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ROBIN WINCHESTER KESSLERTOPAZ MELTZERCHECK LLP	QUESTCOR PHARMACUTICALS INC - HP ACHAR GEL NDA 022-432 FORMULATION
2014-1687	03/05/2014 04/02/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARSHAL P LEVINE ESPALIER GLOBAL	QUESTCOR PHARMS 0 HP ACTHAR GEL NDA 22-432 RPTS 12/13/13
2014-1688	03/05/2014 04/02/2014	FDA/OC/OES/DFOI/	MANLEY, BERYLE W	CURRENT LIST OF FDA APRVD RX WAREHOUSES FOR HUMAN DRUGS, BIOLOGICAL PRODS, MEDICAL DVCS, ETC THAT SERVICES THE NORTHEAST, SOUTHEAST, MIDWEST, SOUTHWEST AND WEST
2014-1689	03/05/2014 04/02/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/	AMBER PERRY CHOLAKIAN & ASSOCIATES	TRADER JOE'S, CA, WA, NV - PREPARED SALAD E COLI OUTBREAK INVESTIGATION RECS
2014-1690	03/05/2014 04/02/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELENA HOWELL HOGAN LOVELLS LLP	NDA 205-109 - SBA, EXCLUSIVITY SUMMARY
2014-1691	03/05/2014 04/02/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELENA HOWELL HOGAN LOVELLS LLP	NDA 20-292 - EXCLUSIVITY SUMMARY PG 3

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2014-1692	03/05/2014 04/02/2014	FDA/OMPT/CDRH/OCER/DFOI/	PERRY ROSENTHAL MD BOSTON EYE PAIN FOUNDATION	DOCUMENT CPT1300487
2014-1693	03/05/2014 04/02/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-676, 2014-685 REQUEST LETTERS
2014-1694	03/05/2014 04/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Norbert Gottesman Avet Capital Management, LLC	ACTHAR GEL REPORT
2014-1695	03/05/2014 04/02/2014	FDA/OGROP/ORAC/CE-FO/CHI-DO/CHI-CB/ OC/CVM/OCD/	Suzanne C. Radcliff COZEN O'CONNOR	Recall #V-006-2010,FDA ICSR ID 1020236
2014-1696	03/05/2014 04/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LENNIE F BOLLINGER WORMINGTON LAW GROUP PLLC	ALLERGAN INC - ACZONE (DAPSONE) GEL NDA 21-794 LBLG, CORR, MINS, ETC
2014-1697	03/05/2014 04/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Susan Lee Lee, Susan	ACTHAR GEL RECORDS 11/04/2013 - 02/27/2014
2014-1698	03/05/2014 04/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Roberts THE INDAGO GROUP	ACTHAR GEL REPORT
2014-1699	03/05/2014 04/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Victoria St. Martin THE WASHINGTON POST	ORAL CONTRACEPTIVES - AERS LAST FIVE YEARS
2014-1700	03/05/2014 04/02/2014	OC/CVM/OCD/	Suzanne C. Radcliff COZEN O'CONNOR	RECALL #V-070-2011 TO #V-090-2011
2014-1701	03/05/2014 04/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CLAUDE DAGENAIS B PHARM PHD HOPITAL RIVIERE DES PRAIRES	ABILIFY - AERS 2002 TO RPRESENT

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ET INSTITUT PHILLIPPE PINEL	
2014-1702	03/05/2014 04/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Biren Amin Jefferies LLC	ACTHAR GEL REPORT
2014-1703	03/05/2014 04/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Faryal Hasan Hyman, Phelps & McNamara P.C.	A list, by year, from 1984 to 1989 and 2010 to 2014, of all patents submitted to FDA for listing in FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations," including the date each patent was considered listed in such publication pursuant to 21 C.F.R. 314.53(d)(5) and the New Drug Application with respect to which such patent information was submitted.
2014-1704	03/05/2014 04/02/2014	FDA/OMPT/CDRH/OCER/DFOI/	ANGELA BOUSE TELEFLEX MEDICAL	ARBOR TECHNOLOGIES INC - SYRINGE FILLER K960928
2014-1705	03/05/2014 04/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bryan Sayler Hound Partners	NDA 008372, 022432
2014-1706	03/05/2014 04/02/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Elizabeth Barrows AABB	REPORTS ON FATALITIES RELATED TO BLOOD COLLECTION OR TRANSFUSION 01/01/2010 - 12/31/2012
2014-1707	03/05/2014 04/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	STEFANIE SOLOMON Biogen Idec Inc.	TECFIDERA (DIMETHYL FUMERATE) DELAYED RELEASE CAPS, DIMETHYL FUMERATE AS BULK ACTIVE INGREDIENT - CERTIFICATE OF A PHARMACEUTICAL PROD
2014-1708	03/05/2014 04/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Margaux L. Birdsall K&L Gates LLP	NDA 020845 - FORM 3542
2014-1709	03/05/2014 04/02/2014	FDA/OFVM/CFSAN/OCD/EOS/	TNO Triskelion on behalf of DSM Coatings Resins (NL) TNO Triskelion bv	FCN 918
2014-1710	03/05/2014 04/02/2014	FDA/OMPT/CDRH/OCER/DFOI/	Laurie Cartwright ARTHROCARE CORP	K122437
2014-1711	03/05/2014 04/02/2014	FDA/OMPT/CDRH/OCER/DFOI/	Laurie Cartwright ARTHROCARE CORP	K130033

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2014-1712	03/05/2014 04/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	mary ann vendola Vendola, Mary Ann	MINOXIDIL - AERS
2014-1713	03/05/2014 04/02/2014	OC/CVM/OCD/	Rob MacKay UNIVERSITY OF FLORIDA	INAD 092012
2014-1714	03/05/2014 04/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	UNION QUIMICO FARMACEUTICA SA, BARCELONA - EIR 7/27/12
2014-1715	03/05/2014 04/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Paul Shields Enteris Biopharma, Incorporated	NDA 020011
2014-1716	03/05/2014 04/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Margaux L. Birdsall K&L Gates LLP	NDA 020845
2014-1717	03/05/2014 04/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	UNION QUIMICO FARMACEUTICA SA, BARCELONA - 483 7/27/12
2014-1718	03/05/2014 04/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gunther R. Geiss, Ph.D. Gunther R. Geiss, Ph.D.	NDA020479
2014-1719	03/05/2014 04/02/2014	OC/CVM/OCD/	Robert MacKay UNIVERSITY OF FLORIDA	INAD 012219
2014-1720	03/05/2014 04/02/2014	FDA/OMPT/CDRH/OCER/DFOI/	LIANE LAROCHELLE DEKA RESEARCH & DEVELOPMENT CORP	FUJIREBIO DIAGNOSTICS INC - FDI LEVEL I, LEVEL II GLUCOSE CONTROLS FOR THE EMBRACE NO CODE K133197
2014-1721	03/05/2014 04/02/2014	FDA/OMPT/CDRH/OCER/DFOI/	LIANE LAROCHELLE DEKA RESEARCH & DEVELOPMENT CORP	FRESENIUS MEDICAL CARE NORTH AMERICA - OPTIFLUX ULTRA DIALYZER K123262

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2014-1722	03/05/2014 04/02/2014	FDA/OMPT/CDRH/OCER/DFOI/	LIANE LAROCHELLE DEKA RESEARCH & DEVELOPMENT CORP	MARVAO MEDICAL DEVICES LTD - NEXSITE HD HEMODIALYSIS FOR LONG TERM USE K133796
2014-1723	03/05/2014 04/02/2014	FDA/OMPT/CDRH/OCER/DFOI/	LIANE LAROCHELLE DEKA RESEARCH & DEVELOPMENT CORP	SD BIOSENSOR INC - GLUCOMENTOR BLOOD GLUCOSE MONITORING SYS; GLUCOMENTOR MULTI BLOOD GLUCOSE MONITORING SYS K123517
2014-1724	03/05/2014 04/02/2014	FDA/OMPT/CDRH/OCER/DFOI/	LIANE LAROCHELLE DEKA RESEARCH & DEVELOPMENT CORP	ACON LABORATORIES INC - ACON ON CALL DIABETES MANAGEMENT SOFTWARE K131469
2014-1725	03/05/2014 04/02/2014	OC/ORA/OCI/ OC/ORA/OCI/	Doe J	INDIVIDUAL RECS
2014-1726	03/05/2014 04/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HERMAN HH-5241, JAMES	LEVOTHYROXINE - AERS, INGREDIENTS, PRESCRIPTION INSTRUCTIONS, ETC
2014-1727	03/05/2014 04/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CAUDLE #20711-058, BRANDON LEE	ATRIPLIA, COMPLERA, SUSTIVA, ETC - PI
2014-1728	03/05/2014 04/02/2014	FDA/OC/OES/DFOI/	MORELAND #147565, SAMUEL	CP 2004P-0472
2014-1729	03/06/2014 04/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	JANET ROUNCE TURNER REID DUNCAN ET AL	MDRS 8043933-2005-00001, 8043933-2009-00003, 8043999- 2007-00003,ETC
2014-1730	03/06/2014 04/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KELLIE B COMBS ROPES & GRAY LLP	QUESTCOR PHARMS - HP ACTHAR NDA 22-432 RECS
2014-1731	03/06/2014 04/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	PHUONG NGUYEN NOBEL BIOCARE	IMPLANT DIRECT SYBRON MFG - INERACTIVE, SWISH2 IMPLANT SYS K130572
2014-1732	03/06/2014 04/03/2014	FDA/OGROP/ORA/SW-FO/DEN- DO/DEN-CB/	ANDY SWENSON VITAMIN RESEARCH PRODUCTS	UST CORP, LAYTON, UT - 483 RESP
2014-1733	03/06/2014 04/03/2014	FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/	RANDI MICHELSON Donna B Michelson PA	MCNEIL CONSUMER & SPECIALTY PHARMS, FT WASHINGTON, PA - EIR 1/27-30/04
2014-1734	03/06/2014	FDA/OGROP/ORA/NE-FO/NYK-	JENNIFER HSIEH	CONMED CORP, UTICA, NY 1/11-26/11, 7/21/11-8/1/11;

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	04/03/2014	DO/NYK-DCB/ FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	DEERFIELD INSTITUTE	LINVATEC CORP, LARGO, FL 3/15-25/11 - 483S
2014-1735	03/06/2014 04/03/2014	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	483S, EIRS - CLOSED FOI REQUESTS 9/13 TO PRESENT
2014-1736	03/06/2014 04/03/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	LEON AMARIGLIO Lexington Medical, Inc.	94 510KS
2014-1737	03/06/2014 04/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	TETRAGENX ANALYTICAL LAB, ST LAURENT, QUEBEC - EIR 4/30/12
2014-1738	03/06/2014 04/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	SANDOZ, KUNDL, AUSTRIA - EIR 10/3/12
2014-1739	03/06/2014 04/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	SANDOZ, KUNDL, AUSTRIA - EIR 8/16/12
2014-1740	03/06/2014 04/03/2014	FDA/OC/OES/DFOI/	SHARPE 04642032, IAN	HOW TO WAGE A CMLPNT
2014-1741	03/06/2014 04/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID J. HEYER LAW OFFICE OF DAVID J HEYER LTD	GEODON; ZIPRASIDONE - LBLG, WARNINGS 2010
2014-1742	03/06/2014	FDA/OGROP/ORR/CE-FO/CHI-	BRENDA M GARTZ	ABBVIE (ABBOTT LABS), ABBOTT PARK, IL - EIR 4/23/13

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	04/03/2014	DO/CHI-CB/	ELI LILLY & CO	
2014-1743	03/06/2014 04/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	MUSTAFA NEVZAT ILAC SANAYII, YENIBOSNA, ISTANBUL - EIR 4/20/12
2014-1744	03/06/2014 04/03/2014	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	BRENDA M GARTZ ELI LILLY & CO	PACKAGING COORDINATORS (ANDERSON BRECON)(ANDERSON PACKAGING), ROCKFORD, IL - EIR 3/19/12
2014-1745	03/06/2014 04/03/2014	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	MARTIN S BALIN MD PHD, CHICAGO, IL - EIR, 483, CO RESP 8/17/12
2014-1746	03/06/2014 04/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dr. Donald Lamprecht, PharmD, BCPS, CLS Kasier Permanente of Colorado	CYCLOSPORINE AND HMG-COA REDUCTASE INHIBITOR - AERS
2014-1747	03/06/2014 04/03/2014	FDA/OGROP/ORASE-FO/ATLDO/ATL-CB/	Margaret Groves DUKE UNIVERSITY	ASHWIN PATKAR, MD, DUKE ADDICTION PROGRAMS - EIR, CLOSE OUT 02/05/2013 - 02/28/2014
2014-1748	03/06/2014 04/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Russell Smith Chiefist	CITRON RESEARCH LAB REPORTS RE ACTHAR GEL 01/01/2013 - 02/28/2014
2014-1749	03/06/2014 04/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Catherine Larkin BLOOMBERG NEWS	ACTHAR GEL LAB REPORTS
2014-1750	03/06/2014 04/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michael k fuller individual citizen	QUESTCOR COMPLAINTS, ANDREW LEFT RECS
2014-1751	03/06/2014 04/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	APOTEX INC, RICHMOND HILL - EIR, 483, CO RESP 10/26/12
2014-1752	03/06/2014 04/03/2014	FDA/OGROP/ORACE-FO/PHIDO/PHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	ACCUPAC INC, MAINLAND, PA - EIR, 483, CO RESP 7/19/13

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			(SCIENTIFIC) SAS	
2014-1753	03/06/2014 04/03/2014	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	BELL PHARMACEUTICALS INC, BELLE PLAINE, MN - EIR, 483, CO RESP 4/5/13
2014-1754	03/06/2014 04/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	ALEMBIC PHARMACEUTICALS LTD, VADODARA, INDIA - EIR, 483, CO RESP 4/18/13
2014-1755	03/06/2014 04/03/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Todd Cameron Hamilton Todd Cameron Hamilton	OCTAPHARMA PLASMA INC, KALAMAZOO, MI - INVESTIGATION RECS 01/01/2013 - 03/01/2014
2014-1756	03/06/2014 04/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	Lawrence Paul Mead Mead, Lawrence P	ALARIS P6000 - AERS
2014-1757	03/06/2014 04/03/2014	FDA/OFVM/CFSAN/OCD/EOS/	Warren Lehrenbaum Warren Lehrenbaum	FCN 510
2014-1758	03/06/2014 04/03/2014	FDA/OFVM/CFSAN/OCD/EOS/	Warren Lehrenbaum Warren Lehrenbaum	FCN 511
2014-1759	03/06/2014 04/03/2014	FDA/OFVM/CFSAN/OCD/EOS/	Warren Lehrenbaum Warren Lehrenbaum	FCN 511
2014-1760	03/06/2014 04/03/2014	FDA/OFVM/CFSAN/OCD/EOS/	Warren Lehrenbaum Warren Lehrenbaum	FCN 539
2014-1761	03/06/2014 04/03/2014	FDA/OFVM/CFSAN/OCD/EOS/	Warren Lehrenbaum Warren Lehrenbaum	FCN 539
2014-1762	03/06/2014 04/03/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Jane Campbell J&D Campbell Associates, Inc.	SALTILLO CORPORATION, MILLERSBURG, OH - 483 SEPTEMBER 2013
2014-1763	03/06/2014 04/03/2014	FDA/OC/OES/DFOI/	Michael Felberbaum THE ASSOCIATED PRESS	CTP FOIA REQUESTS 07/01/2013 - 03/04/2014
2014-1764	03/06/2014 04/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 202093
2014-1765	03/06/2014 04/03/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Bryan McGurn Bryan McGurn	Date K981318
2014-1766	03/06/2014 04/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	James McNab Slate Path Capital	NDA 017861

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2014-1767	03/06/2014 04/03/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 2/1-28/2014
2014-1768	03/06/2014 04/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 202286
2014-1769	03/06/2014 04/03/2014	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	WALTER E CHALKLEY THOMSON REUTERS	BRIAN L FERRIS MD, KIRKLAND, WA - EIR, 483, CO RESP 4/24/13
2014-1770	03/06/2014 04/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Guy C Ruble ELI LILLY AND COMPANY - PHARMACEUTICAL DIVISION	NDA 021344 S012
2014-1771	03/06/2014 04/03/2014	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	CARACO PHARMACEUTICAL LABORATORIES LTD, CRANBURY, NJ - EIR, 483, CO RESP 5/16/13
2014-1772	03/06/2014 04/03/2014	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	WALTER E CHALKLEY THOMSON REUTERS	LONZA BIOLOGICS INC, HOPKINTON, MA - EIR, 483, CO RESP 5/2/13
2014-1773	03/06/2014 04/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jake McDowell The Weinberg Group	ANDA 78215
2014-1774	03/06/2014 04/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Anna Edney BLOOMBERG NEWS	BUPROPRION - AERS
2014-1775	03/06/2014 04/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	Dane Macintyre Regxia Inc.	K952443
2014-1776	03/06/2014 05/08/2014	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	GILEAD SCIENCES INC, FOSTER CITY, CA - EIR, 483, CO RESP 1/15/14
2014-1777	03/06/2014 04/03/2014	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	Blake Goodner Bridger Corporation	VALEANT PHARMACEUTICALS, ROCHESTER, NY - 483, RESPONSE, WARNING LETTERS 01/02/2013 - 03/03/2014

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2014-1778	03/06/2014 04/03/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	CATALENT PHARMA SOLUTIONS LLC, WINCHESTER, KY - EIR, 483, CO RESP 2/5/13
2014-1779	03/06/2014 04/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	ERIS BARILLAS WEXCO	SHOWER CHAIR - AERS
2014-1780	03/06/2014 04/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kiran Kumar Gande Appco Pharmaceuticals Corporation	ANDA 089686 - SBA
2014-1781	03/06/2014 04/03/2014	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	WALTER E CHALKLEY THOMSON REUTERS	BIOGEN IDEC INC, RESEARCH TRIANGLE PARK, NC - EIR, 483, CO RESP 8/2/13
2014-1782	03/06/2014 04/03/2014	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Blake Goodner Bridger Corporation	VALEANT PHARMACEUTICALS, GREENVILLE, SC 483, RESPONSE, WARNING LETTER 01/01/2013 - 03/03/2014
2014-1783	03/06/2014 04/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kiran Kumar Gande Appco Pharmaceuticals Corporation	NDA 017681 - SBA
2014-1784	03/06/2014 04/03/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Joseph W. Moss, Jr. Erwin Bishop Capitano & Moss, PA	K053593
2014-1785	03/06/2014 04/03/2014	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	J. ROBERT YEOMAN B&R COMPLIANCE ASSOCIATES LLC	HAWKINS CHEMICAL CO INC, MINNEAPOLIS, MN; HAWKINS PHARMACEUTICAL GROUP, MINNEAPOLIS, MN - EIR
2014-1786	03/06/2014 04/03/2014	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	PATRICIA L. REGENYE Celgene Corporation	PHILIP MEASE, MINOR JAMES MED, SEATTLE, WA - 483 6/09 TO PRESENT
2014-1787	03/06/2014 04/03/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDRH/OCER/DFOI/	JOHN DIONIS, Ph.D. ADVANCED SURGICAL	COOK UROLOGICAL INC - SURGICAL TISSUE POUCH K910914
2014-1788	03/06/2014 04/03/2014	OC/ORA/ OC/ORA/ FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	BENJAMIN L ENGLAND & ASSOCIATES LLC	FUXING FOODS - EDAMAME ENTRY NO 551-3178928-7
2014-1789	03/06/2014 04/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN R. RUNYAN SACHS WALDMAN O'HARE ET AL	ROCKWELL MEDICAL TECHNOLOGIES INC - SOLUBLE FERRIC PHYROPHOSPHATE (SFP) CLNCL TRIAL MTG MINS 6/30/10, 1/14/11, ETC

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2014-1790	03/06/2014 04/03/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	MELISSA L. KORFHAGE, Esq DINSMORE & SHOHL	PARCELL LABORATORIES LLC; ALPHATEC HOLDINGS INC; EVOLUTION MEDICAL - PUREGEN OSTEOPROGENITOR CELL ALLOGRAFT - HISTORICAL FORMS
2014-1791	03/06/2014 04/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GARY L. WILSON ROBINS KAPLAN ET AL	OTSUKA PHARMACEUTICAL CO, OTSUKA AMERICA PHARMACEUTICAL INC, BRISTOL-MYERS SQUIBB - ABILIFY (ARIPIRAZOLE) LBLG CORR, AERS
2014-1792	03/06/2014 04/03/2014	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	JOHN DIONIS, Ph.D. ASTRA ZENECA	ASTRA ZENECA LP, WESTBOROUGH, MA - EIR 8/27/12
2014-1793	03/07/2014 04/04/2014	FDA/OO/OIM/OPILS/FDAHO/ FDA/OC/OES/DDM/	Eric Juhnke Briar Cliff University	Laetrile Records relating to the following: 1. 42 Fed Reg 29768- 39806, Docket Number 77-0048 (Announcement of 8/5/77) 2. 42 Fed Reg 10066-10069, Docket Number 77-00481 (Announcement of 8/5/77 correction) 3. John Beard Memorial Foundation (FDA History Office)
2014-1794	03/07/2014 04/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Carol Schmidt SEATTLE GENETICS INC	Breakthrough Therapy Designation for Ibrutinib in the treatment of Mantle Cell Lymphoma
2014-1795	03/07/2014 04/04/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Kim Tingley Kim Tingley (for The New York Times Magazine)	Written public comments submitted to the FDA committee for the Cellular, Tissue, and Gene Therapies Advisory Committee Meeting, Feb. 25-26, Hilton Washington D.C. North/Gaithersburg
2014-1796	03/07/2014 04/04/2014	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	CPT 1300688
2014-1797	03/07/2014 04/04/2014	FDA/OO/OFBA/OAGS/	Patrick Kennedy SILLIKER INC	List of all FDA contracts awarded for laboratory testing of food (NAICS 541380) during the previous two fiscal years. I am interested in contracts involving the microbiological and/or chemical testing of food
2014-1798	03/07/2014 04/04/2014	FDA/OGROP/ORA/CE-FO/CIN- DO/CIN-CB/ FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/ FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/	DIONNE SEARCEY THE WALL STREET JOURNAL	CBR SYSTEMS, TUCSON, AZ, VIACORD LLC, CAMBRIDGE, MA, VIACORD PROCESSING LABORATORY, HEBRON, KY ETC - 483, EIR, RESPONSE
2014-1799	03/07/2014 04/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Innopharma INNOPHARMA INC	NDA 19185

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2014-1800	03/07/2014 04/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Slate Path Capital Slate Path Capital	CITRON RESEARCH ACTHAR GEL LETTER 10/01/2013 - 03/04/2014
2014-1801	03/07/2014 04/04/2014	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	Blake Goodner Bridger Corporation	VALEANT PHARMACEUTICALS, ST LOUIS, MO - 483, RESPONSE, WARNING LETTERS 01/01/2013 - 03/03/2014
2014-1802	03/07/2014 04/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 20658 S13
2014-1803	03/07/2014 04/04/2014	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	Blake Goodner Bridger Corporation	VALEANT PHARMACEUTICALS, CLEARWATER, FL - 483, RESPONSE, WARNING LETTER 01/01/2013 - 03/03/2014
2014-1804	03/07/2014 04/04/2014	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Lori Munoz ZipLine Medical, Inc.	ZIPLINE MEDICAL, SECOND SOURCE MEDICAL, SAN JOSE, CA - EIR CERTIFICATE 01/01/2013 - 02/28/2014
2014-1805	03/07/2014 04/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	James McNab Slate Path Capital	ACTHAR GEL APPROVAL RECS
2014-1806	03/07/2014 04/04/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Joseph W. Moss, Jr. Erwin Bishop Capitano & Moss, PA	K073118
2014-1807	03/07/2014 04/04/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Joseph W. Moss, Jr. Erwin Bishop Capitano & Moss, PA	K060467
2014-1808	03/07/2014 04/04/2014	FDA/OMPT/CDRH/OCER/DFOI/	Julie Morris GE Healthcare	Medical Device Listing Number for a Toshiba PVT-375BT ultrasound probe
2014-1809	03/07/2014 04/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Andrea Demakas ADVERSEEVENTS INC	IMBRUVICA (IBRUTINIB), JETREA (OCRIPLASMIN), LINZESS (LINACLOTIDE), ETC - AERS
2014-1810	03/07/2014 04/04/2014	FDA/OMPT/CDRH/OCER/DFOI/	Scott Dunkle TEXAS CHRISTIAN UNIVERSITY	CDRH ANNUAL REPORT 0211078
2014-1811	03/07/2014	FDA/OGROP/ORA/SE-FO/FLA-	Blake Goodner	VALEANT PHARMACEUTICALS, TAMPA, FL - 483,

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	04/04/2014	DO/FLA-CB/	Bridger Corporation	RESPONSE, WARNING LETTERS 01/01/2013 - 03/03/2014
2014-1812	03/07/2014 04/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SQUAILIA, WILLIAM	SINEQUAN; DOXEPIN - AER
2014-1813	03/07/2014 04/04/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	GEORGE M. KELLER CUSTOMS ADVISORY SERVICES INC	ENTRY # 595-4907339-9; ENTRY # 60016705-0
2014-1814	03/07/2014 04/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KRISTI O. SMEDLEY, Ph.D. Center for Regulatory Services, Inc.	SERUMWERK BERNBURG, BERNBURG, GERMANY - 483 11/11 TO PRESENT
2014-1815	03/07/2014 04/04/2014	OC/CVM/OCD/	KRISTI O. SMEDLEY, Ph.D. Center for Regulatory Services, Inc.	FRUIT POMACE FOR USE IN ANIMAL FEED
2014-1816	03/07/2014 04/04/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/	MICHAEL J. VILLEGIANTE, Esq. WELTIN STREB & WELTIN	MOON MARINE USA CORP, MMI FOOD CORP, MOON FISERY PVT LTD INDIA - INVESTIGATIONS
2014-1817	03/07/2014 04/04/2014	OC/ORO/ORM/ OC/ORO/ORM/ OC/ORO/OE/ OC/ORO/OE/ OC/ORO/ORM/ OC/ORO/ORM/	DIONNE SEARCEY WALL STREET JOURNAL	CORD BLOOD FACILITIES - 483
2014-1818	03/07/2014 04/04/2014	OC/ORO/ORM/ OC/ORO/ORM/	RUI BOAVISTA MARQUES AICEP PORTUGAL GLOBAL	PORTUGUESE FACILITIES INSPECTED UNDER FOOD MODERNIZATION ACT
2014-1819	03/07/2014 04/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SUSANNE COLLINS PATHEON INC	TOMITA PHARMACEUTICAL CO LTD, TOKUSHIMA, JAPAN - EIR, 483 9/10

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2014-1820	03/07/2014 04/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHRIS SZECHENYI ON POINT INVESTIGATIONS	DURECT CORP - POSIDUR (SABER-BUPIVACAINE) COMPLETE RESP LTR 2/12/14
2014-1821	03/07/2014 04/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	AUDREY ALIBRANTI EGAN ETHYPHARM USA CORP	NEXIUM (ESOMEPRAZOLE MAGNESIUM) DELAYED- RELEASE CAPS NDA 21-153/S045,S047,S048 - RVW RECS FOR MFG CHANGE OR ADDITION
2014-1822	03/07/2014 04/04/2014	OC/ORO/ORM/ OC/ORO/ORM/	ROBERT KING FDA NEWS	ALL PHARMACEUTICAL, MEDICAL DVC, CLNCL TRIAL FACILITIES - 483 NOTICES 2/14
2014-1823	03/07/2014 04/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	AUDREY ALIBRANTI EGAN ETHYPHARM USA CORP	ETHYPHARM USA CORP - SUBOXONE (BUPRENORPHINE AND NALOXONE) NDA 22-410/S011 RVW RECS FOR MFG CHANGE/ADDITION
2014-1824	03/07/2014 04/04/2014	OC/CVM/OCD/	JOHN HALBERG, D.V.M, Ph.D. Zoetis Inc.	NADA 009-576; TERRAMYCIN SOLUBLE POWER NADA 008- 622 - APRVL, FOI SUMMARY
2014-1825	03/07/2014 04/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN R. RUNYAN SACHS WALDMAN O'HARE ET AL	ROCKWELL MEDICAL TECHNOLOGIES INC - SOLUBLE FERRIC PHYROPHOSPHATE (SFP) CLNCL TRIAL MTR MINS 6/30/10, 1/14/11, ETC
2014-1826	03/07/2014 04/04/2014	FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OO/OHR/ FDA/OC/OCC/ FDA/OFVM/CFSAN/OCD/EOS/	POLISKY, SCOTT	HIRING OF DR DANIEL FABRICANT 2/11 MINS, MEMOS, MTG AGENDAS, ETC
2014-1827	03/07/2014 04/04/2014	FDA/OMPT/CDRH/OCER/DFOI/	SABAH MALEK EISAI INC	BECKMAN COULTER INC - ACCESS HYBRITECH P2PSA P090026 CLNCL AND ANALYTICAL SECTIONS OF THE PMA
2014-1828	03/07/2014 04/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Russell Smith Chiefist	ACTHAR APPROVAL RECS
2014-1829	03/07/2014 04/04/2014	FDA/OMPT/CDRH/OCER/DFOI/	SABAH MALEK EISAI INC	DIASORIN INC - PRO-TRAC II TACROLIMUS ELISA KIT P970025 CLNCL AND ANALYTICAL SECTIONS OF THE PMA

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2014-1830	03/07/2014 04/04/2014	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORA/ OC/ORA/	Randall Schreckhise Randall Schreckhise	PINE NUTS, PINE MOUTH - QUESTIONNAIRE, ANALYSIS, SAMPLE RESULTS ETC
2014-1831	03/07/2014 04/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	CATALENT PHARMA SOLUTIONS, BRUSSELS, BELGIUM - EIR 1/23/13
2014-1832	03/07/2014 04/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LORI EYRE CAREY & DANIS LLC	REGLAN (METOCLOPRAMIDE) - BLACK BOX WARNING 2/27/09
2014-1833	03/07/2014 04/04/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	BRENDA M GARTZ ELI LILLY & CO	BEAMONE/SYNERGY HEALTH/APPLIED STERILIZATION TECHNOLOGIES, LIMA, OH - EIR 1/22/13
2014-1834	03/07/2014 04/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	GLAND PHARMA LTD, HYDERABAD, INDIA - EIR 8/30/12
2014-1835	03/07/2014 04/04/2014	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Stephanie Snyder KAUFMAN BORGEEST & RYAN LLP	ARJO - PATIENT LIFT RECALL RECS 2004
2014-1836	03/07/2014 04/04/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/OIP/	KIMBERLY KINDY WASHINGTON POST	THRESHOLD OF REGULATION SUBMISSION #05-006
2014-1837	03/07/2014 04/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ketamine -AE Michael E. DeBakey VAMC	KETAMINE - AERS
2014-1838	03/07/2014 04/04/2014	FDA/OC/OES/DDM/ FDA/OFVM/CFSAN/OCD/EOS/	KIMBERLY KINDY WASHINGTON POST	CARRAGEENA - DKT 2008P-0347
2014-1839	03/07/2014 04/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Blake Goodner Bridger Corporation	VALEANT PHARMACEUTICALS, WATERFORD, IRELAND - 483, RESPONSE, WARNING LETTER 01/01/2013 - 03/03/2014
2014-1840	03/10/2014	FDA/OFVM/CFSAN/OCD/EOS/	Mark Prinz	Fayrefield FoodTec, Ltd., United Kingdom, Haldiram Snacks Pvt Ltd, India, Haldiram Manufacturing Co. Pvt. Ltd., India etc - 483

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	04/07/2014		Registrar Corp	MOST RECENT
2014-1841	03/10/2014 04/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jen Feranil KM PHARMACEUTICAL CONSULTING LLC	NDA 020103
2014-1842	03/10/2014 04/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dr Santosh Patel Pennine Acute NHS Trust	WRONG DRUGS DURING SPINAL OR EPIDURAL ANESTHESIA OR ANALGESIA
2014-1843	03/10/2014 04/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anusha Kambhampaty Retrophin Inc.	INSMED CORPORATION - CORR WITH FDA RE IPLEX 01/01/2003 - 03/05/2014
2014-1844	03/10/2014 04/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	T. Christian Miller PROPUBLICA	JANET WOODCOCK - RECS RE PROPUBLICA, THIS AMERICAN LIFE 09/01/2013 - 03/01/2014
2014-1845	03/10/2014 04/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Andrea Demakas ADVERSEEVENTS INC	NITHIODOTE (SODIUM NITRITE, SODIUM THIOSULFATE), DOCEFREZ (DOCETAXEL), KEDBUMIN (ALBUMIN (HUMAN)) ETC - AERS
2014-1846	03/10/2014 04/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Andrea Demakas ADVERSEEVENTS INC	NITHIODOTE (SODIUM NITRITE, SODIUM THIOSULFATE), DOCEFREZ (DOCETAXEL), KEDBUMIN (ALBUMIN (HUMAN)), ETC - AERS
2014-1847	03/10/2014 04/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Andrea Demakas ADVERSEEVENTS INC	LYMPHOSEEK (TECHNETIUM TC-99M TILMANOCEPT), DOTAREM (GADOTERATE MEGLUMINE), KARBINAL ER (CARBINOXAMINE MALEATE), ETC - AERS
2014-1848	03/10/2014 04/07/2014	FDA/OGROP/ORP/PA-FO/SAN- DO/SAN-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bryan Saylor Hound Partners	QUESTCOR PHARMACEUTICALS, CHARLOTTETOWN, CAN, HAYWARD, CA ETC- 483

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2014-1849	03/10/2014 04/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joshua Gaynor CBS NEWS	PHARMACEUTICAL FACILITIES IN CHINA - 483
2014-1850	03/10/2014 04/07/2014	OC/CVM/OCD/	Doe J	INDIVIDUAL RECS
2014-1851	03/10/2014 04/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	Bao Tran Tran Associates	K040554
2014-1852	03/10/2014 04/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	Bao Tran Tran Associates	K080545
2014-1853	03/10/2014 04/07/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Dominik Wiedemann Vienna University Hospital (AKH)	K093595
2014-1854	03/10/2014 04/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K101600
2014-1855	03/10/2014 04/07/2014	FDA/OGROP/ORR/SW-FO/DEN-DO/DEN-CB/	Andy Swenson VITAMIN RESEARCH PRODUCTS	UST CORPORATION, LAYTON, UT - 483, 482 01/01/2013 - 03/05/2014
2014-1856	03/10/2014 04/07/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	CJ Goebig SurgiCount Medical	K060076
2014-1857	03/10/2014 04/07/2014	FDA/OFVM/CFSAN/OCD/EOS/	Ian Cooper Smithers Pira Ltd	FCN 40, FCN 165, FCN 1083, FCN 1180
2014-1858	03/10/2014 04/07/2014	FDA/OGROP/ORR/PA-FO/SEA-DO/SEA-CB/	Arianna Yanes CNN	SNOKIST GROWERS, YAKIMA, WA - LETTERES RE RECALL 01/01/2010 - 01/01/2012
2014-1859	03/10/2014 04/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	Cora Sim Ellipse Technologies, Inc.	K133904
2014-1860	03/10/2014 04/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jerome Lew JEROME LEW	K112444, K041197
2014-1861	03/10/2014 04/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	Giovanni De Paolini Velferd Srl	K941048
2014-1862	03/10/2014 04/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lana Vostrova Lana Vostrova	ANDA 076369

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-1863	03/10/2014 04/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K110809
2014-1864	03/10/2014 04/07/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michelle Elizabeth Legiec Eagle Pharmaceuticals, Inc.	NDA 022249
2014-1865	03/10/2014 04/07/2014	FDA/OFVM/CFSAN/OCD/EOS/	Eleanor DaCosta United States Pharmacopeial Convention (USP)	BANABA - AERS
2014-1866	03/10/2014 04/07/2014	FDA/OFVM/CFSAN/OCD/EOS/	Eleanor DaCosta United States Pharmacopeial Convention (USP)	Adverse event reports (AERs) related to exposure from dietary supplement products containing 5-HTP (also called 5-Hydroxytryptophan or L-5-Hydroxytryptophan or L-Hydroxytryptophan)
2014-1867	03/10/2014 04/07/2014	FDA/OFVM/CFSAN/OCD/EOS/	Eleanor DaCosta United States Pharmacopeial Convention (USP)	Adverse event reports (AERs) related to exposure from dietary supplement products containing Northern Schisandra (also spelled as Northern Schizandra) botanical name Schisandra chinensis (also spelled as Schizandra chinensis)
2014-1868	03/10/2014 04/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	Julie K. Tibbets Alston and Bird LLP	K051709
2014-1869	03/10/2014 04/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	Mark Lonsinger ViOptix Inc	K042657
2014-1870	03/10/2014 04/07/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	JOSEPH WALKER Walker, Joseph	NEUROMODULATION, NEUROSTIMULATION, SPINAL CORD STIMULATION ETC - FOIA REQUESTS 01/01/2010 - 03/07/2014
2014-1871	03/10/2014 04/07/2014	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	Emil Khalikov Yost Capital Management	UNILIFE, YORK, PA - EIR 02/01/2013 - 04/01/2013
2014-1872	03/10/2014 04/07/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 202880
2014-1873	03/10/2014 04/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	KIM CAMPBELL TELEFLEX MEDICAL	SMITHS MEDICAL ASD INC - PORTEX EPIDURAL FILTER K083451
2014-1874	03/10/2014 04/07/2014	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	BRENDA M GARTZ ELI LILLY & CO	HOSPIRA, MCPHERSON, KS - EIRS 7/29/13
2014-1875	03/10/2014	FDA/OGROP/ORA/PA-FO/SEA-	BRENDA M GARTZ	HOLISTER-STLER, SPOKANE, WA - EIRS 4/15/13

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	04/07/2014	DO/SEA-CB/	ELI LILLY & CO	
2014-1876	03/10/2014 04/07/2014	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	BRENDA M GARTZ ELI LILLY & CO	HOLISTER-STIER, SPOKANE, WA - EIRS 12/4/12
2014-1877	03/10/2014 04/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	MICHELE L BUENAFE MORGAN LEWIS COUNSELORS AT LAW	ROCHE DIAGNOSTICS CORP - SENSEWEAR ARMBAND CO30022 APPENDICES, EXHIBITS, CORR
2014-1878	03/10/2014 04/07/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID BURTON BURTON & SIMKIN	EPIDURAL STEROID INJ, KENALOG, TRAMCINOLINE, ETC - AERS 2004 TO PRESENT
2014-1879	03/10/2014 04/07/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SIDNEY M WOLF MD Health Research Group of Public Citizen	ENDO - AVEED REVERSE DECISION
2014-1880	03/10/2014 04/07/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID LOHMAN MILLENNIUM MANAGEMENT LLC	QUESTOCOR - HP ACTHAR GEL LAB RPT 11/1/13 TO PRESENT
2014-1881	03/10/2014 04/07/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TORREY COPE SIDLEY AUSTIN LLP	PROMOTIONAL MATERIALS PROMPTED THE UNTITLED LTRS - DECAPEPTYL (TRIPTORELIN PAMOATE) NDA 20-715; EDEX (ALPROSTADI INJ) NDA 20-649; DILTAXT (DILLITAZEM HCL) ER CAPS ANDA 74-852
2014-1882	03/10/2014 04/07/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	NAMBO, HELEN	NODARI RIZUN, LOS ANGELES, CA; NODARI B RIZUN, PASADENA, CA; ADAPTOGENESIS, LOS ANGELES, CA, ETC - PURBLACK, SHILAJIT, SHILAJIT RESIN, ETC - RECS
2014-1883	03/10/2014 04/07/2014	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	MICHELLE POULK Burleson's Pure Honey	NATURES NATE'S HONEY OR NORTH DALLAS HONEY CO, FRISCO, TX - OPINIONS, ORDERS, JUDGMENTS, ETC; CMLPNT 125652 STATUS UPDATE 6/13 TO PRESENT
2014-1884	03/10/2014 04/07/2014	FDA/OC/OES/ FDA/OMPT/CDRH/OCER/DFOI/	KURT, SERHAT	PUBLIC CALANDAR - MOBILE MEDICAL APPL TOPICS, ISSUES, CONCLUSION 12/13
2014-1885	03/10/2014 04/07/2014	OC/ORAP/ OC/ORAP/ FDA/OGROP/ORASE-FO/ATL-	DINGLE, MARCIA	CMLPNT 135627

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		DO/ATL-CB/		
2014-1886	03/10/2014 04/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Eric Walter Camil, Sr. CAMIL CONSULTING CORP	BIOVECTRA - 483 01/01/2010 - 03/05/2014
2014-1887	03/10/2014 04/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bocar Guisse SANDOZ CANADA INC.	ANDA 078215
2014-1888	03/10/2014 04/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jessica Swanson Innovative Science Solutions	ANDA 091135
2014-1889	03/10/2014 04/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ted Keller Sigma Capital Management	SOFOBUVIR - AERS
2014-1890	03/10/2014 04/07/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Elizabeth Capone CAPONE, A	TENS UNIT - AERS, WARNINGS, RESEARCH ETC
2014-1891	03/10/2014 04/07/2014	FDA/OC/OCC/	Doe J	INDIVIDUAL RECS
2014-1892	03/10/2014 04/07/2014	FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECS
2014-1893	03/10/2014 04/07/2014	OC/OCS/NCTR/OD/ FDA/OFVM/CFSAN/OCD/EOS/	BRIAN BIENKOWSKI ENVIRONMENTAL HEALTH NEWS	BARRY DELCLOS, DANIEL R DOERGE - EMAILS 4/1/13 TO 2/20/14
2014-1894	03/10/2014 05/06/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/ FDA/OGROP/ORO/ORO/DIOP/	BENJAMIN L ENGLAND BENJAMIN L ENGLAND & ASSOCIATES LLC	INCOMFISH - IMPORT ALERT 16-124 PETITION RESP
2014-1895	03/10/2014 04/07/2014	FDA/OC/OES/DFOI/	GRADES, LINDA	GRANTS 2014 TO 2015
2014-1896	03/11/2014	FDA/OO/OFBA/OFO/OFM/BTAMS /	Rachel Johnson	MANUFACTURER, IMPORTER OF TOBACCO PRODUCTS - USER FEES 01/01/14 TO PRESENT

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	04/08/2014	FDA/OMPT/CTP/OD/	FOI Services, Inc.	
2014-1897	03/11/2014 04/08/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Anthony E Zamparelli Advance Biosource	FDA LICENSED OR REGISTERED PLASMAPHERESIS CENTERS COLLECTING PLASMA FROM CHAGAS POSITIVE DONORS
2014-1898	03/11/2014 04/08/2014	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	SPECTRUM CIGARETTES - RECS RE NICOTINE RESEARCH
2014-1899	03/11/2014 04/08/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Robert I. Moskowitz Moskowitz, Robert I	REMICADE - AERS
2014-1900	03/11/2014 04/08/2014	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/ FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	Andree Askew New Orleans Center for Clinical Research	CETERO RESEARCH, ST CHARLES, MO - 483 07/01/2010 - 07/09/2010
2014-1901	03/11/2014 04/08/2014	OC/ORAS/ OC/ORAS/ FDA/OGROP/ORASORO/DIOP/	Anna Edney BLOOMBERG NEWS	SPOT TESTS PERFORMED BY FDA OF PRESCRIPTION DRUGS IMPORTED INTO US
2014-1902	03/11/2014 04/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	Matthew Smith Economic Alliance Snohomish County	WASHINGTON MEDICAL DEVICE COMPANIES REGISTERED
2014-1903	03/11/2014 04/08/2014	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	JOSEPH WALKER Walker, Joseph	MEDTRONIC, JUNCOS, PR; MEDTRONIC HUMACO, PR MEDTRONIC, MINNEAPOLIS, MN ETC 483 01/01/2008 - 03/07/2014
2014-1904	03/11/2014 04/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	Virginia Anello Douglas & London, P.C.	K801590
2014-1905	03/11/2014 04/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	Virginia Anello Douglas & London, P.C.	K900129
2014-1906	03/11/2014	FDA/OGROP/ORACE-FO/PHI-	Angelia Slayton	MERCK, SHARPE & DOHME, WEST POINT, PA -

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	04/08/2014	DO/PHI-CB/	INC RESEARCH CONSULTING & SUBMISSIONS	ORGANIZATIONAL CHART EXHIBIT 9/11/12
2014-1907	03/11/2014 04/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	Virginia Anello DOUGLAS & LONDON	K061095
2014-1908	03/11/2014 04/08/2014	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/ FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	MERCK & CO, ARECIBO, PR - ORGANIZATIONAL CHART EXHIBITS 3/28/11
2014-1909	03/11/2014 04/08/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Farah Ali SPI Pharma, Inc.	CMIC, CRANBURY, NJ - EIR, 483 11/04/2013 - 12/30/2013
2014-1910	03/11/2014 04/08/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sharon Rowland Cerecor Inc. Attn: Sharon Rowland	NDA 18731
2014-1911	03/11/2014 04/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	Tamala Wampler Captiva Spine	K121178
2014-1912	03/11/2014 04/08/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bocar Guisse SANDOZ CANADA INC.	ANDA 078215
2014-1913	03/11/2014 04/08/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	ELI LILLY, INDIANAPOLIS, IN - ORGANIZATIONAL CHART EXHIBIT 2/11/13
2014-1914	03/11/2014 04/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	Virginia Anello Douglas & London, P.C.	K892233
2014-1915	03/11/2014 04/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	Virginia Anello Douglas & London, P.C.	K855047
2014-1916	03/11/2014 04/08/2014	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Raluca Ciobanu Adamas Pharmaceuticals, Inc.	RAMON GIL, MD, PORT CHARLOTTE, FL - 483 10/01/2013 - 11/30/2013
2014-1917	03/11/2014 04/08/2014	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Micky N. Das Micky Das	MEDTRONIC SYNCHROMED II, SYNCHROMED EL - APPLICATIONS, SUBMISSIONS, RECALLS ETC 01/01/1995 - 03/06/2014
2014-1918	03/11/2014	FDA/OC/OES/DFOI/	Lauren Farruggia	2013-9382

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	04/08/2014		Hyman, Phelps & McNamara P.C.	
2014-1919	03/11/2014 04/08/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dale Moore Dale Moore	CONCERTA - AERS
2014-1920	03/11/2014 04/08/2014	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Misty Rosskamp Martin & Helms, P.C.	Class 2 Recall, Echelon 60 mm Endoscopic Linear Cutter Reloads Black (recall number Z-1530-2013; recall event ID 65330 - CORR WITH FDA
2014-1921	03/11/2014 04/08/2014	FDA/OO/OFBA/OAGS/	ISAIAS ALBA PILIERO MAZZA PLLC	CONTRACT #HHSF223201210016B 5/1/12 TO 3/1/14
2014-1922	03/11/2014 04/08/2014	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	Andy Swenson VITAMIN RESEARCH PRODUCTS	UST CORPORATION - 482, 483, RESPONSES 01/04/2012 - 03/06/2014
2014-1923	03/11/2014 04/08/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	RANDI MICHELSON Donna B Michelson PA	PSEUDOEPHEDRINE - AERS
2014-1924	03/11/2014 04/08/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LEAH R CAPITINI ANDRUS WAGSTAFF PC	ELI LILLY & CO, ACRUX PHARMA PTY LTD - AXIRON NDA 22-504 CMLPNTS, APRVLS RECS
2014-1925	03/11/2014 04/08/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ROBERT K LU ROBBINS GELLER ET AL	2014-1316 - DELETED RECS
2014-1926	03/11/2014 04/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	KENT L KLAUDT LIEFF, CABRASER, HEIMANN & BERNSTEIN, LLP	MEDTRONIC - INFUSE BONE GRAFT P000058 MDRS, INVESTIGATIONIS, CORR, ETC
2014-1927	03/11/2014 04/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	EDGAR ASEBEY-BIRKHOLM ROETZEL & ANDRESS	KENDALL CO - FILAC FAS TEMP ELECTRONIC THERMOMETER K003313 FORM 2892
2014-1928	03/11/2014 04/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	EDGAR ASEBEY-BIRKHOLM ROETZEL & ANDRESS	NIHON KOHDEN AMERICA INC - NIHON KOHDEN TEC-7531 CADRIOLIFE PORTABLE DEFIBRILLATOR & ACCESSORIES K971355 FDA FORM 2892
2014-1929	03/11/2014 04/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	EDGAR ASEBEY-BIRKHOLM ROETZEL & ANDRESS	TYCO HEALTHCARE - PURITAN BENNETT GOODKNIGHT 420 EVOLUTION MODEL M-113903-US K031470 FDA FORM 2892

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2014-1930	03/11/2014 04/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	EDGAR ASEBEY-BIRKHOLM ROETZEL & ANDRESS	ALOKA CO LTD - ALOKA SSD-3500 ULTRASOUND SYS K023996 FORM FDA 2892
2014-1931	03/11/2014 04/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	EDGAR ASEBEY-BIRKHOLM ROETZEL & ANDRESS	MIDMARK CORP - STRETCHER/BED & #530 ED/TRAUMA STR MODEL #535 K894335 FORM FDA 2892
2014-1932	03/11/2014 04/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	EDGAR ASEBEY-BIRKHOLM ROETZEL & ANDRESS	COHERENT MEDICAL GROUP - COHERENT NOVUS 3000 ARGON PHOTOCOAGULATOR K913127 FORM FDA 2892
2014-1933	03/11/2014 04/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	EDGAR ASEBEY-BIRKHOLM ROETZEL & ANDRESS	HILL-ROM MANUFACTURING INC - WATCHCHILD OBSTETRICAL PATIENT DATA MANAGEMENT SYS K014094 FORM FDA 2892
2014-1934	03/11/2014 04/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	EDGAR ASEBEY-BIRKHOLM ROETZEL & ANDRESS	OLYMPUS AMERICA INC/SCIENTIFIC EQUIPMENT GROUP - VIRTUAL SLIDE SYS, OLYMPUS VS800 SYS K111914 FORM FDA 2892
2014-1935	03/11/2014 04/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	EDGAR ASEBEY-BIRKHOLM ROETZEL & ANDRESS	CARL ZEISS INC - OPMI TWINER SURGICAL MICROSCOPE K983868 FORM FDA 2892
2014-1936	03/11/2014 04/08/2014	FDA/OC/OES/DFOI/	Jane Orr Holston Valley Medical Cen ter	2013-1368, 2013-1073
2014-1937	03/11/2014 04/08/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Anne Kuan Neovii Biotech	SANOFI GENZYME, LYON, FRANCE - 483, APPROVAL 01/01/2008 - 03/07/2014
2014-1938	03/11/2014 04/08/2014	FDA/OC/OES/DFOI/	Lauren Farruggia Hyman, Phelps & McNamara P.C.	2013-7691
2014-1939	03/11/2014 04/08/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORA/OCI/ OC/ORA/OCI/ FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/ FDA/OGROP/ORA/SE-FO/SJN- DO/SJN-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	joanne moskovic Moskovic & Associates, Ltd.	Complaints and Inquiries of different dosage capsules of Symbyax being packaged by Eli Lilly in the same bottle
2014-1940	03/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	Virginia Anello	K083519

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	04/08/2014		Douglas & London, P.C.	
2014-1941	03/11/2014 04/08/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Alaska Burr NORTH RUN CAPITAL LP	ALLIANCE MEDICAL PRODUCTS, IRVINE, CA - 483 07/01/2013 - 03/01/2014
2014-1942	03/11/2014 04/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	EDGAR ASEBEY-BIRKHOLM ROETZEL & ANDRESS	PURITAN BENNETT CORP - RENAISSANCE SPIROMETRY SYS WITH OPTIONAL RENAISSANCE DB DATA MANAGEMENT SOFTWARE K944762 FORM FDA 2892
2014-1943	03/11/2014 04/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	EDGAR ASEBEY-BIRKHOLM ROETZEL & ANDRESS	HEALTHDYNE INC - APNEA/HEART MONITOR K903287 FORM FDA 2892
2014-1944	03/11/2014 04/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	EDGAR ASEBEY-BIRKHOLM ROETZEL & ANDRESS	VALLEYLAB INC - ELECTROSURGICAL GENERATOR K823924 FORM FDA 2892
2014-1945	03/11/2014 04/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	EDGAR ASEBEY-BIRKHOLM ROETZEL & ANDRESS	VALLEYLAB - LIGASURE VESSEL SEALING SYS K043273 FORM FDDA 2892
2014-1946	03/11/2014 04/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	EDGAR ASEBEY-BIRKHOLM ROETZEL & ANDRESS	SOMANETICS CORP - SOMANETICS INVOS 3100A CEREBRAL OXIMETER K960614 FORM FDA 2892
2014-1947	03/11/2014 04/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	EDGAR ASEBEY-BIRKHOLM ROETZEL & ANDRESS	TYCO HEALTHCARE/KENDALL - SED EXPRESS PORTABLE COMPRESSION SYS K040511 FORM FDA 2892
2014-1948	03/11/2014 04/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	EDGAR ASEBEY-BIRKHOLM ROETZEL & ANDRESS	MALLINCKRODT DEVELOPMENT FRANCE - SANDMAN DUO, DUO ST K082237 FORM FDA 2892
2014-1949	03/11/2014 04/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	EDGAR ASEBEY-BIRKHOLM ROETZEL & ANDRESS	ALLERGAN HUMPHREY - A/B SCAN MODEL 835 K902582 FORM FDA 2892
2014-1950	03/11/2014 04/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	EDGAR ASEBEY-BIRKHOLM ROETZEL & ANDRESS	HERAEUS-CHRIST GMBH - CENTRIFUGES K840768 FORM FDA 2892
2014-1951	03/11/2014 04/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	EDGAR ASEBEY-BIRKHOLM ROETZEL & ANDRESS	TYCO HEALTHCARE NANCY - PURITAN BENNETT GOODKNIGHT VENTILATOR K020886 FORM FDA 2892
2014-1952	03/11/2014 04/08/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Sandy Figueroa Nubenco Enterprises Inc.	NUBENCO - WARNING LETTER CLOSE OUT 01/02/2001 - 02/11/2001
2014-1953	03/11/2014 04/08/2014	FDA/OC/OES/DFOI/ FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	Doe J	TESTOSTERONE INJ; CORIZON HEALTH INC, MI DEPT OF CORRECTIONS - RECS
2014-1954	03/11/2014 04/08/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WRIGHT 05449-010, JAMES	BUSIPRONE - AER

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-1955	03/12/2014 04/09/2014	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	BRENDA M. GARTZ ELI LILLY & CO	LONZA BIOLOGICS, PORTSMOUTH, NH - EIR 8/26/13
2014-1956	03/12/2014 04/09/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENDA M. GARTZ ELI LILLY & CO	ORION CORP, TURKU, FINLAND - EIR 5/20/13
2014-1957	03/12/2014 04/09/2014	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	BRENDA M. GARTZ ELI LILLY & CO	LONZA BIOLOGICS, PORTSMOUTH, NH - EIR 8/26/13
2014-1958	03/12/2014 04/09/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENDA M. GARTZ ELI LILLY & CO	ORION CORP, ESPOO FINLAND - EIR 12/10/12
2014-1959	03/12/2014 04/09/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENDA M. GARTZ ELI LILLY & CO	ORION CORP, TURKU, FINLAND - EIR 5/20/13
2014-1960	03/12/2014 04/09/2014	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ OC/ORA/ORM/ OC/ORA/ORM/	JENNA HUFF WFXL FOX 31 NEWS	DOUGHERTY, LEE, TERRELL, GA - BLOOD BANK INSP 1/12 TO 12/13
2014-1961	03/12/2014 04/09/2014	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OMPT/CDRH/OCER/DFOI/	Curbell Inc. Curbell	CORR RE CURBELL 10/01/2013 - 03/07/2014
2014-1962	03/12/2014 04/09/2014	FDA/OFVM/CFSAN/OCD/EOS/	Ureka Idstrom The Eureka Law Firm	Memorandum of FDA meetings with individual companies to discuss serving sizes 06/15/1990 - 06/26/1991
2014-1963	03/12/2014 04/09/2014	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	David J Marklein David J Marklein	DYNAMIC PET PRODUCTS, WASHINGTON, MO; FRICK'S FINE MEATS, WASHINGTON, MO - COMPLAINTS, INVESTIGATION RECS
2014-1964	03/12/2014 04/09/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dustin Block IPD Analytics, LLC	NDA 022345
2014-1965	03/12/2014	FDA/OMPT/CDER/GRP/DIDP/	Pinaki Kar	PCSK9 - AERS

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	04/09/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DSM Capital Partners	
2014-1966	03/12/2014 04/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kimberly Smith SMITH, KIMBERLY	K103224
2014-1967	03/12/2014 04/09/2014	FDA/OFVM/CFSAN/OCD/EOS/	SILVIA ULM BURDOCK GROUP	CAS #10597-60-1
2014-1968	03/12/2014 04/09/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Jennifer Bravo Agilux Laboratories	AGILUX LABORATORIES, WORCESTER, MA - 483 7/8/13
2014-1969	03/12/2014 04/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	Ned Feder PROJECT ON GOVERNMENT OVERSIGHT	CDRH ODE/OIVD SOP 2010-001: Documentation of Meetings with Sponsors and Applicants, Version 1, (effective July 19, 2010); Document 2. CDRH ODE/OIVD SOP 2011-001: Documentation of Informal Conversations and Communications Regarding Premarket Submissions, Version 1, (effective July 1, 2011) etc
2014-1970	03/12/2014 04/09/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Arvind Bansal NIPER	Regulatory status of chitosan as an ingredient for nano-carrier based drug delivery system
2014-1971	03/12/2014 04/09/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Arvind Bansal NIPER	regulatory status for use of phytantriol (CAS No.74563-64-7) as an ingredient through oral route
2014-1972	03/12/2014 04/09/2014	OC/ORANE/ORM/ OC/ORANE/ORM/	Jason DeYoung Protective Industrial Polymers	FIRMS INSPECTED LAST THREE YEARS IN MICHIGAN, INDIANA AND OHIO
2014-1973	03/12/2014 04/09/2014	FDA/OMPT/OSMP/OOPD/	Raymond J.ray mallet	HemaXellerate1 orphan drug status under Bio-Matrix Scientific Group Regen Biopharma
2014-1974	03/12/2014 04/09/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Nathan Sadeghi-Nejad Palkon Capital Management	Adcetris - AERS
2014-1975	03/12/2014 04/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	Hogan Lovells US LLP Russell, Jason M	K954737
2014-1976	03/12/2014 04/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	Donna Stauffer TELA Bio, Inc.	K111695

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2014-1977	03/12/2014 04/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	Mike Hoftman American Medical MFG./ Advanced Medical Innovations, Inc.	K915067
2014-1978	03/12/2014 04/09/2014	FDA/OC/OES/DFOI/	MORIAH SLAUGHTER URBAN INVESTMENT RESEARCH GROUP	COST OF INITIAL OCCUPATION AT 12709 TWINBROOK PWKY
2014-1979	03/12/2014 04/09/2014	FDA/OC/OES/DFOI/	MORIAH SLAUGHTER URBAN INVESTMENT RESEARCH GROUP	COST OF INITIAL OCCUPATION AT 2098 GAITHER ROAD, ROCKVILLE, MD
2014-1980	03/12/2014 04/09/2014	FDA/OC/OES/DFOI/	MORIAH SLAUGHTER URBAN INVESTMENT RESEARCH GROUP	COST OF INITIAL OCCUPATION AT 5630 FISHERS LN, ROCKVILLE, MD
2014-1981	03/12/2014 04/09/2014	FDA/OC/OES/DFOI/	MORIAH SLAUGHTER URBAN INVESTMENT RESEARCH GROUP	COST OF INITIAL OCCUPATION AT 11510 EST 80TH, LENEXA, KS
2014-1982	03/12/2014 04/09/2014	FDA/OC/OES/DFOI/	MORIAH SLAUGHTER URBAN INVESTMENT RESEARCH GROUP	COST OF INITIAL OCCUPATION AT 2094 GAITHER RD, ROCKVILLE, MD
2014-1983	03/12/2014 04/09/2014	FDA/OC/OES/DFOI/	MORIAH SLAUGHTER URBAN INVESTMENT RESEARCH GROUP	COST OF INITIAL OCCUPATION AT 12720 TWINBROOK PWKY, ROCKVILLE, MD
2014-1984	03/12/2014 04/09/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SUSANE G. YESNICK DRINKER BIDDLE REATH LLP	EFFEXOR - LBLG
2014-1985	03/12/2014 04/09/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	BRUCE J. DOUGLAS OGLETREE DEAKINS	MTG MINUTES BETWEEN CBER & AABB 5/29/09 & 11/1/12
2014-1986	03/12/2014 04/09/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MICHAEL A. CAROME, MD PUBLIC CITIZEN	TESTOSTERONE DRUG PRODUCTS - RVWS REGARDING RISKS
2014-1987	03/12/2014 04/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kimberly Smith SMITH, KIMBERLY	K133867
2014-1988	03/12/2014 04/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	Satoru Ogami FUJIFILM Corporation	K132065

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2014-1989	03/12/2014 04/09/2014	FDA/OMPT/OSMP/OCP/ FDA/OMPT/OSMP/OOPD/	Rachel Johnson FOI Services, Inc.	Orphan drug info for Juxtapid, approved for HoFH
2014-1990	03/12/2014 04/09/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Katwijk Chemie bv GENERICHEM CORP.	Katwijk Chemie bv - Netherlands SEPTEMBER 2013 FDA AUDIT
2014-1991	03/12/2014 04/09/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Matt Medlin Cato Research Ltd.	NDA 204671 BREAKTHROUGH THERAPY DESIGNATION
2014-1992	03/12/2014 04/09/2014	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/ FDA/OMPT/CDRH/OCER/DFOI/	MARK A. DELANEY BLOCK & LEVITON LLP	ATOSSA GENETICS INC - FORECYTE BREAST HEALTH TEST 501K
2014-1993	03/12/2014 04/09/2014	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/ FDA/OMPT/CDRH/OCER/DFOI/	MARK A. DELANEY BLOCK & LEVITON LLP	ATOSSA - MAMMARY ASPIRATION SPECIMEN CYTOLOGY TEST SYS KIT & PATIENT SPL KIT 501K
2014-1994	03/12/2014 04/09/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDRH/OCER/DFOI/	CHRISTOPHER D. VIEIRA IRELL & MANELLA LLP	NATURAL BALANCE COBRA SEXUAL ENERGY - DOCS
2014-1995	03/12/2014 04/09/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LEAH R. CAPITINI ANDRUS WAGSTAFF PC	ABBVIE INC - ANDRO GEL NDA 21-015, 22-309
2014-1996	03/12/2014 04/09/2014	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	MAUREEN JAROSCAK JAROSCAK, MAUREEN	JONATHAN FIELDING MD, LOS ANGELES COUNTY DEPT OF PUBLIC HEALTH - RECS, CORR; ALLERGAN INC - LAP BAND ADVERTISEMENTS, CORR, ETC
2014-1997	03/13/2014 04/10/2014	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Donna Cohen Donna Cohen	ZIOPHARM ONCOLOGY, CHARLESTOWN, MA - INSPECTION REPORT AUGUST 2013
2014-1998	03/13/2014 04/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Matt Medlin Cato Research Ltd.	IMBRUVICA - BREAKTHROUGH THERAPY RECS

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2014-1999	03/13/2014 04/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Matt Medlin Cato Research Ltd.	GAZYVA - BREAKTHROUGH THERAPY RECS
2014-2000	03/13/2014 04/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Farah Ali SPI PHARMA INC	KEMWELL BIOPHARMA, INDIA - EIR 12/01/2012 - 01/31/2013
2014-2001	03/13/2014 04/10/2014	FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jennifer Iuppa BARNES-JEWISH HOSPITAL	CELLCEPT - AERS
2014-2002	03/13/2014 04/10/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OFVM/CFSAN/OCD/EOS/	Michael C Valdez Andrews and Thornton	OXYElite Pro Ultra-Intense Thermo (USPLabs), OXYElite Pro Super Thermo (USPLabs), OxyElite Pro Super Thermo Powder (USPLabs), Versa-1 (USPLabs) ETC - AERS
2014-2003	03/13/2014 04/10/2014	FDA/OMPT/OSMP/OOPD/ FDA/OMPT/OSMP/OOPD/	Elinore Mercer Cote Orphan Consulting	TENOFOVIR - ORPHAN DESIGNATION
2014-2004	03/13/2014 04/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Scott Hodes Scott A. Hodes, Attorney at Law	LETTERS TO SANOFI, REGENERON, AMGEN RE PCSK 09/01/2013 - 03/09/2014
2014-2005	03/13/2014 04/10/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Tirunelveli Ramalingam OCT Medical Imaging Inc	K111338, K120273, K102599 ETC
2014-2006	03/13/2014 04/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lauren Welling Phillips Law Firm	NDA 021015, NDA 022309
2014-2007	03/13/2014 04/10/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Aisha Meah US SURGITECH INC	K130669
2014-2008	03/13/2014	FDA/OMPT/CDER/ORP/DIDP/	Terri Sabin	BOTOX, SOLIFENACIN - SBA

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	04/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TheraVida	
2014-2009	03/13/2014 04/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bao Le ARIAD Pharmaceuticals, Inc	ICLUSIG - SBA
2014-2010	03/13/2014 04/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	ORGAON, OSS, NL - EIRS 5/14/09 TO 4/5/13
2014-2011	03/13/2014 04/10/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	BRENDA M GARTZ ELI LILLY & CO	OSO BIOPHARMACEUTICALS, ALBUQUERQUE, NM - EIRS 8/19/13
2014-2012	03/13/2014 04/10/2014	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	BRENDA M GARTZ ELI LILLY & CO	PACKAGING COORDINATORS (ANDERSON BRECON, ANDERSON PACKAGING), ROCKFORD, IL - EIRS 9/18/13
2014-2013	03/13/2014 04/10/2014	FDA/OFVM/CFSAN/OCD/EOS/	SARA M GAINES Keller and Heckman LLP	ZINC PYRITHIONE - MIGRATION STUDIES
2014-2014	03/13/2014 04/10/2014	FDA/OFVM/CFSAN/OCD/EOS/	KATHRYN C SKAGGS Keller and Heckman LLP	DOW CHEMICAL CO - FCN 909 INTERNAL RVW MEMO
2014-2015	03/13/2014 04/10/2014	FDA/OFVM/CFSAN/OCD/EOS/	KATHRYN C SKAGGS Keller and Heckman LLP	LYDONDELL BASELL INDUSTRIES - FCN 1086 INTERNAL RVW MEMO
2014-2016	03/13/2014 04/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	KRISTI O SMEDLEY Center for Regulatory Services, Inc.	CONGNIS DEUTSCHLAND GMBH & CO , KG - FCN ATTACHMENTS 1-18
2014-2017	03/13/2014 04/10/2014	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	ANDREW HACK MILLENNIUM MANAGEMENT LLC	BARTOR PHARMACAL , RYE, NY - EIRS, 483S UNTITLED LTRS, ETC 1/130 TO PRESENT
2014-2018	03/13/2014 04/10/2014	FDA/OFVM/CFSAN/OCD/EOS/	KEVIN I GOLDBERG GOLDBERG FINNEGAN & MESTER LLC	MONSTER ENERY DRINK, RED BULL, FIVE HOUR ENERGY, ETC - AERS, FACTS INTERFACE FORMS, FORM 3500, ETC 10/13/13 TO 3/10/14
2014-2019	03/13/2014 04/10/2014	FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECS

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2014-2020	03/13/2014 05/07/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Doe J	INDIVIDUAL RECS
2014-2021	03/13/2014 04/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bhagwan S chaudhary INDIVIDUAL	ALEMBIC PHARMACEUTICALS LIMITED, INDIA - 483 04/15/2013 - 04/26/2013
2014-2022	03/13/2014 04/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Paul E. Greenberg Analysis Group, Inc.	DR PETER BUTLER ET AL SUBMISSION RE PANCREATITIS AND PRE-CANCEROUS FINDINGS FROM INCRETIN MIMETIC DRUGS ETC
2014-2023	03/13/2014 04/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Stephen Albert Stephen Albert	NERIDRONATE - ORPHA STATUS
2014-2024	03/13/2014 04/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Paul E. Greenberg Analysis Group, Inc.	INCRETIN-BASED DRUGS - STUDIES, REPORTS, MEMOS ETC 01/01/2013 - 03/11/2014
2014-2025	03/13/2014 04/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jake McDowell The Weinberg Group	GENERAMEDIX - NULECIT ANDA 78-215 CHEMISTRY RVW
2014-2026	03/13/2014 04/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Paul E. Greenberg Analysis Group, Inc.	OFFICE OF SAFETY AND EPIDEMIOLOGY REVIEWS FOR INCRETIN-BASED THERAPIES, AERS 12/01/2013 - 03/11/2014
2014-2027	03/13/2014 04/10/2014	FDA/OC/OES/DFOI/	Russell Smith Chiefist	FOIA REQUESTS RE CINTRON RESEARCH LAB REPORTS RE ACTHAR 01/01/2014 - 03/11/2014
2014-2028	03/13/2014 04/10/2014	FDA/OGROP/ORO/SW-FO/DEN- DO/DEN-CB/	Jessica Dyer Albuquerque Journal	BUENO FOODS, EL ENCANTO - GREERN CHILE SAMPLES 03/31/2012 - 03/11/2014
2014-2029	03/13/2014 04/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Paul E. Greenberg Analysis Group, Inc.	INCRETIN-BASED DRUGS - OND STUDIES, REPORTS, MEMOS ETC 01/01/2013 - 03/11/2014

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-2030	03/13/2014 04/10/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sian Bigora QUESTCOR PHARMACEUTICALS INC	CINTRON RESEARCH REPORT TO FDA RE HP ACTHAR GEL
2014-2031	03/13/2014 04/10/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ketaki Gokhale BLOOMBERG NEWS	STRIDES ARCOLAB LTD - 483 03/01/2012 - 03/11/2014
2014-2032	03/13/2014 04/10/2014	FDA/OFVM/CFSAN/OCD/EOS/	Nancy Vold, Nancy	DYNAMIC GREENS WHEATGRASS - APPROVAL RECS
2014-2033	03/13/2014 04/10/2014	FDA/OC/OCC/ FDA/OC/OES/ FDA/OFVM/CFSAN/OCD/EOS/ OC/CVM/OCD/	Amy Van Saun CENTER FOR FOOD SAFETY	SHELLFISH AQUACUTLURE - RECS RE PESTICIDES
2014-2034	03/13/2014 04/10/2014	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/ FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/ FDA/OGROP/ORA/SW-FO/DEN- DO/DEN-CB/	Kristin Arpin Arpin Quality Consulting Inc.	BEST LIFE PHARMANATURALS, NUTRICAP LABS LLC, KABCO PHARMACEUTICALS ETC - EIR LAST THREE YEARS
2014-2035	03/13/2014 04/10/2014	FDA/OMPT/OSMP/OOPD/	Rachel Johnson FOI Services, Inc.	KYNAMRO - ORPHAN DRUG RECS
2014-2036	03/13/2014 04/10/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Andrea Demakas ADVERSEEVENTS INC	CLARINEX, PHENERGAN, XYZAL ETC - AERS
2014-2037	03/13/2014 04/10/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lauren Farruggia Hyman Phelps and McNamara PC	CORR FROM FDA TO PAR PHARMACEUTICALS RE PREMATURE NOTIFICATION OF PARAGRAPH IV CERTIFICATION
2014-2038	03/13/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Stephen Fowler	MDS Pharma Services, Fehraltorf, Switzerland - EIR MARCH 2010

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	04/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Celerion, Inc.	
2014-2039	03/13/2014 04/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kristin Cooklin CROWELL & MORING	HP ACTHAR GEL - June 1, 1977 Labeling Revision (Supplement Number 015); October 5, 1977 Labeling Revision (Supplement Number 016); March 14, 1978 Labeling Revision (Supplement Number 017) ETC
2014-2040	03/13/2014 04/10/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Donald Tyson montiffinc	ANALYSIS OF THE AMINO ACID L-CITRULLINE CRYSTALLINE PURE FORM
2014-2041	03/13/2014 04/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	valin Saint Antoine	ST ANTOINE HOSPITAL, PARIS, FRANCE - EIR
2014-2042	03/13/2014 04/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Joanne Grego CSL Berhing	PRIVIGEN, HIZENTRA - VAERS
2014-2043	03/13/2014 04/10/2014	FDA/OMPT/CTP/OD/	Toni Clarke REUTERS	E-CIGARETTES - AERS
2014-2044	03/13/2014 06/24/2014	FDA/OMPT/CTP/OD/ FDA/OC/OES/DFOI/	Eric Donny UNIVERSITY OF PITTSBURGH	DATA FROM TOBACCO INDUSTRY TO FDA RE INITIAL LIST OF HARMFUL AND POTENTIALLY HARMFUL CONSTITUENTS BY BRAND AND SUB-BRAND 03/01/2012 - 03/12/2014
2014-2045	03/13/2014 04/10/2014	FDA/OMPT/CTP/OD/	Eric Donny UNIVERSITY OF PITTSBURGH	DATA FROM TOBACCO INDUSTRY TO FDA RE INITIAL LIST OF HARMFUL AND POTENTIALLY HARMFUL CONSTITUENTS BY BRAND AND SUB-BRAND 03/01/2012 - 03/12/2014
2014-2046	03/14/2014 04/11/2014	FDA/OC/OES/DDM/ FDA/OC/OES/DDM/	Benjamin Zegarelli Epstein Becker & Green, P.C.	Reply Comment No. RCO04, Docket No. 76N-052T, Dockets Management Branch, Report No. RPT002, Docket No. 76N-052T, Dockets Management Branch

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		FDA/OC/OES/DFOI/		
2014-2047	03/14/2014 04/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mahidhar Chinta Micro Labs USA, Inc	NDA 020064, ANDA 076648, ANDA 077066
2014-2048	03/14/2014 04/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John F. Weet Durata Therapeutics	NDA 19698 MEDICAL REVIEW
2014-2049	03/14/2014 04/11/2014	FDA/OC/OES/ FDA/OGROP/OIP/	Toni Clarke REUTERS	DR HAMBURG FEB 2014 VISIT TO INDIA - MTG MINUTES, LETTERS, ETC 10/01/2013 - 03/12/2014
2014-2050	03/14/2014 04/11/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/	Earl Shero Farmacy LLC	FARMACY, WILLIAM SHERO - INFORMATION SENT TO FDA 09/01/2013 - 03/12/2014
2014-2051	03/14/2014 04/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kim Tompkins Tompkins Consultants	K100999
2014-2052	03/14/2014 04/11/2014	FDA/OFVM/CFSAN/OCD/EOS/	Kevin Goldberg Goldberg, Kevin I	MONSTER ENERGY DRINKS - AERS, FACTS, MEDWATCH FORMS ETC
2014-2053	03/14/2014 04/11/2014	FDA/OGROP/ORO/NE-FO/NWE-DO/NWE-CB/	Robert Z. Phillips SIEMENS HEALTHCARE DIAGNOSTICS INC	SIEMENS HEALTHCARE, EAST WALPOLE, MA - EIR 02/04/2013 - 03/31/2013
2014-2054	03/14/2014 04/11/2014	FDA/OFVM/CFSAN/OCD/EOS/	Lauren Somers Lauren Somers	GNC Women's Ultra Mega Energy & Metabolism Vitapak supplement; GNC CLA soft chew supplement; GNC Vitamin B-12 soft chew supplement - AERS
2014-2055	03/14/2014 04/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WF Yeung the University of Hong Kong	SILENOR TRIAL RECS
2014-2056	03/14/2014 04/11/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-9149
2014-2057	03/14/2014 04/11/2014	FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/	Doe J	INDIVIDUAL RECS

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2014-2058	03/14/2014 04/11/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-9057
2014-2059	03/14/2014 04/11/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-2705
2014-2060	03/14/2014 04/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	Monica Minarelli Thema srl	K071561
2014-2061	03/14/2014 04/17/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Marco Lacanna Thema srl	BK120048
2014-2062	03/14/2014 04/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jameel Husain Fresenius Kabi USA, LLC	BASF SE, GERMANY - EIR 01/02/2006 - 03/03/2014
2014-2063	03/14/2014 04/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Christine Livoti BIOPHARM INSIGHT	BOEHRINGER INGELHEIM, RHEIN, GERMANY - DRUGS MANUFACTURED
2014-2064	03/14/2014 04/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K100284
2014-2065	03/14/2014 04/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K083531
2014-2066	03/14/2014 04/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K082993
2014-2067	03/14/2014 04/11/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-7573
2014-2068	03/14/2014 04/11/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-7734
2014-2069	03/14/2014 04/11/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-9119
2014-2070	03/14/2014 04/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	Marcus Susen Koch Parafinczuk & Wolf, PA	ESSURE, ESSURE SYSTEM - PMA
2014-2071	03/14/2014 04/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Christine Livoti BIOPHARM INSIGHT	BOEHRINGER INGELHEIM, RHEIN GERMANY - 483, WARNING LETTER, RESPONSE

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		FDA/OMPT/CDER/ORP/DIDP/		
2014-2072	03/14/2014 04/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sylvia Chen ScinoPharm Taiwan	SCINOPHARM TAIWAN - EIR 03/26/2012- 03/29/2012
2014-2073	03/14/2014 04/11/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-9024
2014-2074	03/14/2014 04/11/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Mark Palmieri Novo Nordisk Inc.	K103825
2014-2075	03/14/2014 04/11/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-8843
2014-2076	03/14/2014 04/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K122446
2014-2077	03/14/2014 04/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K110184
2014-2078	03/14/2014 04/11/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K102076
2014-2079	03/14/2014 04/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K100284
2014-2080	03/14/2014 04/11/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K101276
2014-2081	03/14/2014 04/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jeremy Oczek Bond, Schoeneck & King PLLC	K893851
2014-2082	03/14/2014 04/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Steve Usdin BIOCENTURY	ACTHAR GEL REPORT 01/01/2013 - 03/13/2014
2014-2083	03/14/2014 04/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K123936
2014-2084	03/14/2014 04/11/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-8682
2014-2085	03/14/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2013-8586

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	04/11/2014		MERCK & CO., INC.	
2014-2086	03/14/2014 04/11/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-8143
2014-2087	03/14/2014 04/11/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-8119
2014-2088	03/14/2014 04/11/2014	FDA/OFVM/CFSAN/OCD/EOS/	Kevin I. Goldberg Goldberg, Kevin I	GRAS STATUS OF MONSTER ENERGY DRINK ETC
2014-2089	03/14/2014 04/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K130474
2014-2090	03/14/2014 04/11/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ketaki Gokhale BLOOMBERG NEWS	SUN PHARMACEUTICAL, MUBAI - 483 09/01/2013 - 03/13/2014
2014-2091	03/14/2014 04/11/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Brian Beers Marathon Pharmaceuticals, LLC	OPIUM TINCTURE - AERS 01/01/2008 - 03/13/2014
2014-2092	03/14/2014 04/11/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bradley Ritter Perrigo Co, plc	NDA 020132 - SBA
2014-2093	03/14/2014 04/11/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	NYQUIST, PATTI	FLU VACCINE LOT UI793AA
2014-2094	03/14/2014 04/11/2014	FDA/OFVM/CFSAN/OCD/EOS/	ZDIEK, MARK	DIATOMACEOUS EARTH - NEW DIETARY INGREDIENT
2014-2095	03/14/2014 04/11/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-9201
2014-2096	03/14/2014 04/11/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-9323
2014-2097	03/14/2014 04/11/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-508
2014-2098	03/14/2014 04/11/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-9591

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2014-2099	03/14/2014 04/11/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-446
2014-2100	03/14/2014 04/11/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-9589
2014-2101	03/14/2014 04/11/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-396
2014-2102	03/14/2014 04/11/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-9797
2014-2103	03/14/2014 04/11/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-9604
2014-2104	03/14/2014 04/11/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-9596
2014-2105	03/14/2014 04/11/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-37
2014-2106	03/14/2014 04/11/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-9995
2014-2107	03/14/2014 04/11/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-10107
2014-2108	03/14/2014 04/11/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-83
2014-2109	03/14/2014 04/11/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-10082
2014-2110	03/14/2014 04/11/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-9593
2014-2111	03/14/2014 04/11/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-9837
2014-2112	03/14/2014 04/11/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-10099
2014-2113	03/14/2014 04/11/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-9693
2014-2114	03/14/2014 04/11/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-9394
2014-2115	03/14/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2013-9595

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	04/11/2014		MERCK & CO., INC.	
2014-2116	03/14/2014 04/11/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-9800
2014-2117	03/14/2014 04/11/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-9801
2014-2118	03/14/2014 04/11/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-398
2014-2119	03/14/2014 04/11/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-9395
2014-2120	03/14/2014 04/11/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-10088
2014-2121	03/14/2014 04/11/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-10101
2014-2122	03/14/2014 04/11/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-10091
2014-2123	03/14/2014 04/11/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-9374
2014-2124	03/14/2014 04/11/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-9935
2014-2125	03/14/2014 04/11/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-9377
2014-2126	03/14/2014 04/11/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-9370
2014-2127	03/14/2014 04/11/2014	FDA/OFVM/CFSAN/OCD/EOS/	POTICNKO, VALENTINA	ARTICHOKE; BLACKCURRANT, BLACK RADISH - GRAS
2014-2128	03/14/2014 04/11/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-9385
2014-2129	03/14/2014 04/11/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-9781
2014-2130	03/14/2014 04/11/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-411
2014-2131	03/14/2014 04/11/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-9845

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2014-2132	03/14/2014 04/11/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KIMBERLY KINDY WASHINGTON POST	PERCHLORATE; SODIUM PERCHLORATE MONOHYDRATE - AER
2014-2133	03/14/2014 04/11/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-202
2014-2134	03/14/2014 04/11/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-9798
2014-2135	03/14/2014 04/11/2014	FDA/OFVM/CFSAN/OCD/EOS/	KIMBERLY KINDY WASHINGTON POST	QUORN (MYCOPROTEIN) - CITIZEN PETITIONS
2014-2136	03/14/2014 04/11/2014	FDA/OFVM/CFSAN/OCD/EOS/	KIMBERLY KINDY WASHINGTON POST	QUORN - AER
2014-2137	03/14/2014 04/11/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LAUREN RICE Reckitt Benckiser Pharmaceuticals, Inc.	ZUBSOLV - SBA PRVL 7/3/13
2014-2138	03/14/2014 04/11/2014	FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECS
2014-2139	03/14/2014 04/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	COURTNEY G. WEINBERGER MCALOON & FRIEDMAN	CONCEPTIS INC - ESSURE SYSTEM FOR PERMANENT BIRTH CONTROL PMA P020014/S034
2014-2140	03/14/2014 04/11/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	PATRICK KELLY CONWAY HOMER & CHIN- CAPLAN PC	INDIVIDUAL RECS
2014-2141	03/14/2014 04/11/2014	FDA/OFVM/CFSAN/OCD/EOS/	FRIEDMAN, ROBERT	ARCHWAY; KI-DEL; PAMELAS COOKIES - CAERS 1969 TO PRESENT
2014-2142	03/14/2014 04/11/2014	FDA/OFVM/CFSAN/OCD/EOS/	FRIEDMAN, ROBERT	FRUIT GUSHERS; FRIUT BY THE FOOT - CAERS 1969 TO PRESENT
2014-2143	03/18/2014 04/15/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Diana Phipps FirmLogic of Womble Carlyle	EVALUATION OF ELECTRONIC CIGARETTES 05/01/2008 - 05/05/2009
2014-2144	03/18/2014	FDA/OMPT/CDER/GRP/DIDP/	Rachel Roberts	FDA CORR WITH QUESTCOR, BLUE STREAM LABORATORIES RE CINTRON RESEARCH REPORT

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	04/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Roberts	
2014-2145	03/18/2014 04/07/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joseph Safdie Caligor Rx, Inc.	LIST OF TREATMENT IND, EMERGENCY IND 1/1/10 TO 12/31/13
2014-2146	03/18/2014 04/15/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/	Joseph Safdie Caligor Rx, Inc.	LIST OF DRUGS IMPORTED INTO THE US, DETAINED BY FDA FOR CLEARANCE AT US BORDER 1/1/10 TO 12/31/13
2014-2147	03/18/2014 04/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ronald Cuchetti Individual / NA	ERYTHROMYCIN - SHELF LIFE EXTENSION PROGRAM TESTING RECS
2014-2148	03/18/2014 04/15/2014	FDA/OFVM/CFSAN/OCD/EOS/	Steve Hentges AMERICAN CHEMISTRY COUNCIL	COMMENTS SUBMITTED BY FDA TO EFSA RE DRAFT SCIENTIFIC OPINION ON THE RISKS TO PUBLIC HEALTH RELATED TO THE PRESENCE OF BISHPHENOL A IN FOODSTUFFS
2014-2149	03/18/2014 04/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	Lukasz M. Geraga Lukasz Geraga	FDA Investigational Training Manual FDA 84-4191 Medical Device GMP Guidance for FDA Investigator
2014-2150	03/18/2014 04/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	David Asbury Innerspace Neuro Solutions	K862160
2014-2151	03/18/2014 04/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	David Asbury Innerspace Neuro Solutions	K30222
2014-2152	03/18/2014 04/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	David Asbury Innerspace Neuro Solutions	K961113
2014-2153	03/18/2014 04/15/2014	FDA/OC/OCC/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Matea Gold WASHINGTON POST	ALL REPORTS FROM GOOGLE TO FDA RE EFFORTS TO COMPLY WITH NONPROSECUTION AGREEMENT RE ONLINE ADVERTISING OF ILLEGAL PHARMACEUTICALS
2014-2154	03/18/2014	FDA/OMPT/CDER/ORP/DIDP/	Rebecca L. Dandeker	TARO PHARMACEUTICALS, ONTARIO, CANADA - EIR 7/1/08 TO 7/31/08

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	04/15/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Morgan, Lewis & Bockius LLP	
2014-2155	03/18/2014 04/15/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rebecca L. Dandeker Morgan, Lewis & Bockius LLP	TARO PHARMACEUTICALS, ONTARIO, CANADA - EIR SUMMARIES 07/01/2008 - 07/31/2008
2014-2156	03/18/2014 04/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	JOSEPH WALKER Walker, Joseph	SPINAL FUSION, VERTEBRAE FUSION MDR 01/01/2009 - 03/17/2014
2014-2157	03/18/2014 04/15/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rebecca L. Dandeker Morgan, Lewis & Bockius LLP	HALCYON LABS PVT LTD, INDIA - 483, EIR SUMMARIES
2014-2158	03/18/2014 04/15/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jason W. Sapsin FOX ROTHSCHILD LLP	THIRD PARTY LETTERS SENT TO FDA RE PRIVATE TESTING AND ANALYSIS OF QUESTCOR PHARMACEUTICALS HR ACTHAR GEL
2014-2159	03/18/2014 04/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	Holiven Ji AMSINO INTERNATIONAL, INC.	K072652
2014-2160	03/18/2014 04/15/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Prashant Premkumar East Bridge Capital Management Limited	AUROBINDO PHARMA - 483 01/01/2013 - 03/14/2014
2014-2161	03/18/2014 04/15/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kristin Cooklin Crowell & Moring LLP	NDA 008372
2014-2162	03/18/2014 04/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kevin Minnich B. Braun Medical Inc.	K131249
2014-2163	03/18/2014 04/15/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Peter Sarda Creechlaw Firm	FLUZONE - VAERS 01/01/2011 - 12/31/2012
2014-2164	03/18/2014 04/15/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tariq Ata REMS Logic, LLC	Number of REMS Drug Error Reports from 2008 through 2013

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2014-2165	03/18/2014 04/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Prashant Premkumar East Bridge Capital Management Limited	SUN PHARMACEUTICAL INDUSTRIES, INDIA - 483 01/02/2013 - 03/14/2014
2014-2166	03/18/2014 04/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Christine Livoti BIOPHARM INSIGHT	BOEINGER INGELHEIM, RHEIN, GERMANY - LIST OF DRUGS
2014-2167	03/18/2014 04/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	Holiven Ji AMSINO INTERNATIONAL, INC.	K061432
2014-2168	03/18/2014 04/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	Doron Harlev Affera LLC	PMA SUBMISSIONS FOR CATHETER ABLATION DEVICES FOR TREATMENT OF CARDIAC ARRHYTHMIA 12/01/2001 - 03/01/2014
2014-2169	03/18/2014 04/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Uday Shetty Drug Regulations	SUN PHARMACEUTICALS, INDIA - 483 01/01/2013 - 03/15/2014
2014-2170	03/18/2014 04/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jen Feranil KM PHARMACEUTICAL CONSULTING LLC	NDA 020007 - SBA
2014-2171	03/18/2014 04/17/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Julio Rivera GlaxoSmithKline	CATALENT PHARMA SOLUTIONS, BRUSSELS, BELGIUM - EIR MOST RECENT
2014-2172	03/18/2014 04/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Timothy P. Bohan PhD MD Timothy P. Bohan PhD MD PA	AZITHROMYCIN - AERS
2014-2173	03/18/2014	FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson	GRANDFATHERED TOBACCO STATUS DETERMINATION

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	04/15/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CTP/OD/	FOI Services, Inc.	RECS 5/10/13 TO 3/10/14
2014-2174	03/18/2014 04/15/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/ FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	Michael Jungling Morgan Stanley	GETINGE - 483 01/01/2011 - 03/14/2014
2014-2175	03/18/2014 04/15/2014	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	Patrick Wood Morgan Stanley	APP PHARMACEUTICALS, GRAND ISLAND, NY - 483 01/01/2011 - 03/14/2014
2014-2176	03/18/2014 04/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	Peter A. Takes, Ph.D. Kypha, Inc.	K874379
2014-2177	03/18/2014 04/15/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Soma Das The Economic Times, The Times of India	SUN PHARMA, INDIA - 483 06/02/2013 - 03/15/2014
2014-2178	03/18/2014 04/15/2014	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	GRANDFATHERED TOBACCO PRODUCT STATUS DETERMINATION FOR ECLIPSE TOBACCO
2014-2179	03/18/2014 04/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	Nurul Alsyah Kong Hartalega Sdn. Bhd.	K111589
2014-2180	03/18/2014 04/15/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Milt Friedman Milton Friedman	K092362, - APPENDIX A
2014-2181	03/18/2014 04/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	Carrie Neuberger Use by consultant	K031810
2014-2182	03/18/2014 04/15/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Robert Cormack ICON CLINICAL RESEARCH	Pre-IND consultation letter from FDA (Myfortic; mycophenolic acid; NDA 050791; Novartis)
2014-2183	03/18/2014 04/15/2014	FDA/OMPT/OSMP/OOPD/	Robert Cormack ICON CLINICAL RESEARCH	Orphan drug designation review file (Gilotrif; afatinib dimaleate; NDA 201292; Boehringer Ingelheim)
2014-2184	03/18/2014	OC/ORA/		CONSUMER COMPLAINT, EIR

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	04/21/2014	OC/ORO/ FDA/OGROP/ORO/CE-FO/DET-DO/DET-CB/	Doe J	
2014-2185	03/18/2014 04/15/2014	FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/	Ian Pritchard Orbis Investment Advisory Ltd	QUESTCOR PHARMACEUTICALS INC, HAYWARD, CA - 483 11/01/2013 - 11/14/2013
2014-2186	03/18/2014 04/15/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORO/CE-FO/DET-DO/DET-CB/	Laura G Sigrist Sigrist, Laura G	COMPLAINT RECS, RECALL INFORMATION 02/26/2014 - 04/30/2014
2014-2187	03/18/2014 04/15/2014	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Ian Pritchard Orbis Investment Advisory Ltd	REPORT TO FDA RE ACTHAR GEL 12/05/2013 - 12/20/2013
2014-2188	03/18/2014 04/15/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Bob Sowinski AESCULAP INC	K110560
2014-2189	03/18/2014 04/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	Becky Donahue MASIMO CORP	K081285
2014-2190	03/18/2014 04/15/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	KRISTEN S MOYERS WRIGHT LINDSEY & JENNINGS	KIMBERLY-CLARK - KOTEX NATURAL BALANCE SECURITY TAMPON PRODS RECALL INVESTIGATION RECS
2014-2191	03/18/2014 04/15/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/ FDA/OFVM/CFSAN/OCD/EOS/	ROUSE, CORINNA	KRATOM, MITRAGYNA SPECIOSA - IMPORT ALERT RECS
2014-2192	03/18/2014 04/15/2014	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	SHILPA MEDICARE LTD, CHIKSUGUR POST RAICHUR, INDIA - EIR, 483, CO RESP 3/5/13
2014-2193	03/18/2014 04/15/2014	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	ACS DOBFAR SPA, MILAN, ITALY - EIR, 483, CO RESP 7/4/13

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2014-2194	03/18/2014 04/15/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	MEDIMMUNE LLC, PHILADELPHIA, PA - EIR, 483, CO RESP 5/22/13
2014-2195	03/18/2014 04/15/2014	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	WALTER E. CHALKLEY THOMSON REUTERS	ONYX PHARMACEUTICALS INC, SOUTH SAN FRANCISCO, CA - EIR, 483, CO RESP 5/17/13
2014-2196	03/18/2014 04/15/2014	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	PATHEON PUERTO RICO INC, CAGUAS PR - EIR, 483, CO RESP 3/28/13
2014-2197	03/18/2014 04/15/2014	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/ OC/ORA/ORO/DDFI/ OC/ORA/ORO/DDFI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	RECIPHARM MONTS, MONTS, FRANCE - EIR, 483, CO RESP 2/26/13
2014-2198	03/18/2014 04/15/2014	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	WALTER E. CHALKLEY THOMSON REUTERS	SEATTLE GENETICS INC, BOTHELL, WA - EIR, 483, CO RESP 3/20/13
2014-2199	03/18/2014 04/15/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	WALTER E. CHALKLEY THOMSON REUTERS	TRIHEALTH IRB, CINCINNATI, OH - EIR, 483, CO RESP 4/8/13
2014-2200	03/18/2014 04/15/2014	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	WALTER E. CHALKLEY THOMSON REUTERS	PHARMACEUTICS INTL INC, COCKEYSVILLE, MD - EIR, 483, CO RESP 9/13/13
2014-2201	03/18/2014 04/15/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	ROBERT KING FDA NEWS	CARDIAC ASSIST INC, PITTSBURGH, PA; AMICI INC, SPRING CITY, PA - 483S 2/1-28/14
2014-2202	03/18/2014 04/15/2014	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	ROBERT KING FDA NEWS	PACSGEAR INC, PLEASANTON, CA; LUMIQUICK DIAGNOSTICS INC, SANTA CLARA, CA; IBA MOLECULAR NORTH AMERICA INC, GILROY, CA - 483S 2/1-28/14
2014-2203	03/18/2014 04/15/2014	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	YANGZHOU PHARMACEUTICAL CO LTD, YANGZHOU, JIANGSU, CHINA - EIR, 483, CO RESP 3/22/13
2014-2204	03/18/2014 04/15/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	WALTER E. CHALKLEY THOMSON REUTERS	ADVANCED MEDICAL, ALBUQUERQUE, NM - EIR, 483, CO RESP 1/18/13

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2014-2205	03/18/2014 04/15/2014	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	ROBERT KING FDA NEWS	CYTOPHIL INC, EAST TROY, WI; MAR COR PURIFICATION, MINNEAPOLIS, MN; AMERICAN MEDICAL SYSTEMS INC, MINNETONKA, MN, ETC - 483S 2/1-28/14
2014-2206	03/18/2014 04/15/2014	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	WALTER E. CHALKLEY THOMSON REUTERS	BAXTER HEALTHCARE CORP, ROUND LAKE, IL - EIR, 483, CO RESP 9/17/13
2014-2207	03/18/2014 04/15/2014	FDA/OGROP/ORACE-FO/NWJDO/NWJ-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	CELGENE CORP, BERKELEY HEIGHTS, NJ - EIR, 483, CO RESP 4/24/13
2014-2208	03/18/2014 04/15/2014	FDA/OGROP/ORAPA-FO/SEADO/SEA-CB/	ROBERT KING FDA NEWS	VIDCO INC, BEAVERTON, OR; LIGHTSCALPEL LLC, WOODINVILLE, WA; FORMULA CORP, AUBURN, WA - 483S 2/1-28/14
2014-2209	03/18/2014 04/15/2014	FDA/OGROP/ORACE-FO/BLTDO/BLT-CB/	WALTER E. CHALKLEY THOMSON REUTERS	CHILDREN'S NATIONAL MEDICAL CTR IRB, SILVER SPRING, MD - EIR, 483, CO RESP 3/13/13
2014-2210	03/18/2014 04/15/2014	FDA/OGROP/ORASE-FO/FLADO/FLA-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	DAVID H. FLAHERTY, NORTH MIAMI, FL - EIR, 483, CO RESP 4/1/13
2014-2211	03/18/2014 04/15/2014	FDA/OGROP/ORASE-FO/FLADO/FLA-CB/ FDA/OC/OES/DFOI/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	BAUSCH & LOMB INC, TAMPA, FL - EIR, 483, CO RESP 7/12/13
2014-2212	03/18/2014 04/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	CANTON LABORATORIES PRIVATE LTD, VADODARA, INDIA - EIR, 483, CO RESP 4/1-9/13
2014-2213	03/18/2014 04/15/2014	FDA/OGROP/ORACE-FO/NWJDO/NWJ-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	FOREST RESEARCH INSTITUTE INC, JERSEY CITY, NJ - EIR, 483, CO RESP 2/21/13
2014-2214	03/18/2014 04/15/2014	FDA/OGROP/ORACE-FO/DETDO/DET-CB/ OC/OR/ OC/OR/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	NORA APOTHECARY & ALTERNATIVES THERAPIES INC, INDIANAPOLIS, IN - EIR, 483, CO RESP 3/19-21/13
2014-2215	03/18/2014 04/15/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	WALTER E. CHALKLEY THOMSON REUTERS	PALLIMED SOLUTIONS INC, WOBURN, MA - EIR, 483, CO RESP 3/20-29/13
2014-2216	03/18/2014 04/15/2014	FDA/OGROP/ORASW-FO/KANDOKAN-CB/	WALTER E. CHALKLEY THOMSON REUTERS	GRATO INC, WOODBINE, IA - EIR, 483, CO RESP 6/19/13
2014-2217	03/18/2014 04/15/2014	FDA/OGROP/ORAPA-FO/LOSDO/LOS-CB/	WALTER E. CHALKLEY THOMSON REUTERS	KENNETH B DECK MD, LUGUNA HILLS, CA - EIR, 483, CO RESP 4/3/13

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2014-2218	03/18/2014 04/15/2014	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	ROBERT KING FDA NEWS	BAXTER HEALTHCARE CORP, JAYUYA, PR; BRISTOL MYERS SQUIBB MANUFACTURING CO, HUMACAO, PR - 483S 2/1-28/14
2014-2219	03/18/2014 04/15/2014	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	WALTER E. CHALKLEY THOMSON REUTERS	LINCARE INC, IDAHO FALLS, ID - EIR, 483, CO RESP 3/8/13
2014-2220	03/18/2014 04/15/2014	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	ROBERT KING FDA NEWS	ALVA-AMCO PHARMACAL COMPANIES INC, NILES, IL; DENTSPLY INTERNATIONAL-PROFESSIONAL DIVISION, DES PLAINES, IL; COSMEDENT INC, CHICAGO, IL, ETC - 483S 2/1-28/14
2014-2221	03/18/2014 04/15/2014	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	ROBERT KING FDA NEWS	AMNEAL PHARMACEUTICALS OF NEW YORK LLC, HAUPPAUGE, NY; ANGIODYNAMICS INC, QUEENSBURY, NY; CROWN DELTA CORP, YORKTOWN HEIGHTS, NY, ETC - 483S 2/1-28/14
2014-2222	03/18/2014 04/15/2014	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	ROBERT KING FDANEWS	CNMC COMPANY INC, NASHVILLE, TN; MOTION VIEW SOFTWARE LLC, HIXSON, TN; CROWN LABS, JOHNSON CITY, TN - 483S 2/1-28/14
2014-2223	03/18/2014 04/15/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	ROBERT KING FDA NEWS	INTERGEL PHARMACEUTICALS LLC, IRVINGTON, NJ; WEST-WARD PHARMACEUTICAL CORP, EATONTOWN, NJ - 483S 2/1-28/14
2014-2224	03/18/2014 04/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	K LINH PHAM. LL.B. MERCHANT LAW GROUP LLP	HOFFMAN LA ROCHE LTD - ACCUTANE (ISOTRETINOIN), VESANOID (TRETINOIN) DOG STUDIES, APRVL
2014-2225	03/18/2014 04/15/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	ROBERT KING FDA NEWS	SURGICAL TABLES INC, MIDDLETON, MA; CANDELA CORP, WAYLAND, MA; LYNE LABORATORIES INC, BROCKTON, MA - 483S 2/1-28/14
2014-2226	03/18/2014 04/15/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	ROBERT KING FDANEWS	PACIRA PHARMACEUTICALS INC, SAN DIEGO, CA; B BRAUN MEDICAL INC, LOS ANGELES, CA; KOROS USA INC, MOORPARK, CA, ETC - 483S 2/1-28/14
2014-2227	03/18/2014 04/15/2014	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	ROBERT KING FDANEWS	NOSTRUM LABORATORIES INC, KANSAS CITY, MO; UHC-PET IMAGING CETNER, IOWA CITY, IA; BURKE INC, KANSAS CITY, KS, ETC - 483S 2/1-28/14
2014-2228	03/18/2014 04/15/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	KENNETH HOADLEY NCS PEARSON	K020800
2014-2229	03/18/2014 04/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	ROBERT KING FDA NEWS	BOULE MEDICAL AB, STOCKHOLM, SWEDEN; I-SENS INC. SEOUL, SOUTH KOREA; VIRAMED BIOTECH AG, PLANEGG, GERMANY, ETC - 483S 2/1-28/14
2014-2230	03/18/2014 04/15/2014	FDA/OC/OES/DFOI/	LAURA LETENDRE MERIAL A SANOFI COMPANY	MECTIZAN - DOCS

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2014-2231	03/18/2014 04/15/2014	FDA/OC/OES/DFOI/	GAIL LESSICK LACHMAN CONSULTANT SERVICES INC	FOREIGN & DOMESTIC INSPS FOR DRUG COMPANIES, DVC MFRS, BIORESEARCH MONITORING ETC 8/13
2014-2232	03/18/2014 04/15/2014	FDA/OGROP/ORACE-FO/CIN- DO/CIN-CB/ FDA/OGROP/ORACE-FO/DET- DO/DET-CB/	STEVEN ELDER CAMPBELL TOBACCO REHANDLING COMPANY INC	CELTAB INC, MADISON, WI - EIR
2014-2233	03/18/2014 04/15/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ROBERT KING FDA NEWS	BIOFER SPA, MEDOLLA, ITALY; FARMEA, ANGERS CEDEX, FRANCE; TARO PHARMS, BRAMPTON, CANADA, ETC - 483S 2/1-28/14
2014-2234	03/18/2014 04/15/2014	FDA/OGROP/ORASE-FO/FLA- DO/FLA-CB/	ROBERT KING FDA NEWS	BELCHER PHARMACEUTICALS LLC, LARGO, FL; PURE SOURCE INC, DORAL, FL; AMS DIAGNOSTICS LLC, WESTON, FL, ETC - 483S 2/1-28/14
2014-2235	03/18/2014 04/15/2014	FDA/OGROP/ORAPA-FO/SAN- DO/SAN-CB/	SEAN YOHEY HAEMONETICS	HAEMONETICS , EL DORADO HILLS, CA - EIR, INSP
2014-2236	03/18/2014 04/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	CRISTINA MENDONSA KXTV NEWS 10	CONCEPTUS - ESSURE STERILIZATION DVC PMA
2014-2237	03/18/2014 04/15/2014	FDA/OGROP/ORACE-FO/DET- DO/DET-CB/	ROBERT KING FDA NEWS	JHP PHARMACEUTICALS LLC, ROCHESTER, MI; HILL-ROM INC, BATESVILLE, IN; APPLIED LABORATORIES INC,COLUMBUS, IN, ETC - 483S 2/1-28/14
2014-2238	03/18/2014 04/15/2014	FDA/OGROP/ORASW-FO/DEN- DO/DEN-CB/	ROBERT KING FDA NEWS	ENDEVR LLC, ST GEORGE, UT; DOHMEN LIFE SCIENCE SERVICES LLC, WHEAT RIDGE, CO; MEDTRONIC NAVIGATION INC, LOUISVILLE, CO - 483S 2/1-28/14
2014-2239	03/18/2014 04/15/2014	FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/	ROBERT KING FDANEWS	CELL GEN THERAPEUTICS, DALLAS, TX; MISSION PHARMACAL CO, BOERNE, TX; CBI LABORATORIES INC, FT WORTH, TX, ETC - 483S 2/1-28/14
2014-2240	03/18/2014 04/15/2014	FDA/OGROP/ORACE-FO/CIN- DO/CIN-CB/	ROBERT KING FDA NEWS	PI PHARMA INC, CAMPTON, KY; MILLER ARTIFICIAL EYE LABORATORY INC, TOLEDO, OH; AT SQUARED, BLUE ASH, OH, ETC - 483S 2/1-28/14
2014-2241	03/18/2014 04/15/2014	FDA/OGROP/ORACE-FO/BLT- DO/BLT-CB/	ROBERT KING FDA NEWS	PHARMACEUTICS INTERNATIONAL INC, HUNT VALLEY, MD; NOVASOM INC, GLEN BURNIE, MD; ROWNEY SYSTEMS (ANTIGEN PLUS), BETHESDA, MD, ETC - 483S 2/1-28/14
2014-2242	03/18/2014 04/15/2014	FDA/OGROP/ORASE-FO/ATL- DO/ATL-CB/	ROBERT KING FDA NEWS	HAEMONETICS CORP, UNION, SC; QUALITEST PHARMS, CHARLOTTE, NC; STEWART PHARMACEUTICAL INC, FAYETTEVILLE, NC - 483S 2/1-28/14
2014-2243	03/19/2014 04/16/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Josh Littlejohn MOTLEY RICE LLC	NDA 21366

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2014-2244	03/19/2014 04/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sebastian Jayaraj Rutgers Business School, Rutgers University, New Jersey	FDA Orange Book Drug patents from 2004-2014
2014-2245	03/19/2014 04/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	JOSEPH WALKER Walker, Joseph	SPINAL CORD STIMULATOR MDRs RE PARALYSIS 1/1/09 TO 3/17/14
2014-2246	03/19/2014 04/16/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Doe J	HEPATITIS A VACCINE AVAILABILITY
2014-2247	03/19/2014 04/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Daniel Balaban BALABAN, ALAN	KENALOG - CORR, EMAIL, MEDWATCH ETC
2014-2248	03/19/2014 04/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dave Garman Toronto Western Research Institute	NDA020191 - SBA
2014-2249	03/19/2014 04/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca L. Dandeker Morgan, Lewis & Bockius LLP	Halcyon Labs Pvt. Ltd. - EIR 1/1/10 TO 1/1/14
2014-2250	03/19/2014 04/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Daryl Loo BLOOMBERG NEWS	SHENZHEN HEPALINK PHARMACEUTICAL CO - 483 01/01/2011 - 03/18/2014
2014-2251	03/19/2014 04/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Daryl Loo BLOOMBERG NEWS	ZHEJIANG HUAHAI PHARMACEUTICAL CO - 483 01/01/2011 - 03/18/2014
2014-2252	03/19/2014 04/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Daryl Loo BLOOMBERG NEWS	ZHEJIANG KANGLE PHARMACEUTICAL CO - 483 01/01/2011 - 03/18/2014

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		FDA/OMPT/CDER/ORP/DIDP/		
2014-2253	03/19/2014 04/16/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Mark Lonsinger ViOptix Inc	K040684
2014-2254	03/19/2014 04/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Trung Huynh Jefferies LLC	JETREA - AERS
2014-2255	03/19/2014 04/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Pillsbury Winthrop Shaw Pittman LLP Pillsbury Winthrop Shaw Pittman LLP	ACTHAR GEL REPORT 01/04/2012 - 03/18/2014
2014-2256	03/19/2014 04/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Pillsbury Winthrop Shaw Pittman LLP PILLSBURY WINTHROP SHAW PITTMAN LLP	ACTHAR GEL REPORT AND LAB RESULTS
2014-2257	03/19/2014 04/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K120236
2014-2258	03/19/2014 04/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	Garry Hayeck STRYKER SPINE	K091088
2014-2259	03/19/2014 04/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 091135
2014-2260	03/19/2014 04/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	Gina To Sirius Engineering LLC	K080987
2014-2261	03/19/2014 04/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	Larry Robinette Larry Robinette	K133013
2014-2262	03/19/2014 04/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Stephen L. Richards Law Office of Stephen L. Richards	ACTHAR GEL REPORT DEC 2013
2014-2263	03/19/2014 04/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Cindy A. Arre Saalfeld Shad Stokes Inclan	AZITHROMYCIN - AERS

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Stoudemire & Stone, PA	
2014-2264	03/19/2014 04/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jerome Green Jerome Green	FDA approved drugs for the treatment of Bulimia Nervosa and Binge Eating Disorder
2014-2265	03/19/2014 04/16/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDRH/OCER/DFOI/	Delphine YSVELAIN DIAGNOSTICA STAGO INC	FDA DETERMINATION LETTER RE PREAMENDMENT STATUS OF THE POOLED NORMAL PLASMA FROM GEORGE KING BIO-MEDICAL INC
2014-2266	03/19/2014 04/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WF Yeung the University of Hong Kong	SILENOR - UNPUBLISHED DATA
2014-2267	03/19/2014 04/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PATEL, SANTOSH	POTASSIUM CHLORIDE, MAGNESIUM SULPHATE, OXYTOCIN, ETC - DRUG ERROR RPTS
2014-2268	03/19/2014 04/16/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	J. DONALD HENSON, SR Henson, J. Donald	P980022 - RECS
2014-2269	03/19/2014 04/16/2014	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 2/3-7/14
2014-2270	03/19/2014 04/16/2014	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 2/10-14/14
2014-2271	03/19/2014 04/16/2014	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 2/17-21/14
2014-2272	03/19/2014 04/16/2014	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 2/24-28/14
2014-2273	03/19/2014 04/16/2014	OC/CVM/OCD/	KIMBERLY OCKENE Humane Society of the United States	IMMUNOCONTRACEPTIVE DRUGS OR VACCINES FOR ANIMALS - APRVL RECS, MEMOS OF UNDERSTANDING (MOU)
2014-2274	03/19/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP	FOI DAILY LOG 2/3-7/14

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	04/16/2014	FDA/OC/OES/DFOI/	CanReg, Inc.	
2014-2275	03/19/2014 04/16/2014	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 2/10-14/14
2014-2276	03/19/2014 04/16/2014	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 2/17-21/14
2014-2277	03/19/2014 04/16/2014	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 2/24-28/14
2014-2278	03/19/2014 04/16/2014	FDA/OC/OES/DFOI/	DEBI L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 1/27-31/14
2014-2279	03/19/2014 04/16/2014	FDA/OC/OES/DFOI/	DEBI L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 2/3-7/14
2014-2280	03/19/2014 04/16/2014	FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 2/10-14/14
2014-2281	03/19/2014 04/16/2014	FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 2/17-21/14
2014-2282	03/19/2014 04/16/2014	FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 2/24-28/14
2014-2283	03/19/2014 04/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	A LUKE SMITH ESQ RADICE LAW FIRM	ANDA 77-571 - MEMO TO RECORD
2014-2284	03/19/2014 04/16/2014	FDA/OC/OES/DFOI/	GLADYS B TONKIN Center for Regulatory Services,Inc.	FOI DAILY LOG 1/27-31/14
2014-2285	03/19/2014 04/16/2014	FDA/OC/OES/DFOI/	GLADYS B TONKIN Center for Regulatory Services,Inc.	FOI DAILY LOG 2/3-7/14
2014-2286	03/19/2014 04/16/2014	FDA/OC/OES/DFOI/	GLADYS B TONKINS Center for Regulatory Services,Inc.	FOI DAILY LOG 2/10-14/14
2014-2287	03/19/2014 04/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	NATHANIEL FICK FICK & MAY LAW OFCS	V MUELLERHURST ESOPHAGEAL BOUGIE DILATOR - MDRS
2014-2288	03/19/2014	FDA/OC/OES/DFOI/	GLADYS B TONKIN	FOI DAILY LOG 2/17-21/14

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	04/16/2014		Center for Regulatory Services, Inc.	
2014-2289	03/19/2014 04/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WANDA BROWN NESMITH FELDMAN SHEPHERD ET AL	MIRALAX, POLYETHYLENE GLYCOL (PEG) LAXATIVES - RECALLS, AERS, Cmplnts, etc 1/00 TO PRESENT
2014-2290	03/19/2014 04/16/2014	FDA/OC/OES/DFOI/	GLADYS B TONKIN Center for Regulatory Services, Inc.	FOI DAILY LOG 2/24-28/14
2014-2291	03/19/2014 04/16/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 2/3-7/14
2014-2292	03/19/2014 04/16/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 2/10-14/14
2014-2293	03/19/2014 04/16/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WANDA BROWN NESMITH FELDMAN SHEPHERD ET AL	POLYETHYLENE GLYCOL (PEG) LAXATIVES - AERS, RECALLS, Cmplnts, etc 1/00 TO PRESENT
2014-2294	03/19/2014 04/16/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 2/17-21/14
2014-2295	03/19/2014 04/16/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 2/24-28/14
2014-2296	03/19/2014 04/16/2014	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 2/3-7/14
2014-2297	03/19/2014 04/16/2014	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 2/10-14/14
2014-2298	03/19/2014 04/16/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	LORI A CARR LORI A CARR INC	HA PMI FLANGED ACETABULAR COMPONENT K030861
2014-2299	03/19/2014 04/16/2014	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 2/17-21/14
2014-2300	03/19/2014 04/16/2014	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 2/24-28/14
2014-2301	03/19/2014 04/16/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 2/3-8/14
2014-2302	03/19/2014	FDA/OC/OES/DFOI/		FOI DAILY LOG 2/10-15/14

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	04/16/2014		FOI Services, Inc.	
2014-2303	03/19/2014 04/16/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 2/17-22/14
2014-2304	03/19/2014 04/16/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 2/24/14-3/1/14
2014-2305	03/19/2014 04/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	LORI A CARR LORI A CARR INC	NOVATION CROWN CUP WITH INTERGRIP ACETABULAR, SHELL CLUSTER-HOLE K102975
2014-2306	03/19/2014 04/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	LORI A CARR LORI A CARR INC	TRIATHLON TRITANIUM TIBIAL BASE PLATE K123486
2014-2307	03/19/2014 04/16/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Zeidberg, David	CADENCE PHARMS - OFIRMEV (IV ACETAMINOPHEN) STORAGE CONDITIONS, STABILITY, STERILITY RECS, ETC
2014-2308	03/19/2014 04/16/2014	OC/ORO/ OC/ORO/	LANGELLOTTI, JOSEPH	DRUGS ARE US INC (HOPEWELL PHARMACY), HOPEWELL, NJ - EIR, 483, CORR, ETC 3/18-21/13
2014-2309	03/19/2014 04/16/2014	FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	LESLIE SHOJI INTEREX INDUSTRIES LTD	MICRO QUALITY LABS, BURBANK, CA - EIR
2014-2310	03/19/2014 04/16/2014	FDA/OC/OES/DFOI/	GAIL LESSICK LACHMAN CONSULTANT SERVICES INC	DRUG COMPANIES, MEDICAL DVC MFRS, BIORESEARCH MONITORING (BIMO), ETC - FOREIGN AND DOMESTIC INSPS, 483S 9/1-30/13
2014-2311	03/19/2014 04/16/2014	FDA/OGROP/ORO/CE-FO/CHI-DO/CHI-CB/	BRENDA M GARTZ ELI LILLY & CO	PACKAGING COORDINATORS (ANDERSON BRECON)(ANDERSON PACKAGING), ROCKFORD, IL - EIR 8/20/13
2014-2312	03/19/2014 04/16/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mark Murray Aegerion Pharmaceuticals Inc	JUXTAPID - 9442885, 9680546, 9757565 ETC
2014-2313	03/19/2014 04/16/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ketaki Gokhale BLOOMBERG NEWS	USV LIMITED, INDIA - 483, RESPONSE, WARNING LETTER RESPONSE ETC 03/01/2012 - 03/19/2014
2014-2314	03/19/2014 04/16/2014	FDA/OGROP/ORO/CE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Maquet Mahler, Hans	MAQUET - 483 01/01/2012 - 01/01/2014

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2014-2315	03/19/2014 04/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	Diane Burnside KSPINEINC	K133904
2014-2316	03/19/2014 04/16/2014	FDA/OFVM/CFSAN/OCD/EOS/	Charleen Kubota Public Health Library, University of California Berkeley	HHE OF CAFFEINE SUBMITTED BY OAK RIDGE NATIONAL LABORATORY TO CFSAN
2014-2317	03/19/2014 04/16/2014	OC/ORA/ OC/ORA/ FDA/OGROP/ORPA-FO/LOS-DO/LOS-CB/ FDA/OC/OES/DFOI/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Doe J	INDIVIDUAL RECS
2014-2318	03/19/2014 04/16/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORPA-FO/SAN-DO/SAN-CB/	Oliver Alan Ruiz Malloy & Malloy, P.L.	CYTOSPORT - RECS RE WARNING LETTER; MUSCLE MILK RECS 01/01/2011 - 03/18/2014
2014-2319	03/19/2014 04/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dennis W, Raisch UNIVERSITY OF NEW MEXICO	NATALIZUMAB - AERS, MEDWATCH
2014-2320	03/19/2014 04/16/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Bryan Scholnick MULLIN LAW GROUP PLLC	GENERIC MEDICAL DEVICES, J-PAC - 483, RESPONSES, 510K ETC 01/01/2008 - 01/01/2013
2014-2321	03/19/2014 04/16/2014	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	NOVEL DETERMINANTS AND MEASURES OF SMOKELESS TOBACCO - INTERIM REPORT
2014-2322	03/19/2014 04/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Tobi Loreth Cangene Corporation dba Emergent Biosolutions	JEHANGIR CLINICAL DEVELOPMENT CENTER, INDIA - EIR 09/17/2012 - 09/22/2012
2014-2323	03/19/2014 04/29/2014	FDA/OC/OES/DFOI/	David Mangione Govzilla, Inc.	510K RELEASED 08/01/2013 - 03/19/2014
2014-2324	03/19/2014	OC/ORA/ORM/	David Mangione	LISTING OF 483, INSPECTION, EIR 01/17/2014 - 03/19/2014

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	04/16/2014	OC/ORO/ORM/	Govzilla, Inc.	
2014-2325	03/19/2014 04/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	B&H Consulting Services, Inc., Sandy Lee B&H Consulting Services, Inc.	SUN PHARMACEUTICAL INDUSTRIES LIMITED - EIR 11/13/2013 - 03/18/2014
2014-2326	03/19/2014 04/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	PATHEON, MONZA, ITALY - EIR 2/18/13
2014-2327	03/19/2014 04/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	PATHEON, FERENTINO, ITALY - EIR 6/3/13
2014-2328	03/19/2014 04/16/2014	FDA/OC/OES/DFOI/	JOHN H HNATIO ED PHD FoodQuestTQ LLC	FOODQUEST TQ VS FDA - INTELLECTUAL PROPERTY RECS
2014-2329	03/19/2014 04/16/2014	FDA/OC/OES/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jennifer Spotila Jennifer Spotila	Diagnostic Criteria for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome - FDA FINANCIAL CONTRIBUTION, FDA COMMUNICATIONS WITH OWH OR OAS
2014-2330	03/19/2014 05/05/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDRH/OCER/DFOI/	O'LAUGHLIN, TIMOTHY	MEDICAL TESTING EXPERIMENTAL RADIO LICENSES
2014-2331	03/19/2014 04/16/2014	FDA/OC/OES/DFOI/	John F. Weet Durata Therapeutics	FOIA LOG 02/14/2014 - 03/14/2014
2014-2332	03/19/2014 04/16/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-1172 -REQUEST LETTER ONLY
2014-2333	03/19/2014 04/16/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-1287 - REQUEST LETTER ONLY
2014-2334	03/19/2014 04/16/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-1399 - REQUEST LETTER ONLY
2014-2335	03/19/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2014-879 - REQUEST LETTER ONLY

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	04/16/2014		MERCK & CO., INC.	
2014-2336	03/19/2014 04/16/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-832 - REQUEST LETTER ONLY
2014-2337	03/19/2014 04/16/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-1074 - REQUEST LETTER ONLY
2014-2338	03/19/2014 04/16/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-823 - REQUEST LETTER ONLY
2014-2339	03/19/2014 04/16/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-1528 - REQUEST LETTER ONLY
2014-2340	03/19/2014 04/16/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-1547 - REQUEST LETTER ONLY
2014-2341	03/19/2014 04/16/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-1479 - REQUEST LETTER ONLY
2014-2342	03/19/2014 04/16/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-1119 - REQUEST LETTER ONLY
2014-2343	03/19/2014 04/16/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-1111 - REQUEST LETTER ONLY
2014-2344	03/19/2014 04/16/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-1130 - REQUEST LETTER ONLY
2014-2345	03/19/2014 04/16/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-1456 - REQUEST LETTER ONLY
2014-2346	03/19/2014 04/16/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-847 - REQUEST LETTER ONLY
2014-2347	03/19/2014 04/16/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-838 - REQUEST LETTER ONLY
2014-2348	03/20/2014 04/17/2014	FDA/OFVM/CFSAN/OCD/EOS/	Dr. John Hnatio FoodQuestTQ LLC	FOOD DEFENSE PLAN BUILDER ETC - SOURCE CODE ETC
2014-2349	03/20/2014 04/17/2014	FDA/OC/OCC/ FDA/OFVM/CFSAN/OCD/EOS/	Dr. John Hnatio FoodQuestTQ LLC	JIFSAN - ORGANIZATIONAL CHART, INTELLECTUAL PROPERTY POLICIES 03/01/2009 - 03/14/2014
2014-2350	03/20/2014 04/17/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/OIP/	Dr. John Hnatio FoodQuestTQ LLC	NATIONAL FOOD PROTECTION PLAN ETC - COOPERATION WITH FOREIGN GOVERNMENTS ETC 01/01/2006 - 03/17/2014
2014-2351	03/20/2014 04/17/2014	FDA/OO/OFBA/OAGS/	Dr. John H. Hnatio FoodQuestTQ LLC	BATTELLE, VALBREA TECHNOLOGIES, LEAVITT PARTNERS ETC - CONTRACTS RE NATIONAL FOOD PROTECTION PLAN ETC

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2014-2352	03/20/2014 04/17/2014	FDA/OC/OEXA/OMA/ FDA/OFVM/CFSAN/OCD/EOS/	John Hnatio FoodQuestTQ LLC	DISCUSSIONS BETWEEN FDA, HHS, AND MEDIA RE FOODQUEST TQ V. FDA AND HHS 01/01/2012 - 03/17/2014
2014-2353	03/20/2014 04/17/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OO/OFBA/OAGS/	Dr. John Hnatio FoodQuestTQ LLC	DR JENNIFER MCENTIRE - CONTRACT RECS, INVOLVEMENT WITH NATIONAL FOOD PROTECTION PLAN ETC 01/01/2006 - 03/17/2014
2014-2354	03/20/2014 04/17/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OO/OFBA/OAGS/ FDA/OO/OHR/	Dr. John H. Hnatio FoodQuestTQ LLC	DR ROBERT BUCHANAN - EMPLOYEE RECS, CONTRACTS, ETHICS TRAINING ETC
2014-2355	03/20/2014 04/17/2014	FDA/OFVM/CFSAN/OCD/EOS/	Dr. John H. Hnatio FoodQuestTQ LLC	FOOD DEFENSE TEAM - ETHICS TRAINING 01/01/2006 - 03/17/2014
2014-2356	03/20/2014 04/17/2014	FDA/OC/OES/DFOI/	Dr. John Hnatio FoodQuestTQ LLC	RECS RE SECRETARY OF HHS, FOODQUEST TQ 01/01/2012 - 03/17/2014
2014-2357	03/20/2014 04/17/2014	FDA/OC/OL/ FDA/OC/OES/DFOI/	Dr. John Hnatio FoodQuestTQ LLC	COMMUNICATIONS WITH CONGRESS RE FOODQUEST TQ 01/01/2012 - 03/17/2014
2014-2358	03/20/2014 04/17/2014	FDA/OFVM/CFSAN/OCD/EOS/	Dr. John Hnatio FoodQuestTQ LLC	DR JOHN HNATIO, DR BART MICHELSON, MR DAVID PARK ETC - SIGN IN SHEETS
2014-2359	03/20/2014 04/17/2014	FDA/OC/OES/DFOI/	Dr, John H. Hnatio FoodQuestTQ LLC	DALE BERKELEY RECS RE FOODQUEST TQ
2014-2360	03/20/2014 04/17/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OO/OFBA/OAGS/ FDA/OO/OHR/	Dr. John Hnatio FoodQuestTQ LLC	DR ACHESON - EMPLOYMENT RECS, CONTRACTS, ETHICS TRAINING ETC
2014-2361	03/20/2014 04/17/2014	FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OCC/	Dr. John Hnatio FoodQuestTQ LLC	NATIONAL FOOD PROTECTION PLAN - PATENT RECS
2014-2362	03/20/2014 04/17/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WRIGHT 05449-010, JAMES	CELEXA, ZOLOFT, PROZAC, ETC - AERS
2014-2363	03/20/2014 04/17/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GARY L WILSON ROBINS KAPLAN MILLER & CIRESI LLP	DAIICHI SANKYO INC, DAIICHI SANKYO US HOLDINGS, RANBAXY LABORATORIES INC, ETC - BENICAR (OLMESARTAN MEDOXOMIL) AERS, COMM
2014-2364	03/20/2014 04/17/2014	FDA/OFVM/CFSAN/OCD/EOS/	ROBERT BENINCASA NPR National Public Radio	CAERS - COMM, NOTES, ANNOTATIONS, ETC

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2014-2365	03/20/2014 04/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	MOSHE ROSENBERG A STEIN REGULATORY AFFAIRS CONSULTING LTD	BL HEALTHCARE INC - TCX-I REMOTE CARE MANAGEMENT SYS K113493
2014-2366	03/20/2014 04/17/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARSHALL P LEVINE ESPALIER GLOBAL	QUESTCOR PHARMS - HP ACTHAR GEL, SYNACTHEN, ACTH FORM 1572 1/1/09 TO 3/17/14
2014-2367	03/20/2014 04/17/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WILLIAM MCCONAHA SIDLEY AUSTIN LLP	COLGATE TOTAL NDA 20-231 - PHARMACOLOGY AND TOXICOLOGY RVW
2014-2368	03/20/2014 05/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOANNE MOSKOVIC Moskovic & Associates, Ltd.	SYMBYAX - CMLPNTS 1/05 TO PRESENTS
2014-2369	03/20/2014 04/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	AMANDA JOHNSON SPECTRANETICS CORP	CPT1300565 - INVESTIGATION RECS
2014-2370	03/20/2014 04/17/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TYLER J SCHNEIDER TOR HOERMAN LAW LLC	MINASTRIN 24 FE (NORETHINDRONE ACETATE AND ETHINYL ESTRADIOL TABS AND FERROUS FUMARATE TABS) - SAFETY RPTS, LAB EVALUATIONS, CLNCL PHARMACOLOGY RVWS, ETC
2014-2371	03/20/2014 04/17/2014	OC/ORO/OCI/ OC/ORO/OCI/	BRASSEUR, KYLE	USE OF PERFORMANCE-ENHANCING DRUGS BY FORMER MAJOR LEAGUE BASEBALL ALL-STAR KEN CAMINITI - RECS
2014-2372	03/20/2014 04/17/2014	OC/CVM/OCD/	PATTERSON, KELSEY	GENETICALLY ENGINEERED ANIMALS - NUMBER OF INADS AND NADAS RECEIVED BY CALENDAR YEAR OR FISCAL YEAR
2014-2373	03/20/2014 04/17/2014	FDA/OGROP/ORO/SE-FO/FLA- DO/FLA-CB/ FDA/OC/OES/DFOI/	ANN ALBOLOTE RITEDOSE CORP	NEPHRON PHARMACEUTICALS CORP, ORLANDO, FL - 483 2/14
2014-2374	03/20/2014 04/17/2014	FDA/OC/OCC/ FDA/OFVM/CFSSAN/OCD/EOS/	SMITH, MICHAEL P	DRAFT FEDERALISM IMPACT STATEMENTS FOR THE FOOD SAFETY MODERNIZATION ACT (FSMA) STANDARDS FOR THE GROWING, HARVESTING,PACKING,AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION (PRODUCE RULE)
2014-2375	03/20/2014 04/17/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Zeidberg, David	CADENCE PHARMS - OFIRMEV (IV ACETAMINOPHEN) STABILITY, STERILITY RECS, STORAGE CONDITIONS, ETC

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2014-2376	03/20/2014 04/17/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Flock, Andrew J	IMPAX, TEVA - BUDEPRION XL 300MG AERS AFTER SWITCHING FROM WELLBUTRIN
2014-2377	03/20/2014 04/17/2014	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	JENNIFER HSIEH DEERFIELD INSTITUTE	CONMED CORP, CENTENNIAL, CO - 483 8/12/13-9/20/13
2014-2378	03/20/2014 04/17/2014	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	KRISTIN RIZZO RIZZO LAW PC	PLANNED PARENTHOOD, CHULA VISTA, CA - PHARMACEUTICAL AUDIT/MEDICATION HANDLING CITATION 1/14 OR 2/14
2014-2379	03/20/2014 04/17/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SUSANNE COLLINS PATHEON INC	TOMITA PHARMACEUTICAL CO LTD, TOKUSHIMA, JAPAN - EIR, 483 9/10
2014-2380	03/20/2014 05/22/2014	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	STELLA K HERRERA GRIFOLS BIOLOGICALS INC	HOSPIRA, ROCKY MOUNT, NC - EIRS, 483S 1/11 TO 2/14
2014-2381	03/20/2014 04/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	BILLAKANTI, SAM	MANNKIND CORP - TECHNOSPHERE AERS 1/09 TO PRESENT
2014-2382	03/20/2014 04/17/2014	FDA/OFVM/CFSAN/OCD/EOS/	FRIEDMAN, ROBERT	GREY POUPON, KRAFT MIRACLE WHIP, HELLMAN'S, ETC - CAERS 1969 TO 2014
2014-2383	03/20/2014 04/17/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	A LUKE SMITH ESQ FARUQI & FARUQI LLP	SANDOZ - REGAGLINIDE ANDA 78-555 APRVL ROUTING SUMMARY
2014-2384	03/20/2014 04/17/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	A LUKE SMITH ESQ FARUQI & FARUQI LLP	PADDOCK - REGAGLINIDE ANDA 201-189 APRVL ROUTING SUMMARY
2014-2385	03/20/2014 04/17/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	A LUKE SMITH ESQ FARUQI & FARUQI LLP	MYLAN - REGAGLINIDE ANDA 90-252 APRVL ROUTING SUMMARY

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2014-2386	03/20/2014 04/17/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	A LUKE SMITH ESQ FARUQI & FARUQI LLP	AUROBINDO - REGAGLINIDE ANDA 203-820 APRVL ROUTING SUMMARY
2014-2387	03/20/2014 04/17/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	A LUKE SMITH ESQ FARUQI & FARUQI LLP	ACTAVIS TOTOWA - REGAGLINIDE ANDA 90-008 APRVL ROUTING SUMMARY
2014-2388	03/20/2014 04/17/2014	FDA/OC/OES/DFOI/	ELENA HOWELL HOGAN LOVELLS US LLP	2013-1466
2014-2389	03/20/2014 04/17/2014	FDA/OC/OES/DFOI/	ELENA HOWELL HOGAN LOVELLS US LLP	2014-1467
2014-2390	03/20/2014 04/17/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	PROLIA - RECS
2014-2391	03/20/2014 04/17/2014	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 1/27/13-1/31/14
2014-2392	03/20/2014 04/17/2014	FDA/OC/OES/DFOI/	JH BARR & ASSOCIATES LLC	DAILY LOG 2/24-28/13
2014-2393	03/20/2014 04/17/2014	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 2/17-21/13
2014-2394	03/20/2014 04/17/2014	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 2/10-14/13
2014-2395	03/20/2014 04/17/2014	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 2/3-7/13
2014-2396	03/20/2014 04/17/2014	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 1/27-31/13
2014-2397	03/20/2014 04/17/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 2/24-28/14
2014-2398	03/20/2014 04/17/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 2/17-21/14

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2014-2399	03/20/2014 04/17/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 1/27-31/14
2014-2400	03/20/2014 04/17/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 2/3-7/14
2014-2401	03/20/2014 04/17/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 2/10-14/14
2014-2402	03/20/2014 04/17/2014	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 2/17-21/14
2014-2403	03/20/2014 04/17/2014	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 1/27-31/14
2014-2404	03/20/2014 04/17/2014	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 2/24-28/14
2014-2405	03/20/2014 04/17/2014	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 1/27-2/1/14
2014-2406	03/20/2014 04/17/2014	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 2/10-14/14
2014-2407	03/20/2014 04/17/2014	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 2/3-7/14
2014-2408	03/20/2014 04/17/2014	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DAVID MacFARLAND FDA REVIEW/FDA WEBVIEW	DAILY CLOSED LOG 2/24-28/14
2014-2409	03/20/2014 04/17/2014	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DAVID MacFARLAND FDA REVIEW/FDA WEBVIEW	DAILY CLOSED LOG 2/17-21/14
2014-2410	03/20/2014 04/17/2014	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DAVID MacFARLAND FDA REVIEW/FDA WEBVIEW	DAILY CLOSED LOG 2/10-14/14
2014-2411	03/20/2014 04/17/2014	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DAVID MacFARLAND FDA REVIEW/FDA WEBVIEW	DAILY CLOSED LOG 2/3-7/14
2014-2412	03/20/2014 04/17/2014	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DAVID McFARLAND FDA REVIEW/FDA WEBVIEW	DAILY CLOSED LOG 1/27-31/14
2014-2413	03/20/2014 04/17/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 1/27-2/1/14
2014-2414	03/20/2014	FDA/OC/OES/DFOI/		DAILY CLOSED LOG 2/24-3/1/14

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	04/17/2014		FOI Services, Inc.	
2014-2415	03/20/2014 04/17/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 2/17-22/14
2014-2416	03/20/2014 04/17/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 1/27-2/1/14
2014-2417	03/20/2014 04/17/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 2/10-15/14
2014-2418	03/20/2014 04/17/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 2/3-8/14
2014-2419	03/20/2014 04/17/2014	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 1/27-31/14
2014-2420	03/20/2014 04/17/2014	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	CLOSED LOG 1/27-31/14
2014-2421	03/21/2014 04/18/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Adrienne E Faerber - Phone 608.345.5380 Dartmouth Inst. Cent. For Med. Media.	NDA 019962 S 33, BLA 103795 S 1004, 5051, 5097, 5110; NDA 022399 S 3 ETC
2014-2422	03/21/2014 04/18/2014	FDA/OC/OES/DFOI/	Tao Li UNIVERSITY OF WARWICK	FDA FOIA LOG 01/01/2007 - 12/31/2013
2014-2423	03/21/2014 04/18/2014	FDA/OMPT/CDRH/OCER/DFOI/	David Livingston Dave Livingston	K885306 - PH, TESTING INFORMATION FOR BIOCOMPATIBILITY
2014-2424	03/21/2014 04/18/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jonathan Balk Houston Methodist Hospital	FERRIC CARBOXYMALTOSE - AERS
2014-2425	03/21/2014 04/18/2014	FDA/OMPT/CDRH/OCER/DFOI/	Shan Siddiqui Mediflex, A Division of Flexbar	K103726, K113407
2014-2426	03/21/2014 04/18/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Robert Blanks Blanks, Robert	SODIUM POLYSTYRENE SULFONATE - AERS
2014-2427	03/21/2014	FDA/OC/OES/DFOI/	Adam J. Gomez	RANCHO FEEDING CORPORATION, PETALUMA, CA - RECALL RECS 01/01/2013 - 03/19/2014

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	04/18/2014		WADE CLARK MULCAHY	
2014-2428	03/21/2014 04/18/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/	DONALD N BLUE ZETETIC	ALL SHIPMENTS REGULATED BY FDA 2/26/14-3/19/14
2014-2429	03/21/2014 04/18/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	BRETT PARK CONWAY HOMER & CHIN- CAPLAN PC	INDIVIDUAL RECS (CERTIFIED)
2014-2430	03/21/2014 04/18/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	BRETT PARK CONWAY HOMER & CHIN- CAPLAN PC	INDIVIDUAL RECS (CERTIFIED)
2014-2431	03/21/2014 04/18/2014	FDA/OO/OHR/ FDA/OGROP/ORO/NE-FO/NYK- DO/NYK-DCB/	DAVID H MATOLA DAVID H MATOLA ESQ	INDIVIDUAL RECS (CERTIFIED)
2014-2432	03/21/2014 04/18/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Adrienne E Faerber - 608.345.5380 Dartmouth Inst. Cent. For Med. Media.	NDA 018164, NDA 020204, NDA 20353 ETC
2014-2433	03/21/2014 04/18/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Adrienne E Faerber - Phone 608.345.5380 Dartmouth Inst. Cent. For Med. Media.	NDA 019810 S 55, 61, 74; NDA 019558; NDA 019766 S 56 ETC
2014-2434	03/21/2014 04/18/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sara Xiao Hisun Pharmaceuticals USA, Inc.	NDA 019856
2014-2435	03/21/2014 04/18/2014	OC/CVM/OCD/ FDA/OC/OCC/ FDA/OC/OES/	Jesse Newman THE WALL STREET JOURNAL	PED VIRUS AND ANIMAL FEED 04/01/2013 - 03/19/2014
2014-2436	03/21/2014 04/18/2014	FDA/OGROP/ORO/CE-FO/CHI- DO/CHI-CB/	TAMERA A SMITH NORTH AUDITS INC	DURATA THERAPEUTICS - INSP, RPTS, COMM 5/2/02 TO 3/18/14
2014-2437	03/21/2014 04/18/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MICHAEL R COHEN INSTITUTE FOR MEDICATION PRACTICES	MEDWATCH RPTS CODED AS MEDICATION ERRORS 2/1- 28/14

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2014-2438	03/21/2014 04/18/2014	FDA/OC/OES/DFOI/	Cody Claassen DeVaughn James Injury Lawyers	INDIVIDUAL RECS
2014-2439	03/21/2014 04/18/2014	FDA/OMPT/CDRH/OCER/DFOI/	MICHELE L BUENAFE MORGAN LEWIS COUNSELORS AT LAW	513(G) REQUESTS - CORR, RESP 1/12 TO PRESENT
2014-2440	03/21/2014 04/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	AMY MITCHELL GlaxoSmithKline	WARE - QAP
2014-2441	03/21/2014 04/18/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	Mark Steinke The Spine Education and Research Institute	CENTER FOR SPINE DISORDERS, THORNTON, CO - COMPLAINT INVESTIGATION 01/01/2013 - 12/31/2013
2014-2442	03/21/2014 04/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TAMI T MARTIN SUPERNUS PHARMACEUTICALS INC	UPSHER SMITH LABS - QUDEXY XR NDA 205-122 MEDICAL RVWS, STATISTICAL RVWS, CLNCL PHARMACOLOGY RVW, ETC
2014-2443	03/21/2014 04/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANURAG PATEL DR REDDY'S	WATSON LABS INC - LIDOCAINE ANDA 200-675 SBA
2014-2444	03/21/2014 04/18/2014	FDA/OFVM/CFSAN/OCD/EOS/	SUSAN MATTHEES GENERAL MILLS	WRIGLEY JR CO - SYNTHETIC IRON OXIDE DKT FDA-2013-C-1008
2014-2445	03/21/2014 04/18/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORAPPA-FO/SEA-DO/SEA-CB/	CARRIE P MORGAN OLSSON FRANK WEEDA TERMAN MATZ PC	METAGENICS INC - WARNING LTR SEA 13-27 MEETINGS, ATTACHMENTS, EXHIBITS
2014-2446	03/21/2014 04/18/2014	FDA/OFVM/CFSAN/OCD/EOS/	SUZANNE D JENSEN KLEINFELD KAPLAN & BECKER	HHE #8579, HHE #8082
2014-2447	03/21/2014 04/18/2014	FDA/OC/OES/DFOI/	MORELAND 147565, SAMUEL	CP 2004P-0472
2014-2448	03/21/2014 04/18/2014	FDA/OFVM/CFSAN/OCD/EOS/	GARCIA, MERCEDES	POLIGONO INDUSTRIAL FINZA LACY II, ELDA (ALICANTE), SPAIN - CERTIFICATE OF DIETARY SUPPL
2014-2449	03/21/2014 04/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ross Gibson Ross Gibson	ORAL ISOTRETINOIN, ACCUTANE, ROACCUTANE - AERS

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		FDA/OMPT/CDER/ORP/DIDP/		
2014-2450	03/21/2014 04/18/2014	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	Carrie O'Halloran NOW FOODS	GARDEN OF LIFE - EIR, 483 10/01/2013 - 12/31/2013
2014-2451	03/21/2014 04/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nicole Maisch St. John's University	Xartemis XR - APPROVAL RECS
2014-2452	03/21/2014 04/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Vince H. Suneja TwoFour Insight Group, LLC	RANBAXY DEWAS, INDIA - 483 02/01/2008 - 04/01/2008
2014-2453	03/21/2014 04/18/2014	FDA/OC/OES/ FDA/OC/OCC/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	CHERYL BLUME, PHARMACUETICAL DEVELOPMENT GROUP - CALENDAR ENTRIES, VISITOR LOGS, SIGN IN SHEETS ETC
2014-2454	03/21/2014 04/25/2014	FDA/OMPT/CTP/OD/	Stacy Ehrlich Kleinfeld Kaplan and Becker LLP	RECS SUBMITTED TO CTP IN RESPONSE TO REQUESTS ISSUED BY CTP TO TOBACCO PRODUCT MANUFACTURERS OR IMPORTERS UNDER 904(b) OF 21 U.S.C. 387d(b)
2014-2455	03/21/2014 04/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ustekinumab and autoimmune hepatitis WEST VIRGINIA UNIVERSITY	USTEKINUMAB - AERS
2014-2456	03/21/2014 04/18/2014	FDA/OMPT/CDRH/OCER/DFOI/	Phyllis Scalettar Scalettar, Phyllis G	HIP IMPLANTS - FRETTING AND HEAD/NECK AND/OR NECK-STEM JUNCTURE - REPORTS OF FRETTING, RESULTS OF TESTS FOR FRETTING ETC
2014-2457	03/21/2014 04/18/2014	FDA/OGROP/ORR/PA-FO/SEA-DO/SEA-CB/	Thuc-Chinh Nguyen FRED HUTCHINSON CANCER RESEARCH CENTER	WILLIAM BENSINGER, SEATTLE, WA - 483 05/17/2004 - 05/17/2004
2014-2458	03/21/2014 04/18/2014	FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OES/DDM/	Lena Gomez Keller and Heckman LLP	98P-0683
2014-2459	03/21/2014	FDA/OC/OES/DFOI/	John Bonasera	K102733, K072073, K122134

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	04/18/2014	FDA/OMPT/CDRH/OCER/DFOI/	Medrobotics Corporation	
2014-2460	03/21/2014	FDA/OMPT/CDER/ORP/DIDP/	David L. Rosen , BS Pharm, JD	NDA 760305
	04/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	FOLEY & LARDNER LLP	
2014-2461	03/24/2014	FDA/OGROP/ORR/CE-FO/BLT-DO/BLT-CB/	Rachel Johnson	UNILEVER LIPTON, SUFFOLK, VA - EIR, 483
	04/21/2014		FOI Services, Inc.	
2014-2462	03/24/2014	FDA/OMPT/CDER/ORP/DIDP/	LyCynthia Baskin	CONTAMINATED MYFORTIC - INVESTIGATION RECS, TEST RESULTS 12/01/2013 - 03/28/2014
	05/01/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	Baskin, LyCynthia	
2014-2463	03/24/2014	FDA/OMPT/CDER/ORP/DIDP/	David L. Rosen, BS Pharm, JD	ACTHAR GEL REPORT DECEMBER 2013
	04/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOLEY & LARDNER LLP	
2014-2464	03/24/2014	FDA/OMPT/CDER/ORP/DIDP/	Daniel Balaban	BRISTOL MYERS SQUIBB - 483, EIR RE KENALOG, RECALL RECS 01/11/2000 - 01/11/2012
	04/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Balaban, Daniel K	
2014-2465	03/24/2014	FDA/OGROP/ORR/SW-FO/DEN-DO/DEN-CB/	Jason Ahlmann	ZIJA INTERNATIONAL, LEHI, UT - INVEVSTIGATION RECS, VIOLATIONS, COMPLAINTS 09/01/2013 - 03/20/2014
	04/21/2014		Zija International, Inc.	
2014-2466	03/24/2014	FDA/OMPT/CDER/ORP/DIDP/	Kristin Cooklin	NDA 008372
	04/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Crowell & Moring LLP	
2014-2467	03/24/2014	FDA/OMPT/CDER/ORP/DIDP/	Victoria St. Martin	ORAL CONTRACEPTIVES WITH ESTROGEN AND PROGESTERONE - AERS
	04/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	THE WASHINGTON POST	
2014-2468	03/24/2014	FDA/OMPT/CBER/OCOD/DDOM/	Joan Stitt (UG2CD-16)	MERCK AND CO, DURHAM, NC - INSPECTOR NOTES

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	04/21/2014	ALFB/	MERCK & CO., INC.	AUGUST 2012
2014-2469	03/24/2014 04/21/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K935955
2014-2470	03/24/2014 04/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K121609
2014-2471	03/24/2014 04/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K9408835
2014-2472	03/24/2014 04/21/2014	FDA/OGROP/ORASE-FO/ATL- DO/ATL-CB/	Andrew O'Hara PRODIGY DIABETES CARE, LLC	PRODIGY DIABETES CARE LLC, CHARLOTTE, NC - EIR 01/07/2014 - 03/21/2014
2014-2473	03/24/2014 04/21/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Linnea Robbins Robbins, Linnea	EVERGREEN HOSPITAL MEDICAL CENTER - ADVERSE EVENT RECORDS 6/4/2013
2014-2474	03/24/2014 04/21/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	EARL GOEHRING THE DEGGE GROUP LTD	GABAPENTIN - AERS
2014-2475	03/24/2014 04/21/2014	FDA/OGROP/ORASW-FO/KAN- DO/KAN-CB/	Legal seca Corporation	CARDINAL SCALE MANUFACTURING CO DBA DETECTO SCALE, WEBB CITY, MO - ENFORCEMENT RECS 07/25/2012 - 03/21/2014
2014-2476	03/24/2014 04/21/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	William Stahovec Catalyst Pharmaceutical Partners	ANDA 074346
2014-2477	03/24/2014 04/21/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jeffrey Peart Hyperion Therapeutics, Inc.	NDA 203284
2014-2478	03/24/2014 04/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	Mark Palmieri NOVO NORDISK INC	K120206
2014-2479	03/24/2014 04/21/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KATE REYNOLDS ROCKY MOUNTAIN POISON & DRUG CENTER	COUGH AND COLD PREPARATIONS - ISRS 8995919, 8999980, 9067651, ETC

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2014-2480	03/24/2014 04/21/2014	FDA/OFVM/CFSAN/OCD/EOS/	RICHARD N KESSLER MCDONALD HOPKINS LLC	KEFIR - LBLG CORR LAST 18 MONTHS
2014-2481	03/24/2014 04/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	JACK E HOLT III GROWER KETCHAM ET AL	WILLIAM Y LU MD, ORLANDO NEUROSURGERY CONSULTANTS - ANCHOR FIXATION IDE G100019 RESEARCH STUDY RECS
2014-2482	03/24/2014 04/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	AUDREY ALIBRANTI EGAN ETHYPHARM USA CORP	SUBOXONE (BUPRENORPHINE AND NALOXONE) SUBLINGUAL FILM NDA 22-410/S014 - RVW RECS FOR MFG CHANGE OR ADDITION
2014-2483	03/24/2014 04/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JENNIFER RICHNAFSKY SCHULTE, ROTH & ZABEL LLP	GW PHARMS/GW PHARMA; CANNABIDIOL/CBD, SATIVEX, EPIDIOLEX, ETC - EMAILS 1/12 TO PRESENT
2014-2484	03/24/2014 04/21/2014	FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JENNIFER RICHNAFSKY SCHULTE, ROTH & ZABEL LLP	RAPTOR PHARMS; CYSTAGON, PROCYSBI, RP103, ETC - EMAILS 1/12 TO PRESENT
2014-2485	03/24/2014 04/21/2014	FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	JENNIFER RICHNAFSKY SCHULTE, ROTH & ZABEL LLP	EDWARDS LIFESCIENCES; SAPIEN, COREVALVE, SURTAVI, ETC - EMAILS 1/11 TO PRESENT
2014-2486	03/24/2014 04/21/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/SEA-DO/SEA-CB/	DARROCH H CAHEN FRYE ELECTRONICS, INC.	AUDIO PRECISION INC - CMLPNT 132609
2014-2487	03/24/2014 04/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHERISSE SANDERS-HARALSON COMMUNITY ACTION AGAINST ADDICTION	CONSENT TO METHADONE TREATMENT FD-2635 FORM 12/72
2014-2488	03/24/2014 04/21/2014	FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/	JOHN J APPELL ESQ JOHN J APPELL LAW OFCS	MONGIELLO ITALIAN CHEESE SPECIALTIES INC (FORMAGGIO), HURLEYVILLE, NY - EIRS, RECALL NOTICES, FOOD ASSESSMENTS, ETC LAST FIVE YRS
2014-2489	03/24/2014 04/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID J FISCHMAN JAROSLAWICZ & JAROS LAW OFCS	BISPHOSPHONATES - FDA ALERT 1/7/08 (CERTIFIED)

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2014-2490	03/24/2014 04/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/OIP/	S ALBERT EDWARDS, PHARM D	EMA, FDA - FLUOROQUINOLONES MEMORANDUM OF UNDERSTANDING, WARNING LABEL
2014-2491	03/24/2014 04/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	JENNIFER HSIEH DEERFIELD INSTITUTE	KLEINER PERKINS CAUFIELD & BYERS DIAGNOSTICS - MTG MINS, AGENDA, CORR, ETC 3/12/14
2014-2492	03/24/2014 04/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	GLIMEPIRIDE TABS ANDA 76-875 - BIOEQV RVW
2014-2493	03/24/2014 04/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	GLIMEPRIRIDE TABS ANDA 77-370 - BIOEQV RVW
2014-2494	03/24/2014 04/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	CHARLES CELESTE EAS CONSULTING GROUP LLC	BEN VENUE LABORATORIES INC, BEDFORD, OH - EIRS, 483S, WARNING LTRS 1/09 TO PRESENT
2014-2495	03/24/2014 04/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	UMBERGER, CHRIS	LYRICA, CYMBALTA, LUNESTA, ETC - RECS
2014-2496	03/24/2014 04/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	INDIVIDUAL RECS
2014-2497	03/24/2014 04/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ketaki Gokhale BLOOMBERG NEWS	CRO FIRMS IN INDIA - 483 1/1/13 TO 3/14/14

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2014-2498	03/25/2014 04/22/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	B&H Consulting Services, Inc., Sandy Lee B&H Consulting Services, Inc.	CORR BETWEEN FDA AND KELLOGG CANCER CENTER 01/30/2014 - 03/19/2014
2014-2499	03/25/2014 04/22/2014	FDA/OFVM/CFSAN/OCD/EOS/	Roger Golden Roger N. Golden, APC	SHAN BEST CHOICE FOOD CO, LTD - REGISTRATION RECS 03/01/2009 - 03/20/2014
2014-2500	03/25/2014 04/22/2014	FDA/OFVM/CFSAN/OCD/EOS/	Roger N. Golden Roger N. Golden, APC	ASIACORP INC - REGISTRATION RECS 03/01/2009 - 03/20/2014
2014-2501	03/25/2014 04/22/2014	FDA/OFVM/CFSAN/OCD/EOS/	Roger N. Golden Roger N. Golden, APC	SINO GREAT CORPORATION - REGISTRATION RECS 03/01/2009 - 03/20/2014
2014-2502	03/25/2014 04/22/2014	FDA/OC/OES/DFOI/	Robert Blaskiewicz Skeptics for the Protection of Cancer Patients	AMPOLGEN PHARMACEUTICALS, HOUSTON, TX - 483 01/01/1995 - 03/20/2014
2014-2503	03/25/2014 04/22/2014	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	Steven Zeig, MD Steven Zeig, MD	STEVEN ZEIG - 483 03/04/1993 - 09/15/1993
2014-2504	03/25/2014 04/22/2014	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lee D. Cope Peters, Murdaugh, Parker, Eltzroth & Detrick	PROPOFOL AT AIKEN SURGERY CENTER, AIKEN, SC - INVESTIGATION REPORT 12/12/2011 - 12/12/2012
2014-2505	03/25/2014 04/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	Simona Fiori Thema s.r.l.	K032572
2014-2506	03/25/2014 04/22/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Michael Gusel Topcon Medical Systems, Inc.	K100202
2014-2507	03/25/2014 04/22/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tobramycin 0.3% Ophthalmic Solution NDA 050541 Altaire Pharmaceuticals, Inc.	NDA 050541
2014-2508	03/25/2014 04/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	Martine Schneider CooperVision, Inc.	K133740

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2014-2509	03/25/2014 04/22/2014	FDA/OC/OCC/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OO/OFBA/OAGS/	DENNIS C GUCCIARDO Hogan Lovells, ILP	ANTONI (TONY) NARGOL, UNIV HOSP OF NORTH TEES, UK & FDA - EMAILS, CORR, MINS, ETC
2014-2510	03/25/2014 04/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	DENNIS C GUCCIARDO Hogan Lovells, ILP	DR. DAVID LANGTON, PXD, NEWCASTLE UNIV, THE NORTHERN RETRIEVAL REGISTRY OR NORTH TEES EXPLANT CENTRE - CORR TELEPHONE MTGS, MINS
2014-2511	03/25/2014 04/22/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OO/OFBA/OAGS/	DENNIS C GUCCIARDO Hogan Lovells, ILP	DR DAVID LANGTON, PXD, NEWCASTLE UNIV, THE NORTHERN RETRIEVAL REGISTRY OR NORTH TEES EXPLANT CENTRE - CONTRACTS, CONFLICT OF INTEREST FORMS, LITIGATION
2014-2512	03/25/2014 04/22/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Juan Pedro Rodriguez Juan Pedro Rodríguez	HILTONOL - IND 43984
2014-2513	03/25/2014 04/22/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Juan Pedro Rodriguez Juan Pedro Rodríguez	TIRASEMTIV - SAFETY AND EFFICACY DATA
2014-2514	03/25/2014 04/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	K Jameson K Jameson	MICROMED CARDIOVASCULAR - IDE APPROVAL LETER, ASSIGNMENT TO RELIANTHEART
2014-2515	03/25/2014 04/22/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Fabrice GANKAM Fabrice GANKAM	SAMCA - AERS
2014-2516	03/25/2014 04/22/2014	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	DISTRIBUTION OF CIGARETTES AT GOLDEN GLOBE AWARDS
2014-2517	03/25/2014 04/22/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ellen Camos ANI Pharmaceuticals, Inc.	ANDA 61591, ANDA 80215, ANDA 77641 ETC
2014-2518	03/25/2014 04/22/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	DENNIS C GUCCIARDO Hogan Lovells, ILP	2011-6159, 2011-4996, 2011-2585, ETC
2014-2519	03/25/2014 04/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	QUINN, THOMAS J	510k ASSERTION
2014-2520	03/25/2014	FDA/OMPT/CBER/OCOD/DDOM/		INDIVIDUAL RECS

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	04/22/2014	ALFB/	Doe J	
2014-2521	03/25/2014 04/22/2014	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	STEVENS, LESLIE	MYOFUNCTIONAL RESEARCH CO - TRAINER SYS MYOBRAC & TMJ SYS EIRS
2014-2522	03/25/2014 04/22/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	ANGELA KELVER HALL FAEGRE BAKER DANIELS	DUROM ACETABULAR COMPONENT & METASUL LARGE DIAMETER HEADS K053536
2014-2523	03/25/2014 04/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	WILLIAM J GORMAN GORMAN CONSULTING INC	K1223361
2014-2524	03/25/2014 04/22/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	JARRETT, JEREMY	RISPONDEINE, CELEKA - AERS
2014-2525	03/25/2014 04/22/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	ROBERTA HIGGINS MEDETECT CLINICAL INFORMATION ASSOCIATES INC	REJECTION RATES FOR PROPRIETARY NAMES SUMMITTED FOR IND, NDA ANDA FY2013
2014-2526	03/25/2014 04/22/2014	FDA/OO/OFBA/OAGS/	ESTEE SHAKOVITSKY GRIER FORENSICS	NUMBER OF APPLS RECIEVED FOR SBIR, WOSB, SDB, HUBXONE FOR PHASE 1 & II 2007-2012
2014-2527	03/25/2014 04/22/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OES/DDM/	RANDI MICHELSON Donna B Michelson PA	DKT 1995-0304 - EPHEDRINE ALKALOIDS RPTS
2014-2528	03/25/2014 05/05/2014	FDA/OMPT/CTP/OD/	JASPER CRAVEN MUCKROCK NEWS	LIQUID NICOTINE IN E-CIGARETTES - RPTS
2014-2529	03/25/2014 04/22/2014	FDA/OMPT/CTP/OD/	NOEL J FRANCISCO JONES DAY	ELECTRONIC CIGARETTTS USE AMONG MIDDLE & HIGH SCHOOL STUDENTS IN USA - RECS 2011, 2012
2014-2530	03/26/2014 04/23/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	B Sundaram Sundaram, B	BLA 125472/0
2014-2531	03/26/2014 04/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	Dan Voell Patch Medical	K030336

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2014-2532	03/26/2014 04/23/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	MALARONE - AERS 03/21/2000 - 03/21/2014
2014-2533	03/26/2014 04/23/2014	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Robert Di Nicola Victor Technologies Inc.	VICTOR TECHNOLOGIES FNA THERMADYNE INC - 483 2011
2014-2534	03/26/2014 04/23/2014	FDA/OO/OFBA/OAGS/	Lauren Farruggia Hyman, Phelps & McNamara P.C.	CONTRACTS, GRANTS RE TESTING OF GENERIC DRUGS SINCE 10/1/12
2014-2535	03/26/2014 04/23/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lauren Farruggia Hyman, Phelps & McNamara P.C.	STUDY PROTOCOLS, STUDY RESULTS, CORR ETC RE TESTING OF GENERIC ATONASTATIN
2014-2536	03/26/2014 04/23/2014	OC/ORA/OCI/ OC/ORA/OCI/	Rakesh Padigala EASTERN MICHIGAN UNIVERSITY	LIST OF CONTERFEITING CASES RE LIPITOR 01/01/1997 - 03/20/2014
2014-2537	03/26/2014 04/25/2014	FDA/OC/OES/DDM/	Karen M Starko Karen M Starko	DRUG LABELING REFERENCES IN DOCKET
2014-2538	03/26/2014 04/23/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Thomas Sims Baron & Budd, PC	FLUOROQUINOLONE - LABEL CHANGE RECS 01/01/2010 - 03/14/2014
2014-2539	03/26/2014 04/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	Joseph W. Moss, Jr. Erwin Bishop Capitano & Moss PA	K122338
2014-2540	03/26/2014 04/23/2014	FDA/OFVM/CFSAN/OCD/EOS/	Carla R. Scarmazzi KING & SPALDING	FAP 9M4673
2014-2541	03/26/2014 04/23/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	BLA 125289 S 77, 78, 19
2014-2542	03/26/2014 04/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	Joseph W. Moss, Jr. Erwin Bishop Capitano & Moss, PA	K122340
2014-2543	03/26/2014 04/23/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Prashant Premkumar East Bridge Capital Management Limited	PIRAMAL ENTERPRISES, INDIA - 483 01/01/2013 - 03/24/2014

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2014-2544	03/26/2014 04/23/2014	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sancilio and Company QAP and EIR Sancilio and Company, Inc.	SANCILIO AND COMPANY, INC, RIVIERA BEACH, FL - QAP, EIR 01/01/2008 - 03/24/2014
2014-2545	03/26/2014 04/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	D.C. LANSLOWNE RESEARCH INSTRUMENTS LTD	ZILOS TK - HAMILTON THORNE BIOSCIENCES K063636
2014-2546	03/26/2014 04/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	D.C. LANSLOWNE RESEARCH INSTRUMENTS LTD	HAMILTON THORNE INC - LYKOS K120055
2014-2547	03/26/2014 04/23/2014	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2014-1696
2014-2548	03/26/2014 04/23/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dr. Cathy Rosenbaum TriHealth - Bethesda North Hospital Pharmacy	ACETAMINOPHEN AERS
2014-2549	03/26/2014 04/23/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Thomas Sims Baron & Budd, PC	FLUROQUINOLONES - STUDIES, DATA, REPORTS ETC 01/01/2000 - 03/24/2014
2014-2550	03/26/2014 04/23/2014	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	Debbie Metzger Segal McCambridge Singer and Mahoney	CRAVE BROTHERS FARMSTEAD CHEESE, WATERLOO, WI - COMPLAINTS, CORR, INSPECTIONS ETC 01/01/2004 - 03/24/2014
2014-2551	03/26/2014 04/23/2014	FDA/OFVM/CFSAN/OCD/EOS/	Linda M. Dougherty, Esq. Kane Kessler, P.C.	NDI COVER LETTER FOR PYRROLOQUINOLONE QUINONE FILED BY NASCENT HEALTH SCIENCE LLC, FDA RESPONSE
2014-2552	03/26/2014 04/23/2014	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	Caraco Pharmaceutical Laboratories, Ltd. Caraco Pharmaceutical Laboratories, Ltd	CARACO PHARMACEUTICAL LABORATORIES, DETROIT, MI - EIR 01/01/2013 - 01/30/2014;
2014-2553	03/26/2014 04/23/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Laura Pike BIRD & BIRD LLP	NDA 017555

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-2554	03/26/2014 04/23/2014	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	BRENDA M. GARTZ ELI LILLY & CO	PATHEON, CINCINNATI, OH - EIR 5/16/13
2014-2555	03/26/2014 04/23/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	James E Ford Ford, James E	LAMOTRIGINE - AERS
2014-2556	03/26/2014 04/23/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lisa Girion LOS ANGELES TIMES	OXYCONTIN - CORR, CITIZEN PETITION, ETC RE LABEL CHANGE 12/01/1995 - 04/01/2014
2014-2557	03/26/2014 04/23/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	B Sundaram Sundaram, B	BLA125118/122 SBA
2014-2558	03/26/2014 04/23/2014	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	BRENDA M. GARTZ ELI LILLY & CO	PHILLIPS PLASTICS CORP, MENOMONIE, WI 5/2/13 - EIR
2014-2559	03/26/2014 04/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	Joseph W. Moss, Jr. Erwin Bishop Capitano & Moss PA	K042005
2014-2560	03/26/2014 04/23/2014	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	BRENDA M. GARTZ ELI LILLY & CO	PATHEON, CINCINNATI, OH - EIR 8/13/13
2014-2561	03/26/2014 04/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	TOMMY GESKE Sunrise Medical Technology, Inc.	PICKER 1200SX - 510K
2014-2562	03/26/2014 04/23/2014	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	JESSICA SIMOES PREG O'DONNELL GILLET PLLC	EVER FRESH FRUIT CO, BORING, OR - INSP
2014-2563	03/26/2014 04/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	JANE LIU NEW DEANTRONICS TAIWAN	NEW DEANTRONICS GROUP - EIR UNREDACTED 4/17-20/06
2014-2564	03/26/2014 04/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	GERALYN MURRAY VITAL SIGNS INC	VITAL SIGNS INC - ADJUSTABLE PEEP VALVE K904874
2014-2565	03/26/2014 04/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	GERALYN MURRAY VITAL SIGNS INC	VITAL SIGNS INC - GAS SAMPLING INTERFACES K914337
2014-2566	03/26/2014	FDA/OMPT/CDRH/OCER/DFOI/	GERALYN MURRAY	VITAL SIGNS INC - INTERCEPT K843591

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	04/23/2014		VITAL SIGNS INC	
2014-2567	03/26/2014 04/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARY GAINSBURGH BENJAMIN ET AL	CLOZARIL NDA 19-758 - STUDIES, RPTS, CORR, ETC
2014-2568	03/26/2014 04/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	Peter R. Mathers Kleinfeld, Kaplan, and Becker LLP	REQUESTS SUBMITTED UNDER 21 CFR 801.55 FOR AN EXCEPTION FROM OR ALTERNATIVE TO A UNIQUE DVC IDENTIFIER (UID)
2014-2569	03/26/2014 04/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	Peter R. Mathers Kleinfeld, Kaplan Becker, LLP	INQUIRIES & RESPONSES SUBMITTED TO UNIQUE DVC IDENTIFIERS HELP DESK
2014-2570	03/26/2014 04/23/2014	OC/OR/ OC/OR/ FDA/OGROP/OR/SE-FO/FLA-DO/FLA-CB/	JOHN F. JOHNSON III, Esq. BENJAMIN L ENGLAND & ASSOCIATES LLC	MAHI MAHI ENTRY NO 406-0499772-2 - COLLECTION, SPL CUSTODIAN'S RECEIPT, TEST RPTS
2014-2571	03/26/2014 04/23/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Mark Palmieri Novo Nordisk Inc.	Animas Corporation's One Touch Ping Insulin Pump - 510K
2014-2572	03/26/2014 04/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	Mark Palmieri Novo Nordisk Inc.	K122370
2014-2573	03/26/2014 04/23/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Mark Palmieri Novo Nordisk Inc.	K111210
2014-2574	03/26/2014 04/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	Bryan McGurn Bryan McGurn	K860434
2014-2575	03/26/2014 04/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	Bryan McGurn Bryan McGurn	K861276
2014-2576	03/26/2014 04/23/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Mark Palmieri Novo Nordisk Inc.	K103825
2014-2577	03/26/2014 04/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	Mark Palmieri Novo Nordisk Inc.	K111669
2014-2578	03/26/2014 04/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John Newman CANACCORD GENUITY	NDA 204031
2014-2579	03/26/2014 04/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	EARL GOEHRING THE DEGGE GROUP LTD	GABAPENTIN - AERS

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2014-2580	03/26/2014 04/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	EARL GOEHRING THE DEGGE GROUP LTD	GABAPENTIN - AERS
2014-2581	03/26/2014 04/23/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Angie King King, Angie N	DR RICHARD MIYAMOTO - COMPLAINTS 12/01/2007 - 02/28/2013
2014-2582	03/26/2014 04/23/2014	FDA/OC/OES/DFOI/	Russell Edem Russell Edem	ELECTRONIC CIGARETTES
2014-2583	03/27/2014 04/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lewis M Mashburn Lewis M Mashburn	MEDICATION ERROR RATES SUMMARY DATA (HUMAN DRUGS) 04/01/2005 - 02/28/2014
2014-2584	03/27/2014 04/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K123567
2014-2585	03/27/2014 04/24/2014	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Adam J. Gomez WADE CLARK MULCAHY	GARDEN FRESH FOODS, INC, MILWAUKEE, WI - RECALL RECS 01/01/2007 - 03/26/2014
2014-2586	03/27/2014 04/25/2014	FDA/OMPT/CTP/OD/ FDA/OC/OES/DFOI/	Kyle Rozema CORNELL UNIVERSITY	QUANTITIES OF NICOTINE, TAR, CO, ETC IN EACH CIGARETTE BY BRAND, SUB-BRAND 01/01/2000 - 03/24/2014
2014-2587	03/27/2014 04/24/2014	FDA/OMPT/CTP/OD/	John B John B	GRIZZLE WINTERGREEN SNUFF INGREDIENTS
2014-2588	03/27/2014 04/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	Meryl Grenadier Stein Mitchell Muse & Cipollone LLP	LETTER FROM LYNN DEUTSCH TO ANN SEMONEAU 4/24/07
2014-2589	03/27/2014 04/24/2014	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	David Hofmann Charles Taylor Adjusting	GARDEN FRESH FOOD, INC, MILWAULKEE, WI - LAB RESULTS 07/01/2012 - 10/30/2013
2014-2590	03/27/2014 04/24/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OES/DFOI/	Kari L. Twaite BEVERIDGE & DIAMOND PC	CFSAN FOIA REQUESTS 02/25/2014 - 03/26/2014
2014-2591	03/27/2014 04/24/2014	FDA/OFVM/CFSAN/OCD/EOS/	FRIEDMAN, ROBERT	BETTY CROCKER, THOMAS ENGLISH MUFFINS, ENER-G FOODS, ETC - CAERS 1969 TO 2014
2014-2592	03/27/2014 04/24/2014	FDA/OFVM/CFSAN/OCD/EOS/	FRIEDMAN, ROBERT	BACARDI MIXERS, MINUTE MAID, KEMPS, ETC - CAERS 1969 TO 2014

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2014-2593	03/27/2014 04/24/2014	FDA/OFVM/CFSAN/OCD/EOS/	FRIEDMAN, ROBERT	LIEUTENANT BLENDER'S, HOLLAND HOUSE, BAJA BOB'S - CAERS 1969 TO 2014
2014-2594	03/27/2014 04/24/2014	FDA/OFVM/CFSAN/OCD/EOS/	MARY ANN C MAY PARR BROWN GEE ET AL	BASIC RESEARCH LLC - FORM FDA 3500, 3500A, 3500B, AERS
2014-2595	03/27/2014 04/24/2014	FDA/OFVM/CFSAN/OCD/EOS/	MARY ANN C MAY PARR BROWN GEE ET AL	LIMITLESS WORLDWIDE LLC , SALT LAKE CITY, UT- FORM FDA 3500, 3500A, 3500B, AERS
2014-2596	03/27/2014 04/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANDREW EDGE MCGINNIS LOCHRIDGE	BOTOX - ISR 1210364US, 1216520US, 1215658US MEDWATCH FORMS
2014-2597	03/27/2014 04/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PETE MAI TAMMY TRAN & ASSOCS ATTYS	SMITHKLINE BEECHAM, GLAXOSMITHKLINE - PAXIL ASSESMENT, EVALUATION, MISREPRESENTED RECS
2014-2598	03/27/2014 04/24/2014	FDA/OC/OEXA/OMA/ FDA/OGROP/OIP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PETER HARRIS PREMIER DUE DILIGENCE	EUROPEAN MEDICINES AGENCY - RPTS, MEMOS, PRESENTATIONS, ETC 2/26/14; RODNEY ROUSE ET AL- HIGH FAT DIET & GLP- 1 DRUGS INDUCE PANCREATIC INJURY IN MICE RPTS, ARTICLES, ABSTRACTS, ETC 1/30/14, ETC
2014-2599	03/27/2014 04/24/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/	EMILY ROLLINS UNIV OF GUELPH	CANADIAN AGRICULTURAL COMMODITIES LISTED BY PRODUCT - IMPORT ALERTS 2000-2013
2014-2600	03/27/2014 04/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	TENNANT, TERRY L	PICKER MARCONI PHILLIPS, THOMAS J QUINN - NO 510K CLEARANCE INVESTIGATION 2001 TO PRESENT
2014-2601	03/27/2014 04/24/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORO/CE-FO/CIN-DO/CIN-CB/ OC/ORO/OCI/	WILSON W GREENE GREENE LAW FIRM PLLC	MIRENA IUD - LTRS, CORR, E-MAILS, ETC

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		OC/ORa/OCI/		
2014-2602	03/27/2014 04/24/2014	FDA/OC/OES/DFOI/	dhiren aaytee EASTERN MICHIGAN UNIVERSITY	ORPHAN DRUG RECS
2014-2603	03/27/2014 04/24/2014	FDA/OGROP/ORa/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORa/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORa/SE-FO/ATL-DO/ATL-CB/	Camilla Harrison Taconic Capital Advisors UK LLP	GETINGE GROUP - WARNING LETTER, 483, EIR 01/01/2000 - 03/27/2014
2014-2604	03/28/2014 04/25/2014	FDA/OGROP/ORa/SW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CDRH/OCER/DFOI/ OC/ORa/OCI/ OC/ORa/OCI/ FDA/OC/OES/DFOI/	KRISTEN S MOYERS WRIGHT LINDSEY & JENNINGS	KIMBERLY-CLARK - KOTEX NATURAL BALANCE SECURITY TAMPON PRODS MEMOS, RPTS, Cmplnts, ETC
2014-2605	03/28/2014 04/25/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LEE H ROSEBUSH BAKER & HOSTETLER, LLP	HYDROCORTISONE ACETATE NDA 17-351 - APRVL STUDIES 12/81
2014-2606	03/28/2014 04/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	Christian Hunt Comfortrac	K122566
2014-2607	03/28/2014 04/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	John Chappell CERICON LLC	K123049
2014-2608	03/28/2014 04/25/2014	FDA/OGROP/ORa/PA-FO/LOS-DO/LOS-CB/	STEVENS, LESLIE	MYOFUNCTIONAL RESEARCH CO - TRAINER SYS, MYOBRACE, TMJ SYS, ETC EIRS
2014-2609	03/28/2014 04/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	Cheryl Wagoner Wagoner Consulting LLC	K941048
2014-2610	03/28/2014 04/25/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K070054
2014-2611	03/28/2014 04/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K123436
2014-2612	03/28/2014 04/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K123436
2014-2613	03/28/2014	FDA/OGROP/ORa/SE-FO/ATL-	Jane Bentley	CIBA VISION, DULUTH, GA - EIR 09/11/2012 - 09/13/2012

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	04/25/2014	DO/ATL-CB/	Alcon Labs, Inc.	
2014-2614	03/28/2014 04/25/2014	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	GEORGE F INDEST III JD MPA LLM HEALTH LAW FIRM	DIGITAL RADIOLOGY CENTER INC - RECS
2014-2615	03/28/2014 04/25/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	BRETT PARK CONWAY HOMER & CHIN-CAPLAN PC	INDIVIDUAL RECS
2014-2616	03/28/2014 04/25/2014	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	ADAM DIEDERICH SCHIFF HARDIN LLP	STEPHEN A LANGMAID 5/1/12, ROBERTS RANCH OF OKLAHOMA LLC 9/11/12, KUIPER DAIRY LLC 12/19/12, ETC - WARNING LTRS, EIRS
2014-2617	03/28/2014 04/25/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	LETTER FROM BRIAN BAKER AND TIMOTHY ULATOWSKI TO RAY ELLIOITT RE WARNING LETTER (CERTIFIED)
2014-2618	03/28/2014 04/25/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Scott Eaker Prolacta Bioscience, Inc.	PROLACTA BIOSCIENCE, CITY OF INDUSTRY ,CA - EIR 04/18/2006 - 12/31/2006
2014-2619	03/28/2014 04/25/2014	OC/ORAOCI/ OC/ORAOCI/	Nicholas Basta Pharmaceutical Commerce	NUMBER OF OCI CASES IN FY 2013 RE COUNTERFEIT DRUGS
2014-2620	03/28/2014 04/25/2014	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	Rose Gillespie Rose Gillespie	CHABANI YOGURT - FINAL MOLD RESULTS, POSITIVE RESULTS 05/01/2013 - 03/27/2014
2014-2621	03/28/2014 04/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	Nicole Dove Summit Medical Inc.	K030605
2014-2622	03/28/2014 04/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	Mei Feng Chen Chung Yuan Christian University	P110033
2014-2623	03/28/2014 04/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	Mei Feng Chen Chung Yuan Christian University	K131251
2014-2624	03/28/2014 04/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	K932553 CERTIFIED
2014-2625	03/28/2014 04/25/2014	FDA/OO/OFBA/OAGS/	Francis Logan Americhip, Inc.	FDA-SOL-13-1115725
2014-2626	03/28/2014 04/25/2014	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	ADAM DIEDERICH SCHIFF HARDIN LLP	DORSEY FARMS INC 3/2/12, BOX CANYON DAIRY 3/6/12, DE JONG DAIRY 10/11/12, ETC - WARNING LTRS, EIRS
2014-2627	03/28/2014 04/25/2014	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	ADAM DIEDERICH SCHIFF HARDIN LLP	RANCHO CANTERA 1/18/13; WALK ED 1/23/13, OAK GROVE PORK INC 4/3/13 - WARNING LTRS, EIRS
2014-2628	03/28/2014	FDA/OGROP/ORASE-FO/FLA-	ADAM DIEDERICH	FIESTER DAIRY INC 2/7/12, SUWANNEE DAIRY 8/8/12 -

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	04/25/2014	DO/FLA-CB/	SCHIFF HARDIN LLP	WARNING LTRS, EIRS
2014-2629	03/28/2014 04/25/2014	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	ADAM DIEDERICH SCHIFF HARDIN LLP	MARK D LECAPTAIN 1/13/12, KEN GONNERING LIVESTOCK INC 2/3/12, MEADOWLARK DAIRY LLC 2/13/12, ETC - WARNING LTRS, EIRS
2014-2630	03/28/2014 04/25/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	ADAM DIEDERICH SCHIFF HARDIN LLP	ERNEST P SHOUP FARM 5/22/12, SNELLMAN FARMS 6/1/12, MAERLAND DAIRY LLC 11/27/12, ETC - WARNING LTRS, EIRS
2014-2631	03/28/2014 04/25/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	ADAM DIEDERICH SCHIFF HARDIN LLP	HILLSIDE VEAL 11/17/12, GRIEBEL DAIRY FARMS 3/6/12, SULLIVAN LANE FARM 3/26/12. ETC - WARNING LTRS, EIRS
2014-2632	03/28/2014 04/25/2014	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	ADAM DIEDERICH SCHIFF HARDIN LLP	CHUCTANUDA FARMS 2/1/12, BUTTERNUT BROOK FARM 2/24/12, CARUSO CATTLE CO 4/23/12, ETC - WARNING LTRS, EIRS
2014-2633	03/28/2014 04/25/2014	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	ADAM DIEDERICH SCHIFF HARDIN LLP	GRAHAM DAIRY - WARNING LTR 2/21/13, EIRS
2014-2634	03/28/2014 04/25/2014	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	ADAM DIEDERICH SCHIFF HARDIN LLP	KOENEN DAIRY INC 6/5/12, STARDELL FARMS INC 3/19/13 - WARNING LTRS, EIRS
2014-2635	03/28/2014 04/25/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	ADAM DIEDERICH SCHIFF HARDIN LLP	BRENNER BROTHERS & SONS 4/3/12, DE SEAGHER CATTLE LLC 4/19/12, MANCHESTER VEAL LLC 1/22/13, ETC - WARNING LTRS, EIRS
2014-2636	03/28/2014 04/25/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	ADAM DIEDERICH SCHIFF HARDIN LLP	DOUBLE AUGHT DAIRY 3/9/12, CROSS COUNTRY DAIRY 12/13/12, MARCELLINA DAIRY 12/26/12, ETC - WARNING LTRS, EIRS
2014-2637	03/28/2014 04/25/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	ADAM DIEDERICH SCHIFF HARDIN LLP	MONIZ DAIRY FARM 3/16/12, BROUILLETTE FARM INC INC 6/11/12, ARCHIE DOMINA FARM 9/13/12, ETC - WARNING LTRS, EIRS
2014-2638	03/28/2014 04/25/2014	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	ADAM DIEDERICH SCHIFF HARDIN LLP	GALHANO DAIRY 1/11/12, A & M FARMS 3/13/12, GOLDEN GENES DAIRY 4/10/12, ETC - WARNING LTRS, EIRS
2014-2639	03/28/2014 04/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	QUINN, TOM	K020913 - PREDICATE DVC RECS
2014-2640	03/31/2014 04/28/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	LESLIE OSTLER BIOMEDICAL RESEARCH LABORATORIES	E EXCEL NORTH AMERICA, SANDY, UT - 483 7/12 TO PRESENT
2014-2641	03/31/2014 04/28/2014	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	LESLIE OSTLER BIOMEDICAL RESEARCH LABORATORIES	POUCH TEC INDUSTRIES LLC, FOLEY, MN - 483 7/2012 TO PRESENT
2014-2642	03/31/2014	FDA/OGROP/ORAPA-FO/LOS-	LESLIE OSTLER	ARIZONA NUTRITIONAL SUPPLEMENTS, CHANDLER, AZ -

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	04/28/2014	DO/LOS-CB/	BIOMEDICAL RESEARCH LABORATORIES	483 7/12 TO PRESENT
2014-2643	03/31/2014 04/28/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	LESLIE OSTLER BIOMEDICAL RESEARCH LABORATORIES	SOFT GEL TECHNOLOGIES INC - 483 7/12 TO PRESENT
2014-2644	03/31/2014 04/28/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	LESLIE OSTLER BIOMEDICAL RESEARCH LABORATORIES	LA BELLE INC, OGDEN, UT - 483 7/12 TO PRESENT
2014-2645	03/31/2014 04/28/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	LESLIE OSTLER BIOMEDICAL RESEARCH LABORATORIES	VMI NUTRITION, SALT LAKE CITY, UT - 483 7/12 TO PRESENT
2014-2646	03/31/2014 04/28/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	LESLIE OSTLER BIOMEDICAL RESEARCH LABORATORIES	DESERET LABS, ST GEORGE, UT - 483 7/12 TO PRESENT
2014-2647	03/31/2014 04/28/2014	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	LESLIE OSTLER BIOMEDICAL RESEARCH LABORATORIES	NATIONAL ENZYME CO, FORSYTH, MO - 483 7/12 TO PRESENT
2014-2648	03/31/2014 04/28/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	LESLIE OSTLER BIOMEDICAL RESEARCH LABORATORIES	CSB NUTRITION CORP, SPANISH FORK, UT - 483 7/12 TO PRESENT
2014-2649	03/31/2014 04/28/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	LESLIE OSTLER BIOMEDICAL RESEARCH LABORATORIES	ASEPTIC SLOUTIONS USA, CORONA, CA - 483 7/12 TO PRESENT
2014-2650	03/31/2014 04/28/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	LESLIE OSTLER BIOMEDICAL RESEARCH LABORATORIES	J&D LABS INC, VISTA, CA - 483 7/12 TO PRESENT
2014-2651	03/31/2014 04/28/2014	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	LESLIE OSTLER BIOMEDICAL RESEARCH LABORATORIES	BETTY LOU'S INC, MCMINNVILLE, OR - 483 7/12 TO PRESENT
2014-2652	03/31/2014 04/28/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	LESLIE OSTLER BIOMEDICAL RESEARCH LABORATORIES	POWDER PROCESSORS INC, OGDEN, UT - 483 7/12 TO PRESENT
2014-2653	03/31/2014 04/28/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	LESLIE OSTLER BIOMEDICAL RESEARCH LABORATORIES	KELATRON, OGDEN, UT - 483 7/12 TO PRESENT
2014-2654	03/31/2014 04/28/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	LESLIE OSTLER BIOMEDICAL RESEARCH	APS BIOGROUP, PHOENIX, AZ - 483 7/12 TO PRESENT

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			LABORATORIES	
2014-2655	03/31/2014 04/28/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	LESLIE OSTLER BIOMEDICAL RESEARCH LABORATORIES	CORNERSTONE RDI INC, OGDEN, UT - 483 7/12 TO PRESENT
2014-2656	03/31/2014 04/28/2014	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Susan Weinbach CONVENTUS BIOMEDICAL SOLUTIONS INC	WUXI APPTTEC, INC, ST PAUL, MN - 483, EIR
2014-2657	03/31/2014 04/28/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Satoru Ogami FUJIFILM Corporation	K040148
2014-2658	03/31/2014 04/28/2014	FDA/OMPT/CDRH/OCER/DFOI/	Satoru Ogami FUJIFILM Corporation	K102764
2014-2659	03/31/2014 04/28/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K120472
2014-2660	03/31/2014 04/28/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K102556
2014-2661	04/01/2014 04/29/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Heilmann, PharmD Kasier Permanente of Colorado	DENOSUMAB - MEDWATCH REPORTS 07/01/2010 - 03/24/2014
2014-2662	04/01/2014 04/29/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Justin McGinnis UNIVERSITY OF SOUTHERN CALIFORNIA	NDA, BLA DATA 01/01/1990 - 01/01/2014
2014-2663	04/01/2014 04/29/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Megan Lutz The Doctors TV Show	NUVARING - AERS
2014-2664	04/01/2014 04/29/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Stefanie Emanuel Johnson and Johnson	Pharmacovigilance review regarding OTC topical acne drug products and serious hypersensitivity events ETC
2014-2665	04/01/2014	FDA/OMPT/CDER/GRP/DIDP/	Christine	TENOFOVIR - AERS

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	04/29/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Christine Tsai	
2014-2666	04/01/2014 04/29/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Carol Donahue FOX ROTHSCHILD LLP	Forms 3454 and 3455 relating to (1) studies for which Questcor Pharmaceuticals is a sponsor or affiliate or (2) studies undertaken involving the evaluation of HP Acthar Gel
2014-2667	04/01/2014 04/29/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jim Tumbrink Broadfin Capital	NDA 205109
2014-2668	04/01/2014 04/29/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nathaniel August Mangrove Partners	ALIMERA SCIENCE - COMPLETE RESPONSE CORR 10/01/2013 - 01/01/2014
2014-2669	04/01/2014 04/29/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Susan Boklage Otsuka America Pharmaceutical Inc.	SAMSCA 7499864 8060244 8192074 ETC
2014-2670	04/01/2014 04/29/2014	FDA/OMPT/CDRH/OCER/DFOI/	JOSEPH WALKER Walker, Joseph	ADVANCED NEUROMODULATION SYSTEMS - MDR 1627487-2008-00042, CORR ETC
2014-2671	04/01/2014 04/29/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Laura Pike BIRD & BIRD LLP	SINEMT CR - NDA 019856
2014-2672	04/01/2014 04/29/2014	FDA/OGROP/ORP/PA-FO/SAN- DO/SAN-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dave Milton Coker, Schickel, Sorenson & Posgay, P.A.	EPOGEN, PROCIT - INVESTIGATION RECS RE SMALL FLAKES OF GLASS ETC 09/24/2009 - 09/24/2012
2014-2673	04/01/2014 04/29/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Willene Brondum Insys Therapeutics, Inc.	NDA 202788 - SBA

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2014-2674	04/01/2014 04/29/2014	FDA/OMPT/CDRH/OCER/DFOI/	Avital Levertov - Elcam Medical ELCAM MEDICAL	K945592
2014-2675	04/01/2014 04/29/2014	FDA/OMPT/CDRH/OCER/DFOI/	Nicole Dove Summit Medical Inc	K991212
2014-2676	04/01/2014 04/29/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Claus Fuxen Siegfried AG	OXYCODONE HCI - IMPURITY 14-hydroxycodeinone
2014-2677	04/01/2014 04/29/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sara Xiao Hisun Pharmaceuticals USA, Inc.	NDA 050718
2014-2678	04/01/2014 04/29/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ayesha Adil The Weinberg Group	ANDA 203690
2014-2679	04/01/2014 04/29/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/	Barbara Ellison ELITE LABORATORIES INC	Notification to FDA of sale or assignment of any business assets, such as buildings, equipment or inventory
2014-2680	04/01/2014 04/29/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rosalie A. Lowe TWi International, LLC	NDA 022249 S015
2014-2681	04/01/2014 04/29/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Pamela Ryland CONSUMER	BENZONATATE - AERS
2014-2682	04/01/2014	FDA/OMPT/CDER/ORP/DIDP/	Marc Spangner	ORINETRAM - MEDICAL REVIEW AND SUMMARY MEDICAL REVIEW

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	04/29/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Actelion Pharmaceuticals US, Inc.	
2014-2683	04/01/2014 04/29/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	Barbara Ellison ELITE LABORATORIES INC	Notification to FDA of sale or assignment of any business assets, such as buildings, equipment or inventory. US District Court Civil No. 08-cv-05656
2014-2684	04/01/2014 04/29/2014	FDA/OMPT/CDRH/OCER/DFOI/	Thambiah Sundaram SNS Biosystems Inc	STERI-SPOR - PREAMENDMENT APPROVAL, 510K, PMA ETC
2014-2685	04/01/2014 04/29/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Donna Ward DT Ward, PC	K99351
2014-2686	04/01/2014 04/29/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Bryan McGurn Bryan McGurn	K101385
2014-2687	04/01/2014 04/29/2014	FDA/OMPT/CDRH/OCER/DFOI/	Bryan McGurn Bryan McGurn	K962801
2014-2688	04/01/2014 04/29/2014	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/ORO/DIOP/	Kate Qualmann Master's student at Universidad de Chile	Import Refusal Reports and Import Alerts form imports from Chile to the U.S.
2014-2689	04/01/2014 04/29/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Donna Ward DT Ward, PC	K993951
2014-2690	04/01/2014 04/29/2014	FDA/OMPT/CDRH/OCER/DFOI/	BIJAN ESFANDIARI BAUM HEDLUND ET AL	OP-1 PUTTY, OP-1 IMPLANT - PI, PATIENT INFORMATION BOOKLET (CERTIFIED)
2014-2691	04/01/2014 04/29/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OO/OFBA/OAGS/	EMILY MARDEN SIDLEY AUSTIN LLP	SAGENT - VENOFER (IRON SUCROSE) ANDA CORR; FDA-SOL-1120929 COMM; NULECIT, FERRLECIT THERAPEUTIC EQUIVALENCE NOTES, CORR, ETC
2014-2692	04/01/2014 04/29/2014	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORA/SE-FO/SJN- DO/SJN-CB/	ROD TENNYSON ESQ ROD TENNYSON LAW OFCS	INDIVIDUAL RECS
2014-2693	04/01/2014	OC/ORA/	JAMES V LOPEZ	FOUR SEASONS HOTEL RESTAURANT - FOOD POSIONING

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	04/29/2014	OC/OR/ FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	WILSON ELSER ET AL	INVESTIGATION RECS 12/25/11
2014-2694	04/01/2014 04/29/2014	FDA/OMPT/CDRH/OCER/DFOI/	ELIANE H TSENG KING & SPALDING	INTUITIVE SURGICAL INC - DA VINCI SI SURGEON SIDE CART Z-1686-3013; DA VINCI SI VISION SYS CART Z-1687-2013; DA VINCI DEIAL CAMERA CONTROLLER Z-1688-2013, ETC RECALL RECS
2014-2695	04/01/2014 04/29/2014	FDA/OFVM/CFSAN/OCD/EOS/	DAILEY, MICHAEL R	LIST OF FOOD FACILITIES IN DENVER CITY, CO 4/13 TO 3/14
2014-2696	04/01/2014 04/29/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LYNNE MILLICAN RN BSN LUPRON VICTIMS HUB	DR DAVID REDWINE LUPRON RVW - FDA RESP 2011 TO 2013
2014-2697	04/01/2014 04/29/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BENJAMIN L ENGLAND ESQ BENJAMIN L ENGLAND & ASSOCIATES LLC	API/BULK INGREDIENT DRUG LISTING DATA
2014-2698	04/01/2014 04/29/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WAYNE SADOWSKI NOVARTIS PHARMACEUTICAL CORPORATION	KERCKHOFF-KLINIK GMBH, BAD NAUHEIM, GERMANY 11/10-14/13; KLINIKA KARDIOLOGI OSRODEK CHROROB SERCA, WROCLAW, POLAND 11/19-22/13; ZIV MEDICAL CENTER HEART INSTITUTE, SAFED, ISRAEL 1/27-31/14 - EIRS, 483S, CORR
2014-2699	04/01/2014 04/29/2014	FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECS
2014-2700	04/01/2014 04/29/2014	FDA/OFVM/CFSAN/OCD/EOS/	JANPAUL PORTAL ESQ FERRARO LAW FIRM	GNC - BURN 60 CMLPNTS, LBLG, CLNCL TESTING, ETC
2014-2701	04/01/2014 04/29/2014	FDA/OC/OES/DFOI/	Bennie Lee Cheatham, Jr.	INDIVIDUAL RECS
2014-2702	04/01/2014 04/29/2014	FDA/OMPT/CDRH/OCER/DFOI/	GONZALES, TODD	RED CORAL ACUPUNCTURE SUPPLIES PTY LTD - MYOTECH DRY NEEDLES RECS 11/12 TO PRESENT
2014-2703	04/01/2014 04/29/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	EMILY MARDEN SIDLEY AUSTIN LLP	SAGENT - VENOFER (IRON SUCROSE) COMPLETE RESP LTR 12/13
2014-2704	04/01/2014	FDA/OMPT/CDER/ORP/DIDP/	TORREY COPE	BENZYL ALCOHOL, IVERMECTIN, LINDANE, ETC - WARNING LTRS, LTRS OF INQUIRY, ADVISORY COMMENTS,

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	04/29/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	SIDLEY AUSTIN LLP	ETC
2014-2705	04/01/2014 04/29/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TORREY COPE SIDLEY AUSTIN LLP	MALATHION, PERMETHRIN, SPINOSAD, ETC - WARNING LTRS, UNTITLED LTRS, ADVISORY COMMENT LTRS, ETC
2014-2706	04/01/2014 04/29/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Doe J	ALLERGAN - LAPBAND PORT RECALL RECS
2014-2707	04/01/2014 04/29/2014	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	LYNX - SUPRAPUBIC MID-URETHRAL SYS - RECALLS, WARNINGS, REGULATION GUIDELINES
2014-2708	04/01/2014 04/29/2014	FDA/OC/OES/DFOI/	Doe J	HIP ARTHROPLASTY - RECALL RECS
2014-2709	04/01/2014 04/29/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	PROSTASOL - WHAT INGREDIENTS WERE REMOVED
2014-2710	04/01/2014 04/29/2014	FDA/OMPT/CDRH/OCER/DFOI/	LIANE LAROCHELLE DEKA RESEARCH & DEVELOPMENT CORP	VERIZON WIRELESS - CONVERGED HEALTH MANAGEMENT SYS K134004
2014-2711	04/01/2014 04/29/2014	OC/ORA/ORM/ OC/ORA/ORM/	SASHA L PERKINS THOMSON REUTERS	DRUG MFRS, REPACKERS/PACKERS, LABELERS, ETC - FOREIGN AND DOMESTIC DRUG INSPS 9/13 TO PRESENT
2014-2712	04/01/2014 04/29/2014	FDA/OC/OES/DFOI/	Doe J	GRANUFLO, NATUR-LYTE - RECS
2014-2713	04/01/2014 04/29/2014	FDA/OFVM/CFSAN/OCD/EOS/	WILBUR JOHNSON JR COSMETIC INGREDIENT REVIEW	STYRENE, POLYSTYRENE, STYRENE/BUTADIENE COPOLYMER - CHEMICAL AND PHYSICAL PROPERTIES, TOXICITY, DERMAL PENETRATION, ETC
2014-2714	04/01/2014	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	BRENDA M GARTZ	REXAM, BUFFALO GROVE, IL - EIR 7/1/13

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	04/29/2014		ELI LILLY & CO	
2014-2715	04/01/2014 04/29/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	BRENDA M GARTZ ELI LILLY & CO	TECH GROUP, TEMPE, AZ - EIR 2/7/13
2014-2716	04/01/2014 04/29/2014	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	BRENDA M GARTZ ELI LILLY & CO	UNITED THERAPEUTICS, MD - EIR 7/31/12
2014-2717	04/01/2014 04/29/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	THERESA A GRESL PERKINS COIE	GENENTECH - RITUXAN (RITUXIMAB) BLA 103705 INDICATIONS AND USAGE FOR NON-HODGKIN'S LYMPHOMA AND RHEUMATOID ARTHRITIS
2014-2718	04/02/2014 04/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Drew LaFramboise, Esq. ASHCRAFT & GEREL, LLP	AXIRON - APPROVAL ETC
2014-2719	04/02/2014 04/30/2014	FDA/OC/OES/DDM/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Drew LaFramboise, Esq. ASHCRAFT & GEREL, LLP	DELATESTRYL - APPROVAL RECS ETC
2014-2720	04/02/2014 05/16/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OC/OES/DFOI/	Corey Grad ROBBINS ARROYO LLP	RHEIN BIOTECH, GERMANY - 483 8/23/12 ETC
2014-2721	04/02/2014 04/30/2014	FDA/OGROP/OIP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ryan L Thompson Watts Guerra LLP	RECS BETWEEN FDA AND EMA RE INCRETIN MIMETIC CLASS OF DRUGS 01/01/2013 - 03/28/2014
2014-2722	04/02/2014 04/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sharon Prisco Sharon Prisco	METHOTREXATE INJECTION - AERS
2014-2723	04/02/2014 04/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ryan L. Thompson Watts Guerra LLP	INCRETIN BASED DRUGS - NONCLINICAL ASSESSMENTS COMPLETED AS PART OF ALL MARKETING APPLICATIONS 01/02/2013 - 03/28/2014 ETC

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-2724	04/02/2014 04/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ryan L Thompson Watts Guerra LLP	INCRETIN MIMETIC CLASS OF DRUGS - OFFICE OF SAFETY AND EPIDEMIOLOGY REVIEWS RE PANCREATIC CANCER 01/01/2013 - 03/28/2014
2014-2725	04/02/2014 04/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	Nalini Sundaram SNS Biosystems Inc	STERI-SPOR - SPORES, APPROVAL
2014-2726	04/02/2014 04/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	Satoru Oogami FUJIFILM Corporation	K061222
2014-2727	04/02/2014 04/30/2014	FDA/OC/OES/DDM/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Drew LaFramboise, Esq. ASHCRAFT & GEREL, LLP	ANDRODERM - APPROVAL RECS ETC 01/01/1994 - 03/28/2014
2014-2728	04/02/2014 04/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Drew LaFramboise, Esq. ASHCRAFT & GEREL, LLP	ANDROGEL 1%, 1.62% - APPROVAL RECS ETC 04/29/1999 - 03/28/2014
2014-2729	04/02/2014 04/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ryan L Thompson Watts Guerra LLP	PANCREATIC SAFETY OF INCRETIN-BASED DRUGS FDA AND EMA ASSESSMESNT - DATA AND INFORMATION
2014-2730	04/02/2014 04/30/2014	FDA/OC/OES/DDM/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Drew LaFramboise, Esq. ASHCRAFT & GEREL, LLP	FORTESTA - APPROVAL RECS ETC
2014-2731	04/02/2014 04/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ryan L Thompson Watts Guerra LLP	INTERNAL CORR, EMAIL RE INCRETIN MIMETIC CLASS OF DRUGS THAT REFERENCE PANCREATIC CANCER 01/01/2013 - 03/28/2014
2014-2732	04/02/2014 04/30/2014	FDA/OC/OES/ FDA/OMPT/CDER/GRP/DIDP/	Ryan L Thompson Watts Guerra LLP	CORR BETWEEN FDA AND AMERICAN DIABETES ASSOCIATION, NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES ETC RE INCRETIN

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		MIMETIC CLASS OF DRUGS AND PANCREATIC CANCER 01/01/2013 - 03/28/2014
2014-2733	04/02/2014 04/30/2014	FDA/OC/OES/DDM/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Drew LaFramboise, Esq. ASHCRAFT & GEREL, LLP	STRIANT - APPROVAL RECS ETC
2014-2734	04/02/2014 04/30/2014	FDA/OC/OES/DDM/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Drew LaFramboise, Esq. ASHCRAFT & GEREL, LLP	TESTIM - APPROVAL RECS ETC
2014-2735	04/02/2014 04/30/2014	FDA/OC/OES/DFOI/	Doe J	NORPLANT - WARNING LETTER, MEDWATCH REPORTS, 483 ETC 01/01/1990 - 01/01/2014
2014-2736	04/02/2014 04/30/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SW-FO/DAL- DO/DAL-CB/ FDA/OGROP/ORO/SW- FO/SWID/SWID-CB/	Juan Carlos Martinez SUNRISE PRODUCE LLC	HP7-00178601-1 - AFFIDAVIT 05/31/2011
2014-2737	04/02/2014 04/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ryan L Thompson Watts Guerra LLP	PANCREATIC SAFETY OF INCRETIN-BASED DRUGS - DATA FOR ARTICLE 01/01/2013 - 03/28/2014
2014-2738	04/02/2014 04/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sharon Prisco Sharon Prisco	MERCAPTOPYRINE - AERS RE TUMORS
2014-2739	04/02/2014 04/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jackson Thies Columbia Business School	DECEMBER 2013 CITRUS RESEARCH REPORT RE ACTHAR GEL, INVESTIGATION RECS 2/01/2013 - 03/27/2014
2014-2740	04/02/2014	FDA/OGROP/ORO/SE-FO/FLA-	Michael Rabin	CORR BETWEEN FDA AND CAPILLUS LLC FROM 10/1/13 TO

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	04/30/2014	DO/FLA-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Advanced Healthcare Technologies, Inc.	3/29/14
2014-2741	04/02/2014 04/30/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Richard Ray Richard Ray	RECS RE THREE FATALITIES DUE TO GRAFT V HOST REPORTED IN ANNUAL REPORTS 01/01/2005 - 12/31/2011
2014-2742	04/02/2014 04/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 204655
2014-2743	04/02/2014 04/30/2014	FDA/OGROP/ORASW-FO/DEN- DO/DEN-CB/ FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/	Haley Steinert UNIVERSITY OF COLORADO	DR TIMOTHY VOLLMER - 483 09/20/1994 - 09/21/1994
2014-2744	04/02/2014 04/30/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Ebony McKinnies BIO-RAD LABORATORIES, INC.	K951361
2014-2745	04/02/2014 04/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	Innovative Neurotronics INNOVATIVE NEUROTRONICS	K072566
2014-2746	04/02/2014 04/30/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Leon Amariglio Lexington Medical, Inc.	K021736
2014-2747	04/02/2014 04/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	Leon Amariglio Lexington Medical, Inc.	K031925
2014-2748	04/02/2014 04/30/2014	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/ OC/ORO/ FDA/OGROP/ORA/ORO/DIOP/ OC/ORO/ORO/DFS/ OC/ORO/ORO/DFS/	Andrew Glazer Vice News	APPLE JUICE FROM CHINA - TEST RESULTS, IMPORTS 01/01/2000 - 03/30/2014
2014-2749	04/02/2014 04/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	John Devine Digital Heat Corporation	K803177, K770686, K963887 ETC
2014-2750	04/02/2014 04/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	Gary Schmirer Cornerstone Research	OMONTYS - FOIA REQUESTS 08/01/2012 - 03/31/2013

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2014-2751	04/02/2014 04/30/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Lisa Robertson Rawls McNelis + Mitchell	INDIVIDUAL RECS
2014-2752	04/02/2014 05/12/2014	FDA/OGROP/ORACE-FO/CIN- DO/CIN-CB/ FDA/OMPT/CTP/OD/	MIKE DENNEY TANTUS TOBACCO	TANTUS INVESTIGATIONS ETC
2014-2753	04/02/2014 04/30/2014	FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/	MICHAEL MORISY MUCKROCK NEWS	BLOOD BANK INSP IN MASSACHUSETTS 1/09 TO PRESENT
2014-2754	04/02/2014 04/30/2014	FDA/OGROP/ORACE-FO/CIN- DO/CIN-CB/	CRAIG ROUSH ROCKLINE INDUSTRIES	GOJO INDUSTRIES INC, CUYAHOGA FALLS, OH - 483, EIR, CORR 11/13
2014-2755	04/02/2014 04/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	FANISH T. ENGINEER UA MEDICAL PRODUCTS INC	UA MEDICAL PRODUCTS INC - HYSTEROSALPINGOGRAPHY & SONOHYSTEROGRAPHY CATHETER SET K990387
2014-2756	04/02/2014 04/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARY B. SZALKOWSKI PRISMA CORP	SANSERT NDA 12-516 - RVWS, A/C MTGS
2014-2757	04/02/2014 04/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARY B. SZALKOWSKI PRISMA CORP	METHYSERGIDE - FAERS
2014-2758	04/02/2014 04/30/2014	FDA/OGROP/ORACE-FO/CIN- DO/CIN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	J. DAVID STANDEFFER STANDEFFER AND HARBIN LLP	INVACARE - POWER WHEELCHAIR RECALL
2014-2759	04/02/2014 04/30/2014	FDA/OGROP/ORACE-FO/MIN- DO/MIN-CB/	Jennifer Franklin Gerber Products Company dba Nestle Nutrition - Eau Claire	GERBER PRODUCTS COMPANY DBA NESTLE NUTRITION - EIR 09/23/2013 - 09/27/2013
2014-2760	04/02/2014 04/30/2014	FDA/OGROP/ORAPA-FO/SEA- DO/SEA-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Linnea Robbins N/A	EVERGREEN HOSPITAL MEDICAL CENTER - ADVERSE EVENT RECS
2014-2761	04/02/2014 04/30/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Eric Martin Unapplicable	MERCK - LETTER RE EXPEDITED APPLICATION TO EXPAND LABELING TO HPV VACCINE
2014-2762	04/02/2014	FDA/OMPT/CDER/ORP/DIDP/	David Wainer	TEVA, INDIA - 483 01/01/2000 - 04/02/2014

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	04/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BLOOMBERG NEWS	
2014-2763	04/02/2014 04/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 204031
2014-2764	04/02/2014 04/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lawrence Marcus Blue Biologics	TEKTURNA - AERS
2014-2765	04/02/2014 04/30/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Mark Zanecki Zanecki, Irene	ST JOSEPH MERCY OAKLAND IRB - ADDITIONAL EXHIBITS, WARNING LETTER 04/01/2013 - 03/31/2014
2014-2766	04/02/2014 04/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Linda Bowen SANOFI	NDA 21536 S033
2014-2767	04/02/2014 04/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Renea Vollmer Parent of Patient	KENALOG INJECTIONS - AERS
2014-2768	04/02/2014 04/30/2014	FDA/OO/OHR/	CALLOWAY, BRIDGET LORRAINE	SELECTIONS FOR VACANCY ANN 929933
2014-2769	04/02/2014 04/30/2014	FDA/OC/OES/DFOI/	Hyman Phelps and McNamara PC	FDA 2013-N-1430
2014-2770	04/02/2014 04/30/2014	FDA/OC/OES/DFOI/	FDA NEWS	FDA 2013-D-0811
2014-2771	04/02/2014 04/30/2014	FDA/OC/OES/DFOI/	HOGAN LOVELLS LLP	FDA-2012-1-1107
2014-2772	04/02/2014 04/30/2014	FDA/OC/OES/DFOI/	HOGAN LOVELLS LLP	FDA-2013-D-1566
2014-2773	04/02/2014 04/30/2014	FDA/OC/OES/DFOI/	HOGAN LOVELLS LLP	FDA 2011-N-0899

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2014-2774	04/02/2014 04/30/2014	FDA/OC/OES/DFOI/	HOGAN LOVELLS LLP	FDA-1985-P-0300
2014-2775	04/02/2014 04/30/2014	FDA/OC/OES/DFOI/	FDA NEWS	FDA-2014-N-0032
2014-2776	04/02/2014 04/30/2014	FDA/OC/OES/DFOI/	HOGAN LOVELLS LLP	2013-P-0058; 0119; 0471
2014-2777	04/02/2014 04/30/2014	FDA/OC/OES/DFOI/	KING & SPALDING	FDA-2013-N-0500
2014-2778	04/02/2014 04/30/2014	FDA/OC/OES/DFOI/	HOGAN LOVELLS LLP	FDA-2013-D-1675
2014-2779	04/02/2014 04/30/2014	FDA/OC/OES/DFOI/	SIDLEY AUSTIN LLP	FDA-2005-P-0426
2014-2780	04/02/2014 04/30/2014	FDA/OC/OES/DFOI/	BUCHANAN INGERSOLL & ROONEY PC	FDA-2013-D-0880
2014-2781	04/02/2014 04/30/2014	FDA/OC/OES/DFOI/	OFW LAW	FDA-1995-N-0063-0014
2014-2782	04/02/2014 04/30/2014	FDA/OC/OES/DFOI/	Wilson Sonsini Goodrich & Rosati	FDA-2013-N-0500; P-1375; N-1434; P-0148; P-1641-0004, 0005
2014-2783	04/02/2014 04/30/2014	FDA/OC/OES/DFOI/	FDA NEWS	FDA-2013-N-0500
2014-2784	04/02/2014 04/30/2014	FDA/OC/OES/DFOI/	BANCROFF PLLC	89P-0025-CP ETC
2014-2785	04/02/2014 04/30/2014	FDA/OC/OES/DFOI/	INDEPENDENCE LEGAL SUPPORT	ADVISORY COMMITTEE MTG 1/19-20/95
2014-2786	04/02/2014 04/30/2014	FDA/OC/OES/DFOI/	SCARBROUGH CONSULTANTS	DKT 1996-D-0513
2014-2787	04/02/2014 04/30/2014	FDA/OC/OES/DFOI/	COVINGTON & BURLING LLP	OTC VOLUMES 070099 ETC
2014-2788	04/02/2014 04/30/2014	FDA/OC/OES/DFOI/	COVINGTON & BURLING LLP	FDA-2013-P-1641-0004
2014-2789	04/02/2014 04/30/2014	FDA/OC/OES/DFOI/	FDANEWS	FDA-2013-N-1524; FDA-2013-N-1437

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2014-2790	04/02/2014 04/30/2014	FDA/OC/OES/DFOI/	FDA NEWS	FDA-2013-N-1523; 2013--D-1464
2014-2791	04/03/2014 05/01/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K111170
2014-2792	04/03/2014 05/01/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Thomas Sims Baron & Budd, PC	LEVAQUIN, LEVOFLOXACIN, CIPRO ETC - POST MARKET REPORTS, SAFETY REVIEWS BY FDA OFFICE OF PHARMACOVIGILANCE AND EPIDEMIOLOGY 01/01/2010 - 02/28/2014
2014-2793	04/03/2014 05/01/2014	FDA/OMPT/CDRH/OCER/DFOI/	Cyril Rastoll Systems Micro Technology Inc	K071230
2014-2794	04/03/2014 05/01/2014	FDA/OMPT/CDRH/OCER/DFOI/	Cyril Rastoll Systems Micro Technology Inc	K090484
2014-2795	04/03/2014 05/01/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kinnari Shah MEDIVATORS INC	K991999
2014-2796	04/03/2014 05/01/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lauren Welling Phillips Law Firm	RISPERDAL - APPROVAL, LABEL CHANGES, AERS ETC
2014-2797	04/03/2014 05/01/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Peter Bean Peter Bean	NDA 021752
2014-2798	04/03/2014 05/14/2014	FDA/OC/OES/DDM/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Drew LaFramboise, Esq. ASHCRAFT & GEREL, LLP	ANDROGEL, ANDRODERM, AXIRON ETC - APPROVAL RECS, ADVISORY COMMITTEE RECS, AERS ETC
2014-2799	04/03/2014 05/01/2014	FDA/OC/OES/DDM/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Peter Bean Peter Bean	NDA 021752 TRUVADA - CLINICAL TRIAL RECS, ADVISORY COMMITTEE TRANSCRIPT 5/10/12
2014-2800	04/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kinnari Shah	K102330

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	05/01/2014	FDA/OC/OES/DFOI/	Medivators Inc.	
2014-2801	04/03/2014 05/01/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tracy Fritz VENABLE LLP	QUESTCOR PHARMACEUTICALS - INVESTIGATION RECS 01/01/2011 - 04/02/2014
2014-2802	04/03/2014 05/01/2014	FDA/OC/OES/DDM/	Nancy Clementi Clementi and Associates	ANESTHETIC AND LIFE SUPPORT ADVISORY COMMITTEE MEETING - TRANSCRIPT 06/01/1994 - 07/02/1994
2014-2803	04/03/2014 05/01/2014	FDA/OFVM/CFSAN/OCD/EOS/	Mary Buckley Sedgwick, LLP	MATERIALS CITED IN 79 FR 7934-01
2014-2804	04/03/2014 05/01/2014	FDA/OMPT/CDRH/OCER/DFOI/	Leon Amariglio Lexington Medical, Inc.	K101851
2014-2805	04/03/2014 05/01/2014	FDA/OGROP/ORACE-FO/BLT- DO/BLT-CB/	Helen Lysy PPD	PPD DEVELOPMENT LCC, RICHMOND, VA - EIR 11/14/2011 - 11/01/2013
2014-2806	04/03/2014 05/01/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Vincent P. Andolina AuroMedics Pharma LLC	HOSPIRA HEALTHCARE INDIA PRIVATE LIMITED - 483 12/01/2013 - 12/31/2013
2014-2807	04/03/2014 05/01/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca Dandeker Morgan, Lewis & Bockius LLP	PCAS FINLAND - 483, EIR SUMMARIES 01/01/2010 - 01/01/2014
2014-2808	04/03/2014 05/01/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Shannon Kindilien UNIVERSITY OF NEW MEXICO	ORANGE BOOK APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE 01/01/1997 - 12/31/2013
2014-2809	04/03/2014 05/01/2014	FDA/OMPT/CDRH/OCER/DFOI/	Alon Mozes Neocis Inc	K023424, K052840
2014-2810	04/03/2014 05/01/2014	FDA/OMPT/CDRH/OCER/DFOI/	Melissa Whalen Hutton & Hutton (Attention: Melissa Whalen)	INDIVIDUAL RECS
2014-2811	04/03/2014 05/01/2014	OC/CVM/OCD/	Doe J	INDIVIDUAL RECS
2014-2812	04/03/2014	FDA/OMPT/CDER/ORP/DIDP/	Tariq Ata	REMS DRUG ERROR REPORTS 2008 TO 2013

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	05/01/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	REMS Logic, LLC	
2014-2813	04/03/2014 05/01/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bao Le ARIAD Pharmaceutical Inc.	NDA 022068 - SBA
2014-2814	04/03/2014 05/01/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Linda Bowen SANOFI	NDA 20986 S061
2014-2815	04/03/2014 05/01/2014	FDA/OC/OES/DFOI/	Kenneth Orce Jr Orce Global Intelligence LLC	QUESTCOR - FOIA REQUESTS
2014-2816	04/03/2014 05/01/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bryan Saylor Hound Partners	NDA 8372 - CHEMISTRY SUPP 47
2014-2817	04/03/2014 05/01/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Mohit Bhat Kline & company Inc.	PANASONIC, BAYER HEALTHCARE ETC - EIR, EXHIBITS RE BLOOD GLUCOSE TEST STRIPS 01/01/2009 - 03/31/2014
2014-2818	04/03/2014 05/01/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rebecca Dandeker Morgan, Lewis & Bockius LLP	PCAS FINLAND OY - EIR 01/01/2010 - 01/01/2014
2014-2819	04/03/2014 05/01/2014	FDA/OC/OES/DDM/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Hannah Harris Hannah Harris	CYMBALTA - ADVISORY COMMITTEE MEETING RECS, REPORT
2014-2820	04/03/2014 05/01/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Billy Yoder T.I.N.N.	STUDIES RE CANNABIS, HEMP, MARIJUANA RE MEDICAL VALUE 01/01/1919 - 12/31/1940

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2014-2821	04/03/2014 05/01/2014	FDA/OMPT/CDRH/OCER/DFOI/	Loren Jacobson WATERS & KRAUS LLP	CORR WITH ATRIUM RE ICAST 01/01/2004 - 12/31/2006
2014-2822	04/03/2014 05/01/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K081406
2014-2823	04/03/2014 05/01/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K111006
2014-2824	04/03/2014 05/01/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Cyril Rastoll Systems Micro Technology Inc	K061405
2014-2825	04/03/2014 05/01/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Kinnari Shah Medivators Inc.	K023290
2014-2826	04/03/2014 05/01/2014	FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/	Joy Flynn flynn, joy	CRODA INC, MILL HALL, PA - EIR
2014-2827	04/03/2014 05/01/2014	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OC/OES/DFOI/ FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	Maria Ortiz-Briones Vida en el Valle	HELADOS LA TAPATIA, FRESNO, CA - 483 , EIR 03/03/2012 - 04/01/2014
2014-2828	04/03/2014 05/01/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Alon Mozes Neocis Inc	K072806
2014-2829	04/03/2014 05/01/2014	FDA/OMPT/CDRH/OCER/DFOI/	Andrea Young c/o CIS Compliance Information Systems	K130082
2014-2830	04/03/2014 05/01/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	XELLIA (AXELLIA) PHARMACEUTICALS APS, COPENHAGEN, DENMARK - EIRS 10/8/12
2014-2831	04/03/2014 05/01/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	VETTER PHARMA FERTIGUNG GMBH & CO KG, RAVENSBURG SCHUENTZENSTRASSE (88212), GERMANY - EIRS 12/2/13
2014-2832	04/03/2014 05/01/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	VETTER PHARMA FERTIGUNG GMBH & CO KG, RAVENSBURG M00SWIESENSTRASSE RF (88241), GERMANY - EIRS 7/17/12
2014-2833	04/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	MEGHALL KHAKHAR	BAYLIS MEDICAL - OSTEOCOOL ABLATION SYS K111523

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	05/01/2014		BAYLIS MEDICAL	REVIEWER'S NOTES, CLEARANCE LTR 5/26/11, 3/13/12
2014-2834	04/03/2014 05/01/2014	FDA/OMPT/CDRH/OCER/DFOI/	GRACE BOOTH SPECTRANETICS CORP	P91001/S005 - APRVL LTR
2014-2835	04/03/2014 05/01/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	WITCZAK, KIM	SECTION 906(B) DIRECT-TO-CONSUMER TELEVISION PHARMACEUTICAL ADVERTISEMENTS PL 110-85 (FDAAA) SECTION 906B - RECS
2014-2836	04/03/2014 05/01/2014	FDA/OGROP/ORO/PA-FO/SEA-DO/SEA-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	JACQUELINE J CHAN K&L GATES	JOHN P TROUP PHD,METAGENICS INC, GIG HARBOR, WA - WARNING LTR SEA 13-27 CORR, MINS, NOTES, ETC 11/13 TO PRESENT
2014-2837	04/03/2014 05/01/2014	FDA/OC/OES/DFOI/	ALBERTO ROSSI UNIV OF MARYLAND/SMITH SCHOOL OF BUSINESS	600 FOI REQUESTS
2014-2838	04/03/2014 05/01/2014	OC/ORO/ OC/ORO/	PERRINE, STEPHEN M	ORADSS - RECS
2014-2839	04/03/2014 05/01/2014	FDA/OC/OCC/	BETH SABAN EGON ZEHNDER	ADVANCED STERILIZATION PRODUCTS - SETTLEMENT AGREEMENT
2014-2840	04/03/2014 05/01/2014	FDA/OFVM/CFSAN/OCD/EOS/	CHRISTINE L KEGGINS IGENE BIOTECHNOLOGY INC	UNIVERSAL FOODS CORP, MILWAUKEE, WI - 13-WEEK DIETARY TOXCITY STUDY WITH RED STAR PHAFFIA YEAST IN RATS VOL I & II 2/28/85
2014-2841	04/03/2014 05/01/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TODD FEATHERS MUCKROCK NEWS	WITHDRAWL OF APRVL OF NEW DRUG APPLICATIONS (NDA) - LTRS 1/13 TO PRESENT
2014-2842	04/03/2014 05/01/2014	FDA/OO/OFBA/OAGS/	CHANDRESH I HARJIVAN PRICEWATERHOUSE COOPERS LLP	ICETECH - HHSF23301210393A
2014-2843	04/04/2014	FDA/OMPT/CDER/ORP/DIDP/	Ryan L Thompson	LETTER DATED MARCH 2014 FROM JANET WOODCOCK TO

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	05/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Watts Guerra LLP	ELIZABETH BARBEHENN AND SIDNEY WOLFE - RELATED RECS
2014-2844	04/04/2014 05/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ryan L. Thompson Watts Guerra LLP	INCRETIN MIMETIC CLASS OF DRUGS - CORR RE PANCREATIC CANCER 01/01/2009 - 04/01/2014
2014-2845	04/04/2014 05/02/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Kelsey Stevenson Terumo BCT, Inc.	BK070001
2014-2846	04/04/2014 05/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michael Bouchon Chelsea Therapeutics Inc.	DR LYUDMYLA DZYAK - EIR 1/20/12
2014-2847	04/04/2014 05/02/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/	Matthew Dotray TEXAS TECH UNIVERSITY	LIST OF BLOOD BANKS AND DONATION CENTERS WHO FAILED TO MEET SAFETY REQUIREMENTS IN SECTION 351 OF THE PUBLIC HEALTH SERVICE ACT 2010 TO 2012
2014-2848	04/04/2014 05/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	AMLODIPINE - AERS
2014-2849	04/04/2014 05/02/2014	FDA/OFVM/CFSAN/OCD/EOS/	Scott Vincent Green River Asset Management	FORMULA FORTIFIED WITH DHA - AERS
2014-2850	04/04/2014 05/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Paul E. Greenberg Analysis Group, Inc.	VICTOZA - SAFETY RVWS 01/01/2013 - 04/01/2014
2014-2851	04/04/2014 05/02/2014	FDA/OGROP/ORASW-FO/FLA- DO/FLA-CB/ FDA/OC/OES/DFOI/	Sharon Tiffany, Esq. The Law Offices of Maria L. Rubio, P.A.	DE LA PEDRAJA RADIOLOGY ASSOCIATES, PA, CORAL GABLES, FL - INSPECTION RECS 01/01/2000 - 12/31/2010
2014-2852	04/04/2014 05/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Shin Kang WELLS FARGO	KALYDECO, TECFIDERA, SOVALDI ETC - AERS

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2014-2853	04/04/2014 05/02/2014	FDA/OGROP/ORPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Ms. Kelly Rowland IMPAC Medical Systems, Inc.	IMPAC MEDICAL SYSTEMS INC - EIR 06/06/2011 - 12/31/2011
2014-2854	04/04/2014 05/02/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michael Bouchon Chelsea Therapeutics Inc.	DR DMYTRO LEBEDNYET - EIR 1/16/12
2014-2855	04/04/2014 05/02/2014	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	CIGARETTE DISTRIBUTION TRACKING, TRACING, DIGIAL ENCRYPTION OF TAX STAMPS ETC 01/01/2010 TO PRESENT
2014-2856	04/04/2014 05/02/2014	FDA/OMPT/CDRH/OCER/DFOI/	Lori Burns DSM Biomedical	K071271
2014-2857	04/04/2014 05/02/2014	FDA/OMPT/CDRH/OCER/DFOI/	Lori Burns DSM Biomedical	K924141
2014-2858	04/04/2014 05/02/2014	FDA/OMPT/CDRH/OCER/DFOI/	Lori Burns DSM Biomedical	K882967
2014-2859	04/04/2014 05/02/2014	FDA/OMPT/CDRH/OCER/DFOI/	Lori Burns DSM Biomedical	K972327
2014-2860	04/04/2014 05/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 3/1-31/2014
2014-2861	04/04/2014 05/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	CLOSED FOIA REQUESTS MARCH 2013
2014-2862	04/04/2014 05/02/2014	FDA/OMPT/CTP/OD/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Peter IC Lang Peter Lang MS, CIH	CHEMICAL ANALYSIS OF E-CIGARETTE LIQUIDS
2014-2863	04/04/2014 05/02/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Pallavi Ail The Financial Express	SUN PHARMACEUTICALS, INDIA - INSPECTION RECORDS RE IMPORT ALERT MARCH 2014
2014-2864	04/04/2014 05/02/2014	FDA/OMPT/CDRH/OCER/DFOI/	Susan Weinbach CONVENTUS BIOMEDICAL SOLUTIONS INC	K111495

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2014-2865	04/04/2014 05/02/2014	FDA/OGROP/OROPA-FO/SEA-DO/SEA-CB/	Amanda Kell Cell Therapeutics, Inc.	CELL THERAPEUTICS, INC, SEATTLE, WA - EIR 11/01/2009 - 09/01/2010
2014-2866	04/04/2014 05/02/2014	FDA/OC/OES/DFOI/	Richard Newman RND Services, LLC	50 STATE MEETING RE PHARMACY COMPOUNDING - AGENDA, TRANSCRIPT 03/20/2014 - 03/21/2014
2014-2867	04/04/2014 05/02/2014	FDA/OO/OHR/ FDA/OC/OES/DFOI/	Jennifer Silverstone NATIONAL TREASURY EMPLOYEES UNION	AGGREGATE PERFORMANCE SCORES FOR EACH AWARD POOL 01/01/2013 - 02/15/2014
2014-2868	04/04/2014 05/02/2014	FDA/OFVM/CFSAN/OCD/EOS/	DIANNE L CHAMBERS HOGAN LOVELLS LLP	PROPYLENE OXIDE (PPO) IN ALMONDS AND TREE NUTS - EFFICACY STUDY
2014-2869	04/04/2014 05/02/2014	FDA/OC/OL/	JOHN COTTER AMERICAN BRIDGE 21ST CENTURY	SEN MITCH MCCONNELL, COMMISSIONER OF FOOD AND DRUGS, ASSOCIATE COMMINSSIONER FOR LEGISLATION - CORR 1985 TO PRESENT
2014-2870	04/04/2014 05/02/2014	FDA/OC/OES/DDM/ FDA/OFVM/CFSAN/OCD/EOS/	MAHMOUD AYESH Zx Pharma, LLC	DKT 1995S-0039
2014-2871	04/04/2014 05/02/2014	FDA/OC/OES/DFOI/	Mark Greenblatt Scripps News D.C. Bureau	WRITTEN OPINIONS SUBMITTED BY DAEO 01/01/2011 - 04/01/2014
2014-2872	04/04/2014 05/02/2014	FDA/OC/OES/DFOI/	KATHRYN QUERUBIN COOLEY LLP	HEPLISAV - RECS
2014-2873	04/04/2014 05/02/2014	FDA/OC/OES/ FDA/OFVM/CFSAN/OCD/EOS/	MITRA JAFARY-HARIRI HONIGMAN MILLER SCHWARTZ & COHN	5-HOUR ENERGY - CAERS, CORR, INVESTIGATION RECS, ETC
2014-2874	04/04/2014 05/02/2014	FDA/OMPT/OSMP/OOPD/	FARYAL A HASAN Hyman, Phelps & McNamara P.C.	ALPROLIX (COAGULATION FACTOR IX RECOMBINANT, FE FUSION PROTEIN) - ORPHAN DRUG DESIGNATION
2014-2875	04/07/2014 05/05/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Shannon Kindilien UNIVERSITY OF NEW MEXICO	LIST OF ALL DRUGS PER PATENT USER CODE, NDC CODE
2014-2876	04/07/2014 05/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michael Bouchon Chelsea Therapeutics Inc.	DR VALERY BITNESKYY - EIR 1/27/12
2014-2877	04/07/2014	OC/CVM/OCD/	PEGGY COUSINEAU	ENVIRONMENTAL ASSESSMENT - OXYTETRACYCLINE WATER SOLUBLE AND PREMIX FORMULATIONS FOR FOOD

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	05/05/2014		INFOTRIEVE INC	PRODUCING ANIMALS
2014-2878	04/07/2014 05/05/2014	OC/CVM/OCD/	Rachel Johnson FOI Services, Inc.	DE MINIMIS STANDARD FOR RECALLS REGARDING ALL PRODUCT AND INGREDIENTS DEEMED ADULTERATED WITH ADDED CHLORAMPHENICOL AND CHLORPYROFOS
2014-2879	04/07/2014 05/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ryan L. Thompson Watts Guerra LLP	CORR BETWEEN FDA AND NOVO NORDISK, ELI LILLY AND COMPANY, AMYLIN ETC RE INCRETIN MIMETIC DRUGS AND PANCREATIC CANCER
2014-2880	04/07/2014 05/05/2014	OC/ORO/OCI/ OC/ORO/OCI/	Rakesh Padigala EASTERN MICHIGAN UNIVERSITY	COUNTERFEIT CASES RE LIPITOR AND VIAGRA FROM APPROVAL TO PRESENT
2014-2881	04/07/2014 05/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Barbara Schiember Barbara Schiember	LEVULAN KERASTICK AND BLUE-U LIGHT TREATMENT - AERS
2014-2882	04/07/2014 05/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Laurel Aitelli Laurel Aitelli	ISOTRETOIN - AERS
2014-2883	04/07/2014 05/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA EXCLUSIVITY ASSESSMENT
2014-2884	04/07/2014 05/05/2014	OC/ORO/ OC/ORO/	Mark Lyons Lyons, Mark	TRIANGLE COMPOUNDING, CARY, NC - INSPECTION RECS, RESPONSE 02/19/2013 - 04/03/2014
2014-2885	04/07/2014 05/05/2014	FDA/OGROP/ORO/CE-FO/CIN-DO/CIN-CB/	Sarah Jane Tribble WCPN	CLEVELAND CLINIC FOUNDATION - EIR 6/12/13, 04/03/13, 08/15/12 ETC
2014-2886	04/07/2014 05/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Screen Mammo Facilities Info at the County Level Over Years Harvey L. Neiman Health Policy Institute	MAMMOGRAPHY DATA 01/01/2004 - 12/31/2013
2014-2887	04/07/2014 05/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Shadi Al-Jureidini Palmetto Health Richland	MEDWATCH REPORTS POLYMYXIN B

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2014-2888	04/07/2014 05/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K111877
2014-2889	04/07/2014 05/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K112909.
2014-2890	04/07/2014 05/05/2014	OC/ORA/ OC/ORA/	Michael Koch CENTRAL ADMIXTURE PHARMACY SERVICES INC	ADVANCED PHARMA, INC, HOUSTON, TX - 483 03/01/2014
2014-2891	04/07/2014 05/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K132216
2014-2892	04/07/2014 05/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	BAVITUXIMAB - PHASE I AND PHASE II TRIALS
2014-2893	04/07/2014 05/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Andrew Bronson Tender Corporation	K102299
2014-2894	04/07/2014 05/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Andrew Bronson Tender Corporation	K052458
2014-2895	04/07/2014 05/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Andrew Bronson Tender Corporation	K112126
2014-2896	04/07/2014 05/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Lori Burns DSM Biomedical	K880309
2014-2897	04/07/2014 05/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Lori Burns DSM Biomedical	K914374
2014-2898	04/07/2014 05/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Lori Burns DSM Biomedical	K874919
2014-2899	04/07/2014 05/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michael R. Rudnick, MD Penn Presbyterian Medical Center - Michael Rudnick MD	POLYETHYLENE GLYCOL 3550 PRODUCTS - REPORTS
2014-2900	04/07/2014 05/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tim Henkel Tim Henkel	NDA 050685, NDA 050686

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2014-2901	04/07/2014 05/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Lori Burns DSM Biomedical	K103797
2014-2902	04/07/2014 05/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Lori Burns DSM Biomedical	K030256
2014-2903	04/07/2014 05/05/2014	FDA/OFVM/CFSAN/OCD/EOS/	Delaney Enterprises LLC Delaney Enterprises LLC	NDI NOTIFICATION FOR GYMNEMA SYLVESTRE
2014-2904	04/07/2014 05/05/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Marie Evangelisto Doyle Teva Pharmaceuticals	BEN BENUE LABORATORIES, BEDFORD, OH - EIR 05/01/2011 - 01/01/2013
2014-2905	04/07/2014 05/05/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Stephen Westover Cook MyoSite Incorporated	DENDREON, MORRIS PLAINS, NJ - EIR, 483 02/01/2007 - 03/06/2010
2014-2906	04/07/2014 05/05/2014	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2014-2224
2014-2907	04/07/2014 05/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jennie Laton HASSARD BONNINGTON LLP	FLIR TELETHERMOGRAPHIC CAMERA - APPROVAL RECS, COMPLAINTS, DEAR DR LETTERS ETC
2014-2908	04/07/2014 05/05/2014	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	EARL GOEHRING THE DEGGE GROUP, LTD.	GABAPENTIN REPORTS
2014-2909	04/07/2014 05/05/2014	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Anupam Dokeniya Sefacor	IND Gliadel Wafers
2014-2910	04/07/2014 05/05/2014	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Cari Ledbetter PERRIGO CO	NDA 205352 ALEVE PM - SBA
2014-2911	04/07/2014 05/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Leah Amir Institute for Quaiity Resource Management	K102521
2014-2912	04/07/2014 05/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Leah Amir Institute for Quaiity Resource Management	GUIDANCE ISO 7405, ISO 10993 - 510K RECS

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2014-2913	04/07/2014 05/05/2014	OC/ORO/ OC/ORO/	Michael Koch CENTRAL ADMIXTURE PHARMACY SERVICES INC	REGION CARE, INC, GREAT NECK, NY - 483 03/01/2014 - 03/25/2014
2014-2914	04/07/2014 05/05/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Sara Fuks The Rosen Law Firm	CORR BETWEE FDA, CBER, TISSUE REFERENCE GROUP, MIMEDX, SURGICAL BIOLOGICS ETC
2014-2915	04/07/2014 05/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Saagar Patel Whitney Medical Solutions	K101689
2014-2916	04/07/2014 05/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	EARL GOEHRING THE DEGGE GROUP, LTD.	FAERS REPORTS
2014-2917	04/07/2014 05/05/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/NE-FO/NYK- DO/NYK-DCB/	Charles Gabbert ATALANTA CORPORATION	ENTRY DP4-0706155-6
2014-2918	04/07/2014 05/05/2014	FDA/OMPT/CDRH/OCER/DFOI/ OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/	Doe J	INDIVIDUAL RECS
2014-2919	04/08/2014 05/06/2014	FDA/OC/OCC/ FDA/OC/OES/DDM/ FDA/OC/OES/DFOI/	Jason R Williams none	ELIZABETH DICKINSON ORANGE BOOK MEETING 06/17/2012 - 04/04/2014; FDA-2013-P-0148-0001; FDA-2013-P-0148-0001 ETC
2014-2920	04/08/2014 05/06/2014	FDA/OMPT/CDRH/OCER/DFOI/	Russ Garrison Garrison, Bill	VERATHON MEDICAL, CANADA - 483, EIR 11/01/2013 - 04/01/2014
2014-2921	04/08/2014 05/06/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/	Miss M Foa REPRIEVE	PENTOBARBITAL IMPORTS 8/21/13 TO PRESENT
2014-2922	04/08/2014 05/06/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K113353
2014-2923	04/08/2014 05/06/2014	FDA/OMPT/CDRH/OCER/DFOI/	Stephen McKelvey Zimmer, Inc.	K873005, K882922, K883922 ETC
2014-2924	04/08/2014 05/06/2014	FDA/OMPT/CDRH/OCER/DFOI/	Brian Cran Aqueduct Critical Care	K121248

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2014-2933	04/08/2014 05/06/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TANJA WYNN HAMPTON MD MERCK & CO., INC.	MIRENA (LEVONORGESTREL-RELEASING IUD) NDA 21-225/S027 - MEDICAL,SAFETY, CLNCL PHARMACOLOGY RECS
2014-2934	04/08/2014 05/06/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WARREN WILLIAMS FOREST RESEARCH INSTITUTE	ABILIFY (ARIPIRAZOLE) TABS NDA 21-436/S005 - POSTMARKETING COMMITMENT PROTOCOL, FINAL STUDY RPT
2014-2935	04/08/2014 05/06/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	LEON WORTHAM WORTHAM LABORATORIES INC USA	TOPICAL THROMBIN BOVINE (FASTACT) IND 10400 - AMENDMENT 17
2014-2936	04/08/2014 05/06/2014	FDA/OC/OES/DDM/ FDA/OFVM/CFSAN/OCD/EOS/	SARENA HOLDER TUCKER ELLIS LLP	TALC, ASBESTOS, TREMOLITE, ETC - REGULATIONS, GUIDANCE, PROPOSED RULES, ETC 1962 TO 1992
2014-2937	04/08/2014 05/06/2014	OC/ORO/ OC/ORO/ FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GREGORY J MAY NELSON MULLINS RILEY & SCARBOROUGH LLP	AMERIDOSE LLC, WESTBOROUGH, MA; FRAMINGHAM, MA - INSP RPTS, YEARLY RPTS, CITATIONS, ETC
2014-2938	04/08/2014 05/06/2014	FDA/OC/OES/DFOI/	ELENA HOWELL HOGAN LOVELLS US LLP	2014-1467
2014-2939	04/08/2014 05/06/2014	FDA/OFVM/CFSAN/OCD/EOS/	JOHN H COX INTERNATIONAL ASSOCIATION OF COLOR MANUFACTURERS	WM WRIGLEY JR CO - PETITION PROPOSING THAT COLOR ADDITIVE REGULATIONS BE AMENDED TO EXPAND THE USE OF SYNTHETIC IRON OXIDE TO INCLUDE SOFT & HARD CANDY, MINTS, CHEWING GUM
2014-2940	04/08/2014 05/06/2014	FDA/OFVM/CFSAN/OCD/EOS/ OC/CVM/OCD/	BRYAN SHAND AGROPHARM LTD	WITHDRAWAL OF HEXACHLOROETHAN (HCE) - RECS
2014-2941	04/08/2014 05/06/2014	FDA/OMPT/CDRH/OCER/DFOI/	JEFF OVERLEY Law360	AZOI INC - WELLO CORR, RECS 1/1/13
2014-2942	04/08/2014 05/06/2014	FDA/OMPT/CDRH/OCER/DFOI/	THERESA BRANDNER-ALLEN MEDINA MEDICAL INC	K140048

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2014-2943	04/08/2014 05/06/2014	FDA/OC/OES/DFOI/	ELENA HOWELL HOGAN LOVELLS LLP	2014-1466
2014-2944	04/08/2014 05/06/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OC/OES/DFOI/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	SHEPLEY, KEN	DELAVALU LLC, PHILADELPHIA, PA - EIR, 483, CORR 9/13
2014-2945	04/08/2014 05/06/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	VETTER PHARMA FERTIGUNG GMBH & CO KG, RAVENSBURG, MOOSWIESENSTRASSE - EIR 9/2/13
2014-2946	04/08/2014 05/06/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	VETTER PHARMA FERTIGUNG GMBH & CO KG, HELMUT-VETTER-STRASSE - EIR 3/11/13
2014-2947	04/08/2014 05/06/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	VETTER PHARMA FERTIGUNG GMBH & CO KG, RAVENSBURG MOOSWIESENSTRASSE - EIR 10/12/13
2014-2948	04/08/2014 05/06/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	PAUL B CALLAHAN CHARLES RIVER LABS	CHARLES RIVER LABORATORIES INC, WILMINGTON, MA - EIR 9/14/06
2014-2949	04/08/2014 05/06/2014	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	PAUL B CALLAHAN CHARLES RIVER LABS	CHARLES RIVER LABORATORIES INC CLINICAL SERVICES, CARY, NC - EIR 12/20-21/06
2014-2950	04/08/2014 05/06/2014	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	PAUL B CALLAHAN CHARLES RIVER LABS	CHARLES RIVER LABORATORIES INC INTERVENTIONAL & SURGICAL SERVICES WISCONSIN, OSCEOLA, WI - EIR 1/31/06
2014-2951	04/08/2014 05/13/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PAUL B CALLAHAN CHARLES RIVER LABS	CHARLES RIVER LABORATORIES INC, BALLINA, COUNTY MAYO, IRELAND - EIR 3/15/06

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		FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/		
2014-2952	04/08/2014 05/06/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	A LUKE SMITH ESQ FARUQI & FARUQI LLP	SANDOZ - REGAGLINIDE ANDA 78-555 APRVL ROUTING SUMMARY
2014-2953	04/08/2014 05/06/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	A LUKE SMITH ESQ FARUQI & FARUQI LLP	AUROBINDO - REGAGLINIDE ANDA 203-820 APRVL ROUTING SUMMARY
2014-2954	04/09/2014 05/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Christine Livoti BIOPHARM INSIGHT	XELJANZ, OTELZA, - MEDWATCH REPORTS
2014-2955	04/09/2014 05/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Christine Livoti BIOPHARM INSIGHT	SOVALDI, OLYSIO - MEDWATCH REPORTS
2014-2956	04/09/2014 05/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	Cheryl Segawa Salt Creek Medical	RESTLESS LEG DEVICE - DE NOVO SUMMARY AND FDA DECISION LETTER
2014-2957	04/09/2014 05/07/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K090650

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		FDA/OC/OES/DFOI/		
2014-2958	04/09/2014 05/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	Alex Pawlowski Septodont, Inc.	K063237
2014-2959	04/09/2014 05/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K110152
2014-2960	04/09/2014 05/07/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Patrick Vallely SHAPIRO HABER & URM LLP	BIOVEST INTERNATIONAL, INC - COMMUNICATIONS RE IND 5427, MEETING MINUTES 01/01/2004 - 04/17/2014
2014-2961	04/09/2014 05/07/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Subhash Patel MD Reg Consulting, LLC	K010514
2014-2962	04/09/2014 05/07/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Adam Fountain Broadmark Capital, LLC	OMS302 NDA FILING DATE
2014-2963	04/09/2014 05/07/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jiye Ahn Qurient Inc.	NDA 20471
2014-2964	04/09/2014 05/07/2014	FDA/OGROP/ORR/CE-FO/PHI- DO/PHI-CB/	John Walsh James Alexander Corporation	J PENNER CORPORATION, DOYLESTOWN, PA - EIR, 483, RECALLS 04/08/2009 - 04/08/2014
2014-2965	04/09/2014 05/07/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Kim Good Mani, Ellis & Layne	COVIDIEN ENDO CLIP III - 510K, WARNING LETTER, MAUDE ETC 01/02/2007 - 12/31/2008
2014-2966	04/09/2014 05/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	edward wulfman Vadiswire Corp	K903606
2014-2967	04/09/2014 05/07/2014	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2014-2555
2014-2968	04/09/2014 05/07/2014	FDA/OO/OFBA/OAGS/	Rachel Johnson FOI Services, Inc.	FDA-RFQ-1120913
2014-2969	04/09/2014 05/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	edward wulfman Vadiswire Corp	K925419

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2014-2970	04/09/2014 05/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K091417
2014-2971	04/09/2014 05/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CYNTHIA BERRINGER Kadmon Pharmaceuticals, LLC	DMF 12659
2014-2972	04/09/2014 05/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Erica Pollock Sygene Technologies Corporation	XALATAN OPHTHALMIC SOLUTION 0.005% - APPROVAL LETTER, LABELING, PATENT/EXCLUSIVITY ETC
2014-2973	04/09/2014 05/07/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Jennifer Carragher ALMAC GROUP	MORTON SALT, RITTMAN, OH - EIR 7/15/13
2014-2974	04/09/2014 05/07/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Jennifer Carragher ALMAC GROUP	WELSH LABORATORIES, HOLLAND, MI - EIR 12/4/12
2014-2975	04/09/2014 05/07/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Jennifer Carragher ALMAC GROUP	CHURCH AND DWIGHT, OLD FORT, OH - EIR 12/21/12
2014-2976	04/09/2014 05/07/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Jennifer Carragher ALMAC GROUP	AVANTOR PERFORMANCE MATERIALS, PARIS, KY - EIR 8/17/12
2014-2977	04/09/2014 05/07/2014	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	Jennifer Carragher ALMAC GROUP	DOW CHEMICAL CO, HAHNVILLE, LA - EIR 8/24/11
2014-2978	04/09/2014 05/07/2014	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	Jennifer Carragher ALMAC GROUP	CHURCH AND DWIGHT, GRAND RIVER, WY - EIR 10/25/11
2014-2979	04/09/2014 05/07/2014	FDA/OFVM/CFSAN/OCD/EOS/	FRIEDMAN, ROBERT	JELLO - CAERS 1969 TO 2014
2014-2980	04/09/2014 05/07/2014	FDA/OFVM/CFSAN/OCD/EOS/	FRIEDMAN, ROBERT	PLANTER'S, NESTLE, NESTLE CREAM - CAERS 1969 TO 2014
2014-2981	04/09/2014 05/07/2014	FDA/OFVM/CFSAN/OCD/EOS/	FRIEDMAN, ROBERT	SIMPLY ORGANIC, UNCLE DAN'S, ROAD'S END - CAERS 1969 TO 2014
2014-2982	04/09/2014 05/07/2014	FDA/OFVM/CFSAN/OCD/EOS/	FRIEDMAN, ROBERT	ARROWHEAD MILLS, GLUTINO, NAMASTE, ETC - CAERS 1969 TO 2014
2014-2983	04/09/2014 05/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	DAVID A BORES THURMAN LAW FIRM	SMITHS MEDICAL MD INC - CADD-SOLIS MEDICATION SAFETY SOFTWARE K082783 (CERTIFIED)

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2014-2984	04/09/2014 05/07/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MICHAEL R COHEN INSTITUTE FOR SAFE MEDICATION PRACTICES	MEDWATCH RPTS CODED AS MEDICATION ERRORS 3/1-31/14
2014-2985	04/09/2014 05/07/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID J BURTON BURTON & SIMKIN	KENALOG, TRIAMANOLITE, DEPO MEDOL, ETC - ISRS
2014-2986	04/09/2014 05/07/2014	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	JACKIE CHRISTENSEN AMERICAN RED CROSS	AMERICAN RED CROSS, TUCSON, PHOENIX, AZ - EIRS 3/17-18/10, 9/9/10/10, 9/5/12
2014-2987	04/09/2014 05/07/2014	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	ARTHUR MEISEL Arthur Meisel, Esq.	2014-1156 - EIR EXHIBIT 11.1-11.7 UMTB DEVIATION RPT D11-112, 482 1/03/12, 483 12/14/12
2014-2988	04/09/2014 05/07/2014	FDA/OC/OES/DFOI/	ELENA HOWELL HOGAN LOVELLS US LLP	2014-1089
2014-2989	04/09/2014 05/07/2014	FDA/OC/OES/DFOI/	AMIE N VANELLA FAEGRE BAKER DANIELS	SIMPLY THICK, OR SIMPLY THICK LLC - FOI REQUEST LETTERS 2/8/13 TO PRESENT
2014-2990	04/09/2014 05/07/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BARKLEY SBI#861070-B, RASHON	CERVICAL CANCER DRUGS APVD FOR USE TO THE AMERICAN PUBLIC; URETHANE, POLYURETHANE - RECS
2014-2991	04/10/2014 05/08/2014	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dana Thompson/Kathy Grant FULBRIGHT & JAWORSKI LLP	VIRTUS PHARMACEUTICALS, NHK LABORATORIES - EIR, WARNING LETTERS, AERS 01/01/2011 - 04/08/2014
2014-2992	04/10/2014 05/08/2014	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	Richard O. Wood the Wood Burditt group	ORGAN RECOVERY SYSTEMS, ITASCA, IL - CORR, EIR, 483 ETC 01/01/2012 - 04/09/2014
2014-2993	04/10/2014 05/08/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Christine Livoti BIOPHARM INSIGHT	BOEHRINGER INGELHEIM - 483, SUMMARIES

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-2994	04/10/2014 05/08/2014	FDA/OFVM/CFSAN/OCD/EOS/	Mark Prinz Registrar Corp	CONSTANZA AGROINDUSTRIAL, DOMINICAN REPUBLIC - EIR MOST RECENT; DARRELL LEA, AUSTRALIA, LIFE FOOD PRODUCT ECUADOR, ETC - 483 MOST RECENT
2014-2995	04/10/2014 05/08/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Jing Gu W.H.P.M., Inc	K133140, K041408
2014-2996	04/10/2014 05/08/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Brian Brockway VivaQuant, LLC	K043380
2014-2997	04/10/2014 05/08/2014	FDA/OMPT/CTP/OD/	Michael Felberbaum THE ASSOCIATED PRESS	LIST OF MODIFIED RISK TOBACCO PRODUCTS SUBMITTED TO CTP 06/22/2009 - 04/09/2014
2014-2998	04/10/2014 05/08/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DANIEL BALABAN Balaban, Daniel K	RECS RE TRACKED SAFETY ISSUE FOR NEUROLOGIC COMPLICATIONS WITH EPIDURAL INJECTION OF CORTICOSTEROIDS; OSE DIVISION OF MED ERROR ANALYSIS FEB 2011
2014-2999	04/10/2014 05/08/2014	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	Laurie Peterson, CCRC Spokane Joint Replacement Center	SPOKANE JOINT REPLACEMENT CENTER - EIR 02/27/2012 - 02/27/2012
2014-3000	04/10/2014 05/08/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	John Franolic Ve	ANDA 075860 - SBA
2014-3001	04/10/2014 05/08/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KAVITA SRIVASTAVA TARO PHARMACEUTICALS USA INC	HIKMA PHARMS - DOXYCYCLIN HYCLATE ANDA 65-095 SBA, MOR, LBLG, ETC
2014-3002	04/10/2014 05/08/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KAVITA SRIVASTAVA TARO PHARMACEUTICALS USA INC	PFIZER - VIBRAMYCIN N050007- SBA, MEDICAL RVW, CHEMISTRY RVW, LBLG
2014-3003	04/10/2014 05/08/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KAVITA SRIVASTAVA TARO PHARMACEUTICALS USA INC	APOTHECON - MYCOLOG II (NYSTATIN, TRIAMCINOLONE ACETONIDE) ANDA 060576 and 062606 SBA, MOR, LBLG, ETC
2014-3004	04/10/2014 05/08/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KAVITA SRIVASTAVA TARO PHARMACEUTICALS USA	SAVAGE LABS - MYTEX F A062597 SBA, MEDICAL RVW, CHEMISTRY RVW, LBLG

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	INC	
2014-3005	04/10/2014 05/08/2014	FDA/OC/OES/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MICHAEL BEKESHA JUDICIAL WATCH	AMERICAN ASSOCIATION FOR JUSTICE - REGULATORY CHANGES REGARDING GENERIC DRUG LBLG RECS, CORR 2/25/13
2014-3006	04/10/2014 05/08/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ALLISON TARANTINO ARIAD PHARMACEUTICALS INC	ICLUSIG (PONATINIB) - AERS THROUGH 4/8/14
2014-3007	04/10/2014 05/08/2014	FDA/OC/OES/DFOI/	TOWNSEND 13003-076, JIM	CHRIZO - INGREDIENTS
2014-3008	04/10/2014 05/08/2014	FDA/OFVM/CFSAN/OCD/EOS/	HOLLY J. BAYNE BAYNE & ASSOCIATES	ACCERA INC - AXONA; NVN THERAPEUTICS - GLUCOREIN PCOS; METAGENICS INC - ULTRACLEAR, GI SUSTAIN, ULTRAMEAL PLUS, ETC LBLG, WARNING LTRS
2014-3009	04/10/2014 05/08/2014	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/ OC/ORO/ FDA/OGROP/ORO/NE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORO/ORO/DIOP/ FDA/OGROP/ORO/SW-FO/SWID/SWID-CB/	BENJAMIN L. ENGLAND, Esq. BENJAMIN L ENGLAND & ASSOCIATES LLC	SOUTHEAST ASIAN PACKAGING AND CANNING LTD - CMLPNTS 135083, 124763 TEST RESULTS, IMPORT ALERT MEMOS, ETC
2014-3010	04/10/2014 05/08/2014	FDA/OGROP/ORO/SW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORO/SW-FO/DEN-DO/DEN-CB/	MAY, SAM	AMGEN - RESP TO 483, ATTACHMENTS
2014-3011	04/10/2014 05/08/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MUCKROCK NEWS	NALOXONE - SAFETY AND EFFECTIVENESS STUDIES 2012 TO PRESENT
2014-3012	04/10/2014 05/08/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	CHLOE BOWER SYNGEN INC	BIOE INC - PREPACYTE BK070067

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2014-3013	04/11/2014 05/09/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Amanda Schmidt Schmidt, Amanda	REESE'S PINWORM MEDICINE - CLINICAL TRIALS OR RESEARCH RE LIVER AND GUT 01/01/2000 - 04/09/2014
2014-3014	04/11/2014 05/09/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	David Lin David Lin	ONCASPAR - APPROVAL RECS
2014-3015	04/11/2014 05/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	Dee Dee White Luvera Law Firm	MDR: 2029214-2012-00262
2014-3016	04/11/2014 05/09/2014	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	FAP 3B4369
2014-3017	04/11/2014 05/09/2014	FDA/OC/OES/DFOI/	Michael Felberbaum THE ASSOCIATED PRESS	2013-7721, 2013-8007, 2014-311
2014-3018	04/11/2014 05/09/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Elizabeth Nunez - CNN CNN AMERICA INC	XOLAIR - WARNINGS, LABEL REVIEWS, ETC
2014-3019	04/11/2014 05/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	Donna T. Ward Ward, Donna T	K993951 STATEMENT POSTED DATE
2014-3020	04/11/2014 05/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	Andrew L Cote Sr. PLF Product Concepts, LLC	K130023
2014-3021	04/11/2014 05/09/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Adverse effects of Tetracycline Ross Gibson	TETRACYCLINE - AERS
2014-3022	04/11/2014 05/09/2014	FDA/OC/OES/DFOI/	Desmond Jenson Tobacco Control Legal Consortium	CTP FOIA REQUEST LOG
2014-3023	04/11/2014 05/09/2014	FDA/OFVM/CFSAN/OCD/EOS/	Lynn P. Tordo Thor Specialties, Inc.	FCN 1143
2014-3024	04/11/2014 05/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jennifer Butsch riverain technologies	K133442
2014-3025	04/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	CHRIS SZECHENYI	THORATEC CORP - HEARTMATE II LEFT VENTRICULAR

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	05/09/2014		ON POINT INVESTIGATIONS	ASSIST SYS MDRS, COMM
2014-3026	04/11/2014 05/09/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Zeidberg, David	CADENCE PHARMS - OFIRMEV 1000 MG (IV ACETAMINOPHEN) STABILITY, STORAGE CONDITIONS, STERILITY RECS
2014-3027	04/11/2014 05/09/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	OLENA IZHAK UNIV OF HELSINKI	ORANGE BOOK - DATA BASE PHARAGRPH IV LISTINGS, ETC
2014-3028	04/11/2014 05/09/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	MARC ULLMAN ULLMAN SHAPIRO & ULLMAN LLP	FDA RECALL SOP'S
2014-3029	04/11/2014 05/09/2014	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	BETTY NAHMIAS BLADDER & PROSTATE HEALTH INVESTIGATIONS	DR ANGELO GOUSE'- 483S 3/2-30/11PHARAGRPH
2014-3030	04/11/2014 05/09/2014	FDA/OFVM/CFSAN/OCD/EOS/	ALEXANDER S RINN Carlson Caspers	CYANOTECH CORP - BIOASTIN, BIOASTIN SUPREME, EYEASTIN, ETC NOTIFICATION OF STATEMENTS OF STRUCTURE FUNCTION SUPPORT
2014-3031	04/11/2014 05/09/2014	FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECS
2014-3032	04/11/2014 05/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	Adam Gross Medacta USA	CPT1400164 COMPLIANCE REPORT
2014-3033	04/11/2014 09/10/2014	OC/ORAE/ OC/ORAE/ OC/ORAE/ORM/ OC/ORAE/ORM/	Rob Barry WALL STREET JOURNAL	FACTS DATA TABLES
2014-3034	04/11/2014 05/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jeffrey Fox Jeffrey Fox	CDRH WORKSHOP ADVANCING REGULATORY SCIENCE FOR HIGH THROUGHPUT SEQUENCING DEVICES FOR MICROBIAL IDENTIFICATION AND DETECTION OF ANTIMICROBIAL RESISTANCE MARKERS - LIST OF ATTENDEES
2014-3035	04/11/2014 05/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	Joseph W. Moss, Jr. Erwin Bishop Capitano & Moss PA	K090609
2014-3036	04/11/2014 05/09/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ketaki Gokhale BLOOMBERG NEWS	SMRUTHI ORGANICS LTD, INDIA - 483 04/01/2012 - 04/10/2014

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-3037	04/11/2014 05/09/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Edmonds Bafford TIG Advisors	CORR BETWEEN JOHN FUSON, THIRD POINT AND FDA RE ACTHAR GEL 01/01/2012 - 04/10/2014
2014-3038	04/11/2014 05/09/2014	FDA/OFVM/CFSAN/OCD/EOS/	Michael C Valdez Andrews and Thornton	OxyELITE - RECS RE OUTBREAK
2014-3039	04/11/2014 05/09/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Robert Bexton Aristotle Capital Management	SUN PHARMACEUTICALS - MARCH 2014 IMPORT ALERT, 483S
2014-3040	04/11/2014 05/09/2014	OC/ORA/ OC/ORA/	William Holden William Holden	PROCUDURES USED TO SELECT ORA FOREIGN TRAVELERS FOR INSPECTIONS, ORGANIZATION CHART
2014-3041	04/14/2014 05/12/2014	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	Rachel Johnson FOI Services, Inc.	EARNDARDT CAMPGROUND, BRISTOL, TN - EIR, 483, WARNING LETTERS, ETC BRISTOL, TN 03/15/2013; MILWAUKEE JOURNAL SENTINEL SPORT SHOW, MILWAUKEE, WI - EIR, 483, WARNING LETTERS, ETC 03/10/2013, ETC
2014-3042	04/14/2014 05/12/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Doe J	VAERS RECS
2014-3043	04/14/2014 05/12/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Bruce Robie FBC Device ApS	K080537
2014-3044	04/14/2014 05/12/2014	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	John M. Bruce Schober Schober & Mitchell S.C.	TMV FEED & SUPPLY, KIEL, WI - EIR, 483 01/02/2004 - 01/02/2014
2014-3045	04/14/2014 05/12/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Karl G Trass Versartis, Inc.	NDA 20280 - SBA
2014-3046	04/14/2014 05/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	Scott Thiel Thiel, Scott	K082367
2014-3047	04/14/2014	FDA/OMPT/CDER/GRP/DIDP/	Silvia Gambardella	LUPRON - AERS

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	05/12/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WTVD-TV/ ABC	
2014-3048	04/14/2014 05/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K132742
2014-3049	04/14/2014 05/12/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Rachel Johnson FOI Services, Inc.	PUNKIN CHUNKIN, BRIDGEVILLE, DE - EIR, 483 ETC
2014-3050	04/14/2014 05/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	Carla R. Scarmazzi, Specialist KING & SPALDING	DEKA RESEARCH AND DEVELOPMENT - REQUESTS FOR APPROVAL OF MEDICAL DEVICES INVOLVING WATER PURIFICATION 01/01/2001 - 04/11/2014
2014-3051	04/14/2014 05/12/2014	OC/ORACE/OCI/ OC/ORACE/OCI/	Doe J	INDIVIDUAL RECORDS
2014-3052	04/14/2014 05/12/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca Dandeker Morgan, Lewis & Bockius LLP	SHARON BIO-MEDICINE LTD, INDIA - 483, EIR SUMMARIES 01/01/2010 - 01/01/2014
2014-3053	04/14/2014 05/12/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca Dandeker Morgan, Lewis & Bockius LLP	SHARON BIO-MEDICINE LTD, INDIA - EIR 01/01/2010 - 01/01/2014
2014-3054	04/14/2014 05/12/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANGELINA NGUYEN Labaton Sucharow LLP	SPECTRUM PHARMACEUTICAL INC - FUSILEV (LEVOLEUCOVORIN) APRVL RECS, CORR, BIOEQV, ETC
2014-3055	04/14/2014 05/12/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	AUDREY ALIBRANTI EGAN ETHYPHARM USA CORP	BUPRENORPHINE HCI AND NALOXONE DIHYDRATE SUBLINGUAL TABS ANDA 91-422 - APRVL RECS
2014-3056	04/14/2014 05/12/2014	OC/ORACE/ OC/ORACE/ FDA/OGROP/ORACE/ORO/DIOP/	DONALD N BLUE ZETETIC INC	SHIPMENTS REGULATED BY FDA 1/12 TO 12/12
2014-3057	04/14/2014 05/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	JONATHAN A PARRISH WAYNE GRANT PC	MEDTRONIC - ARCTIC FRONT CRYOABLATION CATHETER SYS P100010 MINS, TRANS, CORR, ETC
2014-3058	04/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	JONATHAN A PARRISH	FLEXCATH ADVANCE STEERABLE SHEATH AND DIALATOR

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	05/12/2014		WAYNE GRANT PC	STEERABLE CATHETER K123591 - MINS, TRANS, CORR, ETC
2014-3059	04/14/2014 05/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	JONATHAN A PARRISH WAYNE GRANT PC	FLEXCATH STEERABLE SHEATH AND DIALATOR K102176 - MINS, TRANS, CORR, ETC
2014-3060	04/14/2014 05/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	JONATHAN A PARRISH WAYNE GRANT PC	FLEXCATH STEERABLE SHEATH AND DIALATOR K081049 - MINS, TRANS, CORR, ETC
2014-3061	04/14/2014 05/12/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	JONATHAN A PARRISH WAYNE GRANT PC	ANGIODYNAMICS - NANOKNIFE SYS K102329 MINS, TRANS, CORR, ETC
2014-3062	04/14/2014 05/12/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANURAG PATEL PHD DR REDDY'S LABORATORIES INC	PERRIGO NEW YORK - PERMETHRIN TOPICAL CREAM ANDA 76-369 SBA
2014-3063	04/14/2014 05/12/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANURAG PATEL PHD DR REDDY'S LABORATORIES INC	ACTAVIS MID ATLANTIC - PERMETHRIN TOPICAL CREAM ANDA 74-086 SBA
2014-3064	04/14/2014 05/12/2014	FDA/OO/OFBA/OAGS/ FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/	JOHN H HNATIO EDD PHD FoodQuestTQ LLC	BATTELLE MEMORIAL INSTITUTE, VALBREA TECHNOLOGIES - PASS THROUGH CONTRACT RECS
2014-3065	04/14/2014 05/12/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OO/OHR/	JOHN H HNATIO EDD PHD FoodQuestTQ LLC	COLIN BARTHEL - EMPLOYMENT RECS, WORKING ASSIGNMENTS 2/13 TO PRESENT
2014-3066	04/14/2014 05/12/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LISA CASTRO UCB INC	LAMICTAL XR (LAMOTRIGINE) NDA 22-115/S006 - SBA
2014-3067	04/14/2014 05/12/2014	FDA/OGROP/OIP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	S ALBERT EDWARDS, PHARM D	EMA, FDA - MEMORANDUM OF UNDERSTANDING, MYASTHENIA GRAVIS EXACERBATION WARNING LABEL
2014-3068	04/14/2014 05/12/2014	FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/ OC/ORPA/ OC/ORPA/	SAMANTHA MYERS ROANOKE CLAIMS SERVICES	GRUPO CORAMICH S DE RL DE CV - ENTRY #AM402330725 & AM402332994

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		FDA/OC/OES/DFOI/ FDA/OGROP/ORA/SW-FO/SWID/SWID-CB/		
2014-3069	04/15/2014 05/13/2014	FDA/OC/OES/DFOI/	mark zanecki Zanecki, Irene	Earliest date that FDA and OHRP IRB registration information was made accessible via internet for public browse only search of IRB name, FWA number, IORG name
2014-3070	04/15/2014 05/13/2014	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Yvonne Higgins COPERNICUS GROUP IRB	COPERNICUS GROUP IRB - EIR 07/11/2013 - 07/18/2013
2014-3071	04/15/2014 05/13/2014	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Rachel Johnson FOI Services, Inc.	RUNAWAY COUNTRY MMU1, MELBOURNE, FL; KENTUCKY DEER & TURKEY EXPO, LOUISVILLE, KY; ANNUAL WORLD DEER EXPO, BIRMINGHAM, AL ETC - EIR, 483, RESPONSE ETC
2014-3072	04/15/2014 05/13/2014	OC/ORA/ OC/ORA/ OC/ORA/ORM/ OC/ORA/ORM/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Rob Bossler Biometrix Corporation	BOSTON DISTRICT - WORKPLANS, LIST OF REGISTERED FIRMS 04/11/2013 - 04/11/2014
2014-3073	04/15/2014 05/13/2014	FDA/OMPT/OSMP/OOPD/	Matt Medlin Cato Research Ltd.	REVLIMID - ORPHAN DESIGNATION REQUEST, OOPD REVIEW
2014-3074	04/15/2014 05/13/2014	FDA/OMPT/OSMP/OOPD/	Stacie Wehling Sciluent, LLC	QUTENZA - ORPHAN DRUG DESIGNATION REVIEW
2014-3075	04/15/2014 05/13/2014	FDA/OMPT/CDRH/OCER/DFOI/	James A, Boiani Epstein Becker Green	DYANSYS INDIA PVT PTD - P-STIM RECS
2014-3076	04/15/2014 05/13/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Steven Woloshin The Dartmouth Institute for Health Policy and Clinical Practice	NDA 076168 S 0

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-3077	04/15/2014 05/13/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sarah Lynch Schachter, Hendy & Johnson, PSC	NDA 022504
2014-3078	04/15/2014 05/13/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kermit L. Jones Hyman Phelps and McNamara PC	CHEMODEOXYCHOLIC ACID - AERS
2014-3079	04/15/2014 05/13/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kevin Minnich B. Braun Medical Inc.	K093625
2014-3080	04/15/2014 05/13/2014	FDA/OMPT/CDRH/OCER/DFOI/	K131383 ISS Integrated Scientific Services AG	K131383
2014-3081	04/15/2014 05/13/2014	FDA/OMPT/CDRH/OCER/DFOI/	K932176 Innomed Technologies Inc.	K932176
2014-3082	04/15/2014 05/13/2014	FDA/OMPT/CDRH/OCER/DFOI/	K952732 Innomed Technologies Inc.	K952732
2014-3083	04/15/2014 05/13/2014	FDA/OMPT/CDRH/OCER/DFOI/	Walter Cordiglia Reflexion Health, Inc.	K130847
2014-3084	04/15/2014 05/13/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/ OC/ORP/ORM/ OC/ORP/ORM/	GAIL LESSICK LACHMAN CONSULTANT SERVICES INC	DSRUG COMPANIES, MEDICAL DVC MFRS, BIORESEARCH MONITORING (BIMO) - FOREIGN & DOMESTIC INSPS 2/1-28/14
2014-3085	04/15/2014 05/13/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	GAIL LESSICK LACHMAN CONSULTANT SERVICES INC	LIST OF ALL DOMESTIC & FOREIGN INSP 10/1-31/13

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		OC/ORR/ORM/ OC/ORR/ORM/		
2014-3086	04/15/2014 05/13/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/ OC/ORR/ORM/ OC/ORR/ORM/	GAIL LESSICK LACHMAN CONSULTANT SERVICES INC	DRUG COMPANIES, MEDICAL DVC MFRS, BIORESEARCH MONITORING (BIMO) - FOREIGN & DOMESTIC INSPS 9/1-30/13
2014-3087	04/15/2014 05/13/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/ OC/ORR/ORM/ OC/ORR/ORM/ FDA/OC/OES/DFOI/	GAIL LESSICK LACHMAN CONSULTANT SERVICES INC	DRUG COMPANIES, MEDICAL DVC MFRS, BIORESEARCH MONITORING (BIMO) - FOREIGN & DOMESTIC INSPS 8/1-31/13
2014-3088	04/15/2014 05/13/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/ OC/ORR/ORM/ OC/ORR/ORM/	GAIL LESSICK LACHMAN CONSULTANT SERVICES INC	DRUG COMPANIES, MEDICAL DVC MFRS, BIORESEARCH MONITORING (BIMO) - FOREIGN & DOMESTIC INSPS 11/1-30/13
2014-3089	04/15/2014 05/13/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GAIL LESSICK LACHMAN CONSULTANT SERVICES INC	DRUG COMPANIES, MEDICAL DVC MFRS, BIORESEARCH MONITORING (BIMO) - FOREIGN & DOMESTIC INSPS 12/1-31/13

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/ OC/ORP/ORM/ OC/ORP/ORM/		
2014-3090	04/15/2014 05/13/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/ OC/ORP/ORM/ OC/ORP/ORM/	GAIL LESSICK LACHMAN CONSULTANT SERVICES INC	DRUG COMPANIES, MEDICAL DVC MFRS, BIORESEARCH MONITORING (BIMO) - FOREIGN & DOMESTIC INSPS 1/1- 31/14
2014-3091	04/15/2014 05/13/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SILVIA GAMBARELLA WTV-D-TV/ ABC	LUPRON - AERS
2014-3092	04/15/2014 05/13/2014	OC/CVM/OCD/	KRISTI O SMEDLEY Center for Regulatory Services, Inc.	POLYETHYLENE IN CATTLE - FAP
2014-3093	04/16/2014 05/14/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ms. Rosa Seungjin Lee Samsung Bioepis Co., Ltd.	BLA 125084/153 - REVIEW OF AMENDMENT
2014-3094	04/16/2014 05/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	Mark Barbieri Barbieri, Mark H	K133252
2014-3095	04/16/2014 05/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	Chelsea Kopta KATU News	ESSURE - AERS
2014-3096	04/16/2014 05/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K082420
2014-3097	04/16/2014 05/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K952266
2014-3098	04/16/2014	FDA/OFVM/CFSAN/OCD/EOS/	Elizabeth Dederick	THIODIPROPIONIC ACID - FINAL REPORT 01/01/1947 - 01/01/1947

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	05/14/2014		Critical Path Services	
2014-3099	04/16/2014 05/14/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Amy Riggleman Amy Riggleman	DEPO PROVERA - BLACK BOX WARNINGS, RELATION TO PCOS
2014-3100	04/16/2014 05/14/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sandra Dalton ARNALL GOLDEN GREGORY LLP	SERTRALINE - AERS
2014-3101	04/16/2014 05/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	Michael Spitz Auxilium Pharmaceuticals, Inc	K941781
2014-3102	04/16/2014 05/14/2014	FDA/OC/OES/DDM/ FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	FDA-2008-D-0128
2014-3103	04/16/2014 05/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	K063704
2014-3104	04/16/2014 05/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	K110888
2014-3105	04/16/2014 05/14/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gordon Johnston GORDON JOHNSTON REGULATORY CONSULTANTS LLC	VANTIN - SUMMARY OF APPROVAL
2014-3106	04/16/2014 05/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kim Fonda CORDIS CORPORATION	K110133
2014-3107	04/16/2014 05/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kaushal Solanki Eyenuk Inc	K132667
2014-3108	04/16/2014 05/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	Garrett Schwab Ziva Medical	K033728
2014-3109	04/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jessica Van Douser	MAUDE REPORT 2530130-2009-00061

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	05/14/2014		Jaburg Wilk	
2014-3110	04/16/2014 05/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kaushal Solanki Eyenuk Inc	K110869
2014-3111	04/16/2014 05/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kaushal Solanki Eyenuk Inc	P090012
2014-3112	04/16/2014 05/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	John S Samorajczyk Samorajczyk Regulatory Consultants, LLC	K130218
2014-3113	04/16/2014 05/14/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joseph Carrado Joseph Carrado	NDA 18705, S 006
2014-3114	04/16/2014 05/14/2014	OC/ORA/OCI/ OC/ORA/OCI/	SANDRA SNADEN KUWAYE GOLDBERG SEGALLA	ENERGY BRANDS INC, COCA-COLA CO - VITAMIN WATER ZERO XXX INVESTIGATION RECS, LAB RESULTS, CORR, ETC
2014-3115	04/16/2014 05/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	HOWARD L NATIONS NATIONS LAW FIRM	SYNTHES INC (NORIAN CORP) - NORIAN XR REQUEST FOR DEPOSITION
2014-3116	04/16/2014 05/14/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HATTON 1519223, ROLAND	BOEHRINGER INGELHEIM - MIRAPEX (AICA PRAMIPAXOLE) CORR 1/00 TO 12/05
2014-3117	04/16/2014 05/14/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DANA DOIDGE COZEN O'CONNOR	DRYSOL SOL, XERAC AC, EXPERDRY FORTE, ETC - AERS
2014-3118	04/16/2014 05/14/2014	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	DOUGLAS N BLUE II ZETETIC INC	JOHN PAUL MITCHELL SYSTEMS - HAIR PREPARATIONS ENTRY #823-0160021-7
2014-3119	04/16/2014 05/14/2014	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	DOUGLAS N BLUE II ZETETIC INC	JOHN PAUL MITCHELL SYSTEMS - HAIR PREPARATIONS, SHAMPOOS, CONDITIONERS ENTRY #823-0160143-9
2014-3120	04/16/2014 05/14/2014	FDA/OFVM/CFSAN/OCD/EOS/	VALENTINA POTIENKO Europharma US	BUTHCER'S BROOM, JAVA TEA, ECHINACEA ROOTS, ETC - GRAS
2014-3121	04/16/2014 05/14/2014	OC/ORA/ OC/ORA/ OC/ORA/ORM/	KIM C CAPONE PORZIO LIFE SCIENCES	PDMA INSPS DATABASE 2009 TO PRESENT

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		OC/ORR/ORM/		
2014-3122	04/16/2014 05/14/2014	FDA/OGROP/ORR/CE-FO/CIN-DO/CIN-CB/	CRAIG ROUSH ROCKLINE INDUSTRIES	PAXICO LLC, BATAVIA, OH - EIRS, 483S, CORR 12/13
2014-3123	04/16/2014 05/14/2014	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	COLEMAN, GEORGE	TYRA TECH - VAMOUSSE CMLPNT #CC136721
2014-3124	04/16/2014 05/14/2014	OC/ORR/ORM/ OC/ORR/ORM/	ROBERT KING FDA NEWS	PHARMACEUTICAL, BIOLOGICS, MEDICAL DVC MFG, CLNCL TRIAL FACILITIES IN AND OUTSIDE THE US - 483S 3/1-31/14
2014-3125	04/16/2014 05/14/2014	FDA/OFVM/CFSAN/OCD/EOS/	DOTSON #12146457, ANDRE	WINDSOR FOODS - CMLPNTS; BHA, BHT - CAERS
2014-3126	04/16/2014 05/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	LIANE LAROCHELLE DEKA RESEARCH & DEVELOPMENT CORP	TANDEM DIABETES CARE INC - T SLIM INSULIN DELIVERY SYS K133593
2014-3127	04/16/2014 05/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	LIANE LAROCHELLE DEKA RESEARCH & DEVELOPMENT CORP	NXSTAGE MEDICAL INC - NXSTAGE SYSTEM ONE WITH NXVIEW K133547
2014-3128	04/16/2014 05/14/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARY B SZALKOWSKI PRISMA CORP	METHYSERGIDE-CONTAINING MEDICINES - AERS THROUGH 1999
2014-3129	04/16/2014 05/14/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARY B SZALKOWSKI PRISMA CORP	ZICAM (OXYMETAZOLINE HCL) - AERS FROM US APRVL TO PRESENT
2014-3130	04/16/2014 05/14/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARY B SZALKOWSKI PRISMA CORP	CETACAINE (TETRACAINE HCI, BENZOCAINE, BUTAMBEN) - AERS FROM US APRVL TO PRESENT
2014-3131	04/17/2014 05/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Max Antony LAW OFFICES	ACTHAR GEL - THIRD PARTY SUBMISSIONS, LAB REPORTS, INVESTIGATIONS ETC 11/02/2013 - 04/14/2014
2014-3132	04/17/2014 05/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	Garrett Schwab Ziva Medical	K992655
2014-3133	04/17/2014	FDA/OMPT/CDER/ORP/DIDP/	Peter Mione	NDA 65455

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	05/15/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CutisPharma, Inc.	
2014-3134	04/17/2014 05/15/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Moumita Rawal G&W Laboratories, Inc.	CANASA 1GM SUPPOSITORIES - SBA, S 019, S 018 ETC
2014-3135	04/17/2014 05/15/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Lisa Robertson Rawls McNelis + Mitchell	INDIVIDUAL RECS
2014-3136	04/17/2014 05/15/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Nabil Naouli LUBRIZOL CORP	LIST OF DRUGS APPROVED IN TOPICAL AND TRANSDERMAL APPLICATION
2014-3137	04/17/2014 05/15/2014	FDA/OGROP/ORAP/PA-FO/LOS- DO/LOS-CB/	NORLIE BUSTALENA VEGE KURL, INC.	VEGE KURL, INC - EIR DECEMBER 2011
2014-3138	04/17/2014 05/15/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Chirag Talati Espirito Santo Securities	LUPIN, CIPLA, CADILA ETC - 483, EIR
2014-3139	04/17/2014 05/15/2014	FDA/OFVM/CFSAN/OCD/EOS/	Imogene Treble EXPONENT, INC.	FCN 62
2014-3140	04/17/2014 05/15/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Moumita Rawal G&W Laboratories, Inc.	NDA 019141
2014-3141	04/17/2014 05/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	Michael Spitz Auxilium Pharmaceuticals, Inc	K896207, K895406
2014-3142	04/17/2014 05/15/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Andrea Demakas ADVERSEEVENTS INC	OLYSIO - AERS
2014-3143	04/17/2014 05/15/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Andrea Demakas ADVERSEEVENTS INC	LUCENTIS, VICTRELIS, INCIVEK ETC - AERS

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2014-3144	04/17/2014 05/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	David Martin Al Jazeera America	LARIAM - AERS
2014-3145	04/17/2014 05/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	David Martin Al Jazeera America	SEROQUEL - AERS
2014-3146	04/17/2014 05/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	Michael Spitz Auxilium Pharmaceuticals, Inc	K912736, K974173, K020082 ETC
2014-3147	04/17/2014 05/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Thomas Sims Baron & Budd, PC	OSE REVIEWS
2014-3148	04/17/2014 05/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Moumita Rawal G&W Laboratories, Inc.	NDA 018642
2014-3149	04/17/2014 05/15/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	MICHAEL DOYLE INSULET CORPORATION	K111210
2014-3150	04/17/2014 05/15/2014	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	Jeffrey B Vick JB Vick	12-ATL-18 - WARNING LETTER RECS
2014-3151	04/17/2014 05/15/2014	FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/	Scott Hodes Scott A. Hodes, Attorney at Law	ENDO INTERNATIONAL PLC - WARNING LETTER, 483 ETC
2014-3152	04/17/2014 05/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	Dennis McLaughlin Philips	K133705
2014-3153	04/17/2014 05/15/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-2246 - REQUEST LETTER ONLY
2014-3154	04/17/2014 05/15/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-2020 - REQUEST LETTER ONLY
2014-3155	04/17/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2014-1908 - REQUEST LETTER ONLY

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	05/15/2014		MERCK & CO., INC.	
2014-3156	04/17/2014 05/15/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-2230 - REQUEST LETTER ONLY
2014-3157	04/17/2014 05/15/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-2036 - REQUEST LETTER ONLY
2014-3158	04/17/2014 05/15/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-1906 - REQUEST LETTER ONLY
2014-3159	04/17/2014 05/15/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-2520 - REQUEST LETTER ONLY
2014-3160	04/17/2014 05/15/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-2434 - REQUEST LETTER ONLY
2014-3161	04/17/2014 05/15/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-2490 - REQUEST LETTER ONLY
2014-3162	04/17/2014 05/15/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Pamela Deschenes Veltek Associates, Inc.	FEI 3001342291
2014-3163	04/17/2014 05/15/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-1598 - REQUEST LETTER ONLY
2014-3164	04/17/2014 05/15/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-1599 - REQUEST LETTER ONLY
2014-3165	04/17/2014 05/15/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-2289 - REQUEST LETTER ONLY
2014-3166	04/17/2014 05/15/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-2541 REQUEST LETTER ONLY
2014-3167	04/17/2014 05/15/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-2549 - REQUEST LETTER ONLY
2014-3168	04/17/2014 05/15/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-2553 - REQUEST LETTER ONLY
2014-3169	04/17/2014 05/15/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-1632 - REQUEST LETTER ONLY
2014-3170	04/17/2014 05/15/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-1656 - REQUEST LETTER ONLY
2014-3171	04/17/2014 05/15/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-2489 - REQUEST LETTER ONLY

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2014-3172	04/17/2014 05/15/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-1899 - REQUEST LETTER ONLY
2014-3173	04/17/2014 05/15/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-2010 - REQUEST LETTER ONLY
2014-3174	04/17/2014 05/15/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/	DONALD N BLUE ZETETIC	ENTRY RECS - AIR, LAND, OCEAN MODES, ETC 3/19/14-4/15/14
2014-3175	04/17/2014 05/15/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/	DONALD N BLUE ZETETIC	JOHN PAUL MITCHELL SYSTEMS - HAIR PREPARATIONS ENTRY #823-0160392-2
2014-3176	04/17/2014 05/15/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/	DONALD N BLUE ZETETIC	HAIR PREPARATIONS - ENTRY 823-0160805-3 PICTURES, OASIS COMPUTER SCREEN SHOTS, EMAILS, ETC
2014-3177	04/17/2014 05/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	SMITH, ELIZABETH	NESTLE HEALTH CARE INC - NUTRION COMPAT ENTERAL DELIVERY SYS INFUSION PUMP MODEL 199255 FINAL RPT
2014-3178	04/17/2014 05/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	SMITH, ELIZABETH	NESTLE HEALTH CARE NUTRITION INC - COMPAT ENTERAL DELIVERY SYS INFUSION PUMP MODEL 199235 FINAL RPT
2014-3179	04/17/2014 05/15/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORO/CE-FO/MIN-DO/MIN-CB/	SMITH, ELIZABETH	NESTLE HEALTHCARE NUTRITION INC - NESTLE HEALTHCARE NUTRITION COMPAT ENTERAL DELIVERY SYS INFUSION PUMP MODEL 199235 FINAL RPT
2014-3180	04/17/2014 05/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	KATZ, RICHARD B	RECORDS SENT TO, OR FROM, OR MENTIONING LISDSAY D BOWER, KAREN AMOS, DRUDY V SEALING 8/11 TO PRESENT, ETC
2014-3181	04/17/2014 05/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JENNIFER HSIEH DEERFIELD INSTITUTE	RAPTOR PHARMS - PROCYSBI (CYSTEAMINE BITARTATE) AERS
2014-3182	04/17/2014 05/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELIZABETH SILVA FARUQI & FARUQI LLP	WATSON LABORATORIES INC - LIDODERM ANDA 2000-675 APRVL PKG
2014-3183	04/17/2014	FDA/OFVM/CFSAN/OCD/EOS/	PATTI WALLER	JIMMY JOHN'S RESTAURANTS, GR PRODUCE, COLO-PAC PRODUCE INC - CUCUMBERS E COLI CLUSTER

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	06/06/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	MARLER CLARK ATTYS	1310MNEXH-1 COMM, EMAILS, LAB RESULTS, ETC 10/13
2014-3184	04/17/2014 05/15/2014	FDA/OFVM/CFSAN/OCD/EOS/	JENNIE M HAUSLER COLSON HICKS EIDSON LAW FIRM	USPLABS - OXYELITE PRO LTR 11/6/13
2014-3185	04/17/2014 05/15/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/ OC/ORAOI/ OC/ORAOI/	Jennifer Kuzman, Esq. Lotz, Doggett & Rawers, LLP	REGENTS OF THE UNIVERSITY OF CALIFORNIA - CLINICAL TRIAL, IRB REC 01/01/2005 - 12/31/2013
2014-3186	04/17/2014 05/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	AeroView 510K
2014-3187	04/18/2014 05/16/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-9245
2014-3188	04/18/2014 05/16/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-1296
2014-3189	04/18/2014 05/16/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-10054
2014-3190	04/18/2014 05/16/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-7249
2014-3191	04/18/2014 05/16/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-8713
2014-3192	04/18/2014 05/16/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-7203
2014-3193	04/18/2014 05/16/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-8597
2014-3194	04/18/2014 05/16/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-6242
2014-3195	04/18/2014 05/16/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-8595
2014-3196	04/18/2014 05/16/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-9748

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2014-3197	04/18/2014 05/16/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-10085
2014-3198	04/18/2014 05/16/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-1647
2014-3199	04/18/2014 05/16/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-515
2014-3200	04/18/2014 05/16/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-409
2014-3201	04/18/2014 05/16/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-8529
2014-3202	04/18/2014 05/16/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-406
2014-3203	04/18/2014 05/16/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-8292
2014-3204	04/18/2014 05/16/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-407
2014-3205	04/18/2014 05/16/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-10087
2014-3206	04/18/2014 05/16/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-400
2014-3207	04/18/2014 05/16/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-397
2014-3208	04/18/2014 05/16/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-9592
2014-3209	04/18/2014 05/16/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-10103
2014-3210	04/18/2014 05/16/2014	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	THOMPSON, RAY	PROTEK MEDICAL PRODUCTS INC, CORALVILLE, IA 1/16-21/14; SIGMA-ALDRICH MFG LLC, SAINT LOUIS, MO 12/2-9/13; MARIANNA INDUSTRIES INC, OMAHA, NE 1/4-9/14, ETC - 483'S
2014-3211	04/18/2014 05/16/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	THOMPSON, RAY	CORE LABS LLC, ENGLEWOOD, CO 12/16/13 TO 1/3/14; TOLMAR INC, FORT COLLINS, CO 1/29-31/14; NYTONE MEDICAL PRODUCTS INC, BLUFFDALE, UT 1/3-10/14, ETC - 483'S
2014-3212	04/18/2014	FDA/OGROP/ORASW-FO/DAL-		4M VENTURES, MEDICAL INC (DBA BTI FILTRATION),

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	05/16/2014	DO/DAL-CB/	THOMPSON, RAY	OKLAHOMA CITY, OK 12/11-12/13; NEUROLUMEN LLC, OKLAHOMA CITY, OK 12/10/13/13; ARGON MEDICALS DEVICES INC, ATHENS, TX 12/9-13/13, ETC - 483'S
2014-3213	04/18/2014 05/16/2014	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	THOMPSON, RAY	BIOMEDICA BIOLOGICAL TESTING LABS, SAN GERMAN, PR 1/16-24/14; COOPER VISION CARIBBEAN CORP, JUANA DIAZ, PR 12/10/13 TO 1/10/14; PRAXAIR INC PUERTO RICO BV, HUMACAO, PR 1/23-28/14, ETC - 483'S
2014-3214	04/18/2014 05/16/2014	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	THOMPSON, RAY	ALTASOURCE LLC (DBA METALABS LLC), ROSWELL, GA 1/14-21/14; SCHOLLE CHEMICAL CORP, COLLEGE PARK, GA 1/21-23/14; OWEN MUMFORD USA INC, MARIETTA, GA 12/3-12/13, ETC - 483'S
2014-3215	04/18/2014 05/16/2014	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	THOMPSON, RAY	BAXTER HEALTHCARE CORP, CLEVELAND, MS 1/7/23/14; CHATTEM CHEMICALS INC, CHAATTANOOGA, TN 1/13-17/14; PHARMA PAC LLC, DE KALB, MS 11/18/13-12/6/13, 483'S
2014-3216	04/18/2014 05/16/2014	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	THOMPSON, RAY	AUTOMATED OPHTHALMICS INC, ELKRIDGE, MD 12/4-11/13; KERMA MEDICALS PRODUCTS INC, SUFFOLK, VA 1/13-23/14; EISAI INC, BALTIMORE, MD 12/9-17/13, ETC - 483'S
2014-3217	04/18/2014 05/16/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	THOMPSON, RAY	KVK-TECH INC, NEWTON, PA 11/14/13-12/9/13; SHARP CORP, ALLENTOWN, PA 1/9-15/14 - 483'S
2014-3218	04/18/2014 05/16/2014	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	THOMPSON, RAY	AYRSHIRE ELECTONICS MINNESOTA, OAKDALE, MN 12/17/13 TO 1/7/14; BROOKFIELD PRESCRIPTION CENTER INC, BROOKFIELD, WI 12/3-10/13; FONTAROME CHEMICAL INC, ST FRANCIS, WI 1/6-10/14, ETC - 483'S
2014-3219	04/18/2014 05/16/2014	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	THOMPSON, RAY	CATALENT PHARMA SOLUTIONS LLC, SAINT PETERSBURG, FL 12/9-30/13; GERMAN INSTRUMENTS FOR SURGERY INC, SUNRISE, FL 1/6-9/14; NEUROTRONIC INC, GAINESVILLE, FL 12/2-4/13, ETC - 483'S
2014-3220	04/18/2014 05/16/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	THOMPSON, RAY	CONAIR CORP, STAMFORD, CT 1/8-21/14; O2 CONCEPTS, NEWTON, CT 12/3-6/13; BRAINTREE LABORATORIES INC, RANDOLPH, MA 12/6-13/13, ETC - 483'S
2014-3221	04/18/2014 05/16/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	THOMPSON, RAY	ASCEND LABORATORIES LLC, MONTVALE, NJ 11/25/13-12/11/13; CMIC CMO USA CORP, CRANBURY, NJ 11/20/13-12/4/13; GENZYME (SANOFI CO), RIDGEFIELD, NJ 1/7/21/14, ETC - 483'S
2014-3222	04/18/2014 05/16/2014	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	THOMPSON, RAY	VISCOT MEDICAL LLC, EAST HANOVER, NJ 12/11-19/13; AIR INNOVATIONS INC, NORTH SYRACUSE, NY 1/6-23/14; ALLIED HEALTHCARE PRODUCTS INC, STUYVESANT FALLS, NY 12/9-11/13, ETC - 483'S
2014-3223	04/18/2014 05/16/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	THOMPSON, RAY	GIBSON LABORATORIES LLC, LEXINGTON, KY 12/9/12/13; KUTOL PRODUCTS CO, SHARONVILLE, OH 12/11/13 TO 1/2/14; PIEZOSURGERY INC, COLUMBUS, OH 12/9-16/13, ETC

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				- 483'S
2014-3224	04/18/2014 05/16/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	SMITH, ELIZABETH	NESTLE HEALTH CARE NUTRITION - COMPAT ENTERAL DELIVERY SYS IN FUSION PUMP
2014-3225	04/18/2014 05/16/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	THOMPSON, RAY	ANALYTICAL CONTROL SYSTEMS INC, FISHERS, IN 10/29/13 TO 12/3/13; CENTURY PHARMACEUTICALS INC, INDIANAPOLIS, IN 1/13-14/14; DOW CORNING CORP, HEMLOCK, MI 1/21-24/14, ETC - 483'S
2014-3226	04/18/2014 05/16/2014	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	THOMPSON, RAY	ABB VIE INC, NORTH CHICAGO, IL 12/3-13/13; H2O PLUS LLC, CHICAGO, IL 1/22-29/14; SAGE PRODUCTS INC, CARY, IL 12/12/13 TO 1/5/14, ETC - 483'S
2014-3227	04/18/2014 05/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	CELEXA (CITALOPRAM) - PI
2014-3228	04/18/2014 05/29/2014	FDA/OGROP/ORASE-FO/FLADO/FLA-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	F CATFISH ABBOT ABBOTT LAW GROUP PA	INDIVIDUAL RECS
2014-3229	04/18/2014 05/16/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	THOMPSON, RAY	ANCHEN PHARMACEUTICALS INC, IRVINE, CA 12/2-20/13; AERAN SCIENTIFIC INC, ONTARIO, CA 1/6-8/14; APNEA SCIENCES CORP, LAGUNA HILLS, CA 1/7-28/14, ETC - 483S
2014-3230	04/18/2014 05/16/2014	FDA/OGROP/ORASE-FO/FLADO/FLA-CB/	F CATFISH ABBOTT ABBOTT LAW GROUP PA	INDIVIDUAL RECS
2014-3231	04/18/2014 05/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEVIN D EVANS STEESE EVANS FRANKEL PC	ERIC HOFFMAN, AGADA, REVERAGEN - ETEPLIRSEN APRVL, STUDIES, CORR, ETC
2014-3232	04/18/2014 05/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	JAN M EBERTH PHD UNIV OF SOUTH CAROLINA DEPT OF EPIDEMIOLOGY AND BIostatISTICS	MQSA CERTIFIED MAMMOGRAPHY FACILITIES - NUMBER OF MAMMOGRAM MACHINES AS OF THE MOST RECENT INSP
2014-3233	04/18/2014 05/16/2014	FDA/OFVM/CFSAN/OCD/EOS/	TERI JENNER DELL TECH LABORATORIES LTD	FMC CORP - FCN 000880; ENVIROTECH CHEMICAL SERVICES INC - FCN 001132; VALLEY CHEMICAL SOLUTIONS - FCN 1247
2014-3234	04/18/2014 05/16/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	HOWLEY, JOHN	SCHWEBEL'S BAKING CO, BOARDMAN, OH - EIR 3/6/14

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2014-3235	04/18/2014 10/30/2014	FDA/OC/OES/DDM/ FDA/OFVM/CFSAN/OCD/EOS/	DARREN L BROWN PROVOST UMPHREY LAW FIRM	EVAPORATED CANE JUICE - CORR 5/12; DKT 2009D-0430
2014-3236	04/18/2014 05/16/2014	FDA/OFVM/CFSAN/OCD/EOS/	THOMAS J KEEGAN JR KEEGAN & KEEGAN ROSS & ROSNER LLP	UNILEVER UNITED STATES INC - TCB NATURALS COARSE NO-LYE RELAXER ACCIDENT INVESTIGATION RPTS, DATA SUMMARIES, HAZARD ANALYSES, ETC
2014-3237	04/18/2014 05/16/2014	FDA/OGROP/ORR/PA-FO/SEA-DO/SEA-CB/	THOMPSON, RAY	HEMCON MEDICAL TECHNOLOGIES INC, PORTLAND, OR 12/4-18/13; SHASTA TECHNOLOGIES LLC, SHERWOOD, OR 12/2-9/13; RIVERPOINT MEDICAL LLC, PORTLAND, OR 11/20/13-12/2/13, ETC - 483S
2014-3238	04/18/2014 05/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	THOMPSON, RAY	ABBOTT POINT OF CARE CANADA LTD, OTTOWA, CANADA - 483 12/2-5/13
2014-3239	04/18/2014 05/16/2014	FDA/OGROP/ORR/PA-FO/SAN-DO/SAN-CB/	THOMPSON, RAY	ALEXZA PHARMACEUTICALS INC, MOUNTAIN VIEW, CA 1/8-22/14; IQ TECHNOLOGIES INC, LAS VEGAS, NV 1/24/14; FLEXTRONICS AMERICAN LLC, MILPITAS, CA 12/16-27/13 - 483S
2014-3240	04/18/2014 05/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	THOMPSON, RAY	KABS LABORATORIES INC, SAINT-HUBERT, CANADA - 483 12/9-11/13
2014-3241	04/18/2014 05/16/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	THOMPSON, RAY	CHOKSI LABORATORIES LTD, INDORE, INDIA - 483 1/7-12/14
2014-3242	04/18/2014 05/16/2014	FDA/OC/OES/DFOI/	Christopher Phillips Chris Phillips	FOOD POISONING CASES 04/01/2012 - 04/01/2013
2014-3243	04/21/2014 05/19/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-661
2014-3244	04/21/2014 05/19/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-826
2014-3245	04/21/2014 05/19/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-9369
2014-3246	04/21/2014 05/19/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-681
2014-3247	04/21/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2014-686

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	05/19/2014		MERCK & CO., INC.	
2014-3248	04/21/2014 05/19/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-1593
2014-3249	04/21/2014 05/19/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-713
2014-3250	04/21/2014 05/19/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-2021
2014-3251	04/21/2014 05/19/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-750
2014-3252	04/21/2014 05/19/2014	OC/ORO/ORM/ OC/ORO/ORM/	David Mangione Govzilla, Inc.	LISTING OF ALL 483, INSPECTIONS, EIR 03/15/2014 - 04/16/2014
2014-3253	04/21/2014 05/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	Pavle Sedic LELO Inc.	K120107, K091754
2014-3254	04/21/2014 05/19/2014	OC/CVM/OCD/	Jill Franks MARS PETCARE US	CORR BETWEEN CVM AND P&G PETCARE, IAMS COMPANY 01/01/2012 - 04/18/2014
2014-3255	04/21/2014 05/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jessica Benson Atlantic Biologicals	ANDA040151
2014-3256	04/21/2014 05/19/2014	FDA/OC/OES/DFOI/	Russell Smith Chiefist	ACTHAR GEL, QUESTCOR - FOIA REQUESTS 01/01/2003 - 04/17/2014
2014-3257	04/21/2014 05/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	James W. Monroe FUJIFILM Corporation	K133987
2014-3258	04/21/2014 05/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K101158
2014-3259	04/21/2014 05/27/2014	FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/ FDA/OC/OES/DFOI/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Robert Pyrtle Pyrtle, Robert	SCANTIBODIES BIOLOGICS - LETTER, AUDIT REPORT 10/31/2013 - 04/16/2014
2014-3260	04/21/2014 05/19/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K102996
2014-3261	04/21/2014 05/19/2014	FDA/OC/OES/DFOI/	Yujin Kim UC Berkeley Graduate School of	LIST OF ORPHAN DESIGNATIONS AND APPROVALS 01/01/1983 - 04/16/2014

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2014-3262	04/21/2014 05/19/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Brian Mangal Mangal, Brian	PROPECIA - PERIODIC SAFETY UPDATE REPORTS 12/19/1997 - 12/01/2012
2014-3263	04/21/2014 05/19/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Steven Woloshin The Dartmouth Institute for Health Policy and Clinical Practice	NDA 19787 S 38
2014-3264	04/21/2014 05/19/2014	FDA/OFVM/CFSAN/OCD/EOS/	FRIEDMAN, ROBERT	GERBER - CAERS 1969 - 2014
2014-3265	04/21/2014 05/19/2014	FDA/OFVM/CFSAN/OCD/EOS/	FRIEDMAN, ROBERT	DHEA, ESTRO CREAM, WOMAN ZONE, ETC - CAERS 1969 TO 2014
2014-3266	04/21/2014 05/19/2014	FDA/OFVM/CFSAN/OCD/EOS/	FRIEDMAN, ROBERT	ALOE VERA GEL, COLLASTIN LINIMENT, AQUAFRESH, ETC - CAERS 1969 TO 2014
2014-3267	04/21/2014 05/19/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PETER S. REICHERTZ SHEPPARD MULLIN ET AL	LUITPOLD PHARMACEUTICALS INC - VENOFER NDA 21- 135 AER 1997 TO PRESENT
2014-3268	04/21/2014 05/19/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PETER S. REICHERTZ SHEPPARD MULLIN ET AL	AMAG PHARMACEUTICALS INC - FERAHEME NDA 22-180 AER 1997 TO PRESENT
2014-3269	04/21/2014 05/19/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PETER S. REICHERTZ SHEPPARD MULLIN ET AL	SANOFI AVENTIS - FERRLECIT NDA 20-955 1997 TO PRESENT
2014-3270	04/21/2014 05/19/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PETER S. REICHERTZ SHEPPARD MULLIN ET AL	LUITPOLD PHARMACEUTICALS - DEXFERRUM NDA 40-024
2014-3271	04/21/2014 05/19/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PETER S. REICHERTZ SHEPPARD MULLIN ET AL	LUITPOLD PHARMACEUTICALS - INJECTAFER NDA 203-565 AER 1997 TO PRESENT

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2014-3272	04/21/2014 05/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PETER S. REICHERTZ SHEPPARD MULLIN ET AL	INFED NDA 017-441 - AER 1997 TO PRESENT
2014-3273	04/21/2014 05/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PETER S. REICHERTZ SHEPPARD MULLIN ET AL	GENERAMEDIX - NULECIT ANDA 789-215 1997 TO PRESENT
2014-3274	04/21/2014 05/19/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Grab, William	ACETAMINOPHEN - AER
2014-3275	04/21/2014 05/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	LORI A CARR INC	BIOMET - CUSTOM FLANGED ACETABULAR COMPONENT K983035
2014-3276	04/21/2014 05/19/2014	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	STEPHEN HELLER HELLER LACHAPPELLE	2014-961 RECONSIDERATON OF DELETIONS
2014-3277	04/22/2014 05/20/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nina Yin TULANE UNIVERSITY	HISTORICAL DATA - DRUG EXCLUSIVITY
2014-3278	04/22/2014 05/20/2014	FDA/OGROP/ORR/SW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORR/SW-FO/DEN-DO/DEN-CB/	Sam May MAY, SAMUEL	2014-301 - UNREDACTED RECS
2014-3279	04/22/2014 05/20/2014	FDA/OMPT/CDRH/OCER/DFOI/	Philip Digiglio UNIVERSITY OF CALIFORNIA, DAVIS	K020808
2014-3280	04/22/2014 05/20/2014	FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/	Christopher Ott Neutraderm, Inc.	NEUTRADERM, INC - EIR 01/16/2011 - 04/17/2014
2014-3281	04/22/2014	FDA/OMPT/CDER/ORP/DIDP/	Stefan Hubanov	ANDA 085635

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	05/20/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Hubanov, Stefan	
2014-3282	04/22/2014 05/20/2014	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Rachel Johnson FOI Services, Inc.	AJD LABORATORIES - EIR, PARK RAPIDS, MN
2014-3283	04/22/2014 05/20/2014	FDA/OMPT/CDRH/OCER/DFOI/	William Slevin TWSL LLC	K090670
2014-3284	04/22/2014 05/20/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	JANKOWIAK, MARY ANNE	INDIVIDUAL RECS
2014-3285	04/22/2014 06/02/2014	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	O'Brien, Larry Thomas	INDIVIDUAL RECS
2014-3286	04/22/2014 05/20/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	BENJAMIN A WINTERHALTER SMITH & BRINK PC	SYNAPTIC CORP - SYNAPTIC 2000, 3000 MFG AND MARKETING RECS, ETC
2014-3287	04/22/2014 05/20/2014	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	483S - 2013-2952, 2013-3646, 2013-5642, ETC
2014-3288	04/22/2014 05/20/2014	FDA/OC/OES/DFOI/	SawyerKnoll, Jo Anne	STRYKER - REJUVENATOR RECS
2014-3289	04/22/2014 05/20/2014	FDA/OMPT/CDRH/OCER/DFOI/	BROWN, SHAUN	K041280; NEEDLE-FREE INJECTORS FOR MEDICAL USE - RECS
2014-3290	04/22/2014 05/20/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALLACE EM3049, JOE	RITALIN, METHYLPHENODATE - WARNINGS, RECS
2014-3291	04/22/2014 05/20/2014	FDA/OC/OES/DFOI/	MORRISON, AUDREY	INDIVIDUAL RECS
2014-3292	04/23/2014	FDA/OMPT/CDER/GRP/DIDP/	Anthony Fiorino	TRANSMUCOSAL IMMEDIATE RELEASE FENTANYL - AERS

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	05/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Greywall Asset Management	
2014-3293	04/23/2014 05/21/2014	OC/ORAOE/ OC/ORAOE/	Mark Prinz Registrar Corp	GREEN LIST IMPORT ALERTS
2014-3294	04/23/2014 05/21/2014	FDA/OC/OES/DFOI/	Andrew T. Ryan Ryan Law, APLC	BAXTER HEALTHCARE, CLEVELAND, MS - INSPECTION RECS
2014-3295	04/23/2014 05/21/2014	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	PROTOCOL, BACKGROUND RECS RE STUDIES
2014-3296	04/23/2014 05/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jason Lee ORBIMED ADVISORS LLC	LINZESS - AERS
2014-3297	04/23/2014 05/21/2014	FDA/OFVM/CFSAN/OCD/EOS/	Merle Zimmermann (ext. 106) AMERICAN HERBAL PRODUCTS ASSOCIATION	RECS SUBMITTED BY INGREDIENT MANUFACTURERS OR DISTRIBUTORS UNDER 21 CFR 190.6 (01/01/2012 - 01/31/2014)
2014-3298	04/23/2014 05/21/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Mary Gustafson PLASMA PROTEIN THERAPEUTICS ASSOCIATION	LIST OF CBER APPROVALS OF REQUESTS FOR IMPORT OF PLASMA 09/02/2002 - 04/17/2014
2014-3299	04/23/2014 05/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Haige Lu ORBIMED ADVISORS LLC	GATTEX - AERS
2014-3300	04/23/2014 05/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	BLA125289/103
2014-3301	04/23/2014 05/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Russell Smith Chiefist	SUPPORT DOC RE ACTHAR GEL
2014-3302	04/23/2014 05/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Russell Smith Chiefist	SUPPORT REC RE ACTHAR GEL

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-3303	04/23/2014 05/21/2014	FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/	Stephen B Fowler Celerion, Inc.	MDS PHARMA - EIR 02/05/2013 - 02/07/2013
2014-3304	04/23/2014 05/21/2014	FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/	Stephen B Fowler Celerion, Inc.	MDS PHARMA - EIR 08/07/2013 - 08/09/2013
2014-3305	04/23/2014 05/21/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lauren Karalis Robbins Geller Rudman & Dowd LLP	COMMUNICATIONS BETWEEN FDA AND GLAXOSMITHKLINE, CHEMOCENTRYZ RE TWO DRUGS 01/01/2013 - 12/31/2013
2014-3306	04/23/2014 05/21/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sybil Hoffman Executive Producer of Special Projects KTVK-TV	NUVARING - AERS
2014-3307	04/23/2014 05/21/2014	FDA/OC/OES/DFOI/	Timothy B. Woodward WINSTON & STRAWN	FOIA REQUEST LOG 01/01/2013 - 04/18/2014
2014-3308	04/23/2014 05/21/2014	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	Celia D. Keller RTI International	RTI INTERNATIONAL, TRIANGLE PARK, NC - EIR 03/04/2013 - 03/06/2013
2014-3309	04/23/2014 05/21/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jennifer Miller ELI LILLY & CO	NDA 022200/S-008 - SBA
2014-3310	04/23/2014 05/21/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Aaron Bindman Sterne Kessler Goldstein & Fox PLLC	NDA 021487 - PAGES 71-73
2014-3311	04/23/2014 05/21/2014	FDA/OO/OFBA/OAGS/	Rose Santos FOIA Group, Inc.	HHSF2232009500261
2014-3312	04/23/2014 05/21/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shin Kang WELLS FARGO SECURITIES	FDA GUIDANCE LETTER TO SERAPTA THERAPEUTICS RE SAFETY AND EFFICACY OF ETEPLIRSEN
2014-3313	04/23/2014 05/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	Maneesh Gujrati Case Western Reserve University	P860067

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			Biomedical Engineering Department	
2014-3314	04/23/2014 05/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	Dennis McLaughlin Philips	K133424 SUMMARY
2014-3315	04/23/2014 05/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Patrick Moriarty ATP Early Harvest Fund	SAREPTA - CORR, MEETING MINUTES RE ETEPLIRSEN
2014-3316	04/23/2014 05/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	David Martin Timeline Productions	ZYPREXA - AERS
2014-3317	04/23/2014 05/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	David Martin Timeline Productions	RISPERDAL - AERS
2014-3318	04/23/2014 05/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	Patrick Cheng Children's National Health System	K954140
2014-3319	04/23/2014 05/21/2014	OC/CVM/OCD/	Rachel Johnson - 6202632 FOI Services, Inc.	Information regarding anti-viral testing by CVM for Waggin Train and Canyon Creek.
2014-3320	04/23/2014 05/21/2014	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	Doe J	INDIVIDUAL RECS
2014-3321	04/23/2014 05/21/2014	FDA/OGROP/ORAP/CE-FO/CIN-DO/CIN-CB/	Matt Bauza Granite Microsystems, Inc.	PHILIPS MEDICAL SYSTEMS, INC CLEVELAND - EIR, 483 01/04/2012 - 04/21/2014
2014-3322	04/23/2014 05/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sara DeSotel Sara DeSotel	MIRALAX - AERS
2014-3323	04/23/2014 05/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jeffrey Morrison Critech, Inc	ABRAXANE - SBA
2014-3324	04/23/2014 05/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Roger Bate Roger Bate	CORR RE DR PRESTON MASON AND ATORVASTATIN; RECS RE DR HARRY LEVER AND RANBAXY; RECS RE DR HARRY LEVER AND WOCKHARDT 2/20/14-4/16/14

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2014-3325	04/24/2014 05/22/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bhagwan S Chaudhary National Institute of Securities Markets, Mumbai	AGILA SPECIALTIES PRIVATE LIMITED SPECIALTY FORMULATION FACILITY - 483 06/17/2013 - 06/27/2013
2014-3326	04/24/2014 05/22/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bhagwan S Chaudhary National Institute of Securities Markets, Mumbai	AGILA SPECIALTIES PRIVATE LTD STERILE PRODUCT DIVISION - 483 08/02/2013 - 08/12/2013
2014-3327	04/24/2014 05/22/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bhagwan S Chaudhary National Institute of Securities Markets, Mumbai	AGILA SPECIALTIES PRIVATE LTD BETA LACTAM DIVISION - 483 08/12/2013 - 08/22/2013
2014-3328	04/24/2014 05/22/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bhagwan S Chaudhary National Institute of Securities Markets, Mumbai	AGILA SPECIALTIES PVT - 483 09/05/2012 - 09/13/2013
2014-3329	04/24/2014 05/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kelly A. Fitzpatrick The Jacob D. Fuchsberg Law Firm, LLP	CORR WITH ABBOTT RE BLOOD GLUCOSE TEST STRIPS 12/22/2010 - 02/19/2014
2014-3330	04/24/2014 05/22/2014	OC/CVM/OCD/	P.J. Huffstutter Thomson Reuters/Reuters News	RACTOPAMINE - AERS
2014-3331	04/24/2014 05/22/2014	FDA/OGROP/ORR/SE-FO/ATL- DO/ATL-CB/	Brandy Quarles Georgia Regents University- Neurology Dept.	DR MICHAEL H RIVER MEDICAL COLLEGE OF GEORGIA AUGUSTA, GA - 483, EIR 12/20/1994 - 12/20/1997
2014-3332	04/24/2014 05/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rick Roesner SurgiPros	K123234
2014-3333	04/24/2014 05/22/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Cindy Gilbert Gilbert	GOLYTELY - AERS
2014-3334	04/24/2014 05/22/2014	FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECS

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2014-3335	04/24/2014 05/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	Patrick Cheng Children's National Medical Center, Sheikh Zayed Institute	K040549
2014-3336	04/24/2014 05/22/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	MCNEIL PPC, LITITZ, PA - EIR, 483, RESPONSE JUNE 2010
2014-3337	04/24/2014 05/22/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	Shay Mockelmann Shay Mockelmann Feedyard	MIDWEST PMS, FT MORGAN, CO - 483, EIR, CORR
2014-3338	04/24/2014 05/22/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 21187
2014-3339	04/24/2014 05/22/2014	FDA/OC/OEXA/OMA/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	CORR BETWEEN FDA AND CNN RE NUVARING
2014-3340	04/24/2014 05/22/2014	FDA/OC/OEXA/OMA/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	CORR BETWEEN FDA AND NPR RE NUVARING
2014-3341	04/24/2014 05/22/2014	FDA/OC/OES/DFOI/	Elissa Flynn-Poppey Mintz Levin Cohn Ferris Glovsky & Popeo	ARIAD, ICLUSIG, PONATINIB - FOIA RQUESTS 06/01/2013 - 04/22/2014
2014-3342	04/24/2014 06/13/2014	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Jacquelyn Hurd Therapeutic Proteins International, LLC	ALLERGY LABORATORIES - EIR, 483 RESPONSE RE WARNING LETTER 04/16/2013 - 04/22/2014
2014-3343	04/24/2014 05/22/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jacquelyn Hurd Therapeutic Proteins International, LLC	GLAXOSMITHKLINE - EIR, 483 RE WARNING LETTER 10/18/2013 - 04/22/2014
2014-3344	04/24/2014 05/22/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Charlotte Arce Charlotte Arce	LO LOESTRIN FE TABLETS - AERS

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2014-3345	04/24/2014 05/22/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	PENTEC HEALTH INC, BOOTHWYN, PA - EIR, 483, CO RESP 3/18/13-4/1/13
2014-3346	04/24/2014 05/28/2014	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	GLAXOSMITHKLINE, RESEARCH TRIANGLE PARK, NC - EIR, 483, CO RESP 10/18-23/13
2014-3347	04/24/2014 05/22/2014	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	RALF ZIMMERMAN MD, COLUMBIA UNIV MEDICAL CENTER, NY - EIR, 483, CO RESP 6/5-25/13
2014-3348	04/24/2014 05/22/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	SANOBI PASTEUR BIOLOGICS CO, CANTON, MA - EIR, 483, CO RESP 4/26/13-5/2/13
2014-3349	04/24/2014 05/22/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	MERCK SHARPE & DOHME CORP, WEST POINT, PA - EIR, 483, CO RESP 1/15/13-2/6/13
2014-3350	04/24/2014 05/22/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	ALLERMED LABORATORIES INC, SAN DIEGO, CA - EIR, 483, CO RESP 8/6-12/13
2014-3351	04/24/2014 05/22/2014	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	ANIP ACQUISTIONS INC, BAUDETTE, MN - EIR, 483, CO RESP 9/27/13
2014-3352	04/24/2014 05/22/2014	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	JANSSEN ORTHO LLC, GURABO, PR - EIR. 483, CO RESP 1/17/13-2/22/13
2014-3353	04/24/2014 05/22/2014	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	VIVUS INC, MOUNTAIN VIEW, CA - EIR, 483, CO RESP 4/22-26/13
2014-3354	04/24/2014 05/22/2014	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	REGENERON PHARMACEUTICALS INC, TARRYTOWN, NY - EIR, 483, CO RESP 2/6-22/13
2014-3355	04/24/2014 05/22/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	SRIKEM LABORATORIES PVT LTD, NAVI MUMBAI, INDIA - EIR, 483, CO RESP 2/11-15/13

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2014-3356	04/24/2014 05/22/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	ALPHAPHARM PTY LTD, CAROLE PARK, AUSTRALIA - EIR, 483, CO RESP 7/15-18/13
2014-3357	04/24/2014 05/22/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	PATHEON PHARMACEUTICALS INC, CINCINNATI, OH - EIR, 483, CO RESP 5/6-13/13
2014-3358	04/24/2014 05/22/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	PF LABORATORIES INC, TOTOWA, NJ - EIR, 483, CO RESP 4/6-22/13
2014-3359	04/24/2014 05/22/2014	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	MYLAN LLC, CAGUAS, PR - EIR, 48S, CO RESP 3/20/13-4/24/13
2014-3360	04/24/2014 05/22/2014	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	DANIEL L PETERSON MD, INCLINE VILLAGE, NV - EIR, 483, CO RESP 1/2-9/13
2014-3361	04/24/2014 05/22/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	HAROLD C YANG MD, HARRISBURG, PA - EIR, 483, CO RESP 3/22-28/13
2014-3362	04/24/2014 05/22/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	EXCELLIUM PHARMACEUTICALS INC, FAIRFIELD, NJ - EIR, 483, CO RESP 6/5-12/13
2014-3363	04/24/2014 05/22/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	PRECISION DERMATOLOGY INC, CUMBERLAND, RI - EIR, 483, CO RESP 6/24-28/13
2014-3364	04/24/2014 05/22/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	SIGMAPHARM LABORATORIES LLC, BENSLEM, PA - EIR, 483, CO RESP 8/12-13/13
2014-3365	04/24/2014 05/22/2014	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	GEORGE S ALLEN MD, VANCOUVER, WA - EIR, 483, CO RESP 4/22/13-5/5/13
2014-3366	04/24/2014 05/22/2014	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	ORGANON TEKNIKA INC, DURHAM, NC - EIR, 483, CO RESP 3/19-25/13

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2014-3367	04/24/2014 05/22/2014	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	AFTON SCIENTIFIC LLC, CHARLOTTESVILLE, VA - EIR, 483, CO RESP 6/24/13
2014-3368	04/24/2014 05/22/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	BOEHRINGER LABORATORIES INC, PHOENIXVILLE, PA - EIR, 483, CO RESP 8/12-13/13
2014-3369	04/24/2014 05/22/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	PARKS, ROBERT	PHILIPS MEDICAL, CLEVELAND, OH - PICKER 1200/600 CT SCANNER INVESTIGATION RECS, 483S, MEMOS, ETC
2014-3370	04/24/2014 05/22/2014	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	SMRUTHI ORGANICS LTD, SOLAPUR, INDIA - EIR, 483, CO RESP 11/15-18/13
2014-3371	04/24/2014 05/22/2014	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	LABOR L&S AG, BAD BOCKET, GERMANY - EIR, 483, CO RESP 1/24-28/13
2014-3372	04/24/2014 05/22/2014	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	STILLMEADOW LABS, SUGARLAND, TX - EIR, 483, CO RESP 4/24/13 -6/6/13
2014-3373	04/24/2014 05/22/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	DALAVAU LLC, PHILADELPHIA, PA - EIR, 483, CO RESP 9/19-30/13
2014-3374	04/24/2014 05/22/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	LANNETT COMPNAY INC, PHILADELPHIA, PA - EIR, 483, CO RESP 7/8/13 - 8/6/13
2014-3375	04/24/2014 05/22/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	HEARTSINE TECHNOLOGIES INC, NEWTON, PA - EIR, 483, CO RESP 8/13-22/13
2014-3376	04/24/2014 05/22/2014	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	WALTER E. CHALKLEY THOMSON REUTERS	FOREST PHARMACEUTICALS INC, EARTH CITY, MO - EIR, 483, CO RESP 11/12-26/13
2014-3377	04/24/2014 05/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	Joshua A. Malamud Hyman, Phelps & McNamara P.C.	K131549, K130197, K123213
2014-3378	04/24/2014 05/22/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	PIRAMAL CRITICAL CARE INC, BETHLEHEM, PA - EIR, 483, CO RESP 7/11-26/13

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2014-3379	04/24/2014 05/22/2014	FDA/OFVM/CFSAN/OCD/EOS/ OC/CVM/OCD/	KRISTI O. SMEDLEY, Ph.D. Center for Regulatory Services, Inc.	FAP 2278, 2282, 2281, 2280
2014-3380	04/24/2014 05/22/2014	FDA/OC/OES/DFOI/	THOMPSON, RAY	ATUL LTD, VALSAD, INDIA - 483 12/16-21/13
2014-3381	04/24/2014 05/22/2014	OC/ORR/ORM/ OC/ORR/ORM/	ROBERT KING FDA NEWS	LIST OF PHARMACEUTICAL, BIOLOGIC, MEDICAL DVC, CLNCL TRIAL FACILITIES - 483'S 3/14
2014-3382	04/24/2014 05/22/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SANG LE STASON PHARMACEUTICALS INC	SELEGILINE - LBLG
2014-3383	04/24/2014 05/22/2014	FDA/OGROP/ORR/SE-FO/NOL- DO/NOL-CB/	DOTSON 12146457, ANDRE	WINDSOR FOODS - CMLPNTS; BHA & BHT - AERS
2014-3384	04/24/2014 05/22/2014	FDA/OFVM/CFSAN/OCD/EOS/	IRINA PATYKA SCHWARTZ GOLDSTONE ET AL	INDIVIDUAL RECS
2014-3385	04/24/2014 05/22/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SHOBHA REDDY CHAGAM DR REDDYS LABORATORIES INC	SANDOZ - METAXALONE ANDA 40-445 SBA
2014-3386	04/24/2014 05/22/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SHOBH REDDY CHAGAM DR REDDYS LABORATORIES INC	AMNEAL PHARMACEUTICALS - METAXALONE ANDA 203399 SBA
2014-3387	04/24/2014 05/22/2014	FDA/OFVM/CFSAN/OCD/EOS/ OC/CVM/OCD/	BYRAN SHAND AGROPHARM LTD	HCE - CARCINOGENICITY
2014-3388	04/24/2014 05/22/2014	FDA/OFVM/CFSAN/OCD/EOS/	GALE, MARIE	HANDCRAFTED SOAPS - ALL COMMUNICATIONS 1/13 TO 4/1/14
2014-3389	04/24/2014 05/22/2014	OC/ORR/OCI/ OC/ORR/OCI/ FDA/OGROP/ORR/CE-FO/MIN- DO/MIN-CB/ FDA/OGROP/ORR/CE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORR/PA-FO/LOS- DO/LOS-CB/	DAVID J. MARCK, Esq. SILLS CUMMIS ET AL	INDIVIDUAL RECS

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		OC/ORO/OCI/ OC/ORO/OCI/ FDA/OC/OCC/ FDA/OGROP/ORO/CE-FO/NWJ- DO/NWJ-CB/		
2014-3390	04/24/2014 05/22/2014	FDA/OC/OES/DFOI/	MELISSA B. HIRST JONES DAY	CRONOBACTER SAKAZAKII, ENTEROBACTER SAKAZAKII - INVESTIGATION
2014-3391	04/24/2014 05/22/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-1281
2014-3392	04/25/2014 05/23/2014	FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/	Jacquelyn Hurd Therapeutic Proteins International, LLC	AMGEN INC - EIR, 483 RE WARNING LETTER 1/27/14
2014-3393	04/25/2014 05/23/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	David von Wiegandt Branstetter Stranch & Jennings	AMNEAL GENERIC METAXALONE - APPROVAL PACKAGE
2014-3394	04/25/2014 05/23/2014	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	FDA & TPSAC reviews of Warner, KE & Mndez, D (2012). Accuracy and Importance of Projections from a Dynamic Model of Smoking Prevalence in the United States. American Journal of Public Health, 102(11): 2045-2048
2014-3395	04/25/2014 05/23/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Aaron Bindman Sterne, Kessler, Goldstein & Fox	NAMENDA (NDA 021487)/Approval History/10-16-2003 Review/Bioequivalence Review(s) Part 2 - pages 72, 73
2014-3396	04/25/2014 05/23/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Gal Neuman The Hospital for Sick Children	CEFTRIAXONE - AERS
2014-3397	04/25/2014 05/23/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Roberts Rachel Roberts	ACTH - AERS
2014-3398	04/25/2014 05/23/2014	FDA/OC/OES/DDM/	Christopher Brennan WESTLAW COURT EXPRESS	Report of the Bioequivalence Task Force on Recommendations from the Bioequivalence Hearing Conducted by the Food and Drug Administration September 29 - October 1, 1986

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2014-3399	04/25/2014 05/23/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kennen MacKay MacKay, Kennen	LETTERS FROM FDA TO SAREPTA THERAPEUTICS RE ETEPLIRSEN 10/01/2013 - 04/22/2014
2014-3400	04/25/2014 05/23/2014	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	Atty. Jordan D. Taylor DeWitt Ross & Stevens SC	KANGADIS FOOD INC DBA GOURMET FACTORY, HAPPAGUE, NY - PERMITS, IMPORTS, INSPECTIONS
2014-3401	04/25/2014 05/23/2014	FDA/OC/OCC/	Emily Evans Obsidian Reseach Group	INVACARE - CONSENT DECREE REPORTS, CORR, ETC (12/21/2012 - 04/22/2014)
2014-3402	04/25/2014 05/23/2014	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	Jacquelyn Hurd Therapeutic Proteins International, LLC	HOLLISTERSTIER - EIR, 483 RESPONSE RE WARNING LETTER 04/15/2013 - 04/22/2014
2014-3403	04/25/2014 05/23/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Danielle Schatten Otsuka America Pharmaceutical Inc.	DR AHMAD HATIM SULAIMAN - EIR 04/09/2012 - 04/13/2012
2014-3404	04/25/2014 05/23/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mahidhar Chinta Micro Labs USA, Inc	ANDA 080439 - SBA
2014-3405	04/25/2014 05/23/2014	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	Annette Kenser Bayer Animal Health	VETERINARY RESOURCES, INC - 483 02/21/2012 - 02/28/2012
2014-3406	04/25/2014 05/23/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ellen Camos ANI Pharmaceuticals, Inc.	ANDA 075126 AMENDMENTS
2014-3407	04/25/2014 05/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	Vik Bajnath ARTHREX, INC.	Device event key:3677168 MDR Report key: 3657416 Event key: 3553951 Report number: 3657416
2014-3408	04/25/2014 05/23/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Chris Hernandez Scott & White Healthcare	Gazyva - AERS
2014-3409	04/25/2014 05/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	Greg Smock Vascular Solutions, Inc.	K953133

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2014-3410	04/25/2014 05/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	ZOYA LEE DEGANIA SILICONE LTD	K112511, K100163, K060944, ETC
2014-3411	04/25/2014 05/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kae Miller Gambro Renal Products, Inc.	Z-1455-2014 - HEALTH HAZARD ANALYSIS
2014-3412	04/25/2014 05/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jing Gu W.H.P.M., Inc	K103227
2014-3413	04/25/2014 05/23/2014	FDA/OC/OES/DDM/	pauliana Hall PCH integrated Regulatory Services, Inc.	FDA Advisory committee on Paxil NDA 20-031 post traumatic stress disorder- 1999 meeting transcripts, FDA briefing document and Lilly (sponsor) briefing document
2014-3414	04/25/2014 05/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 10417
2014-3415	04/25/2014 05/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lisa Schwartz The Dartmouth Institute for Health Policy & Clinical Practice	"FY 2013 Performance Report to the President and Congress" - DATA
2014-3416	04/25/2014 05/23/2014	FDA/OGROP/ORR/SW-FO/DEN-DO/DEN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	MCKENZIE CATO Hyman, Phelps & McNamara P.C.	PLANET INC (RCA SYMPHONIX) - SALES OF PERSONAL SOUND AMPLIFICATION PRODS (PSAPS)
2014-3417	04/25/2014 05/23/2014	FDA/OGROP/ORR/CE-FO/DET-DO/DET-CB/ FDA/OMPT/CDRH/OCER/DFOI/	MCKENZIE CATO Hyman, Phelps & McNamara P.C.	FOCUS EAR (AUDIOVOX ACCESSORIES CORP) - SALES OF PERSONAL SOUND AMPLIFICATION PRODS (PSAP) CORR
2014-3418	04/25/2014 05/23/2014	FDA/OC/OES/ FDA/OMPT/CTP/OD/	JIM SHEHAN Hyman Phelps and McNamara PC	MENTHOL IN CIGARETTES BEFORE 7/23/13
2014-3419	04/25/2014 05/23/2014	FDA/OC/OES/ FDA/OMPT/CTP/OD/ FDA/OMPT/CTP/OD/	JIM SHELAN Hyman, Phelps & McNamara P.C.	MENTHOL IN CIGARETTES AFTER 7/23/13
2014-3420	04/25/2014 05/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	TESS RUALO FROMMER LAWRENCE & HAUG LLP	VICRYL - K810428
2014-3421	04/25/2014 05/23/2014	FDA/OC/OEXA/OMA/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NUVARING - CORR WITH MEDIA 12/1/13 TO PRESENT

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2014-3422	04/25/2014 05/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	TESS RUALO FROMMER LAWRENCE & HAUG LLP	VICRYL & MESH - PMA
2014-3423	04/25/2014 05/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	CHRISTOPHER M SLOAN QUINTILES CONSULTING	ST JUDE MEDICAL INC - ANGIO-SEAL VASCULAR CLOSURE DVC P30038/S040 APRVL, CORR, MINS, ETC 9/13/04
2014-3424	04/25/2014 05/23/2014	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	Atty. Jordan D. Taylor DeWitt Ross & Stevens SC	KRINOS HOLDINGS, LONG ISLAND CITY, NY - PERMITS, INSPECTIONS ETC
2014-3425	04/25/2014 05/23/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Prashant Premkumar East Bridge Capital Management Limited	AUROBINDO PHARMA, INDIA - 483 MARCH, APRIL 2014
2014-3426	04/25/2014 05/23/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FARYAL HASAN Hyman, Phelps & McNamara P.C.	ETHY ESTERS ANDA 09-1028 - SBA
2014-3427	04/25/2014 05/23/2014	FDA/OC/OCC/ OC/CVM/OCD/	Tish Pahl Tish Pahl, Olsson Frank Weeda Terman Matz PC	DECISION BY CVM TO REQUIRE ENVIRONMENTAL ASSESSMENT FOR NEW, ABBREVIATED, AND SUPPLEMENTAL APPLICATIONS FOR ANIMAL DRUGS CONTAINING IVERMECTIN UNDER NEPA
2014-3428	04/25/2014 05/23/2014	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	Melissa Youd Truth in Advertising, Inc.	TOMMIE COOPER, MOUNT KISCO, NY - COMPLAINTS, INVESTIGATIONS 01/01/2010 - 04/24/2014
2014-3429	04/25/2014 05/23/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KRISTINE K KRAFT SCHLICHTER BOGARD & DENTON LLP	PRADAXA - NDA 22-512/S007; IDENTITY OF PERSON WHO VISITED THE FDA OFFICE, WASHINGTON DC 12/1-3/11
2014-3430	04/25/2014 05/23/2014	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/ FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/ FDA/OMPT/CDRH/OCER/DFOI/	MCKENZIE CATO Hyman, Phelps & McNamara P.C.	NEUTRONIC EAR OR GENERAL HEARING INSTRUMENTS INC - SALES OF PERSONAL SOUND AMPLIFICATION PRODS (PSAP)
2014-3431	04/25/2014 05/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	Dean Ilijasic The Adcom Group	EXPORT OF ELECTRO-MEDICAL EQUIPMENT 01/01/2013 - 12/31/2013
2014-3432	04/25/2014	FDA/OGROP/ORA/PA-FO/SEA-	JAMIE RYAN LOCKMAN	CMPLNT 136744

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	05/23/2014	DO/SEA-CB/	KAMUT INTERNATIONAL LTD	
2014-3433	04/25/2014 05/23/2014	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	SCOTT ELLIOT SMITH SMITH LAW OFC	OTTOBOCK NORTH AMERICAN - CUSTOM MOLDED DOUBLE UPRIGHT PLASTIC KNEE, ANKLE, FOOT ORTHOTICS LIMITED MOTION ANKLE JOINT, SOFT INTERFACE FOR BK SECTION MODED PLASTIC, MFR, APRVL,CLNCL TRIAL, ETC
2014-3434	04/25/2014 05/23/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDRH/OCER/DFOI/	ADAM DEMETRI DEMETRI LAW FIRM PLLC	CONAIR CORP - HP15RB HEATING PAD CMLPNTS, CORR, MEMOS, ETC
2014-3435	04/25/2014 05/23/2014	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OMPT/CDRH/OCER/DFOI/	DONALD J WARD III SEARCY DENNEY ET AL	PALMS WEST HOSPITAL, PALM BEACH COUNTY, FL - KNEE REPLACEMENT SURGERY AERS, GUIDELINES, MDRS
2014-3436	04/25/2014 05/23/2014	FDA/OC/OES/DFOI/	SISENSTEIN, KYLE	FOI REQUEST LETTERS 1/1/13 TO 4/14/14
2014-3437	04/28/2014 05/27/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mahidhar Chinta Micro Labs USA, Inc	ANDA 083386
2014-3438	04/28/2014 05/27/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Pauliana Hall PCH integrated Regulatory Services, Inc.	FDA Psychopharmacological drug products Advisory Committee meeting materials (briefing documents, presentation, meeting transcripts) on Sertraline NDA 19-839 for post traumatic stress disorder
2014-3439	04/28/2014 05/27/2014	FDA/OMPT/CDRH/OCER/DFOI/	Greg Smock Vascular Solutions, Inc.	K932616
2014-3440	04/28/2014 05/27/2014	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Rachel Johnson FOI Services, Inc.	CONAGRA, AFTON, MO - EIR, 483
2014-3441	04/28/2014 05/27/2014	FDA/OMPT/CDRH/OCER/DFOI/	Greg Smock Vascular Solutions, Inc.	P860019 S040
2014-3442	04/28/2014 05/27/2014	FDA/OMPT/CDRH/OCER/DFOI/	Greg Smock Vascular Solutions, Inc.	P860019 S064
2014-3443	04/28/2014 05/27/2014	FDA/OMPT/CDRH/OCER/DFOI/	Greg Smock Vascular Solutions, Inc.	K123765
2014-3444	04/28/2014 05/27/2014	FDA/OMPT/CDRH/OCER/DFOI/	Greg Smock Vascular Solutions, Inc.	K935292
2014-3445	04/28/2014	FDA/OC/OES/DFOI/	Kari Twaite	CFSAN FOIA REQUESTS 03/26/2014 - 04/24/2014

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	05/27/2014		BEVERIDGE & DIAMOND PC	
2014-3446	04/28/2014 05/27/2014	FDA/OMPT/CDRH/OCER/DFOI/	Greg Smock Vascular Solutions, Inc.	K961294
2014-3447	04/28/2014 05/27/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Skorek Karolina SciencePharma	ANDA 090446, 090860, 090892
2014-3448	04/28/2014 05/27/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	NDA 202570 S 006
2014-3449	04/28/2014 05/27/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K133338
2014-3450	04/28/2014 05/27/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jonathan J. Darrow BRIGHAM AND WOMEN'S HOSPITAL	NDA 050601, NDA 019459, NDA 019082 ETC - MEDICAL REVIEWS
2014-3451	04/28/2014 05/27/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Caryl Burke Medpace, Inc	MIDAZOLAM - AERS
2014-3452	04/28/2014 05/27/2014	FDA/OGROP/ORR/SE-FO/FLA- DO/FLA-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Angela Priest Priest, Angela	MARK H FELDMAN - WARNING LETTER RECS 12/01/2001 - 04/25/2014
2014-3453	04/28/2014 05/27/2014	FDA/OMPT/CDRH/OCER/DFOI/	Orly Maor Orly Maor	K071845, K111763
2014-3454	04/28/2014 05/27/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Laura Grablutz Auxilium Pharmaceuticals, Inc.	NDA 020497
2014-3455	04/28/2014 05/27/2014	FDA/OMPT/CDRH/OCER/DFOI/	Curt Strenk Dick's Formalwear	K050913

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2014-3456	04/28/2014 05/27/2014	OC/ORO/ OC/ORO/ FDA/OC/OES/DFOI/	NAMBO, HELEN	NODARI RIZUN - ADAPTOGENESIS PRIOR NOTICE SYSTEM INTERFACE WEB ENTRY SUMMARY CONFIRMATION
2014-3457	04/28/2014 05/27/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/OIP/	TOM NELTNER NATURAL RESOURCES DEFENSE COUNCIL	CATECHINS FROM GREEN TEA EXTRACT - GRAS 259
2014-3458	04/28/2014 05/27/2014	FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Doe J	INDIVIDUAL RECS
2014-3459	04/28/2014 05/27/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	DR ALVARO BETANCUR BOCA DENTAL SUPPLY LLC	INTRA-SPIN SYS BK120048
2014-3460	04/28/2014 05/27/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	DR ALVARO BETANCUR BOCA DENTAL SUPPLY LLC	INTRA-SPIN SYS BK120048
2014-3461	04/28/2014 05/27/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/OIP/	DUFF WILSON THOMSON REUTERS	GILLES-ERIC SERALINI, STUDY OF ROUNDUP IN RATS - RPTS, RVWS, ANALYSIS, ETC 9/12 TO PRESENT
2014-3462	04/28/2014 05/27/2014	FDA/OFVM/CFSAN/OCD/EOS/	KEVIN S FRIES COSMETIC INGREDIENT REVIEW	METHYLISOTHIAZOLINONE (MIT) - RECS
2014-3463	04/28/2014 05/27/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID LOHMAN MILLENNIUM MANAGEMENT LLC	JANSSEN, MALLINCKRODT, KUDCO - CONCERTA (METHYLPHENIDATE HCL EXTENDED RELEASE TABS) AERS
2014-3464	04/28/2014 05/27/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	NARVANE, PAXIL, CELEXA - AERS
2014-3465	04/28/2014 05/27/2014	FDA/OMPT/CDRH/OCER/DFOI/	O'LAUGHLIN, TIMOTHY	WIRELESS MEDICAL TELEMETRY DVC - RECS
2014-3466	04/28/2014 05/27/2014	FDA/OGROP/ORO/CE-FO/BLT- DO/BLT-CB/	Misty York York, Misty	INDIVIDUAL RECS
2014-3467	04/28/2014 05/27/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OCS/NCTR/OCD/ FDA/OGROP/ORO/CE-FO/CIN- DO/CIN-CB/	Ho Leung Ng University of Hawaii, Manoa	Chemical and toxicology analysis of OxyElite Pro formulation containing aegeline
2014-3468	04/28/2014	OC/ORO/		INDIVIDUAL RECS

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	05/27/2014	OC/ORO/ FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	Doe J	
2014-3469	04/28/2014 06/27/2014	OC/ORO/ OC/ORO/	Merle Zimmermann (ext. 106) AMERICAN HERBAL PRODUCTS ASSOCIATION	DIETARY SUPPLEMENT INSPECTIONS - EIR, 483 01/01/2012 - 12/31/2013
2014-3470	04/28/2014 05/27/2014	OC/CVM/OCD/ OC/ORO/ OC/ORO/	Kaitlyn Wells The Wall Street Journal/MarketWatch	JERKY PET TREATS - CONSUMER COMPLAINTS 01/01/2007 - 04/20/2014
2014-3471	04/28/2014 05/27/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Angela Birchall Bio Products Laboratory Limited	BIO PRODUCTS LABORATORY TLD, ELSTREE, UK - EIR 6/24/13; GAMMAPLEX AERS
2014-3472	04/28/2014 05/27/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jacquelyn Hurd Therapeutic Proteins International, LLC	HUMIRA PEN DEVICE - APPROVAL LETTER
2014-3473	04/28/2014 05/27/2014	FDA/OMPT/CDRH/OCER/DFOI/	Sharon Young on behalf of Roderick Castillo FOCUS DIAGNOSTICS	K113433 - CLIA ROUTING SLIP ETC
2014-3474	04/28/2014 05/27/2014	FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/	doletta sue tuck richmond Doletta Sue Tuck Richmond	PET SCRIPT INC - 483, WARNING LETTER 01/01/2002 - 04/24/2014
2014-3475	04/29/2014 05/28/2014	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	ROSS, DAVID	ACTHAR - REQUESTS 2012 TO 2013
2014-3476	04/29/2014 05/28/2014	FDA/OMPT/CDRH/OCER/DFOI/	GREGORY W. ALBERT HAGENS BERMAN SOBOL SHAPIRO LLP	CRYSTALENS DVC - APRVL
2014-3477	04/29/2014 05/28/2014	FDA/OFVM/CFSAN/OCD/EOS/	Silvia Volkmann Orion Engineered Carbons GmbH	FCN 0011381
2014-3478	04/29/2014 05/28/2014	FDA/OMPT/CDRH/OCER/DFOI/	Sharon Young on behalf of Roderick Castillo FOCUS DIAGNOSTICS	K133621 CLIA RECS
2014-3479	04/29/2014 05/28/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kimberly Ammiano Columbia Graduate School of Journalism	VIBRATORS, LUBRICANTS - COMPLAINTS, APPROVALS 01/09/2009 - 04/25/2014
2014-3480	04/29/2014	FDA/OGROP/ORO/NE-FO/NYK-	Walid Gardezi	ALBANY MOLECULAR RESEARCH INC - EIR 01/01/2000 -

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	05/28/2014	DO/NYK-DCB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Walid Gardezi	04/25/2014
2014-3481	04/29/2014 05/28/2014	FDA/OMPT/OSMP/OOPD/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	XALKORI - ORPHAN DRUG DESIGNATION APPLICATION
2014-3482	04/29/2014 05/28/2014	FDA/OFVM/CFSAN/OCD/EOS/	Linda A. Ajawara Lee, Hong, Degerman, Kang & Waimey	KHEE TRADING INC - RECALL RECS 04/01/2012 TO PRESENT
2014-3483	04/29/2014 05/28/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Julie Jirousek WorldCare Clinical, LLC	WORLDCARE CLINICAL, CAMBRIDGE, MA - EIR 10/31/2006 - 05/23/2007
2014-3484	04/29/2014 05/28/2014	FDA/OFVM/CFSAN/OCD/EOS/	Linda A. Ajawara Lee, Hong, Degerman, Kang & Waimey	MARISOL - COMMUNICATIONS WITH FDA ETC SINCE 1/1/2011
2014-3485	04/29/2014 05/28/2014	FDA/OMPT/CTP/OD/ FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	LIST OF FEFUSAL TO FILE OR EXTENDED REVIEW FOR AN ECTD SUBMISSION
2014-3486	04/29/2014 06/11/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDRH/OCER/DFOI/	Americord Registry Americord Registry	BK960043, BK860040, K791673 ETC
2014-3487	04/29/2014 05/28/2014	FDA/OMPT/OSMP/OOPD/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	GILOTRIF - ORPHAN PRODUCT DESIGNATION APPLICATION
2014-3488	04/29/2014 05/28/2014	FDA/OMPT/CDRH/OCER/DFOI/	Toshio Murata Nidek Incorporated	510(k) summary for VX-120 manufactured by Luneau SA (or distributed by Visionix)
2014-3489	04/29/2014 05/28/2014	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	Nick DiBerardinis VWR International LLC	VWR, BATAVIA, IL - INSPECTION RECS 03/12/2014 - 03/21/2014
2014-3490	04/29/2014 05/28/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	NORLIE BUSTALENA VEGE KURL, INC.	VEGE KURL - RESPONSE LETTER TO CORRECTIVE ACTIONS 11/22/2011 - 12/31/2013;
2014-3491	04/29/2014 05/28/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	KELLY A. CHRISTIAN MORRIS MANNING ET AL LLP	FORWARD SCIENCE LLC - ORALLD K123169
2014-3492	04/29/2014	OC/ORAI/	RICH LORD	RPT OF ASSETS PAID FROM THE ASSETS FORFEITURE

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	05/28/2014	OC/ORO/ OC/ORO/OCI/ OC/ORO/OCI/	PITTSBURGH POST-GAZETTE	FUND
2014-3493	04/29/2014 05/28/2014	FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/	SAMUEL TSENG SANTEN INC	SANTEN, EMERYVILLE, CA - EIR 2/13
2014-3494	04/30/2014 05/29/2014	FDA/OGROP/ORO/CE-FO/DET-DO/DET-CB/	TANK, LAURA	COOK GENERAL BIOTECHNOLOGY LLC, INDIANAPOLIS, IN -483S 2008 TO 2014
2014-3495	04/30/2014 05/29/2014	FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/	TANK, LAURA	AMERICORD REGISTRY LLC, NEW YORK, NY - HCT/PS (UMBILICAL CORD BLOOD STEM CELLS, UMBILICAL CORD TISSUE STEM CELLS & PLACENTA STEM CELLS) 483S 2008 TO 2014
2014-3496	04/30/2014 05/29/2014	FDA/OGROP/ORO/CE-FO/DET-DO/DET-CB/ FDA/OMPT/CDRH/OCER/DFOI/	LEANIE F BOLINGER WORMINGTON LAW GROUP PLLC	STRYKER - NEPTUEN 1 SILVER WAST MANAGEMENT SYS (NEPTUNE 1 SILVER); NEPTUNE 2 UTRA WASTE MANAGEMENT SYS DVC (NEPTUNE 2 ULTRA) CONSUMER CMLPNTS, MDRS (AERS), CERTIFICATE OF MEDICAL NECESSITY, ETC
2014-3497	04/30/2014 05/29/2014	FDA/OMPT/CDRH/OCER/DFOI/	RONALD L SMITH OCLARO	KOMORO FACILITY, NAGANO, JAPAN - LASER PRODS ASSESSION #8221468 LTR
2014-3498	04/30/2014 05/29/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	BRETT PARK CONWAY HOMER & CHIN-CAPLAN PC	HITACHI AMERICAN LTD - INDIVIDUAL RECS (CERTIFIED)
2014-3499	04/30/2014 05/29/2014	FDA/OMPT/CDRH/OCER/DFOI/	George Vazquez Panasonic Consumer Electronics Company	PANASONIC HOME APPLIANCES MICROWAVE OVEN SHANGHAI CO; PANASONIC CORPORATION, HOME APPLIANCES COMPANY, KITCHEN APPLIANCES BUSINESS UNIT - EIR 04/01/2009 - 04/01/2014
2014-3500	04/30/2014 05/29/2014	FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/	Rachel Johnson FOI Services, Inc.	CLEANWELL, SAN FRANCISCO, CA - WARNING LETTER RESPONSE
2014-3501	04/30/2014 05/29/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kevin Liang MileStone Research Organization	K080712
2014-3502	04/30/2014 05/29/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Kevin Liang MileStone Research Organization	K001194
2014-3503	04/30/2014 05/29/2014	FDA/OGROP/ORO/SW-FO/DEN-DO/DEN-CB/	Kirsten Stewart The Salt Lake Tribune	UTAH CELL THERAPY, SALT LAKE CITY, UT - EIR 03/03/2011 - 08/30/2013
2014-3504	04/30/2014 05/29/2014	FDA/OMPT/CDRH/OCER/DFOI/	Leon Amariglio Lexington Medical, Inc.	K061555
2014-3505	04/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kevin Liang	K090338

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	05/29/2014		MileStone Research Organization	
2014-3506	04/30/2014 05/29/2014	FDA/OMPT/CDRH/OCER/DFOI/	Valerie Staffey MMJ Labs	K031036, K032671
2014-3507	04/30/2014 05/29/2014	FDA/OFVM/CFSAN/OCD/EOS/	Liz Sonnenberg AkzoNobel Packaging Coatings	FCN 1192
2014-3508	04/30/2014 05/29/2014	FDA/OC/OES/DFOI/	Sarah Robberson Maplewood Richmond Heights High School	EFFECTS OF COFFEE ON THE BODY
2014-3509	04/30/2014 05/29/2014	FDA/OMPT/CDRH/OCER/DFOI/	Leon Amariglio Lexington Medical, Inc.	K855047
2014-3510	04/30/2014 05/29/2014	OC/ORO/ OC/ORO/	Kathy Reichbach Childress Ahlheim Cary, LLC	MICHAELS FOODS - HARD COOKED EGG TESTING, RECALL RECS
2014-3511	04/30/2014 05/29/2014	FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/	Anna Edney BLOOMBERG NEWS	INTUITIVE SURGICAL - 483 02/01/2014 - 04/29/2014
2014-3512	04/30/2014 05/29/2014	FDA/OGROP/ORO/CE-FO/MIN-DO/MIN-CB/	Maura Robertson BloodCenter of Wisconsin, Inc.	BLOOD CENTER OF WISCONSIN, KENOSHA, WI - EIR 01/06/2012 - 01/06/2012
2014-3513	04/30/2014 05/29/2014	FDA/OC/OES/DFOI/ FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	Michelle Ye Hee Lee THE ARIZONA REPUBLIC	FIRMS IN ARIZONA OAI, VAI 01/01/2013 - 12/31/2013
2014-3514	04/30/2014 05/29/2014	FDA/OC/OES/DFOI/	MARK CHEN NANOVA INC	K003273, K031932, K040098 ETC
2014-3515	05/01/2014 05/30/2014	FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Luke Brean BreanLaw, LLC	CALMS, CALMS FORTE, CALMS FORTE 4 KIDS - CORR BETWEEN STANDARD HOMEOPATHIC INC AND FDA 01/01/2000 - 04/25/2014
2014-3516	05/01/2014 05/30/2014	FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ben Crair THE NEW REPUBLIC	RECS RE CARLO MUSSO, CORRECTHEALTH, RAINBOW MEDICAL 01/01/1990 - 04/28/2014
2014-3517	05/01/2014	FDA/OMPT/CDER/ORP/DIDP/	Scott Bergeson	BIOCRAFT LABORATORIES, INC, TEVA PHARMACEUTICAL INDUSTRIES, LTD, ETC - APPROVAL TO MARKET SODIUM

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	05/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ARENT FOX LLP	OXYBATE OR GAMMA HYDROXYBATE FOR TREATMENT OF NARCOLEPSY OR CATAPLEXY IN NARCOLEPSY ETC
2014-3518	05/01/2014 05/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Karl G Trass Versartis, Inc.	NDA 19774 - SBA
2014-3519	05/01/2014 05/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ryan Smith Janus Capital Group Attn: Rachelle Lyon	IMBRUVICA - AERS
2014-3520	05/01/2014 05/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ryan Smith Janus Capital Group Attn: Rachelle Lyon	XTANDI - AERS
2014-3521	05/01/2014 05/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Andrew Mahon Nanometics	PYRIDOXAMINE - IND
2014-3522	05/01/2014 05/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sephy Philip, RPh, PharmD ScientificExchange	NDA 204977
2014-3523	05/01/2014 05/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Stella Stergiopoulos TUFTS CENTER FOR THE STUDY OF DRUG DEVELOPMENT	FAERS DATA
2014-3524	05/01/2014 05/30/2014	FDA/OFVM/CFSAN/OCD/EOS/	Thomas A. Tucker Ronzetti Kozyak Tropin & Throckmorton, P.A.	RECS RE ACCERA INC WARNING LETTER 01/02/2013 - 04/29/2014
2014-3525	05/01/2014 05/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	BLA 125472

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-3526	05/01/2014 05/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Paige Stradley Merchant & Gould P.C.	NDA 021223
2014-3527	05/01/2014 05/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Nimish Shah Venrock Associates	FLAMEL TECHNOLOGIES - COMPLETE RESPONSE LETTER
2014-3528	05/01/2014 05/30/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ryan L Thompson Watts Guerra LLP	RECS RE MARCH 24 LETTER FROM JANET WOODCOCK TO ELIZABETH BARBEHENN RE VICTOZA; CORR FROM DR WOODCOCK AND NOVO NORDISK; STUDIES, ADVERSE EVENTS, RESEARCH ETC RELIED ON OR REFERRED TO IN LETTER
2014-3529	05/01/2014 05/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bradley Scott Dickinson Dickinson, Bradley S	POZEN PA8140, PA32540 COMPLETE RESPONSE LETTER
2014-3530	05/01/2014 05/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Emily Krulewitz The Weinberg Group	BOEHRINGER INGELHEIM PHARMA GMBH - 483 02/01/2014 - 04/29/2014
2014-3531	05/01/2014 05/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lauren Quinn Novartis Consumer Health Inc.	NDA 204623
2014-3532	05/01/2014 05/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Neal L. Moskow Ury & Moskow, LLC	GLP-1 AGONISTS IN THE TREATMENT OF TYPE 2 DIABETES - CORR, EMAIL, CALENDAR ETC
2014-3533	05/01/2014 05/30/2014	FDA/OFVM/CFSAN/OCD/EOS/	Alison Young USA TODAY	DRIVEN SPORTS - RESPONES TO WARNING LETTER 12/02/2013 - 05/16/2014
2014-3534	05/01/2014	FDA/OMPT/CDER/GRP/DIDP/	Andrea Canavero	CYSTAGON - AERS

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	05/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Raptor Pharmaceuticals Inc	
2014-3535	05/01/2014 05/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Stefan Hubanov Kaiser Gornick LLP	ANDA 085635
2014-3536	05/01/2014 05/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	Leon Amariglio Lexington Medical, Inc.	K090821
2014-3537	05/01/2014 05/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	Leon Amariglio Lexington Medical, Inc.	K111845
2014-3538	05/01/2014 05/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	Dora Fong KARL STORZ ENDOSCOPY AMERICA INC	K101077
2014-3539	05/01/2014 05/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Marie Evangelisto Doyle Teva Pharmacueticals	NATCO PHARMA LIMITED - 483, EIR 05/17/2004 - 04/30/2014
2014-3540	05/01/2014 05/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	David von Wiegandt Branstetter Stranch & Jennings	AMNEAL GENERIC METAXALONE - APPROVAL PACKAGE CERTIFIED
2014-3541	05/01/2014 05/30/2014	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	Alison Young USA TODAY	BACTOLAC PHARMACEUTICAL, HAUPPAUGE, NY - 483, CORR 01/01/2011 - 05/01/2014
2014-3542	05/01/2014 05/30/2014	FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	EMILY K STRUNK JONES DAY	QUESTCOR PHARMS - ACTHAR GEL (CORTICOTROPIN INJ) 482S, 483S, WARNING LTRS, ETC
2014-3543	05/01/2014 05/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHOBHA REDDY CHAGAM Dr.Reddys Laboratories Inc	JANSSEN PHARMS - ELMIRON (PENTOSAN POLYSULFATE SODIUM) CAPS NDA 20-193 SBA

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2014-3544	05/01/2014 05/30/2014	FDA/OC/OES/DDM/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GREGORY D BROWN FLEMING NOLEN & JEZ LLP	ABBVIE, ABBOTT LABS - ANDROGEL CORR, LBLG, AERS, ETC
2014-3545	05/01/2014 05/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	CYMBALTA, XANAX - RECS
2014-3546	05/01/2014 05/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	Coffman, Donnie	DOCUMENT NUMBER CPT1300467
2014-3547	05/01/2014 05/30/2014	OC/ORO/ OC/ORO/	PARIZHER, VLADIMIR	NODARI RIZUN, ADAPTOGENESIS - MINERAL PATCH (SHILAJIT, MOOMIE) RECS
2014-3548	05/01/2014 05/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	HELEN LEWIS DENTSPLY INTERNATIONAL	K123215
2014-3549	05/01/2014 05/30/2014	FDA/OMPT/CTP/OD/	STANTON A GLANTZ PHD UNIV OF CALIFORNIA SAN FRANCISCO	REAL COST CAMPAIGN - MARKETING RPTS, RESEARCH, ANALYSIS, ETC
2014-3550	05/01/2014 05/30/2014	FDA/OC/OES/DDM/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELIZABETH SMITHHART ESQ BUTLER SNOW LLP	PROSCAR, PROPECIA, FINASTERIDE - CITIZEN'S PETITIONS
2014-3551	05/01/2014 05/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHIPMAN, KIM	MEDWATCH RPT
2014-3552	05/01/2014 05/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DR REENA HARJAI APCER Pharma Solutions, Inc	EXUBERA (HUMAN INSULIN) - AERS

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2014-3553	05/01/2014 05/30/2014	FDA/OC/OES/DFOI/	SPENCER C THOMAS GIDEON COOPER & ESSARY	NECC, FARMINGHAM, MA - INVESTIGATION MEMO 1/26/05
2014-3554	05/01/2014 05/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WENDY BEDALE PHD DELTANOID PHARMACEUTICALS INC	FDA STAFF MANUAL GUIDE 4850.7
2014-3555	05/01/2014 05/30/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORACE-FO/DET- DO/DET-CB/	PETER J SOMERA JR ESQ SOMERA & SILVA LLP	STRYKER - NEPTUNE 2 ULTRA MANAGEMENT SYS MDRS, RECALLS, OPERATING MANUALS, ETC 3/7/13 TO PRESENT
2014-3556	05/01/2014 05/30/2014	OC/CVM/OCD/	MICHAEL H BURKE CHANELLE PHARMACEUTICALS MFG LTD	CHANELLE PHARMACEUTICALS MANUFACTURING LTD - CHANAZINE (XYLAZINE HCL) ANAD 200-139, ANAD 200-184 RECS
2014-3557	05/01/2014 05/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	THOMPSON, RAY	HOSPIRA HEALTHCARE INDIA PVT LTD, KANCHIPURAM, INDIA 12/2-10/13; RANBAXY LABORATORIES LTD (TOANSA), PUNJAB, INDIA 1/5-11/14 - 483S
2014-3558	05/01/2014 05/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SAMMY ALMASHAT MD MPH PUBLIC CITIZEN	INCRETIN MIMETIC DRUGS - PANCREATIC AERS
2014-3559	05/01/2014 05/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SAMMY ALMASHAT MD MPH PUBLIC CITIZEN	INCRETIN-BASED DRUGS - ANIMAL AND HUMAN DATA
2014-3560	05/01/2014 05/30/2014	FDA/OC/OES/DDM/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHRIS SZECHENYI ON POINT INVESTIGATIONS	MEDICINES CO - CANGRELOR CHAMPION TRIALS, RPTS, LTRS, ETC 2010 TO 2014
2014-3561	05/01/2014 05/30/2014	FDA/OC/OES/DFOI/	Joan Stitt UG2CD-16 MERCK & CO., INC.	FOIA REQUESTS CLOSED APRIL 2014

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2014-3562	05/01/2014 05/30/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 4/1-30/2014
2014-3563	05/02/2014 06/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mahidhar Chinta MICRO LABS USA INC	ANDA 075222
2014-3564	05/02/2014 06/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Eleanor DaCosta United States Pharmacopeial Convention (USP)	VITAMIN C - AERS
2014-3565	05/02/2014 06/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mahidhar Chinta MICRO LABS USA INC	ANDA 075228
2014-3566	05/02/2014 06/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Molly Rapp Fresenius Kabi USA LLC	REVIEW FOR S 27 TO NDA 021602
2014-3567	05/02/2014 06/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 204655
2014-3568	05/02/2014 06/02/2014	FDA/OMPT/CTP/OD/	Stanton A. Glantz UNIVERSITY OF CALIFORNIA, SAN FRANCISCO	REAL COST CAMPAIGN RECS
2014-3569	05/02/2014 06/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Paul L. Hallenbeck Hallenbeck, Paul L	NDA OMACETAXINE
2014-3570	05/02/2014 06/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Barbara Mills MOTLEY RICE LLC	WELLBUTRIN NDA

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2014-3571	05/02/2014 06/02/2014	FDA/OMPT/CDRH/OCER/DFOI/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	K080631
2014-3572	05/02/2014 06/02/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Farah Ali SPI Pharma, Inc.	PARTICLE SIZE TECHNOLOGY, QUAKERTOWN, PA - EIR, 483 06/01/2012 - 09/01/2012
2014-3573	05/02/2014 06/02/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Jing Gu W.H.P.M., Inc	WHPM, IRWINDALE, CA - EIR 12/01/2010 - 05/01/2011
2014-3574	05/02/2014 06/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	David Kim David Kim	HOSPIRA, INDIA - 483, UNTITLED LETTER 12/02/2013 - 04/30/2014
2014-3575	05/02/2014 06/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rowena Dodaro ALKERMES INC	9157293 9149115 9162648 ETC - SOURCE RECS
2014-3576	05/02/2014 06/02/2014	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Kim Sobien BD Rx Inc.	BD RX INC, WILSON, NC - EIR 04/01/2014 - 05/02/2014
2014-3577	05/02/2014 06/02/2014	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	TANK, LAURA	NEWBORN BLOOD BANKING INC, LAND O LAKES, FL - UNBILICAL CORD BLOOD STEM CELLS (HCT/PS) EIRS, 483S, ETC
2014-3578	05/02/2014 06/02/2014	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	TANK, LAURA	CORD BLOOD AMERICA INC, LAS VEGAS, NV - UNBILICAL CORD BLOOD CELLS (HCT/PS) EIRS, 483S, ETC
2014-3579	05/02/2014 06/02/2014	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	TANK, LAURA	CORD:USE CORD BLOOD BANK, ORLANDO, FL - UMBILICAL CORD BLOOD STEM CELLS (HCT/P'S) EIRS, 483S, ETC
2014-3580	05/02/2014 06/02/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	TANK, LAURA	VIACORD PROCESING LABORATORY, HEBRON, KY - UMBILICAL CORD BLOOD STEM CELLS (HCT/PS) EIRS, 483S, ETC
2014-3581	05/02/2014 06/02/2014	OC/ORARM/ OC/ORARM/	LESLIE RAMSEY FDA NEWS	LIST OF 483'S FOR BIOLOGICS, MEDICAL DVC MFG & CLNCL TRIAL FACILITIES IN THE US & OUTSIDE THE US 4/1-30/14
2014-3582	05/02/2014 06/02/2014	FDA/OMPT/CDRH/OCER/DFOI/	MARIA E WAGNER I-FLOW LLC	ARROW INTERNTIONAL - BRACHIAL PLEXUS CATHETER K874106
2014-3583	05/02/2014 06/02/2014	OC/ORAM/ OC/ORAM/	GAIL LESSICK LACHMAN CONSULTANT	LIST OF ALL DOMESTIC & FOREIGN INSP 3/1-31/14

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		OC/ORR/ORM/ OC/ORR/ORM/	SERVICES INC	
2014-3584	05/02/2014 06/02/2014	FDA/OMPT/CDRH/OCER/DFOI/	ANN CHAREST ARTERIOCYTE	HARVEST ADIPREP HARVEST TECHNOLOGIES - K121005
2014-3585	05/05/2014 06/03/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-2195
2014-3586	05/05/2014 06/03/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-2214
2014-3587	05/05/2014 06/03/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-1668
2014-3588	05/05/2014 06/03/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-2800
2014-3589	05/05/2014 06/03/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-1640
2014-3590	05/05/2014 06/03/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-1782
2014-3591	05/05/2014 06/03/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-1658
2014-3592	05/05/2014 06/03/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-2808
2014-3593	05/05/2014 06/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Becky Hartman Teva Pharmaceuticals	QNASL 202813 - FAERS
2014-3594	05/05/2014 06/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Becky Hartman Teva Pharmaceuticals	ADUSAVE - FAERS
2014-3595	05/05/2014 06/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ashkan K Yazdi THE UNIVERSITY OF TEXAS AT AUSTIN	ORANGE BOOKS 25 TO 33
2014-3596	05/05/2014	FDA/OMPT/CDER/GRP/DIDP/	Becky Hartman	GRANIX - AERS

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	06/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Teva Pharmaceuticals	
2014-3597	05/05/2014 06/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	HERNAN ROJAS HERNAN ROJAS	K101366
2014-3598	05/05/2014 06/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dennis W, Raisch UNIVERSITY OF NEW MEXICO	TYSABRI - FAERS
2014-3599	05/05/2014 06/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Becky Hartman Teva Pharmaceuticals	QUARTETTE - APPROVAL RECS
2014-3600	05/05/2014 06/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Becky Hartman Teva Pharmaceuticals	SYNRIBO - AERS
2014-3601	05/05/2014 06/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Yamil Hernandez Cerium Pharmaceuticals, Inc.	NDA 020666
2014-3602	05/05/2014 06/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jay Pensler,MD Jay Pensler,MD	K974497
2014-3603	05/05/2014 06/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Janaya Williams ARADIGM	NDA 50704
2014-3604	05/05/2014 06/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Janaya Williams Aradigm Corporation	NDA 21041
2014-3605	05/05/2014 06/03/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-810

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2014-3606	05/05/2014 06/03/2014	FDA/OGROP/OROPA-FO/SEA-DO/SEA-CB/	Michelle E Legiec Eagle Pharmaceuticals, Inc.	COMPREHENSIVE CLINICAL DEVELOPMENT, INC, TACOMA, WA - EIR 01/01/2013 - 03/31/2013
2014-3607	05/05/2014 06/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Yamil Hernandez Cerium Pharmaceuticals, Inc.	NDA 017989
2014-3608	05/05/2014 06/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Yamil Hernandez Cerium Pharmaceuticals, Inc.	NDA 016093
2014-3609	05/05/2014 06/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Yamil Hernandez Cerium Pharmaceuticals, Inc.	NDA 016785
2014-3610	05/05/2014 06/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Yamil Hernandez Cerium Pharmaceuticals, Inc.	NDA 019194
2014-3611	05/05/2014 06/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHARLES CELESTE EAS Consulting Group, LLC	HALDOL - NDA 15923 APRVL LTR MEDICAL RVWS, PHARMACOLOGY RVWS, ETC
2014-3612	05/05/2014 06/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHARLES EAS Consulting Group, LLC	DEPO-PROVERA - NDA 125-41 APRVL LTR, LBLG, MEDICAL RVWS, ETC
2014-3613	05/05/2014 06/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHARLES CHRIS EAS Consulting Group, LLC	DEPO-PROVERA - NDA 202-46 APRVL LTR, LBLG, MEDICAL RVWS, ETC
2014-3614	05/05/2014 06/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHARLES CELESTE EAS Consulting Group, LLC	KENALOG-40 - NDA 149-01 APRVL LTR, LBLG, MEDICAL RVWS, ETC

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2014-3615	05/05/2014 06/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS Consulting Group, LLC	CYTOXAN - NDA 121-42 APRVL LTR LBLG, MEDICAL RVW, ETC
2014-3616	05/05/2014 06/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS Consulting Group, LLC	NIMBEX - NDA 205-51 APRVL LTR, LBLG, MEDICAL RVW, ETC
2014-3617	05/05/2014 06/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS Consulting Group, LLC	ENOXAPARIN SODIUM - ANDA 78-660 APRVL LTR, LBLG, CHEMISTRY RVW, ETC
2014-3618	05/05/2014 06/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS Consulting Group, LLC	ENOXAPARIN SODIUM - ANDA 778-57 APRVL LTR, LBLG, CHEMISTRY RVW, ETC
2014-3619	05/05/2014 06/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS Consulting Group, LLC	ENOXAPARIN SODIUM - ANDA 766-84 APRVL LTR, LBLG, CHEMISTRY RVW, ETC
2014-3620	05/05/2014 06/03/2014	FDA/OFVM/CFSAN/OCD/EOS/	CHARLES CELESTE EAS CONSULTING GROUP LLC	ACACIA - FAP1A4730 APRVL, RVW, MEMO, ETC
2014-3621	05/05/2014 06/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	CHARLES CELESTE EAS CONSULTING GROUP LLC	ACACIA - FAP 1A4784 APRVL, RVW, MEMO, ETC
2014-3622	05/05/2014 06/03/2014	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	CHARLES CELESTE EAS Consulting Group, LLC	ALASKA SPRING PHARM, WESTBURY, NY - EIRS, 483S, ETC 1/14
2014-3623	05/05/2014 06/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS Consulting Group, LLC	ENOXAPARIN SODIUM ANDA 78-600- APRVL LTR, LBLG, CMC RVW, ETC

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-3624	05/05/2014 06/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHARLES CELESTE EAS Consulting Group, LLC	ENOXAPARIN SODIUM - ANDA 76-857 - APRVL LTR, LBLG, CMC RVW, ETC
2014-3625	05/05/2014 06/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHARLES CELESTE EAS Consulting Group, LLC	GLIMEPRIDE TABS - ANDA 768-75 APRVL LTR LBLG, CMC RVW, ETC
2014-3626	05/05/2014 06/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHARLES CELESTE EAS Consulting Group, LLC	GLIMEPIRIDE TABS - ANDA 773-70 APRVL LTR, LBLG, CMC RVW, ETC
2014-3627	05/05/2014 06/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHARLES CELESTE EAS Consulting Group, LLC	NAPROXEN SODIUM ER TABS - ANDA 754-16 APRVL LTR, LBLG, CMC RVW, ETC
2014-3628	05/05/2014 06/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHARLES EAS Consulting Group, LLC	QUDEXY XR - NDA 205-122 APRVL LTR, LBLG, MEDICAL RVW, ETC
2014-3629	05/05/2014 06/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHARLES CELESTE EAS Consulting Group, LLC	TROKENDY XR - NDA 201-635 APRVL LTR, LABELING, MEDICAL RVW, ETC
2014-3630	05/05/2014 06/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHARLES CELESTE EAS Consulting Group, LLC	HALDOL - NDA 18-701 APRVL LTR, LBLG, MEDICAL RVW, ETC
2014-3631	05/05/2014 06/03/2014	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORA/SW-FO/SWID/SWID-CB/ FDA/OMPT/CBER/OCOD/DDOM/	GREGORY M KASH GREGORY M KASH LAW OFC	INDIVIDUAL RECS

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		ALFB/		
2014-3632	05/05/2014 06/03/2014	FDA/OGROP/ORА/SE-FO/ATL-DO/ATL-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	GTREGORY M KASH GREGORY M KASH LAW OFC	INDIVIDUAL RECS
2014-3633	05/05/2014 06/03/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DLONICIA JOANN REBLANDO TRI-STAR CONSULTING	INS INTRAOPERATIVE SURVEILLANCE SYS K002677; AVSO ARIA MONITORING PROBE & AVS AIRA PROBE DILATORS K110419
2014-3634	05/05/2014 06/03/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	PATRICK KELLY CONWAY HOMER & CHIN-CAPLAN PC	INDIVIDUAL RECS (CERTIFIED)
2014-3635	05/05/2014 06/03/2014	FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/	Doe J	RESPERDOL - AERS
2014-3636	05/05/2014 06/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	LORI A CARR LORI A CARR INC	MENTOR CORP - ARIS TANS-OBTURATOR TAPE & SURGICAL KIT K050148
2014-3637	05/05/2014 06/03/2014	FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/ FDA/OC/OES/DFOI/	ROBERT VAN OSDEL Nexgen Pharma	WOCKHARDT - BROMFED-DM ANDA88-811SBA
2014-3638	05/05/2014 06/03/2014	FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/	THOMPSON, RAY	NECTAR LIFESCIENCES LTD, PUNJAB, NEAR CHANDIGARH, INDIA - 483S 1/22-24/14; NECTAR LIFESCIENCES LTD, NALAGARH, INDIA - 483S 1/14-21/14
2014-3639	05/05/2014 06/03/2014	FDA/OGROP/ORА/CE-FO/PHI-DO/PHI-CB/	Howard L. Nations The Nations Law Firm	SYNTHEС INC, NORIAN CORP - JOSEPH DESPIN RECS CERTIFIED 01/01/1999 - 01/01/2009
2014-3640	05/05/2014 06/03/2014	FDA/OGROP/ORА/CE-FO/BLT-DO/BLT-CB/	GREGORY R HISLOP MCNAMEE HOSEA ATTY	C-CARE LLC - VIOLATIONS, INVESTIGATION, COMM, ETC 1/10 TO PRESENT
2014-3641	05/05/2014 06/03/2014	FDA/OFVM/CFSAN/OCD/EOS/	VISAGINE VIJAYAKULASINGAM IOVATE HEALTH SCIENCES INTERNATIONAL INC	IOVATE, HYDROXYCUT, SMARTBURN, ETC - CAERS
2014-3642	05/06/2014	FDA/OMPT/CDER/ОРP/DIDP/	Dana Thompson	COMM BETWEEN RHETT DANIELS AND JANET WOODCOCK, KATHLEEN JOYCE, HUASCAR BATISTA ETC

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	06/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FULBRIGHT & JAWORSKI LLP	01/02/2010 - 05/01/2014
2014-3643	05/06/2014 06/04/2014	FDA/OMPT/CDRH/OCER/DFOI/	Laura Doolittle Law Offices of Eugene C. Tenney, PLLC	PHILIPS FLUOROSCOPY MACHINE - MALFUNCTION RECS 01/01/2007 - 05/01/2014
2014-3644	05/06/2014 06/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Robert Bexton Aristotle Capital Management	HOSPIRA, VIZAG, INDIA - 483 MARCH 2014
2014-3645	05/06/2014 06/04/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	James G. O'Brien Zoll, Kranz & Borgess, LLC	STRYKER CERVICORE - IDE RECS ETC 01/01/1990 - 05/01/2014
2014-3646	05/06/2014 06/04/2014	FDA/OMPT/CDRH/OCER/DFOI/	James G. O'Brien Zoll, Kranz & Borgess, LLC	STRYKER CERVICORE - IDE RECS ETC 01/01/1990 - 05/01/2014
2014-3647	05/06/2014 06/04/2014	FDA/OMPT/CDRH/OCER/DFOI/	Nore MacRegor Nore MacRegor	PRODESCO, INC, SECANT MEDICAL, LLC, SECANT MEDICAL LLC - MEDICAL DEVICE REGISTRATION RECS, CORR WITH FDA, REGISTERED COMPANY PROFILE 1990- 2014
2014-3648	05/06/2014 06/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SHOBHA REDDY CHAGAM DR REDDY'S LABORATORIES INC	KING PHARM - SKELAXIN (METAXALONE) NDA 13-217 SBA
2014-3649	05/06/2014 06/04/2014	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C TOWNSEND GRADIENT TECHNOLOGIES LLC	GRADIENT TECHNOLOGIES LLC - QUADRABLOC QMA K130592 REVIEWER NOTES
2014-3650	05/06/2014 06/04/2014	FDA/OC/OES/DFOI/	STEPHEN J FORSYTHE NOTTINGHAM TRENT UNIV	CRONOBACTER MALONATICUS - CLNCL RECS, BACTERIAL CHARACTERISTICS
2014-3651	05/06/2014 06/04/2014	OC/ORO/ OC/ORO/ FDA/OFVM/CFSAN/OCD/EOS/	SALAZAR, JOYCE E	ROCKSTAR ENERGY DRINK - CERTIFICATE OF FREE SELL, CERTIFICATE HEALTH (CERTIFIED)
2014-3652	05/06/2014 06/04/2014	FDA/OMPT/CDRH/OCER/DFOI/	RON JEFFREY CAS MEDICAL SYSTEMS INC	REFLECTANCE MEDICAL INC - K133923
2014-3653	05/06/2014 06/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Yamil Hernandez Cerium Pharmaceuticals, Inc.	NDA 020772

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-3654	05/06/2014 06/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GARDINER HARRIS NEW YORK TIMES	PLANTS IN CHINA THAT MANUFACTURE ACTIVE PHARMACEUTICAL INGREDIENTS (API) APPROVED FOR SALE IN THE US
2014-3655	05/06/2014 06/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Nebojsa Zlatanovic N/A	MEFLOQUINE - AERS
2014-3656	05/06/2014 06/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHRIS SZECHENYI ON POINT COMMUNICATIONS LLC	ACORDA THERAPEUTICS INC - PLUMIAZ NASAL SPRAY COMPLETE RESP LTR, CORR
2014-3657	05/06/2014 06/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Pallavi Ail The Financial Express	WOCKHARDT LTD, WALUJ, CHIKALHANA, INDIA - 483 01/01/2013 - 12/31/2013
2014-3658	05/06/2014 06/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Anna Edney BLOOMBERG NEWS	APOTEX, MICRO LABS, RPG LIFE SCIENCES ETC - 483 01/01/2012 - 05/02/2014
2014-3659	05/06/2014 06/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Yamil Hernandez Cerium Pharmaceuticals, Inc.	NDA 016885
2014-3660	05/06/2014 06/04/2014	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Paras Shah Newtyn Management	MASIMO CORPORATION - 483 05/02/2012 - 05/02/2014
2014-3661	05/06/2014 06/04/2014	FDA/OC/OES/DFOI/	WINTERS 411079, BRANDON	FDA AUTHORIZE WISCONSIN RESOURCE CENTER TO USE PSYCHOTRONICS, BIOMOLECULAR DVCS, ELECTRONIC SENSORY DVCS, ETC
2014-3662	05/06/2014 06/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bianca Chang Bianca Chang	IMURAN, TYSABRI - AERS

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2014-3663	05/06/2014 06/04/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-1638
2014-3664	05/07/2014 06/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Roberts Rachel Roberts	ACTH ADVERSE EVENTS
2014-3665	05/07/2014 06/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Roberts Rachel Roberts	ACTHAR - AERS
2014-3666	05/07/2014 06/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Roberts Rachel Roberts	88 FAERS/AERS
2014-3667	05/07/2014 06/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Roberts Rachel Roberts	97 FAERS/AERS
2014-3668	05/07/2014 06/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Roberts Rachel Roberts	95 FAERS/AERS
2014-3669	05/07/2014 06/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John Aitken GILEAD SCIENCES INC	ABT-450 APPROVAL COVER LETTER
2014-3670	05/07/2014 06/05/2014	FDA/OFVM/CFSSAN/OCD/EOS/	Hao Chen Huazhong Agricultural Univeristy	Biotechnology Consultation BNF140 Submission
2014-3671	05/07/2014 06/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Allison Tarantino ARIAD Pharmaceuticals, Inc.	ICLUSIG - AERS
2014-3672	05/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	Bruce Robie	K031672

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	06/05/2014	FDA/OC/OES/DFOI/	Robie Device Group, LLC	
2014-3673	05/07/2014 06/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Bruce Robie Robie Device Group, LLC	K132790
2014-3674	05/07/2014 06/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Bruce Robie Robie Device Group, LLC	K083186
2014-3675	05/07/2014 06/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K022730
2014-3676	05/07/2014 06/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K022730 REVIEWERS NOTES
2014-3677	05/07/2014 06/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Fiore Mastroianni Hofstra North Shore LIJ School of Medicine	BUPROPRION - AERS
2014-3678	05/07/2014 06/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Sandra White, Mgr Scientific Affairs, Aniara Diagnostica LLC Aniara Diagnostica	HYPHEN BIOMED, FRANCE - EIR 02/10/2014 - 02/13/2014
2014-3679	05/07/2014 06/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K000881
2014-3680	05/07/2014 06/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K000881
2014-3681	05/07/2014 06/05/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K091656 REVIEWERS NOTES
2014-3682	05/07/2014 06/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K081997 REVIEWERS NOTES
2014-3683	05/07/2014 06/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K081997
2014-3684	05/07/2014 06/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K091989
2014-3685	05/07/2014 06/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K091989
2014-3686	05/07/2014 06/05/2014	FDA/OC/OES/DFOI/	Lauren Farruggia Hyman Phelps and McNamara PC	2014-2174

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2014-3687	05/07/2014 06/05/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Julie Klinker Arizona Oncology Associates, PC	ARIZONA ONCOLOGY ASSOCIATES, PC - 483 05/01/2014 - 05/05/2014
2014-3688	05/07/2014 06/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Janette Bennett Cenorin, LLC	K810311
2014-3689	05/07/2014 06/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	510K-K130944 Nanyang Technological University	K130944
2014-3690	05/07/2014 06/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	FDA Approval Letter Siemens Mammomat Novation DR DigitalDent Services	Free sale Certification of Siemens Mammography System
2014-3691	05/07/2014 07/10/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	TERESA HUGGINS, Esq. LAW OFFICES OF GARY A DORDICK	USP LABS - OXYELITE PRO - INVESTIGATION GENERAL NUTRITION CENTER, IN2IT FITNESS
2014-3692	05/07/2014 06/05/2014	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	BROZANSKI, TED	WHOLEFOODS, ROSWELL, GA - INVESTIGATION RECS
2014-3693	05/07/2014 06/05/2014	FDA/OFVM/CFSAN/OCD/EOS/	ERIN FRANKEL ELF ENTERTAINMENT INC	2013 FOOD CODE HANDBOOK
2014-3694	05/07/2014 07/15/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	D. CHRISTOPHER CHUNG, MD, FAAP NATUS MEDICAL INC	CINCINNATI SUB ZERO - DOCUMENT NUMBER GEN 0901398
2014-3695	05/07/2014 06/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	STEPHEN BYRNE, PhD., CFA BANK OF AMERICA BIOTECH EQUITY RESEARCH	ADCETRIS (BRENTUXIMAB VEDOTIN) - FAERS 1/12 TO PRESENT
2014-3696	05/07/2014 06/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	GONZALES, TODD	MYOTECH DRY NEEDLES - RECS 11/12 TO PRESENT
2014-3697	05/07/2014 06/05/2014	FDA/OFVM/CFSAN/OCD/EOS/	ERIC F. GREENBERG ERIC F GREENBERG PC	REQUIREMENTS FOR AUTOMATIC MILKING INSTALLATIONS ISSUED BY FDA - 4/21/14 GUIDANCE
2014-3698	05/07/2014 06/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PUBLIC CITIZEN	XARELTO (RIVAROXABAN) CASE #8701898
2014-3699	05/07/2014 06/05/2014	FDA/OC/OES/DDM/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GREGORY D. BROWN FLEMING NOLEN & JEZ LLP	OTSUKA - ABILIFY (ARIPIPRAZOLE) LBLG, STUDIES, CMPLNTS, APRVL

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2014-3700	05/07/2014 06/05/2014	FDA/OC/OES/DFOI/	TOM NELTNER NRDC	2014-1324 CFSAN REDACTIONS
2014-3701	05/08/2014 06/06/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Jennifer Palmer THE OKLAHOMAN	OKLAHOMA BLOOD INSTITUTE UMBILICAL CORD BLOOD CENTER - APPROVAL RECS
2014-3702	05/08/2014 06/06/2014	FDA/OC/OEXA/OMA/	Charles Seife NEW YORK UNIVERSITY	NEWS EMBARGO RECS
2014-3703	05/08/2014 06/06/2014	FDA/OC/OES/DDM/	HEATHER WENGER Self	PEDIATRIC SUBCOMMITTEE OF ANTI-INFECTIVE DRUG ADVISORY COMMITTEE 10/29/2003
2014-3704	05/08/2014 06/06/2014	FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Abhishek K. Gurnani Amin Talati LLC	GALDERMA LABORATORIES, CETAPHIL - 483, WARNING LETTER, COMPLAINTS, ETC
2014-3705	05/08/2014 06/06/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jonathan Marks KATTEN MUCHIN ROSENMAN LLP	ELITE MEDICAL SUPPLY OF NEW YORK - PMD-2000 APPROVAL RECS; PHOENIX MEDICAL DEVICE 01/01/2002 - 05/05/2014
2014-3706	05/08/2014 06/06/2014	FDA/OC/OES/DDM/ FDA/OMPT/CDRH/OCER/DFOI/	Patti Green Patti Green - Aylstock Witkin Kreis & Overholtz	GMD UNIVERSAL URINARY INCONTINENCE SLING - APPROVAL RECS, CORR, ADVISORY COMMITTEE ETC 01/01/2001 - 05/05/2014
2014-3707	05/08/2014 06/06/2014	OC/ORAS/ OC/ORAS/ OC/ORAS/OE/ OC/ORAS/OE/	Marian Boardley Marian Boardley Consulting LLC	FY 2013 Inspections Citations
2014-3708	05/08/2014 06/06/2014	FDA/OGROP/ORASW-FO/KAN- DO/KAN-CB/	Mary Emily Monroe McDowell Knight Roedder & Sledge, LLC	RAYE'S INC DBA WHEELCHAIRS OF KANSAS - 482, 483, COMPLAINTS ETC
2014-3709	05/08/2014 06/06/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lori Hurlbert John Muir Concord California	ANGIOTENSIN CONVERTING ENZYME INHIBITOR, TAMIFLU - AERS

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2014-3710	05/08/2014 06/06/2014	FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/	Mary Emily Monroe McDowell Knight Roedder & Sledge, LLC	SUNFLOWER MEDICAL - 482, 483, COMPLAINTS ETC
2014-3711	05/08/2014 06/06/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Andrea Demakas ADVERSEEVENTS INC	AUBAGIO, AVONEX, BETASERONETC - FAERS
2014-3712	05/08/2014 06/06/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Andrea Demakas ADVERSEEVENTS INC	XARELTO, ELIQUIS- FAERS
2014-3713	05/08/2014 06/06/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jessica Van Douser Jaburg Wilk	MAUDE 2530130-2014-00006, 2530130-2010-0029, 2530130-2009-0061 ETC
2014-3714	05/08/2014 06/06/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Haige Lu ORBIMED ADVISORS LLC	GATTEX - MEDICAL RECORDS, REPORTS FOR NINE CASES
2014-3715	05/08/2014 06/06/2014	FDA/OMPT/CDRH/OCER/DFOI/	Reliable Test Kits, LLC Reliable Test Kits, LLC	K103574
2014-3716	05/08/2014 06/06/2014	FDA/OMPT/CDRH/OCER/DFOI/	Puja Ahluwalia Puja Ahluwalia	K071907
2014-3717	05/08/2014 06/06/2014	FDA/OMPT/CDRH/OCER/DFOI/	Martin Cooke ANGLE Technology Ltd.	K870196
2014-3718	05/08/2014 06/06/2014	FDA/OFVM/CFSAN/OCD/EOS/	Kelly A Magurany Nalco, An Ecolab Company	FCN 1277, FCN 18 ETC
2014-3719	05/08/2014 06/06/2014	FDA/OMPT/CDRH/OCER/DFOI/	Reliable Test Kits, LLC Reliable Test Kits, LLC	K123703
2014-3720	05/08/2014 06/06/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHANDRAN TIRUATTAR DR REDDY'S LABORATORIES INC	NOVEN - FENTANYL-100 ANDA 77-775 CHEMISTRY RVW
2014-3721	05/08/2014 06/06/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHANDRAN TIRUVATTAR DR REDDY'S LABORATORIES INC	MALLINCKRODT INC - FENTANYL-100 CHEMISTRY RVW

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2014-3722	05/08/2014 06/06/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHANDRAN TIRUATTAR DR REDDY'S LABORATORIES INC	LAVIPHARM LABS - FENTANYL-100 CHEMISTRY RVW
2014-3723	05/08/2014 06/06/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHANDRAN TIRUVATTAR DR REDDY'S LABORATORIES INC	WATSON LABS - FENTANYL-100 CHEMISTRY RVW
2014-3724	05/08/2014 06/06/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHANDRAN TIRUVATTAR DR REDDY'S LABORATORIES INC	PAR PHARMA INC - FENTANYL-100 CHEMISTRY RVW
2014-3725	05/08/2014 06/06/2014	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	MICHELE COULALOGLOU ATRIUM INNOVATIONS	ARIZONA NUTRITIONAL SUPPLEMENTS, CHANDLER, AZ - 483'S, WARNING LTRS 2013, 1/4 TO 4/14
2014-3726	05/08/2014 06/06/2014	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	MICHELE COULALOGLOU ATRIUM INNOVATIONS	ARIZONA NUTRITIONAL SUPPLEMENTS, CHANDLER, AZ - EIRS 2013, 1/4 TO 4/14
2014-3727	05/08/2014 06/06/2014	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	MICHELE COULALOGLOU ATRIUM INNOVATIONS	21ST CENTURY HEALTHCARE INC, TEMPE, AZ - 483S, WARNING LTRS 2013, 1/4 TO 4/14
2014-3728	05/08/2014 06/06/2014	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	MICHELE COULALOGLOU ATRIUM INNOVATIONS	21ST CENTURY HEALTHCARE INC, TEMPE, AZ - EIRS 2013, 1/4 TO 4/14
2014-3729	05/08/2014 06/06/2014	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	MICHELE COULALOGLOU ATRIUM INNOVATIONS	ARIZON NUTRITIONAL SUPPLEMENTS - EIRS, 2013, 1/4 TO 4/14
2014-3730	05/08/2014 06/06/2014	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	MICHELE COULAOGLOU ATRIUM INNOVATIONS	ARZONA NUTRITIONAL SUPPLEMENTS, CHANDLER, AZ - 483S, WARNING LTRS 2013, 1/4 TO 4/14
2014-3731	05/08/2014 06/06/2014	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	DONALD N BLUE ZETETIC	JOHN PAUL MITCHELL SYSTEMS, SANTA CLARITA, CA - HAIR CARE ITEMS ENTRY #1302296-4 PICTURES, OASIS COMPUTER SCREEN SHOTS, EMAILS, ETC
2014-3732	05/08/2014 06/06/2014	FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/ FDA/OGROP/ORA/SW- FO/SWID/SWID-CB/	DONALD N BLUE ZETETIC	JOHN PAUL MICHELL SYSTEMS, BEVERLY HILLS, CA - SHAMPOOS & CONDITIONERS ENTRY #601-0150057-1 PICTURES , OASISCOMPUTER SCREEN SHOTS, EMAILS, ETC
2014-3733	05/08/2014	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	DONALD N BLUE	ABBOTT IRELAND IABETES CARE, DONEGAL TOWN, IRELAND - GLUCOSE TEST STRIPS PICTURES, OASIS

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	06/06/2014		ZETETIC	COMPUTER SCREEN SHOTS, EMAIL, ETC
2014-3734	05/08/2014 06/06/2014	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	DONALD N BLUE ZETETIC	JOHN PAUL MITCHELL SYSTEMS, BEVERLY HILLS, CA - SHAMPOOS, HAIR CONDITIONERS ENTRY #913-0321757-3 PICTURES, OASIS COMPUTER SCREEN SHOTS, EMAILS, ETC
2014-3735	05/08/2014 06/06/2014	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	DONALD N BLUE ZETETIC	JOHN PAUL MITCHELL SYSTEMS, BEVERLY HILLS, CA - SHAMPOOS & HAIR CONDITIONERS ENTRY #823-0160805-3 PICTURES & OASIS COMPUTER SCREEN SHOTS, EMAIL, ETC
2014-3736	05/08/2014 06/06/2014	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	DONALD N BLUE ZETETIC	JOHN PAUL MITCHELL SYSTEMS, BEVERLY HILL, CA - SHAMPOOS, HAIR CONDITIONERS ENTRY #823-0160392-2 PICTURES , OASIS COMUTER SCREEN SHOTS, EMAILS, ETC
2014-3737	05/08/2014 06/06/2014	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	DONALD N BLUE ZETETIC	ABBOTT IRELAND DIABETES CARE, DONEGAL TOWN, IRELAND - GLUOSE TEST STRIPS ENTRY FY6-2008519-8 PICTURES , OASIS COMPUTER SREEN SHOTS, EMAILS, ETC
2014-3738	05/08/2014 06/06/2014	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	DONALD N BLUE ZETETIC	ABBOTT IRLAND DIABETES CARE, DONEGAL TOWN, IRELAND - GLUCOSE TEST STRIPS ENTRY #AV3-0040984-2 PICTURES, OASIS COMPUTER SCREEN SHOTS, EMAILS, ETC
2014-3739	05/08/2014 06/06/2014	FDA/OFVM/CFSAN/OCD/EOS/	BENJAMIN L ENGLAND BENJAMIN L ENGLAND & ASSOCIATES LLC	ACCERA INC - AXONA WARNING LTR 409208 FORMS, RPTS, COMM RELATED TO RVW; RESP TO WARNING LTR, CLOSE OUT LTR, ETC
2014-3740	05/08/2014 08/14/2014	FDA/OC/OES/ FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OES/DFOI/	CENTER FOR SCIENCE IN PUBLIC INTEREST	ASPARTAME - LTRS, EMAILS, MIN, ETC 2000 TO PRESENT
2014-3741	05/08/2014 06/06/2014	FDA/OC/OES/DFOI/ OC/OR/ OC/OR/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	CHRISTY BINGHMAN EDELMAN & THOMPSON	BOWMAR/TIC, INC - TEST RESULTS, NOTIFICATIONS, COMPLIANCE CITATIONS, ETC 1/1/68 TO 1/1/80
2014-3742	05/09/2014 06/09/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lis Riley HUNTINGDON LIFE SCIENCES INC	CDER presentations for 2012/13 http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm074833.htm
2014-3743	05/09/2014	FDA/OMPT/CDER/ORP/DIDP/	Linda Bowen	NOVACYL THAILAND - 483 04/01/2014 - 05/06/2014

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	06/09/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SANOFI	
2014-3744	05/09/2014 06/09/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nathaniel Morris University of the Sciences	AMFONELIC ACID - CLINICAL TRIAL RECS 01/01/1965 - 01/01/1977
2014-3745	05/09/2014 06/09/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/	Anusha Kambhampaty RETROPHIN INC	CORR BETWEEN FDA AND MANUFACTURERS OF PIRACETAM IN THE US 01/01/2005 - 05/06/2014
2014-3746	05/09/2014 06/09/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	William B. Monahan William B. Monahan, Sullivan & Cromwell LLP	ULURU INC APHTHASOL - PDUFA FEES, FEE WAIVER, INGREDIENT SUPPLIER ETC
2014-3747	05/09/2014 06/12/2014	FDA/OC/OES/DFOI/ FDA/OGROP/ORR/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORR/CE-FO/DET-DO/DET-CB/ FDA/OGROP/ORR/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORR/CE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORR/SE-FO/NOL-DO/NOL-CB/	Wendy Cromwell ANIMAL LEGAL DEFENSE FUND	HORSE SLAUGHTER, HORSE MEAT RECS 01/01/2004 - 05/06/2014
2014-3748	05/09/2014 06/09/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	ABBOTT, OTTAWA, CANADA - EIR, 483, ETC

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		FDA/OMPT/CDRH/OCER/DFOI/		
2014-3749	05/09/2014 06/09/2014	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Stephen Curtis Center for Clinical Studies	STEPHEN TYRING, UTMB CENTER FOR CLINICAL STUDIES - WARNING LETTER, 483 01/01/1994 - 12/31/1994
2014-3750	05/09/2014 06/09/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-1781
2014-3751	05/09/2014 07/16/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Mario Vesnaver Vesnaver, Mario	LENSX, ALISO VIEJO, CA - EIR 08/01/2012 - 08/31/2012
2014-3752	05/09/2014 06/09/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Tania Lupu Case Medical, Inc.	RECALL Z0434-2014, Event # 06502 - TEST RESULTS
2014-3753	05/09/2014 06/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	Lillie Thomas ORTHOFIX INC.	K131833
2014-3754	05/09/2014 06/09/2014	OC/ORASW-FO/DAL-DO/DAL-CB/ OC/ORASW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Reynaldo Roman Marken	IMPORT ENTRY LINE DATA 01/01/2013 - 02/28/2013
2014-3755	05/09/2014 06/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K112372
2014-3756	05/09/2014 06/09/2014	FDA/OC/OES/DFOI/	Kari L. Twaite Beveridge & Diamond, PC	2014-3461
2014-3757	05/09/2014 06/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jessica Czamanski Biomedika Consulting LLC	K120088
2014-3758	05/09/2014 06/09/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	HEATHER WENGER Self	WEAVER J POSTMARKETING SAFETY REVIEW PID D010141
2014-3759	05/09/2014 06/09/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Yukyeong Lee Samsung Bioepis Co., Ltd.	FDA's Review Report on the Amendment of Erbitux (BLA 125084/153) submitted by Eli Lilly (Action date: Nov 07, 2011)
2014-3760	05/09/2014 06/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jim Bates Medical Imaging Solutions USA, LLC	DUNLEE DURA AKRON Q CT X-RAY TUBE 561746KM42700

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2014-3761	05/09/2014 06/09/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kim J. Kinsler GIDEON COOPER & ESSARY	INTRAVENOUS PROMETHAZINE HYDROCHLORIDE - AERS
2014-3762	05/09/2014 06/09/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/OSMP/OOPD/	David Geier David Geier	CYPROTERONE ACETATE - APPLICATIONS, MEMOS, ETC RE APPROVAL, SAFETY, AND EFFECTIVENESS 01/01/1960 - 05/07/2014
2014-3763	05/09/2014 06/09/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Julia Valentine ELC Group s.r.o.	NDA 020723
2014-3764	05/09/2014 06/09/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kermit Jones / Joshua Malamud Hyman Phelps and McNamara PC	Chenodiol, Chenodeoxycholic Acid, Xenbilox, etc - AERS
2014-3765	05/09/2014 06/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K132695
2014-3766	05/09/2014 06/09/2014	FDA/OO/OFBA/OAGS/	US7565 eCivis, Inc.	WINNING GRANT APPLICATION FROM A CITY OR COUNTY FOR MOST RECENT AWARD CYCLE FOR INNOVATIVE FOOD DEFENSE PROJECTS
2014-3767	05/09/2014 06/09/2014	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	JACQUELINE J CHAN K&L GATES	BESTCO, MOORESVILLE, NC - EIRS, 483S, RECALLS, ETC 1/04 TO PRESENT
2014-3768	05/09/2014 06/09/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ayesha Adil The Weinberg Group	ANDA 91354 SBA
2014-3769	05/09/2014 06/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	VICTOR ARELLANO SECHRIST INDUSTRIES INC	SECHRIST INDUSTRIES INC - LSP DVC INHALATOR VALVE K884543
2014-3770	05/09/2014 06/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	VICTOR ARELLANO SECHRIST INDUSTRIES INC	SECHRIST INDUSTRIES INC - HYPERBARIC INTRAVENOUS INFUSION EXTENSION SET K884156
2014-3771	05/09/2014 06/09/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	LORI C GREENBERG ESQ LORI C GREENBERG &	LAPAROSCOPIC HYSTERECTOMY BAN - RECS

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			ASSOCIATES	
2014-3772	05/09/2014 06/09/2014	FDA/OC/OES/DFOI/	DOMINION GROUP INC	FOI DAILY LOG 4/14-18/14
2014-3773	05/09/2014 06/09/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 4/14-18/14
2014-3774	05/09/2014 06/09/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 4/14-19/14
2014-3775	05/09/2014 06/09/2014	FDA/OMPT/OSMP/OOPD/	FARYAL A. HASAN Hyman, Phelps & McNamara P.C.	CONJUGATED BILE ACIDS (COBARTIN) - ORPHAN DRUG DESIGNATION FILE FOR TREATMENT OF STEATORRHEA 7/18/03
2014-3776	05/09/2014 06/09/2014	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	FOI DIALY LOG 4/7-11/14
2014-3777	05/09/2014 06/09/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DIALY LOG 4/7-11/14
2014-3778	05/09/2014 06/09/2014	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD Center for Regulatory Services, Inc.	FOI DAILY LOG4/7-11/14
2014-3779	05/09/2014 06/09/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DIALY LOG 4/7-11/14
2014-3780	05/09/2014 06/09/2014	FDA/OMPT/OSMP/OOPD/	FARYAL A. HASAN Hyman, Phelps & McNamara P.C.	OPIUM TINCTURE - ORPHAN DRUG DESIGNATION FILE FOR TREATMENT OF CHRONIC DIARRHEA 12/2/11
2014-3781	05/09/2014 06/09/2014	FDA/OMPT/OSMP/OOPD/	FARYAL A. HASAN Hyman, Phelps & McNamara P.C.	GLUTAMINE - ORPHAN DRUG DESIGNATION FILE FOR TREATMENT OF SHORT BOWEL SYNDROME 3/6/95
2014-3782	05/09/2014 06/09/2014	FDA/OMPT/OSMP/OOPD/	FARYAL A. HASAN Hyman, Phelps & McNamara P.C.	SOMATROPIN (ZORBTIVE) - ORPHAN DRUG DESIGNATION FILFOR TREATMENT OF SHORT BOWEL SYNDROME3/6/95
2014-3783	05/09/2014 06/09/2014	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DIALY LOG 4/7-11/14
2014-3784	05/09/2014 06/09/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 4/7-11/14
2014-3785	05/09/2014 06/09/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 4/7-12/14
2014-3786	05/09/2014 06/09/2014	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 3/31/14-4/4/14

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2014-3787	05/09/2014 06/09/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 3/31/14-4/4/14
2014-3788	05/09/2014 06/09/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	CRAIG ROUSH ROCKLINE INDUSTRIES	PLAYTEX MANUFACTURING INC, SYDNEY, OHIO - 483, EIR, CORR 2/14
2014-3789	05/09/2014 06/09/2014	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD Center for Regulatory Services, Inc.	FOI DAILY LOG 3/31/14-4/4/14
2014-3790	05/09/2014 06/09/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 3/31/14-4/4/14
2014-3791	05/09/2014 06/09/2014	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 3/31/14-4/4/14
2014-3792	05/09/2014 06/09/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MICHAEL R. COHEN INSTITUTE FOR SAFE MEDICATION PRACTICES	MEDWATCH RPTS CODED AS MEDICATION ERRORS 4/1-30/14
2014-3793	05/09/2014 06/09/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LIZETTE MILLER-RADOVIC, Esq. MILLER-RADOVIC LLC	SEROQUEL (QUETIAPINE FUMARATE) - AER
2014-3794	05/09/2014 06/09/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CLEVELAND, CATHY	BAXTER - MIDAZOLAM AER
2014-3795	05/12/2014 07/10/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	DOUGLAS J UELMEN JR INVACARE CORP	INVACARE CORP, ELYRIA, OH; SANFORD, FL - EIRS, EXHIBITS, ADDENDA, ETC 8/11/10-12/17/10, ETC
2014-3796	05/12/2014 06/10/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 3/10-14/14
2014-3797	05/12/2014 06/10/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 3/17-21/14
2014-3798	05/12/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP	FOI DAILY LOG 3/24-28/14

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	06/10/2014		CanReg, Inc.	
2014-3799	05/12/2014 06/10/2014	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 3/10-14/14
2014-3800	05/12/2014 06/10/2014	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 3/17-21/14
2014-3801	05/12/2014 06/10/2014	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 3/24-28/14
2014-3802	05/12/2014 06/10/2014	FDA/OC/OES/DFOI/	GLADYS B TONKIN Center for Regulatory Services,Inc.	FOI DAILY LOG 3/3-7/14
2014-3803	05/12/2014 06/10/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	WARREN WILLIAMS FOREST RESEARCH INSTITUTE	DR RICHARD CASABURI, LA BIOMED RESEARCH INST, TORRANCE, CA - 483S 2/14
2014-3804	05/12/2014 06/10/2014	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	DOUGLAS N BLUE II ZETETIC INC	VETERINARY ORTHOPEDIC IMPLANTS - FORCEPS, RETRACTOR, SPONGE, ETC ENTRY #799-3427533-4
2014-3805	05/12/2014 06/10/2014	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	DOUGLAS N BLUE II ZETETIC INC	NOVARTIS CONSUMER HEALTH - KERI MOISTURIZING LOTION ENTRY #AV3-0041172-3
2014-3806	05/12/2014 06/10/2014	FDA/OC/OES/DFOI/	GLADYS B TONKIN Center for Regulatory Services,Inc.	FOI DAILY LOG 3/10-14/14
2014-3807	05/12/2014 06/10/2014	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	DOUGLAS N BLUE II ZETETIC INC	NOVARTIS CONSUMER HEALTH - KERI MOISTURIZING LOTION ENTRY #AV3-0041118-6
2014-3808	05/12/2014 06/10/2014	OC/ORAI/ OC/ORAI/ FDA/OGROP/ORAI/ORO/DIOP/	DOUGLAS N BLUE II ZETETIC INC	SHIPMENTS REGULATED BY FDA 4/15/14-5/15/14
2014-3809	05/12/2014 06/10/2014	FDA/OC/OES/DFOI/	WILLIAM A OLSON PH.D Center for Regulatory Services,Inc.	FOI DAILY LOG 3/17-21/14
2014-3810	05/12/2014 06/10/2014	FDA/OC/OES/DFOI/	WILLIAM A OLSON PH.D Center for Regulatory Services,Inc.	FOI DAILY LOG 3/24-28/14
2014-3811	05/12/2014 06/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Aydin H. Harston ROTHWELL, FIGG, ERNST & MANBECK, P.C.	VENTOLIN, VENTOLIN HFA - LABELING 01/01/1980 - 12/31/1989
2014-3812	05/12/2014 06/10/2014	FDA/OC/OES/DFOI/	IAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 3/10-14/14
2014-3813	05/12/2014	FDA/OC/OES/DFOI/	LAUREN S BARR	FOI DAILY LOG 3/17/21/14

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	06/10/2014		JH BARR & ASSOCIATES LLC	
2014-3814	05/12/2014 06/10/2014	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	Richard O. Wood the Wood Burditt group	COVIDIEN, AUGUSTA, GA - 483, EIR, PROFILE, ETC 01/01/2010 - 05/09/2014
2014-3815	05/12/2014 06/10/2014	FDA/OFVM/CFSAN/OCD/EOS/	MICHAEL F JACOBSON PHD CENTER FOR SCIENCE IN THE PUBLIC INTEREST	RAMAZZINI INSTITUTE, EUROPEAN RAMAZZINI FOUNDATION OF ONCOLOGY AND ENVIRONMENTAL SCIENCES - STUDIES, PROCEDURES, CORR, ETC
2014-3816	05/12/2014 06/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Karin Kerber Karin Kerber	NDA 020599
2014-3817	05/12/2014 06/10/2014	FDA/OFVM/CFSAN/OCD/EOS/	Michael C Valdez Andrews and Thornton	CAERS 128534; 135642; 136828 ETC
2014-3818	05/12/2014 06/10/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 3/24-28/14
2014-3819	05/12/2014 06/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	S ALBERT EDWARDS, PHARM D	ARTHROCARE - TOPAZ ARTHROWANDS K053567
2014-3820	05/12/2014 06/10/2014	FDA/OGROP/ORR/SW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORR/SW-FO/DEN-DO/DEN-CB/	Rachel Johnson FOI Services, Inc.	WESTONE, COLORADO SPRINGS, CO - EIR, EXHIBITS
2014-3821	05/12/2014 06/10/2014	FDA/OGROP/ORR/CE-FO/MIN-DO/MIN-CB/	Rachel Johnson FOI Services, Inc.	AJD LABORATORIES, PARK RAPIDS, MN - EIR EXHIBITS
2014-3822	05/12/2014 06/10/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 3/31/14-4/4/14
2014-3823	05/12/2014 06/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Elaine Duncan Paladin Medical, Inc.	K090107
2014-3824	05/12/2014 06/10/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 3/31/14-4/5/14
2014-3825	05/12/2014 06/10/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORR/NE-FO/NWE-DO/NWE-CB/	Alex Wong BlueMountain Capital	ABIOMED - CORR WITH FDA RE PMA AND 515 PATHWAY OF IMPELLA 01/01/2013 - 05/08/2014
2014-3826	05/12/2014 06/10/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 3/10-15/14
2014-3827	05/12/2014	FDA/OFVM/CFSAN/OCD/EOS/	Bobby Schochet	FAP 2A4738

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	06/10/2014		OLSSON FRANK & WEEDA	
2014-3828	05/12/2014 06/10/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 3/17-22/14
2014-3829	05/12/2014 06/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ayesha Adil The Weinberg Group	ANDA 91349
2014-3830	05/12/2014 06/10/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 3/24-29/14
2014-3831	05/12/2014 06/10/2014	FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 3/3-7/14
2014-3832	05/12/2014 06/10/2014	FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 3-10-14/14
2014-3833	05/12/2014 06/10/2014	FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 3/17-21/14
2014-3834	05/12/2014 06/10/2014	FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 3/24-28/14
2014-3835	05/12/2014 06/10/2014	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 3/3-7/14
2014-3836	05/12/2014 06/10/2014	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 3/10-14/14
2014-3837	05/12/2014 06/10/2014	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 3/17-21/14
2014-3838	05/12/2014 06/10/2014	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 3/24-28/14
2014-3839	05/12/2014 06/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ROSS C OPSAHL AKZO NOBEL CHEMICALS INC	AKZONOBEL SA DE CV, LA PAZ, MEXICO - EIRS, 483S, WARNING LTRS, ETC 3/26-30/12

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-3840	05/12/2014 06/10/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 4/21-25/13
2014-3841	05/12/2014 06/10/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOI REQUESTS 4/21-25/14
2014-3842	05/12/2014 06/10/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 4/21-25/14
2014-3843	05/12/2014 06/10/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 4/21-25/14
2014-3844	05/12/2014 06/10/2014	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOI REQUESTS 4/21-25/14
2014-3845	05/12/2014 06/10/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 4/21-25/14
2014-3846	05/12/2014 06/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Ankit K. Shah MEDTRONIC SOFAMOR DANEK	K133455
2014-3847	05/12/2014 06/10/2014	FDA/OC/OES/DDM/ FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Christine Butler-Cole Butler-Cole, Christine	FDA FINES RECEIVED BY 19 COMPANIES 01/01/2003 - 12/31/2013
2014-3848	05/12/2014 06/10/2014	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Heather Neely Kinamed Inc.	KINAMED, CAMARILLO, CA - EIR 03/14/2014 - 03/13/2014
2014-3849	05/12/2014 06/10/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 4/14-18/14
2014-3850	05/12/2014 06/10/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOI REQUESTS 4/14-18/14
2014-3851	05/12/2014 06/10/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 4/14-18/14
2014-3852	05/12/2014 06/10/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michael R Metschl ORBIMED ADVISORS LLC	VELCADE - AERS

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2014-3853	05/12/2014 06/10/2014	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOI REQUESTS 4/14-18/14
2014-3854	05/12/2014 06/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michael R Metschl ORBIMED ADVISORS LLC	KYPROLIS - AERS
2014-3855	05/12/2014 06/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michael R Metschl ORBIMED ADVISORS LLC	FERAHEME - AERS
2014-3856	05/12/2014 06/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michael R Metschl ORBIMED ADVISORS LLC	BELVIQ - AERS
2014-3857	05/12/2014 06/10/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 4/14-18/14
2014-3858	05/12/2014 06/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ayesha Adil The Weinberg Group	NDA 020622 S 089 SBA
2014-3859	05/12/2014 06/10/2014	FDA/OGROP/ORAN/NE-FO/NWE- DO/NWE-CB/	Rachel Johnson FOI Services, Inc.	PHARMACLUCENCE, BEDFORD, MA - EIR, CORR
2014-3860	05/12/2014 06/13/2014	OC/ORAN/ OC/ORAN/ FDA/OC/OCC/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Irina B. Elgart, Esq. Fox Rothschild, LLP	MED PREP, TINTON FALLS, NJ - INSPECTIONS, RECALLS, CORR ETC 01/01/2007 - 05/08/2014

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2014-3861	05/12/2014 06/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	David Pieratos Becton, Dickinson & Company	BECTON DICKINSON, SAN AUGUSTINE - EIR 09/10/2012 - 09/13/2012
2014-3862	05/12/2014 06/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Satoru Ogami FUJIFILM Corporation	K012864
2014-3863	05/12/2014 06/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Frederick Haller Frederick Haller	K944220, K020824
2014-3864	05/12/2014 06/10/2014	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Rigoberto Sanchez Comparative Medicine, University of Maryland School of Medicine	THOMAS D MORRIS, INC, REISTERSTOWN, MD - 483 09/04/2007 - 09/13/2007
2014-3865	05/12/2014 06/10/2014	FDA/OMPT/CTP/OD/	Richard G. Higby Richard G. Higby	Business names and addresses of the 107 domestic tobacco establishments registered with the FDA and cited in the CTP Compliance and Enforcement Report
2014-3866	05/12/2014 06/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Satoru Ogami FUJIFILM Corporation	K902736
2014-3867	05/12/2014 06/10/2014	FDA/OC/OES/DFOI/	Carol Donahue Fox Rothschild, LLP	QUESTCOR, ACTHAR GEL - FOIA REQUESTS, RESPONSES 01/01/2014 - 05/09/2014
2014-3868	05/12/2014 06/10/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 4/7-11/14
2014-3869	05/12/2014 06/10/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOI REQUESTS 4/7-11/14
2014-3870	05/12/2014 06/10/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 4/7-11/14
2014-3871	05/12/2014 06/10/2014	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOI REQUESTS 4/7-11/14
2014-3872	05/12/2014 06/10/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 4/7-11/14
2014-3873	05/12/2014 06/10/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 3/31/14-4/4/14
2014-3874	05/13/2014 06/11/2014	OC/ORACE/ORM/ OC/ORACE/ORM/ FDA/OFVM/CFSAN/OCD/EOS/	Mark Prinz Registrar Corp	FOREIGN FOOD FACILITIES REGISTERED IN EACH COUNTRY
2014-3875	05/13/2014 06/11/2014	OC/ORACE/ORM/ OC/ORACE/ORM/	Mark Prinz Registrar Corp	FOREIGN FOOD FACILITIES THAT RECEIVED 483 02/01/2014 - 04/30/2014

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2014-3876	05/13/2014 06/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	EARL GOEHRING JR THE DEGGE GROUP LTD	NEURONTIN AERS
2014-3877	05/13/2014 06/11/2014	FDA/OC/OES/DFOI/	MICHAEL MOSKOWITZ HOGAN LOVELLS LLP	DKT 2013D-1675
2014-3878	05/13/2014 06/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Elisabeth Kmpfe (our ID 4400835) INFOTRIEVE GMBH	Community-acquired Bacteria pneumonia 1998 - DRAFT GUIDANCE
2014-3879	05/13/2014 06/11/2014	FDA/OC/OES/DFOI/	ROBERT KING FDA NEWS	FDA-2013-D-1675
2014-3880	05/13/2014 06/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	Doxycycline Hyclate 50 mg - AERS
2014-3881	05/13/2014 06/11/2014	FDA/OC/OES/DFOI/	ELSPETH CALLAHAN INDEPENDENCE LEGAL SUPPORT	FDA-2010-P0491 - DRAFT 1897
2014-3882	05/13/2014 06/11/2014	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/ORM/ OC/ORO/ORM/ FDA/OFVM/CFSAN/OCD/EOS/	Justin Zhang Pan-Pacific Biopharma, Inc.	CHINESE FIRMS REGISTERED AS DIETARY SUPPLEMENT FIRMS - DATA
2014-3883	05/13/2014 06/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 21567/S25
2014-3884	05/13/2014 06/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 205786
2014-3885	05/13/2014 06/11/2014	FDA/OC/OES/DFOI/	ROSS RENDELMAN HOGAN LOVELLS LLP	DKT 2013D-1675, 2013P-0058, 2013P-0119, ETC

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2014-3886	05/13/2014 06/11/2014	FDA/OFVM/CFSAN/OCD/EOS/	Ernest H. Short Burrage Law Firm	ENERGY DRINKS - AERS
2014-3887	05/13/2014 06/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	AMSINO MEDICAL - EIR
2014-3888	05/13/2014 06/11/2014	OC/ORa/OCI/ OC/ORa/OCI/	Minhyuk Lee Korean Institute of Criminology	OCI INVESTIGATIONS, ARRESTS, CONVICTIONS; FOOD RELATED CRIMES 01/01/2009 - 05/09/2014
2014-3889	05/13/2014 06/11/2014	FDA/OC/OES/DFOI/	CARLA ZCCRMAZZI KING & SPALDING	FDA 2012N-0378 - DRAFT 0272, 0286, 0048, ETC
2014-3890	05/13/2014 06/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Jon Harris Jon Harris	Approval package for Prolastin (Alpha1-Proteinase Inhibitor)
2014-3891	05/13/2014 06/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ann Maloney Maloney, Ann	Summary Basis of Approval Application No. A040811 Indocyanine Green Injection 25 mg/vial, Pulsion Medical Inc
2014-3892	05/13/2014 06/11/2014	FDA/OC/OES/DFOI/	ROBERT KING FDA NEWS	FDA-2014-N-0168, FDA-2014-N-0200
2014-3893	05/13/2014 06/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ann Maloney Maloney, Ann	NDA 011525 - SBA
2014-3894	05/13/2014 06/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ann Maloney Maloney, Ann	ANDA 077393 - SBA
2014-3895	05/13/2014 06/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rowena Dodaro Alkermes LLC	ABILIFY - AERS
2014-3896	05/13/2014	FDA/OMPT/CDER/ORP/DIDP/	Rowena Dodaro	VIVITROL - AERS

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	06/11/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ALKERMES INC	
2014-3897	05/13/2014 06/11/2014	FDA/OC/OES/DFOI/	SARA ELSPEHT CALLAHAN INDEPENDENCE LEGAL SUPPORT	FDA-1987-P-0199
2014-3898	05/13/2014 06/11/2014	FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/	Bowman Cox Informa Healthcare	WEST WARD PHARMACEUTICALS, EATONTOWN, NJ - 483 08/01/2012 - 09/30/2012
2014-3899	05/13/2014 06/11/2014	OC/CVM/OCD/	Kimberly Schwartz Kimberly Schwartz	DRUGS APPROVED FOR USE IN FEED ANIMALS BY SPECIES 05/12/2004 - 05/12/2014
2014-3900	05/13/2014 06/11/2014	FDA/OC/OES/DFOI/	SARA ELSPEHT CALLAHAN INDEPENDENCE LEGAL SUPPORT	CANOLA COUNCIL OF CANADA - DKT FDA-1987-P-0199
2014-3901	05/13/2014 06/11/2014	FDA/OC/OES/DFOI/	KEEFE JOHNSON HOGAN LOVELLS LLP	DKT FDA-2014-N-0238
2014-3902	05/13/2014 06/11/2014	FDA/OC/OES/DFOI/	ROBERT KING FDA NEWS	DKT FDA-2013-N-1430
2014-3903	05/13/2014 06/11/2014	FDA/OC/OES/DFOI/	ROBERT KING FDA NEWS	DKT FDA-2009-D-0136
2014-3904	05/13/2014 06/11/2014	FDA/OC/OES/DFOI/	CARLA SCARMAZZI KING & SPALDING	DKT FDA2014-P-0017
2014-3905	05/13/2014 06/11/2014	FDA/OC/OES/DFOI/	ROBERT KING FDA NEWS	DKT FDA-2014-D-0071
2014-3906	05/13/2014 06/11/2014	FDA/OC/OES/DFOI/	GRACE BALIAN EPSTEIN BECKER & GREEN PC	DKT FDA-2013-D-1446
2014-3907	05/13/2014 06/11/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rowena Dodaro ALKERMES INC	VIVITROL - AERS
2014-3908	05/13/2014 06/11/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	axiron ACORD, BOBBY R	AXIRON - WAIVER FORMS, 120 DAY JUSTIFICATION
2014-3909	05/13/2014	FDA/OMPT/CDER/GRP/DIDP/	Prashant Premkumar	AUROBINDO PHARMA - 483 03/01/2014 - 05/12/2014

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	06/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	East Bridge Capital Management Limited	
2014-3910	05/13/2014 06/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	PAUL R ERVIN Quintiles	MD ANDERSON CANCER CENTER - APRVL LTRS, APPL; SLOAN KETTERING - EGFR MUTATION ANALYSIS ASSAYS 1/1/05 TO 5/8/14
2014-3911	05/13/2014 06/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Pamela Wilson Alkermes Inc.	BLA 103293
2014-3912	05/13/2014 06/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rowena Dodaro Alkermes LLC	ABILIFY - FAERS
2014-3913	05/13/2014 06/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jaya Ayyagari Dr.Reddys Laboratories Inc	ANDA 087955 - SBA CMC
2014-3914	05/13/2014 06/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ryan Dunnegan Kennedy Capital Management	FERAHEME - AERS
2014-3915	05/13/2014 06/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	FARYAL HASAN Hyman, Phelps & McNamara P.C.	NICO CORP - BRAIN PORT K120691; DEPUY SPINE INC - SPOTLIGHT ACCESS SYS K112913; DEPUY SPINE INC - SPOTLIGHT PL K113273
2014-3916	05/13/2014 06/11/2014	FDA/OGROP/ORP/PA-FO/SEA- DO/SEA-CB/ FDA/OMPT/CDRH/OCER/DFOI/	JIM MOORE UPPER PAYETTE GROUP INC	MULHOLLAND POSITIONING SYSTEMS, BURLEY, ID; MULHOLLAND POSTIONING SYSTEM, SANTA PAULA, CA - EIRS, 510KS, PMA, ETC
2014-3917	05/13/2014 06/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DR GIL TOMER UNIPHARM LTD	ABILIFY NDA 21-436/S021 - SBA
2014-3918	05/13/2014 06/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PHOEBE MOUNTS MORGAN LEWIS & BOCKIUS LLP	BIOGEN IDEC INC (BIOGEN) - ALPROLIX (COAGULATION FACTOR IX RECOMBINANT, FC FUSION PROTEIN) COMM, APPL, LTRS GRANTING EXCLUSIVITY, ETC

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/OSMP/OOPD/		
2014-3919	05/13/2014 06/11/2014	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	THOMAS A CHANEY LIVING HEALTH INTERGRATIVE MEDICINE LLC	LIVING HEALTH INTEGRATIVE MEDICINE LLC, ANNAPOLIS, MD - INQUIRY 5/7/14
2014-3920	05/13/2014 06/11/2014	OC/ORACE/ OC/ORACE/ FDA/OGROP/ORACE/ORO/DIOP/	DEVA SUNDARARAJAN GLOBAL TRADE INTELLIGENCE INC	IMPORT REFUSAL RECS - 201300905-1 3/6/14 TO PRESENT
2014-3921	05/13/2014 06/11/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORACE/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORACE/PA-FO/LOS-DO/LOS-CB/	MICHAEL L HOLT DEFECTIVE MEDICAL DEVICES CONSULTING GROUP	ST JUDE MEDICAL - IMPLANTABLE CARDIOVERTER DEFIBRILLATORS (ICDS) & PACEMAKERS EIRS, RVW, FINAL CONCLUSIONS, ETC
2014-3922	05/13/2014 06/11/2014	FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECS
2014-3923	05/13/2014 06/11/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOI REQUESTS 3/31/14-4/4/14
2014-3924	05/13/2014 06/11/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 3/31/14-4/4/14
2014-3925	05/13/2014 06/11/2014	FDA/OC/OES/ FDA/OC/OES/DDM/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	ERIC B HERMANSON WHITE & WILLIAMS LLP	ACTION PLAN FOR PROVISION OF USEFUL PRESCRIPTION MEDICINE RECS (KEYSTONE ACTION PLAN) - PURPOSE, ORGIN, DEVELOPMENT, ETC; USEFUL CONSUMER MEDICATION GUIDANCE DOCUMENT - PURPOSE, ORGIN, DEVELOPMENT, ETC 7/06
2014-3926	05/13/2014	OC/ORACE/	ANDREW M PARISH	PACKING PRODUCTS COMPANY INC - ENTRY #826-

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	06/11/2014	OC/OR/ FDA/OGROP/OR/SE-FO/FLA-DO/FLA-CB/	ANDREW M PARISH PA	01560186, ENTRY #826-01559717 IMPORT RECS 2012, 2013
2014-3927	05/13/2014 06/11/2014	FDA/OGROP/OR/CE-FO/CHI-DO/CHI-CB/ FDA/OGROP/OR/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/OR/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/OR/PA-FO/LOS-DO/LOS-CB/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/OR/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/OR/ORO/DIOP/	Jordan Taylor DeWitt Ross & Stevens SC	ARTHUR SCHUMAN, INC - PERMITS, INSPECTION REPORTS RE IMPORTATION OF FOOD PRODUCTS ETC 1/1/2010 TO PRESENT
2014-3928	05/13/2014 06/11/2014	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOI REQUESTS 3/31/14-4/4/14
2014-3929	05/13/2014 06/11/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 3/31/14-4/4/14
2014-3930	05/13/2014 06/11/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 3/24-28/14
2014-3931	05/13/2014 06/11/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOI REQUESTS 3/24-28/14
2014-3932	05/13/2014 06/11/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 3/24-28/14
2014-3933	05/13/2014 06/11/2014	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOI REQUESTS 3/24-28/14
2014-3934	05/13/2014 06/11/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 3/24-28/14
2014-3935	05/13/2014 06/11/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 3/17-21/14
2014-3936	05/13/2014 06/11/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOI REQUESTS 3/17-21/14
2014-3937	05/13/2014	FDA/OC/OES/DFOI/	DEBI COHEN	CLOSED FOI REQUESTS 3/17-21/14

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	06/11/2014		WOLTERS KLUWER LAW & BUSINESS	
2014-3938	05/13/2014 06/11/2014	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOI REQUESTS 3/17-21/14
2014-3939	05/13/2014 06/11/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 3/17-21/14
2014-3940	05/13/2014 06/11/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 3/10-14/14
2014-3941	05/13/2014 06/11/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOI REQUESTS 3/10-14/14
2014-3942	05/13/2014 06/11/2014	FDA/OC/OES/DFOI/	DEBICOHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 3/10-14/14
2014-3943	05/13/2014 06/11/2014	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOI REQUESTS 3/10-14/14
2014-3944	05/13/2014 06/11/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 3/10-14/14
2014-3945	05/13/2014 06/11/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 3-3-7-14
2014-3946	05/13/2014 06/11/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOI REQUESTS 3/3-7/14
2014-3947	05/13/2014 06/11/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 3/3-7/14
2014-3948	05/13/2014 06/11/2014	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOI REQUESTS 3/3-7/14
2014-3949	05/13/2014 06/11/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 3/3-7/14
2014-3950	05/14/2014 06/12/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Aaron Bindman Sterne Kessler Goldstein & Fox PLLC	NAMENDA NDA 021487 - GRAPHS
2014-3951	05/14/2014 06/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	Gregory Calvitt NEOGENIX LLC	K112634

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2014-3952	05/14/2014 06/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	Toshio Murata Nidek Incorporated	K121043
2014-3953	05/14/2014 06/12/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Olivier Rossier, Vifor SA Vifor SA	VERTELLUS HEALTH & SPECIALTY PRODUCTS, ZEELAND, MI - EIR 06/13/2011 - 05/13/2014
2014-3954	05/14/2014 06/12/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Larry Kesler Clariant Corporation	DMF 2880
2014-3955	05/14/2014 06/12/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ting Chen Shionogi Inc.	NDA 203505 MEDWATCH REPORTS
2014-3956	05/14/2014 06/12/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kristina Cooke REUTERS	VIVITROL - AERS, INTERNAL MEMOS, LETTERS ETC 05/01/2014 - 05/14/2014
2014-3957	05/14/2014 06/12/2014	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Gwendolyn Prophet Soha & Lang, P.S.	MOLDY OATMEAL INVESTIGATION MARCH 2013 - CORR, NOTES, LAB RESULTS ETC
2014-3958	05/14/2014 06/12/2014	FDA/OO/OFBA/OAGS/	Nicole Corwine (for Hartzema) University of Florida, College of Pharmacy, Department of Pharmaceutical Outcomes & Policy	1U01FD004855-01
2014-3959	05/14/2014 06/12/2014	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Casey Toner Mobile Press-Register	SHAVER FOODS LLC, FAYETTEVILLE, AR - INSPECTIONS ETC 01/01/2009 - 05/13/2014
2014-3960	05/14/2014 06/12/2014	FDA/OFVM/CFSAN/OCD/EOS/	VISAGINE VIJAYAKULASINGAM IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 175154
2014-3961	05/14/2014 06/12/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARY B SZALKOWSKI PRISMA CORP	HURRICAIN (BENSOCAIN SPRAY) - AERS, EVENT TALLY RPT
2014-3962	05/14/2014 06/12/2014	FDA/OC/OES/DFOI/	ANNIE N VANELLA FAEGRE BAKER DANIELS	SIMPLY THICK, SIMPLY THICK LLC - FOI REQUEST LTRS 4/3/14 TO PRESENT

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2014-3963	05/14/2014 06/12/2014	FDA/OO/OHR/ FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECS
2014-3964	05/14/2014 06/12/2014	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JESSICA WARREN INTERCEPT PHARMACEUTICALS INC	VIGAYSRI ORGANICS, JINNARAM MANDAL, INDIA 11/9/10; PHARMAZELL PRIVATE LTD, VISHAKHAPATNAM, INDIA 4/1/11; PHARMAZELL GMBH, RAUBLING, GERMANY 12/8/11, ETC - 483S
2014-3965	05/14/2014 06/12/2014	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JESSICA WARREN INTERCEPT PHARMACEUTICALS INC	ALMAC PHARMA SERVICES, CRAIGAVON, GREAT BRITAIN 4/26/13; UNIV OF IOWA PHARMACEUTICALS LAB, CORALVILLE, IA 11/11/11; ALMAC SERVICES LTD, CRAIGAVON, GREAT BRITAIN 2/22/12, ETC - 483S
2014-3966	05/14/2014 06/12/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/CVM/OCD/	JESSICA WARREN INTERCEPT PHARMACEUTICALS INC	LIFESCIENCE LOGISTICS, BROWNSBURG, INDIANA 8/21/12; HOVIONE LTD, RINGASKIDDY CO CORK 3/16/12; JOHNSON MATTHEY PHARMA SERVICES, DEVENS, MA 11/7/11, ETC - 483S
2014-3967	05/14/2014 06/12/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JAYA AYYAGARI DR REDDY'S LABORATORIES INC	HOSPIRA - VITAMIN K1 (PHYTONADIONE) INJ ANDA 87-955 SBA
2014-3968	05/14/2014 06/12/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JAYA AYYAGARI DR REDDY'S LABORATORIES INC	SANOFI AVENTIS US - JEVANA KIT (CABAZITAXEL) NDA 201-023 SBA
2014-3969	05/14/2014 06/12/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JAYA AYYAGARI DR REDDY'S LABORATORIES INC	HOSPIRA - VITAMIN K1 (PHYTONADIONE) INJ ANDA 87-954 SBA

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-3970	05/14/2014 06/12/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	ADVANCED INTERVENTIONAL PAIN CENTER, LAFAYETTE, IN - EIR, 483, CO RESP 9/30/13 TO 10/24/13
2014-3971	05/14/2014 06/12/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JUN SHAO PHD EVENUS PHARMACEUTICAL LABORATORIES INC	JIANGSU HENGRUI MEDICINE CO LTD - IRINOTECAN HCL ANDA 90-675; GABAPENTIN ANDA 91-008; VINORELBINE TARTRATE ANDA 91-106, ETC APRVL LTRS
2014-3972	05/14/2014 06/12/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	ADVANCED INTERVENTIONAL PAIN CENTER, KOKOMO, IN - EIR, 483, CO RESP 9/16-27/13
2014-3973	05/14/2014 06/12/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	WEST WARD PHARMACEUTICAL CORP, EATONTOWN, NJ - EIR, 483, CO RESP 4/29/13 TO 6/7/13
2014-3974	05/14/2014 06/12/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHUCK MCCLUNG FLORIDA TODAY	CIALIS, VIAGRA, LEVITRA - AERS LAST 10 YRS
2014-3975	05/14/2014 06/12/2014	FDA/OC/OES/ FDA/OO/OFBA/OAGS/	THOMAS WOOD GENESIS INTEGRATIVE SOLUTIONS	FDA IT HELPDESK PROJECT - REQUIREMENT FOR 8(A) PARTICIPATION, BUDGET FOR 2012-2014, STATUS OF INCLUSION OF 8(A) FIRMS, ETC
2014-3976	05/14/2014 06/12/2014	FDA/OC/OES/DFOI/	NELSON #309318, JERMAINE	CHICKEN, PORK, BEEF, ETC - RECS
2014-3977	05/14/2014 06/12/2014	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	BAYER HEALTH CARE, SHAWNEE, KS - EIR, 483, CO RESP 10/23/13 TO 11/1/13
2014-3978	05/14/2014 06/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	MATTHEW WALKER POST MEDICAL INC	SHARPS CONTAINMENT SYS K925816
2014-3979	05/14/2014 06/12/2014	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	KOOTENAI HOSPITAL DISTRICT IRB, COEUR D'ALENE, ID - EIR, 483, CO RESP 5/14-29/13
2014-3980	05/14/2014 06/12/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	GLENMARK GENERICS LTD, COLVALE BARDEZ, INDIA - EIR, 483, CO RESP 9/23-25/13

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2014-3981	05/14/2014 06/12/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	WEST WARD PHARMACEUTICAL CORP, EATONTOWN, NJ - EIR, 483, CO RESP 8/28/12
2014-3982	05/14/2014 06/12/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	COLORADO HISTO-PREP, FT COLLINS, CO - EIR, 483, CO RESP 4/10/13-5/10/13
2014-3983	05/14/2014 06/12/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	BAXTER CORPORATION ENGLEWOOD, ENGLEWOOD, CO - EIR, 483, CO RESP 10/21-30/13
2014-3984	05/14/2014 06/12/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	GLENMARK GENERICS LTD, COLVALE BARDEZ, INDIA - EIR, 483, CO RESP 7/15-19/13
2014-3985	05/14/2014 06/12/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	WALTER E CHALKLEY THOMSON REUTERS	INSTITUTO BIOCOLEN SA DE VA, MEXICO CITY, MEXICO - EIR, 483, CO RESP 1/14-23/14
2014-3986	05/14/2014 06/12/2014	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	WALTER E. CHALKLEY THOMSON REUTERS	MALLINCKRODT INC, MARYLAND HEIGHTS, MO - EIR, 483, CO RESP 3/11-27/13
2014-3987	05/14/2014 06/12/2014	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	NEOPHARMA INC, CAGUAS, PR - EIR, 483, CO RESP 2/20 TO 3/7/13
2014-3988	05/14/2014 06/12/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	RANBAXY LABORATORIES LTD, PUNJAB, INDIA - EIR, 483, CO RESP 1/5-11/14
2014-3989	05/14/2014 06/12/2014	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	WALTER E. CHALKLEY THOMSON REUTERS	NOSTRUM LABORATORIES INC, KANSAS CITY, MO - EIR, 483, CO RESP 1/7-30/13
2014-3990	05/14/2014 06/12/2014	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	PFIZER PHARMACEUTICALS LLC, BARCELONETA, PR - EIR, 483, CO RESP 8/5-20/13
2014-3991	05/14/2014 06/12/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	PROXY LABORATORIES BV, LEIDEN THE NETHERLANDS - EIR, 483, CO RESP 3/14-18/13

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-3992	05/14/2014 06/12/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	SHIRE HUMAN GENETIC THERAPIES INC, LEXINGTON, MA - EIR, 483, CO RESP 5/6-23/13
2014-3993	05/14/2014 06/12/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	TEVA PHARMACEUTICALS USA, HORSHAM, PA - EIR, 483, CO RESP 1/30/13
2014-3994	05/14/2014 06/12/2014	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	WALTER E. CHALKLEY THOMSON REUTERS	WARNER CHILCOTT CO LLC, FAJARDO, PR - EIR, 483, CO RESP 3/13 TO 4/11/13
2014-3995	05/14/2014 06/12/2014	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	SAMUEL N LEDERMAN MD, LAKE WORTH, FL - EIR, 483, CO RESP 5/10/13 TO 6/3/13
2014-3996	05/14/2014 06/12/2014	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	BERNARD CORBETT MD, MOORE, SC - EIR, 483, CO RESP 4/29/13 TO 5/18/12
2014-3997	05/14/2014 06/12/2014	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	WINTER HAVEN HOSPITAL IRB, WINTER HAVEN, FL - EIR, 483, CO RESP 7/30/13 TO 8/7/13
2014-3998	05/14/2014 06/12/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	SUNIL VERMA MD, TORONTO, CANADA - EIR, 483, CO RESP 10/29/12 TO 11/2/12
2014-3999	05/14/2014 06/12/2014	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	TG UNITED INC, BROOKSVILLE, FL - EIR, 483, CO RESP 3/30/12
2014-4000	05/14/2014 06/12/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	WALTER E. CHALKLEY THOMSON REUTERS	MATTHEW CORNISH MD, OREM, UT - EIR, 483, CO RESP 2/25/13 TO 3/1/13
2014-4001	05/14/2014 06/12/2014	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	JOSEPH B DOMACHOWSKIE, SYRACUSE, NY - EIR, 483, CO RESP 2/5-14/13
2014-4002	05/14/2014 06/12/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	AIRGAS USA LLC, BILLERICA, MA - EIR, 483, CO RESP 5/3-22/13
2014-4003	05/14/2014 06/12/2014	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	WALTER E. CHALKLEY THOMSON REUTERS	BAYER HEALTH CARE, SHAWNEE, KS - EIR, 483, CO RESP 5/8-21/13
2014-4004	05/14/2014	FDA/OMPT/CDER/GRP/DIDP/	WALTER E. CHALKLEY	CIPLA LTD, VERNA SALCETTE GOA, INDIA - EIR, 483, CO

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	06/12/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	THOMSON REUTERS	RESP 5/20-30/13
2014-4005	05/15/2014 06/13/2014	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	TIFFANY PHILLIPS COLORESCIENCE	COLORESCIENCE, D/B/A BODY CHEMISTRY INC - EIRS 12/11, 9/13
2014-4006	05/15/2014 06/20/2014	FDA/OC/OES/DFOI/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	PRESTON J DUGAS III McDONALD LAW FIRM	LUMENIS LTD - VERSACUT TISSUE MORCELLATOR - AERS, ENFORCEMENT RPTS, PHOTOGRAPHS/VIDEOTAPES, ETC
2014-4007	05/15/2014 06/13/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	PRESTON J DUGAS III McDONALD LAW FIRM	ETHICON INC - GYNECARE X-TRACT MORCELLATOR MDRS, ENFORCEMENT RPTS, PHOTOGRAPHS/VIDEOTAPES, ETC
2014-4008	05/15/2014 06/13/2014	FDA/OC/OES/DDM/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TIFFANY KARY BLOOMBERG FINANCIAL MARKETS COMMODITIES NEWS	COLGATE-PALMOLIVE - TOTAL TOOTHPASTE NDA 20-231 MEMBERS OF THE A/C, MINS, APRVL PKG, ETC
2014-4009	05/15/2014 06/13/2014	FDA/OMPT/CTP/OD/	CHRISTOPHER A KREINER WOMBLE CARLYLE ET AL	SNUS - TOBACCO PRODS AERS
2014-4010	05/15/2014 06/13/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DANA DOLGE COZEN O'CONNOR	ALCHOL/ALUMINUM CHLORIDE - CAERS 5756335, 5757543, 6297835, ETC
2014-4011	05/15/2014 07/08/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	ELAINE JANKE EMERGENT BIOSOLUTIONS	CANGENE - WINRHO SD ISRS 5460102, 5460125, 5460430, ETC
2014-4012	05/15/2014 06/13/2014	FDA/OFVM/CFSAN/OCD/EOS/	Juliette Torikashvili Juliette Torikashvili	Material Safety Data Sheet and the Ingredients list for the Cover Girl Professional Lash Primer which had been discontinued in 1991 but had been on the market in 1989 through 1991.
2014-4013	05/15/2014 06/13/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Brian Depew Enstrom, Lipscomb & Lack	Pancreatic toxicology studies with exenatide and accompanying data that was used to write the journal article "Pancreatic Safety

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		of Incretin-Based Drugs FDA and EMA Assessment"
2014-4014	05/15/2014 06/13/2014	FDA/OFVM/CFSAN/OCD/EOS/	Sharon E Jacob LOMA LINDA UNIVERSITY	TEMPORARY TATTOOS - AERS
2014-4015	05/15/2014 06/13/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Emily Krulewitz The Weinberg Group	NDA 204300
2014-4016	05/15/2014 06/13/2014	FDA/OMPT/CDRH/OCER/DFOI/	Mark Barbieri Qualcomm Life, Inc.	K132930
2014-4017	05/15/2014 06/13/2014	FDA/OMPT/CDRH/OCER/DFOI/	Sumit Jain AXOGEN INC	K934368
2014-4018	05/15/2014 06/13/2014	FDA/OMPT/CDRH/OCER/DFOI/	Sumit Jain AXOGEN INC	K103081
2014-4019	05/15/2014 06/13/2014	FDA/OMPT/CDRH/OCER/DFOI/	Sumit Jain AXOGEN INC	K100382
2014-4020	05/15/2014 06/13/2014	FDA/OMPT/CDRH/OCER/DFOI/	Sumit Jain AXOGEN INC	K130557
2014-4021	05/15/2014 06/13/2014	FDA/OMPT/CDRH/OCER/DFOI/	Sumit Jain AXOGEN INC	K112267
2014-4022	05/15/2014 06/13/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Emily R. Greene Aaronson Rappaport Feinstein & Deutsch, LLP	EPOGEN, PROCIT - DEATH REPORTS
2014-4023	05/15/2014 06/13/2014	FDA/OMPT/CDRH/OCER/DFOI/	Pamela Papineau Delphi Medical Device Consulting, Inc.	K031128
2014-4024	05/15/2014 06/13/2014	FDA/OMPT/CDRH/OCER/DFOI/	Sumit Jain AXOGEN INC	K923963
2014-4025	05/15/2014 06/13/2014	FDA/OMPT/CDRH/OCER/DFOI/	Sumit Jain AXOGEN INC	K914056
2014-4026	05/15/2014 06/13/2014	FDA/OMPT/CDRH/OCER/DFOI/	Sumit Jain AXOGEN INC	K132660

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2014-4027	05/15/2014 06/13/2014	FDA/OMPT/CDRH/OCER/DFOI/	Sumit Jain AXOGEN INC	K131541
2014-4028	05/15/2014 06/13/2014	FDA/OMPT/CDRH/OCER/DFOI/	Mark Barbieri Qualcomm Life, Inc.	K101242
2014-4029	05/15/2014 06/13/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Lan Herrington BECKMAN COULTER INC	BECKMAN COULTER INC, CARLSBAD, CA- EIR 01/01/2012 - 12/26/2012
2014-4030	05/15/2014 06/13/2014	OC/ORA/ OC/ORA/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Doe J	INDIVIDUAL RECS
2014-4031	05/15/2014 06/13/2014	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	Robin Sullivan CellRight Technologies	STERIS ISOMEDIX, LIBERTYVILLE, IL - EIR 01/01/2013 - 05/14/2014
2014-4032	05/15/2014 06/13/2014	FDA/OGROP/ORACE-FO/CINDO/CIN-CB/	Chuck Soder Crain's Cleveland Business	PHILIPS HEALTHCARE, HIGHLAND HEIGHTS, OH - 483 01/01/2013 - 12/31/2013
2014-4033	05/15/2014 06/13/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-1752
2014-4034	05/15/2014 06/13/2014	FDA/OC/OES/DFOI/	Mark Gaikowski U.S. Geological Survey, Upper Midwest Environmental Sciences Center	AEH-13-EUGNL-05 in INAD I 011766
2014-4035	05/15/2014 06/13/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-1654
2014-4036	05/15/2014 06/13/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-1677
2014-4037	05/15/2014 06/13/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-1633
2014-4038	05/15/2014 06/13/2014	FDA/OMPT/CDRH/OCER/DFOI/	Mark Barbieri Qualcomm Life, Inc.	K113446
2014-4039	05/15/2014 06/13/2014	FDA/OC/OES/DFOI/	Stuart Goldberg Litespeed Partners	HP ACTHAR GEL RECS
2014-4040	05/16/2014 06/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DON J MIZERK HUSCH BLACKWELL LLP	WATSON LABORATORIES INC - LIDODERM (LIDOCAINE PATCH) ANDA 200-675 PI, LBLG

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2014-4041	05/16/2014 06/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	AMAURY SANCHEZ NOVEN PHARMACEUTICALS INC	XULANE (ETHINYL ESTRADIOL; NORELGESTROMIN) TRANSDERMAL SYS ANDA 200-910 - SBA
2014-4042	05/16/2014 06/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANIL SACHDEVA AGLIA SPECIALTIES INC	HOSPIRA - NALBUPHINE HCI INJ ANDA 70-914 LBLG
2014-4043	05/16/2014 06/16/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	INDIVIDUAL RECS
2014-4044	05/16/2014 06/16/2014	FDA/OFVM/CFSAN/OCD/EOS/	KRISTI O SMEDLEY Center for Regulatory Services,Inc.	VERXITE - FAP
2014-4045	05/16/2014 06/16/2014	OC/CVM/OCD/ FDA/OFVM/CFSAN/OCD/EOS/	KRISTI O SMEDLEY Center for Regulatory Services,Inc.	VERXITE - FAP
2014-4046	05/16/2014 06/16/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	JACQUELINE S BERNARD WICKLIFFE VETERINARY PHARMACY	SPL 487958 - TEST RESULTS
2014-4047	05/16/2014 06/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ORTEGO, JUANITA	KETORALAC - AERS
2014-4048	05/16/2014 06/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TAMMY ROSE GENENTECH INC	LUCENTIS (RANIBIZUMAB) SBA UNREDACTED, APRVL 8/10/12
2014-4049	05/16/2014 06/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	SINEVA, ANNA	HUBBARD E-METER, ELECTRO PSYCHOMETER, SCIENTOLOGY E-METER, ETC - RECS 1/11 TO PRESENT
2014-4050	05/16/2014 07/17/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	SUZANNE O. GALBATO BOND SCHOENECK & KING	CONMED CORP/McGREEVY 8-0600-12-126
2014-4051	05/16/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	PATRICIA L. REYENYE	DANNY LEE, IRVINE CENTER FOR CLINICAL RESEARCH INC, IRVINE, CA - 483 1/09 TO PRESENT

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	06/16/2014		Celgene Corporation	
2014-4052	05/16/2014 06/16/2014	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	PATRICIA L. REGENYE Celgene Corporation	BORIS KERZNER, HEALTH TRENDS RES, BALTIMORE MD - 483 3/08 TO PRESENT
2014-4053	05/16/2014 06/16/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	LESLIE RAMSEY FDA NEWS	MYCONE DENTAL SUPPLY CO, GIBBSTOWN, NJ; AIRWAYS DEVELOPMENT LLC, KENILWORTH, NJ; CONVATEC INC, SKILLMAN, NJ, ETC - 483S 4/1-30/14
2014-4054	05/16/2014 06/16/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	PATRICIA L. REGENYE Celgene Corporation	WILLIAM HEIM, HEMATOLOGY & ONCOLOGY ASSOC OF NE PA, DUNMORE, PA - 483 7/04 TO PRESENT
2014-4055	05/16/2014 06/16/2014	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	LESLIE RAMSEY FDA NEWS	LASER ENGINEERING INC, FRANKLIN, TN - 483 4/1-30/14
2014-4056	05/16/2014 06/16/2014	OC/ORACE-FO/PHI-DO/PHI-CB/ FDA/OMPT/CDRH/OCER/DFOI/	LESLIE RAMSEY FDA NEWS	SUZHOU MEIFU MEDICAL PLASTICS CO LTD, SUZHOU, CHINA - 483S 4/1-30/14
2014-4057	05/16/2014 06/16/2014	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	PATRICIA L. REGENYE Celgene Corporation	TALHA SHAMIM, HEARTLAND CLINICAL RES INC, OMAHA, NE - 483 10/08 TO PRESENT
2014-4058	05/16/2014 06/16/2014	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	PATRICIA L. REGENYE Celgene Corporation	WILLIAM JENNINGS, RADIANT RESEARCH INC, SAN ANTONIO, TX - 483 11/06 TO PRESENT
2014-4059	05/16/2014 06/16/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	LESLIE RAMSEY FDA NEWS	FRAGRANCE MANUFACTURING INC, ALLENTOWN, PA; AXCENTRIA PHARMACEUTICALS LLC, TELFORD, PA; AUXILLIUM PHARMACEUTICALS INC, HORSHAM, PA, ETC - 483S 4/1-30/14
2014-4060	05/16/2014 06/16/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	PATRICIA L. REGENYE Celgene Corporation	IRA FELMAN, WILSHIRE ONCOL MED GROUP, MONTEBELLO, CA - 483 6/06 TO PRESENT
2014-4061	05/16/2014 06/16/2014	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	LESLIE RAMSEY FDA NEWS	HS INTERNATIONAL CORP, CONCORD, CA; ASANTE SOLUTIONS INC, SUNNYVALE, CA; NIDEK INC, FREMONT, CA - 483S 4/1-30/14
2014-4062	05/16/2014 06/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PATRICIA L. REGENYE Celgene Corporation	JOHAN MAERTENS, LEUVEN, BELGIUM - 483 6/04 TO PRESENT
2014-4063	05/16/2014 06/16/2014	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	LESLIE RAMSEY FDA NEWS	HEALTH & HERBS, ALBANY, OR; SPACELABS HEALTHCARE INC, GYNEX CORP, REDMOND, WA, ETC - 483S 4/1-30/14
2014-4064	05/16/2014 06/16/2014	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	PATRICIA L. REGENYE Celgene Corporation	EDWARD KAPLAN, RUSH PRESBYTERIAN ST LUKES MEDICAL CENTER, CHICAGO, IL - 483 2/91 TO PRESENT
2014-4065	05/16/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	LESLIE RAMSEY	STREM CHEMICALS INC, NEWBURYPORT, MA; PRECISE PACKAGING LLC, FALL RIVER, MA; MILLSTONE MEDICAL

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	06/16/2014		FDA NEWS	OUTSOURCING LLC, FALL RIVER, MA - 483 4/14
2014-4066	05/16/2014 06/16/2014	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	LESLIE RAMSEY FDA NEWS	HOSPIRA INC, McPHERSON, KS; GLOBAL MEDICAL HOLDINGS LLC, ADEL, IA; TITONICS RESEARCH & DEVELOPMENT, TIFFIN, IA - 483 4/14
2014-4067	05/16/2014 06/16/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	LESLIE RAMSEY FDA NEWS	P&L DEVELOPMENTS LLC, LYNWOOD, CA; ST JUDE MEDICAL CARDIAC RHYTHM MGMT DIV, SYLMAR, CA; INTEGRA NEURO SCIENCES, SAN DIEGO, CA - 483 4/14
2014-4068	05/16/2014 06/16/2014	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	LESLIE RAMSEY FDA NEWS	AMERICAN CONTRACT SYS INC, WAUNAKEE, WI - 483 4/14
2014-4069	05/16/2014 06/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	LESLIE RAMSEY FDA NEWS	SHANGHAI ISO MEDICAL PRODUCTS CO LTD, SHANGHAI, CHINA; ARKAY SHANGHAI LTD, PUDONG SHANGHAI, CHINA; CM INSTRUMENTE GMBH, TUTTLINGEN, GERMANY - 483 4/14
2014-4070	05/16/2014 06/16/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	LESLIE RAMSEY FDA NEWS	IPAX INC; ENGLEWOOD, CO; EDWARDS LIFESCIENCES LLC, DRAPER, UT - 483 4/14
2014-4071	05/16/2014 06/16/2014	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	LESLIE RAMSEY FDA NEWS	BETA BIOMED SERVICES INC, ROWLETT, TX - 483 4/14
2014-4072	05/16/2014 06/16/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	LESLIE RAMSEY FDA NEWS	ZOETIS P&U LLC, KALAMAZOO, MI; JOSNOE MEDICAL INC, CHELSEA, MI; ACUMEDIA MANUFACTURERS INC, LANSING, MI - 483 4/14
2014-4073	05/16/2014 06/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	LIANE LAROCHELLE DEKA RESEARCH & DEVELOPMENT CORP	MARCOR PURIFICATION INC - BIOPURE HX2 REVERSE OSMOSIS WATER PURIFICATION SYS K133149
2014-4074	05/16/2014 06/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	LIANE LAROCHELLE DEKA RESEARCH & DEVELOPMENT CORP	NIPRO MEDICAL CORP - ELISIO-H HEMODIALYZER K140191
2014-4075	05/16/2014 06/16/2014	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	LESLIE RAMSEY FDA NEWS	AFAM CONCEPT INC, CHICAGO, IL; NANOSPHERE, INC, NORTHBROOK, IL; SCALE TRONIX INC, CAROL STREAM, IL - 483 4/14
2014-4076	05/16/2014 06/16/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	LESLIE RAMSEY FDA NEWS	PHARMAFORCE INC, HILLIARD, OH; TOLEDO, OH; AMRESKO LLC, SOLON, OH - 483 4/14
2014-4077	05/16/2014 06/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	LIANE LAROCHELLE DEKA RESEARCH & DEVELOPMENT CORP	AMERIOWATER - AMERIOWATER CENTURION 1500+ REVERSE OSMOSIS SYS WITH HEAT SANITATION K133783
2014-4078	05/16/2014 06/16/2014	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	LESLIE RAMSEY FDA NEWS	AGFA CORP, GREENVILLE, SC; MEDICAL TECHNOLOGIES OF GA, COVINGTON, GA - 483 4/14
2014-4079	05/16/2014	FDA/OFVM/CFSAN/OCD/EOS/	JOSEPH R KATZ	MIRA HEALTH PRODUCTS LTD - DIETARY SUPPLEMENTS CORR, CITATIONS, INVESTIGATION RECS, ETC 2009 TO

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	06/16/2014	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OC/OCC/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MEAGHER & MEAGHER PC	2013
2014-4080	05/16/2014 06/16/2014	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	LESLIE RAMSEY FDA NEWS	CELGENE BIOPHARMA INC, BALTIMORE, MD; AFTON SCIENTIFIC LLC, CHARLOTTESVILLE, VA; ANGELINI PHARMA INC, GAITHERSBURG, MD - 483 4/14
2014-4081	05/16/2014 06/16/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOSEPH R KATZ MEAGHER & MEAGHER PC	HEALTHY LIFE CHEMISTRY INC - DIETARY SUPPLEMENTS CORR, CITATIONS, INVESTIGATIONS, ETC 2009 TO 2013
2014-4082	05/16/2014 06/16/2014	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	LESLIE RAMSEY FDA NEWS	TG UNITED INC, BROOKSVILLE, FL; TG UNITED LIQUID INC, BROOKSVILLE, FL; BALASSA LABORATORIES INC, PORT ORANGE, FL - 483 4/14
2014-4083	05/16/2014 06/16/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LESLIE RAMSEY FDA NEWS	SHIONOGI & CO INC LTD, ISAWA-GUN, JAPAN; MICRO LABS LTD, BANGALORE, INDIA; FERMION OY, HANKO, FINLAND - 483 4/14
2014-4084	05/16/2014 06/16/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDRH/OCER/DFOI/	DAVID J. DIAMOND GOLDBERG & OSBORNE	SMITH & NEPHEW - HEALICOIL PK SUTURE ANCHOR - RECALL Z -2165-2012, AER
2014-4085	05/19/2014 06/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	Eben Gordn SOTERA WIRELESS	K052160
2014-4086	05/19/2014 06/17/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 200295
2014-4087	05/19/2014 06/17/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 90326

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2014-4088	05/19/2014 06/17/2014	FDA/OGROP/ORAC/CE-FO/BLT-DO/BLT-CB/	Rachel Johnson FOI Services, Inc.	Most recent EIR for Covance, Chantilly, VA
2014-4089	05/19/2014 06/17/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 90097
2014-4090	05/19/2014 06/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	John Gill SteriDesign	K092996
2014-4091	05/19/2014 06/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	Elaine Duncan Paladin Medical, Inc.	K082384
2014-4092	05/19/2014 06/17/2014	FDA/OGROP/ORAC/CE-FO/MIN-DO/MIN-CB/	James Schaefer Ortho Molecular Products	ORTHO MOLECULAR PRODUCTS, STEVENS POINT, WI - EIR ETC 01/01/2013 - 05/15/2014
2014-4093	05/19/2014 06/17/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Virginia Beakes-Read Eisai Inc.	Letter from Johnson & Johnson, Ms. Susan Merchant, to FDA, Dr. Russell Katz, dated November 11, 2005, filed to NDA 21-615
2014-4094	05/19/2014 06/17/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sarah Weiser Retro Report, Mirror Mirror Productions, Inc.	PROZAC - APPROVAL LETTER
2014-4095	05/19/2014 06/17/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kerrie Nagrod NOVARTIS PHARMACEUTICAL CORPORATION	NDA 22-083 SBA
2014-4096	05/19/2014 06/17/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rowena Dodaro ALKERMES INC	9182026, 905799, 9152609
2014-4097	05/19/2014 06/17/2014	FDA/OFVM/CFSSAN/OCD/EOS/ FDA/OGROP/ORAC/PA-FO/SAN-DO/SAN-CB/	PETA People for the Ethical Treatment of Animals (PETA)	RANCHO FEEDING CORPORATION, PETALUMA, CA - RECALL RECS, INSPECTION RECS, INVESTIGATIONS ETC

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2014-4098	05/19/2014 06/17/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Christy Meng InnoPharma Inc.	NDA 018243 - SBA
2014-4099	05/19/2014 06/17/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ayesha Adil The Weinberg Group	ANDA 076777 S025
2014-4100	05/19/2014 06/17/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Kristin Nekeman Kristin Nekeman	ROTARIX - VAERS LINE LISTING
2014-4101	05/19/2014 06/17/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dave Milton Coker, Schickel, Sorenson & Posgay, P.A.	DMF 14760
2014-4102	05/19/2014 06/17/2014	FDA/OGROP/ORAPA-FO/SAN- DO/SAN-CB/	HENRY BISHOP BAYER HEALTHCARE	CONCEPTUS INC, MOUNTAIN VIEW, CA - EIR 05/15/2013 - 06/28/2013
2014-4103	05/19/2014 06/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	Renata Lavach-Savy SCIMEDX CORPORATION	GOLD STANDARD DIAGNOSTICS - WARNING LETTER RECS 12/02/2013 - 05/15/2014
2014-4104	05/19/2014 06/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K083812
2014-4105	05/19/2014 06/17/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kerrie Nagrod Novartis Pharmaceuticals, Corp.	NDA 22-083 S-019 SBA
2014-4106	05/19/2014 06/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	Elizabeth Rafferty BRAEBON Medical Corporation	AIRAIDSLEEP SENSOR, ORTHOMITER, THERMON - 513(g), 510(k) RECS
2014-4107	05/19/2014 06/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	K091763-Full Submission- not just 510(k) summary Paladin Medical, Inc.	K091763
2014-4108	05/19/2014 06/17/2014	OC/ORPA/ OC/ORPA/ FDA/OGROP/ORASE-FO/NOL- DO/NOL-CB/	Doe J	INDIVIDUAL RECS

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2014-4109	05/19/2014 06/17/2014	OC/ORR/ORM/ OC/ORR/ORM/	David Mangione Govzilla, Inc.	LIST OF 483, INSPECTIONS, EIR 04/17/2014 - 05/17/2014
2014-4110	05/19/2014 06/17/2014	FDA/OGROP/ORR/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORR/CE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Laura Strickler CBS NEWS	ASCEND LABORATORIES, NJ, OH, INDIA - EIR, 483 01/01/2012 - 05/16/2014
2014-4111	05/19/2014 06/17/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ferena Salek, PharmD NORTHWEST MEDICAL CENTER	FDA Safety Alert: Sodium Phosphate OTC Products: Drug Safety Communication-Possible Harm From Exceeding Recommended Dose
2014-4112	05/19/2014 06/17/2014	FDA/OMPT/CTP/OD/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	CTP CORR RE RUYAN ELECTRONIC CIGARETTES OR CARTRIDGES OR SOTTERA CORPORATION
2014-4113	05/19/2014 06/17/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	NDA 21977 S 001
2014-4114	05/19/2014 06/17/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	BLA 125084 S 001
2014-4115	05/19/2014 06/17/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	NDA 21999 S 004
2014-4116	05/19/2014 06/17/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JESSICA WARREN INTERCEPT PHARMACEUTICALS INC	PHARMAZELL PVT LTD, VISHAKHAPATNAM, INDIA 4/1/11; PHARMAZELL PVT LTD, TAMILNADU, CHENAI, INDIA 11/10/11; PHARMAZELL GMBH, RAUBLING, GERMANY 12/8/11 - 483S

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		FDA/OMPT/CDER/ORP/DIDP/		
2014-4117	05/19/2014 06/17/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	PATRICK KELLY CONWAY HOMER & CHIN- CAPLAN PC	INDIVIDUAL RECS
2014-4118	05/19/2014 06/17/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KATRINA REILING Parexel International	JANSSEN PHARM - RISPERDAL CONSTA (RISPERIDONE) NDA 21-346/S025,S028 RECS
2014-4119	05/19/2014 06/17/2014	OC/ORA/ OC/ORA/ FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/ FDA/OGROP/ORASW- FO/SWID/SWID-CB/	SAMANTHA MYERS ROANOKE CLAIMS SERVICES	RR IMPORTACIONES - ENTRY #DV101484629 NOTICES FOR REQUEST OF INFORMATION, NOTICE OF ACTION, CBP REDELIVER NOTICES
2014-4120	05/19/2014 06/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	STEPHEN T FOWLER REED SMITH LLP	ST JUDE NEUROMODULATION DIVISION - P010032 REVIEWER DECISION NOTES, TELECONFERENCE MINS
2014-4121	05/19/2014 06/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	STEPHEN T FOWLER REED SMITH LLP	ST JUDE MEDICAL NEUROMODULATION DIVISION - P010032/S006 REVIEWER DECISION NOTES, TELECONFERENCE MINS
2014-4122	05/19/2014 06/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	STEPHEN T FOWLER REED SMITH LLP	ST JUDE MEDICAL NEUROMODULATION DIVISION - P010032/S014 REVIEWER DECISION NOTES, TELECONFERENCE MINS
2014-4123	05/19/2014 06/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	STEPHEN T FOWLER REED SMITH LLP	ST JUDE MEDICAL NEUROMODULATION DIVISION - P101132/S023 REVIEWER DECISION NOTES, TELECONFERENCE MINS
2014-4124	05/19/2014 06/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	STEPHEN T FOWLER REED SMITH LLP	ST JUDE MEDICAL NEUROMODULATION DIVISION - P010032/S054 REVIEWER DECISION NOTES, TELECONFERENCE MINS
2014-4125	05/19/2014 06/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	STEPHEN T FOWLER REED SMITH LLP	ST JUDE MEDICAL NEUROMODULATION DIVISION - P010032/S058 REVIEWER DECISION NOTES, TELECONFERENCE MINS
2014-4126	05/19/2014 06/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	STEPHEN T FOWLER REED SMITH LLP	ST JUDE MEDICAL NEUROMODULATION DIVISION - P010032/S025 REVIEWER DECISION NOTES, TELECONFERENCE MINS
2014-4127	05/19/2014 06/17/2014	FDA/OGROP/ORASW-FO/LOS- DO/LOS-CB/	LESLIE OSTER BIOMEDICAL RESEARCH LABORATORIES	ATLAS BIOSCIENCES, TUCSON, AZ - 483 1/12 TO PRESENT
2014-4128	05/19/2014	FDA/OGROP/ORASW-FO/DEN-	LESLIE OSTLER	MILLER LABS, OGDEN, UT - 483 1/12 PRESENT

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	06/17/2014	DO/DEN-CB/	BIOMEDICAL RESEARCH LABORATORIES	
2014-4129	05/19/2014 06/17/2014	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	LESLIE OSTLER BIOMEDICAL RESEARCH LABORATORIES	COVANCE, MADISON, WI - 483 1/12 TO PRESENT
2014-4130	05/19/2014 06/17/2014	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	LESLIE OSTLER BIOMEDICAL RESEARCH LABORATORIES	HEALTH LEVEL ONE INC, HAUPPAUGE, NY - 483 1/12 TO PRESENT
2014-4131	05/19/2014 06/17/2014	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	LESLIE OSTLER BIOMEDICAL RESEARCH LABORATORIES	FLORA RESEARCH LABS, GRANTS PASS, OR - 483 1/12 TO PRESENT
2014-4132	05/19/2014 06/17/2014	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	LESLIE OSTLER BIOMEDICAL RESEARCH LABORATORIES	EUROFINS, NEW ORLEANS, LA - 483 1/12 TO PRESENT
2014-4133	05/19/2014 06/17/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	LESLIE OSTLER BIOMEDICAL RESEARCH LABORATORIES	ADVANCED LABORATORIES INC, SALT LAKE CITY, UT - 483 1/12 TO PRESENT
2014-4134	05/19/2014 06/17/2014	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	LESLIE OSTLER BIOMEDICAL RESEARCH LABORATORIES	SILLIKER INC, CRETE, IL - 483 1/12 TO PRESENT
2014-4135	05/19/2014 06/17/2014	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	LESLIE OSTLER BIOMEDICAL RESEARCH LABORATORIES	MEDALLION LABS, MINNEAPOLIS, MN - 483 1/12 TO PRESENT
2014-4136	05/19/2014 06/17/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	LESLIE OSTLER BIOMEDICAL RESEARCH LABORATORIES	GENYSIS NUTRITIONAL LABS, SALT LAKE CITY, UT - 1/12 TO PRESENT
2014-4137	05/19/2014 06/17/2014	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	PATRICIA L. REGENYE Celgene Corporation	DANIEL SULLIVAN, H LEE MOFFITT CA CENTER, TAMPA, FL - 483 8/04 TO PRESENT
2014-4138	05/19/2014 06/17/2014	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	PATRICIA L. REGENYE Celgene Corporation	SAGAR LONIAL, EMORY CLINIC, ATLANTA, GA - 483 10/06 TO PRESENT
2014-4139	05/19/2014 06/17/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	PATRICIA L. REGENYE Celgene Corporation	SCOTT ROWLEY, CA CTR AT HACKENSACK UNIV MED CTR, HACKENSACK, NJ - 483 7/04 TO PRESENT
2014-4140	05/19/2014 06/17/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	PATRICIA L. REGENYE Celgene Corporation	GURKAMAL CHATTA, UPMC CA PAVILION, PITTSBURGH, PA - 483 5/07 PRESENT
2014-4141	05/19/2014 06/17/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	PATRICIA L. REGENYE Celgene Corporation	BENJAMIN DJULBEGOVIC, UNIV OF LOUISVILLE, LOUISVILLE, KY - 483 10/06 TO PRESENT

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2014-4142	05/19/2014 06/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	STEPHEN T FOWLER REED SMITH LLP	ST JUDE MEDICAL NEUROMODULATION DIVISION - P010032/S047 REVIEWER DECISION NOTES, TELECONFERENCE MINS
2014-4143	05/19/2014 06/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	STEPHEN T FOWLER REED SMITH LLP	DT JUDE MEDICAL NEUROMODULATION DIVISION - P010032/S059 REVIEWER DECISION NOTES, TELECONFERENCE MINS
2014-4144	05/19/2014 06/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	STEPHEN T FOWLER REED SMITH LLP	ST JUDE MEDICAL NEUROMODULATION DIVISION - P010032/S002 REVIEWER DECISION NOTES, TELECONFERENCE MINS
2014-4145	05/19/2014 06/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	STEPHEN T FOWLER REED SMITH LLP	ST JUDE MEDICAL NEUROMODULATION DIVISION - P010032/S003 REVIEWER DECISION NOTES, TELECONFERENCE MINS
2014-4146	05/19/2014 06/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	STEPHEN T FOWLER REED SMITH LLP	ST JUDE MEDICAL NEUROMODULATION DIVISION - P010032/S019 REVIEWER DECISION NOTES, TELECONFERENCE MINS
2014-4147	05/19/2014 06/17/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	SPENCER C THOMAS GIDEON COOPER & ESSARY	METHYLPREDNISOLONE ACETATE SHORTAGES FOR THE LAST TEN YRS - CORR, RPTS, WEBPAGES,E TC
2014-4148	05/19/2014 06/17/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	HEMA PATEL PREMIER RESEARCH	ONDANSETRON ORAL SOLUBLE FILM - PEDIATRIC STUDY RPTS
2014-4149	05/20/2014 06/18/2014	FDA/OMPT/CDRH/OCER/DFOI/	Robert Peck BD MEDICAL SYSTEMS	ANGIOPLAST PRIVATE LIMITED, AHMEDABAD, INDIA - EIR12/10/2012 - 12/13/2012
2014-4150	05/20/2014 06/18/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/ OC/CVM/OCD/	Daryl Loo BLOOMBERG NEWS	CHINESE DRUG COMPANIES WITH IMPORT ALERT - 483 01/01/2013 - 05/16/2014

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2014-4151	05/20/2014 06/18/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Richard Gonnello Faruqi & Faruqi, LLP	GERON CORPORATION - AERS
2014-4152	05/20/2014 06/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	BLA 103795 S 5322
2014-4153	05/20/2014 06/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mahidhar Chinta Micro Labs USA, Inc	WOCKHARDT LIMITED, INDIA; USV LIMITED, INDIA - 483 03/01/2013 - 05/01/2014
2014-4154	05/20/2014 06/18/2014	FDA/OC/OCC/	Jeff Gerth PROPUBLICA	GSK, DAN TROY - EMAILS RE TWO SEALED COMPLAINTS
2014-4155	05/20/2014 06/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Steven Woloshin The Dartmouth Institute for Health Policy and Clinical Practice	NDA, NDA SUPPLEMENTS CURRENTLY AVAILABLE
2014-4156	05/20/2014 06/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Shelby Thompson Thompson, Shelby L	CEDAX AERS
2014-4157	05/20/2014 06/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Hampus Rystedt BRANN AB	ALLN-177
2014-4158	05/20/2014 06/18/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	STN 102821, TICE BCG (BCG Live)
2014-4159	05/20/2014 06/19/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	STN 103289 S 5189, TheraCys (BCG Live)

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2014-4160	05/20/2014 06/18/2014	FDA/OMPT/CDRH/OCER/DFOI/	Heather Munday-McGinley BENNETT BIGELOW & LEEDOM PS	MAUDE RECS 0001825034-2012-00263
2014-4161	05/20/2014 06/18/2014	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/ORO/DIOP/	Megan Lindwall Zepol Corporation	ZEPOL - UPDATE TO SHIPMENT REFUSAL REPORTS
2014-4162	05/20/2014 06/18/2014	FDA/OMPT/CDRH/OCER/DFOI/	Med-Rite Laboratories Med-Rite Laboratories, LLC c/o Griggs Bergen LLP	K04264
2014-4163	05/20/2014 06/18/2014	FDA/OMPT/CDRH/OCER/DFOI/	William Birdsall MicroMed Cardiovascular Inc.	MIRCROMED CARDIOVASCULAR INC - IDE RECS
2014-4164	05/20/2014 06/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Silvia Gambardella WTVTD-ABC	LUPRON - AERS
2014-4165	05/20/2014 06/18/2014	FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	Melissa Pong Dohmen Life Science Services	CORCEPT THERAPEUTICS INC, MENLO PARK, CA - EIR 05/05/2014 - 05/09/2014
2014-4166	05/20/2014 06/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tina Babos IPD ANALYTICS LLC	ANDA 078949 - APPROVAL LTR
2014-4167	05/20/2014 06/18/2014	FDA/OGROP/ORA/CE-FO/BLT- DO/BLT-CB/ FDA/OMPT/CDRH/OCER/DFOI/	MCKENZIE CATO Hyman, Phelps & McNamara P.C.	PERFECT CHOICE HD/OR STEALTH S.S.A. - SALE OF PERSONAL SOUND AMPLIFICATION PRODS (PSAPS)
2014-4168	05/20/2014 06/18/2014	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	MCKENZIE CATO Hyman, Phelps & McNamara P.C.	WALKERS LLC AND/OR AUDIEUS INC - PERSONAL SOUND AMPLIFICATION PRODS (PSAPS) CORR
2014-4169	05/20/2014 06/18/2014	FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/ FDA/OMPT/CDRH/OCER/DFOI/	MCKENZIE CATO Hyman, Phelps & McNamara P.C.	EAR TECHNOLOGY CORP AND/OR HEARING ASSIST LLC (THE MAKER OF THE LEE MAJORS BIONIC HEARING AID) - THE SALE OF PERSONAL SOUND AMPLIFICATION PRODS (PSAPS) CORR
2014-4170	05/20/2014 06/18/2014	FDA/OGROP/ORA/CE-FO/CHI- DO/CHI-CB/ FDA/OMPT/CDRH/OCER/DFOI/	MCKENZIE CATO Hyman, Phelps & McNamara P.C.	MDHEARINGAID AND/OR MSA 30X - PERSONAL SOUND AMPLIFICATION PRODS (PSAPS) CORR

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2014-4171	05/20/2014 06/18/2014	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	MCKENZIE CATO Hyman, Phelps & McNamara P.C.	AMPLIEAR/AND/OR FOUR CORNERS DIRECT INC - (THE MAKER OF EAR-PRO IQ) THE SALE OF PERSONAL SOUND AMPLIFICATION PRODS (PSAPS) CORR
2014-4172	05/20/2014 06/18/2014	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/ FDA/OMPT/CDRH/OCER/DFOI/	MCKENZIE CATO Hyman, Phelps & McNamara P.C.	SOUND WORLD SOLUTIONS AND/OR VOXX ACCESORIES CORP - THE SALE OF PERSONAL SOUND AMPLIFICATION PRODS (PSAPS) CORR
2014-4173	05/20/2014 06/18/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDRH/OCER/DFOI/	MCKENZIE CATO Hyman, Phelps & McNamara P.C.	BOSE CORP AND/OR EAR MACHINE LLC - THE SALE OF PERSONAL SOUND AMPLIFICATION PRODS (PSAP) CORR
2014-4174	05/20/2014 06/18/2014	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	MCKENZIE CATO Hyman, Phelps & McNamara P.C.	GEORGIA EAR INSTITUTE/OR JOHNSON HEARING TECHNOLOGY & COMMUNICATIONS - THE SALE OF PERSONAL SOUND AMPLIFICATION PRODS (PSAPS)
2014-4175	05/20/2014 06/18/2014	FDA/OGROP/ORAPA-FO/LOSDO/LOS-CB/	MCKENZIE CATO Hyman Phelps and McNamara PC	TUNEAMP AND/OR TV EARS INC - THE SALE OF PERSONAL SOUND AMPLIFICATION PRODS (PSAPS) CORR
2014-4176	05/20/2014 06/18/2014	FDA/OMPT/CDRH/OCER/DFOI/	CHESTER, VICKI	SPECTRANETICS CORP - CLIRPATH TURBO PLUS EXCIMER LASER CAHTETER K052514
2014-4177	05/20/2014 06/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	DON J MIZERK HUSCH BLACKWELL LLP	WATON LABORATORIES INC -LLIDODERM (LIDOCAINE PATCH 5%) ANDA 200-0675 LBLG, PI, PRESCRIBING RECS
2014-4178	05/20/2014 06/18/2014	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	ROGER RAND MEDICAL DEVICE CGMP CONSULTANT	BOSSONG HOSIERY MILLS, ASHEBORO, NC - EIR 3/14
2014-4179	05/20/2014 06/18/2014	FDA/OGROP/ORACE-FO/CINDO/CIN-CB/ OC/ORA/ OC/ORA/ FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORACE-FO/CINDO/CIN-CB/	FRANK T BECKER FRANK T BECKER ATTY	WILLOW OAK FARM, LEXINGTON, KY - 2 EMPTY TUBES & 3 FULL TUBES OF TOLTRAZURIL/ PYRAMETHAMINE PASTE SPL 487967 LAB RPTS, TEST RESULTS
2014-4180	05/20/2014 06/18/2014	OC/ORA/ OC/ORA/	STEWART, DONNA	CMPLNT 132070

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		FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/ FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/		
2014-4181	05/20/2014 07/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	MITESH J BORAD MD MAYO CLINIC ARIZONA	IND 14347 - ORIGINAL IND SUBMISSION
2014-4182	05/20/2014 06/18/2014	FDA/OC/OES/DFOI/	NELSON #309318, JERMAINE	TEGRATOL, TYLENOL, ADVIL, ETC - AERS
2014-4183	05/20/2014 08/06/2014	FDA/OFVM/CFSAN/OCD/EOS/	SILVIA ULM BURDOCK GROUP	POTASSIUM FERROCYANIDE, POTASSIUM FERROCYANTE, POTASSIUM HEXACYANOFERRATE (CAS #13943-58-3), ETC - REGULATORY STATUS, CONSUMPTION, SAFETY RECS
2014-4184	05/20/2014 07/01/2014	OC/ORAS/ OC/ORAS/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ OC/ORAS/OE/ OC/ORAS/OE/ FDA/OFVM/CFSAN/OCD/EOS/	MELVIN N KRAMER EHA CONSULTING GROUP INC	ATHERSTONE FOODS - SALAD E COLI OUTBREAK COMM, LAB RPTS, NOTEBOOKS, ETC
2014-4185	05/21/2014 06/19/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	DIANNE L CHAMBERS HOGAN LOVELLS LLP	GUGGISBERG CHEESE INC (DBA DEUTSCH HAUS) - WARNING LTR 2/23/09 CORR
2014-4186	05/21/2014 06/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WILLIAM WHITNEY CAHILL GORDON & REINDEL LLP	GLAXOSMITHKLINE LLC - LOVAZA PI. LTR 4/24/14
2014-4187	05/21/2014 06/19/2014	FDA/OC/OES/DFOI/	HINOJOSA #1899630, BENITO	DEPUY, JOHNSON & JOHNSON - HIP IMPLANT RPTS
2014-4188	05/21/2014 06/19/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	K MICHELLE VASSALLO LINCARE INC	WRIGHT & FILIPPIS INC, MI - EIRS, 483S, WARNING LTRS 1/98 TO PRESENT
2014-4189	05/21/2014 06/19/2014	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	K MICHELLE VASSALLO LINCARE INC	ALL MED LLC (SABER MEDICAL LLC), WV - EIRS, 483S, WARNING LTRS 1/98 TO PRESENT

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2014-4190	05/21/2014 06/19/2014	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	K MICHELLE VASSALLO LINCARE INC	PREFERRED HOMECARE, TX, UT - EIRS, 483S, WARNING LTRS 1/98 TO PRESENT
2014-4191	05/21/2014 06/19/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	K MICHELLE VASSALLO LINCARE INC	HOT SPRINGS COUNTY MEMORIAL HOSPITAL, WY - EIRS, 483S, WARNING LTRS 1/98 TO PRESENT
2014-4192	05/21/2014 06/19/2014	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/ FDA/OMPT/CDRH/OCER/DFOI/	AMBER C COISMAN Tressler LLP	TRINITY HEALTH CORP/LOYOLA UNIV MEDICAL CENTER, MAYWOOD, IL - MEDICAL MONITORING EQUIPMENT DAMAGED IN A FLOOD 4/18/13 RECS
2014-4193	05/21/2014 06/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	AMY L. GOERSS HODGSON RUSS LLP	CAM STRUCTSURE PRECISION MILLED BARS - BIOMET 3I INC K080864
2014-4194	05/21/2014 06/19/2014	FDA/OC/OES/DFOI/	AMBER C COISMAN Tressler LLP	TRINITY HEALTH CORP, CENTER FOR MEDICARE & MEDICAID SERVICES - MEDICAL MONITORING EQUIPMENT DAMAGED IN A FLOOD 4/18/13 CORR, RECS
2014-4195	05/21/2014 06/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	AMY L. GOERSS HODGSON RUSS LLP	ATLANTIS STRAUMANN BONE LEVEL ABUTMENT - DENTSPLY IMPLANT K130216
2014-4196	05/21/2014 06/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	LORI A CARR LORI A CARR INC	MEDICAL MODELING INC - VSP SYS DRIVER, WIRE, BONE DRILL MANUAL K133907
2014-4197	05/21/2014 06/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	AMY L. GOERSS HODGSON RUSS LLP	ISUS IMPLANT SUPRASTRUCTURES - DENTSPLY INTL INC K122424
2014-4198	05/21/2014 06/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	AMY L. GOERSS HODGSON RUSS LLP	STRAUMANN USA LLC - STRAUMANN VARIOBASE ABUTMENT NNC, STRAUMANN VARIOBASE ABUTMENT RN, STRAUMANN VARIOBASE ABUTMENT WN K132219
2014-4199	05/21/2014 06/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	AMY L. GOERSS HODGSON RUSS LLP	STRAUMANN USA - STRAUMANN CARES SCREW RETAINED BRIDGE TITANIUM, STRAUMANN CARES DOLDER BAR TITANIUM K112280
2014-4200	05/21/2014 06/19/2014	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Renata Lavach-Savy SCIMEDX CORPORATION	GOLD STANDARD DIAGNOSTICS - 483 12/19/2013 - 01/08/2014
2014-4201	05/21/2014 06/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John Huang Carlsbad Technology, Inc.	ANDA 75382 - APPROVAL LETTER

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		FDA/OMPT/CDER/ORP/DIDP/		
2014-4202	05/21/2014 06/19/2014	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	Aram Roston Buzzfeed News	HARMONEX NEUROSCIENCE - EIR, 483, COMPLAINTS ETC 01/01/2008 - 05/15/2014
2014-4203	05/21/2014 06/19/2014	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	Yvonne K Rumsey Rumsey, Marilyn	ALLINA HEALTH SYSTEM, MINNEAPOLIS, MN - 483, CORR, EIR 06/10/2013 - 09/09/2013
2014-4204	05/21/2014 06/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	james bennett DoseMe Pty LTd	K851573
2014-4205	05/21/2014 06/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jeff Cobb Jeff Cobb	K083720
2014-4206	05/21/2014 06/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	LORI A CARR LORI A CARR INC	MEDICAL MODELING INC - VSP SYS DRIVER, WIRE, BONE DRILL MANUAL K120956
2014-4207	05/21/2014 06/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	Karen Denny TECHLAB, Inc.	K021423
2014-4208	05/21/2014 06/19/2014	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Rachel Johnson FOI Services, Inc.	ASCEND, MONTVALE, NJ - EIR, 483, ETC
2014-4209	05/21/2014 06/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kylie Osterloh Leventhal, Brown, & Puga P.C.	DIAMONDBACK ORBITAL ATHERECTOMY DEVICE - CLINICAL TRIAL RECS 01/21/2009 - 05/20/2014
2014-4210	05/21/2014 06/19/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-10109
2014-4211	05/21/2014 06/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	AMY L. GOERSS HODGSON RUSS LLP	INSTITUTE STRAUMANN AG - STRAUMANN CARES BRIDGE; STRAUMANN CARES DOLDER BAR K101465
2014-4212	05/21/2014 06/19/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-679
2014-4213	05/21/2014 06/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SUSAN BEHRENS SUSAN BEHRENS	AVASTIN AERS
2014-4214	05/21/2014 06/19/2014	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Jay Trivedi Breeder's Choice Pet Foods	SAMPLE 802488 - ANALYTICAL RESULTS
2014-4215	05/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	AMY L. GOERSS	STRAUMANN NN CARES TITANIUM & CERAMIC

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	06/19/2014		HODGSON RUSS LLP	ABUTMENTS - INSTITUTE STRAUMANN AG K082545
2014-4216	05/21/2014 06/19/2014	FDA/OMPT/CTP/OD/	Stacy Ehrlich and Celeste Wheeler Kleinfeld, Kaplan, and Becker LLP	All submissions to CTP by Kleinfeld, Kaplan and Becker's client, Ioto USA, LLC and all CTP correspondence with Ioto.
2014-4217	05/21/2014 06/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	AMY L. GOERSS HODGSON RUSS LLP	STRAUMANN USA - STRAUMANN COMPUTER AIDED RESTORATION SERVICE CERAMIC COPING K061277
2014-4218	05/21/2014 06/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Girija Prasad Patro Natco Pharma Limited	ABRAXANE - SBA
2014-4219	05/21/2014 06/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Girija Prasad Patro Natco Pharma Limited	DOXIL - SBA
2014-4220	05/21/2014 06/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Girija Prasad Patro Natco Pharma Limited	LIPOSOMAL - SBA
2014-4221	05/21/2014 06/19/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	AMY L. GOERSS HODGSON RUSS LLP	NT TRADING GMBH & CO KG - TI BASE ABUTMENT 1 CONNECT ABUTMENT K111935
2014-4222	05/21/2014 06/19/2014	FDA/OGROP/ORAC/CE-FO/NWJ-DO/NWJ-CB/	Blake Goodner BRIDGER BIOMED INC	VALEANT PHARMACEUTICALS, BRIDGEWATER, NJ - 483, WARNING LETTERS, RESPONSE LETTERS 01/01/2013 - 05/19/2014
2014-4223	05/21/2014 06/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	AMY L. GOERSS HODGSON RUSS LLP	BIOMET 3I INC - CAM STRUCTSURE BARS K101582
2014-4224	05/21/2014 06/19/2014	FDA/OC/OES/DFOI/	Brian Depew Enstrom, Lipscomb & Lack	FOIA LOG 10/01/2013 TO 5/20/14
2014-4225	05/21/2014 06/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	AMY L. GOERSS HODGSON RUSS LLP	ZIMMER DENTAL INC - ZFX TITANIUM ABUTMENT, BASE ABUTMENT & ABUTMENT BLANK FOR NOBELACTIVE IMPLANT SYS K134045
2014-4226	05/21/2014 06/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Marc Elia BRIDGER CAPITAL LLC	QUESTCOR PHARMACEUTICALS, CANADA - 483, EIR, WARNING LETTER ETC 01/01/2012 - 05/19/2014
2014-4227	05/21/2014	FDA/OMPT/CDER/ORP/DIDP/		GERON CORP - IMETELSTAT LIVER TOXICITY RECS

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	06/19/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	VATZ, BERNARD W	
2014-4228	05/21/2014 06/19/2014	FDA/OC/OES/DFOI/	CAROLLO, RUSSELL	FOIA DATABASE SINCE 1/13
2014-4229	05/21/2014 06/19/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CLYTIE ADAMS CLYTIE ADAMS SCHOOL OF BALLET	LEVOFLOXACIU - AER
2014-4230	05/21/2014 06/19/2014	FDA/OC/OCC/ FDA/OGROP/ORAP/PA-FO/SAN- DO/SAN-CB/ FDA/OGROP/ORAP/PA-FO/SEA- DO/SEA-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	JOHN AGUIRRE TREON & AGUIRRE	ENDOGASTRIC SOLUTIONS INC - TRANSORAL INCISIONLESS FUNDOPLICATION RECS
2014-4231	05/21/2014 06/19/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FARYAL HASAN Hyman, Phelps & McNamara P.C.	GLAXOSMITHKLINE LLC - LOVAZA (OMEGA-3-ACID ETHYL ESTERS) NDA 21-654 LTR 4/24/14
2014-4232	05/21/2014 06/19/2014	FDA/OC/OES/DFOI/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	CDER, CBER, CDRH FOI DAILY LOGS 1/14 TO PRESENT
2014-4233	05/21/2014 06/19/2014	FDA/OGROP/ORAP/SW-FO/DEN- DO/DEN-CB/	MONTY CURRY ZYNEX MEDICAL	ZYNEX MEDICAL, LONE TREE, CO - EIR 6/3-10/09
2014-4234	05/22/2014 06/20/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Catherine Vassilkova INDEPENDENCE LEGAL SUPPORT	NDA 020638 - ORIGINAL LABELING
2014-4235	05/22/2014 06/20/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Laura Hobbs LexisNexis CourtLink Document Retrieval	FOIA REQUESTS RE FARNESOID X RECEPTOR ETC

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2014-4236	05/22/2014 06/20/2014	FDA/OC/OES/ FDA/OMPT/CDRH/OCER/DFOI/	Jim Finkle Reuters News	EMAIL, CORR BETWEEN FDA AND BARNABY JACK RE MEDICAL DEVICE SECURITY 06/01/2011 - 09/10/2013
2014-4237	05/22/2014 06/20/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Megan Sullivan Faruqi & Faruqi, LLP	Chelsea Therapeutics International - SPA
2014-4238	05/22/2014 06/20/2014	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	Department of Army Brooke Army Medical Center Maloney, Tabitha J	OSIRIS - 483 RESPONSE 06/04/2014 - 05/20/2014
2014-4239	05/22/2014 06/20/2014	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	Rachel Johnson FOI Services, Inc.	JUBILANT HOLLISTER-STIER, SPOKANE, WA - EIR
2014-4240	05/22/2014 06/20/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Matt Wiechert Uni Exporter (Texas) LLC	ANI PHARMACEUTICALS - 11/9/12 LETTER TO FDA, CDER CONFERENCE CALL NOTES CORR ETC
2014-4241	05/22/2014 06/20/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Matt Wiechert Uni Exporter (Texas) LLC	OPIUM TINCTURE - AERS
2014-4242	05/22/2014 06/20/2014	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	Gwendolyn Soha & Lang, PS	CONANGRA, RALCORP, CEDAR RAPIDS, IA - CORR, NOTES, LAB RESULTS ETC
2014-4243	05/22/2014 06/20/2014	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2013-8252
2014-4244	05/22/2014 06/20/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Peter Gerold Gerold, Peter J	LEXISCAN - AERS
2014-4245	05/22/2014 06/20/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	OMT LLC OMT LLC	K042454
2014-4246	05/22/2014 06/20/2014	FDA/OMPT/CDRH/OCER/DFOI/	Vik Bajnath ARTHREX INC	Device event key 3774068, Device key 3787237
2014-4247	05/22/2014 06/20/2014	FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	Jane Bentley Alcon Labs, Inc.	COOPER VISION CARIBBEAN CORPORATION, JUANA DIAZ, PUERTO RICO - 483 12/10/2013 - 01/10/2014

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2014-4248	05/22/2014 06/20/2014	OC/CVM/OCD/	Jim Strickland WSB-TV	CVM ADE Comprehensive Clinical Data Report for Spinosad, Milbemycin Dog with Oral route of administration
2014-4249	05/22/2014 06/20/2014	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Matt Wiechert Uni Exporter (Texas) LLC	ANIP ACQUISITION COMPANY MINNESOTA - 483 01/01/2010 - 06/30/2014
2014-4250	05/22/2014 06/20/2014	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	Health information summary for Timber Wolf Fine Cut Wintergreen
2014-4251	05/22/2014 06/20/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jaya Ayyagari DR. REDDY'S LABORATORIES INC	NDA 021602 SBA
2014-4252	05/22/2014 06/20/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Allison Adonizio Digitas Health	COPAXONE PI FROM 1996
2014-4253	05/22/2014 06/20/2014	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	Health information summary for Oliver Twist Original Chewing Tobacco Bits
2014-4254	05/22/2014 08/11/2014	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Rachel Johnson FOI Services, Inc.	EIR for Bayer Healthcare, Berkeley, CA
2014-4255	05/22/2014 06/20/2014	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Matt Wiechert Uni Exporter (Texas) LLC	ANIP ACQUISITION INC, BAUDETTE, MN - EIR, 483 09/27/2013 - 10/31/2013
2014-4256	05/22/2014 06/20/2014	FDA/OMPT/CDRH/OCER/DFOI/	MINH KHOA MINH KHOA	K072859, K102592, K130735
2014-4257	05/22/2014 06/20/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Lily Huang Lily Huang	CDJ Holding, Inc., DBA Pacific BioLogic Co, Concord, CA - EIR MARCH 2013
2014-4258	05/22/2014 06/20/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Paul Ma Ma, Paul	QUARTERLY AERS DATA PRE 2004
2014-4259	05/22/2014 06/20/2014	FDA/OC/OES/DFOI/	Matt Wiechert Uni Exporter (Texas) LLC	AMNEAL PHARMACEUTICALS - 483 LAST FIVE YEARS 01/01/2010 - 06/30/2014
2014-4260	05/22/2014 06/20/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LESLIE SANDS LUPIN PHARMACEUTICALS, INC	HYCROCORTISON SNEOMYCIN SULFATE & POLYMYXIN B SULFATE - ANDA 65-219 SBA

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2014-4261	05/22/2014 06/20/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LESLIE SANDS LUPIN PHARMACEUTICALS, INC	LUPIN BIORESEARCH CENTER, PUNE, INDIA - EIRS 3/19-23/12
2014-4262	05/22/2014 06/20/2014	FDA/OMPT/CDRH/OCER/DFOI/	CHARLES YOO JUNG & ASSOCIATE	ENDOTEC - G990332 ORIGINAL IDE SUBMISSION, IDE AMENDMENTS & SUPPL 1 & 2, ETC 1/1/98 TO 6/30/06
2014-4263	05/22/2014 06/20/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KHALD M MOHAMED MEDAC PHARMA	ONCOTEC PHARMA PRODUKTION GMBH, SAXONY-ANHALT, GERMANY - EIRS, 483S 4/10/17/14
2014-4264	05/22/2014 06/20/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/CIN-DO/CIN-CB/	MICHAEL P CASEY CASEY BAILEY & MAINES PLLC	WICKLIFFE VETERINARY PHARMACY, LEXINGTON, KY - TOLTRAZURIL/PYRAMETHAMINE TESTING 3/14, 4/14
2014-4265	05/22/2014 06/20/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	YVONNE WU FROMMER LAWRENCE & HAUG LLP	ADVANCED TISSUE SCIENCES - G900155 (IDE) INVESTIGATIONAL DVC EXEMPTION
2014-4266	05/23/2014 06/23/2014	FDA/OMPT/CTP/OD/ FDA/OMPT/CDRH/OCER/DFOI/	Deepak Chadha SUNEVA Medical	DCPT1400405
2014-4267	05/23/2014 06/23/2014	FDA/OC/OES/DFOI/	Unknown Adi Mangafic	CORR TO ADI MANGAFIC
2014-4268	05/23/2014 06/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Binay Shah St Joseph Regional Medical Center	Pemetrexed induced Aseptic Meningitis
2014-4269	05/23/2014 06/23/2014	FDA/OGROP/ORO/SE-FO/NOL-DO/NOL-CB/	Jean Trimbo Integrity Nutraceuticals	RIDGECREST, COLUMBIA, TN - EIR 08/23/2011 - 11/28/2012
2014-4270	05/23/2014 06/23/2014	FDA/OFVM/CFSAN/OCD/EOS/	Brenda Goodman Consumer's Digest Magazine	DIETARY SUPPLEMENTS - NUMBER OF CAERS, MEDWATCH REPORTS LAST FIVE YEARS; REPORTS FOR DEXAPRINE XL; REPORTS FOR ROCK HARD FOR MEN,

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				ROCK HARD WEEKEND
2014-4271	05/23/2014 06/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dustin Block IPD ANALYTICS LLC	5/19/14 Effective Approval Letter for ANDA No. 078908 for Dexmethylphenidate Hydrochloride; 5/19/14 Effective Approval Letter for ANDA No. 079108 for Dexmethylphenidate Hydrochloride; 5/19/14 Effective Approval Letter for ANDA No. 202731 for Dexmethylphenidate Hydrochloride
2014-4272	05/23/2014 06/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Keith Paluch Bipore Inc.	FDA potential approval, notification or denial for the sale and marketing of Xenodine or Xenoderm (Iodine) Solution
2014-4273	05/23/2014 06/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	CONTRACEPTIVES - AERS
2014-4274	05/23/2014 06/23/2014	FDA/OGROP/ORO/ORO/DIOP/	Denise Malan Investigative News Network	OASIS DATA 2013
2014-4275	05/23/2014 06/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Jing Gu W.H.P.M., Inc.	WHPM BIORESEARCH & TECHNOLOGY CO, LTD - EIR 12/01/2010 - 01/31/2011
2014-4276	05/23/2014 06/23/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	BLA 103770 S 5161
2014-4277	05/23/2014 06/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K040049
2014-4278	05/23/2014 06/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Roberts Rachel Roberts	DEATH OUTCOMES FAERS
2014-4279	05/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	Lori Burns	K921480

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	06/23/2014		DSM Biomedical	
2014-4280	05/23/2014 06/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca Dandeker MORGAN LEWIS & BOCKIUS LLP	TARO PHARMACEUTICAL LTD, ONTARIO, CANADA - EIR 02/01/2014 - 02/28/2014
2014-4281	05/23/2014 06/23/2014	FDA/OC/OES/DFOI/	Lee Tilson Lee Tilson, individual	FDA-2014-N-0238 TRANSCRIPT
2014-4282	05/23/2014 06/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca Dandeker Morgan, Lewis & Bockius LLP	TARO PHARMACEUTICAL LTD, ONTARIO, CANADA - 483, EIR SUMMARY 02/01/2014 - 02/28/2014
2014-4283	05/23/2014 06/23/2014	FDA/OC/OES/DFOI/	Brian Depew Enstrom, Lipscomb & Lack	FOIA LOG 10/01/2013 TO 5/22/14
2014-4284	05/23/2014 06/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Adam Grossman Praedicat	HEPSERA, LETAIRIS, CAYSTON ETC - AERS
2014-4285	05/23/2014 06/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gretchen Devlin Gretchen Devlin	ACTH - AERS
2014-4286	05/23/2014 06/23/2014	FDA/OC/OES/DFOI/	Melissa McGuire Bass, Berry & Sims PLC	LIST OF LICENSED GRAIN ELEVATORS IN ARKANSAS
2014-4287	05/23/2014 06/23/2014	FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/	WALTER E. CHALKLEY THOMSON REUTERS	VICTOR BITON MD, LITTLE ROCK, AR - EIR, 483, CO RESP 5/6-10/13
2014-4288	05/23/2014 06/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	Becky Donahue Becky Donahue	K043194, K060505
2014-4289	05/23/2014 06/23/2014	FDA/OGROP/ORACE-FO/MIN- DO/MIN-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	UPSHER SMITH LABORATORIES, MAPLE GROVE, MN - EIR, 483, CO RESP 2/19 TO 3/3/14
2014-4290	05/23/2014 06/23/2014	FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	MASSIMO CORP, IRVINE, CA - EIR, 483, CO RESP 8/13/13 - 10/3/13
2014-4291	05/23/2014	FDA/OGROP/ORACE-FO/CHI-	WALTER E. CHALKLEY	CAREFUSION 2200 INC, VERNON HILLS, IL - EIR, 483, CO

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	06/23/2014	DO/CHI-CB/	THOMSON REUTERS (SCIENTIFIC) SAS	RESP 9/9/13 - 11/5/13
2014-4292	05/23/2014 06/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	CIPLA LTD, DHAR, INDIA - EIR, 483, CO RESP 2/25/13 - 3/1/13
2014-4293	05/23/2014 06/23/2014	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	BRISTOL MYERS SQUIBB MANUFACTURING CO, HUMACAO, PR - EIR, 483, CO RESP 1/29/14 - 2/20/14
2014-4294	05/23/2014 06/23/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	THOMAS E. YOUNG MD, LLC, LANSDALE, PA - EIR, 483, CO RESP 12/19/11 TO 1/12/12
2014-4295	05/23/2014 06/23/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	PI PHARMA INC, CAMPTON, KY - EIR, 483, CO RESP 1/29/13 - 2/22/13
2014-4296	05/23/2014 06/23/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	GE HEALTHCARE MEDICAL DIAGNOSTICS, PRINCETON, NJ - EIR, 483, CO RESP 1/8-30/13
2014-4297	05/23/2014 06/23/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	BIOCHEM LABORATORIES INC, LYNDHURST, NJ - EIR, 483, CO RESP 5/1-14/12
2014-4298	05/23/2014 06/23/2014	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	BIOTEST LABORATORIES INC, BROOKLYN PARK, MN - EIR, 483, CO RESP 8/28/13 - 9/13/13
2014-4299	05/23/2014 06/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	SUN PHARMACEUTICAL INDUSTRIES LTD, MUMBAI, INDIA - EIR, 483, CO RESP 11/13-16/13
2014-4300	05/23/2014 06/23/2014	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	IMPLADENT LTD, HOLLIS, NY - EIR, 483, CO RESP 9/12/13 - 10/3/13
2014-4301	05/23/2014 06/23/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	CARDIAC ASSIST INC, PITTSBURGH, PA - EIR, 483, CO RESP 1/24/14 - 2/7/14
2014-4302	05/23/2014 06/23/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	WALTER E. CHALKLEY THOMSON REUTERS	RUEME E. BIRHIRAY, INDIANAPOLIS, IN - EIR, 483, CO RESP 8/12/13 - 9/5/13

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			(SCIENTIFIC) SAS	
2014-4303	05/23/2014 06/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	SANUM KEHLBECK GMBH & CO KG, HOYA, GERMANY - EIR, 483, CO RESP 3/18-26/13
2014-4304	05/23/2014 06/23/2014	FDA/OGROP/ORR/SE-FO/SJN-DO/SJN-CB/ FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/	TRAVIS SCHAFTENAAR MANULIFE ASSET MANAGEMENT	COOPER COMPANIES, JUANA DIAZ, PR - 483 12/13 TO 1/14; STAFFORD TX 7/12 TO 8/12
2014-4305	05/23/2014 06/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	STEVEN R. SCOTT IPSEN BIOPHARMACEUTICALS INC	SOMAVERT (PEGVISOMANT) NDA 21-106 EFFICACY
2014-4306	05/23/2014 06/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TAMYRA TOOLE , JD, RN INFINITY PHARMACEUTICALS	IMBRUVICA (IBRUTINIB) NDA 205-552 - APRVL, MEDICAL RVW, STATISTICAL RVW
2014-4307	05/23/2014 06/23/2014	FDA/OGROP/ORR/CE-FO/CHIDO/CHI-CB/ FDA/OGROP/ORR/CE-FO/CINDO/CIN-CB/ FDA/OGROP/ORR/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORR/CE-FO/PHIDO/PHI-CB/ FDA/OGROP/ORR/NE-FO/NWEDO/NWE-CB/ FDA/OGROP/ORR/PA-FO/LOSDO/LOS-CB/ FDA/OGROP/ORR/PA-FO/SEADO/SEA-CB/ FDA/OMPT/CDRH/OCER/DFOI/	ROBERT KING FDA NEWS	PHILIPS HEALTHCARE, SAN DIEGO, CA; PHILIPS BURTON, FRANKLIN PARK, IL; PHILIPS MEDICAL SYSTEMS NORTH AMERICA INC, BETHELL, WA - 483
2014-4308	05/27/2014 06/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	BARRY G STANIFORD NIPRO Diagnostics	NIPRO DIAGNOSTICS, FORT LAUDERDALE, FL - MW5035580
2014-4309	05/27/2014 06/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	ERIC THORN NATIONAL ASSOCIATION OF	807.37 ESTABLISHMENT REGISTRATION & DVC LISTING RECS ON KNOWN IMPORTERS; OF DENTAL DVCS

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		FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORO/CE-FO/CIN-DO/CIN-CB/	NAKAMURA	
2014-4318	05/27/2014 06/24/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Aydin Harston ROTHWELL, FIGG, ERNST & MANBECK, P.C.	QUTENZA, NDA 022395 EXCLUSIVITY DETERMINATION RECS
2014-4319	05/27/2014 06/24/2014	FDA/OC/OES/DFOI/	Adam Grossman Praedicat	2014-2955
2014-4320	05/27/2014 06/24/2014	FDA/OC/OES/DFOI/	Gretchen Devlin Gretchen Devlin	2014-3542
2014-4321	05/27/2014 06/24/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dawn VanBallegooyen Van Ballegooyen, Dawn P	MINOCIN - ADVERSE EVENTS
2014-4322	05/27/2014 06/24/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rosalie A. Lowe TWi International, LLC	NDA 019962
2014-4323	05/27/2014 06/24/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kevin Clay DRADIS Capital	PROVACTUS LETTER 5/16/14
2014-4324	05/27/2014 06/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	Lisa Bartakovics AVERY DENNISON	K811871
2014-4325	05/27/2014 06/24/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jordan Da Mauer Da Mauer, Jordan	TIROSINT - AERS
2014-4326	05/27/2014 06/24/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ting Chen Shionogi Inc.	NDA 203505 - MEDWATCH REPORTS

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2014-4327	05/27/2014 06/24/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2013-5658
2014-4328	05/27/2014 06/24/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2013-10119
2014-4329	05/27/2014 06/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	Lisa Bartakovics Avery Dennison	K801550
2014-4330	05/27/2014 06/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	Gary Syring Gary Syring	K934599
2014-4331	05/27/2014 06/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	Lori Burns DSM Biomedical	K931271
2014-4332	05/27/2014 06/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Genevieve Ness Belmont University	MEDWATCH REPORTS
2014-4333	05/27/2014 06/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jaya Ayyagari Dr.Reddys Laboratories Inc	ZANTAC 75 - LABELING
2014-4334	05/27/2014 06/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Leslie Gerwin PRINCETON UNIVERSITY	INVOKANA, FARXIGA - AERS
2014-4335	05/27/2014 06/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	Lyudmila Kipnis Datum Dental Ltd	K102531
2014-4336	05/27/2014 06/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sabrina Adams Adams, Sabrina	ESCITALOPRAM - AERS
2014-4337	05/27/2014 06/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Weston Nichols SunTrust	Transcript of the April 1, 2014 Meeting of the Endocrinologic and Metabolic Drugs Advisory Committee
2014-4338	05/27/2014	FDA/OGROP/ORR/SE-FO/ATL-	James Starr	ENCO Pharmaceutical Services Inc., Cary, NC - INSPECTION

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	06/24/2014	DO/ATL-CB/	James Starr (Personal)	RECS 12/01/2013 TO PRESENT
2014-4339	05/27/2014 06/24/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OCC/	Connor Sheets International Business Times	NANOMATERIALS, NANOPARTICLES, NANOFOODS ETC - RECS WITH FDA 01/01/2007 - 05/20/2014
2014-4340	05/27/2014 06/24/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Jan Keppeler HSBC	MAQUET - 483 01/01/2013 - 05/26/2014
2014-4341	05/27/2014 06/24/2014	FDA/OC/OES/DFOI/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Lauren Gilger KNXV-TV	CONCEPTUS, BAYER HEALTHCARE - 483 01/01/1999 - 05/26/2014
2014-4342	05/27/2014 06/24/2014	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	James Starr James Starr (Personal)	ENCO PHARMACEUTICALS, JACKSONVILLE, FL - INSPECTION RECS 12/01/2013 - 06/30/2014
2014-4343	05/27/2014 06/24/2014	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Dalena DeGrazia Grunenthal USA, Inc.	TEIKOKU SEIYAKU CO LTD - 482, 483, EIR ETC RE MARCH 2014 INSPECTION
2014-4344	05/27/2014 06/24/2014	FDA/OC/OES/DFOI/ FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	Chirag Talati Espirito Santo Investment Bank	MORTON GROVE PHARMACEUTICALS - 483, EIR 01/01/2010 - 05/27/2014
2014-4345	05/27/2014 06/24/2014	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	Pallavi Ail The Financial Express	WOCKHARDT MORTON GROVE, IL - MOST RECENT 483 01/01/2013 - 05/27/2014
2014-4346	05/27/2014 06/24/2014	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	Prashant Premkumar East Bridge Capital Management Limited	MORTON GROVE PHARMACEUTICALS - 483 01/01/2012 - 05/27/2014
2014-4347	05/28/2014 06/25/2014	FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECS
2014-4348	05/28/2014 06/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	DAVID G ADAMS VENABLE LLP	MEDIFOCUS - P030006
2014-4349	05/28/2014 06/25/2014	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	ALEXANDER RODRIGUEZ III BOONE & ROCHELEAU	CABERGOLINE - AERS 2002 TO 2012
2014-4350	05/28/2014 06/25/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OO/OFBA/OAGS/	DAVID L FERRERA NUTTER MCCLENNEN & FISH LLP	DAVID J LANGTON PHD, PXD LTD, UNIV HOSPITAL OF NORTH TEES - FDA-SOL-13-1119630; DEPUY - PINNACLE HIP IMPLANT, ETC RECS
2014-4351	05/28/2014	FDA/OMPT/CDRH/OCER/DFOI/	DAVID L FERRERA	THOMAS J JOYCE PHD, NEWCASTLE UNIV, UK - FDA-SOL-13-1119630, PROSTHETIC HIP IMPLANTS, ETC RECS

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	06/25/2014	FDA/OO/OFBA/OAGS/	NUTTER MCCLENNEN & FISH LLP	
2014-4352	05/28/2014 06/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	DAVID L FERRERA NUTTER MCCLENNEN & FISH LLP	ANTONI V F NARGOL PHD, UNIV HOSPITAL OF NORTH TEES, UK - PROSTHETIC HIP IMPLANTS; DEPUY - PINNACLE HIP IMPLANT RECS, ETC
2014-4353	05/28/2014 06/25/2014	FDA/OFVM/CFSAN/OCD/EOS/	JOHN R ENDRES AIBMR LIFE SCIENCES, INC	BASF CORP - SYNTHETIC LYCOPENE GRN 000119
2014-4354	05/28/2014 07/17/2014	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	AARON J FREIHALD LAYSER & FREIHALD PC	ST JAMES SMOKEHOUSE INC, MIAMI, FL - INSP RECS, VIOLATION NOTICES, MEMOS, ETC
2014-4355	05/28/2014 06/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	NICOLA PRICE XENON PHARMACEUTICALS INC	WYETH - PONDIMI (FENFLURAMINE HCL) NDA 16-618 SBA
2014-4356	05/28/2014 06/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	AZAPT - RPT
2014-4357	05/28/2014 06/25/2014	FDA/OC/OES/DFOI/	ROSS, DAVID	ACTHAR - FOIA LOG 2/1/14 TO PRESENT
2014-4358	05/28/2014 06/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	PREMARIN - AERS
2014-4359	05/28/2014 06/25/2014	FDA/OC/OES/DFOI/	Toni Clarke REUTERS	PREVIOUSLY RELEASED 483S FOR INDIAN DRUG COMPANIES 01/01/2013 - 05/28/2014
2014-4360	05/28/2014 06/25/2014	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2014-3570
2014-4361	05/29/2014 06/26/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Munjal Sheladia PureTek Corporation	ANDA 062124
2014-4362	05/29/2014 06/26/2014	FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/	Rachel Johnson FOI Services, Inc.	CON AGRA, AFTON, MO - COMPANY RESPONSES

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2014-4363	05/29/2014 06/26/2014	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	Uday Shetty Drug Regulations	WOCKHARDT, MORTON GROVE, IL - 483 01/01/2014 - 05/28/2014
2014-4364	05/29/2014 07/24/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	John Lockwood Safis Solutions LLC	BK060008
2014-4365	05/29/2014 06/26/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Paul E. Greenberg Analysis Group, Inc.	JANUVIA/JANUMET, BYETTA/BYDUREON, ONGLYZA ETC - REVIEWS 01/01/2013 - 05/27/2014
2014-4366	05/29/2014 06/26/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Brady Miller Brady Miller	SANOFI OPTICLIK 3ML CARTRIDGES OF LANTUS - ORANGE BOOK RECS 08/01/2004 - 05/27/2014
2014-4367	05/29/2014 06/26/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	Most recent QAP for WellSpring Pharmaceutical Canada
2014-4368	05/29/2014 06/26/2014	FDA/OMPT/CDRH/OCER/DFOI/	Chinedum Ojinnaka Chinedum Ojinnaka	MAMMOGRAPHY DATA 01/01/2010 - 05/30/2013
2014-4369	05/29/2014 06/26/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	sandy johnson Johnson, sandy W	LIPITOR - AERS
2014-4370	05/29/2014 06/26/2014	OC/CVM/OCD/	David L Fisher Freeport-McMoRan Sales Company	Manufacturing Chemistry technical section for Triangle Brand Copper Sulfate - Identifier INADA 010-046-Hoo6 dated 05/04/1999
2014-4371	05/29/2014 06/26/2014	OC/CVM/OCD/	Carolyn McKune DVM DACVAA Mythos Veterinary LLC	Ketamine Hydrochloride Injection (Ketaject) RECS
2014-4372	05/29/2014 06/26/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORAPPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Doe J	INDIVIDUAL RECS
2014-4373	05/29/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Alan Lucero	BIOLOGISCHE HEILMITTEL HEEL GMBH, GERMANY - 483 10/22/2012 - 10/31/2012

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	06/26/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GUNA Inc	
2014-4374	05/29/2014 06/26/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michael Metschl ORBIMED ADVISORS LLC	VELCADE - FAERS
2014-4375	05/29/2014 06/26/2014	OC/CVM/OCD/	Wendy Day Day, Wendy	NEXGARD - AERS
2014-4376	05/29/2014 06/26/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michael Metschl ORBIMED ADVISORS LLC	BELVIQ - ISR
2014-4377	05/29/2014 06/26/2014	FDA/OMPT/OSMP/OOPD/	H. Greg Thomas Kiel Laboratories, Inc.	PROTHROMBIN COMPLEX CONCENTRATE - ORPHAN DRUG DESIGNATION RECS
2014-4378	05/29/2014 06/26/2014	FDA/OC/OES/DFOI/	Doe J	SURGICAL MESH - RECALLS, AERS
2014-4379	05/29/2014 06/26/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Matthew C. Ashby Meyer Darragh Buckler Bebenek & Eck, PLLC	DRIVE MEDICAL ALUMINUM SHOWER CHAIR - AERS, INVESTIGATIONS, STUDIES ETC
2014-4380	05/29/2014 06/26/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jamey Duckworth Duckworth, Jamey	G070197 - WITHDRAWAL, INVESTIGATION, ETC
2014-4381	05/29/2014 06/26/2014	FDA/OMPT/CDRH/OCER/DFOI/	Blesson Abraham OsteoMed LLC	K933101, K971692
2014-4382	05/29/2014 06/26/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-1444
2014-4383	05/29/2014 06/26/2014	FDA/OMPT/CDRH/OCER/DFOI/	Mara Caler ALERE	K121214
2014-4384	05/29/2014 06/26/2014	FDA/OFVM/CFSAN/OCD/EOS/	Ann Oxford Albemarle Corporation	FCN 792
2014-4385	05/29/2014	FDA/OC/OES/DDM/	Donald Segal	MORE THAN MINIMALLY MANIPULATED ALLOGRAFT HEART VALVE RECS 01/01/2012 - 05/28/2014

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	06/26/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDRH/OCER/DFOI/	ALSTON & BIRD	
2014-4386	05/29/2014 06/26/2014	FDA/OMPT/CDRH/OCER/DFOI/	Lisa K. Klinedinst Roche Diagnostics Operations, Inc.	K011568
2014-4387	05/29/2014 06/26/2014	FDA/OGROP/ORR/SW-FO/DEN- DO/DEN-CB/	Andy Hsi Albuquerque Clinical Trials / Dr. Elizabeth M. Bretton	DR ELIZABETH BRETTON - INSPECTION RECS 10/22/2012 - 05/28/2014
2014-4388	05/29/2014 06/26/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Chirag Talati Espirito Santo Securities	SUN PHARMA - EIR, 483 01/01/2012 - 05/28/2014
2014-4389	05/29/2014 06/26/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PAMELA SHEPPARD TARO PHARMACEUTICALS USA INC	JACOBUS - DAPSONE TABS ANDA 86-842 SBA, MOR, LBLG, ETC
2014-4390	05/29/2014 06/26/2014	FDA/OMPT/CDRH/OCER/DFOI/	ANGELA BOUSE ARROW INTERNATIONAL INC	ARROW INTERNATIONAL INC - AVID-NIT LOSS OF RESISTANCE SYRINGE K001731
2014-4391	05/29/2014 06/26/2014	FDA/OMPT/CDRH/OCER/DFOI/	DAVID G ADAMS VENABLE LLP	P030006
2014-4392	05/29/2014 06/26/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORR/PA-FO/LOS- DO/LOS-CB/	GREGORY S WESTON WESTON FIRM	VIMAX - CONSUMER WARNING
2014-4393	05/29/2014 06/26/2014	FDA/OMPT/CDRH/OCER/DFOI/	MARCIA L BENEDICT STERIS CORP	IDSS SLC K133413
2014-4394	05/29/2014 06/26/2014	FDA/OC/OCC/ FDA/OMPT/OSMP/OCP/	GERALD STEEL Gerald Steel PE	RFD 130072, 130073, 130074
2014-4395	05/30/2014 06/27/2014	FDA/OFVM/CFSAN/OCD/EOS/	Richard Brogle Richard Brogle	PHENIBUT - AERS
2014-4396	05/30/2014 06/27/2014	OC/ORR/ OC/ORR/	Amy Harris Walters Bender Strohhahn &	RECORDS RE IMPORTATION OF ANIMAL FEED INGREDIENTS TO IOWA, INDIANA, MINNESOTA ETC 01/01/2012 - 05/01/2014

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		FDA/OGROP/ORO/ORO/DIOP/	Vaughan P.C.	
2014-4397	05/30/2014 06/27/2014	OC/CVM/OCD/ OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/CIN- DO/CIN-CB/	Amy Harris Walters Bender Strohhahn & Vaughan P.C.	FDA INVESTIGATION OF PORCINE EPIDEMIC DIARRHEA VIRUS 01/01/2012 - 05/01/2014
2014-4398	05/30/2014 06/27/2014	FDA/OMPT/CDRH/OCER/DFOI/	Mark H. Barbieri Barbieri, Mark H	K132447
2014-4399	05/30/2014 06/27/2014	FDA/OC/OES/DFOI/	ANDREW HACK, MD, PhD. MILLENNIUM MANAGEMENT LLC	2014-1629, 2014-2004, 2014-2158 ETC
2014-4400	05/30/2014 06/27/2014	FDA/OGROP/ORO/NE-FO/NYK- DO/NYK-DCB/ FDA/OC/OES/DFOI/ FDA/OGROP/ORO/CE-FO/PHI- DO/PHI-CB/	Adam Gomez WADE CLARK MULCAHY	MONGIELLO ITALIAN CHEESES DBA FORMAGGIO, HURLEYVILLE, NY - RECALL RECS; EURO FOODS, INC DBA CRITTERIO USA CORP, FREELAND, PA - CONTAMINATION RECS
2014-4401	05/30/2014 06/27/2014	FDA/OMPT/CDRH/OCER/DFOI/	Mark Burton AUDET & PARTNERS, LLP	K081275
2014-4402	05/30/2014 06/27/2014	FDA/OGROP/ORO/SE-FO/SJN- DO/SJN-CB/	Alfred Chester JOHNSON & JOHNSON	COOPER VISION, JUANA DIAZ, PR - 483 12/10/2013 - 01/10/2014
2014-4403	05/30/2014 06/27/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jessica Czamanski Biomedika Consulting LLC	K853770
2014-4404	05/30/2014 06/27/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Dr. Gareth James Simpleware Inc.	K073468
2014-4405	05/30/2014 06/27/2014	OC/ORO/ORM/ OC/ORO/ORM/	Robin Robin Guy Consulting, LLC	LIST OF LABORATORIES THAT RECEIVED 483 UNDER 21 CFR PART 58 10/01/2012 - 09/30/2013
2014-4406	05/30/2014 06/27/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 5/1-31/2014
2014-4407	05/30/2014 06/27/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	A list of all FOIA requests closed 5/1-31/2014
2014-4408	05/30/2014 06/27/2014	OC/ORO/OE/ OC/ORO/OE/	George Ball UNIVERSITY OF MINNESOTA	DRUG RECALL DATA 01/01/1974 - 01/01/2000
2014-4409	05/30/2014 06/27/2014	FDA/OMPT/CDRH/OCER/DFOI/	Gerwin Schalk WADSWORTH CENTER	K845035, K845042
2014-4410	05/30/2014	FDA/OO/OHR/	Dr. Thomas V. Montgomery, III	HHS-FDA-MP-14-1001027 SELECTION RECS

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	06/27/2014		Private Citizen - N/A	
2014-4411	05/30/2014 06/27/2014	FDA/OC/OES/DFOI/	Leslie Gerwin PRINCETON UNIVERSITY	2013-8569
2014-4412	05/30/2014 06/27/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/MIN-DO/MIN-CB/	Doe J	NEWMAN INC - NEWMAN O'S
2014-4413	05/30/2014 06/27/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CAROLINE STOUT ECOR1 CAPITAL LLC	LIST OF COMPANIES THAT HAVE REQUESTED BREAKTHROUGH THERAPY DESIGNATIONS TO THE FDA SINCE 1/13
2014-4414	05/30/2014 06/27/2014	FDA/OC/OES/DFOI/	CHRIS SZECHENYI ON POINT INVESTIGATIONS	THORATEC - EIRS, WARNING LTRS, CO RESP SINCE 2010
2014-4415	05/30/2014 06/27/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOSEPH SHUFORD LEGAL SERVICES OF SOUTHERN PIEDMONT	AH ROBINS - AMBAR AER, LBLG, RECALLS 3/69
2014-4416	05/30/2014 06/27/2014	FDA/OMPT/CDRH/OCER/DFOI/	KEVIN CHRISANTHOPOULOS ROBINSON DONOVAN MADDEN & BARRY	SMITH & NEPHEW ORTHOPAEDICS INC - CATALOG NO 71800113 6/7/06
2014-4417	05/30/2014 06/27/2014	FDA/OMPT/CDRH/OCER/DFOI/	KEVIN CHRISANTHOPOULOS ROBINSON DONOVAN MADDEN & BARRY	SMITH & NEPHEW ORTHOPAEDICS INC - CATALOG NO 71800113 4/29/11
2014-4418	05/30/2014 06/27/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OES/DFOI/ FDA/OGROP/ORO/CE-FO/PHI-DO/PHI-CB/	MARK R. KASTER DORSEY & WHITNEY LLP	SONOPTA GLOBAL ORGANIC INGREDIENTS INC, ALLENTOWN, PA - EIRS, CORR
2014-4419	05/30/2014 06/27/2014	FDA/OMPT/CDRH/OCER/DFOI/	CHRISTINA M. MIRACLE HILL ROM	LUNG ASSIST INC K132988
2014-4420	05/30/2014 06/27/2014	FDA/OGROP/ORO/CE-FO/CIN-DO/CIN-CB/	TOM QUINN Medical Resource Alliance	PHILIPS MEDICAL SYSTEMS, CLEVELAND, OH - 483 9/24/13 - 1/28/14
2014-4421	06/02/2014 06/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kevin Clay DRADIS Capital	PROVACTUS PHARMACEUTICALS - MTG MINUTES, TRANCRIPSTS 04/08/2010 - 12/16/2013

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2014-4422	06/02/2014 06/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca Dandeker Morgan, Lewis & Bockius LLP	TARO PHARMACEUTICALS, ONTARIO, CANADA - 483 02/01/2014 - 02/28/2014
2014-4423	06/02/2014 06/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anne Toland ATL Regulatory Consulting	SUN PHARMACEUTICALS - EIR, 483 NOV 2013 11/08/2013 - 05/28/2014
2014-4424	06/02/2014 06/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rosalie A. Lowe TWi International, LLC	NDA 022264 - QUALITATIVE FORMATION RECS
2014-4425	06/02/2014 06/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	reem mohamed FDB Health, First Databank	Structured Product Labeling for all products with the marketing category of Bulk Ingredients for Human Prescription Compounding
2014-4426	06/02/2014 06/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michael Metschl ORBIMED ADVISORS LLC	BELVIQ - ISR
2014-4427	06/02/2014 06/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ryan Dunnegan Kennedy Capital Management	INFeD - AERS
2014-4428	06/02/2014 06/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ryan Dunnegan Kennedy Capital Management	OMONTYS - AERS
2014-4429	06/02/2014 06/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ryan Dunnegan Kennedy Capital Management	VENOFER - AERS

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-4430	06/02/2014 06/30/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tariq REMS Logic, LLC	Number of REMS Drug Error Reports (by drug) from 2008 through 2013
2014-4431	06/02/2014 06/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	ANDROGEL - REPORTS, STUDIES, MEMOS ETC RE SPERM COUNT
2014-4432	06/02/2014 06/30/2014	FDA/OC/OES/DDM/ OC/CVM/OCD/	Claas Kirchhelle UNIVERSITY OF OXFORD	FDA COMMITTEE ON THE VETERINARY AND NON-MEDICAL USES OF ANTIBIOTICS - FINAL REPORTS
2014-4433	06/02/2014 06/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	Andrew Barlow ALKERMES INC	HANGZHOU FST PHARMACEUTICAL COMPANY LTD - QAP, EIR 05/05/2011 - 05/30/2014
2014-4434	06/02/2014 06/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Cecilia Cheung BIRD & BIRD LLP	NDA 020667 DRUG LABELS
2014-4435	06/02/2014 06/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	PAREXEL, UK - EIR , 483
2014-4436	06/02/2014 06/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	Helen Lewis DENTSPLY INTERNATIONAL	Request for Determination submitted by Medtronic Sofamor Danek USA for product line MD05-P novel regenerative bone substitute material for surgical treatment of periodontal disease, comprised of recombinant human growth factor and differentiation factor (rhGDF-5) and inorganic carrier beta-tricalcium phosphate (-TCP)
2014-4437	06/02/2014 06/30/2014	FDA/OGROP/ORAP/PA-FO/LOS- DO/LOS-CB/	Rachel Johnson FOI Services, Inc.	PAREXEL, GLENDALE, CA - EIR, 483
2014-4438	06/02/2014	FDA/OGROP/ORAP/NE-FO/NWE-	Rachel Johnson	PAREXEL, BILLERICA, MA - EIRs, 483

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	06/30/2014	DO/NWE-CB/	FOI Services, Inc.	
2014-4439	06/02/2014 06/30/2014	FDA/OC/OES/DFOI/	Kari L. Twaite BEVERIDGE & DIAMOND PC	CFSAN FOIA REQUESTS 04/25/2014 - 05/30/2014
2014-4440	06/02/2014 06/30/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-2761 - REQUEST LETTER ONLY
2014-4441	06/02/2014 06/30/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-3143 - REQUEST LETTER ONLY
2014-4442	06/02/2014 06/30/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-3262 - REQUEST LETTER ONLY
2014-4443	06/02/2014 06/30/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-3306 - REQUEST LETTER ONLY
2014-4444	06/02/2014 06/30/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-3322 - REQUEST LETTER ONLY
2014-4445	06/02/2014 06/30/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-3349 - REQUEST LETTER ONLY
2014-4446	06/02/2014 06/30/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-2704 - REQUEST LETTER ONLY
2014-4447	06/02/2014 06/30/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-3366 - REQUEST LETTER ONLY
2014-4448	06/02/2014 06/30/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-2663 - REQUEST LETTER ONLY
2014-4449	06/02/2014 06/30/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-3427 - REQUEST LETTER ONLY
2014-4450	06/02/2014 06/30/2014	FDA/OC/OES/DFOI/ FDA/OO/OFBA/OAGS/	Julie Pierce Capacity Builders Inc	DISTANCE LEARNING TELEMEDINCE - TOP RATED AWARD PROPOSAL
2014-4451	06/02/2014 06/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bindu Adhikari St Joseph Regional Medical Centre	PEMETREXED - AERS
2014-4452	06/02/2014 06/30/2014	FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/	David Mangione Govzilla, Inc.	HOSPIRA, MCPHERSON, KS - 483 04/14/2014 - 04/23/2014
2014-4453	06/02/2014 06/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELLIOT FAVUS FAVUS INSTITUTIONAL	IMBRUVICA (IBRUTINIB) - AERS 11/13/13 TO PRESENT

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RESEARCH LLC	
2014-4454	06/02/2014 06/30/2014	FDA/OC/OES/ FDA/OC/OES/DDM/ FDA/OFVM/CFSAN/OCD/EOS/	ANNA J FRANK FAEGRE BAKER DANIELS	SUNFLOWER SEED PRODS - SODIUM LBLG, CITIZENS PETITIONS 1/10 TO PRESENT; NATIONAL COMSUMERS LEAGUE - DAVID SUNFLOWER SEEDS PRODS LTR 7/28/11
2014-4455	06/02/2014 06/30/2014	FDA/OC/OES/DFOI/	KELLA BOWLES HANCE & SRINIVASAN	ZIMMER - TRILOGY AB HIP DVC P040048 WITHDRAWL STATUS
2014-4456	06/02/2014 06/30/2014	FDA/OFVM/CFSAN/OCD/EOS/	ALISA BOUCHEER BASF Chem. Co.	BASF CORP (CONGNIS CORP) - FCN 54 1999 TO 2001
2014-4457	06/02/2014 06/30/2014	FDA/OFVM/CFSAN/OCD/EOS/	ALISA BOUCHER BASF Chem. Co.	BASF CORP (COGNIS) - FCN 618 2006 TO 2007
2014-4458	06/02/2014 07/01/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Dustin Strickland GREER LABORATORIES, INC.	STALLERGENES - PRE-APPROVAL EIR, 483 06/01/2013 - 06/01/2014
2014-4459	06/03/2014 07/01/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED REQUESTS 5/19-23/14
2014-4460	06/03/2014 07/01/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS Consulting Group, LLC	ZHEJIANG JIUZHOU PHARMACEUTICAL CO LTD, ZHEJIANG, CHINA - 483, IMPORT ALERT 66-40
2014-4461	06/03/2014 07/01/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CLARLES CELESTE EAS Consulting Group, LLC	FRAGMIN NDA 20-287 - LBLG MEDICAL RVW, CHEMISTRY RVW, APRVL
2014-4462	06/03/2014 07/01/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	ERYTHROMYCIN NDA 61-621 - APRVL, LBLG, MEDICAL RVW, PHARMACOLOGY RVW, CHEMISTRY RVW
2014-4463	06/03/2014 07/01/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 5/19-23/14

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2014-4464	06/03/2014 07/01/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 5/19-23/14
2014-4465	06/03/2014 07/01/2014	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOI REQUESTS 5/19-23/14
2014-4466	06/03/2014 07/01/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 5/19-23/14
2014-4467	06/03/2014 07/01/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS Consulting Group, LLC	XINXIANG TUOXIN BIOCHEMICAL TECHNOLOGY & SCIENCE CO LTD, XINXIANG HENAN, CHINA - EIR, 483, 1/11 TO PRESENT
2014-4468	06/03/2014 07/01/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/	CHARLES CELESTE EAS Consulting Group, LLC	THE HEMISPHERE GROUP INC - ENTRY NO 595-48875752
2014-4469	06/03/2014 07/01/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOI REQUESTS 5/12-16/14
2014-4470	06/03/2014 07/01/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 5/12-16/14
2014-4471	06/03/2014 07/01/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 5/12-16/14
2014-4472	06/03/2014 07/01/2014	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	2014-3348
2014-4473	06/03/2014 07/01/2014	FDA/OMPT/CDRH/OCER/DFOI/	Victoria Shoemaker CASSIDAY SCHADE LLP	KIMBERLY CLARK IN-LINE CLOSED SYSTEM SUCTION CATHETERS - AERS
2014-4474	06/03/2014 07/01/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Linda Bowen SANOFI	NOVACYL THAILAND LIMITED, THAILAND - EIR 04/21/2014 - 04/25/2014
2014-4475	06/03/2014 07/01/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Andrea Demakas ADVERSEEVENTS INC	QSYMIA AERS
2014-4476	06/03/2014	FDA/OMPT/CDER/ORP/DIDP/	Andrea Demakas	QUDEXY XR, AVEED AERS

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	07/01/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ADVERSEEVENTS INC	
2014-4477	06/03/2014 07/01/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Andrea Demakas ADVERSEEVENTS INC	ZOCOR, CRESTOR, PRAVACHOL- AERS
2014-4478	06/03/2014 07/01/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	SUNOVION PHARMACEUTICALS, MARLBOROUGH, MA - EIR April 24 - May 24, 2013
2014-4479	06/03/2014 07/01/2014	FDA/OMPT/CDRH/OCER/DFOI/	Anna Sineva myself	HUBBARD E-METER, SCIENTOLOGY E-METER, SCIENTOLOGY AUDITING DEVICE ETC 01/01/2011 - 06/02/2014
2014-4480	06/03/2014 07/01/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Houria Khelifati SANDOZ CANADA INC.	OMIDRIA RELEASABLE RECS
2014-4481	06/03/2014 07/01/2014	OC/ORA/ORM/ OC/ORA/ORM/	Michael Pfeiffer NORTHCOAST RESEARCH	MEDICAL DEVICE FACILITY INSPECTIONS LIST 06/01/2013 - 06/02/2014
2014-4482	06/03/2014 07/01/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K112870
2014-4483	06/03/2014 07/01/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Andrea Demakas ADVERSEEVENTS INC	LIPTRUZET- AERS
2014-4484	06/03/2014 07/01/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	GENZYME, CAMBRIDGE, MA - EIR, 483, RESPONSE 9/30/13
2014-4485	06/03/2014 07/01/2014	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	Richard O. Wood the Wood Burditt group	DECEMBER 2003 LETTER RE CONSENT DECREE BETWEEN FDA AND ABBOTT
2014-4486	06/03/2014 07/01/2014	FDA/OMPT/CDRH/OCER/DFOI/	MELISSAEGAN, PhD. WATERS CORP	WATERS CORP, MANCHESTER, UK - IDE NO 1040123
2014-4487	06/03/2014 07/01/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JESSICA WARREN INTERCEPT PHARMACEUTICALS INC	VIGAYSRI ORGANICS, JINNARAM MANDEL, INDIA; ALMAC PHARMA SERVICES, CRAIGAVON, GREAT BRITAIN; PIRAMAL HEALTHCARE PHARMA SOLUTIONS, MORPETH,

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		GREAT BRITAIN - 483
2014-4488	06/03/2014 07/01/2014	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOI REQUESTS 5/12-16/14
2014-4489	06/03/2014 07/01/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 5/12-16/14
2014-4490	06/03/2014 07/01/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JEFFERS DC U26978, DAVID	TERAZOSIN - AER, LIST OF FL FDA OFFICES
2014-4491	06/03/2014 07/01/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOI REQUESTS 5/5-9/14
2014-4492	06/03/2014 07/01/2014	FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Lindsey Goldstein Bell Nunnally and Martin LLP	CORR FROM CHRISTOPHER PULLING TO FDA RE EMKINETICS, DR DANIEL BURNETT 11/03/2012 - 06/02/2014
2014-4493	06/03/2014 07/01/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 5/5-9/14
2014-4494	06/03/2014 07/01/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 5/5-9/14
2014-4495	06/03/2014 07/01/2014	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOI REQUESTS 5/5-9/14
2014-4496	06/03/2014 07/01/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 5/5-9/14
2014-4497	06/03/2014 07/01/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Linda Bowen SANOFI	EMCURE PHARMACEUTICALS LIMITED, INDIA - 483 FEBRUARY 2014
2014-4498	06/03/2014 07/01/2014	FDA/OGROP/ORO/CE-FO/DET-DO/DET-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Soma Das The Economic Times, The Times of India	SUN PHARMA CARACO, DETROIT, INDIA - 483 08/01/2013 - 06/03/2014

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-4499	06/03/2014 07/01/2014	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	DUONG NGUYEN, MD, LITTLE ROCK, AR - EIR 10/7/11
2014-4500	06/03/2014 07/01/2014	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	THOMAS A GRUGLE, MD, DALLAS, TX - EIR 9/20/11
2014-4501	06/03/2014 07/01/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Allison Tarantino ARIAD Pharmaceuticals, Inc.	ICLUSIG - AERS
2014-4502	06/03/2014 07/01/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lisa Wright Cote Orphan Consulting	NDA 020357
2014-4503	06/03/2014 07/01/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Beatriz Proy Vega Medic science Department, Medicine Faculty of Albacete	TETRAZEPAM - AERS
2014-4504	06/03/2014 07/01/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	DYNAMIT NOBEL GMBH, GERMANY - EIR, 483, RESPONSE 7/18/13
2014-4505	06/03/2014 07/01/2014	FDA/OMPT/CTP/OD/	Toni Clarke REUTERS	REVIEW OF EMAIL FROM JED ROSE TO MITCHELL ZELLER 09/26/2013 - 06/02/2014
2014-4506	06/03/2014 07/01/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOI REQUESTS 4/28/14-5/2/14
2014-4507	06/03/2014 07/01/2014	FDA/OMPT/CDRH/OCER/DFOI/	Bob Janisch Ativa Medical	K032677
2014-4508	06/03/2014 07/01/2014	FDA/OO/OFBA/OAGS/	PRADEEP KUMAR ALL AMERICAN BIO PHARMA	FOOD ALLERGEN MULTIPLEX ASSAY SOLICITATION FDA-SOL-1113543
2014-4509	06/03/2014 07/01/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 4/28/14-5/2/14

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2014-4510	06/03/2014 07/01/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	HELFAND, ARTHUR	CMPLNT 136876
2014-4511	06/03/2014 07/01/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 4/28/14-5/2/14
2014-4512	06/03/2014 07/01/2014	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOI REQUESTS 4/28/14-5/2/14
2014-4513	06/03/2014 07/01/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 4/28/14-5/2/14
2014-4514	06/03/2014 07/01/2014	FDA/OC/OES/DFOI/	SPENCER C. THOMAS GIDEON COOPER & ESSARY	2003-8962, 2003-10347, 2003-11962, 2003-15060, 2004-607, 2004-18508 ETC
2014-4515	06/03/2014 07/01/2014	FDA/OMPT/CTP/OD/	GREGORY N. CONNOLLY, DMD, MPH HARVARD SCHOOL OF PUBLIC HEALTH CENTER FOR GLOBAL TOBACCO CONTROL	LIST OF HARMFUL CONSTITUENTS
2014-4516	06/03/2014 07/01/2014	FDA/OMPT/CTP/OD/	GREGORY N. CONNOLLY DMD, MPH HARVARD SCHOOL OF PUBLIC HEALTH CENTER FOR GLOBAL TOBACCO CONTROL	LIST OF INGREDIENTS
2014-4517	06/03/2014 07/01/2014	FDA/OMPT/CTP/OD/	GREGORY N. CONNOLLY DMD, MPH HARVARD SCHOOL OF PUBLIC HEALTH CENTER FOR GLOBAL TOBACCO CONTROL	CIGARETTES - CONTENT
2014-4518	06/03/2014 07/01/2014	FDA/OMPT/CTP/OD/	GREGORY N. CONOLLY DMD, MPH HARVARD SCHOOL OF PUBLIC HEALTH CENTER FOR GLOBAL TOBACCO CONTROL	NUMBER OF DOCUMENTS SUBMITTED TO FDA REGARDING PHYSIOLOGICAL EFFECTS OF TOBACCO PRODUCTS
2014-4519	06/04/2014 07/02/2014	FDA/OC/OES/DFOI/	DEBI L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 4/28/14-5/2/14
2014-4520	06/04/2014 07/02/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 5/5-9/14

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2014-4521	06/04/2014 07/02/2014	FDA/OC/OES/DFOI/	DEBI L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 5/12-16/14
2014-4522	06/04/2014 07/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JEREMY SCHULZE MICHAELS & MAY, PC	BAXTER, SCIENTIFIC PROTEIN LABORATORIES LLC, CHANGZHOU SPL - HEPARIN AERS, INVESTIGATIONS, ANALYSIS, ETC 2007 TO PRESENT
2014-4523	06/04/2014 07/02/2014	FDA/OC/OES/DFOI/	WILLIAM A OLSON Center for Regulatory Services,Inc.	FOI DAILY LOG 4/28/14-5/2/14
2014-4524	06/04/2014 07/02/2014	FDA/OC/OES/DFOI/	WILLIAM A OLSON Center for Regulatory Services,Inc.	FOI DAILY LOG 5/5-9/14
2014-4525	06/04/2014 07/02/2014	FDA/OC/OES/DFOI/	WILLIAM A OLSON Center for Regulatory Services,Inc.	FOI DAILY LOG 5/12-16/14
2014-4526	06/04/2014 07/02/2014	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 4/28/14-5/2/14
2014-4527	06/04/2014 07/02/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OES/DDM/	MICHAEL F JACOBSON PHD CENTER FOR SCIENCE IN THE PUBLIC INTEREST	H LEE, F ELLISON - ADVANTAME MEMOS 7/28/09, 12/26/12, 11/24/09, ETC
2014-4528	06/04/2014 07/02/2014	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 5/5-9/14
2014-4529	06/04/2014 07/02/2014	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 5/12-16/14
2014-4530	06/04/2014 07/02/2014	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 4/28/14-5/2/14
2014-4531	06/04/2014 07/02/2014	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 5/5-9/14
2014-4532	06/04/2014 07/02/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 4/28/14-5/3/14
2014-4533	06/04/2014 07/02/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 5/5-10/14
2014-4534	06/04/2014 07/02/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 5/12-17/14

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2014-4535	06/04/2014 07/02/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 4/28/14-5/2/14
2014-4536	06/04/2014 07/02/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 5/5-9/14
2014-4537	06/04/2014 07/02/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 4/28/14-5/2/14
2014-4538	06/04/2014 07/02/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 5/5-9/14
2014-4539	06/04/2014 07/02/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 5/12-16/14
2014-4540	06/04/2014 07/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ayesha Adil The Weinberg Group	ANDA 076775 S018
2014-4541	06/04/2014 07/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michelle Elizabeth Legiec Eagle Pharmaceuticals, Inc.	OLON SPA, RODANO, ITALY - EIR 02/01/2014 - 03/01/2014
2014-4542	06/04/2014 07/02/2014	FDA/OMPT/CDRH/OCER/DFOI/	Bob Janisch Ativa Medical	K032013
2014-4543	06/04/2014 07/02/2014	FDA/OMPT/CDRH/OCER/DFOI/	Bob Janisch Ativa Medical	K120771
2014-4544	06/04/2014 07/02/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Bob Janisch Ativa Medical	K060656
2014-4545	06/04/2014 07/02/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Helen Lewis DENTSPLY INTERNATIONAL	K130025
2014-4546	06/04/2014 07/02/2014	FDA/OMPT/CDRH/OCER/DFOI/	Todd Hildebrandt MEDIVATORS INC	K964264
2014-4547	06/04/2014 07/02/2014	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2014-506
2014-4548	06/04/2014 07/02/2014	FDA/OGROP/ORAC/CE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORAC/CE-FO/CIN-	Robin Guy ROBIN GUY CONSULTING LLC	CHANTEST, CLEVELAND, OH; AGILUX LABORATORIES, WORCESTER, MA; ALLERGENT INC, IRVINE, CA ETC - 483 FY 2013

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		DO/CIN-CB/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/ FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2014-4549	06/04/2014 07/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joanne Grego CSL BEHRING	8422586 9015516 9036193 ETC
2014-4550	06/04/2014 07/02/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kevin Liang MileStone Research Organization	K100237
2014-4551	06/04/2014 07/02/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Christina Jewett The Center for Investigative Reporting	SPINAL SOLUTIONS, MURRIETA, CA - EIR, 483, COMPLAINTS ETC 01/01/2009
2014-4552	06/04/2014 07/02/2014	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ OC/CVM/OCD/	KELLI J STILES JONES DAY	SCOTTS MIRACLE-GRO CO - WILD BIRD FOOD TESTING RECS
2014-4553	06/04/2014 07/02/2014	FDA/OMPT/CDRH/OCER/DFOI/	Bret Andre EyeReg Consulting, Inc.	K051430

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2014-4554	06/04/2014 07/02/2014	FDA/OMPT/CDRH/OCER/DFOI/	Bret Andre EyeReg Consulting, Inc.	K964528
2014-4555	06/04/2014 07/02/2014	FDA/OMPT/CDRH/OCER/DFOI/	Bret Andre EyeReg Consulting, Inc.	K062854
2014-4556	06/04/2014 07/02/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kevin Liang MileStone Research Organization	K974127
2014-4557	06/04/2014 07/02/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kevin Liang MileStone Research Organization	K871242
2014-4558	06/04/2014 07/02/2014	FDA/OMPT/CDRH/OCER/DFOI/	Bob Janisch Ativa Medical	K051215
2014-4559	06/04/2014 07/02/2014	FDA/OC/OES/ FDA/OFVM/CFSAN/OCD/EOS/	STEPHEN V D'AMORE WINSTON & STRAWN LLP	WESTERN SUGAR COOPERATIVE, MICHIGAN SUGAR CO, C & H SUGAR COMPANY INC, ETC - HIGH FRUCTOSE CORN SYRUP CORR, CMLPNTS, RPTS, ETC
2014-4560	06/04/2014 07/02/2014	FDA/OMPT/CDRH/OCER/DFOI/	Bob Janisch Ativa Medical	K972354
2014-4561	06/04/2014 07/02/2014	FDA/OMPT/CDRH/OCER/DFOI/	Bret Andre EyeReg Consulting, Inc.	K051430
2014-4562	06/04/2014 07/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michelle Elizabeth Legiec Eagle Pharmaceuticals, Inc.	ZYDUS BSV PHARMA PVT LTD, INDIA - EIR 01/01/2014 - 01/31/2014
2014-4563	06/04/2014 07/02/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Victoria Rothwell Immunexpress	K070310
2014-4564	06/04/2014 07/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rowena Dodaro Alkermes Gainesville LLC	VIVITROL - 9293681, 9277381, 9310932
2014-4565	06/04/2014 07/02/2014	FDA/OMPT/CDRH/OCER/DFOI/	Helen Lewis DENTSPLY CAULK	K133752
2014-4566	06/04/2014 07/02/2014	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Genevive Blanchette ALGORITHMHE PHARMA INC	ADVANCE PHARMACEUTICALS INC, HOLTSVILLE, NY; CRI LIFE TREE LLC, MARLTON, NJ; INVENTIV HEALTH CLINIQUE INC, QUEBEC, CANADA ETC - 483 01/01/2013 - 12/31/2013

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		FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/		
2014-4567	06/04/2014 07/02/2014	FDA/OC/OES/DDM/ FDA/OMPT/CTP/OD/	JAMES S SHEHAN Hyman, Phelps & McNamara P.C.	REGULATION OF MENTHOL IN CIGARETTES - RECS 1/10 TO 12/11
2014-4568	06/04/2014 07/02/2014	FDA/OMPT/CDRH/OCER/DFOI/	Sandra Hansen Cutera, Inc.	K121695
2014-4569	06/04/2014 07/02/2014	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2014-3570
2014-4570	06/04/2014 07/02/2014	FDA/OMPT/CDRH/OCER/DFOI/	MICHELLE SIMARD KISSEL HIRSCH & WILMER LLP	23ANDME INC - PERSONAL GENOME SERVICES WARNING LTR 11/22/13; 3/12/13, 5/21/13 LTRS
2014-4571	06/04/2014 07/02/2014	FDA/OGROP/ORR/CE-FO/DET-DO/DET-CB/	Cheryl Profenius Quintiles Reseach	CLARITA KETELS, ST CLAIRE SHORES, MI - 483 2005
2014-4572	06/04/2014 07/02/2014	FDA/OFVM/CFSAN/OCD/EOS/	Eduardo Alarcon personal	EXCEL LIST OF MANUFACTURERS THAT HAVE FILED FORM 2511 06/01/1995 - 06/03/2014
2014-4573	06/04/2014 07/02/2014	FDA/OMPT/CDRH/OCER/DFOI/	ALLY BADUEL OSTEOMED CORP	NICO CORP - BRAIN PORT K120691
2014-4574	06/04/2014 07/02/2014	FDA/OMPT/CDRH/OCER/DFOI/	ALLY BADUEL OSTEOMED CORP	VYCOR - SURGICAL ACCESS SYSTEMS K060973
2014-4575	06/04/2014 07/02/2014	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DIALY LOG 5/19-23/14
2014-4576	06/04/2014 07/02/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DIALY LOG 5/19-23/14
2014-4577	06/04/2014 07/02/2014	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD Center for Regulatory Services, Inc.	FOI DIALY LOG 5/19-23/14
2014-4578	06/04/2014 07/02/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DIALY LOG 5/19-23/14
2014-4579	06/04/2014 07/02/2014	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION	FOI DIALY LOG 5/19-23/14

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2014-4580	06/04/2014 07/02/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DIALY LOG 5/19-23/14
2014-4581	06/04/2014 07/02/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DIALY LOG 5/19-23/14
2014-4582	06/04/2014 07/02/2014	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 5/12-16/14
2014-4583	06/04/2014 07/02/2014	FDA/OC/OES/DFOI/	LISA TARRISOIN-SCHRAMP CanReg, Inc.	FOI DIALY LOG 5/12-16/14
2014-4584	06/05/2014 07/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	LAVENIA FORD CARDINAL HEALTH	CARDINAL HEALTH 200 LLC - ACTI-GARD ANTIMICROBIAL INCISE DRAPE K000442
2014-4585	06/05/2014 07/03/2014	FDA/OGROP/ORAP/PA-FO/SAN-DO/SAN-CB/	DARREN K MCCARTNEY RUMBERGER KIRK & CALDWELL ATTY	FOSTER POULTRY FARMS, LIVINGSTON, CA - USDA COMM REGARDING STANDARDS FOR CLEANLINESS, SANITATION, PEST CONTROL, ETC
2014-4586	06/05/2014 07/03/2014	FDA/OO/OHR/	Doe J	INDIVIDUAL RECS
2014-4587	06/05/2014 07/03/2014	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORAP/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	ANDREA HENRY 23andMe	23ANDME INC - PERSONAL GENOME SERVICE (PGS) K121918, K122706
2014-4588	06/05/2014 07/03/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Doe J	HEPATITIS A & B VACCINE, FLU VACCINE - RECS
2014-4589	06/05/2014 07/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DON J MIZERK HUSCH BLACKWELL LLP	MYLAN PHARMA - CRESTOR (ROSUVASTATIN CALCIUM) ANDA 79-161 TENTATIVE APRVL LTS 7/2/13, LBLG; TEVA PHARMS - CRESTOR (ROSUVASTATIN CALCIUM) ANDA 79- 161 TENTATIVE APRVL LTR 3/11/14, LBLG, ETC
2014-4590	06/05/2014 07/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WARD, ADAM	ORTHO-MCNEIL, JANSSEN - RISPERDAL RECS
2014-4591	06/05/2014	FDA/OFVM/CFSAN/OCD/EOS/		STANDARD PROCESS INC, PALMYRA, WI - PROD RECALL NOTICE 6/29/12

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	07/03/2014	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	GUNTER, STEPHEN R	
2014-4592	06/05/2014 07/03/2014	OC/ORACE/ORM/ OC/ORACE/ORM/	LESLIE RAMSEY FDA NEWS	PHARMACEUTICAL, BIOLOGICS, MEDICAL DVC MFG, CLNCL TRIAL FACILITIES IINSIDE AND OUTSIDE THE US - 483S 4/1-31/14
2014-4593	06/05/2014 07/03/2014	FDA/OC/OES/DFOI/	WARREN ROJEWSKI NATIONWIDE INSURANCE	AXIOBIONICS LLC, ANN ARBOR, MI - RECALLS, WARNING LTRS, CO RESP
2014-4594	06/05/2014 07/03/2014	FDA/OC/OES/DFOI/	TOOTHE #234958, JAMES RAY	PROZAC, RITALIN, ZOLOFT, ETC - RECS
2014-4595	06/05/2014 07/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MICHAEL R COHEN RPH MS SCD INSTITUTE FOR SAFE MEDICATION PRACTICES	MEDWATCH RPTS CODED AS MEDICATION ERRORS 5/1-31/14
2014-4596	06/05/2014 07/03/2014	FDA/OGROP/ORACE-FO/LOS-DO/LOS-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	PRIMA PHARM INC, SAN DIEGO, CA - EIR, 483, CO RESP 6/10-18/13
2014-4597	06/05/2014 07/03/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	PETNET SOLUTIONS INC, CINCINNATI, OH - EIR, 483, CO RESP 5/13-17/13
2014-4598	06/05/2014 07/03/2014	FDA/OO/OFBA/OAGS/	EMILY SHAW ALL-SHRED INC	JCMCS - SHREDDING CONTRACT
2014-4599	06/05/2014 07/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	MERCK SERONO SPA, GUIDONIA MONTECELLO, ITALY - EIR, 483, CO RESP 3/11-14/13
2014-4600	06/05/2014 07/03/2014	FDA/OGROP/ORACE-FO/KAN-DO/KAN-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	MARCUS RESEARCH LAB INC, SAINT LOUIS, MO - EIR, 483, CO RESP 3/8-14/11
2014-4601	06/05/2014 07/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	WOCKHARDT LIMITED BADDI, NALAGARB, INDIA - EIR, 483, CO RESP 9/9-13/13
2014-4602	06/05/2014 07/03/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	RUGER CHEMICAL CO INC, LINDEN, NJ - EIR, 483, CO RESP 8/12-20/13

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2014-4603	06/05/2014 07/03/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	GURMEET S MULTANI MD, COLTON, CA - EIR, 483 CO RESP 1/14-29/13
2014-4604	06/05/2014 07/03/2014	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	OCTAPHARMA PLASMA INC, RICHMOND, VA - EIR, 483, CO RESP 8/20-26/13
2014-4605	06/05/2014 07/03/2014	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	WALTER E CHALKLEY THOMSON REUTERS	PARAGON RESEARCH CENTER, SAN ANTONIO, TX - EIR, 483, CO RESP 3/12-15/13
2014-4606	06/05/2014 07/03/2014	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	WATKINS INC, WINONA, MN - EIR, 483, CO RESP 6/26-28/13
2014-4607	06/05/2014 07/03/2014	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	LIFESOURCE, ROSEMONT, IL - EIR, 483, CO RESP 3/26/13 - 5/22/13
2014-4608	06/05/2014 07/03/2014	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	STEMCYTE INC, COVINA, CA - EIR, 483, CO RESP 3/4-12/13
2014-4609	06/05/2014 07/03/2014	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	ANA J FANDINO MD, MIAMI, FL - EIR, 483, CO RESP 5/6-22/13
2014-4610	06/06/2014 07/07/2014	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	SHARON SCANLON ALDI INC	ALDI INC, O'FALLON, MO - EIR 12/9/13
2014-4611	06/06/2014 07/07/2014	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Arthur Meisel, Esq.	2014-1156 - EXHIBIT 11.1-11.7, UMTB DEVIATION RPT D11-112, 482 1/3/12, 483 12/14/12, ETC
2014-4612	06/06/2014 07/07/2014	FDA/OFVM/CFSAN/OCD/EOS/	CYNTHIA B LIEBERMAN Keller and Heckman LLP	SMITHERS PIRA - FCN 1408
2014-4613	06/06/2014 07/07/2014	FDA/OC/OL/	THOMAS H JONES 339 GROUP LLC	CONGRESSMAN TRAVIS CHILDERS - CONGRESSIONAL CORR 5/08 TO 1/11
2014-4614	06/06/2014 07/07/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	McClanahan, Patrick	HOFFMAN-LA ROCHE, NUTLEY, NJ - EIR 12/6/02-1/9/03; LARIAM TABS NDA 19-591 - APRVL LTR, MOR, CHEMISTRY RVWS, ETC
2014-4615	06/06/2014	FDA/OFVM/CFSAN/OCD/EOS/	KEVIN D MICALE	INGREDION - PURIMUNE (GALACTO LOIGOSACCHARIDE)

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	07/07/2014	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	SMITH STAG LLC	RECALL RECS (CERTIFIED)
2014-4616	06/06/2014 07/07/2014	FDA/OC/OES/DFOI/	SHERIDAN, KEVIN L	AMINO ACID - RECS
2014-4617	06/06/2014 07/07/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELAINE S WALLER PHARM D MBA SEATTLE GENETICS INC	ADCETRIS (BRENTUXIMAB VEDOTIN) - AERS 9/13 TO 5/14
2014-4618	06/06/2014 07/07/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/ OC/ORA/ OC/ORA/	JAMIE GREY KTVB NEWS	EVERGREEN FRESH SPROUTS LLC, MOYIE, ID - E COLI OUTBREAK INVESTIGATION, TEST RESULTS
2014-4619	06/06/2014 07/07/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/ OC/ORA/ OC/ORA/	RUSS WALKER KING 5 TV	EVERGREEN FRESH SPROUTS LLC, MOYIE SPRINGS, ID - E COLI OUTBREAK INVESTIGATION RECS, TEST RESULTS
2014-4620	06/06/2014 07/07/2014	FDA/OC/OL/	THOMAS H JONES 339 GROUP LLC	CONGRESSMAN BRUCE BRALEY - CONGRESSIONAL CORR 1/07 TO PRESENT
2014-4621	06/06/2014 07/07/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	CHRIS SZECHENYI ON POINT INVESTIGATIONS	OVASCIENCE - THORATEC COMM 2012, 2013
2014-4622	06/06/2014 07/07/2014	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Rachel Johnson FOI Services, Inc.	HEINZ - EIR, 483
2014-4623	06/06/2014 07/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dr. Nayan Patel Central Drugs	ASPRO NICOLAS COMPANY - REPORT RE APPROVAL FOR HYDROQUINONE
2014-4624	06/06/2014 07/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John Schueler John Schueler	EIKEN CHEMICAL COMPANY, JAPAN - WARNING LETTER RECS, 483, RESPONSE ETC 11/01/2012 - 06/04/2014

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/		
2014-4625	06/06/2014 07/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	David von Wiegandt Branstetter Stranch & Jennings	AMNEAL GENERIC METAXALONE - APPROVAL PACKAGE
2014-4626	06/06/2014 07/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sam May- Refer to File 2013-8989 MAY, SAM	BPDR SUBMITTED BY AMGEN FOR EPOGEN, ARANESP, ETC
2014-4627	06/06/2014 07/07/2014	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	Dimitri Kollaras Dimitri Kollaras	THOMAS P TREVISANI - STUDY RECS, INVESTIGATION 01/01/2002 - 12/30/2004
2014-4628	06/06/2014 07/07/2014	FDA/OGROP/ORR/PA-FO/SAN-DO/SAN-CB/ OC/CVM/OCD/	Lauren Welling Phillips Law Firm	FOSTER FARMS - TESTING, INVESTIGATION 01/01/2012 - 06/04/2014
2014-4629	06/06/2014 07/07/2014	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	Matt Taylor BARCLAYS	HEARTWARE INTERNATIONAL - EIR, WARNING LETTER 01/01/2014 - 06/04/2014
2014-4630	06/06/2014 07/07/2014	OC/ORR/ OC/ORR/ FDA/OGROP/ORR/CE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORR/SW-FO/SWID/SWID-CB/	GM PRODUCE SALES GM PRODUCE SALES	MANGO LAB ANALYSIS
2014-4631	06/06/2014 07/07/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-1661
2014-4632	06/06/2014 07/07/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-1643
2014-4633	06/06/2014 07/07/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jonathan J. Darrow BRIGHAM AND WOMEN'S HOSPITAL	NME, BIOLOGICS APPROVED UNDER FAST TRACK PROGRAMS 6/1/10 TO 12/31/10
2014-4634	06/06/2014	FDA/OFVM/CFSAN/OCD/EOS/	Emilia Lonardo	STANDARDS OF IDENTITY RE PARTIALLY HYDROGENATED, HYDROGENATED OILS, TRANS FATS ETC 01/01/1906 -

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	07/07/2014		GROCERY MANUFACTURERS ASSOCIATION	06/30/1958
2014-4635	06/06/2014 07/07/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-2204
2014-4636	06/06/2014 07/07/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-1546
2014-4637	06/06/2014 07/07/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-541
2014-4638	06/06/2014 07/07/2014	FDA/OC/OES/DFOI/	Jennifer Edwards Wicker Smith O'Hara McCoy & Ford, P.A.	CONFORMIS KNEE PROSTHESIS - ADVERSE EVENTS, RECALLS 01/01/1990 - 06/04/2014
2014-4639	06/06/2014 07/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	Todd Hildebrandt MEDIVATORS INC	K120652
2014-4640	06/06/2014 07/07/2014	FDA/OC/OES/DFOI/	Jennifer Edwards Wicker Smith O'Hara McCoy & Ford, P.A.	MAKO KNEE PROSTHESIS - ADVERSE EVENTS, RECALLS 01/01/1990 - 06/04/2014
2014-4641	06/06/2014 07/07/2014	OC/ORO/ORM/ OC/ORO/ORM/	Michelle Ye Hee Lee THE ARIZONA REPUBLIC	LIST OF INSPECTED FACILITIES IN ARIZONA WITH OAI, VAI 01/01/2014 - 06/05/2014
2014-4642	06/06/2014 07/07/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Devon Morgan PERRIGO COMPANY	CIBA VISION CANADA, INC - EIR, 483 01/01/2009 - 06/05/2014
2014-4643	06/06/2014 07/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lisa McLaurin McLaurin, Lisa	LIST OF MEDICATIONS WITH FLUORINE
2014-4644	06/06/2014 07/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Martin Binnes Luthi & Co.	AVAPRO - APPROVED LABELING 09/30/1997
2014-4645	06/06/2014 07/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kristen Stewart Deutsche Bank / Kristen Stewart	SAPIEN XT - APPROVAL LETTER, INDICATIONS FOR USE; CLINICAL DATA
2014-4646	06/06/2014	FDA/OMPT/CDER/ORP/DIDP/	Kevin Minnich	NDA 020309, NDA 020488

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	07/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	B. Braun Medical Inc.	
2014-4647	06/06/2014 07/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOSEPH WALKER Walker, Joseph	OCA - AERS
2014-4648	06/06/2014 07/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John Huang Carlsbad Technology, Inc.	ANDA 75382 APPROVAL LETTER (CERTIFIED)
2014-4649	06/06/2014 07/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	Steven Meyer RetroVascular, Inc.	K040067
2014-4650	06/06/2014 07/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	Steven Meyer RetroVascular, Inc.	K080637
2014-4651	06/09/2014 07/08/2014	FDA/OC/OES/DFOI/	TORREY COPE SIDLEY AUSTIN LLP	2007-11314
2014-4652	06/09/2014 07/08/2014	FDA/OC/OES/DFOI/	TORREY COPE SIDLEY AUSTIN LLP	FOI REQUESTS 2007-1194 TO 2007-11384
2014-4653	06/09/2014 07/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	LEON AMENGLIO Lexington Medical, Inc.	OPTICAL SEPARTOR- K032676; BIOMARAC PRELOADED TISSUE MARKER DVC - K040720; MICROMEDICS FIBRIJET AIR ASSISTED ENDOSCOPIC APPLICATOR - K042741, ETC
2014-4654	06/09/2014 07/08/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PETER S REICHERTZ SHEPPARD MULLILN RICHTER ET AL	LUITPOLD PHARMACEUTICALS INC - SPRIX KETOROLAC TROMETHAMINE NASAL SPRAY NDA 22-382 AERS 4/13 TO PRESENT
2014-4655	06/09/2014 07/08/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JAMES E VALENTINE Hyman, Phelps & McNamara P.C.	NESINA (ALOGLIPTIN) TABS NDA 22-271 - RESULTS OF THE ONGOING EXAMINE TRIAL REFERRED TO AS STUDY 402 7/1/11 TO 1/31/13
2014-4656	06/09/2014 07/08/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORACE-FO/MIN- DO/MIN-CB/	DR STEPHEN R GUNTER GUNTER, STEPHEN R	STANDARD PROCESS INC, PALMYRA, WI - LOT NO 114 CONTAMINATED PRODS 2011, PRODUCT RECALL 6/29/12
2014-4657	06/09/2014	FDA/OC/OES/DFOI/	JENNIFER K REGISTER	BARD - COMPOSIX KEGEL MESH PATCH RECALL RECS

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	07/08/2014		BLASINGAME BURCH ET AL ATTYS	12/22/05
2014-4658	06/09/2014 07/08/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rohit Vanjani OPPENHEIMER	TIRF PRODUCTS - REMS
2014-4659	06/09/2014 07/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	CDRH/OC/DRMO Filed Operations Memo, Dated 09/20/2013 (ORA Concurrence No. 2013091301)
2014-4660	06/09/2014 07/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	Steven Meyer RetroVascular, Inc.	K032031
2014-4661	06/09/2014 07/08/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tariq Ata REMS Logic, LLC	Number of REMS Drug Error Reports (by drug) - from 2008 through 2013
2014-4662	06/09/2014 07/08/2014	FDA/OC/OES/DFOI/ FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Grant Morris Sanford Heisler, C/O Grant Morris	DEPUY ORTHOPAEDICS, INC, DEPUY INTERNATIONAL LTD, DEPUY SPINE - EIR 04/28/2009 - 02/16/2012
2014-4663	06/09/2014 07/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	Joshua Malamud Hyman, Phelps & McNamara P.C.	RECS REFLECTING HOW MANY HOURS IT TAKES TO REVIEW A 510K AND PMA FOR APPROVAL 01/01/2009 - 06/06/2014
2014-4664	06/09/2014 07/08/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	David Stone TransformativeMed Inc.	K071713
2014-4665	06/09/2014 07/08/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anna Edney BLOOMBERG NEWS	MICRO LABS, RPG LIFE SCIENCES, SENTISS PHARMA - 483
2014-4666	06/09/2014 07/08/2014	FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	Katie Griffith Truco Enterprises, LP	WARNOCK FOODS PRODUCTS, MADERA, CA - REPORT IN RESPONSE TO CALIFORNIA DEPARTMENT OF PUBLIC HEALTH INSPECTION 03/01/2014 - 03/31/2014
2014-4667	06/09/2014 07/08/2014	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	Susan Lewis Atlas Global Consulting	NEPHRON PHARMACEUTICALS CORPORATION, ORLANDO, FL - 483 02/10/2014 - 02/28/2014
2014-4668	06/09/2014 07/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	k122075 documents Besmed Health Business Corp.	K122075
2014-4669	06/09/2014	FDA/OMPT/CDER/ORP/DIDP/	Marc Elia	ACTHAR GEL - AERS

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	07/08/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRIDGER CAPITAL LLC	
2014-4670	06/09/2014 07/08/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Marc Elia BRIDGER CAPITAL LLC	Summary basis of approval for H.P. Acthar Gel for IS and other indication
2014-4671	06/09/2014 07/08/2014	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Jim C Illuminati Illuminati, Jim C	ASCEND LABORATORIES LLC, MONTVALE, NJ - 483 01/01/2013 - 12/30/2013
2014-4672	06/09/2014 07/08/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nathaniel Asamere PFIZER	NDA 19012 - SBA
2014-4673	06/09/2014 07/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	Dvir Lev-Ran Pinook usa	K132563
2014-4674	06/09/2014 07/08/2014	FDA/OC/OCC/ FDA/OFVM/CFSAN/OCD/EOS/	Michael O'Flaherty OLSSON FRANK WEEDA TERMAN MATZ PC	CFSAN/ONLDS DISCUSSION WITH OCC 01/01/2014 - 06/06/2014
2014-4675	06/09/2014 07/08/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ting Chen Shionogi Inc.	OSPHENA - AERS
2014-4676	06/09/2014 07/08/2014	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Chastity Rodriguez Rodriguez, Chastity	MED-LOGICS - WARNING LETTER, 483 LAST THREE YEARS
2014-4677	06/09/2014 07/08/2014	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Chastity Rodriguez Rodriguez, Chastity	INNOVATIVE HEALTHCARE CORPORATION - WARNING LETTER, 483 06/06/2011 - 06/06/2014
2014-4678	06/09/2014 07/08/2014	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ OC/ORA/ OC/ORA/	Michael Koch CENTRAL ADMIXTURE PHARMACY SERVICES INC	BANNER HEALTH, CHANDLER, AZ - 483, EIR 12/26/2013 - 06/05/2014
2014-4679	06/09/2014 07/08/2014	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Chastity Rodriguez Rodriguez, Chastity	KONAN MEDICAL USA - 483, WARNING LETTER 06/09/2011 - 06/09/2014

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2014-4680	06/09/2014 07/08/2014	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Chastity Rodriguez Rodriguez, Chastity	JEDMED INSTRUMENT CO - WARNING LETTER, 483 06/09/2011 - 06/09/2014
2014-4681	06/09/2014 07/08/2014	FDA/OC/OES/DFOI/	Chastity Rodriguez Rodriguez, Chastity	KIMBERLY CLARK, ROSWELL, GA - 483, WARNING LETTER 06/06/2011 - 06/06/2014
2014-4682	06/09/2014 07/08/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Chastity Rodriguez Rodriguez, Chastity	BECTON DICKINSON, CANAAN, CT - 483, WARNING LETTER 06/06/2011 - 06/06/2014
2014-4683	06/10/2014 07/09/2014	FDA/OC/OES/ FDA/OFVM/CFSAN/OCD/EOS/	Nathaniel Herz FasterSkier.com	All email correspondence between FDA executive staff and any email address with the domain @krispykreme.com
2014-4684	06/10/2014 07/09/2014	OC/ORASORM/ OC/ORASORM/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Leslie Ramsey FDA NEWS	LIST OF 483 05/01/2014 - 05/31/2014
2014-4685	06/10/2014 07/09/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Andrew Parker Wright MASSACHUSETTS GENERAL HOSPITAL	PRAVASTATIN, LOVASTATIN, FLUVASTATIN ETC - CONCENTRATION MAXIMUM, AREA UNDER THE CURVE 12/01/1986 - 01/01/1994
2014-4686	06/10/2014 07/09/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Alicia Holsey PFIZER	NDA 20516 SBA; NDA 19784 SBA
2014-4687	06/10/2014 07/09/2014	FDA/OC/OES/DFOI/	Meredith Wiegman NEPHRON PHARMACEUTICALS CORPORATION	NEPHRON PHARMACEUTICALS CORPORATION, ORLANDO, FL - FOIA REQUESTS FOR 483 02/01/2014 - 06/06/2014
2014-4688	06/10/2014 07/09/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	LEON AMARIGLIO Lexington Medical, Inc.	K133938
2014-4689	06/10/2014 07/09/2014	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Chastity Rodriguez Rodriguez, Chastity	ARKANSAS LIONS EYE BANK & LABORATORY - WARNING LETTER, 483 06/09/2011 - 06/09/2014
2014-4690	06/10/2014 07/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	LEON AMARIGLIO Lexington Medical, Inc.	K132493
2014-4691	06/10/2014 07/09/2014	FDA/OC/OES/DDM/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Alessandra Bazzano TULANE UNIVERSITY	DOMPERIDONE - TRANSCRIPTS, MEETING NOTES 01/01/1994 - 06/07/2004

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2014-4692	06/10/2014 07/09/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Doe J	INDIVIDUAL RECS
2014-4693	06/10/2014 07/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	LEON AMARIGLIO Lexington Medical, Inc.	K131705
2014-4694	06/10/2014 07/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	LEON AMARIGLIO Lexington Medical, Inc.	K130717
2014-4695	06/10/2014 07/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	LEON AMARIGLIO Lexington Medical, Inc.	K103263
2014-4696	06/10/2014 07/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	LEON AMARIGLIO Lexington Medical, Inc.	K102291
2014-4697	06/10/2014 07/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	LEON AMARIGLIO Lexington Medical, Inc.	K083519
2014-4698	06/10/2014 07/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	LEON AMARIGLIO Lexington Medical, Inc.	K082659
2014-4699	06/10/2014 07/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	LEON AMARIGLIO Lexington Medical, Inc.	K081169
2014-4700	06/10/2014 07/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	LEON AMARIGLIO Lexington Medical, Inc.	K113706
2014-4701	06/10/2014 07/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	LEON AMARIGLIO Lexington Medical, Inc.	K122352
2014-4702	06/10/2014 07/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	LEON AMARIGLIO Lexington Medical, Inc.	K111411
2014-4703	06/10/2014 07/09/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	LEON AMARIGLIO Lexington Medical, Inc.	K111622
2014-4704	06/10/2014 07/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	LEON AMARIGLIO Lexington Medical, Inc.	K103508
2014-4705	06/10/2014 07/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	LEON AMARIGLIO Lexington Medical, Inc.	K103509
2014-4706	06/10/2014 07/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	LEON AMARIGLIO Lexington Medical, Inc.	K103510
2014-4707	06/10/2014 07/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	LEON AMARIGLIO Lexington Medical, Inc.	K112358
2014-4708	06/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	LEON AMARIGLIO	K090821

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	07/09/2014		Lexington Medical, Inc.	
2014-4709	06/10/2014 07/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	LEON AMARIGLIO Lexington Medical, Inc.	K120215
2014-4710	06/10/2014 07/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	LEON AMARIGLIO Lexington Medical, Inc.	K101378
2014-4711	06/10/2014 07/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	LEON AMARIGLIO Lexington Medical, Inc.	K100723
2014-4712	06/10/2014 07/09/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	LEON AMARIGLIO Lexington Medical, Inc.	K121474
2014-4713	06/10/2014 07/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	LEON AMARIGLIO Lexington Medical, Inc.	K131303
2014-4714	06/10/2014 07/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	LEON AMARIGLIO Lexington Medical, Inc.	K133499
2014-4715	06/10/2014 07/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	LEON AMARIGLIO Lexington Medical, Inc.	K130738
2014-4716	06/10/2014 07/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	LEON AMARIGLIO Lexington Medical, Inc.	K131511
2014-4717	06/11/2014 07/10/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Kelly Castaneda - Lead Internal Auditor SUNQUEST INFORMATION SYSTEMS INC	PARTNERSHIP HEALTHCARE SYSTEM, CAMBRIDGE, MA-EIR 01/01/2010 - 06/06/2014
2014-4718	06/11/2014 07/10/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tim Garabedian Garabedian, Tim W	GLAXO SENSODYNE REPAIR & PROTECT - APPROVAL, COMMUNICATIONS
2014-4719	06/11/2014 07/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Dr. Len W. Morrow Dr. Len W. Morrow	LETTER TO FDA FROM WALKUP, MELODIA, KELLY & SCHOENBERGER RE DEPUY - 07/01/2013 - 10/01/2013
2014-4720	06/11/2014 07/10/2014	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Chastity Rodriguez Rodriguez, Chastity	LIFESHARE OF THE CAROLINAS - 483, WARNING LETTER 06/09/2011 - 06/09/2014
2014-4721	06/11/2014 07/10/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Paul Knoepfler UC DAVIS SCHOOL OF MEDICINE	CELL SURGICAL NETWORK - INSPECTION RECS, CORR 01/02/2013 - 06/09/2014

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		FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/		
2014-4722	06/11/2014 07/10/2014	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Mary B. Baller Baller, Mary B	NEUROSCIENCE, INC, PHARMASAN LABS - INVESTIGATION RECS 01/01/2014 - 06/01/2014
2014-4723	06/11/2014 07/10/2014	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	CORR FROM FDA TO ALTRIA CLIENT SERVICES, PHILIP MORRIS UNSA INC, AND SMOKELESS TOBACCO LLC RE DETERMINATION THAT A TOBACCO PRODUCT WAS NOT COMMERCIALY MARKETED IN THE US AS OF 2/15/07
2014-4724	06/11/2014 07/10/2014	FDA/OC/OES/DFOI/	Patrick Moriarty ATP Early Harvest Fund	FOIA REQUEST LOG
2014-4725	06/11/2014 07/10/2014	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Paul Knoepfler UC DAVIS SCHOOL OF MEDICINE	STEM MD - INSPECTION RECS, CORR 01/02/2013 - 06/09/2014
2014-4726	06/11/2014 07/10/2014	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Paul Knoepfler University of California Davis School of Medicine	INTERNATIONAL CELL SURGICAL SOCIETY - 483, UNTITLED LETTERS, ETC 01/01/2014 - 06/09/2014
2014-4727	06/11/2014 07/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Craig Shivers Ramsey and Murray PC	THE LIFEGUARD STORE, NORMAL, IL - REGISTRATION RECS, DEVICE LISTINGS, APPROVAL ETC
2014-4728	06/11/2014 07/10/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ OC/CVM/OCD/	Tom Polansek REUTERS	RECS REC DRIED PORCINE PLASMA SUSPECTED OF CONTAINING PEDV 01/01/2009 - 06/09/2014
2014-4729	06/11/2014	FDA/OMPT/CDER/ORP/DIDP/	Blake Goodner	VALEANT PHARMACEUTICALS - 483, WARNING LETTERS, RESPONSES 01/01/2013 - 06/09/2014

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	07/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bridger Healthcare	
2014-4730	06/11/2014 07/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	DIRECT REPORTS, MEDWATCH REPORTS and ANY SOURCE DOCUMENTS for THE FOLLOWING THIRTY-FIVE (35) CASES, ISR NUMBERS: 9000850, 9004390, 9004545, ETC
2014-4731	06/11/2014 07/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	DIRECT REPORTS, MEDWATCH REPORTS and ANY SOURCE DOCUMENTS 9004618, 9015355, 9028226, ETC
2014-4732	06/11/2014 07/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	Approval, pre-approval & QIDP info for Dalvance
2014-4733	06/11/2014 07/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	DIRECT REPORTS, MEDWATCH REPORTS and ANY SOURCE DOCUMENTS for THE FOLLOWING SIX (6) CASE NUMBERS: 9014848, 9118323, 9119769 ETC
2014-4734	06/11/2014 07/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Craig Shivers Ramsey and Murray PC	ASIA CONNECTION CO., LTD. 16f-1, No.16, Jian Ba Road Chung Ho District, New Taipei City, TAIWAN (CHINA) - REGISTRATION, DEVICE LISTING, APPROVALS ETC
2014-4735	06/11/2014 07/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	DIRECT REPORTS, MEDWATCH REPORTS and ANY SOURCE DOCUMENTS for THE FOLLOWING TWELVE (12) CASE NUMBERS: 9000277, 9000310, 9013464, ETC
2014-4736	06/11/2014 07/10/2014	FDA/OGROP/ORR/SE-FO/NOL-DO/NOL-CB/	Chastity Rodriguez Rodriguez, Chastity	BATON ROUGE REGIONAL EYE BANK - 483, WARNING LETTER LAST THREE YEARS
2014-4737	06/11/2014 07/10/2014	FDA/OGROP/ORR/PA-FO/SEA-DO/SEA-CB/	Paul Knoepfler University of California, Davis School of Medicine	ICMS - 483, UNTITLED LETTER, ETC
2014-4738	06/11/2014 07/10/2014	OC/ORR/ OC/ORR/ FDA/OGROP/ORR/PA-FO/LOS-	Doe J	INDIVIDUAL RECS

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		DO/LOS-CB/		
2014-4739	06/11/2014 07/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kevin Walls Regulatory Insight, Inc.	K101366
2014-4740	06/11/2014 07/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ann Agnor BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.	BLA 125084/46
2014-4741	06/11/2014 07/10/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-1666
2014-4742	06/11/2014 07/10/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-1635
2014-4743	06/11/2014 07/10/2014	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2012-2812
2014-4744	06/11/2014 07/10/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Kevin Walls Regulatory Insight, Inc.	K111501
2014-4745	06/11/2014 07/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	DIRECT REPORTS, MEDWATCH REPORTS and ANY SOURCE DOCUMENTS for THE FOLLOWING NINE (9) CASE NUMBERS: 8889350, 8889391, 8889430, ETC
2014-4746	06/11/2014 07/10/2014	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2014-3055
2014-4747	06/11/2014 07/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kevin Walls Regulatory Insight, Inc.	K130341
2014-4748	06/11/2014 07/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Marc Elia BRIDGER CAPITAL LLC	LABEL MODERNIZATION NDA8372 to NDA 22432
2014-4749	06/11/2014 07/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	DIRECT REPORTS, MEDWATCH REPORTS and ANY SOURCE DOCUMENTS for THE FOLLOWING THIRTY-EIGHT (38) CASE NUMBERS: 8816620, 8816838, 8819411 ETC
2014-4750	06/11/2014	OC/ORAI/	Mark Nelson / Bay Area Warehouse	ENTRY #458-0064353-3

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	07/10/2014	OC/OROA/ FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/	Bay Area Warehouse Co.	
2014-4751	06/11/2014 07/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	DIRECT REPORTS, MEDWATCH REPORTS and ANY SOURCE DOCUMENTS for THE FOLLOWING SIXTEEN (16) CASES, ISR NUMBERS: 8839506, 8846902, 8855685, ETC
2014-4752	06/11/2014 07/10/2014	OC/ORO/ORM/ OC/ORO/ORM/ FDA/OMPT/CTP/OD/	Lisa Isgett Counter Tools	LIST OF TOBACCO RETAILERS IN MINNESOTA 01/01/2014 - 06/01/2014
2014-4753	06/11/2014 07/10/2014	FDA/OGROP/ORO/CE-FO/PHI-DO/PHI-CB/	Chastity Rodriguez Rodriguez, Chastity	NORTHEAST PENNSYLVANIA LIONS EYE BANK - 483, WARNING LETTERS 06/10/2011 - 06/10/2014
2014-4754	06/11/2014 07/10/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	Sam Biddle GAWKER MEDIA	ROSA LABS, LLC - EMAILS WITH FDA 01/01/2012 - 06/01/2014
2014-4755	06/11/2014 07/10/2014	FDA/OGROP/ORO/NE-FO/NWE-DO/NWE-CB/	Chastity Rodriguez Rodriguez, Chastity	MOORE MEDICAL, LLC, FARMINGTON, CT - WARNING LETTER, 483 06/09/2011 - 06/09/2014
2014-4756	06/11/2014 07/10/2014	FDA/OMPT/OSMP/OCP/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	John Newman Canaccord Genuity, LLC	LIST OF APPROVED COMBINATION PRODUCTS 01/01/2010 - 06/01/2014
2014-4757	06/11/2014 07/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	DIRECT REPORTS, MEDWATCH REPORTS and ANY SOURCE DOCUMENTS for THE FOLLOWING TWO (2) CASE NUMBERS: 8932558, 8996759
2014-4758	06/11/2014 07/10/2014	FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/	Chastity Rodriguez Rodriguez, Chastity	,LIONS EYE BANK OF TEXAS AT BAYLOR COLLEGE OF MEDICINE - WARNING LETTER, 483 06/10/2011 - 06/10/2014
2014-4759	06/11/2014 07/10/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-2053
2014-4760	06/11/2014	FDA/OGROP/ORO/CE-FO/DET-	Elliot Wilbur	PERRIGO CO, ALLEGAN, MI - 483 11/01/2013 - 06/04/2014

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	07/10/2014	DO/DET-CB/	Elliot Wilbur	
2014-4761	06/11/2014 07/10/2014	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	Clifford Karchmer Clifford Karchmer	MEMPHIS PECAN - FDA ACTIONS 01/01/1958 - 12/31/1970
2014-4762	06/11/2014 07/10/2014	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Karla Worley-Ham FSC Laboratories Inc	BUSHU PHARMACEUTICALS, FSC LABORATORIES - EIR 03/01/2011 - 06/10/2014
2014-4763	06/11/2014 07/10/2014	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Chastity Rodriguez Rodriguez, Chastity	MID AMERICA TRANSPLANT SERVICES - WARNING LETTER, 483 06/10/2011 - 06/10/2014
2014-4764	06/11/2014 07/10/2014	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Chastity Rodriguez Rodriguez, Chastity	ROCHESTER EYE AND HUMAN PARTS BANK, INC - WARNING LETTER, 483 06/10/2011 - 06/10/2014
2014-4765	06/11/2014 07/10/2014	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	Chastity Rodriguez Rodriguez, Chastity	MIDSOUTH EYE BANK FOR SIGHT RESTORATION - WARNING LETTER, 483 06/10/2011 - 06/10/2014
2014-4766	06/11/2014 07/10/2014	FDA/OC/OES/DFOI/	MICHAEL NEMEROFF SIDLEY AUSTIN LLP	2013-7526
2014-4767	06/11/2014 07/10/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	BANKS, SEDRIC E	SMITH & NEPHEW INC - NEGATIVE PRESSURE WOUND TREATMENT PUMPS OR WOUND VACS RPTS, INVESTIGATIONS, CMPLNTS, ETC
2014-4768	06/11/2014 07/10/2014	OC/ORA/ OC/ORA/ FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Doe J	INDIVIDUAL RECS
2014-4769	06/11/2014 07/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	J. DONALD HENSON, SR Henson, J. Donald	2011-8503 - ADMINISTRATIVE RECS
2014-4770	06/11/2014 07/10/2014	FDA/OFVM/CFSAN/OCD/EOS/	GARY J BURIN PHD TECHNOLOGY SCIENCES GROUP INC	FCN 1025
2014-4771	06/11/2014 07/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	KYUNG-AH KIM PHD PRINCETON BIOMEDITECH CORP	RESPONSE BIIMEDICAL CORP - RAMP NT-PROBNP ASSAY K063662
2014-4772	06/11/2014	FDA/OMPT/CDER/GRP/DIDP/	Jesse McLean	APOTEX INC, CANADA - 483, EIR 12/19/2008 - 08/20/2013

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	07/10/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Toronto Star	
2014-4773	06/11/2014 07/10/2014	FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/	Dr. Diane Sudduth Imangel Consulting	DEXCOM - EIR 07/01/2012 - 10/31/2012
2014-4774	06/11/2014 07/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Craig Shivers Ramsey and Murray PC	K890795
2014-4775	06/11/2014 07/10/2014	FDA/OFVM/CFSAN/OCD/EOS/	Jason Fournier Jason Fournier	TAED FCN REFERENCE
2014-4776	06/11/2014 07/10/2014	FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/	Chastity Rodriguez Rodriguez, Chastity	OKLAHOMA LIONS EYE BANK - 483, WARNING LETTER 06/10/2011 - 06/10/2014
2014-4777	06/12/2014 07/11/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ismail Elchagea INTERNATIONAL TRADING PHARMACEUTICALS LABORATORIES INC	ANDA of contraseed vaginal spermicide submitted by Rose Laboratories, Madison, CT and the approval letter of FDA to Rose Laboratories to market the contraseed vaginal spermicide as OTC with no prior approval required to market the drug
2014-4778	06/12/2014 07/11/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Brown BROWN, JOAN L	MEDROL DOSE PACK - AERS
2014-4779	06/12/2014 07/11/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jesse McLean Toronto Star	ACTIVA CANADA - EIR, 483 05/27/2010 - 07/31/2013
2014-4780	06/12/2014 07/11/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Jesse McLean Toronto Star	VALEANT, BANNER, SGC LIFE SCIENCE SERVICES, ETC, CANADA - EIR, 483 10/30/2008 - 01/01/2013
2014-4781	06/12/2014 07/11/2014	OC/CVM/OCD/	Rachel Johnson FOI Services, Inc.	CVM REVIEW OF REED SEDGE PEET, HUMIC ACIDE, FULVIC ACID ETC BEFORE 01/01/2013

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2014-4782	06/12/2014 07/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joanne Grego CSL BEHRING	9093233, 9287344, 9300731 ETC
2014-4783	06/12/2014 07/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jesse McLean Toronto Star	GLAXOSMITHKLINE, TEVA, KABS LABORATORIES, ETC, CANADA - EIR, 483 0/24/2008 - 06/09/2014
2014-4784	06/12/2014 07/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDRH/OCER/DFOI/	Jesse McLean Toronto Star	DR ANDRE POIRIER, DR ANSON CHEUNG, DR CHRISTOPHER BULLER, ETC - 483, EIR 01/01/2009 - 06/10/2014
2014-4785	06/12/2014 07/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jesse McLean Toronto Star	DR ANDRE POIRIER, DR ANSON CHEUNG, DR CHRISTOPHER BULLER, ETC - 483, EIR 01/01/2009 - 06/10/2014
2014-4786	06/12/2014 07/11/2014	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2011-1405
2014-4787	06/12/2014 07/11/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/NE-FO/NWE- DO/NWE-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	SAMPLE RECS
2014-4788	06/12/2014 07/11/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-2215
2014-4789	06/12/2014 07/11/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-2551
2014-4790	06/12/2014 07/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	Angelia Slayton INC RESEARCH CONSULTING &	K953405

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			SUBMISSIONS	
2014-4791	06/12/2014 07/11/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-3036
2014-4792	06/12/2014 07/11/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-4178
2014-4793	06/12/2014 07/11/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Dennis R. Gwaltney DePuy Orthopaedics, Inc.	DEPUY ORTHOPAEDICS, WARSAW, IN - EIR MAY 2011 UNREDACTED
2014-4794	06/12/2014 07/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	Geeth Vijay-Rao Neotech Products Inc.	K912434, K032922
2014-4795	06/12/2014 07/11/2014	FDA/OC/OES/DDM/	Mike Weinstein WEINSTEIN, MICHAEL	FDA-2014-P-0654 CITIZEN PETITION
2014-4796	06/12/2014 07/11/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	SHEPLEY, KEN	DELAVALU LLC, PHILADELPHIA, PA - 483, 482, CMLPNT 91598, CMLPNT 113319, CO RESP
2014-4797	06/12/2014 07/11/2014	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/ OC/ORACE/OCI/ OC/ORACE/OCI/	GINGER D. SERPAS LEWIS KULLMAN ET AL	INDIVIDUAL RECS
2014-4798	06/12/2014 07/11/2014	OC/ORACE/ OC/ORACE/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	HOLT, RONNIE	CMLPNT 135087
2014-4799	06/12/2014 07/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TAMI T. MARTIN SUPERNUS PHARMACEUTICALS INC	SUPERNAUS PHARMACEUTICALS INC, TOPAMAX NDA 20-505, 20-844 - CLNCL TRIAL DATA
2014-4800	06/12/2014 07/11/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	KIN HENDERSON SANOFI PASTEUR	ID BIOMEDICAL CORP, QUEBEC, CANADA - 483
2014-4801	06/12/2014 07/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SUZIE KESCHAMRUS SANOFI PASTEUR	NUDEXTA NDA 21-879 - FAERS
2014-4802	06/12/2014	FDA/OFVM/CFSAN/OCD/EOS/	DAN PADEN	LINDA BEANS MAINE LOBSTER, ROCKLAND, ME -

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	07/11/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	PETA	INVESTIGATION
2014-4803	06/12/2014 07/11/2014	FDA/OFVM/CFSAN/OCD/EOS/	ELIZABETH SWEIS INTERTEK	RIKEN VITAMIN CO LTD - ETHOXYLATED ALCOHOLS FCN 1313
2014-4804	06/12/2014 07/11/2014	FDA/OFVM/CFSAN/OCD/EOS/	KRISTI O. SMEDLEY, Ph.D. Center for Regulatory Services, Inc.	MITSUI CHEMICALS INC - FCN 1120
2014-4805	06/12/2014 07/11/2014	FDA/OFVM/CFSAN/OCD/EOS/	KRISTI O. SMEDLEY, Ph.D. Center for Regulatory Services, Inc.	DOW CHEMICAL CO - FCN 741
2014-4806	06/12/2014 07/11/2014	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/ OC/CVM/OCD/	CHRISTINE A. DORCHAK, Esq. GREY2K USA WORLDWIDE	VICTORY GREYHOUND FEEDS - JASON HAYNES CMLNT 1/13 TO PRESENT
2014-4807	06/12/2014 07/11/2014	OC/ORAOCI/ OC/ORAOCI/	Doe J	INDIVIDUAL RECS
2014-4808	06/12/2014 07/11/2014	FDA/OC/OES/DFOI/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	SAMUEL Y. KIM EMISON HULLVERSON LLP	CORR TO & FROM STANFORD HOSPITALS AND CLINICS REGARDING NONCOMPLIANCE
2014-4809	06/12/2014 07/11/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	McKENZIE CATO Hyman, Phelps & McNamara P.C.	REQUEST FOR EXEMPTION FROM THE PROHIBITION AGAINST POOLING HUMAN CELLS OR TISSUE FROM TWO MORE DONORS
2014-4810	06/12/2014 07/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOYCE E PRENDERGAST	VERENICLINE (CHANTIX) - AERS
2014-4811	06/12/2014 07/11/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	KIM HENDERSON SANOFI PASTEUR	PROTEIN SCIENCES CORP, MERIDEN, CT - 483 2014
2014-4812	06/12/2014	FDA/OMPT/CDER/ORP/DIDP/	DON J. MIZERK	NDA 79-161, 79-166 TENTATIVE APRVL LTR. LBLG

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	07/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HUSCH BLACKWELL LLP	
2014-4813	06/12/2014 07/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	JUSTIN C. KANTER GAIDO AND FINTZEN	MEDICAMAT - NEOGRAFT SYS WARNING LTR, CORR, INVESTIGATIONS
2014-4814	06/12/2014 07/11/2014	FDA/OC/OES/DDM/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TORREY COPE SIDLEY AUSTIN LLP	ORIGINAL REGULATIONS GOVERNING RX DRUG ADVERTISING - PRE HEARING CONFERENCE 9/26/63, 10/3/63, 10/7/63
2014-4815	06/12/2014 07/11/2014	FDA/OC/OES/DDM/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TORREY COPE SIDLEY AUSTIN LLP	AMENDMENT OF ORIGINAL REGULATIONS GOVERNING RX DRUG ADVERTISING
2014-4816	06/13/2014 07/14/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Vassilios Christodoulopoulos SANDOZ CANADA INC.	NDA 020246 S048 THROUGH S052
2014-4817	06/13/2014 07/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	Laurie DiLiddo DaVINCI Biomedical	K042026
2014-4818	06/13/2014 07/14/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Laurie DiLiddo DaVINCI Biomedical	K061445
2014-4819	06/13/2014 07/14/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Stephen Jones Cleveland Clinic	K061855
2014-4820	06/13/2014 07/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	Astrid Berthe Oraya Therapeutics	K062967
2014-4821	06/13/2014 07/14/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John Newman John Newman	NDA 017992, 4/6/1979 NDA 019640, 3/8/1987 NDA 020168, ETC
2014-4822	06/13/2014 07/14/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Donna Bitzelberger VENABLE LLP	DEPAKOTE NDA CERTIFIED

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2014-4823	06/13/2014 07/14/2014	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Karla Worley-Ham FSC Laboratories Inc	ESAI CO LTD, JAPAN, NORTH CAROLINA - EIR 01/02/2010 - 06/04/2014
2014-4824	06/13/2014 07/14/2014	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	Neetu Dhaliwal VISIUM ASSET MANAGEMENT LLC	EDWARDS LIFESCIENCES, DRAPER, UT - 483 02/22/2013 - 05/01/2014
2014-4825	06/13/2014 07/14/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joe McCann Slingshot Insights	ANDA TIOPRONIN
2014-4826	06/13/2014 08/21/2014	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Elliot Wilbur WILBUR, ELLIOT	IMPAX LABORATORIES, HAYWARD, CA - 483, RESPONSE, MEETING 07/01/2013 - 06/11/2014
2014-4827	06/13/2014 07/14/2014	OC/CVM/OCD/	David Yates Intervet Inc (d/b/a Merck Animal Health)	RACTOPAMINE, ZILPATEROL - AERS FOR HUMAN EXPOSURE 01/01/1987 - 06/11/2014
2014-4828	06/13/2014 07/14/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sue Corbett THE RESEARCH INVESTMENT, INC.	XALATAN - SBA UNPUBLISHED DATA
2014-4829	06/13/2014 07/14/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-2239
2014-4830	06/13/2014 07/14/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mahidhar Chinta Micro Labs USA, Inc	EMCURE PHARMACEUTICALS LIMITED, INDIA - 483 01/01/2014 - 06/11/2014
2014-4831	06/13/2014 07/14/2014	FDA/OC/OES/DFOI/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Marc Elia Bridger Healthcare	ALEXION PHARMACEUTICALS, SMITHFIELD, RHODE ISLAND - WARNING LETTER, INSPECTION REPORTS, 483 ETC 01/01/2011 - 06/11/2014
2014-4832	06/13/2014	OC/ORA/	Center for Food Safety	ANIMAL FEED CONSUMER COMPLAINTS

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	07/14/2014	OC/OR/ OC/CVM/OCD/ OC/OR/ OC/OR/	CENTER FOR FOOD SAFETY	
2014-4833	06/13/2014 07/14/2014	FDA/OGROP/OR/SE-FO/NOL-DO/NOL-CB/	Chastity Rodriguez Rodriguez, Chastity	SOUTHERN EYE BANK - WARNING LETTER, 483 06/11/2011 - 06/11/2014
2014-4834	06/13/2014 07/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	Bret Andre EyeReg Consulting, Inc.	MAF 700
2014-4835	06/13/2014 07/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	Bret Andre EyeReg Consulting, Inc.	MAF 816
2014-4836	06/13/2014 07/14/2014	FDA/OGROP/OR/CE-FO/CHI-DO/CHI-CB/	Greg Gentry Gentry Law, LLC	TC BAUER COMPANY, CHICAGO, IL - 483, ACTIONS 04/01/2014 - 06/12/2014
2014-4837	06/13/2014 07/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	Robert Devaney MX Orthopedics	K124045
2014-4838	06/13/2014 07/14/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-215
2014-4839	06/13/2014 07/14/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-219
2014-4840	06/13/2014 07/14/2014	FDA/OGROP/OR/CE-FO/NWJ-DO/NWJ-CB/	Tris Pharma Novel Laboratories	TRIS PHARMA, MONMOUTH JUNCTION, NJ - 483 04/04/2011 - 01/21/2014
2014-4841	06/13/2014 07/14/2014	FDA/OMPT/CTP/OD/	Stacy Ehrlich and Celeste Wheeler Kleinfeld, Kaplan, and Becker LLP	Copies of all submissions made by Ioto-Brazil to CTP as well as copies of all CTP correspondence with Ioto-Brazil
2014-4842	06/13/2014 07/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	Astrid Berthe Oraya Therapeutics	K984563
2014-4843	06/13/2014 07/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	Leon Amariglio Lexington Medical, Inc.	K040602
2014-4844	06/13/2014 07/14/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	W VELLON #08A5665, NOUCHIE	ANTI DEPRESSANTS, PSYCHOTICS - STUDIES
2014-4845	06/13/2014 07/14/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Delaney, Diane	ALLERGAN - LUMIGAN AERS

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-4846	06/13/2014 07/14/2014	FDA/OGROP/ORR/SW-FO/DEN-DO/DEN-CB/	CHRISTINE LIVOTI DEERFIELD INSTITUTE	EDWARDS LIFESCIENCES LLC - 483S 3/3/14-4/11/14
2014-4847	06/13/2014 07/14/2014	FDA/OC/OES/DFOI/	JENNIFER K REGISTER BLASINGAME BURCH ET AL ATTYS	C R BARD INC OR DAVOL INC - EIRS, 483S, RESP TO 483S, ETC
2014-4848	06/13/2014 07/14/2014	FDA/OO/OHR/	MICHAEL C THEODORAKIS NTEU-CHAPTER 282	EMPLOYEES HIRED AT FDA HEADQUARTERS & BALTIMORE DISTRICT - TITLE OF POSITION, RACE, GENDER, ETC 1/1/10 TO 6/1/14
2014-4849	06/13/2014 07/14/2014	OC/ORR/OCI/ OC/ORR/OCI/	JUSTIN D GROSZ MORELLI ALTERS RATNER LAW FIRM	INDIVIDUAL RECS
2014-4850	06/13/2014 07/14/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BUTLER J02866, JERMIAH	RIPERDAL (RISPERDRONE) - AERS
2014-4851	06/13/2014 07/14/2014	FDA/OGROP/ORR/PA-FO/SAN-DO/SAN-CB/ FDA/OFVM/CFSAN/OCD/EOS/	Scott Eaker Prolacta Bioscience, Inc.	MOTHERS MILK BANK, SAN JOSE, CA - CORR WITH FDA 01/01/2013 - 06/11/2014
2014-4852	06/13/2014 07/14/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Peter Smith freelance	Public Workshop: Fecal Microbiota for Transplantation - AUDIO RECORDING
2014-4853	06/13/2014 07/14/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Monica Gorman CANTOR FITZGERALD	PHASE II MEETING MINUTES FOR IOMAB-B AND ACTIMAB-A, CORR WITH SPONSOR 01/01/2011 - 06/11/2014
2014-4854	06/13/2014 07/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	Sevrina Ciucci Lince Consulting	DR THOMAS ZELLER, BAD KROZINGEN - 483, RESPONSE
2014-4855	06/13/2014	FDA/OFVM/CFSAN/OCD/EOS/	Daren Bakst	PARTIALLY HYDROGENATED OIL RECS 01/02/2012 -

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	07/14/2014		The Daily Signal	06/12/2014
2014-4856	06/13/2014 07/14/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORANE-FO/NYK- DO/NYK-DCB/	George Kimbrell CENTER FOR FOOD SAFETY	RECS RE INTERPRETATION OF 21 C.F.R. Part 110 RE USE OF WOODEN SHELVES OR BOARDS FOR CHEESE; FDA COMMUNICATIONS WITH FINGER LAKES CHEESE
2014-4857	06/13/2014 07/14/2014	FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/	Scott Talbot Novel Laboratories	EMCURE PHARMACEUTICALS USA, INC, EAST BRUNSWICK, NJ - 483 11/13/2013 - 01/08/2014
2014-4858	06/13/2014 07/14/2014	FDA/OGROP/ORACE-FO/BLT- DO/BLT-CB/	John Walsh James Alexander Corporation	STONE INDUSTRIAL INC, COLLEGE PARK, MD - EIR, 483, RECALLS 11/17/2011 - 06/12/2014
2014-4859	06/13/2014 07/14/2014	FDA/OGROP/ORACE-FO/BLT- DO/BLT-CB/	John Walsh James Alexander Corporation	MICROBIOLOGICAL CONSULTANTS, INC - EIR, 483, RECALLS 05/23/2013 - 06/12/2014
2014-4860	06/13/2014 07/14/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joshua Malamud Hyman, Phelps & McNamara P.C.	RISEDRONATE - 180 DAY MARKETING EXCLUSIVITY RECS
2014-4861	06/13/2014 07/14/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Wei wei Chang NuTec Incorporated	ANDA 40904, ANDA 90779
2014-4862	06/13/2014 07/14/2014	FDA/OGROP/ORAPA-FO/SEA- DO/SEA-CB/	Thomas G. Sowa The Spokesman Review	HOLLISTERSTIER, SPOKANE, WA - WARNING LETTER RESPONSES 06/21/2012 - 06/11/2014
2014-4863	06/13/2014 07/14/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Wei wei Chang NuTec Incorporated	NDA 12945 S037, S038
2014-4864	06/13/2014 07/14/2014	FDA/OC/OES/DFOI/	Lauren Farruggia Hyman, Phelps & McNamara P.C.	2014-4340
2014-4865	06/16/2014 07/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	Vicki Chester Ra Medical Systems, Inc.	K072776
2014-4866	06/16/2014 07/15/2014	FDA/OC/OCC/ FDA/OC/OES/ FDA/OC/OPP/OP/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OPP/OP/	Anthony Brino HIMSS Media	RECS RE MOBILE HEALTH TECHNOLOGY 01/01/2013 - 06/13/2014;

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2014-4867	06/16/2014 07/15/2014	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	William M Troetel, Ph.D. William M Troetel, Ph.D., LLC, RAC	DPT LABS, SAN ANTONIO, TX - INSPECTION RECS 01/01/2010 - 06/13/2014
2014-4868	06/16/2014 07/15/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Monica Gorman CANTOR FITZGERALD	CELSION - END OF PHASE II MEETING MINUTES FOR THERMODEX; DISCUSSIONS RE PHASE II HEAT TRIAL; DISCUSSIONS RE POST-HOC ANALYSIS IN HEAT TRIAL 04/01/2011 - 06/13/2014
2014-4869	06/16/2014 07/15/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Aram Sethian Quad Capital	H.P. ACTHAR GEL - AERS
2014-4870	06/16/2014 07/15/2014	FDA/OC/OES/DFOI/	Aram Sethian Quad Capital	HP ACTHAR GEL, QUESTCOR - FOIA REQUESTS 06/13/2012 - 06/13/2014
2014-4871	06/16/2014 07/15/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	MEDWATCH REPORT
2014-4872	06/16/2014 07/15/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Peter R. Breggin, MD Center for the Study of Psychiatry	ZOLOFT - MEDWATCH AERES SUMMARY
2014-4873	06/16/2014 07/15/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Peter R. Breggin, MD Center for the Study of Psychiatry	XANAX - MEDWATCH SUMMARY OF AERS
2014-4874	06/16/2014 07/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	Robert Devaney MX Orthopedics	K1331715
2014-4875	06/16/2014 07/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rob Devaney MX Orthopedics	K080295
2014-4876	06/16/2014 07/15/2014	FDA/OC/OES/DDM/	CHRISTINE LIVOTI DEERFIELD INSTITUTE	EDWARDS LIFESCIENCES LLC - DKT 2014-P-0654-0003, 2014-P-0654-0004, 2014-P-0654-0005, 2014-P-0654-0006
2014-4877	06/16/2014 07/15/2014	FDA/OFVM/CFSAN/OCD/EOS/	PETER C. WHITFIELD BAKER & HOSTETLER, LLP	ENVIRO TECH CHEMICAL SERVICES INC - FCN 699
2014-4878	06/16/2014	FDA/OGROP/ORANE-FO/NYK-	BRIAN D. KURTZ	SEXY HAIR CONCEPTS, LOS ANGELES, CA - ENTRY NO

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	07/15/2014	DO/NYK-DCB/	ZETETIC	823-0161396-2
2014-4879	06/16/2014 07/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELAINE CHANG GLANCY BINKOW & GOLDBERG LLP	PROSENSA - DRISAPERSEN APRVL,
2014-4880	06/16/2014 07/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	HOWARD S. HOGAN GIBSON DUNN & CRUTCHER LLP	MACRO CURE LTD IND SINCE 5/1/10 CORR, RECORDINGS, PHOTOGRAPHS, ETC
2014-4881	06/16/2014 07/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	Diane M Jacquinot Diane M. Jacquinot	VITA-STAT MEDICAL SERVICES - APPROVAL RECS
2014-4882	06/16/2014 07/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gail Javitt DLA PIPER LLP US	FLAMMACERIUM - EMERGENCY USE RECS
2014-4883	06/17/2014 07/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	Sarot Stratong Onyx Industries, Inc.	510 (k) files for Studex Ear Piercing Guns
2014-4884	06/17/2014 07/16/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORASE-FO/ATL- DO/ATL-CB/	Maureen White, Director of Quality Systems for LifePoint, In LifePoint, INc.	LIFEPOINT, INC, CHARLESTON, SC - EIR 05/09/2005 - 05/12/2005
2014-4885	06/17/2014 07/16/2014	FDA/OGROP/ORASE-FO/ATL- DO/ATL-CB/	Maureen White, Director of Quality Systems for LifePoint,Inc LifePoint, INc.	LIFEPOINT, COLUMBIA, SC - EIR 11/20/2006 - 11/20/2006
2014-4886	06/17/2014 07/16/2014	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2012-3140
2014-4887	06/17/2014 07/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jennifer Ensign Jennifer Ensign	All correspondence and review documents for the original New Drug Application for Cortifoam NDA 017351 from February 1982
2014-4888	06/17/2014 07/16/2014	FDA/OGROP/ORASE-FO/ATL- DO/ATL-CB/	Maureen White, Director of Quality Systems for LifePoint,Inc LifePoint, INc.	LIFEPOINT, GREENVILLE, SC - EIR 12/15/2006 - 12/18/2006

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2014-4889	06/17/2014 07/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	Victoria Rothwell Immunexpress	K133883
2014-4890	06/17/2014 07/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	Victoria Rothwell Immunexpress	K131706
2014-4891	06/17/2014 07/16/2014	FDA/OC/OES/DFOI/	TORREY COPE SIDLEY AUSTIN LLP	2010-5874
2014-4892	06/17/2014 07/16/2014	FDA/OC/OES/DFOI/	TORREY COPE SIDLEY AUSTIN LLP	2010-5581
2014-4893	06/17/2014 07/16/2014	FDA/OC/OES/DFOI/	TORREY COPE SIDLEY AUSTIN LLP	2012-6879
2014-4894	06/17/2014 07/16/2014	FDA/OC/OES/DFOI/	TORREY COPE SIDLEY AUSTIN LLP	2009-3571
2014-4895	06/17/2014 07/16/2014	FDA/OC/OES/DFOI/	TORREY COPE SIDLEY AUSTIN LLP	2014-829
2014-4896	06/17/2014 07/16/2014	FDA/OC/OES/DFOI/	TORREY COPE SIDLEY AUSTIN LLP	2009-8413
2014-4897	06/17/2014 07/16/2014	FDA/OC/OES/DFOI/	TORREY COPE SIDLEY AUSTIN LLP	2014-3216
2014-4898	06/17/2014 07/16/2014	FDA/OC/OES/DFOI/	TORREY COPE SIDLEY AUSTIN LLP	2010-5299
2014-4899	06/17/2014 07/16/2014	FDA/OC/OES/DFOI/	ETORREY COPE SIDLEY AUSTIN LLP	2010-5814
2014-4900	06/17/2014 07/16/2014	FDA/OC/OES/DFOI/	TORREY COPE SIDLEY AUSTIN LLP	2013-1519
2014-4901	06/17/2014 07/16/2014	FDA/OC/OES/DFOI/	TORREY COPE SIDLEY AUSTIN LLP	2013-5113
2014-4902	06/17/2014 07/16/2014	FDA/OC/OES/DFOI/	TORREY COPE SIDLEY AUSTIN LLP	2011-489
2014-4903	06/17/2014 07/16/2014	FDA/OC/OES/DFOI/	TORREY COPE SIDLEY AUSTIN LLP	2013-8530
2014-4904	06/17/2014 07/16/2014	FDA/OC/OES/DFOI/	TORREY COPE SIDLEY AUSTIN LLP	2013-5798
2014-4905	06/17/2014	FDA/OC/OES/DFOI/	TORREY COPE	2009-5135

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	07/16/2014		SIDLEY AUSTIN LLP	
2014-4906	06/17/2014 07/16/2014	FDA/OC/OES/DFOI/	TORREY COPE SIDLEY AUSTIN LLP	2011-6346
2014-4907	06/17/2014 07/16/2014	FDA/OC/OES/DFOI/	TORREY COPE SIDLEY AUSTIN LLP	2013-4434
2014-4908	06/17/2014 07/16/2014	FDA/OC/OES/DFOI/	TORREY COPE SIDLEY AUSTIN LLP	2010-4215
2014-4909	06/17/2014 07/16/2014	FDA/OC/OES/DDM/	LYNN WALSH E W SCRIPPS CO	RIN: 0910-AG38 - DEEMING TOBACCO PRODUCTS TO BE SUBJECT TO THE FOOD, DRUG AND COSMETIC ACT
2014-4910	06/17/2014 07/16/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	EMILY K STRUNK JONES DAY	CANGENE, BIOVERTA, CL BEHRING - CORTICOTROPIN EIRS, 483S, WARNING LTRS, ETC 1/01 TO PRESENT
2014-4911	06/17/2014 07/16/2014	FDA/OFVM/CFSAN/OCD/EOS/	MICHAEL F JACOBSON PHD CENTER FOR SCIENCE IN THE PUBLIC INTEREST	DETERMINATION OF SEVEN CERTIFIED COLOR ADDITIVES IN FOOD PRODUCTS USING LIQUID CHROMATOGRAPHY - STUDY RECS
2014-4912	06/17/2014 07/16/2014	FDA/OC/OES/DFOI/	AL-MUJAHIDIN 103968, MUHAMMAD	THORAZINE, HALDOL, RITALIN, ETC - PURPOSE, USES, DERIVATIVES, ETC
2014-4913	06/17/2014 07/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	JACK MEYERSON MEYERSON & O'NEILL ATTY	INFUSE BONE GRAFT P050053
2014-4914	06/17/2014 07/16/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELENA HOWELL Hogan Lovells, ILP	DR REDDY'S LABORATORIES INC - SUMATRIPTAN SUCCINATE NDA 90-495 RVWS
2014-4915	06/17/2014 07/16/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	AUDREY ALIBRANTI EGAN ETHYPHARM USA CORP	SUBOXONE (BUPREMORPHONE AND NALOXONE) SUBLINGUAL FILM NDA 22-410/S016 RVWS
2014-4916	06/17/2014 07/16/2014	FDA/OGROP/ORACE-FO/LOS-DO/LOS-CB/	PATRICIA L REGENYE Celgene Corporation	ST JOHN'S HEALTH CENTER, SANTA MONICA, CA 0 EIRS, 483S, CORR 11/13 TO PRESENT
2014-4917	06/17/2014	FDA/OMPT/CDER/GRP/DIDP/	JEANNIE BAUMANN	MANOJ K PATEL, ALTA LOMA, CA - NIDPOE LTR 4/30/14

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	07/16/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BLOOMBERG BNA	
2014-4918	06/17/2014 07/16/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-1379
2014-4919	06/17/2014 07/16/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-1636
2014-4920	06/17/2014 07/16/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-1666
2014-4921	06/17/2014 07/16/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-1792
2014-4922	06/17/2014 07/16/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-2195
2014-4923	06/17/2014 07/16/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-2656
2014-4924	06/17/2014 07/16/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-10072
2014-4925	06/17/2014 07/16/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-810
2014-4926	06/17/2014 07/16/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-3343
2014-4927	06/17/2014 07/16/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-9594
2014-4928	06/17/2014 07/16/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-1159
2014-4929	06/17/2014 07/16/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-301
2014-4930	06/17/2014 09/26/2014	FDA/OFVM/CFSAN/OCD/EOS/	BOB MCQUATE GRAS ASSOCIATES LLC	FCN 70
2014-4931	06/17/2014 07/16/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-1126
2014-4932	06/17/2014 07/16/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	SCHUMAN, ALEX	ALLERMED LABORATORIES INC - MITE D P (DERMATOPHAGOIDES PTERONYSSINUS) SBA, CLNCL RVWS

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2014-4933	06/17/2014 07/16/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	SCHUMAN, ALEX	ALLERGY LABORATORIES INC - SHORT RAGWEED SBA, CLNCL RVWS
2014-4934	06/17/2014 07/16/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	SCHUMAN, ALEX	ALLERGY LABORATORIES INC - MITE D P SBA, CLNCL RVWS
2014-4935	06/17/2014 07/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	SCHUMAN, ALEX	ANTIGEN LABORATORIES INC - SHORT RAGWEED SBA, CLNCL RVW
2014-4936	06/17/2014 07/16/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	SCHUMAN, ALEX	ANIGEN LABORATORIES INC - MITE D P SBA, CLNCL RVWS
2014-4937	06/17/2014 07/16/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	SCHUMAN, ALEX	ALLERMED LABORATORIES INC - SHORT RAGWEED SBA, CLNCL RVWS
2014-4938	06/17/2014 07/16/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	SCHUMAN, ALEX	JUBILANT HOLLISTERSTIER LLC - SHORT RAGWEED SBA, CLNCL RVWS
2014-4939	06/17/2014 07/16/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	SCHUMAN, ALEX	JUBILANT HOLLISTERSTIER LLC - MITE D P SBA, CLNCL RVWS
2014-4940	06/17/2014 07/16/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	SCHUMAN, ALEX	GREER LABROATORIES INC - MITE D P SBA, CLNCL RVWS
2014-4941	06/17/2014 07/16/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	SCHUMAN, ALEX	GREER LABORATORIES INC - SHORT RAGWEED SBA, CLNCL RVWS
2014-4942	06/17/2014 07/16/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	SCHUMAN, ALEX	ALK-ABELLO INC - SHORT RAGWEED SBA, CLNCL RVWS
2014-4943	06/17/2014 07/16/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	SCHUMAN, ALEX	ALK-ABELLO INC - MITE D P SBA, CLNCL RVWS
2014-4944	06/18/2014 07/17/2014	FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/	Compliance Specialists Compliance Specialists, LLC	STANDARD HOMEOPATHIC COMPANY, INC - CORR WITH FDA 09/24/2014 - 06/16/2014
2014-4945	06/18/2014 07/17/2014	FDA/OC/OES/DFOI/ FDA/OGROP/ORO/SE-FO/FLA- DO/FLA-CB/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Doug Smith WTVT-TV	STEVEN WELDON, MD, LUTZ, FLORIDA - AUDITS, COMPLAINTS, ETC
2014-4946	06/18/2014	FDA/OMPT/CDRH/OCER/DFOI/	Shane Sullivan	A list of x-ray and fluoroscopic machines registered in the US

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	07/17/2014		ORTHOSCAN INC	
2014-4947	06/18/2014 07/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	Geeth Vijay-Rao Neotech Products Inc.	K792018
2014-4948	06/18/2014 07/17/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	Patrick Moriarty ATP Early Harvest Fund	ADCENTRIS - AERS
2014-4949	06/18/2014 07/17/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Chastity Rodriguez Rodriguez, Chastity	TRANSPLANT FOR LIFE - 483, WARNING LETTER 06/17/2011 - 06/17/2014
2014-4950	06/18/2014 07/23/2014	FDA/OC/OES/DFOI/	David Mangione Govzilla, Inc.	483 RELEASED ISSUED SINCE 1/1/2010 AND RELEASED SINCE 11/21/13
2014-4951	06/18/2014 07/17/2014	FDA/OC/OES/DFOI/ OC/ORO/ORM/ OC/ORO/ORM/	David Mangione Govzilla, Inc.	LIST OF INSPECTIONS 03/15/2014 - 06/17/2014
2014-4952	06/18/2014 07/17/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Wendy Lam Morgan Stanley	ADCENTRIS, KADCYLCA, IMBRUVICA - AERS 08/01/2011 - 06/17/2014
2014-4953	06/18/2014 07/17/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Richard Goss Leerink Partners	IMBRUVICA - AERS
2014-4954	06/18/2014 07/17/2014	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	Chastity Rodriguez Rodriguez, Chastity	TENNESSEE DISTRICT 12-1 LIONS EYE BANK - 483, WARNING LETTER 06/17/2011 - 06/17/2014
2014-4955	06/18/2014 07/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K133879
2014-4956	06/18/2014 07/17/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Abbott Wootten CANTOR FITZGERALD	ADCETRIS - AERS
2014-4957	06/18/2014 07/17/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Shelley LePage Shelley LePage	MELOXICAM - AERS

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2014-4958	06/18/2014 07/17/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K113215
2014-4959	06/18/2014 07/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	Geeth Vijay-Rao Neotech Products Inc.	K790056, K871157
2014-4960	06/18/2014 07/17/2014	FDA/OGROP/ORACE-FO/CIN- DO/CIN-CB/	Chastity Rodriguez Rodriguez, Chastity	UNIVERSITY OF LOUISVILLE LIONS EYE BANK - 483, WARNING LETTER 06/17/2011 - 06/17/2014
2014-4961	06/18/2014 07/17/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 204485
2014-4962	06/18/2014 07/17/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 5/26-30/13
2014-4963	06/18/2014 07/17/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 5/26-31/14
2014-4964	06/18/2014 07/17/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 5/26-30/14
2014-4965	06/18/2014 07/17/2014	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 5/26-30/14
2014-4966	06/18/2014 07/17/2014	FDA/OC/OES/DFOI/	SANDY FRIEDMAN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 5/26-30/14
2014-4967	06/18/2014 07/17/2014	FDA/OGROP/ORACE-FO/NWE- DO/NWE-CB/	LIANE LAROCHELLE DEKA RESEARCH & DEVELOPMENT CORP	DEKA RESEARCH & DEVELOPMENT, MANCHESTER, NH - EIR 3/14
2014-4968	06/18/2014 07/17/2014	FDA/OGROP/ORACE-FO/CIN- DO/CIN-CB/	CRAIG ROUSH ROCHLINE INDUSTRIES	PLAYTED MANUFACTURING INC, SIDNEY, OH - EIRS, 483S, CORR 2/11
2014-4969	06/18/2014 07/17/2014	FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/	VANDAMME, NONA	BRAVO PACKING, CARNEY'S POINT, NJ - RPT
2014-4970	06/18/2014 07/17/2014	FDA/OGROP/ORACE-FO/DET- DO/DET-CB/ FDA/OMPT/CDRH/OCER/DFOI/	PETER J SOMERA SOMERA & SILVA LLP	STRYKER - UPDATED INSTUCTIONS FOR 510K APRVL
2014-4971	06/18/2014	FDA/OFVM/CFSAN/OCD/EOS/	WILLIAM A OLSON	CIBA-GEIGY - IRGANOX 1098 (CAS #23128-74-7) FAP

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	07/17/2014		Center for Regulatory Services,Inc.	
2014-4972	06/18/2014 07/17/2014	OC/ORO/ORM/ OC/ORO/ORM/	GAIL LESSICK LACHMAN CONSULTANT SERVICES INC	LIST OF DOMESTIC & FOREIGN INSP - dRUG cOMPANIES, MEDICAL DVC MFRS, BLOODL ESTABLISHMENTS, ETC 4/1-30/14
2014-4973	06/18/2014 07/17/2014	FDA/OC/OES/DFOI/	GBIKPI 32174016, KOFFI M	RISPERDONE, SERTRALINE, HYDROCHLOROTHIAZIDE - MFG COMPANIES, ADDRESS
2014-4974	06/18/2014 07/17/2014	FDA/OGROP/ORO/SW-FO/DEN-DO/DEN-CB/	SHAY MOCKELMANN Shay Mockelmann Feedyard	2014-3337 - EXHIBITS
2014-4975	06/18/2014 07/17/2014	FDA/OGROP/ORO/SW-FO/KAN-DO/KAN-CB/	NORA SCHNEIDER ARNOLD & PORTER	ASPEN API INC (DIOSYNTH, ORGANON OR MERCK/MSD), SIOUX CITY, IA - EIRS 2008 TO PRESENT
2014-4976	06/18/2014 07/17/2014	FDA/OGROP/ORO/CE-FO/DET-DO/DET-CB/	DIANNE CHAMBERS HOGAN LOVELLS LLP	GUGGISBERG CHEESE - RESP LTRS
2014-4977	06/18/2014 07/17/2014	FDA/OC/OES/DDM/	ELAINE C ALLIGOOD BOSTON VA HEALTH CARE SYSTEM	DKT 1989N-0431 - CENTRAL VENOUS CATHETERS TIP PLACEMENT
2014-4978	06/18/2014 07/17/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	TOSHKO J LISSITCHKOV MD, SOFIA, BULGARIA - EIR, 483, CO RESP 1/21-25/13
2014-4979	06/18/2014 07/17/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	OLEKSANDRA V STASYSHYN MD PHD, LVIV, UKRAINE - EIR, 483, CO RESP 1/21-25/13
2014-4980	06/18/2014 07/17/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OC/OES/DFOI/	WALTER E. CHALKLEY THOMSON REUTERS	JACQUES HEBERT MD, QUEBEC, CA - EIR, 483, CO RESP 7/15-19/13
2014-4981	06/18/2014 07/17/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	MIPHARM SPA, MILANO, ITALY - EIR, 483, CO RESP 2/13-14/14
2014-4982	06/18/2014 07/17/2014	FDA/OGROP/ORO/SE-FO/SJN-DO/SJN-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	BAXTER HEALTHCARE CORP, JAYUYA, PR - EIR, 483, CO RESP 1/15/14-2/11/14

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2014-4983	06/18/2014 07/17/2014	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	GENENTECH INC, SOUTH SAN FRANCISCO, CA - EIR, 483, CO RESP 2/4-21/14
2014-4984	06/18/2014 07/17/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	AMKS TIME RELEASE LABORATORIES - ISMAIL ELCHAGEA PHD, PATERSON, NJ - EIR, 483, CO RESP 6/17/13 - 7/12/13
2014-4985	06/18/2014 07/17/2014	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	COLUMBIA UNIVERSITY MEDICAL CENTER - ROGERIO A LOBO MD, NEW YORK, NY - EIR, 483, CO RESP 6/5-25/13
2014-4986	06/18/2014 07/17/2014	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	MICHELE A SEWELL MD, LITHONIA, GA - EIR, 483, CO RESP 6/17 - 8/13/13
2014-4987	06/18/2014 07/17/2014	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	WALTER E. CHALKLEY THOMSON REUTERS	LINCARE INC, WISTMINSTER, MD - EIR, 483, CO RESP 8/7-9/13
2014-4988	06/18/2014 07/17/2014	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	ALAMANCE REGIONAL MEDICAL CENTER IRB, BURLINGTON, NC - EIR, 483, CO RESP 6/18-20/13
2014-4989	06/18/2014 07/17/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	METRO HEALTH MEDICAK CTR IRB, CLEVELAND, OH - EIR, 483, CO RESP 7/25/13-8/13/13
2014-4990	06/18/2014 07/17/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	BRISTOL MYERS SQUIBB CO, PENNINGTON, NJ - EIR, 483, CO RESP 4/24/13-5/3/13
2014-4991	06/18/2014 07/17/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	CUBIST PHARMACEUTICALS INC, LEXINGTON ,MA - EIR, 483, CO RESP 3/18-26/13
2014-4992	06/18/2014 07/17/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	PHARMACIA & UPJOHN LLC, KALAMAZOO, MI - EIR, 483, CO RESP 6/10-20/13
2014-4993	06/18/2014 07/17/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	BAYER HEALTHCARE PHARMACEUTICALS - EIR, 483, CO RESP 7/31/13-8/14/13
2014-4994	06/18/2014 07/17/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	ANCHEN PHAMACEUTICALS, IRVINE, CA - EIR, 483, CO RESP 12/12-20/13
2014-4995	06/18/2014	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	WALTER E. CHALKLEY	NELSON KAREN, PUGET SOUND BLOOD CENTER, SETTLE, WA - EIR, 483, CO RESP 8/27/13-9/3/13

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	07/17/2014		THOMSON REUTERS (SCIENTIFIC) SAS	
2014-4996	06/18/2014 07/17/2014	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	OZARKS INC - VANDEWALKER MARK MD, COLUMBIA, MO - EIR, 483, CO RESP 8/5-9/13
2014-4997	06/18/2014 07/17/2014	OC/ORASORM/ OC/ORASORM/ FDA/OFVM/CFSAN/OCD/EOS/ OC/ORASORM/ OC/ORASORM/	SHERYL L. RHODES-BUENGER BUDDY TREATS LLC	FDA INSPECTED MEAT MANUFACTURING FACILITIES THAT PRODUCE HUMAN GRADE SHELF STABLE MEATY SNACK PRODUCTS
2014-4998	06/18/2014 07/17/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	ALLEN, JAMES F	ROCHE DIAGNOSTICS - COAGU CHEK XS SYS APRVL
2014-4999	06/18/2014 07/17/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELENA HOWELL Hogan Lovells, ILP	SAGENT AGILA - SUMATRIPTAN SUCCINATE NDA 90-641 - RVWS
2014-5000	06/18/2014 07/17/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ OC/ORAS/ OC/ORAS/	CHRISTOPHER A. BERRY, Esq. ANIMAL LEGAL DEFENSE FUND	EGG PRODUCTION FACILITIES IN PA SINCE 6/11 - EIRS, CONSUMER HEALTH RPTS, ENVIRONMENTAL TESTS, ETC
2014-5001	06/18/2014 07/17/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	LEVAQUIN - AER
2014-5002	06/18/2014 07/17/2014	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	JAMES E SWAUGER RAI SERVICES CO	WHITAKER PARK, WINSTON-SALEM, NC - EIR, CORR, ENDORSEMENTS, ETC 2/10/13 TO 3/1/13; TOBACCOVILLE, ROBACCOVILLE, NC - EIR, CORR, ENDORSEMENTS, ETC 3/25/13 TO 4/2/13; SFNTC'S OXFORD, OXFORD, NC - EIR, CORR ENDORSEMENTS, ETC 5/13-17/13
2014-5003	06/19/2014 07/18/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 5/26-30/14
2014-5004	06/19/2014 07/18/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 6/2-6/14
2014-5005	06/19/2014	FDA/OC/OES/DFOI/	LAUREN S BARR	CLOSED FOIA REQUESTS 6/2-6/13

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	07/18/2014		JH BARR & ASSOCIATES LLC	
2014-5006	06/19/2014 07/18/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	2014-3968
2014-5007	06/19/2014 07/18/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 5/26-30/14
2014-5008	06/19/2014 07/18/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 6/2-6/14
2014-5009	06/19/2014 07/18/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 6/2-6/14
2014-5010	06/19/2014 07/18/2014	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 6/2-6/14
2014-5011	06/19/2014 07/18/2014	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOFI DAILY LOG 5/26-30/14
2014-5012	06/19/2014 07/18/2014	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DALY LOGS 6/2-6/14
2014-5013	06/19/2014 07/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mark Nasca Ghost Tree Capital	VELPHORO - MEDICAL REVIEWS
2014-5014	06/19/2014 07/18/2014	OC/ORO/ OC/ORO/ OC/CVM/OCD/	Jill Lennox Jill Lennox	Blue buffalo Dog Food Analysis and Necropsy report; FDA Pet Food Report- ICSR 1034568
2014-5015	06/19/2014 07/18/2014	OC/CVM/OCD/	Tim Schwab Food & Water Watch	AQUABOUNTY - MTG MINUTES
2014-5016	06/19/2014 07/18/2014	FDA/OC/OES/DFOI/ FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	Beth Shapiro Beth Shapiro	DEMMA NUTRITION COMPANY - COMPLAINTS, EIR, 483 ETC 01/01/2009 - 06/16/2014
2014-5017	06/19/2014 07/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	James Marchetti N/A	VORICONAZOLE - AERS
2014-5018	06/19/2014 07/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dustin Block IPD Analytics, LLC	ANDA 091002 - EFFECTIVE APPROVAL LETTER

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2014-5019	06/19/2014 07/18/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Philip Roberts Post-Finasteride Syndrome Foundation	FINASTERIDE - AERS
2014-5020	06/19/2014 07/18/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Richard Goss Leerink Partners	ADCETRIS - AERS
2014-5021	06/19/2014 07/18/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Olena Izhak University of Helsinki (FINLAND)	PATENT NUMBERS CHALLENGED BY PARAGRAPH IV ANDA
2014-5022	06/19/2014 07/18/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Leslie Gerwin PRINCETON UNIVERSITY	INVOKANA - AERS
2014-5023	06/19/2014 07/18/2014	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	PHILIP A SEALS SEALS, PHILIP A	HEARTWARE INTERNATIONAL, INC - 483, EIR, RESPONSE TO 483 ETC
2014-5024	06/19/2014 07/18/2014	FDA/OC/OEXA/OC/ FDA/OFVM/CFSAN/OCD/EOS/	Michelle Minton The Competitive Enterprise Institute	PARTIALLY HYDROGENATED OIL - RECORDS OF ANTIQUITY
2014-5025	06/19/2014 07/18/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Veronica Munoz Munoz, Veronica	Filings by Aduro with regard to Listeria monocytogenes vaccine vectors for treating prostate cancer
2014-5026	06/19/2014 07/18/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lani Questembert Questembert, Lani D	IND or NDA filings with the FDA that relate to the treatment of Hepatitis C Virus (HCV)
2014-5027	06/19/2014 07/18/2014	FDA/OC/OES/DDM/	Rachel Englander MILES & STOCKBRIDGE	Public comments, objections or memorandums/briefs in support of objections to F.R. Doc 70-5865. filed May 12th 1970
2014-5028	06/19/2014	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	David Pieratos	BECTON DICKINSON, SUMTER, SC - EIR 08/23/2010 - 08/27/2010

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	07/18/2014		BECTON, DICKINSON AND COMPANY	
2014-5029	06/19/2014 07/18/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kim Wiersema STRYKER CORP	K132671
2014-5030	06/19/2014 07/18/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kim Wiersema STRYKER CORPORATION	K133786
2014-5031	06/19/2014 07/18/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Christina Jewett The Center for Investigative Reporting	RECALL 64578
2014-5032	06/19/2014 07/18/2014	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	David Pieratos BECTON, DICKINSON AND COMPANY	BECTON DICKINSON DIAGNOSTIC SYSTEMS, BALTIMORE, MD - EIR 05/25/2011 - 06/01/2011
2014-5033	06/19/2014 07/18/2014	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	David Pieratos BECTON, DICKINSON AND COMPANY	PREANALYTICAL SYSTEMS - EIR 08/05/2013 - 08/14/2013
2014-5034	06/19/2014 07/18/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	John Aitken GILEAD SCIENCES INC	NDA 205552
2014-5035	06/19/2014 07/18/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K140133
2014-5036	06/19/2014 07/18/2014	FDA/OMPT/CDRH/OCER/DFOI/	Meredith May NeuroStructures, inc.	K120515, K131374
2014-5037	06/19/2014 07/18/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 5/26-31/14
2014-5038	06/19/2014 07/18/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 6/2-7/14
2014-5039	06/19/2014 07/18/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 6/2-7/14
2014-5040	06/19/2014 07/18/2014	FDA/OC/OES/DFOI/	DEBI L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 5/26-30/14
2014-5041	06/19/2014 07/18/2014	FDA/OC/OES/DFOI/	DEBI L COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 6/2-6/14

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2014-5042	06/19/2014 07/18/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	All Warning Letters for Musculoskeletal Transplant Foundation May 2013 to present
2014-5043	06/19/2014 07/18/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	William Ferguson UNIVERSITY OF SOUTH ALABAMA	K091989 K081997 K022730 etc
2014-5044	06/19/2014 07/18/2014	FDA/OC/OES/DFOI/	DEBI L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 6/2-6/14
2014-5045	06/19/2014 07/18/2014	FDA/OC/OES/DFOI/	WILLIAM A OLSON Center for Regulatory Services, Inc.	FOI DAILY LOG 5/26-30/14
2014-5046	06/19/2014 07/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/OSMP/OOPD/	Robert Lawrence Robert Lawrence	SILVERGATE PHARMACEUTICALS - ORPHAN DESIGNATION, NDA SUBMISSION 01/04/2012 - 08/13/2013
2014-5047	06/19/2014 07/18/2014	FDA/OC/OES/DFOI/	WILLIAM A OLSON Center for Regulatory Services, Inc.	FOI DAILY LOG 6/2-6/14
2014-5048	06/19/2014 07/18/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jeremy Oczek Bond, Schoeneck & King PLLC	K093259
2014-5049	06/19/2014 07/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Eric Joseph JMP Securities	IMBRUVICA - AERS
2014-5050	06/19/2014 07/18/2014	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 5/26-30/14
2014-5051	06/19/2014 07/18/2014	FDA/OGROP/ORR/SW-FO/KAN- DO/KAN-CB/	David Pieratos BECTON, DICKINSON AND COMPANY	BECTON DICKINSON AND COMPANY, BROKEN BOW, NE - EIR 04/20/2009 - 04/24/2009
2014-5052	06/19/2014 07/18/2014	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 6/2-6/14
2014-5053	06/19/2014	FDA/OGROP/ORR/SW-FO/KAN- DO/KAN-CB/	David Pieratos	BD HOLDREGE, NE - EIR 05/06/2014 - 05/09/2014

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2014-5054	06/19/2014 07/18/2014	FDA/OO/OFBA/OAGS/	JOHN EVANS STORSOFT TECHNOLOGY CORP	CONTRACT NO HHSF22301210971P
2014-5055	06/19/2014 07/18/2014	FDA/OMPT/CTP/OD/	GREGORY N CONNOLLY HARVARD SCHOOL OF PUBLIC HEALTH	TOBACCO INDUSTRY RPTS FILED UNDER S904 (A) FOR ALL CONSTITUENTS - PROD TYPE, DATE RECORD WAS REC'D, MFR, ETC
2014-5056	06/20/2014 07/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	Lauren Costantini Prima-Temp Inc	K102499
2014-5057	06/20/2014 07/21/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Kenny Bastes Adam Nutrition	ADAM NUTRITIONALS, MIRA LOMA, CA - EIR 2009
2014-5058	06/20/2014 07/21/2014	FDA/OC/OES/DFOI/	David Pieratos BECTON, DICKINSON AND COMPANY	EIR FOR WARNING LETTER 05/11/2009 - 05/11/2009
2014-5059	06/20/2014 07/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	Lauren Costantini Prima-Temp, Inc	K121696
2014-5060	06/20/2014 07/21/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Patrick Moriarty ATP Early Harvest Fund	IMBRUVICA - AERS
2014-5061	06/20/2014 07/21/2014	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	David Pieratos BECTON, DICKINSON AND COMPANY	BD DIAGNOSTIC SYSTEMS, MADISON, WI - EIR 01/21/2014 - 01/24/2014
2014-5062	06/20/2014 07/21/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Doe J	INDIVIDUAL RECS
2014-5063	06/20/2014 07/21/2014	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Riley Dandurand Dakota Style, Inc.	DAKOTA STYLE, INC, CLARK, SD - EIR 04/01/2011 - 08/31/2011
2014-5064	06/20/2014 07/21/2014	FDA/OFVM/CFSAN/OCD/EOS/	Adam Dieker Chelepis & Associates	LIST OF REGISTERED WATER BOTTLING PLANTS IN US 01/01/2014 - 06/18/2014
2014-5065	06/20/2014 07/21/2014	FDA/OC/OES/DFOI/	Lasse Milinski Universität Passau	Generic overview of enforcements events (483s, warranty letters, product recalls, consent decrees) in 4 fields (drugs; medical devices; vaccines, blood & biologics; radiation-emitting products) from 01/01/2000 to 12/31/2013
2014-5066	06/20/2014 07/21/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michael Curtis Ataxion Therapeutics	NDA 020599

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2014-5067	06/20/2014 07/21/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Teresa Letcher PROVIDENCE HEALTH & SERVICES	PROVIDENCE HEALTH & SERVICES - FORM FDA 3177
2014-5068	06/20/2014 07/21/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Gavin Richey Hirzel Capital	BIBF 1120 APPLICATION RECS
2014-5069	06/20/2014 07/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	Lauren Costantini Prima-Temp, Inc	K122337
2014-5070	06/20/2014 07/21/2014	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	JANSSEN-CILAG MANUFACTURING, LLC, SAN JUAN, PR - 483 12/09
2014-5071	06/20/2014 07/21/2014	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	MCNEIL HEALTHCARE, LLC, SAN JUAN, PR - 483 12/09
2014-5072	06/20/2014 07/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	Paul Swift BD	K140407
2014-5073	06/20/2014 07/21/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Nicholas Wu ClearBridge	IMBRUVICA - AERS
2014-5074	06/20/2014 07/21/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Nicholas Wu ClearBridge	GAZYVA - AERS
2014-5075	06/20/2014 07/21/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Scott Moore Brancaster Pharma Limited	NDA 019815
2014-5076	06/20/2014 07/21/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Carol Muniz RTI Surgical, Inc	MUSCULOSKELETAL TRANSPLANT FOUNDATION - 483 MAY 2014
2014-5077	06/20/2014	FDA/OGROP/ORASE-FO/ATL-	Rachel Johnson	OLAM EDIBLE NUTS, EDENTON, NC - INSPECTION RECS

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	07/21/2014	DO/ATL-CB/	FOI Services, Inc.	
2014-5078	06/20/2014 08/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K131962
2014-5079	06/20/2014 07/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anne Daub VISIUM ASSET MANAGEMENT LLC	IMBRUVICA - AERS
2014-5080	06/20/2014 07/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Andy Washkowitz Stifel Nicolaus & Co	IMBRUVICA - AERS
2014-5081	06/20/2014 07/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Fadi Hamam West-Ward Pharmaceutical Corp.	JAZEERA PHARMACEUTICAL INDUSTRIES, SAUDIA ARABIA - EIR 04/20/2012 - 05/11/2012
2014-5082	06/20/2014 07/28/2014	FDA/OC/OES/ FDA/OMPT/CTP/OD/	Jason Plotz PLOTZKER, RICHARD	COMMUNICATIONS WITH THE CAMPAIGN FOR TOBACCO FREE KIDS SINCE 1/1/13
2014-5083	06/20/2014 08/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K131861
2014-5084	06/20/2014 07/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	Deepak Chadha SUNEVA Medical	PMA P070013 WITHDRAWAL LETTER
2014-5085	06/20/2014 07/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Daniel Kolitz N/A	NDA 11522
2014-5086	06/20/2014 07/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michael S Sawaya Altaire Pharmaceuticals, Inc.	NDA 008883
2014-5087	06/20/2014 07/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ryan Smith Janus Capital Management	IMBRUVICA - AERS

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2014-5088	06/20/2014 07/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	Carolyn Cochenour Children's National Health System	K063677
2014-5089	06/20/2014 07/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	Carolyn Cochenour Children's National Health System	K933094
2014-5090	06/20/2014 07/21/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	MIRTAZAPINE, TRILEPTAL, LAMACTIL, OLANZAPINE - AER
2014-5091	06/20/2014 07/21/2014	FDA/OC/OES/DFOI/	Thomas Wood PIF Enterprise	VOLUME OF CALLS TO IT HELP DESK 2012, 2013
2014-5092	06/20/2014 07/21/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FARYAL A. HASAN Hyman, Phelps & McNamara P.C.	PUBLIC HEARING DECISION ON CARDIOVASCULAR OUTCOMES SAFETY TRIALS 8/11/14
2014-5093	06/20/2014 08/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	Heiko Frerichs Xenios AG	K133598
2014-5094	06/20/2014 07/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	Carolyn Cochenour childrens national health system	K033936
2014-5095	06/20/2014 07/21/2014	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	FARYAL A. HASAN Hyman, Phelps & McNamara P.C.	XOFT INC - WARNING LTR, RESPONSE LTR, RECALL, AER
2014-5096	06/20/2014 07/21/2014	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	KATHY GARZE MARSHALLS BUSINESS RECORDS	USP LABS INC - INSP CERTIFIED 2/7-21/12
2014-5097	06/20/2014 07/21/2014	FDA/OMPT/CTP/OD/	ANDRES VALLEJO MORRISON & FOERSTER LLP	LIST OF LICENSED TOBACCO MANUFACTURERS
2014-5098	06/20/2014 07/21/2014	FDA/OC/OES/DFOI/	DREW ESQ, ALAN	INDIVIDUAL RECS
2014-5099	06/20/2014 07/21/2014	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	DIANNE L. CHAMBERS HOGAN LOVELLS LLP	PULSED FIELD GEL ELECTROPHORESIS PATTERN OF SALMONELLA ISOLATES - WARNING LTR 2/12/14
2014-5100	06/20/2014 07/21/2014	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	LAW OFFICES OF HANCE & SRINIVASAN	INDIVIDUAL RECS
2014-5101	06/20/2014	FDA/OC/OES/DFOI/	KELLY A. BOWLES	ST ELIZABETHS HEALTHCARE, EDGEWOOD, KY - POSEY

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	07/21/2014		LAW OFFICES OF HANCE & SRINIVASAN	MEDICAL DVC DEATHS 2008 TO 2012
2014-5102	06/20/2014 07/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	CHRISTOPHER CHAN UCSF Medical Center	NUMBER OF DVCS FOR EXPEDITED RVW SEEKING PREMARKET APRVL 1/09 TO 6/14
2014-5103	06/23/2014 07/22/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Margaret W. Becker Becker, Margaret W	NEXIUM RECS RE KIDNEY INJURY
2014-5104	06/23/2014 07/22/2014	FDA/OFVM/CFSAN/OCD/EOS/	Linda M. Dougherty, Esq. Kane Kessler, P.C.	NASCENT HEALTH SCIENCE LLC - CORR TO AND FROM FDA ON OR AFTER 3/6/14 RE PQQ
2014-5105	06/23/2014 07/22/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jeroen Bos NOVARTIS PHARMA	BR-ALEXION-A201200760 - FAERS
2014-5106	06/23/2014 07/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	Michael Chibbaro Accord Media - Michael Chibbaro	K122711
2014-5107	06/23/2014 07/22/2014	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	Norman Woo International Brotherhood of Teamsters - SRC Dept.	MBM CORPORATION AKA MEADOWBROOK MEATS - EIR
2014-5108	06/23/2014 07/22/2014	FDA/OGROP/ORAP/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Vicki Byrnes Maris & Lanier, P.C.	BOTOX, MEDS4LESS, MEDSLESS.COM RECS 01/01/2009 - 06/19/2014
2014-5109	06/23/2014 07/22/2014	FDA/OGROP/ORAP/SE-FO/ATL-DO/ATL-CB/	Calin Pop MD Calin Pop MD	METAUGUS - WARNING LETTER RESPONSE 10/01/2012 - 07/01/2013
2014-5110	06/23/2014 07/22/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Vicki Byrnes Maris & Lanier, P.C.	ONLINE BOTOX PHARMACY, ONLINE BOTOX.COM, ONLINEBOTOX - RECS 01/01/2009 - 06/19/2014
2014-5111	06/23/2014 07/22/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Vicki Byrnes Maris & Lanier, P.C.	AXONMEDICALSUPPLIES.COM BOTOX RECS 01/01/2009 - 06/19/2014

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-5112	06/23/2014 07/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	510 (k): K021936 AlphaMed Inc	K021936
2014-5113	06/23/2014 07/22/2014	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	Pat Wedge DRUG SAFETY ALLIANCE	Date Range: 08/05/2013 - 09/24/2013; DRUG SAFETY ALLIANCE, DURHAM, NC - REDACTED EIR AUGUST 2013
2014-5114	06/23/2014 07/22/2014	FDA/OGROP/ORR/NE-FO/NYK-DO/NYK-DCB/ FDA/OMPT/CDRH/OCER/DFOI/	Barb Danson Vascular Solutions, Inc.	Z-0739-2012 RECALL RECS
2014-5115	06/23/2014 07/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	Krystal Colucci, Quality Manager Healthlink	K933121
2014-5116	06/23/2014 07/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jing Gu W.H.P.M., Inc.	K132167
2014-5117	06/23/2014 07/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	Krystal Colucci, Quality Manager Healthlink	K933122, K945911, K950196, ETC
2014-5118	06/23/2014 07/22/2014	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	Leslie Paul PERRIGO CO	BIOGEN IDEC, RESEARCH TRIANGLE PARK, NC - EIR, 483, RESPONSE 01/20/2009 - 06/20/2014
2014-5119	06/23/2014 07/22/2014	FDA/OC/OES/DDM/	845 SALAMANDRA LLC	EFFEXOR - MEETING MATERIALS FOR 1993 ADVISORY COMMITTEE
2014-5120	06/23/2014 07/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	Meghan Arreaza STRYKER INSTRUMENTS	K992931 TRANSFER LETTER
2014-5121	06/23/2014 07/22/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Marc Elia BRIDGER CAPITAL LLC	KYNAMRO - AERS
2014-5122	06/23/2014 08/01/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	Redacted 510(k)s 02/2014 - 05/2014
2014-5123	06/23/2014 07/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	Krystal Colucci, Quality Manager Healthlink	K921822
2014-5124	06/23/2014 07/22/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	ADCETRIS - AERS

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2014-5125	06/23/2014 07/22/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	REBECCA L DANDEKER MORGAN LEWIS & BOCKIUS LLP	SOCIETA ITALIANA MEDICINALI SCANDICCI (S.I.M.S), FIRENZE, ITALY - EIRS 1/1/10-12/31/10, 2/1/14-5/31/14
2014-5126	06/23/2014 07/22/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	REBECCA L DANDEKER MORGAN LEWIS & BOCKIUS LLP	SOCIETA ITALIANA MEDICINALI SCANDICCI, FIRENZE ITALY - 483S 1/1/10-12/31/10, 1/1/14-5/31/14
2014-5127	06/23/2014 07/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	LIANE LA ROCHELLE DEKA RESEARCH & DEVELOPMENT CORP	BRIDGE SENTRY BEDSIDE UNIT, BRIDGE SENTRY PHARMACY UTILITY, BRIDGE SENTRY ADMINISTRATION SETS - K973593
2014-5128	06/23/2014 07/22/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MCDONALD, BRANDON	TEGRETOL, BENADRYL, RISPERDAL, ETC - AERS
2014-5129	06/23/2014 07/22/2014	FDA/OGROP/ORACE-FO/CHI- DO/CHI-CB/ FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/ FDA/OGROP/ORANE-FO/NYK- DO/NYK-DCB/	JACQUELINE J CHAN K&L GATES	AKRON INC, SOMERSET, NJ, VERON HILLS, IL, DECATUR, IL, HI-TECH PHARMACAL INC, AMITYVILLE NY, COPIAGUE, NY - EIRS, 483S, WARNIG LTRS
2014-5130	06/23/2014 07/22/2014	OC/ORAC/ OC/ORAC/ FDA/OGROP/ORAC/ORO/DIOP/	DONALD N BLUE ZETETIC	SHIPMENTS REGULATED BY THE FDA 5/15/14-6/19/14
2014-5131	06/23/2014 07/22/2014	FDA/OC/OCC/ FDA/OFVM/CFSSAN/OCD/EOS/	JOHN H HNATIO FoodQuestTQ LLC	FOODQUEST TQ LLC, FREDERICK, MD - INDEPENDENT FORENSIC DEEP DIVE CURRENT & ARCHIVAL FDA & DHHS COMPUTER DATABASES DELETED ELECTRONIC RECS, EMAILS, EMAIL STRINGS
2014-5132	06/24/2014 07/23/2014	FDA/OGROP/ORASE-FO/ATL- DO/ATL-CB/	Lisa Fischer SPI Pharma, Inc.	DIXON INVESTMENTS, INC - 483 12/06/2013
2014-5133	06/24/2014 07/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	CPT1400285 Baseil, Philip A	CPT1400285
2014-5134	06/24/2014 07/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	Shane Sullivan ORTHOSCAN INC	x-ray and fluoroscopic units that are registered with each state

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2014-5135	06/24/2014 07/23/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ OC/ORAOCI/ OC/ORAOCI/	Parsley recall New England Greens, LLC	RAW DEAL INC - SAMPLE RESULTS
2014-5136	06/24/2014 07/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	Paula Schmidt Gerresheimer Medical Plastic Systems Dongguan Co. Ltd	GERRESHEIMER MEDICAL PLASTIC SYSTEMS DONGGUAN CO, LTD, CHINA - EIR 08/12/2012 - 06/20/2014
2014-5137	06/24/2014 07/23/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Melissa Nann Burke The News Journal	SERPE & SONS, INC - WILMINGTON, DE - INSPECTION RECS, CORR 02/01/2014 - 06/20/2014
2014-5138	06/24/2014 07/23/2014	FDA/OMPT/CTP/OD/	Celeste D. Wheeler Kleinfeld, Kaplan, and Becker LLP	Quarter 1 Report and Labeling Analysis Tool cited in 2014 Tobacco Control Article prepared by FDA officials
2014-5139	06/24/2014 07/23/2014	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	Lisa Fischer SPI Pharma, Inc.	CROWN LABORATORIES, INC - 483 01/01/2014 - 04/24/2014
2014-5140	06/24/2014 07/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Theis Terwey NB Capital Research GmbH	IMBRUVICA - AERS
2014-5141	06/24/2014 07/23/2014	FDA/OC/OES/DFOI/	Karen Brown Karen Brown	DIALYSIS CATHETER ADVERSE EVENTS FROM PNRS NORTHWEST RENAL, TUALATIN, OR, DR KENNEFICK, DR CHANDRAN 01/01/2011 - 01/01/2014
2014-5142	06/24/2014 07/23/2014	OC/ORAO/ OC/ORAO/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORASW-FO/SWID/SWID-CB/	Doe J	INDIVIDUAL RECS
2014-5143	06/24/2014 07/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dru West Dru West	NUVARING - AERS
2014-5144	06/24/2014 07/23/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-3550 - REQUEST LETTER ONLY
2014-5145	06/24/2014 07/23/2014	FDA/OC/OES/DFOI/	Kari L. Twaite BEVERIDGE & DIAMOND PC	CFSAN FOIA REQUESTS 05/30/2014 - 06/23/2014

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2014-5146	06/24/2014 07/23/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-3631, 2014-3632 - REQUEST LETTER ONLY
2014-5147	06/24/2014 07/23/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-3974 - REQUEST LETTER ONLY
2014-5148	06/24/2014 07/23/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-4043 - REQUEST LETTER ONLY
2014-5149	06/24/2014 07/23/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-4365 - REQUEST LETTER ONLY
2014-5150	06/24/2014 07/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K131249
2014-5151	06/24/2014 07/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	INVOKANA - AERS
2014-5152	06/24/2014 07/23/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CAROLINE STOUT ECOR1 CAPITAL LLC	RAVICTI (GLYCEROL PHENYLBUTYRATE), LIZNESS (LINACLOTIDE), REVOLIXYS (PEGNIVACOGIN AND ANIVAMERSEN), ETC - AERS; ADCETRIS - FOI REQUESTS, ETC
2014-5153	06/24/2014 07/23/2014	FDA/OC/OES/	ELIZABETH JUNGMAN PEW CHARITABLE TRUSTS	PHARMACEUTICAL MANUFACTURERS AND RESEARCHERS OF AMERICA (PHRMA) - COMMISSIONER HAMBURG LTR 9/13
2014-5154	06/24/2014 07/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	STEPHEN J ELLIOTT SULLIVAN & CROMWELL LLP	GELFOAM POWDER - CORR, TESTING, PHOTOGRAPHS, ETC
2014-5155	06/24/2014 07/23/2014	FDA/OC/OES/DFOI/	CAROLINE STOUT ECOR1 CAPITAL LLC	BREAKTHROUGH DESIGNATION APPLICATIONS - FOIA REQUESTS 1/13 TO PRESENT
2014-5156	06/24/2014 07/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRODY MULLINS WALL STREET JOURNAL	REP ED WHITFIELD - CORR 9/30/12 TO PRESENT
2014-5157	06/24/2014 07/23/2014	FDA/OC/OES/ FDA/OC/OL/	BRODY MULLINS WALL STREET JOURNAL	REP ED WHITFIELD - CORR 9/30/12 TO PRESENT
2014-5158	06/24/2014 07/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRODY MULLINS WALL STREET JOURNAL	LASERLOCK - CORR 9/30/12

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2014-5159	06/24/2014 07/23/2014	FDA/OC/OL/	BRODY MULLINS WALL STREET JOURNAL	REP ED WHITFIELD - CORR 9/30/12
2014-5160	06/24/2014 07/23/2014	FDA/OC/OES/	BRODY MULLINS WALL STREET JOURNAL	LASERLOCK - CORR 9/30/12
2014-5161	06/25/2014 07/24/2014	FDA/OFVM/CFSAN/OCD/EOS/	Lauren Hruska Villa San-Juliette	DIAM CORKS - RECS RE RADIATION 06/01/2000 - 06/20/2014
2014-5162	06/25/2014 07/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	Greg Hopper SCBMA	SMITH & NEPHEW BIRMINGHAM HIP STUDY RECS
2014-5163	06/25/2014 07/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joe Malone Joe Malone	PARAGUARD, MIRENA, IMPLANON ETC AERS
2014-5164	06/25/2014 07/24/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jesse McLean Toronto Star	APOTEX 483 12/01/2010 - 08/24/2012
2014-5165	06/25/2014 07/24/2014	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	David J Mangione Govzilla, Inc.	HOSPIRA, MCPHERSON, KS - EIR 04/01/2014 - 05/30/2014
2014-5166	06/25/2014 07/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	Greg Hopper SCBMA	SMITH & NEPHEW - PMA BIRMINGHAM HIP
2014-5167	06/25/2014 07/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	Greg Hopper SCBMA	BIRMINGHAM HIP REPLACEMENT SYSTEM - STUDY RECS
2014-5168	06/25/2014 07/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	Greg Hopper SCBMA	SMITH & NEPHEW BIRMINGHAM HIP REPLACEMENT SYSTEM STUDY RECS
2014-5169	06/25/2014 07/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	Greg Hopper SCBMA	SMITH & NEPHEW RECS RE CHROMIUM, COBALT, METAL POISONING
2014-5170	06/25/2014 07/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	INDIVIDUAL RECS

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-5171	06/25/2014 07/24/2014	FDA/OC/OES/DDM/ FDA/OMPT/CDRH/OCER/DFOI/	Brad Hathaway Far View Capital Management	STEEN SOLUTION - HDE APPROVAL RECS
2014-5172	06/25/2014 07/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jeffrey K. Shapiro Hyman, Phelps & McNamara P.C.	K063357, K991843, K991702
2014-5173	06/25/2014 07/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	Carole Sykes Carole Sykes	K840207
2014-5174	06/25/2014 07/24/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Maire Colhoun on behalf of Martina O'Sullivan Mylan Institutional LLC	ANDA 080854 APPROVAL DATE, DISCONTINUATION DATE, REASON FOR DISCONTINUATION
2014-5175	06/25/2014 07/24/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jennifer Wood BRISTOL-MYERS SQUIBB	FAERS CASE NUMBERS 9667919, 9703762
2014-5176	06/25/2014 07/24/2014	FDA/OGROP/ORAC/CE-FO/DET-DO/DET-CB/	Alexander Barney The Karmel Law Firm	HILL-ROM, BATESVILLE, IN - RECS 03/01/2011 - 06/24/2014
2014-5177	06/25/2014 07/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	LISA ANDERSON ConMed Corporation	K132522
2014-5178	06/25/2014 07/24/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	LISA ANDERSON ConMed Corporation	K132512
2014-5179	06/25/2014 07/24/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ADRIAN KAEMPFER ACTELION PHARMACEUTICALS LTD	PARTNERSHIP FOR SAFE MEDICINES INTERCHANGE 2010 - LIST OF 1,000 PHARMACEUTICAL INGREDIENTS WHICH ARE POTENTIALLY EXPOSED TO ECONOMICALLY-MOTIVATED ADULTERATION
2014-5180	06/25/2014 07/24/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LORI HURLBERT John Muir Concord California	LOTENSIN (BENAZEPRIL) (,CAPTOPRIL, ENALAPRIL (VASOTEC), ETC - AERS

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		FDA/OMPT/CDER/ORP/DIDP/		
2014-5181	06/25/2014 07/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	EMILY MARDEN SIDLEY AUSTIN LLP	CONCERTA (METHYLPHENIDATE HCL ER TABS) - NOTES, LTRS, AERS
2014-5182	06/25/2014 07/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	EMILY MARDEN SIDLEY AUSTIN LLP	FUNDING FOR PHARMACOKINETIC/PHARMACODYNAMIC STUDIES OF METHYLPHENIDATE ER PRODS - NOTES, INTERNAL CONSIDERATIONS, COMM
2014-5183	06/25/2014 07/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	MICHAEL DAUCHOT ALLIANZGI RCM	BOSTON SCIENTIFIC CORP - WATCHMAN COMM, RECS 1/1/14-6/17/14
2014-5184	06/25/2014 07/24/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Doe J	CONFORMIS - ITOTAL KNEE REPLACEMENT SYS MODEL NO, SERIAL NO
2014-5185	06/25/2014 07/24/2014	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	HERBERT J FRIEDMAN FRIEDMAN LAW OFC PC	NEURORESEARCH CLINICS - NEUROREPLETE 40% D5 MUCCNA, CYSREPLETE & REPLETEEXTRA DEFENDANTS COMPLIED WITH CONSENT ORDER, REC
2014-5186	06/25/2014 07/24/2014	FDA/OFVM/CFSAN/OCD/EOS/	GARY J BURIN TECHNOLOGY SCIENCES GROUP INC	FCN 0053
2014-5187	06/25/2014 07/24/2014	FDA/OMPT/CTP/OD/	JEFF NOAH MIDWEST TOBACCO TUBE INC	LIST OF TOBACCO PRODS (OTHER THAN SMOKELESS TOBACCO) THAT THE FDA HAS DETERMINED ARE GRANDFATHERED PRODS MARKETED IN THE US 2/15/07 - BRAND NAME, TRACKING NUMBER, GF SUBMISSION
2014-5188	06/25/2014 07/24/2014	FDA/OFVM/CFSAN/OCD/EOS/	DAMON, KARA	HOW SWEET IT IS : ALL ABOUT SUGAR SUBSTITUTES - AUTHORS & TITLES OF THE 37 STUDIES
2014-5189	06/25/2014 07/24/2014	FDA/OC/OES/DFOI/	GREEN V53932 D3-149, LANCE WILLIAM	DEXTROAMPHETAMINE SULFATE, METHAMPHETAMINE HCL - CHEMICAL PROCESSES, INGREDIENTS, HOW TO APPLY FOR PERMIT TO MAKE THESE DRUGS, ETC
2014-5190	06/25/2014 07/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORAOCI/ OC/ORAOCI/	MICHAEL M ROSENSAFT KATTEN MUCHIN ROSENMAN LLP	PHARMACOLOGICAL INC (MEDICAL DEVICE KING), WILLIAM SCULLY, SHAHRAD RODI LAMEH - EMAILS, INVESTIGATIVE NOTES, CMLPNTS, ETC

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		FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2014-5191	06/25/2014 07/24/2014	FDA/OGROP/ORAO/RO/DIOP/	EMILY ROLLINS UNIV OF GUELPH	LIST OF CANADIAN FIRMS FOR FOOD PRODS 2002-2013
2014-5192	06/25/2014 07/24/2014	FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/	CAROLLO, RUSSELL	2012-6232, 2013-362, 2013-903, ETC
2014-5193	06/26/2014 07/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Hamilton Borden Blount Discount Pharmacy	TESTOSTERONE & VTE CASE REPORTS
2014-5194	06/26/2014 07/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Beth Glasgow GOJO Industries, Inc.	NDA 020111 SBA
2014-5195	06/26/2014 07/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dhaval N Desai Zydus Pharmaceuticals USA Inc.	NDA 204977 SBA
2014-5196	06/26/2014 07/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dhaval N Desai Zydus Pharmaceuticals USA Inc.	NDA 050606 SBA
2014-5197	06/26/2014 07/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dr. Vinay Bhatt Cadila Healthcare Ltd	SALSALATE - AERS
2014-5198	06/26/2014 07/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ibrutinib Ken Tong	IMBRUVICA - AERS

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-5199	06/26/2014 07/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	Brent Ireland none	MQSA EXAMS PER YEAR, FDA MQSA ID - NEW JERSEY FACILITIES 01/01/2012 - 06/01/2014
2014-5200	06/26/2014 07/25/2014	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	Cheryl Profenius Quintiles Research	RICHARD C DART - 483 2005
2014-5201	06/26/2014 07/25/2014	FDA/OC/OES/DDM/ FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Greg Hopper SCBMA	SMITH & NEPHEW BIRMINGHAM HIP RESURFACING SYSTEM PMA 040033 - ADVISORY COMMITTEE RECS, MAUDE REPORTS, INSPECTION RECS ETC
2014-5202	06/26/2014 07/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	PULMONETICS SYSTEMS, CAREFUSION LTV 1150 VENTILATOR - INVESTIGATION RECS 01/27/2014 - 04/30/2014
2014-5203	06/26/2014 07/25/2014	OC/ORA/OCI/ OC/ORA/OCI/	shontay dessart shontay dessart	SAMPLE RESULTS 8191592, FACTS 725329, OCI CASE NUMBERS
2014-5204	06/26/2014 07/25/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Lisa Robertson Rawls McNelis + Mitchell	INDIVIDUAL RECS
2014-5205	06/26/2014 07/25/2014	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	J. Fred Pruden Sprout Pharmaceuticals, Inc.	MIKART INC, ENTERPRISE - EIR 04/01/2014 - 06/24/2014
2014-5206	06/26/2014 07/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Faruqi & Faruqi, LLP Faruqi & Faruqi, LLP	IMETELSTAT - IND
2014-5207	06/26/2014 07/25/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Lisa Robertson Rawls McNelis + Mitchell	INDIVIDUAL RECS
2014-5208	06/26/2014 07/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	COSMETIC BOTULISM - AERS
2014-5209	06/26/2014 07/25/2014	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	Cheryl Profenius Quintiles Research	CLARITA KETELS, MD - 483 12/11
2014-5210	06/26/2014 07/25/2014	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OMPT/CDRH/OCER/DFOI/	JESSICA M LAVIN NICHOLAS LAW FIRM	MEDISOUND INC, DIGITAL RADIOLOGY CENTER INC - CORR, INVESTIGATIONS, CMPLNTS, ETC 2009 TO PRESENT
2014-5211	06/26/2014	FDA/OC/OES/DFOI/	TAMELA E ESHAM	HYDROCHLOROTHIAZIDE - AERS, CMPLNTS, RECALL RECS, ETC

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	07/25/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ARMBRECHT JACKSON LLP	
2014-5212	06/26/2014 08/28/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/ OC/ORA/OCI/ OC/ORA/OCI/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	TIMOTHY L SIFERS ESQ Potts Law Firm	NOVACARE LLC, CARSON CITY, NV - STIFF NIGHTS INSPS, MEMOS, RPTS, ETC
2014-5213	06/26/2014 07/25/2014	FDA/OC/OES/DFOI/	MARGARET B KWOKA UNIV OF DENVER STURM COLLEGE OF LAW	FOIA REQUESTS - REQUESTER NAMES, IDENTITIES, CATEGORIES, ETC 2013
2014-5214	06/26/2014 07/25/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELIZABETH BARBEHENN PHD PUBLIC CITIZEN	NESINA (ALOGLIPTIN) NDA 22-271: THREE CONSULTS FROM FDA HEPTATOLOGIST DR LEONARD SEEFF 2/22/12, 5/8/12, 11/10/12
2014-5215	06/26/2014 07/25/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/ OC/ORA/ OC/ORA/	CHRISTOPHER A BERRY ESQ ANIMAL LEGAL DEFENSE FUND	EGG PRODUCTION IN IOWA - EIRS, ENVIRONMENTAL TESTS, HEALTH RPTS, ETC 7/11 TO PRESENT
2014-5216	06/26/2014 07/25/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	KIM HENDERSON SANOFI PASTEUR	GSK BIOLOGICALS, QUEBEC, CANADA - 483 2014
2014-5217	06/26/2014 07/25/2014	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	ABRAHAM PAYTON AMERICAN BRIDGE 21ST CENTURY	KOCH AGRICULTURE SERVICES, GREAT FALLS, MT - EIR 5/23/95; KOCH INDUSTRIES - WARNING LTR 5/13/93

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2014-5218	06/26/2014 07/25/2014	FDA/OGROP/ORPA/FO/SAN-DO/SAN-CB/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	VALERIE ALARCON Second Image National	GENENTECH, AVELLA OF PHOENIX II INC, MIRAMAR EYE SURGICAL ASSOCIATES MEDICAL CLINIC INC - AVASTIN RECS; INDIVIDUAL RECS
2014-5219	06/26/2014 09/29/2014	FDA/OGROP/ORANE/FO/NWE-DO/NWE-CB/ FDA/OGROP/ORASE/FO/SJN-DO/SJN-CB/ FDA/OGROP/ORASW/FO/DEN-DO/DEN-CB/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	CHRIS GEGELYS Covance Inc.	AMGEN INC - 482S, 483S, EIRS, WARNING LTRS, ETC 1/09 TO PRESENT
2014-5220	06/26/2014 08/26/2014	FDA/OGROP/ORAPA/FO/SAN-DO/SAN-CB/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	CHRIS GEGELYS Covance Inc.	GILEAD SCIENCES INC, GILEAD SCIENCES LLC - 482S, 483S, EIRS, WARNING LTRS, ETC 1/09 TO PRESENT
2014-5221	06/26/2014 09/15/2014	FDA/OGROP/ORACE/FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORASE/FO/ATL-DO/ATL-CB/ FDA/OGROP/ORASE/FO/NOL-DO/NOL-CB/ FDA/OGROP/ORASE/FO/SJN-DO/SJN-CB/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	CHRIS GEGELYS Covance Inc.	MERCK & CO INC, MERCK SHARP AND DOMHE CORP - 482S, 483S, EIRS, WARNING LTRS, ETC 1/09 TO PRESENT
2014-5222	06/26/2014 07/25/2014	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	TORREY COPE SIDLEY AUSTIN LLP	AMBI, ESOTERICA - CORR THAT RELATES TO THE MARKETING WITHOUT AN NDA OF ANY PROD THAT

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		CONTAINS 2% HYDROQUINONE
2014-5223	06/26/2014 07/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TORREY COPE SIDLEY AUSTIN LLP	PROSTIGMIN (NEOSTIGMINE BROMIDE) TABS - CORR THAT RELATES TO THE MARKETING WITHOUT AN NDA
2014-5224	06/26/2014 07/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TORREY COPE SIDLEY AUSTIN LLP	NU-DERM, CONDITION & ENHANCE, OBAGI-C RX, ELASTIDERM - CORR THAT RELATES TO MARKETING, WITHOUT AN NDA, OF ANY PROD THAT CONTAINS 4% HYDROQUINONE
2014-5225	06/26/2014 07/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TORREY COPE SIDLEY AUSTIN LLP	CORR THAT RELATES TO THE MARKETING, WITHOUT AN NDA, OF BENSAL HP TOPICAL OINTMENT
2014-5226	06/26/2014 07/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TORREY COPE SIDLEY AUSTIN LLP	NEPHROCAPS, NEPHROCAPS-QT - MARKETING WITHOUT AN NDA CORR
2014-5227	06/26/2014 07/25/2014	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	THOMAS, LEANNE	LNK INTERNATIONAL INC, HAUPPAUGE, NY - INSPS, RESULTS LAST 2 YRS
2014-5228	06/26/2014 07/25/2014	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	THOMAS, LEANNE	COSTCO WHOLESALE CORP, SEATTLE, WA - 81 MG LOW DOSE ASPRIRIN INSPS, RESULTS
2014-5229	06/26/2014 07/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	THOMAS, LEANNE	COSTCO WHOLESALE CORP - KIRKLAND BRAND CALCIUM CITRATE, ENTERIC FISH OIL, GLUCOSAMINE, ETC MANUFACTURED ACCORDING TO FDA GUIDELINES

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2014-5230	06/26/2014 07/25/2014	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	LINH CHU DYNAVAX TECHNOLOGIES	NOVARTIS VACCINES AND DIAGNOSTICS INC, HOLLY SPRINGS, NORTH CA - EIR 2014
2014-5231	06/26/2014 07/25/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELLIOT FAVUS MD FAVUS INSTITUTIONAL RESEARCH LLC	ISRS 9542938, 9624442, 9853736, ETC
2014-5232	06/26/2014 07/25/2014	OC/ORR/ORM/ OC/ORR/ORM/ FDA/OC/OES/DFOI/	SASHA PERKINS THOMSON REUTERS	FOREIGN AND DOMESTICS INSPS 12/13 TO PRESENT
2014-5233	06/27/2014 09/02/2014	FDA/OMPT/CDRH/OCER/DFOI/	Maria Fagerberg HemoCue AB	K121752
2014-5234	06/27/2014 07/28/2014	FDA/OMPT/CDRH/OCER/DFOI/	Maria Fagerberg HemoCue AB	K122553
2014-5235	06/27/2014 07/28/2014	FDA/OMPT/CDRH/OCER/DFOI/	Maria Fagerberg HemoCue AB	K111403, K110028
2014-5236	06/27/2014 08/26/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Maria Fagerberg HemoCue AB	BK110036
2014-5237	06/27/2014 07/28/2014	FDA/OMPT/CDRH/OCER/DFOI/	Maria Fagerberg HemoCue AB	K031898
2014-5238	06/27/2014 07/28/2014	FDA/OMPT/CDRH/OCER/DFOI/	Maria Fagerberg HemoCue AB	K032482
2014-5239	06/27/2014 07/28/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Tim Alamenciak Toronto Star	ID BIOMEDICAL CORP, STE-FOY, QUEBEC - EIR 01/01/2009 - 05/01/2011
2014-5240	06/27/2014 07/28/2014	FDA/OC/OES/DFOI/	Liza Meak NBC Bay Area News (KNTV)	CORD BLOOD FACILITIES
2014-5241	06/27/2014 07/28/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K121618
2014-5242	06/27/2014 07/28/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K121736
2014-5243	06/27/2014 07/28/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K121736
2014-5244	06/27/2014 07/28/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K073693

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2014-5245	06/27/2014 07/28/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K073693
2014-5246	06/27/2014 07/28/2014	FDA/OMPT/CDRH/OCER/DFOI/	nadia hermiz Cliniqa Corporation	K955690
2014-5247	06/27/2014 07/28/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/	Doe J	INDIVIDUAL RECS
2014-5248	06/27/2014 07/28/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Helen Branswell The Canadian Press	ID BIOMEDICAL CORPORATION OF QUEBEC - 483, CORRESPONDENCE
2014-5249	06/27/2014 07/28/2014	FDA/OC/OES/DDM/ FDA/OFVM/CFSAN/OCD/EOS/	Michaela Oldfield MICHIGAN STATE UNIVERSITY	TRANSCRIPTS OF FSMA RULEMAKING, NOTES FROM FARM TOURS RE FSMA RULEMAKING, MEETING NOTES WITH STAKEHOLDERS 01/04/2010 - 12/31/2014
2014-5250	06/27/2014 07/28/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORO/NE-FO/NWE- DO/NWE-CB/ FDA/OC/OES/DFOI/	Zohar Zephrani BOSTON MEDTECH ADVISORS INC	CPGM 7382.845 2004-2006
2014-5251	06/27/2014 07/28/2014	FDA/OC/OES/DDM/	Lawrence Tracey TRACEY LAW FIRM	TRANSCRIPT, MTG MINUTES FROM PART 15 HEARING ON PREGNANCY LABELING CATEGORIES 09/12/1997
2014-5252	06/27/2014 07/28/2014	FDA/OMPT/CDRH/OCER/DFOI/	AERIA BOLDEN BERTLING & CLAUSEN LLC	CODMAN & SHURTLEFF INC - SURGICAL PATTIES & STripES, DEVICE EXPERIENCE DATA RTPS
2014-5253	06/27/2014 07/28/2014	FDA/OFVM/CFSAN/OCD/EOS/	VISAGINE VIJAYAKULASINGAM IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS - 175897, 176164
2014-5254	06/27/2014 07/28/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANDREW HACK, MD, Ph.D. MILLENNIUM MANAGEMENT LLC	PHARMACYCICS - IMBRUVICA (IBRUTINIB) FAERS
2014-5255	06/27/2014 07/28/2014	FDA/OGROP/ORO/NE-FO/NYK- DO/NYK-DCB/	KELLY CONNELLY POWERS & SANTOLA	CARENET MEDICAL GROUP, SCHENECTADY, NY - WARNING LTR, INSP 2007 TO 2014
2014-5256	06/27/2014 07/28/2014	OC/ORO/ORM/ OC/ORO/ORM/	LEWIS, NORMAN	LIST OF REGISTERED PHARMACEUTICAL & DIETARY SUPPLEMENT COMPANIES FOREIGN AND DOMESTIC
2014-5257	06/27/2014 07/28/2014	FDA/OGROP/ORO/CE-FO/DET- DO/DET-CB/	HU, QIYONG	TERUMO CARDIOVASCULAR GROUP, ANN ARBOR, MI - INSP, CO RESP 2011

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2014-5258	06/27/2014 07/28/2014	OC/ORO/ORM/ OC/ORO/ORM/	HUGE, GARY	FOOD FACILITITES 6/25/11 - 6/25/14 FDA INSPECTED
2014-5259	06/27/2014 07/28/2014	FDA/OC/OES/DFOI/	CARRIE MORGAN OLSSON FRANK & WEEDA	2013-6922 REDACTIONS
2014-5260	06/27/2014 07/28/2014	FDA/OC/OES/ FDA/OC/OEXA/OC/ FDA/OC/OL/	CRAIG ROBINSON PATRIOTS FOUNDATON	ALL FDA EMPLOYEE CORR REGARDING SENATOR HARRY REID
2014-5261	06/27/2014 07/28/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	SHALL JIANG AMERICAN RED CROSS	RED BLOOD CELLS FROZEN - SBA
2014-5262	06/27/2014 08/15/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	PETRICCIANI MD, JOHN	NIH CONFERENCE ON PRODUCTION & TESTING & REQUIREMENTS FOR LIVE POLIOVIRUS VACCINE 8/1960
2014-5263	06/30/2014 07/29/2014	FDA/OGROP/ORO/SW-FO/DEN- DO/DEN-CB/	Monty Curry ZYNEX MEDICAL	ZYNEX MEDICAL - ROI REPORT 06/10/2009 - 06/10/2010
2014-5264	06/30/2014 07/29/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K121618
2014-5265	06/30/2014 07/29/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K080432
2014-5266	06/30/2014 07/29/2014	FDA/OMPT/CDRH/OCER/DFOI/	Andy Hu Globe Medical Tek	K131157
2014-5267	06/30/2014 07/29/2014	FDA/OMPT/CDRH/OCER/DFOI/	Amarjit Jowandha Sony Electronics Inc.	K973436
2014-5268	06/30/2014 07/29/2014	FDA/OMPT/CDRH/OCER/DFOI/	Andy Hu Globe Medical Tek	K111632
2014-5269	06/30/2014 07/29/2014	FDA/OFVM/CFSAN/OCD/EOS/	Kenneth Grant Compliance Engineering, Inc.	FCN 1054, FCN 454
2014-5270	06/30/2014 07/29/2014	FDA/OMPT/CDRH/OCER/DFOI/	MCKENZIE CATO Hyman, Phelps & McNamara P.C.	TRIA BEAUTY INC - TRIA FAN SYS K130459
2014-5271	06/30/2014 07/29/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DIANA RUTOWSKI ORRICK HERRINGTON & SUTCLIFFE LLP	ZIMMER GMBH - BIOTOX DELTA CERAMIC FERNORAL HEADS K130899, K071535; MICROPORT ORTHOPEDICS INC - DYNASTY SHELL A-CLASS CTROSSLINKED POLY LINER, BIOLOX DELTA FEMORAL HEADS K140043, ETC
2014-5272	06/30/2014 07/29/2014	FDA/OC/OES/DFOI/	SANDRA E WIDLAN SCHROETER GOLDMARK & BENDER	AMANTE PIZZA & PASTA LLC - MEATBALL DISH COMPLNTS, INVESTIGATIONS

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2014-5273	06/30/2014 07/29/2014	FDA/OFVM/CFSAN/OCD/EOS/	CYNWTHIA B LIEBERMAN Keller and Heckman LLP	CENTER FOR REGULATORY SERVICES (UTSUMI RCYLCE SYS) - POLYEHTYLENE TERPHTHALATE NOL 159; KELLER & HECKMAN (SELENIS CANADA INC) - POLYETHYLENE TEREPTHALATE NOL 162; KELLER & HECKMAN (ALPHAPET INC) - POLYETHYLENE TEREPTHALATE NOL 167, ETC
2014-5274	06/30/2014 07/29/2014	FDA/OFVM/CFSAN/OCD/EOS/	CYNTHIA B LIEBERMAN Keller and Heckman LLP	FRAUNHOFER INSTITUT VERFAHRENSTECHNIC UND VERPACKUNG (WASTE & RESOURCE ACTION PROGRAM) - HIGH DENSITY POLYETHYLENE NOL 108; UNION CARBIDE CORP - HIGH DENSITY POLYETHYLENE NOLS 52 & 36; SCIENTIFIC CERTIFICATON SYSEMS (ENVIROPLASTIC) - HIGH DENSISTY POLYETHYLENE NOLS 50 & 41, ETC
2014-5275	06/30/2014 07/29/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	CHERRY #618920, JOHN	DEPUY ORTHOPAEDIC INC, WARSAW, IN - HIP IMPLANT DVC WARNING LTRS, MELATOSIS, EFFECTS OF PROLONGED EXPOSURE TO CHROMIUM & COBALT, ETC
2014-5276	07/01/2014 07/30/2014	FDA/OC/OES/DFOI/	Garrett M. Brief Becker Law Group	2012-2135
2014-5277	07/01/2014 07/30/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-2194
2014-5278	07/01/2014 07/30/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-2189
2014-5279	07/01/2014 07/30/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-2198
2014-5280	07/01/2014 07/30/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-8595
2014-5281	07/01/2014 07/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kaylee White SALAMANDRA LLC	BLA 101995 SBA
2014-5282	07/01/2014 07/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kevin J. Freise Nexycon Pharmaceuticals, Inc.	NDA 20732, NDA PHARM, TOX RVWS
2014-5283	07/01/2014 07/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ibrutinib - individual cases Ken Tong	IMBRUVICA - SIX CASES

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2014-5284	07/01/2014 07/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rena Heer Bell Media	ONDANSETRON - AERS
2014-5285	07/01/2014 07/30/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K080432
2014-5286	07/01/2014 07/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Scott Edelsberg Kopelowtiz Ostrow	All submissions on behalf of manufacturers regarding the standardized testing prescribed in 21 CFR section 201.327(7). (water resistant sunscreen testing). Any test results submitted to the FDA that deal with 21 CFR section 201.327(7).
2014-5287	07/01/2014 07/30/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anon Anon	ANDA 88676, ANDA 86661; PBA APPROVALS, FOIA REQUESTS
2014-5288	07/01/2014 07/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sara Grossman LIU Pharmacy	FDA approval letter for generic tamsulosin manufactured by Sandoz, ANDA 078015
2014-5289	07/01/2014 07/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dhaval N Desai Zydus Pharmaceuticals USA Inc.	NDA 020622 SBA
2014-5290	07/01/2014 07/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/CVM/OCD/	Debra B. Rose Debra B. Rose, RN,MS,PNP	AUROBINDO PHARMA LTD - INSPECTION RECS, ACTIONS, ETC
2014-5291	07/01/2014 07/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Moumita Rawal G&W Laboratories Inc.	NDA 017950, NDA 021794, ANDA 075172 ETC
2014-5292	07/01/2014	FDA/OMPT/CDER/ORP/DIDP/	Tony Nguyen	TARO PHARMACEUTICAL INDUSTRIES LTD - 483 01/01/2008

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	07/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RTW Investments LLC	- 06/26/2014
2014-5293	07/01/2014 07/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Matthew Ventresca MCMaster UNIVERSITY	PATIENT DATA, CLINICAL STUDY REPORTS SAVE-ONCO:NCT00694382 PROTECHT:NCT00951574 PROSPECT-CONKO:NCT00785421 FAMOUS:NCT00951574
2014-5294	07/01/2014 07/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	Michael Kaminski PROCTER & GAMBLE	K140481
2014-5295	07/01/2014 07/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Andy Washkowitz Stifel Nicolaus & Co	NERATINIB - AERS
2014-5296	07/01/2014 07/30/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Meghan Homa MEDTRONIC, INC	K003288
2014-5297	07/01/2014 07/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	Andy Hu Globe Medical Tek	K041991
2014-5298	07/01/2014 07/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	Meghan Homa MEDTRONIC, INC	K13869
2014-5299	07/01/2014 07/30/2014	FDA/OC/OES/DFOI/	Patrick McKillop Patrick McKillop / Maxim Group	IMBRUVICA - AERS
2014-5300	07/01/2014 07/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	TRIDESILON CREAM NDA 17-010 - APRVL, LBLG, CHEMISTRY RVW, BIOEQUIV RVW
2014-5301	07/01/2014 07/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	DES OWEN CREAM NDA 19-048 - APRVL, CHEMISTRY RVW, BIOEQUIV RVW
2014-5302	07/01/2014 07/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	DESONIDE OINTMENT NDA 74-254 - LBLG, APRVL, CHEMISTRY RVW, BIOEQUIV

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2014-5303	07/01/2014 07/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	DESONIDE CREAM NDA 74-027 - APRVL, LBLG, CHEMISTRY RVW, BIOEQUIV
2014-5304	07/01/2014 07/30/2014	OC/CVM/OCD/	KRISTI O. SMEDLEY, Ph.D. Center for Regulatory Services, Inc.	KEMIRA PETITION FOR AMMONIUM FORMATE
2014-5305	07/01/2014 07/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M. GARTZ ELI LILLY & CO	DR KLAUS WEYLAND, INGELHEIM, GERMANY - EIR
2014-5306	07/01/2014 07/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	S ALBERT EDWARDS, PHARM D	DONNATOL - APRVL 88-676, 86-661
2014-5307	07/01/2014 09/08/2014	FDA/OO/OHR/	AMOS M. WHITNEY WEINBERG & SCHWARTZ LLC	INDIVIDUAL RECS
2014-5308	07/01/2014 07/30/2014	FDA/OGROP/ORAP/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	LIZA MEAK NBC Bay Area News (KNTV)	BAY AREA CORD BLOOD INSP RECORDS
2014-5309	07/01/2014 07/30/2014	FDA/OGROP/ORAP/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAP/SE-FO/FLA-DO/FLA-CB/ FDA/OMPT/CDRH/OCER/DFOI/	BENJAMIN L. ENGLAND, Esq. BENJAMIN L ENGLAND & ASSOCIATES LLC	A1 ENGINEERING - NEUROTIS SX SERIES FEI 3007008050; BEAUTIFUL IMAGE LLC - BEAUTIFUL IMAGE MODEL 900 FEI 3009161186; TAVTECH LTD - JETPEEL FEI 9615063 - EIR, INSP
2014-5310	07/01/2014 07/30/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Matt Cine/Jeremy Cain GIDEON COOPER & ESSARY	DOCUMENTATION OF MPA SHORTAGES
2014-5311	07/01/2014 08/29/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	D. MICHAEL NOONAN SHAHEEN & GORDON PA	INDIVIDUAL RECS
2014-5312	07/01/2014	FDA/OMPT/CDER/ORP/DIDP/	CHRISTOPHER L. SCHNIEDERS	CLOMID; SEROPHENE; CLOMIPHENE CITRATE - APRVL,

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2014-5313	07/01/2014 07/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHANDRAN TIRUVATTAR DR REDDYS LABORATORIES INC	3M - PROVENTIL NDA 20-503 - SBA
2014-5314	07/01/2014 07/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID HOFFMEISTER WILSON SONSINI ET AL	TEVA - NDA 21-457/S-026
2014-5315	07/01/2014 07/30/2014	FDA/OFVM/CFSAN/OCD/EOS/	DEBORAH C. ATTWOOD Keller and Heckman LLP	FCN 719 - TOXICITY DATA
2014-5316	07/01/2014 07/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	KELLY A. BOWLES HANCE & SRINIVASAN	INDIVIDUAL RECS
2014-5317	07/02/2014 07/31/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Megan M. Sullivan FARUQI & FARUQI LLP	RENTSCHLER BIOTECHNOLOGIES GMBH - INSPECTION RECS 01/01/2010 - 06/26/2014
2014-5318	07/02/2014 07/31/2014	FDA/OMPT/CDRH/OCER/DFOI/	Andy Hu Globe Medical Tek	K072330
2014-5319	07/02/2014 07/31/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Charles E. Adler Adler Law Offices, Ltd.	XARELTO - AERS
2014-5320	07/02/2014 07/31/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	ONFI - 33 MEDWATCH CASES
2014-5321	07/02/2014 07/31/2014	FDA/OMPT/CDRH/OCER/DFOI/	Diana Rutowski Orrick, Herrington & Sutcliffe LLP	Biolog Delta Master File and 510(k)s
2014-5322	07/02/2014 07/31/2014	FDA/OMPT/CDRH/OCER/DFOI/	Debbie Koeneman Debbie Koeneman	STRONTIUM 90 BETA SOURCE - DEVICE LISTING INFO

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2014-5323	07/02/2014 07/31/2014	FDA/OMPT/CDRH/OCER/DFOI/	Debbie Koeneman Debbie Koeneman	STRONTIUM 90 BETA SOURCE, ISOTOPE PRODUCTS, INC - DEVICE LISTING INFO
2014-5324	07/02/2014 07/31/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	William B. Monahan William B. Monahan, Sullivan & Cromwell LLP	NDA 020511 CASE REPORTS
2014-5325	07/02/2014 07/31/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jasper D. Ward JONES WARD PLC	REVLIMID - AERS; CORR WITH CELGENE RE REVLIMID
2014-5326	07/02/2014 07/31/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Christine Blumhardt BLUMHARDT CONSULTING	ANDA 201331, ANDA 202189
2014-5327	07/02/2014 07/31/2014	FDA/OMPT/CDRH/OCER/DFOI/	Robert E Blanton, Jr., Esq. Hardin, Kundla, McKeon & Poletto, P.A.	MAI Hydrogel Implant for Scleral Buckling
2014-5328	07/02/2014 07/31/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	William B. Monahan SULLIVAN & CROMWELL LLP	ULURU INC - PDUFA FEES, FEE WAIVER, COMMUNICATIONS ETC
2014-5329	07/02/2014 07/31/2014	OC/ORR/ORM/ OC/ORR/ORM/	Jeremy Singer-Vine Buzzfeed News	FOOD PROCESSING FACILITY DATA 01/01/2000 - 06/27/2014
2014-5330	07/02/2014 07/31/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OCS/NCTR/OCD/ OC/ORR/ OC/ORR/	Ho Leung Ng UNIVERSITY OF HAWAII	OXYELITE PRO - LAB RESULTS 08/01/2013 - 06/28/2014
2014-5331	07/02/2014 07/31/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CTP/OD/	andrew martz Martz Inc.	K113618
2014-5332	07/02/2014 07/31/2014	FDA/OMPT/CDRH/OCER/DFOI/	andrew martz CONSUMER	K123348
2014-5333	07/02/2014 07/31/2014	FDA/OGROP/ORR/NE-FO/NWE-DO/NWE-CB/	Peter Maurer BOSTON SCIENTIFIC	BOSTON SCIENTIFIC - EIR 10/17/2013 - 06/30/2014

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2014-5334	07/02/2014 07/31/2014	FDA/OMPT/CDRH/OCER/DFOI/	Andy Hu Globe Medical Tek	K130616
2014-5335	07/02/2014 07/31/2014	FDA/OMPT/CDRH/OCER/DFOI/	BEO MedConsulting Berlin GmbH BEO MedConsulting Berlin GmbH	K831320 TECHNICAL SPECIFICATIONS
2014-5336	07/02/2014 07/31/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	K090845
2014-5337	07/02/2014 07/31/2014	FDA/OMPT/CDRH/OCER/DFOI/	Andy Hu Globe Medical Tek	K112945
2014-5338	07/02/2014 07/31/2014	FDA/OMPT/CDRH/OCER/DFOI/	Richard A. Basler Med-Visory Consulting, Inc.	K953746
2014-5339	07/02/2014 07/31/2014	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	Justin M. Lugar GENTRY LOCKE ET AL	GOLDEN PEANUT COMPANY, LLC, DAWSON, GA - EIR, 483 01/11/2009 - 03/01/2009
2014-5340	07/02/2014 07/31/2014	FDA/OFVM/CFSAN/OCD/EOS/	Nancy Foust SimplyInfo.org	RADIONUCLIDE FOOD TESTING APRIL 2005 TO PRESENT AS PART OF TOTAL DIET STUDY
2014-5341	07/02/2014 07/31/2014	FDA/OC/OES/DFOI/ FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Paul Knoepfler UNIVERSITY OF CALIFORNIA DAVIS	CELLTEX - INSPECTIONS, CORR 07/01/2013 - 07/01/2014
2014-5342	07/02/2014 07/31/2014	FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/	Adam Cox Sparhawk Laboratories, Inc.	SPARHAWK LABORATORIES, LEXENA, KS - EIR 01/21/2014 - 01/31/2014
2014-5343	07/02/2014 07/31/2014	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	FCN 55, FAP 9A4677
2014-5344	07/02/2014 07/31/2014	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	FCN 74, FAP 9A4640
2014-5345	07/02/2014 07/31/2014	OC/ORR/ORM/ OC/ORR/ORM/ FDA/OFVM/CFSAN/OCD/EOS/	Brad Jones Oldways Preservation and Exchange Trust	LIST OF CHEESE INSPECTIONS 12/01/2013 - 07/01/2014
2014-5346	07/02/2014 07/31/2014	FDA/OMPT/CDRH/OCER/DFOI/	TEORREY COPE SIDLEY AUSTIN LLP	OSSIX PLUS - K053260
2014-5347	07/02/2014 07/31/2014	FDA/OMPT/CDER/ORR/DIDP/ FDA/OMPT/CDER/ORR/DIDP/ FDA/OMPT/CDER/ORR/DIDP/	TORREY COPE SIDLEY AUSTIN LLP	VISUDYNE (VERTEPORFIN FOR INJ) NDA 21-119 - CORR 9/24/12 TO PRESENT

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		FDA/OMPT/CDER/ORP/DIDP/		
2014-5348	07/02/2014 07/31/2014	FDA/OMPT/CDRH/OCER/DFOI/	TORREY COPE SIDLEY AUSTIN LLP	BIAFINE - K943910
2014-5349	07/02/2014 07/31/2014	FDA/OMPT/CDRH/OCER/DFOI/	TORREY COPE SIDLEY AUSTIN LLP	RESTYLANDE (HYALURONIC ACID) INJECTABLE GEL P040024; RESTULANE-L (HYALURONIC ACID) INJECTABLE GEL WITH LIDOCAINE P040024; PERLANE (HYALURONIC ACID) INJECTABLE GEL P040024, ETC - CORR 12/11/12 TO PRESENT
2014-5350	07/02/2014 07/31/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TORREY COPE SIDLEY AUSTIN LLP	ZOVIRAX (ACYCLOVIR) OINTMENT NDA 18-604; ZOVIRAX (ACYCLOVIR) CAPS NDA 18-828; ZOVIRAX (ACYCLOVIR) SUSPENSION NDA 19-909, ETC - CORR 2/1/11 TO PRESENT
2014-5351	07/02/2014 07/31/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TORREY COPE SIDLEY AUSTIN LLP	CARDIZEM (DILITAZEM HCL) DIRECT COMPRESSION TABS NDA 18602; CARDIZEN CD (DILITAZEN HCL) CAPS NDA 20-062; CARDIZEM LA (DILITAZEN HCL) ER TABS NDA 21-392 - CORR 9/28/10 TO PRESENT
2014-5352	07/02/2014 07/31/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TORREY COPE SIDLEY AUSTIN LLP	TARGRETIN (BEXAROTENE) GEL NDA 21-056; TARGRETIN (BEXAROTENE) CAPS NDA 21-055 - CORR 2/20/13 TO PRESENT
2014-5353	07/02/2014 07/31/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TORREY COPE SIDLEY AUSTIN LLP	BENSAL HP (SALICYLIC ACID) OINTMENT; GLYQUIN (HYDROQUINONE USP 4%) SKIN BLEACHING MOISTURIZING CREAM WITH SUNSCREENS (SPF 15); KINERASE PRO + THERAPY (HYDROQUINONE USP 4%) CREAM - CORR 6/20/12 TO PRESENT
2014-5354	07/02/2014 07/31/2014	FDA/OMPT/CDRH/OCER/DFOI/	TORREY COPE SIDLEY AUSTIN LLP	THERMAGE CPT SYS - K132431; CLEAR + BRILLIANT LASER SYS - K120433, K110349; LIPOSONIX SYS - K100874, ETC - CORR 6/20/13 TO PRESENT
2014-5355	07/02/2014 07/31/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TORREY COPE SIDLEY AUSTIN LLP	RETIN-A (TRETINOIN) SOL CREAM - NDA 16-921, NDA 17-340, 17-522, ETIN-A MICRO (TRETINOIN) GEL NDA 17-579, NDA 17-955; ERTACZO (SERTACONAZOLE NITRATE) CREAM - NDA 21-385, ETC - CORR 12/12/11 TO PRESENT
2014-5356	07/02/2014 07/31/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TORREY COPE SIDLEY AUSTIN LLP	OBAGI NU-DERM BLENDER (HYDROQUINONE USP4%) SKIN BLEACHING CREAM; OBAGI NU-DERM CLEAR (HYDROQUINONE USP %) SKIN BLEACHING CREAM; OBAGI NU-DERM SUNFADER (HYDROQUINONE USP 4%) OXTINOXATE USP, ETC - CORR 4/25/13 TO PRESENT

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2014-5357	07/02/2014 07/31/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TORREY COPE SIDLEY AUSTIN LLP	SOLODYN (MINOCYCLINE HCL) ER TABS NDA 50-808; DYSPOX (ABOBOTULINUMTOXINA) INJ BLA 125-274; LOPROX (CICLOPIROX) CREAM NDA 18-748, SUSPENSION NDA 19824, ETC - CORR 12/11/12 TO PRESENT
2014-5358	07/02/2014 07/31/2014	FDA/OMPT/CDRH/OCER/DFOI/	TORREY COPE SIDLEY AUSTIN LLP	SCULPTRA (INJECTABLE POLY-L-LACTIC ACID) - P030050; SCULPTRA AESTHETIC (INJECTABLE POLY-L-LACTIC ACID) - P030050 - CORR 12/16/11 TO PRESENT
2014-5359	07/02/2014 07/31/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TORREY COPE SIDLEY AUSTIN LLP	MEPHYTON (PHYTONADIONE) TABS NDA 10-104 - CORR 5/27/10 TO PRESENT
2014-5360	07/02/2014 07/31/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TORREY COPE SIDLEY AUSTIN LLP	ACANDYA (CLINDAMYCIN PHOSPHATE & BENZOYL PEROXIDE) GEL NDA 50-819; ARESTIN (MINOCYCLINE HCL) MICROSPHERES NDA 50-781; ATRALIN (TRETINOIN) GEL NDA 22-070, ETC - CORR 6/20/12 TO PRESENT
2014-5361	07/02/2014 07/31/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARY L REITZ GREENSFELDER HEMKER & GALE PC	KLEIN SOLUTION - AERS
2014-5362	07/02/2014 07/31/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARY L REITZ GREENSFELDER HEMKER & GALE PC	SODIUM BICARBONATE - AERS 8/13 TO PRESENT
2014-5363	07/02/2014 07/31/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARY L REITZ GREENSFELDER HEMKER & GALE PC	TUMESCENT SOL - AERS
2014-5364	07/02/2014 07/31/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ALESSANDRO NOSEDA SIGMA-TAU RESEARCH	EXISULIND (SULINDAC SULPHONE) - RECS
2014-5365	07/02/2014 07/31/2014	FDA/OGROP/ORP/PA-FO/LOS- DO/LOS-CB/	RANIL LM FERNANDO BIOSCREEN TESTING SERVICES INC	MICRO QUALITY LABS INC, BURBANK, CA - EIRS, 483S, WARNING LTRS LAST 5 YRS

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2014-5366	07/02/2014 07/31/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GARLAND 080656, ROBERT	RISPERDAL (RISPERIDONE) - AERS
2014-5367	07/02/2014 07/31/2014	FDA/OC/OES/DFOI/	CAUDLE #20711-058, BRANDON	HOW TO MAKE A DFOI REQUEST
2014-5368	07/02/2014 07/31/2014	OC/CVM/OCD/	DANIELA SOLOMON, DVM LALLEMAND ANIMAL NUTRITON	LEVUCCELL SC (SACCHARMYCES CEREVISAE CNCM 1-077) - RECS
2014-5369	07/03/2014 08/01/2014	FDA/OMPT/CDRH/OCER/DFOI/	Debbie Koeneman Debbie Koeneman	DEVICE LISTING AMERSHAM/SEARLE STRONTIUM 90 BETA SOURCE
2014-5370	07/03/2014 08/01/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Guy C Ruble ELI LILLY & CO	NDA 022059/S-007
2014-5371	07/03/2014 08/01/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angela Mikroulis Auxilium Pharmaceuticals, Inc.	NDA 022219
2014-5372	07/03/2014 08/01/2014	FDA/OFVM/CFSSAN/OCD/EOS/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	Jason Ahlmann Zija International, Inc.	ZIJA INTERNATIONAL INC, RODNEY LARSEN, KENNETH BRAILSFORD - RECS 03/20/2014 - 06/30/2014
2014-5373	07/03/2014 08/01/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	K111699
2014-5374	07/03/2014 08/01/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Charles E. Adler Adler Law Offices, Ltd.	XARELTO - AERS
2014-5375	07/03/2014 08/01/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	K072417
2014-5376	07/03/2014 08/01/2014	FDA/OMPT/CDRH/OCER/DFOI/	Margaux Nair K&L Gates LLP	K121021, K113272, K093922 ETC
2014-5377	07/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	Alan Hamlet	K050036, K112844

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	08/01/2014		MYOLYN	
2014-5378	07/03/2014 08/01/2014	FDA/OMPT/CDRH/OCER/DFOI/	Andy Hu Globe Medical Tek	K120002
2014-5379	07/03/2014 08/01/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	K081124
2014-5380	07/03/2014 08/01/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Karl Gallegos Gallegos Bio-Pharma	ETHACRYNIC ACID - AERS
2014-5381	07/03/2014 08/01/2014	FDA/OMPT/CDRH/OCER/DFOI/	Margaux Nair K&L Gates LLP	K131686; K130605, K110344
2014-5382	07/03/2014 08/01/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Keith Drake Geisel School of Medicine at Dartmouth	ORANGE BOOK - PATENT EXPIRATION DATES NOLVADEX, ZANTAC, ORTHO TRI-CYCLEN ETC
2014-5383	07/03/2014 08/01/2014	FDA/OMPT/OSMP/OOPD/	Alex Silverstein EverPoint Asset Management	CORR REC ORPHAN DRUG STATUS - rAAV2-CB-hRPE65 ETC
2014-5384	07/03/2014 08/01/2014	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	MANOJ K PATEL MD, RIVERSIDE, CA - EIR, 483, CO RESP 4/4/11 - 5/3/11
2014-5385	07/03/2014 08/01/2014	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	MANOJ K PATEL MD, RIVERSIDE, CA - EIR, 483, CO RESP 11/2-23/10
2014-5386	07/03/2014 08/01/2014	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAP/SE-FO/FLA-DO/FLA-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	ONE BLOOD INC, OCALA, FL - EIR, 483, CO RESP 1/28-30/13
2014-5387	07/03/2014 08/01/2014	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	BAXTER HEALTHCARE CORP, LOS ANGELES, CA - EIR, 483, CO RESP 9/5-20/12
2014-5388	07/03/2014 08/01/2014	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	WALTER E. CHALKLEY THOMSON REUTERS	MICHAEL M. DAO MD, GARDEN GROVE, CA - EIR, 483, CO RESP 1/17-18/13
2014-5389	07/03/2014 08/01/2014	FDA/OGROP/ORAP/SW-FO/DEN-DO/DEN-CB/	WALTER E. CHALKLEY THOMSON REUTERS	EASTER COLORADO HEALTH CARE SYS, DENVER, CO - EIR, 483, CO RESP 1/9-14/13

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2014-5390	07/03/2014 08/01/2014	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	WALTER E. CHALKLEY THOMSON REUTERS	BAY AREA HOSPITAL IRB#1, COOS BAY, OR - EIR, 483, CO RESP 1/7-15/13
2014-5391	07/03/2014 08/01/2014	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	WALTER E. CHALKLEY THOMSON REUTERS	RICHARD DE LA GRAZA II PhD, HOUSTON, TX - EIR, 483, CO RESP 11/8/11 - 1/23/12
2014-5392	07/03/2014 08/01/2014	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	GLUCORELL INC, ORLANDO, FL - EIR, 483, CO RESP 7/24/12 - 8/7/12
2014-5393	07/03/2014 08/01/2014	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	ANAFIT INC, ORLANDO, FL - EIR, 483, CO RESP 7/26/12 - 8/7/12
2014-5394	07/03/2014 08/01/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-2219
2014-5395	07/03/2014 08/01/2014	FDA/OC/OES/DDM/	Mary Beth Buckley Sedgwick, LLP	Comments cited in 79 Fed. Reg. 33057, comments 16, 17 and 18
2014-5396	07/03/2014 08/01/2014	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	WALTER E. CHALKLEY THOMSON REUTERS	ELGE INC, ROSENBERG, TX - EIR, 483, CO RESP 1/18/13 - 2/5/13
2014-5397	07/03/2014 08/01/2014	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Blake Goodner Bridger Healthcare	ALBANY MOLECULAR RESEARCH, RENNELAER, NY - 483, WARNING LETTERS, RESPONSE LETTERS 01/01/2010 - 07/02/2014
2014-5398	07/03/2014 08/01/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Blake Goodner Bridger Healthcare	VALEANT PHARMACEUTICALS, BRIDGEWATER, NJ - 483, WARNING LETTERS, RESPONSE LETTERS 01/02/2012 - 07/02/2014
2014-5399	07/03/2014 08/01/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shin Kang WELLS FARGO FUNDS MANAGEMENT GROUP	KALYDECO, TECFIDERA, JAKAFI ETC - AERS
2014-5400	07/03/2014 08/01/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	EASTERN CONNECTICUT HEALTH NETWORK INC IRC, MANCHESTER, CT - EIR, 483, CO RESP 1/14-24/13
2014-5401	07/03/2014 08/01/2014	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	WALTER E. CHALKLEY THOMSON REUTERS	THE BLOOD CENTER, HARVEY, LA - EIR, 483, CO RESP 1/17/13
2014-5402	07/03/2014 08/01/2014	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	WALTER E. CHALKLEY THOMSON REUTERS	JERRY TOMASOVIC MD, SAN ANTONIO, TX - EIR, 483, CO RESP 1/14-18/13
2014-5403	07/03/2014 08/01/2014	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	LABORATORY CORPORATION OF AMERICA VIROMED LABS, HOPKINS, MN - EIR, 483, CO RESP 6/10-24/13

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2014-5404	07/03/2014 08/01/2014	FDA/OC/OES/DFOI/ OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORO/PA-FO/SEA-DO/SEA-CB/	SANDRA E. WIDLAN SCHROETER GOLDMARK & BENDER	INDIVIDUAL RECS
2014-5405	07/03/2014 08/01/2014	FDA/OGROP/ORO/SW-FO/KAN-DO/KAN-CB/	GREGORY P. BERGT PENNFIELD OIL CO	PENNFIELD OIL CO, OMAHA, NE - EIR 2/4-6/14
2014-5406	07/03/2014 08/01/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MITCHELL 06A6873, LAYSHAWN	DEPO TESTOSTERONE - WARNING
2014-5407	07/03/2014 08/01/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TORREY COPE SIDLEY AUSTIN LLP	NU DERM CONDITION & ENHANCE, OBAGI-C RX (4% HYDROQUINONE), ETC
2014-5408	07/03/2014 08/01/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GUTTERMAN, LEONARD	PROLIA VACCINE - GUILLAIN BARRE SYNDROME, VAERS
2014-5409	07/03/2014 08/01/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CAROLINE STOUT ECOR1 CAPITAL LLC	ALDER BIOPHARMACEUTICALS - CLAZAKIZUMAB; ELI LILLY - LY2951742; LABRYS BIOLOGICS LBR-101 - AER
2014-5410	07/07/2014 08/04/2014	FDA/OMPT/CDRH/OCER/DFOI/	Corey Jaseph ULTRADENT PRODUCTS, INC	K131799
2014-5411	07/07/2014 08/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joanne Grego CSL BEHRING	HIZENTRA, PRIVIGEN - ICSR

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/		
2014-5412	07/07/2014 08/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tariq Ata REMS Logic, LLC	Number of REMS Drug Error Reports (by drug) - from 2005 through 2013
2014-5413	07/07/2014 08/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Becky Hartman Teva Pharmaceuticals	ASMANEX - AERS
2014-5414	07/07/2014 08/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Becky Hartman Teva Pharmaceuticals	ALVESCO - AERS
2014-5415	07/07/2014 08/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Himanish Mandava EASTERN MICHIGAN UNIVERSITY	OFFICE OF PRESCRIPTION DRUGS PROMOTION LETTERS, DIVISION OF DRUG MARKETING - NUMBER OF EMPLOYEES, BUDGET 06/03/2004 - 06/30/2014
2014-5416	07/07/2014 08/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jeffrey Peterson Jeffrey Peteson - Mind's Eye Services	RIBAVIRIN - AERS
2014-5417	07/07/2014 08/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Becky Hartman Teva Pharmaceuticals	BECLOMETHASONE - AERS
2014-5418	07/07/2014 08/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Becky Hartman Teva Pharmaceuticals	PULMICORT - AERS
2014-5419	07/07/2014 08/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Becky Hartman Teva Pharmaceuticals	FLOVENT - AERS

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2014-5420	07/07/2014 08/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Becky Hartman Teva Pharmaceuticals	AEROSPAN - AERS
2014-5421	07/07/2014 08/04/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K100504
2014-5422	07/07/2014 08/04/2014	FDA/OMPT/CDRH/OCER/DFOI/	Bob Janisch Bob Janisch	K032203
2014-5423	07/07/2014 08/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Reena Desai Novotech Consulting	LIST OF DESI DRUGS
2014-5424	07/07/2014 08/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Joanne Grego CSL BEHRING	HIZENTRA, PRIVIGEN - ICSR
2014-5425	07/07/2014 08/04/2014	FDA/OMPT/CDRH/OCER/DFOI/	Steven Meyer RetroVascular, Inc.	K073057
2014-5426	07/07/2014 08/04/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Christina Henza Regulatory Compliance Associates, Inc	K110288
2014-5427	07/07/2014 08/04/2014	FDA/OGROP/ORP/PA-FO/SAN- DO/SAN-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Greg Butz Forward Asymmetry Healthcare	IMPAX LABS, HAYWARD, CA; TAIWAN - 483, WARNING LETTER, EIR ETC 01/01/2009 - 06/30/2014
2014-5428	07/07/2014 08/04/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K111924
2014-5429	07/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson	K093065

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	08/04/2014		FOI Services, Inc.	
2014-5430	07/07/2014 08/04/2014	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Jamie Jackson Jamie Jackson	SEBOTEK HEARING SYSTEMS, TULSA, OK - EIR 04/01/2014 - 07/02/2014
2014-5431	07/07/2014 08/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Robert Sahr Choate Hall & Stewart LLP	ORANGE BOOK NDA 021436
2014-5432	07/07/2014 08/04/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Blake Goodner Bridger Healthcare	ALBANY MOLECULAR RESEARCH, BURLINGTON, MA - 483, WARNING LETTERS, RESPONSE LETTERS 01/01/2010 - 07/02/2014
2014-5433	07/07/2014 08/04/2014	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Blake Goodner Bridger Healthcare	ALBANY MOLECULAR RESEARCH, ALBANY, NY - 483, WARNING LETTER, RESPONSE LETTERS 01/01/2010 - 07/02/2014
2014-5434	07/07/2014 08/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Vincent Andolina AUROBINDO PHARMA USA INC	Division of Bioequivalence Waiver Request for ANDA 072652 (formerly denoted as 72-652) for Albuterol Sulfate Inhalation Solution 0.083%
2014-5435	07/07/2014 08/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Fredrik Hieronymus University of Gothenburg	NDA 019839
2014-5436	07/07/2014 08/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Allison Tarantino Ariad Pharmaceuticals, Inc.	ICLUSIG - AERS
2014-5437	07/07/2014 08/04/2014	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Blake Goodner Bridger Healthcare	ALBANY MOLECULAR RESEARCH, RENSSELAER, NY - 483, WARNING LETTER, RESPONSE LETTER 01/02/2010 - 07/02/2014
2014-5438	07/07/2014 08/04/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-2876
2014-5439	07/07/2014 08/04/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-2854
2014-5440	07/07/2014 08/04/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-823
2014-5441	07/07/2014	FDA/OC/OES/DFOI/	Rachel Johnson	2014-2953

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	08/04/2014		FOI Services, Inc.	
2014-5442	07/07/2014 08/04/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-2952
2014-5443	07/07/2014 08/04/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2013-2604
2014-5444	07/07/2014 08/04/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2013-10124
2014-5445	07/07/2014 08/04/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-2846
2014-5446	07/07/2014 08/04/2014	FDA/OMPT/CDRH/OCER/DFOI/	LESLIE RAMSEY FDA NEWS	UNISENSE FERTLILTECH A/S, VIBY J, DENMARK; TP ORTHODONTIC APPLIANCE (WUXI) CO, LTD, WUXI, CHINA; SOPRO COMEG GMBH, TUTTLINGEN, GERMANY, ETC - 483S 5/1-31/14
2014-5447	07/07/2014 08/04/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	LESLIE RAMSEY FDA NEWS	NORVARTIS VACCINES & DIAGNOSTICS GMBH & CO KG, MARBURG, GERMANY - 483S 5/1-31/14
2014-5448	07/07/2014 08/04/2014	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	LESLIE RAMSEY FDA NEWS	CENORIN LLC, KENT, WA; MICRO POWER ELECTRONIC INC, BEAVERTON, OR; SCIENTIFIC BOTANICALS COMPANY INC, MUKILTTEO, WA - 483S 5/1-31/14
2014-5449	07/07/2014 08/04/2014	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	LESLIE RAMSEY FDA NEWS	SONOCINE INC, RENO, NV; SI-BONE INC, SAN JOSE, CA ; ABBOTT HEALTHCARE (PUERTO RICO) LTD, BARCELONETA, PR - 483S 5/1-31/14
2014-5450	07/07/2014 08/04/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	LESLIE RAMSEY FDA NEWS	OAKWORKS INC, NEW FREEDOM, PA - 483S 5/1-31/14
2014-5451	07/07/2014 08/04/2014	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	LESLIE RAMSEY FDA NEWS	A & Z PHARMACEUTICALS INC, DEER PARK, NY; TOPIDERM INC, NORTH AMITYVILLE, NY; AMEAL PHARMACEUTICAL, BROOKHAVEN, NY - 483S 5/1-31/14
2014-5452	07/07/2014 08/04/2014	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	LESLIE RAMSEY FDA NEWS	PMC BIOGENIX INC, MEMPHIS, TN; WRIGHT MEDICAL TECHNOLOGY INC, MEMPHIS, TN - 483S 5/1-31/14
2014-5453	07/07/2014 08/04/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	LESLIE RAMSEY FDA NEWS	US PHARMACEUTICALS LINC, BELLEVILLE, NJ; MEDIN CORP, PASSAIC, NJ; THERAKOS INC, BRIDGEWATER, NJ, ETC - 483S 5/1-31/14
2014-5454	07/07/2014 08/04/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	LESLIE RAMSEY FDA NEWS	RANFAC CORP, AVON, MA; AHLSTROM NONWOVENS LLC, WINDSOR LOCKS, CT; MASSBIOLOGICS, BOSTON, MA, ETC - 483S 5/1-31/14
2014-5455	07/07/2014 08/04/2014	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	LESLIE RAMSEY FDA NEWS	VESTA FUNDING INC, FRANKLIN, WI - 483S 5/1-31/14

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2014-5456	07/07/2014 08/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JESSICA WARREN INTERCEPT PHARMACEUTICALS INC	PHARMAZELL GMBH, LIESTAL, SWITZERLAND 12/4/09; JETPHARMA SA, BALERNA, SWITZERLAND 2/16/11; ALMAC SERVICES LTD, CRAIGAVON, GREAT BRITAIN 2/22/12 - 483S
2014-5457	07/07/2014 08/04/2014	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	LESLIE RAMSEY FDA NEWS	CARDINAL HEALTH 414 LLC, COLTON, CA; MEDAIRE INC, PHOENIX, AZ; RESPIRONICS CALIFORNIA INC, CARLSBAD, CA, ETC - 483S 5/1-31/14
2014-5458	07/07/2014 08/04/2014	FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/	LESLIE RAMSEY FDA NEWS	ABS CORP, OMAHA, NE - 483S 5/1-31/14
2014-5459	07/07/2014 08/04/2014	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	LESLIE RAMSEY FDA NEWS	ENGLER ENGINEERING CORP, HIALEAH, FL; POWERS DEVICE TECHNOLOGIES INC, DELRAY BEACH, FL; ACUDERM INC, FT LAUDERDALE, FL, ETC - 483S 5/1-31/14
2014-5460	07/07/2014 08/04/2014	FDA/OC/OES/DFOI/ FDA/OC/OES/ FDA/OC/OES/DDM/ FDA/OC/OPP/OP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Doe J	INDIVIDUAL RECS
2014-5461	07/07/2014 08/04/2014	FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/ FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/	LESLIE RAMSEY FDA NEWS	AXIOBIONICS LLC, ANN ARBOR, MI; ZIMMER INC, WARSAW, IN - 483S 5/1-31/14
2014-5462	07/07/2014 08/04/2014	OC/ORA/ORM/ OC/ORA/ORM/	LESLIE RAMSEY FDA NEWS	PHARMACEUTICAL, BIOLOGICS, MEDICAL DVC MFG, CLNCL TRIAL FACILITIES INSIDE AND OUTSIDE THE US - 483S 6/1- 30/14
2014-5463	07/07/2014 08/04/2014	FDA/OGROP/ORA/SW-FO/DEN- DO/DEN-CB/	LESLIE RAMSEY FDA NEWS	SHIPPERT MEDICALTECHNOLOGIES, CENTENNIAL, CO; AMEDICA CORP, SALT LAKE CITY; STERIGEAR, LLC, PROVO, UT, ETC - 483S 5/1-31/14
2014-5464	07/07/2014 08/04/2014	FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	LESLIE RAMSEY FDA NEWS	NELSON ENVIROMENTAL TECHNOLOGIES INC, MCALLEN, TX; INOVEON CORP, OKLALHOMA CITY, OK; HOSPIRA INC, AUSTIN, TX - 483S 5/1-31/14
2014-5465	07/07/2014 08/04/2014	FDA/OC/OES/DFOI/	MARIA K TOUGAS SCOTT & SCOTT LLP	STRYKER CORP, HOWMEDICA OSTEONICS CORP - TRIDENT ACETABULAR SYS HIP REPLACEMENT CMLPNTS 2003 TO PRESENT

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2014-5466	07/07/2014 08/04/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	LESLIE RAMSEY FDA NEWS	MERIDIAN MEDICAL SYSTEMS LLC, AURORA, OH; ZUGA MEDICAL INC, CLEVELAND, OH - 483S 5/1-31/14
2014-5467	07/07/2014 08/04/2014	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	LESLIE RAMSEY FDA NEWS	UNIVERSAL HOLDINGS I LLC (SMITH BROTHERS) CO, CHICAGO, IL; TELFLEX MEDICAL, ARLINGTON HEIGHTS, IL - 483S 5/1-31/14
2014-5468	07/07/2014 08/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	R LAUREN HORNER JONES WARD PLC	BAYER HEALTHCARE - MIRENA NDA 21-225/S033 RPTS, CORR, LABEL CHANGE
2014-5469	07/07/2014 08/04/2014	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	LESLIE RAMSEY FDA NEWS	CAMTEC INC, CHURCH CREEK, MD - 483 (MPT EIRS) 5/1-31/14
2014-5470	07/07/2014 08/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	POWDER PHARMACEUTICALS INC, SHATIN, HONG KONG - EIR, 483, CO RESP 1/28-31/13
2014-5471	07/07/2014 08/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LESLIE RAMSEY FDA NEWS	UNIMED PHARMACEUTICALS INC, SEOUL, SOUTH KOREA; BIOCON LTD, WORK SITE I, HEBBAGODIA, BANGALORE, INDIA; HANGZHOU ZHONGMEI HUADONG PHARMACEUTICAL CO LTD, HANZHOU, CHINA, ETC 483S 5/1-14/31
2014-5472	07/07/2014 08/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	ZHEJIANG CHIRAL MEDICINE CHEMICALS CO LTD, HANGZHOU, CHINA - EIR, 483, CO RESP 1/25-29/13
2014-5473	07/07/2014 08/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	HOSPIRA HEALTHCARE INDIA PVT LTD, SRIPERUMBUDUR, INDIA - EIR, 483, CO RESP 10/3-10/12
2014-5474	07/07/2014 08/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	HUNTINGDON LIFE SCIENCES LTD (NDA ANALYTICS LTD), HUNTINGDON, BG - EIR, 483, CO RESP 6/6-12/13
2014-5475	07/07/2014 08/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	CHARLES RIVER LABORATORIES PRECLINICAL SERVICES, TRANENT, GB - EIR, 483, CO RESP 9/10-12/12

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2014-5476	07/07/2014 08/04/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	JERZY WINDYGA MD PHD, INSTYTUT HEMATOLOGII I TRANSFUZJOLOGII, WARSAW, POLAND - EIR, 483, CO RESP 1/14-18/13
2014-5477	07/07/2014 08/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	BECTON DICKINSON FRANCE, DIV PHARMA SYSTEMS, LE PONT DE CLAIX, FRANCE - EIR, 483, CO RESP 1/14-25/13
2014-5478	07/07/2014 08/04/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	WALTER E CHALKLEY THOMSON REUTERS	ID BIOMEDICAL CORPORATION OF QUEBEC (GLAXOSMITHKLINE BIOLOGICALS), QUEBEC, CANADA - EIR, 483, CO RESP 3/31/14-4/9/14
2014-5479	07/07/2014 08/04/2014	FDA/OGROP/ORAP/PA-FO/LOS- DO/LOS-CB/	WALTER E CHALKLEY THOMSON REUTERS	ANIL KUMAR MD, LANCASTER, CA - EIR, 483, CO RESP 10/11/11-11/2/11
2014-5480	07/07/2014 08/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	TIANJIN ZHONGAN PHARMACEUTICAL CO LTD, TIANJIN, CHINA - EIR, 483, CO RESP 9.23-27/14
2014-5481	07/07/2014 08/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	APOTEX INC, TORONTO, ON, CANADA - EIR, 483, CO RESP 1/27-31/14
2014-5482	07/07/2014 09/08/2014	FDA/OGROP/ORASW/FO/DEN- DO/DEN-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	JOHN D PAPILION MD, DENVER, CO - EIR, 483, CO RESP 6/27/11-8/11/11
2014-5483	07/07/2014 08/04/2014	FDA/OFVM/CFSAN/OCD/EOS/	Bradley Lampe NSF International	FCN 805
2014-5484	07/07/2014 08/04/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORAP/PA-FO/LOS- DO/LOS-CB/	Eric Walter Camil, sr. CAMIL CONSULTING CORP	STARR SURGICAL - WARNING LETTER CORR 02/01/2014 - 04/30/2014
2014-5485	07/07/2014 08/04/2014	FDA/OC/OES/DFOI/	Kari Twaite BEVERIDGE & DIAMOND PC	2014-4339 - CORR WITH REQUESTER
2014-5486	07/07/2014 08/04/2014	FDA/OGROP/ORAP/PA-FO/LOS- DO/LOS-CB/	Eric Walter Camil, sr. CAMIL CONSULTING CORP	STARR SURGICAL - INSPECTIONS RE: WARNING LETTER 02/01/2014 - 07/02/2014
2014-5487	07/07/2014 08/04/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	CRITICAL DIAGNOSTICS - CORR FROM FDA 11/01/2013 - 06/20/2014

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2014-5488	07/07/2014 08/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	Information regarding a structural alert for ABUKs
2014-5489	07/07/2014 08/04/2014	FDA/OC/OES/DFOI/	Anon Anon	FOIA LOG JUNE 2014
2014-5490	07/07/2014 08/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Elena Vidal Baruch College - City University of New York	DRUG PATENT DATA
2014-5491	07/07/2014 08/04/2014	FDA/OMPT/CDRH/OCER/DFOI/	Danielle Montero The Boesch Law Group	GAMMA NAIL, LONG LENGTH DYAX NAIL - FORM FDA 3500A 07/02/2004 - 07/02/2014
2014-5492	07/07/2014 08/04/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K133707
2014-5493	07/07/2014 08/04/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	Victoria Sheomaker Cassiday Schade, LLP	RIATA - AERS
2014-5494	07/07/2014 08/04/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jeanine Lindsay University of Delaware	CARDIAC MONITOR, TELEMETRY ALARMS - AERS
2014-5495	07/07/2014 08/04/2014	FDA/OMPT/CDRH/OCER/DFOI/	Carl Jenkins WOOD BURDITT GROUP	K101104
2014-5496	07/07/2014 08/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dhaval N Desai Zydus Pharmaceuticals USA Inc.	NDA 020222 - SBA
2014-5497	07/07/2014 08/04/2014	FDA/OC/OES/DFOI/	Kylie Osterloh Leventhal, Brown, & Puga P.C.	DEVICE EVENT RECS
2014-5498	07/07/2014 08/04/2014	FDA/OC/OES/DDM/ FDA/OMPT/CTP/OD/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jeremy Singer-Vine Buzzfeed News	CIVIL MONEY PENALTIES RECS 09/01/2007 - 07/03/2014

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/		
2014-5499	07/07/2014 08/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Elissa Flynn-Poppey Mintz Levin Cohn Ferris Govsky & Popeo	ICLUSIG - COMMUNICATIONS TO AND FROM FDA ETC 07/01/2013 - 07/03/2014
2014-5500	07/07/2014 08/04/2014	FDA/OMPT/CDRH/OCER/DFOI/	Liane LaRochelle DEKA R&D	K133941
2014-5501	07/07/2014 08/04/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Heiko Frerichs Xenios AG	K991864
2014-5502	07/07/2014 08/04/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Heiko Frerichs Xenios AG	K102726
2014-5503	07/07/2014 08/04/2014	FDA/OMPT/CTP/OD/	Grace Park The Park Group	ALLIANCE ONE - REGISTRATION RECS
2014-5504	07/08/2014 08/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	M ELIZABETH BIERMAN MORGAN LEWIS & BOCKIUS LLP	SMITH & NEPHEW RESASYS PRODS & ACCESSORIES - CORR, EMAILS, MINS OF TELEPHONE CONFERENCE, BETWEEN FDA & SMITH & NEPHEW, ETC 5/1/14-7/3/14
2014-5505	07/08/2014 08/05/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	MAZANEC, JOHN	SWAY BALANCE - K121590; KOREBALANCE - K070676; KINESTHETIC ABILITY TRAINER 1000 - K911795
2014-5506	07/08/2014 08/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	JONATHAN LEE SUN NUCLEAR CORP	DOSISOFA SA, LINCOLN, CA - ISOGRAY TREATMENT PLANNING SYS K103146
2014-5507	07/08/2014 08/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	TRAVIS SCHAFTENAAR MANULIFE ASSET MANAGEMENT	COOPER VISION, UK - 483S 2013 OR 2014
2014-5508	07/08/2014 08/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MICHAEL R COHEN INSTITUTE FOR SAFE MEDICATION PRACTICES	MEDWATCH RPTS CODED AS MEDICATION ERRORS 6/1- 30/14
2014-5509	07/08/2014 08/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	NORTON, RICHARD	INNOVATIVE PRODUCTS - IND 116423 RVWS, MEETING, MINS, ETC
2014-5510	07/08/2014	FDA/OMPT/CDER/ORP/DIDP/		POLYETHYLENE GLYCOL 3350 - AERS

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	08/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WARD, JEANIE	
2014-5511	07/08/2014 08/05/2014	FDA/OC/OES/DFOI/	DOMINIQUE ALLEN PRICE ICE MILLER	FOIA REQUESTS RE MIXED DOSAGES OF SYMBYAX 2014
2014-5512	07/08/2014 08/05/2014	FDA/OC/OES/DFOI/	MIKE HENDERSON CAPITAL TRISTATE	FDA CENTRAL UTILITY PLANT, SILVER SPRING, MD - PAYMENT & PERFORMANCE BOND
2014-5513	07/08/2014 08/05/2014	FDA/OC/OES/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Doe J	INDIVIDUAL RECS
2014-5514	07/08/2014 08/05/2014	FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Lawrence F Muscarella, PhD LFM Healthcare Solutions, LLC	MYCOBACTERIA ABSCESS DEATH RECS, GREENVILLE, SC 03/01/2014 - 07/05/2014
2014-5515	07/08/2014 08/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dheeresh Pathak PATHAK, ANUPAM	SHILPA MEDICARE - 483 01/01/2013 - 07/06/2014
2014-5516	07/08/2014 08/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Freedom of information Law Request about Zyprexa and Prozac Dr A. Gssime	ZYPREXA, PAXIL, PROZAC - APPROVAL RECS, AERS, SALES ETC
2014-5517	07/08/2014 08/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Victoria Rothwell Immunexpress	K040887
2014-5518	07/08/2014 08/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Bryan Ehret MobileMedTek	K112052, K102610, K080546
2014-5519	07/08/2014 08/05/2014	FDA/OFVM/CFSAN/OCD/EOS/	Barbara Schneeman Barbara Schneeman	Memos or statement to the administrative file for the Food Labeling Proposed rules to update nutrition and supplement facts labeling. Materials requested are statements that are not part of the referenced material in the proposed rule but any statements from CFSAN-ONLDS staff that were added to the administrative record.
2014-5520	07/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	Liane LaRochelle	K103477

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	08/05/2014		DEKA RESEARCH & DEVELOPMENT CORP	
2014-5521	07/08/2014 08/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kara Johnson DEKA RESEARCH & DEVELOPMENT CORP	K041346
2014-5522	07/08/2014 08/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Srivani.Y NATCO PHARMA CANADA INC	ANDA 77851
2014-5523	07/08/2014 08/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Liane LaRochelle DEKA Research and Development	K112815
2014-5524	07/08/2014 08/05/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Kara Johnson DEKA RESEARCH & DEVELOPMENT CORP	K011993
2014-5525	07/08/2014 08/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kara Johnson DEKA RESEARCH & DEVELOPMENT CORP	K022993
2014-5526	07/08/2014 08/05/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OL/	Christine Prentice Reuters News	Revision of the Nutrition and Supplement Facts Labels and Serving Sizes of Foods
2014-5527	07/08/2014 08/05/2014	FDA/OMPT/OSMP/OOPD/	Robb Lawrence Chesapeake Therapeutics	ILARIS - ORPHAN PRODUCT DESIGNATION 01/01/2008 - 09/30/2008
2014-5528	07/08/2014 08/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Emily Hall Polaris Pharmaceuticals, Inc.	BLA 103411 - SBA
2014-5529	07/08/2014 08/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Hayley Lewis Carbylan Therapeutics, Inc	Original Approval Letter for Kenalog-10
2014-5530	07/08/2014 08/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Hisatoshi Tsuchida Kyorin Pharmaceutical Co., Ltd.	DMSO - AERS
2014-5531	07/08/2014	FDA/OMPT/CDER/ORP/DIDP/	Emily Hall	NDA 019818 SBA

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	08/05/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Polaris Pharmaceuticals, Inc.	
2014-5532	07/08/2014 08/05/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	David Mangione Govzilla, Inc.	BEN VENUE LABORATORIES INC, BEDFORD, OH - 483, EIR 06/02/2014 - 06/06/2014
2014-5533	07/08/2014 08/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kara Johnson DEKA RESEARCH & DEVELOPMENT CORP	K991119
2014-5534	07/08/2014 08/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kara Johnson DEKA RESEARCH & DEVELOPMENT CORP	K092612
2014-5535	07/08/2014 08/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	mark arceneaux BioRed	K101567
2014-5536	07/08/2014 08/05/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	David Bruser Toronto Star	KONG TENG TAN, TORONTO, CANADA; JOE TR CLARKE, TORONTO, CANADA; DAVID FORD, VAUGHAN, CANADA - 483, EIR
2014-5537	07/08/2014 08/05/2014	FDA/OC/OES/DFOI/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Grant Morris Sanford Heisler, LLP	DEPUY - EIR
2014-5538	07/08/2014 08/05/2014	OC/CVM/OCD/	Jennifer Schneider State License Servicing	NADA 008763
2014-5539	07/08/2014 08/05/2014	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	David Mangione Govzilla, Inc.	HOSPIRA, INC, AUSTIN, TX - EIR, 483 05/12/2014 - 05/23/2014
2014-5540	07/08/2014 08/05/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	David Mangione Govzilla, Inc.	GILEAD SCIENCES INC, SAN DIMAS, CA - EIR, 483 05/07/2014 - 05/16/2014
2014-5541	07/08/2014 08/05/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	David Mangione Govzilla, Inc.	HOSPIRA, LISCATE, ITALY - 483, EIR 05/05/2014 - 05/13/2014
2014-5542	07/08/2014 08/05/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CBER/OCOD/DDOM/	David Mangione Govzilla, Inc.	NOVARTIS VACCINES AND DIAGNOSTICS GMGH & CO, MARBURG, GERMANY - EIR, 483 04/29/2014 - 05/06/2014

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		ALFB/		
2014-5543	07/08/2014 08/05/2014	FDA/OMPT/OSMP/OCP/	Rachel Johnson FOI Services, Inc.	RFD filings for Osiris
2014-5544	07/08/2014 08/05/2014	FDA/OMPT/OSMP/OCP/	Rachel Johnson FOI Services, Inc.	RFD filings for Amniox
2014-5545	07/08/2014 08/05/2014	FDA/OMPT/OSMP/OCP/	Rachel Johnson FOI Services, Inc.	RFD filings for Seed Biotech
2014-5546	07/08/2014 08/05/2014	FDA/OMPT/OSMP/OCP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/OSMP/OCP/	Rachel Johnson FOI Services, Inc.	RFD filings for Bio-Tissue
2014-5547	07/09/2014 08/06/2014	FDA/OO/OFBA/OAGS/ FDA/OO/OFBA/OAGS/	KEAVEN NEELY ASE Direct Inc.	HHS GOVERNMENT PURCHASE CARD HOLDER'S NAMES AND PHONE NUMBERS LAST 2 YRS
2014-5548	07/09/2014 08/06/2014	FDA/OC/OES/DDM/ FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JUSTIN BROWN ESQ JANET, JENNER & SUGGS, LLC	PFIZER INC, WARNER LAMBERT CO, PARKE DAVIS - LIPITOR (ATORVASTATIN) SAFETY COMM, CRESTOR (ROSUVASTATIN) LABEL CHANGE, ETC
2014-5549	07/09/2014 09/10/2014	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/ORO/DIOP/	SARAH S PROSSER FedEx Express	TOTAL NUMBER OF FDA IMPORT REVIEWERS, ELECTRONIC IMPORT ENTRY LINES, FDA SHIPMENTS AT EACH US IMPORT GATEWAY LOCATION, ETC 5/11 TO PRESENT
2014-5550	07/09/2014 08/06/2014	FDA/OGROP/ORA/CE-FO/CIN- DO/CIN-CB/ FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/ FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/	ARTHUR Y TSIEN OLSSON FRANK & WEEDA	ANIMAL PRODUCERS, DISTRIBUTORS, MFRS USING MEDICATED FEEDS CONTAINING VETERINARY FEED DIRECTIVE (VFD) ANIMAL DRUGS - INSPS 3/14 TO 5/14
2014-5551	07/09/2014	FDA/OMPT/CDER/ORP/DIDP/	DAVID RISLEY	GE HEALTHCARE - MAA (KIT FOR THE PREPARATION OF

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	08/06/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GE Healthcare	TECHNETIUM TC99M ALBUMIN AGGREGATED INJ) NDA 17-773
2014-5552	07/09/2014 08/06/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS Consulting Group, LLC	BROCOCRIPTINE MESYLATE NDA 17-962 - APRVL LTR, LBLG, RVWS
2014-5553	07/09/2014 08/06/2014	FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CDRH/OCER/DFOI/	TRAVIS SCHAFTENAAR MANULIFE ASSET MANAGEMENT	COOPERVISION, JUANA DIAZ, PR 12/13 TO 1/14; COOPERSURGICAL, STAFFORD, TX 7/12 TO 8/12; COOPERVISION, UK 2013-2014 - RESP TO 483S
2014-5554	07/09/2014 08/06/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	IRONWOOD PHARMS, FOREST LABS, ACTAVIS - LIZNESS (LINACLOTIDE) AERS 11/1/12 TO PRESENT
2014-5555	07/09/2014 08/06/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELAINE M STEELE RN BSN JONES SKELTON & HOGHULI	METHADONE - AERS, MEDICATION ERROR RPTS
2014-5556	07/09/2014 08/06/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	STALEY A BROD MD UNIV OF TEXAS HOUSTON	ACTHAR GEL - MORTALITIES 2000 TO 2011, 2012 TO PRESENT; NUMBER OF PRESCRIPTIONS 2000 TO 2011, 2012 TO PRESENT
2014-5557	07/09/2014 08/06/2014	FDA/OC/OES/DFOI/	Alan Glazier Shady Grove Eye and Vision Care	INDIVIDUAL RECS
2014-5558	07/09/2014 08/06/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kevin Walls Regulatory Insight, Inc.	K082891
2014-5559	07/09/2014 08/06/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Kevin Walls Regulatory Insight, Inc.	K030719
2014-5560	07/09/2014 08/06/2014	FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/	Sue Corbett THE RESEARCH INVESTMENT, INC.	Priority-based assessment of food additives (PAFA) Database
2014-5561	07/09/2014	FDA/OGROP/ORA/PA-FO/LOS-	Rebecca Maciel	BIOSCREEN TESTING SERVICES, INC, TORRANCE, CA - EIR

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	08/06/2014	DO/LOS-CB/	Autumn Harp	06/16/2014 - 06/18/2014
2014-5562	07/09/2014 08/06/2014	FDA/OFVM/CFSAN/OCD/EOS/	Lauren Farruggia Hyman, Phelps & McNamara P.C.	The Regulatory Control of Plastic Food-Packing Materials in the United States
2014-5563	07/09/2014 08/06/2014	FDA/OFVM/CFSAN/OCD/EOS/	Lauren Farruggia Hyman, Phelps & McNamara P.C.	E.B. Detwiler, FDA, Synthetic Polymers and the Federal Food, Drug, and Cosmetic Act, spe journal 61 (Jan. 1965)
2014-5564	07/09/2014 08/06/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Thomas Payne Payne, Thomas	GALDERMA MIRVASO - APPROVAL RECS, AERS
2014-5565	07/09/2014 08/06/2014	FDA/OFVM/CFSAN/OCD/EOS/	Scott Thenell THENELL & ASSOCIATES LLC	Biotechnology Notification File No. 42, Safety and nutritional assessment of transgenic virus resistant papaya line 55-1 (Unique ID CUH-CP551-8)
2014-5566	07/09/2014 08/06/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tom Namsavanh IntelGenx Corp.	CIALIS - ISR
2014-5567	07/09/2014 08/06/2014	FDA/OMPT/CDRH/OCER/DFOI/	Susan Erickson UnitedHealthcare	DA Certified Mammography Facilities list, all locations
2014-5568	07/09/2014 08/06/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Andrea Demakas ADVERSEEVENTS INC	RISPERDAL, INVEGA, FANAPT ETC - AERS
2014-5569	07/09/2014 08/06/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gail Underiner Gail Underiner	FABBRICA ITALIANA SINTETICI, ITALY - EIR 01/01/2012 - 12/31/2013
2014-5570	07/09/2014 08/06/2014	FDA/OMPT/CDRH/OCER/DFOI/	Tim LAWTON C-REG MEDICAL	K093937
2014-5571	07/09/2014 08/06/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 205580 TENTATIVE APPROVAL LETTER
2014-5572	07/09/2014 08/06/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Shane McSpedden Pfizer Australia	VOTRIENT - REVIEW OF POST MARKETING STUDIES

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2014-5573	07/09/2014 08/06/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	A list of all FOIA requests closed 6/1-30/2014 on CD
2014-5574	07/09/2014 08/06/2014	OC/ORR/ORM/ OC/ORR/ORM/	Pallavi Ail The Financial Express	LIST OF 483 ISSUED TO INDIAN COMPANIES WITH CLASSIFICATION 04/01/2013 - 07/09/2014
2014-5575	07/09/2014 08/06/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 6/1-30/2014
2014-5576	07/09/2014 08/06/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Srivani.Y NATCO PHARMA CANADA INC	ANDA 203478
2014-5577	07/09/2014 08/06/2014	FDA/OMPT/CDRH/OCER/DFOI/	Erik Zalewski Have Dummy Will Travel, Inc.	AUTOMATED EXTERNAL DEFIBRILLATOR IN NY - OWNER NAME, CONTACT, ADDRESS ETC 01/03/1990 - 07/03/2014
2014-5578	07/10/2014 08/07/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sara Xiao Hisun Pharmaceuticals USA, Inc.	NDA 020690
2014-5579	07/10/2014 08/07/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	INVOKANA - AERS
2014-5580	07/10/2014 08/07/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sara Xiao Hisun Pharmaceuticals USA, Inc.	ANDA 203263
2014-5581	07/10/2014 08/07/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rohit VAnjani OPPENHEIMER	FENTANYL PRODUCTS - AERS, REMS
2014-5582	07/10/2014 09/08/2014	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	SE SUBMISSIONS
2014-5583	07/10/2014	OC/ORR/	Thomas Nicholl	WICLIFFE PHARMACY, LEXINGTON, KY - RECS RE DRUG

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	08/07/2014	OC/ORAI/	Thomas Nicholl Law Firm	FORMULATION 01/01/2014 - 07/01/2014
2014-5584	07/10/2014 08/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anna Edney BLOOMBERG NEWS	AADIVIGHNESH CHEM PVT LTD, MUMBAI, INDIA; AMSAL CHEM PVT LTD, GUJARAT, INDIA; GLOBAL CALCIUM PROVATE LTD,BANGALORE, INDIA- 483 MOST RECENT 01/01/2012 - 07/09/2014
2014-5585	07/10/2014 08/07/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OES/DDM/	Chris Noonan HealthGuidance, Inc.	The complete file and all available documentation for new dietary ingredient submission RPT799 submitted by Twinlab Corporation for the ingredient Zinc Carnosine
2014-5586	07/10/2014 08/07/2014	FDA/OGROP/ORAI/SW-FO/DAL-DO/DAL-CB/	MARTI GROS, MARTI	PROCORE LABORATORIES, LLC - INSPECTION RECS, RESPONSES 09/01/2011 - 07/09/2014
2014-5587	07/10/2014 08/07/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Gina U. Puzzuoli Puzzuoli, Gina U	MEDTRONICA PROTECTA - ENFORCEMENT RECS, RECALL NOTICES, APPROVAL ETC XT CRT-D MODEL 314TRM
2014-5588	07/10/2014 08/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	G. Srinivas Zydus Pharmaceuticals USA Inc.	NDA 020189 FELBATOL - SBA
2014-5589	07/10/2014 08/07/2014	FDA/OFVM/CFSAN/OCD/EOS/	Ureka Idstrom The Eureka Law Firm	Information relating to reference amounts for the "spray types" subcategory of the "Fats and Oils" product category in 21 C.F.R. 101.12
2014-5590	07/10/2014 08/07/2014	FDA/OMPT/CTP/OD/	Everett W. Gee III of S&M Brands, Inc. S&M Brands, Inc.	The Technical Project Lead (TPL) Memoranda prepared by the Center for Tobacco Products (CTP) for S&M Brands, Inc SE Reports SE0003503 through SE0003524 and SE00010338 through SE0010359
2014-5591	07/10/2014 08/07/2014	FDA/OC/OL/	Curt Devine Cable News Network (CNN)	SEN ROBERT MENENDEZ - CORR 1/1/11 TO 12/31/12
2014-5592	07/10/2014 08/07/2014	FDA/OC/OES/DFOI/	Ed Estriplet Jr Ed Estriplet Jr	CLIA DIAGNOSTIC/CLINICAL REFERENCE LABORATORIES IN EACH STATE
2014-5593	07/10/2014 08/07/2014	FDA/OO/OHR/	Dr. Thomas V. Montgomery, III Private Citizen/FDA Employee	FDA-CTP-14-MP-1113900LMD - NUMBER OF APPLICANTS ETC
2014-5594	07/10/2014 08/07/2014	FDA/OO/OHR/	Dr. Thomas V. Montgomery, III Private Citizen/FDA Employee	SELECTION RECS OMPT/CDER/OEP/DLOD
2014-5595	07/10/2014 08/07/2014	FDA/OGROP/ORAI/PA-FO/LOS-DO/LOS-CB/	Summer Pack Greer Laboratories, Inc.	HARDY DIAGNOSTICS - EIR, 483 04/06/2011 - 04/15/2011
2014-5596	07/10/2014 08/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	AMBER HOFF Second Image National	INDIVIDUAL RECS

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2014-5597	07/10/2014 08/07/2014	FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/	QASRAWI, AIMY	CMPLNT 130815
2014-5598	07/10/2014 08/07/2014	FDA/OC/OES/DFOI/	BROWN, ANN S	PLATES & SCREWS
2014-5599	07/10/2014 08/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PAMELA SHEPPARD TARO PHARMACEUTICALS USA INC	VALEANT BERMUDA - RETIN A N017522 -SBA, CHEMISTRY RVW, MEDICAL RVW
2014-5600	07/10/2014 08/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PAMELA SHEPPARD TARO PHARMACEUTICALS USA INC	RENAISSANCE PHARMA - ELIMITE N019855 SBA, CHEMISTRY RVW, MEDICAL RVW
2014-5601	07/10/2014 08/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PAMELA SHEPPARD TARO PHARMACEUTICALS USA INC	VALEANT BERMUDA - RETIN A N017340 SBA, CHEMISTRY RVW, MEDICAL RVW
2014-5602	07/10/2014 08/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PAMELA SHEPPARD TARO PHARMACEUTICALS USA INC	ACTAVIS MID ATLANTIC - PERMETHRIN ANDA 74-806 SBA, MOR, CHEMISTRY RVW, ETC
2014-5603	07/10/2014 08/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PAMELA SHEPPARD TARO PHARMACEUTICALS USA INC	PERRIGO NEW YORK - PERMETHRIN ANDA 76-369 - SBA, MOR, CHEMISTRY RVW, ETC
2014-5604	07/10/2014 08/07/2014	FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/	MITZI HG CLARK Keller and Heckman LLP	PNC 561
2014-5605	07/10/2014 08/07/2014	FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/	Doe J	PNC 1132
2014-5606	07/10/2014 08/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DON J. MIZERK HUSCH BLACKWELL LLP	WATSON LABS INC - AZILECT (RASAGILINE MESYLATE) ANDA 201-823 APRVL LTR 7/1/13; APOTEX INC - AZILECT (RASAGILINE MESYLATE) ANDA 201-950 APRVL LTR 9/12/13; AZILECT (RASAGILINE MESYLATE) ANDA 201-971 APRVL

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		FDA/OMPT/CDER/GRP/DIDP/		LTR 201-971
2014-5607	07/10/2014 08/07/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KEENE U26500, DOUGLAS	PARKE DAVIS - LYRICA - ADVISORIES, AERS, ETC
2014-5608	07/10/2014 08/07/2014	OC/CVM/OCD/	GUESS, ANDIE	PORCINE ZONA PELLUCIDA - FINANCIAL COSTS OF THE STUDIES, AMOUNT PAID BY THE US, ETC
2014-5609	07/11/2014 08/08/2014	FDA/OO/OFBA/OAGS/	Frank Dominick Wolf Den Associates	HHSF223201210022I TASK ORDER
2014-5610	07/11/2014 08/08/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Mr Holger Reusch IXICO Technologies Ltd	NeuroQuant 510K
2014-5611	07/11/2014 08/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K992209
2014-5612	07/11/2014 08/08/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dr. Tassie Collins Myelin Repair Foundation	NDA 020497
2014-5613	07/11/2014 08/08/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Brandon Bergman PURDUE UNIVERSITY	Cyclophosphamide (oral formulation), cyclophosphamide (IV formulation), melphalan (oral formulation), ETC - AERS
2014-5614	07/11/2014 08/08/2014	FDA/OMPT/OSMP/OOPD/	Lauren Farruggia Hyman, Phelps & McNamara, P.C.	NDA No. 022249 ORPHAN DRUG DESIGNATION RECS
2014-5615	07/11/2014 08/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	Hassaan W. Ahmad Suneris, Inc.	K080818, K090620
2014-5616	07/11/2014 08/08/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Matt Daniel Prosight Capital	RETROPHIN, INC - TREATMENT IND PKAN RECS
2014-5617	07/11/2014 08/08/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dr. Tassie Collins Myelin Repair Foundation	NDA 017970

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-5618	07/11/2014 08/08/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Matt Daniel Prosight Capital	NOVARTIS, RETROPHIN, INC - SYNTOCINON NASAL SPRAY RELAUNCH RECS
2014-5619	07/11/2014 08/08/2014	FDA/OGROP/ORA/SW-FO/DEN- DO/DEN-CB/	Bronwyn Binaxas Bronwyn Binaxas	ROCKY MOUNTAIN POISON & DRUG CONTROL CENTER, DENVER, CO - EIR 07/10/2012 - 07/16/2012
2014-5620	07/11/2014 08/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	Justin Davison Justin Davison	HANSEN ARTISAN EXTEND CONTROL CATHETER, HANSEN SENSIE ROBOTIC SYSTEM - INSTRUCTIONS FOR USE
2014-5621	07/11/2014 08/08/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Partha Radadiya Tedor Pharma Inc.	NDA 020666 STUDY DATA
2014-5622	07/11/2014 08/08/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	KIM HENDERSON SANOFI PASTEUR	BIOCSSL, PARKVILLE, VICTORIA, AUSTRALIA - 483S 2014
2014-5623	07/11/2014 08/08/2014	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	KIM HENDERSON SANOFI PASTEUR	NOVARTIS VACCINES & DIAGNOSTICS, HOLLY SPRINGS, NC - 483S 2014
2014-5624	07/11/2014 08/08/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	KIM HENDERSON SANOFI PASTEUR	GLAXOSMITHKLINE, WAVRE, BELGIUM - 483S 2014
2014-5625	07/11/2014 08/08/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	KIM HENDERSON SANOFI PASTEUR	NOVARTIS VACCINES DIAGNOSTICS GMBH & CO KG, MARBURG, GERMANY - 483S 2014
2014-5626	07/11/2014 08/08/2014	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/ FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CAROLINE STOUT ECOR1 CAPITAL LLC	CORR BTWN FDA & REGRADO BIOSCIENCES; CORR BTWN FDA & ARATANA THERAPEUTICS - RECS
2014-5627	07/11/2014	FDA/OO/OHR/		INDIVIDUAL RECS

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	08/08/2014		ABI DOCUMENT SUPPORT SERVICES	
2014-5628	07/11/2014 08/08/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dr. Tassie Collins Myelin Repair Foundation	NDA 011751
2014-5629	07/11/2014 08/08/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Katherine Eban FORTUNE MAGAZINE	ANDA 076477
2014-5630	07/11/2014 08/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	Priyangi Perera Pro-Lab Diagnostics	K123423
2014-5631	07/11/2014 08/08/2014	OC/CVM/OCD/	Kerri O'Brien WRIC-TV	I request the Comprehensive data ADE numbers both electronic and paper from the STARS and PV works data bases for Spinosad + Milbemycin Oxime for dog with oral or unknown administration
2014-5632	07/11/2014 08/08/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Steve Rogers Zoetis Inc.	WIL RESEARCH LABORATORIES, ASHLAND, OH - EIR, 483
2014-5633	07/11/2014 08/08/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dr. Tassie Collins Myelin Repair Foundation	NDA 010775
2014-5634	07/11/2014 08/08/2014	OC/ORACE/ OC/ORACE/	Medical Device Recalls Olga Novoselova, PhD Student, Department of Sociology, The University of Iowa	MEDICAL DEVICE RECALL DATA
2014-5635	07/11/2014 08/08/2014	FDA/OC/OES/DFOI/ OC/ORACE/ OC/ORACE/	SEDA, RAYMONDA	MEDICAL DEVICE COMPANIES IN PUERTO RICO - 483S, WARNING LTRS, UNTITLED LTRS, ETC 2009-2014
2014-5636	07/14/2014 08/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	Laura Boll Medovations Inc.	K000086
2014-5637	07/14/2014 08/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	Laura Boll Medovations Inc.	K972505

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2014-5638	07/14/2014 08/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	Laura Boll Medovations Inc.	K140763
2014-5639	07/14/2014 08/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	Laura Boll Medovations Inc.	K091355
2014-5640	07/14/2014 08/11/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Eric Lintula Active Spine Group, LLC	K082406
2014-5641	07/14/2014 08/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	ANDA 200910
2014-5642	07/14/2014 08/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	BRISTOL-MYERS SQUIBB, ANAGNI, ITALY - EIR
2014-5643	07/14/2014 08/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	SINEQUAN - AERS
2014-5644	07/14/2014 08/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	Laura Boll Medovations Inc.	K103611
2014-5645	07/14/2014 08/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	Laura Boll Medovations Inc.	K131991
2014-5646	07/14/2014 08/11/2014	FDA/OGROP/ORACE-FO/MIN- DO/MIN-CB/	Alison Nicoli Nicoli, Alison A	Any complaints and follow-up related to Henna Tattoo complaints in Minnesota
2014-5647	07/14/2014 08/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	Laura Boll Medovations Inc.	K123223
2014-5648	07/14/2014 08/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	Laura Boll Medovations Inc.	K133987
2014-5649	07/14/2014 08/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	Laura Boll Medovations Inc.	K131700
2014-5650	07/14/2014 08/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	Laura Boll Medovations Inc.	K051637
2014-5651	07/14/2014	FDA/OFVM/CFSAN/OCD/EOS/	Adam Dieker	LIST OF WATER BOTTLING PLANTS

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	08/11/2014		Chelepis Utility Services	
2014-5652	07/14/2014 08/11/2014	OC/CVM/OCD/	Sandra O'Kelley Merial Limited	MILBEMYCIN - AERS
2014-5653	07/14/2014 08/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	Laura Boll Medovations Inc.	K133513
2014-5654	07/14/2014 08/11/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jason Bablak Thar Pharmaceuticals, Inc	BLA 125320 S 7
2014-5655	07/14/2014 08/11/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Matt Daniel Prosight Capital	RETROPHIN - IND ACTH
2014-5656	07/14/2014 08/11/2014	FDA/OGROP/ORAN/NE-FO/NWE-DO/NWE-CB/	705446 WESTLAW COURT EXPRESS	JOHN MURPHY, MD, DANBURY, CT - INSPECTION RECS
2014-5657	07/14/2014 08/11/2014	FDA/OC/OES/DFOI/	Brady Dennis THE WASHINGTON POST	Log of FOIA requests related to smallpox discovery
2014-5658	07/14/2014 08/11/2014	FDA/OFVM/CFSAN/OCD/EOS/	Mary Rait Craft Brew Alliance, Inc.	MARCH 13, 2014 MTG WITH CFSAN RE GLUTEN FREE LABELING OF FERMENTED BEVERAGES, BEER - MINUTES
2014-5659	07/14/2014 08/11/2014	FDA/OGROP/ORAN/SE-FO/FLA-DO/FLA-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mehul Govani P&L Developments LLC	SWISS CAPS USA, MIAMI, FL, SWITZERLAND - EIR 01/01/2011 - 07/11/2014
2014-5660	07/14/2014 08/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	William Francis william francis	K090303
2014-5661	07/14/2014 08/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	Laura Boll Medovations Inc.	K122462
2014-5662	07/14/2014 08/11/2014	FDA/OGROP/ORAN/CE-FO/CHI-DO/CHI-CB/	Greg Gentry Gentry Law, LLC	TC BAUER, CHICAGO, IL - 483 04/01/2013 - 06/12/2014
2014-5663	07/14/2014 08/11/2014	FDA/OC/OES/DFOI/	Melissa Walker Graematter, Inc.	FOIA REQUEST LOG 01/01/2000 - 06/30/2014

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2014-5664	07/14/2014 08/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	JACQUELINE J CHAN K&L Gates LLP	TRANSCRANIAL DIRECT CURRENT STIMULATION DVCS, TRANSCRANIAL ELECTRICAL STIMULATION DVCS - REGULATORY STATUS CORR
2014-5665	07/14/2014 08/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	HUERTA, ALBERTO	NUANCE MEDICAL LLC - NURANCE CRYO-FREEZE SPRAY, CRYO-IN-A-CAN, VANDOLAY FREEZE SPRAY K130995; 3JT ENTERPRISES LLC - CRYONIZE TM K103310
2014-5666	07/14/2014 08/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	AMAURY SANCHEZ NOVEN PHARMACEUTICALS INC	WATSON LABS INC - LIDOCAINE 5% PATCH ANDA 200-675 RECS
2014-5667	07/14/2014 08/11/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORACE-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	DIVYA SRIVASTAV-SETH LAMPF LIPKIND PRUPIS & PETIGROW	ADVANCED STERILIZATION PRODUCTS, IRVINE, CA - STERITITE CONTAINER RECALL, 483, RPTS, ETC
2014-5668	07/14/2014 08/11/2014	FDA/OGROP/ORACE-FO/ATL-DO/ATL-CB/ FDA/OMPT/CDRH/OCER/DFOI/	ASHLEE EDWARDS PARHAM SMITH & ARCHENHOLD LLC	GREENVILLE HEALTH SYSTEMS, GREENVILLE, SC - MYCOBACTERIUM INFECTIONS RECS 1/13 TO PRESENT
2014-5669	07/14/2014 08/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	BRADY ESCH VENCLOSE INC	VNUS MEDICAL TECHNOLOGIES INC - K061373
2014-5670	07/14/2014 08/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	BRADY ESCH VENCLOSE INC	NORTHEAST SCIENTIFIC INC - K090661
2014-5671	07/14/2014 08/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HAROLD H FOX Step toe & Johnson LLP	ADCETRIS (BRENTUXIMAB VEDOTIN) - AERS 7/1/13 TO PRESENT
2014-5672	07/14/2014 08/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HAROLD H FOX Step toe & Johnson LLP	GAZYVA (OBINUTUZUMAB) - AERS
2014-5673	07/14/2014 08/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HAROLD H FOX Step toe & Johnson LLP	JAKAFI (RUXOLITINIB) - AERS, PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY SAFETY ISSUES
2014-5674	07/14/2014	FDA/OMPT/CDER/ORP/DIDP/	HAROLD H FOX	IMBRUVICA - AERS, LYSIS SYNDROME RECS

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	08/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Step toe & Johnson LLP	
2014-5675	07/14/2014 08/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CAROLINE PLEETWOOD SIDLEY AUSTIN LLP	MAGERY B ROTHENBERG, LEWIS & GRACE - LTR 9/14/89
2014-5676	07/14/2014 08/11/2014	FDA/OGROP/OR A/SE-FO/ATL- DO/ATL-CB/	PATRICIA L REGENYE Celgene Corporation	SURESH RAMALINGAM, EMORY WINSHIP CANCER INSTITUTE, ATLANTA, GA - 483S 5/10 TO PRESENT
2014-5677	07/14/2014 08/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JASON SMATHERS MUCKROCK NEWS	RU-486 (MIFEPRISTONE), ELLA (ULIPRISTAL ACETATE), PLAN B (LEVONOGESTREL), MIRENA, ETC - Cmplnts
2014-5678	07/14/2014 08/11/2014	FDA/OGROP/OR A/SW-FO/KAN- DO/KAN-CB/	CHARLENE LAUDENBACH- PERSCHALL WALKER'S FOOD PRODUCTS CO	WALKER'S FOOD PRODUCTS, NORTH KANSAS CITY, MO - TUNA HAACP PLAN EXHIBIT 2 OF 9/16-18/08 INSP
2014-5679	07/14/2014 08/11/2014	FDA/OFVM/CFSAN/OCD/EOS/	CUNNINGHAM, SHEILA K	SPSS RAW DATA FROM THE SPRING 2005 FOOD LABEL USAGE SURVEY
2014-5680	07/14/2014 08/11/2014	OC/CVM/OCD/	KRISTI O SMEDLEY Center for Regulatory Services, Inc.	FORMIC ACID IN ANIMAL FEED - ANIMAL FAP 2258
2014-5681	07/14/2014 08/11/2014	FDA/OGROP/OR A/CE-FO/PHI- DO/PHI-CB/	ROSANNA SEVERINI TELEFLEX	ARROW INTERNATIONAL, READING, PA - EIR 12/18/09
2014-5682	07/14/2014 08/11/2014	FDA/OGROP/OR A/CE-FO/BLT- DO/BLT-CB/ FDA/OGROP/OR A/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/OR A/PA-FO/SAN- DO/SAN-CB/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	QUESTOR PHARMACEUTICALS, ANAHEIM HILLS, CA; HAYWARD, CA; ELLICOT, MD - EIRS, 483S, UNTITLED LTRS 1/13 TO PRESENT
2014-5683	07/14/2014 08/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	JOHN H FUSON, CROWELL MORING - HP ACTHAR GEL NDA 22-432 CORR
2014-5684	07/14/2014 08/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	BIO VECTRA INC, CHARLOTTETOWN, PRINCE EDWARD ISLAND, CANADA; CHESAPEAKE BIOLOGICAL, BALTIMORE, MD - 483S, WARNING LTRS, 1/13 TO PRESENT

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/		
2014-5685	07/15/2014 08/12/2014	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORA/ OC/ORA/	Doe J	WEN HAIR PRODUCTS - COMPLAINTS 01/01/2010 - 07/11/2014
2014-5686	07/15/2014 08/12/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	Exclusivity Summary for NDA 22272 S14
2014-5687	07/15/2014 08/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	Howard Davison Davison, Howard C	ST JUDE MEDICAL SAFIRE BLU MEDIUM SWEEP IRRIGATED ABLATION CATHETER - INSTRUCTIONS FOR USE
2014-5688	07/15/2014 08/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kedar Pai Medivators Inc.	K031809 SUMMARY
2014-5689	07/15/2014 08/12/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Vivian Beauford Beauford, Sandy	VYVANSE - AERS
2014-5690	07/15/2014 08/12/2014	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Chris Lahiff McDermott Will & Emery LLP	CHARLES PRODUCTS DECORATIVE PINT AND SHOT GLASSES - RECALL RECS 01/01/2014 - 07/11/2014
2014-5691	07/15/2014 08/12/2014	FDA/OC/OES/DDM/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Daniel Kolitz N/A	NDA 11522 - ADVISORY COMMITTEE TRANSCRIPTS 05/01/1993 - 03/30/1996
2014-5692	07/15/2014 08/12/2014	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	STEPHEN GUTER DR STEPHEN R GUNTER PRACTICE OF CHIROPRACTIC	STANDARD PROCESS INC, PALMYRA, WI - RECALL NUMBERS F-1764-2010 THROUGH F-17662012; EIRS 6/18/12-7/2/12
2014-5693	07/15/2014	FDA/OFVM/CFSAN/OCD/EOS/	STEPHEN GUNTER	RECALL NUMBERS F-1764-2010 TRHOUGH F-1766-2012 - CAERS, STATUS RPTS, FINAL RPTS

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	08/12/2014	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ OC/CVM/OCD/	DR STEPHEN R GUNTER PRACTICE OF CHIROPRACTIC	
2014-5694	07/15/2014 08/12/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDRH/OCER/DFOI/	PAMELA LEVIN MOORE O'BRIEN YELENK ET AL	DAVID BROWAN, BRIDGEPORT HOSP, BRIDGEPORT, CT - PATIENTS BURNED DURING ARTHROSCOPIC SURGERY
2014-5695	07/15/2014 08/12/2014	FDA/OGROP/ORAPA-FO/SEADO/SEA-CB/ FDA/OMPT/CDRH/OCER/DFOI/	PATRICIA L KELLY ESDAILE BARRETT JACOBS & MONE	QQ-TECH - RED LASER POINTER STAGE LASER LIGHT PEN 650 MM INVESTIGATION RECS, CMPLNTS, RPTS, ETC
2014-5696	07/15/2014 08/12/2014	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	FOI Services, Inc.	DEXFENFLURAMINE HCL - DISCLOSABLE PORTIONS IN REFERENCE 12 CLNCL RVW
2014-5697	07/15/2014 08/12/2014	FDA/OGROP/ORASE-FO/FLADO/FLA-CB/	MOHAMED BARAKAT PRIME PACKAGING INC	PRIME PACKAGING, INC, MIAMI, FL - EIRS 4/16-29/14
2014-5698	07/15/2014 08/12/2014	FDA/OFVM/CFSAN/OCD/EOS/	ARLENE MORALES BURDOCK GROUP	HYDROXYTYROSOL, HYTOLIVE, OLEA25, ETC - RPTS
2014-5699	07/15/2014 08/12/2014	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	MICHELLE LEE ARIZONA REPUBLIC	AUTHENTICATING FDA RECORD
2014-5700	07/15/2014 08/12/2014	FDA/OC/OES/DFOI/	AMANDA J KLINGLER King & Spalding LLP	KYLE THOMAS ROZEMA - CASE 5:14-CV-00495 (N.D.N.Y.) DENIAL & APPEAL RECS
2014-5701	07/16/2014 08/13/2014	OC/ORAE/ OC/ORAE/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Doe J	INDIVIDUAL RECS
2014-5702	07/16/2014 08/13/2014	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Malia Segar Cote Orphan Consulting	ACCUTANE - SUPPLEMENTAL NDA 12/31/00
2014-5703	07/16/2014 08/13/2014	OC/ORAE/ORM/ OC/ORAE/ORM/	Gary Huge ASI Food Safety Consultants	LIST OF FDA INSPECTED FOOD MANUFACTURERS AND DISTRIBUTORS 01/01/2010 - 04/30/2014
2014-5704	07/16/2014	FDA/OMPT/CDER/ERP/DIDP/	Silvia Sanles	NDA 020472 - SBA

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	08/13/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Watson Laboratories, Inc.	
2014-5705	07/16/2014 08/13/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	James Harworth Beale Beale, James H	LEVAQUIN, FLUOROQUINOLONES - AERS
2014-5706	07/16/2014 08/13/2014	FDA/OMPT/CDRH/OCER/DFOI/	Cindy C. Buky Tripp Scott, P.A.	Medtronic Sofamor Danek BRYAN Cervical Disc - MDR
2014-5707	07/16/2014 08/13/2014	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	Lily Huang Lily Huang	ALBERT MAX INC DBA VITA SPRINGS HEALTH, CHINO, CA - EIR 05/01/2013 - 06/15/2013
2014-5708	07/16/2014 08/13/2014	OC/CVM/OCD/	Jackie Callaway WFTS TV	TRIFEXIS - AERS, COMM WITH VETERINARIANS
2014-5709	07/16/2014 08/13/2014	FDA/OMPT/CDRH/OCER/DFOI/	Howard Davison Davison, Howard C	ST JUDE ULTIMUM SHEATHES - INSTRUCTIONS FOR USE
2014-5710	07/16/2014 08/13/2014	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	LESLIE RAMSEY FDA NEWS	CBD CORP, LELAND, NC - 483 6/2014
2014-5711	07/16/2014 08/13/2014	FDA/OGROP/ORA/CE-FO/BLT- DO/BLT-CB/	LESLIE RAMSEY FDA NEWS	SURGICAL DESIGN INC, LORTON, VA - 483 6/2014
2014-5712	07/16/2014 08/13/2014	FDA/OGROP/ORA/CE-FO/CHI- DO/CHI-CB/	LESLIE RAMSEY FDA NEWS	AKORN INC, DECATUR, IL; MYERSON LLC, CHICAGO, IL - 483 6/2014
2014-5713	07/16/2014 08/13/2014	FDA/OGROP/ORA/CE-FO/CIN- DO/CIN-CB/	LESLIE RAMSEY FDA NEWS	PROCTOR & GAMBLE CO, CINCINNATI, OH; MEASUREMENT SPECIALTIES INC, DAYTON, OH; BEN VENUE LABORATORIES INC, BEDFORD, OH - 483 6/2014
2014-5714	07/16/2014 08/13/2014	FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	LESLIE RAMSEY FDA NEWS	BANISTER TOOL INC, PFLUGERVILLE, TX; DHALIWAL LABORATORIES LLC, DALLAS, TX; CAREFUSION 2200 INC, MANNFORD, OK - 483 6/2014
2014-5715	07/16/2014 08/13/2014	FDA/OGROP/ORA/SW-FO/DEN- DO/DEN-CB/	LESLIE RAMSEY FDA NEWS	IMDS INC, LOGAN, UT; INTERNATIONAL HEALTH TECHNOLOGIES, SALT LAKE CITY, UT - 483 6/2014
2014-5716	07/16/2014 08/13/2014	FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/	LESLIE RAMSEY FDA NEWS	HELMER INC, NOBLESVILLE, IN; CENTRAL ADMIXTURE PHARMACY SERVICES INC, NOBLESVILLE, IN; CENTRAL ADMIXTURE PHARMACY SERVICES INC, LIVONIA, MI - 483 6/2014
2014-5717	07/16/2014 08/13/2014	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	LESLIE RAMSEY FDA NEWS	LCR HALLCREST LLC, TAMPA, FL; WELLS PHARMACY NETWORK LLC, OCALA, FL - 483 6/2014

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2014-5718	07/16/2014 08/13/2014	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	LESLIE RAMSEY FDA NEWS	PARTICLE DYNAMICS INT'L LLC, BRENTWOOD, MO; OCEANIC MEDICAL PRODUCTS INC, ATCHISON, KS; MARCUS RESEARCH LAB INC, SAINT LOUIS, MO - 483 6/2014
2014-5719	07/16/2014 08/13/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	LESLIE RAMSEY FDA NEWS	ALERE SAN DIEGO, SAN DIEGO, CA; CALDON BIOTECH INC, VISTA, CA; ACON LABS INC, SAN DIEGO, CA - 483 6/2014
2014-5720	07/16/2014 08/13/2014	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	LESLIE RAMSEY FDA NEWS	XTEN INDUSTRIES LLC, KENOSHA, WI; EXPRESS DIAGNOSTICS INT'L INC, BLUE EARTH, MN - 483 6/2014
2014-5721	07/16/2014 08/13/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	LESLIE RAMSEY FDA NEWS	ORIGINAL BRADFORD SOAP WORKS INC, WEST WARWICK, RI; CITRA LABS LLC, BRAINTREE MA; GENERAL HOSPITAL CORP, BOSTON, MA - 483 6/2014
2014-5722	07/16/2014 08/13/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	LESLIE RAMSEY FDA NEWS	ELITE LABORATORIES INC, NORTHVALE, NJ; NANO DITECH CORP, CRANBURY, NJ; GUEST PACKAGING LLC; RAHWAY, MJ - 483 6/2014
2014-5723	07/16/2014 08/13/2014	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	LESLIE RAMSEY FDA NEWS	AIONEX INC, GOODLETTSVILLE, TN; WE CARE DESIGNS LLC, MANDEVILLE, LA; LIFE SENSING INSTRUMENTS INC, TULLAHOMMA, TN - 483 6/2014
2014-5724	07/16/2014 08/13/2014	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	LESLIE RAMSEY FDA NEWS	A&Z PHARMACEUTICAL INC, HAUPPAUGE, NY; VASOMEDICALINC, WESTBURY, NY; METROPOLIS INTL LLC, LONG ISLAND CITY, NY - 483 6/2014
2014-5725	07/16/2014 08/13/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	LESLIE RAMSEY FDA NEWS	ZOLL LIFECOR CORP, PITTSBURGH, PA - 483 6/2014
2014-5726	07/16/2014 08/13/2014	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	LESLIE RAMSEY FDA NEWS	MEDRITE SUPPLY INC, WALNUT CREEK, CA; COMPUTERIZED SCREENING INC, RENO, NV; THOES MEDICAL SYSTEMS, SANTA CANTA, CA - 483 6/2014
2014-5727	07/16/2014 08/13/2014	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	LESLIE RAMSEY FDA NEWS	ZIMMER MANUFACTURING BV, MERCEDITA, PR - 483 6/2014
2014-5728	07/16/2014 08/13/2014	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	LESLIE RAMSEY FDA NEWS	FRYE ELECTRONICS INC, TIGARD, OR; COMP VIEW MEDICAL LLC, BEVERTON, OR; ONEMEDNET CORP, SEATTLE, WA - 483 6/2014
2014-5729	07/16/2014 08/13/2014	FDA/OMPT/CDRH/OCER/DFOI/	LESLIE RAMSEY FDA NEWS	A&D CO LTD, KITAMOTO SHI, JAPAN; HAIYANG FUJING CO LTD, HAIYANG FUJING FIBER CO LTD, HAIYANG, CHINA; LOCKDOWN MEDICAL LTD, REDDITCH, UK - 483 6/2014
2014-5730	07/16/2014 08/13/2014	FDA/OC/OES/DFOI/	DACKO, DENISE	INSECTICIDES; ROACH PRUF - INFORMATION
2014-5731	07/16/2014 08/13/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	QUINN, TOM	2014-2519
2014-5732	07/16/2014	FDA/OO/OFBA/OAGS/	ROSE SANTOS	FLEET & TRAVEL CARDHOLDERS CREDIT CARD PROGRAM

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	08/13/2014		FOIA GROUP INC	
2014-5733	07/16/2014 08/13/2014	FDA/OC/OES/DFOI/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDRH/OCER/DFOI/	MARIA TOUGAS SCOTT & SCOTT LLP	STRYKER CORP - TRIDENT ACETABULAR HIP SYS 483
2014-5734	07/17/2014 08/14/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Priyangi Perera Pro-Lab Diagnostics	K100818
2014-5735	07/17/2014 08/14/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Pallavi Ail The Financial Express	RANBAXY LABORATORIES LIMITED - 483; DR REDDY'S LABORATORY LTD - 483
2014-5736	07/17/2014 08/14/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ryan Dunnegan Kennedy Capital Management	OTREXUP - ADVERSE EVENTS
2014-5737	07/17/2014 08/14/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Jesse McLean Toronto Star	PAUL W O'CONNOR, TORONTO, CANADA, LAWRENE KOMER, BURLINGTON, CANADA; JACK BARKIN, NORTH YORK, CANADA - EIR
2014-5738	07/17/2014 08/14/2014	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Brenda Van Goethem Schwabe North America dba Natures Way	SCHWABE NORTH AMERICA DBA NATURE'S WAY - 01/28/2013 - 02/04/2013
2014-5739	07/17/2014 08/14/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ryan Dunnegan Kennedy Capital Management	BLOXIVERZ - AERS
2014-5740	07/17/2014 08/14/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Eric Bean DiabetOmics Inc.	K031604, K023763
2014-5741	07/17/2014 08/14/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ryan Dunnegan Kennedy Capital Management	NEOSTIGMINE METHYSULFATE - RECS RE INVENTORY SHORTAGES 06/03/2013 - 07/14/2014
2014-5742	07/17/2014	FDA/OMPT/CDER/GRP/DIDP/	Joanna Ma	PROAMATINE - EFFICACY TRIAL RECS

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	08/14/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	OptumRx	
2014-5743	07/17/2014 08/14/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Emily Mathieu Toronto Star	APOTEX, INDIA - 483 01/01/2014 - 07/14/2014
2014-5744	07/17/2014 08/14/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 202946
2014-5745	07/17/2014 08/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	Mark Barbieri Qualcomm Life, Inc.	K130821
2014-5746	07/17/2014 08/14/2014	FDA/OGROP/ORR/SE-FO/ATL- DO/ATL-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Drew Smith WSPA-TV	MYOBACTERIA ABSCESS GREENVILLE MEMORIAL HOSPITAL - ALL RECS, MDR
2014-5747	07/17/2014 08/14/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ryan Dunnegan Kennedy Capital Management	COMM BETWEEN FDA, FLAMEL TECHNOLOGIES SA; FDA, ECLAT PHARMACEUTICALS 07/02/2013 - 07/14/2014
2014-5748	07/17/2014 08/14/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Theresa Ritter NDA Partners	NDA 19645
2014-5749	07/17/2014 08/14/2014	FDA/OGROP/ORR/SE-FO/FLA- DO/FLA-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OGROP/ORR/SE-FO/NOL- DO/NOL-CB/	Mohit Bhat Kline & company Inc.	SANMINA-SCI CORPORATION, HUNTSVILLE, AL - EIR; SANMINA-SCI CORPORATION FERMOY, IRELAND - EIR; FLEXTRONICS, SHENZHEN, CHINA, ETC - EIR
2014-5750	07/17/2014 08/14/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Colin Harvey, Director, Veterinary Oral Health Council Veterinary Oral Health Council	GREENIES DENTAL CHEW DOG TREATS MILK-BONE BRUSHING CHEWS FOR DOGS MINTIES TREATS FOR DOGS - AERS

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		OC/CVM/OCD/		
2014-5751	07/17/2014 08/14/2014	FDA/OFVM/CFSAN/OCD/EOS/	ALISA BOUCHER BASF CORP	FCN 1022 2010 TO 2012
2014-5752	07/17/2014 08/14/2014	FDA/OFVM/CFSAN/OCD/EOS/	ALISA BOUCHER BASF CORP	FCN 408 2003 TO 2005
2014-5753	07/17/2014 08/14/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/NWJ-DO/NWJ-CB/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORO/CE-FO/DET-DO/DET-CB/ OC/ORO/ OC/ORO/	MARIAN I KELLY ESQ POPJOY & KELLY LLC	INDIVIDUAL RECS
2014-5754	07/17/2014 08/14/2014	FDA/OC/OES/DFOI/	TRISH MCGRADY PRITZKER OLSEN	MASU SUSHI RESTAURANT - SALMONELLA OUTBREAK RECS; INDIVIDUAL RECS
2014-5755	07/17/2014 08/14/2014	FDA/OFVM/CFSAN/OCD/EOS/	PAMELA L LANGHORN Keller and Heckman LLP	FCN 1398
2014-5756	07/17/2014 08/14/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KATE REYNOLDS ROCKY MOUNTAIN POISON & DRUG CENTER	COUGH AND COLD PREPARATIONS - ISRS 7653805, 7689458, 7695933, ETC
2014-5757	07/17/2014 09/26/2014	FDA/OMPT/CTP/OD/ FDA/OGROP/ORO/CE-FO/BLT-DO/BLT-CB/	MARILYNN WHITNEY COVINGTON & BURLING LLP	TOBACCO PROD MFRS - EIRS, 483S, CORR, ETC 11/2/12 TO PRESENT; FIFTY TOBACCO PRODS FOR WHICH FDA ISSUES SUBSTANTIALLY EQUIVALENT (SE) ORDERS 6/14, ETC
2014-5758	07/17/2014 08/14/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	COOPER, LARRY	PFIZER - LIPITOR NDA 20-702 DRAFT LABEL 7/10/08, CHANGE TO AERS, CLNCL PHARMACOLOGY COMMENTS, ETC
2014-5759	07/17/2014 08/14/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORO/NE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORO/NE-FO/NWE-DO/NWE-CB/	PATTI WALLER MARLER CLARK ATTYS	E COLI OUTBREAK IN CT - INVESTIGATION 12/13, 1/14, CORR, LAB RESULTS, ETC

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		OC/ORO/ OC/ORO/		
2014-5760	07/17/2014 08/14/2014	FDA/OGROP/ORO/CE-FO/CIN-DO/CIN-CB/	K MICHELLE VASSALLO LINCARE INC	ADVANCED LIFELINE SERVICES INC, LOUISVILLE, KY - EIRS, 483S, WARNING LTRS 1/198 TO PRESENT
2014-5761	07/17/2014 08/14/2014	FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	ANDREW D FREEMAN BROWN GOLDSTEIN & LEVY LLP	MEDTRONIC MINIMED, NORTHRIDGE, CA - MINIMED 530G EIRS, 483S LAST 2 YRS, CLNCL TRIAL RECS, CORR, ETC
2014-5762	07/17/2014 08/14/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	B EUGENE GUTHERY MD INNOVATIVE PHARMACEUTICALS, LLC	IND 116423 - CORR, RVWS, MINS, ETC
2014-5763	07/17/2014 08/14/2014	FDA/OGROP/ORO/SW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/	R MICHELLE VASSALLO LINCARE INC	CENTRAL VALLEY MEDICAL CENTER, NEPHI, UT - EIRS, 483S, WARNING LTRS 1/98 TO PRESENT
2014-5764	07/17/2014 08/14/2014	FDA/OC/OES/DFOI/	JONATHAN C MIESEN Land O'Lakes, Inc	KC DAIRIES LLP, ELKTON, SD - INSP RECS FROM THE SOUTH DAKOTA DEPT OF AGRICULTURE
2014-5765	07/17/2014 08/14/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MCDONALD, BRANDON	VALIUM, LEXAPRO, WELLBUTRIN, ETC - AERS
2014-5766	07/17/2014 08/14/2014	FDA/OC/OES/DFOI/	ANNIE N VANELLA FAEGRE BAKER DANIELS	SIMPLY THICK LLC - SIMPLY THICK FOI REQUEST LTRS 5/9/14 TO PRESENT
2014-5767	07/17/2014 08/14/2014	FDA/OC/OES/DFOI/	LIU, YINMENG	LIST OF RADIATION-EMITTING MEDICAL DVCS APPROVED OR FACED RECALLS IN THE US 2013
2014-5768	07/17/2014 08/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	LEIGH ANN DAVIS WOMBLE CARLYLE SANDRIDGE & RICE, PLLC	CDRH CPT 1300384
2014-5769	07/17/2014 08/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	JAN ASTROM PERMOBIL AB	PERMOBIL AB, TIMRA, SWEDEN - EIR 10/12
2014-5770	07/17/2014 08/14/2014	FDA/OFVM/CFSAN/OCD/EOS/	ARLENE MORALES BURDOCK GROUP	HIDROX, HYTOLIVE, OLEA25, ETC - REGULATORY STATUS, CONSUMPTION, SAFETY INFO, ETC
2014-5771	07/17/2014 08/14/2014	OC/ORO/ORM/ OC/ORO/ORM/	GAIL LESSICK LACHMAN CONSULTANT SERVICES INC	DRUG COMPANIES, MEDICAL DVC MFRS, BLOOD ESTABLISHMENTS, ETC - FOREIGN AND DOMESTIC INSPS, 483S 5/1-31/14

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2014-5772	07/17/2014 08/14/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PATRICIA L REGENYE Celgene Corporation	MUSTAFA OZGUROGLU, ISTANBUL UNIV, ISTANBUL, TURKEY - 483S 5/10 TO PRESENT
2014-5773	07/17/2014 08/14/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PATRICIA L REGENYE Celgene Corporation	TUDOR CIULEANU, ONCOLO INST ION CHIRICUTA, CLUJ NAPOCA, ROMANIA - 483S 8/07 TO PRESENT
2014-5774	07/17/2014 08/14/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHLOE BIRD PCCA	LIST OF FOREIGN IMPORTED DRUG PRODS, NDC NUMBERS ISSUED TO FOREIGN DRUG FIRMS, US DRUG MFRS, ETC
2014-5775	07/17/2014 08/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	LEE GRANT MEDTRONIC SOFAMOR DANEK	ZIMMER SPINE INC - VIRAGE OCT SPINAL FIXATION SYS K133556; PIONEER SURGICAL TECHNOLOGY - STREAMLINE OCT OCCIPITO-CERVICO THORACIC SYS K133374
2014-5776	07/18/2014 08/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WAYNE SADOWSKI NOVARTIS PHARMACEUTICAL CORPORATION	DR JACEK SZEPIETOWSKI, POLAND 55/5-15/14; DR KIM PAPP 4/28/14-5/9/14, CANADA - EIRS, 483S, 482S, ETC
2014-5777	07/18/2014 08/15/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WAYNE SADOWSKI NOVARTIS PHARMACEUTICAL CORPORATION	SYNE QUA NON LTD, NORFOLK, UK 3/5-10/14; PERCEPTIVE INFORMATICS INC, BILLERICA, MA 5/19-30/14 - EIRS, 483S, 482S, ETC
2014-5778	07/18/2014 08/15/2014	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WAYNE SADOWSKI NOVARTIS PHARMACEUTICAL CORPORATION	PROF VESELIN MITROVIC, BAD NEIHAUM, GERMANY 1/27-31/14; DR ALICE SHAW, BOSTON, MA 2/13-21/14; DR RANEE MEHRA, PHILADELPHIA, PA, 1/29/14-2/25/14 - EIRS, 483S, 482S, ETC

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2014-5779	07/18/2014 08/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TORREY COPE SIDLEY AUSTIN LLP	VALEANT PHARMACEUTICALS INTERNATIONAL INC, QUEBEC, CANADA - EIRS, 483S, 482S, ETC 1/10 TO PRESENT
2014-5780	07/18/2014 08/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TORREY COPE SIDLEY AUSTIN LLP	TRILLIUM HEALTH CARE PRODUCTS INC, BROCKVILLE, ONTARIO, CANADA - EIRS, 483S, 482S, ETC 1/12 TO PRESENT
2014-5781	07/18/2014 08/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TORREY COPE SIDLEY AUSTIN LLP	MERCK SHARP & DOHME-CHIBRET, CLERMONT-FERRAND CEDEX, FRANCE - EIRS, 483S, 482S, ETC 1/10 TO PRESNET
2014-5782	07/18/2014 08/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TORREY COPE SIDLEY AUSTIN LLP	JUBILANT DRAXIMAGE INC, QUEBEC, CANADA - EIRS, 483S, 482S, ETC 1/10 TO PRESENT
2014-5783	07/18/2014 08/15/2014	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	TORREY COPE SIDLEY AUSTIN LLP	MEDICIS (VALEANT PHARMACEUTICAL NORTH AMERICA), BRIDGEWATER, NJ - EIRS, 483S, 482S, ETC 1/10 TO PRESENT
2014-5784	07/18/2014 08/15/2014	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	TORREY COPE SIDLEY AUSTIN LLP	ATON PHARMA INC, LAWRENCEVILLE, NJ - EIRS, 483S, 482S, ETC 1/10 TO PRESENT
2014-5785	07/18/2014 08/15/2014	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	TORREY COPE SIDLEY AUSTIN LLP	DPT LAKEWOOD, LLC, LAKEWOOD, NJ - EIRS, 483S, 482S, ETC 1/10 TO PRESENT
2014-5786	07/18/2014 08/15/2014	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	TORREY COPE SIDLEY AUSTIN LLP	PATHEON MANUFACTURING SERVICES LLC, GREENVILLE, NC - EIRS, 483S, 482S, ETC 1/10 TO PRESENT
2014-5787	07/18/2014 08/15/2014	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	TORREY COPE SIDLEY AUSTIN LLP	MERCK SHARP & DOHME CORP, WEST POINT, PA - EIRS, 483S, 482S, ETC 1/10 TO PRESENT
2014-5788	07/18/2014	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	TORREY COPE	PHARMACEUTICS INTERNATIONAL INC, HUNT VALLEY, MD - EIRS, 483S, 482S, ETC 1/10 TO PRESENT

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	08/15/2014		SIDLEY AUSTIN LLP	
2014-5789	07/18/2014 08/15/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TORREY COPE SIDLEY AUSTIN LLP	VALEANT PHARMACEUTICALS INTERNATIONAL INC, STEINBACH, MANITOBA, CANADA - EIRS, 483S, 482S, ETC 1/10 TO PRESENT
2014-5790	07/18/2014 08/15/2014	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	TORREY COPE SIDLEY AUSTIN LLP	BIOVAIL TECHNOLOGIES LTD, BRIDGEWATER, NJ - EIRS, 483S, 482S, ETC 1/10 TO PRESENT
2014-5791	07/18/2014 08/15/2014	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	TORREY COPE SIDLEY AUSTIN LLP	ACCUPAC INC, MAINLAND, PA - EIRS, 483S, 482S, ETC 1/12 TO PRESENT
2014-5792	07/18/2014 08/15/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TORREY COPE SIDLEY AUSTIN LLP	SANOFI-AVENTIS SPA, ANAGNI, ITALY - EIRS, 483S, 482, ETC 1/11 TO PRESENT
2014-5793	07/18/2014 08/15/2014	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	TORREY COPE SIDLEY AUSTIN LLP	EISAI INC, RESEARCH TRIANGLE PARK, NC - EIRS, 483S, 482S, ETC 1/13 TO PRESENT
2014-5794	07/18/2014 08/15/2014	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	TORREY COPE SIDLEY AUSTIN LLP	CATALENT PHARMA SOLUTIONS LLC, PETERSBURG, FL - EIRS, 483S, 482S, ETC 1/13 TO PRESENT
2014-5795	07/18/2014 08/15/2014	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	TORREY COPE SIDLEY AUSTIN LLP	DPT LABORATORIES, LTD, SAN ANTONIO, TX - EIRS, 483S, 482S, ETC 1/13 TO PRESENT
2014-5796	07/18/2014 08/15/2014	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	TORREY COPE SIDLEY AUSTIN LLP	GLAXOSMITHKLINE, LLC, RESEARCH TRIANGLE PARK, NC - EIRS, 483S, 482S, ETC 1/11 TO PRESENT
2014-5797	07/18/2014 08/15/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TORREY COPE SIDLEY AUSTIN LLP	GLAXOSMITHKLINE INC, MISSISSAUGA, ONTARIO, CANADA - EIRS, 483S, 482S, ETC 1/11 TO PRESENT
2014-5798	07/18/2014 08/15/2014	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	TORREY COPE SIDLEY AUSTIN LLP	PRODUCT QUEST MFG, LLC, DAYTONA BEACH, FL - EIRS, 483S, 482S, ETC 1/12 TO PRESENT
2014-5799	07/18/2014 08/15/2014	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	TORREY COPE SIDLEY AUSTIN LLP	VEE PAK, INC, HODGKINS, IL - EIRS, 483S, 482S, ETC 1/12 TO PRESENT
2014-5800	07/18/2014 08/15/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TORREY COPE SIDLEY AUSTIN LLP	KIK CUSTOM PRODUCTS, ETOBICOKE, ONTARIO, CANADA - EIRS, 483S, 482S, ETC 1/12 TO PRESENT

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2014-5801	07/18/2014 08/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	CYCLOBENZAPAR 10 MG, TRAMADOL, HALOPERIDOL 5 MG, ETC - AERS
2014-5802	07/18/2014 08/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID MANGIONE Govzilla, Inc.	HOSPIRA SPA, LISCATE, ITALY - 483S 5/13/14
2014-5803	07/18/2014 08/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MICHAEL D SHUMSKY KIRLAND & ELLIS	STANDARDS, METHODS OFFICE OF GENERIC DRUGS IS APPLYING TO EVALUATE THE COMPARATIVE ADHESION OF A GENERIC TRANSDERMAL PROD RELATIVE TO THE BRAND NAME TRANSDERMAL PROD IT REFERENCES
2014-5804	07/18/2014 08/15/2014	FDA/OC/OES/DFOI/	SHARPE 04642032, IAN	MASSACHUSETTS DIVISION OF YOUTH SERVICES, BOSTON, MA - MAILING ADDRESS
2014-5805	07/18/2014 08/15/2014	FDA/OC/OES/DFOI/	Melissa Walker Graematter, Inc.	PREVIOUSLY RELEASED 483S
2014-5806	07/18/2014 08/15/2014	FDA/OC/OCC/ FDA/OC/OES/ FDA/OC/OEXA/OC/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OC/OEXA/OMA/	Brady Dennis THE WASHINGTON POST	COMM RELATED TO FDA PUBLIC RESPONSE TO VIALS OF SMALLPOX AT CBER LAB ON NIH CAMPUS 07/01/2013 - 07/11/2014
2014-5807	07/18/2014 08/15/2014	FDA/OC/OCC/ FDA/OC/OES/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Brady Dennis THE WASHINGTON POST	COMM RE DISCOVERY OF VIALS OF SMALLPOX AT CBER LAB AT NIH CAMPUS 06/30/2014 - 07/11/2014

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2014-5808	07/21/2014 09/19/2014	FDA/OMPT/CTP/OD/	Mark Schneider Charles River Associates	HPHC records or (Tar, Nicotine, and Carbon Monoxide reports) regarding Length, Filter, Flavor, Package, etc
2014-5809	07/21/2014 08/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jaya Ayyagari DR. REDDY'S LABORATORIES INC	ANDA 085635 - SBA
2014-5810	07/21/2014 08/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Peter R. Breggin, MD Center for the Study of Empathic Therapy	PAXIL - AERS
2014-5811	07/21/2014 08/18/2014	FDA/OGROP/ORACE-FO/MIN- DO/MIN-CB/	Noelle Sechrest Noelle Sechrest c/o Nestle' Infant Nutrition	GERBER PRODUCTS CORP DBA NESTLE NUTRITION EAU CLAIRE, EAU CLAIRE, WI - EIR
2014-5812	07/21/2014 08/18/2014	FDA/OGROP/ORACE-FO/DET- DO/DET-CB/	Chris Gansen Gansen Law Group, P.C.	THE STANDING COMPANY - WARNING LETTER RECS
2014-5813	07/21/2014 08/18/2014	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	SODIUM CAPRATE SAFETY AS FOOD ADDITIVE
2014-5814	07/21/2014 08/18/2014	FDA/OMPT/CDRH/OCER/DFOI/	Gregory Nelson Donahue Davies	GENEMAX MEDICAL PRODUCTS INDUSTRY CORP - MECHANICAL WHEELCHAIR RECS
2014-5815	07/21/2014 08/18/2014	FDA/OGROP/ORAPA-FO/SAN- DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Gregory Nelson Donahue Davies	AMERICAN BANTEX CORPORATION - MECHANICAL WHEELCHAIR RECS
2014-5816	07/21/2014 08/18/2014	OC/CVM/OCD/	Paul Summer Ajinomoto North America, Inc.	AMENDMENT OF DEFINITION 6.10 L-TRYPTOPHAN IN OFFICIAL PUBLICATION OF THE ASSOCIATION OF AMERICAN FEED CONTROL OFFICIALS
2014-5817	07/21/2014 08/18/2014	FDA/OMPT/CDRH/OCER/DFOI/	orhan techneon	INFUSION PUMP - REPORTS OF UNDER INFUSION, OVER INFUSION
2014-5818	07/21/2014 08/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Matt Schmitt Kellogg School of Management	LAMICTAL TENTATIVE APPROVAL LETTERS
2014-5819	07/21/2014	FDA/OMPT/CDER/ORP/DIDP/	Faryal Hasan	NDA 021436 FORM FDA 3542

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	08/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Hyman Phelps and McNamara PC	
2014-5820	07/21/2014 08/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dr. Tassie Collins Myelin Repair Foundation	NDA 010571, NDA 011552, NDA 017661 - APPROVAL, REVIEW RECS
2014-5821	07/21/2014 08/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	Chris Lahiff McDermott Will & Emery LLP	Letter from Christine J. Lewis, Ph.D., Director, Office of Nutritional Products, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition, FDA, to Richard Peterson, Executive Director, California Prune Board (Jun. 6, 2000)
2014-5822	07/21/2014 08/18/2014	OC/ORAO/OE/ OC/ORAO/OE/	Olga Novoselova Olga Novoselova, PhD Student, Department of Sociology, The University of Iowa	FOOD RECALL DATA
2014-5823	07/21/2014 08/18/2014	FDA/OO/OFBA/OAGS/	Rafael Marrero-Gonzalez Spotswood Consulting	2010 FDA Prescription Drug User Fee RFP and the copy of the winning proposal
2014-5824	07/21/2014 08/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Denise Hammang BIOPHARMA COMPLIANCE SERVICES, LLC	ONCOTEC PHARMA PRODUKTION GMBH - EIR APRIL 2014
2014-5825	07/21/2014 09/11/2014	FDA/OGROP/ORAO/NE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORAO/SW-FO/DEN-DO/DEN-CB/	Jordan Graham The Boston Herald	FRESENIUS MEDICAL CARE NORTH AMERICA - INVESTIGATIONS, RECALLS
2014-5826	07/21/2014 08/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mary Ann Adelfio MD Mary Ann Adelfio MD	FORTEO - AERS

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-5827	07/21/2014 08/18/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	JEROME LEW JEROME LEW	K112444
2014-5828	07/21/2014 08/18/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Martha Soley Martha E. Soley/CPW Law	INDIVIDUAL RECS
2014-5829	07/21/2014 08/18/2014	FDA/OMPT/CDRH/OCER/DFOI/	Christopher Parrella The Health Law Offices of Anthony C. Vitale, P.A.	K110515
2014-5830	07/21/2014 08/18/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	David Kim David Kim	ANDA 090811, ANDA 090816
2014-5831	07/21/2014 08/18/2014	OC/ORO/OE/ OC/ORO/OE/	Olga Novoselova Olga Novoselova, PhD Student, Department of Sociology, The University of Iowa	DRUG RECALL DATA
2014-5832	07/21/2014 08/18/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OO/OFBA/OFO/OFM/BTAMS /	John Fauber MILWAUKEE JOURNAL SENTINEL	PDUFA ANNUAL PAYMENTS
2014-5833	07/21/2014 08/18/2014	FDA/OGROP/ORO/NE-FO/NWE- DO/NWE-CB/	Bob Blackburn Blackburn, Bob	CUBIST PHARMACEUTICALS, LEXINGTON, MA - 483 05/01/2014 - 07/17/2014
2014-5834	07/21/2014 08/18/2014	FDA/OGROP/ORO/NE-FO/NYK- DO/NYK-DCB/	Blake Goodner Bridger Healthcare	JEROME STEVENS PHARMACEUTICALS, BOHEMIA, NY - 483 01/02/2013 - 07/17/2014
2014-5835	07/21/2014 08/18/2014	FDA/OGROP/ORO/CE-FO/PHI- DO/PHI-CB/	Blake Goodner Bridger Healthcare	LANNETT COMPANY, PHILADELPHIA, PA - 483, WARNING LETTER, RESPONSE LETTER 01/02/2013 - 07/17/2014
2014-5836	07/21/2014 08/18/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michael S Sawaya Altaire Pharmaceuticals, Inc.	ANDA 040074

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2014-5837	07/21/2014 08/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	PREDNISONE - AERS
2014-5838	07/21/2014 08/18/2014	FDA/OC/OES/DFOI/ FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORR/CE-FO/CIN-DO/CIN-CB/	Tyler D. Henkel Henkel, Tyler D	INVACARE - MAUDE REPORTS, 483, RESPONSES ETC
2014-5839	07/21/2014 08/18/2014	FDA/OGROP/ORR/CE-FO/NWJ-DO/NWJ-CB/	Chris Hotary INDIVIDUAL	MUSCULOSKELETAL TRANSPLANT FOUNDATION - 483 01/01/2014 - 07/17/2014
2014-5840	07/21/2014 08/18/2014	FDA/OMPT/CDRH/OCER/DFOI/	Darren Clarke Prometheus Laboratories Inc.	CORR BETWEEN FDA AND NDA GENOTEK INC RE WARNING LETTER 12/20/13
2014-5841	07/21/2014 08/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	prolia side effects marsh, anita	PROLIA - AERS
2014-5842	07/21/2014 08/18/2014	FDA/OC/OES/DFOI/	Thomas Austin Eastern Pharmacy of Ocala Florida	EASTERN PHARMACY, OCALA, FL
2014-5843	07/21/2014 09/04/2014	FDA/OGROP/ORR/CE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORR/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORR/CE-FO/DET-DO/DET-CB/ FDA/OGROP/ORR/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORR/CE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORR/NE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORR/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/	SIDNEY M WOLFE MD PUBLIC CITIZEN'S HEALTH RESEARCH GROUP	AMERICAN RED CROSS BLOOD SERVICES FACILITIES - 483S 1/12 TO 1/14

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2014-5844	07/21/2014 08/18/2014	FDA/OC/OCC/ FDA/OC/OES/ FDA/OGROP/OIP/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SARA REARDON NATURE	DISCOVERY OF SMALLPOX VIALS ON THE BETHESDA CAMPUS - COMM 6/30/14-7/8/14
2014-5845	07/21/2014 08/18/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TORREY COPE SIDLEY AUSTIN LLP	CP PHARMACEUTICALS LTD, WEXHAM, UK - 482S, 483S, EIRS, ETC 1/12 TO PRESENT
2014-5846	07/21/2014 08/18/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TORREY COPE SIDLEY AUSTIN LLP	3M HEALTH CARE LTD, LEICESTERSHIRE, UK - 482S, 483S, EIRS, ETC 1/12 TO PRESENT
2014-5847	07/21/2014	FDA/OGROP/ORAPA-FO/LOS-	TORREY COPE	PURE TEK CORP, SAN FERNANDO, CA - 482S, 483S, EIRS,

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	08/18/2014	DO/LOS-CB/	SIDLEY AUSTIN LLP	ETC 1/13 TO PRESENT
2014-5848	07/21/2014 08/18/2014	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	TORREY COPE SIDLEY AUSTIN LLP	3M DRUG DELIVERY SYSTEMS, NORTHRIDGE, CA - 482S, 483S, EIRS, ETC 1/12 TO PRESENT
2014-5849	07/21/2014 08/18/2014	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	TORREY COPE SIDLEY AUSTIN LLP	MEDICIS PHARMACEUTICAL CORP, SCOTTSDALE, AZ - 482S, 483S, EIRS, ETC 1/12 TO PRESENT
2014-5850	07/21/2014 08/18/2014	FDA/OGROP/ORAP/PA-FO/SEA-DO/SEA-CB/	TORREY COPE SIDLEY AUSTIN LLP	SOLTA MEDICAL INC, BOTHELL, WA - 482S, 483S, EIRS, ETC 1/13 TO PRESENT
2014-5851	07/21/2014 08/18/2014	FDA/OGROP/ORAP/PA-FO/SAN-DO/SAN-CB/	TORREY COPE SIDLEY AUSTIN LLP	SOLTA MEDICAL INC, HAYWARD, CA - 482S, 483S, EIRS, ETC 1/13 TO PRESENT
2014-5852	07/21/2014 08/27/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	TORREY COPE SIDLEY AUSTIN LLP	PAR STERILE PRODUCTS LLC, ROCHESTER, MI - 482S, 483S, EIRS, ETC 1/12 TO PRESENT
2014-5853	07/21/2014 08/18/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	TORREY COPE SIDLEY AUSTIN LLP	VALEANT PHARMACEUTICALS INTERNATIONAL, BRIDGEWATER, NJ - 482S, 483S, EIRS, ETC 1/11 TO PRESENT
2014-5854	07/21/2014 08/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TORREY COPE SIDLEY AUSTIN LLP	JANSSEN-CLAG, VAL DE REUIL, FRANCE - 482S, 483S, EIRS, ETC 1/11 TO PRESENT
2014-5855	07/21/2014 08/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TORREY COPE SIDLEY AUSTIN LLP	VALEANT GROUPE COSMEDERME INC, LAVAL, QC, CANADA - 482S, 483S, EIRS, ETC 1/10 TO PRESENT
2014-5856	07/21/2014 08/18/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	TORREY COPE SIDLEY AUSTIN LLP	PACON MANUFACTURING CORP, SOMERSET, NJ - 482S, 483S, EIRS, ETC 1/12 TO PRESENT
2014-5857	07/21/2014 08/18/2014	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	TORREY COPE SIDLEY AUSTIN LLP	UNIVERSAL PACKAGING SYSTEMS INC, COMMACK, NY - 482S, 483S, EIRS, ETC 1/12 TO PRESENT
2014-5858	07/21/2014 08/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TORREY COPE SIDLEY AUSTIN LLP	IPSEN BIOPHARM LTD, WEXHAM, UK - 482S, 483S, EIRS, ETC 1/12 TO PRESENT
2014-5859	07/21/2014 08/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TORREY COPE SIDLEY AUSTIN LLP	CONTRACT PHARMACEUTICALS LTD CANADA, WREXHAM, UK - 482S, 483S, EIRS, ETC 1/12 TO PRESENT

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2014-5860	07/21/2014 08/18/2014	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	TORREY COPE SIDLEY AUSTIN LLP	EI LLC, KANNAPOLIS, NC - 482S, 483S, EIRS, ETC 1/12 TO PRESENT
2014-5861	07/21/2014 08/18/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TORREY COPE SIDLEY AUSTIN LLP	WELLSPRING PHARMACEUTICAL CANADA CORP, OAKVILLE, ON, CANADA - 482S, 483S, EIRS, ETC 1/12 TO PRESENT
2014-5862	07/21/2014 08/18/2014	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	TORREY COPE SIDLEY AUSTIN LLP	OBAGI MEDICAL PRODUCTS INC, MILFORD, CT - 482S, 483S, EIRS, ETC 1/13 TO PRESENT
2014-5863	07/21/2014 08/18/2014	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	TORREY COPE SIDLEY AUSTIN LLP	GS COSMECEUTICAL USA INC, LIVERMORE, CA - 482S, 483S, EIRS, ETC 1/13 TO PRESENT
2014-5864	07/21/2014 08/18/2014	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	TORREY COPE SIDLEY AUSTIN LLP	SHARP CORP, ALLENTOWN, PA - 482S, 483S, EIRS, ETC 1/12 TO PRESENT
2014-5865	07/21/2014 08/18/2014	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	TORREY COPE SIDLEY AUSTIN LLP	DPT LABORATORIES LTD, SAN ANTONIO, TX - 482S, 483S, EIRS, ETC 1/12 TO PRESENT
2014-5866	07/21/2014 08/18/2014	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	TORREY COPE SIDLEY AUSTIN LLP	DPT LABORATORIES LTD, SAN ANTONIO, TX - 482S, 483S, EIRS, ETC 1/12 TO PRESENT
2014-5867	07/21/2014 08/18/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TORREY COPE SIDLEY AUSTIN LLP	PATHEON INC, MISSISSAUGA, ONTARIO, CANADA - 482S, 483S, EIRS, ETC 1/12 TO PRESENT
2014-5868	07/21/2014 08/18/2014	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	TORREY COPE SIDLEY AUSTIN LLP	SHARP CORP, CONSHOHOCKEN, PA - 482S, 483S, EIRS, ETC 1/12 TO PRESENT
2014-5869	07/21/2014 08/18/2014	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	TORREY COPE SIDLEY AUSTIN LLP	MILBAR LABORATORIES INC, EAST HAVEN, CT - 482S, 483S, EIRS, ETC 1/13 TO PRESENT
2014-5870	07/21/2014 08/18/2014	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	TORREY COPE SIDLEY AUSTIN LLP	SWISS AMERICAN PRODUCTS INC, CARROLLTON, TX - 482S, 483S, EIRS, ETC 1/13 TO PRESENT
2014-5871	07/21/2014 10/01/2014	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	TORREY COPE SIDLEY AUSTIN LLP	TOLMAR INC, FORT COLLINS, CO - 482S, 483S, EIRS, ETC 1/13 TO PRESENT

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2014-5872	07/21/2014 08/18/2014	FDA/OGROP/ORR/SE-FO/SJN-DO/SJN-CB/	TORREY COPE SIDLEY AUSTIN LLP	JANSSEN ORTHO LLC, MANATI, PR - 482S, 483S, EIRS, ETC 1/11 TO PRESENT
2014-5873	07/22/2014 08/19/2014	FDA/OGROP/ORR/ORO/DIOP/OC/CVM/OCD/ FDA/OGROP/ORR/CE-FO/CIN-DO/CIN-CB/	Jeffrey Pierce ANIMAL LEGAL DEFENSE FUND	EQUINE INFORMATION DOCUMENTS IN POSSESSION OF FDA 07/01/2004 - 07/17/2014
2014-5874	07/22/2014 08/19/2014	FDA/OC/OES/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Christina Farr REUTERS	MEETING MEMORANDA - APPLE, RONI ZEIGER, ZACH LIU ETC
2014-5875	07/22/2014 08/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	Andrey Godes Multi Radiance Medical	K050668 - CLINICAL DATA
2014-5876	07/22/2014 08/19/2014	FDA/OGROP/ORR/CE-FO/MIN-DO/MIN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Trisha Volpe KARE-TV	ACCESS GENETICS, EDEN PRAIRIE, MN - WARNING LETTER RECS
2014-5877	07/22/2014 08/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	Oliver Prichard NORTH RUN CAPITAL LP	GETINGE GROUP - 483 07/01/2013 - 07/17/2014
2014-5878	07/22/2014 08/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	Andrey Godes Multi Radiance Medical	K050342 CLINICAL DATA
2014-5879	07/22/2014 08/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	Andrey Godes Multi Radiance Medical	K012580 CLINICAL DATA
2014-5880	07/22/2014 08/19/2014	FDA/OO/OFBA/OAGS/	Stacy Kauffman Beacon Associates, Inc.	HHSF223200850020I, HHSF22301005T
2014-5881	07/22/2014 08/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jesse McLean Toronto Star	PREVIOUSLY DISCLOSED INSPECTION RECORDS RE CANADIAN DOCTORS
2014-5882	07/22/2014 08/19/2014	FDA/OGROP/ORR/SW-FO/DEN-DO/DEN-CB/	Blake Goodner Bridger Healthcare	LANNETT COMPANY, CODY, WY - 483, WARNING LETTERS, RESPONSES 01/02/2013 - 07/17/2014
2014-5883	07/22/2014 08/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	Andrey Godes Multi Radiance Medical	K132940
2014-5884	07/22/2014	FDA/OC/OES/DFOI/	Rachel Johnson	2014-3370

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	08/19/2014		FOI Services, Inc.	
2014-5885	07/22/2014 08/19/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-1671
2014-5886	07/22/2014 08/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Peter R. Breggin, MD Center for the Study of Psychiatry	VYVANSE - MEDWATCH
2014-5887	07/22/2014 08/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Malia Segar Cote Orphan Consulting	NDA 018662 - LABELING SUPP
2014-5888	07/22/2014 08/19/2014	FDA/OC/OES/DDM/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Audrey Zhang HARVARD UNIVERSITY	Transcript of the Antiviral Drugs Advisory Committee Meeting. (Discussion of CD4 as a surrogate marker or surrogate endpoint for the evaluation of AIDS therapies)
2014-5889	07/22/2014 08/19/2014	FDA/OC/OES/DDM/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Audrey Zhang HARVARD UNIVERSITY	Transcript of the Anti-Infective Drugs Advisory Committee Meeting. (Discussion of NDA for Retrovir / Zidovudine / AZT)
2014-5890	07/22/2014 08/19/2014	FDA/OFVM/CFSAN/OCD/EOS/	Bob Hatch Organic Defoamer Group	REQUEST TO USE SODIUM (C14-16) OLEFIN SULFONATE FOR ANY INDIRECT OR DIRECT FOOD PROCESSING ADDITIVES
2014-5891	07/22/2014 08/19/2014	FDA/OGROP/ORAC/CE-FO/DET-DO/DET-CB/	Phillip Tocco Michigan State University Extension	KUTCHEY FAMILY FARMS, MACOMB, MI - SAMPLING RECS 01/01/2013 - 01/10/2014
2014-5892	07/22/2014 08/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	David Moynham ArjoHuntleigh Inc	K100902
2014-5893	07/22/2014 08/19/2014	FDA/OFVM/CFSAN/OCD/EOS/	Chris Lahiff McDermott Will & Emery LLP	EMAIL FROM GERALDINE JUNE RE FOODNAVIGATOR-USA.COM INQUIRY 03/01/2008 - 04/30/2008
2014-5894	07/22/2014 08/19/2014	FDA/OFVM/CFSAN/OCD/EOS/	Marcos Garza H-E-B	LETTER TO FDA FROM INTERNATIONAL BOTTLED WATER ASSOCIATION 3/23/00
2014-5895	07/22/2014 08/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K082396

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2014-5896	07/22/2014 08/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	David Moynham ArjoHuntleigh Inc	K100909
2014-5897	07/22/2014 08/19/2014	FDA/OC/OES/DDM/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Audrey Zhang HARVARD UNIVERSITY	Transcript of the Endocrinologic and Metabolic Drugs Advisory Committee. (Discussion of endpoints for atherosclerosis)
2014-5898	07/22/2014 08/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K071920
2014-5899	07/22/2014 08/19/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Peter R. Breggin, MD Center for the Study of Psychiatry	METHYLPHENIDATE - MEDWATCH
2014-5900	07/22/2014 08/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	Avital Merl BD	K071587
2014-5901	07/22/2014 08/19/2014	FDA/OC/OES/DDM/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Audrey Zhang HARVARD UNIVERSITY	Transcript of the Antiviral Drugs Advisory Committee Meeting. (Both days; discussion of the NDA for Videx / Didanosine / ddl)
2014-5902	07/22/2014 08/19/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	SGS TAIWAN LTD, NEW TAIPEI CITY, TAIWAN - EIR, 483, CO RESP 10/14-17/13
2014-5903	07/22/2014 08/19/2014	FDA/OGROP/ORR/CE-FO/CHI-DO/CHI-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	IIT RESEARCH INSTITUTE, CHIGAGO, IL - EIR, 483, CO RESP 9/22/10 TO 10/5/10
2014-5904	07/22/2014 08/19/2014	FDA/OGROP/ORR/PA-FO/SEA-DO/SEA-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	SNBL USA LTD, EVERETT, WA - EIR, 483, CO RESP 9/19-27/11
2014-5905	07/22/2014 08/19/2014	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	BELCHER PHARMACEUTICALS LLC, LARGO, FL - EIR, 483, CO RESP 11/14/12 - 3/22/13
2014-5906	07/22/2014	FDA/OGROP/ORR/CE-FO/MIN-	WALTER E. CHALKLEY	ANIP ACQUISITION, BAUDEETTE, MN - EIR, 483, CO RESP

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	08/19/2014	DO/MIN-CB/	THOMSON REUTERS (SCIENTIFIC) SAS	1/3-6/12
2014-5907	07/22/2014 08/19/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	RTI BIOLOGICS INC, ALLENDALE, NJ - EIR, 483, CO RESP 12/3/13 - 1/9/14
2014-5908	07/22/2014 08/19/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	SMITH KLINE BEECHAM, CORK, IRELAND - EIR, 483, CO RESP 10/18-23/13
2014-5909	07/22/2014 08/19/2014	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	HILL DERMACEUTICALS INC, SANFORD, FL - EIR, 483, CO RESP 7/30 - 8/10/12
2014-5910	07/22/2014 08/19/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	ARUP LABORATORIES INC, SANDY, UT - EIR, 483, CO RESP 2/11-15/13
2014-5911	07/22/2014 08/19/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	GRIFOLS BIOMAT USA INC, AURORA, CO - EIR, 483, CO RESP 2/4/13
2014-5912	07/22/2014 08/19/2014	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	WALTER E. CHALKLEY THOMSON REUTERS	MICHAEL T. JARRATT MD, AUSTIN, TX - EIR, 483, CO RESP 1/29 - 2/4/13
2014-5913	07/22/2014 08/19/2014	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	CARDINAL HEALTH 414 LLC, MEMPHIS, TN - EIR, 483, CO RESP 2/4-7/13
2014-5914	07/22/2014 08/19/2014	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	JCB LABS LLC, WICHITA, KS - EIR, 483, CO RESP 2/12-27/13
2014-5915	07/22/2014 08/19/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	TRIFARMA SPA, MILANO, ITALY - EIR, 483, CO RESP 1/27-29/14
2014-5916	07/22/2014 08/19/2014	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	IIT RESEARCH INSTITUTE, CHICAGO, IL - EIR, 483, CO RESP 11/18-20/13
2014-5917	07/22/2014 08/19/2014	FDA/OGROP/ORACE-FO/PHIDO/PHI-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	QPS LLC, NEWARK, DE - EIR, 483, CO RESP 6/17-21/13

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2014-5918	07/22/2014 08/19/2014	FDA/OGROP/ORPA-FO/SEA-DO/SEA-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	SNBL USA LTD, EVERETT, WA - EIR, 483, CO RESP 11/18-22/13
2014-5919	07/22/2014 08/29/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	WALTER EE. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	MPI RESEARCH INC, MATTAWAN, MI - EIR, 483, CO RESP 6/28/10-7/7/10
2014-5920	07/22/2014 08/19/2014	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	CHARLES RIVER, RENO, NV - EIR, 483, CO RESP 10/19-23/09
2014-5921	07/22/2014 08/19/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	CHARLES RIVER LABORATORIES, SHREWSBURY, MA - EIR, 483, CO RESP 2/22/10-3/3/10
2014-5922	07/22/2014 08/19/2014	FDA/OC/OCC/ FDA/OMPT/OSMP/OCP/	Gerald Steel PE	PUBLIC WATER FLOURIDATION PRODUCTS
2014-5923	07/22/2014 08/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ROBERTS, HEATHER	AEGERION PHARMACEUTICALS - JUXTAPID (LOMITAPIDE) AER
2014-5924	07/22/2014 08/19/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	EVANGELINE RAGUINDIN Diamond Wipes International, Inc.	DIAMOND WIPES INT'L INC, BUCYRUS, OH - EIR 2/27/12
2014-5925	07/22/2014 08/19/2014	FDA/OFVM/CFSAN/OCD/EOS/	ELIZABETH SWEIS INTERTEK	NOVA CHEMICAL - TOR 1998-015
2014-5926	07/22/2014 08/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/CVM/OCD/	CAROLINE STOUT ECOR1 CAPITAL LLC	CORR BTWN FDA & REGADO BIOSCIENCES REGARDING PEGNIVACOGIN/ANIVAMERSEN BULUS - REGI REVOLYXIS
2014-5927	07/22/2014 08/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ASHLEY R. PALMER ROBBINS UMEDA LLP	ABBOTT LABS - DEPAKOTE - MARKETING PRACTICE
2014-5928	07/22/2014 08/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	ELENA L. MACK AUTHENTIDATE	K0900801
2014-5929	07/22/2014	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	JONATHAN C. MIESEN	KC DAIRIES LLP, ELKTON, SD - SD DEPT OF AGRICULTURE RECS

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	08/19/2014		Land O'Lakes, Inc	
2014-5930	07/22/2014 08/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORA/ OC/ORA/	JAY C. BREITLING GOODWIN PROCTER LLP	NEW ENGLAND COMPOUNDING CENTER (NECC), AMERIDOSE - LAB NOTES, STERILITY TESTS, CMLPTS, ETC
2014-5931	07/23/2014 08/20/2014	FDA/OFVM/CFSAN/OCD/EOS/	Sapna Chandra Deep Foods Inc.	RAJ INTERNATIONAL - INSPECTION REPORT 11/01/2013 - 12/31/2013
2014-5932	07/23/2014 08/20/2014	FDA/OMPT/CDRH/OCER/DFOI/	Avital Merl BD	K053196
2014-5933	07/23/2014 08/20/2014	FDA/OMPT/CDRH/OCER/DFOI/	Julia Arnous - Shapiro Haber & Urmy LLP SHAPIRO HABER & URMY LLP	INVIVO THERAPEUTICS HOLDINGS CORP - RECS RE APPROVAL OF IDE
2014-5934	07/23/2014 08/20/2014	FDA/OFVM/CFSAN/OCD/EOS/	Mark Prinz Registrar Corp	DARRELL LEA CONFECTIONARY CO PTY LTD, AUSTRALIA; HOCHREITER FLEISCHWAREN GMBH, AUSTRIA, RUPSHA FISH & ALLIED INDUSTRIES LIMITED, BANGLADESH ETC - 483
2014-5935	07/23/2014 08/20/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Robert Frederich BRISTOL-MYERS SQUIBB	A dose-ranging study of eplerenone versus placebo and spironolactone in patients with symptomatic heart failure. G.D. Searle & Co., Protocol No. IE3-97-02-011, 21 May 1997
2014-5936	07/23/2014 08/20/2014	FDA/OMPT/CDRH/OCER/DFOI/	Avital Merl BD	K060133
2014-5937	07/23/2014 08/20/2014	FDA/OMPT/CDRH/OCER/DFOI/	Avital Merl BECTON DICKINSON	K955629
2014-5938	07/23/2014 08/20/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K093845
2014-5939	07/23/2014 08/20/2014	FDA/OMPT/CDRH/OCER/DFOI/	Dr. Tracy Onega DARTMOUTH COLLEGE	Total number of FDA Mammography Devices per mammography location in the US
2014-5940	07/23/2014 08/20/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Srivani.Y Natco Pharma Limited	Granisetron tablets USP 1 mg- ANDA # 78-969 Anastrozole Tablets 1 mg-ANDA # 79-220 Letrozole Tablets USP, 2.5 mg ANDA# 200161 Rizatirptan benzoate tablets 5 mg and 10 mg ANDA # 200482 Lansoprazole DR Capsules USP 15 mg and 30mg ANDA # 201921

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2014-5941	07/23/2014 08/20/2014	FDA/OC/OES/DDM/ FDA/OFVM/CFSAN/OCD/EOS/	Riley John Step toe & Johnson LLP	FINAL RULE REFERENCES - INDIRECT FOOD ADDITIVES
2014-5942	07/23/2014 08/20/2014	FDA/OMPT/CDRH/OCER/DFOI/	Ophir Lotan Tyto Care	K091040, K113141, K062364 ETC
2014-5943	07/23/2014 08/20/2014	OC/CVM/OCD/	PAUL KIM ELKAHMCO BIO	NADA 128409, NADA 138955, NADA 141068
2014-5944	07/23/2014 08/20/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	(Mr.) Taro Kanai (First/Last Name) MIC International Corporation	K083291, K111157
2014-5945	07/23/2014 08/20/2014	FDA/OMPT/CDRH/OCER/DFOI/	David Moynham ArjoHuntleigh Inc	K011192
2014-5946	07/23/2014 08/20/2014	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2014-2882
2014-5947	07/23/2014 08/20/2014	FDA/OFVM/CFSAN/OCD/EOS/	Shana Mueller Truth in Advertising, Inc.	LANCOME, L'OREAL - RESPONSE TO WARNING LETTER 09/07/2012 - 11/19/2012
2014-5948	07/23/2014 08/20/2014	FDA/OMPT/CDRH/OCER/DFOI/	Nancy MacDonald Health Policy Associates, Inc.	K112390
2014-5949	07/23/2014 08/20/2014	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	Quantitative Testing as Used by the Food and Drug Administration Center for Tobacco Products (OMB Control Number 0910-NEW)
2014-5950	07/23/2014 08/20/2014	FDA/OMPT/CDRH/OCER/DFOI/	Health Policy Associates, Inc. Health Policy Associates, Inc.	K101801
2014-5951	07/23/2014 08/20/2014	FDA/OMPT/CDRH/OCER/DFOI/	Michael Kircheisen osmed gmbh	K121949
2014-5952	07/23/2014 08/20/2014	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	Dave Cohen Realm Labs LLC	REALM LABS - INVESTIGATION RECS
2014-5953	07/23/2014 08/20/2014	FDA/OMPT/CDRH/OCER/DFOI/	Health Policy Associates, Inc. Health Policy Associates, Inc.	K130002
2014-5954	07/23/2014 08/20/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	David Moynham ArjoHuntleigh Inc	K012403
2014-5955	07/23/2014 08/20/2014	FDA/OMPT/CDRH/OCER/DFOI/	Health Policy Associates, Inc. Health Policy Associates, Inc.	K131889.

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2014-5956	07/23/2014 08/20/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JENNIFER RICHNAFSKY SCHULTE, ROTH & ZABEL LLP	DIGOXIN, LEVOTHYROXINE - WHAT MFRS SUBMITTED ANDA 9/13 TO PRESENT; ACTIVE INGREDIENT
2014-5957	07/23/2014 08/20/2014	FDA/OC/OL/	COLCORD, JARED S	SEN LAMAR ALEXANDER, SEN TOM COBURN, SEN RICHARD BURR - RESP TO LTR 6/16/14
2014-5958	07/23/2014 08/20/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PETER S REICHERTZ SHEPPARD MULLIN RICHTER & HAMPTON, LLP	HOSPIRA - TPN ELECTROLYTES NDA 18-895 SBA, RVWS
2014-5959	07/23/2014 08/20/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/	DONALD N BLUE ZETETIC	SHIPMENTS REGULATED BY THE FDA 6/20/14-7/21/14
2014-5960	07/23/2014 08/20/2014	FDA/OGROP/ORO/CE-FO/DET-DO/DET-CB/	CHRIS COFFEY WMAQ TV CHICAGO	MARIGOLD INC, HAMMOND, IN; CHICAGO, IL; UNIVERSITY PARK, IL - INSP RESULTS 7/1-21/14
2014-5961	07/23/2014 08/20/2014	FDA/OMPT/CDRH/OCER/DFOI/	GERALYN MURRAY VITAL SIGNS INC	MARQUEST MEDICAL PRODUCTS INC - OMNISTICK K830310
2014-5962	07/23/2014 08/20/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ALAN SCHWARZ NEW YORK TIMES	ISRS 3932082, 3942303, 3943163, ETC
2014-5963	07/23/2014 08/20/2014	FDA/OMPT/CDRH/OCER/DFOI/	CHANDRIKA SRINIVASAN HANCE & SRINIVASAN	INDIVIDUAL RECS
2014-5964	07/23/2014 08/20/2014	OC/CVM/OCD/	SHARON A BENZ PHD ALSTON & BIRD LLP	ALLIANCE GRAIN TRADERS INC - AAFCO FEED INGREDIENT DEFINITION FOR PULSE FIBER, PULSE FLOUR, PULSE PROTEIN, ETC
2014-5965	07/23/2014 08/20/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	JOANNE S HAWANA ARENT FOX LLP	BISCO INC - THERACAL LC K063237
2014-5966	07/23/2014 08/20/2014	FDA/OC/OES/DFOI/	ROBERT G SHUSTER ROBERT G SHUSTER LAW OFCS	CONTRACT #27822
2014-5967	07/23/2014 08/20/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	XIAODONG LI PHD LUXENA PHARMACEUTICALS INC	KYTRIL NDA 20-239 - MEDICAL RVWS, CHEMISTRY RVWS, PHARMACOLOGY RVWS, ETC

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2014-5968	07/23/2014 08/20/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	XIAODONG LI PHD LUXENA PHARMACEUTICALS INC	ZOFRAN NDA 20-007 - MEDICAL RVWS, CHEMISTRY RVWS, PHARMACOLOGY RVWS, ETC
2014-5969	07/23/2014 08/20/2014	FDA/OFVM/CFSAN/OCD/EOS/	ELENA HOWELL HOGAN LOVELLS LLP	CLAIMS REGARDING LOWERING OR REDUCING TRIGLYCERIDE LEVELS ON DIETARY SUPPLEMENTS - CORR
2014-5970	07/23/2014 08/20/2014	FDA/OFVM/CFSAN/OCD/EOS/	ELENA HOWELL HOGAN LOVELLS LLP	UNIV OF CALIFORNIA DAVIS STUDY CONDUCTED TO EVALUATE WHETHER PROPYLENE OXIDE (PPO) HAS THE SAME EFFICACY IN ALMONDS AND OTHER TREE NUTS
2014-5971	07/23/2014 08/20/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	REBECCA L DANDEKER MORGAN LEWIS & BOCKIUS LLP	MOEHS CATALANA SL, BARCELONA, SPAIN - EIRS 1/10 TO 5/14
2014-5972	07/23/2014 08/20/2014	FDA/OGROP/ORAP/PA-FO/LOS- DO/LOS-CB/	COLCORD, JARED S	PEREGRINE PHARMACEUTICALS (AVID BIOSERVICES INC), TUSTIN, CA - 483, CO RESP MOST RECENT
2014-5973	07/23/2014 08/20/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CURTIS A THURSTON JR THURSTON LAW OFFICES	SEPTOCAINE NDA 20-971/S007,S017 - CORR, STUDIES, APRVL RECS, ETC
2014-5974	07/23/2014 08/20/2014	FDA/OMPT/CDRH/OCER/DFOI/	DAVID MOYNHAM ArjoHuntleigh Inc	K100902
2014-5975	07/23/2014 08/20/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TALMA GOTTEINER PHARM D BIOLINERX	KAYEXALATE (SODIUM POLYSTYRENE SULFONATE) NDA 11-287 - SBA
2014-5976	07/23/2014 08/20/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	REBECCA L DANDEKER MORGAN LEWIS & BOCKIUS LLP	MOEHS CATALANA SL, BARCELONA, SPAIN - EIRS, 483S 1/10 TO 5/14
2014-5977	07/23/2014 08/20/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	HEATHER ROBERTS 11:11 CAPITAL	AEGERION PHARMACEUTICALS - JUXTAPID (IOMITAPIDE) AERS 1/13 TO PRESENT

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2014-5978	07/23/2014 08/20/2014	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD Center for Regulatory Services,Inc.	2012-8536
2014-5979	07/23/2014 08/20/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	LESLIE OSTLER BIOMEDICAL RESEARCH LABORATORIES	MIDI LABS INC, NEWARK, DE - 483 1/12 TO PRESENT
2014-5980	07/23/2014 08/20/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	LESLIE OSTLER BIOMEDICAL RESEARCH LABORATORIES	ADAMSON ANALYTICAL LABORATORIES INC, CORONA, CA - 483 1/12 TO PRESENT
2014-5981	07/23/2014 08/20/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	LESLIE OSTLER BIOMEDICAL RESEARCH LABORATORIES	ALKEMIST LABS, COSTA MESA, CA - 483 1/12 TO PRESENT
2014-5982	07/23/2014 08/20/2014	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	LESLIE OSTLER BIOMEDICAL RESEARCH LABORATORIES	LA BELLE INC, BELLINGHAM, WA - 483 1/12 TO PRESENT
2014-5983	07/23/2014 08/20/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	LESLIE OSTLER BIOMEDICAL RESEARCH LABORATORIES	ENVIROPRO LABORATORIES, WEST VALLEY CITY, UT - 483 1/12 TO PRESENT
2014-5984	07/23/2014 08/20/2014	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	LESLIE OSTLER BIOMEDICAL RESEARCH LABORATORIES	MICHAEL FOODS INC, MINNETONKA, MN - 483 1/12 TO PRESENT
2014-5985	07/23/2014 08/20/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	LESLIE OSTLER BIOMEDICAL RESEARCH LABORATORIES	EXOVA, SANTA FE SPRINGS, CA - 483 1/12 TO PRESENT
2014-5986	07/23/2014 08/20/2014	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	LESLIE OSTLER BIOMEDICAL RESEARCH LABORATORIES	OREGON DEPT OF AGRICULTURE, PORTLAND, OR - 483 1/12 TO PRESENT
2014-5987	07/23/2014 08/20/2014	FDA/OC/OCC/ FDA/OC/OES/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KELLEE KIM ECOR1CAP	INTERNAL AND EXTERNAL DISCUSSIONS AND DECISIONS N ENDPOINTS IN CLNCL TRIALS FOR PULMONARY NONTUBERCULOUS MYCOBACTERIAL INFECTIONS 1/13 TO 7/14
2014-5988	07/24/2014 08/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	MICHAEL AGEBOH INDIVIDUAL	K973929
2014-5989	07/24/2014 08/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	510K REDACTED IN JUNE 2014

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2014-5990	07/24/2014 08/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mikhail Martchenko Keck Graduate Institute	NDA 006441
2014-5991	07/24/2014 08/21/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Kerri-Anne Mallet K-Med Regulatory Services	K021478, K030941
2014-5992	07/24/2014 08/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Austin Nelson Sterne Agee	VIZAG, INDIA - 483 01/01/2014 - 07/22/2014
2014-5993	07/24/2014 08/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	G. Srinivas Zydus Pharmaceuticals USA Inc.	ANDA 074019 SBA
2014-5994	07/24/2014 08/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dorie Flynn Dorie Flynn	PROAIR - AERS
2014-5995	07/24/2014 08/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lauren Farruggia Hyman Phelps and McNamara PC	NDA 021121 LABELING
2014-5996	07/24/2014 08/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	G. Srinivas Zydus Pharmaceuticals USA Inc.	ANDA 072894 SBA
2014-5997	07/24/2014 08/21/2014	OC/ORO/ORM/ OC/ORO/ORM/	David Mangione Govzilla, Inc.	LIST OF INSPECTIONS 03/15/2014 - 07/22/2014
2014-5998	07/24/2014 08/21/2014	FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/	Melissa Daggerhart, MBA, CCRP / Scott D. Segal, MD, MBA Scientific Clinical Trials, Inc.	SCOTT D SEGAL, MD - EIR 06/01/2014 - 06/30/2014
2014-5999	07/24/2014 08/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Susanna Carou REGENERON PHARMACEUTICALS INC	LUCENTIS - NARRATIVE REPORTS

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2014-6000	07/24/2014 08/21/2014	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	FCN 342
2014-6001	07/24/2014 08/21/2014	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	NEPHRON, ORLANDO, FL - 483
2014-6002	07/24/2014 08/21/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ibrutinib - direct Ken Tong	IBRUTINIB - ISR
2014-6003	07/24/2014 08/21/2014	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	Alla Konson Royal Oak Medical Devices, LLC	ROYAL OAK MEDICAL DEVICES LLC, ROCHESTER HILLS, MI - 483 01/04/2012 - 07/01/2014
2014-6004	07/24/2014 08/21/2014	FDA/OC/OES/DFOI/	Ryan Dunnegan Kennedy Capital Management	INTERCEPT PHARMACEUTICALS - FOIA REQUEST 03/01/2014 - 05/30/2014
2014-6005	07/24/2014 08/21/2014	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Paul B. Murphy King & Spalding LLP	HI-TECH PHARMACEUTICALS - CERTIFICATES OF FREE SALE, CORR, 483 ETC
2014-6006	07/24/2014 08/21/2014	FDA/OFVM/CFSAN/OCD/EOS/	Vicki Whitsitt NATURAL PRODUCTS ASSOCIATION	DIETARY SUPPLEMENTS - AERS
2014-6007	07/24/2014 08/21/2014	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	ACCUMETRICS INC, SAN DIEGO, CA - 483 4/17/13
2014-6008	07/24/2014 08/21/2014	FDA/OC/OES/DFOI/	Kari Twaite BEVERIDGE & DIAMOND PC	CFSAN FOIA REQUESTS 06/23/2014 - 07/23/2014
2014-6009	07/24/2014 08/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kathy Simpson Celleration, Inc.	K131096
2014-6010	07/24/2014	FDA/OMPT/CDER/GRP/DIDP/	Chunwon Jung	NDA 20471

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	08/21/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Qurient Co., Ltd.	
2014-6011	07/24/2014 08/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	PAUL E. DRYDEN PROMEDIC INC	INTERNATIONAL BIOPHYSICS CORP - K122480
2014-6012	07/24/2014 08/21/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	SCOTT M. CARROLL BOYLE SHAUGHNESSY & CAMPO PC	TRIBE MEDITERRANEAN FOODS INC - EIRS, CORR, CITATIONS, ETC 1/04 TO PRESENT
2014-6013	07/24/2014 08/21/2014	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	STELLA K. HERRERA GRIFOLS BIOLOGICALS INC	APP PHARMACEUTICALS LLC, GRAND ISLAND, NY - EIR 1/1/12 TO 6/30/14
2014-6014	07/24/2014 08/21/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	HISATOSHI TSUCHIDA Kyorin Pharmaceutical Co., Ltd.	PSUR WHICH EXPLAINS DSMO POST MKTG SAFETY
2014-6015	07/24/2014 08/21/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PETER S. REICHERTZ SHEPPARD MULLIN ET AL	HOSPIRA - CUPRIC CHLORIDE INJ NDA 18-960 - SBA
2014-6016	07/24/2014 08/21/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PETER S. REICHERTZ SHEPPARD MULLIN ET AL	HOSPIRA - MAMGANESE CHLORIDE INJ NDA 18-962 - SBA
2014-6017	07/24/2014 08/21/2014	OC/ORAN/ OC/ORAN/	SPENCER S. THOMAS GIDEON COOPER & ESSARY	NECC - SURFACE SPL, AIR SPL TEST RESULTS 10/12
2014-6018	07/24/2014 08/21/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELAINE CHANG GLANCY BINKOW & GOLDBERG LLP	REGADO BIOSCINCES - REVOLIXYS CLNCL TRIALS, EFFICACY
2014-6019	07/24/2014 11/05/2014	FDA/OMPT/CTP/OD/	NATALIE N. SANDERS LATHAM WATKINS LLP	SE0004017, SE0004018, SE0004019 ETC - SUBSTANTIAL EQUIVALENCE RPTS, TOBACCO PRODS
2014-6020	07/24/2014 08/21/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MICHAEL A. CAROME, MD PUBLIC CITIZEN	MEDWATCH RPTS 3453987, 6253817, 6810161 ETC

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-6021	07/24/2014 08/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	GERALYN MURRAY VITAL SIGNS INC	MARQUEST MEDICAL PRODUCTS INC - TEMP MARQ TEMPERATURE TREND INDICATOR K903307
2014-6022	07/24/2014 08/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	GERALYN MURRAY VITAL SIGNS INC	MARQUEST MEDICAL PRODUCTS INC - TEMP MARK CONVECTIVE WARNING SYS K904690
2014-6023	07/25/2014 08/22/2014	FDA/OC/OES/DFOI/	Allie Feldman NYCLASS	EIR - HORSES BOUND FOR SLAUGHTER
2014-6024	07/25/2014 08/22/2014	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Genevive Blanchette ALGORITHM PHARMA INC	PRACS INSTITUTE LTD, FARGO, ND, MIAMI GARDEN, FL, CETERO - 483
2014-6025	07/25/2014 08/22/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/ORA/OCI/ OC/ORA/OCI/ FDA/OC/OES/DFOI/	Vicki Byrnes Maris & Lanier, P.C.	BOTOX, JUVEDERM - SALE IN US VIA INTERNET AND FAX BLASTS 2009-2010
2014-6026	07/25/2014 08/22/2014	OC/ORA/ OC/ORA/ OC/ORA/ORM/ OC/ORA/ORM/ FDA/OFVM/CFSAN/OCD/EOS/ OC/ORA/ OC/ORA/	Vicki Whitsitt NATURAL PRODUCTS ASSOCIATION	CMS DATA SUMMARY BY YEAR, PODS DATA, FACTS DATA RE DIETARY SUPPLEMENTS
2014-6027	07/25/2014 08/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	Andy Hu Globe Medical Tek	K123815
2014-6028	07/25/2014 08/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	Andy Hu Globe Medical Tek	K132889
2014-6029	07/25/2014 08/22/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Paul Buccetti APLICARE INC	NDA 21555 LABEL CHANGES

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-6030	07/25/2014 08/22/2014	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	Taylor Goldenstein Tampa Bay Times	CRYO-CELL INTERNATIONAL, INC, OLDSMAR, FL - COMPLAINTS, INSPECTION RECS
2014-6031	07/25/2014 08/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	Andy Hu Globe Medical Tek	K133922
2014-6032	07/25/2014 08/22/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Peter Mione CutisPharma, Inc.	NDA 50606
2014-6033	07/25/2014 08/22/2014	FDA/OGROP/ORR/CE-FO/BLT-DO/BLT-CB/	Rachel Johnson FOI Services, Inc.	MICROBIOTEST INTERNAL IRB, STERLING, VA - EIR, 483, CORR
2014-6034	07/25/2014 08/22/2014	FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/	Bridget Dunnion The Dolan Law Firm	VENTURA, CA - VIBRIO VULNIFICUS IN TILAPIA, OYSTERS LAST FIVE YEARS
2014-6035	07/25/2014 08/22/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ayesha Adil The Weinberg Group	ANDA 203690 CMC REVIEW
2014-6036	07/25/2014 09/15/2014	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORR/ OC/ORR/	Vicki Whitsitt NATURAL PRODUCTS ASSOCIATION	CFSAN INTERNAL GMP TRAINING - PRESENTATIONS ETC RE DIETARY SUPPLEMENTS MAY 2014
2014-6037	07/25/2014 08/22/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-2210
2014-6038	07/25/2014 08/22/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-2560
2014-6039	07/25/2014 08/22/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-2613
2014-6040	07/25/2014 08/22/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-414
2014-6041	07/25/2014 08/22/2014	OC/ORR/ OC/ORR/ OC/ORR/ORM/ OC/ORR/ORM/	Kiran Awate THE OHIO STATE UNIVERSITY	ENFORCEMENT REPORTS 1994 TO 2003

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2014-6042	07/25/2014 08/22/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	(Mr.) Taro Kanai (First/Last Name) MIC International Corporation	K133217, K112184
2014-6043	07/28/2014 08/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	Allie Huttler STRYKER SPINE	K102606
2014-6044	07/28/2014 08/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	Allie Huttler STRYKER SPINE	K102332
2014-6045	07/28/2014 08/25/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Zeba Siddiqui THOMSON REUTERS	IPCA LABORATORIES LTD, INDIA - 483 07/01/2014 - 07/25/2014
2014-6046	07/28/2014 08/25/2014	FDA/OC/OES/DDM/ FDA/OC/OCC/	Rachel Johnson FOI Services, Inc.	ADMIN RECORD CASE 14-CV-0324
2014-6047	07/28/2014 08/25/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	FLONASE LABELING
2014-6048	07/28/2014 08/25/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ryan Smith Janus Capital Group Attn: Rachelle Lyon	LINZESS - AERS
2014-6049	07/28/2014 08/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	Cora Sim Ellipse Technologies, Inc.	K092381
2014-6050	07/28/2014 08/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	Eric Bean DiabetOmics Inc.	K854010
2014-6051	07/28/2014 08/25/2014	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	Gerd Kochendoerfer DEPOMED INC	MORTON GROVE PHARMACEUTICALS - EIR 3/26/2014
2014-6052	07/28/2014 08/25/2014	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Lori Munoz Second Source Medical	SECOND SOURCE MEDICAL, SAN JOSE, CA - EIR 05/01/2014 - 09/23/2014
2014-6053	07/28/2014 08/25/2014	FDA/OC/OES/DFOI/ OC/CVM/OCD/ OC/ORA/ OC/ORA/	Ryan T. Kearney, Esq. COZEN O'CONNOR	CHICKEN JERKY PET TREATS - INSPECTION, INVESTIGATION, TESTING RECS
2014-6054	07/28/2014	OC/ORA/	Vicki Whitsitt	CMS DATA SUMMARIES, PODS DATA SUMMARIES, FACTS

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	08/25/2014	OC/ORO/ OC/ORO/ORM/ OC/ORO/ORM/	NATURAL PRODUCTS ASSOCIATION	SUMMARIES RE DIETARY SUPPLEMENTS 2008 TO PRESENT
2014-6055	07/28/2014 09/19/2014	FDA/OFVM/CFSAN/OCD/EOS/	Michelle Baker Zeon Chemicals L.P.	CHANG CHUN PETROCHEMICAL - FORM 3480, REVIEW MEMO
2014-6056	07/28/2014 08/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dan Keravich KERAVICH, DAN	NEXIUM OTC - SBA
2014-6057	07/28/2014 08/25/2014	FDA/OGROP/ORO/CE-FO/CHI-DO/CHI-CB/	Elizabeth Elfeld Elfeld, Elizabeth	CIPRIANIS PASTA, CHICAGO HEIGHTS, IL - DATES OF INSPECTION
2014-6058	07/28/2014 08/25/2014	FDA/OFVM/CFSAN/OCD/EOS/	Michelle Baker Zeon Chemicals L.P.	ASAHI DENKA KOGYO - FORM 3480, REVIEW MEMO
2014-6059	07/28/2014 08/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Emily Krulewitz The Weinberg Group	NDA 205777
2014-6060	07/28/2014 09/10/2014	FDA/OGROP/ORO/CE-FO/DET-DO/DET-CB/	Elisa Burger SPI Pharma, Inc.	SPI PHARMA, GRAND HAVEN, MI - EIR REDACTED 10/29/2013 - 11/19/2013
2014-6061	07/28/2014 08/25/2014	FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORO/SW-FO/KAN-DO/KAN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Austin S. Nelson Sterne Agee	HOSPIRA INC, LISCATE, ITALY, AUSTIN, TX, MCPHERSON, KS - 483, UNTITLED LETTERS 03/01/2014 - 07/22/2014
2014-6062	07/28/2014 08/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	Uday Shetty Drug Regulations	IPCA, RETLAM, INDIA - 483 07/02/2013 - 07/25/2014
2014-6063	07/28/2014 08/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Wilson Jiao SANTEC CHEMICALS CORP	TETRACYCLINE HYDROCHLORIDE USP - NDC NUMBER

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2014-6064	07/28/2014 08/25/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	Prashant Premkumar East Bridge Capital Management Limited	IPCA LABS, INDIA - 483
2014-6065	07/28/2014 08/25/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Fabian Somers Uteron Pharma	Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) 1980 - 1985
2014-6066	07/28/2014 08/25/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Peter Mione. CutisPharma, Inc.	NDA 61667 - SBA
2014-6067	07/28/2014 08/25/2014	FDA/OFVM/CFSAN/OCD/EOS/	Michelle Baker Zeon Chemicals L.P.	DOVER CHEMICAL CORP - FORM 3480, REVIEW MEMO
2014-6068	07/28/2014 08/25/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Morton Bassan Morton Bassan	NDC 0143-1140-10
2014-6069	07/28/2014 08/25/2014	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORACE/ORM/ OC/ORACE/ORM/ OC/ORACE/ OC/ORACE/	Devon Powell Devon Powell	CGMP OF DIETARY SUPPLEMENTS - INSPECTOR TRAINING MODULE 01/01/2011 - 05/31/2014
2014-6070	07/28/2014 08/25/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lauren Farruggia Hyman, Phelps & McNamara P.C.	FLONASE - LABELING
2014-6071	07/28/2014	FDA/OMPT/CDER/ORP/DIDP/	Joanne Grego	HIZENTRA, PRIVIGEN - ICSR 8422586 9036193 9123600 ETC

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	08/25/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CSL BEHRING	
2014-6072	07/28/2014 08/25/2014	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	TOBACCO ESTABLISHMENTS, PRODUCT LISTINGS 01/01/2014 - PRESENT
2014-6073	07/28/2014 08/25/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Donna Paynter Donna Paynter	CYMBALTA - AERS
2014-6074	07/28/2014 08/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	Allie Huttler STRYKER SPINE	K120869
2014-6075	07/28/2014 08/25/2014	FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/	BRIAN E FRITZ SALTZ MONGELUZZI ET AL	BRISTOL MYERS SQUIBB, PRINCETON, NJ - RPTS, CORR, INVESTIGATIVE STATEMENTS, ETC 1/06 TO 1/11
2014-6076	07/28/2014 08/25/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELIZABETH BARBEHENN PHD PUBLIC CITIZEN	NESINA (ALOGLIPTIN) - ISRS 9157967, 9159774, 9233363, ETC
2014-6077	07/28/2014 08/25/2014	FDA/OGROP/ORACE-FO/SAN- DO/SAN-CB/	MICHAEL J MUNDA JD M ED RENOWN HEALTH	INSTITUTIONAL REVIEW BOARD (IRB) AT RENOWN HEALTH AND/OR RENOWN REGIONAL MEDICAL CENTER, RENO, NV - RPTS, LTRS, SURVEY RECS, ETC 7/23/07 TO 7/23/14
2014-6078	07/28/2014 08/25/2014	FDA/OGROP/ORACE-FO/PHI- DO/PHI-CB/	BUCHHOLZ, KRISTI	RECALL #F-0808/23-2012 - RECS
2014-6079	07/28/2014 08/25/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PETER S REICHERTZ SHEPPARD MULLIN RICHTER & HAMPTON, LLP	ABRAXIS PHARMACEUTICALS INC - CUPRIC SULFATE INJ NDA 19-350 SBA, RVWS
2014-6080	07/28/2014 08/25/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PETER S REICHERTZ SHEPPARD MULLIN RICHTER & HAMPTON, LLP	ABRAXIS PHARMACEUTICALS INC - MANGANESE SULFATE INJ NDA 19-228 SBA, RVWS
2014-6081	07/28/2014 08/25/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PETER S REICHERTZ SHEPPARD MULLIN RICHTER & HAMPTON, LLP	ABRAXIS PHARMACEUTICALS INC - ZINC SULFATE INJ NDA 19-229 SBA, RVWS

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2014-6082	07/28/2014 08/25/2014	FDA/OC/OES/DFOI/	ANDREW J FUCHS SKADDEN, ARPS, SLATE, MEAGHER & FLOM, LLP	BAXTER - COLLEAGUE INFUSION PUMP FOI REQUESTS 2008 TO 2010
2014-6083	07/28/2014 08/25/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 6/30/14-7/4/14
2014-6084	07/28/2014 08/25/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 6/23-27/14
2014-6085	07/28/2014 08/25/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 6/16-20/14
2014-6086	07/28/2014 08/25/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 6/9-13/14
2014-6087	07/28/2014 08/25/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 6/9-13/14
2014-6088	07/28/2014 08/25/2014	FDA/OGROP/ORACE-FO/CHI- DO/CHI-CB/	KRISTI O SMEDLEY PHD Center for Regulatory Services, Inc.	CARTHAGE VETERINARY SERVICE LTD, CARTHAGE, IL - EIRS, 483S 1/09 TO PRESENT
2014-6089	07/28/2014 08/25/2014	FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 6/9-13/14
2014-6090	07/28/2014 08/25/2014	FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 6/9-13/14
2014-6091	07/28/2014 08/25/2014	FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 6/16-20/14
2014-6092	07/28/2014 08/25/2014	FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 6/23-26/14
2014-6093	07/28/2014 08/25/2014	FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 6/30/14-7/4/14
2014-6094	07/28/2014 08/25/2014	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 6/9-13/14
2014-6095	07/28/2014 08/25/2014	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 6/16-20/14
2014-6096	07/28/2014	FDA/OC/OES/DFOI/	DAVID MCFARLAND	CLOSEDL FOIA REQUESTS 6/23-27/14

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	08/25/2014		FDA REVIEW/FDA WEBVIEW	
2014-6097	07/28/2014 08/25/2014	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 6/30/14-7/4/14
2014-6098	07/28/2014 08/25/2014	FDA/OC/OES/DFOI/	NANOVA INC	K080521, K082609, K122282
2014-6099	07/28/2014 08/25/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 6/9-14/14
2014-6100	07/28/2014 08/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	Allie Huttler STRYKER SPINE	K112095
2014-6101	07/28/2014 08/25/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 6/9-14/14
2014-6102	07/28/2014 08/25/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joel Phibbs Maurice Blackburn Lawyers	MOXDUO - NO AGREEMENT LETTERS, CORR, COMPLETE RESPONSE LETTERS ETC 01/03/2011 - 07/25/2014
2014-6103	07/28/2014 08/25/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 6/16-21/14
2014-6104	07/28/2014 08/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	Allie Huttler STRYKER SPINE	K132505
2014-6105	07/28/2014 08/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	Allie Huttler STRYKER SPINE	K141217
2014-6106	07/28/2014 08/25/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 6/23-28/14
2014-6107	07/28/2014 08/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	Allie Huttler STRYKER SPINE	K093670
2014-6108	07/28/2014 08/25/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESWTS 6/30/14-7/5/14
2014-6109	07/28/2014 08/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	william francis william francis	K120680
2014-6110	07/28/2014 08/25/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 6/9-13/14
2014-6111	07/28/2014 08/25/2014	FDA/OFVM/CFSAN/OCD/EOS/	Nathan A. Beaver FOLEY & LARDNER LLP	GRAS 400 TABLE 8

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2014-6112	07/28/2014 08/25/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 6/9-13/14
2014-6113	07/28/2014 08/25/2014	FDA/OFVM/CFSAN/OCD/EOS/	Nathan A. Beaver FOLEY & LARDNER LLP	OLESTRA - FAP
2014-6114	07/28/2014 08/25/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SIDNEY K KANAZAWA MCGUIREWOODS LLP	NICHOLAS M FLEISCHER, WEINBERG GROUP - NEOSTIGMINE METHYLSULFATE RECS
2014-6115	07/28/2014 08/25/2014	FDA/OMPT/OSMP/OOPD/	Lynde Herzbach Birch, Stewart, Kolasch & Birch, LLP	MYZOZYME, LUMIZYME - ORPHAN DESIGNATION RECS
2014-6116	07/28/2014 08/25/2014	FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/	Corrina Kreuze Roman-Kreuze, Corrina	CUBIST PHARMACEUTICALS - MOST RECENT 483 05/01/2014 - 07/18/2014
2014-6117	07/28/2014 08/25/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 6/16-20/14
2014-6118	07/28/2014 08/25/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SIDNEY K KANAZAWA MCGUIREWOODS LLP	ECLAT PHARMACEUTICALS LLC, WEINBERG GROUP, NICHOLAS M FLEISCHER - BLOXIVERZ (NEOSTIGMINE METHYLSULFATE) RECS, CORR
2014-6119	07/28/2014 08/25/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 6/23-27/14
2014-6120	07/28/2014 08/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Wilson Jiao SANTEC CHEMICALS CORP	CYCLOBENZAPRINE - NDC NUMBER
2014-6121	07/28/2014 08/25/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 6/30/14-7/4/14
2014-6122	07/28/2014 08/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bhagwan S. Chaudhary National Institute of Securities Markets, Mumbai, India	IPCA LABORATORIES, LTD, INDIA - 483 07/01/2014 - 07/25/2014

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		FDA/OC/OES/DFOI/		
2014-6123	07/28/2014 08/25/2014	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 6/9-13/14
2014-6124	07/28/2014 08/25/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Shahid Ahmed Nexus Pharmaceuticals Inc	NDA 010742
2014-6125	07/28/2014 08/25/2014	FDA/OC/OES/DFOI/	WILLIAM A OLSON Center for Regulatory Services,Inc.	FOI DAILY LOG 6/9-13/14
2014-6126	07/28/2014 08/25/2014	FDA/OC/OES/DDM/	E. Madison Walker Univ. of South Carolina School of Law - Student	2002N-0276, 2002N-0278 MEETING TRANSCRIPTS
2014-6127	07/28/2014 08/25/2014	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 6/9-13/14
2014-6128	07/28/2014 08/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	Blair Clinton Heninger Garrison Davis, LLC	K101458
2014-6129	07/28/2014 08/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	Blair Clinton Heninger Garrison Davis, LLC	K011841, K010346
2014-6130	07/28/2014 08/25/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Blair Clinton Heninger Garrison Davis, LLC	K100280, K061050, K993801 ETC
2014-6131	07/29/2014 08/26/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	JOHN J. DUFFY DONOHUE BROWN MATHEWSON ET AL	HARSCO CORP - CRYOGENIC TANKS, RECS, RPTS 1995 TO PRESENT
2014-6132	07/29/2014 08/26/2014	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OMPT/CDRH/OCER/DFOI/	JOHN J. DUFFY DONOHUE BROWN MATHEWSON ET AL	HORIZON SCIENTIFIC - CRYOGENIC RECS, RPTS 1995 - PRESENT
2014-6133	07/29/2014 08/26/2014	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/ FDA/OMPT/CDRH/OCER/DFOI/	JON J. DUFFY DONOHUE BROWN MATHEWSON ET AL	TAYLOR WHARTON - CRYOGENICS LLC RECS, RPTS 1995 TO PRESENT
2014-6134	07/29/2014 08/26/2014	FDA/OMPT/CDRH/OCER/DFOI/	JOHN J. DUUFY DONOHUE BROWN	PACER DIGITAL SUSTEMS INC - CRYOGENIC TANKS RECS, RPTS 1995 TO PRESENT

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2014-6135	07/29/2014 08/26/2014	FDA/OC/OES/DFOI/ FDA/OGROP/ORPA/FO/LOS-DO/LOS-CB/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Jason Sapsin FOX ROTHSCHILD LLP	HP ACTHAR GEL - RECS REVIEWED, PREPARED RE COMPOSITION AND MANUFACTURE, WARNING LETTERS, UNTITLED LETTERS ETC
2014-6136	07/29/2014 08/26/2014	FDA/OGROP/ORPA/FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Christina Jewett The Center for Investigative Reporting	SPINAL SOLUTIONS, ORTHOPEDIC ALLIANCE, MURRIETA, CA - AFFIDAVITS, DECLARATIONS ETC
2014-6137	07/29/2014 08/26/2014	FDA/OC/OES/DFOI/	GUNTER, STEPHEN	2014-4656
2014-6138	07/29/2014 08/26/2014	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Molly Rapp Fresenius Kabi USA LLC	NDA 017422 S 37 SBA
2014-6139	07/29/2014 08/26/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 205777
2014-6140	07/29/2014 08/26/2014	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 205777 - EXCLUSIVITY SUMMARY
2014-6141	07/29/2014 08/26/2014	FDA/OMPT/CDRH/OCER/DFOI/	Cora Sim Ellipse Technologies, Inc.	K973812
2014-6142	07/29/2014 08/26/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-2603
2014-6143	07/29/2014 08/26/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-2171
2014-6144	07/29/2014 08/26/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-1667

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2014-6145	07/29/2014 08/26/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Michele Sinoway LACHMAN CONSULTANT SERVICES, INC.	CELGENE, BERKELEY HEIGHTS, NJ - EIR 04/02/2013 - 06/24/2013
2014-6146	07/29/2014 08/26/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Patricia Ottosen HumanYou	AERS REPORTS 9384206 9397011 9397695 ETC
2014-6147	07/29/2014 08/26/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-3372
2014-6148	07/29/2014 08/26/2014	OC/CVM/OCD/	Hunter Champion HPPE LLC	NADA 106772, NADA 134708 - FOI SUMMARY
2014-6149	07/29/2014 08/26/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-450
2014-6150	07/29/2014 08/26/2014	FDA/OMPT/CDRH/OCER/DFOI/	Cora Sim Ellipse Technologies, Inc.	K140750
2014-6151	07/29/2014 08/26/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kirsten Franco JOHNSON & JOHNSON	K132272
2014-6152	07/29/2014 08/26/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Michele Sinoway LACHMAN CONSULTANT SERVICES, INC.	CELGENE, PHOENIX, AZ - EIR 06/01/2012 - 08/30/2012
2014-6153	07/29/2014 08/26/2014	FDA/OMPT/OSMP/OOPD/	Elinore Mercer Cote Orphan Conulstin	CUVPOSA - ORPHAN DESIGNATINO RECS
2014-6154	07/29/2014 08/26/2014	FDA/OMPT/CDRH/OCER/DFOI/	Parkell, Inc. Parkell, Inc.	K896719
2014-6155	07/29/2014 09/18/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Jennii F. Kamesch Kamesch, Jennii F	Musculoskeletal Transplant Foundation (MTF) FDA letters for DBX putty paste/mix, bone plugs, bone chips for clavicle, FlexHD, cracked blister pads/parts
2014-6156	07/29/2014 08/26/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	TERRA L. REYNOLDS PAUL HASTINGS ET AL	CORR BTWN DAIICHI SANKYO CO LTD & FDA EMPLOYEES REGARDING RANBAXY INVESTIGATION 2007, 2008
2014-6157	07/29/2014 08/26/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	RACHEL TACKETT POLITY NEWS	MICHAEL TAYLOR - MONSANTO, SYGENTA AG BASF, ETC CORR 7/1/09 TO 7/27/14

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2014-6158	07/29/2014 08/26/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GEORGIANNA HARRIS, Ph.D. ALKERMES INC	TARGINIQ ER (OXYCODONE HCI) NDA 206-777 - SBA
2014-6159	07/29/2014 08/26/2014	FDA/OMPT/CDRH/OCER/DFOI/	DEBORAH N. KLOOS MEDICAL ACTION INDUSTRIES INC	MEDEFIL INC - NORMAL SALINE IV FLUSH SYRINGE K091583
2014-6160	07/29/2014 08/26/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KANIKA G. SHAH QUINN EMANUEL ET AL	MEDICARE HEALTH PLAN QUALITY DOCUMENTS CREATED BY HHS
2014-6161	07/29/2014 08/26/2014	FDA/OFVM/CFSAN/OCD/EOS/	SILVIA ULM BURDOCK GROUP	USE OF POTASSIUM FERROCYANIDE
2014-6162	07/29/2014 08/26/2014	FDA/OC/OES/DFOI/	JAMES RIGARO RIGARO LLC	CHLOROQUINE - RECS
2014-6163	07/29/2014 08/26/2014	FDA/OMPT/CDRH/OCER/DFOI/	ADAM BLOCH PRO TECH	PERMAFLEX PERMANENT SOFT DENTURE RELINER K925062; PROTECH PLUS K983547
2014-6164	07/29/2014 08/26/2014	OC/ORO/ORM/ OC/ORO/ORM/	JANET M. FLAHERTY Abbott Nutrition	LIST MANUFACTURING PLANTS IN THE US & OUTSIDE THE US 1/113 TO 7/25/14
2014-6165	07/29/2014 08/26/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	EDWARD F. SMITH III, Ph.D. ZOGENIX INC	TARGINIQ ER NDA 205-777 - SBA
2014-6166	07/30/2014 08/27/2014	FDA/OGROP/ORO/SE-FO/ATL- DO/ATL-CB/	Margaret Groves, JD, CRA, CCRP DUKE UNIVERSITY	PAMELA S DOUGLAS, DUKE CLINICAL RESEARCH INSTITUTE IMAGING PROGRAM - EIR 9/19/13
2014-6167	07/30/2014 08/27/2014	FDA/OC/OES/DFOI/	Ryan Dunnegan Kennedy Capital Management	FAVUS RESEARCH - PREVIOUS FOIA REQUEST 03/01/2014 - 05/31/2014
2014-6168	07/30/2014 08/27/2014	FDA/OMPT/CDRH/OCER/DFOI/	Gail Prindiville McNally Peterson SC	HEN-O-LOK - ADVERSE EVENTS
2014-6169	07/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	Maria Pronina	K050776 K070313 K062471

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	08/27/2014		Tenex Health	
2014-6170	07/30/2014 08/27/2014	FDA/OFVM/CFSAN/OCD/EOS/	Avik Debnath The Doctors Company	REPORTS RE MATERIALS USED IN COMMERCIALY AVAILABLE COSMETICS 07/29/2013 - 07/29/2014
2014-6171	07/30/2014 08/27/2014	FDA/OC/OES/DDM/ FDA/OMPT/CDRH/OCER/DFOI/	Len W. Morrow CONSUMER	DATA RE PROPOSED RULE: EFFECTIVE DATE OF REQUIREMENT FOR PREMARKET APPROVAL FOR TWO CLASS III PREAMENDMENT DEVICES
2014-6172	07/30/2014 08/27/2014	FDA/OMPT/CDRH/OCER/DFOI/	Victoria Rothwell Immunexpress	K132843, K122514
2014-6173	07/30/2014 08/27/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	James Bertini Earthdog Denver	EARTHDOG DENVER, LLC, DENVER, CO - COMPLAINTS, INSPECTION REPORTS ETC 08/01/2013 - 12/31/2013
2014-6174	07/30/2014 08/27/2014	FDA/OMPT/CDRH/OCER/DFOI/	Len W. Morrow CONSUMER	DATA, RESULTS FROM POST MARKET SURVEILLANCE OF METAL-ON-METAL HIP REPLACEMENT SYSTEMS
2014-6175	07/30/2014 08/27/2014	FDA/OMPT/CDRH/OCER/DFOI/	Elaine Larkin PHILIPS RESPIRONICS	K133868
2014-6176	07/30/2014 08/27/2014	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Rasean Thayer Hodge Rasean Thayer Hodge	RASEAN THAYER HODGE, MD - INSPECTION RECS
2014-6177	07/30/2014 08/27/2014	FDA/OMPT/CDRH/OCER/DFOI/	Juma Hoshino BD	K962938
2014-6178	07/30/2014 08/27/2014	FDA/OMPT/CDRH/OCER/DFOI/	William Vondersmith Atlanta Biomedical Corporation	K111386
2014-6179	07/30/2014 08/27/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K140750
2014-6180	07/30/2014 08/27/2014	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	James Rogers Valinor Management	EXACT SCIENCES, MADISON, WI - 483 10/02/2013 - 07/28/2014
2014-6181	07/30/2014 08/27/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Robert Pyrtle Pyrtle, Robert	SCANTIBODIES BIOLOGICS - EIR, 483, CONSENT DECREE
2014-6182	07/30/2014 08/27/2014	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	BRENDA M GARTZ ELI LILLY & CO	LORAY BLAIR-BRITT, DAYTONA BEACH, FL - 483 11/2/12
2014-6183	07/30/2014 08/27/2014	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	BRENDA M GARTZ ELI LILLY & CO	HELENA ROBARD, ROCKVILLE, MD - 483 5/18/10
2014-6184	07/30/2014 08/27/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	PIRAMAL HEALTHCARE (CANADA) LTD, AUORA, CANADA - EIRS 10/7/08 TO 7/15/11

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2014-6185	07/30/2014 08/27/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	BRENDA M GARTZ ELI LILLY & CO	JEAN-LOUISE SELAM, TUSTIN, CA - 483 6/7/10
2014-6186	07/30/2014 08/27/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	PIRAMAL HEALTHCARE (CANADA) LTD, AUORA, CANADA - EIRS 10/17/08 TO 7/15/11
2014-6187	07/30/2014 08/27/2014	FDA/OMPT/CDRH/OCER/DFOI/	MICHAEL ZIMOWSKI PHD UNIV OF COLORADO AT DENVER	SEPRAMESH IP BIORESORBABLE COATING/PERMANENT MESH K063739 - APPEALS, APRVL LTRS, RECESSION LTRS, ETC
2014-6188	07/30/2014 08/27/2014	FDA/OMPT/CDRH/OCER/DFOI/	MICHAEL ZIMKOWSKI PHD UNIV OF COLORADO AT DENVER	COMPOSIX L/P MESH WITH ECHOS PS POSITIONIG SYS K102766 - APPEALS, APRVL LTRS, RECESSION LTRS, ETC
2014-6189	07/30/2014 08/27/2014	FDA/OMPT/CDRH/OCER/DFOI/	ANKITA PHOPHALIA MAQUET CARDIOVASCULAR	K101274 -(UNREDACTED)
2014-6190	07/30/2014 08/27/2014	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	J RICE FERRELLE JR FERRELLE BURNS ATTY	RTI BIOLOGICS INC, ALACHUA, FL - DEVIATIONS FROM THE REGULATIONS GOVERNING HUMMAN CELL, ETC 2000 TO PRESENT
2014-6191	07/30/2014 12/11/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OO/OHR/	ANNA C SWEENEY SADAKA ASSOCIATES LLC	ZOSTAVAX - OBE RECOMMENDATIONS FOR POSTMARKETING STUDIES 5/17/06; SAFETY SUMMARY 2/8/06; MEDICAL OFFICER'S RVWS VAERS, EMAILS, CURRICULUM VITAE, ETC
2014-6192	07/30/2014 08/27/2014	OC/ORPA/ OC/ORPA/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	JASON SUN UNIWAY CUSTOMS SERVICES	JAPONICUS DWC CRAB MEAT BLOCKS - ENTRY BDN-0079805-3 LAB RPT
2014-6193	07/30/2014 08/27/2014	FDA/OO/OHR/	BRIAN S PEARSON IHC FINANCIAL GROUP	ALL CURRENT EMPLOYEES WHOSE RECS MAY BE RELEASED UNDER THE PRIVACY ACT OF 1974 - NAME, WORK ADDRESSES, EMAIL, ETC
2014-6194	07/30/2014 08/28/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	THOMAS H OSBORN SPEER LAWL FIRM	ROLLING ROAD PARTNERS FACILITY, YORK SPRINGS, PA - POULTRY OPERATIONS COMM, RECS, APRVL/DISAPPROVAL 1/11 TO PRESENT
2014-6195	07/30/2014 08/27/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	AVRIL CHANG NANG KUANG PHARMACEUTICAL CO LTD	DR REDDYS LABORATORIES LTD, ANDHRA PRADESH, INDIA - EIR 2/6/09
2014-6196	07/30/2014	FDA/OC/OES/DFOI/		2014-2598 (CERTIFIED)

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	08/27/2014		HARRIS, PETER	
2014-6197	07/31/2014 08/28/2014	FDA/OMPT/CDRH/OCER/DFOI/	JOHN R MILLER SORING INC	SORING GMBH MEDIZINTECHNIK, QUICKBORN, GERMANY -ULTRASONIC SURGICAL INSTRUMENT K052183
2014-6198	07/31/2014 08/28/2014	FDA/OMPT/CDRH/OCER/DFOI/	JOHN R MILLER SORING INC	SORING GMBH MEDIZINTECHNIK, QUICKBORN, GERMANY - ELECTROSURGICAL CONDUCTIVE GAS COAGULATION K012753
2014-6199	07/31/2014 08/28/2014	FDA/OMPT/CDRH/OCER/DFOI/	JOHN R MILLER SORING INC	SORING GMBH MEDIZINTECHNIK, QUICKBORN, GERMANY - ULTRASOUND WOUND CLEANER K072904
2014-6200	07/31/2014 08/28/2014	FDA/OMPT/CDRH/OCER/DFOI/	JOHN R MILLER SORING INC	SORING GMBH MEDIZINTECHNIK, QUICKBORN, GERMANY - INSTRUMENTULTRASONIC SURGICAL INSTRUMENT K012753
2014-6201	07/31/2014 08/28/2014	FDA/OMPT/CDRH/OCER/DFOI/	JOHN R MILLER SORING INC	SORING GMBH MEDIZINTECHNIK, QUICKBORN, GERMANY - ELECTROSURGICAL CONDUCTIVE GAS COAGULATION K993265
2014-6202	07/31/2014 08/28/2014	FDA/OMPT/CDRH/OCER/DFOI/	JOHN R MILLER SORING INC	SORING GMBH MEDIZINTECHNIK, QUICKBORN, GERMANY - ULTRASONIC SURGICAL INSTRUMENT K992026
2014-6203	07/31/2014 08/28/2014	FDA/OMPT/CDRH/OCER/DFOI/	JOHN R MILLER SORING INC	SORING GMBH MEDIZINTECHNIK, QUICKBORN, GERMANY - ELECTROSURGICAL CUTTING DVC K093511
2014-6204	07/31/2014 08/28/2014	FDA/OMPT/CDRH/OCER/DFOI/	JOHN R MILLER SORING INC	SORING GMBH MEDIZINTECHNIK, QUICKBORN, GERMANY - ELECTROSURGICAL CONDUCTIVE GAS COAGULATION K024059
2014-6205	07/31/2014 08/28/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	David Mangione Govzilla, Inc.	NOVARTIS VACCINES AND DIAGNOSTICS GMBH & CO, GERMANY - EIR 06/23/2014 - 06/30/2014
2014-6206	07/31/2014 08/28/2014	FDA/OFVM/CFSAN/OCD/EOS/	Thomas O'Reardon Blood Hurst & O'Reardon, LLP	ROTTA PHARMACEUTICALS, WEIDER NUTRITION INTERNATIONAL - COMM RE HEALTH CLAIM PETITIONS 04/30/2003 - 02/01/2005
2014-6207	07/31/2014 09/16/2014	FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/	Susan Lee Cadian Capital	GETINGE, WAYNE, NJ - 483, WARNING LETTER, CORR 01/01/2010 - 07/30/2014
2014-6208	07/31/2014 08/28/2014	OC/OR/ OC/OR/ FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/	Doe J	UNCLE EDDIES OATMEAL CHOCOLATE CHIP VEGAN COOKIES - LAB RESULTS 03/01/2014 - 06/28/2014
2014-6209	07/31/2014 08/28/2014	FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/	Nicholas Fava Ash Stevens Inc.	MICROTEST LABORATORIES, AGAWAM, MA - 483 09/01/2013 - 09/30/2013
2014-6210	07/31/2014 08/28/2014	FDA/OC/OES/DDM/ FDA/OFVM/CFSAN/OCD/EOS/	Avik Debnath The Doctors Company	TALC - ADVERSE EVENTS, DOCKETS

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2014-6211	07/31/2014 08/28/2014	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	NANCY A MCGEE LEMCO ENTERPRISES INC	LEMCO ENTERPRISES INC, ARDMORE, OK - AUDIT RPT 5/1/14-6/30/14
2014-6212	07/31/2014 08/28/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	FARYAL A HASAN Hyman, Phelps & McNamara P.C.	RAW DEAL - KUDZU POWDER, PYGEUM BARK POWDER, KOREAN GINSENG POWDER SALMONELLA TEST RESULTS, CAERS, ETC
2014-6213	07/31/2014 08/28/2014	FDA/OC/OES/DFOI/	FRANK FRITZ AUCELLA DRUGS & GIFTS	ORANGE BOOK
2014-6214	07/31/2014 08/28/2014	FDA/OC/OES/DFOI/	GILMORE #344879, PERRY	INDUCED PLURIPOTENT STEM CELLS, EMBRYONIC STEM CELLS - PROJECTS, PHOTOGRAPHS
2014-6215	07/31/2014 08/28/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	CRYSTAL WOODARD Golden & Walters, PLLC	SOUTHERN STATES COOPERATIVE INC, JAMIE SMITH, JEREMY SMITH, SMITH BROTHERS - FEED FERTILIZER, MILK SEED & SOIL LAB TESTS, FINDINGS, LOGS, ETC
2014-6216	07/31/2014 08/28/2014	FDA/OMPT/CDRH/OCER/DFOI/	BYRON B MILLER Marynell Maloney Law Firm	CEREBRAL ANGIOGRAM WITH CONTRAST - MDRS
2014-6217	07/31/2014 08/28/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 6/16-20/14
2014-6218	07/31/2014 08/28/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 6/23-27/14
2014-6219	07/31/2014 08/28/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 6/30/14-7/4/14
2014-6220	07/31/2014 08/28/2014	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 6/16-20/14
2014-6221	07/31/2014 08/28/2014	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 6/23-27/14
2014-6222	07/31/2014 08/28/2014	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 6/30/14-7/4/14
2014-6223	07/31/2014 08/28/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 6/16-21/14
2014-6224	07/31/2014 08/28/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 6/23-28/14
2014-6225	07/31/2014 08/28/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 6/30/14-7/5/14
2014-6226	07/31/2014 08/28/2014	FDA/OC/OES/DFOI/	Center for Regulatory Services, Inc.	DAILY LOG 6/16-20/14

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2014-6227	07/31/2014 08/28/2014	FDA/OC/OES/DFOI/	Center for Regulatory Services, Inc.	DAILY LOG 6/23-27/14
2014-6228	07/31/2014 08/28/2014	FDA/OC/OES/DFOI/	GLADYS B. TONKIN Center for Regulatory Services, Inc.	DAILY LOG 6/30/14-7/4/14
2014-6229	07/31/2014 08/28/2014	FDA/OC/OES/DFOI/	DEBRA L. COHEN MEDIREGS INC	DAILY LOG 6/16-20/14
2014-6230	07/31/2014 08/28/2014	FDA/OC/OES/DFOI/	DEBRA L. COHEN WOLTERS KLUWER	DAILY LOG 6/23-27/14
2014-6231	07/31/2014 08/28/2014	FDA/OC/OES/DFOI/	DEBRA L. COHEN WOLTERS KLUWER	DAILY LOG 6/30/14-7/4/14
2014-6232	07/31/2014 08/28/2014	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 6/23-27/14
2014-6233	07/31/2014 08/28/2014	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 6/16-20/14
2014-6234	07/31/2014 08/28/2014	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 6/30/14-7/4/14
2014-6235	07/31/2014 08/28/2014	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 6/23-27/14
2014-6236	07/31/2014 08/28/2014	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 6/16-20/14
2014-6237	07/31/2014 08/28/2014	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 6/30/14-7/4/14
2014-6238	08/01/2014 08/29/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Royalty Pharma ROYALTY PHARMA AG	BLA 125104 UNREDACTED REVIEW
2014-6239	08/01/2014 09/09/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Rebekah O'Sullivan O'Sullivan, Rebekah L	NCT02038972 RECS RE CORD BLOOD VALIDATION
2014-6240	08/01/2014 08/29/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Robert Frederich BRISTOL-MYERS SQUIBB	The BNP and endothelin summary data by dose from A dose-ranging study of eplerenone versus placebo and spironolactone in patients with symptomatic heart failure. G.D. Searle & Co., Protocol No. IE3-97-02-011, 21 May 1997

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-6241	08/01/2014 08/29/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bindu Adhikari St Joseph Regional Medical Centre	PEMETREXED ISR
2014-6242	08/01/2014 08/29/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Terrance Coyne ROYALTY PHARMA AG	BLA 125104 UNREDACTED CHEMISTRY REVIEW
2014-6243	08/01/2014 08/29/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Chris Kuehnle Surveyor Capital	IMPAX TAIWAN - 483 07/21/2014 - 07/29/2014
2014-6244	08/01/2014 08/29/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	NDA 0552
2014-6245	08/01/2014 08/29/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bonnie Safyurtlu Allergan, Inc.	NDA 22315 S009
2014-6246	08/01/2014 08/29/2014	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Andrew Ryan Ryan Law, APLC	BAXTER MINICAP RECALL RECS 05/01/2014 - 07/29/2014
2014-6247	08/01/2014 08/29/2014	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/ FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	David Kim Partner Fund Management	HOSPIRA - 483 04/01/2014 - PRESENT

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2014-6248	08/01/2014 08/29/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Moumita Rawal G & W Laboratories Inc.	ANDA 072354, ANDA 075860, ANDA 075751 ETC SBA
2014-6249	08/01/2014 08/29/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Allison Tarantino ARIAD Pharmaceuticals, Inc	ICLUSIG - REPORTS, DETAILED REPORT, FAERS ETC
2014-6250	08/01/2014 08/29/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kenneth Daly BURGSIMPSON	DEPAKOTE - REMOVAL FROM PATIENT INFORMATION LEAFLET
2014-6251	08/01/2014 08/29/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Chirag Talati Kotak Securities	IPCA LABORATORIES RATLAM FACILITY - EIR, 483 01/01/2010 - 07/29/2014
2014-6252	08/01/2014 08/29/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Alaska Burr NORTH RUN CAPITAL LP	HOSPIRA IKKT - UNTITLED LETTERS, EMAIL, CORR 12/30/2013 - 07/30/2014
2014-6253	08/01/2014 08/29/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Susan Lee Cadian Capital Management	HOSPIRA VIZAG, INDIA - 483, RESPONSE, UNTITLED LETTER 01/01/2014 - 07/30/2014
2014-6254	08/01/2014 08/29/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Enrique Cruz Chemo España	VICTOZA NDA
2014-6255	08/01/2014 08/29/2014	FDA/OMPT/CDRH/OCER/DFOI/	SHIRLEY BROWN Elastic Therapy, LLC	K925643
2014-6256	08/01/2014 08/29/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ketaki Gokhale BLOOMBERG NEWS	IPCA LABORATORIES LTD - 483 7/30/12 TO PRESENT

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-6257	08/01/2014 08/29/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	Alaska Burr NORTH RUN CAPITAL LP	HOSPIRA, LAKE FOREST, IL - 483 03/16/2014 - 07/01/2014
2014-6258	08/01/2014 08/29/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Alaska Burr NORTH RUN CAPITAL LP	HOSPIRA IKKT - UNTITLED LETTERS, EMAIL, CORR 01/01/2014 - 07/29/2014
2014-6259	08/01/2014 08/29/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Alaska Burr NORTH RUN CAPITAL LP	HOSPIRA VIZAG - UNTITLED LETTERS, EMAIL, CORR 01/01/2014 - 07/29/2014
2014-6260	08/01/2014 08/29/2014	FDA/OMPT/CDRH/OCER/DFOI/	Naama Shani ParaSonic	LOUSEBUSTER - CLINICAL TRIAL RECS
2014-6261	08/01/2014 08/29/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	David Kim Partner Fund Management	HOSPIRA VIZAG - 483 RESPONSE 04/01/2014 - 07/30/2014
2014-6262	08/01/2014 08/29/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Paola Teegarden Kinex Pharmaceuticals Inc.	NDA 020449
2014-6263	08/01/2014 08/29/2014	FDA/OMPT/CDRH/OCER/DFOI/	Victoria Rothwell Immunexpress	K080896
2014-6264	08/01/2014 08/29/2014	FDA/OMPT/CDRH/OCER/DFOI/	Mark Adams personal	K123427
2014-6265	08/01/2014 08/29/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Chris Letter Odom & Des Roches, LLP	ANDA 200675 OGD ROUTING SUMMARIES
2014-6266	08/01/2014 08/29/2014	FDA/OFVM/CFSAN/OCD/EOS/	JR Whaley Whaley Law Firm	PLEXUS WORLDWIDE - RECS TO AND FROM FDA RE DMAA OR GERANAX
2014-6267	08/01/2014	FDA/OMPT/CDER/GRP/DIDP/	Andrew Thibault	ALPRAZOLAM, ARIPIRAZOLE, FLUVOXAMINE ETC CASE

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	08/29/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Parents Against Pharmaceutical Abuse (PAPA)	REPORTS
2014-6268	08/01/2014 08/29/2014	FDA/OFVM/CFSAN/OCD/EOS/	JR Whaley Whaley Law Firm	NATURE 4 U, CSB NUTRITION - RECS TO OR FROM FDA RE DMAA OR GERANAX
2014-6269	08/01/2014 08/29/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tiffany Yu L.E.K. CONSULTING	COMMERCIAL IND SUBMITTED ANNUALLY 01/01/2005 - 12/31/2013
2014-6270	08/01/2014 08/29/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dheeresh Pathak Dheeresh Pathak	CADILA HEALTHCARE, INDIA - 483 07/02/2013 - 07/31/2014
2014-6271	08/01/2014 08/29/2014	OC/ORA/ OC/ORA/ OC/ORA/ OC/ORA/	burgess BURGESS, BERNIE	SCREEN SHOT OF COMSTAT CMS ENTRY FOR FACTS 808885 10/2/2006
2014-6272	08/01/2014 08/29/2014	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2012-8951
2014-6273	08/01/2014 08/29/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Lisa Severy BAXTER HEALTHCARE CORPORATION	BAXTER ORTH DONAU AUSTRIA - EIR 01/01/2013 - 07/31/2014
2014-6274	08/01/2014 08/29/2014	FDA/OGROP/ORACE-FO/CIN- DO/CIN-CB/	Kurt Buckman Pinnacle Foods Group LLC	BELLISO FOODS INC, JACKSON, OH - 483, EIR, RESPONSE
2014-6275	08/01/2014 08/29/2014	FDA/OMPT/CDRH/OCER/DFOI/	Yumiko Kida SGS United Kingdom Limited	STEREX INTERNATIONAL LIMITED, UK - 483
2014-6276	08/01/2014 08/29/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Victoria Rothwell Immunexpress	K062694
2014-6277	08/01/2014 08/29/2014	FDA/OC/OES/DDM/	Robb Lawrence Chesapeake Therapeutics	EXHIBIT 1, 2 SUBMITTED BY KIRKPATRICK & LOCKHART RE REQUEST TO WAIVE PEDIATRIC STUDY REQUIREMENTS ASSOCIATED WITH A NEW FORMULATION OF METHOTREXATE

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2014-6278	08/01/2014 08/29/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Prashant Premkumar East Bridge Capital Mgmt	CADILA HEALTHCARE, INDIA - 483 01/01/2013 - 07/31/2014
2014-6279	08/01/2014 08/29/2014	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Sandra Kenison Central Insurance	ANDERSPM CANDY COMPANY, BLOSSOM, TX - FOOD SAFETY INSPECTION RECS 01/01/2013 - 07/31/2014
2014-6280	08/01/2014 08/29/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Patrick Mevs GORDON & SILBER PC	LUPRON APPROVAL RECS
2014-6281	08/01/2014 08/29/2014	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	b. burgess BURGESS, BERNIE	FACTS ASSIGNMENT ROUTING SHEET 808885
2014-6282	08/01/2014 08/29/2014	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	Nicholas LaBella TARSA THERAPEUTICS INC	PHARMACEUTICS INTERNATIONAL, INC - 483 03/01/2014 - 07/30/2014
2014-6283	08/01/2014 08/29/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LAURA MCKINLEY PHD PFIZER INC	BEVACIZUMAB IND 117-038 - CORR
2014-6284	08/01/2014 08/29/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DANIEL FRECH ESQ SPANGENBERG SHIBLEY & LIBER LLP	QUESTCOR PHARMACEUTICALS INC - HP ACTHAR GEL NDA 22-432 CORR, CHEMICAL COMPOSITION RECS, LAB RPTS, ETC
2014-6285	08/01/2014 08/29/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PHILIP A LEWIS KELLER ROHRBACK LLP	AMBIEN - CORR, RPTS, APRVLS, ETC
2014-6286	08/01/2014 08/29/2014	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/ OC/ORA/OCI/ OC/ORA/OCI/	GINGER D SERPAS LEWIS KULLMAN ET AL	GABRIEL PEREZ LASALA MD, TC CELLULAR THERAPY LLC - INSPS, COMPLIANCE, CRIMINAL INVESTIGATION, ETC 1/11 TO PRESENT
2014-6287	08/01/2014 08/29/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	AARON L EMBREY ANDRUS WAGSTAFF PC	JANSSEN PHARMACEUTICALS INC - RISPERDAL NDA 20-588 CMLPNTS, APRVL RECS, COMM, ETC

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2014-6288	08/01/2014 08/29/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	AARON L EMBREY ANDRUS WAGSTAFF PC	JANSSEN PHARMACEUTICALS INC - RISPERDAL CONSTA NDA 21-346 CMLPNTS, APRVL RECS, COMM, ETC
2014-6289	08/01/2014 08/29/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	AARON L EMBREY ANDRUS WAGSTAFF PC	JANSSEN PHARMACEUTICALS INC - RISPERDAL NDA 20- 272 CMLPNTS, APRVL RECS, COMM, ETC
2014-6290	08/01/2014 08/29/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	AARON L EMBREY ANDRUS WAGSTAFF PC	JANSSEN PHARMACEUTICALS INC - RISPERDAL M-TAB NDA 21-444 CMLPNTS, APRVL RECS, COMM, ETC
2014-6291	08/01/2014 08/29/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CLARK #501659, KEVIN D	ATIVAN, CELEXA - AERS
2014-6292	08/01/2014 08/29/2014	FDA/OMPT/CDRH/OCER/DFOI/	SCHMIDT, DAVID	DAVOL INC (CR BARD INC) - 3D MAX MESH 510K CLEARANCE, MARKETING RECS
2014-6293	08/01/2014 08/29/2014	OC/CVM/OCD/	ARLENE MORALES BURDOCK GROUP	KRILL (EUPHAUSIA SUPERBA) - REGULATORY STATUS, CONSUMPTION, SAFETY INFORMATION, ETC
2014-6294	08/01/2014 08/29/2014	FDA/OFVM/CFSAN/OCD/EOS/	ROBERT S MCQUATE PHD GRAS ASSOCIATES LLC	INTERNATIONAL VERMOUTH INSTITUTE, FEDERAZIONE ITALIANA INDUTRIE, VINI & LIQUORI, ETC - FAP 1318 RECS; ROSELLE OR HIBISCUS SABDARIFFA EXTRACT REGULATION, PRIOR SANCTIONS, ETC
2014-6295	08/01/2014 08/29/2014	FDA/OMPT/CDRH/OCER/DFOI/	LEON M WILKINS CYTOPROCESS CONSULTING LLC	KERATEC LTD - KERAGEL, KERAFOAM, KERADERM K080949
2014-6296	08/01/2014 08/29/2014	FDA/OFVM/CFSAN/OCD/EOS/	JANET M FLAHERTY Abbott Nutrition	INFANT FORMULA NOTIFICATIONS SUBMITTED UNDER SECTION 412 OF THE FEDERAL FOOD, DRUG AND COSMETIC ACT 1/13 TO 7/14
2014-6297	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-3541
2014-6298	08/04/2014	FDA/OC/OES/DFOI/	Rachel Johnson	2014-2617

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	09/02/2014		FOI Services, Inc.	
2014-6299	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-3360
2014-6300	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-3347
2014-6301	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4660
2014-6302	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-3982
2014-6303	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4643
2014-6304	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4803
2014-6305	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4848
2014-6306	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4851
2014-6307	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4870
2014-6308	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-5118
2014-6309	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-5119
2014-6310	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-5123
2014-6311	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-5128
2014-6312	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-6366
2014-6313	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4341
2014-6314	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-5194

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2014-6315	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-5197
2014-6316	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-5200
2014-6317	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-5208
2014-6318	08/04/2014 09/02/2014	FDA/OMPT/CDRH/OCER/DFOI/	Sheryl Dixon COVIDIEN	K122235
2014-6319	08/04/2014 09/02/2014	FDA/OMPT/CDRH/OCER/DFOI/	Sheryl Dixon COVIDIEN	K133173
2014-6320	08/04/2014 09/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Uday Shetty Drug Regulations	CADILA HEALTHCARE LTD, INDIA - 483 01/01/2014 - 08/01/2014
2014-6321	08/04/2014 09/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dr Lawrence Moon King's College London	RECOMBINANT NEUROTROPHIN 3 - IND RECS
2014-6322	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-9521
2014-6323	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1831
2014-6324	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4287
2014-6325	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4321
2014-6326	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4336
2014-6327	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4339
2014-6328	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4340
2014-6329	08/04/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2013-5129

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	09/02/2014		MERCK & CO., INC.	
2014-6330	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-5131
2014-6331	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4344
2014-6332	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4350
2014-6333	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4351
2014-6334	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4359
2014-6335	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4360
2014-6336	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4413
2014-6337	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4440
2014-6338	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-5189
2014-6339	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4428
2014-6340	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4533
2014-6341	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4611
2014-6342	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4619
2014-6343	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-5186
2014-6344	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4633
2014-6345	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4583

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2014-6346	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-5180
2014-6347	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-5213
2014-6348	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4624
2014-6349	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4625
2014-6350	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-5225
2014-6351	08/04/2014 09/02/2014	FDA/OMPT/OSMP/OOPD/	Robb Lawrence Chesapeake Therapeutics	ACTEMRA - ORPHAN DESIGNATION RECS
2014-6352	08/04/2014 09/02/2014	FDA/OMPT/OSMP/OOPD/	Robb Lawrence Chesapeake Therapeutics	RHEUMATREX - ORPHAN DESIGNATION RECS
2014-6353	08/04/2014 09/02/2014	FDA/OMPT/CDRH/OCER/DFOI/	Minh Khoa MINH KHOA	K022269, K043539, K053636 ETC
2014-6354	08/04/2014 09/02/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bhagwan S. Chaudhary National Institute of Securities Markets, Mumbai, India	CADILA HEALTHCARE LIMITED, INDIA - 483 07/07/2014 - 07/11/2014
2014-6355	08/04/2014 09/02/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bhagwan S. Chaudhary National Institute of Securities Markets, Mumbai, India	CIPLA LIMITED RAJ PLAZA, INDIA - 483 06/23/2014 - 06/27/2014
2014-6356	08/04/2014 09/02/2014	FDA/OMPT/CDRH/OCER/DFOI/	Barbara Kobo Epcal Inc.	K090109, K061597 REVIEWERS NOTES, CLIA REVIEW NOTES, SCORE BREAKDOWN
2014-6357	08/04/2014 09/02/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shin Kang WELLS FARGO SECURITIES	IMBRUVICA - AERS
2014-6358	08/04/2014 09/02/2014	FDA/OGROP/ORR/SE-FO/SJN-DO/SJN-CB/	Vince H Suneja TwoFour Insight Group, LLC	MYLAN, PUERTO RICO - 483 01/01/2012 - 12/02/2013
2014-6359	08/04/2014	FDA/OMPT/CDER/GRP/DIDP/	GENE MAURILLO	QUOTINET CLINICAL, NOTTINGHAM, UK - EIRS, 483S 2009

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	09/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CORCEPT THERAPEUTICS INC	TO PRESENT
2014-6360	08/04/2014 09/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GENE MAURILLO CORCEPT THERAPEUTICS INC	PCAS (EXP), ARAMON, FRANCE - EIRS, 483S 2009 TO PRESENT
2014-6361	08/04/2014 09/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GENE MAURILLO CORCEPT THERAPEUTICS INC	PCAS (VLG), VILLENEUVE-LA -GARENE, FRANCE - EIRS, 483S 2009 TO PRESENT
2014-6362	08/04/2014 09/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GENE MAURILLO CORCEPT THERAPEUTICS INC	MICRON TECHNOLOGIES, CROSSWAYS, DARTFORD KENT, UK - EIRS, 483S 2009 TO PRESENT
2014-6363	08/04/2014 09/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GENE MAURILLO CORCEPT THERAPEUTICS INC	IDIS LTD, WEYBRIDGE SURREY, UK - EIRS, 483S 2009 TO PRESENT
2014-6364	08/04/2014 09/02/2014	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	GENE MAURILLO CORCEPT THERAPEUTICS INC	FORMEX, SAN DIEGO, CA - EIRS, 483S 2009 TO PRESENT
2014-6365	08/04/2014 09/02/2014	FDA/OGROP/ORAP/SW-FO/DAL-DO/DAL-CB/	GENE MAURILLO CORCEPT THERAPEUTICS INC	PHARMAFORM LLC, AUSTIN, TX - EIRS, 483S 2009 TO PRESENT
2014-6366	08/04/2014 09/02/2014	FDA/OGROP/ORAP/SE-FO/ATL-DO/ATL-CB/	GENE MAURILLO CORCEPT THERAPEUTICS INC	AAI PHARMA SERVICES, WILMINGTON, NC - EIRS, 483S 2009 TO PRESENT
2014-6367	08/04/2014 09/02/2014	FDA/OGROP/ORAP/SE-FO/ATL-DO/ATL-CB/	GENE MAURILLO CORCEPT THERAPEUTICS INC	QUALITY COMPLIANCE LABS (QCL), WILMINGTON, NC - EIRS, 483S 2009 TO PRESENT
2014-6368	08/04/2014 09/02/2014	FDA/OGROP/ORAP/CE-FO/PHI-DO/PHI-CB/	GENE MAURILLO CORCEPT THERAPEUTICS INC	SHARP CLINICAL SUPPLIES, PHOENIXVILLE, PA - EIRS, 483S 2009 TO PRESENT
2014-6369	08/04/2014 09/02/2014	FDA/OGROP/ORAP/CE-FO/CIN-DO/CIN-CB/	GENE MAURILLO CORCEPT THERAPEUTICS INC	RICERCA, CONCORD, OH - EIRS, 483S 2009 TO PRESENT
2014-6370	08/04/2014 09/02/2014	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	GENE MAURILLO CORCEPT THERAPEUTICS INC	MICROCONSTANTS, INC, SAN DIEGO, CA - EIRS, 483S 2009 TO PRESENT

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2014-6371	08/04/2014 09/02/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	GENE MAURILLO CORCEPT THERAPEUTICS INC	MPI RESEARCH, MATTAWAN, MI - EIRS, 483S 2009 TO PRESENT
2014-6372	08/04/2014 09/02/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	GENE MAURILLO CORCEPT THERAPEUTICS INC	CHARLES RIVER LABS, HORSHAM, PA - EIRS, 483S 2009 TO PRESENT
2014-6373	08/04/2014 09/02/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	GENE MAURILLO CORCEPT THERAPEUTICS INC	XENOBIOTIC LABS, PLAINSBORO, NJ - EIRS, 483S 2009 TO PRESENT
2014-6374	08/04/2014 09/02/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	GENE MAURILLO CORCEPT THERAPEUTICS INC	AAI PHARMA SERVICES, EDISON, NJ - EIRS, 483S 2009 TO PRESENT
2014-6375	08/04/2014 09/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GENE MAURILLO CORCEPT THERAPEUTICS INC	ALMAC PHARMA SERVICES, CRAIGAVON, UK - EIRS, 483S 2009 TO PRESENT
2014-6376	08/04/2014 09/02/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	GENE MAURILLO CORCEPT THERAPEUTICS INC	MEDAVANTE, HAMILTON, NJ - EIRS, 483S 2009 TO PRESENT
2014-6377	08/04/2014 09/02/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	GENE MAURILLO CORCEPT THERAPEUTICS INC	ICON CLINICAL RESEARCH, NORTH WALES, PA - EIRS, 483S 2009 TO PRESENT
2014-6378	08/04/2014 09/02/2014	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	GENE MAURILLO CORCEPT THERAPEUTICS INC	DOHMEN LIFE SCIENCE SERVICES (CENTRIC), CHESTERFIELD, MO - EIRS, 483S 2009 TO PRESENT
2014-6379	08/04/2014 09/02/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	GENE MAURILLO CORCEPT THERAPEUTICS INC	INTEGRATED COMMERCIALIZATION SOLUTIONS (ICS), BROOKS, KY - EIRS, 483S 2009 TO PRESENT
2014-6380	08/04/2014 09/02/2014	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	GENE MAURILLO CORCEPT THERAPEUTICS INC	PHARMACEUTICS INTERNATIONAL, BALTIMORE, MD - EIRS, 483S 2009 TO PRESENT
2014-6381	08/04/2014 09/02/2014	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	GENE MAURILLO CORCEPT THERAPEUTICS INC	DOHMEN LIFE SCIENCE SERVICES (BIOSOTERIA & MEDCOMM MEDICAL INFORMATION SERVICES) - EIRS, 483S 2009 TO PRESENT
2014-6382	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-7052
2014-6383	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-7195
2014-6384	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-7197
2014-6385	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-7199
2014-6386	08/04/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2013-7210

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	09/02/2014		MERCK & CO., INC.	
2014-6387	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-7212
2014-6388	08/04/2014 09/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John Suedbeck Mayne Pharma USA	DIPHARMA FRANCIS SRL BARANZATE - EIR 06/01/2012 - 08/01/2012
2014-6389	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-6353
2014-6390	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-6397
2014-6391	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-6398
2014-6392	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-6404
2014-6393	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-6416
2014-6394	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-6479
2014-6395	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-6589
2014-6396	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-6732
2014-6397	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-6740
2014-6398	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-6836
2014-6399	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-6842
2014-6400	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-6862
2014-6401	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-6862

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2014-6402	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-5394
2014-6403	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-5462
2014-6404	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-5519
2014-6405	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-5530
2014-6406	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-5538
2014-6407	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-5552
2014-6408	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-5560
2014-6409	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-5577
2014-6410	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-5566
2014-6411	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-5580
2014-6412	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-5583
2014-6413	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-5636
2014-6414	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-5751
2014-6415	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-5801
2014-6416	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-8581
2014-6417	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-8484
2014-6418	08/04/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2013-8255

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	09/02/2014		MERCK & CO., INC.	
2014-6419	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-4685
2014-6420	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-8151
2014-6421	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-8144
2014-6422	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-8059
2014-6423	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-8054
2014-6424	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-7922
2014-6425	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-7921
2014-6426	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-7807
2014-6427	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-7565
2014-6428	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-7557
2014-6429	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-7521
2014-6430	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-7499
2014-6431	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-7243
2014-6432	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-7237
2014-6433	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-6348
2014-6434	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-6344

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2014-6435	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-6338
2014-6436	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-6334
2014-6437	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-6337
2014-6438	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-6329
2014-6439	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-5951
2014-6440	08/04/2014 09/02/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-5857
2014-6441	08/05/2014 09/03/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-4692 - REQUEST LETTER
2014-6442	08/05/2014 09/03/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-4797 - REQUEST LETTER
2014-6443	08/05/2014 09/03/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-5019 - REQUEST LETTER
2014-6444	08/05/2014 09/03/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-5143 - REQUEST LETTER
2014-6445	08/05/2014 09/03/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-5163 - REQUEST LETTER
2014-6446	08/05/2014 09/03/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-4975 - REQUEST LETTER
2014-6447	08/05/2014 09/03/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-5062 - REQUEST LETTER
2014-6448	08/05/2014 09/03/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-5170 - REQUEST LETTER
2014-6449	08/05/2014 09/03/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-4588 - REQUEST LETTER
2014-6450	08/05/2014 09/03/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-4477 - REQUEST LETTER
2014-6451	08/05/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2014-5211 - REQUEST LETTER

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	09/03/2014		MERCK & CO., INC.	
2014-6452	08/05/2014 09/03/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-4483 - REQUEST LETTER
2014-6453	08/05/2014 09/03/2014	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Austin Nelson Sterne Agee	HOSPIRA, LAKE FOREST, IL, CHENNAI, INDIA, VIZAG, INDIA - 483, UNTITLED LETTERS 03/01/2014 - 08/01/2014
2014-6454	08/05/2014 09/03/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-5231 - REQUEST LETTER
2014-6455	08/05/2014 09/03/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-5221 - REQUEST LETTER
2014-6456	08/05/2014 09/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K122324
2014-6457	08/05/2014 09/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K133009
2014-6458	08/05/2014 09/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHIRAG SHAH Chirag Shah	ANDA 078179 BIOEQUIVALENCE REVIEW
2014-6459	08/05/2014 09/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Luigi Brunetti RUTGERS UNIVERSITY	TWO UNPUBLISHED CASES OF ALCOHOL INTOXICATION SECONDARY TO DOCETAXEL INFUSION
2014-6460	08/05/2014 09/03/2014	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Mandy Williams Integrus Health	JAMES LONG, MD, INTEGRIS BAPTIST MEDICAL CENTER - CORR 01/03/2013 - 06/01/2013
2014-6461	08/05/2014 09/03/2014	FDA/OFVM/CFSAN/OCD/EOS/	Jeff Inada Wakou USA, Inc.	FULL LIST OF FOOD ALLERGENS
2014-6462	08/05/2014 09/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bhagwan S. Chaudhary National Institute of Securities Markets, Mumbai, India	FDC LIMITED B-8, INDIA - 483 04/28/2014 - 05/08/2014

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2014-6463	08/05/2014 09/03/2014	FDA/OC/OES/DFOI/	Barry Novick Kitchen Table Bakers	COMPLAINT
2014-6464	08/05/2014 09/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Elizabeth Jordan Capital Appeals Project	EPHEDRINE ALKALOID PRODUCTS - AERS
2014-6465	08/05/2014 09/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jineane Venci UNIVERSITY OF ROCHESTER MEDICAL CENTER	AFREZZA - MEDICAL AND SUMMARY REVIEW
2014-6466	08/05/2014 09/03/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/NE-FO/NYK- DO/NYK-DCB/ FDA/OGROP/ORO/CE-FO/NWJ- DO/NWJ-CB/	Doe J	INDIVIDUAL RECS
2014-6467	08/05/2014 09/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dr. Esperanza Welsh DR. Welsh	ISOTRETINOIN - AERS
2014-6468	08/05/2014 09/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHIRAG SHAH Chirag Shah	ANDA 078970 BIOEQUIVALENCE REVIEWS
2014-6469	08/05/2014 09/03/2014	FDA/OC/OES/DFOI/ FDA/OGROP/ORO/CE-FO/PHI- DO/PHI-CB/	Edward Donnelly none	ZOLL MANUFACTURING, LIFEVEST, PITTSBURGH, PA - 483 06/01/2014 - 08/01/2014
2014-6470	08/05/2014 09/03/2014	FDA/OGROP/ORO/CE-FO/DET- DO/DET-CB/	LaShawn Young CSL Plasma aka CSL Behring aka CSL Limited	CSL PLASMA, MICHIGAN - INSPECTION REPORT, UPDATES
2014-6471	08/05/2014 09/03/2014	FDA/OC/OES/DFOI/	Anon Anon	FOIA LOG JULY 2014
2014-6472	08/05/2014 09/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joshua Korzenik BRIGHAM AND WOMEN'S HOSPITAL	ANTI-TNF AGENTS AERS

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2014-6473	08/05/2014 09/03/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	Doe J	INDIVIDUAL RECS
2014-6474	08/05/2014 09/03/2014	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Doe J	INDIVIDUAL RECS
2014-6475	08/05/2014 09/03/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	CATHY BRUSS APN HEALTH LLC	ENSITE SYS - ENDOCARDINAL SPOLUTIONS K033211
2014-6476	08/05/2014 09/03/2014	OC/ORO/ORM/ OC/ORO/ORM/	LESLIE RAMSEY FDA NEWS	483'S FOR PHARMACEUTICALS, BIOLOGIC, MEDICAL DVC, CLNCL TRIAL FACILITIES 7/1-31/14
2014-6477	08/05/2014 09/03/2014	FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/ FDA/OMPT/CDRH/OCER/DFOI/	MATTHEW B. STODDARD STODDARD FRIM	SMITH & NEPHEW - GENESIS II KNEE IMPLANT MDRS
2014-6478	08/05/2014 09/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	McDONALD 311643, BRANDON	LITHIUM; DEPAKOT; VALIUM - AER
2014-6479	08/05/2014 09/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	S ALBERT EDWARDS PHARM D	EVISTA - RALOXIFENE MEDCAL RVW
2014-6480	08/05/2014 09/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JAMIE BELCASTRO INTEGRATED SOLUTIONS, CORP	PHARM VENTURES - TRIHEXYPHENIDYL HYDROCHLORIDE ANDA 89-514 APRVL
2014-6481	08/05/2014 09/03/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	2014-4366

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		FDA/OC/OES/DFOI/		
2014-6482	08/05/2014 09/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	S ALBERT EDWARDS PHARM D	EVISTA - AER
2014-6483	08/05/2014 09/03/2014	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	CLARK KAUFFMAN REGISTER MEDIA	INSP OF EGG PRODUCING FACILIITES IN IOWA 2-13 TO 2013
2014-6484	08/05/2014 09/03/2014	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	ELAINE CHANG GLANCY BINKOW & GOLDBERG LLP	SUBSYS (FENTANYL SUBLINGUAL SPRAY) TRANSMUCOSAL IMMEDIATE RELEASE FENTANYL (TIRF) RISK EVALUATION AND MITIGATION STRATEGY (REMS)
2014-6485	08/06/2014 09/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHANDRAN TIRUVATTAR DR REDDY'S LABORATORIES INC	FOUGERA - LIDOCAINE ANDA 80-S015, S017,S019, S020 RVWS
2014-6486	08/06/2014 09/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHANDRAN TIRUVATTAR DR REDDY'S LABORATORIES INC	FOUGERA - LIDOCAINE ANDA 80-198 CLNCL PHARMACOLOGY BIOPHARMACEUTICS RVWS
2014-6487	08/06/2014 09/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHANDRAN TIRUVATTAR DR REDDY'S LABORATORIES INC	FOUGERA - LIDOCINE ANDA 80-198 CHEMISTRY RVWS
2014-6488	08/06/2014 09/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CURTIS A THURSTON THURSTON LAW OFFICES	SEPTOCAINES S023 - NDA 20-971/S021,S-023 CORR, STUDIES, RPTS, ETC
2014-6489	08/06/2014 09/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KATE REYNOLDS ROCKY MOUNTAIN POISON & DRUG CENTER	ISRS 7532846, 7653805, 8290213, ETC

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2014-6490	08/06/2014 09/04/2014	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	M ELIZABETH BIERMAN MORGAN LEWIS COUNSELORS AT LAW	SMITH & NEPHEW, ST PETERSBURG, FL - EIRS, 483S 11/13
2014-6491	08/06/2014 09/04/2014	FDA/OGROP/ORR/CE-FO/CIN-DO/CIN-CB/	JAMES E HEUBI UNIV OF CINCINNATI COLLEGE OF MEDICINE/CHILDREN'S HOSP MEDICAL CTR	CINCINNATI CHILDREN'S HOSPITAL MEDICAL CENTER, CINCINNATI, OH - EIR 7/14-18/14
2014-6492	08/06/2014 09/04/2014	FDA/OC/OES/DFOI/	Tommie Yeiter - Vicknair The Merman Law Firm	CHOBANI RECS
2014-6493	08/06/2014 09/04/2014	FDA/OFVM/CFSAN/OCD/EOS/	CLAY DETLEFSEN INTERNATIONAL DAIRY FOODS ASSOCIATION	MICROBIOLOGICAL (SWAB) SPL AT MILK POWDER PLANTS TESTED FOR SALMONELLA & CRONBACTER SAKAZAKI
2014-6494	08/06/2014 09/04/2014	OC/ORR/ORM/ OC/ORR/ORM/	Graematter, Inc. Graematter, Inc.	INSPECTIONS SPREADSHEET
2014-6495	08/06/2014 09/04/2014	FDA/OC/OES/DFOI/	Melissa Walker Graematter, Inc.	510K SUBMITTED BUT NOT CLEARED
2014-6496	08/06/2014 09/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	INC RESEARCH, UTRECHT, NETHERLANDS - EIR SEPTEMBER 2013
2014-6497	08/06/2014 09/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ingenol mebulate (Picato) topical drug product Consultant for CPI, Inc	PICATO - SBA RECS
2014-6498	08/06/2014 09/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Barbara Morrison BIOMARIN PHARMACEUTICAL INC	BLA 125291 S 136
2014-6499	08/06/2014 09/04/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K113288
2014-6500	08/06/2014 09/04/2014	OC/ORR/ OC/ORR/	Chuck Ross The Daily Caller	COCA COLA - MCDONALDS INVESTIGATION RECS 08/04/2000 - 08/02/2014
2014-6501	08/06/2014	FDA/OMPT/CTP/OD/	Michael Lavery	COMM BETWEEN FDA AND OMB RE MENTHOL

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	09/04/2014	FDA/OC/OCC/ FDA/OC/OES/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CLSA	CIGARETTES 07/17/2013 - 07/23/2013
2014-6502	08/06/2014 09/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ibrutinib Ken Tong	IMBRUVICA AERS
2014-6503	08/06/2014 09/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Pallavi Ail The Financial Express	MYLAN LABORATORIES PITHAMPUR MARCH 2014, WATSON PHARMA SALCETTE MARCH 2014, HOSPIRA HEALTHCARE INDIA MARCH 2014 -EIR, 483
2014-6504	08/06/2014 09/04/2014	FDA/OC/OES/DFOI/	CHRISTINE A DORCKAK GREY2K USA WORLDWIDE	2014-4806 - MINOR DELETIONS
2014-6505	08/06/2014 09/04/2014	FDA/OC/OES/DFOI/	SMITH 10329, CHRIS	LEGAL & REGULATORY REQUIREMENTS A PHARMAEUTICAL COMPANY HAS TO GO THROUGH TO GET A DRUG APPVD
2014-6506	08/06/2014 09/04/2014	FDA/OO/OHR/	ANNA C SWEENEY SADAKA ASSOCIATES LLC	PATRICIA ROHAN MD; DOUGLASS R PRATT MD, MPH; PHILIP KRAUSE MD - POSITIONS HELD WHILE EMPLOYED AT THE FDA, CV
2014-6507	08/06/2014 09/04/2014	FDA/OC/OES/DFOI/	MANOJ GARG DSP Merrill Lynch	IPCA LABORATORIES LTD, MADYA PRADESH, INDIA - 483 7/14-18/14
2014-6508	08/06/2014 09/04/2014	FDA/OC/OES/DFOI/	Rakesh Nayudu Espirito Santo Investment Bank	IPCA LABORATORIES LTD, INDIA - 483 07/07/2014 - 08/18/2014
2014-6509	08/06/2014 09/04/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 7/1-31/2014
2014-6510	08/06/2014 09/04/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	A list of all FOIA requests closed 7/1-31/2014 on CD
2014-6511	08/06/2014 09/04/2014	FDA/OC/OES/DFOI/	Dr Girish Bakhru HSBC	IPCA, INDIA - 483 JULY 2014
2014-6512	08/07/2014 09/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Allison Tarantino ARIAD Pharmaceuticals, Inc	ICLUSIG AERS

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2014-6513	08/07/2014 09/05/2014	FDA/OFVM/CFR/OC/EO/OS/ FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	Michael Francisco Michael Francisco	ROYAL TONGAN LIMU - HEALTH CLAIM RECS
2014-6514	08/07/2014 09/05/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Megan Babula AmbioPharm, Inc.	CITRON RESEARCH REPORT RE ACHTHAR GEL
2014-6515	08/07/2014 09/05/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	ANDA 202946
2014-6516	08/07/2014 09/05/2014	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	Meera Mehta Westmed, Inc.	WESTMED, INC, TUCSON, AZ - EIR 06/16/2014 - 06/20/2014
2014-6517	08/07/2014 09/05/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Pallavi Ail The Financial Express	CADILA PHARMA, ORCHID CHEMICALS, BIOCON LTD - EIR, 483
2014-6518	08/07/2014 09/05/2014	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/ FDA/OC/OES/DFOI/	Blake Goodner Bridger Healthcare	BAUSCH AND LOMB, TAMPA, FL - 483, RESPONSE LETTERS, WARNING LETTERS 01/02/2013 - 08/05/2014
2014-6519	08/07/2014 09/16/2014	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/	Jennette McCloskey AMERICAN RED CROSS	RED CROSS EIR
2014-6520	08/07/2014 09/05/2014	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	Blake Goodner Bridger Healthcare	BAUSCH AND LOMB, GREENVILLE, SC - 483, RESPONSE LETTER, WARNING LETTER 01/02/2013 - 08/05/2014
2014-6521	08/07/2014 09/05/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Subrat Rout CTK Biotech	K121397
2014-6522	08/07/2014 09/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Cara Ahern Pepex Biomedical, Inc.	HANDHELD BLOOD GLUCOSE TESTING DEVICES - ORIGINAL 510K
2014-6523	08/07/2014 09/05/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Stephen Lyons Stephen Lyons	CYTOXAN - AERS

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2014-6524	08/07/2014 09/05/2014	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Lan Herrington Beckman Coulter Inc.	BECKMAN COULTER INC, CARLSBAD, CA - EIR
2014-6525	08/07/2014 09/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jhung Won Vojir Lutronic, Inc.	K133319
2014-6526	08/07/2014 09/05/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Pankaj Desai UNIVERSITY OF CINCINNATI	LETROZOLE - SAFETY, CLINICAL PHARMACOLOGY
2014-6527	08/07/2014 09/05/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Laura Michelle Vaughn SEARHC	FLEXIRIL - APPROVAL RECS
2014-6528	08/07/2014 09/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Allie Huttler STRYKER SPINE	K130820
2014-6529	08/07/2014 09/05/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	b. burgess BURGESS, BERNIE	LIST OF CONSUMER COMPLAINTS WITH NUMBERS RECEIVED BY OSI SEPT 2006 TO JUNE 2007, LIST OF BIMO COMPLAINTS RECEIVED BY CDER WITH NUMBERS RECEIVED
2014-6530	08/07/2014 09/05/2014	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ OC/ORA/ OC/ORA/	b. burgess BURGESS, BERNIE	LIST OF CONSUMER COMPLAINTS WITH NUMBERS ENTERED INTO FACTS FOR LOS-DO SEPT 2006 TO JUNE 2007
2014-6531	08/07/2014 09/05/2014	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Robin Sullivan CellRight Technologies	ADVANCED BIOLOGICS LLC - EIR 01/01/2012 - 02/01/2012
2014-6532	08/07/2014 09/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Allie Huttler STRYKER SPINE	K140411
2014-6533	08/07/2014 09/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Allie Huttler STRYKER SPINE	K140162
2014-6534	08/07/2014 09/05/2014	FDA/OC/OES/DDM/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Taya J. Fernandes Fernandes, Taya J	VICODIN - APPROVAL RECS, TRANSCRIPT, LABELING

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2014-6535	08/07/2014 09/05/2014	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ OC/ORA/ORM/ OC/ORA/ORM/	b.burgess BURGESS, BERNIE	List of BIMO complaints with numbers received by LOS-DO between September 2006-June 2007; Inspections carried out by LOS- DO because of Consumer complaint between October 2006- June 2007
2014-6536	08/07/2014 09/05/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tariq Ata REMS Logic, LLC	REMS DRUG ERROR REPORTS BY DRUG 01/01/2005 - 12/31/2013
2014-6537	08/07/2014 09/05/2014	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Joanne Pilot KBI Biopharma	KBI BIOPHARMA, DURHAM, NC - EIR 08/28/2012 - 09/30/2012
2014-6538	08/07/2014 09/05/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	Marv Garrett Marv Garrett	PROTOCOL 206207-01 EIR
2014-6539	08/07/2014 09/05/2014	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Bhanu Singhal Goldman Sachs Investment Partners	QUESTCOR - 483 01/01/2007 - 08/05/2014
2014-6540	08/07/2014 09/05/2014	OC/CVM/OCD/	Rachel Irvington Veterinary Clinic	TRIFEXIS - AERS 07/26/2010 - 08/02/2014
2014-6541	08/07/2014 09/05/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Courtney Bond Retrophin Inc.	PHYSICIAN SPONSORED IND DATA SET
2014-6542	08/07/2014	FDA/OMPT/CDER/GRP/DIDP/	Paul Greenberg	VICOTZA, BYETTA, BYDUREON ETC - RECS RE PANCREATIC CANCER WARNING 01/01/2012 - 08/05/2014

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	09/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Analysis Group, Inc.	
2014-6543	08/07/2014 09/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	LINDA SCHULTZ PAXMED INTL	CORE 3D PRTECH SL - ABUTMENT SYS FOR DIGITAL PROSTHETIC SOLUTIONS K122295
2014-6544	08/07/2014 09/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JENNIFER SCHLESINGER CNBC	CYTOTEC (MISOPROSTOL) - AERS
2014-6545	08/07/2014 09/05/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	SPENCER C. THOMAS GIDEON COOPER & ESSARY	NECC EXHIBITS/ATTACHMENTS
2014-6546	08/07/2014 09/05/2014	FDA/OFVM/CFSAN/OCD/EOS/	VISAGINE VIJAYAKULASINGAM IOVATE HEALTH SCIENCES INTERNATIONAL INC	IOVATE; HDROXYCUT; SMARTBURM ETC - AER SINCE 5/1/14
2014-6547	08/07/2014 09/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WILLIAM SEITZ IOVATE HEALTH SCIENCES INTERNATIONAL INC	FINE TECH PHARMACEUTICAL LTD - XALATAN (LATANOPROST) ANDA 03-862
2014-6548	08/08/2014 09/08/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	MEDWATCH FOR FAERS 8476781, 8477663
2014-6549	08/08/2014 09/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	POLARIS IMAGING SYSTEM 510(K)
2014-6550	08/08/2014 09/08/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jen Feranil KM PHARMACEUTICAL CONSULTING LLC	NDA 17577
2014-6551	08/08/2014 09/08/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	William Hobart Hobart, William	NDA 020563
2014-6552	08/08/2014	FDA/OMPT/CDER/ORP/DIDP/	JESSICA WARREN	HOVIONE LTD, RINGASKIDDY, CO CORK - 483S 3/16/12

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	09/08/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	INTERCEPT PHARMACEUTICALS INC	
2014-6553	08/08/2014 09/08/2014	OC/CVM/OCD/	Jennifer Fiala VIN News Service	IVERMECTIN/PYRANTEL PAMOATE, MILBEMYCIN OXIME, SELAMECTIN ETC - AERS
2014-6554	08/08/2014 09/08/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nicole Edwards Myelin Repair Foundation	Donepezil/Aviccept, Escitalopram/Lexapro, Quetiapine ETC - SBA
2014-6555	08/08/2014 09/08/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	NoahRoth ICON CLINICAL RESEARCH	K022623 K983583 K992168 ETC
2014-6556	08/08/2014 09/08/2014	FDA/OGROP/ORASW-FO/DEN- DO/DEN-CB/	Rachel Johnson FOI Services, Inc.	PRAXAIR, LOVELAND, CO - MOST RECENT EIR
2014-6557	08/08/2014 09/08/2014	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2014-5994
2014-6558	08/08/2014 09/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kristen Stewart Kristen Stewart - Deutsche Bank	P130009 CLINICAL TRIAL DATA
2014-6559	08/08/2014 09/08/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Andrea Demakas ADVERSEEVENTS INC	ACTEMRA, ARAVA, ORENCIAETC - AERS
2014-6560	08/08/2014 09/08/2014	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	A copy of protocols, supporting documents and other background documents for the following study: Generic Clearance for the Collection of Qualitative Data on Tobacco Products and Communications (OMB Control Number 0910-NEW)
2014-6561	08/08/2014 09/08/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	John Bals John Bals	NCT01344993, NCT01345006, NCT02122159 - CORR ETC
2014-6562	08/08/2014 09/08/2014	FDA/OC/OES/ FDA/OMPT/CDRH/OCER/DFOI/	JOSEPH WALKER Walker, Joseph	CDRH ADVISORY COMMITTEES - RECS SUBMITTED TO ADVISORY COMMITTEE OVERSIGHT AND MANAGEMENT STAFF RE NOMINATION OF PERSONS TO ADVISORY COMMITTEES 01/01/2008 - 07/31/2014
2014-6563	08/08/2014 09/08/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	david gortler GEORGETOWN UNIVERSITY	ANDA 080254, ANDA 080276, ANDA 080741 ETC

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		FDA/OMPT/CDER/ORP/DIDP/		
2014-6564	08/08/2014 09/08/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Andrea Demakas ADVERSEEVENTS INC	ADCETRIS, STENDRA, SUBSYSETC - AERS
2014-6565	08/08/2014 09/08/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rose Santos FOIA Group, Inc.	JUXTAPID - AERS
2014-6566	08/08/2014 09/08/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/OSMP/OOPD/	Robb Lawrence Chesapeake Therapeutics	MERCAPTOPURINE ORAL SOLUTION - ORPHAN PRODUCT DESIGNATION RECS
2014-6567	08/08/2014 09/08/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	James J. Nicklaus HAGENS BERMAN SOBOL SHAPIRO LLP	CORR BETWEEN FDA AND POZEN, ASTRAZENECA, HORIZON PHARMA ETC RE VIMOVO APPLICATION
2014-6568	08/08/2014 09/08/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Eric Lintula Active Spine Group, LLC	K091445
2014-6569	08/08/2014 09/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jimmy Lam, MD TriMed Inc.	K112837
2014-6570	08/08/2014 09/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	Lacey J. Chessor PERMOBIL INC	K930676
2014-6571	08/08/2014 09/08/2014	FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/	LAUREN GILGER KNXV-TV	CONCEPTUS INC - CORRECTIVE ACTIO PLAN, NOTES, EMAILS ETC RELATED TO 483S 6/25/03-7/7/03, 12/8/10-1/6/11
2014-6572	08/08/2014 09/08/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JENNIFER EMERT WGCL TELEVISION	MAPP BIOPHARMACEUTICALS INC, LEAFBIO, DEYYRUS INC, PUBLIC HEALTH AGENCY OF CANADA - ZMAPP CORR 5/1/14 TO 8/6/14

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OCC/ FDA/OC/OES/ FDA/OGROP/OIP/		
2014-6573	08/08/2014 09/08/2014	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 7/7-11/14
2014-6574	08/08/2014 09/08/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 7/7-11/14
2014-6575	08/08/2014 09/08/2014	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD Center for Regulatory Services, Inc.	FOI DAILY LOG 7/7-11/14
2014-6576	08/08/2014 09/08/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 7/7-11/14
2014-6577	08/08/2014 09/08/2014	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 7/7-11/14
2014-6578	08/08/2014 09/08/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 7/7-11/14
2014-6579	08/08/2014 09/08/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 7/21-25/14
2014-6580	08/08/2014 09/08/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOI REQUESTS 7/21-25/14
2014-6581	08/08/2014 09/08/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 7/21-25/14
2014-6582	08/08/2014 09/08/2014	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOI REQUESTS 7/21-25/14
2014-6583	08/08/2014 09/08/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 7/21-25/14
2014-6584	08/08/2014 09/08/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 7/14-18/14
2014-6585	08/08/2014 09/08/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOI REQUESTS 7/14-18/14
2014-6586	08/08/2014	FDA/OC/OES/DFOI/	DEBI COHEN	CLOSED FOI REQUESTS 7/14-18/14

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	09/08/2014		WOLTERS KLUWER LAW & BUSINESS	
2014-6587	08/08/2014 09/08/2014	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOI REQUESTS 7/14-18/14
2014-6588	08/08/2014 09/08/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 7/14-18/14
2014-6589	08/08/2014 09/08/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 7/7-11/14
2014-6590	08/08/2014 09/08/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOI REQUESTS 7/7-11/14
2014-6591	08/08/2014 09/08/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 7/7-11/14
2014-6592	08/08/2014 09/08/2014	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOI REQUESTS 7/7-11/14
2014-6593	08/11/2014 09/09/2014	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	b. burge BURGESS, BERNIE	MIN-DO/ORACE financial records for assignment 600682 issued 12/24/04
2014-6594	08/11/2014 09/09/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	P.K.Parker P.K.Parker	PROTOPIC - POST MARKETING DATA RE CANCER 01/01/2005 - 08/01/2014
2014-6595	08/11/2014 09/09/2014	FDA/OGROP/ORACE-SW-FO/KAN-DO/KAN-CB/	Nick Kemphaus Darling Ingredients	TRI STAR, LLC, KANSAS CITY, KA - INSPECTION RECS, APPLICATIONS, REGISTRATIONS
2014-6596	08/11/2014 09/09/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jonathan Riches GOLDWATER INSTITUTE	ZMAPP - APPROVAL RECS
2014-6597	08/11/2014 09/09/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	G. Srinivas Zydus Pharmaceuticals USA Inc.	LIDEX TOPICAL SOLUTION SBA
2014-6598	08/11/2014 09/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jessica J Graham Chamblee Ryan Kershaw & Anderson	ANULEX X-CLOSE TISSUE REPAIR SYSTEM - AERS

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2014-6599	08/11/2014 09/09/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	INDIVIDUAL RECS
2014-6600	08/11/2014 09/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K000281
2014-6601	08/11/2014 09/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	Melissa Gilden Precision for Medicine	K110994
2014-6602	08/11/2014 09/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jimmy Lam, MD TriMed Inc.	K070031
2014-6603	08/11/2014 09/09/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Deborah Hilts Biohaven Pharmaceuticals	NDA 20599
2014-6604	08/11/2014 09/09/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/	chris johns CHRIS JOHNS & ASSOCS	HEP B VACCINE RECALL RECS 08/01/1985 - 05/23/1988
2014-6605	08/11/2014 09/09/2014	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	b. burge BURGESS, BERNIE	LOS-DO EI record and endorsement 3/19/07 for CI ID#451454 , Santa Ana, CA LOS-DO EI record and endorsement 09/04/07 for CI ID #209085, LA, 90095
2014-6606	08/11/2014 09/09/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Shea Shaver REILLY POZNER LLP	NDA 18936 LY110140 Prozac; Sequence No. 0036 and 0017
2014-6607	08/11/2014 09/09/2014	FDA/OGROP/ORA/CE-FO/BLT- DO/BLT-CB/	Elliot Wilbur Elliot Wilbur	MYLAN PHARMACEUTICALS, MORGANTOWN, WV - 483 03/01/2014 - 08/07/2014
2014-6608	08/11/2014 09/09/2014	FDA/OGROP/ORA/CE-FO/BLT- DO/BLT-CB/	Elliot Wilbur Elliot Wilbur	MYLAN PHARMACEUTICALS, MORGANTOWN, WV - 483, RESPONSE MARCH 2014
2014-6609	08/11/2014 09/09/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	John Zulkey Hinkhouse Williams Walsh, LLP	WRIGHT MEDICAL TECHNOLOGY CONSERVE, DYNASTY, LINEAGE HIP IMPLANTS - APPROVAL RECS, AERS, ETC 08/01/2004 - 08/07/2014
2014-6610	08/11/2014 09/09/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Elliot Wilbur Elliot Wilbur	MYLAN INSTITUTIONAL IRELAND - 483, CORR 05/01/2014 - 08/07/2014

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2014-6611	08/11/2014 09/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	John Scheker Aptis Medical	K094032 REVIEWER NOTES
2014-6612	08/11/2014 09/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kinnari Shah Medivators Inc.	K920025
2014-6613	08/11/2014 09/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K113510
2014-6614	08/11/2014 09/09/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Vivek Gupta Keck Graduate Institute	NDA 15052
2014-6615	08/11/2014 09/09/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 7/14-19/14
2014-6616	08/11/2014 09/09/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 7/21-26/14
2014-6617	08/11/2014 09/09/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 7/7/12/14
2014-6618	08/11/2014 09/09/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 7/7-11/14
2014-6619	08/11/2014 09/09/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 7/14-18/14
2014-6620	08/11/2014 09/09/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 7/21-25/14
2014-6621	08/11/2014 09/09/2014	FDA/OC/OES/DFOI/	DEBRA LL COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 7/14-18/14
2014-6622	08/11/2014 09/09/2014	FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 7/21-25/14
2014-6623	08/11/2014 09/09/2014	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 7/14-18/14
2014-6624	08/11/2014 09/09/2014	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 7/21-25/14

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2014-6625	08/11/2014 09/09/2014	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 7/14-18/14
2014-6626	08/11/2014 09/09/2014	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 7/21-25/14
2014-6627	08/11/2014 09/09/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 7/14-18/14
2014-6628	08/11/2014 09/09/2014	FDA/OC/OES/DFOI/	LISAS TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 7/21-25/14
2014-6629	08/11/2014 09/09/2014	FDA/OC/OES/DFOI/	WILLIAM A OLSON Center for Regulatory Services,Inc.	FOI DAILY LOG 7/14-18/14
2014-6630	08/11/2014 09/09/2014	FDA/OC/OES/DFOI/	WILLIAM A OLSON Center for Regulatory Services,Inc.	FOI DAILY LOG 7/21-25/14
2014-6631	08/12/2014 09/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Deborah Hilts Biohaven Pharmaceuticals	RILUZOLE - DATA REVIEWS SUBMITTED TO NDA 01/01/1996 - 08/08/2014
2014-6632	08/12/2014 09/10/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-2133
2014-6633	08/12/2014 09/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Robb Lawrence Chesapeake Therapeutics	PURIXAN - REVIEW DEVISION ASSESSMENT OF FDA SUBMISSION
2014-6634	08/12/2014 09/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	John Scheker Aptis Medical	K120309 REVIEWER NOTES
2014-6635	08/12/2014 09/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K060323
2014-6636	08/12/2014 09/10/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/	William Beadle KH International, Inc.	ALIFRUT - IMPORT RECS
2014-6637	08/12/2014 09/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K030769
2014-6638	08/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson	K062750

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	09/10/2014		FOI Services, Inc.	
2014-6639	08/12/2014 09/10/2014	FDA/OMPT/CTP/OD/	Kyle Rozema Kyle Rozema at Cornell University	I am requesting a copy of the Modified Risk Tobacco Product (MRTP) application from Swedish Match
2014-6640	08/12/2014 09/10/2014	OC/ORA/ OC/ORA/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Karie Fugate Fugate, Karie	MALLINCKRODT LLC RECALL - LAB RESULTS 05/01/2011 - 12/31/2011
2014-6641	08/12/2014 09/10/2014	FDA/OFVM/CFSAN/OCD/EOS/	GUY MCWHORTER ABC RESEARCH LABORATORIES	FDA Division of Food Science "LIB 2957, Examination of Dried Fish for Microscopic Filth"
2014-6642	08/12/2014 09/10/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Victoria E. Boggs Napier Gault Schupbach & Moore PLC	Abington Health Mary T. Sachs Breast Imaging Center, Willow Grove, PA - MQSA RECS
2014-6643	08/12/2014 09/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K101530
2014-6644	08/12/2014 09/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jennifer Miller Eli Lilly and Company, Inc.	F3Z-EW-IOPY LILLY CLINIC SINGAPORE EIR
2014-6645	08/12/2014 09/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Noah Roth ICON Group	K140010
2014-6646	08/12/2014 09/10/2014	FDA/OMPT/OSMP/OOPD/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Susan M. Sutter [no person],	BIOMARIN PHARMACEUTICALS - RECS RE PRIORITY REVIEW VOUCHER FOR VIMIZIM 01/02/2014 - 01/31/2014
2014-6647	08/12/2014 09/10/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Karen Jones Nevada Donor Network, Inc	NEVADA DONOR NETWORK - INSPECTION REPORT 01/01/2014 - 08/08/2014
2014-6648	08/12/2014 09/10/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-6178
2014-6649	08/12/2014 09/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K042065

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2014-6650	08/12/2014 09/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K061877
2014-6651	08/12/2014 09/10/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/OSMP/OOPD/	Amy E. Burke Conkle, Kremer & Engel	EPIDIOLEX - NDA RECS
2014-6652	08/12/2014 09/10/2014	FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORAPA-FO/SAN- DO/SAN-CB/	Tom Namsavanh IntelGenx Corp.	JOHNSON & JOHNSON, BOEHRINGER INGELHEIM FREMONT, APOTEX PHARMACHEM INDIA ETC - 483 Inspection end: Apr 17, 2010 Location: Bangalore, India FEI: 3005466325 4.LTS Lohmann Therapy Systems Corp Inspection end: Sep 11, 2012 Location: West Caldwell, United States FEI: 1000121692 5.Hospira Healthcare India Pvt. Ltd. Inspection end: Oct 10, 2012 Location: Sriperumbudur, India FEI: 3008386908 6.Ranbaxy Laboratories Limited (Toansa) Inspection end: Dec 14, 2012 Location: Punjab, India FEI: 3002807972 7.Wockhardt Limited Inspection end: Mar 22, 2013 Location: Aurangabad, India FEI: 3005289335 8.Wockhardt Limited Inspection end: Jul 31, 2013 Location: Aurangabad, Maharashtra 431 210, India FEI: 3002808503 End of list. Please provide these documents in electronic format instead of hard copies. ;
2014-6653	08/12/2014 09/10/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Raj Sardesai Raj Sardesai	K030198 K032705 K051567 ETC
2014-6654	08/12/2014 09/10/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Austin Nelson Sterne Agee	AKORN INC KILITCH, INDIA - 483 03/01/2014 - 08/11/2014
2014-6655	08/12/2014 09/10/2014	FDA/OFVM/CFSAN/OCD/EOS/	Scott Burya akzonobel	FCN918
2014-6656	08/12/2014 09/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Liane LaRochelle DEKA R&D	K134005
2014-6657	08/12/2014 09/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Liane LaRochelle DEKA R&D	K134005
2014-6658	08/12/2014 09/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Liane LaRochelle DEKA R&D	K141119
2014-6659	08/12/2014 09/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Liane LaRochelle DEKA R&D	K141193

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2014-6660	08/12/2014 09/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Liane LaRoche DEKA R&D	K141145
2014-6661	08/12/2014 09/10/2014	FDA/OMPT/CTP/OD/	Lisa Isgett Counter Tools	MOST RECENT LIST OF TOBACCO RETAILERS IN SOUTH DAKOTA
2014-6662	08/12/2014 09/10/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michelle Elizabeth Legiec Eagle Pharmaceuticals, Inc.	NDA 205579 - SBA
2014-6663	08/12/2014 09/10/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Wendy Gabriel South College School of Pharmacy	NEW MOLECULAR ENTITY PACKAGE INSERTS 01/01/1995 - 12/31/2007
2014-6664	08/12/2014 09/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Melissa Walker Graematter, Inc.	510K RECISSION LETTERS 05/28/1976 - 07/31/2014
2014-6665	08/12/2014 09/10/2014	FDA/OFVM/CFSAN/OCD/EOS/	Scott Burya akzonobel	FCN 1192
2014-6666	08/12/2014 09/10/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Alec White HEALTHCOR MANAGEMENT LP	XIAFLEX - AERS
2014-6667	08/12/2014 09/10/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	PLAQUENIL - AERS
2014-6668	08/12/2014 09/10/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Soma Das The Economic Times, The Times of India	RANBAXY - VIOLATIONS FOR FINE 06/01/2012 - 08/11/2014
2014-6669	08/12/2014 09/10/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	HEATHER ROBERTS 11:11 CAPITAL	SANOFI - KYMANRO (MIPOMERSEN) AER
2014-6670	08/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	JOHN R. MILLER	SORING GMBH CPC - ELECTROSURGAL CONDUCTIVE GAS

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	09/10/2014		SORING INC	COAGULATION K030028
2014-6671	08/12/2014 09/10/2014	FDA/OFVM/CFSAN/OCD/EOS/	WILLIAM A. OLSON, Ph.D. Center for Regulator Services, Inc	FCN 1180
2014-6672	08/12/2014 09/10/2014	FDA/OFVM/CFSAN/OCD/EOS/	WILLIAM A. OLSON, Ph.D. Center for Regulator Services, Inc	CHEVRON PHILLIPS CHEMICAL COMPANY LP - POLYPHENYLENE SULFIDE FCN 1083
2014-6673	08/12/2014 09/10/2014	FDA/OFVM/CFSAN/OCD/EOS/	BARRETT, DONNIE R	SOY (ULTRA-SOY) - INGREDIENTS
2014-6674	08/12/2014 09/10/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/	SIMUEL 0371512, DONTEZ	FOOD & NUTRITION MANAGEMENT MANUAL
2014-6675	08/12/2014 09/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	TRICIA CREGGER STERIS CORP	MEDIAVATORS REPROCESSING SYS - REMODULAR DISINFECTION SYS K063876
2014-6676	08/12/2014 09/10/2014	FDA/OC/OCC/ FDA/OC/OPP/OP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHRISTIN H. CAREY AKIN GUMP ET AL	BIOLOGICAL PRODUCT DEFINITION
2014-6677	08/12/2014 09/10/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	MICHAEL MANCINELLI CONWAY HOMER & CHIN-CAPLAN PC	INDIVIDUAL RECS
2014-6678	08/12/2014 09/16/2014	FDA/OC/OCC/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	CAROLINE STOUT ECOR1 CAPITAL LLC	RAC RVW AND PUBLIC DISCUSSION RELATED TO AVALANCNE BIOTECHNOLGYS PIPELINE PRODUCT AVA-101
2014-6679	08/13/2014 09/11/2014	FDA/OC/OES/DFOI/	MARILYNN WHITNEY COVINGTON & BURLING LLP	ANTIVIRAL DRUGS/NONPRESCRIPTION DRUGS JOINT A/C - TRANS 1/12/95
2014-6680	08/13/2014 09/11/2014	FDA/OC/OES/DFOI/	CHRIS CELESTE EAS CONSULTING GROUP LLC	FR PAGE 12652-12654 8/8/70
2014-6681	08/13/2014	FDA/OC/OES/DFOI/	CHRIS CELESTE	DKT 2014N-0202

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	09/11/2014		EAS CONSULTING GROUP LLC	
2014-6682	08/13/2014 09/11/2014	FDA/OC/OES/DFOI/	JOSHUA MAHAMULD Hyman, Phelps & McNamara P.C.	DKT 2013N-1525
2014-6683	08/13/2014 09/11/2014	FDA/OC/OES/DFOI/	LISA WEDDIG National Fisheries Institute	DKTS 2011D-0287, 2004N-0258-0006, 2013N-0013-0001
2014-6684	08/13/2014 09/11/2014	FDA/OC/OES/DFOI/	MICHAEL QIAN THORN RUN PARTNERS	BLOOD GLUCOSE MONITROING TEST; SELF-MONITORING BLOOD GLUCOSE - COMMENTS
2014-6685	08/13/2014 09/11/2014	FDA/OC/OES/DFOI/	ROSS RENDELMAN HOGAN LOVELLS LLP	DKTS 2007P-0065, 2007P-0186
2014-6686	08/13/2014 09/11/2014	FDA/OC/OES/DFOI/	WALTER SMITH ARNOLD & PORTER	DKT 2009P-0216-001-0005; DRAFT -0003
2014-6687	08/13/2014 09/11/2014	FDA/OC/OES/DFOI/	CHRIS CELESTE EAS CONSULTING GROUP LLC	DKTS 2004F-0066, 1994F-0152
2014-6688	08/13/2014 09/11/2014	FDA/OC/OES/DFOI/	DANIEL MANELLI MANELLI & FISHER	DKT 197N-0001
2014-6689	08/13/2014 09/11/2014	FDA/OC/OES/DFOI/	JOYCE MUTCHERSON-RIDLEY WOLTERS KLUWER LAW & BUSINESS	DKTS 2014S-0024, 2013S-0024, 2012S-1144
2014-6690	08/13/2014 09/11/2014	FDA/OC/OES/DFOI/	JACQUELINE PROSCIA Wilson Sonsini Goodrich & Rosati, P.C.	DKT 2014D-0234
2014-6691	08/13/2014 09/11/2014	FDA/OC/OES/DFOI/	ROBERT KING FDA NEWS	DKT 2014N-0833
2014-6692	08/13/2014 09/11/2014	FDA/OC/OES/DFOI/	MARCY SUSSMAN GlaxoSmithKline	OTC VOL 060045, 120015, 120046, ETC
2014-6693	08/13/2014 09/11/2014	FDA/OC/OES/DFOI/	ROBERT KING FDA NEWS	DKTS 2041D-0310, 2014D-0313, 2014N-0233
2014-6694	08/13/2014 09/11/2014	FDA/OC/OES/DFOI/	BAUR, PATRICK	DKTS 2011N-0921, 2011N-0920, 2011N-0146
2014-6695	08/13/2014 09/11/2014	FDA/OC/OES/DFOI/	LAUREN FAMUGGIA Hyman, Phelps & McNamara P.C.	DKT 2013N-1676
2014-6696	08/13/2014 09/11/2014	FDA/OC/OES/DFOI/	MARILYNN WHITNEY COVINGTON & BURLING LLP	DKT 1995S-0316
2014-6697	08/13/2014	FDA/OC/OES/DFOI/		DKT 1977N-0318

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	09/11/2014		PACHICO, ELYSSA	
2014-6698	08/13/2014 09/11/2014	FDA/OC/OES/DFOI/	JAXQUELINE PROSCIA Wilson Sonsini Goodrich & Rosati, P.C.	DKT 2014P-0404
2014-6699	08/13/2014 09/11/2014	FDA/OC/OES/DFOI/	MARILYNN WHITNEY COVINGTON & BURLING LLP	DKT 1996N-0048
2014-6700	08/13/2014 09/11/2014	FDA/OC/OES/DFOI/	MARILYNN WHITNEY COVINGTON & BURLING LLP	DKT 1991N-0074
2014-6701	08/13/2014 09/11/2014	FDA/OC/OES/DFOI/	ROBERT KING FDA NEWS	DKT 2014N-0504-0001
2014-6702	08/14/2014 09/12/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 7/28/14-8/1/14
2014-6703	08/14/2014 09/12/2014	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 7/28/14-8/1/14
2014-6704	08/14/2014 09/12/2014	FDA/OC/OES/DFOI/	WILLIAM A OSLON Center for Regulatory Services, Inc.	FOI DAILY LOG 7/28/14-8/1/14
2014-6705	08/14/2014 09/12/2014	FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 7/28/14-8/1/14
2014-6706	08/14/2014 09/12/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 7/28/14-8/1/14
2014-6707	08/14/2014 09/12/2014	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 7/28/14-8/1/14
2014-6708	08/14/2014 09/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	CATHY BRUSS APN HEALTH LLC	GE HEALTHCARE - INNOVA EPVISION K130069
2014-6709	08/14/2014 09/12/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	DAVE OBERHELMAN MedTek Lighting Corporation	SUNMAKER INC - K803090; SUNMAKER TANNING SYSTEMS LTD - K854111
2014-6710	08/14/2014 09/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	FERENSTEIN, GREGORY	23ANDME - COMM, EMAILS, MEMOS, ETC 1/11 TO 12/13
2014-6711	08/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	RICHARD W MARK	THERANOS INC - ANALYZER DVC 510K, COMM,

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	09/12/2014		GIBSON DUNN & CRUTCHER LLP	VALIDATION DATA VALIDATION, ETC 2013
2014-6712	08/14/2014 09/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	PHIL JONES DYNAVISION INTERNATIONAL LLC	PERFORMANCE ENTERPRISES - DYNAVISION 200 K911938
2014-6713	08/14/2014 09/12/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SANG LEE STASON PHARMACEUTICALS INC	DIPHARMA FRANCIS SRL ACTIVE PHARMACEUTICAL INGREDIENT MFG, BARANZATE DI BOLLATE (MI), ITALY - EIR MOST RECENT; DIPHARMA - SELEGILINE HCL TABS ANDA 749-12 SBA
2014-6714	08/14/2014 09/12/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	WILLIAM WHITNEY CAHILL GORDON & REINDEL	EPA/DHA - CLAIMS MADE BY NUTRITIONAL SUPPLEMENT MFRS, DISTRIBUTORS, AND AND SERETAILERS CONCERNING CARDIOVASCULAR BENEFITS, EFFECTS ON HEART HEALTH, RISK OF CORONARY HEART DISEASE
2014-6715	08/14/2014 09/12/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	GABAPENTIN - AERS
2014-6716	08/14/2014 09/12/2014	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	DAVID SCOTT BLUE ZETETIC INC	LIFESCAN INC, MILPITAS, CA - ONE TOUCH ULTRA BLUE (STONER MEDICALREG #3008770202) ENTRY AMI-0191060-3
2014-6717	08/14/2014 09/12/2014	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	DAVID SCOTT BLUE ZETETIC INC	LIFESCAN INC, MILPITAS, CA - ONE TOUCH ULTRA BLUE (STONER MEDICAL (REG #3008770202) ENTRY AMI-0191339-1
2014-6718	08/14/2014 09/12/2014	FDA/OO/OFBA/OAGS/	BERYL LIPTON MUCKROCK NEWS	MAPP BIOPHARMACEUTICAL - CONTRACTS, AMENDMENTS
2014-6719	08/14/2014 09/12/2014	OC/ORR/ OC/ORR/ FDA/OGROP/ORR/CE-FO/BLT-DO/BLT-CB/	Doe J	CONSUMER CMLPNT
2014-6720	08/14/2014 09/12/2014	OC/ORR/ OC/ORR/ FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/	SHAWN KAPLAN HAMIYA BIOMEDICAL CO	CLEAR CHEM DIAGNOSTICS - CC #136967 INVESTIGATION, CONCLUSION
2014-6721	08/14/2014 09/12/2014	OC/ORR/ OC/ORR/	Doe J	CONSUMER CMLPNT

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		FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/		
2014-6722	08/14/2014 10/10/2014	FDA/OGROP/ORA/ORO/DIOP/	BENJAMIN L ENGLAND BENJAMIN L ENGLAND & ASSOCIATES LLC	IMPORT EXAMINATIONS, DETENTIONS, REFUSALS, ETC 10/13 TO 7/14
2014-6723	08/14/2014 09/12/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Alec White HEALTHCOR MANAGEMENT LP	CUBIST PHARMACEUTICALS - COMMUNICATIONS RE INSPECTION 01/01/2014 - 08/11/2014
2014-6724	08/14/2014 09/12/2014	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	Jeme Wallace GE Healthcare IT	GE HEALTHCARE, BARRINGTON, IL - EIR SEPT 2013
2014-6725	08/14/2014 09/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	Denise Wrestler Austco	K112650
2014-6726	08/14/2014 09/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	Choi, Hyunk Sik, M.D. Medical Standard Co., Ltd (PACSPartner) c/o Kress M. Stein	K042311
2014-6727	08/14/2014 09/12/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Karisa King CHICAGO TRIBUNE	LAMOTRIGINE - AERS
2014-6728	08/14/2014 09/12/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Anna Edney BLOOMBERG NEWS	VIGNESH LIFE SCIENCES, INDIA - 483 MOST RECENT
2014-6729	08/14/2014 09/12/2014	FDA/OC/OES/DFOI/	Julie Schamp MYLAN INC	IPCA - 483 07/18/2014 - 08/11/2014
2014-6730	08/14/2014 09/12/2014	OC/ORACE/ OC/ORACE/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Leo Pepper Slade Gorton & Co., Inc.	ENTRY 316-1930495-4 - ANAYLYSIS RECS
2014-6731	08/14/2014 09/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	510 (k) Premarket Notification - K071964 Mauna Kea Technologies	K071964
2014-6732	08/14/2014 09/12/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bortezomib of patients with renal impairment Envision Communication	BORTEZOMIB - AERS, TRIAL RECS

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2014-6733	08/14/2014 09/12/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Clark Sullivan TROUTMAN SANDERS LLP	NDA A080778
2014-6734	08/14/2014 09/12/2014	FDA/OFVM/CFSAN/OCD/EOS/	David C. Steinberg Cosmetics Preservative Council	The number of cosmetic formulations registered with the FDA under the VCRP. The number of uses of the registered ingredients.
2014-6735	08/14/2014 09/12/2014	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Kia Habisreitinger Kia Habisreitinger	OCTAPHARMA - COMPLAINTS, INVESTIGATIONS 01/01/2012 - 08/31/2014
2014-6736	08/15/2014 09/15/2014	FDA/OFVM/CFSAN/OCD/EOS/	Carol Chittenden Empire State Consumer Project, Inc	ETHYLENE GLYCOL, DIETHYLENE GLYCOL IN POLYETHYLENE GLYCOL 3350 PRODUCTS 01/01/2000 - 08/11/2014
2014-6737	08/15/2014 09/15/2014	FDA/OGROP/ORR/PA-FO/SEA-DO/SEA-CB/	Ryan Dunnegan Kennedy Capital Management	SPACELABS HEALTHCARE, INC - WARNING LETTER RECS 07/15/2014 - 08/11/2014
2014-6738	08/15/2014 09/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jerzy Wojcik EdgeOne Medical Inc	FURLS, DRLM DATA
2014-6739	08/15/2014 09/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kelly H. Sheridan Corr Cronin Michelson Baumgardner & Preece LLP	PHILIPS HEALTHCARE AVALON FETAL HEART MONITORS FM20, FM30, FM 40, FM50 - COMPLAINTS, INVESTIGATIONS; GE MEDICAL SYSTEMS TECHNOLOGIES COROMETRICS 250CX SERIES FETAL HEART MONITORS - INVESTIGATION RECS
2014-6740	08/15/2014 09/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Deborah Brashear Mylan Inc.	IPCA, INDIA - 483 7/18/14
2014-6741	08/15/2014 09/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	Serban P. Georgescu InfoBionic Inc	K121197 - INSTRUCTIONS FOR USE
2014-6742	08/15/2014 09/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	Serban P. Georgescu InfoBionic Inc	K121197 INSTRUCTIONS FOR USE
2014-6743	08/15/2014 09/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	Serban P. Georgescu InfoBionic Inc.	K121197 CLINICAL STUDIES
2014-6744	08/15/2014 09/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca L. Dandeker MORGAN LEWIS & BOCKIUS LLP	ATUL LIMITED - EIR 01/01/2012 - 04/01/2014

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-6745	08/15/2014 09/15/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Allan Reine Lombard Odier	CHENODAL, THIOLA - APPROVAL RECS
2014-6746	08/15/2014 09/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	Serban P. Georgescu, MD InfoBionic, Inc	K121197 HUMAN FACTORS TESTING
2014-6747	08/15/2014 09/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	Serban P. Georgescu, MD InfoBionic Inc.	K121197 VALIDATION TESTING
2014-6748	08/15/2014 09/15/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	David Petrocine Aceto Corporation	AARTI DRUGS, INDIA - 483
2014-6749	08/15/2014 09/15/2014	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	Travis Siverson BIRCHWOOD LABORATORIES INC	SIMPLE SCIENCE LLC, MINNEAPOLIS, MN - EIR, 483, RESPONSE LETTERS 02/15/2014 - 03/25/2014
2014-6750	08/15/2014 09/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	Ryan Bouchard Ryan Bouchard - Ora	K063304
2014-6751	08/15/2014 09/15/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DDM/	Lauren Farruggia Hyman, Phelps & McNamara P.C.	NOTICE ON INTERNATIONAL DRUG SCHEDULING: CONVENTION ON PSYCHOTROPIC SUBSTANCES; WORLD HEALTH ORGANIZATION SCHEDULING RECOMMENDATIONS FOR SEVEN DRUG SUBSTANCES
2014-6752	08/15/2014 09/15/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	James Wong HARMAN LAW LLC	BIOGEN IDEC - RECS RE MARKETING APPROVAL FOR TECFIDERA, AERS
2014-6753	08/15/2014 09/15/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Andrea Demakas ADVERSEEVENTS INC	IMBRUVICA - AERS
2014-6754	08/15/2014 09/15/2014	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Richard O. Wood the Wood Burditt group	COVIDIEN LP, AUGUSTA, GA - EIR EXHIBIT 2

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2014-6755	08/15/2014 11/04/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	John Chapman Stem Cell Partners LLC	BK100014, BK050055, BK090048 ETC
2014-6756	08/15/2014 09/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca L. Dandeker MORGAN LEWIS & BOCKIUS LLP	ATUL LIMITED, INDIA - 483, EIR SUMMARIES
2014-6757	08/15/2014 09/15/2014	FDA/OFVM/CFSAN/OCD/EOS/	Stewart Immelman Warrior Nutrition	UPPER LIMITS SPECIFIED FOR AMINO ACIDS IN A FINISHED FOOD PER CFR 172.320
2014-6758	08/15/2014 09/15/2014	FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/	Elizabeth Aguilera Southern California Public Radio	ROGER WILLIAMS, MARY SISLER WILLIAMS, SPINAL SOLUTIONS ETC - INSPECTIONS, INSPECTOR NOTES, RESPONSES ETC 01/01/2010 - 08/12/2014
2014-6759	08/15/2014 09/15/2014	FDA/OGROP/ORASE-FO/NOL- DO/NOL-CB/	Alec White HEALTHCOR MANAGEMENT LP	QUALITEST PHARMACEUTICALS, HUNTSVILLE, AL - 483 CORR 07/01/2014 - 08/12/2014
2014-6760	08/15/2014 09/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	Avital Merl Becton and Dickinson	CEQUR PAQ DEVICE - PREMARKET NOTIFICATION
2014-6761	08/15/2014 09/15/2014	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	CORR BETWEEN FDA AND LORILLARD TOBACCO COMPANY RE SE0003730 & SE0003731
2014-6762	08/15/2014 09/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Pr Fabrice GANKAM Pr Fabrice GANKAM -	SAMSCA ORIGINAL NARRATIVE REPORTS
2014-6763	08/15/2014 09/15/2014	FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	N THIBODEAUX 5 STAR RESOURCES	A-1 ENGINEERING, CA; BEAUTIFUL IMAGE LLC, CA; TAVTECH LTD, ISRAEL, ETC - REGISTRATIONS, PROD LISTINGS, EIRS, ETC
2014-6764	08/15/2014 09/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SHEILA S BEE MD TOUCHSTONE INTERNAL MEDICINE	TORADOL - AERS
2014-6765	08/15/2014 09/15/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 7/28/14-8/1/14
2014-6766	08/15/2014 09/15/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 8.4-8/14
2014-6767	08/15/2014 09/15/2014	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 8/4-8/14

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2014-6768	08/15/2014 09/15/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 8/4-8/14
2014-6769	08/15/2014 09/15/2014	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD Center for Regulatory Services, Inc.	FOI DAILY LOG 8/4-8/14
2014-6770	08/15/2014 09/15/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DIALY LOG 8/4-8/14
2014-6771	08/15/2014 09/15/2014	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 8/4-8/14
2014-6772	08/15/2014 09/15/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-4343
2014-6773	08/15/2014 09/15/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	Robert Bexton Aristotle Capital Management	HOSPIRA - UNTITLED LETTER, 483, LAKE FOREST, INDIA
2014-6774	08/15/2014 09/15/2014	FDA/OFVM/CFSAN/OCD/EOS/	Frank Domino Frank Domino	ASBESTOS CONTAINING GASKETS APPROVED FOR USE IN FOOD CONTACT APPLICATIONS
2014-6775	08/15/2014 09/15/2014	FDA/OFVM/CFSAN/OCD/EOS/	Stephen Gardner, Center for Science in the Public Interest Center for Science in the Public Interest	BLACK COHOSH DIETARY SUPPLEMENTS - AERS
2014-6776	08/15/2014 09/15/2014	FDA/OC/OES/DFOI/	David Petrocine Aceto Corporation	IPCA, INDIA - 483
2014-6777	08/15/2014 09/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	Nataly Cohen EI Global Trade LTD	K140255
2014-6778	08/15/2014 09/15/2014	FDA/OGROP/ORACE/SW-FO/DAL-DO/DAL-CB/	Scott Fawcett Carroll Quality Consult, Inc.	ARL BIOPHARMA DBA ANALYTICAL RESEARCH LABORATORIES, OKLAHOMA CITY, OK - EIR, 483 02/01/2010 - 11/30/2012
2014-6779	08/15/2014 09/15/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-4414
2014-6780	08/15/2014 09/15/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-4343

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2014-6781	08/15/2014 09/15/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-5046
2014-6782	08/15/2014 09/15/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2010-2473
2014-6783	08/15/2014 09/15/2014	FDA/OFVM/CFSAN/OCD/EOS/	Stephen Gardner, Center for Science in the Public Interest CENTER FOR SCIENCE IN THE PUBLIC INTEREST	ECHINACEA - AERS
2014-6784	08/15/2014 09/15/2014	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2014-6467
2014-6785	08/15/2014 09/15/2014	FDA/OFVM/CFSAN/OCD/EOS/	Stephen Gardner, Center for Science in the Public Interest CENTER FOR SCIENCE IN THE PUBLIC INTEREST	GINKO BILOBA DIETARY SUPPLEMENTS - AERS
2014-6786	08/15/2014 09/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Alexis Valenti Valenti, Alexis	ADDERALL - AERS
2014-6787	08/15/2014 09/15/2014	FDA/OFVM/CFSAN/OCD/EOS/	Stephen Gardner, Center for Science in the Public Interest Center for Science in the Public Interest	GINSENG - AERS
2014-6788	08/15/2014 09/15/2014	FDA/OC/OES/DFOI/	 FOI Services, Inc.	FOI DAILY LOG 8/4-8/14
2014-6789	08/15/2014 09/15/2014	FDA/OGROP/ORR/SW-FO/DEN- DO/DEN-CB/	Jack Castro Native Remedies LLC	VITALITY WORKS INC., ALBUQUERQUE, NM - 482, 483
2014-6790	08/15/2014 09/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOSEPH WALKER Walker, Joseph	SOVALDI - AERS
2014-6791	08/15/2014 09/15/2014	FDA/OFVM/CFSAN/OCD/EOS/	Stephen Gardner, Center for Science in the Public Interest CENTER FOR SCIENCE IN THE PUBLIC INTEREST	ST JOHNS WORT - AERS
2014-6792	08/15/2014	FDA/OFVM/CFSAN/OCD/EOS/	Stephen Gardner, Center for	SAW PALMETTO - AERS

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	09/15/2014		Science in the Public Interest Center for Science in the Public Interest	
2014-6793	08/15/2014 09/15/2014	FDA/OFVM/CFSAN/OCD/EOS/	Stephen Gardner, Center for Science in the Public Interest CENTER FOR SCIENCE IN THE PUBLIC INTEREST	GOLDEN SEAL - AERS
2014-6794	08/18/2014 09/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	First-Party Request Joan Stitt (UG2CD-16) MERCK & CO., INC.	NDA 552
2014-6795	08/18/2014 09/16/2014	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	John Walsh James Alexander Corporation	BECKMAN COULTER ,PALATINE, IL - EIR, 483, RECALL 08/01/2011 - 08/13/2014
2014-6796	08/18/2014 09/16/2014	FDA/OMPT/CTP/OD/	Uriel Acevedo. American Trademarks Inc	BELCORP OF AMERICA DERBY BRAND CIGARETTES - SUBMISSIONS TO CTP
2014-6797	08/18/2014 09/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	Grant Morris Sanford Heisler, LLP	REVIEW PANEL RECS - K040627, K080991, ETC
2014-6798	08/18/2014 09/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Xudong Yuan RB	NDA 012126
2014-6799	08/18/2014 09/16/2014	FDA/OGROP/ORACE-FO/PHIDO/PHI-CB/	James Ypma Initiative Foods LLC	SUNOPTA GLOBAL INGREDIENTS, ALLENTOWN, PA - WARNING LETTER, 483 06/25/2014 - 06/30/2014
2014-6800	08/18/2014 09/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Charles E. Adler Adler Law Offices, Ltd.	XARELTO - BOXED WARNINGS, LABELING, PACKAGING ETC
2014-6801	08/18/2014 09/16/2014	FDA/OGROP/ORASE-FO/NOLDO/NOL-CB/	Andrew Finkelstein Susquehanna Financial Group	QUALITEST PHARMACEUTICALS, ENDO PHARMACEUTICALS, HUNTSVILLE, AL - 483 08/01/2014 - 08/01/2014
2014-6802	08/18/2014 09/16/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-4110
2014-6803	08/18/2014 09/16/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-3989
2014-6804	08/18/2014	FDA/OGROP/ORACE-FO/CIN-	Stephen Lang	DR BERNADETTE D'SOUZA - 483 06/12/2006 - 12/12/2006

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	09/16/2014	DO/CIN-CB/	Alkermes PLC	
2014-6805	08/18/2014 09/16/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Rachel Johnson FOI Services, Inc.	MUSCULOSKELETAL TRANSPLANT FOUNDATION - EIRs 483
2014-6806	08/18/2014 09/16/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Stephen Lang Alkermes PLC	DR BERNADETTE D'SOUZA, DAYTON, OH - EIR 06/12/2006 - 08/13/2014
2014-6807	08/18/2014 09/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	Nataly Cohen EI Global Trade LTD	K130793
2014-6808	08/18/2014 09/16/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	NDA 012675
2014-6809	08/18/2014 09/16/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	NDA 12674
2014-6810	08/18/2014 09/16/2014	OC/ORACE/ OC/ORACE/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	JoAnn Lennon Pure Edge Nutrition	SAMPLE 859487
2014-6811	08/18/2014 09/16/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	NDA 013304
2014-6812	08/18/2014 09/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	Alex Johnson Inter Med / Vista Dental Products	K121282
2014-6813	08/18/2014 09/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K133616
2014-6814	08/18/2014 09/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	Alex Johnson Inter Med / Vista Dental Products	K121282
2014-6815	08/18/2014 09/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K141241
2014-6816	08/18/2014 09/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	Alex Johnson Inter Med / Vista Dental Products	K033033

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2014-6817	08/18/2014 09/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	Alex Johnson Inter Med / Vista Dental Products	K123215
2014-6818	08/18/2014 09/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	Alex Johnson Inter Med / Vista Dental Products	K970114
2014-6819	08/18/2014 09/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	Alex Johnson Inter Med / Vista Dental Products	K943372
2014-6820	08/18/2014 09/16/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/NWJ- DO/NWJ-CB/	JoAnn Lennon JoAnn Lennon	SAMPLE RESULTS 855992
2014-6821	08/18/2014 09/16/2014	FDA/OGROP/ORO/SE-FO/FLA- DO/FLA-CB/	Liz DeAngelo THE INSTITUTE FOR TRANSFUSION MEDICINE	COMMUNITY BLOOD CENTERS OF FLORIDA - RESPONSE TO WL
2014-6822	08/18/2014 09/16/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/NWJ- DO/NWJ-CB/	JoAnn Lennon Pure Edge Nutrition	SAMPLE RESULTS 855993
2014-6823	08/18/2014 09/16/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/NWJ- DO/NWJ-CB/	JoAnn Lennon Pure Edge Nutrition	SAMPE RESULTS 855995
2014-6824	08/18/2014 09/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	Alex Johnson Inter Med / Vista Dental Products	K003995
2014-6825	08/18/2014 09/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	Lauren Farruggia Hyman, Phelps & McNamara P.C.	K140481
2014-6826	08/18/2014 09/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOSEPH WALKER Walker, Joseph	KYPROLIS - AERS
2014-6827	08/18/2014 09/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	Himanshu.parikh@atriummed.com Atrium Medical Corporation	K130210
2014-6828	08/18/2014 09/16/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/NWJ- DO/NWJ-CB/	JoAnn Lennon Pure Edge Nutrition	SAMPLE RESULTS 856486

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2014-6829	08/18/2014 09/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	Reinhold imtmedical AG	K090468, K092148, K102775 ETC
2014-6830	08/18/2014 09/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	Ayelet Peer SLP	K061764
2014-6831	08/18/2014 09/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	NDA 020430
2014-6832	08/18/2014 09/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	Ayelet Peer SLP	K112514
2014-6833	08/18/2014 09/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	Alex Johnson Inter Med / Vista Dental Products	K060920
2014-6834	08/18/2014 09/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	Alex Johnson Inter Med / Vista Dental Products	K961158
2014-6835	08/18/2014 09/16/2014	FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/	John Crabill Perrigo Nutritionals	KANPAK, ARKANSAS CITY, KS - EIR 08/14/2012 - 08/14/2014
2014-6836	08/18/2014 09/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Steven Woloshin The Dartmouth Institute for Health Policy and Clinical Practice	NDA, NDA SUPPLEMENTS
2014-6837	08/18/2014 09/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	Ayelet Peer SLP	K083575
2014-6838	08/18/2014 09/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	NDA 013132
2014-6839	08/18/2014 09/16/2014	FDA/OC/OES/DFOI/	JOSEPH WALKER Walker, Joseph	ORTHOPEDIC AND REHABILITATION DEVICES PANEL - MEETING TRANSCRIPT 8/18/09
2014-6840	08/18/2014 09/16/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Thomy Tonia Institute of Social and Preventive Medicine	CLINICAL STUDY REPORTS, APPENDICES, ANNEXES, ETC

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2014-6841	08/18/2014 09/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	Azimun Jamal CapsoVision	K111450
2014-6842	08/18/2014 09/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	Robert Eberle Intellirod Spine	K964933
2014-6843	08/18/2014 09/16/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	NDA 014694
2014-6844	08/18/2014 09/16/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	02840.00312 Wilson Eler, LLP	MEDWATCH REPORT
2014-6845	08/18/2014 09/16/2014	FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/ FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/	Austin Nelson Sterne Agee	QUALITEST, ENDO PHARMACEUTICALS - 483 05/01/2013 - 08/14/2014
2014-6846	08/18/2014 09/16/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sandra Colantuono Colantuono, Sandra	PANTHEON INC, MISSISSAUGA, CANADADate - 483 04/01/2013 - 05/31/2013
2014-6847	08/18/2014 09/16/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Luchiana Wesley Accenture	ACCENTURE SERVICES PVT LTD, INDIA - EIR 05/05/2014 - 05/07/2014
2014-6848	08/18/2014 09/16/2014	FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/	Nick Kemphaus Darling Ingredients	TRI STAR LLC, KANSAS CITY, MO - ATTACHMENTS
2014-6849	08/18/2014 09/16/2014	OC/CVM/OCD/	Chris Hamby Buzzfeed News	NARMS DATA
2014-6850	08/18/2014 09/16/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOANNE HAWANA ARENT FOX LLP	CASE NUMBERS 9002046, 9009674, 9010598 ETC
2014-6851	08/18/2014 09/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	STEPHANIE A.S. HARRINGTON, M.S	DIAGNOSTIC PHOTONICS INC - FORSEE (FC) IMAGING SYS K133209; AGFA HEALTHCARE NV - SKINTELL K132800

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			MATRIX MEDICAL DEVICES LLC	
2014-6852	08/18/2014 09/16/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MICHAEL R. COHEN INSTITUTE FOR SAFE MEDICATION PRACTICES	MEDWATCH MEDCIATOIN ERRORS 7/14
2014-6853	08/18/2014 09/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	INDIVIDUAL MDRS
2014-6854	08/18/2014 09/16/2014	FDA/OC/OES/DFOI/	David Mangione Govzilla, Inc.	PREVIOUSLY RELEASED EIRS 01/01/2013 - 08/11/2014
2014-6855	08/19/2014 09/17/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	PATIENT RECS
2014-6856	08/19/2014 09/17/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ellen Heavner Mary Kay Inc.	KOLMAR, KOREA - EIR 01/01/2014 - 08/09/2014
2014-6857	08/19/2014 09/17/2014	FDA/OO/OHR/ FDA/OMPT/CTP/OD/	Michael Toland No Association	FDA-CTP-14-MP-1123330SL - SELECTION RECS
2014-6858	08/19/2014 10/16/2014	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	TOBACCO ADVERSE REACTIONS
2014-6859	08/19/2014 09/17/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jolanta Piszczek Island Health	Sulfamethoxazole-trimethoprim - Case Reports
2014-6860	08/19/2014 09/17/2014	FDA/OGROP/ORACE-FO/MIN- DO/MIN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Jamie Jackson Jamie Jackson	STARKEY LABORATORIES, OTICON INC - EIR 05/16/2013 - 08/15/2014
2014-6861	08/19/2014 09/17/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	James Wong HARMAN LAW LLC	TEVA PHARMACEUTICALS - RECS RE REQUEST TO DENY TECFIDERA APPROVA

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2014-6862	08/19/2014 09/17/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Raja Agnihotram Fresenius Kabi USA, LLC	ANDA 090495 SBA
2014-6863	08/19/2014 09/17/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Eric Walter Camil Sr. CAMIL CONSULTING CORP	TIRF REMS DOCTORS, PHARMACIES
2014-6864	08/19/2014 09/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	Daniel BUrnett UCSF	K091241
2014-6865	08/19/2014 09/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	Daniel Burnett UCSF	K070375
2014-6866	08/19/2014 09/17/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anthony Bongiorno N /A	ANDA 090824
2014-6867	08/19/2014 09/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	(Mr.) Taro Kanai (First/Last Name) MIC International Corporation	K072259
2014-6868	08/19/2014 09/17/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	Mary E. Lynn The Windward Company	COLORADO HISTO-PREP, FORT COLLINS, CO - EIR 04/10/2013 - 05/10/2013
2014-6869	08/19/2014 09/17/2014	OC/ORASORM/ OC/ORASORM/	David Mangione Govzilla, Inc.	LIST OF INSPECTIONS 03/15/2014 - 08/18/2014
2014-6870	08/19/2014 09/17/2014	OC/CVM/OCD/	Anthony Bongiorno N/A	SERGEANT'S PET CARE PRODUCTS - APPLICATION FOR PRONYL OTC FOR CATS
2014-6871	08/19/2014 09/17/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kiran Awate THE OHIO STATE UNIVERSITY	LIST OF DRUG ESTABLISHMENTS CURRENT REGISTRATION SITE
2014-6872	08/19/2014 09/17/2014	OC/ORAS/ OC/ORAS/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	Louis L. Underbakke Louis L. Underbakke, P.C.	COMPLAINT RECS
2014-6873	08/19/2014	FDA/OFVM/CFSAN/OCD/EOS/	Michael J. O'Flaherty	WARNING LETTER SEA 13-27 METAGENICS - RECS FROM CFSAN, SEATTLE DISTRICT

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	09/17/2014	FDA/OGROP/ORPA/FO/SEA-DO/SEA-CB/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	OLSSON FRANK WEEDA TERMAN MATZ PC	
2014-6874	08/19/2014 09/17/2014	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	LESLIE RAMSEY FDA NEWS	ANGIODYNAMICS INC, MANCHESTER, GA - 483S 7/1-31/14
2014-6875	08/19/2014 09/17/2014	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	LESLIE RAMSEY FDA NEWS	PHARMACEUTICS INTERNATIONAL INC, COCKEYSVILLE, MD; NEW HORIZONS DIAGNOSTICS CORP, BALTIMORE, MD - 483S 7/1-31/14
2014-6876	08/19/2014 09/17/2014	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	LESLIE RAMSEY FDA NEWS	MARTIN AVENUE PHARMACY INC, NAPERVILLE, IL - 483S 7/1-31/14
2014-6877	08/19/2014 09/17/2014	FDA/OGROP/ORACE-FO/CINDO/CIN-CB/	LESLIE RAMSEY FDA NEWS	TANGO3 LLC, SIMPSONVILLE, KY; CUMSEE ENTERPRISE, CINCINNATI, OH; GENDRON INC, BRYAN, OH, ETC - 483S 7/1-31/14
2014-6878	08/19/2014 09/17/2014	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	LESLIE RAMSEY FDA NEWS	MDSYSO LLC, AUSTIN, TX; MASSCO DENTAL, ROGERS, AR; PEOPLES PHARMACY INC #2, AUSTIN, TX - 483S 7/1-31/14
2014-6879	08/19/2014 09/17/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	LESLIE RAMSEY FDA NEWS	OSO BIOPHARMACEUTICALS MANUFACTURING LLC, ALBUQUERQUE, NM; SANDHILL SCIENTIFIC INC, LITTLETON, CO - 483S 7/1-31/14
2014-6880	08/19/2014 09/17/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	LESLIE RAMSEY FDA NEWS	AMERICAN FAMILY PHARMACY LLC, INDIANAPOLIS, IN; VERTELLUS HEALTH & SPECIALTY PRODUCTS LLC, ZEELAND, MI; PIONEER SURGICAL TECHNOLOGY, INC, ETC - 483S 7/1-31/14
2014-6881	08/19/2014 09/17/2014	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	LESLIE RAMSEY FDA NEWS	SOUTHEAST AESTHETIC LTD CO, TALLAHASSEE, FL; MEDICOMP INC, MELBOURNE, FL; HHCS PHARMACY, INC (FREEDOM PHARMACY), ORLANDO, FL - 483S 7/1-31/14
2014-6882	08/19/2014 09/17/2014	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	LESLIE RAMSEY FDA NEWS	PENNER MFG INC, AURORA, NE - 483S 7/1-31/14
2014-6883	08/19/2014 09/17/2014	FDA/OGROP/ORACE-FO/MINDO/MIN-CB/ FDA/OGROP/ORAPA-FO/LOSDO/LOS-CB/	LESLIE RAMSEY FDA NEWS	SOUTH COAST SPECIALITY COMPOUNDING INC, IRVINE, CA; IRVINE SCIENTIFIC SALES CO INC, SANTA ANA, CA; DE NOVO SOFTWARE, LOS ANGELES, CA, ETC - 483S 7/1-31/14
2014-6884	08/19/2014 09/17/2014	FDA/OGROP/ORACE-FO/MINDO/MIN-CB/	LESLIE RAMSEY FDA NEWS	MAYO CLINIC PET RADIOCHEMISTRY FACILITY (MCPRF), ROCHESTER, MN; NEMSCHOFF CHAIRS INC, SHEBOYGAN, WI - 483S 7/1-31/14

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2014-6885	08/19/2014 09/17/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	LESLIE RAMSEY FDA NEWS	BIOGEN IDEC INC, CAMBRIDGE, MA; CUBIST PHARMACEUTICALS INC, LEXINGTON, MA; BOSTON BRACE INTERNATIONAL INC, AVON, MA, ETC - 483S 7/1-31/14
2014-6886	08/19/2014 09/17/2014	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	LESLIE RAMSEY FDA NEWS	DEROYAL INDUSTRIES INC, POWELL, TN; NAIMCO INC (RICHMAR INC), CHATTANOOGA, TN - 483S 7/1-31/14
2014-6887	08/19/2014 09/17/2014	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	LESLIE RAMSEY FDA NEWS	MEDICAL DIGITAL DEVELOPERS LLC, BROOKLYN, NY; PHARBEST PHARMACEUTICALS INC, FARMINGDALE, NY; CROSSTEX INTERNATIONAL, HAUPPAUGE, NY, ETC - 483S 7/1-31/14
2014-6888	08/19/2014 09/17/2014	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	LESLIE RAMSEY FDA NEWS	BIOGENEX LABORATORIES INC, FREMONT, CA; ANATOMAGE INC, SAN JOSE, CA; AFTON MEDICAL LLC, CARSON CITY, NV, ETC - 483S 7/1-31/14
2014-6889	08/19/2014 09/17/2014	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	LESLIE RAMSEY FDA NEWS	ABBVIE BIOTECHNOLOGY LTD, BARCELONETA, PR - 483S 7/1-31/14
2014-6890	08/19/2014 09/17/2014	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	LESLIE RAMSEY FDA NEWS	BEEVERS MANUFACTURING & SUPPLY INC, MCMINNVILLE, OR; CUSTOM OCULAR PROSTHETICS, SEATTLE, WA; VERATHON INC, BOTHELL, WA - 483S 7/1-31/14
2014-6891	08/19/2014 09/17/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LESLIE RAMSEY FDA NEWS	APOTEX RESEARCH PRIVATE LTD, BANGALORE, INDIA; NOVACYL ROUSSILLON, ROUSSILLON, FRANCE; SYMBIOTICA SPECIALITY INGREDIENTS, SDN. BHD., KULIM, MALAYSIA - 483S 7/1-31/14
2014-6892	08/19/2014 09/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	LESLIE RAMSEY FDA NEWS	DIMA S.L., CALATAYUD, ZARA-GOZA, SPAIN; PETER LAZIC GMBH, TUTTLINGEN, GERMANY; BIOX INSTRUMENTS CO LTD, WXSH, CHINA, ETC - 483S 7/1-31/14
2014-6893	08/19/2014 09/17/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TORREY COPE SIDLEY AUSTIN LLP	GLAXOSMITHKLINE INC, MISSISSAUGA ONTARIO, CANADA - 7/16/10; CP PHARMACEUTICALS LTD, WREXHAM, UK - 9/10/13; 3M HEALTH CARE LTD, LEICESTERSHIRE, UK, - 483S 4/15/13, ETC
2014-6894	08/19/2014 09/17/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ED QUIGGLE JR SUNBURY AMERICAN	MEDICAL MARIJUANA OR CANNABIDIOL (CBD) PILOT RESEARCH PROGRAM PA,FL;RECS, EMAILS, MEMOS, ETC
2014-6895	08/19/2014 09/17/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LARRY COOPER COOPER, LARRY	PFIZER - LIPITOR, CATARACT APRVL LTR, LBLG 10/21/14

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2014-6896	08/19/2014 09/17/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LAURENCE STINSON STINSON LAW GROUP	DURAGESIC - ESI SENT TO DOCTORS, WARNINGS, ACUTE PAIN MANAGEMENT, ETC
2014-6897	08/19/2014 09/17/2014	FDA/OFVM/CFSAN/OCD/EOS/	SILVIA ULM BURDOCK GROUP	INORGANIC CALCIUM ORTHOPHOSPHATE CAS# 7758-87-4 - REGULATORY STATUS, CONSUMPTION SAFETY INFORMATION, ETC
2014-6898	08/19/2014 09/17/2014	FDA/OO/OHR/	JAMES G CONCH CONCH, JAMES G	COPIES OF EMPLOYEES NAMES, SALARIES, WORK LOCATION IN MEMPHIS, TN, ETC
2014-6899	08/19/2014 09/18/2014	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	MARIAN S ROSEN ROSEN SPEARS ATTY	EQUITECH ENTERPRISES INC (BLOOD DONATION CTR), KERRVILLE, TX - RPTS, EIRS, SURVEYS, ETC 1/11 TO PRESENT
2014-6900	08/19/2014 09/17/2014	OC/CVM/OCD/ OC/ORAO/OCI/ OC/ORAO/OCI/	JOHN PASTUOVIC PASTUOVIC, JOHN	ANIMAL & VETERINARY SENTENCING IN ANIMAL DRUG SMUGGLING CASE - NAMES OF INDIVIDUALS INVOLVED
2014-6901	08/19/2014 09/17/2014	FDA/OC/OES/DFOI/	MARK S FORESTER PEAVLER GOUP ATTYS & COUNSELORS	FACTORS POTENTIALLY CONTRIBUTING TO THE CONTAMINATION OF FRESH WHOLE CANTALOUPE IMPLICATED IN MULTI-STATE OUTBREAK OF LISTERIOSIS - RPT10/19/11 (CERTIFIED)
2014-6902	08/20/2014 09/18/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Neel Tanna YCM	IPCA WARNING LETTER
2014-6903	08/20/2014 09/18/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Arista Calamos calamos LLC	DMF 17883, 25341, HP ACTHAR GEL DRUG LABEL/MONOGRAPH
2014-6904	08/20/2014 09/18/2014	FDA/OMPT/CDRH/OCER/DFOI/	Connie Parker Parker, Connie	RIIVIA LLC - 510K
2014-6905	08/20/2014 09/18/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Mark Georgescu BLOOD SYSTEMS, INC.	IRWIN MEMORIAL BLOOD CENTER OF SAN FRANCISCO MEDICAL SOCIETY - LICENSURE APPROVAL LETTER
2014-6906	08/20/2014 09/18/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Magali Lurquin Jubilant Draximage Inc.	NDA 019414

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2014-6907	08/20/2014 09/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Wafa Nguyen QUALITEST PHARMACEUTICALS INC	FAERS CASE NUMBERS 9472298 8805840 8571781 ETC
2014-6908	08/20/2014 09/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Eli Nathaniel Deal BARNES-JEWISH HOSPITAL	APIXABAN, DIALYSIS - UNREDACTED RECS
2014-6909	08/20/2014 09/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	Walid Gardezi Walid Gardezi	AASTROM BIOSCIENCES - CMC CORR 08/18/2010 - 08/18/2014
2014-6910	08/20/2014 09/18/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Daniel Burnett UCSF	K130210, K080212
2014-6911	08/20/2014 09/18/2014	FDA/OMPT/CTP/OD/	Jay Worthy MP Group	APPROVED LIST OF TOBACCO SELLERS
2014-6912	08/20/2014 09/18/2014	FDA/OMPT/OSMP/OOPD/	H. Greg Thomas codaDOSE, Inc.	TOCILIZUMAB - ORPHAN DRUG DESIGNATION RECS
2014-6913	08/20/2014 09/18/2014	FDA/OMPT/OSMP/OOPD/	H. Greg Thomas codaDOSE, Inc.	ADALIMUMAB - ORPHAN DRUG DESIGNATION RECS
2014-6914	08/20/2014 09/18/2014	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	Liz DeAngelo THE INSTITUTE FOR TRANSFUSION MEDICINE	FLORIDA'S BLOOD CENTERS, COMMUNITY BLOOD CENTERS OF FLORIDA, INC, AND FLORIDA'S BLOOD SERVICES, INC. - EIR 08/01/2012 - 08/18/2014
2014-6915	08/20/2014 09/18/2014	FDA/OMPT/CDRH/OCER/DFOI/	Daniel Burnett UCSF	K030886
2014-6916	08/20/2014 09/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Richard A Mecall DDS.,MS Richard A Mecall DDS.,MS	DEPUY ASR, ASR XL HIP RELACEMENT DEVICES - AERS

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2014-6917	08/20/2014 09/18/2014	FDA/OMPT/CDRH/OCER/DFOI/	Scott Kellogg Akili Interactive Labs, Inc.	K854903
2014-6918	08/20/2014 09/18/2014	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Shane Ray Shane Ray	MUSCULOSKELETAL TRANSPLANT FOUNDATION - 483 01/01/2014 - 08/19/2014
2014-6919	08/20/2014 09/18/2014	FDA/OMPT/CDRH/OCER/DFOI/	Alan Scharf Scharf, Alan	P110008 - POST APPROVAL STUDIES
2014-6920	08/20/2014 09/18/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michael Wei Michael Wei	APO866 - IND
2014-6921	08/20/2014 09/18/2014	FDA/OMPT/CDRH/OCER/DFOI/	Michael Zilm UNIVERSITY OF CONNECTICUT	K012751
2014-6922	08/20/2014 09/18/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CRAIGE TRAUTMAN INTAGRAS INC	DRUG LISTING NOT CURRENTLY POSTED ON THE NATIONAL LIBRARY OF MEDICINE (NLM) WEBSITE, ESTABLISHMENT REGISTRATIONS, AND LABELER CODES
2014-6923	08/20/2014 09/18/2014	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	PATTI WALLER MARLER CLARK ATTYS	INDIVIDUAL RECS
2014-6924	08/20/2014 09/18/2014	FDA/OC/OES/DFOI/	GEORGE HAMILTON HAMILTON, GEORGE	REGULATIONS THAT PROHIBIT FOOD VENDORS FROM FALSELY LABELING FOODS AS KOSHER
2014-6925	08/20/2014 09/18/2014	FDA/OFVM/CFSAN/OCD/EOS/	MELVIN N KRAMER PHD MPH EHA CONSULTING GROUP INC	ATHERSTONE FOODS INC, RICHMOND, CA - E COLI OUTBREAK INVESTIGATION RECS
2014-6926	08/20/2014 09/18/2014	FDA/OC/OES/DFOI/	MATTHEW PERRONE ASSOCIATED PRESS	APPLE, APPLETOOLBOX - MEMO
2014-6927	08/20/2014 09/18/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID HOFFMEISTER Wilson Sonsini Goodrich & Rosati	APOTEX - ANDA 202-958 TENTATIVE APRVL LTR
2014-6928	08/20/2014 09/18/2014	OC/ORA/ OC/ORA/	Doe J	CMPLNT

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2014-6929	08/20/2014 09/18/2014	FDA/OMPT/CDRH/OCER/DFOI/	MARTHA FARLOW FARLOW, MARTHA	K122061
2014-6930	08/20/2014 09/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SHEILA BEE MD TOUCHSTONE INTERNAL MEDICINE	TORADOL - HYPOTENSION EFFECT DOSE DEPENDENT
2014-6931	08/20/2014 09/18/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	2011-5055
2014-6932	08/20/2014 09/18/2014	FDA/OFVM/CFSAN/OCD/EOS/	SILVIA ULM BURDOCK GROUP	CALCIUM SALTS OF SUCROSE PHOSPHATE ESTERS - REGULATORY STATUS, CONSUMPTION, SAFETY INFORMATION, ETC
2014-6933	08/20/2014 09/18/2014	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	TONYA VINEYARD VINEYARD, TONYA	CHOBANI PLANT, TWIN FALLS, ID - CMPLNTS, LAB RESULTS
2014-6934	08/20/2014 09/18/2014	FDA/OFVM/CFSAN/OCD/EOS/	LAURA ANDERSON ARKEMA INC	FCN 56, FCD 345
2014-6935	08/20/2014 09/18/2014	FDA/OC/OES/DFOI/	MANOJ GARG DSP Merrill Lynch	IPCA LABORATORIES LTD, MADYA PRADESH, INDIA - 483 7/14-18/14
2014-6936	08/21/2014 09/19/2014	OC/ORACE/ORM/ OC/ORACE/ORM/	Mark Prinz Registrar Corp	FOREIGN FOOD FACILITIES LIST
2014-6937	08/21/2014 09/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	Dorothy Latta LATTA, DOROTHY	K111622
2014-6938	08/21/2014 09/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Liz King Oxford Pharmascience	NDA 17463 SBA
2014-6939	08/21/2014 09/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	Belinda Jackson Helix Medical, LLC	K851082, K800563
2014-6940	08/21/2014 09/19/2014	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Caroline Powell Cornerstone Bulldogs	DIAMOND PET FOOD CORPORATION, META, MO - RECALL, COMPLAINTS ETC 03/01/2012 - 12/01/2013
2014-6941	08/21/2014 09/19/2014	OC/CVM/OCD/	Michelle Giuffrida University of Pennsylvania Veterinary Clinical Investigations Center	DONEZEPIL - FOIA SUMMARY

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2014-6942	08/21/2014 09/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sarah Sellers q-Vigilance, LLC	COMPOUNDED TOPICAL MIXTURES - AERS
2014-6943	08/21/2014 09/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Barbara Goll Cape Ann Fluoride Action Network	FLUORIDE SUPPLEMENTS - RECORDS RE DISAPPROVAL
2014-6944	08/21/2014 09/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	Robert Stavert Stavert, Robert R	REPORT FOLLOW UP
2014-6945	08/21/2014 09/19/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Karen Marshall TARSA THERAPEUTICS INC	SHARP CLINICAL SERVICES, ALLENTOWN, PA - 483, EIR
2014-6946	08/21/2014 09/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	Shalabh Jain Hyalo Technologies	K073417
2014-6947	08/21/2014 09/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	Peter Sacchetti ALCOR Scientific	SEDIPLAST WESTERGREN ESR E990048- CLIA WAIVER RECS
2014-6948	08/21/2014 09/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	CHARLES W. LEITER LEITERS COMPOUNDING	LEITER COMPOUNDING PHARMACY, SAN JOSE, CA - EIR 2/18/14 TO 3/6/14
2014-6949	08/21/2014 09/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CALEB MARKER RIDOUT LYON ET AL	IMMUNEX CORP - ETANERCEPT (ENBREL) SHIPIING DOCUMENTATION, INVESTIGATIONS
2014-6950	08/21/2014 09/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOANNE S. HAWANA ARENT FOX LLP	MEDWATCH 589200, 9210073, 9290073, 9359729

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2014-6951	08/21/2014 09/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOANNE S. HAWANA ARENT FOX LLP	MEDWATCH 9393064, 9697947, 9725420, 9765099
2014-6952	08/21/2014 09/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOANNE S. HAWANA ARENT FOX LLP	MEDWARCH 9460090
2014-6953	08/21/2014 09/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELIZABETH BARBEHENN, Ph.D. PUBLIC CITIZEN	UNREDACTED SBA NDA 22-271; 22-426
2014-6954	08/21/2014 09/19/2014	OC/ORA/ OC/ORA/	CHARLES W. LEITER LEITERS COMPOUNDING	LEITERS COMPOUNDING PHARMACY, SAN JOSE CA - EIR 10/22/13 TO 11/5/13
2014-6955	08/21/2014 09/19/2014	FDA/OC/OES/DFOI/	Elliott Graham Society of Quality Assurance (SQA)	7348.001 - In Vivo Bioequivalence, 7348.808 - Good Laboratory Practice (Nonclinical Laboratories), 7348.808A - Good Laboratory Practice (Nonclinical Laboratories) ETC - 483
2014-6956	08/21/2014 09/19/2014	FDA/OMPT/CTP/OD/	DANIEL MEYERS KAYE SCHOLER LLP	HEALTH CONSEQUENCES OF SMOKING 50 YEARS OF PROGRESS - RPTS, EMAILS, ETC
2014-6957	08/22/2014 09/22/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Suhasini Kanagala Tonix Pharmaceuticals, Inc.	INTERMEZZO - PHARMACOLOGY, TOXICOLOGY REVIEW 6/29/09
2014-6958	08/22/2014 09/22/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joseph Tal TechnoSTAT Ltd.	NCT01343966 - STATISTICAL ANALYSIS PLAN
2014-6959	08/22/2014 09/22/2014	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Tony Sapp Nice-Pak Products, Inc.	DIAMOND WIPES INTERNATIONAL, INC, CHINO, CA - 483 01/01/2003 - 08/20/2014
2014-6960	08/22/2014 09/22/2014	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Heather Baierl Nature's Way Product	UNITED ONE INTERNATIONAL LABS, CARROLTON, TX - EIR, 483
2014-6961	08/22/2014 09/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	Scott Kellogg Akili Interactive Labs, Inc.	K040894
2014-6962	08/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	Scott Kellogg	K020800

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	09/22/2014		Akili Interactive Labs, Inc.	
2014-6963	08/22/2014 09/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	Liane LaRochelle DEKA R&D	K863204
2014-6964	08/22/2014 09/22/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	lucia sibillin lucia sibillin	CHAMPORI - INGREDIENTS
2014-6965	08/22/2014 09/22/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	ILARIS - AERS
2014-6966	08/22/2014 09/22/2014	FDA/OFVM/CFSAN/OCD/EOS/	Daniel Paznek ClorDiSys Solutions, Inc.,	FAP 4A4415
2014-6967	08/22/2014 09/22/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jennifer Schumacher The Invus Group	XIAFLEX - AERS
2014-6968	08/22/2014 09/22/2014	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	Dr. W. Steven Pray Dr. W. Steven Pray	STANDARD HOMEOPATHIC COMPANY - FDA CORR 09/25/2013 - 08/20/2014
2014-6969	08/22/2014 09/22/2014	FDA/OC/OES/DDM/	Sara Anderson, Esq. ASHCRAFT & GEREL, LLP	Docket 77N-0094, C44, Volume 15, Docket 77N-0094, RC5, Volume 40 ETC CERTIFIED
2014-6970	08/22/2014 09/22/2014	FDA/OFVM/CFSAN/OCD/EOS/	Daniel Paznek ClorDiSys Solutions, Inc.,	FAP 0A4721
2014-6971	08/22/2014 09/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	Karina Rubinstein K. Factory	K133382
2014-6972	08/22/2014 09/22/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Moumita Rawal G & W Laboratories Inc.	ANDA 201511 SBA
2014-6973	08/22/2014 09/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	Regina Novak Medtronic TYRX Inc.	K140306
2014-6974	08/22/2014 09/22/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K071177

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2014-6975	08/22/2014 09/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	Karen Denny TECHLAB, Inc.	K042644
2014-6976	08/22/2014 09/22/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Alicia Dethloff SJRMC - Inpatient Pharmacy ATTN: Alicia Dethloff	TOBI PODHALER - AERS
2014-6977	08/22/2014 09/22/2014	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	LAWRANCE A BOHM BOHM LAW GROUP	BLOODSOURCE INC - Cmplnts, Investeigations, Comm, etc
2014-6978	08/22/2014 09/22/2014	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/ORO/DIOP/	DONALD N BLUE ZETETIC INC	ALL SHIPMENTS REGULATED BY FOOD & DRUG ADMINISTRATION 7/22/14-8/20/14
2014-6979	08/22/2014 09/22/2014	FDA/OC/OES/DFOI/	L CULLEN MOORE RYMER MOORE JACKSON ETA	CORPUS CHRISTI MEDICAL CENTER-BAY AREA; CORPUS CHRISTI MEIDCAL CENTER-DOCTORS HOSPITAL, CORPUS CHRISTI, TX - RECS 7/1/13-9/30/13
2014-6980	08/22/2014 09/22/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELAINE S WALKER SEATTLE GENETICS INC	ISRS 8486800, 966724, 9056013, ETC
2014-6981	08/22/2014 09/22/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANDREA FARAH SCOTT & SCOTT LLP	SANDOZ (EON LABS INC) - AMIODARONE HCL ANDA 75-315; TEVA PHARM - AMIDARONE HCL ANDA 74-739; UPSHER-SMITH LBABORATORIES INC - PACERONE ANDA 75-315 LABEL REVISION, APRVL LTR 1/02 TO PRESENT
2014-6982	08/22/2014 09/22/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ETHEL GOLDFINGER GOLDFINGER, ETHEL	AMGEN - PROLIA AERS, RECS
2014-6983	08/22/2014 09/22/2014	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	TODD R STARTZEL KIRKPATRICK & STARTZEL ATTY	EVERGREEN FRESH SPROUTS LLC, MOYIE SPRINGS, ID - MULTISTATE E COLI OUTBREAK OF RAW CLOVER SPROUTS CORR, NOTES, PHOTOGRAPHS, ETC
2014-6984	08/22/2014 09/22/2014	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	RICHARD LEONARD Oxygen Development LLC	OXYGEN DEVELOPMENT LLC, PALM SPRINGS, FL - EIRS 11/12-22/13
2014-6985	08/22/2014 09/22/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-5787 - REQUEST LETTER ONLY

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2014-6986	08/22/2014 09/22/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-5781 - REQUEST LETTER ONLY
2014-6987	08/22/2014 09/22/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-5596 - REQUEST LETTER ONLY
2014-6988	08/22/2014 09/22/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-5460 - REQUEST LETTER ONLY
2014-6989	08/22/2014 09/22/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-5548 - REQUEST LETTER ONLY
2014-6990	08/22/2014 09/22/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-5417 - REQUEST LETTER ONLY
2014-6991	08/22/2014 09/22/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-5828 - REQUEST LETTER ONLY
2014-6992	08/22/2014 09/22/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-5413 - REQUEST LETTER ONLY
2014-6993	08/22/2014 09/22/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-5311 - REQUEST LETTER ONLY
2014-6994	08/22/2014 09/22/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-5940 - REQUEST LETTER ONLY
2014-6995	08/22/2014 09/22/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-6191 - REQUEST LETTER ONLY
2014-6996	08/22/2014 09/22/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-5962 - REQUEST LETTER ONLY
2014-6997	08/22/2014 09/22/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-6020 - REQUEST LETTER ONLY
2014-6998	08/22/2014 09/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	Karen Denny TECHLAB, Inc.	K032571
2014-6999	08/22/2014 09/22/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K082215
2014-7000	08/22/2014 09/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	Karen Denny TECHLAB, Inc.	K011566
2014-7001	08/22/2014 09/22/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	James Ferris Consumer Request	MULTIHANCE - AERS

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-7002	08/22/2014 09/22/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-5019
2014-7003	08/22/2014 09/22/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Nora Udell Kara Hadican Samuels & Associates, LLC	The FDA label approved for Allopurinol in effect from August to October 2006
2014-7004	08/22/2014 09/22/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Chris Klein Christopher Klein	K072809
2014-7005	08/25/2014 09/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	Josiah M. Prendergast EMED Technologies Corporation	K935642
2014-7006	08/25/2014 09/23/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Christian McLaughlin McLaughlin, Christian	TRAMADOL - ADVERSE EVENTS
2014-7007	08/25/2014 09/23/2014	FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	maha sabawi pogorzelski research institute for mathematics	MOHAMED GHRAOWI, CORPUS CHRISTI, TX - LETTERS ABOUT RISKS OF PURCHASING MEDICATIONS FROM FOREIGN OR UNLICENSED SUPPLIERS, CORR
2014-7008	08/25/2014 09/23/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ted Barraco Ted A. Barraco, Attorney	RITILIN, CONCERTA - MEDICATION GUIDE
2014-7009	08/25/2014 09/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	Elena Mack Authentidate Holding Corp.	K122285
2014-7010	08/25/2014 09/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	Chunhong (Emma) Tao ROCHE DIAGNOSTICS	K130886
2014-7011	08/25/2014 09/23/2014	FDA/OFVM/CFSAN/OCD/EOS/	Robin Lourie Watkins, Lourie, Roll & Chance, PC	HYDROXYCUT - AERS
2014-7012	08/25/2014 09/23/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K070722
2014-7013	08/25/2014 09/23/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rebecca Dandeker Morgan, Lewis & Bockius LLP	TRIFARMA, ITALTY - 483, EIR SUMMARY 01/01/2010 - 04/01/2014

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2014-7014	08/25/2014 09/23/2014	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Brett Watson, Esq. BROWN GOLDSTEIN & LEVY LLP	MEDTRONIC MINIMED 530G SYSTEM - INVESTIGATION RECS 05/23/2014 - 08/21/2014
2014-7015	08/25/2014 09/23/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rebecca Dandeker Morgan, Lewis & Bockius LLP	TRIFARMA, ITALY - EIR 01/01/2010 - 04/01/2014
2014-7016	08/25/2014 09/23/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	Jon Ward Aspen Clinical Research	MICHAEL W HARRIS, DO - 483, REPONSE 01/01/2013 - 02/28/2014
2014-7017	08/25/2014 09/23/2014	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	Report Here / Fred Roehm Report Here	HIROSHI'S FISH, PORTLAND, OR - 483 06/10/2014 - 08/21/2014
2014-7018	08/25/2014 09/23/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Morten Nissen, Esq. MNIlaw	PFIZER, IRELAND PHARMACEUTICALS - EIR, 483
2014-7019	08/25/2014 09/23/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Janet Arrowsmith Arrowsmith Consulting LLC	STUART NIGHTINGALE DISCUSSION OF OFF-LABEL USE OF APPROVED MEDICATIONS - DRUG BULLETIN 03/01/1982 - 06/30/1982
2014-7020	08/25/2014 09/23/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Morten Nissen, Esq. MNIlaw	BOEHRINGER INGELHEIM RCV GHBH & CO KG, VIENNA, AUSTRIA - EIR, 483
2014-7021	08/25/2014 09/23/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mike Houchin Law Offices of Ronald A. Marron	NATURE'S WAY - CORR, EIR, ETC 01/01/2008 - 08/21/2014

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2014-7022	08/25/2014 09/23/2014	FDA/OC/OES/DFOI/	Alan Russo epipeline, inc	CORR WITH REGISTRANTS RE INCIDENTS IN WHICH ANIMALS CONSUMED USDA REGULATED BIOTECH MATERIALS
2014-7023	08/25/2014 09/25/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/DET-DO/DET-CB/ FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORO/CE-FO/CHI-DO/CHI-CB/ FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORO/PA-FO/SEA-DO/SEA-CB/ FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORO/SW-FO/DEN-DO/DEN-CB/	Joshua Malamud Hyman, Phelps & McNamara P.C.	FY 14 Inspection and Environmental Sampling Nut Butter Facilities, DFIG #14-03, ORO Concurrence #2014010301, FACTS #8740841; op id#7157483.
2014-7024	08/25/2014 09/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Howard Pomeranz, MD, PhD North Shore Long Island Jewish Health System	SILDENAFIL, TADALAFIL, VERDENAFIL ETC - AERS
2014-7025	08/25/2014 09/23/2014	FDA/OGROP/ORO/CE-FO/PHI-DO/PHI-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Leslie Caliguri Buchanan & Buchanan	ARROW 12 FRENCH 20 CM HEMODIALYSIS CATHETER - PACKAGE INSPERTS, ADVERSE EVENTS, ETC
2014-7026	08/25/2014 09/23/2014	FDA/OGROP/ORO/CE-FO/PHI-DO/PHI-CB/	Rachel Johnson FOI Services, Inc.	MCNEIL, LILITZ, PA - EIR, 483
2014-7027	08/25/2014 09/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K132426
2014-7028	08/25/2014 09/23/2014	OC/CVM/OCD/	Michael A Jacobson Michael A. Jacobson, PS, Inc	ANADA 200257 STUDY RECS
2014-7029	08/25/2014 09/23/2014	OC/CVM/OCD/	Michael A Jacobson Michael A. Jacobson, PS, Inc	KETAMINE - OVERDOSE DEATH RECS
2014-7030	08/25/2014 09/23/2014	FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	Brenda Van Goethem Nature's Way Product	STANDARD HOMEOPATHIC COMPANY - RESPONSE TO WL ISSUED 4/29/2011

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2014-7031	08/25/2014 09/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	William J Gorman Gorman Consutling	K113259
2014-7032	08/25/2014 09/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Greg Butz Butz, Greg	REVANCE THERAPEUTICS, INC - CORR WITH FDA 01/01/2010 - 08/22/2014
2014-7033	08/25/2014 09/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kacy Dicke K&L Gates LLP	K141145
2014-7034	08/25/2014 09/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	William J Gorman Gorman Consutling	K073581
2014-7035	08/25/2014 09/23/2014	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	FDA assignment memos for tobacco inspections
2014-7036	08/25/2014 09/23/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	William Coogan Coogan, William	LAWRENCE C. PARISH, MD, PHILADELPHIA, PA - EIR, ATTACHMENTS
2014-7037	08/25/2014 09/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHANDREN TIRUVATTAR DR REDDYS LABORATORIES INC	FOUGERA - LIDOCAINE TOPICAL OINTMENT ANDA 80-198/S018 LBLG
2014-7038	08/25/2014 09/23/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	JADE KONDO INTUITIVE SURGICAL	SINGLE-SITE GYN, XI PSC BOLT, LARGE CLIP APPLIER, ETC - HEALTH HAZARD EVALUATION ASSESSMENTS
2014-7039	08/25/2014 09/23/2014	FDA/OC/OES/DFOI/	THOMAS #P-64423, EDWARD	CYMBALTA, GABAPENTIN, IBUPROFEN, ETC - AERS
2014-7040	08/25/2014 09/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	MARVIN SMOLLAR MEDSCIENCE RESEARCH GROUP LLC	LINCOLN DIAGNOSTICS INC - MULTI-TEST II DVC K961918
2014-7041	08/25/2014 09/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORA/ OC/ORA/ FDA/OGROP/ORASE-FO/FLA-	SARAH F KAAS CANNON & DUNPHY SC ATTYS	BAUSCH & LOMB - MURO 128 (SODIUM CHLORIDE HYPERTONICITY OPHTHALMIC OINTMENT 5%) - Cmplnts, TEST RESULTS, INVESTIGATIONS, ETC

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		DO/FLA-CB/		
2014-7042	08/25/2014 09/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	GERALYN MURRAY VITAL SIGNS INC	BIOMEDICAL DYNAMICS CORP - PRESSURE INFUSOR FOR IV BAGS K890268
2014-7043	08/25/2014 09/23/2014	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	BALIN MARTIN MD PHD, CHICAGO, IL - EIR, 483, CO RESP 3/13/13
2014-7044	08/25/2014 09/23/2014	FDA/OGROP/ORACE-FO/NWJDO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	BAYER HEALTHCARE PHARMACEUTICALS INC, PINE BROOK, NJ - EIR, 483, CO RESP 3/28/13
2014-7045	08/25/2014 09/23/2014	FDA/OGROP/ORASW-FO/KANDO/KAN-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	AAI PHARMA ANALYTICAL SERVICES ST LOUIS INC, AFFTON, MO - EIR, 483, CO RESP 1/31/14
2014-7046	08/25/2014 09/23/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	WALTER E CHALKLEY THOMSON REUTERS	AMGEN INC, LONGMONT, CO - EIR, 483, CO RESP 3/29/13
2014-7047	08/25/2014 09/23/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	WALTER E CHALKLEY THOMSON REUTERS	ARUP LABORATORIES INC, SALT LAKE CITY, UT - EIR, 483, CO RESP 2/22/13
2014-7048	08/25/2014 09/23/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	ASENTRAL IRB INC, NEWBURYPORT, MA - EIR, 483, CO RESP 5/14/13
2014-7049	08/25/2014 09/23/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	CARACO PHARMACEUTICAL LABORATORIES LTD, DETROIT, MI - EIR, 483S, CO RESP 1/11/13
2014-7050	08/25/2014 09/23/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	OPADA ALSOHAILI MD, DEARBORN, MI - EIR, 483, CO RESP 7/18/13-8/14/13
2014-7051	08/25/2014 09/23/2014	FDA/OGROP/ORASE-FO/FLADO/FLA-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	DR GILBERT A WEINER, MIAMI GARDENS-CETERO RESEARCH, MIAMI, FL - EIR, 483, CO RESP 9/23/13-11/25/13
2014-7052	08/25/2014 09/23/2014	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORASE-FO/FLADO/FLA-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	D'ARCY ACQUISITION LLC (DBA D'ARCY LABORATORIES), POMPANO BEACH, FL - EIR, 483, CO RESP 3/12/13
2014-7053	08/25/2014 09/23/2014	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	WALTER E CHALKLEY THOMSON REUTERS	PARTOW KEBRIAEI MD, HOUSTON, TX - EIR, 483, CO RESP 2/26/13
2014-7054	08/25/2014 09/23/2014	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	WALTER E CHALKLEY THOMSON REUTERS	SANDOZ INC, WILSON, NC - EIR, 483, CO RESP 4/23/13

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			(SCIENTIFIC) SAS	
2014-7055	08/25/2014 09/23/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	TOLMAR INC, FORT COLLINS, CO - EIR, 483, CO RESP 5/31/13
2014-7056	08/25/2014 09/23/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	CSL PLASMA, WEST LAFAYETTE, IN - EIR, 483, CO RESP 5/22/13
2014-7057	08/25/2014 09/23/2014	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	NOVARTIS VACCINES AND DIAGNOSTICS INC, EMERYVILLE, CA - EIR, 483, CO RESP 5/10/13
2014-7058	08/25/2014 09/23/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	MEDTRONIC INC, TEMPE, AZ - EIR, 483, CO RESP 5/14/13
2014-7059	08/25/2014 09/23/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	LORICON ANALYTICAL TESTING LAB, KEYPORT, NJ - EIR, 483, CO RESP 4/12/13
2014-7060	08/25/2014 09/23/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	INTERNATIONAL BIOLOGICS LLC, SCOTTSDALE, AZ - EIR, 483, CO RESP 2/1/13
2014-7061	08/25/2014 09/23/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	HOSPIRA BOULDER INC, BOULDER, CO - EIR, 483, CO RESP 5/15/13
2014-7062	08/25/2014 09/23/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	EMCURE PHARMACEUTICALS USA INC, EAST BRUNSWICK, NJ - EIR, 483, CO RESP 1/8/14
2014-7063	08/25/2014 09/23/2014	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	FRANCO FELIZARTA MD, BAKERSFIELD, CA - EIR, 483, CO RESP 5/24/13
2014-7064	08/25/2014 09/23/2014	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	GILEAD SCIENCES INC, FOSTER CITY, CA - EIR, 483, CO RESP 4/16/13
2014-7065	08/26/2014 09/24/2014	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Karie Fugate Fugate, Karie	AMERICAN REAGENT - RECALL RECS 02/14/2011 - 12/31/2011

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		FDA/OMPT/CDER/ORP/DIDP/		
2014-7066	08/26/2014 09/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jennifer Burlingame Burlingame, Jennifer L	SCREENING MAMMOGRAMS DONE IN 2013 IN NJ
2014-7067	08/26/2014 09/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	XVIVO PERFUSION SYSTEM (XPS) WITH STEEN - HDE RECS
2014-7068	08/26/2014 09/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	XVIVO PERFUSION SYSTEM WITH STEEN - HDE REVIEWER NOTES
2014-7069	08/26/2014 10/06/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Angela Herchy Bosley & Bratch	HEPATITIS VACCINE - RECALL RECS
2014-7070	08/26/2014 09/24/2014	FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/	Erin Gomes MASSACHUSETTS GENERAL HOSPITAL	MASSACHUSETTS GENERAL HOSPITAL, NUCLEAR MEDICINE PRODUCTION OF FDG - 483 06/01/2014 - 08/22/2014
2014-7071	08/26/2014 09/24/2014	FDA/OGROP/ORAPA-FO/SEA- DO/SEA-CB/	Joshua Malamud Hyman, Phelps & McNamara P.C.	NSPIRED NATURAL FOODS, ASHLAND, OR - 483, EIR 12/01/2013 - 08/22/2014
2014-7072	08/26/2014 09/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	INDIVIDUAL RECS
2014-7073	08/26/2014 09/24/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	KENDRA Y GOLDBIRSCHE WEITZ & LUXEMBERG PC	TYOKLAMED, ROTOCUT, GYNOCORE, ETC - MODIFICATIONS FOR PMA'S, 510KS, MDRS, ETC
2014-7074	08/26/2014 09/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	DAWN BENNETT PAGE GREENBERG TRAUER LLP	ULTRA LOW PROFILE RONGEUR - K062711; MICROBLADE SHAVERS & ACCESSORIES - K063231; ULTRA LOW PROFILE RONGEUR SYS - K040494, ETC
2014-7075	08/26/2014 09/24/2014	FDA/OGROP/ORACE-FO/CIN- DO/CIN-CB/ FDA/OGROP/ORACE-FO/DET- DO/DET-CB/ FDA/OGROP/ORACE-FO/PHI- DO/PHI-CB/ FDA/OGROP/ORANE-FO/NYK- DO/NYK-DCB/	CRASIG ROUSH ROCHLINE INDUSTRIES	US NONWOVENS CORP, BRENTWOOD, NY 4/14; FIRST QUALITY HYGIENIC, MCELHATTAN, PA 5/2014; FIRST QUALITY RETAIL SERVICES, KING OF PRUSSIA, AP, ETC - 5/13, EIRS, 483S, CORR
2014-7076	08/26/2014 09/24/2014	FDA/OC/OES/DFOI/	MARISA K COMMERFORD COMMERFORD LEGAL	TOWSNEND FARMS - ORGANIC ANTIOXIDANT BLEND, FROZEN BLEND CONTAINING POMEGRANATE SEED MIX INVESTIGATION
2014-7077	08/26/2014 09/24/2014	FDA/OC/OES/DFOI/	ROGER WHITE EMORY UNIV GOIZUETA BUSINESS SCHOOL	PUBLIC FINANCIAL DISCLOSURE RPT FORM SF 278 - FDA EMPLOYEES 2009-2013
2014-7078	08/26/2014	FDA/OMPT/CBER/OCOD/DDOM/		HEPATITIS B VACCINE - VAERS

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	09/24/2014	ALFB/	Doe J	
2014-7079	08/26/2014 09/24/2014	FDA/OC/OES/DFOI/	LAUREN S, BARR JH BARR & ASSOCIATES LLC	DAILY LOG 8/4-8/8/14
2014-7080	08/26/2014 09/24/2014	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 7/28/14-8/1/14
2014-7081	08/26/2014 09/24/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 7/28/14-8/2/14
2014-7082	08/26/2014 09/24/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 8/4-9/14
2014-7083	08/26/2014 09/24/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED DAILY LOG 8/4-8/14
2014-7084	08/26/2014 09/24/2014	FDA/OC/OES/DFOI/	SANDY FRIEDMAN WOLTERS KLUWER LAW & BUSINESS	CLOSED DAILY LOG 7/28/14-8/1/14
2014-7085	08/26/2014 09/24/2014	FDA/OC/OES/DFOI/	LISA TARRISON SCHRAMP CanReg, Inc.	DAILY LOG 8/4-14/14
2014-7086	08/26/2014 09/24/2014	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY CLOSED LOG 7/28/14-8/1/14
2014-7087	08/26/2014 09/24/2014	FDA/OC/OES/DFOI/	DAVID McFARLAND FDA REVIEW/FDA WEBVIEW	DAILY CLOSED LOG 7/28/14-8/1/14
2014-7088	08/26/2014 09/24/2014	FDA/OC/OES/DFOI/	DAVID McFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED DAILY LOG 8/4-14/14
2014-7089	08/26/2014 09/24/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OO/OHR/ FDA/OC/OES/DFOI/ FDA/OC/OES/	DUNCAN, HILARIO	CORR REGARDING ANNOUNCEMENT PH-NM-13-764407
2014-7090	08/26/2014 09/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANDREA FARAH SCOTT & SCOTT	SANDOZ - AMIODARONE HYDROCHLORIDE ANDA 75-315 LBLG 1/02 TO PRESENT
2014-7091	08/26/2014 09/24/2014	OC/ORO/OCI/ OC/ORO/OCI/	JOHN M. PADILLA PADILLA & RODRIGUEZ LLP	INDIVIDUAL RECS

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2014-7092	08/26/2014 10/24/2014	FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OES/DFOI/ FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/	JONI M. BORZCIK GORDON & REES LLP	PETITIONS SUBMITTED BY FDA BY AIIC OR PIGMENTS
2014-7093	08/26/2014 09/24/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	M. MELISSA BALTZ BUTLER SNOW ET AL	ETHICON INC - POLYPROPYLENE SUTURE USP NDA 16- 374 SUBMISSION LTR
2014-7094	08/26/2014 09/24/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	M. MELISSA BALTZ BUTLER SNOW ET AL	US SURGICAL CORP - NONABSORBABLE POLYPROPYLENE SURGICAL SUTURE 7/5/90 RECLASSIFICATION
2014-7095	08/26/2014 09/24/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	M. MELISSA BALTZ BUTLER SNOW ET AL	ETHICON - PROLENEPOLYPROPYLENE MESH 510K
2014-7096	08/26/2014 09/24/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	M. MELISSA BALTZ BUTLER SNOW ET AL	CERTIFIED LTR TO ETHICON FROM GEORGE LEONG OF FDA 4/26/73
2014-7097	08/26/2014 09/24/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	S. ALBERT EDWARDS S ALBERT EDWARDS PHARM D	SKELAXIN (METAXALONE) NDA 13-217
2014-7098	08/26/2014 09/24/2014	FDA/OGROP/ORASW-FO/FLA- DO/FLA-CB/	CHARLES CELESTE EAS CONSULTING GROUP LLC	ORTHOSENSOR INC, SUNRISE, FL - EIR, 483, CO RESP
2014-7099	08/27/2014 09/25/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OES/	Kerry Young Congressional Quarterly Roll Call	DEPUTY COMMISSIONER SKLAMBERG - MEETING WITH AMAZON 06/22/2014 - 08/21/2014

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2014-7100	08/27/2014 09/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	FOIA-8-25-2014-KLasers Erchonion Corporation	K-LASER - ENFORCEMENT RECS
2014-7101	08/27/2014 09/25/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	FOIA-8-25-2014_Larry Lylte Erchonion Corporation	LARRY LYLTE - ENFORCEMENT RECS
2014-7102	08/27/2014 09/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	FOIA-8-25-2014 Erchonion Corporation	STRAWBERRY LASER - ENFORCEMENT RECS
2014-7103	08/27/2014 09/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ryan Woods PRA Health Sciences	PRA EARLY DEVELOPMENT SERVICES, NETHERLANDS - EIR
2014-7104	08/27/2014 09/25/2014	FDA/OFVM/CFSAN/OCD/EOS/	Chris Lahiff McDermott Will & Emery LLP	GRAS NOTIFICATION 520 - DATE OF RECEIPT, POSTING
2014-7105	08/27/2014 10/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	Sara N. Kerrane K&L Gates LLP	ANEURX STENT GRAFT SYSTEM - APPLICATION RECS
2014-7106	08/27/2014 09/25/2014	OC/CVM/OCD/	Michelle Giuffrida University of Pennsylvania Veterinary Clinical Investigations Center	DONEZEPIL - PRECLINICAL RECS
2014-7107	08/27/2014 09/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	M. MELISSA BALTZ BUTLER SNOW ET AL	ETHICON INC - POLYPROPYLENE SUTURE USP TYPE A IND 1688 (CERTIFIED)
2014-7108	08/27/2014 09/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	FOIA-8-25-2014-Cutting Edge Erchonion Corporation	CUTTING EDGE LASER - ENFORCEMENT RECS
2014-7109	08/27/2014 09/25/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	James Gibson INTEGRITY LIFE SCIENCES	K102293
2014-7110	08/27/2014 09/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kiran Kumar Gande Appco Pharmaceuticals Corporation	NDA 020936 SBA
2014-7111	08/27/2014 09/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Brian Depew Engstrom Lipscomb and Lack	Electronic copies of the slides that were used to write the journal article "High fat diet and GLP-1 drugs induce pancreatic injury in mice" by Rodney Rouse published in Toxicology and Applied

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2014-7112	08/27/2014 09/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	FOIA-8-25-2014-Multi Radiance Erchonja Corporation	MULTI RADIANCE - ENFORCEMENT RECS
2014-7113	08/27/2014 09/25/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORR/SE-FO/FLA- DO/FLA-CB/	FOIA-8-25-2014-UltraSlim Erchonja Corporation	ULTRASLIM - ENFORCEMENT RECS
2014-7114	08/27/2014 09/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sarah Sellers q-Vigilance, LLC	COMPOUNDED TOPICAL PAIN CREAM, KETAMINE - AERS
2014-7115	08/27/2014 09/25/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Dave Kim Mtech Group	K023290
2014-7116	08/27/2014 09/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	David Petrocine Aceto Corporation	DELTA SYNTHETIC - 483, EIR
2014-7117	08/27/2014 09/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	Karen Denny TECHLAB, Inc.	K112422
2014-7118	08/27/2014 09/25/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2014-934 CERTIFIED
2014-7119	08/27/2014 09/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Donna Bitzelberger VENABLE LLP	NDA 19794 - APPROVAL LETTER (CERTIFIED)
2014-7120	08/27/2014 09/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Donna Bitzelberger VENABLE LLP	NDA 22267 APPROVABLE LETTER (CERTIFIED)
2014-7121	08/27/2014 09/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Donna Bitzelberger VENABLE LLP	NDA 21168 APPROVAL LETTER CERTIFIED
2014-7122	08/27/2014 09/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	Ana Maria Saaibi Biomedika Consulting	K053418, K982322

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2014-7123	08/27/2014 09/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sephy Philip Sephy Philip, RPh, PharmD	NDA 205060 - MEDICAL REVIEW
2014-7124	08/27/2014 09/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	HOSPIRA, LISCATE, ITALY - 483 MOST RECENT
2014-7125	08/27/2014 09/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kiran Kumar Gande Appco Pharmaceuticals Corporation	ANDA 077873, ANDA 091427 - SBA
2014-7126	08/27/2014 09/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	ANDA 075877 CERTIFIED
2014-7127	08/27/2014 09/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Donna Bitzelberger VENABLE LLP	NDA 18081, NDA 18082 CERTIFIED
2014-7128	08/27/2014 09/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	ANDA 200122 CERTIFIED
2014-7129	08/27/2014 09/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Donna Bitzelberger VENABLE LLP	NDA 20593 APPROVAL LETTER - CERTIFIED
2014-7130	08/27/2014 09/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	ANDA 078630 CERTIFIED
2014-7131	08/27/2014	FDA/OMPT/CDER/GRP/DIDP/	Jaime Vassallo	ANDA 076770 CERTIFIED

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	09/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LexisNexis CourtLink Document Retrieval	
2014-7132	08/27/2014 09/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	ANDA 076853 CERTIFIED
2014-7133	08/27/2014 09/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	ANDA 076887 CERTIFIED
2014-7134	08/27/2014 09/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	ANDA 078151 CERTIFIED
2014-7135	08/27/2014 09/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	A LUKE SMITH RADICE LAW FIRM	ANDA 90-446 - APRVL PKG
2014-7136	08/27/2014 09/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	A LUKE SMITH RADICE LAW FIRM	ANDA 200-484 - APRVL PKG
2014-7137	08/27/2014 09/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	A LUKE SMITH RADICE LAW FIRM	ANDA 200-484 - ROUTING SHEETS
2014-7138	08/27/2014 09/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	A LUKE SMITH RADICE LAW FIRM	ANDA 200-484 - APRVL LTRS
2014-7139	08/27/2014 09/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	A LUKE SMITH RADICE LAW FIRM	ANDA 090-446 - APRVL ROUTING SHEETS

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		FDA/OMPT/CDER/ORP/DIDP/		
2014-7140	08/27/2014 09/25/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	A LUKE SMITH RADICE LAW FIRM	ANDA 090-446 - APRVL LTRS
2014-7141	08/27/2014 09/25/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHANDRAN TIRUVATTAR DR REDDY'S LABORATORIES INC	PERRIGO, NY - PERMETHRIN ANDA 076-369 CHEMISTRY RVWS
2014-7142	08/27/2014 09/25/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHANDRAN TIRUVATTAR DR REDDY'S LABORATORIES INC	ACTAVIS - PERMETHRIN ANDA 074-086/S002 CHEMISTRY RVWS
2014-7143	08/27/2014 09/25/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHANDRAN TIRUVATTAR DR REDDY'S LABORATORIES INC	RENAISSANCE PHARMA - ELIMITE 019- 855/S006,S007,S004,S000 MFG CHANGE OR ADDITION, CHEMISTRY RVWS
2014-7144	08/27/2014 09/25/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELLIZABETH BARBCHENN PUBLIC CITIZEN	ONGLYZA (SAXAGLIPTIN) - NDA 22-350 TYPE 2 DIABETES MELLITUS RECS
2014-7145	08/27/2014 09/25/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	THOMAS J KEEGAN JR KEEGAN & KEEGAN ROSS & ROSNER LLP	PREMPRO - AERS
2014-7146	08/27/2014 09/25/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	JON P WIESMAN HR PHARMACUTICALS INC	BYK-GULDEN, INC, DAY-BALDWIN INC (DAY-BALDWIN, INC), DAY CHEMICAL CO, ETC - SURGILUBE OR FOILPAC FROMULATION CHANGE NOTICE, COMM, PHOTOS, ETC
2014-7147	08/28/2014 09/26/2014	FDA/OMPT/CDRH/OCER/DFOI/	DORI GLENN CARTIVA INC	ORTHOPAEDIC MEDICAL DVC - POST APRVL STUDY PROTOCOL
2014-7148	08/28/2014	OC/ORA/	BENJAMIN L ENGLAND ESQ	YANTAI CHINA PET FOODS CO LTD - PET CHEWS ENTRY

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	09/26/2014	OC/ORO/ FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	BENJAMIN L ENGLAND & ASSOCIATES LLC	NUMBERS WIG-4052047-8, WIG-4052076-7, WIG-4052098-1, ETC ENTRY PACKAGE, PRIVATE LABORATORY ANALYTICAL PACKAGES, NOTICES OF ACTION
2014-7149	08/28/2014 09/26/2014	FDA/OGROP/ORO/PA-FO/SEA-DO/SEA-CB/	JOSEPH E GRAFF JR GEORGIA-PACIFIC CHEMICALS LLC	GEORGIA-PACIFIC CHEMICALS LLC, ALBANY, OR - EIR 1/21-23/14 (CERTIFIED)
2014-7150	08/28/2014 09/26/2014	FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECS
2014-7151	08/28/2014 09/26/2014	FDA/OMPT/CDRH/OCER/DFOI/	RON KIM KIM, RON	RIFE MACHINE, GLOBAL WELLNESS PLUS, MICROCURRENT FREQUENCY GENERATOR RPTS, NOTES, INVESTIGATIONS, ETC 2005 TO PRESENT
2014-7152	08/28/2014 09/26/2014	FDA/OMPT/CDRH/OCER/DFOI/	D JEFFREY EZRA EZRA & ASSOCIATES LLC	LIFESTREAM PURIFICATION SYSTEMS LLC - ANGEL OF WATER CM-1 COLONIC HYDROTHERAPY SYS FDA FORM 3500A
2014-7153	08/28/2014 09/26/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	VAUGHN TUNSTALL NOVARTIS CORPORATION	NOVARTIS CORP, VACAVILLE, CA - RHPDGF PAI EIR 10/29/12-11/2/12
2014-7154	08/28/2014 09/26/2014	OC/ORO/ORM/ OC/ORO/ORM/	GAIL LESSICK LACHMAN CONSULTANT SERVICES, INC.	DRUG COMPANIES, MEDICAL DVC MFRS, BLOOD ESTABLISHMENTS, ETC - FOREIGN AND DOMESTIC INSPS 6/1-30/14
2014-7155	08/28/2014 09/26/2014	OC/CVM/OCD/	KRISTI O SMEDLEY Center for Regulatory Services, Inc.	LUITPOLD - ADEQUAN NADA 140-901 ANALYTICAL METHOD AND VALIDATION RPT
2014-7156	08/28/2014 09/26/2014	OC/CVM/OCD/	KRISTI O SMEDLEY Center for Regulatory Services, Inc.	LOHMANN ANIMAL HEALTH GMBH - PHYTASE FROM BIOENGINEERED PHICHIA PASTORIS FAP 2281
2014-7157	08/28/2014 09/26/2014	OC/CVM/OCD/	KRISTI O SMEDLEY PHD Center for Regulatory Services, Inc.	EXCENTIALS BV - L-SELENOMETHIONINE FAP 2278
2014-7158	08/29/2014 09/29/2014	FDA/OMPT/CDRH/OCER/DFOI/	Dave Kim Mtech Group	K110025
2014-7159	08/29/2014 09/29/2014	FDA/OGROP/ORO/PA-FO/SEA-DO/SEA-CB/	Sam Wheeler Mail Tribune	NSPIRED NATURAL FOODS, INC - EIR, 483 07/01/2014 - 08/22/2014
2014-7160	08/29/2014	FDA/OFVM/CFSAN/OCD/EOS/	Agriculture, Forestry, Fisheries and	TOKYO SHOKUHIN SANGYO CO LTD, YOKOI VINEGAR

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	09/29/2014		Food Research Division JETRO	BREWING CO, LTD - INSPECTION REPORTS
2014-7161	08/29/2014 09/29/2014	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Doe J	INTERSTATE BLOOD AND PLASMA, MADISON, WI - VIOLATIONS
2014-7162	08/29/2014 09/29/2014	FDA/OMPT/CDRH/OCER/DFOI/	Michael Zilm UNIVERSITY OF CONNECTICUT	K964970
2014-7163	08/29/2014 09/29/2014	FDA/OMPT/CDRH/OCER/DFOI/	Michael Zilm UNIVERSITY OF CONNECTICUT	K000696
2014-7164	08/29/2014 09/29/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Hayley Lewis Carbylan Therapeutics, Inc	AMRI, BURLINGTON, MA - EIR 01/01/2014 - 08/26/2014
2014-7165	08/29/2014 09/29/2014	FDA/OC/OES/DFOI/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Reed Schifferman Law Offices of Reed Schifferman	BAXANO IO-FLEX SYSTEM
2014-7166	08/29/2014 09/29/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K091934
2014-7167	08/29/2014 09/29/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K122106
2014-7168	08/29/2014 09/29/2014	FDA/OC/OES/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Miguel Echavarri InteliMap, Inc.	TEKMIRA - EMAIL WITH FDA OCTEC 07/21/2014 - 08/28/2014
2014-7169	08/29/2014 09/29/2014	FDA/OO/OHR/ FDA/OFVM/CFSAN/OCD/EOS/	Veronica Moten Veronica Moten	JUSTIFICATION FOR NEW HIRES, BACKFILLS SUBMITTED BY OMS OM 04/01/2011 - 08/30/2012
2014-7170	08/29/2014 09/29/2014	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Rachel Johnson FOI Services, Inc.	HP HOOD, WINCHESTER, VA - 483
2014-7171	08/29/2014 09/29/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-4452
2014-7172	08/29/2014 09/29/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-4780
2014-7173	08/29/2014 09/29/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	John A. Gorney Elba Laboratories	ELBA LABORATORIES, TROY, MI - EIR 01/01/2011 - 08/20/2014

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2014-7174	08/29/2014 09/29/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-4972
2014-7175	08/29/2014 09/29/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-4987
2014-7176	08/29/2014 09/29/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED DAILY LOG 8/18-22/14
2014-7177	08/29/2014 09/29/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED DAILY LOG 8/11-15/14
2014-7178	08/29/2014 09/29/2014	FDA/OC/OES/DFOI/	DAVID McFARLAND FDA REVIEW/FDA WEBVIEW	DAILY LOG 8/11-15/14
2014-7179	08/29/2014 09/29/2014	FDA/OC/OES/DFOI/	DAVID McFARLAND FDA REVIEW/FDA WEBVIEW	DAILY CLOSED LOGS 8/18-22/14
2014-7180	08/29/2014 09/29/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED DAILY LOG 8/11-16/14
2014-7181	08/29/2014 09/29/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 8/18-23/14
2014-7182	08/29/2014 09/29/2014	FDA/OC/OES/DFOI/	LAUREN S, BARR JH BARR & ASSOCIATES LLC	CLOSED DAILY LOG 8/18-22/14
2014-7183	08/29/2014 09/29/2014	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY CLOSED LOG 8/11-15/14
2014-7184	09/02/2014 09/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	Genevieve DellaFera FERA PHARMACEUTICALS	K843919
2014-7185	09/02/2014 09/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	Michael Joliat Anderson, Helgen, Davis & Nissen PA	T SPOT-TB TEST - PMA RECS
2014-7186	09/02/2014 09/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Donna Bitzelberger VENABLE LLP	NDA 18723 CERTIFIED
2014-7187	09/02/2014 09/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	BRICANYL NDA 017466 - APPROVED LABELING S 24 (CERTIFIED)

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-7188	09/02/2014 09/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	BRICANYL NDA 017618 - APPROVED LABELING S036 (CERTIFIED)
2014-7189	09/02/2014 09/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	M MELISSA BALTZ BUTLER SNOW ET AL	ETHICON - GYNECARE PROSIMA PELVIC FLOOR REPAIR SYS SUBMISSION OF SUBSTANTIAL EQUIVALENCE LTR K063562, 1/25/07, 2/26/07 (CERTIFIED)
2014-7190	09/02/2014 09/30/2014	OC/CVM/OCD/	Tom Polansek REUTERS	ZILMAX, ZILPATEROL - COMM WITH FDA, PATHOLOGICAL STUDIES, ETC
2014-7191	09/02/2014 09/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	BRETHINE NDA 017848 S 039 - LABELING (CERTIFIED)
2014-7192	09/02/2014 09/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	ANDA 077152 - APPROVAL PACKAGE, SBA (CERTIFIED)
2014-7193	09/02/2014 09/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Donna Bitzelberger VENABLE LLP	NDA 20320 - APPROVAL LETTER (CERTIFIED)
2014-7194	09/02/2014 09/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	NDA 20398
2014-7195	09/02/2014 09/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sarah Sellers q-Vigilance, LLC	AERS - 8484587 8525697 8565290 ETC
2014-7196	09/02/2014 09/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Donna Bitzelberger VENABLE LLP	NDA 19680 - APPROVAL LETTER (CERTIFIED)

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2014-7197	09/02/2014 09/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	James McNab Slate Path Capital	ACTHAR GEL - AERS
2014-7198	09/02/2014 09/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	M MELISSA BLATZ BUTLER SNOW ET AL	ETHICON - GYNECARE PROLIFT & PROLIFT+ M PELVIC FLOOR REPAIR SYS 510K SUBMISSION OF SUBSTANTIAL EQUIVALENCE, LTR 9/19/07, 5/15/2008 (CERTIFIED)
2014-7199	09/02/2014 09/30/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Roy Strait Roy D. Strait	EPIDURAL STEROIDS - STUDIES, AERS, WARNING LETTERS 08/01/2013 - 08/01/2014
2014-7200	09/02/2014 09/30/2014	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Katherine Eban FORTUNE MAGAZINE	CETERO RESEARCH - STUDIES, CORR ETC 01/01/1990 - 08/26/2014
2014-7201	09/02/2014 09/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	James McNab Slate Path Capital	NDA 008372 - DESI UPGRADE REVIEW
2014-7202	09/02/2014 09/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	BRICANYL NDA 018000 - ORIGINAL APPROVED LABELING (CERTIFIED)
2014-7203	09/02/2014 09/30/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CTP/OD/	Desmond Jenson Tobacco Control Legal Consortium	CAPSULE CIGARETTES - COMM, ADVERTISEMENTS, ETC
2014-7204	09/02/2014 09/30/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Laura Chico ROBERT W. BAIRD & CO INC	ALEXION PHARMACEUTICALS, SMITHFIELD, RI - 483 08/01/2014 - 08/31/2014
2014-7205	09/02/2014 09/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dilek Necioglu Orken Istanbul Bilim University	GLATIRAMER ACETATE - AERS

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2014-7206	09/02/2014 10/15/2014	FDA/OC/OES/ OC/ORO/ OC/ORO/	Stacy Ehrlich KKB	MEETING BETWEEN HOWARD SKLAMBERG AND AMAZON - CORR, RECS
2014-7207	09/02/2014 09/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Charles E. Adler Adler Law Offices, Ltd.	XARELTO - AERS FROM ILLINOIS
2014-7208	09/02/2014 09/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	M MELISSA BALTZ BUTLER SNOW ET AL	ETHICON - GYNEMESH PROLENE SOFT K013718 SUBMISSION OF SUBSTANTIAL EQUIVALENCE 11/6/01, LTR ACKNOWLEDGING RECEIPT OF K013718 SUBMISSION 11/9/01, SUBSTANTIAL EQUIVALENCE LTR FOR K013718 WITH INDICATIONS FOR USE (CERTIFIED)
2014-7209	09/02/2014 09/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	M MELISSA BALTZ BUTLER SNOW ET AL	ETHICON - MODIFIED PROLENE SOFT 510K SUBSTANTIAL EQUIVALENCE 4/6/00, PROLENE SOFT K001122 SUBSTANTIAL EQUIVALENCE LTR 5/23/00
2014-7210	09/02/2014 09/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	M MELISSA BALTZ BUTLER SNOW ET AL	ETHICON - GYNECARE TVT ABBREVO CONTINENCE SYS 510K SUBSTANTIAL EQUIVALENCE 4/2/10, K100936 RECEIPT LTR 4/5/10; ETHICON, SUSAN LIN; GYNECARE TVT ABBREVO CONTINENCE SYS DVC EMAIL, LTR, ATTACHMENTS I & II REVISED IFU, ETC (CERTIFIED)
2014-7211	09/02/2014 09/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	K090845
2014-7212	09/02/2014 09/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	M MELISSA BALTZ BUTLER SNOW ET AL	ETHICON - TVT SYS 510K SUBMISSION OF SUBSTANTIAL EQUIVALENCE 10/29/97; ETHICON - TVT SYS K974098 LTR ACKNOWLEDGING RECEIPT 10/31/97; ETHICON - TVT SYS K974098 LTR PROVIDING UPDATED PI 1/21/98, ETC (CERTIFIED)
2014-7213	09/02/2014 09/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DDM/	Charles Wescott Charles Wescott	DKT 84D-0115 FINAL GUIDELINE
2014-7214	09/02/2014 09/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Pallavi Ail The Financial Express	GENERIC DRUGS - AERS
2014-7215	09/02/2014	FDA/OMPT/CDRH/OCER/DFOI/	Emre Yilmaz	K053088, K061176, K123627 ETC

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	09/30/2014	FDA/OC/OES/DFOI/	Kaiser Technology	
2014-7216	09/02/2014 09/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sarah Sellers q-Vigilance, LLC	AERS 8025025, 8026148, 8031996, ETC
2014-7217	09/02/2014 09/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	M MELISSA BALTZ BUTLER SNOW ET AL	ETHICON - GYNECARE TVT EXACT CONTINENCE SYS 510K SUBSTANTIAL EQUIVALENCE 2/18/10; ETHICON - TVT EXACT CONTINENCE SYS K100485 LTR ACKNOWLEDGING RECEIPT 2/19/10; ETHICON - GYNECARE TVT EXACT CONTINENCE SYS K100485 WITH INDICATIONS FOR USE SUBSTANTIAL EQUIVALENCE LTR 3/16/10 (CERTIFIED)
2014-7218	09/02/2014 09/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	FDA 510K - K042018 Simply Clean Air & Water	K042018
2014-7219	09/02/2014 09/30/2014	OC/CVM/OCD/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KRISTI O SMEDLEY Center for Regulatory Services,Inc.	IPCA LABORATORIES LTD, MUMBAI, MAHARASHTRA, INDIA - EIRS, 483S 1/10 TO PRESENT
2014-7220	09/02/2014 09/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KRISTI O SMEDLEY Center for Regulatory Services,Inc.	SHANDONG LUKANG SHELILE PHARMACEUTICAL CO , JINING CITY, SHANDGIONG, CHINA - EIRS, 483S 5/11 TO PRESENT
2014-7221	09/02/2014 09/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	MICHAEL E TOMPKINS HANGER INC	HANGER INC - CRANIAL BAND K001669
2014-7222	09/02/2014 09/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JEREMY C CAIN GIDEON COOPER & ESSARY	PFIZER, TEVA - METHYLPREDNISOLONE ACETATE INJ SUSPENSION 80 MG/ML APRVL RECS
2014-7223	09/02/2014 09/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANDREA FARAH SCOTT & SCOTT LLP	SANDOZ (EON LABS INC) - AMIODARONE HCL LABEL, APRVL LTRS, ARPPROVING LBLG, REVISIONS UPDATES 5 MOST RECENT
2014-7224	09/02/2014 09/30/2014	FDA/OC/OES/DDM/	MCKENZIE CATO Hyman, Phelps & McNamara P.C.	DKT 1976N-0406 - COMMENTS, ATTACHMENTS
2014-7225	09/02/2014	FDA/OMPT/CDER/ORP/DIDP/	TAMYRA TOOLE	ZYDELIG (IDELALLISIB) - NDA 205-858 SUMMARY RVW,

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	09/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	INFINITY PHARMACEUTICALS	MEDICAL RVW, STATISTICAL RVW
2014-7226	09/02/2014 09/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TEAGUE H SCOTT SCOTT B-78780, TEAGUE H	ELAVILLE (AMITRIPTYLINE HCL) - BLACK BOX WARNINGS
2014-7227	09/02/2014 09/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ALBERT EDWARDS S ALBERT EDWARDS PHARM D	SKELAXIN (METAXALONE) 800 MG LTABS - NDA 13-217 APRVL LTR 10/62 THRU 9/87, NAS/NRC RECS 1968, DESI-2 RECS 1987, ETC
2014-7228	09/02/2014 09/30/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OO/OHR/	HILARIO R DUNCAN DUNCAN, HILARIO	PH-NM-13-764407
2014-7229	09/02/2014 09/30/2014	FDA/OMPT/CDRH/OCER/DFOI/ OC/CVM/OCD/	Rachel Johnson FOI Services, Inc.	ABBOTT MEDICAL OPTICS, UPPSALA, SWEDEN - EIR 08/29/2013 - 09/06/2013
2014-7230	09/02/2014 09/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	Amy Englebert Parker Hannifin Corp Porter Instrument Division	K884879, K945722
2014-7231	09/02/2014 09/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOSEPH WALKER Walker, Joseph	SOVALDI - CASE REPORTS
2014-7232	09/02/2014 09/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	ANDA 076770, ANDA 076853, ANDA 076887 ETC - APPROVAL, SBA (CERTIFIED)
2014-7233	09/02/2014 09/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	JOSEPH WALKER Walker, Joseph	Copies of the Meeting Participant List for COI Screening Package documents or related documents that were created CDRH Medical Devices Advisory Committee Panels.
2014-7234	09/02/2014 09/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	Christopher Gansen Gansen Law Group, P.C.	THE STANDING COMPANY - MDR RECS
2014-7235	09/02/2014 09/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 22219

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		FDA/OMPT/CDER/ORP/DIDP/		
2014-7236	09/02/2014 09/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joshua Malamud Hyman, Phelps & McNamara P.C.	ANDA 091424 APPROVAL LETTER
2014-7237	09/02/2014 09/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	ZANTAC 150 MG - AERS
2014-7238	09/02/2014 09/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joshua Malamud Hyman, Phelps & McNamara P.C.	A copy of any determination by FDA that the first company to submit an ANDA for Minocycline HCl Extended-release Tablets, 80 mg and 105 mg, containing a Paragraph IV certification forfeited eligibility for 180-day exclusivity for such strengths, or otherwise maintains eligibility for such exclusivity
2014-7239	09/02/2014 09/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Beverly W. Henderson Beverly W. Henderson	PROLIA - COMPLAINTS, RECOMMENDATIONS FOR USE
2014-7240	09/02/2014 09/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Emily Krulewitz The Weinberg Group	VASOPRESSIN NDA 204485 - LABEL
2014-7241	09/02/2014 09/30/2014	OC/CVM/OCD/	Krista Bockstahler Bockstahler, Krista	ED50 and LD50 of oral glycopyrrolate in humans and animals to include any graph or chart
2014-7242	09/02/2014 09/30/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Seth Weaver INDIVIDUAL	MUSCULOSKELETAL TRANSPLANT FOUNDATION - 483
2014-7243	09/02/2014 09/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	MARCK BIOSCIENCES LTD, TAL MARAR, KEDA, INDIA - 483S 10/29/13-11/01/13

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2014-7244	09/02/2014 09/30/2014	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	Andrew T Ryan Ryan Law, APLC	MINICAPS - RECS RE DESTRUCTION 04/11/2013 - 08/28/2014
2014-7245	09/02/2014 09/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	DR RAJA T ABOUD, (SEYMOUR MEDICAL CLINIC), VANCOUVER, CANADA - 483S 4/14-25/14
2014-7246	09/02/2014 09/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	K133540 ProMedic, Inc.	K133540
2014-7247	09/02/2014 09/30/2014	FDA/OC/OES/DFOI/	ZACHARY MARKER Center For Food Safety	USDA AUTHORITY TO REGULATE THE USE OF, OR LABEL SEEDS TREATED WITH NEONICOTINOIDS, PESTICIDES OR FUNGICIDES, ETC
2014-7248	09/02/2014 09/30/2014	OC/ORACE/ OC/ORACE/	Doe J	SEIZED FUNDS
2014-7249	09/02/2014 09/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/CVM/OCD/	KRISTI O. SMEDLEY, Ph.D. Center for Regulatory Services, Inc.	IPCA LABORATORIES LTD, AURANGABAD, MAHARASHTRA, INDIA - 483S, EIRS 2010 TO PRESENT
2014-7250	09/02/2014 09/30/2014	OC/CVM/OCD/	KRISTI O. SMEDLEY, Ph.D. Center for Regulatory Services, Inc.	IPCA LABORATORIES LTD, MADHYA PRADESH, INDIA - EIR, 483 1/10 TO PRESENT
2014-7251	09/02/2014 09/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KRISTI O. SMEDLEY, Ph.D. Center for Regulatory Services, Inc.	ZHEJIANG APELOA KANGYU PHARMACEUTICAL, DONGYANG, ZHEJIANG, CHINA - 483, EIR 1/11 TO PRESENT
2014-7252	09/02/2014 09/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/CVM/OCD/	KRISTI O. SMEDLEY, Ph.D. Center for Regulatory Services, Inc.	HUVEPHARMA, PESHTERA, BULGARIA - EIR, 483 1/10 TO PRESENT
2014-7253	09/02/2014 09/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KRISTI O. SMEDLEY, Ph.D. Center for Regulatory Services, Inc.	BIOVET JCS, RAZGRA, BULGARIA - EIR, 483 2009 TO PRESENT

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-7254	09/02/2014 09/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KRISTI O. SMEDLEY, P.h.D. Center for Regulatory Services,Inc.	BIOVET JSC, SHIP, MACEDONIA - EIR, 483 1/09 TO PRESENT
2014-7255	09/02/2014 09/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KRISTI O. SMEDLEY, Ph.D. Center for Regulatory Services,Inc.	HUVEPHARMA, BOTEVGRAD, BULGARIA - EIR, 483 1/09 TO PRESENT
2014-7256	09/02/2014 09/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/CVM/OCD/	KRISTI O. SMEDLE, Ph.D. Center for Regulatory Services,Inc.	NINGXIA TAIRUI PHARMACEUTICAL CO LTD, WANG YUAN ECONOMIC ZONE, YINCHAUN, NINGXIA, CHINA - EIR, 483 1/10 TO PRESENT
2014-7257	09/02/2014 09/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/CVM/OCD/	KRISTI O. SMEDLEY, Ph.D. Center for Regulatory Services,Inc.	SHANDONG LUKANG BIOMANUFACTURING CO LTD, ZOUCHENG INDUSTRIAL ZONE, JINING, SHANDONG, CHINA - EIR, 483 1/11 TO PRESENT
2014-7258	09/02/2014 09/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KRISTI O. SMEDLEY, Ph.D. Center for Regulatory Services,Inc.	ZHEJIANG APELAO KANGYU BIOPHARMACEUTICAL, GESHAN INDUSTRIAL ZONE, DONGYANG, ZHEJIANG, CHINA - EIR, 483 1/11 TO PRESENT
2014-7259	09/02/2014 09/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHOBHA REDDY CHAGAM DR REDDYS LABORATORIES INC	AMEDRA PHARMACEUTICALS - ALBENZA NDA 20-666 SBA
2014-7260	09/03/2014 10/01/2014	FDA/OC/OES/DFOI/	Melissa Walker Graematter, Inc.	LIST OF CLEARED 510K NUMBERS
2014-7261	09/03/2014 10/01/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Heather DeAtley Loop Compounding Pharmacy	Adenosine 5 monophosphate chemical/drug removed from market due to the lack of safety/effectiveness information

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2014-7262	09/03/2014 10/01/2014	FDA/OMPT/CDRH/OCER/DFOI/	Vik Bajnath ARTHREX INC.	MW50356513 - FACILITY NAME, PHONE NUMBER
2014-7263	09/03/2014 10/01/2014	FDA/OMPT/CDRH/OCER/DFOI/	Joseph Pergolizzi NativeCardioVascular	K944957
2014-7264	09/03/2014 10/01/2014	FDA/OMPT/CDRH/OCER/DFOI/	Native CardioVascular NativeCardioVascular	K935674
2014-7265	09/03/2014 10/01/2014	FDA/OC/OES/DFOI/ FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Grant Morris Sanford Heisler, LLP	DEPUY ORTHOPAEDICS, INC - EIR EXHIBITS
2014-7266	09/03/2014 10/01/2014	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	Hana Hakim Hakim, Hana	ST JUDE CHILDREN'S RESEARCH HOSPITAL, MEMPHIS, TN - TEST RESULTS 06/27/2014 - 08/22/2014
2014-7267	09/03/2014 10/01/2014	FDA/OMPT/CDRH/OCER/DFOI/	Laurie DiLiddo DaVINCI Biomedical Research	K120025
2014-7268	09/03/2014 10/01/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Victoria Rothwell Immunexpress	K073482
2014-7269	09/03/2014 10/01/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Ross Comeaux COMEAX, DESIREE T	FDA LICENSED US BASED PLASMA COLLECTION CENTERS 2011-2013
2014-7270	09/03/2014 10/01/2014	FDA/OMPT/CDRH/OCER/DFOI/	Dorothy Latta LATTA, DOROTHY	K102452
2014-7271	09/03/2014 10/01/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	INDIVIDUAL RECS
2014-7272	09/03/2014 10/01/2014	FDA/OMPT/CDRH/OCER/DFOI/	Joseph Pergolizzi NativeCardioVascular	K024071
2014-7273	09/03/2014 10/03/2014	FDA/OC/OES/	Brady Dennis THE WASHINGTON POST	COMM MARGARET HAMBURG - WEEKLY SCHEDULES, LISTS OF MEETINGS, TRAVEL PLANS 05/22/2009 - 08/29/2014
2014-7274	09/03/2014 10/01/2014	FDA/OFVM/CFSAN/OCD/EOS/	Jason TEixeira Mid-Atlantic Supplements	SAFETY REPORTING PORTAL - REPORT RESULTS 28646 ICSR 1035798
2014-7275	09/03/2014 10/01/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Brady Dennis THE WASHINGTON POST	JANET WOODCOCK - WEEKLY SCHEDULES, LISTS OF MEETINGS, TRAVEL PLANS 01/21/2013 - 08/29/2014

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2014-7276	09/03/2014 10/01/2014	FDA/OFVM/CFSAN/OCD/EOS/	Brady Dennis THE WASHINGTON POST	MICHAEL TAYLOR - WEEKLY SCHEDULES, LISTS OF MEETINGS, TRAVEL PLANS 01/20/2013 - 08/29/2014
2014-7277	09/03/2014 10/01/2014	FDA/OO/OFBA/OAGS/	Brian K. Cummings, Federal Compliance Manager LexisNexis, a division of Reed Elsevier, Inc.	CONTRACTS AND PURCHASE ORDERS ETC FOR ONLINE LEGAL, NEWS, FINANCIAL ETC WITH THOMSON-WEST, WESTLAW, THOMSON REUTERS ETC
2014-7278	09/03/2014 10/01/2014	OC/CVM/OCD/	Breanne Hughes Merial Ltd.	IVERMECTIN - HEARTWORM CASES
2014-7279	09/03/2014 10/01/2014	FDA/OC/OES/DFOI/	Kari Twaite BEVERIDGE & DIAMOND PC	FOIA REQUESTS FOR CFSAN 7/23/14 TO 8/29/14
2014-7280	09/03/2014 10/01/2014	FDA/OGROP/ORAP/PA-FO/SEA-DO/SEA-CB/	Lynne Terry THE OREGONIAN	NSPIRED NATURAL FOODS INC, ASHLAND, OR - 483 12/01/2013 - 08/21/2014
2014-7281	09/03/2014 10/01/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kathryn Donnelly Donnelly, Kathryn	FIRST MEDICAL DEVICES APPROVED BY FDA TO TEST HUMAN THYROID STIMULATING HORMONE
2014-7282	09/03/2014 10/01/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Todd Cameron Hamilton Todd Cameron Hamilton	OCTAPharma PLASMA INC, KALAMAZOO, MI, CHARLOTTE, NC - INSPECTIONS, COMM ETC 05/01/2014 - 08/30/2014
2014-7283	09/03/2014 10/01/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	david gortler Georgetown University	ANDA 085635
2014-7284	09/03/2014 10/01/2014	FDA/OFVM/CFSAN/OCD/EOS/	Kuen Lee Maha food safety consulting	DAE SANG FOOD PLANT, KI HEUNG, KOREA - 483 12/02/2014 - 09/01/2014
2014-7285	09/03/2014 10/01/2014	FDA/OC/OES/DFOI/	Barry Sands MCPHS	WARNING LETTERS TO IRBS
2014-7286	09/03/2014 10/01/2014	FDA/OMPT/CDRH/OCER/DFOI/	Hassaan Ahmad Sunaris, Inc.	K071519
2014-7287	09/03/2014 10/01/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dean Gresham GRESHAM PC ATTY AT LAW	QUESTCOR - CORR WITH FDA RE MISLABELING OF HP ACTHAR GEL

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		FDA/OMPT/CDER/ORP/DIDP/		
2014-7288	09/03/2014 10/01/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	G. Srinivas Zydus Pharmaceuticals USA Inc.	EXPAREL - SBA
2014-7289	09/03/2014 10/01/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Aydin Harston ROTHWELL, FIGG, ERNST & MANBECK, P.C.	NDA 010374 - APPROVAL LETTER
2014-7290	09/03/2014 10/01/2014	FDA/OC/OES/DDM/	G. Srinivas Zydus Pharmaceuticals USA Inc.	CORE PHARMA - CITIZEN PETITION 11/5/02
2014-7291	09/03/2014 10/01/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Herbert Spann Snyder Industries, Inc.	K944121, K980179
2014-7292	09/03/2014 10/01/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Aydin Harston ROTHWELL, FIGG, ERNST & MANBECK, P.C.	NDA 012102 APPROVAL LETTER
2014-7293	09/03/2014 10/01/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Aydin Harston ROTHWELL, FIGG, ERNST & MANBECK, P.C.	NDA 016126 APPROVAL LETTER
2014-7294	09/03/2014 10/01/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Aydin Harston ROTHWELL, FIGG, ERNST & MANBECK, P.C.	NDA 013296 APPROVAL LETTER
2014-7295	09/03/2014 10/01/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	G. Srinivas Zydus Pharmaceuticals USA Inc.	CELESTONE SOLUSPAN - SBA
2014-7296	09/03/2014 10/01/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Stacie Wehling Scilucent, LLC	NDA 012250 - SBA

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2014-7297	09/03/2014 10/01/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	MICHAEL MANCINELLI CONWAY HOMER & CHIN- CAPLAN PC	INDIVIDUAL RECS
2014-7298	09/03/2014 10/08/2014	FDA/OC/OES/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	NELL GREENFIELDBOYCE NPR	MARGARET HAMBURG, JANET WOODCOCK, KAREN MIDTHUN, ETC - EMAILS CONTAINING THE WORD EBOLA AND/OR EVD 3/14/14 TO 8/24/14
2014-7299	09/03/2014 10/01/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	JEFFREY, HAU HAU, JEFFREY	DEPUY, SYNTHES, STRYKER, ETC - SPINAL FUSION/PROCEDURE IMPLANTS WARNING LTRS, EFFICACY STUDIES
2014-7300	09/03/2014 10/01/2014	FDA/OMPT/CDRH/OCER/DFOI/	PHIL JONES PERFORMACE ENTERPRISES	PERFORMANCE ENTERPRISES - DYNAVISION 2000 K911938
2014-7301	09/03/2014 10/01/2014	FDA/OFVM/CFSAN/OCD/EOS/	KRISTIE INMON INMON, KRISTIE	HOME PRESSURE CANNING POTATOES WITH THE PEELING - RESEARCH, STUDIES
2014-7302	09/03/2014 10/01/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TAMYRA TOOLE JD RN INFINITY PHARMACEUTICALS	IMBRUVICA (IBRUTINIB) NDA 205-552 - SUMMARY RVW, MEDICAL RVWS, STATISTICAL RVWS
2014-7303	09/03/2014 10/01/2014	OC/ORA/ORM/ OC/ORA/ORM/	RAY THOMPSON THOMPSON, RAY	GMP, GLP, GCP INSPS 2/1/14 TO 8/1/14
2014-7304	09/04/2014 10/02/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kerry Beckett NORTHWEST CLINICAL RESEARCH GROUP	K123803
2014-7305	09/04/2014 10/02/2014	FDA/OMPT/CDRH/OCER/DFOI/	Dennis Genito MAQUET CARDIOVASCULAR	K140603
2014-7306	09/04/2014 10/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Allison Tarantino ARIAD Pharmaceuticals, Inc.	ICLUSIG - AERS
2014-7307	09/04/2014 10/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Denise Hein N/A	MERCK - WARNING LETTER INSPECTION RECS, RESPONSES 06/01/2011 - 07/01/2011

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		FDA/OMPT/CDER/ORP/DIDP/		
2014-7308	09/04/2014 10/02/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Alexandra Scranton Women's Voices for the Earth	K071827
2014-7309	09/04/2014 10/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michelle Vaughn SouthEast Alaska Regional Health Consortium	TRICYCLIC ANTIDEPRESSANT - AERS
2014-7310	09/04/2014 10/02/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Kelly Feil, Paralegal MINTZER, SAROWITZ, ZERIS, LEDVA & MEYERS, LLP	FEI INC, HARRISBURG, PA - RECS RE POSSIBLE ANHYDROUS AMONIA LEAK
2014-7311	09/04/2014 10/02/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Denise Hein N/A	MERCK AND COMPANY - 483 ETC 11/26/2007 - 04/28/2008
2014-7312	09/04/2014 04/02/2015	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Denise Hein N/A	FDA INFORMATION ON GARDISIL - PRESENCE OF DNA FRAGMENTS EXPECTED, NO SAFETY RISK - REPORTS, RESEARCH ETC
2014-7313	09/04/2014 10/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Olena Izhak University of Helsinki (FINLAND)	ANDA APPROVAL LETTERS
2014-7314	09/04/2014 10/02/2014	FDA/OFVM/CFSAN/OCD/EOS/	Steven Overly THE WASHINGTON POST	STAR SCIENTIFIC - WARNING LETTER RECS 11/01/2013 - 09/02/2014
2014-7315	09/04/2014 10/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Vassilios Christodouloupoulos Euro-Pharm International Canada Inc.	NDA 020064 S000 TO S022
2014-7316	09/04/2014 10/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Robin Huff Quintiles	STUDY 87-1D - MEDICAL REVIEWS
2014-7317	09/04/2014 10/02/2014	FDA/OC/OES/DFOI/	G David Godwin Carroll Burdick & McDonough LLP	TOWNSEND FARMS - OUTBREAK RECS 2013
2014-7318	09/04/2014 10/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Paul Greenberg Analysis Group, Inc.	JOHN BUSE, MARY PARKS, HYLTON JOFFEE ETC - COMMUNICATIONS RE AMERICAN DIABETES ASSOCIATION CONFERENCE IN NEW ORLEANS 2009 04/01/2009 - 02/01/2010

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2014-7319	09/04/2014 10/02/2014	FDA/OC/OES/DFOI/ FDA/OGROP/ORAP/FO/SAN-DO/SAN-CB/	ANDREW MENSAH MENSAH, ANDREW	S&W FINE FOODS, INC, SAN FRANCISCO, CA - INSPECTION REPORTS
2014-7320	09/04/2014 10/02/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	510K REDACTED IN AUGUST 2014
2014-7321	09/04/2014 10/02/2014	OC/ORAP/ORM/ OC/ORAP/ORM/	Jason DeYoung DeYoung, Jason	LIST OF FIRMS INSPECTED LAST FIVE YEARS IN MICHIGAN, INDIANA, PENNSYLVANIA, OHIO
2014-7322	09/04/2014 10/02/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ryan Smith Janus Capital Group ATTN: RYAN SMITH	IMBRUVICA - AERS
2014-7323	09/04/2014 10/02/2014	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2014-6727
2014-7324	09/04/2014 10/02/2014	FDA/OMPT/CDRH/OCER/DFOI/	Serban P. Georgescu, MD InfoBionic Inc	K121197
2014-7325	09/04/2014 10/02/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	M MELISSA BALTZ BUTLER SNOW ET AL	ETHICON - PROLENE POLYPROPYLENE SUTURE NDA 16-374 10/29/73 LTR SUBMITTING CHANGES TO NDA, 2/26/75 SUPPLEMENTAL SUBMISSION, 5/22/75 LTR SENDING SOME ADDITIONAL RECS AS REQUESTED IN THE 2/26/75 SUBMISSION, ETC (CERTIFIED)
2014-7326	09/04/2014 10/02/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	M MELISSA BALTZ BUTLER SNOW ET AL	ETHICON - PROLENE POLYPROPYLENE SUTURE NDA 16-374 5/8/70 LTR APPROVING SUPPLEMENTAL APPL SUBMITTED 10/30/69, 6/14/71 LTR SUBMITTING SECOND SEMI-ANNUAL EXPERIENCE RPT, 5/15/72 LTR SUBMITTING AMENDMENT TO THE NDA, ETC (CERTIFIED)
2014-7327	09/04/2014 10/02/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	M MELISSA BALTZ BUTLER SNOW ET AL	ETHICON - PROLENE POLYPROPYLENE SUTURE NDA 16-374 7/15/76 LTR SUBMITTING: ANNUAL EXPERIENCE RPT FROM 4/75 TO 4/76, 10/22/76 LTR STATING THEY ARE TREATING THE 7/15/76 SUBMISSION AS A SUPPLEMENTAL APPL & APPROVING IT (S011), 11/16/77 LTR SUBMITTING CHANGES TO NDA (S012), ETC (CERTIFIED)

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		FDA/OMPT/CDRH/OCER/DFOI/		
2014-7328	09/04/2014 10/02/2014	FDA/OMPT/CDRH/OCER/DFOI/	M MELISSA BALTZ BUTLER SNOW ET AL	ETHICON - TVT OBDURATOR 510K SUBMISSION OF SUBSTANTIAL EQUIVALENCE LTR 11/10/03, 11/12/03 LTR ACKNOWLEDGING RECEIPT OF K033568 SUBMISSION, K033568 SUBSTANTIAL EQUIVALENCE LTR 12/8/03, ETC (CERTIFIED)
2014-7329	09/04/2014 10/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	M MELISSA BALTZ BUTLER SNOW ET AL	ETHICON - PROLENE POLYPROPYLENE SUTURE NDA 16-374 2/10/78 LTR SUBMITTING SUPPLEMENTAL CHANGES TO NDA REVISED LBLG, 6/30/78 LTR SUBMITTING SUPPLEMENTAL TO THE NDA, 10/12/78 LTR FOLLOWING UP THE 6/30/78 LBLG, ETC (CERTIFIED)
2014-7330	09/04/2014 10/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	M MELISSA BALTZ BUTLER SNOW ET AL	ETHICON - PROLENE POLYPROPYLENE SUTURE NDA 16-374 12/28/79 LTR SUBMITTING SUPPLEMENTAL NDA TO CHANGE TESTING FACILITY, 5/7/80 LTR SUBMITTING A SUPPLEMENT TO THE NDA, 12/17/80 LTR APPROVING SUPPLEMENT SUBMITTED 9/19/80, ETC (CERTIFIED)
2014-7331	09/04/2014 10/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	M MELISSA BALTZ BUTLER SNOW ET AL	ETHICON - PROLENE POLYPROPYLENE SUTURE NDA 16-374 2/29/84 LTR SUBMITTING SUPPLEMENT TO NDA, 6/10/85 LTR APPROVING 2/29/84 SUBMISSION AMENDED (S28), 11/22/85 LTR SUBMITTING SUPPLEMENT TO NDA, ETC (CERTIFIED)
2014-7332	09/04/2014 10/02/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JESSICA HARRIS JOHNSON FEDERAL DEFENDER SERVICES OF EASTERN TENNESSEE INC	NAMES & ADDRESSES OF HOSPITALS; PHYSICIAN, MFRS, ECT (INTERNATIONAL & US) THAT CAN LEGALLY SELL GMP INSPECTED PHENOBARBITAL INJ, PHENOBARBITAL API
2014-7333	09/04/2014 10/02/2014	OC/ORO/ORM/ OC/ORO/ORM/	LESLIE RAMSEY FDA NEWS	LISTING OF 483'S FOR PHARMACEUTICAL, BIOLOGICS & MEDICAL DVC MFG & CLNCL TRIAL FACILITIES IN THE US & OUTSIDE THE US 8/1-31/14
2014-7334	09/04/2014 10/02/2014	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	ANDREW HACK MILLENNIUM MANAGEMENT LLC	PACIRA PHARMACEUTICAL INC, PARSIPPANY, NJ, SAN DIEGO, CA - EIRS, 483S, UNTITLED LTRS 9/13 TO PRESENT
2014-7335	09/04/2014 10/02/2014	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	RICHARD W MARK GIBSON DUNN & CRUTCHER LLP	THERANOS INC - COMM, CLNCL LABORATORY IMPROVEMENT AMENDMENTCERTIFICATION
2014-7336	09/04/2014	FDA/OMPT/CDER/ORP/DIDP/	NILDA BADEA-PATTERSON	RAPAMUNE - NON-CLNCL STUDY RPTS

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	10/02/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SANTEN INCCORPORATED	
2014-7337	09/04/2014 10/02/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CURTIS A THURSTON THURSTON LAW OFFICES	SEPTOCOCIANE SUPPL NDA'S 20-973/S007, 20-971/S017 - STUDIES, RPTS, CORR
2014-7338	09/04/2014 10/02/2014	FDA/OC/OES/DFOI/	ANDREW JOHNSON JOHNSON DC#R36083, ANDREW	QUALITEST PHARMS - ACETAMINOPHEN & HYDROCODONE BITARTRATE
2014-7339	09/04/2014 10/02/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	MARLER CLARK MARLER CLARK ATTYS	WAWONA PACKING CO - RECALL OF FRESH WHOLE PEACHES, PLUMS NECTARINES, PLUOTS UTBREAK CONTAMINATION OF LISTRERIA MONCYTOGENES 7/19/14, 7/31/14
2014-7340	09/05/2014 10/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOSEPH GALLAGHER EVENUS PHARMACEUTICAL LABORATORIES INC	JIANGSU HENGRUI MEDICINE CO LTD - OXALIPLATIN USP ANDA 203-869 APRVL LTR (CERTIFIED)
2014-7341	09/05/2014 10/03/2014	FDA/OO/OHR/	Doe J	INDIVIDUAL RECS
2014-7342	09/05/2014 10/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	AVRIL CHANG NANG KUANG PHARMACEUTICAL CO LTD	PHARMACIA AND UPJOHN - SOLU-MEDROL NDA 11-856 APRVL
2014-7343	09/05/2014 10/03/2014	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	BILL HERRERA HERRERA, BILL	RECS IN THE DALLAS AND FORT WORTH COCA COLA REFRESHMENTS ON PREMISE DEPT
2014-7344	09/05/2014 10/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELAINE S. WALLER SEATTLE GENETICS INC	ADCETRIS (BRENTUXIMAB VEDOTIN) - FAERS
2014-7345	09/05/2014 10/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ROBERT MILLS SEATTLE GENETICS INC	AUTHORIZATION TO CROSS REFERENCE IND 117532

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2014-7346	09/05/2014 10/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	JUDY F. GORDON CLINREG CONSULTING SERVICES INC	OCULUS OPTIKGERAETE GMBH K-113066
2014-7347	09/05/2014 10/03/2014	FDA/OC/OES/DFOI/	CHRISTINA JEWETT CENTER FOR INVESTIGATIVE REPORTING	MINOR DELETIONS
2014-7348	09/05/2014 10/03/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ROBERT McCLURE INVESTIGATE WEST	PHARMACEUTICALS IN THE ENVIRONMENT WORK GROUP - PHARMACEUTICALS AND PERSONAL CARE
2014-7349	09/05/2014 10/10/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	PROMEDIC INC	K133873, K091871, K011212 ETC
2014-7350	09/05/2014 10/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	Takanashi, Satohiko Kowa Company, Ltd.	K123101
2014-7351	09/05/2014 10/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	James Guthlein Freedom Orthopedics	K040022
2014-7352	09/05/2014 10/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	James Guthlein Freedom Orthopedics	K091644
2014-7353	09/05/2014 10/03/2014	FDA/OO/OFBA/OAGS/	Tiffany Prentice CNI Global Solutions, LLC	HHSF223200850020I, HHSF22301005T
2014-7354	09/05/2014 10/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	NDA 17849
2014-7355	09/05/2014 10/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	Michelle Hagedorn GE Healthcare	K951110
2014-7356	09/05/2014 10/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jeffrey A. Travers The Miller Firm LLC	LETTER FROM DR DAVID COCCHETTO OF GLAXOSMITHKLINE TO THOMAS ABRAMS OF DDMAC RE COMPLAINT ABOUT PROMOTIONAL ACTIVITIES OF TAKEDA 06/04/2007 - 01/02/2008
2014-7357	09/05/2014 10/03/2014	FDA/OFVM/CFSAN/OCD/EOS/	Fran Silverman TRUTH IN ADVERTISING	MAXXTEST 300 - AERS
2014-7358	09/05/2014	FDA/OMPT/CDER/ORP/DIDP/	Rebecca Dandeker	TARO PHARMACEUTICALS, BRAMPTON, ONTARIO, CANADA

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	10/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Morgan, Lewis & Bockius LLP	- EIR 02/01/2014 - 02/28/2014
2014-7359	09/05/2014 10/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOSEPH WALKER Walker, Joseph	SOVALDI - CASE REPORTS
2014-7360	09/05/2014 10/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca Dandeker Morgan, Lewis & Bockius LLP	TARO PHARMACEUTICALS, ONTARIO, CANADA - EIR SUMMARIES FEB 2014
2014-7361	09/05/2014 10/03/2014	OC/ORA/ OC/ORA/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORASW-FO/SWID/SWID-CB/	Alejandro R. Zamudio Alejandro R. Zamudio	IMPORT SAMPLE RESULTS
2014-7362	09/05/2014 10/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	Amy Herrington Herren and Adams	MEDWATCH REPORT
2014-7363	09/05/2014 10/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	NDA 17618 CERTIFIED
2014-7364	09/05/2014 10/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Eric Walter Camil, sr. CAMIL CONSULTING CORP	TIRF REMS
2014-7365	09/05/2014 10/03/2014	FDA/OFVM/CFSAN/OCD/EOS/	Fran Silverman TRUTH IN ADVERTISING	XTREME NITRO - AERS
2014-7366	09/05/2014 10/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Valerie Galvan Turner, MD University of California Irvine Gynecologic Oncology, ATTN: Leslie Randall, MD	XARELTO - AERS
2014-7367	09/05/2014	FDA/OMPT/CDER/ORP/DIDP/	Roy strait	Depo-Medrol - AERS

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	10/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Strait, Roy D	
2014-7368	09/05/2014 10/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	Lynn Fu Shenzhen Rendermed Consulting CO LTD	K102652 PROMOTIONAL MATERIALS
2014-7369	09/05/2014 10/03/2014	FDA/OFVM/CFSAN/OCD/EOS/	Kathy Lee General Mills, Inc.	Food Safety through the Hazard Analysis and Critical Control Point System. The Pillsbury Company. Contract No. FDA 72-59. February, 1973. The Pillsbury Company, Research & Development Department, Minneapolis, MN
2014-7370	09/05/2014 10/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K140159
2014-7371	09/05/2014 10/03/2014	FDA/OC/OES/DFOI/	Karen Ellis Lawson, Pushor, Mote & Gamso LLC	STRATTERA - PRESCRIBERS INFORMATION ON THE LABEL (CERTIFIED)
2014-7372	09/05/2014 10/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Per Bundgaard Larsen NOVO NORDISK	FAERS CASE 144783 (ISR F91447831)
2014-7373	09/05/2014 10/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	Hirotsu Yamaguchi Sunflare company limited	K000748
2014-7374	09/08/2014 10/06/2014	FDA/OC/OES/ FDA/OMPT/CDRH/OCER/DFOI/	JOSEPH WALKER Walker, Joseph	OBSTETRICS AND GYNECOLOGY DEVICES PANEL - EMAIL AND CORR RE SELECTION OF PANEL MEMBERS TO EVALUATE POWER MORCELLATOR DEVICES
2014-7375	09/08/2014 10/06/2014	FDA/OC/OES/ FDA/OMPT/CDRH/OCER/DFOI/	JOSEPH WALKER Walker, Joseph	CIRCULATORY SYSTEM DEVICES PANEL - EMAIL AND CORR RE SELECTION OF PANEL MEMBERS RE WATCHMAN
2014-7376	09/08/2014 10/06/2014	FDA/OMPT/CDRH/OCER/DFOI/	Gina To Sirius Engineering LLC	K101591
2014-7377	09/08/2014 10/06/2014	FDA/OFVM/CFSAN/OCD/EOS/	Sonia Hudson EXPONENT	PAFA DATATASE
2014-7378	09/08/2014 10/06/2014	FDA/OGROP/ORR/SW-FO/DAL- DO/DAL-CB/	Sandra Kenison Central Insurance	ANDERSON CANDY COMPANY, BLOSSOM, TX - INSPECTION RECS 07/01/2014 - 09/05/2014
2014-7379	09/08/2014 10/06/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K133938
2014-7380	09/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson	K130997

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	10/06/2014		FOI Services, Inc.	
2014-7381	09/08/2014 10/06/2014	FDA/OO/OFBA/OAGS/	Zachary Fullbright Chickasaw Nation Industries	HHSF22301001T
2014-7382	09/08/2014 10/06/2014	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Blake Goodner Bridger Healthcare	JEROME STEVENS - 483, WARNING LETTERS, RESPONSE LETTERS 01/01/2011 - 09/05/2014
2014-7383	09/08/2014 10/06/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Blake Goodner Bridger Healthcare	LANNETT COMPANY, PHILDELPHIA, PA - 483, WARNING LETTERS, RESPONSE LETTERES 01/01/2011 - 09/05/2014
2014-7384	09/08/2014 10/06/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	Blake Goodner Bridger Healthcare	LANNETT COMPANY, CODY, WY - 483, WARNING LETTER, RESPONSE LETTER 01/01/2011 - 09/05/2014
2014-7385	09/08/2014 10/06/2014	FDA/OMPT/CDRH/OCER/DFOI/	Greg Levine ROPES & GRAY	CPT1300454
2014-7386	09/08/2014 10/06/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ibrutinib - direct Ken Tong	IBRUTINIB - ISR
2014-7387	09/08/2014 10/06/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joanne Grego CSL BEHRING	9015516 9297593 9360037 ETC
2014-7388	09/08/2014 10/15/2014	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	TOBACCO SURVEY RECS
2014-7389	09/08/2014 10/06/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	lbrutinib - all Ken Tong	IMBRUVICA, PCI-32765, CRA-032765 - AERS
2014-7390	09/08/2014 10/06/2014	FDA/OMPT/CDRH/OCER/DFOI/	Michael Righter Michael Righter	K944524
2014-7391	09/08/2014 10/06/2014	FDA/OMPT/CDRH/OCER/DFOI/	Regina Novak Medtronic TYRX Inc.	K140306
2014-7392	09/08/2014 10/06/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lyn Olson Campbell University	ADALIMUMAB - AERS

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2014-7393	09/08/2014 10/06/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lyn Olson Campbell University	ADALIMUMAB - AERS
2014-7394	09/08/2014 10/06/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lyn Olson Campbell University	ETANERCEPT - AERS
2014-7395	09/08/2014 10/06/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lyn Olson Campbell University	GOLIMUMAB
2014-7396	09/08/2014 10/06/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Margaux Nair K&L Gates LLP	NDA 020845 - FORM 3542
2014-7397	09/08/2014 10/06/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lyn Olson Campbell University	CERTOLIZUMAB PEGOL - AERS
2014-7398	09/08/2014 10/06/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lyn Olson Campbell University	INFLIXIMAB - AERS
2014-7399	09/09/2014 10/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	Peter Frenken PHILIPS CONSUMER LIFESTYLE	K020518
2014-7400	09/09/2014 10/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	9232827 9310859 9314015 ETC
2014-7401	09/09/2014 10/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mark Pohl Health Science Funding, LLC	ANDA 090796 - APPROVAL LETTER

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-7402	09/09/2014 10/07/2014	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	Tony Bennett ENCO Pharmaceutical Development, Inc.	CORERX, INC, CLEARWATER, FL - 483, EIR, ADVERSE EVENTS 01/02/1980 - 09/08/2014
2014-7403	09/09/2014 10/07/2014	FDA/OGROP/ORR/CE-FO/MIN-DO/MIN-CB/	John Walsh James Alexander Corporation	BEMIS, OSHKOSH, WI - 483, EIR, RECALLS 09/08/2011 - 09/08/2014
2014-7404	09/09/2014 10/07/2014	FDA/OC/OES/DFOI/	Joy Lazaroff INDIVIDUAL	INDIVIDUAL RECS
2014-7405	09/09/2014 10/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	James R. Cyre Philips Lighting Company	K910767, K021092
2014-7406	09/09/2014 10/07/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	CLOSED FOIA REQUESTS AUGUST 2014
2014-7407	09/09/2014 10/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	Leon Amariglio Lexington Medical, Inc.	K141367
2014-7408	09/09/2014 10/07/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	9209576 9209844 9212941 ETC
2014-7409	09/09/2014 10/07/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 8/1-31/2014
2014-7410	09/09/2014 10/07/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	BLA 125514
2014-7411	09/09/2014 10/07/2014	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	Michele Sinoway LACHMAN CONSULTANT SERVICES INC	CELGENE, PHOENIX - EIR SEPT 2013
2014-7412	09/09/2014 10/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	Peter Frenken PHILIPS CONSUMER LIFESTYLE	K100435
2014-7413	09/09/2014	FDA/OMPT/CDER/GRP/DIDP/	Stephen Porter	TREVASE - IND, NDA

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	10/07/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	VDDI PHARMACEUTICALS	
2014-7414	09/09/2014 10/07/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rebecca Dandeker Morgan, Lewis & Bockius LLP	SHASUN PHARMACEUTICALS, INDIA - 483, EIR SUMMARIES
2014-7415	09/09/2014 10/07/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	9227153, 9229933, 9229942, ETC
2014-7416	09/09/2014 10/07/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rebecca Dandeker Morgan, Lewis & Bockius LLP	SHASUN PHARMACEUTICALS, INDIA - EIR 01/01/2010 - 04/01/2014
2014-7417	09/09/2014 10/07/2014	FDA/OFVM/CFSAN/OCD/EOS/	Lisa W. DeVetter Washington State University	RECS RE MULCH AS FOOD CONTACT SUBSTANCES
2014-7418	09/09/2014 10/07/2014	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Carlsbad Technology, Inc. Carlsbad Technology, Inc.	CARLSBAD TECHNOLOGY - EIR 2001-2014
2014-7419	09/09/2014 10/07/2014	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	Ryan Woods PRA Health Sciences	PRA INTERNATIONAL, LEXENA, KS - EIR
2014-7420	09/09/2014 10/07/2014	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Melissa Johnson UNIVERSITY OF CALIFORNIA, SAN FRANCISCO	UCSF HOME THERAPY SERVICES, SAN FRANCISCO, CA - 483 08/01/2004 - 09/30/2004
2014-7421	09/09/2014 10/07/2014	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/ FDA/OC/OES/ OC/ORA/ OC/ORA/	Vicki Whatsitt NATURAL PRODUCTS ASSOCIATION	FDA analytical methods related to the identification, determination, and quantitation of mitragynine and 7-hydroxymitragynine (indole alkaloids from the plant Mitragyna speciosa, also known as Kratom) in all matrices
2014-7422	09/09/2014 10/07/2014	FDA/OC/OES/DFOI/	PORTNOY, DAVID	FOI REQUESTS 1/12 TO PRESENT

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2014-7423	09/09/2014 10/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BENJAMIN L ENGLAND ESQ BENJAMIN L ENGLAND & ASSOCIATES LLC	API/BULK INGREDIENT DRUG LISTING DATA 4/14 TO PRESENT
2014-7424	09/09/2014 10/07/2014	OC/ORa/OCI/ OC/ORa/OCI/ OC/ORa/OCI/ OC/ORa/OCI/ FDA/OC/OCC/	EMILY NEWHOUSE DILLINGHAM PAUL HASTINGS LLP	SHELDON T BRADSHAW, HUNTON & WILLIAMS LLP, DALICHI SANKYO CO LTD, ETC - CORR REGARDING THE ABILITY OF SHELDON T BRADSHAW TO SERVE AS AN EXPERT WITNESS IN ICC CASE 19074/CYK
2014-7425	09/09/2014 10/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	JUSTIN BROWNE ESQ JANET, JENNER & SUGGS, LLC	GEMA GONZALEZ, AAMI RENAL DISEASE AND DETOXIFICATION COMMITTEE - ANSI/AAMI RD61:2006M DIALYSATE
2014-7426	09/09/2014 10/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANIL SACHDEVA MYLAN INC	ALLERGAN INC - ZYMAR (GATIFLOXACIN SOL) LBLG
2014-7427	09/09/2014 10/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	KRIS J KONTIS PHD MEDICAL CHEMICAL CORP	MERIDIAN DIAGNOSTICS INC - PARAPAK C&S K792712
2014-7428	09/09/2014 10/07/2014	OC/ORa/ OC/ORa/ FDA/OGROP/ORa/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORa/PA-FO/LOS-DO/LOS-CB/	PATTI WALLER MARLER CLARK ATTYS	VR GREEN FARMS - JARRED FOOD PRODUCTS BOTULISM INFECTIONS INVESTIGATIONS
2014-7429	09/09/2014 10/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	TRICIA CREGGER STERIS CORP	MINNTECH CORP (MEDIVATORS REPROCESSING SYSTEMS) - MEDIVATORS ADVANTAGE PLUS ENDOSCOPE REPROCESSING SYS AND RAPICIDE PA HIGH LEVEL DISINFECTANT K082988
2014-7430	09/09/2014 10/07/2014	FDA/OFVM/CFSAN/OCD/EOS/	MADHU SONI PHD SONI & ASSOCIATES INC	OLIVE PULP EXTRACT - GRAS 000459 MEMOS & CORR
2014-7431	09/09/2014 10/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	WILLIAM J GORMAN GORMAN CONSULTING INC	EU LIFESCIENCES INC - K113259
2014-7432	09/09/2014 10/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	R O DEAN COMPLIANCE SYSTEMS INTERNATIONAL LLC	APLAN WELL ENT AV FISTULA SER FOR SINGLE USE K112734
2014-7433	09/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	R O DEAN	JMS CO - JMS AV FISTULA NEEDLE SET K990470

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	10/07/2014		COMPLIANCE SYSTEMS INTERNATIONAL LLC	
2014-7434	09/09/2014 10/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	R O DEAN COMPLIANCE SYSTEMS INTERNATIONAL LLC	SHARGH PHARMACEUTICAL CO - SHARGH PAV FISTULA NEEDLE K013384
2014-7435	09/09/2014 10/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	R O DEAN COMPLIANCE SYSTEMS INTERNATIONAL LLC	EXEL INTERNATIONAL CO - EXEL A V FISTULA NEEDLE K013037
2014-7436	09/09/2014 10/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	KETOROLAC TROMETHAMINE INJ ANDA 74-802 APRVL LTR, LBLG, CHEMISTRY (CMC) RVW, ETC
2014-7437	09/09/2014 10/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	NALOXONE HCL INJ ANDA 70-256 - APRVL LTR, LBLG, CHEMISTRY (CMC) RVW, ETC
2014-7438	09/09/2014 10/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	NALOXONE HCL INJ ANDA 70-257 - APRVL LTR, LBLG, CHEMISTRTY (CMC) RVW, ETC
2014-7439	09/10/2014 10/08/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bob van Osdel Nexgen Pharma, Inc	ANDA 203546 SBA
2014-7440	09/10/2014 10/08/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	9396921, 9397641, 9402342, ETC
2014-7441	09/10/2014 10/08/2014	OC/ORO/ORM/ OC/ORO/ORM/	Gary Huge ASI FOOD SAFETY CONSULTANTS	LIST OF INSPECTED FOOD PROCESSING, FOOD DISTRIBUTION, FOOD STORAGE FACILITIES
2014-7442	09/10/2014 10/08/2014	FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/	Sallie Kim GCA Law Partners LLP	STATE UNIVERSITY OF NY, UPSTATE MEDICAL UNIVERSITY - 483, CORR 01/02/2013 - 09/01/2014
2014-7443	09/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Chris Smith	K032445

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	10/08/2014		Symmetry Surgical	
2014-7444	09/10/2014 10/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	Chris Smith Chris Smith	K032813
2014-7445	09/10/2014 10/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	Chris Smith Symmetry Surgical	K935755
2014-7446	09/10/2014 10/08/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Liz King Oxford Pharmascience	NDA 17581 - SBA
2014-7447	09/10/2014 10/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	Helen Lewis DENTSPLY INTERNATIONAL	P040013
2014-7448	09/10/2014 10/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	Chris Smith Symmetry Surgical	K113776
2014-7449	09/10/2014 10/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	Chris Smith Symmetry Surgical	K871202
2014-7450	09/10/2014 10/08/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Karisa King CHICAGO TRIBUNE	LAMICTAL - AERS
2014-7451	09/10/2014 10/08/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tina Burgett Burgett Law Firm	SUBOXONE - RESEARCH, STUDY RESULTS RE SUICIDAL THOUGHTS
2014-7452	09/10/2014 10/08/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/	Rose Ciotta WIVB-TV	OASIS DATA FOOD AND DRUGS
2014-7453	09/10/2014 10/08/2014	FDA/OC/OES/DFOI/	Prashant Premkumar East Bridge Capital Management Limited	MORTON GROVE, CHICAGO, IL 0 483 01/01/2014 - 09/09/2014
2014-7454	09/10/2014 10/08/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	9387191, 9396812, 9403151, ETC

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2014-7455	09/10/2014 10/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	Chris Smith Symmetry Surgical	K993535
2014-7456	09/10/2014 10/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	Chris Smith Symmetry Surgical	K012105
2014-7457	09/10/2014 10/08/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Becky Hartman Teva Pharamcueticals	SYNRIBO - AERS
2014-7458	09/10/2014 10/08/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Becky Hartman Teva Pharamcueticals	QUARTETTE - AERS
2014-7459	09/10/2014 10/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	Chris Smith Symmetry Surgical	K040223
2014-7460	09/10/2014 10/08/2014	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	PMA950034 (CERTIFIED)
2014-7461	09/10/2014 10/08/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	9390958, 9392506, 9402363 ETC
2014-7462	09/10/2014 10/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	Chris Smith Symmetry Surgical	K120117
2014-7463	09/10/2014 10/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	Cheryl Segawa Salt Creek Medical	K102707
2014-7464	09/10/2014 10/08/2014	FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Austin Nelson Sterne Agee	IMPAX LABORATORIES - 483, UNTITLED LETTERS 08/04/2014 - 09/09/2014
2014-7465	09/10/2014 10/08/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Linda Kariya NIHON KOHDEN AMERICA	K032519
2014-7466	09/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Linda Kariya	K060980

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	10/08/2014	FDA/OC/OES/DFOI/	NIHON KOHDEN AMERICA	
2014-7467	09/10/2014 10/08/2014	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Scott Fawcett Carroll Quality Consult, Inc.	ARL BIOPHARMA DBA ANALYTICAL RESEARCH LABORATORIES, OKLAHOMA CITY, OK - EIR 11/01/2012 - 11/01/2013
2014-7468	09/10/2014 10/08/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Becky Hartman Teva Pharamcueticals	QNASL AERS
2014-7469	09/10/2014 10/08/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Becky Hartman Teva Pharamcueticals	ADASUVE - FAERS
2014-7470	09/10/2014 10/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	Chris Smith Symmetry Surgical	K944025
2014-7471	09/10/2014 10/08/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Becky Hartman Teva Pharamcueticals	TBO-FILGRASTIM - AERS 05/01/2014 - 08/31/2014
2014-7472	09/10/2014 10/08/2014	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Sidney Lewis Sidney Lewis	LEGACY PHARMACEUTICAL PACKAGING - EARTH CITY, MO
2014-7473	09/10/2014 10/08/2014	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	John Voliva PCCA	MARTIN AVENUE PHARMACY - EIR 06/01/2014 - 07/31/2014
2014-7474	09/10/2014 10/08/2014	OC/CVM/OCD/	KRISTI O SMEDLEY Center for Regulatory Services,Inc.	BIOVET, PESHTERA, BULGARIA - 483S, FMD 145 LTR 7/26/13
2014-7475	09/10/2014 10/08/2014	OC/CVM/OCD/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KRISTI O SMEDLEY Center for Regulatory Services,Inc.	NINGXIA TAIRUI PHARMACETICAL CO LTD, WANG YUAN ECONOMIC ZONE, YINCHAUN, NINGXIA, CHINA - 483S 9/28/12
2014-7476	09/10/2014 10/08/2014	FDA/OFVM/CFSAN/OCD/EOS/	KRISTO SMEDLEY Center for Regulatory Services,Inc.	SPIRULINA EXTRACT- CAP 2C0297
2014-7477	09/10/2014 10/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	JEFF S GIBSON COHEN & MALAD LLP	RENAL SYSTEMS INC - K843963
2014-7478	09/10/2014	FDA/OMPT/CDER/GRP/DIDP/	ELAINE CHANG	TIRF REMS

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	10/08/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GLANCY BINKOW & GOLDBERG LLP	
2014-7479	09/10/2014 10/08/2014	FDA/OC/OL/	MARILYNN WHITNEY COVINGTON BURLING LLP	NUTRITION FACTS LABEL PROPOSED RULE (79 FED REG 11879) & PROPOSED RULE ON SERVING SIZES (79 FED REG 11989) 3/3/14 - CONGRESSIONAL INQUIRIES, RESP TO INQUIRIES, CORR
2014-7480	09/10/2014 10/08/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Doe J	INDIVIDUAL RECS
2014-7481	09/11/2014 10/09/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-3993
2014-7482	09/11/2014 10/09/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-4188
2014-7483	09/11/2014 10/09/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-3994
2014-7484	09/11/2014 10/09/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-3985
2014-7485	09/11/2014 10/09/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-3986
2014-7486	09/11/2014 10/09/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2013-4539
2014-7487	09/11/2014 10/09/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8654
2014-7488	09/11/2014 10/09/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-5139
2014-7489	09/11/2014 10/09/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-4665
2014-7490	09/11/2014 10/09/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jason E Moore PLx Pharma LLC	NDA 203697 UNREDACTED
2014-7491	09/11/2014 10/09/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Donald J. Harrigan KAD Validation and Consultants	IND 72756

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-7492	09/11/2014 10/09/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Raphael Lewis The Boston Company	Guidance for Industry/Upper Facial Lines: Developing Botulinum Toxin Drug Products CORR, MEMOS, PRESENTATIONS ETC
2014-7493	09/11/2014 10/09/2014	FDA/OC/OES/DFOI/ OC/ORA/ORM/ OC/ORA/ORM/	Cassie White IMPERIAL WESTERN PRODUCTS	LIST OF FOOD MANUFACTURERS IN NM, CO, OK, TX
2014-7494	09/11/2014 10/09/2014	OC/CVM/OCD/ FDA/OFVM/CFSAN/OCD/EOS/ OC/ORA/ OC/ORA/ OC/ORA/ OC/ORA/	Barbara Blakistone National Fisheries Institute	AQUACULTURE DRUG RESIDUE DATA
2014-7495	09/11/2014 10/09/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TODD LEVINE MD AND LYNNE FLYNN CCRC PNA NEUROLOGICAL RESEARCH	1571 AND 1572 FOR IND 116871
2014-7496	09/11/2014 10/09/2014	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2014-5312
2014-7497	09/11/2014 10/09/2014	FDA/OC/OES/DFOI/	Aneliz Jimenez Lyons Magnus	FORM 2541e
2014-7498	09/11/2014 10/09/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-4682
2014-7499	09/11/2014 10/09/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2518
2014-7500	09/11/2014 10/09/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-4110
2014-7501	09/11/2014 10/09/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-4129
2014-7502	09/11/2014 10/09/2014	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	John Walsh James Alexander Corporation	MAXIM BIOMEDICAL, ROCKVILLE, MD - 483, EIR, RECALL 09/10/2011 - 09/10/2014

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2014-7503	09/11/2014 10/09/2014	FDA/OMPT/OSMP/OOPD/	Elinore Mercer Cote Orphan Conulstin	RIBAVIRIN - ORPHAN DESIGNATION RECS
2014-7504	09/11/2014 10/09/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	LETTER TO FDA FROM DR STEVEN NISSEN RE DATA ACCESS PLAN FOR CV TRIALS
2014-7505	09/11/2014 10/09/2014	FDA/OC/OES/DFOI/	Karen Dobmeier Horizon Technology	FDA-14-1138724 CONTRACT BID RECORDS
2014-7506	09/11/2014 10/09/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nancy Rizkalla LONG ISLAND JEWISH MEDICAL CENTER	FEBUXOSTAT - AERS
2014-7507	09/11/2014 10/09/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-4729
2014-7508	09/11/2014 10/09/2014	FDA/OGROP/ORR/SE-FO/NOL-DO/NOL-CB/	Joseph A. Zarzaur, Jr. Zarzaur Law	MARKET TECHNOLOGIES - WARNING LETTER RECS
2014-7509	09/11/2014 10/09/2014	FDA/OFVM/CFSAN/OCD/EOS/	Catherine Rentz THE BALTIMORE SUN/WASHINGTON BUREAU	CRAB MEAT INSPECTION REPORTS
2014-7510	09/11/2014 10/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	Caitlin Sirico Fudge & McArthur, P.A.	WESTCHASE SURGERY CENTER, LTD, TAMPA, FL - FORM 2579 01/01/2008 - 09/11/2014
2014-7511	09/11/2014 10/09/2014	FDA/OFVM/CFSAN/OCD/EOS/	WILLIAM A. OLSON, Ph.D. Center for Regulatory Services,Inc.	SIAM QUALITY STARCH CO LTD - FCN 1227
2014-7512	09/11/2014 10/09/2014	FDA/OFVM/CFSAN/OCD/EOS/	WILLIAM A. OLSON, Ph.D. Center for Regulatory Services,Inc.	ROQUETTE FRERES - FCN 439
2014-7513	09/11/2014 10/09/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KRISTI O. SMEDLEY, Ph.D. Center for Regulatory Services,Inc.	ZHEJIANG APELOA JIAYUAN PHARMACEUTICAL, DONGYANG, ZHEJIANG, CHINA - 483 5/11/12
2014-7514	09/11/2014 10/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	JONATHAN LEE Center for Regulatory Services,Inc.	MOBIUS MEDICAL SYSTEMS LP - MOBIUS 3D K140660
2014-7515	09/11/2014 10/09/2014	OC/ORR/ OC/ORR/	Doe J	CMPLNT 135446

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		FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/		
2014-7516	09/11/2014 10/09/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	RAUL GONZALEZ-TORO RAUL GONZALEZ TORO LAW OFFICES LLC	CMPLNT 13640
2014-7517	09/11/2014 10/09/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	W. PATRICK NOONAN W PATRICK NOONAN	MICRO QUALITY LABS, BURBANK, CA - 482, 483, CO RESP, EIR
2014-7518	09/11/2014 10/09/2014	FDA/OC/OES/DFOI/	HEWITT 303283, STEVEN	EFFEXOR XL, TEGRATOL, TRIZADON, ETC - AER
2014-7519	09/11/2014 10/09/2014	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	RAY HAUSER SATIS PHARMA LLC	WALTMAN PHARMACEUTICALS INC - ZAPZYT
2014-7520	09/11/2014 10/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	RO DEAN COMPLIANCE SYSTEMS INTERNATIONAL LLC	HONG BO MEDICAL PRODUCTS CO LTD, DUPU TOWN, JIA YU COUNTY, XIANNING CITY, CHINA - 483, EIR
2014-7521	09/11/2014 10/09/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	BERRYMAN, THOMAS J	VAGINAL PESSARY - K060526
2014-7522	09/11/2014 10/09/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DOUGLAS VAN PELT ACCEL RX LABS LLC	CARISOPRODOL ANDA 40-576
2014-7523	09/11/2014 10/09/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	M. MELISSA BALTZ BUTLER SNOW ET AL	POLYPROPYLENE SUTURE NDA 16-374 (CERTIFIED)
2014-7524	09/12/2014 10/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K110744
2014-7525	09/12/2014 10/10/2014	FDA/OC/OES/DFOI/	Paul Giovannoni FMI	LIST OF REGISTERED FOOD AND BEVERAGE FACILITIES 09/01/2013 - 09/11/2014

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2014-7526	09/12/2014 10/10/2014	FDA/OC/OES/DFOI/	Liz Barr Liz Barr	ADVISORY COMMITTEE TRANSCRIPT
2014-7527	09/12/2014 10/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Paola Teegarden Kinex Pharmaceuticals Inc.	NDA 020571
2014-7528	09/12/2014 10/10/2014	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Patrick Lynch Microgenics Corporation	MICROGENICS CORPORATION, FREMONT, CA - EIR OCTOBER 2013
2014-7529	09/12/2014 10/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Edward Kobus Invado Pharmaceuticals	K964240
2014-7530	09/12/2014 10/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K080779
2014-7531	09/12/2014 10/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Michael DeSalvo NeuroDx Development	K112017
2014-7532	09/12/2014 10/10/2014	FDA/OC/OES/DFOI/	Travis Siverson BIRCHWOOD LABORATORIES INC	FOIA REQUEST LOG 07/01/2012 - 06/30/2013
2014-7533	09/12/2014 10/10/2014	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Gerald Keisler Rhythmink International LLC	RHYTHMLINK INTERNATIONAL LLC - EIR 08/01/2014 - 09/11/2014
2014-7534	09/12/2014 10/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Ryan McKeegan Law Offices of Robert Vaage	RECS RE FDA APPROVAL OR CLEARANCE OF SPINAL INTERVERTEBRAL BODY FIXATION DEVICE BEFORE AND 5/11/09 ASSIGNED TO MEDTRONIC, INC
2014-7535	09/12/2014 10/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Ryan McKeegan Law Offices of Robert Vaage	FDA APPROVAL, CLEARANCE OF CERVICAL CORPECTOMY DEVICE IN EFFECT BEFORE 5/11/09; FDA APPROVAL, CLEARANCE OF CERVICAL CORPECTOMY DEVICE ASSIGNED TO MEDTRONIC, INC BEFORE 5/11/09
2014-7536	09/12/2014 10/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Ryan McKeegan Law Offices of Robert Vaage	FDA APPROVAL, CLEARANCE OF VERTEBRAL BODY REPLACEMENT DEVICE FOR USE IN THE CERVICAL SPINE IN EFFECT BEFORE 05/11/09; FDA APPROVAL, CLEARANCE OF VERTEBRAL BODY REPLACEMENT DEVICE FOR USE IN THE CERVICAL SPINE IN EFFECT BEFORE 05/11/09 AND ASSIGNED TO MEDTRONIC, INC
2014-7537	09/12/2014 10/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Ryan McKeegan Law Offices of Robert Vaage	K070173
2014-7538	09/12/2014 10/10/2014	OC/ORA/ OC/ORA/	FABIAN STRUCK STRUCK, FABIAN	MEDICAL DVC RECALLS 7/20/14

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		OC/ORO/ORM/ OC/ORO/ORM/		
2014-7539	09/12/2014 10/10/2014	FDA/OC/OCC/ FDA/OC/OES/ OC/ORO/ OC/ORO/ FDA/OC/OEXA/OMA/	TODD FEATHERS MUCKROCK NEWS	ANGELA HAOGUE, KELLY PALMER, LISA BARCLAY, ETC - EMAILS 1/13 TO PRESENT
2014-7540	09/12/2014 10/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	STEFAN ELLIS PEPPER HAMILTON LLP	ZOLOFT NDA 19-839/S002 - RVWS, CORR, DRAFTS, ETC
2014-7541	09/12/2014 10/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	STEFAN ELLIS PEPPER HAMILTON LLP	PAXIL NDA 20-031/S007,S009.S052 - CORR, DRAFTS, RVWS, ETC
2014-7542	09/12/2014 10/10/2014	FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	LESLIE RAMSEY FDA NEWS	AMPHASTAR PHARMACEUTICALS INC, RANCHO CUCAMONGA, CA; ABRAXIS BIOSCIENCE LLC, PHOENIX, AZ; TENACORE HOLDINGS INC, ETC - 483S 8/1-31/14
2014-7543	09/12/2014 10/10/2014	FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/	LESLIE RAMSEY FDA NEWS	STRUCTURE MEDICAL LLC, NAPLES, FL; BIOMET 3I LLC, PALM BEACH GARDENS, FL; GENO LLC, COCOA, FL, ETC - 483S 8/1-31/14
2014-7544	09/12/2014 10/10/2014	FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/	LESLIE RAMSEY FDA NEWS	UE LIFESCIENCES INC, BOHEMIA, NY; PRAXAIR INC, TONAWANDA, NY; SONOMED INC, NEW HYDE PARK, NY, ETC - 483S 8/1-31/14
2014-7545	09/12/2014 10/10/2014	FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	LESLIE RAMSEY FDA NEWS	AIR PRODUCTS AND CHEMICALS INC, CONYERS, GA; LINDE LLC, CARTERSVILLE, GA; MMJ LABS LLC, ATLANTA, GA, ETC - 483S 8/1-31/14
2014-7546	09/12/2014 10/10/2014	FDA/OGROP/ORO/CE-FO/BLT-DO/BLT-CB/	LESLIE RAMSEY FDA NEWS	KONSYL PHARMACEUTICALS INC, EASTON, MD; INDUSTRIAL WATER SOLUTIONS INC, ROANOKE, VA; PERELANDRA LTD, JEFFERSONTON, VA, ETC - 483S 8/1-31/14
2014-7547	09/12/2014 10/10/2014	FDA/OGROP/ORO/CE-FO/CHI-DO/CHI-CB/	LESLIE RAMSEY FDA NEWS	VANTAGE OLEOCHEMICALS INC, CHICAGO, IL; ZEPEDA DENTAL LAB, OGLESBY, IL - 483S 8/1-31/14
2014-7548	09/12/2014 10/10/2014	FDA/OGROP/ORO/CE-FO/CIN-DO/CIN-CB/	LESLIE RAMSEY FDA NEWS	DAWN OF TIME LLC, BLOOMINGDALE, OH; NUVASIVE INC, FAIRBORN, OH - 483S 8/1-31/14
2014-7549	09/12/2014	FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/	LESLIE RAMSEY	METHODIST HOSPITAL RESEARCH INSTITUTE PET FACILITY, HOUSTON, TX; METRO OPTICS INC, DALLAS, TX;

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	10/10/2014		FDA NEWS	MIDWEST MEDICAL ISOTOPES LLC, ETC - 483S 8/1-31/14
2014-7550	09/12/2014 10/10/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	LESLIE RAMSEY FDA NEWS	XANACARE TECHNOLOGIES LLC, DENVER, CO; BROWN'S COMPOUNDING CENTER INC, ENGLEWOOD, CO - 483S 8/1-31/14
2014-7551	09/12/2014 10/10/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	LESLIE RAMSEY FDA NEWS	HEALTH DIMENSIONS INC, FARMINGTON HILLS, MI; SIGNAL MEDICAL CORP, MARYSVILLE, MI; TOPSPINS INC, ANN ARBOR, MI, ETC - 483S 8/1-31/14
2014-7552	09/12/2014 10/10/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	LESLIE RAMSEY FDA NEWS	JOHNSON MEMORIAL CANCER CENTER, ENFIELD, CT; RHODES TECHNOLOGIES, COVENTRY, RI; DOREL JUVENILE GROUP INC, FOXBOROUGH, MA, ETC - 483S 8/1-31/14
2014-7553	09/12/2014 10/10/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	LESLIE RAMSEY FDA NEWS	ETHICON INC, SOMERVILLE, NJ; ACINO PRODUCTS LLC, EXCELSIOR MEDICAL CORP - 483S 8/1-31/14
2014-7554	09/12/2014 10/10/2014	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	LESLIE RAMSEY FDA NEWS	QUALITEST PHARMACEUTICALS, HUNTSVILLE, AL - 483S 8/1-31/14
2014-7555	09/12/2014 10/10/2014	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	LESLIE RAMSEY FDA NEWS	VIVEVE INC, SUNNYVALE, CA; ACCESSCLOSURE INC, SANTA CLARA, CA; SUNI MEDICAL IMGAGING, SAN JOSE, CA - 483S 8/1-31/14
2014-7556	09/12/2014 10/10/2014	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	LESLIE RAMSEY FDA NEWS	PATHEON PUERTO RICO INC, MANATI, PR; COVIDIEN, PONCE, PR - 483S 8/1-31/14
2014-7557	09/12/2014 10/10/2014	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	LESLIE RAMSEY FDA NEWS	MEDSTREAMING LLC, REDMOND, WA; SAGEMAX BIOCERAMICS INC, FEDERAL WAY, WA - 483S 8/1-31/14
2014-7558	09/12/2014 10/10/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LESLIE RAMSEY FDA NEWS	PFIZER IRELAND PHARMACEUTICALS INC, RINGASKIDDY, COUNTY CORK, IRELAND; CHANGZHOU QIANHONG BIO PHARMA CO LTD, CHANGZHOU, CHINA; AGILA SPECIALTIES PVT LTD, BANGALORE, KAMATAKA, INDIA - 483S 8/1-31/14
2014-7559	09/12/2014 10/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	LESLIE RAMSEY FDA NEWS	XIAMEN TAFT MEDICAL CO LTD, XIAMEN, CHINA; EMCISION LTD, LONDON, UK; REKA HEALTH PTE LTD, ETC - 483S 8/1-31/14
2014-7560	09/12/2014 10/10/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TAMYRA TOOLE JD RN INFINITY PHARMACEUTICALS	IMBRUVICA (IBRUTINIB) NDA 205-552/S001 -SUMMARY RVWS, MEDICAL RVWS, STATISTICAL RVWS
2014-7561	09/15/2014 10/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kristen stewart Kristen Stewart - Deutsche Bank	PMA 130009 TWO YEAR FOLLOW UP DATA
2014-7562	09/15/2014	FDA/OMPT/CDER/GRP/DIDP/	Lyn Olson	REMICADE, ENBREL, HUMIRA - AERS

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	10/14/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Campbell University	
2014-7563	09/15/2014 10/14/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORO/SW-FO/DAL- DO/DAL-CB/	Weerawan (Birda) Misch CALAVO GROWERS, INC.	SAMPLE 678430, SAMPLE 868073 SUMMARY REPORT
2014-7564	09/15/2014 10/14/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	ANDA 91018
2014-7565	09/15/2014 10/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	Victoria Rothwell Immunexpress	K130914
2014-7566	09/15/2014 10/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	Victoria Rothwell Immunexpress	K113450
2014-7567	09/15/2014 10/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	Mary Ann Twitchell OEC Medical Systems, Inc.	K132094
2014-7568	09/15/2014 10/14/2014	FDA/OC/OES/DDM/	Gregory Mariano ENVIRON International Corporation	COMMENTS SUBMITTED TO PROPOSED ANALYTICAL METHOD
2014-7569	09/15/2014 10/14/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	ANDA 91028
2014-7570	09/15/2014 10/14/2014	FDA/OFVM/CFSSAN/OCD/EOS/ OC/CVM/OCD/	Rachel Johnson FOI Services, Inc.	DHA GOLD FAP - CORR, MEMO 2002
2014-7571	09/15/2014 10/14/2014	FDA/OC/OES/DFOI/	James Wong Geragos & Geragos, APC	TOWNSEND FARMS OUTBREAK RECS
2014-7572	09/15/2014 10/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kelly A. Christian Morris Manning Martin	K123169
2014-7573	09/15/2014 10/14/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bryan Czyzewski JMP Securities	XTANDI - AERS

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		FDA/OMPT/CDER/ORP/DIDP/		
2014-7574	09/15/2014 10/14/2014	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Doe J	INDIVIDUAL RECS
2014-7575	09/15/2014 10/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	TORREY COPE SIDLEY AUSTIN LLP	CENTRIX INC, SHELTON, CT - SENZZZZ AWAY K120176
2014-7576	09/15/2014 10/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	TORREY COPE SIDLEY AUSTIN LLP	SYLP HAR NV, DEURTE, BELGIUM - REMESENSE FOR SENSITIVE TEETH K122708
2014-7577	09/15/2014 10/14/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	TORREY COPE SIDLEY AUSTIN LLP	REMEDENT NV, DEURLE, BELGIUM - REMESSENSE K082594
2014-7578	09/15/2014 10/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	TORREY COPE SIDLEY AUSTIN LLP	BISCO INC, SCHAUMBURG, IL - BISBLOCK K033521
2014-7579	09/15/2014 10/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	TORREY COPE SIDLEY AUSTIN LLP	CENTIX INC, SHELTON, CT - D/SENSE 1-STEP K021146
2014-7580	09/15/2014 10/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	TORREY COPE SIDLEY AUSTIN LLP	PHOENIX DENTAL INC, PENTON, MI - SUPER SEAL K983477
2014-7581	09/15/2014 10/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	TORREY COPE SIDLEY AUSTIN LLP	SYLP HAR NV, DEURTE, BELGIUM - REMESENSE SENSITIVITY RELIEF STRIPS K132426
2014-7582	09/15/2014 10/14/2014	OC/ORAO/ORM/ OC/ORAO/ORM/	GAIL LESSICK LACHMAN CONSULTANT SERVICES INC	LIST OF ALL DOMESTIC & FOREIGN INSP 7/1-31/14
2014-7583	09/15/2014 11/28/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDRH/OCER/DFOI/	SUSAN F CONNORS MONTGOMERY CHAPIN & FETTEN PC	DIAGNOSTICA STAGO INC, PARISPANY, NJ, CANADA, OR ABROAD - CMLPNTS REGARDING MFR, PRODUCTION, INSP, ETC 1/04 TO PRESENT
2014-7584	09/15/2014 10/14/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SARAH WESTBY FARUQI & FARUQI LLP	BARR LABS -NIASPAN (NIACIN ER TABS) ANDA 076-378, LUPIN LTD ANDA 090-860, 090-892, SUN PHARMACEUTICAL INDUSTRIES LTD - ANDA 201-273 APRVL PKG
2014-7585	09/15/2014 10/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	SUSAN COLEMAN COLEMAN, SUSAN	MEDTRONIC INC - THE SUDDEN CARDIAC DEATH IN HEART FAILURE TRIAL MARQUIS ICD MODEL #7277, MODEL #7303, RECS, ETC
2014-7586	09/16/2014 10/23/2014	FDA/OC/OES/DFOI/	Robert Sloman Inteum Co. LLC	EMAIL FROM BRANDI SADDLER, LINDA ALEXANDER, AND ALICE WELCH RE FDA-SOL-14-1135796
2014-7587	09/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	Alexis Connell	HENRY SCHEIN MASTER TORQUE E-TYPE MODEL 11102-

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	10/15/2014		Quintairos, Prieto, Wood & Boyer, P.A.	7294, HENRY SCHEIN SC 300, SAFECO SC-300 ETC - CORR TO OR FROM MANUFACTURER, SAFETY NOTICES, RECALLS, COMPLAINTS
2014-7588	09/16/2014 10/15/2014	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Eric Glynn Hiscock & Barclay	BAUSCH AND LOMB AKREOS - DESIGN SPECIFICATION, TESTING, STERILIZATION ETC
2014-7589	09/16/2014 10/15/2014	FDA/OMPT/OSMP/OOPD/	Arundhati Ghosh Cote Consulting	MODAFINIL - ORPHAN DRUG REGS
2014-7590	09/16/2014 10/15/2014	FDA/OMPT/OSMP/OOPD/	Arundhati Ghosh Cote Consulting	OXYBATE - ORPHAN DESIGNATION RECS
2014-7591	09/16/2014 10/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	Chris Henza rca	K030974
2014-7592	09/16/2014 10/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Uday Shetty Drug Regulations	SUN PHARMA, INDIA - 483 08/01/2014 - 09/15/2014
2014-7593	09/16/2014 10/15/2014	OC/ORR/ OC/ORR/	Erik Daniel Ling PROTEIN SCIENCES CORP	FDA ORR Laboratory Manual 2004
2014-7594	09/16/2014 10/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	Zeba Siddiqui THOMSON REUTERS	SUN PHARMACEUTICALS INDUSTRIES, INDIA - 483 09/01/2014 - 09/15/2014
2014-7595	09/16/2014 10/15/2014	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	Maureen White LifePoint, INc.	LIFEPOINT, INC, GREENVILLE, SC - EIR 03/30/2010 - 03/31/2010
2014-7596	09/16/2014 10/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Linda Bowen SANOFI	BLA 103964 S 5204 SBA
2014-7597	09/16/2014 10/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	Brian Cran Aqueduct Critical Care	K061568
2014-7598	09/16/2014 10/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	Brian Cran Aqueduct Critical Care	K030289
2014-7599	09/16/2014	FDA/OMPT/CDER/ORP/DIDP/	Linda Bowen	BLA 103780 S 5121 - SBA

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	10/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SANOFI	
2014-7600	09/16/2014 10/15/2014	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	Information regarding FDA's financial disclosure and conflict of interest/bias review and decision-making process with respect to the members of the 2014-2015 class of FDA Tobacco and Regulatory Science Fellows
2014-7601	09/16/2014 10/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Linda Leikness Deltanoid Pharmaceutical, Inc.	Supplemental ANDA for calcitriol vials/injection submitted by Rockwell Medical
2014-7602	09/16/2014 10/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Faruqi & Faruqi, LLP FARUQI & FARUQI LLP	IMETELSTAT AERS 01/01/2010 - 09/15/2014
2014-7603	09/16/2014 10/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	Melissa Walker Graematter, Inc.	K053156
2014-7604	09/16/2014 10/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	Melissa Walker Graematter, Inc.	K031024
2014-7605	09/16/2014 10/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Linda Leikness Deltanoid Pharmaceutical, Inc.	NDA 020819
2014-7606	09/16/2014 10/15/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Melissa Walker Graematter, Inc.	K040723
2014-7607	09/16/2014 10/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORO/OCI/ OC/ORO/OCI/	LISA A PORT BARRACK RODOS & BACINE	ALLERGAN INC - BOTOX INVESTIGATION RECS, SALES, MARKETING, ETC
2014-7608	09/16/2014 10/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	KELLY A CHRISTIAN MORRIS MANNING & MARTIN LLP	FORWARD SCIENCE LLC - ORALD K123169

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2014-7609	09/16/2014 10/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	ARMOUR THYROID - COMPUND CHANGE RECS
2014-7610	09/16/2014 10/15/2014	FDA/OFVM/CFSAN/OCD/EOS/	DEBORAH C ATTWOOD Keller and Heckman LLP	MILLIKEN & CO - FCN 1310
2014-7611	09/16/2014 10/15/2014	FDA/OFVM/CFSAN/OCD/EOS/	DEBORAH C ATTWOOD Keller and Heckman LLP	MILLIKEN & CO - FCN 1351
2014-7612	09/16/2014 10/15/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OES/DFOI/	DEBORAH C ATTWOOD Keller and Heckman LLP	MILLIKEN & CO - FCN 1348
2014-7613	09/16/2014 10/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	SHIRE LLC - AGRYLN (ANAGRELIDE HCL) NDA 20-333; WATSON PHARMS - CONDYLOX (PODOFILOX) NDA 20-529; FOUGERA PHARMS - PANDEL (HYDROCORTISONE PROBUTATE) NDA 20-453, ETC - APRVL LTR, LBLG
2014-7614	09/16/2014 10/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	EMD SERONO - GONAL-F (FOLLITROPIN ALFA/BETA NDA 20-378; BAYER HEALTHCARE - CIPRO (CIPROFLOXACIN) NDA 20-780; VIIV HEALTHCARE - COMBIVIR (LAMIVUDINE, ZIDOVUDINE) NDA 20-857, ETC - APRVL LTR, LBLG
2014-7615	09/16/2014 10/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	GE HEALTHCARE - OPTISON (ALBUMIN HUMAN) NDA 20- 899; PALADIN LABS - ANTIZOL (FOMEPIZOLE) NDA 20-696; AVENTIS - STREPTASE (STREPTOKINASE) BLA 103750, ETC - APRVL LTR, LBLG
2014-7616	09/16/2014 10/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	ROCHE - CELLCEPT (MYCOPHENOLATE MOLETIL) NDA 50- 723; PROSTRAKAN - FARESTON (TOREMIFENE CITRATE) NDA 20-497; AVENT - PYTEST (UREA C-14) NDA 20-617, ETC - APRVL LTR, LBLG
2014-7617	09/16/2014 10/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	VALEANT - DIASTAT (DIAZEPAM) NDA 20-648; ABBVIE - NIASPAN (NIACIN) NDA 20-381; CNTY LINE PHARMS - LOPROX (CICLOPIROX) NDA 20-519, ETC - APRVL LTR, LBLG
2014-7618	09/16/2014 10/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	NOVO NORDISK INC - PRANDIN (REPAGLINIDE) NDA 20- 741 RVWS

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2014-7619	09/16/2014 10/15/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	ASTRAZENECA - SEROQUEL (QUETIAPINE FUMARATE) NDA 20-639/S026 RVWS
2014-7620	09/16/2014 10/15/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	NOVO NORDISK INC - PRANDIN (REPAGLINIDE) NDA 20-741 APRVL LTR, LBLG
2014-7621	09/16/2014 10/15/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHRIS SZECHENYI ON POINT COMMUNICATIONS LLC	REGARDO BIOSCIENCES - REG1 (REVOLIXYS KIT) AERS, EMAILS, LTRS, ETC
2014-7622	09/16/2014 10/15/2014	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	CHRIS SZECHENYI ON POINT COMMUNICATIONS LLC	STAAR SURGICAL, MONROVIA, CA - EIR 2/10/14-3/21/14, WARNING LTR 5/21/14, MDRS, ETC
2014-7623	09/16/2014 10/15/2014	FDA/OC/OES/DFOI/	KAITLIN A CANTY DAY PITNEY LLP	SEASONAL DAILY WATER TEMPERATURES AT NORWALK HARBOR, CT 2009 TO 2012
2014-7624	09/16/2014 10/15/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MICHAEL R COHEN RPH MS SCD INSTITUTE FOR SAFE MEDICATION PRACTICES	MEDWATCH RPTS CODED AS MEDICATION ERRORS 8/1-31/14
2014-7625	09/16/2014 10/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	R O DEAN COMPLIANCE SYSTEMS INTERNATIONAL LLC	FRESENIUS MEDICAL CARE - BLOOD TUBING SET K120823
2014-7626	09/16/2014 10/15/2014	FDA/OFVM/CFSAN/OCD/EOS/	WILLIAM A OLSON PHD Center for Regulatory Services, Inc.	GUIDELINES FOR MAXIMUM AMOUNT OF SUCROSE IN INFANT FORMULA
2014-7627	09/16/2014 10/15/2014	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	EVAN TUNIS TUNIS, EVAN	ADVANCED CELL TECHNOLOGY - MTG NOTES
2014-7628	09/17/2014 10/16/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jennifer Day, PharmD KAISER PERMANENTE	NDA 204353 LISTING AS NME

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2014-7629	09/17/2014 10/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K133769
2014-7630	09/17/2014 10/16/2014	OC/ORO/OCI/ OC/ORO/OCI/	Doe J	INVESTIGATION RECS
2014-7631	09/17/2014 10/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	Noah Roth ALS	K103004, K954530, K963591 ETC
2014-7632	09/17/2014 10/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	Noah Roth ALS	K112205
2014-7633	09/17/2014 10/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K140880
2014-7634	09/17/2014 10/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	Noah Roth ALS	K954530
2014-7635	09/17/2014 10/16/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	FOIA LOG TYSABRI, ANTEGREN, NATALIZUMAB
2014-7636	09/17/2014 10/16/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bioequivalence study report of Aprepitant capsule DAEWOONG AMERICA INC	ANDA 090999
2014-7637	09/17/2014 10/16/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jineane Venci UNIVERSITY OF ROCHESTER MEDICAL CENTER	AFREZZA - SUMMARY REVIEW, MEDICAL REVIEW
2014-7638	09/17/2014 10/16/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Linda Bowen SANOFI	BLA 103780 S 5121
2014-7639	09/17/2014 10/16/2014	FDA/OC/OES/DFOI/	Anna Edney BLOOMBERG NEWS	2014-1847 ENCLOSURE 32
2014-7640	09/17/2014 10/16/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lyn Olson Campbell University	TNF BLOCKERS - DATA, INTERNAL REPORTS OF MALIGNANCY

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2014-7641	09/17/2014 10/16/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Christine Burns Discovery Laboratories, Inc.	DISCOVERY LABORATORIES, INC, WARRINGTON, PA - EIR FEB 2014
2014-7642	09/17/2014 10/16/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Scott Barnhart ARx, LLC	ANDA 076166 SBA
2014-7643	09/17/2014 10/16/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Andrea Demakas ADVERSEEVENTS INC	ACCUPRIL, ACEON, BENICAR ETC - AERS
2014-7644	09/17/2014 10/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	YONEJI MIZUNO NIDEK CO LTD	CARL ZEISS MEDITEC AG - FORUM GLAUCOMA WORKPLACE K130648
2014-7645	09/17/2014 10/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	AERIA BOLDEN BERTLING & CLAUSEN LLC	DEROYAL - SURGICAL PATTIES & STRIPS DVC EXPERIENCE RPTS, CORR
2014-7646	09/17/2014 10/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	MARILYNN WHITNEY COVINGTON BURLING LLP	CDRH RESPONSE TO 513 (G) REQUESTS 2010 TO PRESENT
2014-7647	09/17/2014 10/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	JP SAWYER SAWYER LAW FIRM INC	BERLIN HEART INC - FDA FORM 3500A SUBMISSIONS, MDRS, CORR
2014-7648	09/17/2014 10/16/2014	FDA/OO/OFBA/OAGS/	MARIA OLSON NEWS USA	NORTH AMERICAN PRECIS SYNDICATE INC - CONTRACT, INVOICES, PLACEMENT RPTS
2014-7649	09/17/2014 10/16/2014	FDA/OFVM/CFSAN/OCD/EOS/	ROBERT BUTLER Butler, Robert	AZODICARBONAMIDE - SUMMARY, ARTICLES
2014-7650	09/18/2014 10/17/2014	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	Aaron DeMent Sterigenics	ISOMEDIX, LIBERTYVILLE, IL - EIR, 483 01/01/2014 - 09/17/2014
2014-7651	09/18/2014 10/17/2014	OC/ORACE/ OC/ORACE/ FDA/OGROP/ORACE-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORACE-FO/SEA-DO/SEA-CB/	Randal Yoshida Yoshida, Randal	SAMPLE RESULTS
2014-7652	09/18/2014 10/17/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jeffrey A. Wolfson Strides Acrolab Limited	ONCO THERAPIES LIMITED, AGILA SPECIALTIES PRIVATE LIMITED - EIR 12/01/2013 - 09/17/2014

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2014-7653	09/18/2014 10/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	Lyric Xia Shenzhen Hlongmed Biotech Co.,Ltd	K093508
2014-7654	09/18/2014 10/17/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Lyric Xia Shenzhen Hlongmed Biotech Co.,Ltd	K093218
2014-7655	09/18/2014 10/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	Lyric Xia Shenzhen Hlongmed Biotech Co.,Ltd	K111291
2014-7656	09/18/2014 10/17/2014	OC/ORO/ORM/ OC/ORO/ORM/	David Mangione Govzilla, Inc.	LIST OF INSPECTIONS 03/15/2014 - 09/17/2014
2014-7657	09/18/2014 10/17/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Steven Victor Intellicell Biosciences	LETTER TO FDA FROM SARAH YOUNG RE INTELLICELL BIOSCIENCES
2014-7658	09/18/2014 10/17/2014	FDA/OC/OES/DFOI/	Andrea Loewen-Rodriguez Vital Therapies, Inc.	PREMIER RESEARCH GROUP, SWITZERLAND - EIR, 483 01/01/2014 - 09/15/2014
2014-7659	09/18/2014 10/17/2014	FDA/OGROP/ORO/CE-FO/PHI- DO/PHI-CB/	MARK R. KASTER DORSEY & WHITNEY LLP	SUN OPTA GLOBAL ORGANIC INGREDIENTS, ALLENTOWN, PA - EIR
2014-7660	09/18/2014 10/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	HERMAL MEHTA DepuySynthes	FLOW FX LLC - FLOW NAIL K140601
2014-7661	09/18/2014 10/17/2014	FDA/OC/OES/DDM/	KRISTI O. SMEDLEY, Ph.D. Center for Regulatory Services,Inc.	DCK 95S-0316, PRT 169
2014-7662	09/18/2014 10/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	JUDY F. GORDON CLIN REG CONSULTING SERVICES	LEICA FL800 - K141136
2014-7663	09/18/2014 10/17/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	MICHAEL MANCINELLI CONWAY HOMER & CHIN- CAPLAN PC	INDIVIDUAL RECS
2014-7664	09/18/2014 10/17/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	MICHAEL MANCINELLI CONWAY HOMER & CHIN- CAPLAN PC	INDIVIDUAL RECS
2014-7665	09/18/2014 10/17/2014	FDA/OGROP/ORO/PA-FO/SAN- DO/SAN-CB/ FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/	JASON M. KERR PRICE PARKINSON & KERR PLLC	NOTICE OF FDA ACTION REGARDING WEIGHT LOSS BEND
2014-7666	09/18/2014 10/17/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORO/CE-FO/CIN-	JIM FRANCIS FRANCIS LAW OFFICE PLLC	ALE 8 ONE - INVESTIGATIONS 1/09 TO PRESENT

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		DO/CIN-CB/		
2014-7667	09/18/2014 10/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	DEEP BRAIN STIMULATION - BROADEN TRIAL RECS
2014-7668	09/19/2014 10/20/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/	Jeremy Johnson Traditional Medicinals, Inc.	MARTIN BAUER GROUP, SECAUSUS, NJ; GERMANY - INSPECTION RECS, RECALL RECS, RFR RECS ETC
2014-7669	09/19/2014 10/20/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Janet B. Arrowsmith M.D. Arrowsmith Consulting LLC	Presentation to a Safe Use Initiative Committee by Dr. Judy Racoosin
2014-7670	09/19/2014 10/20/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/	Heather Baierl Nature's Way Product	CAPTEK SOFTGEL INTERNATIONAL INC; DENMARK; SOFTGEL TECHNOLOGIES, LOS ANGELES; WELLINGTON FOODS, CORONA, CA ETC - EIR, 483 ,
2014-7671	09/19/2014 10/20/2014	OC/ORACE/ OC/ORACE/ FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/	Jeannie Huang Southwind Foods LLC DBA Great American S	LAB REPORT 1692695
2014-7672	09/19/2014 10/20/2014	FDA/OFVM/CFSAN/OCD/EOS/	Jeremy Johnson Traditional Medicinals, Inc.	WORLEE NATURPRODUCKTE GMBH, GERMANY - INSPECTIONS, RECALL RECS, FRF REPORTS
2014-7673	09/19/2014 10/20/2014	OC/ORACE/ OC/ORACE/ FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/	John LoMonaco Ref # 137942 LoMonaco, John	INDIVIDUAL RECS
2014-7674	09/19/2014 10/20/2014	FDA/OC/OES/DFOI/	Elizabeth Thomas Kroll Background Screening, a HireRight company	INDIVIDUAL RECS
2014-7675	09/19/2014 10/20/2014	FDA/OFVM/CFSAN/OCD/EOS/	Zach Devier Selective Micro Technologies	FCN 1052
2014-7676	09/19/2014 10/20/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michael S Sawaya Altaire Pharmaceuticals, Inc.	ANDA 080027
2014-7677	09/19/2014 10/20/2014	OC/ORACE/ OC/ORACE/ FDA/OGROP/ORASW-	Weerawan (Birda) Misch CALAVO GROWERS, INC.	SAMPLE DI412699 LAB RESULTS

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		FO/SWID/SWID-CB/		
2014-7678	09/19/2014 10/20/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2013-7599
2014-7679	09/19/2014 10/20/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KATE REYNOLDS ROCKY MOUNTAIN POISON & DRUG CENTER	COUGH AND COLD PREPARATIONS - ISRS 8617002, 8759800, 8761992, ETC
2014-7680	09/19/2014 10/20/2014	FDA/OGROP/ORACE-FO/BLT- DO/BLT-CB/ FDA/OGROP/ORACE-FO/CHI- DO/CHI-CB/ FDA/OGROP/ORACE-FO/CIN- DO/CIN-CB/ FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORACE-FO/PHI- DO/PHI-CB/ FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/ FDA/OGROP/ORANE-FO/NYK- DO/NYK-DCB/ FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORAPA-FO/SAN- DO/SAN-CB/ FDA/OGROP/ORASE-FO/ATL- DO/ATL-CB/ FDA/OGROP/ORASE-FO/FLA- DO/FLA-CB/ FDA/OGROP/ORASE-FO/NOL- DO/NOL-CB/ FDA/OGROP/ORASW-FO/DEN- DO/DEN-CB/ FDA/OGROP/ORASW-FO/KAN- DO/KAN-CB/ FDA/OGROP/ORAPA-FO/SAN- DO/SAN-CB/ FDA/OMPT/CBER/OCOD/DDOM/	LIZA MEAK NBC Bay Area News (KNTV)	CORD BLOOD INSPS

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		ALFB/ FDA/OGROP/ORANE-FO/NYK- DO/NYK-DCB/		
2014-7681	09/19/2014 10/20/2014	FDA/OMPT/CDRH/OCER/DFOI/	MARILYNN WHITNEY COVINGTON BURLING LLP	CDRH UNTITLED LTRS RELATING TO PROMOTION OR LBLG OF DVCS; CDRH UNTITLED LTRS RELATING TO FAILURE TO HAVE A 510K OR PMA FOR A DVC 11/3/12 TO PRESENT
2014-7682	09/19/2014 10/20/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	IAIN A MCINTYRE PHD Carlson Caspers	NDA 200-603 - APPL HOLDER NAME AND ADDRESS
2014-7683	09/19/2014 10/20/2014	FDA/OC/OES/DFOI/	WILLIAM MCCONAGHA SIDLEY AUSTIN LLP	2013-66
2014-7684	09/19/2014 10/20/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PETER HARWIN TAVISTOCK LIFE SCIENCES	ENZALUTAMIDE - MEDICAL RVW
2014-7685	09/19/2014 10/20/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PETER HARWIN TAVISTOCK LIFE SCIENCES	ABIRATERONE ACETATE - MEDICAL RVW
2014-7686	09/22/2014 10/30/2014	FDA/OC/OES/DFOI/	David Mangione Govzilla, Inc.	483 ISSUED AFTER 1/1/10 RELEASED SINCE 6/18/14
2014-7687	09/22/2014 10/21/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2013-9555
2014-7688	09/22/2014 10/21/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ryan Woods PRA Health Sciences	PRA HEALTH SCIENCES - EIR 01/26/2009 - 04/26/2013
2014-7689	09/22/2014 10/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	Andrew T Ryan Ryan Law, APLC	BAXTER HEATHCARE CORPORATION, BAXTER INTERNATION - CORRECTIONS AND REMOVALS, REPORTS, ANNUAL REPORTS
2014-7690	09/22/2014 10/21/2014	OC/ORR/ORM/ OC/ORR/ORM/	Lauren Candreva Haley & Aldrich	LIST OF BOTTLED WATER FACILITIES IN NEVADA, ILLINOIS, MISSOURI 09/15/1994 - 09/18/2014
2014-7691	09/22/2014 10/21/2014	FDA/OGROP/ORR/SE-FO/ATL- DO/ATL-CB/	Steve Rogers Zoetis Inc.	TRS LABS INC, ATHENS, GA - EIR, 483

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2014-7692	09/22/2014 10/21/2014	OC/ORa/ORM/ OC/ORa/ORM/	rank E. Zeiss SIGMEDICS, INC.	SIGMEDICS, INC, FAIRBORN, OH - LIST OF INSPECTIONS 01/01/1995-12/31/2003
2014-7693	09/22/2014 10/21/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDRH/OCER/DFOI/	Jack Gillum ASSOCIATED PRESS	EMAILS FROM SENIOR STAFF IN CDRH, CBER TO OR FROM APPLE 08/01/2014 - 09/18/2014
2014-7694	09/22/2014 10/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	Ketaki Gokhale BLOOMBERG NEWS	SUN PHARMACEUTICALS - 483 09/01/2014 - 09/18/2014
2014-7695	09/22/2014 10/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K122511
2014-7696	09/22/2014 10/21/2014	FDA/OGROP/ORa/CE-FO/DET- DO/DET-CB/	Dennis R. Gwaltney DePuy Orthopaedics, Inc.	DEPUY ORTHOPAEDICS FACILITY, WARSAW, IN - EIR UNREDACTED 10/01/2012 - 11/30/2012
2014-7697	09/22/2014 10/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K082619
2014-7698	09/22/2014 10/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K120898
2014-7699	09/22/2014 10/21/2014	FDA/OGROP/ORa/CE-FO/CHI- DO/CHI-CB/	Megan Fierst Nature's Way Product	BASF CONGIS CORPORATION - EIR, 483 01/01/2010 - 09/17/2014
2014-7700	09/22/2014 10/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K111788
2014-7701	09/22/2014 10/21/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Ellie White Terumo BCT	BK950035-0
2014-7702	09/22/2014 10/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Elissa Flynn-Poppey Mintz Levin Cohn Ferris Glovsky & Popeo PC	ICLUSIG - AERS
2014-7703	09/22/2014 10/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 3392
2014-7704	09/22/2014	FDA/OMPT/CDER/ORP/DIDP/	ibrutinib - direct August 2014	IMBRUVICA - AERS

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	10/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ken Tong	
2014-7705	09/22/2014 10/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PAMELA SHEPPARD TARO PHARMACEUTICALS USA INC	MEDA PHARMS - EPIFOAM 086-457 SBA
2014-7706	09/22/2014 10/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PAMELA SHEPPARD TARO PHARMACEUTICALS USA INC	MEDA PHARMS - PROCTOFOAM HC 086-195 SBA
2014-7707	09/22/2014 10/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	LEROY L HAMILTON HAMILTON PHD, LEROY L	MEDICAL DVCS A/C - ORTHOPAEDIC & REHABILITATION PANEL RECS 5/21/13
2014-7708	09/22/2014 10/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Hisatoshi Tsuchida Kyorin Pharmaceutical Co., Ltd.	DMSO - AERS
2014-7709	09/22/2014 10/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/ FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/ FDA/OGROP/ORA/PA-FO/SEA- DO/SEA-CB/	ROBERT STAVERT ROBERT STAVERT MD	INDIVIDUAL RECS
2014-7710	09/22/2014 10/21/2014	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	ARNOLD S WEINTRAUB WEINTRAUB GROUP PLC	CONSOLIDATED MARKETING UNLIMITED INC - RECS WHICH ESTABLISH EITHER COMPLIANCE OR
2014-7711	09/22/2014 10/21/2014	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/ORO/DIOP/	DONALD N BLUE ZETETIC INC	SHIPMENTS REGULATED BY THE US FDA 8/20/14-9/20/14
2014-7712	09/22/2014	FDA/OC/OES/DFOI/	MICHELE BOOTH KREISMAN	AHCC (MUSHROOM EXTRACT) - RECS

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	10/21/2014	FDA/OFVM/CFSAN/OCD/EOS/	KREISMAN, MICHELE BOOTH	
2014-7713	09/23/2014 10/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	Andrey Godes Multi Radiance Medical	K123014
2014-7714	09/23/2014 10/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kevin Croteau Impact Medical Sales & Supply, LLC	K112800
2014-7715	09/23/2014 10/22/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Publicly disclosable version of the EIR 3010776677 CROSS Research SA	CROSS RESEARCH SA - EIR
2014-7716	09/23/2014 10/22/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Amy Wilson ABL Medical, LLC	SilvrSTAT - AERS
2014-7717	09/23/2014 10/22/2014	FDA/OC/OES/DFOI/	Stephen C. Earnhart The O'Brien Firm, P.C.	INDIVIDUAL RECS
2014-7718	09/23/2014 10/22/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	HYLAND'S 4KIDS CALM AND RESTFUL - AERS
2014-7719	09/23/2014 11/20/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Delaine Williams NOVARTIS VACCINES AND DIAGNOSTICS INC	Typhim Vi Polysaccharide Vaccine; Typhoid Vaccine Live Oral Ty21a - CLINICAL REVIEW RECORDS, CORR, RESPONSES ETC (09/01/2005 - 09/01/2014
2014-7720	09/23/2014 10/22/2014	FDA/OFVM/CFSAN/OCD/EOS/	Cliff Rieders, Esq. Rieders Travis Law Firm	FDA's investigation of aegeline in the vitamin supplement OxyElite Pro marketed by USPLabs
2014-7721	09/23/2014 10/22/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-2991
2014-7722	09/23/2014 10/22/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Pallavi Ail The Financial Express	IPCA LABORATORIES LTD, INDIA - 483 01/02/2013 - 09/19/2014
2014-7723	09/23/2014 10/22/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	APTUIT, VERONA, ITALTY - 483

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2014-7724	09/23/2014 10/22/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Andrey Godes Multi Radiance Medical	K120938
2014-7725	09/23/2014 10/22/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	David L Keller David L Keller, MD, FACP	IPILIMUMAB - AERS
2014-7726	09/23/2014 10/22/2014	FDA/OC/OES/DFOI/ FDA/OGROP/ORAC/CE-FO/MIN- DO/MIN-CB/	Lee W. Mayberry WHOLE FOODS MARKET	Quincy Bioscience Manufacturing Inc. Quincy Bioscience Prevagen Mark Y. Underwood
2014-7727	09/23/2014 10/22/2014	OC/CVM/OCD/	Scott Fawcett Carroll Quality Consult, Inc.	BIOVET, BULGARIA - 483, EIR 03/01/2010 - 09/22/2014
2014-7728	09/23/2014 10/22/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Lance Connor Reliable Engineering Services, Inc.	K130025
2014-7729	09/23/2014 10/22/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Sara Wexler Koblitz Fish and Richardson P.C.	NDA 019201
2014-7730	09/23/2014 10/22/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sara Wexler Koblitz Fish and Richardson P.C.	NDA 017581
2014-7731	09/23/2014 10/22/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sara Wexler Koblitz Fish and Richardson P.C.	NDA 018922
2014-7732	09/23/2014 10/22/2014	FDA/OC/OES/DFOI/	Birchwood Laboratories Inc BIRCHWOOD LABORATORIES INC	2013-6338
2014-7733	09/23/2014 10/22/2014	FDA/OFVM/CFSSAN/OCD/EOS/	Kristi O. Smedley Center for Regulatory Services, Inc.	FAP 2234
2014-7734	09/23/2014	FDA/OMPT/CDER/GRP/DIDP/	Karla Ham	IPCA Laboratories LTD - EIR, 483, WARNING LETTER

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	10/22/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FSC Laboratories Inc	
2014-7735	09/23/2014 10/22/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sara Wexler Koblitz Fish and Richardson P.C.	NDA 018989
2014-7736	09/23/2014 10/22/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sara Wexler Koblitz Fish and Richardson P.C.	NDA 018851
2014-7737	09/23/2014 10/22/2014	FDA/OC/OES/DFOI/	Travis Siverson BIRCHWOOD LABORATORIES INC	2013-1428
2014-7738	09/23/2014 10/22/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Serene Chen YALE SCHOOL OF MEDICINE	DRUGS THAT HAD NEW SHORTAGES 01/01/2005 - 08/30/2014
2014-7739	09/23/2014 10/22/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tariq Ata REMS Logic, LLC	Number of REMS Drug Error Reports (by drug) - from 2005 through 2013
2014-7740	09/23/2014 10/22/2014	FDA/OGROP/ORO/ORO/DIOP/	Mark Prinz Registrar Corp	List of the companies that submitted petitions to the Division of Import Operations for removal or exemption from Detention Without Physical Examination
2014-7741	09/23/2014 10/31/2014	FDA/OFVM/CFSAN/OCD/EOS/	Mark Prinz Registrar Corp	List of 2,443 LACF importers
2014-7742	09/23/2014 10/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	jonathon lawrie lawrie, jonathon	K131417
2014-7743	09/23/2014 10/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	jonathon lawrie lawrie, jonathon	K123497
2014-7744	09/23/2014 10/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	jonathon lawrie lawrie, jonathon	K120340
2014-7745	09/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	jonathon lawrie	K113011

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	10/22/2014		lawrie, jonathon	
2014-7746	09/23/2014 10/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	jonathon lawrie lawrie, jonathon	K112097
2014-7747	09/23/2014 10/22/2014	FDA/OC/OES/DFOI/	Robert Beck Software Regulatory, LLC	MEDICAL DEVICE RECALLS RELATED TO SOFTWARE
2014-7748	09/23/2014 10/22/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michael Man FIRST DATABANK	NDA 020703, ANDA 075863
2014-7749	09/23/2014 10/22/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Anubhav Aggarwal Aggarwal, Anju D	SUN PHARMACEUTICAL INDUSTRIES, INDIA - 483 09/17/2014 - 09/24/2014
2014-7750	09/23/2014 10/22/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	Chirag Talati Kotak Securities	SUN PHARMA, INDIA - 483 SEPT 2014
2014-7751	09/23/2014 10/22/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Chirag Talati Kotak Securities	LUPIN, GLENMARK, CIPLA ETC - 483, EIR 01/01/2010 - 09/22/2014
2014-7752	09/23/2014 10/22/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	Soma Das The Economic Times, The Times of India	SUN PHARMA, INDIA - 483 SEPT 2014
2014-7753	09/23/2014 10/22/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	Darshan Mehta ET Now	SUN PHARMA, INDIA - 483 SEPT 2014
2014-7754	09/23/2014	OC/ORAI/	Pranay Patel	CONSUMER PROCESSED FOOD PRODUCTS -

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	10/22/2014	OC/OROA/ OC/OROA/ORM/ OC/OROA/ORM/	groceryratingscom	SPREADSHEET OF TEST RESULTS 01/01/2010 - 09/22/2014
2014-7755	09/23/2014 10/22/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mark Pohl Health Science Funding, LLC	CHEMO IBERICA SA MADRID - AGENT NAME, ADDRESS
2014-7756	09/23/2014 10/22/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mark Pohl Health Science Funding, LLC	CTX LIFE SCIENCES PVT LTD - AGENT NAME, ADDRESS
2014-7757	09/23/2014 10/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	Lance Connor Reliable Engineering Services, Inc.	K022328
2014-7758	09/23/2014 10/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kevin Ackermann MEDELA INC	K141437
2014-7759	09/23/2014 10/22/2014	OC/CVM/OCD/	Hannah Connor Humane Society of the United States	NADA 130-736, NADA 38-878, NADA 140-939 ETC - SUMMARIES OF SAFETY AND EFFECTIVENESS DATA, FINDINGS OF NO SIGNIFICANT IMPACT, ENVIRONMENTAL ASSESSMENTS ETC
2014-7760	09/23/2014 10/22/2014	FDA/OC/OES/DFOI/	Emeline Harris RRP Solutions Inc.	FDA-223-SOL-00125 - EVALUATION NOTES, SCORES
2014-7761	09/23/2014 10/22/2014	OC/OROA/ORM/ OC/OROA/ORM/	Robert Beck Software Regulatory, LLC	MEDICAL DEVICE SOFTWARE - 483 DATA 01/01/2010 - 06/30/2014
2014-7762	09/23/2014 10/22/2014	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	2014-3348
2014-7763	09/23/2014 10/22/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHRISTIAAN A. MARCUM, Esq. RICHARDSON PATRICK ET AL	RED RIBBON POLICY (CERTIFIED)
2014-7764	09/23/2014 10/22/2014	FDA/OGROP/OROA/CE-FO/PHI- DO/PHI-CB/	KARABELL, I MILTON	KAUFFMAN FRUIT FARM - FALSE LBLG OF JAMS AND PRESERVES CMLPNT
2014-7765	09/23/2014 10/22/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HATTON, ROLAND	BOEHRINGER INGELHEIM - MIRAPEX (PRAMIPEXOLE DIHYDROCHLORIDE) AER 1997 TO PRESENT

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-7766	09/24/2014 10/23/2014	FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/	Cynthia David Sekisui Diagnostics, LLC	ALERE, SAN DIEGO, CA - 483 2014
2014-7767	09/24/2014 10/23/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shaheen Wirk Palkon Management	IDEBENONE - CLINICAL TRIAL RECS
2014-7768	09/24/2014 10/23/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Jennifer Jackson Straumann USA, LLC	K133255
2014-7769	09/24/2014 10/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jennifer Jackson Straumann USA, LLC	K132881
2014-7770	09/24/2014 10/23/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bhagwan S. Chaudhary National Institute of Securities Markets, Mumbai, India	SUN PHARMACEUTICALS, INDIA - 483 09/08/2014 - 09/23/2014
2014-7771	09/24/2014 10/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	Dr. Yossi Muncher REGUCLIN	K071920, K071061
2014-7772	09/24/2014 10/23/2014	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	Rachel Johnson FOI Services, Inc.	OLAM EDIBLE NUTS, EDENTON, NC - 483
2014-7773	09/24/2014 10/23/2014	FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/	Jeremy Johnson Traditional Medicinals, Inc.	MOTHER PARKERS, SANDRA TEA & COFFEE LIMITED, CANADA - INSPECTION DATES, 483, RESPONSES ETC 04/10/2013 - 09/23/2014
2014-7774	09/24/2014 10/23/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	idelalisib - all AEs Ken Tong	ZYDELIG - AERS
2014-7775	09/24/2014 10/23/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rebecca Burch VIVUS, Inc.	NDA 200063

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-7776	09/24/2014 10/23/2014	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	Anna Hwang Advanced Orthopaedic Solutions, Inc.	ADVANCED ORTHOPAEDIC SOLUTIONS, INC - EIR 08/21/2013 - 08/23/2013
2014-7777	09/24/2014 10/23/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kevin Charles Isaac myself	PALIPERIDONE - CLINICAL TRIAL RECS
2014-7778	09/24/2014 10/23/2014	OC/CVM/OCD/	Ruth Weese Boehringer Ingelheim Vetmedica, Inc.	NADA 141015
2014-7779	09/24/2014 10/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	Sanjay Parikh AMBU INC	AMBU SDN BHD, MALAYSIA - EIR 09/01/2013 - 09/22/2014
2014-7780	09/24/2014 10/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K101026
2014-7781	09/24/2014 10/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K063142
2014-7782	09/24/2014 10/23/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michele Sinoway LACHMAN CONSULTANT SERVICES, INC.	SHOUGUANG FUKANG PHARMACEUTICAL CO LTD - 483 06/02/2014 - 06/09/2014
2014-7783	09/24/2014 10/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jennifer Jackson Straumann USA, LLC	K090793
2014-7784	09/24/2014 10/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jennifer Jackson Straumann USA, LLC	K051443
2014-7785	09/24/2014 10/23/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	G. Srinivas Zydus Pharmaceuticals USA Inc.	NDA 050740 - SBA
2014-7786	09/24/2014 10/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	Anita Petito The Hymed Group	K955506
2014-7787	09/24/2014 10/23/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	G. Srinivas Zydus Pharmaceuticals USA Inc.	ANDA 203263

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		FDA/OMPT/CDER/ORP/DIDP/		
2014-7788	09/24/2014 10/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	ROB FRITZENKOTTER PILLAR SURGICAL INC	PROLASTIC SHEETING K954382
2014-7789	09/24/2014 11/18/2014	FDA/OC/OES/DFOI/ OC/ORO/ OC/ORO/ FDA/OC/OES/DFOI/ FDA/OGROP/ORO/CE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORO/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORO/CE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORO/NE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORO/SE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORO/SW-FO/DEN-DO/DEN-CB/ FDA/OC/OES/DFOI/	MARILYNN WHITNEY COVINGTON BURLING LLP	CIGARETTE PROD MFRS - EIRS, 483S , CORR 11/2/12 TO PRESENT
2014-7790	09/24/2014 10/23/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	RICHARD JONES LIFESOUTH COMMUNITY BLOOD CENTERS INC	ALLOCORD, DUOCORD, HEMACORD, ETC - EIRS, 483S, ANNUAL RPTS, ETC 1/1/11 TO 9/16/14
2014-7791	09/24/2014 10/23/2014	FDA/OC/OES/DFOI/	AMIE N VANELLA FAEGRE BAKER DANIELS	SIMPLY THICK LLC - SIMPLY THICK FOI REQUEST LTRS 7/11/14 TO PRESENT
2014-7792	09/24/2014 10/23/2014	FDA/OC/OES/DFOI/	EDWARD THOMAS THOMAS #P-64423, EDWARD	CYMBALTA, TRAMADOL, NAPROXEN, ETC - RECS
2014-7793	09/24/2014	FDA/OO/OFBA/OAGS/	RICHARD D SMITH	NORTH AMERICAN PRECIS SYNDICATE INC - CONTRACT, INVOICES, PLACEMENT RPTS

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	10/23/2014		NEWS USA	
2014-7794	09/24/2014 10/23/2014	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	MOHIT BHAT Kline & Company	SANMINA-SCI CORP, HUNTSVILLE, AL - EIRS BEFORE 2009
2014-7795	09/24/2014 10/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	DOUGLAS JOHNSON JOHNSON, DOUGLAS	DOUGLAS MEDICAL PRODUCTS - EMPTY MIXING CONTAINER K932641
2014-7796	09/24/2014 10/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	DOUGLAS JOHNSON JOHNSON, DOUGLAS	DOUGLAS MEDICAL PRODUCTS - 3-LEAD CONNECTOR K931659
2014-7797	09/24/2014 10/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	DOUGLAS JOHNSON JOHNSON, DOUGLAS	DOUGLAS MEDICAL PRODUCTS - SUBCUTANEOUS INFUSION SET K932637
2014-7798	09/24/2014 10/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	DOUGLAS JOHNSON JOHNSON, DOUGLAS	DOUGLAS MEDICAL PRODUCTS - SOLUTION ADMINISTRATION SET K921391
2014-7799	09/24/2014 10/23/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	JAPAN BCG LAB, TOKYO, JAPAN - 483 1/21-24/13
2014-7800	09/24/2014 10/23/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	TEIKOKU SIEYAKU, KAGAWA, JAPAN - 483 3/10-14/14
2014-7801	09/24/2014 10/23/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/CVM/OCD/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	ELI LILLY AND CO LTD, LIVERPOOL, UK - 483 5/2-9/13
2014-7802	09/24/2014 10/23/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	HOSPIRA SPA, LISCATE, ITALY - 483 5/5-13/14
2014-7803	09/24/2014 10/23/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Annie Waldman PROPUBLICA	MASIMO CORPORATION - 483 08/01/2013 - 11/01/2013
2014-7804	09/25/2014 12/10/2014	OC/ORA/ OC/ORA/ FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORACE-FO/CIN-	Rachel Johnson FOI Services, Inc.	TOBACCO INSPECTION RECORDS

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		DO/CIN-CB/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/		
2014-7805	09/25/2014 10/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Suhasini Kanagala Tonix Pharmaceuticals, Inc.	INTERMEZZO - PHARMACOLOGY, TOXICOLOGY RECS
2014-7806	09/25/2014 10/24/2014	OC/ORAI/ OC/ORAI/	Rachel Johnson FOI Services, Inc.	TOBACCO COMPLAINTS IN FACTS
2014-7807	09/25/2014 10/24/2014	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-4346
2014-7808	09/25/2014 10/24/2014	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-4388
2014-7809	09/25/2014 10/24/2014	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/ OC/ORAI/ORM/ OC/ORAI/ORM/	Rachel Johnson FOI Services, Inc.	2014-4314
2014-7810	09/25/2014	OC/ORAI/	Michael Zelenko	MEDI-FARE DRUG AND HOME CENTER - PHOTOGRAPHS

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	10/24/2014	OC/ORAI/	The Verge	
2014-7811	09/25/2014 10/24/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-4292
2014-7812	09/25/2014 10/24/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K060903
2014-7813	09/25/2014 10/24/2014	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	Annie Waldman PROPUBLICA	MASIMO CORPORATION - EIR 08/01/2013 - 11/01/2013
2014-7814	09/25/2014 10/24/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-4405
2014-7815	09/25/2014 10/24/2014	FDA/OC/OES/DFOI/	Kari L. Twaite BEVERIDGE & DIAMOND PC	CFSAN FOIA REQUESTS 08/29/2014 - 09/24/2014
2014-7816	09/25/2014 10/24/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/CVM/OCD/	Bharat Garg Goldman Sachs Investment Partners	BIOVECTRA - 483 01/01/2013 - 09/24/2014
2014-7817	09/25/2014 10/24/2014	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	Bharat Garg Goldman Sachs Investment Partners	QUESTCOR PHARMACEUTICALS - 483 01/01/2013 - 09/24/2014
2014-7818	09/25/2014 10/24/2014	FDA/OGROP/ORA/CE-FO/BLT- DO/BLT-CB/	Bharat Garg Goldman Sachs Investment Partners	CANGENE BIOPHARMA - 483 01/01/2013 - 09/24/2014
2014-7819	09/25/2014 10/24/2014	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/ FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/ FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bharat Garg Goldman Sachs Investment Partners	MALLINCKRODT PLC - 483 01/01/2013 - 09/24/2014
2014-7820	09/25/2014 10/24/2014	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	WALTER E CHALKLEY THOMSON REUTERS	AMBIOPHARM INC, NORTH AUGUSTA, SC - EIR, 483, CO RESP 3/26-28/13

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			(SCIENTIFIC) SAS	
2014-7821	09/25/2014 10/24/2014	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	WAYNE MEMORIAL HOSPITAL IRB, GOLDSBORO, NC - EIR, 483, CO RESP 2/13-14/13
2014-7822	09/25/2014 10/24/2014	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	UNITED THERAPEUTICS CORP, SILVER SPRING, MD - EIR, 483, CO RESP 5/20-29/13
2014-7823	09/25/2014 10/24/2014	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	OSMOTICA PHARMACEUTICAL CORP, MARIETTA, GA - EIR, 483, CO RESP 4/22-26/13
2014-7824	09/25/2014 10/24/2014	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	CEDARBURG PHARMACEUTICALS INC, GRAFTON, WI - EIR, 483, CO RESP 4/1-4/13
2014-7825	09/25/2014 10/24/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	BUTLER HOSPITAL IRB, PROVIDENCE, RI - EIR, 483, CO RESP 4/3-11/13
2014-7826	09/25/2014 10/24/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	PACIRA PHARMACEUTICALS INC, SAN DIEGO, CA - EIR, 483, CO RESP 3/18-27/13
2014-7827	09/25/2014 10/24/2014	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	WALTER E CHALKLEY THOMSON REUTERS	CARDINAL BIOLOGICALS INC. TYMER, TX - EIR, 483, CO RESP 3/25-27/13
2014-7828	09/25/2014 10/24/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	WALTER E CHALKLEY THOMSON REUTERS	MEDCHEM MANUFACTURING INC (ENOVACHEM MANUFACTURING), TORRANCE, CA - EIR, 483, CO RESP 4/18/13
2014-7829	09/25/2014 10/24/2014	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	NEW YORK CITY DEPT OF HEALTH & MENTAL HYGIENE IRB, LONG ISLAND CITY, NY - EIR, 483, CO RESP 3/28/13-4/1/13
2014-7830	09/25/2014 10/24/2014	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	TAYLOR DRUG, ARKANSAS CITY, KS - EIR, 483, CO RESP 3/26/13-4/1/13
2014-7831	09/25/2014 10/24/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	STERIS ISOMEDIX OPERATIONS INC, NORTHBOROUGH, MA - EIR, 483, CO RESP 1/4/13
2014-7832	09/25/2014 10/24/2014	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	PHARMACEUTICS INTERNATIONAL INC, HUNT VALLEY, MD - EIR, 483, CO RESP 5/20-29/13
2014-7833	09/25/2014	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	WALTER E CHALKLEY	CAREFUSION 213 LLC, EL PASO, TX - EIR, 483, CO RESP 1/28/13-2/8/13

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	10/24/2014		THOMSON REUTERS (SCIENTIFIC) SAS	
2014-7834	09/25/2014 10/24/2014	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	MYLAN SPECIALTY LP, NAPA, CA - EIR, 483, CO RESP 5/15-23/13
2014-7835	09/25/2014 10/24/2014	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	MISAL KHAN MD, PANAMA CITY, FL - EIR, 483, CO RESP 5/6-21/13
2014-7836	09/25/2014 10/24/2014	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	HORIZON PHARMACEUTICALS INC, RIVERA BEACH, FL - EIR, 483, CO RESP 5/13-17/13
2014-7837	09/25/2014 10/24/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	CARDINAL HEALTH 414 LLC, PHOENIX, AZ - EIR, 483, CO RESP 4/23/13-5/1/13
2014-7838	09/25/2014 10/24/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	SIEGFRIED USA INC, PENNSVILLE, NJ - EIR, 483, CO RESP 1/18/13-2/6/13
2014-7839	09/25/2014 10/24/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	DISCUS DENTAL LLC, ONTARIO, CA - EIR, 483, CO RESP 4/25/13-5/6/13
2014-7840	09/25/2014 10/24/2014	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	DOW CHEMICAL CO, PLAQUEMINE, LA - EIR, 483, CO RESP 2/7-13/13
2014-7841	09/25/2014 10/24/2014	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	PHARMACEUTICS INTERNATIONAL INC, HUNT VALLEY, MD - EIR, 483, CO RESP 2/19-26/14
2014-7842	09/25/2014 10/24/2014	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	BOZEMAN URGENT CARE CENTER, BOZEMAN, MT - EIR, 483, CO RESP 3/24-28/14
2014-7843	09/26/2014 10/27/2014	FDA/OMPT/CDRH/OCER/DFOI/	Lance Connor Reliable Enigneering Services, Inc.	K080442
2014-7844	09/26/2014 10/27/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Darren Orton StemSynergy Therapeutics, Inc	NDA 011964 NDA 012485
2014-7845	09/26/2014	FDA/OC/OES/DFOI/	Jennii F. Kamesch	MUSCULOSKELETAL RESEARCH FOUNDATION - 483

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	10/27/2014		MedAssets	01/01/2013 - 09/24/2014
2014-7846	09/26/2014 10/27/2014	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	David Mangione Govzilla, Inc.	CATALENT PHARMA SOLUTIONS, LCC, WOODSTOCK, IL - 483, EIR
2014-7847	09/26/2014 10/27/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Lance Connor Reliable Engineering Services, Inc.	K092224
2014-7848	09/26/2014 10/27/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	David Mangione Govzilla, Inc.	LONZA AG, SWITZERLAND - 483, EIR 08/29/2014 - 08/29/2014
2014-7849	09/26/2014 10/27/2014	FDA/OMPT/CDRH/OCER/DFOI/	Dora Fong KARL STORZ ENDOSCOPY AMERICA INC	K061871
2014-7850	09/26/2014 10/27/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Thomas Sims Baron & Budd, PC	OSE Postmarketing Safety Review entitled "Peripheral Neuropathy with Levofloxacin" by Sally Singer and dated 30 Apr 2001
2014-7851	09/26/2014 10/27/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Gopal Krishna Sharma Novartis Healthcare Pvt Ltd	LAMPRENE - AERS
2014-7852	09/26/2014 10/27/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	David Friedman Scopia Capital	Rivaroxaban, Apixaban, Dabigatran - AERS
2014-7853	09/26/2014 10/27/2014	FDA/OMPT/CDRH/OCER/DFOI/	Liane LaRochelle DEKA Research and Development	K133724
2014-7854	09/26/2014 10/27/2014	FDA/OMPT/CDRH/OCER/DFOI/	Julia S Anastas Auxogyn, Inc.	EmbryoViewer software accessory to the EmbryoScope device - 510K
2014-7855	09/26/2014 10/27/2014	FDA/OFVM/CFSAN/OCD/EOS/	Eva Schornick MERCK KGAA	Hydroxypropyl beta cyclodextrin (CAS 128446-35-5) - DATA, EVALUATIONS, STUDIES
2014-7856	09/26/2014 10/27/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Allison Tarantino ARIAD Pharmaceuticals, Inc.	ICLUSIG - ISR 9869699, 10367822

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-7857	09/26/2014 10/27/2014	FDA/OC/OES/DFOI/	Prashant Premkumar East Bridge Capital Management Limited	SUN PHARMA, INDIA - 483 01/01/2014 - 09/30/2014
2014-7858	09/26/2014 10/27/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	LAURA A HALPER PHD HALPER GROUP	PURICORE INC, MALVERN, PA - EIR 5/30/13; VASHE WOUND SOLUTION K131848, INDICATIONS FOR USE STATEMENT
2014-7859	09/26/2014 10/27/2014	FDA/OGROP/ORAPA-FO/SEADO/SEA-CB/	KELLI WASSGREN FRYE ELECTRONICS, INC.	FRYE ELECTRONICS, TIGARD, OR - EIR (CERTIFIED)
2014-7860	09/26/2014 10/27/2014	FDA/OGROP/ORASE-FO/ATLDO/ATL-CB/	BRENDA CROOK-PETITE-EL CROOK-PETITE-EL, BRENDA	CASTLEBERRY'S FOOD CO - EIR 7/17/07-8/10/07 EXHIBITS
2014-7861	09/26/2014 10/27/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID L SILBERSTEIN Valeant Pharmaceuticals North America LLC	VALEANT PHARMS - PREDNISOLONE SODIUM PHOSPHATE ORAL SOL ANDA 75-250 (UNREDACTED)
2014-7862	09/26/2014 10/27/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID L SILBERSTEIN Valeant Pharmaceuticals North America LLC	VALEANT PHARMS - IPRATROPIUM BROMIDE UNHALATION SOL ANDA 75-835 (UNREDACTED)
2014-7863	09/26/2014 10/27/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID L SILBERSTEIN Valeant Pharmaceuticals North America LLC	VALEANT PHARMS - CROMOLYN SODIUM INHALATION SOL ANDA 75-585 (UNREDACTED)
2014-7864	09/26/2014 10/27/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Abhishek Sharma IIFL Cap	SUN PHARMACEUTICALS, INDIA - 483 09/01/2014 - 09/26/2014
2014-7865	09/26/2014 10/27/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rupali Mukherjee The Times of India	SUN PHARMACEUTICALS, INDIA - 483 01/01/2014 - 09/26/2014

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		FDA/OC/OES/DFOI/		
2014-7866	09/26/2014 10/27/2014	FDA/OC/OES/DFOI/	Saion Mukherjee NOMURA INTERNATIONAL PLC	SUN PHARMACEUTICALS, INDIA - 483 09/08/2014 - 09/26/2014
2014-7867	09/26/2014 10/27/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 205858
2014-7868	09/26/2014 10/27/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	David Mangione Govzilla, Inc.	MERCK SHARPE & DOHME CORP, WEST POINT, PA - 483, EIR
2014-7869	09/26/2014 10/27/2014	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	Jeremy Johnson Traditional Medicinals, Inc.	TROUT LAKE FARM, EPHRATA, WA - EIR, 483 RECALL RECS
2014-7870	09/26/2014 10/27/2014	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Jeremy Johnson Traditional Medicinals, Inc.	BI NUTRICEUTICALS, LONG BEACH, CA; ISLANDIA, NY - DATES OF INSPECTION, 483, RECALL RECS
2014-7871	09/26/2014 10/27/2014	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Jeremy Johnson Traditional Medicinals, Inc.	HIGH QUALITY ORGANICS, RENO, NV - DATES OF INSPECTION, 483, RECALL RECS
2014-7872	09/26/2014 10/27/2014	FDA/OMPT/CDRH/OCER/DFOI/	Alex Clark Alex Clark	K051620, K133149
2014-7873	09/26/2014 10/27/2014	FDA/OC/OES/DFOI/	Vik Bajnath ARTHREX INC.	DEVICE FACILITY RECS
2014-7874	09/26/2014 10/27/2014	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	Heather Baierl NATURES WAY PRODUCTS INC	UNIVERSAL HOLDINGS I, LLS, CHICAGO, IL - EIR
2014-7875	09/26/2014 10/27/2014	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Doe J	INDIVIDUAL RECS
2014-7876	09/26/2014 10/27/2014	FDA/OC/OES/DFOI/	Piyush Nahar Jefferies India	SUN PHARMACEUTICALS, INDIA - 483 09/07/2014 - 09/25/2014
2014-7877	09/29/2014 10/28/2014	FDA/OC/OES/DFOI/	Jayne Poisson Toronto Star	INSPECTIONS OF CANADIAN FOOD FACILITIES 01/01/2000 - 09/18/2014
2014-7878	09/29/2014 10/28/2014	FDA/OMPT/CDRH/OCER/DFOI/	Peter Kollings EMED Technologies Corporation	K101194
2014-7879	09/29/2014 10/28/2014	FDA/OC/OES/DFOI/	Michael Armas Armas, Michael A	RECALL DATA
2014-7880	09/29/2014	FDA/OMPT/CDRH/OCER/DFOI/	None	K870514 K861564 K002768 ETC

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	10/28/2014		none	
2014-7881	09/29/2014 10/28/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Lisa Robertson Rawls McNelis + Mitchell	INDIVIDUAL RECS
2014-7882	09/29/2014 10/28/2014	FDA/OGROP/ORAPA-FO/SEA- DO/SEA-CB/	Eli Rosenblatt Mitra Law Group	SANDY FARMS, BORING, OR - SAFETY RECS
2014-7883	09/29/2014 10/28/2014	FDA/OGROP/ORASW-FO/DEN- DO/DEN-CB/	Lawrence Loretoni Steptoe & Johnson, LLP	RESPONSE TO DEN-14-04-WL
2014-7884	09/29/2014 10/28/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Lisa Robertson Rawls McNelis + Mitchell	INDIVIDUAL RECS
2014-7885	09/29/2014 10/28/2014	FDA/OGROP/ORASE-FO/SJN- DO/SJN-CB/	Blake Goodner Bridger Healthcare	ZIMMER HOLDINGS INC, PONCE, PR - 483, RESPONSE, WARNING LETTER 01/04/2012 - 09/25/2014
2014-7886	09/29/2014 10/28/2014	FDA/OC/OES/DFOI/	Bernadette B. D'Souza, MD Midwest Clinical Research Center	COMPLAINT RECORDS
2014-7887	09/29/2014 10/28/2014	FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/	Mario Vesnaver Mario Vesnaver	ALCON/LENXS, FORT WORTH, TX - 483 03/01/2014 - 06/01/2014
2014-7888	09/29/2014 10/28/2014	FDA/OGROP/ORANE-FO/NYK- DO/NYK-DCB/	Jeanine Gouveia1 Aerie Pharmaceuticals Inc.	STEVEM ROSE, MD, ROCHESTER, NY - EIR
2014-7889	09/29/2014 10/28/2014	FDA/OC/OES/DFOI/	Anne Saker Enquirer Media (The Cincinnati Enquirer/cincinnati.com)	ESSURE - APPROVAL RECS
2014-7890	09/29/2014 10/28/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-6474
2014-7891	09/29/2014 10/28/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-6553 REQUEST LETTER
2014-7892	09/29/2014 10/28/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-6599 - REQUEST LETTER
2014-7893	09/29/2014 10/28/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-6604 - REQUEST LETTER
2014-7894	09/29/2014 10/28/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-6844 - REQUEST LETTER
2014-7895	09/29/2014 10/28/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-6980 - REQUEST LETTER
2014-7896	09/29/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2014-7069 - REQUEST LETTER

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	10/28/2014		MERCK & CO., INC.	
2014-7897	09/29/2014 10/28/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-7078 - REQUEST LETTER
2014-7898	09/29/2014 10/28/2014	FDA/OC/OES/DFOI/	Kartik Ashok Mehta ICICI Securities	SUN PHARMACEUTICALS - 483 09/01/2014 - 09/30/2014
2014-7899	09/30/2014 10/29/2014	FDA/OMPT/CDRH/OCER/DFOI/	PEG GARLITZ REED SMITH LLP	INDIVIDUAL RECS (CERTIFIED)
2014-7900	09/30/2014 10/29/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED REQUESTS 9/1-5/14
2014-7901	09/30/2014 10/29/2014	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOI REQUESTS 9/1-5/14
2014-7902	09/30/2014 10/29/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 9/1-5/14
2014-7903	09/30/2014 10/29/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 9/1-5/14
2014-7904	09/30/2014 10/29/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 8/25-29/14
2014-7905	09/30/2014 10/29/2014	FDA/OC/OES/DFOI/	DAVID MCFARLAND JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 8/25-29/14
2014-7906	09/30/2014 10/29/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 8/25-29/14
2014-7907	09/30/2014 10/29/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 8/25-29/14
2014-7908	09/30/2014 10/29/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 8/18-22/14
2014-7909	09/30/2014 10/29/2014	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIREQUESTS 8/18-22/14
2014-7910	09/30/2014 10/29/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 8/18-22/14
2014-7911	09/30/2014 10/29/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 8/18-22/14

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2014-7912	09/30/2014 10/29/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 8/11-15/14
2014-7913	09/30/2014 10/29/2014	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOI REQUESTS 8/11-15/14
2014-7914	09/30/2014 10/29/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 8/11-15/14
2014-7915	09/30/2014 10/29/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 8/11-15/14
2014-7916	09/30/2014 10/29/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 9/1-5/14
2014-7917	09/30/2014 10/29/2014	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 9/1-5/14
2014-7918	09/30/2014 10/29/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 9/1-5/14
2014-7919	09/30/2014 10/29/2014	FDA/OC/OES/DFOI/	DOMINION GROUP INC	DAILY LOG 7/1-15/24
2014-7920	09/30/2014 10/29/2014	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 8/25-30/14
2014-7921	09/30/2014 10/29/2014	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 8/18-22/14
2014-7922	09/30/2014 10/29/2014	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 8/11-15/14
2014-7923	09/30/2014 10/29/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 8/18-22/14
2014-7924	09/30/2014 10/29/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 9/1-6/14
2014-7925	09/30/2014 10/29/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 8/25-30/14
2014-7926	09/30/2014 10/29/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 8/11-15-14
2014-7927	09/30/2014	FDA/OC/OES/DFOI/	LAUREN S. BARR	DAILY LOG 8/25-29/14

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	10/29/2014		JH BARR & ASSOCIATES LLC	
2014-7928	09/30/2014 10/29/2014	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 8/18-22/14
2014-7929	09/30/2014 10/29/2014	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 8/11-15/14
2014-7930	09/30/2014 10/29/2014	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 8/11-15/14
2014-7931	09/30/2014 10/29/2014	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 8/18-22/14
2014-7932	09/30/2014 10/29/2014	FDA/OC/OES/DFOI/	GLADYS B. TONKIN Center for Regulatory Services,Inc.	DAILY LOG 8/11-15/14
2014-7933	09/30/2014 10/29/2014	FDA/OC/OES/DFOI/	GLADYS B. TONKIN Center for Regulatory Services,Inc.	DAILY LOG 8/18-22/14
2014-7934	09/30/2014 10/29/2014	FDA/OC/OES/DFOI/	GLADYS B. TONKIN Center for Regulatory Services,Inc.	DAILY LOG 9/1-5/14
2014-7935	09/30/2014 10/29/2014	FDA/OC/OES/DFOI/	GLADYS B. TONKIN Center for Regulatory Services,Inc.	DAILY LOG 8/11-15/14
2014-7936	09/30/2014 10/29/2014	FDA/OC/OES/DFOI/	GLADYS B. TONKIN Center for Regulatory Services,Inc.	DAILY LOG 8/18-22/14
2014-7937	09/30/2014 10/29/2014	FDA/OC/OES/DFOI/	GLADYS B. TONKIN Center for Regulatory Services,Inc.	DAILY LOG 8/25-29/14
2014-7938	09/30/2014 10/29/2014	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 8/18-22/14
2014-7939	09/30/2014 10/29/2014	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 8/11-15/14
2014-7940	09/30/2014 10/29/2014	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 8/11-15/14
2014-7941	09/30/2014 10/29/2014	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 8/18-22/14
2014-7942	09/30/2014	FDA/OC/OES/DFOI/		DAILY LOG 8/25-29/14

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	10/29/2014		WASHINGTON INFORMATION SOURCE	
2014-7943	09/30/2014 10/29/2014	FDA/OC/OES/DFOI/	DEBRA L. COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 8/11-15/14
2014-7944	09/30/2014 10/29/2014	FDA/OC/OES/DFOI/	DEBRA L. COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 8/18-22/14
2014-7945	09/30/2014 10/29/2014	FDA/OC/OES/DFOI/	DEBRA COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 8/25-29/14
2014-7946	09/30/2014 10/29/2014	FDA/OC/OES/DFOI/	DEBRA L. COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 8/18-22/14
2014-7947	09/30/2014 10/29/2014	FDA/OC/OES/DFOI/	DEBRA L. COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 8/11-15/14
2014-7948	09/30/2014 10/29/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 8/11-16/14
2014-7949	09/30/2014 10/29/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 8/18-23/14
2014-7950	09/30/2014 10/29/2014	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 8/11-15/14
2014-7951	09/30/2014 10/29/2014	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 8/18-22/14
2014-7952	10/01/2014 10/30/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	ROHN & HASS, CHAUNCY, FRANCE - 483 MARCH 2012
2014-7953	10/01/2014 10/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/CVM/OCD/	Mr G Burton JOHNSON MATTHEY	RECKITT BENCKISER - EIR 01/01/2011 - 09/25/2014

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2014-7954	10/01/2014 10/30/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-7046
2014-7955	10/01/2014 10/30/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-7026
2014-7956	10/01/2014 10/30/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-7018
2014-7957	10/01/2014 10/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DOUGLAS C ROGERS DOUGLAS C. ROGERS	ENBREL - AERS
2014-7958	10/01/2014 10/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	David McFarland Ferdic Inc. -- Publisher of Dickinson's FDA Webview	PROWL-1, PROWL-2 - FINAL REPORT, SURVEY INSTRUMENT
2014-7959	10/01/2014 10/30/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-6377
2014-7960	10/01/2014 10/30/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-6476
2014-7961	10/01/2014 10/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dongsik Kim Celltrion, Inc.	HERCEPTIN - PHARMACOLOGY, TOXICOLOGY, CLINICAL STUDY REPORT
2014-7962	10/01/2014 10/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	b. bugess BURGESS, BERNIE	CDER BIMO COMPLAINTS ENTERED INTO FACTS 9/06 TO 7/07
2014-7963	10/01/2014 10/30/2014	FDA/OC/OES/DFOI/	Gwendolyn Prophet Soha & Lang, P.S.	2014-3957
2014-7964	10/01/2014 10/30/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-4994
2014-7965	10/01/2014 10/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	Damien Nguyen HEALTHCOR MANAGEMENT LP	LDR Holding Corporation - APPROVABLE LETTER
2014-7966	10/01/2014 10/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Robert N. Sahr Choate Hall & Stewart LLP	Date on which Form 3542 was submitted to FDA to requesting to list US Patent No. 8,759,350 in the Orange Book

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2014-7967	10/01/2014 10/30/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-3990
2014-7968	10/01/2014 10/30/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-5980
2014-7969	10/01/2014 10/30/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-4596
2014-7970	10/01/2014 10/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bhagwan S. Chaudhary National Institute of Securities Markets, Mumbai, India	AUROBINDO PHARMA, INDIA - 483 09/15/2014 - 09/26/2014
2014-7971	10/01/2014 10/30/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K023087
2014-7972	10/01/2014 10/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jennifer Jines Young Dental Manufacturing	K062166
2014-7973	10/01/2014 10/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Prashant Premkumar East Bridge Capital Management Limited	AUROBINDO PHARMA, INDIA - 483 06/01/2014 - 09/29/2014
2014-7974	10/01/2014 03/25/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	John Chapman John Chapman	BK100066, BK130068, BK110040
2014-7975	10/01/2014 10/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K811276
2014-7976	10/01/2014 10/30/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	CLOSED FOIA REQUESTS 9/1-30/2014
2014-7977	10/01/2014 10/30/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 9/1-30/2014
2014-7978	10/01/2014 10/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jimmy Jing, Ph. D. Jing, Jimmy	K103227
2014-7979	10/01/2014 10/30/2014	FDA/OGROP/ORA/PA-FO/SEA- DO/SEA-CB/	Pat Hillenmeyer AbbVie	JOHN PAGEL, MD, SEATTLE, WA - 483, EIR 01/30/2008 - 09/30/2014
2014-7980	10/01/2014	FDA/OMPT/CDRH/OCER/DFOI/	Carroll Martin	K113119

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	10/30/2014		United States Endoscopy Group, Inc.	
2014-7981	10/01/2014 10/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SAMMY J ALMASHAT MD PUBLIC CITIZEN	FDA POLICY THAST ALLOWS AN EXPERT WHO SERVES AS A TEMPORARY VOTING MEMBERS OF AN FDA A/C ON A RECURRING BASIC TO ASSUME THE ROLE OF PAID SPEAKER, ON BEHALFL OF A SPONSOR, AT A MTG OF THE A/C MTG
2014-7982	10/01/2014 10/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	ANTHONY T PAVEL MORGAN LEWIS COUNSELORS AT LAW	ALIVECOR INC - HEART MONITOR CLASS II DVC 510K
2014-7983	10/01/2014 10/30/2014	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	M ELIZABETH BIERMAN MORGAN LEWIS COUNSELORS AT LAW	SMITH & NEPHEW, ST PETERSBURG, FL - EIR 11/13
2014-7984	10/01/2014 10/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TROY F TATTING ROBINS KAPLAN MILLER & CIRESI LLP	VIAGRA (SILDENAFIL) - COMM REGARDING WHETHER TO ADD LANGUAGE CONCERNING MELANOME OR SKIN CANCER TO THE LBLG
2014-7985	10/01/2014 10/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TROY F TATTING ROBINS KAPLAN MILLER & CIRESI LLP	ABILIFY (ARIPIPRAZOLE) - COMM REGARDING WHETHER TO ADD LANGUAGE CONCERNING GAMLING TO THE LBLG
2014-7986	10/01/2014 10/30/2014	FDA/OC/OES/DFOI/	MANOJ GARG MERRILL LYNCH	SUN PHARMACEUTICAL INDUSTRIES LTD (HALOL FACILITY), GUJARAT, INDIA - 483 9/19//14
2014-7987	10/01/2014 10/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MANOJ GARG MERRILL LYNCH	AUROBINDO PHARMA, ANDHRA PRADESH, INDIA - 483 9/19/14
2014-7988	10/01/2014 10/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	GERRY WOLFSON-GRANDE CRUSER & MITCHELL LLP	MDRS 1980686, 2007711, 2072674, ETC
2014-7989	10/01/2014 10/30/2014	FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECS
2014-7990	10/01/2014 10/30/2014	FDA/OGROP/ORR/CE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORR/CE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORR/CE-FO/BLT-	BRODY H REID RIED GOODWIN	CUT-N-UP SALON, KING GEORGE, VA - TRANS, AUDIO, VIDEO, ETC 6/15/14

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		DO/BLT-CB/		
2014-7991	10/01/2014 10/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	MARY BETH HENDERSON PHD GISKIT B V - RCRI INC	GISKIT B V (FARCO-PHARMA GMBH) - LUBRICANO ULTRASOUND K083358 UN-REDACTED
2014-7992	10/01/2014 10/30/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	YING-FANG JEFFERS SANOFI PASTEUR	SANOFI PASTEUR - MENACTRA LAB TESTS, MEDICAL HISTORY, HPV MFR, ETC
2014-7993	10/01/2014 10/30/2014	FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/	JAYME POISSON Toronto Star	CANADA HUMAN FOOD INSP - 483S 1/10 TO PRESENT
2014-7994	10/01/2014 10/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	STEPHEN L WILLS WILLS MD, STEPHEN L	ARICEPT (DONEPEZIL) - PRE-CLNCL RECS
2014-7995	10/01/2014 10/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PAUL D RUBIN ROPES & GRAY	ORCHID CHEMICALS & PHARMACEUTICALS LTD, INDIA - EIRS, 483S, REGULATORY CORR 1/14 TO PRESENT
2014-7996	10/01/2014 10/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JACKIE FAYE COLUMBIA UNIV GRADUATE SCHOOL OF JOURNALISM	JOHNSON & JOHNSON, PFIZER, ROCHE, ETC - EMAILS BTWN MEMBERS OF THE DRUG SHORTAGES TASK FORCE 1/10 TO PRESENT
2014-7997	10/01/2014 10/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PETER HARVIN HARVIN, PETER	ZYDELIG (IDELALISB) - AERS
2014-7998	10/01/2014 10/30/2014	FDA/OGROP/ORO/CE-FO/DET- DO/DET-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	JENNIFER A MCLOONE SHOOK HARDY & BACON LLP	STRYKER - NEPTUNE 2 ULTRA WASTE MANAGEMENT SYS APRVL & IMPLEMENTATION OF A CERTIFICATE OF MEDICAL NECESSITY PROGRAM; KI122665, K132671, ETC
2014-7999	10/01/2014 10/30/2014	FDA/OGROP/ORO/NE-FO/NWE- DO/NWE-CB/	WAYNE SADOWSKI NOVARTIS PHARMACEUTICAL CORP	DR ALICE SHAW, BOSTON, MA - EIRS 2/13-21/14
2014-8000	10/01/2014 10/30/2014	FDA/OC/OES/DFOI/ FDA/OGROP/ORO/PA-FO/SEA-	JOSEPH B VIENER SANDERS, SANDERS & BLOCK	NSPIRED NATURAL FOODS - MARANATHA ROASTED CREAMY ALMOND BUTTER RECALL SALMONELLA

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		DO/SEA-CB/		CONTAMINATION INVESTIGATIONS 1/14, 8/14
2014-8001	10/01/2014 10/30/2014	FDA/OFVM/CFSAN/OCD/EOS/	ORLY ENTERPRISES	LIST OF APRVD RICE FACTORIES IN CAMBODIA REGISTERD WITH THE FDA
2014-8002	10/01/2014 10/30/2014	OC/OROA/ OC/OROA/ FDA/OGROP/ORO/CE-FO/CHI-DO/CHI-CB/	WILLIAM P GRIFFIS GRIFFIS, WILLIAM P	SPL 835093 - TEST RESULTS
2014-8003	10/01/2014 10/30/2014	OC/OROA/ OC/OROA/ FDA/OGROP/ORO/CE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORO/CE-FO/CIN-DO/CIN-CB/	RYAN HOUSTON HOUSTON, RYAN	FLINSTONE VITAMINS - CMPLNT 137832, SPL 830934 TEST RESULTS
2014-8004	10/01/2014 10/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/OROA/ OC/OROA/	SHELDON T BRADSHAW HUNTON & WILLIAMS LLP	APOTEX RESEARCH PRIVATE LTD, BANGALORE, INDIA - EIRS 6/23/14-7/1/14
2014-8005	10/01/2014 10/30/2014	OC/OROA/ OC/OROA/ OC/OROA/ORM/ OC/OROA/ORM/	MICHAEL A ARMAS ARMAS, MIVHSRL A	LIST OF EVERY MEDICATION & VACCINE RECALLED OR REMOVED BY FDA
2014-8006	10/01/2014 10/30/2014	FDA/OFVM/CFSAN/OCD/EOS/	SCOTT DALEY MASSACHUSETTS GENERAL HOSPITAL	2008 FDA AMENDMENT TO THE CALCIUM & OSTEOPOROSIS & CALCIUM VITAMIN D OSTEOPOROSIS HEALTH CLAIM ELIMINATES THE REQUIREMENT THAT THE CLAIM LISTS RACE AS A SPECIFIC RISK FACTOR
2014-8007	10/02/2014 10/31/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jenna Chandler ORANGE COUNTY REGISTER	RESEARCH MARIJUANA - IND APPLICATIONS, RESEARCH PROTOCOLS, LETTTERS TO SPONSORS ETC 1996 TO PRESENT
2014-8008	10/02/2014 10/31/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dr. Katherine J. Hahn Medstar Georgetown University Hospital	ENOXAPARIN - AERS

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2014-8009	10/02/2014 10/31/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jolanta Piszczek Island Health	TOTAL AERS, TORSADE DE POINTES, ELECTROCARDIOGRAM QT PROLONGED, ASSOCIATED WITH ANY DRUG
2014-8010	10/02/2014 10/31/2014	FDA/OGROP/ORAP/PA-FO/SAN-DO/SAN-CB/	Wendy Lees NORTHWEST COSMETIC LABS LLC	COLUMBIA COSMETICS MANUFACTURING INC, SAN LEANDRO, CA - EIR, 483 07/01/2010 - 09/29/2014
2014-8011	10/02/2014 10/31/2014	FDA/OGROP/ORAP/CE-FO/NWJ-DO/NWJ-CB/	Wendy Lees NORTHWEST COSMETIC LABS LLC	CHEMAID, SADDLE BROOK, NJ - EIR, 483 07/01/2010 - 09/29/2014
2014-8012	10/02/2014 10/31/2014	FDA/OMPT/OSMP/OOPD/	Malia Segar Cote Orphan Consulting	ENALAPRIL MALEATE - ORPHAN DRUG DESIGNATION RECS 01/02/2013 - 01/31/2014
2014-8013	10/02/2014 10/31/2014	FDA/OGROP/ORAP/CE-FO/PHI-DO/PHI-CB/	John Walsh James Alexander Corporation	BEMIS HEALTHCARE PACKAGING, PHILADELPHIA, PA - EIR, 483, PRODUCT RECALLS 09/01/2011 - 09/29/2014
2014-8014	10/02/2014 10/31/2014	FDA/OGROP/ORAP/PA-FO/SAN-DO/SAN-CB/	Wendy Lees NORTHWEST COSMETIC LABS LLC	ALLURE LABS, HAYWARD, CA - EIR MOST RECENT
2014-8015	10/02/2014 10/31/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K131337
2014-8016	10/02/2014 10/31/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORAP/CE-FO/MIN-DO/MIN-CB/	Mohit Bhat Kline & company Inc.	RR DONNELLEY PLOVER, RR DONNELLEY LODZ, RR DONNELLEY SINGAPORE - EIR 01/01/2009 - 09/29/2014
2014-8017	10/02/2014 10/31/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	Ani Byrne Jamieson Laboratories Ltd.	JAMIESON LABORATORIES LTD - AERS 01/01/1922 - 09/29/2014
2014-8018	10/02/2014 10/31/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Paul T. Kocis, PharmD Penn State Milton S. Hershey Medical Center	DOMPERIDONE - AERS, DOSING RESTRICTIONS
2014-8019	10/02/2014 10/31/2014	FDA/OMPT/CDRH/OCER/DFOI/	Vijay Rangarajan RANGARAJAN, R	K941799, K052188, K120494
2014-8020	10/02/2014	FDA/OFVM/CFSAN/OCD/EOS/	SHAMIKA R. DALOMBA	INDIVIDUAL RECS

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	12/22/2014	OC/ORO/ OC/ORO/	WICKER SMITH ET AL	
2014-8021	10/02/2014 10/31/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Doe J	INDIVIDUAL RECS
2014-8022	10/02/2014 10/31/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TAMMY ROSE GENENTECH INC	REGENERONS - EYLEA SBA
2014-8023	10/02/2014 10/31/2014	FDA/OC/OES/DFOI/	DAVID MANGIONE Govzilla, Inc.	EIRS 1/1/13 - 8/11/14
2014-8024	10/02/2014 10/31/2014	FDA/OMPT/CDRH/OCER/DFOI/	SHWETA SHARMA MEDTRONIC	GLOBUS VIP ANTERIOR CERVICAL PLATE SYS K081391; SYNTHES VECTRA ONE SYS K071677; LIFE SPINE ANTERIOR PLATE SYS K070285, K061698, K040844
2014-8025	10/02/2014 10/31/2014	FDA/OC/OES/DDM/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN E. FITZPATRICK, III ODOM & DES ROCHES LLP	REQUEST REGARDING PETITION FDA-2012-P-1028
2014-8026	10/02/2014 10/31/2014	FDA/OFVM/CFSAN/OCD/EOS/	MARTHA E. MARRAPESE Keller and Heckman LLP	NO OBJECTION LETTERS 65,84
2014-8027	10/02/2014 10/31/2014	FDA/OFVM/CFSAN/OCD/EOS/	MARTHA E. MARRAPESE Keller and Heckman LLP	NO OBJECTION LTRS 60, 93
2014-8028	10/02/2014 10/31/2014	FDA/OFVM/CFSAN/OCD/EOS/	MARTHA E. MARRAPESE Keller and Heckman LLP	NO OBLIGATION LTRS 54, 83, 89
2014-8029	10/02/2014 10/31/2014	FDA/OFVM/CFSAN/OCD/EOS/	MARTHA E. MARRAPESE Keller and Heckman LLP	REQUEST FOR NO OBLIGATION LTRS 43, 75
2014-8030	10/02/2014 10/31/2014	FDA/OFVM/CFSAN/OCD/EOS/	VISAGINE VIJAYAKULASINGAM IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 176429, 176524, 177048, 178476
2014-8031	10/02/2014 10/31/2014	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	CCSVI PROCEDURE
2014-8032	10/02/2014 10/31/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID HAFFMEISTER WILSON SONSINI ET AL	LINEZOLID ANDA 78-061 - APRVL

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-8033	10/02/2014 10/31/2014	FDA/OC/OES/DFOI/	DAREN BAKST DAILY SIGNAL	2014-4855
2014-8034	10/02/2014 10/31/2014	FDA/OC/OES/DFOI/	MARK D. WOLFE Tom Rhodes Law Firm, P.C.	PEOPLES PHARMACY - CALCIUM GLUCONATE RECALL
2014-8035	10/02/2014 10/31/2014	FDA/OC/OES/DFOI/	MARK D. WOLFE Tom Rhodes Law Firm, P.C.	SPECIALTY COMPOUNDING - CALCIUM GLUCONATE RECALL
2014-8036	10/02/2014 10/31/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DR. MARION WENCKER CLINICAL RESEARCH SERVICES MANHEIM GMBH	CRS, MANNHEIM, GERMANY - EIR
2014-8037	10/03/2014 11/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Wendy Gabriel South College School of Pharmacy	Original package inserts for 25 specific new molecular entities approved from 1995-1997 for research purposes.
2014-8038	10/03/2014 11/03/2014	FDA/OFVM/CFSAN/OCD/EOS/	Riley John Stephoe & Johnson LLP	References in the Indirect Food Additives Final Rule issued in the Federal Register on May 9, 2000 regarding Polymers
2014-8039	10/03/2014 11/03/2014	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	Meagan Collins WILSON ELSER MOSKOWITZ EDELMAN & DICKER LLP	Great Lakes Cheese, St. Adams, NY - INSPECTION RECS 08/13/2013
2014-8040	10/03/2014 11/05/2014	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ OC/ORA/ OC/ORA/ FDA/OC/OCTC/OCM/OEO/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	mike Bennett, Michael F	Institutional Pharmacy Solutions, LLC, Irwindale, CA - OUTSOURCING RECORDS, 483 01/30/2014 - 09/30/2014
2014-8041	10/03/2014 11/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kathy McGown FOXKISER	NDA 201923
2014-8042	10/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	Ming-Zher Poh	K052767

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	11/03/2014		Ming-Zher Poh	
2014-8043	10/03/2014 11/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	Ming-Zher Poh Ming-Zher Poh	K023238
2014-8044	10/03/2014 11/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	Ming-Zher Poh Ming-Zher Poh	K130921
2014-8045	10/03/2014 11/03/2014	FDA/OC/OES/DDM/	Vicki Schofield PROCTER & GAMBLE	Information referenced in: the reference from the FR Vol 48, No. 27 Tuesday, Feb 8, 1983. External Analgesic TFM, Comment 7 page 5855. Reference: (11)Comment Nos. CP, SUP002, CR001, AMD, and AMD002, Docket No. 78N-0301
2014-8046	10/03/2014 11/03/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/ FDA/OFVM/CFSAN/OCD/EOS/	Linda Dougherty Kane Kessler, P.C.	Import Detentions of Pyrroloquinoline quinone 01/01/2010 - 10/01/2014
2014-8047	10/03/2014 11/03/2014	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	R. Foston Foston, Rene	Prednisolone acetate ophthalmic suspension, USP - AERS
2014-8048	10/03/2014 11/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	Ming-Zher Poh Ming-Zher Poh	K140933
2014-8049	10/03/2014 11/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	Ming-Zher Poh Ming-Zher Poh	K121932
2014-8050	10/03/2014 11/03/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Ming-Zher Poh Ming-Zher Poh	K080337
2014-8051	10/03/2014 11/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	Ming-Zher Poh Ming-Zher Poh	K132206
2014-8052	10/03/2014 11/03/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Ming-Zher Poh Ming-Zher Poh	K122184
2014-8053	10/03/2014 11/03/2014	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	Correspondence Between Caryn Cohen at CTP & Members of TPSAC 07/01/2014 - Present
2014-8054	10/03/2014 11/03/2014	FDA/OC/OCC/	Matthew Strugar Law Office of Matthew Strugar	PHARMACEUTICAL COMPANY V. UNITED STATES FOOD AND DRUG ADMINISTRATION - SETTLEMENT AGREEMENT
2014-8055	10/03/2014 11/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	Terry Trimmingham Trimingham, Terry	K945271
2014-8056	10/03/2014	FDA/OC/OES/DFOI/	Jaime Vassallo	2014-1904

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	11/03/2014		LexisNexis CourtLink Document Retrieval	
2014-8057	10/03/2014 11/03/2014	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	Albert Salvador WTI QA	Comprehensive Clinical Development, Inc., Miramar, FL - EIR
2014-8058	10/03/2014 11/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	mike Bennett, Michael F	PHARMACY COMPOUNDING ADVISORY COMMITTEE - NOMINEE RECORDS
2014-8059	10/03/2014 11/03/2014	FDA/OGROP/ORR/CE-FO/CHI-DO/CHI-CB/	COLLELEN GRACE DONOFRIO BABST CALLAND CLEMENTS ET AL	PQ CORP, JOLIET, IL - EIR 12/19/13
2014-8060	10/03/2014 11/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID L SILBERSTEIN Valeant Pharmaceuticals North America LLC	MEDICIS PHARMS - PREDNISOLONE SODIUM PHOSPHATE ORAL SOL ANDA 75-250
2014-8061	10/03/2014 11/03/2014	OC/ORR/ OC/ORR/ FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	ADRIAN SMITH Smith, Adrian	MCCALL FOODS - GLORY GREENS RPT
2014-8062	10/03/2014 11/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHRISTIAAN A MARCUM ESQ RICHARDSON PATRICK ET AL	CERTIFIED RECS
2014-8063	10/03/2014 11/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SARAH A WESTBY FARUQI & FARUQI LLP	Niacin ER Tabs ANDA 90860 Bioeqv, Chemistry sections
2014-8064	10/03/2014 11/03/2014	FDA/OC/OES/DFOI/	HUNTLEY WEBB WEBB, HUNTLEY	EXELAN PHARMACEUTICALS INC, LAWRENCEVILLE, GA; INVA GEN PHARMACEUTICAL INC, HAUPPAUGE, NY; HETRO DRUGS LTD, HYDERABAD, INDIA - LISINOPRIL APRVL, MFG RECS, ETC
2014-8065	10/03/2014 11/03/2014	FDA/OFVM/CFSAN/OCD/EOS/	ALISA A KARLSONS Keller and Heckman LLP	FCN 1443
2014-8066	10/03/2014 11/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	ANNE MULVHILL BIOMET 3I	STRAUMANN CARES SCREW-RETAINED BRIDGES AND BARS K140737

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2014-8067	10/03/2014 11/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	ANNE MULVHILL BIOMET 3I	NOBEL BIOCARE AB - NOBELPROCERA OVERDENTURE BAR K132749
2014-8068	10/03/2014 11/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	REBECCA L DANDEKER MORGAN LEWIS & BOCKIUS LLP	HETERO DRUGS LTD, NAKKAPALLY, VISAKHAPATNAM, INDIA - EIRS, 483S, 1/1/10 TO 9/28/14
2014-8069	10/03/2014 11/03/2014	FDA/OC/OES/DFOI/	STEVEN HEWITT 303283 HEWITT 303283, STEVEN	CLARITIN, RITALIN, ADDERAL, ETC - AERS, USES, RECS
2014-8070	10/03/2014 11/03/2014	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	ONA SCANDURRA COUNTRY LIFE LLC	COUNTRY LIFE LLC, HAUPPAUGE, NY - EIRS, 483S 6/12 TO PRESENT
2014-8071	10/03/2014 11/03/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	THOMAS LEE SMITH SMITH, THOMAS LEE	CMPLNT #138430
2014-8072	10/03/2014 11/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	S ALBERT EDWARDS PHARM D EDWARDS, S ALBERT	SKELAXIN (METAXALONE) NDA 13-217 - APRVL LTRS, LBLG 5/31/02. 6/20/02
2014-8073	10/03/2014 11/03/2014	FDA/OFVM/CFSAN/OCD/EOS/	JEANNIE PERRON COVINGTON & BURLING LLP	HAMPTON CREEK FOODS INC - CFSAN LTR 9/19/14
2014-8074	10/03/2014 11/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID L SILBERSTEIN Valeant Pharmaceuticals North America LLC	BAUSCH & LOMB - IPRATROPIUM BROMIDE INHALATION SOL ANDA 75-835; CROMOLYN SODIUM INHALATION SOL ANDA 75-585
2014-8075	10/03/2014 11/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JEAN YUAN NATIONAL INSTITUTE OF HEALTH	PATENT DATA FOR APRVD FDA DRUGS SINCE 1970
2014-8076	10/03/2014 11/03/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDRH/OCER/DFOI/	SUSAN F CONNORS MONTGOMERY CHAPIN & FETTEN PC	DIAGNOSTICA STAGO INC, PARSIPPANY, NJ - REGULATORY NON-COMPLIANCE, MISCONDUCT, CMPLNTS, CORR, ETC
2014-8077	10/03/2014 11/03/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Rachel Johnson FOI Services, Inc.	Campbell Tobacco Rehandling, Mayfield, KY; Heritage Tobacco Group, Perryville, KY; Kentucky Bioprocessing, Owensboro, KY ETC - 483, EIR, WARNING LETTER ETC

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2014-8078	10/03/2014 11/03/2014	FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	Rachel Johnson FOI Services, Inc.	Global Tobacco, Dallas, TX, Xcaliber International, Pryor, OK; Dosal Tobacco, Opa Locka, FL - EIR, 483, WARNING LETTER ETC
2014-8079	10/03/2014 11/03/2014	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	Rachel Johnson FOI Services, Inc.	Sterigenics, Haw River, NC; Dry Storage, Greensboro, NC; Top Tobacco, Lake Waccamaw, NC ETC - EIR, 483, WARNING LETTER ETC
2014-8080	10/03/2014 11/03/2014	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORR/SE-FO/NOL-DO/NOL-CB/	Rachel Johnson FOI Services, Inc.	Southern Tobacco, Statesboro, GA; Scandinavian Tobacco Group Lane, Tucker, GA; Hail & Cotton, Springfield, TN - EIR, WARNING LETTER, 483 ETC
2014-8081	10/03/2014 11/03/2014	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	Rachel Johnson FOI Services, Inc.	Fisher Textiles, Indian Trail, NC; US Flue Cured Tobacco Growers, Timberlake, NC; Rock-Tenn Converting Co, Winston-Salem, NC ETC - 483, EIR, WARNING LETTER ETC
2014-8082	10/03/2014 11/03/2014	FDA/OGROP/ORR/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/ FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	American Packaging, Story City, IA; American Packaging, Columbus, WI - EIR, 483, WARNING LETTER ETC
2014-8083	10/06/2014 11/04/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Eric Forkosh Cooper Union - c/o Eric Forkosh	K022834
2014-8084	10/06/2014 11/04/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	P020004 S103
2014-8085	10/06/2014 11/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Prashant Premkumar East Bridge Capital Management Limited	Strides Arcolab, Beltapharm SPA, Milan, Italy - 483, Warning Letter
2014-8086	10/06/2014 11/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Compliance Specialists Compliance Specialists, LLC	Similasan AG - Corr to FDA
2014-8087	10/06/2014 11/04/2014	FDA/OC/OES/DFOI/	Terumo Cardiovascular Systems SKADDEN ARPS SLATE MEAGHER & FLOM	TERUMO CARDIOVASCULAR SYSTEMS - RECS RELEASED UNDER FOIA RE 2014 INSPECTION
2014-8088	10/06/2014	FDA/OMPT/CDER/ORP/DIDP/	EVANGELOS TSIPOTIS	Bioequivalence studies of FDA-approved generic tacrolimus in

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	11/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ST. ELIZABETH'S MEDICAL CENTER OF BOSTON	healthy volunteers and kidney transplant recipients
2014-8089	10/06/2014 11/04/2014	FDA/OGROP/ORA/SW-FO/DEN- DO/DEN-CB/	Roderick Walker Quintiles Research Pvt. Ltd.	DR RICHARD C DART - EIR 01/01/2005 - 12/31/2005
2014-8090	10/06/2014 11/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	EVANGELOS TSIPOTIS ST. ELIZABETH'S MEDICAL CENTER OF BOSTON	Bioequivalence studies of FDA-approved generic cyclosporine in healthy volunteers and kidney transplant recipients
2014-8091	10/06/2014 11/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	Viibryd - WRITTEN REQUEST RE PEDIATRIC STUDIES
2014-8092	10/06/2014 11/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	NDA 013304
2014-8093	10/06/2014 12/03/2014	FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	David Fintz Friend, Levinson & Turner, Ltd.	Raphe Healthcare Inc., Dallas, TX - LICENSING, COMPLAINTS, INVESTIGATIONS
2014-8094	10/06/2014 11/04/2014	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2014-5468
2014-8095	10/06/2014 11/04/2014	OC/ORA/ OC/ORA/	Kingman Ng NOVARTIS	ORA LABORATORY MANUAL;
2014-8096	10/06/2014 11/04/2014	FDA/OMPT/CDRH/OCER/DFOI/	Chris Adams Ceeable	K121738, K093213
2014-8097	10/06/2014 11/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	EVANGELOS TSIPOTIS ST. ELIZABETH'S MEDICAL CENTER OF BOSTON	Bioequivalence studies of FDA-approved generic mycophenolate in healthy volunteers and kidney transplant recipients
2014-8098	10/06/2014 11/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mohit Bhat Kline & Company, Inc.	SANMINA, CHINA - EIR, EXHIBITS 01/01/2009 - 10/02/2014

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2014-8099	10/06/2014 11/04/2014	FDA/OMPT/CDRH/OCER/DFOI/	Nathan VanSweden STRYKER BIOTECH	K133809
2014-8100	10/06/2014 11/04/2014	FDA/OMPT/CDRH/OCER/DFOI/	Thomas Thompson THOMPSON, T	MEDICAL DEPOT INC - MAUDE REPORTS 01/01/2008 - 01/01/2014
2014-8101	10/06/2014 11/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Andrew Thibault Thibault, Andrew	AERS REPORTS
2014-8102	10/06/2014 11/04/2014	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	Ellen Ateniese Catalent Pharma Solutions	CATALENT, ST PETERSBURG, FL - EIR JUNE 2012
2014-8103	10/06/2014 11/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kathleen Helm-Bychowski Leydig, Voit and Mayer, Ltd	NDA 019452
2014-8104	10/06/2014 11/04/2014	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2014-6210
2014-8105	10/06/2014 11/04/2014	FDA/OC/OES/DDM/	James Pepin Nestle HealthCare Nutrition, Inc.	DKT FDA-2012-F-0138
2014-8106	10/06/2014 11/04/2014	FDA/OMPT/CDRH/OCER/DFOI/	David Morgan LED Dental Inc.	K123169
2014-8107	10/06/2014 11/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jodye Deal APOTEX CORP	Apotex' Diltazem XR Capsules, ANDA 074943 - APPROVAL LETTER
2014-8108	10/06/2014 11/04/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K122202
2014-8109	10/06/2014 11/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Emi Morohashi Sucampo Pharma Americas, LLC	AMITIZA - SBA

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2014-8110	10/06/2014 11/04/2014	FDA/OMPT/CDRH/OCER/DFOI/	Georgiann Keyport anopy Medical	K103110 ;
2014-8111	10/06/2014 11/04/2014	FDA/OMPT/CDRH/OCER/DFOI/	Georgiann Keyport CANOPY MEDICAL INC	K113220
2014-8112	10/06/2014 11/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kenneth Eichenbaum Self	CORR TO OR FROM FDA RE ACELRX, ZALVISO, SUBLINGUAL SUFENTANIL
2014-8113	10/06/2014 11/04/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SE-FO/NOL-DO/NOL-CB/	835926 Jackson Commodities	SAMPLE RESULTS 835926
2014-8114	10/06/2014 11/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/	Mary Yantis BRIGHAM AND WOMEN'S HOSPITAL	DR ALVARO OCAMPO, DR JOHN PADRON - 483 01/01/2014 - 09/01/2014
2014-8115	10/06/2014 11/04/2014	FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/	Peter Anderson ASHCRAFT & GEREL, LLP	MEDTRONIC P120010, P980022 - RECALL RECS
2014-8116	10/06/2014 11/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	ZYDELIG - PHARM, TOX
2014-8117	10/06/2014 11/04/2014	FDA/OGROP/ORO/CE-FO/MIN-DO/MIN-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	Peter Anderson ASHCRAFT & GEREL, LLP	LOT 8 OF PARADIGM INFUSION SETS MEDTRONIC - EMAILS, COMM 10/01/2001 - 10/01/2014
2014-8118	10/06/2014 11/04/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Shin Kang WELLS FARGO SECURITIES	IMBRUVICA, KALYDECO, SOVALDI ETC
2014-8119	10/06/2014	FDA/OMPT/CDER/ORP/DIDP/	Ellen Camos	ANDA 62698, 71800, 71801 ETC

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	11/04/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANI Pharmaceuticals, Inc.	
2014-8120	10/07/2014 11/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Gregg Siegel Biomedical Development Corporation	K092150
2014-8121	10/07/2014 11/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Lee Grant Medtronic Spine and Biologics	K914362
2014-8122	10/07/2014 11/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Lee Grant Medtronic Spine and Biologics	K810271
2014-8123	10/07/2014 11/05/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ken Tong Ken Tong	IBRUTINIB - AERS
2014-8124	10/07/2014 11/05/2014	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	Rachel Johnson FOI Services, Inc.	BIO-TISSUE - EIR, 483, WARNING LETTER ETC
2014-8125	10/07/2014 11/05/2014	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Rachel Johnson FOI Services, Inc.	BIOD LLC - EIRs, 483s, Warning Letters, ETC
2014-8126	10/07/2014 06/22/2015	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Rachel Johnson FOI Services, Inc.	MRF - EIR, 483, WARNING LETTER ETC
2014-8127	10/07/2014 11/05/2014	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Rachel Johnson FOI Services, Inc.	Derma Sciences - EIR, 483, WARNING LETTER ETC
2014-8128	10/07/2014 11/05/2014	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/ FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	Rachel Johnson FOI Services, Inc.	ALLOSOURCE - EIR, 483, WARNING LETTER ETC

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2014-8129	10/07/2014 11/05/2014	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Rachel Johnson FOI Services, Inc.	Bone Bank Allografts - EIR, 483, WARNING LETTER ETC
2014-8130	10/07/2014 11/05/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Rachel Johnson FOI Services, Inc.	Liventa - EIR, 483, WARNING LETTER
2014-8131	10/07/2014 11/05/2014	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Rachel Johnson FOI Services, Inc.	ACell - EIR, 483, WARNING LETTER ETC
2014-8132	10/07/2014 11/05/2014	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Rachel Johnson FOI Services, Inc.	OSIRIS THERAPEUTICS - EIR, 483, WARNING LETTER ETC
2014-8133	10/07/2014 11/05/2014	FDA/OGROP/OIP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jesse McLean Toronto Star	EMAIL, MEMOS, REPORTS BETWEEN FDA AND HEALTH CANADA RE APOTEX IMPORT ALERT 06/23/2014 - 10/06/2014
2014-8134	10/07/2014 11/05/2014	OC/ORASW-FO/SWID/SWID-CB/ OC/ORASW-FO/SWID/SWID-CB/	Weerawan (Birda) Misch CALAVO GROWERS, INC.	LAB RESULTS # 692004
2014-8135	10/07/2014 11/05/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ken Tong Ken Tong	KEYTRUDA - AERS
2014-8136	10/07/2014 11/05/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tariq Ata REMS Logic, LLC	REMS DRUG ERROR REPORTS 2005 TO 2013
2014-8137	10/07/2014 11/05/2014	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Rachel Johnson FOI Services, Inc.	AMNIOX MEDICAL - EIR, 483, WARNING LETTER ETC
2014-8138	10/07/2014 11/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	DAN NICKELSON GENERAL PHYSIOTHERAPY, INC.	K122480
2014-8139	10/07/2014 11/05/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELAINE S WALLER SEATTLE GENETICS INC	SEATTLE GENETICS - ADCETRIS (BRENTUXIMAB VEDOTIN) IRS 9836594, 9916423, 10035648, ETC

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2014-8140	10/07/2014 11/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TORREY COPE SIDLEY AUSTIN LLP	VALEANT PHARMACEUTICALS INTERNATIONAL INC, MANITOBA, CANADA 3/1/12; KIK CUSTOM PRODUCTS, ONTARIO, CANADA 4/27/12; CONTRACT PHARMACEUTICALS LIMITED CANADA, WREXHAM, UK - 483S
2014-8141	10/07/2014 11/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	MEDWATCH 7177217
2014-8142	10/07/2014 11/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOSEPH WALLACE WALLACE, JOSEPH EM3049	RITALIN - LABEL & MEDICATION GUIDE 2000, 2013
2014-8143	10/07/2014 11/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANDREA FARAH SCOTT & SCOTT LLP	TEVA PHARM - AMIODARONE HCL ANDA 74-739 APRVL LTR, 5 MOST RECENT LABEL UPDATES
2014-8144	10/07/2014 11/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	FRANCIS J MARTIN DELPOR INC	JANSSEN PHARMS - RISPERIDONE TABS NDA 20-272, RISPERIDONE ORALLY DISINTERATING TABS NDA 21-444, ETC SBA
2014-8145	10/07/2014 11/05/2014	FDA/OC/OES/DFOI/	KRISTINA HERRMANN AMAZON	2014-7099. 2014-7206
2014-8146	10/07/2014 11/14/2014	OC/ORO/ OC/ORO/	DAVID KRUGLER Cash, Krugler & Fredericks LLC	CLINICAL SPECIALTIES (CLINICAL SPECIALTIES COMPOUNDING PHARMACY), MARTINEZ, GA - EIRS, 483S, LAB RPTS, ETC
2014-8147	10/07/2014 11/05/2014	OC/ORO/ORM/ OC/ORO/ORM/	RUTH IVEY SECOND HARVEST FOOD BANK OF EAST TENNESSEE	FOOD RECALLS BY ENFORCEMENT RPT; LEADING CAUSES OF FOOD RECALLS
2014-8148	10/07/2014 11/05/2014	FDA/OC/OES/DFOI/	MICHAEL MANCINELLI CONWAY HOMER & CHIN-CAPLAN PC	INDIVIDUAL RECS
2014-8149	10/07/2014 11/05/2014	FDA/OMPT/CTP/OD/	MARK E GREENWOLD CAMPAIGN FOR TOBACCO-FREE KIDS	STAR SCIENTIFIC CO - DISSOLVABLE TABACCO PRODS UNREDACTED RVWS

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2014-8150	10/07/2014 11/05/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	DARCI CHEATWOOD CHEATWOOD, DARICI	CMPLNT 138494
2014-8151	10/07/2014 11/05/2014	FDA/OC/OES/DFOI/	STEVEN FINGERHUT IMBESI CHRISTENSEN	GATE GOURMENT INC - CMPLNTS, VIOLATIONS, FINES, ETC
2014-8152	10/07/2014 11/05/2014	FDA/OMPT/CTP/OD/	Doe J	INDIVIDUAL RECS
2014-8153	10/07/2014 11/05/2014	FDA/OFVM/CFSAN/OCD/EOS/	CAITLLIN HOWELL IOVATE HEALTH SCIENCES INTERNATIONAL INC	USP LABS - HIGENAMINE WARNING LTR, RESP TO WARNING LTR, CORR
2014-8154	10/07/2014 11/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OO/OFBA/OAGS/	MICHAEL I FISTEL JOHNSON & WEAVER LLP	BIOTA PHARMACEUTICALS INC - LANINAMIVIR OCTANOATE CORR BTWN HHS, ASPR, BARDA, ETC 3/11 TO PRESENT
2014-8155	10/08/2014 11/06/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Allison Tarantino ARIAD Pharmaceuticals, Inc.	ICLUSIG - AERS
2014-8156	10/08/2014 11/06/2014	FDA/OMPT/OSMP/OOPD/	Rachel Johnson FOI Services, Inc.	ACTERMA - ORPHAN DRUG RECS
2014-8157	10/08/2014 11/06/2014	FDA/OMPT/CDRH/OCER/DFOI/	David Mcfarland Ferdic Inc. -- Publisher of Dickinson's FDA Webview	510K RESCISSION LETTERS 1/99 TO 9/30/14
2014-8158	10/08/2014 11/06/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	ACTEMRA BLA 125276/S64
2014-8159	10/08/2014 11/06/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Prashant Premkumar East Bridge Capital Management Limited	SUN PHARMACEUTICALS, INDIA - 483 SEPT 2014
2014-8160	10/08/2014	FDA/OC/OES/DFOI/	Richard W. Mark	2014-6711

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	11/06/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	GIBSON DUNN & CRUTCHER LLP	
2014-8161	10/08/2014 11/06/2014	FDA/OMPT/CDRH/OCER/DFOI/	Christina Miracle Cincinnati Sub Zero	K843146
2014-8162	10/08/2014 11/06/2014	FDA/OMPT/CDRH/OCER/DFOI/	Terri Wallace Polymed Therapeutics, Inc.	K132834
2014-8163	10/08/2014 11/06/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ken Tong Ken Tong	ZYDELIG - AERS
2014-8164	10/08/2014 11/13/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Richard W. Mark GIBSON DUNN & CRUTCHER LLP	AMPIO PHARMACEUTICALS - BLA, CMC, CORR ETC
2014-8165	10/08/2014 11/06/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Taylor Schreiber Pelican Therapeutics, Inc.	MEDI6383 IND
2014-8166	10/08/2014 11/06/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joseph Malone Joseph Malone	ORTHO EVRA PATCH, NUVARING, ETHINYL ESTRADIOL ETC
2014-8167	10/08/2014 11/06/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Felicia Nowels Akerman LLP	NDA 019941, ANDA 076320, ANDA 076453
2014-8168	10/08/2014 11/06/2014	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	David Wenner Snyder & Wenner, P.C.	SCOTTSDALE HEALTHCARE, SCOTTSDALE, AZ - CLINICAL TRIALS OF ROBOT ASSISTED MITRAL VALVE REPAIR SURGERY
2014-8169	10/08/2014 11/06/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Felicia Nowels Akerman LLP	LIST OF MANUFACTURER NAMES AND ADDRESSES REGISTERED TO MANUFACTURE LIDOCAINE, PRILOCAINE,

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		ETC
2014-8170	10/08/2014 11/06/2014	FDA/OMPT/CDRH/OCER/DFOI/	Amy Fowler Duval & Associates	K131255, K122817, K141573 ETC
2014-8171	10/08/2014 11/06/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Brandon Gufford WASHINGTON STATE UNIVERSITY	ANDA 077239
2014-8172	10/08/2014 11/06/2014	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	LONZA BIOLOGICS, INC, PORTSMOUTH, NH - EIR, 483, RESPONSE
2014-8173	10/08/2014 12/19/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Rachel Johnson FOI Services, Inc.	BK140108
2014-8174	10/08/2014 11/06/2014	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	Scott Nadolski ORA	BOSTON ANALYTICAL, SALEM, NH - EIR 11/06/2012 - 11/09/2012
2014-8175	10/08/2014 11/06/2014	FDA/OC/OES/DFOI/	Dr. Girish Bakhru HSBC	SUN PHARMACEUTICALS, INDIA - 483 09/22/2014 - 09/26/2014
2014-8176	10/08/2014 11/06/2014	FDA/OMPT/CDRH/OCER/DFOI/	Joshua Goldberg Markopollo, Inc.	K842736
2014-8177	10/08/2014 11/06/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Amy Fowler Duval & Associates	K080275
2014-8178	10/08/2014 11/06/2014	FDA/OMPT/CDRH/OCER/DFOI/	Joshua Goldberg Markopollo, Inc.	K842735
2014-8179	10/08/2014 11/06/2014	FDA/OGROP/ORA/CE-FO/CHI- DO/CHI-CB/ FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/ FDA/OGROP/ORA/SW-FO/DEN- DO/DEN-CB/ FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	K. MICHELLE VASSALLO LINCARE INC	CARE MEDICAL INC, VISALIA, CA; HOT SPRINGS COUNTY MEMORIAL HOSP, THERMOPOLIS, WYOMING; MINISTRY HOME CARE SERVICES LLC, RIVER FOREST, IL - 483, WARNNG LTR, EIR 1/98 TO PRESENT
2014-8180	10/08/2014 11/06/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELIZABETH BARBEHENN, Ph.D. PUBLIC CITIZEN	SAMSCA (TOVAPTEN) ISRS - 7499864, 7861985, 8060244 ETC

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2014-8181	10/08/2014 11/06/2014	OC/ORa/ORM/ OC/ORa/ORM/	LESLIE RAMSEY FDA NEWS	LIST OF PHARMACEUTICAL, BIOLOGIC, MEDICAL DVC MANUFACTURING, CLNCL TRIAL FACILIITES - 483S 9/1-30/14
2014-8182	10/08/2014 11/06/2014	FDA/OC/OES/DFOI/	LIESLIE A. RAMSEY FDA NEWS	DAILY LOG 8/1-9/30/14
2014-8183	10/09/2014 11/07/2014	OC/ORa/ OC/ORa/ FDA/OGROP/ORa/ORO/DIOP/	DEVA SUNDARARAJAN GLOBAL TRADE INTELLIGENCE INC	FDA IMPORTS 5/26/14 TO PRESENT
2014-8184	10/09/2014 11/07/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORa/CE-FO/NWJ-DO/NWJ-CB/	IAIN L C KENNEDY SHOOK HARDY & BACON LLP	STRYKER ORTHOPAEDICS - EIUS UNICOMPARTMENTAL KNEE SYS K052917, K992287
2014-8185	10/09/2014 12/03/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	CHRIS SZECHENYI ON POINT INVESTIGATIONS	OVASCIENCE - AUGMENT CORR 2013
2014-8186	10/09/2014 11/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DR ANDREAS SPINRATH HENKEL BREUER & PARTNER	COPOLYMER-1 NDA 20-622 - PHARMACOLOGY TOXICOLOGY DATA
2014-8187	10/09/2014 11/07/2014	FDA/OGROP/ORa/CE-FO/CHI-DO/CHI-CB/	COLLEEN GRACE DONOFRIO BABST CALLAD CLEMENTS ET AL	PQ CORP,UTICA, IL - EIR 12/19/13
2014-8188	10/09/2014 11/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GENEVIEVE MEISENHEIMER HARRISON PENZA LLP	HOFFMAN-LA ROCHE - ACCUTANE APRVL RECS, REGULATORY COMPLIANCE, SALE, ETC
2014-8189	10/09/2014 11/07/2014	FDA/OGROP/ORa/NE-FO/NWE-DO/NWE-CB/	ELIZABETH KROON BOSTON ANALYTICAL	BOSTON ANALYTICAL, SALEM, NH - EIR 8/13
2014-8190	10/09/2014 11/07/2014	FDA/OC/OES/DFOI/ FDA/OFVM/CFsAN/OCD/EOS/	Greg Gentry Gentry Law, LLC	KRATOM - CORR, EMAIL, MEETING NOTES ETC
2014-8191	10/09/2014 11/07/2014	FDA/OGROP/ORa/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	David Wenner Snyder & Wenner, P.C.	CLINICAL TRIALS OF ROBOT ASSISTED HEART BYPASS SURGERY AT SCOTTSDALE HEALTHCARE - DATA 01/01/2002 - 01/01/2006
2014-8192	10/09/2014 11/07/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Barbara Suda Blood Bank of Delmarva	LIST OF FIRMS APPROVED FOR PLATELET ADDITIVE SOLUTION PLATELETS
2014-8193	10/09/2014	FDA/OMPT/CDER/ORP/DIDP/	Rosalie A. Lowe	NDA 019281 - SBA

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	11/07/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Genovi Pharmaceuticals, Inc.	
2014-8194	10/09/2014 11/12/2014	OC/ORA/ OC/ORA/	mike Bennett, Michael F	California Pharmacy and Compounding Center, Newport Beach, CA; UCSF Home Therapy Services, San Francisco, CA.- 483, EIR
2014-8195	10/09/2014 11/07/2014	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Jason Atkinson Mallinckrodt PLC	Mallinckrodt PLC, RALEIGH, NC - EIR
2014-8196	10/09/2014 11/07/2014	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Rachel Johnson FOI Services, Inc.	HERBALIFE, LAKE FOREST, CA - EIR, 483, RESPONSE ETC
2014-8197	10/09/2014 11/07/2014	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Richard Kovach, MD Deborah Heart and Lung Center	DR KOVACH - EIR 01/30/2014 - 07/24/2014
2014-8198	10/09/2014 11/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K133223
2014-8199	10/09/2014 11/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	Gregor Dzialas NxStage Medical, Inc.	K112314
2014-8200	10/09/2014 11/07/2014	OC/ORA/OCI/ OC/ORA/OCI/	Mark Supple Mark Supple	GUIDANT IMPLANTABLE CARDIAC DEFIBRILLATORS - OCI INVESTIGATIONS 03/04/2005 - 12/31/2010
2014-8201	10/09/2014 11/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	Matthew Pike Lhasa OMS, Inc.	K990328
2014-8202	10/09/2014 11/07/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Emily Krulewitz The Weinberg Group	ANDA 201006
2014-8203	10/09/2014 11/07/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Emily Krulewitz The Weinberg Group	ANDA 202077
2014-8204	10/09/2014 11/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	Alan Chivers SRA Developments Ltd	K900003
2014-8205	10/09/2014 11/07/2014	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2014-7450
2014-8206	10/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	Michael Smietana	Gore-Tex™ Cruciate Ligament Prosthesis by W.L. Gore and

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	11/07/2014		University of Michigan - Michael Smietana	Associates approved on October 10, 1986;; Stryker Dacrone Ligament Prosthesis by Meadox Medicals, Inc. approved on December 30, 1988; 3M Kennedy LADTM Ligament Augmentation Device by 3M which was first approved on May 7, 1987 - SAFETY AND EFFECTIVENESS DATA
2014-8207	10/09/2014 11/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dr. Melvyn Rubenfire Dr. Melvyn Rubenfire	STATINS - AERS
2014-8208	10/09/2014 11/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	Scott Kellogg SR-Bio, Inc	K842607
2014-8209	10/09/2014 11/07/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Susan Chalian MARS & CO	NBTY - EIR MOST RECENT
2014-8210	10/09/2014 11/12/2014	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ OC/ORA/ OC/ORA/	mike Bennett, Melissa	UNIQUE PHARMACEUTICALS, TEMPLE, TX - WARNING LETTER RESPONSES
2014-8211	10/09/2014 11/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Emily Krulewitz The Weinberg Group	ANDA 200925
2014-8212	10/09/2014 11/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Emily Krulewitz The Weinberg Group	ANDA 090887
2014-8213	10/09/2014 11/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Emily Krulewitz The Weinberg Group	ANDA 091449

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		FDA/OMPT/CDER/ORP/DIDP/		
2014-8214	10/09/2014 11/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Emily Krulewitz The Weinberg Group	ANDA 077697
2014-8215	10/09/2014 11/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	Alan Chivers SRA Developments Ltd	K961725
2014-8216	10/09/2014 11/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Emily Krulewitz The Weinberg Group	ANDA 076218 APPROVAL LETTER
2014-8217	10/09/2014 11/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	Gregor Dzialas NxStage Medical, Inc.	K103220
2014-8218	10/09/2014 11/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	Gina To Sirius Engineering LLC	K082339
2014-8219	10/09/2014 11/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	Gina To Sirius Engineering LLC	K083833
2014-8220	10/09/2014 11/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Andrea Demakas ADVERSEEVENTS INC	PROZAC, LEXAPRO, CELEXA - AERS
2014-8221	10/09/2014 11/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Andrea Demakas ADVERSEEVENTS INC	SOVALDI, ELIQUIS, XARELTO - AERS
2014-8222	10/09/2014 11/07/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Pallavi Ail The Financial Express	SUN PHARMACEUTICALS, HALOL, INDIA - EIR 01/01/2014 - 10/09/2014
2014-8223	10/09/2014 11/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	Lee Grant Medtronic Spine and Biologics	K091071
2014-8224	10/09/2014 11/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	Lee Grant Medtronic Spine and Biologics	K120092

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2014-8225	10/09/2014 11/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	Lee Grant Medtronic Spine and Biologics	K133194
2014-8226	10/09/2014 11/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	Lee Grant Medtronic Spine and Biologics	K140260
2014-8227	10/09/2014 11/07/2014	FDA/OMPT/CDRH/OCER/DFOI/	Lee Grant Medtronic Spine and Biologics	K131547
2014-8228	10/10/2014 11/10/2014	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	CAROLYN FRANKLIN LAW OFFICE OF CHRISNA D JONES LLC	NORDIC COLD STORAGE LLC, ASTLANTA, GA - EIRS, APPL, CHANGE IN OWNERSHSIP, ETC LAST 10 YRS
2014-8229	10/10/2014 11/10/2014	FDA/OC/OES/DFOI/	Jeremy Thompson Morris Polich & Purdly, LLP	SPINAL SOLUTIONS - RECORDS RELEASED UNDER FOIA
2014-8230	10/10/2014 11/10/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Gregrie A. Willson Benesch, Friedlander, Coplan & Aronoff LLP	BUTTERFLY BAKERY INC, BRENDA ISAAC, CLIFTON, NJ - INSPECTIONS, INVESTIGATIONS
2014-8231	10/10/2014 11/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ OC/ORA/ OC/ORA/	Emily Rand CBS NEWS	NUVISION PHARMACY - AERS
2014-8232	10/10/2014 11/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Heather Munday-McGinley BENNETT BIGELOW & LEEDOM PS	All versions of instructions for use and other materials submitted by St. Jude Medical / Advanced Neuromodulation Systems In. for EON Mini IPG rechargeable neurostimulator model 3788 / product code 65-3788
2014-8233	10/10/2014 11/10/2014	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORA/ OC/ORA/ FDA/OGROP/ORA/ORO/DIOP/	Isaac Peter Isaac Peter	HANUTA - RECS, IMPORT ALERTS
2014-8234	10/10/2014 11/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Sweta Patel BIO-RAD LABORATORIES, INC.	K963040
2014-8235	10/10/2014 11/10/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Anabel Hernandez INVESTIGATIVE REPORTING PROGRAM UC BERKELEY	FRESH PACKING CORP, LOS ANGELES, CA - RECS RE IMPORTS FROM MEXICO

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2014-8236	10/10/2014 11/13/2014	OC/ORO/ OC/ORO/	mike Bennett, Michael F	ALK-ABELLO, INC, PORT WASHINGTON, NY; EDGE PHARMCY SERVICES LLC, COLCHESTER, VT; JUBILANT HOLLISTER STIER LLC, SPOKANE, WA ETC - 483, EIR
2014-8237	10/10/2014 11/10/2014	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	REPORTS ON SAFETY ISSUES WITH TOBACCO PRODUCTS SUBMITTED BY CONSUMERS, HEALTH CARE PROVIDERS, ETC THROUGH PORTAL
2014-8238	10/10/2014 11/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Emily Krulewitz The Weinberg Group	ANDA 202077, 201006, 200925, ETC APPROVAL LETTER
2014-8239	10/10/2014 11/10/2014	OC/ORO/ OC/ORO/	Emily Rand CBS NEWS	NUVISION PHARMACY - RESPONSE TO 483, REQUESTS FOR RECALLS ETC
2014-8240	10/10/2014 11/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Terri Wallace Polymed Therapeutics, Inc.	K142408
2014-8241	10/10/2014 11/10/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Jayson Parker University of Toronto Mississauga	K103785
2014-8242	10/10/2014 11/10/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Jayson Parker University of Toronto Mississauga	K112930
2014-8243	10/10/2014 11/10/2014	FDA/OC/OES/DFOI/	Bharat Celly Research Delta	SUN PHARMACEUTICALS, HALOL, INDIA - 483 09/01/2014 - 10/09/2014
2014-8244	10/10/2014 11/10/2014	FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/	STEVEN EARNHART O'BRIEN FIRM PL	EDIBLE FOODS - RECS
2014-8245	10/10/2014 11/10/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Jayson Parker University of Toronto Mississauga	K111346
2014-8246	10/10/2014 11/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	Z-0006-04 - BATCH NUMBER RECS
2014-8247	10/10/2014 11/10/2014	FDA/OC/OES/DFOI/	LOREN A LARKIN HIGHBRIDGE CAPITAL MANAGEMENT LLC	VALEANT PHARMS - 483S 9/1/13 TO 9/30/14
2014-8248	10/10/2014 11/10/2014	OC/CVM/OCD/	Cristina Stella CENTER FOR FOOD SAFETY	ETHOXYQUIN - RECS RE SAFETY, USE, AND EFFECTS AS AN ADDITIVE TO ANIMAL FEED
2014-8249	10/10/2014 11/10/2014	FDA/OGROP/ORO/CE-FO/NWJ-DO/NWJ-CB/	Ryan Simpson none	RTI SURGICAL - 483, CLOSEOUT LETTER 01/10/2014 - 09/25/2014
2014-8250	10/10/2014 11/10/2014	OC/ORO/ OC/ORO/	WILLIAM M COHEN COHEN, WILLIAM M	COMPLNT 138376

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		FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/		
2014-8251	10/10/2014 11/10/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELENA HOWELL HOGAN LOVELLS LLP	LIST OF APRVD PAPER NDA'S - MOST RECENT
2014-8252	10/10/2014 11/10/2014	FDA/OFVM/CFSAN/OCD/EOS/	JORDAN D KING KING, JORDAN D	CHEMICALS USED IN THE FAST FOOD INDUSTRY - LIST OF BANNED CHEMICALS IN PREPARATION OF FAST FOOD, RPTS ON AZODICARBONAMIDE, CHEMICALS PROHIBITED IN BREAD DOUGH
2014-8253	10/14/2014 11/12/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	James Guro NORAMCO INC	OXYMORPHONE - FIELD ALERT REPORT 09/15/2014 - 10/10/2014
2014-8254	10/14/2014 11/12/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Anna Neill Kenny Nachwalter P.A.	ANDA 040445 , ANDA 203399 CERTIFIED
2014-8255	10/14/2014 11/12/2014	OC/ORR/ OC/ORR/ FDA/OGROP/ORR/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORR/PA-FO/SAN-DO/SAN-CB/	Barry Novick Kitchen Table Bakers	KALI/JACKS PASTRY SMART PARMESAN CRISP - LAB RESULTS 09/01/2013 - 10/10/2014
2014-8256	10/14/2014 11/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	Lorraine M. Hanley, VP Reg Affairs,Vascular Insights, LLC Vascular Insights, LLC	K071468
2014-8257	10/14/2014 11/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	Lorraine M. Hanley, VP Reg Affairs,Vascular Insights, LLC Vascular Insights, LLC	K092119
2014-8258	10/14/2014 11/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	Lorraine M. Hanley, VP Reg Affairs,Vascular Insights, LLC Vascular Insights, LLC	IDE G100252
2014-8259	10/14/2014 11/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	Lorraine M. Hanley, VP Reg Affairs,Vascular Insights, LLC	Pre-IDE I100545

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			Vascular Insights, LLC	
2014-8260	10/14/2014 11/12/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Melanie Cote Medisca Inc.	JIANGSU JIAERKE PHARMACEUTICALS GROUP CO LTD, CHINA - EIR 06/01/2014 - 06/30/2014
2014-8261	10/14/2014 11/12/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michelle Elizabeth Legiec Eagle Pharmaceuticals, Inc.	CIPLA LIMITED - EIR 04/01/2013 - 7/01/2013, ANDA 200540
2014-8262	10/14/2014 11/12/2014	FDA/OC/OES/DFOI/ FDA/OC/OES/	Veronica Moten N/A	EEO COMPLAINTS
2014-8263	10/14/2014 11/12/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Cassandra Sanchez Cassandra Sanchez	STATINS - AERS SUMMARY
2014-8264	10/14/2014 11/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	Gee Lee Win-US Technology Company Limited	K040691
2014-8265	10/14/2014 11/12/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Matthew Davidson Verrica Pharmaceuticals Inc	CANTHARIDIN - IND
2014-8266	10/14/2014 11/12/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/CVM/OCD/	Rachel Johnson FOI Services, Inc.	SOP 03-218, for Tiamulin
2014-8267	10/14/2014 11/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	Edward Kobus Invado Pharmaceuticals	K110172
2014-8268	10/14/2014 11/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	Pawel Buczek PDI PHARMACEUTICALS INC	ACCU-CHEK INFORM II ROCHE - PLASTIC TYPE AND COMPOSITION
2014-8269	10/14/2014 11/12/2014	FDA/OGROP/ORAC/CE-FO/NWJ- DO/NWJ-CB/	Rachel johnson FOI Services, Inc.	RTI SURGICAL, ALLENDALE, NJ - INVESTIGATOR DIARIES

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2014-8270	10/14/2014 11/12/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Rachel Johnson FOI Services, Inc.	RTI SURGICAL, ALLENDALE, NJ - EIR, 483 ETC
2014-8271	10/14/2014 11/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	Zeeshan Safdar N/A	TIANSHI HEALTH PRODUCTS INC - CERTIFICATIONS, K051197, CON1014902
2014-8272	10/14/2014 11/14/2014	OC/ORA/ OC/ORA/	mike Bennett, Michael F	DOWNING LABS - EIR, RESPONSES 01/01/2012 - 10/11/2014
2014-8273	10/14/2014 11/14/2014	OC/ORA/ OC/ORA/	mike Bennett, Michael	AVELLA, DEER VALLEY - EIR, RESPONSES 01/01/2013 - 10/11/2014
2014-8274	10/14/2014 11/12/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Susan Cusack, VP Regulatory Affairs Innocoll, Inc.	PACIRA PHARMACEUTICALS - WARNING LETTER 09/22/2014 - 10/10/2014
2014-8275	10/14/2014 11/14/2014	OC/ORA/ OC/ORA/	mike Bennett, Michael	CENTRAL ADMIXTURE PHARMACY SERVICES, IRVINE, CA - EIR, RESPONSES 01/01/2014 - 10/12/2014
2014-8276	10/14/2014 11/14/2014	OC/ORA/ OC/ORA/	mike Bennett, Michael	CUSTOM COMPOUNDING CENTERS, LOS ALAMITOS, CA - EIR, RESPONSES 01/02/2013 - 10/12/2014
2014-8277	10/14/2014 11/12/2014	FDA/OC/OES/DFOI/	Michael Felberbaum THE ASSOCIATED PRESS	CTP FOIA REQUESTS 03/05/2014 - 10/13/2014
2014-8278	10/14/2014 11/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kim Mejia Perkin Elmer Inc.	SUPPLEMENTAL DEVICE ADVERSE EVENT REPORT
2014-8279	10/14/2014 11/12/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Ronald L. Maddix Langford Infection Control Systems, Inc.	K042648, K063788, K110189
2014-8280	10/14/2014 11/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	Melissa Walker Graematter, Inc.	K122137, K120233
2014-8281	10/14/2014 11/12/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lauren Welling Sanders, Phillips, Grossman, LLC	PATRIOT PHARMACEUTICALS - APPLICATION, INVESTIGATION, TESTING ETC 01/01/1998 - 10/13/2014
2014-8282	10/14/2014 11/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	Camilla Recke BioPorto Diagnostics A/S	DEN130031 ASTUTE MEDICAL, INC / NEPHROCHECK TEST SYSTEM - DECISION SUMMARY, APPROVAL LETTER
2014-8283	10/14/2014	FDA/OFVM/CFSAN/OCD/EOS/	Justin Prochnow	5-Methyltetrahydrofolate (MTHF), including, but not limited to, the Administrative Record regarding the FDA's proposed changes to

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	11/12/2014		GREENBERG TRAURIG LLP	the Nutrition Facts Label announced in February 2014 and the discussion of MTHF as a permissible source of folate or folic acid
2014-8284	10/14/2014 11/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	LeAnn Latham MSquared Associates	P110006, P130017
2014-8285	10/14/2014 11/12/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ibrutinib - individual cases Ken Tong	IBRUTINIB - CASE REPORTS
2014-8286	10/14/2014 11/12/2014	FDA/OC/OES/DFOI/	Robert Bexton Aristotle Capital Management	ORCHID CHEMICALS AND PHARMACEUTICALS LTD, INDIA - 483 04/01/2014 - 04/30/2014
2014-8287	10/14/2014 11/12/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Steven Woloshin The Dartmouth Institute for Health Policy and Clinical Practice	NDA, NDA SUPPLEMENTS
2014-8288	10/14/2014 11/12/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	INFOPIA CO LTD, ANYANG-SI, GYEINGGI-DO, SOUTH KOREA - 483 2/17-20/14
2014-8289	10/14/2014 11/12/2014	FDA/OGROP/ORR/CE-FO/DET-DO/DET-CB/	Juli Bean EMC Insurance Company	RESTAURANT RECYCLING SERVICES LLC - INVESTIGATION RECS 08/01/2014 - 10/14/2014
2014-8290	10/14/2014 11/12/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lauren Welling Sanders, Phillips, Grossman, LLC	INVEGA - APPLICATION, INVESTIGATION, TESTING ETC 01/01/1998 - 10/13/2014
2014-8291	10/14/2014 11/12/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	HOSPIRA AUSTRALIA PTY LTD, VICTORIA, AUSTRALIA - 483 2/24/14 - 3/1/14
2014-8292	10/14/2014 11/12/2014	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	BRAVA, MIAMI, FL - EIR, 483, CO RESP 2/4/14 TO 3/14/14
2014-8293	10/14/2014 11/12/2014	FDA/OGROP/ORR/CE-FO/NWJ-DO/NWJ-CB/	WALTER E. CHALKLEY THOMSON REUTERS	RTI SURGICAL INC, ALLENDALE, NJ - EIR, 483, CO RESP 12/3/13 TO 1/9/14

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			(SCIENTIFIC) SAS	
2014-8294	10/14/2014 11/12/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	WALTER J DOLL PhD, LEXINGTON, KY - EIR, 483, CO RESP 1/14-17/14
2014-8295	10/14/2014 11/12/2014	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	BAYCARE HEALTH SYS IRB - MPM SAH, CLEARWATER, FL - EIR, 483, CO RESP 2/19/14
2014-8296	10/14/2014 11/12/2014	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	MYLAN PHARMACEUTICALS INC, MORGANTOWN, WV - EIR, 483, CO RESP 3/10-21/14
2014-8297	10/14/2014 11/12/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	LONZA BIOLOGICS INC, PORTSMOUTH, NH - EIR, 483, CO RESP 8/26/13 TO 9/30/13
2014-8298	10/14/2014 11/12/2014	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	BIOMAT USA INC, SEATTLE, WA - EIR, 483, CO RESP 9/19-23/13
2014-8299	10/14/2014 11/20/2014	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	GENENTECH INC, VACAVILLE, CA - EIR, 483, CO RESP 8/26/13 TO 9/6/13
2014-8300	10/14/2014 11/12/2014	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	MERCK SHARP & DOHME CORP, ELKTON, VA - EIR, 483, CO RESP 9/23-30/13
2014-8301	10/14/2014 11/12/2014	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	TIMOTHY R. YEKO MD, TEMPLE TERRACE, FL - EIR, 483, CO RESP 9/10-17/13
2014-8302	10/14/2014 11/12/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	SHISHUKA MALHOTRA MD, CANTON, OH - EIR, 483, CO RESP 1/4-14/13
2014-8303	10/14/2014 11/12/2014	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	MEDIMMUNE, SANTA CLARA, CA - EIR, 483, CO RESP 1/30-31/14
2014-8304	10/14/2014 11/12/2014	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	EISAI INC, BALTIMORE, MD - EIR, 483, CO RESP 12/9-17/13
2014-8305	10/14/2014 11/12/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	CHRISTINA JEWETT CENTER FOR INVESTIGATIVE REPORTING	CROWDER MACHINE & TOOL, TEMECULA, CA - EIR 7/30/12

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2014-8306	10/14/2014 11/12/2014	FDA/OFVM/CFSAN/OCD/EOS/	NICHOLAS J. PAROLISI, Jr. LITCHFIELD CAVO LLP	WOLVERINE PACKING CO RECALL 5/14
2014-8307	10/14/2014 11/12/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DALE B ADAMS ADAMS, DALE B	ANTI DEPRESSANTS - DEATHS & SUICIDES
2014-8308	10/14/2014 11/12/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDRH/OCER/DFOI/	ANDREW B. SOMMERMAN SOMMERMAN & QUESADA	VITROLIFE INC - PERFADEX ALL CORRESPONDENCE
2014-8309	10/14/2014 11/12/2014	FDA/OC/OES/DFOI/	Mehul Govani P & L Development, LLC	MICRO LABS - 483, EIR, ETC PREVIOUSLY RELEASED 01/01/2012 - 10/13/2014
2014-8310	10/15/2014 11/13/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Stefan Ellis PEPPER HAMILTON LLP	PROZAC - SAFETY/EFFICACY RECS RE ORIGINAL APPROVAL
2014-8311	10/15/2014 11/13/2014	FDA/OMPT/CDRH/OCER/DFOI/	T A Cox Spinalight Inc.	SPINALIGHT INC, WOODSTOCK, GA - PHONE, FAX NUMBER ON SUBMISSIONS
2014-8312	10/15/2014 11/13/2014	OC/CVM/OCD/	Karen VanLare NOVARTIS ANIMAL HEALTH	NADA 034267 FOIA SUMMARY
2014-8313	10/15/2014 11/13/2014	OC/CVM/OCD/	Karen VanLare NOVARTIS ANIMAL HEALTH	NADA 049725 FOIA SUMMARY
2014-8314	10/15/2014 11/13/2014	FDA/OMPT/CDRH/OCER/DFOI/	Alexander R. Priest Alexander R. Priest	K844918
2014-8315	10/15/2014 11/13/2014	FDA/OC/OES/DFOI/	Carol Donahue Donahue, Carol	QUESTCOR PHARMACUETICALS - FOIA REQUESTS AND RESPONSES 05/09/2014 - 10/14/2014
2014-8316	10/15/2014 11/13/2014	FDA/OMPT/CDRH/OCER/DFOI/	Alexander R. Priest Alexander R. Priest	K902327
2014-8317	10/15/2014 11/13/2014	FDA/OMPT/CDRH/OCER/DFOI/	Advanced Sterilization Products Advanced Sterilization Products	K140392
2014-8318	10/15/2014 11/13/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Maggie Brilhart, PharmD University of Texas MD Anderson Cancer Center (Division of Pharmacy)	MD ANDERSON CANCER CENTER - AERS REPORTED TO MEDWATCH 01/01/2011 - 10/15/2014

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2014-8319	10/15/2014 11/13/2014	FDA/OC/OCC/ OC/ORO/OCI/ OC/ORO/OCI/	Josh Long Informa Exhibitions LLC	CRIMINAL COMPLAINTS FILED BY FDA AGAINST DIETARY SUPPLEMENT COMPANIES 2012-2014
2014-8320	10/15/2014 11/13/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rogelio Balbuena Value Plastics, Inc., A Nordson Company	K862653
2014-8321	10/15/2014 11/13/2014	OC/ORO/OCI/ OC/ORO/OCI/ FDA/OFVM/CFSAN/OCD/EOS/	Brooks Childs Brooks Childs	ADYA CLARITY - INVESTIGATION RECS 01/01/2011 - 12/31/2013
2014-8322	10/15/2014 11/13/2014	FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Denny Darnell Denny Darnell	SKELETAL DYNAMICS WRIST ARTHRODESIS NAIL - COMPLAINTS, INVESTIGATIONS, IMPLANTS ETC 06/01/2014 - 10/14/2014
2014-8323	10/15/2014 11/13/2014	FDA/OC/OCC/ OC/CVM/OCD/	Cristina Stella CENTER FOR FOOD SAFETY	Any and all documents related to nanoparticles in animal feed, including FDA's consultations with non government entities regarding pre-market safety assessments for nanoparticles in animal feed
2014-8324	10/15/2014 11/13/2014	FDA/OMPT/CDRH/OCER/DFOI/	FRANK MACY FRANK MACY	P970051
2014-8325	10/15/2014 11/13/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JENNIFER WILEY ALDER BIOPHAMACEUTICALS	FUJIFILM DIOSYNTH BIOTECHNOLOGIES, BILLINGHAM, UK - 483 7/14
2014-8326	10/15/2014 11/13/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORO/ OC/ORO/	Hannah V. Faddis, Esq. Wong, Wong & Associates, P.C.	GREEN PHARMACY - COMPLAINTS, REGISTRATION, AERS ETC 09/14/2007 -10/14/2014
2014-8327	10/15/2014 11/13/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Janet Oja none	AZATHIOPRINE - BLACK BOX WARNING 04/01/2011 - 12/01/2013
2014-8328	10/15/2014 11/13/2014	FDA/OGROP/ORO/CE-FO/MIN-DO/MIN-CB/	KAI RASMUSSEN ASSOCIATED STUDENTS OF MADISON (ASM)	UNIV OF WISCONSIN-MADISON, WESTERN IRB - COMMERCIAL IRB COOPERATIVE AMENDMENT 2008

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2014-8329	10/15/2014 11/13/2014	FDA/OC/OL/	Kenneth W. Weir Weir, Kenneth	RECS FROM SENATE, HOUSE, LOBBYISTS ON BEHALF OF UPTAKE MEDICAL CORP TO OBTAIN FDA APPROVAL FOR MEDICAL DEVICES
2014-8330	10/15/2014 11/13/2014	FDA/OC/OES/DFOI/	GERALDINE MILLER MILLER, GERALDINE	MEALS ON WHEELS - FROZEN CHICKEN MEALS
2014-8331	10/15/2014 11/13/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PAMELA SHEPPARD TARO PHARMACEUTICALS USA INC	VALEANT INTL - RETIN-A-MICRO NDA 20-475 SBA, MOR, LBLG, ETC
2014-8332	10/15/2014 11/13/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Santana McMurrey Santana McMurrey	ZOLOFT - MEDICAL OFFICER REVIEWS FOR INDICATIONS
2014-8333	10/15/2014 11/13/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jim Hunt The Dunn Group Inc.	HUMIRA BLA - CLINICAL TRIAL PROTOCOL PHASE II STUDY, PATIENT INFORMED CONSENT FORM
2014-8334	10/15/2014 11/13/2014	OC/ORO/ OC/ORO/	GLEN OLSHEIM CALIFORNIA PHARMACY AND COMPOUNDING CENTER	FACEY MEDICAL GROUP - BEVACIZUMAB SPL 86634 TEST RESULTS
2014-8335	10/15/2014 11/13/2014	FDA/OMPT/CDRH/OCER/DFOI/	Anna D'Lima ConMed Corporation	K013695, K050344, K011236 ETC
2014-8336	10/15/2014 11/13/2014	FDA/OFVM/CFSAN/OCD/EOS/	Hannah V. Faddis, Esq. Wong, Wong & Associates, P.C.	ULTRAMAX ELEMENTS - COMPLAINTS, REGISTRATION, AERS ETC 09/14/2007 - 10/14/2014
2014-8337	10/15/2014 11/13/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORO/ OC/ORO/	Hannah V. Faddis, Esq. Wong, Wong & Associates, P.C.	LANDMARK PHARM INTERNATIONAL - COMPLAINTS, AERS, REGISTRATION ETC 09/14/2007 - 10/14/2014
2014-8338	10/15/2014 11/13/2014	OC/ORO/ OC/ORO/	GLEN OLSHEIM CALIFORNIA PHARMACY AND COMPOUNDING CENTER	CALIFORNIA PHARMACY AND COMPOUNDING CENTER, NEWPORT BEACH, CA - EIR 8/18-25/14, SPL NUMBERS 853516, 853518 TEST RESULTS
2014-8339	10/15/2014	FDA/OMPT/CDER/ORP/DIDP/	Hannah V. Faddis, Esq.	GREEN PHARM NY LLC - COMPLAINTS, AERS, REGISTRATION ETC 09/14/2007 - 10/14/2014

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	11/13/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/ORP/ OC/ORP/	Wong, Wong & Associates, P.C.	
2014-8340	10/15/2014 11/13/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	SEPRACOR - XOPENEX (LEVALBUTEROL HCL) NDA 20-837/S006 APRVL RECS
2014-8341	10/16/2014 11/14/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joshua Malamud Hyman, Phelps & McNamara P.C.	CORR FROM FDA TO PAR PHARMACEUTICALS RE PREMATURE NOTIFICATION OF A PARAGRAPH IV CERTIFICATION
2014-8342	10/16/2014 11/14/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OCC/ FDA/OC/OES/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	ANNICA BENNING GOLDWATER INSTITUTE	EMERGENCY IND RECS; EBOLA EMERGENCY USE
2014-8343	10/16/2014 11/14/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Andrea Demakas ADVERSEEVENTS INC	ACTIQ, FENTORA - AERS
2014-8344	10/16/2014 12/04/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Zach Hall Immusoft Corporation	PROVENGE - IND
2014-8345	10/16/2014 11/14/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Zach Hall Immusoft Corporation	RECOMBINANT ALPHA-L-IDURONIDASE - IND

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2014-8346	10/16/2014 11/14/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K081285
2014-8347	10/16/2014 11/14/2014	OC/CVM/OCD/	Dr. Douglass Oeller Douglass Oeller Consulting, Inc.	PRESENTATIONS BY FDA/CVM EMPLOYEES DURING 2013 AND 2014 ANNUAL REGULATOR DAY MTG WITH ANIMAL HEALTH INSTITUTE; WORKING GROUP REPORTS; SPEAKERS' NOTES
2014-8348	10/16/2014 11/14/2014	FDA/OFVM/CFSAN/OCD/EOS/	Garry M. Wiltshire The Dow Chemical Company	FCN 608 FORM 3480
2014-8349	10/16/2014 11/14/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Stephana Biggins ZEE MEDICAL INC	ZEE MEDICAL, INDIANAPOLIS, IN - 483, EIR 10/01/2014 - 10/31/2014
2014-8350	10/16/2014 11/14/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lynn Hadaway Lynn Hadaway Associates, Inc	VANCOMCYIN - AERS
2014-8351	10/16/2014 11/14/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	CASE 9592323, 9723219, 9758264 SOURCE DOCUMENTS
2014-8352	10/16/2014 11/14/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	CASE NUMBER: 9651982 SOURCE DOCUMENTS
2014-8353	10/16/2014 11/14/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	CASE NUMBERS 9752947, 9790061 SOURCE DOCUMENTS
2014-8354	10/16/2014 11/14/2014	FDA/OO/OHR/	Thomas V. Montgomery, III, Ed.D. Thomas V. Montgomery, III, Ed.D.	INTERCHANGE BETWEEN FDA AND NPS RE HIRING; DATE OF TENTATIVE AND OFFICIAL DATE OF JOB OFFER; POSITION ETC
2014-8355	10/16/2014 11/14/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dr. Douglass Oeller Douglass Oeller Consulting, Inc.	DESOXYCORTICOSTERONE PIVALATE, DESOXYCORTICOSTERONE ACETATE - ANIMAL STUDY REPORTS EVALUATING NO OBSERVABLE ADVERSE EFFECTS LEVEL 01/01/1930 - 10/15/2014
2014-8356	10/16/2014 11/14/2014	FDA/OGROP/ORACE-FO/LOS-DO/LOS-CB/	Amanda Dykeman Woman Advocating Reproductive	JAY M COOPER, PHOENIX, AZ, DEC 2002; FEB 2001 - 483

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			Safety	
2014-8357	10/16/2014 11/14/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NASAL MUPIRICIN OINTMENT - SUPP APPROVAL APRIL 1996
2014-8358	10/16/2014 11/14/2014	FDA/OC/OES/DFOI/	Doe J	ULTRASLIM, LUXURIAN 150 RECS
2014-8359	10/16/2014 11/14/2014	OC/CVM/OCD/	John Russell, The Indianapolis Star The Indianapolis Star	TRIFEXIS - AERS, DEATHS
2014-8360	10/16/2014 11/14/2014	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	Karen Marshall Tarsa Therapeutics Inc.	PHARMACEUTICALS INTERNATIONAL INCORPORATED, HUNT VALLEY, MD - INSPECTION REPORTS 06/01/2013 - 10/15/2014
2014-8361	10/16/2014 11/14/2014	FDA/OC/OES/DDM/	Rachel Augustine Potter UNIVERSITY OF VIRGINIA	CITIZEN PETITION DATA 01/01/2000 - 12/31/2013
2014-8362	10/16/2014 11/14/2014	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	LESLIE RAMSEY FDA NEWS	UCSF HOME THERAPY SERVICES , SAN FRANCISCO, CA; INCUMEDX LLC, FREMONT,CA; CARDICA INC, REDWOOD, CITY, CA - 483 9/1-30/14
2014-8363	10/16/2014 03/04/2015	FDA/OC/OCC/ FDA/OC/OES/DFOI/ OC/CVM/OCD/	Zack Marker CENTER FOR FOOD SAFETY	AEDES AEGYPTI MOSQUITOS - RECS RE TEST IN FLORIDA, CONSULT BETWEEN FDA AND FLORIDA KEYS MOSQUITO CONTROL DISTRICT, FDA COMMUNICATIONS BETWEEN FDA AND OXITEC ETC
2014-8364	10/16/2014 11/14/2014	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	LESLIE RAMSEY FDA NEWS	MEDONE SURGICAL INC, SARASOTA, FL; OMEGA MEDICAL IMAGING INC, SANFORD, FL; MAGUIRE ENTERPRISES INC, SUNRISE, FL - 483 9/1-30/14
2014-8365	10/16/2014 11/14/2014	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	LESLIE RAMSEY FDA NEWS	L PERRIGO CO, ALLEGAN, MI; THERAMETRIC TECHNOLOGIES INC, NOBLESVILLE, IN; L PERRIGO CO, HOLLAND, MI - 483 9/1-30/14
2014-8366	10/16/2014 11/14/2014	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	LESLIE RAMSEY FDA NEWS	CONTINENTAL MANUFACTURING CHEMIST INC, MADRID, IA - 483 9/1-30/14
2014-8367	10/16/2014 11/14/2014	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	LESLIE RAMSEY FDA NEWS	ULTRADENT PRODUCTS INC, SOUTH JORDAN, UT - 483 9/1-30/14
2014-8368	10/16/2014 11/14/2014	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	LESLIE RAMSEY FDA NEWS	3D IMAGING DRUG DESIGN, LITTLE ROCK, AR; GOODIER COSMETICS LP, DALLAS, TX; VOSS MEDICAL PRODUCTS, SAN ANTONIO, TX - 483 9/1-30/14
2014-8369	10/16/2014 11/14/2014	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	LESLIE RAMSEY FDA NEWS	WESTERN SCOTT FETZER CO, WESTLAKE, OH; SONOGAGE INC, CLEVELAND, OH; STERIS CORP, MENTOR, OH - 483 9/1-30/14
2014-8370	10/16/2014	FDA/OGROP/ORA/CE-FO/CHI-	LESLIE RAMSEY	NANOPHASE TECHNOLOGIES, ROMEOVILLE, IL - 483 9/1-

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	11/14/2014	DO/CHI-CB/	FDA NEWS	30/14
2014-8371	10/16/2014 11/14/2014	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	LESLIE RAMSEY FDA NEWS	ACTION MEDICAL SYS, HAGERTOWN, MD; OTSUKA AMERICA PHAMACEUTICAL INC, ROCKVILLE, MD - 483 9/1-30/14
2014-8372	10/16/2014 11/14/2014	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	LESLEI RAMSEY FDA NEWS	BEST VASCULAR INC, NORCROSS, GA; ENDO CHOICE INC, ALPHARETTA, GA; PATHEON MANUFACTURING SERVICES LLC, GREENVILLE, NC - 483 9/1-30/14
2014-8373	10/16/2014 11/14/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	LESLIE RAMSEY FDA NEWS	BENTLEY LABS LLC, EDISON, NJ - 483 9/1-30/14
2014-8374	10/16/2014 11/14/2014	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	LESLIE RAMSEY FDA NEWS	KEYSTONE LABS INC, MEMPHIS, TN; TOTAL PHARMACY SERVICES INC, HOUMA, LA - 483 9/1-30/14
2014-8375	10/16/2014 11/14/2014	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	LESLIE RAMSEY FDA NEWS	BRISTOL MYERS SQUIBB INC, EAST SYRACUSE, NY - 483 9/1-30/14
2014-8376	10/16/2014 11/14/2014	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	LESLIE RAMSEY FDA NEWS	MEDTRONIC PUERTO RICO OPERATIONS CO, VILLALBA, PR; COMBE PRODUCTS INC, NAGUABO, PR - 483 9/1-30/14
2014-8377	10/16/2014 11/14/2014	FDA/OC/OES/DFOI/	Debra Sweitzer Kythera Biopharmaceuticals, Inc.	AMRI RENSSLAER, INC, RESSELAER, NY - INSPECTION RECS 2014
2014-8378	10/16/2014 11/14/2014	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	LESLIE RAMSEY FDA NEWS	HERON BOTANICALS, KINGSTON, WA - 483 9/1-30/14
2014-8379	10/16/2014 11/14/2014	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	LESLIE RAMSEY FDA NEWS	ENVOY MEDICAL CORP, SAINT PAUL, MN; BRENNTAG GREAT LAKES LLC, MENOMONEE FALLS, WI; PENRAD TECHNOLOGIES INC, BUFFALO, MN - 483 9/1-30/14
2014-8380	10/16/2014 11/14/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LESLIE RAMSEY FDA NEWS	LABORATORIO MAGNACHEM INTL SA, HAINA, DR; ISHIHARA SANGYO KAISHA LTD, YOKKAICHI SHI, JAPAN; CADILA HEALTHCARE LTD, AHMEDABAD CITY, INDIA - 483 9/1-30/14
2014-8381	10/16/2014 11/14/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	ANDRES GOMEZ KOPLOW NEUROMAGNETICS SA	BRAINSWAY INC - 510K
2014-8382	10/16/2014 11/14/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	LESLIE RAMSEY FDA NEWS	HIGH CHEMICAL CO, LEVITTOWN, PA; ACCUTOME ULTRASOUND INC, MALVERN, PA; MERCK SHARPE & DOHME CORP, WEST POINT, PA - 483 9/1-30/14
2014-8383	10/16/2014 11/14/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	LESLIE RAMSEY FDA NEWS	LIFETECH RESOURCES LLC, CHATSWORTH, CA; MINH CONG VU DBA AURORA MEDBIOCHEM CO, ESCONDIDO, CA; MICRO CONNECTION ENTERPRISES, SANTA FE SPRINGS, CA - 483 9/1-30/14
2014-8384	10/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	LESLIE RAMSEY	UNFORS RAYSAFE AB, BILLDAL, SWEDEN; COMBO AG, LOMMISWIL, SWITZERLAND; CONKIN SURGICAL

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	11/14/2014		FDA NEWS	INSTRUMENTS LTD, TORONTO, CANADA - 483 9/1-30/14
2014-8385	10/16/2014 11/14/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	LESLIE RAMSEY FDA NEWS	GREGORY MANUFACTURING INC, HOLYOKE, MA; PHARMALUCENCE INC, BEDFORD, MA; MALRBOROUGH HOSPITAL, MARBOROUGH, MA - 483 9/1-30/14
2014-8386	10/17/2014 11/17/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joshua Korzenik BRIGHAM AND WOMEN'S HOSPITAL	3229036 3396290 3430678 ETC
2014-8387	10/17/2014 11/17/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	John Gorney Elba Laboratories	ELBA LABORATORIES, TROY, MI - EIR 01/01/2011 - 10/15/2014
2014-8388	10/17/2014 11/17/2014	FDA/OFVM/CFSAN/OCD/EOS/	Jamil Khan Mercatus Center at George Mason University	SPREADSHEET TO CALCULATE ESTIMATE OF BENEFITS FOR STANDARDS FOR THE GROWING, HARVESTING, PACKING, AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION
2014-8389	10/17/2014 11/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	David Livingston Katecho, Inc	K954504
2014-8390	10/17/2014 11/17/2014	FDA/OC/OES/DFOI/	Paul A. Sandford Doctors's Best Viaminms	CAERS CONTACT INFORMATION
2014-8391	10/17/2014 11/17/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Elizabeth M. Coleman Rawls McNelis + Mitchell, PC	VAERS REPORT
2014-8392	10/17/2014 11/17/2014	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Jennii F. Kamesch MedAssets	LIFENET HEALTH, VIRGINIA BEACH, VA - EIR MOST RECENT 01/01/2013 - 10/16/2014
2014-8393	10/17/2014 11/17/2014	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Rachel Johnson FOI Services, Inc.	3M, ST PAUL, MN - EIR
2014-8394	10/17/2014 11/17/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jared Albright University of Kansas Drug Information Center	BETAPLACE, BETAPLACE AF - APPROVAL RECS
2014-8395	10/17/2014 11/17/2014	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OC/OES/DFOI/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Sallie Klm GCA Law Partners LLP	COMM BETWEEN FDA AND MARK POLHEMUS, STATE UNIVERSITY OF NY UPSTATE MEDICAL FACILITY 01/04/2012 - 10/16/2014
2014-8396	10/17/2014 11/17/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Karisa King CHICAGO TRIBUNE	LAMICTAL - AERS

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2014-8397	10/17/2014 11/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	John McCauley Accuray Attn: John McCauley at Reed Smith	IDE G940178
2014-8398	10/17/2014 11/17/2014	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	David Howell Bemis Manufacturing Company	CHARTER MEDICAL LTD - 483 10/16/2004 - 10/16/2014
2014-8399	10/17/2014 11/17/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JEFFREY R ATKINS FINKELSTEIN & PARTNERS	ANTIEPILEPTIC DRUGS & SUICIDALITY - STATISTICAL RVWS & EVALUATION 5/23/08 (CERTIFIED)
2014-8400	10/17/2014 11/17/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JEFFREY R ATKINS FINKELSTEIN & PARTNERS	ANTIEPILEPTIC DRUGS & SUICIDALITY - PATIENT SAFETY NEWS SHOW #89 8/09
2014-8401	10/17/2014 11/17/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JEFFREY R ATKINS FINKELSTEIN & PARTNERS	SUICIDAL THOUGHTS & BEHAVIOR - ANTIEPILEPTIC DRUGS L FDA PODCAST FULL VERSION 12/12/08
2014-8402	10/17/2014 11/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	KATHY A LEE CLINE FARRELL ET AL	C R BARD INC - HICKMAN HEMODIALYSIS APHERESIS DUAL LUMEN CATHETER MDRS
2014-8403	10/17/2014 11/17/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARIA NAVARRO-MONTES LAFOLLETTE JOHNSON	PFIZER LABS - CHANTIX MEDICATION GUIDE12/12 TO PRESENT
2014-8404	10/17/2014 11/17/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID HOFFMEISTER Wilson Sonsini Goodrich & Rosati	METOCLOPRAMIDE HCL ER TABS 80 MG, 105 MG ANDA 202-191 - FORFEITED ELIGIBILITY FOR 180 DAY EXCLUSIVITY, MINOCYCLINE HCL ER TABS 80 MG, 105 MG ANDA 091-118 - FORFEITED ELIGIBILITY FOR 180 DAY EXCLUSIVITY
2014-8405	10/17/2014 11/17/2014	FDA/OGROP/ORA/CE-FO/CHI- DO/CHI-CB/ FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/ FDA/OMPT/CDER/GRP/DIDP/	TANYA L PETERSON GRAY RITTER & GRAHAM ATTYS	INVESTIGATION OF NON-FDA APRVD PRESCRIPTION DRUGS - BILLS SHIPPING LOGS, INVOICES, ETC

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2014-8406	10/17/2014 11/17/2014	FDA/OC/OES/DFOI/	CATHERINE ISABEL Isabel, Catherine	MEDICAL DEVICES - TESTED OVERSEAS, WHERE OVERSEAS, OVERSIGHT BY ANYONE OVERSEAS OR US
2014-8407	10/17/2014 11/17/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ROLAND HATTON HATTON #1529223, ROLAND	MIRAPEX (PRAMIPEXOLE) - INTERNAL & EXTERNAL COMM 1997 TO PRESENT
2014-8408	10/17/2014 11/17/2014	FDA/OFVM/CFSAN/OCD/EOS/	ALEXANDRA SIFFERLIN TIME INC	ROCKSTAR, 5-HOUR ENERGY, RED BULL, ETC - CAERS 1/12 TO PRESENT
2014-8409	10/17/2014 11/17/2014	FDA/OC/OES/DFOI/	DAWN M CHITTY TORRENT PHARMA INC	MICRO LABS LTD, VERNA, GOA, INDIA - 483 RECENT
2014-8410	10/17/2014 11/17/2014	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/ORO/DIOP/	DONALD N BLUE ZETETIC INC	SHIPMENTS REGULATED BY US FDA 9/20/14 -10/15/14
2014-8411	10/17/2014 11/17/2014	FDA/OC/OES/DFOI/	DAWN M CHITTY TORRENT PHARMA INC	SUN PHARMACEUTICAL INDUSTRIES LTD, HOLOL, GUJARAT, INDIA - 483 9/8/14
2014-8412	10/17/2014 11/17/2014	FDA/OFVM/CFSAN/OCD/EOS/	RACHEL GRAVES KOMYATTE LAW FIRM LLC	GLUCOMANNAN, KONJAC, KONYAKU, ETC - CAERS
2014-8413	10/17/2014 11/17/2014	FDA/OO/OFBA/OAGS/ FDA/OC/OES/DFOI/	SARAH AL-SHERRI AL-SHERRI, SARAH	NATIONAL CENTER FOR NATURAL PRODUCTS RESEARCH (NCNPR), OXFORD, MS - GRANT BUDGET 2004-2014
2014-8414	10/17/2014 11/17/2014	FDA/OC/OES/DFOI/	Doe J	MEDICAL MARIJUANA LAW SUIT FILED AGAINST FDA 1994-RECS
2014-8415	10/20/2014 11/18/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jeffrey Hergesheimer Hologic, Inc.	K132270, K140887
2014-8416	10/20/2014 11/18/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jeffrey Hergesheimer Hologic, Inc.	K984631, K012351
2014-8417	10/20/2014 11/18/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jeffrey Hergesheimer Hologic, Inc.	K121710
2014-8418	10/20/2014	FDA/OGROP/ORA/CE-FO/CHI-	Steve Rogers	EXPERIMUR, CHICAGO, IL - 483, EIR

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	11/18/2014	DO/CHI-CB/	Zoetis	
2014-8419	10/20/2014 11/18/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jeffrey Hergesheimer Hologic, Inc.	K080739, K092704
2014-8420	10/20/2014 11/18/2014	FDA/OC/OES/DFOI/	Steve Rogers Zoetis	MPI RESEARCH, MATTAWAN, MI - EIR, 483 10/15/2004 - 10/15/2014
2014-8421	10/20/2014 11/18/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-4423
2014-8422	10/20/2014 11/18/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Hayden Hayden, Rebecca R	3I MINI IMPLANTS - APPROVAL RECS
2014-8423	10/20/2014 11/18/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kevin Hennegan CBR INTERNATIONAL CORP	XEOMIN - SUPPLEMENTAL APPROVAL RECS
2014-8424	10/20/2014 11/18/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Eric Forkosh Cooper Union - c/o Eric Forkosh	K122356
2014-8425	10/20/2014 11/18/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2013-9594
2014-8426	10/20/2014 11/18/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-4656
2014-8427	10/20/2014 11/18/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-4604
2014-8428	10/20/2014 11/18/2014	FDA/OFVM/CFSAN/OCD/EOS/	Lauren Nardella The Rose Sheet	VOLUNTARY COSMETIC REGISTRATION PROGRAM DATA LAST FIVE YEARS
2014-8429	10/20/2014 11/18/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-4458
2014-8430	10/20/2014 11/18/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORO/SW-FO/SWID/SWID-CB/ FDA/OC/OES/DFOI/	Weerawan (Birda) Misch CALAVO GROWERS, INC.	SAMPLE 692001 - LAB RESULTS
2014-8431	10/20/2014 11/18/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Amy E. Goldstone, Paralegal Harris Penn Lowry LLP	TORADOL - DRUG INSERT CERTIFIED 01/01/2003 - 04/30/2004

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2014-8432	10/20/2014 11/18/2014	FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/	Megan Favignano Fulton Sun	BACKER'S POTATO CHIP FACTORY, FULTON, MO - INSPECTION RECS LAST FIVE
2014-8433	10/20/2014 11/18/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	G. Srinivas Zydus Pharmaceuticals USA Inc.	ANDA 203263 DOXORUBICIN HYDROCHLORIDE - SBA, CMC
2014-8434	10/20/2014 11/18/2014	FDA/OC/OES/DFOI/	Patrick Riel University of Massachusetts Amherst	SF 1012
2014-8435	10/20/2014 11/18/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	510(k) full content KJ Pharme tech global research co., ltd	K112909
2014-8436	10/20/2014 11/18/2014	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	Status letters related to grandfathered tobacco product status determination issued by the Center for Tobacco Products, OCE from May, 2013 through July, 2013
2014-8437	10/20/2014 01/08/2015	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	Status letters related to grandfathered tobacco product status determination issued by the Center for Tobacco Products, OCE from March, 2013 through September, 2014
2014-8438	10/20/2014 11/18/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	koyo ogawa Koyo Ogawa	ABILIFY - AERS
2014-8439	10/20/2014 11/18/2014	FDA/OC/OES/DDM/	SIDNEY M WOLFE MD PUBLIC CITIZEN	DKT 20014D-0758
2014-8440	10/20/2014 11/18/2014	FDA/OGROP/ORR/CE-FO/NWJ-DO/NWJ-CB/	WAYNE SADOWSKI NOVARTIS PHARMACEUTICALS CORP	NOVARTIS PAHRMS, EAST HANOVER, NJ 2/3-2814, 7/15/14-8/4/14 - EIRS, 483S, CORR, ETC
2014-8441	10/20/2014 11/18/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TAMELA E ESHAM ARMBRECHT JACKSON LLP	FLOSEAL - AERS, WARNINGS, DEAR DOCTOR LTRS, ETC

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2014-8442	10/20/2014 11/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CAROLINE STOUT ECOR1 CAPITAL LLC	ALDER BIOPHARMS, BRISTOL MYERS SQUIBB - CLAZAKIZUMAB RECS, COMM
2014-8443	10/20/2014 11/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GUY R BUCCI BUCCI BAILEY & JARVIS LC	MYLAN PHARMS, PFIZER INC - DILANTIN KAPSEALS, PHENYTEK BLACK BOX WARNINGS, RPTS, STUDIES, ETC 1995 TO 2008
2014-8444	10/20/2014 11/18/2014	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	APRIL A ROBINSON ESQ BARIATEC CORP	BENTEC MEDICAL INC, WOODLAND, CA - EIR
2014-8445	10/20/2014 11/18/2014	FDA/OMPT/CDRH/OCER/DFOI/	JAMES W PENDERGAST WILMER CUTLER ET AL	INVIVO - PLGA POLY-L-LYSINE SCAFFOLD IDE APPL G110119 LTR 3/29/13
2014-8446	10/20/2014 11/18/2014	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	WALID GARDEZI GARDEZI, WALID	AASTROM BIOSCIENCES - INSP CORR LAST 4 YRS
2014-8447	10/20/2014 11/18/2014	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	JULIE MIKBAKHT NCG CAPITAL PARTNERS	MAYA OVERSEAS FOOD INC, MASPETH, NY - COMPLIANCE AND STANDING RECS
2014-8448	10/20/2014 11/18/2014	FDA/OMPT/CDRH/OCER/DFOI/	ANDRES GOMEZ KOPLOW NEUROMAGNETICS SA	BRAINSWAY INC - K122288
2014-8449	10/21/2014 11/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Karen Beran Point of Care Decision Support	WARFARIN - AERS
2014-8450	10/21/2014	FDA/OC/OES/DFOI/	Bradley T. Weber	MSM BLOOD DONOR BAN RECS

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	11/19/2014		none	
2014-8451	10/21/2014 11/19/2014	FDA/OC/OES/DFOI/	Doe J	MIRACLE EAR HEARING AID
2014-8452	10/21/2014 11/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Alexander Bennett The George Institute for Global Health	ZIAC - CLINICAL TRIAL RECS
2014-8453	10/21/2014 11/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	K020802 full content KJ Pharma tech global research co., ltd.	K020802
2014-8454	10/21/2014 11/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sherrie Pettiford Sigma-Tau Pharmaceuticals, Inc.	ANDA 091019 SBA
2014-8455	10/21/2014 11/19/2014	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	Joshua Malamud Hyman, Phelps & McNamara P.C.	ILLUMINA INC - RECS RE COMPLIANCE
2014-8456	10/21/2014 11/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jennifer Smith BIOPHARM INSIGHT	EXPAREL - MEDWATCH REPORTS
2014-8457	10/21/2014 11/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Cynthia J. Brown, MD Mission Children's Specialists	QVAR - AERS
2014-8458	10/21/2014 11/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Elaine Tronic Elaine Tronic	K090244
2014-8459	10/21/2014 11/19/2014	FDA/OGROP/ORAP/SW-FO/DAL-DO/DAL-CB/	Sam Omulo C.H. Guenther & Son Inc - Pioneer Frozen Foods	CH GUENTHER & SON INC, DUNCAVILLE, TX - EIR, SAMPLE RESULTS 09/28/2014 - 10/25/2014
2014-8460	10/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	Joshua Malamud	K132028, K134032

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	11/19/2014		Hyman Phelps and McNamara PC	
2014-8461	10/21/2014 11/19/2014	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Jennifer Cooper NaturMed Inc.	BACTOLAC PHARMACEUTICALS, HAUPPAUGE, NY - 483 11/05/2010 - 10/20/2014
2014-8462	10/21/2014 11/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	Astrid Marx Heraeus Medical GmbH	K901348
2014-8463	10/21/2014 11/19/2014	FDA/OFVM/CFSAN/OCD/EOS/	Michelle Rychalsky YALE-NEW HAVEN HOSPITAL	ABC DOPHILUS - AERS
2014-8464	10/21/2014 11/19/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mark Bounthavong Veterans Affairs San Diego Healthcare System	AMIODARONE WARFARIN - MEWATCH REPORTS
2014-8465	10/21/2014 11/19/2014	FDA/OFVM/CFSAN/OCD/EOS/ OC/CVM/OCD/	FATIMA ASLAM Keller and Heckman LLP	DSM NUTRITIONAL PRODUCTS - SCHIZOCHYTRIUM FAP
2014-8466	10/21/2014 11/19/2014	FDA/OC/OES/DFOI/	Pallavi Ail The Financial Express	INDIAN DRUG FACILITIES - EIR RELEASED UNDER FOIA
2014-8467	10/21/2014 11/19/2014	FDA/OFVM/CFSAN/OCD/EOS/	FATIMA ASLAM Keller and Heckman LLP	GRN00449
2014-8468	10/21/2014 11/19/2014	FDA/OFVM/CFSAN/OCD/EOS/	James E. Daubert James E. Daubert	BLACK LICORICE - AERS
2014-8469	10/21/2014 11/19/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Allison Tarantino ARIAD Pharmaceuticals, Inc.	ICLUSIG - ISR 10469062
2014-8470	10/21/2014 11/19/2014	FDA/OFVM/CFSAN/OCD/EOS/	ERIC F GREENBERG ERIC F GREENBERG PC	QUESTIONS & ANSWERS FROM FD-578 ADVANCED MILK PROCESSING COURSES HELD IN FY 05 REGIONAL MILK SEMINARS HELD IN FY 06 (M-I-06-15) - ITEM 29 C
2014-8471	10/21/2014 11/19/2014	FDA/OFVM/CFSAN/OCD/EOS/	ERIC F GREENBERG ERIC F GREENBERG PC	QUESTIONS & ANSWERS FROM FD-578 ADVANCED MILK PROCESSING COURSES HELD IN FY05 REGIONAL MILK SEMINARS HELD IN FY 06 (M-I-06-15) - ITEM 29 C
2014-8472	10/21/2014 11/19/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	AUTUMN L BORTON PFIZER	VALEANT, BRIDGEWATER, NJ - EIRS, 483S 6/13-26/14
2014-8473	10/21/2014 11/19/2014	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	JUILE NILKBAKHT NCG CAPITAL PARTNERS	OM REALITY ENTERPRISES INC, MASPETH, NY - COMPLIANCE & STANDING RECS
2014-8474	10/21/2014	FDA/OFVM/CFSAN/OCD/EOS/	JAMES H HARTTEN	NEIMENGGU FUFENG BIOTECHNOLOGIES CO LTD - XANTHAN GUM CORR, MEMOS, RPTS, ETC

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	11/19/2014		ARENT FOX LLP	
2014-8475	10/21/2014 11/19/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ALLISON DAIL 3D CMMUNICATIONS	LIST OF ALL PAID CONSULTANTS USED TO RVW, ADVISE, GUIDE OR RECOMMEND ANY AND ALL BIOSMILAR EVALUATION METHODS & PROCESSES FOR APPL, RVW, ANALYSES INTERPRETATION & THRESHOLD FOR APRVL
2014-8476	10/21/2014 11/19/2014	OC/ORA/ORM/ OC/ORA/ORM/	GAIL LESSICK LACHMAN CONSULTANT SERVICES INC	LIST OF DOMESTIC & FOREIGN INSP 8/1-31/14
2014-8477	10/21/2014 11/19/2014	OC/ORA/ORM/ OC/ORA/ORM/	ADAM DIEKER Chelepis Utility Services	FOOD PROCESSING FACILITIES - LIST OF LOCATIONS
2014-8478	10/21/2014 11/19/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kari Dylhoff PERRIGO COMPANY	ALTAIRE PHARMACEUTICALS, INC, AQUEBOGUE, NY - 483, EIR, RESPONSE ETC 01/01/2011 - 10/16/2014
2014-8479	10/22/2014 11/20/2014	FDA/OFVM/CFSAN/OCD/EOS/	anthony connors Freelance Journalist	CREATINE NITRATE - NDI RECS
2014-8480	10/22/2014 11/20/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Elaine Alambra Dynavax Technologies Corporation	RHEIN BIOTECH GMBH - INSPECTION REC 08/03/2012 - 08/31/2012
2014-8481	10/22/2014 11/20/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jason Bablak Thar Pharmaceuticals	BLA 125320/7
2014-8482	10/22/2014 11/20/2014	FDA/OMPT/CDRH/OCER/DFOI/	Priyangi Perera Pro-Lab Diagnostics	K141520
2014-8483	10/22/2014 11/20/2014	OC/CVM/OCD/	Paul Duquette Phibro Animal Health Corporation	NADA 91-467, NADA 91-513
2014-8484	10/22/2014 11/20/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John Paasch John Paasch	IMBRUVICA - SUPPLEMENTAL NDA

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2014-8485	10/22/2014 11/20/2014	FDA/OFVM/CFSAN/OCD/EOS/	William A. Olson/314/KOS Center for Regulatory Services, Inc.	GRAS 2G0391
2014-8486	10/22/2014 11/20/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Stephen Lang Alkermes PLC	ALKERMES INC - EIR 05/01/2012 - 08/31/2012
2014-8487	10/22/2014 11/20/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	David Bruser Toronto Star	49 FOREIGN VAERS REPORTS - COUNTRY OF ORIGIN
2014-8488	10/22/2014 11/20/2014	FDA/OMPT/CDRH/OCER/DFOI/	Priyangi Perera Pro-Lab Diagnostics	K113358
2014-8489	10/22/2014 11/20/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Gabriel Sustaita, Esq. Jim S. Adler & Associates	XARELTO - AERS
2014-8490	10/22/2014 11/20/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANNA T NEILL Kenny Nachwalter P.A.	ANMEAL PHARMS - APRVL LTR 6/21/13, ROUTING SHEET 6/21/13 (CERTIFIED)
2014-8491	10/22/2014 11/20/2014	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OC/OES/DFOI/ FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/ FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	CHRISTOPHER KENDRIC GOLDBERG SEGALLA	INDIVIDUAL RECS
2014-8492	10/22/2014 11/20/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MICHAEL A ADAM PHD HERON THERAPEUTICS INC	AUROBINDO FACILITY UNIT VIII, HYDERABAD, INDIA - EIR 5/23-26/11
2014-8493	10/22/2014 11/20/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOANNE S HAWANA ARENT FOX LLP	BO YING COMPOUND - AERS
2014-8494	10/22/2014 11/20/2014	FDA/OFVM/CFSAN/OCD/EOS/	FATTIMA ASLAM Keller and Heckman LLP	EMD MILLIPORE CORP - COLOR ADDITIVE PETITION 4C0299
2014-8495	10/22/2014	FDA/OC/OES/DFOI/	PATRICK KELLY	INDIVIDUAL RECS

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	11/20/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	CONWAY HOMER & CHIN-CAPLAN PC	
2014-8496	10/22/2014 11/20/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	PATRICK KELLY CONWAY HOMER & CHIN-CAPLAN PC	INDIVIDUAL RECS
2014-8497	10/22/2014 11/20/2014	FDA/OFVM/CFSAN/OCD/EOS/	LAURA MACCLEERY CENTER FOR SCIENCE IN THE PUBLIC INTEREST	FLAVOR AND EXTRACT MANUFACTURERS ASSOCIATION (FEMA) - GRAS DETERMINATIONS 1960 TO PRESENT
2014-8498	10/22/2014 11/20/2014	FDA/OFVM/CFSAN/OCD/EOS/	LAURA MACCLEERY CENTER FOR SCIENCE IN THE PUBLIC INTEREST	POWDERED PURE CAFFEINE - CAERS 2005 TO PRESENT
2014-8499	10/22/2014 11/20/2014	FDA/OFVM/CFSAN/OCD/EOS/	CHANTHA RANN RANN, CHANTHA	CALIFORNIA SHELLFISH AND SHIPPING PROGRAM - PROGRAM ELEMENT EVALUATION RPT (PEER)
2014-8500	10/22/2014 11/20/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Andy Washkowitz Stifel Nicolaus & Co	SELINEXOR - AERS
2014-8501	10/22/2014 11/20/2014	FDA/OC/OES/DDM/	LUKE BOURASSA OREXIGEN THERAPEUTICS INC	CARDIOVASCULAR AND RENAL DRUGS A/C - BRIEFING RECS, PRESENTATION SLIDES, ETC 1/28/99
2014-8502	10/22/2014 11/20/2014	FDA/OC/OES/DFOI/	PATTI WALLER MARLER CLARK LLP, PS	ORGANIC SPROUTED CHIA SEED - SALMONELLA OUTBREAK RECALL RECS 7/14
2014-8503	10/22/2014 11/20/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LUKE BOURASSA OREXIGEN THERAPEUTICS INC	CONTRAVE (NALTREXONE HCI, BUPROPION HCI) NDA 200-063 - APRVL RECS
2014-8504	10/22/2014 11/20/2014	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	PATRICIA L REGENYE Celgene Corporation	JEFFREY ROSEN, CLINL RES S FLORIDA, CORAL GABLES, FL - 483S 4/02 TO PRESENT
2014-8505	10/22/2014 11/20/2014	OC/ORR/OCI/ OC/ORR/OCI/	MICHAEL THEODORAKIS NTEU CHAPTER 282	INVESTIGATION RECS
2014-8506	10/22/2014 11/20/2014	FDA/OMPT/CDRH/OCER/DFOI/	ERIC CHAMNESS CHAMNESS, ERIC	K060745, K051772, K111338, ETC
2014-8507	10/22/2014 11/20/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARIA FERRARA ACTAVIS PHARMS	ESTRACE (ESTRADIOL VAGINAL CREAM) ANDA 86-069 IND AMENDMENTS

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-8508	10/22/2014 11/20/2014	OC/ORA/ORM/ OC/ORA/ORM/	David Mangione Govzilla, Inc.	LIST OF INSPECTIONS 03/15/2014 - 10/20/2014
2014-8509	10/22/2014 11/20/2014	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	John Walsh James Alexander Corporation	PHARMCO-AAPER PRODUCTS, INC. - EIR, 483, RECALL RECS
2014-8510	10/22/2014 11/20/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Richard A. Vadnal Richard A. Vadnal	ARAVA - NDA, SUPPLEMENTS
2014-8511	10/22/2014 11/20/2014	FDA/OMPT/CDRH/OCER/DFOI/	Margaret Klippel Howmedica Osteonics (aka Stryker Orthopaedics)	K934440
2014-8512	10/22/2014 11/20/2014	FDA/OFVM/CFSAN/OCD/EOS/	Daria Churh Clariant Corporation	RICE BRAN WAX - FAP
2014-8513	10/22/2014 11/20/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Cindy Barnes ProEx Delivery Corporation	K122288
2014-8514	10/22/2014 11/20/2014	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	Patrick Wood Morgan Stanley	BIOMERIEUX - WARNING LETTER 09/01/2014 - 10/22/2014
2014-8515	10/23/2014 11/21/2014	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	Susan Easley Easley, Susan S	LOUISIANA STATE UNIVERSITY HEALTH SCIENCES CENTER, SHREVEPORT, LA - EIR 07/01/2006 - 10/01/2014
2014-8516	10/23/2014 11/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	Michelle Zwernemann Infinite Biomedical Technologies, LLC	K1212215, DEN120016
2014-8517	10/23/2014 11/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	Michelle Zwernemann Infinite Biomedical Technologies, LLC	K123795
2014-8518	10/23/2014 11/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	Michael Zagorski ImPACT Applications, Inc.	K141865
2014-8519	10/23/2014 11/21/2014	FDA/OC/OES/DFOI/	P. Edward Black BLACK, E	CUBIST PHARMACEUTICALS, LEXINGTON, MA - 483 05/01/2014 - 07/31/2014
2014-8520	10/23/2014 11/21/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sam Park WINSTON & STRAWN LLP	NILOTINIB HYDROCHLORIDE MONOHYDRATE - STUDY PROTOCOL 2101

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-8521	10/23/2014 11/21/2014	FDA/OC/OES/DDM/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Steve Reyes PLx Pharma	1988 Tentative Final Monograph FR Vol 53, No 221
2014-8522	10/23/2014 11/21/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Wendy Lam Bank of America Merrill Lynch	IMBRUVICA, ZYDELIG, TECFIDERA ETQ - AERS
2014-8523	10/23/2014 11/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	Anna D'Lima ConMed Corporation	K081442
2014-8524	10/23/2014 11/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	PMA 130024
2014-8525	10/23/2014 11/21/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jaya Ayyagari Dr.Reddys Laboratories Inc	ANDA 202857 SBA
2014-8526	10/23/2014 11/21/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K121700
2014-8527	10/23/2014 11/21/2014	FDA/OGROP/ORR/SW-FO/DEN-DO/DEN-CB/	Christy VanRoosendaal RB Manufacturing LLC	RECKETT BENCKISER, SALT LAKE CITY, UT - EIR 06/01/2014 - 10/22/2014
2014-8528	10/23/2014 11/21/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dr. John Santmann Post-Finasteride Syndrome Foundation	ISR 7023409 7097426 7179247 ETC
2014-8529	10/23/2014 11/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	Heiko Frerichs Xenios AG	K061072
2014-8530	10/23/2014 11/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	Ayelet Peer SLP	K042253
2014-8531	10/23/2014 11/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	Heiko Frerichs Xenios AG	K053025
2014-8532	10/23/2014	FDA/OMPT/CDER/GRP/DIDP/	Dustin Block	ANDA 200653 EFFECTIVE APPROVAL LETTER

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	11/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	IPD Analytics, LLC	
2014-8533	10/23/2014 11/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	CORINNA LEONARDT MEDXPRT	MEDXPRT GMBH, ESCHBACH, GERMANY - EIR 1/20-21/14
2014-8534	10/23/2014 11/21/2014	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	JOSEPH B. VIENER, Esq. SANDERS, SANDERS & BLOCK	NSPIRED NATURAL FOODS - MARANATHA ROASTED CREAMY ALMOND BUTTER - RECALL 1/14
2014-8535	10/23/2014 11/21/2014	FDA/OMPT/CDRH/OCER/DFOI/	DOUGLAS JOHNSON DOUGLAS MEDICAL PRODUCTS	LO PROFILE EXTENSION SET K920788; BLOOD ADMINISTRATION SET K920788; DOUGLAS MEDICAL PRODUCTS INC IRRIGATION SET K922318
2014-8536	10/23/2014 11/21/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID L. SILBERSTEIN Valeant Pharmaceuticals North America LLC	PREDNISOLONE SODIUM PHOSPHATE ORAL SOL ANDA 075-250 - APRVL
2014-8537	10/23/2014 11/21/2014	FDA/OC/OES/DFOI/	GREGG S. LEVIN MOTLEY RICE LLC	IMPAX LABORATORIES INC - RYTARY EIR, 483, WARNING LTR, APRVL 1/13 TO PRESENT
2014-8538	10/23/2014 11/21/2014	FDA/OC/OES/ FDA/OMPT/CTP/OD/ FDA/OO/OFBA/OAGS/	SHELDON T. BRADSHAW HUNTON & WILLIAMS LLP	APOTEX RESEARCH PRIVATE LTD, BANGALORE, INDIA - GENETIC FACTORS IN TASTE PERCEPTION AND TOBACCO USAGE STUDY; REAL-TIME MEASUREMENT AND UPTAKE OF CARCINOGENS BY MENTHOL CIGARETTES SMOKERS STUDY, ETC
2014-8539	10/24/2014 11/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K080613
2014-8540	10/24/2014 11/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	Marc C. Sanchez Contract In-House Counsel and Consultants, LLC	K082391 K121481 K963204 ETC
2014-8541	10/24/2014 11/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	Manish Ahuja BioTex Inc.	K103758
2014-8542	10/24/2014 11/24/2014	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	John Walsh James Alexander Corporation	ULTRA PURE SOLUTIONS, INC, CASTROVILLE, CA - EIR, 483, RECALL RECS 10/01/2011 - 10/23/2014
2014-8543	10/24/2014 11/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	Manish Ahuja BioTex Inc.	K091641
2014-8544	10/24/2014 11/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	Manish Ahuja BioTex Inc.	K131948
2014-8545	10/24/2014	FDA/OFVM/CFSAN/OCD/EOS/	Eleanor DaCosta	GAMMA-AMINOBTYRIC ACID (GABA) - AERS

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	11/24/2014		United States Pharmacopeial Convention (USP)	
2014-8546	10/24/2014 11/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	Manish Ahuja BioTex Inc.	K132317
2014-8547	10/24/2014 11/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	Manish Ahuja BioTex Inc.	K112181
2014-8548	10/24/2014 11/24/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDRH/OCER/DFOI/	Peter Bacas Drop Diagnostics	EZ FLU A+B RAPID FLU DIAGNOSTIC CLEARANCE RECS
2014-8549	10/24/2014 11/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	Manish Ahuja BioTex Inc.	K112226
2014-8550	10/24/2014 11/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	Manish Ahuja BioTex Inc.	K140104
2014-8551	10/24/2014 11/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	Manish Ahuja BioTex Inc.	K103305
2014-8552	10/24/2014 11/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	Manish Ahuja BioTex Inc.	K041551
2014-8553	10/24/2014 11/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	Manish Ahuja BioTex Inc.	K001678
2014-8554	10/24/2014 11/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	LAURIE CHRISTENSEN CARESTREAM HEALTH INC	SIRONA DENTAL SYSTEMS GMBH, HESSEN, GERMANY - ORTHOPHOS-XG-3D/CEDH K990528, VARIANCE RPT
2014-8555	10/24/2014 11/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	LAURIE CHRISTENSEN CARESTREAM HEALTH INC	VATECH CO, GYEONGGIDO, REPUBLIC OF KOREA - PAX-I3D VARIANCE RPT K132983
2014-8556	10/24/2014 11/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	LAURIE CHRISTENSEN CARESTREAM HEALTH INC	IMAGING SCIENCES INTL, HATFIELD, PA - I-CAT SLX K051980, VARIANCE RPT
2014-8557	10/24/2014 11/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	SBRIGITTE LATRILLE RICARIMPEX SAS	MEDICINAL LEECHES - K040187
2014-8558	10/24/2014 11/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	BRIGITTE LATRILLE RICARIMPEX SAS	MEDICINAL LEECHES - K132958
2014-8559	10/24/2014 11/24/2014	FDA/OGROP/ORR/SE-FO/NOL- DO/NOL-CB/	PATRICIA L REGENYE Celgene Corporation	THE SARAH CANNON RESEARCH INSTITUE, NASHVILLE, TN, DENISE YARDLEY- 483S 3/27/12
2014-8560	10/24/2014 11/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PATRICIA L REGENYE Celgene Corporation	GUSTAVO LUGO-ZAMUDIOHOSPITAL JUAREZ, MEXICO CITY- 483S 7/7/08

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		FDA/OMPT/CDER/ORP/DIDP/		
2014-8561	10/24/2014 11/24/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	PATRICIA L REGENYE Celgene Corporation	PETER MERKEL UNIV OF PENN MEDICAL CENTER, PHILADELPHIA, PA - 483S
2014-8562	10/24/2014 11/24/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	PATRICIA L REGENYE Celgene Corporation	KATHY MILLER,INDIANA CANCER PAVILION, INDIANAPOLIS, IN,- 483S 12/6/11
2014-8563	10/24/2014 11/24/2014	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	PATRICIA L REGENYE Celgene Corporation	SOUTHEAST REGIONAL RESEARCH GROUP, COLUMBUS, GA, JEFFREY KINGSLEY - 483S 1/13/14, 2/24/14
2014-8564	10/24/2014 11/24/2014	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	PATRICIA L REGENYE Celgene Corporation	JOHN HAINSWORTH,THE SARAH CANNON RESEARCH INSTIUTE, NASHVILLE, TN, - 483S 2/23/11
2014-8565	10/24/2014 11/24/2014	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	PATRICIA L REGENYE Celgene Corporation	SCOTT LEE,UNIVERSITY OF WASHINGTON MEDICAL CENTER, SEATTLE, WA - 483S 9/3/3
2014-8566	10/24/2014 11/24/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	PATRICIA L REGENYE Celgene Corporation	RONALD FOGEL,HENRY FORD HOSPITAL, DETROIT, MI - 483S 9/5/07
2014-8567	10/24/2014 11/24/2014	FDA/OC/OES/DFOI/	BRANDON LEE CARDLE CARDLE #20711-058, BRANDON LEE	TOTAL SPENT ON STUDENT LOAN REPAYMENT LAST FISCAL YR
2014-8568	10/24/2014 11/24/2014	FDA/OC/OES/DFOI/	BRANDON LEE CARDLE CARDLE #20711-058, BRANDON LEE	LIST OF ENFORCEMENT RPTS LAST FISCAL YR
2014-8569	10/24/2014 11/24/2014	FDA/OC/OES/DFOI/	BRANDON LEE CAVLE CARDLE #20711-058, BRANDON LEE	TOTAL COST TO PROCESS FOA/PA REQUESTS - LAST FISCAL YR
2014-8570	10/24/2014 11/24/2014	FDA/OC/OES/DFOI/	BRANDON LEE CARDLE CARDLE #20711-058, BRANDON LEE	LIST OF ALL MOU IN WHICH FDA ENTERED INTO
2014-8571	10/24/2014 11/24/2014	FDA/OC/OES/DFOI/	BRANDON LEECARDLE CAVDLE #20711-058, BRANDON LEE	RPT SUBMITTED TO CONGRESS REGARDING FDA - MOST RECENT
2014-8572	10/24/2014 11/24/2014	FDA/OC/OES/DFOI/	BRANDON LEE CARDLE CARDLE #20711-058, BRANDON LEE	FOIA LOG - LAST FISCAL YR
2014-8573	10/24/2014 11/24/2014	FDA/OC/OES/DFOI/	BRANDON LEE CARDLE CARDLE #20711-058, BRANDON LEE	BUDGET - CURRENT FISCAL YR
2014-8574	10/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	DAVID B DORTCH	QIAGEN GMBH, HILDEN, GERMANY - EIRS 3/4-5/14

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	11/24/2014		QIAGEN SCIENCES	
2014-8575	10/24/2014 11/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MAKTOUF CHOKRI CHOKRI, MAKTOUF	TOPICAL PARAMOMYCIN WITH OR WITHOUT GENTAMICIN FOR CUTANEOUS LEISHMANIASIS - RECS 6/13/13
2014-8576	10/24/2014 01/06/2015	OC/ORO/ OC/ORO/	RYAN PROBSTFELD MARKUN, ZUSMAN, COMPTON, LLP	OREGON COMPOUNDING CENTER INC (CREATIVE COMPOUNDINGS, AN OREGON PHARMACY) - EIRS, WARNING LTRS, RECALLS, ETC 1/13 TO PRESENT
2014-8577	10/27/2014 11/25/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 203684
2014-8578	10/27/2014 12/08/2014	FDA/OC/OES/DFOI/ OC/CVM/OCD/	Jenny Hopkinson POLITICO	AQUABOUNTY - CORR RE CONSIDERATION OF APPROVAL
2014-8579	10/27/2014 11/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	Patrick Murphy Patrick Murphy	LASERS SOLD AS POINTERS - CDRH RECS RE REGULATION, LETTERS TO MANUFACTURERS, PUBLIC NOTICES
2014-8580	10/27/2014 11/25/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	Eleanor DaCosta United States Pharmacopeial Convention (USP)	UBIQUINOL - MEDWATCH REPORTS
2014-8581	10/27/2014 11/25/2014	FDA/OFVM/CFSAN/OCD/EOS/	Eleanor DaCosta United States Pharmacopeial Convention (USP)	CINAMOMUN VERUM, CINAMOMUN CASSIA - MEDWATCH REPORTS
2014-8582	10/27/2014 11/25/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/DET-DO/DET-CB/ OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/DET-DO/DET-CB/ FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	Adam Moyers Batten Lee PLLC	ENDOPHTHALMITIS AT RETINA & VITREOUS - RECS AND LAB RESULTS ETC

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2014-8583	10/27/2014 11/25/2014	FDA/OFVM/CFSAN/OCD/EOS/	Eleanor DaCosta United States Pharmacopeial Convention (USP)	HESPERIDIN - AERS
2014-8584	10/27/2014 11/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	Julie Haney Reagan Medical Center, LLC	K082761 - ACCESSION NUMBER, DEVICE LISTING NUMBER
2014-8585	10/27/2014 11/25/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Beth L. Rogoff-Gribbins Kardisch Law Group PC	BONIVA - AERS
2014-8586	10/27/2014 11/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kathryn Cole Translational Science Solutions	K130847
2014-8587	10/27/2014 11/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	Manish Ahuja BioTex Inc.	K133725
2014-8588	10/27/2014 11/25/2014	FDA/OGROP/ORR/SE-FO/ATL- DO/ATL-CB/	Adam Moyers Batten Lee PLLC	CLINICAL SPECIALTIES COMPOUNDING PHARMACY, AUGUSTA, GA; ATHENS RETINA CENTER, ATHENS, GA - LAB RESULTS 03/01/2013 - 09/30/2013
2014-8589	10/27/2014 11/25/2014	OC/CVM/OCD/	Terri Gruca KVUE TV	TRIFEXIS - COMPREHENSIVE CLINICAL DETAIL REPORT LISTINGS
2014-8590	10/27/2014 11/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	Sheryl Skinner FISHER DIAGNOSTICS	K032753
2014-8591	10/27/2014 11/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	Patrick J. Doran Archer & Greiner, P.C.	Mindray DS USA, Inc Panorama Wireless Telemetry System - APPROVAL RECS
2014-8592	10/27/2014 11/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	Patrick J. Doran Archer & Greiner, P.C.	DATASCOPE CORP PANORAMA WIRELESS TELEMETRY SYSTEM - APPROVAL RECS
2014-8593	10/27/2014 11/25/2014	FDA/OO/OFBA/OAGS/	Thomas Law Center Thomas Law Center	FDA-SOL-13-1118990
2014-8594	10/27/2014 11/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K060662
2014-8595	10/27/2014 11/25/2014	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	Substantial Equivalence tobacco information for Camel products
2014-8596	10/27/2014 11/25/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ibrutinib - Individual cases Ken Tong	10429529, 10432205, 10433312 ETC

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2014-8597	10/27/2014 11/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	Manish Ahuja BioTex Inc.	K133725
2014-8598	10/27/2014 11/25/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Jonathan Roden MPI RESEARCH	IRDC, MATTAWAN, MI - EIR 01/04/1984 - 12/31/1992
2014-8599	10/27/2014 11/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	Troy Brisby Bio Counsel	UNILIFE MEDICAL SOLUTIONS - 513(G) REQUEST RECS
2014-8600	10/27/2014 11/25/2014	FDA/OGROP/OIP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jesse McLean Toronto Star	CORR WITH CANADA RE SHIRE PHARMACEUTICALS ALLEGED IMPROPER MARKETING AND PROMOTION OF DRUGS
2014-8601	10/27/2014 11/25/2014	FDA/OMPT/OSMP/OOPD/	Elinore Mercer Cote Orphan Consulting	LUTREPULSE - OOPD RECS 01/01/1987 - 01/01/1988
2014-8602	10/27/2014 11/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K072412
2014-8603	10/27/2014 11/25/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bhagwan S. Chaudhary National Institute of Securities Markets, Mumbai, India	IPCA LABORATORIES, INDIA - 483 10/13/2014 - 10/25/2014
2014-8604	10/27/2014 12/29/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Manpreet Hora GEORGIA INSTITUTE OF TECHNOLOGY	DRUG SHORTAGE RECS - 1990 TO 2014
2014-8605	10/27/2014 11/25/2014	OC/ORACE/ OC/ORACE/	mike Bennett, Michael F	SPECIALTY COMPOUNDING - RESPONSES, TESTING 01/01/2013 - 10/25/2014
2014-8606	10/27/2014 11/25/2014	FDA/OC/OES/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JASON LEOPOLD Vice News	CONTINGENCY PLANS FOR EBOLA OUTBREAK - RECS

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2014-8607	10/27/2014 11/25/2014	FDA/OFVM/CFSAN/OCD/EOS/	Lisa Thorsten CAMPBELL SOUP COMPANY	INULIN DERIVED FROM AGAVE TEQUILIANA - FDA CORR RE GRAS STATUS
2014-8608	10/27/2014 11/25/2014	OC/ORO/ OC/ORO/ OC/ORO/ORM/ OC/ORO/ORM/	b. Burge BURGESS, BERNIE	INSPECTION IN FACTS 2005 TO 2006 WITH INSPECTION BASIS COMPLIANCE AND WITH COMPLAINT NUMBER 1000 TO 1800 ETC
2014-8609	10/27/2014 11/25/2014	FDA/OC/OES/DFOI/	Sarah Paterson BBI Solutions OEM Limited	ALERE SAN DIEGO, INC - 483 2012
2014-8610	10/27/2014 11/25/2014	FDA/OO/OFBA/OAGS/	FATEMEH AKHLAGHI PHARM D PHD UNIV OF RHODE ISLAND	SIMULATIONS PLUS INC - MODELING AND SIMULATION FOR OCULAR DOSAGE FORMS PROJECT #1U01FD005211-01; SIMCYP LTD - DEVELOPMENT AND VALIDATION OF DERMAL PBPK PROJECT #1U01FD005225-01
2014-8611	10/27/2014 11/25/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	PATRICK KELLY CONWAY HOMER & CHIN-CAPLAN PC	INDIVIDUAL RECS
2014-8612	10/27/2014 11/25/2014		Doe J	INDIVIDUAL RECS
2014-8613	10/27/2014 12/24/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	CRAIG M SILVERMAN PETER G ANGELOS LAW OFC	ETHICON INC - GYNECARE LAPAROSCOPIC MORCELLATOR K993801; COOK UROLOGICAL INC - COOK TISSUE MORCELLATOR K910939, K925851; LUIMENIS INC - VERSACUT AND TISSUE MORCELLATOR K133272, ETC
2014-8614	10/27/2014 11/25/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BENJAMIN L ENGLAND ESQ BENJAMIN L ENGLAND & ASSOCIATES LLC	BULK INGREDIENT DRUG PROD LISTING 1/11 TO PRESENT
2014-8615	10/27/2014 11/25/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	ALEMBIC PHARMACEUTICALS LTD, GUJARAT, INDIA - EIR 8/27-30/12
2014-8616	10/27/2014 11/25/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JESSICA R MACAULEY HAGENS BERMAN SOBOL SHAPIRO LLP	NOVARTIS PHARMS - NEORAL (CYCLOSPORINE CAPS, ORAL SOL) NDA 50-715, NDA 50-716 LTR 5/8/00; DUPONT MERK PHARMACEUTICAL CO - COUMADIN (WARFRIN SODIUM TABS) NDA 9-218 LTR 8/26/97
2014-8617	10/27/2014 11/25/2014	FDA/OC/OES/DDM/	JESSICA R MACAULEY HAGENS BERMAN SOBOL SHAPIRO LLP	DKT 2001P-0481, DKT 2001P-0122, DKT 2002P-0059, ETC

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2014-8618	10/27/2014 11/25/2014	FDA/OC/OES/	THOMAS M BURTON WALL STREET JOURNAL	EBOLA OUTBREAK PLANNING OR DECISION-MAKING - MEMOS, EMAILS, ANALYSES, ETC 6/14 TO PRESENT
2014-8619	10/27/2014 11/25/2014	FDA/OO/OHR/	BRANDON LEE CARDLE CARDLE #20711-058, BRANDON LEE	TOTAL AMOUNT SPENT ON RECRUITMENT INCENTIVES LAST FISCAL YEAR
2014-8620	10/27/2014 11/25/2014	FDA/OO/OFBA/OAGS/	BRANDON LEE CARDLE CARDLE #20711-058, BRANDON LEE	LIST OF GRANT RECIPIENTS, AMOUNT GIVEN BY FDA LAST FISCAL YEAR
2014-8621	10/27/2014 11/25/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	ALAN G MINSK ARNALL GOLDEN GREGORY LLP	BIOTENE, BIOTENE PBF DRY-MOUTH MOUTHWASH K101477
2014-8622	10/27/2014 11/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	ALAN G MINSK ARNALL GOLDEN GREGORY LLP	BIOTENE ORAL BALANCE, DRY MOUTH ORALRINSE, MOISTURIZING MOUTH SPRAY K123731
2014-8623	10/27/2014 11/25/2014	FDA/OMPT/CDRH/OCER/DFOI/	ALAN G MINSK ARNALL GOLDEN GREGORY LLP	DR FRESH'S DRY MOUTH MOUTHWASH K111250
2014-8624	10/28/2014 11/26/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	Gloria Lin Cheng Yi Optical (Xiamen) Co., LTD	IMPORT REFUSAL AFJ-1917797-6/932/1, 9BM-0025994-8/1/1 - IMPORTER
2014-8625	10/28/2014 11/26/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mahidhar Chinta Micro Lab USA, Inc	ANDA 090656 SBA
2014-8626	10/28/2014 11/26/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mahidhar Chinta Micro Lab USA, Inc	ANDA 078007 SBA
2014-8627	10/28/2014 11/26/2014	FDA/OFVM/CFSAN/OCD/EOS/ OC/CVM/OCD/	Caldbeck Consulting Caldbeck Consulting LLC	HIGH ERUCIC RAPESEED MEAL AS FEED OR FOOD INGREDIENT IN LIVESTOCK OR HUMAN FOOD 01/01/2010 - 10/27/2014
2014-8628	10/28/2014 12/23/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Gardasil latest Biologics License Application Artery Therapeutics, Inc.	GARDISIL - BLA
2014-8629	10/28/2014 11/26/2014	FDA/OMPT/CDRH/OCER/DFOI/	Roscoe Medical Roscoe Medical	ROSCOE MEDICAL SOUNDCARE PLUS - COMPLAINT RECS 01/01/2014 - 08/31/2014
2014-8630	10/28/2014	FDA/OMPT/CDRH/OCER/DFOI/	Noah Roth	K100820

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	11/26/2014		Roth, Noah	
2014-8631	10/28/2014 11/26/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	B. Brown ABC DEVELOPMENT	ORAMED PHARMACEUTICALS, INC - RECS FILED WITH FDA RE DRUG APPLICATIONS 01/01/2008 - 10/21/2014
2014-8632	10/28/2014 11/26/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joseph Golec UNIVERSITY OF CONNECTICUT	BIOSIMILARS DATA 01/01/2006 - 01/01/2013
2014-8633	10/28/2014 11/26/2014	FDA/OMPT/CDRH/OCER/DFOI/	Ramaswamy Sreenivasan MASSACHUSETTS INSTITUTE OF TECHNOLOGY	K093565
2014-8634	10/28/2014 11/26/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Deborah Hilts Biohaven Pharmaceuticals	NDA 20-599 supplements 2-011, S-012 and S-013
2014-8635	10/28/2014 11/26/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	Kari L. Twaite BEVERIDGE & DIAMOND PC	CFSAN FOIA REQUESTS 09/27/2014 - 10/27/2014
2014-8636	10/28/2014 11/26/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jon Kamp WALL STREET JOURNAL	K101458
2014-8637	10/28/2014 11/26/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michael Butcher SOUTHERN ILLINOIS UNIVERSITY	FINASTERIDE, PROPECIA, PROSCAR - REVIEWS, FAERS
2014-8638	10/28/2014 11/26/2014	FDA/OC/OES/ OC/ORO/ OC/ORO/	Ariel Weber American University Washington College of Law	2004 MOU LETTER BETWEEN FDA AND SEC
2014-8639	10/28/2014 12/23/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	David Mangione Govzilla, Inc.	Novartis Vaccines and Diagnostics GmbH & Co. KG Emil-Von-Behring-Str. 76 Marburg, Germany - EIR MAY 6 2014
2014-8640	10/28/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	David Mangione	NOVARTIS VACCINES AND DIAGNOSTICS, MARBURG, GERMANY - EIR 06/30/2014 - 06/30/2014

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	12/23/2014		Govzilla, Inc.	
2014-8641	10/28/2014 11/26/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Donna Bitzelberger Venable, LLP	NDA 18723 S017 - APPROVAL LETTER (CERTIFIED)
2014-8642	10/28/2014 11/26/2014	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ OC/ORA/ OC/ORA/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	BEACON HILL MEDICAL PHARMACY PC, SOUTHFIELD, MI - EIR, 483, CO RESP 7/1-19/13
2014-8643	10/28/2014 11/26/2014	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	NEPHRON PHARMS ORLANDO, FL - EIR, 483, CO RESP 2/10-21/14
2014-8644	10/28/2014 11/26/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	BAXTER SA, LESSINES, BELGIUM - EIR, 483, CO RESP 6/10-18/13
2014-8645	10/28/2014 11/26/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	CHINA RESOURCES SANJIU MEDICAL & PHARMACEUTICAL CO LTD, SHENZHEN, CHINA - EIR, CO RESP, 483 3/24-28/14
2014-8646	10/28/2014 11/26/2014	FDA/OMPT/CDRH/OCER/DFOI/	YANG CHONGQING XINFENG MEDICAL INSTUMENTS CO LTD	CHONGQING XINFENG MEDICAL INSTRUMENTS CO LTD - K043558
2014-8647	10/28/2014 11/26/2014	FDA/OMPT/CDRH/OCER/DFOI/	MICHAL HEGER UNIVERSITY OF AMSTERDAM	ANGIO DYNAMICS - NANOKNIFE SAFETY REPORT
2014-8648	10/28/2014 11/26/2014	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WAYNE SADOWSKI NOVARTIS	DR FENG GU, BEIJING, CHINA - 5/12-16/14; DR MONICA GADELHA, RIO DE JANEIRO, BRAZIL 5/19-23/14, ETC - 482S, 483S, EIRS, ETC

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2014-8649	10/28/2014 11/26/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WAYNE SADOWSKI NOVARTIS	DR KIM PAPP CANADA 4/28/14-5/9/14; JACEK SZEPIETOWSKI, POLAND 5/5-15/14 - 482S, 483S, EIRS, ETC
2014-8650	10/28/2014 11/26/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WAYNE SADOWSKI NOVARTIS	SYNE QUA NON LTD, NORFOLK, UK 3/5-10/14 - 482, 483, EIR, ETC
2014-8651	10/28/2014 11/26/2014	FDA/OMPT/CDRH/OCER/DFOI/	ROBERT DEVEREUX CERVANTES & ASSOCIATES	VASCULAR SOLUTIONS INC - DUETT PRO CLOSURE MDRS (CERTIFIED)
2014-8652	10/28/2014 11/26/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ERYN M. PEDDICORD PEDDICORD AND TOWNSEND LLC	MISOPROSTOL (CYTOTEC) - APRVL, NDA 19268/S037 12/27/88 TO PRESENT
2014-8653	10/28/2014 11/26/2014	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	JOSE E. PANTOJA LIBERTY MUTUAL	PHOENIX MEDICAL DEVICES LLC - EIRS, MDRS, CMLPNTS, ETC
2014-8654	10/28/2014 11/26/2014	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	JOSE E. PANTOJA LIBERTY MUTUAL	ELITE MEDICAL SUPPLY, WEST SENECA, NEW YORK - EIRS, REGULATORY ACTIONS, 510K APRVLS, ETC
2014-8655	10/29/2014 11/28/2014	OC/CVM/OCD/	Cheryl Kantor Kantor, Cheryl A	CASE 2014-23720 - TRIFEXIS AER
2014-8656	10/29/2014 11/28/2014	FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	Mark McBrayer Crenshaw, Dupree & Milam, LLP	MINSA CORPORATION, MULESHOE, TX - 483, RESPONSES 01/01/2012 - 10/28/2014
2014-8657	10/29/2014 11/28/2014	FDA/OMPT/CDRH/OCER/DFOI/	Nadia Hermiz Cliniqa Corporation	K944486
2014-8658	10/29/2014 11/28/2014	FDA/OMPT/OSMP/OOPD/	Jonathan Wall University of Tennessee Medical Center	11-1F4 - ORPHAN DRUG DESIGNATION RECS

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2014-8659	10/29/2014 11/28/2014	FDA/OMPT/CDRH/OCER/DFOI/	Ebony McKinnies BIO-RAD LABORATORIES, INC.	K121610
2014-8660	10/29/2014 11/28/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Ebony McKinnies BIO-RAD LABORATORIES, INC.	K050574
2014-8661	10/29/2014 11/28/2014	FDA/OMPT/CDRH/OCER/DFOI/	Ebony McKinnies BIO-RAD LABORATORIES, INC.	K093548
2014-8662	10/29/2014 11/28/2014	FDA/OFVM/CFSAN/OCD/EOS/	Paul Schilt Mifroma USA	NAME AND ADDRESS OF ALL SWITZERLAND CHEESE EXPORTERS WHO HAVE RECEIVED AN LACF REGISTRATION LACF 01/02/2013 - 10/28/2014
2014-8663	10/29/2014 11/28/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Karin A. Resnick none	HYDROCHLOROTHIAZIDE 12.5 - AERS 10/28/2004 - 10/28/2014
2014-8664	10/29/2014 11/28/2014	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	ECLIPSE, ECLIPSE MENTHOL - SUBSTANTIAL EQUIVALENCE RECS
2014-8665	10/29/2014 11/28/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Ebony McKinnies BIO-RAD LABORATORIES, INC.	K051321, K090413
2014-8666	10/29/2014 11/28/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Emily Krulewitz The Weinberg Group	ANDA 091449, ANDA 076218 - APPRVAL LETTERS
2014-8667	10/29/2014 11/28/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Jami Busemeyer MEDPACE	NELSON WATTS, MD, CINCINNATI, OH - 483 03/03/2014 - 04/30/2014
2014-8668	10/29/2014 11/28/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jesse McLean Toronto Star	MICRO LABS LIMITED, INDIA - 483 01/02/2013 - 10/28/2014
2014-8669	10/29/2014 11/28/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Karin A. Resnick none	ATENOLOL - AERS
2014-8670	10/29/2014 11/28/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Altaire Pharmaceuticals, Inc. Altaire Pharmaceuticals, Inc.	ANDA 084110

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2014-8671	10/29/2014 11/28/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Emily Krulewitz The Weinberg Group	ANDA 203395, 076826, 076616, ETC APPROVAL LETTERS
2014-8672	10/29/2014 11/28/2014	FDA/OGROP/ORAN/NE-FO/NYK-DO/NYK-DCB/	Jami Busemeyer MEDPACE	JOHN BILEZIKIAN, NEW YORK, NY - 483 03/03/2014 - 04/30/2014
2014-8673	10/29/2014 11/28/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-7884 - REQUEST LETTER ONLY
2014-8674	10/29/2014 11/28/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-7868 - REQUEST LETTER ONLY
2014-8675	10/29/2014 11/28/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-7709 - REQUEST LETTER ONLY
2014-8676	10/29/2014 11/28/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-7190 - REQUEST LETTER ONLY
2014-8677	10/29/2014 11/28/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-7562 - REQUEST LETTER ONLY
2014-8678	10/29/2014 11/28/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-7398 - REQUEST LETTER ONLY
2014-8679	10/29/2014 11/28/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-7410 - REQUEST LETTER ONLY
2014-8680	10/29/2014 11/28/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-7312 - REQUEST LETTER ONLY
2014-8681	10/29/2014 11/28/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-7387 - REQUEST LETTER ONLY
2014-8682	10/29/2014 11/28/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-7278 - REQUEST LETTER ONLY
2014-8683	10/29/2014 11/28/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-7311 - REQUEST LETTER ONLY
2014-8684	10/29/2014 11/28/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-7307 - REQUEST LETTER ONLY
2014-8685	10/29/2014	FDA/OC/OES/DFOI/	Carla Scarmazzi, FDA & Life	AMERICAN SNUFF COMPANY LLC, CLARKSVILLS, TN -

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	11/28/2014	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	Sciences Specialist KING & SPALDING	PREVIOUSLY RELEASED INSPECTION RECS 01/01/2011 - 12/31/2012
2014-8686	10/29/2014 11/28/2014	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	RAY THOMPSON THOMPSON, RAY	ABBOTT MOLECULAR, DES PLAINES, IL 6/23/14-7/11/14, AKORN INC, DECATUR, IL 5/28/2014-662014, BMC 1092 INC (SOLO LABS INC), BROADVIEW, IL 2/18/14-3/13/2014, ETC - 483S
2014-8687	10/29/2014 11/28/2014	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	RAY THOMPSON THOMPSON, RAY	MIKART INC, ATLANTA, GA 4/16-23/14, PFEIFFER PHARMACEUTICAL INC, ATLANTA, GA 3/27-31/14, STRADIS HEALTHCARE LLC, LAWRENCEVILLE, GA 3/17-26/14, ETC - 483S
2014-8688	10/29/2014 11/28/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	RAY THOMPSON THOMPSON, RAY	AAA PHARMACEUTICAL INC, LUMBERTON, NJ 3/5-14/14, AAIPHARMA ANALYTICAL SERVICES, EDISON, NJ 6/25/14-7/17/14, AKORN INC, SOMERSET, NJ 4/7/14-5/29/14, ETC - 483S
2014-8689	10/29/2014 11/28/2014	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	RAY THOMPSON THOMPSON, RAY	ALAZA CORP, VACAVILLE, CA 3/4/14/14, BIOGENEX LABORATORIES INC, FREMONT, CA 6/5/14-7/1/14, BIOMARIN PHARMACEUTICAL INC, NOVATO, CA 4/8-17/14, ETC - 483S
2014-8690	10/29/2014 11/28/2014	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	RAY THOMPSON THOMPSON, RAY	API RESOURCES LLC, SAN ANTONIO, TX 3/4-7/14, CBI LABORATORIES INC, FORT WORTH, TX 1/15/14-2/14/14, CEUTICAL LABORATORIES INC, FARMERS BRANCH, TX 2/5-24/14, ETC - 483S
2014-8691	10/29/2014 11/28/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	RAY THOMPSON THOMPSON, RAY	ACME MONACO CORP, NEW BRITAIN, CT 2/18/14-3/7/14, MAREL CORP, WEST HAVEN, CT 5/30/14-6/24/14, CITRA LABS LLC, BRAINTREE, MA 6/2-13/14, ETC - 483S
2014-8692	10/29/2014 11/28/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	RAY THOMPSON; THOMPSON, RAY	3M UNITECK CORP, MONROVIA, CA 3/17-27/14, BAUSH & LOMB INC, IRVINE, CA 7/21-25/14, GILEAD SCIENCES INC, SAN DIMAS, CA 5/7-16/14, ETC - 483S
2014-8693	10/29/2014 11/28/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	RAY THOMPSON THOMPSON, RAY	AMERICAN FAMILY PHARMACY LLC, INDIANAPOLIS, IN 6/11/14-7/8/14, BIOMET INC, WARSAW, IN 6/16-30/14, COVANCE LABORATORIES INC, GREENFIELD, IN 6/2-6/14, ETC - 483S
2014-8694	10/29/2014 11/28/2014	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	RAY THOMPSON THOMPSON, RAY	AMYLIN OHIO LLC, WEST CHESTER, OH 7/7-22/14, MIDMARK CORP, VERSAILLES, OH 5/19/14-6/9/14, PROCTER & GAMBLE CO, CINCINNATI, OH 5/28/14-6/2/14, ETC - 483S
2014-8695	10/29/2014 11/28/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RAY THOMPSON THOMPSON, RAY	TARO PHARMACEUTICALS, BRAMPTON, CANADA 2/24-28/14, VALEANT PHARMACEUTICALS INTERNATIONAL, LAVAL, CANADA 6/11-15/14 483S
2014-8696	10/29/2014 11/28/2014	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	RAY THOMPSON THOMPSON, RAY	ABBOTT HEALTHCARE (PUERTO RICO) LTD, BARCELONETA, PR 5/12-20/14, BAXTER HEALTHCARE CORP, JAYUYA, PR 1/15/14-2/11/14, ABBVIE

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				BIOTECHNOLOGY LTD, BARCELONETA, PR 7/1-16/14, ETC - 483S
2014-8697	10/29/2014 11/28/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	RAY THOMPSON THOMPSON, RAY	SIEMENS HEALTHCARE DIAGNOSTICS INC, NEWARK, DE 3/31/14-4/23/14, CARDIAC ASSIST INC, PITTSBURGH, PA 1/24/14-2/7/14, AUXILIUM PHARMACEUTICALS INC, HORSHAM, PA 4/14-22/14, ETC - 483S
2014-8698	10/29/2014 11/28/2014	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	RAY THOMPSON THOMPSON, RAY	PHARMACEUTICS INTERNATIONAL INC, COCKEYSVILLE, MD 7/7-17/14, MYLAN PHARMACEUTICALS INC, MORGANTOWN, WV 3/10-21/14 - 483S
2014-8699	10/29/2014 11/28/2014	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	RAY THOMPSON THOMPSON, RAY	AVEVA DRUG DELIVERY SYSTEMS INC, MIRAMAR, FL 3/31/14-4/11/14, BELCHER PHARMACEUTICALS LLC, LARGO, FL 1/15-14/2/3/14 PRIME PACKAGING INC, MEDLEY, FL 4/16-29/14, ETC - 483S
2014-8700	10/29/2014 11/28/2014	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	RAY THOMPSON THOMPSON, RAY	ALTAIRE PHARMACEUTICALS INC, AQUEBOGUE, NY 7/14-29/14, AMNEAL PHARMACEUTICALS OF NEW YORK LLC, HAUPAUGE, NY 1/9/14-2/7/14, AMNEAL PHARMACEUTICALS, BROOKHAVEN, NY 5/5-16/14, ETC - 483S
2014-8701	10/29/2014 11/28/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	RAY THOMPSON THOMPSON, RAY	COVIDIEN PLC, BOULDER, CO 5/28/14-6/10/14, EDWARDS LIFESCIENCES LLC, DRAPER, UT 3/3/14-4/11/14, MEDTRONIC NAVIGATION INC, LOUISVILLE, CO 1/30/14-2/19/14 - 483S
2014-8702	10/29/2014 11/28/2014	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	RAY THOMPSON THOMPSON, RAY	VERATHON INC, BOTHELL, WA 7/8-23/14 - 483S
2014-8703	10/29/2014 11/28/2014	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	RAY THOMPSON THOMPSON, RAY	HOSPIRA INC, MEPHERSON, KS 4/14-23/14, K C PHARMACEUTICALS INC, BRENTWOOD, MO 2/21/14 - 483S
2014-8704	10/29/2014 11/28/2014	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	RAY THOMPSON THOMPSON, RAY	AMERICAN MEDICAL SYSTEMS INC, MINNETONKA, MN 2/4-24/14, SMITHS MEDICAL ASD INC, SAINT PAUL, MN 4/8-23/14 - 483S
2014-8705	10/29/2014 11/28/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	RAY THOMPSON THOMPSON, RAY	BAYER PHARMA AG, BERLIN, GERMANY 5/5-13/14, BOEHRINGER INGELHEIM PHARMA GMBH & CO KG, INGELHEIM AM RHEIN, GERMANY 2/24/14-3/7/14, HOLOPACK VERPACKUNG STECHNIK GMBH, ABTSGMUND, UNTERGRONINGEN GERMANY, ETC - 483S
2014-8706	10/29/2014 11/28/2014	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	RAY THOMPSON THOMPSON, RAY	QUALITWEST PHARMS, HUNTSVILLE, AL 7/28/14-8/1/14, MEDTRONIC SOFAMOR DANEK USA INC, MEMPHIS, TN 3/6-11/14 - 483S
2014-8707	10/29/2014 11/28/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SUSANE G YESNICK DRINKER BIDDLE REATH LLP	JANSSEN PHARMACEUTICA - RISPERDAL TABS NDA 20-272 SBA (CERTIFIED)

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2014-8708	10/29/2014 11/28/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	COURTNEY J CROSBY CROSBY, COURTNEY J	ACTOS - TEST RESULTS, LIST OF BAD DRUGS, NORMAL TIME RANGE AN ANTIBIOTIC CAN BE USED ON A HUMAN BEING
2014-8709	10/29/2014 12/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/OIP/ FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	RAYN P KENNEDY ATKINSON ANDELSON LOYA ETAL	REUMOFAN - RECALLS, WARNINGS, TESTS, ETC
2014-8710	10/29/2014 11/28/2014	FDA/OGROP/ORACE-FO/SAN-DO/SAN-CB/	MARK R KASTER DORSEY & WHITNEY LLP	PLUM PBC (PLUM ORGANICS) - RECALL, RPTS, AUDITS, ETC
2014-8711	10/29/2014 11/28/2014	OC/ORACE-FO/ OC/ORACE-FO/ FDA/OGROP/ORACE-FO/NOL-DO/NOL-CB/	Doe J	MILK BASED POWDER SIMILAC ADVANCES COMPLETE NUTRITON INFANT FORMULA WITH IRON - SPL 797456 RECS
2014-8712	10/29/2014 11/28/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MICHAEL MICHALSKI MICHALSKI GJ8047, MICHAEL	MENNEN SPEEDSTICK POWER FRESH DEODORANT WITH ANTIPERSPIRANT - OTC DRUG RVW RECS
2014-8713	10/30/2014 12/01/2014	FDA/OMPT/CDRH/OCER/DFOI/	Hahn Loeser & Parks LLP Hahn Loeser & Parks LLP	HEARTLAND TANNING INC - REPORTS FOR SUNDAZZLER BEDS, RAVE BULBS
2014-8714	10/30/2014 12/01/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Cherita James M SQUARED ASSOCIATES INC	K120187
2014-8715	10/30/2014 12/02/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K133753
2014-8716	10/30/2014 12/01/2014	FDA/OMPT/CDRH/OCER/DFOI/	William Plishker IGI Technologies	K081076
2014-8717	10/30/2014 12/01/2014	OC/CVM/OCD/	Richard Larson Cud Bud Enterprises	BLUE BIRD MEDICATED FEED LABELS

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2014-8718	10/30/2014 12/01/2014	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/ OC/ORO/ OC/ORO/ORM/ OC/ORO/ORM/	Pauline Apling KELLEY DRYE ET AL	HHE CFSAN,4/25/86; FDA ENFORCEMENT REPORT 8/23/89; FDA ENFORCEMENT REPORT 5/19/93
2014-8719	10/30/2014 12/01/2014	FDA/OGROP/ORO/NE-FO/NWE- DO/NWE-CB/	Tracy Helleman John Nagle Co	JOHN NAGLE CO - EIR 07/11/2013 - 07/11/2013
2014-8720	10/30/2014 12/01/2014	OC/CVM/OCD/	MIMI DWYER REUTERS	VETERINARY MEDICINE A/C - CONFLICT OF INTEREST DISCLOSURE RECS AND WAIVERS 1999, 2002, 2004, 2006
2014-8721	10/30/2014 12/01/2014	FDA/OGROP/ORO/CE-FO/NWJ- DO/NWJ-CB/	PAUL B CALLAHAN CHARLES RIVER LABS	HUNTINGDON LIFE SCIENCE, EAST MILLSTONE, NJ - 483 9/14, 10/14
2014-8722	10/30/2014 12/01/2014	FDA/OC/OES/DFOI/	DOMINIQUE F GALLACHER RICHARDS KIBBE & ORBE LLP	QUESTCOR PHARMACEUTICALS INC - HP ACTHAR GEL (REPOSITORY CORTICOTROPIN INJ) FOIA REQUESTS LAST SIX MONTHS
2014-8723	10/30/2014 12/01/2014	FDA/OGROP/ORO/PA-FO/SAN- DO/SAN-CB/	MANOJ GARG MERRILL LYNCH	MALLINCKRODT PHARMS, HAYWARD - RECS
2014-8724	10/30/2014 12/01/2014	FDA/OMPT/CDRH/OCER/DFOI/	MARTIN DAVIS DAVIS, MARTIN	AMERICAN MEDICAL SYSTEMS, ATHLONE, IRELAND - EIR 11/13
2014-8725	10/30/2014 12/01/2014	FDA/OC/OES/DFOI/	Allison Reynolds STUDENT	KENTUCKY FRIED CHICKEN BREADING RECIPE
2014-8726	10/31/2014 12/02/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SE-FO/NOL- DO/NOL-CB/	Joel Buurma Buurma Farms Inc	SAMPLE COLLECTION REPORT 800107
2014-8727	10/31/2014 12/02/2014	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2014-8188
2014-8728	10/31/2014 12/02/2014	FDA/OC/OES/DFOI/	Austin Hilliker STUDENT	FAST FOOD RESTAURANT INSPECTION FAILURES
2014-8729	10/31/2014 12/02/2014	FDA/OC/OES/DFOI/	Vik Bajnath ARTHREX INC.	MAUDE FACILITY INFORMATION
2014-8730	10/31/2014 12/02/2014	FDA/OC/OES/DFOI/	Vik Bajnath ARTHREX INC.	MAUDE FACILITY INFORMATION
2014-8731	10/31/2014	FDA/OC/OES/DFOI/	Vik Bajnath	MAUDE FACILITY INFORMATION

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	12/02/2014		ARTHREX INC.	
2014-8732	11/03/2014 12/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Walid Gardezi Walid Gardezi	TARO PHARMACEUTICALS - EIR, CORR 01/01/2014 TO 10/28/2014
2014-8733	11/03/2014 12/03/2014	FDA/OFVM/CFSAN/OCD/EOS/	Mimi Teoh Plexus Manufacturing Sdn Bhd	PLEXUS, CHINA - EIR 03/10/2014 - 03/14/2014
2014-8734	11/03/2014 12/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	bendamustine - all AE's Ken Tong	TREANDA - FAERS
2014-8735	11/03/2014 12/04/2014	FDA/OC/OES/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Robert Blaskiewicz Skeptics for the Protection of Cancer Patients	COMMUNICATIONS BETWEEN LOBBYIST ANTONIO C MARTINEZ AND FDA 10/10/2010 - 10/28/2014
2014-8736	11/03/2014 12/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	Liane LaRochelle DEKA Research and Development	K093677
2014-8737	11/03/2014 12/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	Liane LaRochelle DEKA RESEARCH & DEVELOPMENT CORP	K030096
2014-8738	11/03/2014 12/03/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Liane LaRochelle DEKA Research and Development	K110097
2014-8739	11/03/2014 12/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	pembrolizumab - Individual Case Report Ken Tong	KEYTRUDA - 10457384, 10329858
2014-8740	11/03/2014 12/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 20468 S35
2014-8741	11/03/2014 12/03/2014	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	Johanna Stamates UNIVERSITY OF MIAMI	DR ALAN W HELDMAN - EIR, ADDITIONAL REC 01/01/2013 - 05/31/2013;

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2014-8742	11/03/2014 12/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	AnnaMarie Daniels ReVENT Medical, Inc	K131603 REVIEW NOTES
2014-8743	11/03/2014 12/03/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Liane LaRochelle DEKA Research and Development	K100577
2014-8744	11/03/2014 12/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 22535
2014-8745	11/03/2014 12/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	lenalidomide - all AE's Ken Tong	REVLIMID - AERS
2014-8746	11/03/2014 12/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joshua Malamud Hyman, Phelps & McNamara P.C.	ESOMEPRAZOLE MAGNESIUM DELAYED-RELEASE - FIRST COMPANY TO SUBMIT ANDA, EXCLUSIVITY
2014-8747	11/03/2014 12/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	K830755 Med-Visory Consulting, Inc.	K830755
2014-8748	11/03/2014 12/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOSEPH WALKER Walker, Joseph	JUXTAPID - COMPLAINTS IN OFFICE OF PRESCRIPTION DRUG PROMOTION
2014-8749	11/03/2014 12/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 205832
2014-8750	11/03/2014 12/03/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	R.O. Wood the Wood Burditt group	ESSENTIAL PHARMACEUTICALS, LLC - CORR, MEMOS
2014-8751	11/03/2014 12/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	Philip J. Phillips Phillips Consulting Group, LLC	K132547
2014-8752	11/03/2014 12/03/2014	FDA/OFVM/CFSAN/OCD/EOS/	Mark Prinz Registrar Corp	TOKAI PICKLING CO, LTD, TAHARA, JAPAN - EIR NOV 2013

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2014-8753	11/03/2014 12/03/2014	FDA/OFVM/CFSAN/OCD/EOS/	Richard O. Wood the Wood Burditt group	PLANTA RIO BRAVO - 483, RESPONSE, EIR ETC
2014-8754	11/03/2014 12/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	Janet Chu UNIVERSITY OF CALIFORNIA, SAN FRANCISCO	LABELING CHANGE SUPPLEMENTS FOR MEDICAL DEVICES SUBMITTED BY SPONSORS 1/1/05 TO 10/31/14
2014-8755	11/03/2014 12/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Helene Saul Helene Saul	EVISTA - AERS
2014-8756	11/03/2014 12/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	Philip J. Phillips Phillips Consulting Group, LLC	K141321
2014-8757	11/03/2014 12/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K102307
2014-8758	11/03/2014 12/03/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 10/1-31/2014
2014-8759	11/03/2014 12/03/2014	FDA/OFVM/CFSAN/OCD/EOS/	Mark Prinz Registrar Corp	ALL RECS RE 10/21/14 COMMUNICATION RE REGISTRAR CORP, 3/21/08 COMMUNICATION ARCHIVING
2014-8760	11/03/2014 12/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	BLA 125514/0
2014-8761	11/03/2014 12/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kevin Lee Kevin Lee	K133546, K132833, K120560 ETC
2014-8762	11/03/2014 12/03/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 10/13-18/14
2014-8763	11/03/2014 12/03/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 10/6/11/14
2014-8764	11/03/2014 12/03/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 9/29/14-10/4/14
2014-8765	11/03/2014 12/03/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 10/13-17/14
2014-8766	11/03/2014 12/03/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW &	CLOSED FOIA REQUESTS 10/6-10/14

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			BUSINESS	
2014-8767	11/03/2014 12/03/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 9/29/14-10/3/14
2014-8768	11/03/2014 12/03/2014	FDA/OC/OES/DFOI/	DAVID FCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 10/13-17/14
2014-8769	11/03/2014 12/03/2014	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA LOGS 10/6-10/14
2014-8770	11/03/2014 12/03/2014	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 9/29/14-10/3/14
2014-8771	11/03/2014 12/03/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 10/13-17/14
2014-8772	11/03/2014 12/03/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 10/6-10/14
2014-8773	11/03/2014 12/03/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 9/29/14-10/3/14
2014-8774	11/03/2014 12/03/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 9/22-26/14
2014-8775	11/03/2014 12/03/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/	DONALD N BLUE ZETETIC INC	SHIPMENTS REGULATED BY THE UNITED STATES FOOD & DRUG ADMINISTRATION 10/15-31/14
2014-8776	11/03/2014 12/03/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	KIM HENDERSON SANOFI PASTEUR	SANOFI PASTEUR LTD, TORONTO ONTARIO CANADA - EIRS 4/10-25/12, 9/9-20/13
2014-8777	11/03/2014 12/03/2014	FDA/OFVM/CFSAN/OCD/EOS/	BRUCE S LEWIS Lewis, Bruce S.	PB-241 959/6 - CARBON DIOXIDE GAS SCIENTIFIC LITERATURE RVW 1920 TO 1974
2014-8778	11/03/2014 12/03/2014	FDA/OC/OES/DDM/	JILL BRODER BRODER, JILL	CHRONOLOGICAL LIST OF PETITIONS 1/97 TO 1/14
2014-8779	11/03/2014 12/03/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	CLOSED FOIA REQUESTS OCTOBER 2014
2014-8780	11/03/2014 12/03/2014	FDA/OGROP/ORO/CE-FO/PHI- DO/PHI-CB/	ALAN G MINSK ARNALL GOLDEN GREGORY LLP	QUALITY PACKING SPECIALISTS INTERNATIONAL LLC, MACUNGIE, PA - EIRS, 483S, WARNING LTR, ETC
2014-8781	11/03/2014 12/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sandy Lee, B&H Consulting Services, Inc. B&H Consulting Services, Inc.	HIKMA FARMACEUTICA, PORTUGAL - 483 MARCH 2014

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2014-8782	11/03/2014 12/03/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2012-6593
2014-8783	11/03/2014 12/03/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2013-5968
2014-8784	11/03/2014 12/03/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2013-893
2014-8785	11/03/2014 12/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/OIP/	LAUREN A FARRUGGIA Hyman, Phelps & McNamara P.C.	INTERNATIONAL DRUG SCHEDULING: CONVENTION ON PSYCHOTROPIC SUBSTANCES: WORLD HEALTH ORGANIZATION SCHEDULING RECOMMENDATIONS FOR SEVEN DRUG SUBSTANCES - MESCARB STUDIES, RPTS, COMMENTS, ETC
2014-8786	11/03/2014 12/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Christiane BOBER Labvatoires Expanscience	IPCA - 483 07/18/2014 - 11/18/2014
2014-8787	11/03/2014 12/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KATE REYNOLDS DENVER HEALTH ROCKY MOUNTAIN POISON & DRUG CENTER	ISR 5933585, 7322363, 8146114, ETC COUGH & COLD PREPARATION
2014-8788	11/03/2014 12/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MELVYN RUBENFIRE MD UNIV OF MICHIGAN HEALTH SYSTEM	ROSUASTATIN, PITIVASTATIN, PRAVASTATIN - AERS
2014-8789	11/03/2014 12/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANDREA FARAH SCOTT & SCOTT LLP	UPSHER-SMITH LABORATORIES INC - PACERONE ANDA 75-315, 5 MOST RECENT LABEL UPDATES, APRVL LTR
2014-8790	11/03/2014 12/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOSEPH P MALCA PROSKAUER ROSE LLP	FELIODIPINE ANA 75-896 , PROPAFENONE ANDA 75-998 - REC

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2014-8791	11/03/2014 12/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JUDY SCHROFF SCHROFF, JUDY	ZOMETA - AERS
2014-8792	11/03/2014 12/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SANG LEE STASON PHARMACEUTICALS INC	CYPROHEPTADINE HCI TABS - APRVD LBLG
2014-8793	11/03/2014 12/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELAINE CHANG GLANCY BINKOW & GOLDBERG LLP	PROVETUS BROPHARMACETWICALS INC - PV-10 MTG MINS 12/16/13
2014-8794	11/03/2014 12/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KRISHNAN LYER SITEC LABS PVT LTD	LABS PVT LTD, NAVI MUMBAI - EIRS 4/28-29/14 NON REDACTED
2014-8795	11/03/2014 12/03/2014	OC/CVM/OCD/	L NEAL ELLIS JR ELLIS & PARKER PLLC	BOEHRINGER-INGELHEIM - PYRAMID 5 (VOVINE RHINOTRACEHETIS-BIRUS DIARRHEA-PARAINFLUEZA3- RESPIRATORY SYNCYTAL VIRUS VACCINE (MODIFIED LIVE VIRUS), PRESPONSE HM PRISM 5 & EXPRESS 5 HM VAERS 2009 TO 2014
2014-8796	11/03/2014 12/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Arnon Lavie UNIVERSITY OF ILLINOIS AT CHICAGO	ERWINAZE IND 125359
2014-8797	11/03/2014 12/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mahidhar Chinta MICRO LABS USA INC	ANDA 078007
2014-8798	11/03/2014 12/03/2014	OC/CVM/OCD/	Ruth Weese Boehringer Ingelheim Vetmedica, Inc.	NADA 102-380
2014-8799	11/03/2014 12/03/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mahidhar Chinta MICRO LABS USA INC	ANDA 090656

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-8800	11/03/2014 12/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K140510
2014-8801	11/03/2014 12/03/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Michael Weiss Carroll & Weiss LLP	RECS TO AND FROM OLYMPUS, GYRUS RE MORCELLATION, MORCELLATORS, REQUESTS 01/01/2010 - 10/31/2014
2014-8802	11/03/2014 12/03/2014	OC/ORA/ OC/ORA/	Travis Venable Thomas J Henry Injury Attorneys	SPECIALTY COMPOUNDING LLC - REPORT, MEMO, STUDIES ETC 03/01/2013 - 11/01/2014
2014-8803	11/03/2014 12/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	Brendan Ryan Mesoblast	K932301
2014-8804	11/03/2014 12/03/2014	FDA/OMPT/CDRH/OCER/DFOI/	Lisa Anderson ConMed Corporation	K140378
2014-8805	11/03/2014 12/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Olena Izhak University of Helsinki (FINLAND)	ANDA APPROVAL LETTERS
2014-8806	11/03/2014 12/03/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	STATINS - LUNG INJURY RECS
2014-8807	11/03/2014 12/03/2014	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	Jonathan Cain Law Firm of Bunch & James	OCCIDENTAL CHEMICAL CORP, OCCIDENTAL PETROLEUM CORP - WARNING LETTERS, INSPECTION NOTES RE 1999 WARNING LETTER
2014-8808	11/03/2014 12/03/2014	FDA/OC/OES/DFOI/ FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Deborah Funk Fundamental Research, LLC	DR VAUGHN H MANCHA JR - 483, WARNING LETTER CLOSE OUT
2014-8809	11/03/2014 12/03/2014	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2014-8396
2014-8810	11/03/2014 12/03/2014	FDA/OC/OES/DFOI/	Anubhav agarwal CREDIT SUISSE	IPCA LABORATORIES, INDIA - 483 10/10/2014 - 10/31/2014

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2014-8811	11/03/2014 12/03/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	Hannah V. Faddis, Esq. Wong, Wong & Associates, P.C.	GREEN PHARM NY LLC, GREEN PHARMACY INC, ULTRAMAX ETC -REGISTRATION, ADVERSE EVENTS, CERTIFICATES OF FREE SALE ETC 09/14/2007 - 10/21/2014
2014-8812	11/03/2014 12/03/2014	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2014-6640
2014-8813	11/03/2014 12/03/2014	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2014-1905
2014-8814	11/04/2014 12/04/2014	FDA/OMPT/CDRH/OCER/DFOI/	CASEY MING BACTERIN INTERNATIONAL INC	CENTINEL SPINE INC - STALIF CTI, STALIF C K142079
2014-8815	11/04/2014 12/04/2014	FDA/OFVM/CFSAN/OCD/EOS/	JAMIL KHAN Mercatus Center at George Mason University	STANDARDS FOR THE GROWING, HARVESTING, PACKING, AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION
2014-8816	11/04/2014 12/04/2014	FDA/OC/OES/DFOI/	KATHLEEN R HENRY Hyman, Phelps & McNamara P.C.	CERUS CORP - INTERCEPT BLOOD SYS (S-59 TREATED FFP) ORPHAN DRUG DESIGNATION
2014-8817	11/04/2014 12/04/2014	FDA/OC/OES/DFOI/	KATHLEEN R HENRY Hyman, Phelps & McNamara P.C.	OCTAPharma USA INC - UNIPLUS ORPHAN DRUG DESIGNATION
2014-8818	11/04/2014 12/04/2014	FDA/OC/OES/DFOI/	KATHLEEN R HENRY Hyman, Phelps & McNamara P.C.	OMEROS CORP - HUMAN MONOCLONAL ANTIBODY INHIBITOR OF MANNAN-BINDING LECTIN-ASSOCIATED SERINE PROTEASE-2 (MASP-2) ORPHAN DRUG DESIGNATION
2014-8819	11/04/2014 12/04/2014	FDA/OC/OES/DFOI/	KATHLEEN R HENRY Hyman, Phelps & McNamara P.C.	ABLYNX NV - ALX-0081 ORPHAN DRUG DESIGNATION
2014-8820	11/04/2014 12/04/2014	FDA/OC/OES/DFOI/	KATHLEEN R HENRY Hyman, Phelps & McNamara P.C.	ARCHEMIX CORP - ANTI-VON WILLEBRAND APTAMER ORPHAN DRUG DESIGNATION
2014-8821	11/04/2014 12/04/2014	FDA/OC/OES/DFOI/	KATHLEEN R HENRY Hyman, Phelps & McNamara P.C.	LFB BIOTECHNOLOGIES SA - COMPLEMENT FACTOR H ORPHAN DRUG DESIGNATION
2014-8822	11/04/2014 12/04/2014	FDA/OC/OES/DFOI/	KATHLEEN R HENRY Hyman, Phelps & McNamara P.C.	CRINOS INTERNATIONAL - DEFIBROTIDE ORPHAN DRUG DESIGNATION
2014-8823	11/04/2014	FDA/OC/OES/DFOI/	KATHLEEN R HENRY	ALEXION PHARMACEUTICALS INC - SOLIRIS (ECULIZUMAB) ORPHAN DRUG DESIGNATION

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	12/04/2014		Hyman, Phelps & McNamara P.C.	
2014-8824	11/04/2014 12/04/2014	FDA/OC/OES/DFOI/	KATHLEEN R HENRY Hyman, Phelps & McNamara P.C.	OMEROS CIORP - MASP-2 ORPHAN DRUG DESIGNATION
2014-8825	11/04/2014 12/04/2014	FDA/OC/OES/DFOI/	KATHLEEN R HENRY Hyman, Phelps & McNamara P.C.	TEIJIN AMERICA INC - HUMANIZED MONOCLONAL ANTIBODY ORPHAN DRUG DESIGNATION
2014-8826	11/04/2014 12/04/2014	FDA/OC/OES/DFOI/	KATHLEEN R HENRY Hyman, Phelps & McNamara P.C.	BAXTER HEALTHCARE CORP - RECOMBINANT DISINTEGRIN AND METALLOPROTEASE WITH THROMBOSPONDIN TYPE 1 MOTIFS ORPHAN DRUG DESIGNATION
2014-8827	11/04/2014 12/04/2014	FDA/OMPT/OSMP/OOPD/ FDA/OC/OES/DFOI/	KATHLEEN R HENRY Hyman, Phelps & McNamara P.C.	ALEXION PHARMACEUTICALS INC - SOLIRIS (ECUZILUMAB) ORPHAN DRUG DESIGNATION
2014-8828	11/04/2014 12/04/2014	FDA/OC/OES/DFOI/	KATHLEEN R HENRY Hyman, Phelps & McNamara P.C.	ADIENNE SA - MUBODINA(R) (RECOMBINANT HUMAN MINIBODY AGAINST COMPLEMENT COMPONENT) ORPHAN DRUG DESIGNATION
2014-8829	11/04/2014 12/04/2014	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOI REQUESTS 9/22-26/14
2014-8830	11/04/2014 12/04/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 9/22-16/14
2014-8831	11/04/2014 12/04/2014	FDA/OC/OES/DFOI/	WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 9/22-26/14
2014-8832	11/04/2014 12/04/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 9/22-26/14
2014-8833	11/04/2014 12/04/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 9/15-19/14
2014-8834	11/04/2014 12/04/2014	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOI REQUESTS 9.15-19/14
2014-8835	11/04/2014 12/04/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 9/15-19/14
2014-8836	11/04/2014 12/04/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 9/15-19/14
2014-8837	11/04/2014 12/04/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 9/8-12/14
2014-8838	11/04/2014	FDA/OC/OES/DFOI/	DAVID MCFARLAND	CLOSED FOI REQUESTS 9/8-12/14

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	12/04/2014		FDA REVIEW/FDA WEBVIEW	
2014-8839	11/04/2014 12/04/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 9/8-12/14
2014-8840	11/04/2014 12/04/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 9/8-12/14
2014-8841	11/05/2014 12/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sara Wexler Koblitz Fish and Richardson P.C.	Releasable records and documents pertaining to the breakthrough designation requests and approvals for approved drug products
2014-8842	11/05/2014 12/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Belinda Labourdette HEINE USA Ltd.	K070270
2014-8843	11/05/2014 12/05/2014	OC/CVM/OCD/	Ruth Weese Boehringer Ingelheim Vetmedica, Inc.	NADA 034-478
2014-8844	11/05/2014 12/05/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OCC/	Mark Prinz Registrar Corp	REGISTRAR - FDA COMM 10/21/14
2014-8845	11/05/2014 12/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Isaac Opper Isaac Opper	DEVICE LISTING DATABASE 01/01/1985 - 01/01/2014
2014-8846	11/05/2014 12/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Anastassios Retzios Bay Clinical R&D Services, LLC	RepelCV DMA - CMC Review Report - Pharmacology Review Report -Toxicology Review Report - Clinical/Biostatistics Review Report
2014-8847	11/05/2014 12/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Emily Krulewitz The Weinberg Group	ANDA 203395, 076826, 076616, ETC APPROVAL RECS
2014-8848	11/05/2014 12/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kelly Smith VA WNY Healthcare System	MEDWATCH EVENT
2014-8849	11/05/2014 12/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nabain Lumosa Therapeutics Co.,Ltd.	NUBAIN - SBA SUMMARY REVIEW, MEDICAL REVIEW ETC

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2014-8850	11/05/2014 12/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Chirag Shah Chirag Shah	Approval Packages/Review of Generic Zolpidem Tartrate Extended Release Tablets 6.25 mg/12.5mg ANDA No. (a) 200266 (b) 090153 (c) 090107 (d) 078970 (e) 078179 (f) 078148
2014-8851	11/05/2014 12/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Dane Thomas Stark Medical	K050738
2014-8852	11/05/2014 12/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Peter R. Breggin, MD Center for the Study of Empathic Therapy	COMPAZINE - AERS
2014-8853	11/05/2014 12/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K122480
2014-8854	11/05/2014 12/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Laurie Phillips Law Office of Laurie Phillips	UNICONDYLAR SLED KNEE PROSTHESIS - ADVERSE EVENTS, APPROVAL RECS 01/01/2003 - 01/01/2014
2014-8855	11/05/2014 12/05/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Brad Budner Bazuji Publishing, LLC	K111501
2014-8856	11/05/2014 01/12/2015	FDA/OGROP/ORO/CE-FO/NWJ-DO/NWJ-CB/	John A. Gorney Elba Laboratories	BIOGENESIS LABS, HACKENSACK, NJ - EIR, 483 01/01/2010 - 11/01/2014
2014-8857	11/05/2014 12/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	INDIVIDUAL RECS
2014-8858	11/05/2014 12/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jaya Ayyagari DR. REDDY'S LABORATORIES INC	ANDA 071961 SBA
2014-8859	11/05/2014 12/05/2014	FDA/OFVM/CFSAN/OCD/EOS/	Eleanor DaCosta United States Pharmacopeial Convention (USP)	GREEN TEA EXTRACT - AERS
2014-8860	11/05/2014 12/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Christopher Leary Christopher Leary	K131696 SUMMARY
2014-8861	11/05/2014 12/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Celeste Wheeler KLEINFELD, KAPLAN & BECKER	BLA 103353

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2014-8862	11/05/2014 12/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Brad Budner Bazuji Publishing, LLC	K120582
2014-8863	11/05/2014 12/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Brad Budner Bazuji Publishing, LLC	K130341
2014-8864	11/05/2014 12/05/2014	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	Gary Chuven Gary Chuven	HARRY J BOSWORTH COMPANY - EIR 2013
2014-8865	11/05/2014 12/05/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	BACLOFEN - AERS
2014-8866	11/05/2014 12/05/2014	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Megan Fierst Nature's Way Product	LILLY OF THE DESERT, MERCEDES, TX - 483, EIR 01/01/2010 - 11/01/2014
2014-8867	11/05/2014 12/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Brad Budner Bazuji Publishing, LLC	K113231
2014-8868	11/05/2014 12/05/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	Garrett Hooe Hancock, Daniel, Johnson and Nagle, P.C.	OSIRIS REGISTRATION OF CARTIFORM HUMAN CELL AND TISSUE PRODUCT WITH FDA, FORM FDA-3356, AERS ETC
2014-8869	11/05/2014 12/05/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Celeste Wheeler KLEINFELD, KAPLAN & BECKER	BLA 125294
2014-8870	11/05/2014 12/05/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Celeste Wheeler KLEINFELD, KAPLAN & BECKER	BLA 125409
2014-8871	11/05/2014 12/05/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2012-7667
2014-8872	11/05/2014 12/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Sheridan Cryotherapeutics GmbH	K033622
2014-8873	11/05/2014 12/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Brad Budner Bazuji Publishing, LLC	K133718

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2014-8874	11/05/2014 12/05/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tariq Ata REMS Logic, LLC	NUMBER OF REMS DRUG ERROR REPORTS 01/01/2005 - 12/31/2013
2014-8875	11/05/2014 12/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Lisa Anderson ConMed Corporation	K070157
2014-8876	11/05/2014 12/05/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-7558
2014-8877	11/05/2014 12/05/2014	FDA/OMPT/CDRH/OCER/DFOI/	Serge Krimnus Cowan, Liebowitz & Latman, P.C.	K070964, K120743
2014-8878	11/05/2014 12/05/2014	FDA/OC/OES/DFOI/	Bharat Celly Research Delta	IPCA - 483 10/16/2014 - 11/05/2014
2014-8879	11/05/2014 12/05/2014	FDA/OC/OES/DFOI/	Rahul Jeewani IIFL Institutional Equities	IPCA - 483 10/13/2014 - 11/17/2014
2014-8880	11/05/2014 12/05/2014	FDA/OC/OES/DFOI/	Dr Girish Bakhru HSBC Securities and Capital Markets	IPCA - 483 10/13/2014 - 10/20/2014
2014-8881	11/05/2014 12/05/2014	FDA/OC/OES/DFOI/	Vaibhav Dusad Morgan Stanley	IPCA Laboratories, India - 483
2014-8882	11/05/2014 12/05/2014	FDA/OC/OES/DFOI/	Saion Mukherjee NOMURA INTERNATIONAL PLC	IPCA - 483 10/01/2014 - 11/05/2014
2014-8883	11/05/2014 12/05/2014	FDA/OC/OES/DFOI/	P Moriarty EHF	FOIA LOG 08/01/2014 - 10/31/2014
2014-8884	11/05/2014 12/05/2014	FDA/OC/OES/DFOI/	Kemp Dolliver Cherrystone Hill Capital Management LLC	HIKMA FARMACEUTICA SA - WARNING LETTER 10/01/2014 - 10/31/2014
2014-8885	11/05/2014 12/05/2014	FDA/OGROP/ORP/SE-FO/SJN-DO/SJN-CB/	CLAUDIA FUENTEALBA-BERKOWITZ EXPEDITORS	EXPEDITOR, CAROLINA, PR - INSP
2014-8886	11/05/2014 12/05/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 9/22-27/14
2014-8887	11/05/2014 12/05/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 9/29 - 10/4/14
2014-8888	11/05/2014	FDA/OC/OES/DFOI/		DAILY LOG 10/6-11/14

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	12/05/2014		FOI Services, Inc.	
2014-8889	11/05/2014 12/05/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 10/13-18/14
2014-8890	11/05/2014 12/05/2014	FDA/OC/OES/DFOI/	GLADYS B. TONKIN Center for Regulatory Services,Inc.	DAILY LOG 9/22-26/14
2014-8891	11/05/2014 12/05/2014	FDA/OC/OES/DFOI/	GLADYS B. TONKIN Center for Regulatory Services,Inc.	DAILY LOG 10/13-17/14
2014-8892	11/05/2014 12/05/2014	FDA/OC/OES/DFOI/	GLADYS B. TONKIN Center for Regulatory Services,Inc.	DAILY LOG 9/29 - 10/3/14
2014-8893	11/05/2014 12/05/2014	FDA/OC/OES/DFOI/	GLADYS B. TONKIN Center for Regulatory Services,Inc.	DAILY LOG 10/6-10/14
2014-8894	11/05/2014 12/05/2014	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 9/22-26/14
2014-8895	11/05/2014 12/05/2014	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 9/29-10/3/14
2014-8896	11/05/2014 12/05/2014	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 10/6-10/14
2014-8897	11/05/2014 12/05/2014	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 10/13-17/14
2014-8898	11/05/2014 12/05/2014	FDA/OC/OES/DFOI/	JH BARR & ASSOCIATES LLC	DAILY LOG 9/22-26/14
2014-8899	11/05/2014 12/05/2014	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 9/29-10/3/14
2014-8900	11/05/2014 12/05/2014	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 10/6-10/14
2014-8901	11/05/2014 12/05/2014	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 10/13-17/14
2014-8902	11/05/2014 12/05/2014	FDA/OC/OES/DFOI/	WASHINGTON INFORMATION SOURCE	DAILY LOG 9/22-26/14
2014-8903	11/05/2014 12/05/2014	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 9/29-10/3/14
2014-8904	11/05/2014	FDA/OC/OES/DFOI/	KENNETH REID	DAILY LOG 10/6-10/14

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	12/05/2014		WASHINGTON INFORMATION SOURCE	
2014-8905	11/05/2014 12/05/2014	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 10/13-17/14
2014-8906	11/05/2014 12/05/2014	FDA/OC/OES/DFOI/	DEBRA L. COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 9/22-26/14
2014-8907	11/05/2014 12/05/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 9/29-10/3/14
2014-8908	11/05/2014 12/05/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 10/6-10/14
2014-8909	11/05/2014 12/05/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 10/13-17/14
2014-8910	11/06/2014 12/08/2014	FDA/OC/OES/DFOI/	Stace Sirmans UNIVERSITY OF ARKANSAS	COPIES OF FOIA REQUESTS
2014-8911	11/06/2014 12/08/2014	FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/	Richard O. Wood the Wood Burditt group	MARATHON VENTURES, INC - 483, EIR, RESPONSES 01/01/2014 - 11/03/2014
2014-8912	11/06/2014 12/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	RICKY THURSTON THURSTON, RICKY D	DEPUY LOT 3247367, 3388543, 249638, ETC - INVESTIGATION, LETTERS TO PHYSICIANS, FAILURE REPORTS
2014-8913	11/06/2014 12/08/2014	FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Terry Tullis Terry Tullis - Knobbe Martens LLP	DUOBLO ULTRASOUND ABLATION PRODUCTS - INVESTIGATION RE UNAUTHORIZED IMPORTATION 11/01/2013 - 10/31/2014
2014-8914	11/06/2014 12/08/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Allison Tarantino ARIAD Pharmaceuticals, Inc.	ICLUSIG - AERS
2014-8915	11/06/2014 12/08/2014	FDA/OMPT/CTP/OD/	James Woodlee Kleinfeld, Kaplan & Becker LLP	ALTERNATIVE BRANDS INC - SUBMISSIONS UNDER CHAPTER IX OF FDCA, CORR RE SUBMISSIONS
2014-8916	11/06/2014 12/08/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Annie Schmidt Odom and DesRoches, LLP	ANDA 200675

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-8917	11/06/2014 12/08/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Anne Waldman PROPUBLICA	JUDGE ROTENBERG EDUCATIONAL CENTER, CANTON, MA - 483 10/3/12
2014-8918	11/06/2014 12/08/2014	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Leon Weckwerth Dianne's Fine Desserts	DIANNE'S FINE DESSERTS, LECENTER, MN - EIR
2014-8919	11/06/2014 12/08/2014	OC/OROA/ OC/OROA/	James R. Greene Colliau Carluccio Keener Morrow Peterson & Parsons	EASTERN PHARMACY, INC, DAOUD A ZAYED, OCALA, FL - INSPECTION REPORTS, COMMUNICATIONS, VIOLATIONS ETC 06/04/2013 - 11/04/2014
2014-8920	11/06/2014 12/08/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/OROA/ OC/OROA/	Access Investigations, LLC Access Investigations, LLC	MATTHEW SCOTT TUCKER, STEVEN PRESSMAN, PURETEK CORPORATION, ETC - WARNING, NOTICE, ADVERSE ACTION
2014-8921	11/06/2014 12/08/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	elena israel elena israel	APRIL 28 2011 MEETING BETWEEN FDA AND NATIONAL REYES SYNDROME FOUNDATION - TRANSCRIPT, PAPERS, POWERPOINTS 01/02/2000 - 01/02/2014
2014-8922	11/06/2014 12/08/2014	OC/OROA/ OC/OROA/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Doe J	INDIVIDUAL RECS
2014-8923	11/06/2014 12/08/2014	FDA/OMPT/CTP/OD/ FDA/OC/OES/ FDA/OMPT/CTP/OD/	James Woodlee Kleinfeld, Kaplan & Becker LLP	CORR BETWEEN FDA AND DK DISTRIBUTOR INC, LIT DISTRIBUTOR INC, KING MOUNTAIN TOBACCO CO INC RE TOBACC PRODUCT USER FEES
2014-8924	11/06/2014 12/08/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dustin Block IPD Analytics, LLC	ANDA 203839 EFFECTIVE APPROVAL LETTER
2014-8925	11/06/2014 12/08/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Patti Oto Chrono Therapeutics	NDA 020165
2014-8926	11/06/2014	FDA/OMPT/CDER/GRP/DIDP/	Brian Coke Ng (patient) and Wai Ng	NDA 017821

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	12/08/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	(his wife) Coke Ng, Brian A	
2014-8927	11/06/2014 12/08/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-3782
2014-8928	11/06/2014 12/08/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-4093
2014-8929	11/06/2014 12/08/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Patti Oto Chronotherapeutics, Inc.	NDA 21928
2014-8930	11/06/2014 12/08/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	ESCITALOPRAM - THERAPEUTIC TESTING, EQUIVALENCIES 01/01/2013 - 11/01/2014
2014-8931	11/06/2014 01/21/2015	FDA/OMPT/CTP/OD/	James Woodlee Kleinfeld, Kaplan & Becker LLP	SE0000282, SE0000283, SE0000284, ETC
2014-8932	11/06/2014 12/08/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2013-7692
2014-8933	11/06/2014 12/08/2014	FDA/OC/OES/DFOI/	Rachel johnson FOI Services, Inc.	2014-4773
2014-8934	11/06/2014 12/08/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-4996
2014-8935	11/06/2014 12/08/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-7356
2014-8936	11/06/2014 12/08/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-3606
2014-8937	11/06/2014 12/08/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nyssa Gesch Mighteor, LLC	APPLICATIONS FOR MALE CONTRCEPTION 1988 - 2014

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		FDA/OMPT/CDRH/OCER/DFOI/		
2014-8938	11/06/2014 12/08/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DALIL LOGS 9/8-12/14
2014-8939	11/06/2014 12/08/2014	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 9/15-19/14
2014-8940	11/06/2014 12/08/2014	FDA/OC/OES/DFOI/	WILLIAM A OLSON Center for Regulatory Services,Inc.	FOI DAILY LOG 9/8-12/14
2014-8941	11/06/2014 12/08/2014	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD Center for Regulatory Services,Inc.	FOI DAILY LOG 9/15-19/14
2014-8942	11/06/2014 12/08/2014	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 9/8-12/14
2014-8943	11/06/2014 12/08/2014	FDA/OC/OES/DFOI/	KLEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 9/15-19/14
2014-8944	11/06/2014 12/08/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 9/8-12/14
2014-8945	11/06/2014 12/08/2014	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 9/15-19/14
2014-8946	11/06/2014 12/08/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 9/8-13/14
2014-8947	11/06/2014 12/08/2014	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 9/15-20/14
2014-8948	11/06/2014 12/08/2014	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 9/8-12/14
2014-8949	11/06/2014 12/08/2014	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 9/15-19/14
2014-8950	11/06/2014 12/08/2014	FDA/OC/OES/DFOI/	LESLIE A RAMSEY FDA NEWS	FOI DAILY LOG 10/1-31/14
2014-8951	11/06/2014 12/08/2014	OC/ORO/ORM/ OC/ORO/ORM/	LESLIE RAMSEY FDA NEWS	LIST OF 483S FOR PHARMACUTICAL, BIOLOGICS, MEDICAL DVC MFG & CLNCL TRIAL FACILITIES 10/1-31/14
2014-8952	11/06/2014	FDA/OGROP/OIP/	GENEVIEVE MEISENHEIMER	F HOFFMANN-LA ROCHE AG, HOFFMANN-LA ROCHE LTD, HOFFMANN-LA ROCHE INC - CORR BTWN

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	12/08/2014		HARRISON PENSA LLP	INTERNATIONAL PROGRAMS & HEALTH CANADA IN REGARDS TO ACCUTANE (ROACCUTANE)
2014-8953	11/06/2014 12/08/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	J P SAWYER SAWYER LAW FIRM INC	FORM 3500A - MDRS
2014-8954	11/06/2014 12/08/2014	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	KEN VESPA VESPA, KEN	DR REDDY'S, SHREVEPORT, LA - CMLNT
2014-8955	11/06/2014 12/08/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GAIL ELBEK ELBEK, GAIL	PREMARIN, PREMPRO, PREMPHASE - MEDWATCH RPTS 1964, 1967 TO PRESENT
2014-8956	11/06/2014 12/08/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LIZSETTE MILLER-RADOVIC MILLER-RADOVIC LLC	ZOLOFT (SETRALINE) - AERS
2014-8957	11/06/2014 12/08/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LIZETTE MILLER-RADOVIC MILLER-RADOVIC LLC	ROCHE PHARMS - KLONOPIN (CLONAZEPAM) AERS
2014-8958	11/06/2014 12/08/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOSEPH GALLGHER EVENUS PHARMACEUTICAL LABORATORIES INC	APRVL LTR 204555 (CERTIFIED)
2014-8959	11/06/2014 12/08/2014	FDA/OFVM/CFSAN/OCD/EOS/	VISAGINE VIJAYAKULASINGAM IOVATE HEALTH SCIENCES INTERNATIONAL INC	IOVATE, HYDROXYCUT, SMARTBURN; ETC -CAERS 8/5/14 TO PRESENT
2014-8960	11/06/2014 12/08/2014	FDA/OC/OES/DFOI/	AMIE N VANELLA FAEGRE BAKER DANIELS	SMPLY THICK, SIMPLY THICK LLC - FOI REQUEST LTRS 9/17/14 TO PRESENT
2014-8961	11/06/2014 12/08/2014	OC/CVM/OCD/	CULLIN A O'BRIEN Robbins Geller Rudman & Dowd LLP	FIRST SHIELD TRIO SPOT-ON CANINE FLEA APPL - CORR BTWN FEDERAL, STATE GOVERMENT, SCHUYLER LLC, CEVA ANIMAL HEALTH, ETC APRVL LABEL, EFFECTS, ETC
2014-8962	11/06/2014 12/08/2014	FDA/OC/OES/DFOI/	STEVEN LIM FINKELSTEIN & PARTNERS	STATSTICAL RVW & EVALUATION - ANTIEPILEPTIC DRUGS & SUCIDALITY 5/23/08 (CERTIFIED)
2014-8963	11/06/2014 12/08/2014	FDA/OFVM/CFSAN/OCD/EOS/	JOHN T ALLAN III INTERNATIONAL DAIRY FOODS	MICROBIOLOGICAL SPLS OF MILK POWDER PLANT ENVIRONMENTS FOR TESTTING FOR SALMONELLA AND CRONOBACTER SAKAZAKII - SAMPLING ASSIGNEMTS

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			ASSN	ISSUED IN 2014
2014-8964	11/07/2014 12/09/2014	FDA/OO/OFBA/OAGS/	Mozaina Kobaisy Kobaisy, Mozaina	UNIVERSITY OF MISSISSIPPI NATIONAL CENTER FOR NATURAL PRODUCTS RESEARCH - GRANT RE SCIENCE BASED AUTHENTICATION OF DIETARY SUPPLEMENT 06/01/2004 - 09/30/2009
2014-8965	11/07/2014 12/09/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Hannah de Jong VU	Historical Datafiles of the Orange Book including expiry dates, market exclusivity dates and approval dates
2014-8966	11/07/2014 12/09/2014	FDA/OFVM/CFSAN/OCD/EOS/	Leon McRae UNIVERSITY OF BIRMINGHAM	THORNE - AERS, CORR 08/05/2013 - 11/01/2014
2014-8967	11/07/2014 12/09/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/DET-DO/DET-CB/	Jody Powell STRYKER INSTRUMENTS	STRYKER INSTRUMENTS - EIR 10/29/2012 - 11/05/2014
2014-8968	11/07/2014 12/09/2014	FDA/OFVM/CFSAN/OCD/EOS/	Sharon L. Lyerly, Paraleal Watkins, Lourie, Roll & Chance, PC	MEDWATCH REPORT RECS
2014-8969	11/07/2014 12/09/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/OSMP/OOPD/	Matthias Dormeyer MDC RegAffairs GmbH	INFLIXIMAB - ORPHAN DESIGNATION RECS
2014-8970	11/07/2014 12/09/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORO/SW-FO/KAN-DO/KAN-CB/	Stacy Montgomery Biolog	BIOMERIEUX - RESPONSE LETTER 10/10/2014 - 11/15/2014
2014-8971	11/07/2014 12/09/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	David Ferreira GMT Capital	LEXICON PHARMACEUTICALS - COMMUNICATIONS WITH FDA RE LX4211 01/01/2010 - 11/05/2014
2014-8972	11/07/2014 12/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	Victoria Rothwell Immunexpress	DEN140019
2014-8973	11/07/2014 12/09/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kenneth Daly BURGSIMPSON	VALPROATES - INDIVIDUAL CASE REPORTS

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2014-8974	11/07/2014 12/09/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	Fran Silverman truthinadvertising.org	GLUCOSAMINE - AERS
2014-8975	11/07/2014 12/09/2014	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	FAP 2289
2014-8976	11/07/2014 12/09/2014	FDA/OC/OES/DFOI/	Vaibhav Dusad Morgan Stanley	SUN PHARMACEUTICALS, INDIA - 483 08/25/2014 - 09/25/2014
2014-8977	11/07/2014 12/09/2014	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	MARLON JACKSON SHIMADZU SCIENTIFIC	SHIMADZU SCIENTIFIC, COLUMBIA, MD - INVESTIGATION RECS
2014-8978	11/07/2014 12/09/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KIMBERLY D BARONE BADEN MOTLEY RICE LLC	PFIZER - VIAGRA NDA 20-895 STUDY #148-215
2014-8979	11/07/2014 12/09/2014	OC/ORACE/ OC/ORACE/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	RYAN HOUSTON HOUSTON, RYAN	FLINTSTONE VITAMINS CMLPNT 137832 & SPL 830934 - TEST RESULTS, CASE SPL SUMMARY RPT (CSSR)
2014-8980	11/07/2014 12/09/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELAINE S WALLER PHARM D MBA SEATTLE GENETICS INC	SEATTLE GENETICS - ADCETRIS (BRENTUXIMAB VEDOTIN) ISRS 10186245, 10190916, 10191646
2014-8981	11/07/2014 12/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	RYAN KAAT SIDLEY AUSTIN LLP	HOWMEDICA OSTEONICS CORP - MODULAR DUAL MOBILITY (MDM) LINER & X3 ACETABULAR INSERT K103233, HIP SYSTEMS K121308; STRYKER CORP - EXETER X3 RIMFIR ACETABULAR CUP K090897, ETC
2014-8982	11/07/2014 12/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	RYAN KAAT SIDLEY AUSTIN LLP	SMITH & NEPHEW - LEGION PRIMARY KNEE SYS K093746 CMLPNTS
2014-8983	11/07/2014 12/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	RYAN KAAT SIDLEY AUSTIN LLP	ZIMMER INC - VIVACIT-E VITAMIN E HIGHLY CROSSLINKED POLYRHTYLENE K120370, BIOLOX DELTA CERAMIC FEMORAL HEAD K130899, BIOLOX OPTION CERAMIC FERMORAL HEAD SYS K073567, ETC CORR, RECS 12/31/11 TO PRESENT

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2014-8984	11/07/2014 12/09/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	KIM HENDERSON SANOFI PASTEUR	GLAXOSMITHKLINE BIOLOGICALS, RIXENSART, BELGIUM - 483 2014
2014-8985	11/07/2014 12/09/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	KIM HENDERSON SANOFI PASTEUR	GLAXOSMITHKLINE BIOLOGICALS, WAVRE, BELGIUM - 483 2014
2014-8986	11/07/2014 12/09/2014	FDA/OMPT/CDRH/OCER/DFOI/	PATRICIA PERRICONE FANN & PETRUCCELLI PA	CUNNINGHAM & RASKIN, DIAGNOSTIC RADIOLOGY & MAMMOGRAPHY, TAMARAC, FL - ANNUAL SURVEY FOR MAMMOGRAPHY QUALTY STANDARDS ACT (MQSA) LTR 2002, 2003
2014-8987	11/07/2014 12/09/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OGROP/ORANE-FO/NYK- DO/NYK-DCB/	Steven Victor Intellicell Biosciences	LETTER SUBMITTED TO FDA BY SARAH YOUNG 03/04/2013 - 09/30/2014
2014-8988	11/07/2014 12/09/2014	FDA/OGROP/ORAPA-FO/SAN- DO/SAN-CB/	Brian Sims Indiana Botanic Gardens, Inc.	ASI MARKETING LLC - EIR, 483, CORR 11/01/2013 - 11/30/2013
2014-8989	11/07/2014 12/09/2014	FDA/OO/OFBA/OAGS/	Rose Santos FOIA Group, Inc.	HHSF223200950015L
2014-8990	11/07/2014 12/09/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jennifer Whitehead Jennifer Whitehead	PROLIA - AERS
2014-8991	11/07/2014 12/09/2014	FDA/OGROP/ORASE-FO/FLA- DO/FLA-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Lawrence H. Liebling Lawrence H. Liebling, P.A.	VF-WORKS, INC, DMX-WORKS, INC - COMPLAINTS, LETTERS, VIOLATIONS ETC 01/01/1996 - 11/06/2014
2014-8992	11/07/2014 12/09/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dr Girish Bakhru HSBC Securities and Capital Markets	IPCA LABORATORIES, INDIA - 483 04/01/2013 - 04/30/2013
2014-8993	11/07/2014 12/09/2014	OC/CVM/OCD/	Kristi O Smedley Center for Regulatory Services, Inc.	FAP 2289
2014-8994	11/07/2014 12/09/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Philip R Torf TORF LAW FIRM	MINOCIN - AERS, MEDWATCH REPORTS
2014-8995	11/07/2014 12/09/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	idealisib - all AE's Ken Tong	IDEALISIB - AERS

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2014-8996	11/10/2014 12/10/2014	FDA/OO/OFBA/OAGS/	Rose Santos FOIA Group, Inc.	HHSF223200950016L
2014-8997	11/10/2014 12/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ibrutinib - all AE's Ken Tong	IMBRUVICA - AERS
2014-8998	11/10/2014 12/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Pembrolizumab - All AE's Ken Tong	KEYTRUDA - AERS
2014-8999	11/10/2014 12/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rahul Jeewani IIFL Institutional Equities	SUN PHARMACEUTICALS, INDIA - 483 09/08/2014 - 09/19/2014
2014-9000	11/10/2014 12/10/2014	FDA/OFVM/CFSAN/OCD/EOS/	Fran Silverman truthinadvertising.org	VEVMA NUTRITION COMPANY - AERS
2014-9001	11/10/2014 12/10/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michelle Kern Hospira, Inc.	MUSTAFA NEVAL ILAC SANAVII, AS, TURKEY - 483, EIR, INVESTIGATOR DIARY 04/20/2012 - 11/06/2014
2014-9002	11/10/2014 12/10/2014	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	Lawrence H. Liebling Lawrence H. Liebling, P.A.	John R. Postlethwaite, D.C., Nu-Best Diagnostic Labs, Inc. and Nu-Best Whiplash Injury Center, Inc. - COMPLAINTS, INSPECTIONS, LETTERS FROM STATE FARM ETC
2014-9003	11/10/2014 12/10/2014	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	Stacey Seidl Ad-Tech Medical Instrument Corporation	AD-TECH MEDICAL INSTRUMENT CORPORATION, RACINE, WI - EIR 01/01/2011 - 11/06/2014
2014-9004	11/10/2014 12/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	John Crocker Perry Baromedical Corporation	K092263
2014-9005	11/10/2014 12/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jamie Byun Advanced Sterilization Products	K121593
2014-9006	11/10/2014 12/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jamie Byun Advanced Sterilization Products	K121484

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2014-9007	11/10/2014 12/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jamie Byun Advanced Sterilization Products	K101910
2014-9008	11/10/2014 12/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jamie Byun Advanced Sterilization Products	K052128
2014-9009	11/10/2014 12/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jamie Byun Advanced Sterilization Products	K004009
2014-9010	11/10/2014 12/10/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ernest Pfadenhauer Applied BioResearch	NDA 008922
2014-9011	11/10/2014 12/10/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Miguel Echavarri InteliMap, Inc.	JUXTAPID - AERS
2014-9012	11/10/2014 12/10/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Carrie Trujillo Carrie Trujillo	IMITREX - AERS
2014-9013	11/10/2014 12/10/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Summer Bowling Golden Living Center Prairie Hills	LIST OF MEDICATIONS WITH BLACK BOX WARNING
2014-9014	11/10/2014 12/10/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel johnson FOI Services, Inc.	K052494
2014-9015	11/10/2014 12/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Advanced Sterilization Products Advanced Sterilization Products	K123546
2014-9016	11/10/2014 12/10/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Wei Yue UNIVERSITY OF OKLAHOMA HEALTH SCIENCES CENTER	STATINS - AERS
2014-9017	11/10/2014	FDA/OMPT/CDER/GRP/DIDP/	Jaya Ayyagari	ANDA 091589 SBA

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	12/10/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dr.Reddys Laboratories Inc	
2014-9018	11/10/2014 12/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K090850
2014-9019	11/10/2014 12/10/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Jamie Byun Advanced Sterilization Products	K103277
2014-9020	11/10/2014 12/10/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Stephen Manogue Zavante Therapeutics, Inc.	MONUROL - SBA
2014-9021	11/10/2014 12/10/2014	FDA/OFVM/CFSAN/OCD/EOS/	Richard G. Higby Richard Higby	CETYL PYRIDINIUM - FAP
2014-9022	11/10/2014 12/10/2014	FDA/OMPT/CDRH/OCER/DFOI/	Eric Forkosh Cooper Union c/o Eric Forkosh	K103214
2014-9023	11/10/2014 12/10/2014	FDA/OGROP/ORAC/CE-FO/PHI- DO/PHI-CB/	David Mangione Govzilla, Inc.	SANOPI PASTEUR, INC, SWIFTWATER, PA - 483, EIR 05/09/2014 - 05/09/2014
2014-9024	11/10/2014 12/10/2014	FDA/OGROP/ORAC/CE-FO/CIN- DO/CIN-CB/	David Mangione Govzilla, Inc.	BEN VENUE LABORATORIES, BEDFORD, OH - 483, EIR 06/06/2014 - 06/06/2014
2014-9025	11/10/2014 12/26/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	David Mangione Govzilla, Inc.	PFIZER IRELAND PHARMACEUTICALS, DUBLIN, IRELAND - 483, EIR 06/17/2014 - 06/17/2014
2014-9026	11/10/2014 12/10/2014	FDA/OC/OES/DFOI/	STEVEN LIM FINKELSTEIN & PARTNERS	TOPAMAX - MEDICATION GUIDE 3/14 (CERTIFIED)
2014-9027	11/10/2014 12/10/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	STEVEN LIM FINKELSTEIN & PARTNERS	TOPAMAX - CORR FROM RUSSELL KATZ 4/23/09 (CERTIFIED)
2014-9028	11/10/2014	FDA/OC/OES/DFOI/	STEVEN LIM	TOPAMAX - MEMO FROM TODD SAHROOT PHD 12/11/96 (CERTIFIED)

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	12/10/2014		FINKELSTEIN & PARTNERS	
2014-9029	11/10/2014 12/10/2014	FDA/OC/OES/DFOI/	STEVEN LIM FINKELSTEIN & PARTNERS	TOPAMAX- APRVL LTR 12/24/96 (CERTIFIED)
2014-9030	11/10/2014 12/10/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	STEVEN LIM FINKELSTEIN & PARTNERS	TOPAMAX - LBLG 4/09 (CERTIFIED)
2014-9031	11/10/2014 12/10/2014	FDA/OC/OES/DFOI/	STEVEN LIM FINKELSTEIN & PARTNERS	TOPAMAX - MEMO FROM PAUL LEBER MD 12/18/98 (CERTIFIED)
2014-9032	11/10/2014 12/10/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	STEVEN LIM FINKELSTEIN & PARTNERS	TOPAMAX - LBLG REVISED 4/08 (CERTIFIED)
2014-9033	11/10/2014 12/10/2014	FDA/OC/OES/DFOI/	STEVEN LIM FINKELSTEIN & PARTNERS	TOPAMAX - STATISTICAL RVWS 5/13/98 (CERTIFIED)
2014-9034	11/10/2014 12/10/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MICHAEL R COHEN INSTITUTE FOR SAFE MEDICATION PRACTICES	MEDWATCH RPTS CODED AS MEDICATION ERRORS 9/1/14-10/31/14
2014-9035	11/10/2014 12/10/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	LINETTE SANTOS ST JOSEPH'S HEALTHCARE SYSTEM	DR MOHAMED S RABBOT, ST JOSEPH'S REGIONAL MEDICAL CENTER, CLIFTON, NJ - DEFICIENCY CODES, INADEQUATE PATIENT CONSENT FORM
2014-9036	11/12/2014 12/11/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jennifer Bragg Veloxis Pharmaceuticals A/S	NDA 204096
2014-9037	11/12/2014 12/11/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jeff Horwitz ASSOCIATED PRESS	SIHUAN PHARMACEUTICALS - INSPECTIONS, APPROVALS 11/11/2011 - 11/10/2014
2014-9038	11/12/2014	FDA/OMPT/CDER/GRP/DIDP/	Natalie Jackson	REPORT SUBMITTED RE TECFIDERA 11/04/2014 - 11/04/2014

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	12/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BriovaRx	
2014-9039	11/12/2014 12/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Chirag Talati Kotak Securities	CIPLA - 483 MOST RECENT 11/01/2014 - 11/10/2014
2014-9040	11/12/2014 12/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dr. Muzaffar Khan Laurus Labs Private Limited	The specification for the process impurity Chloromethyl isopropyl carbonate (CMIC) in the Tenofovir disoproxil fumarate USP draft monograph is NMT 0.15%
2014-9041	11/12/2014 12/11/2014	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	Scott D. Segal, MD, MBA Scientific Clinical Research c/o Segal Institute	SCOTT D SEGAL, NORTH MIAMI, FL - EIR 01/01/2013 - 11/10/2014
2014-9042	11/12/2014 12/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 201486
2014-9043	11/12/2014 12/11/2014	FDA/OGROP/ORR/CE-FO/DET-DO/DET-CB/	Jeff Kasperski Kasperski, Jeffrey	MPI RESEARCH INC, MATTAWAN, MI - EIR 01/01/1999 - 12/31/2013
2014-9044	11/12/2014 12/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	Stefan Schreck Stefan Schreck	K082982, K10052, K102525 ETC
2014-9045	11/12/2014 12/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	Lisa Anderson ConMed Corporation	K781429
2014-9046	11/12/2014 12/11/2014	FDA/OO/OFBA/OAGS/	Zachary Fullbright Chickasaw Nation Industries	Winning proposal for IGF::OT::IGF CDRH CESUB BPA
2014-9047	11/12/2014 12/11/2014	FDA/OO/OFBA/OAGS/	Zachary Fullbright Chickasaw Nation Industries	EXECUTED CONTRACT FOR CDRH CESUB STEADY STATE TASK ORDER
2014-9048	11/12/2014 12/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	Joshua M. Ammerman Ammerman, Joshua M	K140162
2014-9049	11/12/2014 12/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dr. Claudia Mattern, Adjunct Professor Nova Southeastern Uni M et P Pharma	NDA 205488

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-9050	11/12/2014 12/11/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 203667
2014-9051	11/12/2014 12/11/2014	FDA/OC/OES/DFOI/	Saion Mukherjee NOMURA INTERNATIONAL PLC	GLENMARK, INDIA - 483 07/01/2013 - 08/31/2013
2014-9052	11/12/2014 12/11/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Theis Terwey NB Capital Research GmbH	Progressive multifocal leukoencephalopathy FAERS
2014-9053	11/12/2014 12/11/2014	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Jason Randall Jason Randall	LONZA - 483, RESPONSE CLOSEOUT LTR 08/01/2013 - 11/10/2014
2014-9054	11/12/2014 12/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	Larissa DAndrea RESMED CORP	K141522
2014-9055	11/12/2014 12/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	Marc Girardot BioMed Design	K112399
2014-9056	11/12/2014 12/11/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lori Gwinett Georgia Southern University	Amlodipine, Aranidipine, Azelnidipine ETC - SBA
2014-9057	11/12/2014 12/11/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Margaux Nair K&L Gates LLP	FORM 3542 NDA 020845
2014-9058	11/12/2014 12/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	Michael Secondini BOSTON SCIENTIFIC	K140472
2014-9059	11/12/2014 12/11/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Andrea Demakas ADVERSEEVENTS INC	TECFIDERA, IMBRUVICA, ZYDELIG ETC - AERS
2014-9060	11/12/2014 12/11/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Pankajkumar U Patel Piramal Enterprises Limited	NDA 017558

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2014-9061	11/12/2014 12/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dr. Joel Bamford Cochrane Skin Group	Ortiz, L. G. and P. R. Papa (1978). "Topical miconazole nitrate therapy in tinea pedis and tinea versicolor." Clinical Therapeutics 1(6): 444-450 Responses
2014-9062	11/12/2014 12/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Virryan Banzon Deallus Consulting	Last 3 recent Periodic Safety Update Reports (PSURs) for the multiple sclerosis drug fingolimod (Brand name: GILENYA)
2014-9063	11/12/2014 12/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ OC/ORA/ OC/ORA/	Cliff Guidry Walgreens Infusion Services	POTENCY TEST FOR HYDRATION ELASTOMERIC BALLS FOR A SOLUTION WITH MAGNESIUM SULPHATE 32 MEQ PER 500 ML OF NORMAL SALINE
2014-9064	11/12/2014 12/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Miguel Echavarri InteliMap, Inc.	OCTEC CORR WITH TEKMIIRA PHARMACEUTICALS CORPORATION 07/21/2014 - 11/07/2014
2014-9065	11/12/2014 12/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Terrance W. Connolly GENERICHEM CORP	TOMITA PHARMACEUTICAL - 483 10/28/2013 - 11/02/2013
2014-9066	11/12/2014 12/11/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Elaine Alambra Dynavax Technologies Corporation	RHEIN BIOTECH - EIR 01/03/2012 - 12/31/2012
2014-9067	11/12/2014 12/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	Sara Wexler Koblitz Fish and Richardson P.C.	K061381
2014-9068	11/12/2014	FDA/OMPT/CDER/ORP/DIDP/	Randall C. Monroe	MARTIN AVENUE PHARMACY, NAPERVILLE, IL - COMPLAINTS, AERS, INVESTIGATIONS 09/01/2010 -

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	12/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORA/ OC/ORA/	Brenner, Monroe, Scott & Anderson	12/31/2012
2014-9069	11/12/2014 12/11/2014	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	Mehul Govani P & L Development LLC	RECALL D-0041-2015
2014-9070	11/12/2014 12/11/2014	FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/	Rachel Johnson FOI Services, Inc.	EIR for Nektar Therapeutics, Huntsville, AL
2014-9071	11/12/2014 12/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	ACTIQ, FENTORA - REMS
2014-9072	11/12/2014 12/11/2014	FDA/OMPT/CDRH/OCER/DFOI/	Regina Novak Medtronic TYRX Inc.	K130943
2014-9073	11/12/2014 12/11/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rowena Dodaro DODARO, GENE L	ABILIFY - AERS 13Q2 SOURCE DOCUMENTS
2014-9074	11/12/2014 12/11/2014	FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/	Kirk Ernst Lab Telemetric	KMED RESEARCH, ST CLAIRE SHORES, MI - COMPLAINT LETTER, AUDIT REPORT 11/01/2008 - 11/01/2014
2014-9075	11/12/2014 12/11/2014	FDA/OC/OES/DFOI/	Cassandra Mac Donald No Organization	LASER TATTOO REMOVAL
2014-9076	11/12/2014 12/11/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-621
2014-9077	11/12/2014 12/11/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2013-9524
2014-9078	11/12/2014	FDA/OGROP/ORA/CE-FO/DET-	REY G. CORDOVA	ELI LILLY & CO, INDIANAPOLIS, IN - EIR 4/15-19/13

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	12/11/2014	DO/DET-CB/	ELI LILLY & CO	
2014-9079	11/12/2014 12/11/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2013-7749
2014-9080	11/12/2014 12/11/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-654
2014-9081	11/12/2014 12/11/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DDM/	ANGELIQUE M. DIGRACI PEDDICORD AND TOWNSEND LLC	MISOPROSTOL - APRVL, 12/27/88 TO PRESENT
2014-9082	11/12/2014 12/11/2014	FDA/OFVM/CFSAN/OCD/EOS/	GARY J. BURIN, Ph.D. TECHNOLOGY SCIENCES GROUP INC	FCN 607
2014-9083	11/12/2014 12/11/2014	FDA/OFVM/CFSAN/OCD/EOS/	GARY J. BURIN, Ph.D. TECHNOLOGY SCIENCES GROUP INC	FCN 1311
2014-9084	11/12/2014 12/11/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KATE REYNOLDS ROCKY MOUNTAIN POISON DRUG CTR	8043053, 8097355, 8130667 - FAERS
2014-9085	11/12/2014 12/11/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KATE REYNOLDS ROCKY MOUNTAIN POISON DRUG CTR	6241234, 7252037, 7393389 - FAERS
2014-9086	11/12/2014 12/11/2014	FDA/OFVM/CFSAN/OCD/EOS/	CYNTHIA B. LIEBERMAN Keller and Heckman LLP	PNC 1442
2014-9087	11/12/2014 12/11/2014	FDA/OFVM/CFSAN/OCD/EOS/	CYNTHIA B. LIEBERMAN Keller and Heckman LLP	PNC 1443
2014-9088	11/12/2014 12/11/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	AMY MITCHELL GLAXO SMITH KLINE	BARNARD CASTLE, CORK, EVREUX ETC - QAP
2014-9089	11/12/2014 12/11/2014	OC/ORO/ORM/ OC/ORO/ORM/	Anna S. Magann McGowan, Hood & Felder, LLC	CONAGRA FOODS, INC - REPORTS, RECORDS, COMPLAINTS ETC RE ADULATERATED FOOD PRODUCTS

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				01/01/2013 - 11/01/2014
2014-9090	11/12/2014 12/11/2014	FDA/OMPT/OSMP/OOPD/	Raluca Ciobanu Adamas Pharmaceuticals, Inc.	NDA 021264 ORPHAN DRUG REVIEWS
2014-9091	11/13/2014 12/12/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jane Corbett Ice Miller, LLP	2007 ORANGE BOOK PLUS FINAL SUPPLEMENT, 2008 ORANGE BOOK SUPPLEMENT PDF
2014-9092	11/13/2014 12/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	Redacted 510(k)s for October 2014
2014-9093	11/13/2014 12/12/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	TIRF REMS INFORMATION
2014-9094	11/13/2014 12/12/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORASW-FO/SWID/SWID-CB/	Bryan Folger Law Offices of Bryan M. Folger	INVESTIGATION RECS RE 2013 MULTISTATE OUTBREAK OF SALMONELLA SAINTPAUL LINKED TO CUCUMBERS 01/01/2013 - 12/31/2013
2014-9095	11/13/2014 12/12/2014	OC/CVM/OCD/	Rachel Johnson FOI Services, Inc.	FIVE ELANCO METHODS
2014-9096	11/13/2014 12/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	Michael LaChance CURRIE MEDICAL SPECIALTIES	K012715
2014-9097	11/13/2014 12/12/2014	FDA/OC/OES/DDM/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michael Moss THE NEW YORK TIMES	SIBUTRAMINE, VICTOZA, ETC - PREVIOUSLY RELEASED RECORDS, TRANSCRIPTS 01/01/1997 - 11/11/2014
2014-9098	11/13/2014 12/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	Michael LaChance CURRIE MEDICAL SPECIALTIES	K032821
2014-9099	11/13/2014 12/12/2014	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Jacqueline Sinclair Genentech, Inc.	GENENTECH INC - EIR, 483 08/18/2010 - 10/31/2013
2014-9100	11/13/2014 12/12/2014	FDA/OFVM/CFSAN/OCD/EOS/	Emily Marcum Lightfoot, Franklin and White, LLC	HERCULES INC DIOXATHION RESIDUES IN CITRUS FRUIT, DIOXATHION RESIDUES IN GRAPES, DIOXATHION RESIDUES RESULTING FROM APPLICATION TO APPLES

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2014-9101	11/13/2014 12/12/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michelle Vaughn SouthEast Alaska Regional Health Consortium	CYCLOBENZAPRINE - AERS
2014-9102	11/13/2014 12/12/2014	FDA/OC/OES/DFOI/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	William Elliott Elliott, William	MED AWARENESS DBA GENESIS TISSUE SERVICES, POWAY, CA - 483
2014-9103	11/13/2014 12/12/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sandy Lee, B&H Consulting Services, Inc. B&H Consulting Services, Inc.	IPCA LABORATORIES, INDIA - 483 10/01/2014 - 11/12/2014
2014-9104	11/13/2014 12/12/2014	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	Agency Information Collection Activities; Proposed Collection; Comment Request; Establishment of a Tobacco User Panel - PROTOCOLS, BACKGROUND
2014-9105	11/13/2014 12/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	Charles Juhl C.W. Juhl	SCANADU SCOUT - 510K 01/01/2011 - 11/12/2014
2014-9106	11/13/2014 12/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	Brian Rothman PRIVATE CITIZEN	K140853/S003
2014-9107	11/13/2014 12/12/2014	FDA/OC/OES/DFOI/ FDA/OC/OCC/ FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kelly Adams Drexel University School of Public Health	OFF LABEL DRUG PROMOTION INVESTIGATIONS, SETTLEMENTS, WARNING LETTERS ETC
2014-9108	11/13/2014 12/12/2014	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/ FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	BRANDON M SCHWARTZ SCHWARTZ LAW FIRM	RESTAURANT RECYCLING SERVICES LLC, ROANOKE MILLING CO, NEW FASHION PORK, ETC - RESULTS OF SPLS TESTED 1/14 TO PRESENT
2014-9109	11/13/2014 12/12/2014	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	MARILYN J RAMOS SILVER GOLUB & TEITELL	ZIMMER - TRABECULAR METAL PRIMARY HIP FEMORAL STEM ISSUES OF HIGH COBALT, CHROMIUM OR TITANIUM LEVELS IN THE BLOOD CORR, WARNINGS, ETC

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		FDA/OGROP/ORACE-FO/DET-DO/DET-CB/		
2014-9110	11/13/2014 12/12/2014	FDA/OMPT/CTP/OD/ FDA/OC/OCC/	MARK E GREENWOLD CAMPAIGN FOR TOBACCO-FREE KIDS	SWEDISH MATCH NORTH AMERICA - FDA AUTHORITY TO REVISE SMOKELESS TOBACCO WARNING LABELS, ATTACHMENTS
2014-9111	11/13/2014 12/12/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	NINA YIN TULANE UNIVERSITY DEPT OF ECONOMICS	ISSUANCE OF WRITTEN REQUESTS FOR PEDIATRIC STUDIES, DECLINING OF WRITTEN REQUESTS, SUBMISSION DATES, ETC
2014-9112	11/13/2014 12/12/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TORREY COPE SIDLEY AUSTIN LLP	ELIQUIS (APIXABAN), PRADAXA (DABIGATRAN ETEXILATE MESYLATE), XARELTO (RIVAOXABAN) - AERS, MEDICATION ERROS LAST FIVE YRS
2014-9113	11/13/2014 12/12/2014	OC/ORA/ OC/ORA/ FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Doe J	INDIVIDUAL RECS
2014-9114	11/13/2014 12/12/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	ZXPREXA ZYDIS - RECS
2014-9115	11/13/2014 12/12/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Wendy Fox Pegasus Laboratories, Inc	PEGASUS LABORATORIES, INC - PROFILE CLASS CODES 01/01/2006 - 11/30/2014
2014-9116	11/13/2014 12/12/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Jim Austin Arizona Nutritional Supplements	VITALHEALTH TECH, INC, CLIFTON, NJ - 483 06/01/2014 - 07/31/2014
2014-9117	11/13/2014 12/12/2014	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	WAYNE SADOWSKI NOVARTIS PHARMACEUTICALS CORP	JEFFREY SOSMAN MD, VANDERBILT UNIVERSITY MEDICAL CENTER, NASHVILLE, TN - EIRS, 483S, CORR, ETC 9/29/10, 6/13/11, 2/12/07
2014-9118	11/13/2014 12/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	ROBERT IRLLEN PERCEPTUAL DEVELOPMENT CORP	PERCEPTUAL DEVELOPMENT CORP AND/OR IRLLEN INSTITUTE - IRLLEN SPECTRAL FILTERS CMLPNTS 1/90 TO PRESENT;DOCUMENT NUMBER CPT1400751 - RECS, WEBSITES

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2014-9119	11/13/2014 12/12/2014	OC/CVM/OCD/	DAVID W PLUNKETT JD JM CENTER FOR SCIENCE IN THE PUBLIC INTEREST	RAW MILK DRUG RESIDUE SURVWY - SAMPLING DATA
2014-9120	11/13/2014 12/12/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BROCK P ALVARADO ALVAREZ LAW OFC	ABBVIE INC/ABBOTT LABS - ANDROGEL RECS, AERS
2014-9121	11/13/2014 12/12/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHRISTINE LIVOTI DEERFIELD INSTITUTE	RAPTOR PHARMS - PROCYSBI (CYSEAMINE BITARTRATE) AERS, MEDICATION ERRORS
2014-9122	11/13/2014 12/12/2014	FDA/OC/OCC/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID LOHMAN MILLENNIUM MANAGEMENT LLC	NOVO NORDISK, KALUNDBORG, DENMARK - SUBPOENA CORR, RPTS, MFG ISSUES
2014-9123	11/13/2014 12/12/2014	FDA/OC/OES/DFOI/	KEITH THOMAS T-67081 THOMAS T-67081, KEITH	ISOMER, RESIN, AMPHETAMINE, ETC - DEFINITIONS
2014-9124	11/13/2014 12/12/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RICHARD MWAZI Mwazi, Richard	JANSSEN PHARMS - RIDPERDAL AERS 1/00 TO PRESENT
2014-9125	11/13/2014 12/12/2014	FDA/OC/OES/DFOI/	JOHN LOMONACO LoMonaco, John	2014-7673 DELETIONS
2014-9126	11/13/2014 12/12/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Marianne Noonan Marianne Noonan c/o UMASS Medical School, CWM	K122288
2014-9127	11/13/2014 12/12/2014	FDA/OMPT/CDRH/OCER/DFOI/	Sherry Terry InfoBionic Inc	K930564
2014-9128	11/13/2014 12/12/2014	OC/ORR/ORM/ OC/ORR/ORM/	Michelle Urban Iron Mountain	LIST OF HOSPITAL, CRO; ANNUAL HISTOPATHOLOGY TESTS PER YEAR
2014-9129	11/13/2014 12/12/2014	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2014-8510

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2014-9130	11/14/2014 12/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	Lyudmila Kipnis Datum Dental Ltd.	K122894
2014-9131	11/14/2014 12/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	David Windish Newtyn Management	Records related to any order issued by the FDA under 21 CFR 814.45 denying FDA Approval of Augment Bone Graft
2014-9132	11/14/2014 12/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	Dave Hernon SonaCare Medical, LLC	K022894
2014-9133	11/14/2014 12/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	Laura Boll Medovations Inc.	K040324
2014-9134	11/14/2014 12/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	Laura Boll Medovations Inc.	K930348
2014-9135	11/14/2014 12/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	Laura Boll Medovations Inc.	K924104
2014-9136	11/14/2014 12/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	Laura Boll Medovations Inc.	K101298
2014-9137	11/14/2014 12/15/2014	FDA/OMPT/CTP/OD/	Lauren Kass Lempert UCSF	2012 REVIEWER GUIDE DRAFTED BY CTP, REVISIONS, ADDITIONAL GUIDES
2014-9138	11/14/2014 12/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORO/ OC/ORO/	Lila Razmara ANDREWS THORNTON	WELLNESS TORE COMPOUNDING PHARMACY, CLEVELAND, TN - AERS, MEMOS, REPORTS, ETC 01/01/2014 - 10/01/2014
2014-9139	11/14/2014 12/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Robert Wolfangel CERTUS INTERNATIONAL INC	NDA 020314 - SBA
2014-9140	11/14/2014 12/15/2014	FDA/OC/OES/DFOI/	Vik Bajnath ARTHREX INC.	DEVICE REPORT - FACILITY NAME
2014-9141	11/14/2014 12/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	Laura Boll Medovations Inc.	K103437
2014-9142	11/14/2014 12/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K093128
2014-9143	11/14/2014	FDA/OGROP/ORO/CE-FO/MIN-	MARTIN DAVIS	COLOPLAST MANUFACTURING US LLC, MINNEAPOLIS, MN

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	12/15/2014	DO/MIN-CB/	DAVIS, MARTIN	- EIR 9/28/11
2014-9144	11/14/2014 12/15/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	ANNE M KUNDERT RYAN SWANSON & CLEVELAND PLLC	ARJO MED AB LTD, GLOUCESTER, UK - WARNING LTR MDR 9617921-2007-00028, MDR 9617921-2008-00017, MDR 9617921-2008-00018 CORR, WARNINGS, CORRECTIVE ACTIONS, ETC 6/10/09
2014-9145	11/14/2014 12/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	SAMRADMI PATIL CYBERSONICS INC	OMINSONICS MEDICAL TECHNOLOGIES INC - MODIFIED OMINWAVE ENDOVASCULAR SYS K083335
2014-9146	11/14/2014 12/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	MARTIN DAVIS DAVIS, MARTIN	AMERICAN MEDICAL SYSTEMS (AMS), ATHLONE, IRELAND - EIRS 10/20-24/14
2014-9147	11/14/2014 12/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	KACHI ENYINNA 510K TECHNOLOGY GROUP LLC	LUTRONIC CORP - K121481
2014-9148	11/14/2014 12/15/2014	FDA/OMPT/CDRH/OCER/DFOI/	IRWIN KELMAN COHEN MD TISSUE TECHNOLOGIES HOLDING LLC	TISSUE TECHNOLOGIES HOLDINGS LLC, RICHMOND, VA - TT101 510K
2014-9149	11/14/2014 12/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KATE REYNOLDS DENVER HEALTH ROCKY MOUNTAIN POISON & DRUG CENTER	COUGH & COLD PREPARATIONS - ISR 6774174, 8043746, 8293797, ETC
2014-9150	11/14/2014 12/15/2014	FDA/OC/OES/DFOI/	Doe J	WHAT CONSTITUTES A FOOD ALLERGY
2014-9151	11/14/2014 12/15/2014	OC/CVM/OCD/	MCKENZIE CATO Hyman, Phelps & McNamara P.C.	CARU PET FOOD CO - EIRS, COMM, INGREDIENTS VERIFIED OR APRVD, ETC 1/13 TO PRESENT
2014-9152	11/14/2014 12/15/2014	FDA/OGROP/ORA/ORO/DIOP/ OC/ORA/ OC/ORA/	Tina Shang InTec PRODUCTS, INC XIAMEN	Import Alert 89-08
2014-9153	11/14/2014 12/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jaya Ayyagari DR. REDDY'S LABORATORIES INC	ANDA 090943 SBA
2014-9154	11/14/2014 12/15/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jaya Ayyagari DR. REDDY'S LABORATORIES INC	ANDA 091649 SBA
2014-9155	11/14/2014	FDA/OMPT/CDER/ORP/DIDP/	Susan P. Muller, R.N., M.S.	VIVATROL - AERS

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	12/15/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Northwestern Medicine	
2014-9156	11/14/2014 12/15/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Saion Mukherjee NOMURA INTERNATIONAL PLC	TARO PHARMACEUTICALS, BRAMPTON, CANADA - 483 02/01/2014 - 11/14/2014
2014-9157	11/14/2014 12/15/2014	FDA/OC/OES/DFOI/	Michael Weiss Carroll & Weiss LLP	MORCELLATORS - PREVIOUSLY RELEASED RECS 01/01/2013 - 10/31/2014;
2014-9158	11/17/2014 12/16/2014	FDA/OC/OES/DFOI/	Brady Dennis THE WASHINGTON POST	FOIA REQUESTS RECEIVED RE EBOLA 10/01/2014 - 10/31/2014
2014-9159	11/17/2014 12/16/2014	FDA/OFVM/CFSAN/OCD/EOS/	Nadja Popovich The Guardian	5 HOUR ENERGY - COMPLAINTS 01/01/2012 - 11/14/2014
2014-9160	11/17/2014 12/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	Dawn Chang Kyma Medical Technologies, Inc.	K122036
2014-9161	11/17/2014 12/16/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Andrea Demakas ADVERSEEVENTS INC	PRADAXA - AERS
2014-9162	11/17/2014 12/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K140783
2014-9163	11/17/2014 12/16/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Kamen Bliznashki Respiratory Motion, Inc.	K043299, K043590
2014-9164	11/17/2014 12/16/2014	FDA/OGROP/ORR/SE-FO/ATL- DO/ATL-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Peter Loftus THE WALL STREET JOURNAL	MERCK & CO, BAYER HEALTHCARE PHARMACEUTICALS - 483 01/01/2014
2014-9165	11/17/2014 12/16/2014	FDA/OGROP/OIP/	Takanori Eto Echo-news	COMMUNICATIONS BETWEEN FDA AND JAPANESE GOVERNMENT 01/01/2014 - 11/16/2014
2014-9166	11/17/2014 12/16/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Stephen Levine University of Haifa	Drug-placebo trials for autism

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2014-9167	11/17/2014 12/16/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ADITYA KHEMKA AMBIT CAPITAL	TORRENT PHARMACEUTICALS LTD, INDIA - 483 01/02/2013 - 11/17/2014
2014-9168	11/17/2014 12/16/2014	FDA/OC/OES/DFOI/	LIZETTE MILLER-RODOVIC, Esq. MILLER - RADOVIC LLC	ASTRA ZENECA INC - SEROQUEL (QUETIAPINE FUMARATE) AER 7/29/97 - 6/2/97
2014-9169	11/17/2014 12/16/2014	FDA/OFVM/CFSAN/OCD/EOS/ OC/CVM/OCD/ FDA/OC/OES/DDM/	LORRI K. CHAVEZ FARNAM COMPANIES INC	DOCKET FDA-2014-F-1669
2014-9170	11/17/2014 12/16/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	PATRICIA L. REGENYE Celgene Corporation	MAUREEN COOPER, COMM CA CARE, INDIANAPOLIS, IN - 483 7/11 TO PRESENT
2014-9171	11/17/2014 12/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	MICHAEL A. PETRUCCELLI FANN & PETRUCCELLI PA	LTR SENT TO CUNNINGHAM & RASKIN, DIAGNOSTIC RADIOLOGY & MAMMOGRAPHY, TAMARAC, FL 2002, 2003
2014-9172	11/17/2014 12/16/2014	FDA/OFVM/CFSAN/OCD/EOS/ OC/CVM/OCD/	ERIN KENNEDY ALLTECH INC	CORR BETWEEN FDA & DSM NUTRITIONAL PRODUCTS REGARDING FAP FOR SCHIZOCHYTRIUM SP DIREED ALGAE FDA 2014-F-1509
2014-9173	11/17/2014 12/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	JAN ENEMAERKE MED ART	MED ART, COPENHAGEN, DENMARK - EIR
2014-9174	11/17/2014 12/16/2014	OC/ORACE/ OC/ORACE/ FDA/OGROP/ORACE-FO/DIOP/	DONALD N. BLUE ZETETIC INC	RECORD FOR ALL SHIPMENTS FROM 11/1-15/14
2014-9175	11/17/2014 12/16/2014	FDA/OMPT/CTP/OD/	NATALIE N. SANDERS LATHAM & WATKINS LLP	SE0004347, SE0004350
2014-9176	11/17/2014 12/17/2014	FDA/OC/OES/DFOI/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	ALEX C. DAVIS JONES WARD PLC	NUTEK DISPOSABLES INC - BABY WIPES RECALL
2014-9177	11/17/2014 12/16/2014	FDA/OC/OL/ FDA/OMPT/CDRH/OCER/DFOI/	GREGORY D. BROWN FLEMING NOLEN & JEZ LLP	MEDTRONIC - INFUSE BONE GRAFT & LT CAGE DVC - AER, CORR, INVESTIGATIONS
2014-9178	11/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	DUWAYNE KRAMER JR.	SCOUT BOSS K023961

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	12/16/2014		BURKE INC	
2014-9179	11/17/2014 12/16/2014	FDA/OMPT/CDRH/OCER/DFOI/	NATALIE HICHAK TELEFLEX MEDICAL	KMEDIC INTERNAL EXTERNAL FIXATION DVC K070561; AXIOM FASCIAL CLOSURE SYS K103412; AXIOM TECHNOLOGY PARTNERS LLC K103412
2014-9180	11/18/2014 12/17/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	David Bruser Toronto Star	CANTON LABORATORIES, INDIA - 483 01/01/2013 - 11/17/2014
2014-9181	11/18/2014 12/17/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	Scott Compton Mason Group	CYBER LETTERS 01/01/2000 - 12/31/2009
2014-9182	11/18/2014 12/17/2014	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	Irina Rivkind Koffler CANTOR FITZGERALD	CUBIST PHARMACUETICALS - 483, RESPONSE, CORR 07/01/2014 - 11/17/2014
2014-9183	11/18/2014 12/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jill Beyers DePuy Synthes Spine	K923452, K964395, K970346
2014-9184	11/18/2014 12/17/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tammy Hooper Tammy Hooper	NDA 021455 S 016, 017
2014-9185	11/18/2014 12/17/2014	FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	Scott Oliver QSSI	MCDOUGALL'S RIGHT FOODS, INC, SOUTH SAN FRANCISCO, CA - EIR, 483, CORRECTIVE ACTION ETC 01/01/2009 - 10/31/2014
2014-9186	11/18/2014 12/17/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	James Campbell Kinerk Schmidt and Sethi	NDA 017441
2014-9187	11/18/2014 12/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	Bill Maher AddicTechCo	K790738
2014-9188	11/18/2014 12/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	Amy Fowler Duval & Associates	K053223, K053223, K051938 ETC
2014-9189	11/18/2014 12/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	Marc C. Sanchez Contract In-House Counsel Consl. LLC	K030281

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2014-9190	11/18/2014 12/17/2014	FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	Rachel Johnson FOI Services, Inc.	STAAR SURGICAL, MONROVIA, CA - EIR, 483, RESPNSE ETC
2014-9191	11/18/2014 12/17/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 9859
2014-9192	11/18/2014 12/17/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jesse McLean Toronto Star	WINTAC LIMITED, INDIA - 483 01/04/2012 - 11/17/2014
2014-9193	11/18/2014 12/17/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Tim Alamenciak Toronto Star	DR GIDEON KOREN, ONTARIO, CANADA - RECS RE VOLUNTARY ACTION 10/29/2012 - 11/02/2012
2014-9194	11/18/2014 12/17/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	S ALBERT EDWARDS S ALBERT EDWARDS PHARM D	LEVAQUIN (LEVOFLOXACIN) - ISR 3108187-8, 3108125-8, 3228995-2, ETC
2014-9195	11/18/2014 12/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	DAVID SCHMIDT SCHMIDT, DAVID	SURGICAL MESH - INADEQUACY OF LABELS
2014-9196	11/18/2014 12/17/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	STANLEY N COHEN STANFORD UNIV DEPT OF GENETICS	CALBIOCHEM - TRAZURE (AZARIBINE) - PRE-CLINICAL RECS
2014-9197	11/18/2014 12/17/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARK B BROWN BROWN #325519, MARK B	MIRTAZAPINE, DOXEPIN 50MG, PRAZOSIN 2MG, 1MG, ETC - AERS
2014-9198	11/18/2014 01/21/2015	FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	VITCORIA E BLACKISTON MOTLEY RICE LLC	IMPAX LABORATORIES INC - EIRS, COMPLIANCE, ENFORCEMENT INVESTIGATIVE ACTION 1/13 TO PRESENT

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2014-9199	11/18/2014 12/17/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	MEAGAN C FLORY INDIANA UNIV	GARDASIL, HPV CACCINES - VAERS
2014-9200	11/18/2014 12/17/2014	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ROBERT A WEINBERGER WEINBERGER LAW OFC PC	SANOFI-AVENTIS - TAXOTERE (DOCETAXEL) POST-MARKETING RECS, WARNING LTRS, CASE RPTS, ETC
2014-9201	11/18/2014 12/17/2014	FDA/OGROP/ORASE-FO/SJN- DO/SJN-CB/	DAVID LOHMAN MILLENNIUM MANAGEMENT LLC	COOPER VISION CARIBBEAN CORP, JUANA DIAZ, PR - 483S, UNTITLED LTRS, WARNING LTRS, ETC
2014-9202	11/18/2014 12/17/2014	FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/ OC/CVM/OCD/ FDA/OFVM/CFSAN/OCD/EOS/	ZACHARIAH J DEMEOLA Mayer Brown LLP	BLUE BUFFALO COMPANY LTD (BLUE BUFFALO) - CHICKEN BY PROD MEAL, POULTRY BY PROD ARTIFICIAL PRESERVATIVES, SOY, CORN INGREDIENTS NOT RELECTED ON PROD LABELS BILL BISHOP REGARDING THE ISSUE PERTAINING TO WILBUR ELLIS TEXAS PLANT LTR 10/14/14, PET FOOD MISLABELED, COMM, ETC
2014-9203	11/18/2014 12/17/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joe Malone Joe Malone	ETHINYL ESTRADIOL, NORGESROL,NORETHINDRONE ETC - DEATH REPORTS
2014-9204	11/18/2014 12/17/2014	OC/ORAS/ORM/ OC/ORAS/ORM/	David Mangione Govzilla, Inc.	LIST OF INSPECTIONS 03/15/2014 - 11/18/2014
2014-9205	11/18/2014 12/17/2014	FDA/OMPT/CDRH/OCER/DFOI/	Michael Titus W. L. Gore & Associates, Inc.	K111695
2014-9206	11/19/2014 12/18/2014	FDA/OMPT/CTP/OD/	Lauren K. Lempert UCSF	REVIEW GUIDES FOR TRAINING CTP STAFF ON THE SE REVIEW PROCESS 01/01/2011 - 11/13/2014
2014-9207	11/19/2014 12/18/2014	FDA/OGROP/ORACE-FO/PHI- DO/PHI-CB/	Sharon Weeks American Red Cross Donor & Client Support Center	AMERICAN RED CROSS, PHILADELPHIA - EIR 01/01/2012 - 12/31/2013
2014-9208	11/19/2014 12/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	shin kang WELLS FARGO SECURITIES	TECFIDERA - AERS
2014-9209	11/19/2014	FDA/OC/OES/DFOI/	Eden Um	K130191 - CLEARANCE LETTER CERTIFIED

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	12/18/2014		Hans Biomed Corportaion	
2014-9210	11/19/2014 12/18/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	richard margolies Richard Margolies	EXCELSIOR MEDICAL, NEPTUNE, NJ - EIR, 483 07/21/2014 - 08/21/2014
2014-9211	11/19/2014 12/18/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-2209
2014-9212	11/19/2014 12/18/2014	FDA/OMPT/CDRH/OCER/DFOI/	Pierre-Yves Huet OSTESYS	K092381
2014-9213	11/19/2014 12/18/2014	FDA/OMPT/CDRH/OCER/DFOI/	Russ Garrison VerAvanti Inc	K062340
2014-9214	11/19/2014 12/18/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OCC/	Jennifer Bragg Veloxis Pharmaceuticals, Inc.	ASTAGRAF XL - RECS RE DECISION TO GRANT THREE YEAR EXCLUSIVITY ETC 07/01/2012 - 11/18/2014
2014-9215	11/19/2014 12/18/2014	FDA/OMPT/CDRH/OCER/DFOI/	Patricia Maguire TekTeam LLC.	K103059
2014-9216	11/19/2014 12/18/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-2735
2014-9217	11/19/2014 12/18/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-2601
2014-9218	11/19/2014 12/18/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-2462
2014-9219	11/19/2014 12/18/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-2944
2014-9220	11/19/2014 12/18/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-2754
2014-9221	11/19/2014 12/18/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-3376
2014-9222	11/19/2014 12/18/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-2206
2014-9223	11/19/2014 12/18/2014	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-5562
2014-9224	11/19/2014	OC/CVM/OCD/	GENNA REED	OXITEC LTD - MTG NOTES, CORR, INTERNAL COMM, ETC

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	12/18/2014		Food & Water Watch	
2014-9225	11/19/2014 12/18/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	MICHAEL MANCINELLI CONWAY HOMER & CHIN- CAPLAN PC	INDIVIDUAL RECS
2014-9226	11/19/2014 12/18/2014	FDA/OMPT/CDRH/OCER/DFOI/	MATTHEW AURIC AURIC, MATTHEW	PROTECT YOUR VISION PIINHOLE GLASSES - MARKETING RECS
2014-9227	11/19/2014 12/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WILLIAM D BOYLES WILLIAM BOYLES LAW OFC	REGULATORY PROCEEDING AGAINST CARL ANDREW DEABATE MD
2014-9228	11/19/2014 12/18/2014	OC/ORA/ OC/ORA/ FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/	JOSEPH T BLACK SHERRY BLACK GELLER & CAIN LAW OFCS	INDIVIDUAL RECS
2014-9229	11/19/2014 12/18/2014	FDA/OMPT/CTP/OD/	ROBERT ROWLAND ROWLAND, ROBERT	REPUBLIC TOBACCO LP - SMOKER FRIENDLY REAL GOLD KING SIZE FILTERED PAPER TUBES FOR ROLL-YOUR-OWN TOBACCO SUBSTANIAL EQUIVALENCE RPT SE0004347
2014-9230	11/19/2014 12/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JEFFREY LILLY LILLY, JEFFREY	UCB INC - KEPBRA OFF-BRANDING INVESTIGATION RECS
2014-9231	11/19/2014 12/18/2014	FDA/OMPT/OSMP/OOPD/	Leona Saunders Northeastern University School of Law	ORPHAN DRUG APPLICATION
2014-9232	11/19/2014 12/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gregory Mayzus UW-Madison dept Biomedical Eng.	10 MG PHENYLEPHRINE - EFFICACY STUDIES
2014-9233	11/19/2014 12/18/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joe Schatz Joe Schatz	CONCERTA - MEDWATCH FORMS 05/01/2013 - 11/13/2014
2014-9234	11/19/2014 12/18/2014	FDA/OMPT/CDRH/OCER/DFOI/	John Waters Whip Mix Corporation	K041283

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2014-9235	11/19/2014 12/18/2014	FDA/OC/OES/DFOI/	Nishith Sanghvi CIMB	IPCA - 483 09/01/2014 - 11/19/2014
2014-9236	11/20/2014 12/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	Russ Garrison VerAvanti Inc.	K860858
2014-9237	11/20/2014 12/19/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/NE-FO/NYK- DO/NYK-DCB/	Doe J	INDIVIDUAL RECS
2014-9238	11/20/2014 12/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	idelalisib - Individual Case Report Ken Tong	ZYDELIG - 10368556, 10391545, 10539211 ETC
2014-9239	11/20/2014 12/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	Suzanne Lucas Air Techniques, Inc.	K123402
2014-9240	11/20/2014 12/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joe Gallagher EVENUS PHARMACEUTICAL LABORATORIES INC	ANDA 091106 APPROVAL LETTER CERTIFIED
2014-9241	11/20/2014 12/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joe Gallagher EVENUS PHARMACEUTICAL LABORATORIES INC	ANDA 202485 APPROVAL LETTER CERTIFIED
2014-9242	11/20/2014 12/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	Russ Garrison VerAvanti Inc	K911278
2014-9243	11/20/2014 12/19/2014	FDA/OFVM/CFSAN/OCD/EOS/	Christine Keggins igene Biotechnology Inc.	DSM ASTAXANTHIN SUBACUTE - STUDY RECS
2014-9244	11/20/2014 12/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	William J Gorman GORMAN CONSULTING INC	K101641
2014-9245	11/20/2014 12/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Elliot Favus, MD FAVUS INSTITUTIONAL RESEARCH LLC	IMBRUVICA - MEDWATCH REPORTS
2014-9246	11/20/2014	FDA/OMPT/CDER/ORP/DIDP/	Elliot Favus, MD	ADCETRIS - AERS

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	12/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FAVUS INSTITUTIONAL RESEARCH LLC	
2014-9247	11/20/2014 12/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	Russ Garrison VerAvanti Inc	K902329
2014-9248	11/20/2014 12/19/2014	FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/	Sharon Weeks American Red Cross Donor Tulsa Data Management Center	AMERICAN RED CROSS, TULSA, OK - EIR 01/01/2013 - 12/31/2013
2014-9249	11/20/2014 12/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	Russ Garrison VerAvanti Inc	K895159
2014-9250	11/20/2014 12/19/2014	FDA/OGROP/ORASE-FO/ATL- DO/ATL-CB/	Sharon Weeks American Red Cross Donor and Client Support Center	AMERICAN RED CROSS, CHARLOTTE, NC - EIR 01/01/2012 - 12/31/2013
2014-9251	11/20/2014 12/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	Russ Garrison VerAvanti Inc	K914570
2014-9252	11/20/2014 12/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dayton Misfeldt Bay City Capital	EMERGENCY USE IND AND INDIVIDUAL PATIENT IND FOR DRUG PRODUCT 11/07/2009 - 11/19/2014
2014-9253	11/20/2014 12/19/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	S ALBERT EDWARDS PHARM D	LEVAQUIN (LOVOFLOXACIN) - ISR 3108187-8, 3108125-8, 3228995-2
2014-9254	11/20/2014 12/19/2014	FDA/OFVM/CFSAN/OCD/EOS/	CHRISTINE L. KEGGINS S ALBERT EDWARDS PHARM D	CYANOTECH CORP - HAEMATOCOCCUS PLUVIALIS EXTRACT NDI CONTAINING ASTAXANTHIN ESTERS NOTIFICATION 717
2014-9255	11/20/2014 12/19/2014	OC/ORAS/ OC/ORAS/ FDA/OGROP/ORASE-FO/NOL- DO/NOL-CB/	CHRIS J. TARDIO GIDEON COOPER & ESSARY	CARE RITE CLINIC, RIPLEY, TN - JOINT INJECTION INVESTIGATION 9/5/13 TESTING RESULTS, RPTS, ETC
2014-9256	11/20/2014 12/19/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	HARVIN, PETER	HYQVIA - VAERS
2014-9257	11/20/2014 12/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	GERALYN MURRAY VITAL SIGNS INC	WELL LEAD MEDICAL INSTRUMENTS LTD - ENDOTRACHEAL TUBE K042683
2014-9258	11/20/2014	FDA/OFVM/CFSAN/OCD/EOS/	Daniel Dwyer	HAMPTON CREEK, INC - CORR WITH FDA RE JUST MAYO

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	12/19/2014	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Kleinfeld Kaplan and Becker LLP	09/01/2014 - 11/20/2014
2014-9259	11/21/2014 12/22/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Dawn Chang Kyma Medical Technologies, Inc.	K090696
2014-9260	11/21/2014 12/22/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michelle Elizabeth Legiec Eagle Pharmaceuticals, Inc.	CONSUMER COMPLAINT REFERENCED IN CIPLA LIMITED EIR SUMMARY
2014-9261	11/21/2014 12/22/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sandy Lee, B&H Consulting Services, Inc. B&H Consulting Services, Inc.	IPCA LABORATORIES, LTD, INDIA - 483 07/14/2014 - 11/20/2014
2014-9262	11/21/2014 12/22/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Eric White MISSION PHARMACAL COMPANY/PRESIDENT	ANDA 090756
2014-9263	11/21/2014 12/22/2014	OC/ORAP/ OC/ORAP/ FDA/OGROP/ORAP/NE-FO/NWE-DO/NWE-CB/	Peter Mione CutisPharma, Inc.	CUTISPHARMA - EIR 01/01/2014 - 11/20/2014
2014-9264	11/21/2014 12/22/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Yatin Suneja COWEN AND COMPANY	SOLIRIS, TECFIDERA, OTEZLA ETC - AERS
2014-9265	11/21/2014 12/22/2014	FDA/OGROP/ORAP/CE-FO/CHI-DO/CHI-CB/	Eleanor DaCosta United States Pharmacopeial Convention (USP)	IMPORT REFUSAL 231-1235318-3
2014-9266	11/21/2014 12/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	Eric Lintula Active Spine Group, LLC	K924018
2014-9267	11/21/2014 12/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	Kathy L. Remsen Medtronic Spine and Biologics	K0102002
2014-9268	11/21/2014 12/22/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michelle Elizabeth Legiec Eagle Pharmaceuticals, Inc.	WEIJIE - 483, RESPONSE, EIR 09/08/2014 - 09/12/2014

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-9269	11/21/2014 12/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	Mark Estrada RMD, LLC	K020311
2014-9270	11/21/2014 12/22/2014	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	Jonathan Horne, Esq. The Rosen Law Firm, P.A.	IRADIMED CORPORATION - 483, RESPONSES
2014-9271	11/21/2014 12/22/2014	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	Eleanor DaCosta United States Pharmacopeial Convention (USP)	IMPORT REFULSAL 417-0282777-9
2014-9272	11/21/2014 12/22/2014	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Eleanor DaCosta United States Pharmacopeial Convention (USP)	IMPORT REFUSAL FS2-1138289-0
2014-9273	11/21/2014 12/22/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID HOFFMEISTER Wilson Sonsini Goodrich & Rosati	TEVA - OMEGA-3 ACID ETHYL ESTERS ANDA 91-028 APRVL RECS
2014-9274	11/21/2014 12/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	ANDREY GODES Multi Radiance Medical	K123014
2014-9275	11/21/2014 12/22/2014	FDA/OO/OHR/	Dr. Thomas V. Montgomery, III Dr. Thomas V. Montgomery, III	GS-14, GS-15, SES ETC JOB ANNOUNCEMENTS CDER 12/01/2013 - 11/21/2014
2014-9276	11/21/2014 12/22/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bharat Celly Research Delta	DR REDDY VIZAG - 483 11/17/2014 - 11/21/2014
2014-9277	11/21/2014 12/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	Martin J. Conroy Derma Sciences, Inc.	HEALTHPOINT, LTD, SMITH & NEPHEW, INC, ETC - RECS RE MANUKA HONEY 01/01/2009 - 11/20/2014
2014-9278	11/21/2014 12/22/2014	FDA/OMPT/OSMP/OOPD/	Amy Speros LATHAM & WATKINS	AUSPEX PHARMACEUTICALS - OPD REVIEW RECS 01/01/2013 - 11/20/2014; We
2014-9279	11/21/2014 12/22/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Dawn Chang Kyma Medical Technologies, Inc.	K083287
2014-9280	11/21/2014 12/22/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Eric Lintula Active Spine Group, LLC	K090949
2014-9281	11/21/2014 12/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	H. Mark Estrada RMD, LLC	K022423

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2014-9282	11/21/2014 12/22/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Chris Donner SI-TECHNOLOGY, LLC	K021932, K051296, K080398 ETC
2014-9283	11/21/2014 12/22/2014	FDA/OGROP/ORPA/FO/SAN-DO/SAN-CB/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Austin Nelson Sterne Agee	IMPAX LABORATORIES, HAYWARD, CA, TAIWAN - 483, UNTITLED LETTER 08/01/2014 - 11/20/2014
2014-9284	11/21/2014 12/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K984370
2014-9285	11/21/2014 12/22/2014	FDA/OGROP/ORACE/FO/CHIDO/CHI-CB/ FDA/OGROP/ORASW/FO/DALDO/DAL-CB/ FDA/OGROP/ORASW/FO/KANDOKAN-CB/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Austin Nelson Sterne Agee	HOSPIRA INC, VIZAG, INDA; AUSTIN, TX; LAKE FOREST, IL; ETC - 483, UNTITLED LETTER 09/01/2014 - 11/20/2014
2014-9286	11/24/2014 12/23/2014	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	David Bishop David Bishop	THERAFLU - AERS
2014-9287	11/24/2014 12/23/2014	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Steve Usdin BIOCENTURY	CHIMERIX INC BRINCIDOFOVIR - RECS RE ACCESS TO PATIENT
2014-9288	11/24/2014 12/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K121929
2014-9289	11/24/2014 12/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	K141748 Newlife Medical Products, Inc.	K141708
2014-9290	11/24/2014 12/23/2014	OC/CVM/OCD/	Steven Roach FOOD ANIMAL CONCERNS TRUST	COMM BETWEEN FDA AND NOVARTIS ANIMAL HEALTH US, INC RE PROMOTIONAL MATERIALS RE TIAMULIN ETC 01/01/2014 - 11/01/2014

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2014-9291	11/24/2014 12/23/2014	OC/CVM/OCD/	Steven Roach FOOD ANIMAL CONCERNS TRUST	COMM BETWEEN FDA AND SPONSORS OF APPROVED APPLICATIONS FOR NEW ANIMAL DRUGS AND NEW ANIMAL DRUG COMBINATION PRODUCUTS RE MISLEADING PROMOTIONAL MATERIALS ETC 01/01/2010 - 11/01/2014
2014-9292	11/24/2014 12/23/2014	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	Melanie Burkhold Melanie Burkhold	DR STEPHEN C MILLER, WALTERBORO, SC - WARNING LETTER, INVESTIGATION RECS 01/01/2012 - 01/01/2013
2014-9293	11/24/2014 12/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K080550
2014-9294	11/24/2014 12/23/2014	FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/	Padmini Sahoo Immucor GTI Diagnostics, Inc.	ONE LAMBDA, INC - 483 MOST RECENT
2014-9295	11/24/2014 12/23/2014	FDA/OGROP/ORR/CE-FO/MIN-DO/MIN-CB/	Padmini Sahoo Immucor GTI Diagnostics, Inc.	LIFE TECHNOLOGIES, MILWAUKEE, WI - 483 MOST RECENT
2014-9296	11/24/2014 12/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	Padmini Sahoo Immucor GTI Diagnostics, Inc.	BIOKIT - 483 MOST RECENT
2014-9297	11/24/2014 12/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K033954
2014-9298	11/24/2014 12/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K023902
2014-9299	11/24/2014 12/23/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K003277
2014-9300	11/24/2014 12/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	G. Srinivas Zydus Pharmaceuticals USA Inc.	ANDA 065070 - SBA
2014-9301	11/24/2014 12/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ho Phong Pham CRDAMC Family Medicine Residency	ABILIFY - AERS
2014-9302	11/24/2014 12/23/2014	OC/ORR/ORM/ OC/ORR/ORM/	Lori Papp Meritech Inc	LIST OF FOOD AND PET FOOD MANUFACTURERS IN US
2014-9303	11/24/2014 12/23/2014	FDA/OMPT/OSMP/OOPD/	Amy Speros LATHAM & WATKINS LLP	INFANT BACTERIAL THERAPEUTICS - L REUTERI ORPHAN PRODUDCT RECS 01/01/2012 - 11/21/2014
2014-9304	11/24/2014 12/23/2014	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORR/PA-FO/LOS-	Nicki Jacobs Jacobs Compliance Services	ALMA MATTSON, LIQUID HEALTH, MATTSON NUTRTION - WARNING LETTER RECS, UPDATES 01/31/2013 - 11/21/2014

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		DO/LOS-CB/		
2014-9305	11/24/2014 12/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joe Malone Joe Malone	BIRTH CONTROL DRUGS - AERS
2014-9306	11/24/2014 12/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tom Namsavanh IntelGenx Corp.	NOVARTIS CONSUMER HEALTH TRIAMINIC THIN STRIPS - APPROVAL LETTER 01/01/2004 - 12/31/2004
2014-9307	11/24/2014 12/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Charles Goldberg Charles Goldberg	XARELTO - AERS
2014-9308	11/24/2014 12/23/2014	OC/CVM/OCD/	IRENE CLARK NEXCYON PHARMACEUTICALS INC	NEXCYON PHARMACEUTICALS INC - INAD 010-594 CMC TECHNICAL SECTION APPENDIX 1, APPENDIX 3
2014-9309	11/24/2014 12/23/2014	FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/	WARREN WILLIAMS FOREST RESEARCH INSTITUTE	ANDREW O SCHREIBER, IRVINE, CA - EIR, 483 6/4/12
2014-9310	11/24/2014 12/23/2014	FDA/OC/OES/DFOI/	DAVYA SRIVASTAV-SETH LAMPF LIPKIND PRUPIS & PETIGROW	2014-5667 - MINOR DELETIONS
2014-9311	11/24/2014 12/23/2014	FDA/OGROP/ORR/CE-FO/CHI-DO/CHI-CB/	PATRICIA L REGENYE Celgene Corporation	WENDY STOCK, CHICAGO, IL - 483S 6/09 TO PRESENT
2014-9312	11/24/2014 12/23/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	REBECCA L DANDEKER MORGAN LEWIS & BOCKIUS LLP	ZYDUS CADILA HEALTHCARE LTD, GUJARAT, INDIA - EIRS, 483S 6/1/14-8/1/14
2014-9313	11/24/2014 12/23/2014	OC/CVM/OCD/	SILVIA ULM BURDOCK GROUP	SODIUM BUTYRATE RN #156-54-7 - REGULATORY STATUS, CONSUMPTION, USES, ETC
2014-9314	11/24/2014 12/23/2014	FDA/OFVM/CFSAN/OCD/EOS/	SILVIA ULM BURDOCK GROUP	YUCCA SCIDIGERA FOR NATURAL FLAVORING SUBSTANCES FOR USE IN ALCOHOLIC BEVERAGES FAP 4A1318 - REGULATORY STATUS, CONSUMPTION, USES, ETC
2014-9315	11/24/2014 12/23/2014	FDA/OFVM/CFSAN/OCD/EOS/	SILVIA ULM BURDOCK GROUP	KRILL OIL (EUPHASIA SUPERBA) - REGULATORY STATUS, CONSUMPTION, USES, ETC

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2014-9316	11/25/2014 12/24/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-8021 - REQUEST LETTER ONLY
2014-9317	11/25/2014 12/24/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-8060 - REQUEST LETTER ONLY
2014-9318	11/25/2014 12/24/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-8207 - REQUEST LETTER ONLY
2014-9319	11/25/2014 12/24/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-8047 - REQUEST LETTER ONLY
2014-9320	11/25/2014 12/24/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-8069 - REQUEST LETTER ONLY
2014-9321	11/25/2014 12/24/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-8101 - REQUEST LETTER ONLY
2014-9322	11/25/2014 12/24/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-8135 - REQUEST LETTER ONLY
2014-9323	11/25/2014 12/24/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-8528 - REQUEST LETTER ONLY
2014-9324	11/25/2014 12/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 85635 S1, S2
2014-9325	11/25/2014 12/24/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-8575 - REQUEST LETTER ONLY
2014-9326	11/25/2014 12/24/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-8628 - REQUEST LETTER ONLY
2014-9327	11/25/2014 12/24/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-8382 - REQUEST LETTER ONLY
2014-9328	11/25/2014 12/24/2014	FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/	Alexandra Lobach Intertek Health Sciences Inc.	FCN 178
2014-9329	11/25/2014 12/24/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-8300 - REQUEST LETTER ONLY
2014-9330	11/25/2014 12/24/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-8612 - REQUEST LETTER ONLY
2014-9331	11/25/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2014-8263 - REQUEST LETTER ONLY

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	12/24/2014		MERCK & CO., INC.	
2014-9332	11/25/2014 12/24/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-8391 - REQUEST LETTER ONLY
2014-9333	11/25/2014 12/24/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-8596 - REQUEST LETTER ONLY
2014-9334	11/25/2014 12/24/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-8637 - REQUEST LETTER ONLY
2014-9335	11/25/2014 12/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rahul Jeewani IIFL Institutional Equities	DR REDDY'S LABS, INDIA - 483 11/17/2014 - 11/21/2014
2014-9336	11/25/2014 12/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	Bao Tran Tran Associates	K020399
2014-9337	11/25/2014 12/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Elliot Favus, MD FAVUS INSTITUTIONAL RESEARCH LLC	LIST OF DRUGS FDA REJECTED BREAKTHROUGH THERAPY DESIGNATION REQUEST 01/01/2012 - 11/23/2014
2014-9338	11/25/2014 12/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dru West Dru West	BIRTH CONTROL DRUGS - AERS
2014-9339	11/25/2014 12/24/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Bao Tran Tran Associates	K141273, K112370, K100066 ETC
2014-9340	11/25/2014 12/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lawrence Zisman Pulmokine Inc.	NDA 205832
2014-9341	11/25/2014 12/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	Lior Barak Medoc Ltd	K922052
2014-9342	11/25/2014 12/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Andrew Thibault Parents Against Pharmaceutical Abuse (PAPA)	100208311, 100208311, 79802343 ETC

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2014-9343	11/25/2014 12/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jessica Swanson LIFECCELL CORPORATION	K050337
2014-9344	11/25/2014 12/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	Jessica Swanson LIFECCELL CORPORATION	K050337
2014-9345	11/25/2014 12/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Brandon Beagle PhD PFC Devp./New Alliance Pharma	PFC DEVELOPMENTS AKA NEW ALLIANCE PHARMA - OXYGENT IND BB-6195
2014-9346	11/25/2014 12/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jennifer Schumacher The Invus Group	XIAFLEX - AERS
2014-9347	11/25/2014 12/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Brian Overstreet ADVERSEEVENTS INC	MOST CURRENT LIST OF DESIGNATED MEDICAL EVENTS USED IN ADVERSE EVENT MONITORING AND SIGNALING FOR HUMAN DRUGS
2014-9348	11/25/2014 12/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	Matt Kennedy Somnetics International LLC	K070107
2014-9349	11/25/2014 12/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Peter Gerold Gerold, Peter J	LEXISCAN - LABEL CHANGE WARNING LETTER, APPROVAL 2014 09/01/2013 - 09/30/2014
2014-9350	11/25/2014 12/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rowena D. Devlin Bayer Healthcare and Pharmaceuticals Inc	AMIKACIN SULFATE INJECTION - APPROVAL DATES FOR INDICATIONS 01/01/1970 - 12/31/1996
2014-9351	11/25/2014 12/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ryan Smith Janus Capital Group ATTN: RYAN SMITH	TECFIDERA - AERS
2014-9352	11/25/2014	FDA/OMPT/CDER/ORP/DIDP/	Bharat Celly	RANBAXY - LETTER RE VALCYTE, NEXIUM 11/01/2014 - 11/25/2014

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	12/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Research Delta	
2014-9353	11/25/2014 12/24/2014	FDA/OO/OFBA/OAGS/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michael C. Montavon Michael C. Montavon, P.C.	GLOBAL RECORDS SYSTEM - CONTRACTS WITH FDA, INCLUDING RESEARCH COLLABORATION AGREEMENT, COMMUNICATIONS 01/01/2012 - 11/24/2014
2014-9354	11/25/2014 12/24/2014	FDA/OC/OES/DFOI/	Kari L. Twaite BEVERIDGE & DIAMOND PC	CFSAN FOIA REQUESTS 09/27/2014 - 11/24/2014
2014-9355	11/25/2014 12/24/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Jennifer Henderson Novocure	NOVOCURE - EIR PITTSBURG, PARIS, LEON ETC
2014-9356	11/25/2014 12/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Prashant Premkumar East Bridge Capital Management Limited	AUROBINDO PHARMA - 483 01/01/2014 - 11/25/2014
2014-9357	11/25/2014 12/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MANOJ GARG MERRILL LYNCH	DR REDDYS LABS, ANDHRA PRADESH, INDIA - 483
2014-9358	11/25/2014 12/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	SAMRADNI PATIL CYBERSONICS INC	OMNISONICS MEDICAL TECHNOLOGIES INC - MODIFIED ONMIWAVE ENDOVASCULAR SYS K083335
2014-9359	11/25/2014 12/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	BEN EISLER 60 MINUTES	BOSTON SCIENTIFIC - PROTEGEN SLING; ETHICON GYNEMESH PS 510K
2014-9360	11/25/2014 12/24/2014	FDA/OC/OL/	JONES, THOMAS H	CORR FROM SENATOR TED CRUZ 1/13 TO PRESENT
2014-9361	11/25/2014 12/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/OSMP/OOPD/	PETER S. REICHERTZ SHEPPARD MULLIN ET AL	ABB VIE - HUMIRA (ADALIMUMAB) - APLVL

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2014-9362	11/25/2014 12/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CROSBY T-50417, COURTNEY	ACTOS - AER
2014-9363	11/25/2014 12/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/	CHRIS J. TARDIO GIDEON COOPER & ESSARY	CARE RITE CLINIC, RIPLEY, TN - MEDWATCH 9/13
2014-9364	11/25/2014 12/24/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Doe J	BIOSAFETY INCIDENT RPTS FOR CBER LABS
2014-9365	11/25/2014 12/24/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	MICHAEL MANCINELLI CONWAY HOMER & CHIN- CAPLAN PC	INDIVIDUAL RECS
2014-9366	11/25/2014 12/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Stephen Stout Wolters-Kluwer Health	ALMOTRIPTAN, ELETRIPTAN, NARATRIPTAN ETC - AERS
2014-9367	11/25/2014 12/24/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Cari Ledbetter PERRIGO COMPANY	NDA 205352 SBA
2014-9368	11/26/2014 12/26/2014	FDA/OO/OHR/	LESLIE RAMSEY FDA NEWS	ADAM S FREEMAN, ADEMOLA O DARAMOLA, ALICE S TSAO, ETC - CV
2014-9369	11/26/2014 12/26/2014	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	LESLIE RAMSEY FDA NEWS	LONZA BIOLOGICS INC, PORTSMOUTH, NH, NEW ENGLAND HOME THERAPIES INC, SOUTHBOROUGH, MA; ARIAD PHARMACEUTICALS INC, ETC - 483S 10/1-31/14
2014-9370	11/26/2014 12/26/2014	FDA/OMPT/CDRH/OCER/DFOI/	LESLIE RAMSEY FDA NEWS	ARKRAY FACTORY INC, KOKA-SHI, JAPAN; ZIMMER ORTHOPEDIC MFG LTD, SHANNON, IRELAND; MULTIMEDICAL SRL, VIADANA, ITALY, ETC - 483S 10/1- 31/14
2014-9371	11/26/2014	FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/	LESLIE RAMSEY	R & D ENGINEERING OF EARLHAM INC, EARLHAM, IA; COMMUNITY BLOOD CENTER OF GTR KC, KANSAS CITY,

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	12/26/2014		FDA NEWS	MO - 483S 10/1-31/14
2014-9372	11/26/2014 12/26/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	LESLIE RAMSEY FDA NEWS	CIVIC CENTER PHARMACY, SCOTTSDALE, AZ; PADTEST LLC, SCOTTSDALE, AZ; SSCOR INC, SUN VALLEY, CA, ETC - 483S 10/1-31/14
2014-9373	11/26/2014 12/26/2014	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	LESLIE RAMSEY FDA NEWS	PROMED PHARMA LLC, PLYMOUTH, MN; BLUE BELT TECHNOLOGIES INC, PLYMOUTH, MN; TREYMED INC, SUSSEX, WI, ETC - 483S 10/1-31/14
2014-9374	11/26/2014 12/26/2014	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	LESLIE RAMSEY FDA NEWS	TRIS PHARMA INC, MONMOUTH JUNCTION, NJ; AMNEAL PHARMACEUTICALS LLC, PISCATAWAY, NJ; PARKER LABORATORIES INC, FAIRFIELD, NJ, ETC - 483S 10/1-31/14
2014-9375	11/26/2014 12/26/2014	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/ OC/ORA/ OC/ORA/	LESLIE RAMSEY FDA NEWS	GREEN HILLS HEALTH AND WELLNESS PHARMACY, NASHVILLE, TN - 483S 10/1-31/14
2014-9376	11/26/2014 12/26/2014	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	LESLIE RAMSEY FDA NEWS	SPA TECHNOLOGIES INTERNATIONAL INC, CONGERS, NY; LUITPOLD PHARMACEUTICALS INC, SHIRLEY, NY; TEMREX CORP, FREEPORT, NY, ETC - 483S 10/1-31/14
2014-9377	11/26/2014 12/26/2014	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	LESLIE RAMSEY FDA NEWS	BTG INTERNATIONAL LINC, WALES, UK; GLAXO SMITHKLINE-RIXENSART, RIXENSART, BELGIUM - 483S 10/1-31/14
2014-9378	11/26/2014 12/26/2014	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	LESLIE RAMSEY FDA NEWS	KONTUR CONTACT LENS CO INC, HERCULES, CA; STRYKER ENDOSCOPY, SAN JOSE, CA; BIONICA INC, MCCLELLAN, CA, ETC - 483S 10/1-31/14
2014-9379	11/26/2014 12/26/2014	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	LESLIE RAMSEY FDA NEWS	STRAIGHT ARROW PRODUCTS INC, BETHLEHEM, PA; CIMA TECHNOLOGY INC, PITTSBURGH, PA; ANIMAS CORP, WEST CHESTER, PA - 483S 10/1-31/14
2014-9380	11/26/2014 12/26/2014	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	LESLIE RAMSEY FDA NEWS	BAXTER PHARMACEUTICAL SOLUTIONS LLC, BLOOMINGTON, IN; XORAN TECHNOLOGIES LLC, ANN ARBOR, MI; DANMAR PRODUCTS INC, ANN ARBOR, MI - 483S 10/1-31/14
2014-9381	11/26/2014 12/26/2014	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	LESLIE RAMSEY FDA NEWS	HILL DERMACEUTICALS INC, SANFORD, FL; JAS DIAGNOSTICS INC, MIAMI LAKES, FL; INVACARE CORP, SANFORD, FL, ETC - 483S 10/1-31/14
2014-9382	11/26/2014 12/26/2014	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	LESLIE RAMSEY FDA NEWS	ALLERGY LABORATORIES INC, OKLAHOMA CITY, OK; TWO OLD GOATS LLC, HALTOM CITY, TX; OXYSURE SYSTEMS INC, FRISCO, TX, ETC - 483S 10/1-31/14
2014-9383	11/26/2014 12/26/2014	OC/ORA/ OC/ORA/ OC/CVM/OCD/	Michael Niebo PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS	MOU BETWEEN APHIS, NIH, FDA RE LAB ANIMAL WELFARE - POLICIES TO ENSURE COMPLIANCE, GUIDANCE DOCUMENTS, PROCEDURES
2014-9384	11/26/2014	OC/CVM/OCD/	John Russell	ELANO ANIMAL HEALTH, ELI LILLY AND CO - REC RE

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	12/26/2014		The Indianapolis Star	INTERNAL SAFETY REVIEW OF TRIFEXIS 01/01/2014 - 11/24/2014
2014-9385	11/26/2014 12/26/2014	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	LESLIE RAMSEY FDA NEWS	BIOMET SPINE LLC, BROOMFIELD, CO; WATSON LABORATORIES INC, SALT LAKE CITY, UT; WATER PIK INC, FORT COLLINS, CO, ETC - 483S 10/1-31/14
2014-9386	11/26/2014 12/26/2014	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	LESLIE RAMSEY FDA NEWS	RICHARD WOLF MEDICAL INSTRUMENTS CORP, VERNON HILLS, IL - 483S 10/1-31/14
2014-9387	11/26/2014 12/26/2014	FDA/OMPT/CDRH/OCER/DFOI/	Grace LeMieux Abbott Laboratories, Inc	K121610
2014-9388	11/26/2014 12/26/2014	OC/ORASW-FO/CHIDO/CHI-CB/	Selva Kumar Glanbia Performance Nutrition	SAMPLE 849595 ANALYTICAL REPORT
2014-9389	11/26/2014 12/26/2014	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	LESLIE RAMSEY FDA NEWS	REIMERS SYSTEMS INC, LORTON, VA - 483S 10/1-31/14
2014-9390	11/26/2014 12/26/2014	FDA/OMPT/CDRH/OCER/DFOI/	Daniel F Ferguson Ferguson Medical International	K072619
2014-9391	11/26/2014 12/26/2014	FDA/OMPT/CDRH/OCER/DFOI/	Grace LeMieux Abbott Laboratories, Inc	K121291
2014-9392	11/26/2014 12/26/2014	FDA/OGROP/ORAPASW-FO/SAN-DO/SAN-CB/OC/CVM/OCD/	Paymon Khatibi Balaban & Spielberger, LLP	FOSTER FARMS - WARNINGS, NOTICES OF SUSPENSION, ETC 01/01/2014 - 11/25/2014
2014-9393	11/26/2014 12/26/2014	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	LESLIE RAMSEY FDA NEWS	AMBIOPHARMA INC, NORTH AUGUSTA, SC; STEWART COMPOUNDING PHARMACY, FAYETTEVILLE, NC - 483S 10/1-31/14
2014-9394	11/26/2014 12/26/2014	FDA/OC/OES/DFOI/	Doe J	PARKING LOT VIDEO FOOTAGE
2014-9395	11/28/2014 12/29/2014	FDA/OMPT/CDRH/OCER/DFOI/	Hobart Harris UCSF	P810002 S46
2014-9396	11/28/2014 12/29/2014	FDA/OMPT/CDRH/OCER/DFOI/	Louise Higginson Virulite LLC	SUBMISSION RECS RE CLEANING VALIDATING PROTOCOLS 12/12/2008 - 11/25/2014
2014-9397	11/28/2014 12/29/2014	FDA/OC/OES/DFOI/	Ben Mouton Mouton, Benjamin	BAXTER CORPORATION ABACUS TOTAL PARENTERAL NUTRITION CALCULATION SOFTWARE RECALL 01/01/2014 - 11/25/2014
2014-9398	11/28/2014 12/29/2014	FDA/OMPT/CDRH/OCER/DFOI/	Werner Schmid Werner Schmid	K092227, K113273, K101609 ETC

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2014-9399	11/28/2014 12/29/2014	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Daniel J. Podolsky, Esq. Podolsky, Daniel J	CONTINENTAL DENTAL CERAMICS, INC - INVESTIGATION RECS 08/18/2012 - 11/26/2014
2014-9400	11/28/2014 12/29/2014	FDA/OMPT/CDRH/OCER/DFOI/	VASUDEV DOBARIYA Ansell Healthcare Products LLC	K113229
2014-9401	11/28/2014 12/29/2014	FDA/OMPT/CDRH/OCER/DFOI/	VASUDEV DOBARIYA Ansell Healthcare Products LLC	K133223
2014-9402	11/28/2014 12/29/2014	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Stephana Biggins PSS World Medical (McKesson)	STAT RX USA - EIR 01/01/2012 - 11/21/2014
2014-9403	11/28/2014 12/29/2014	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2013-2534
2014-9404	12/01/2014 12/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ibrutinib - individual case report Ken Tong	IMBRUVICA - 10488591, 10494308,10494326, ETC
2014-9405	12/01/2014 12/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Paola Teegarden Kinex Pharmaceuticals Inc.	NDA 021660 S037
2014-9406	12/01/2014 12/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	pembrolizumab - Individual Case Report Ken Tong	KEYTRUDA CASE 10329858
2014-9407	12/01/2014 12/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dr. Girish Bakhru HSBC	DR REDDY LABORATORIES, VIZAG - 483 11/19/2014 - 11/26/2014
2014-9408	12/01/2014 12/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sandy Suh Exeltis	NDA 020472
2014-9409	12/01/2014 12/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sara Wexler Koblitz Fish and Richardson P.C.	ANDA 078251

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2014-9410	12/01/2014 12/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sara Wexler Koblitz Fish and Richardson P.C.	ANDA 076373
2014-9411	12/01/2014 12/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anubhav Aggarwal CREDIT SUISSE	DR REDDY, ANDHRA PRADESH, INDIA - 483 11/09/2014 - 11/25/2014
2014-9412	12/01/2014 12/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Saion Mukherjee NOMURA INTERNATIONAL PLC	DR REDDY, VIZAG, INDIA - 483 11/01/2014 - 11/26/2014
2014-9413	12/01/2014 12/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sara Wexler Koblitz Fish and Richardson P.C.	ANDA 076649
2014-9414	12/01/2014 12/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Vaibhav Dusad Morgan Stanley	DR REDDY LABORATORIES, ANDHRA PRADESH, INDIA - 483 11/15/2014 - 11/30/2014
2014-9415	12/01/2014 12/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rahul Jeewani IIFL Institutional Equities	DR REDDY'S LABS, ANDHRA PRADESH, INDIA - 483 11/18/2014 - 11/21/2014
2014-9416	12/01/2014 12/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Peter R. Breggin, MD Center for the Study of Empathic Therapy	NDA - ABILIFY, CLOZARIL, FANAPT ETC
2014-9417	12/01/2014 12/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Peter R. Breggin, MD Center for the Study of Empathic Therapy	Summary NDA for escitalopram

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-9418	12/01/2014 12/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Peter R. Breggin, MD Center for the Study of Empathic Therapy	Summary of Adverse Events sent to FDA for escitalopram
2014-9419	12/01/2014 12/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	Christina M. Segro Medical Diagnostic Laboratories, LLC	K121039
2014-9420	12/01/2014 12/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Peter R. Breggin, MD Center for the Study of Empathic Therapy	Complete Summary of Adverse Event Reports for venlafaxine
2014-9421	12/01/2014 12/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	Reuters REUTERS	LABCORP INTEGRATED GENETICS, SEQUENOM, ILLUMINA ETC - AERS, COMPLAINTS 11/28/2004 - 11/28/2014
2014-9422	12/01/2014 12/30/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Alex Johnson UNIVERSITY OF WISCONSIN MADISON	K121964
2014-9423	12/01/2014 12/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	Richard O. Wood the Wood Burditt group	BIOTEST MEDICAL CORP, TAIWAN - EIR 01/01/2008 - 11/28/2014
2014-9424	12/01/2014 12/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	Christina M. Segro Medical Diagnostic Laboratories, LLC	K042970
2014-9425	12/01/2014 12/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	Christina M. Segro Medical Diagnostic Laboratories, LLC	K061301
2014-9426	12/01/2014 12/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bharat Celly Research Delta	DR REDDY, ANDHRA PRADESH, INDIA - 483 11/18/2014 - 11/28/2014
2014-9427	12/01/2014 12/30/2014	FDA/OMPT/OSMP/OOPD/	Clark Sullivan Cox Biosciences	ORPHAN PRODUCT APPLICATIONS FOR TREATMENT OF PYRIDOXINE DEPENDENT SEIZURES ETC 01/01/2000 - 11/18/2014
2014-9428	12/01/2014 12/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	Donna T. Ward DT Ward, PC	K033364
2014-9429	12/01/2014	FDA/OMPT/CDRH/OCER/DFOI/	Donna T. Ward	K113111

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	12/30/2014		DT Ward, PC	
2014-9430	12/01/2014 12/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JENNIFER D RAMSAY HOLDEN & CARR	ZOLPIDEM - AERS 2009 TO PRESENT
2014-9431	12/01/2014 12/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES S GAITHER GAITHER, CHARLES S	HISAMITSU AMERICA INC - SALONPAS RECS, Cmplnts
2014-9432	12/01/2014 12/30/2014	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/SEA-DO/SEA-CB/	LAURENCE WEBSTER WEBSTER, LAURENCE	INDIVIDUAL RECS
2014-9433	12/01/2014 12/30/2014	FDA/OGROP/ORO/CE-FO/CHIDO/CHI-CB/ FDA/OGROP/ORO/CE-FO/CINDO/CIN-CB/ FDA/OGROP/ORO/CE-FO/DETDO/DET-CB/	BRANDON M SCHWARTZ SCHWARTZ LAW FIRM	SHUR-GREEN FARMS LLC, ANSONIA, OH; HORIZON ENVIRONMENTAL, GRAND RAPIDS, MI; ZOETIS, FLORHAM PARK, NJ - LASCADOIL/SOYOIL RECALL 69399 TEST RESULTS 1/14 TO PRESENT
2014-9434	12/01/2014 12/30/2014	FDA/OC/OES/DDM/	Teri Krebs Norwegian University of Science and Technology	TRANSCRIPTS OF THE FDA-NIMH PSYCHOTOMIMETIC AGENTS ADVISORY COMMITTEE 01/01/1965 - 12/31/1975
2014-9435	12/01/2014 12/30/2014	FDA/OMPT/CDRH/OCER/DFOI/	Hiroyuki Koide Kowa Company, Ltd.	K141325
2014-9436	12/01/2014 12/30/2014	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/ OC/ORO/ FDA/OGROP/ORO/NE-FO/NWEDO/NWE-CB/	JOHN F NAIZBY MARCARELLI-NAIZBY LAW FIRM	YALE NEW HAVEN HOSPITAL NEONATAL UNIT - SUPPLEMENT CONTAMINATED WITH MOLD RECS 10/14
2014-9437	12/01/2014 12/30/2014	FDA/OC/OES/DFOI/	STEPHEN M AVDEEF AVDEEF, STEPHEN M	ROCKLINE INDUSTRIES - COMM, LAB TESTS, INVESTIGATION RECS 2001 TO PRESENT; NUTEK DISPOSABLES INC - COMM 2008 TO PRESENT, ETC
2014-9438	12/01/2014 12/30/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOANNE S HAWANA ARENT FOX LLP	SPETOCAINE INJ, ARTICAINE HCL - ISRS 9320998, 9858336, 9870214, ETC

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2014-9439	12/01/2014 12/30/2014	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ALLISON DAIL 3D COMMUNICATIONS	LIST OF SPECIAL GOVERNMENT EMPLOYEES (SGE) OR OTHER NON-FDA EXPERTS AND ADVISORS PROVIDING GUIDANCE ON BIOSIMILAR EVALUATION METHODS
2014-9440	12/01/2014 12/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	COURTNEY J CROSBY CROSBY, COURTNEY	ACTOS - SCIENTIFIC STUDY TEST RESULTS
2014-9441	12/01/2014 12/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LESLIE RAMSEY FDA NEWS	SPECIALTY MINERALS LIFFORD, BIRMINGHAM, UK 10/10/14; NATCO PHARMA LTD, KOTHUR MANDAL, INDIA 10/13/14; IPCA LABORATORIES LTD, PITHAMPUR, INDIA 10/17/14 - 483S
2014-9442	12/01/2014 12/30/2014	FDA/OGROP/ORAN/NE-FO/NWE- DO/NWE-CB/	CECILIA REYES MOLECULAR NEUROIMAGING LLC	MOLECULAR NEUROIMAGING LLC, NEW HAVEN, CT - EIR 4/2-5/13
2014-9443	12/01/2014 12/30/2014	FDA/OC/OCC/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	NICHOLAS J LITTLE ESQ Center for Inquiry	DR STANISLAW BURZYNSKI MD PHD - FDA DECISION TO LIFT THE CLNCL HOLD
2014-9444	12/01/2014 12/30/2014	FDA/OFVM/CFSAN/OCD/EOS/	AMY M ANSTEAD GRAS ASSOCIATES LLC	METHYLENE CHLORIDE - FAP
2014-9445	12/01/2014 12/30/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	A list of all FOIA requests closed 11/1-30/2014 on CD
2014-9446	12/01/2014 12/30/2014	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 11/1-30/2014
2014-9447	12/01/2014 12/30/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Allison Tarantino ARIAD Pharmaceuticals, Inc.	ICLUSIG - AERS
2014-9448	12/02/2014 12/31/2014	FDA/OMPT/CDRH/OCER/DFOI/	Victoria Rothwell Immunexpress	DEN130032

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2014-9449	12/02/2014 12/31/2014	FDA/OMPT/CDRH/OCER/DFOI/	Sharon Hughes National Colon Health Center	K840613, K863539, K893531 ETC
2014-9450	12/02/2014 12/31/2014	FDA/OO/OFBA/OAGS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Catherine Saint Louis NEW YORK TIMES	PEG 3350 LAXATIVES IN CHILDREN - GRANT RECS
2014-9451	12/02/2014 12/31/2014	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Takahiro Haruyama Globizz Corp.	K062416
2014-9452	12/02/2014 12/31/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Blake Goodner BRIDGER BIOMED INC	VALEANT PHARMACEUTICALS, STEINBACH, MANITOBA - 483, RESPONSE LETTERS, WARNING LETTERS 01/01/2014 - 12/01/2014
2014-9453	12/02/2014 12/31/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bennett Chiles UCLA Anderson School of Management, Strategy Department	ORANGE BOOK TXT FILES 01/01/2005 - 11/30/2014
2014-9454	12/02/2014 12/31/2014	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Blake Goodner BRIDGER BIOMED INC	VALEANT PHARMACEUTICALS, BRIDGEWATER, NJ - 483, RESPONSE, WARNING LETTERS 01/01/2014 - 12/01/2014
2014-9455	12/02/2014 12/31/2014	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	Blake Goodner BRIDGER BIOMED INC	LANNETT COMPANY, PHILADELPHIA, PA - 483, RESPONSE, WARNING LETTER 01/01/2014 - 12/01/2014
2014-9456	12/02/2014 12/31/2014	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	Blake Goodner BRIDGER BIOMED INC	LANNETT COMPANY, CODY, WYOMING - 483, RESPONSE, WARNING LETTER 01/01/2014 - 12/01/2014
2014-9457	12/02/2014 12/31/2014	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Blake Goodner BRIDGER BIOMED INC	PACIRA PHARMACEUTICALS, SAN DIEGO, CA - 483, RESPONSE, WARNING LETTER 01/01/2014 - 12/01/2014
2014-9458	12/02/2014 12/31/2014	FDA/OMPT/CDRH/OCER/DFOI/	Takahiro Haruyama Globizz Corp.	K121771
2014-9459	12/02/2014 12/31/2014	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Rachel Johnson FOI Services, Inc.	ABBOTT, SANTA CLARA, TEMECULA, CA - EIR
2014-9460	12/02/2014 12/31/2014	FDA/OMPT/OSMP/OOPD/	Sharath Venna INC RESEARCH	ACTEMRA - ORPHAN DRUG DESIGNATION APPLICATION
2014-9461	12/02/2014 12/31/2014	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOSEPH WALKER Walker, Joseph	AEGERION - JUXTAPID PROMOTION WARNING LETTER CLOSEOUT LETTER 01/01/2013 - 12/01/2014

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2014-9462	12/02/2014 12/31/2014	FDA/OMPT/CDRH/OCER/DFOI/	Ashley Santos BOSTON SCIENTIFIC CORPORATION	K1410382
2014-9463	12/02/2014 12/31/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tudor I. Oprea UNIVERSITY OF NEW MEXICO SCHOOL OF MEDICINE	NDA 019645, NDA 019698
2014-9464	12/02/2014 12/31/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Igor Gorlach FOLEY HOAG LLP	DESI report prepared by the NAS/CRS on diphenhydramine hydrochloride
2014-9465	12/02/2014 12/31/2014	FDA/OC/OES/DFOI/	BRANDON LEE CAUDLE CAUDLE #20711-058, BRANDON LEE	FSMA STANDARDS
2014-9466	12/02/2014 12/31/2014	FDA/OC/OES/DFOI/	BRANDON LEE CAUDLE CAUDLE #20711-058, BRANDON LEE	LIST OF RECALLS OVERSEEN BY THE FDA LAST FISCAL YR
2014-9467	12/02/2014 12/31/2014	FDA/OC/OES/DFOI/	BRANDDON LEE CAUDLE CAUDLE #20711-058, BRANDON LEE	NUMBER OF AERS RPTS LAST FISCAL YR
2014-9468	12/02/2014 12/31/2014	FDA/OC/OES/DFOI/	BRANDON LEE CAUDLE CAUDLE #20711-058, BRANDON LEE	FOI DAILY LOG 10/1-31/14
2014-9469	12/02/2014 12/31/2014	FDA/OC/OES/DFOI/	BRANDON LEE CAUDLE CAUDLE #20711-058, BRANDON LEE	NUMBER OF CRIMINAL INVESTIGATIONS CONDUCTED BY FDA LAST YR
2014-9470	12/02/2014 12/31/2014	FDA/OC/OES/DFOI/	BRANDON LEE CAUDLE CAUDLE #20711-058, BRANDON LEE	LIST OF FINES IMPOSED BY FDA LAST FISCAL YR
2014-9471	12/02/2014 12/31/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SUSAN PETERSON PETERSON, SUSAN	MYRBETRIQ - AERS

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2014-9472	12/02/2014 12/31/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KARSTEN BEYER BEYER, KARSTEN	ORANGE BOOK 1984-1999
2014-9473	12/02/2014 12/31/2014	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANIL SACHDEVA MYLAN INC	ACCORD HEALTHCARE - DOCETAXEL INJ CONCENTRATE ANDA 201-195 VIAL LABELS
2014-9474	12/02/2014 12/31/2014	FDA/OFVM/CFSAN/OCD/EOS/	DENNIS JOHNSTON JOHNSTON, DENNIS	OLIVES - CMLPNT
2014-9475	12/02/2014 12/31/2014	FDA/OFVM/CFSAN/OCD/EOS/	KATHLEEN R HENRY Hyman, Phelps & McNamara P.C.	ELECTRIC POWER REASEARCH INSTITUTE - FAP 0A4721
2014-9476	12/02/2014 12/31/2014	FDA/OGROP/ORACE-FO/MIN- DO/MIN-CB/	PETER L CREMA JR COZEN & O'CONNOR	PARKER'S FARM, MINNEAPOLIS, MN - LISTERIA CONTAMINATION RECS
2014-9477	12/02/2014 12/31/2014	FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/	Doe J	INDIVIDUAL RECS
2014-9478	12/02/2014 12/31/2014	FDA/OC/OL/	Michael Felberbaum THE ASSOCIATED PRESS	LETTER FROM JOHN BOEHNER TO FDA REGARDING GRANDFATHER DATE FOR DEEMING REGULATIONS
2014-9479	12/02/2014 12/31/2014	FDA/OC/OES/DDM/	David Reynolds INSIDE WASHINGTON PUBLISHERS	FDA-2014-N-0595 PUBLIC COMMENTS
2014-9480	12/03/2014 01/02/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Elaine Tronic Elaine Tronic	K132887
2014-9481	12/03/2014 01/02/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Beneque Cousin New York University - Wagner	ONCOLOGY, ANESTHESIOLOGY DRUGS - SHORTAGE RECS 12/02/2004 - 12/02/2014
2014-9482	12/03/2014 01/02/2015	FDA/OMPT/CDRH/OCER/DFOI/	Kerri LaPlaca COVIDIEN	K052267
2014-9483	12/03/2014 01/02/2015	FDA/OMPT/CDRH/OCER/DFOI/	Steve Zielinski Medtronic Energy and Component Center	PROCESS VALIDATION FOR MEDICAL DEVICES - COURSE MATERIALS
2014-9484	12/03/2014 01/02/2015	OC/CVM/OCD/	Dawna Campbell Fallon & McKinley, PLLC	DATA, ANALYSES OF ILLNESS OR DEATH IN HORSES RELATED TO FORAGE, FEED CONTAMINATION, ILLEGAL

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				FEED ADDITIVES ETC 01/01/2010 - 12/01/2014
2014-9485	12/03/2014 01/02/2015	FDA/OFVM/CFSAN/OCD/EOS/	CHRIS PIERS SEA ENTERPRISE	LIST OF DRINKING WATER BOTTLERS
2014-9486	12/03/2014 01/02/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	G. Srinivas Zydus Pharmaceuticals USA Inc.	NDA 018081
2014-9487	12/03/2014 01/02/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Melanie Julien MedinCell	NDA 020690
2014-9488	12/03/2014 01/02/2015	FDA/OC/OES/DFOI/ FDA/OC/OES/DDM/	Lisa Girion LOS ANGELES TIMES	FDA-2014-D-0091
2014-9489	12/03/2014 01/02/2015	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	Alan W. Heldman, MD Alan W. Heldman, MD on behalf of University of Miami	DR ALAN W HELDMAN, MIAMI, FL - EIR 01/01/2013 - 12/02/2014
2014-9490	12/03/2014 01/02/2015	FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/	Lisa Swanson Swanson, Lisa	INDIVIDUAL RECS
2014-9491	12/03/2014 01/02/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TJIERRY FILOUX TRISKEL INTEGRATED SERVICES	CAMPTOSAR NDA 20-571 -PHARMACOLOGY RVW
2014-9492	12/03/2014 01/02/2015	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	MICHAEL MANCINELLI CONWAY HOMER & CHIN-CAPLAN PC	INDIVIDUAL RECS
2014-9493	12/03/2014 01/02/2015	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 11/10-14/14
2014-9494	12/03/2014 01/02/2015	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 11-10-14/14
2014-9495	12/03/2014 01/02/2015	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD Center for Regulatory Services,Inc.	FOI DAILY LOG 11/10-14/14
2014-9496	12/03/2014	FDA/OMPT/CDER/ORP/DIDP/	Rosalie A. Lowe	NDA 050442 - SBA

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	01/02/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Genovi Pharmaceuticals, Inc.	
2014-9497	12/03/2014 01/02/2015	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Gerben van der Marel FD Media Group	PHILIPS, CLEVELAND, OH - 483 12/31/2013 - 12/01/2014
2014-9498	12/03/2014 01/02/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rosalie A. Lowe Genovi Pharmaceuticals, Inc.	NDA 016087
2014-9499	12/03/2014 01/02/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rosalie A. Lowe Genovi Pharmaceuticals, Inc.	NDA 007513
2014-9500	12/03/2014 01/02/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rosalie A. Lowe Genovi Pharmaceuticals, Inc.	ANDA 062475
2014-9501	12/03/2014 01/02/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rosalie A. Lowe Genovi Pharmaceuticals, Inc.	ANDA 071583
2014-9502	12/03/2014 01/02/2015	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 11/10-14/14
2014-9503	12/03/2014 01/02/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 11/10-14/14
2014-9504	12/03/2014 01/02/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 11/10-14/14
2014-9505	12/03/2014 01/02/2015	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 11/3-7/14
2014-9506	12/03/2014 01/02/2015	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DIALY LOG 11/3-7/14
2014-9507	12/03/2014	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD	FOI DAILY LOG 11/3-7/14

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	01/02/2015		Center for Regulatory Services,Inc.	
2014-9508	12/03/2014 01/02/2015	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 11/3-7/14
2014-9509	12/03/2014 01/02/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 11/3-7/14
2014-9510	12/03/2014 01/02/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 11/3-7/14
2014-9511	12/03/2014 01/02/2015	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 10/27-31/14
2014-9512	12/03/2014 01/02/2015	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 10/27-31/14
2014-9513	12/03/2014 01/02/2015	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD Center for Regulatory Services,Inc.	FOI DAILY LOG 10/27-31/14
2014-9514	12/03/2014 01/02/2015	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 10/27-31/14
2014-9515	12/03/2014 01/02/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 10/27-31/14
2014-9516	12/03/2014 01/02/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 10/27-31/14
2014-9517	12/03/2014 01/02/2015	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 10/20-24/14
2014-9518	12/03/2014 01/02/2015	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 10/20-24/14
2014-9519	12/03/2014 01/02/2015	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD Center for Regulatory Services,Inc.	FOI DAILY LOG 10/20-24/14
2014-9520	12/03/2014 01/02/2015	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 10/20-24/14
2014-9521	12/03/2014 01/02/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 10/20-24/14
2014-9522	12/03/2014	FDA/OC/OES/DFOI/	LAUREN S BARR	FOI DAILY LOG 10/20-24/14

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	01/02/2015		JH BARR & ASSOCIATES LLC	
2014-9523	12/03/2014 01/02/2015	FDA/OC/OES/DFOI/	LAULREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 10-27-31/14
2014-9524	12/04/2014 01/05/2015	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2013-1452
2014-9525	12/04/2014 01/09/2015	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/ FDA/OMPT/CTP/OD/	Stacy Ehrlich Kleinfeld Kaplan and Becker LLP	RECS FDA IMPORT ALERT 98-05
2014-9526	12/04/2014 01/05/2015	FDA/OMPT/CDRH/OCER/DFOI/	Joanne Lebrun MDC ASSOCIATES LLC	K972706
2014-9527	12/04/2014 01/05/2015	FDA/OGROP/ORO/CE-FO/DET-DO/DET-CB/	Rachel Johnson FOI Services, Inc.	CAYMAN CHEMICAL, ANN ARBOR, MI - EIR, 483
2014-9528	12/04/2014 01/05/2015	FDA/OMPT/CDRH/OCER/DFOI/	Joanne Lebrun MDC ASSOCIATES LLC	K091216
2014-9529	12/04/2014 01/05/2015	FDA/OGROP/ORO/CE-FO/BLT-DO/BLT-CB/	Michelle Puello Michelle Bean	PLASMA CARE AKA GRIFOLS, HAMPTON, VA - INSPECTION RECS 2008
2014-9530	12/04/2014 01/05/2015	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2013-4411
2014-9531	12/04/2014 01/05/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	510K RELEASED NOVEMBER 2014
2014-9532	12/04/2014 01/05/2015	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-2866
2014-9533	12/04/2014 01/05/2015	FDA/OGROP/ORO/CE-FO/PHI-DO/PHI-CB/	Lawrence F Muscarella, PhD LFM Healthcare Solutions, LLC	CUSTOM ULTRASONICS, IVYLAND, PA - 483, CORR 01/01/2013 - 12/03/2014
2014-9534	12/04/2014 01/05/2015	FDA/OMPT/CDRH/OCER/DFOI/	Paul Dryden ProMedic, Inc.	K141967
2014-9535	12/04/2014 01/05/2015	FDA/OMPT/CDRH/OCER/DFOI/	Paul Dryden ProMedic, Inc.	K142303
2014-9536	12/04/2014 01/05/2015	FDA/OMPT/CDRH/OCER/DFOI/	Lawrence F Muscarella, PhD LFM Healthcare Solutions, LLC	CUSTOM ULTRASONICS, IVYLAND, PA - RECS RE RECALL OR PRODUCT CORRECTION 09/01/2012 - 12/02/2014
2014-9537	12/04/2014 01/05/2015	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-2885

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2014-9538	12/04/2014 01/05/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Hugo BARTHELEMY Withings	K080670
2014-9539	12/04/2014 01/05/2015	FDA/OGROP/ORR/SW-FO/DEN-DO/DEN-CB/	Jason Ahlmann on behalf of Zija International, Inc. Zija International, Inc.	ZIJA INTERNATIONAL INC - COMPLAINTS, INVESTIGATIONS, VIOLATIONS 06/30/2014 - 12/03/2014
2014-9540	12/04/2014 01/05/2015	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-2144
2014-9541	12/04/2014 01/05/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Andrea Demakas ADVERSEEVENTS INC	ACTIQ, FENTORA, SUBSYS - AERS
2014-9542	12/04/2014 01/05/2015	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-818
2014-9543	12/04/2014 01/05/2015	FDA/OMPT/CDRH/OCER/DFOI/	Elaine Tronic Elaine Tronic	K112489
2014-9544	12/04/2014 01/05/2015	FDA/OMPT/CDRH/OCER/DFOI/	Hugo BARTHELEMY Withings	K122129
2014-9545	12/04/2014 01/05/2015	FDA/OMPT/CDRH/OCER/DFOI/	Hugo BARTHELEMY Withings	K070795
2014-9546	12/04/2014 01/05/2015	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	Tim Van Diest Hill-Rom Manufacturing Inc.	HILL-ROM MANUFACTURING INC, CHARLESTON, SC - 483 11/12/2013 - 11/15/2013
2014-9547	12/04/2014 01/05/2015	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	Tim Van Diest Hill-Rom Manufacturing Inc.	HILL ROM MANUFACTURING INC, CHARLESTON, SC - EIR 04/06/2009 - 04/14/2009
2014-9548	12/04/2014 01/05/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Iva Klemick Amerigen Pharmaceuticals Inc	AMERIGEN PHARMACEUTICALS INC - SBA ORENITRAM
2014-9549	12/04/2014 01/05/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jeanne Squeglia Interchem Corporation	NDA 050618 SBA
2014-9550	12/04/2014 01/05/2015	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	Andrew McNicoll PATHEON INC	IRIX PHARMACEUTICALS, GREENVILLE, SC; FLORENCE, SC - EIR 01/01/2009 - 12/01/2014

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2014-9551	12/04/2014 01/05/2015	FDA/OMPT/CDRH/OCER/DFOI/	Elaine Tronic Elaine Tronic	K123789
2014-9552	12/04/2014 01/05/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 16087
2014-9553	12/04/2014 01/05/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 13263
2014-9554	12/04/2014 01/05/2015	FDA/OMPT/CDRH/OCER/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	K091131
2014-9555	12/04/2014 01/05/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Maurice B. Klapwald The New York Public Library	All FDA reviews, memoranda, communications and other documents regarding peripheral neuropathy for the drugs Levaquin, levofloxacin and fluoroquinolones during the time period between January 1, 2003 to the present
2014-9556	12/04/2014 01/05/2015	FDA/OGROP/ORR/SE-FO/NOL-DO/NOL-CB/	Liza Lamb AMUSA	AMUSA, NASHVILLE, TN - CLOSEOUT LETTER 11/13/2012 - 12/31/2012
2014-9557	12/04/2014 01/05/2015	FDA/OFVM/CFSAN/OCD/EOS/	WILBUR JOHNSON, Jr. COSMETIC INGREDIENT REVIEW	LECITHIN; HYDROGENATED LECITHIN; LYSOLECITHIN ETC - BIOAVAILABILITY, TOXICITY
2014-9558	12/04/2014 01/05/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Luke Driscoll Standard Chem. and Pharm. Co., Ltd.	ZHEJIANG JINHUA CONBA BIO-PHARM CO LTD, CHINIA - EIR 03/15/2010 - 03/19/2010
2014-9559	12/04/2014 01/05/2015	FDA/OGROP/ORR/NE-FO/NWE-DO/NWE-CB/	Albert C. Cefalo ANALOGIC CORPORATION	ANALOGIC CORPORATION, PEABODY, MA - EIR 09/02/2014 - 09/30/2014
2014-9560	12/04/2014 01/05/2015	FDA/OFVM/CFSAN/OCD/EOS/	WILBUR JOHNSON, Jr. COSMETIC INGREDIENT REVIEW	CENTELIA ASIATICA; CENTELIA ASIATICA CALLUS CULTURE; CENTILIA ASIATICA FLOWER/LEAF/STEM EXTRACT ETC - BIOAVAILABILITY, TOXICITY
2014-9561	12/04/2014 01/05/2015	FDA/OMPT/CDRH/OCER/DFOI/	ANDREAS PIGNI REGENLAB	MEDSEP CORP, COVINA, CA - PALL CELERIS PC SYS BK120026
2014-9562	12/04/2014 01/05/2015	FDA/OMPT/CDRH/OCER/DFOI/	ANDREAS PIGNI REGENLAB	MEDSEP CORP, COVINA, CA - PALL CELERIS PC SYS BK100058

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2014-9563	12/04/2014 01/05/2015	OC/ORO/ORM/ OC/ORO/ORM/	LESLIE RAMSEY FDA NEWS	ALL INSP FOR BIOLOGIC, MEDICAL DVC, CLNCL TRIAL FACILITIES 11/1-30/14
2014-9564	12/04/2014 01/05/2015	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/SEA-DO/SEA-CB/	Doe J	CMPLNT 136716
2014-9565	12/04/2014 01/05/2015	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/	DONALD N. BLUE ZETETIC INC	LIST OF ALL REGULATED SHIPMENTS 11/16-30/14
2014-9566	12/04/2014 01/05/2015	FDA/OC/OES/DFOI/	Zach Fort Fort, Zach	PREVIOUSLY RELEASED RECS RE K-V PHARMACUETICAL COMPANY, ETHEX 01/01/1993 - 12/26/2012
2014-9567	12/04/2014 01/05/2015	FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/	WARREN WILLIAMS FOREST RESEARCH INSTITUTE	ISSAM RAAD MD, HOUSTON, TX - 483 10/2014
2014-9568	12/04/2014 01/05/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELAINE S. WALLER SEATTLE GENETICS INC	ADCETRIS (BRENTUXIMAB VEDOTIN) - FAERS
2014-9569	12/04/2014 01/05/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELAINE S. WALLER SEATTLE GENETICS INC	ADCETRIS (BRENTUXIMAB VEDOTIN) - AERS 3/1/14 TO 11/30/14
2014-9570	12/05/2014 01/06/2015	FDA/OC/OES/DFOI/	DAVID McFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED DAILY LOG 11/3-7/14
2014-9571	12/05/2014 01/06/2015	FDA/OC/OES/DFOI/	DAVID McFARLAND FDA REVIEW/FDA WEBVIEW	DAILY CLOSED LOG 10/20-24/14
2014-9572	12/05/2014 01/06/2015	FDA/OC/OES/DFOI/	DAVID McFARLAND FDA REVIEW/FDA WEBVIEW	WEEKLY CLOSED LOG 10/27-31/14
2014-9573	12/05/2014 01/06/2015	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 11/3-7/14
2014-9574	12/05/2014 01/06/2015	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY CLOSED LOG 11/10-14/14
2014-9575	12/05/2014 01/06/2015	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY CLOSED LOG 10/20-24/14

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2014-9576	12/05/2014 01/06/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 11/3-8/14
2014-9577	12/05/2014 01/06/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 11/10-15/14
2014-9578	12/05/2014 01/06/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 10/20-25/14
2014-9579	12/05/2014 01/06/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 10/27-11/1/14
2014-9580	12/05/2014 01/06/2015	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 11/3-7/14
2014-9581	12/05/2014 01/06/2015	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 10/20-24/14
2014-9582	12/05/2014 01/06/2015	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 10/27-31/14
2014-9583	12/05/2014 01/06/2015	FDA/OC/OES/DFOI/	MARLYNN WHITNEY COVINGTON BURLING LLP	DENTAL PRODS PANEL PLAQUE SUBCOMMITTEE - TRANS; 1981N-033-P
2014-9584	12/05/2014 01/06/2015	FDA/OC/OES/DFOI/	MARLYNN WHITNEY COVINGTON BURLING LLP	1981N-033P
2014-9585	12/05/2014 01/06/2015	FDA/OC/OES/DFOI/	KEVIN SHEPPARD ROPES & GRAY	DKTD-0800
2014-9586	12/05/2014 01/06/2015	FDA/OC/OES/DFOI/	ROBERT KING FDA NEWS	DKT 2006D-0031, 2014D-0447, 2014D-0903
2014-9587	12/05/2014 01/06/2015	OC/ORO/ OC/ORO/ OC/ORO/ORM/ OC/ORO/ORM/	Antonio Gargano UNIVERSITY OF MELBOURNE	LIST OF FIRM ISSUED RECALL DATA DEC 2013 TO PRESENT 12/01/2003 - 12/31/2014
2014-9588	12/05/2014 01/06/2015	FDA/OC/OES/DFOI/	RICARDO CARVAJAL Hyman, Phelps & McNamara P.C.	DKT 2005N-0404, 2005N-0279
2014-9589	12/05/2014 01/06/2015	FDA/OC/OES/DFOI/	BRYAN KOENIG FDA NEWS	DKT 2014D-0901-0001, 2014D-0902-0001
2014-9590	12/05/2014	FDA/OMPT/CDER/ERP/DIDP/	Eric White	NDA 018749

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	01/06/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MISSION PHARMACAL COMPANY/PRESIDENT	
2014-9591	12/05/2014 01/06/2015	FDA/OMPT/CDRH/OCER/DFOI/	Joshua Malamud Hyman, Phelps & McNamara P.C.	ILLUMINA - CORR WITH FDA REGARDING MARKETING AND PROMOTION OR SALE WITHOUT 510K
2014-9592	12/05/2014 01/06/2015	FDA/OC/OES/DFOI/	JAMES SMITH GC AMERICA INC	DKT 1980N-0042
2014-9593	12/05/2014 01/06/2015	FDA/OC/OES/DFOI/	ROBERT KING FDA NEWS	DKT 2014D-0779
2014-9594	12/05/2014 01/06/2015	OC/ORR/ORM/ OC/ORR/ORM/	Mark Prinz Registrar Corp	FOREIGN FOOD FACILITY INSPECTIONS 10/01/2011 - 09/30/2014
2014-9595	12/05/2014 01/06/2015	FDA/OC/OES/DFOI/	ROBERT KING FDA NEWS	DKT 2014N-1008, 2014D-1167
2014-9596	12/05/2014 01/06/2015	FDA/OC/OES/DFOI/	ROSS RENDELMAN Hogan Lovells, ILP	DKT 1998N-0583
2014-9597	12/05/2014 01/06/2015	FDA/OMPT/CDRH/OCER/DFOI/	Erin Kelly Erin Kelly	K133793
2014-9598	12/05/2014 01/06/2015	FDA/OC/OES/DFOI/	MARLYNN WHITNEY COVINGTON BURLING LLP	DKT 1981N-0033
2014-9599	12/05/2014 01/06/2015	FDA/OFVM/CFSAN/OCD/EOS/	Mark Prinz Registrar Corp	FOREIGN FOOD FACILITIES THAT RECEIVED A 483 08/01/2014 - 10/31/2014
2014-9600	12/05/2014 01/06/2015	FDA/OMPT/CDRH/OCER/DFOI/	John Guy NAIMCO, INC DBA RICHMAR, INC	K050469
2014-9601	12/05/2014 01/06/2015	FDA/OC/OES/DFOI/	ROBERT KING FDA NEWS	DKT 2014N-1108
2014-9602	12/05/2014 01/06/2015	FDA/OC/OES/DFOI/	Nathan Jensen Nathan Jensen	INDEX OF RECORDS MAINTAINED BY FDA
2014-9603	12/05/2014 01/06/2015	FDA/OC/OES/DFOI/	RYAN KOAT SIDLEY AUSTIN LLP	DKT 1980N-0042
2014-9604	12/05/2014 01/06/2015	FDA/OC/OES/DFOI/	BRYAN KOENIG FDA NEWS	DKT 2014N-168
2014-9605	12/05/2014 01/06/2015	FDA/OFVM/CFSAN/OCD/EOS/	Timothy Ritschel Bonica Spice, LTD	SYNEPALUM DULCIFICUM (MIRACLE BERRY) - APPROVAL RECS 01/01/1970 - 12/01/2014

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2014-9606	12/05/2014 01/06/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Soby M. Fennell Renaissance Pharma, Inc.	NDA 009190
2014-9607	12/05/2014 01/06/2015	FDA/OC/OES/DFOI/	JAQUELINE PROSCIA WILSON SONSINI ET AL	DKT 2014N-1168
2014-9608	12/05/2014 01/06/2015	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	Carla Scarmazzi, FDA & Life Sciences Specialist KING & SPALDING	ENDOCHOICE, INC, ALPHARETTA, GA - EIR, EXHIBITS, CORR RE SEPTEMBER 2014 INSPECTION
2014-9609	12/05/2014 01/06/2015	FDA/OC/OES/DFOI/	RICHARD KRASKA GRAS ASSOCIATES LLC	GRAS PETITION FOR COCOA BUTTER SUBSTITUTE FROM PALM OIL - 1988G-0388, 1984G-0384, 1988G-0388, ETC
2014-9610	12/05/2014 01/06/2015	FDA/OMPT/CDRH/OCER/DFOI/	Dehui Zeng Shenzhen Salubris Biomedical Engineering Co.,Ltd.	P860019, P880003 - SUMMARY OF SAFETY AND EFFECTIVENESS DATA 2014
2014-9611	12/05/2014 01/06/2015	FDA/OC/OES/DFOI/	JACKI PROSCIA WILSON SONSINI ET AL	DKT 2014N-1491, 2014D-1167, 2014D-0902
2014-9612	12/05/2014 01/06/2015	FDA/OC/OES/DFOI/	GILLY ARIE JFF	DKT 2014N-1243-0001, 2010P-0559
2014-9613	12/05/2014 01/06/2015	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/PA-FO/SEA- DO/SEA-CB/	Doe J	CMPLNT - INVESTIGATION, FOLLOW-UP ACTIVITIES
2014-9614	12/05/2014 01/06/2015	FDA/OFVM/CFSAN/OCD/EOS/	CHRISTINE L KEGGINS IGENE	CYANOTHECH CORP - HAEMATOCOCCUS PLUVIALIS EXTRACT CONTAINING ASTAXANTHIN ESTERS NDI NOTIFICATION NUMBER 717 PARTS I,11,111
2014-9615	12/05/2014 01/06/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN M ROBIN JOHN M ROBIN LAW OFC	MCNEIL PPC INC, JOHNSON & JOHNSON - TYLENOL, MOTRIN, MEMOS, ETC AERS
2014-9616	12/05/2014 01/06/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DANIELLE BRADLEY ROCHELLE MCCULLOUGH LLP	KEPRA, DEAKOTE, LAMICTAL, STEVENS-JOHNSON SYNDROME

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2014-9617	12/05/2014 01/06/2015	FDA/OC/OES/DFOI/	Doe J	REMRUM 15 MG - AERS
2014-9618	12/05/2014 01/06/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	DR SEBASTIAN SCHNEEWEISS HARVARD MEDICAL SCHOOL - ACTOS SCIENTIFIC STUDY
2014-9619	12/05/2014 01/06/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ROBERT J OUNJIAN CARPENTER ZUCKERMAN & ROWLEY LLP	PHENTERMINE - AERS
2014-9620	12/05/2014 01/06/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JEFF BROADFOOT EMERGENT BIOSOLUTIONS	CANGENE CORP - EIR 10/11-19/11
2014-9621	12/05/2014 01/06/2015	FDA/OMPT/CDRH/OCER/DFOI/	KRISTIN PABST GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES INC	GE MEDICAL SYSTEM INFORMATION TECHNOLOGIES INC, WAUWATOSA, WI - MAC 800 RESTING ECG ANALYSIS SYS K090212
2014-9622	12/05/2014 01/06/2015	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2014-9200
2014-9623	12/05/2014 01/06/2015	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2013-6047
2014-9624	12/05/2014 01/06/2015	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2013-6048
2014-9625	12/08/2014 01/07/2015	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 11/24-28/14
2014-9626	12/08/2014 01/07/2015	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 11/7-21/14
2014-9627	12/08/2014 01/07/2015	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION	FOI DAILY LOG 11/7-21/14

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			SOURCE	
2014-9628	12/08/2014 01/07/2015	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 11/24-28/14
2014-9629	12/08/2014 01/07/2015	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 11/24-28/14
2014-9630	12/08/2014 01/07/2015	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 11/17-21/14
2014-9631	12/08/2014 01/07/2015	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 11/24-28/14
2014-9632	12/08/2014 01/07/2015	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 11/17-21/14
2014-9633	12/08/2014 01/07/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 11/24-28/14
2014-9634	12/08/2014 01/07/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 11/17-21/14
2014-9635	12/08/2014 01/07/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 11/24-28/14
2014-9636	12/08/2014 01/07/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 11/17-21/14
2014-9637	12/08/2014 01/07/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 1/24-29/14
2014-9638	12/08/2014 01/07/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 11/17/22/14
2014-9639	12/08/2014 01/07/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 11/24-29/14
2014-9640	12/08/2014 01/07/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 11/17-22/14
2014-9641	12/08/2014 01/07/2015	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 11/17-21/14
2014-9642	12/08/2014	FDA/OMPT/CDRH/OCER/DFOI/	EQUASHIELD SYSTEM and BD	K083152, K120384

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	01/07/2015		Medical PROTECTOR, INJECTOR, CONNEC MAOR, ALON	
2014-9643	12/08/2014 01/07/2015	FDA/OMPT/CDRH/OCER/DFOI/	Peter Frenken PHILIPS CONSUMER LIFESTYLE	K141742
2014-9644	12/08/2014 01/07/2015	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 11/24-28/14
2014-9645	12/08/2014 01/07/2015	FDA/OMPT/CDRH/OCER/DFOI/	Eugenia Dolan Belldev Medical LLC	K013630, K955092, K942120
2014-9646	12/08/2014 01/07/2015	FDA/OC/OES/DFOI/	W3ILLIAM A OLSON PHD Center for Regulatory Services,Inc.	FOI DAILY LOG 11/17-21/14
2014-9647	12/08/2014 01/07/2015	FDA/OC/OES/DFOI/	Shaun Raviv Freelance Journalist	FOIA LOG 01/01/2014 - 12/06/2014
2014-9648	12/08/2014 01/07/2015	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD Center for Regulatory Services,Inc.	FOI DAILY LOG 11/24-28/14
2014-9649	12/08/2014 01/07/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Vimal Bahl BAXTER HEALTHCARE	CAF-DCF, BELGIUM - EIR, RESPONSES MAY 2013
2014-9650	12/08/2014 01/07/2015	FDA/OGROP/ORAP/PA-FO/LOS- DO/LOS-CB/	Deborah Wadkins Allergan, Deborah Wadkins	ALLERGAN - EIR 12/12/2013 - 12/23/2013
2014-9651	12/08/2014 01/07/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Vimal Bahl BAXTER HEALTHCARE	SANQUIN BLOOD SUPPLY FOUNDATION, AMSTERDAM, NETHERLANDS - EIR, 483, RESPONSE 10/01/2014 - 11/30/2014
2014-9652	12/08/2014 01/07/2015	FDA/OC/OES/	Kathleen Doherty Price School of Public Policy University of Southern California	MEASURING CONFLICT OF INTEREST AND EXPERTISE ON FDA ADVISORY COMMITTEES - SPREADSHEET OF DATA 01/01/2008 - 01/01/2010
2014-9653	12/08/2014 01/07/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ibrutinib - All Adverse Events Ken Tong	IMBRUVICA - AERS 11/01/2014 - 11/30/2014
2014-9654	12/08/2014 01/07/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Pembrolizumab - All Adverse Events Ken Tong	KEYTRUDA - AERS 11/01/2014 - 11/30/2014
2014-9655	12/08/2014	FDA/OMPT/CDER/ORP/DIDP/	Idelalisib - All Adverse Events	ZYDELIG - AERS 11/01/2014 - 11/30/2014

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	01/07/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ken Tong	
2014-9656	12/08/2014 01/07/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K093695
2014-9657	12/08/2014 01/07/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K113500
2014-9658	12/08/2014 01/07/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K100669
2014-9659	12/08/2014 01/15/2015	FDA/OC/OES/DFOI/	Anna Edney BLOOMBERG NEWS	APPLE MEETING RECS
2014-9660	12/08/2014 01/15/2015	FDA/OC/OES/DFOI/	Anna Edney BLOOMBERG NEWS	APPLE INC - MEMO OF MEETING DEC 2013
2014-9661	12/08/2014 01/07/2015	FDA/OMPT/CDRH/OCER/DFOI/	Dori Nazem westridge laboratories, Inc	K124044
2014-9662	12/08/2014 01/07/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Peter R. Breggin, MD Center for the Study of Empathic Therapy	HALOPERIDOL, RISPERIDONE - AERS
2014-9663	12/08/2014 01/07/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rowena D. Devlin Bayer HealthCare Pharmaceuticals Inc.	NDA 50495
2014-9664	12/08/2014 01/07/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Vimal Bahl BAXTER HEALTHCARE	CAF-DCF, BELGIUM - EIR, 483, RESPONSE 10/01/2014 - 11/30/2014
2014-9665	12/08/2014 01/07/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K082786
2014-9666	12/08/2014 01/07/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K102029
2014-9667	12/08/2014 01/07/2015	FDA/OC/OES/DFOI/	FATIIMA ASLAM Keller and Heckman LLP	DKT 2014P-0259
2014-9668	12/08/2014 01/07/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K083415

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2014-9669	12/08/2014 01/07/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K102709
2014-9670	12/08/2014 01/07/2015	FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/	John Barrymore CONSUMER	REMEL, KANSAS - 483, EIR 03/03/2014 - 10/01/2014
2014-9671	12/08/2014 01/07/2015	FDA/OC/OES/DFOI/	MCKENZIE CATO Hyman, Phelps & McNamara P.C.	DKT 2014N-1413 - COMMENTS
2014-9672	12/08/2014 01/07/2015	FDA/OGROP/ORR/SW-FO/DEN-DO/DEN-CB/	Marc C. Sanchez Contract In-House Counsel Consl. LLC	DERMA PEN - 483 07/01/2014 - 08/01/2014
2014-9673	12/08/2014 01/07/2015	FDA/OC/OES/DFOI/	BRYAN KOENIG FDA NEWS	DKT 2014D-1292-0001, 2014D-0852-0001, 2014N-1110-0001 - COMMENTS
2014-9674	12/08/2014 01/07/2015	FDA/OMPT/CDRH/OCER/DFOI/	Brenda Niel c/o Peter Schipelliti PHILIPS MEDICAL SYSTEMS	K922770
2014-9675	12/08/2014 01/07/2015	FDA/OC/OES/DFOI/	CELESTE WHEELER Kleinfeld Kaplan and Becker LLP	DKT 2005D-0340
2014-9676	12/08/2014 01/07/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Pallavi Ail The Financial Express	DRUG FACILITIES IN INDIA - 483 09/01/2014 - 12/05/2014
2014-9677	12/08/2014 01/07/2015	FDA/OC/OES/DFOI/	CHRIS CELESTE EAS CONSULTING GROUP LLC	DKT 1998P-0967
2014-9678	12/08/2014 01/07/2015	FDA/OC/OES/DFOI/	JOANNE HAWANA ARENT FOX LLP	DKT 1981N-0015
2014-9679	12/08/2014 01/07/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Erick Turner, M.D. Oregon Health & Science University	NDA 200603 S010, S011
2014-9680	12/08/2014 01/07/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Charlotte Witherspoon GEORGETOWN UNIVERSITY	TOTAL NUMBER OF ANDAS FILED SINCE HATCH-WAXMAN
2014-9681	12/08/2014 01/07/2015	FDA/OC/OES/DFOI/	MARY VIHSTADT VIHSTADT CONSULTING	DKT 1975N-0012

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2014-9682	12/08/2014 01/07/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K073057
2014-9683	12/08/2014 02/09/2015	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OMPT/CDRH/OCER/DFOI/	DAVID S V SHIRLEY McDowell Osburn Professional Association	SIEMENS HEALTHCARE DIAGNOSTIC - VISTA VITAMIN B ASSAY & RELATED COMPONENTS INVESTIGATION, ASSESSMENT RPTS, RECALLS LAST FIVE YRS
2014-9684	12/09/2014 01/08/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joshua Malamud Hyman, Phelps & McNamara P.C.	SUN PHARMACEUTICALS HALOL, INDIA - 483, EIR, ETC 01/01/2013 - 12/05/2014
2014-9685	12/09/2014 01/08/2015	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Akash Tewari Evercore ISI	LIST OF DRUG SHORTAGES 12/01/2008 - 12/01/2014
2014-9686	12/09/2014 01/08/2015	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Vimal Bahl BAXTER HEALTHCARE	SANQUIN BLOOD SUPPLY FOUNDATION, AMSTERDAM, NETHERLANDS - EIR, RESPONSE 05/01/2013 - 06/30/2013
2014-9687	12/09/2014 01/08/2015	FDA/OGROP/ORACE-SW-FO/DAL-DO/DAL-CB/	Zohra Chahal University of Texas Southwestern Medical Center	GRAHAM EMSLIE, MD - EIR, CLOSEOUT
2014-9688	12/09/2014 01/08/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	prashant patel fff pharma pvt ltd	Analytical HPLC method for impurity xyrem (sodium oxybate)
2014-9689	12/09/2014 01/08/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Marc Elia BRIDGER CAPITAL LLC	EXPAREL - BAD ADS COMPLAINTS, PACIRA PHARMACEUTICALS RESPONSE TO WARNING LETTER, LABELING DISCUSSION PRIOR TO WARNING LETTER
2014-9690	12/09/2014 01/08/2015	FDA/OMPT/CDRH/OCER/DFOI/	Marc C. Sanchez Contract In-House Counsel and Consultants, LLC	CYNERGY LLC - WARNING LETTER COMPLIANCE RECS 02/01/2013 - 12/08/2014
2014-9691	12/09/2014 01/08/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	G. Srinivas Zydus Pharmaceuticals USA Inc.	ANDA 077510

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-9692	12/09/2014 01/08/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jaya Ayyagari DR REDDY'S LABORATORIES INC	CADILA PHARMACEUTICALS, INDIA - 483 03/01/2014 - 03/31/2014
2014-9693	12/09/2014 01/08/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Erin Kelm FULD & COMPANY INC	ACTAVIS ODYSSEA, BELGIUM - EIR 08/01/2014 - 12/01/2014
2014-9694	12/09/2014 01/08/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Erica L Nicoll Novum Pharmaceutical Research Services	ANDA 220744
2014-9695	12/09/2014 01/08/2015	FDA/OFVM/CFSAN/OCD/EOS/	Alexandra Lobach Intertek Scientific & Regulatory Consulting	FCN 956
2014-9696	12/09/2014 01/08/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Darci Creer Darci Creer	XENAZINE - AERS
2014-9697	12/09/2014 06/11/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Brandon Beagle PhD PFC Development/New Alliance	IND BB-6195
2014-9698	12/09/2014 01/08/2015	FDA/OMPT/CDRH/OCER/DFOI/	Eric Forkosh Cooper Union - c/o Eric Forkosh	K131509
2014-9699	12/09/2014 01/08/2015	FDA/OMPT/CDRH/OCER/DFOI/	William Plishker IGI Technologies	K130393
2014-9700	12/09/2014 01/08/2015	FDA/OMPT/CDRH/OCER/DFOI/	William Plishker IGI Technologies	K062163
2014-9701	12/09/2014 01/08/2015	FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/	Michelle Petrini Petrini, Beatrice	BVO - TESTING, RESEARCH

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2014-9702	12/09/2014 01/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jaya Ayyagari DR REDDY'S LABORATORIES INC	SUN PHARMACEUTICALS, INDIA - 483 11/01/2013 - 12/02/2013
2014-9703	12/09/2014 01/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jaya Ayyagari DR REDDY'S LABORATORIES INC	DR REDDY'S LABORATORIES, LIMITED, INDIA - 483 11/01/2014 - 12/01/2014
2014-9704	12/09/2014 01/08/2015	FDA/OMPT/CDRH/OCER/DFOI/	William Plishker IGI Technologies	K141860
2014-9705	12/09/2014 01/08/2015	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Erica L Nicoll Novum Pharmaceutical Research Services	JOSEPH LEONARD LILLO, DO - EIR, CORR 02/03/2014 - 02/13/2014
2014-9706	12/09/2014 01/08/2015	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	Erica L Nicoll Novum Pharmaceutical Research Services	SNEEZE, WHEEZE, AND ITCH ASSOCIATES - EIR, CORR 12/03/2012 - 12/10/2012
2014-9707	12/09/2014 01/08/2015	OC/ORA/ OC/ORA/ OC/ORA/ORM/ OC/ORA/ORM/	John Templon Buzzfeed News	FDA ENFORCEMENT REPORTS CVS FORMAT 01/01/2004 - 12/08/2014
2014-9708	12/09/2014 01/08/2015	FDA/OMPT/CDRH/OCER/DFOI/	Teresa Bianchi Biosensors Europe SA	BIOSENSORS INTERNATIONAL PTE, LTD SINGAPORE - EIR 08/02/2010 - 08/05/2010
2014-9709	12/09/2014 01/08/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Anthony Le Poincare Medical	K111201
2014-9710	12/09/2014 01/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	VIPLIN ORCHID CHEMICALS PHARMACEUTICALS	ASTRAL STERI TECH PRIVATE LTD, GUJARAT, INDIA - EIR
2014-9711	12/09/2014 01/08/2015	FDA/OC/OES/DFOI/	CHRIS SZECHENYI ON POINT INVESTIGATIONS	EDAP TECHNOMED INC - ABLATHERM INTEGRATED IMAGING HIGH INTENSITY FOCUSED ULTRASOUND SYS - CLNCL TRIALS, AER, CORR, 2012 TO PRESENT
2014-9712	12/09/2014 01/08/2015	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	CHRISTIANNE C. MARIANO CASE MEDICAL INC	ASP EIR EXHIBITS JFI-JF7
2014-9713	12/09/2014	FDA/OMPT/CDER/ORP/DIDP/	KELLEE KIM	THIOLA (TIOPRONIN) - AER 12/17/88 TO 12/5/14

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	01/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ECOR1 CAPITAL LLC	
2014-9714	12/09/2014 01/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KELLEE KIM ECOR1 CAPITAL LLC	CHENODEOXYCHOLIC ACID (CENODAL) 1/08 TO 12/5/14 - AERS CHENODAL FIRST, CHENODEOXYCHOLIC ACID
2014-9715	12/09/2014 01/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	A LUKE SMITH RADICE LAW FIRM	HOSPIRA - ANGIOMAX ANDA 90-816, 90-811 APRVL LTR 2/3/13
2014-9716	12/09/2014 01/08/2015	OC/ORO/ OC/ORO/ FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/ OC/ORO/	KOERIS, MICHAEL	SEROVARS FREQUENCIES OF OCCURENCE OF SALMONELLA ISOLATES
2014-9717	12/09/2014 01/08/2015	FDA/OMPT/CDRH/OCER/DFOI/	CRAIG M. SILVERMAN PETER G ANGELOS LAW OFC	MINOR DELETIONS
2014-9718	12/09/2014 01/08/2015	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SW-FO/DEN- DO/DEN-CB/	CHARLENE NOVAK HALL & EVANS LLC	JIMMY JOHNS, DENVER, CO - E COLI
2014-9719	12/09/2014 01/08/2015	FDA/OFVM/CFSAN/OCD/EOS/	JEANNIE PERRON COVINGTON BURLING LLP	HAMPTON CREEK FOODS INC - CORR 11/19/14
2014-9720	12/09/2014 01/08/2015	FDA/OGROP/ORO/CE-FO/NWJ- DO/NWJ-CB/	PAUL B. CALLAHAN CHARLES RIVER LABS	HUNTINGDON LIFE SCIENCE, EAST MILLSTONE, NJ - EIR 2014
2014-9721	12/09/2014 01/08/2015	FDA/OGROP/ORO/SW-FO/DAL- DO/DAL-CB/	ARMANDO S. CHIU LITCHFIELD CACO LLP	PRECISION BLEND INC - OXYGEN CYLINDER EXPLOSION INVESTIGATION 9/11/14
2014-9722	12/09/2014 01/08/2015	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORO/NE-FO/NYK- DO/NYK-DCB/ OC/ORO/ OC/ORO/	JAVIER F. FLORES MANION GAYNOR ET AL	WONTON FOOD INC, BROOKYLN, NY - SALMONELLA ENTERIDIS INVESTIGATIONS, RECS, LAB TESTS, CASE RPTS, ETC.
2014-9723	12/10/2014	FDA/OMPT/CDER/ORP/DIDP/	MICHAIL AL-HUSSAYNE 11-B-	NEURONTIN, TOPAMAX - DRUG CLASSIFICATION,

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	01/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	1827 AL-HUSSAYNE, MICHAEL	CHEMICAL COMPOUND, AERS, ETC
2014-9724	12/10/2014 01/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SAMPSON LEE DR REDDY'S LABORATORIES INC	FOREST LAB INC - CARAFATE (SUCRALFATE) NDA 18-333 SBA
2014-9725	12/10/2014 01/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID J HEYER DAVID J HEYER LAW OFC	DR PETER R KOWEY, GEODON, ZIPRASIDONE - CORR, MEMOS, INVOICES, ETC
2014-9726	12/10/2014 01/09/2015	FDA/OMPT/CDRH/OCER/DFOI/	MCKANZIE CATO Hyman, Phelps & McNamara P.C.	BIOFRIEND BIOMASK N95 SURGICAL RESPIRATOR K122702; GLAXOSMITHKLINE CONSUMER HEALTHCARE - ACTIPROTECT UF N95 RESPIRATOR K093161
2014-9727	12/10/2014 01/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORO/ OC/ORO/ FDA/OC/OES/DFOI/	ROY BRASWELL MCKINNEY, BRASWELL & BUTLER LLC	DAVID L SPARKS, PROFESSIONAL COMPOUNDING CENTERS OF AMERICA - DOMPERIDONE WARNING LTRS, CORR, RECS 1/1/02, 1/9/04, 3/5/04
2014-9728	12/10/2014 03/20/2015	FDA/OC/OES/ FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/ OC/ORO/	RYAN NOAH SHAPIRO SHAPIRO, RYAN NOAH	JUST MAYO, JUST COOKIES, HAMPTON CREEK, ETC - EMAILS
2014-9729	12/10/2014 02/10/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Rachel Johnson FOI Services, Inc.	OSIRIS - RECS RE UNTITLED LETTER 09/26/2013
2014-9730	12/10/2014 01/09/2015	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORO/SE-FO/FLA- DO/FLA-CB/	David McKinney David McKinney	NUSCIENCE CORPORATION, LANCASTER, CA; LUMINA HEALTH PRODUCTS, SARASOTA, FL - INVESTIGATION RECS 01/01/2012 - 12/08/2014
2014-9731	12/10/2014 01/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	AMLODIPINE - AERS

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2014-9732	12/10/2014 01/09/2015	FDA/OMPT/OSMP/OCF/	Ken Trbovich MLV & Co.	FY 2013 OCP Performance Report
2014-9733	12/10/2014 01/09/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Darcey Pipinich CROWLEY FLECK PLLP	ADVERSE EVENT REPORT
2014-9734	12/10/2014 01/09/2015	FDA/OMPT/CDRH/OCER/DFOI/	Janice M Sich GE Healthcare	K133226
2014-9735	12/10/2014 01/09/2015	FDA/OFVM/CFSAN/OCD/EOS/	Garry M Wiltshire The Dow Chemical Company	FCN 1315
2014-9736	12/10/2014 01/09/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sara Wexler Koblitz Fish and Richardson P.C.	ANDA 076649 S3, 4, 7; ANDA 076373 S4, 5
2014-9737	12/10/2014 01/09/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Meera Yogarajah Interfaith Medical Center	ADALIMUMAB - AERS
2014-9738	12/10/2014 01/09/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Abhishek Gurnani Amin Talati & Upadhye, LLC	COMPLAINTS, APPLICATIONS, CORR ETC RE CANNABINOID
2014-9739	12/10/2014 01/09/2015	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	BETH ANN MCDERMOTT R&B FEEDS LLC	R&B FEEDS LLC, ATLANTA, IA - CMLPNTS, INSPS, INVESTIGATIONS, ETC
2014-9740	12/10/2014 01/09/2015	FDA/OMPT/OSMP/OCF/	Ken Trbovich MLV & Co.	ZALVISO - OCP CATEGORY CLASSIFICATION, OCP PERFORMANCE REPORT YEAR
2014-9741	12/10/2014 01/09/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Abhishek Gurnani Amin Talati & Upadhye, LLC	GW PHARMACEUTICALS - RECS RE SATIVEX, EPIDIOLEX

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2014-9742	12/10/2014 02/23/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OC/OES/ FDA/OMPT/OSMP/OCP/	Rachel Johnson FOI Services, Inc.	CORR WITH ARENT FOX ETC RE SECTION 361 PRODUCTS
2014-9743	12/10/2014 01/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anita Sapper Anita Sapper	LITHIUM - AERS
2014-9744	12/10/2014 01/09/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Manish Ahuja BioTex Inc.	K031168
2014-9745	12/10/2014 01/09/2015	FDA/OFVM/CFSAN/OCD/EOS/	BETH W TRENOR MILLIKEN CHEMICAL	FCN 608
2014-9746	12/10/2014 01/09/2015	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORAN/NE-FO/NWE- DO/NWE-CB/	Mike McIntire THE NEW YORK TIMES	FRABAZYME - SHORTAGE RECS 01/01/2009 - 12/31/2013
2014-9747	12/10/2014 01/09/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Manish Ahuja BioTex Inc.	K033836
2014-9748	12/10/2014 01/09/2015	FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/	Jake Rosenwasser HBO REAL SPORTS	Dietary Supplement Use in America's Military
2014-9749	12/10/2014 01/09/2015	FDA/OMPT/CDRH/OCER/DFOI/	Manish Ahuja BioTex Inc.	K032590
2014-9750	12/10/2014 01/09/2015	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John Walsh James Alexander Corporation	SWATI MENTHOL & ALLIED CHEMICALS, LTD, INDIA - EIR, 483, RECALL 12/01/2011 - 12/09/2014

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2014-9751	12/10/2014 01/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dustin Block IPD Analytics, LLC	ANDA 201984
2014-9752	12/10/2014 01/09/2015	FDA/OMPT/CDRH/OCER/DFOI/	Gary Conger Conger Consulting	K133225
2014-9753	12/10/2014 01/09/2015	FDA/OMPT/CDRH/OCER/DFOI/	Aaron Hargrave Positron Corporation	K042257, K041543, K050559
2014-9754	12/10/2014 01/09/2015	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	LAWRENCE J BOHANNON BOHANNON ROGERS PACELLA & SIMPSON	MEDTRONIC INC - 8 LEAD SPINAL CORD STIMULATOR RECALLS, CMLPNTS LAST 2 YRS
2014-9755	12/10/2014 01/09/2015	FDA/OGROP/ORACE-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORACE-FO/DAL-DO/DAL-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	EMANUEL CALENOFF MD CALENOFF, EMANUEL	INDIVIDUAL RECS
2014-9756	12/10/2014 01/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID J HEYER DAVID J HEYER LAW OFC	DR HERBERT YALE MELTZER, GEODON, ZIPRASIDONE - CORR, MEMOS, INVOICES, ETC
2014-9757	12/10/2014 01/09/2015	FDA/OC/OCC/	DARREN BATES BATES, DARREN	ELIZABETH DICKENSON LTR 12/5/13
2014-9758	12/11/2014 01/12/2015	FDA/OGROP/ORACE-FO/DAL-DO/DAL-CB/	Rod Walker QUINTILES TRANSNATIONAL CORP	PAHL PHARMACEUTICAL RESEARCH, OKLAHOMA CITY, OK - 483, EIR 01/02/2013 - 12/31/2013
2014-9759	12/11/2014 01/12/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bonnie Safyurtlu Allergan, Deborah Wadkins	ANDA 201894

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2014-9760	12/11/2014 01/12/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Christy Ferrell Bon Secours Richmond Community Hospital	METHYLPREDNISOLONE - AERS
2014-9761	12/11/2014 01/12/2015	FDA/OMPT/CDRH/OCER/DFOI/	Stephen McKelvey Zimmer, Inc.	K852560, K852562
2014-9762	12/11/2014 01/12/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Chi Ho Marciniak Chi Ho Marciniak	NDA 021526 S 004
2014-9763	12/11/2014 01/12/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Thomas A. Marciniak Thomas A. Marciniak, M.D.	NDA 021526 S004
2014-9764	12/11/2014 01/12/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	David Kim Partner Fund Management	SUN PHARMACEUTICAL INDUSTRIES - 483 11/01/2013 - 12/05/2014
2014-9765	12/11/2014 01/12/2015	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORA/ OC/ORA/	Abigail Blodgett and Mark Todzo Lexington Law Group on behalf of the Center for Environmental Health	BABYGANICS FOAMING HAND SANITIZER, BABYGANICS SHAMPOO AND BODY WASH, CETAPHIL RESTORADERM BODY WASH ETC - MEDWATCH REPORTS, CONSUMER COMPLAINTS
2014-9766	12/11/2014 01/12/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rensi Sutaria Banner Life Sciences, LLC	NDA 019821
2014-9767	12/11/2014 01/12/2015	FDA/OC/OES/DDM/ FDA/OMPT/CDRH/OCER/DFOI/	Jose Campo Campo Quality Consulting LLC	DEN140019
2014-9768	12/11/2014 01/12/2015	FDA/OMPT/CDRH/OCER/DFOI/	mark julian mark julian	K121719

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2014-9769	12/11/2014 01/12/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	James Hannon Respira Therapeutics	DMF17864, TYPE 3
2014-9770	12/11/2014 01/12/2015	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	Sybil Talbert ENCO Pharmaceutical Development, Inc.	ENCO PHARMACEUTICAL DEVELOPMENT INC - EIR 07/07/2014 - 12/10/2014
2014-9771	12/11/2014 01/12/2015	FDA/OMPT/CDRH/OCER/DFOI/	mark julian mark julian	K130174
2014-9772	12/11/2014 01/12/2015	FDA/OMPT/CDRH/OCER/DFOI/	mark julian mark julian	K131290
2014-9773	12/11/2014 01/12/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kathy McGown FOXKISER	NDA 206627
2014-9774	12/11/2014 02/24/2015	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Rachel Johnson FOI Services, Inc.	SURGICAL BIOLOGICS - RECS RE UNTITLED LETTER 08/28/2013
2014-9775	12/11/2014 01/12/2015	FDA/OMPT/CDRH/OCER/DFOI/	Janice M Sich GE Healthcare	K103429
2014-9776	12/11/2014 01/12/2015	FDA/OGROP/ORR/CE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORR/CE-FO/CHIDO/CHI-CB/ FDA/OGROP/ORR/CE-FO/CINDO/CIN-CB/ FDA/OGROP/ORR/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORR/NE-FO/NWEDO/NWE-CB/ FDA/OGROP/ORR/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORR/PA-FO/LOSDO/LOS-CB/ FDA/OGROP/ORR/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORR/PA-FO/SEA-	Emma Quail UNITE HERE	FLYING FOOD GROUP, LOS ANGELES, CA, HARBOR CITY, CA, BURLINGAME, CA ETC - 483

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		DO/SEA-CB/ FDA/OGROP/ORR/SE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORR/SW-FO/DEN-DO/DEN-CB/		
2014-9777	12/11/2014 01/12/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	REBECCA L. DANDEKER MORGAN LEWIS & BOCKIUS LLP	TRIFARMA SPA, MILANO, ITALY - EIR
2014-9778	12/11/2014 01/12/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	REBECCA L. DANDEKER MORGAN LEWIS & BOCKIUS LLP	TRIFARMA SPA, MILANO, ITALY - 483 2/1/14 TO 10/31/14
2014-9779	12/11/2014 01/12/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARY STIPANCIC PHARMA MEDICA RESEARCH INC	PHARMA MEDICA RESEARCH INC, MISSISSAUGA, ON - EIR 11/17-21/14
2014-9780	12/11/2014 01/12/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LISA BENNETT bennett, lisa	DIFLORASONE DIACETATE - AER
2014-9781	12/11/2014 01/12/2015	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	ELENA HOWELL HOGAN LOVELLS LLP	2014-9089
2014-9782	12/11/2014 01/12/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MICHAEL BRALKOWSKI GFS CHEMICALS	MEGLUMINE - CLNCL STUDY
2014-9783	12/11/2014 01/12/2015	FDA/OGROP/ORR/CE-FO/CIN-DO/CIN-CB/	LEWIS MORRIS LECLAIR RYAN	PHILIPS MEDICAL SYSTEMS, CLEVELAND, OH - INSP CORR, RECS 9/24/13 TO 1/28/14
2014-9784	12/11/2014 01/12/2015	FDA/OC/OES/DDM/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN T. JASNOCH SCOTT & SCOTT LLP	QRX PHARMA LTD - MOXDUO (MORPHINSE SULFATE, OXYCODONE HCL) NDA 203-077 FDA

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2014-9785	12/11/2014 01/12/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WILLIAM McINTYRE, Ph.D. LUPIN PHARMACEUTICALS INC	KENALOG CREAM NDA 11-601 SBA
2014-9786	12/11/2014 01/12/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SAMPSON LEE DR REDDY'S LABORATORIES INC	FORREST LAB INC - CARAFA NDA 19-183 SBA
2014-9787	12/12/2014 01/13/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bayer Mirena IUD Sandy Hrovat	MIRENA IUD - AERS
2014-9788	12/12/2014 01/13/2015	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	laura Garvey INC RESEARCH	INC RESEARCH, TORONTO, CANADA; MORGANTOWN, VW; RALEIGH, NC, ETC - EIR 07/01/2009 - 09/30/2014
2014-9789	12/12/2014 01/13/2015	FDA/OMPT/CDRH/OCER/DFOI/	Leon Amariglio Lexington Medical, Inc.	P130026, P060019 S029
2014-9790	12/12/2014 01/13/2015	FDA/OMPT/CDRH/OCER/DFOI/	Samuel Choi Norfolk Medical Products	K961088
2014-9791	12/12/2014 01/13/2015	FDA/OFVM/CFSAN/OCD/EOS/	Jason Bagley truthinadvertising.org	LAMININE - AERS
2014-9792	12/12/2014 01/13/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Andrea Demakas ADVERSEEVENTS INC	CONTRAVE, TRULICITY, ORBACTIV ETC - AERS
2014-9793	12/12/2014 01/13/2015	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	Neetu Dhaliwal Visium Asset Mgmt	CONMED DENVER - 483 10/01/2014 - 12/08/2014

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2014-9794	12/12/2014 01/13/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	2014-9200
2014-9795	12/12/2014 01/16/2015	FDA/OMPT/CDRH/OCER/DFOI/	THOMAS J QUINN QUINN, THOMAS J	OFFICE OF THE OMBUDSMAN - COMM
2014-9796	12/12/2014 01/13/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Catherine Riva Catherine Riva	STN: BL 125508/0
2014-9797	12/12/2014 01/13/2015	FDA/OGROP/ORR/SE-FO/FLA- DO/FLA-CB/	ANNE MULVIHILL BIOMET 31	BIOMET 31, PALM BEACH GARDENS, FL - EIRS 8/4-6/14
2014-9798	12/12/2014 01/13/2015	FDA/OC/OES/DFOI/	JOSEPH BECKER BECKER F46642, JOSEPH	FOLGERS BRAND INSTANT COFFEE - ANALYSIS PERFORMED ON CAFFEINE CONTENT, EFFECTS UPON CONSUMING PROD OVER SHORT TIME SPAN
2014-9799	12/12/2014 01/13/2015	FDA/OC/OES/DFOI/	DEVA SUNDARARAJAN GLOBAL TRADE INTELLIGENCE INC	2014-8183 - MINOR DELETIONS
2014-9800	12/15/2014 01/14/2015	FDA/OMPT/CDRH/OCER/DFOI/	John Minier SMALL BONE INNOVATIONS	K012078
2014-9801	12/15/2014 01/14/2015	FDA/OMPT/CTP/OD/	Desmond Jenson Tobacco Control Legal Consortium	All grandfathered product determination letters issued by the Center for Tobacco Products to the R.J. Reynolds Tobacco Company, Reynolds American Inc., RAI Services or any related entity 06/22/2009 - 12/12/2014
2014-9802	12/15/2014 01/14/2015	FDA/OMPT/CDRH/OCER/DFOI/	John Minier SMALL BONE INNOVATIONS	K003033
2014-9803	12/15/2014 01/14/2015	FDA/OMPT/CDRH/OCER/DFOI/	John Minier SMALL BONE INNOVATIONS	K022771
2014-9804	12/15/2014 01/14/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Charles J Cote MD Charles J Cote MD	ANAPHLAXIS - AERS
2014-9805	12/15/2014 01/14/2015	FDA/OGROP/ORR/CE-FO/MIN- DO/MIN-CB/	Rachel Johnson FOI Services, Inc.	3M, ST PAUL, MN - EIR
2014-9806	12/15/2014 01/14/2015	FDA/OFVM/CFSAN/OCD/EOS/	Scott Burya Akzo Nobel Packaging Coatings	FCN 1461
2014-9807	12/15/2014 01/14/2015	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	MANUFACTURER, IMPORTERS OF TOBACCO PRODUCTS - USER FEES STARTING OCT 1, 2014 ETC
2014-9808	12/15/2014	FDA/OMPT/CTP/OD/	Rachel Johnson	TOBACCO ESTABLISHMENT REGISTRATIONS & TOBACCO

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	01/14/2015		FOI Services, Inc.	PRODUCT LISTINGS AUGUST 2014 TO PRESENT
2014-9809	12/15/2014 01/14/2015	FDA/OMPT/CDRH/OCER/DFOI/	John Minier Small Bone Innovvations, Inc	K010847
2014-9810	12/15/2014 01/14/2015	FDA/OMPT/CTP/OD/	Desmond Jenson Tobacco Control Legal Consortium	REVO TOBACCO PRODUCT - CORR, REPORTS, ETC 06/22/2009 - 12/12/2014
2014-9811	12/15/2014 01/14/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jesse McLean Toronto Star	APOTEX, CANADA - 483 01/01/2014 - 12/12/2014
2014-9812	12/15/2014 01/15/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-9235
2014-9813	12/15/2014 01/15/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-8418
2014-9814	12/15/2014 01/15/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-9156
2014-9815	12/15/2014 01/15/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-8300
2014-9816	12/15/2014 01/15/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-8375
2014-9817	12/15/2014 01/15/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-9192
2014-9818	12/15/2014 01/15/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-9338 REQUEST LETTER ONLY
2014-9819	12/15/2014 01/15/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-8848 - REQUEST LETTER ONLY
2014-9820	12/15/2014 01/15/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-9203 - REQUEST LETTER ONLY
2014-9821	12/15/2014 01/15/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-9199 - REQUEST LETTER ONLY
2014-9822	12/15/2014 01/15/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-9164 - REQUEST LETTER ONLY
2014-9823	12/15/2014 01/15/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-8998 - REQUEST LETTER ONLY

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2014-9824	12/15/2014 01/15/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-8969 - REQUEST LETTER ONLY
2014-9825	12/15/2014 01/15/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-8857 - REQUEST LETTER ONLY
2014-9826	12/15/2014 01/15/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-8739 - REQUEST LETTER ONLY
2014-9827	12/16/2014 01/16/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	chris johns CHRIS JOHNS & ASSOCS	HEPTAVAX B - SBA
2014-9828	12/16/2014 01/16/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lauren Farruggia Hyman, Phelps & McNamara P.C.	ANDA 204234 - APPROVAL LETTER
2014-9829	12/16/2014 01/16/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Alina Marciniak Alina Marciniak	NDA 021526 S 004 ACTION PACKAGE
2014-9830	12/16/2014 01/16/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ADITYA KHEMKA AMBIT CAPITAL PVT LTD	IPCA, SILVASSA, INDIA - 483 12/01/2014 - 12/15/2014
2014-9831	12/16/2014 01/16/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Saion Mukherjee NOMURA INTERNATIONAL PLC	IPCA, SILVASSA, INDIA - 483 12/01/2014 - 12/31/2014
2014-9832	12/16/2014 01/16/2015	FDA/OMPT/CDRH/OCER/DFOI/	Ahava Stein Brainsway Ltd.	K122288 - SE LETTER
2014-9833	12/16/2014 01/16/2015	OC/ORA/ OC/ORA/ FDA/OGROP/ORANE-FO/NYK- DO/NYK-DCB/ OC/ORA/ OC/ORA/	Lana Kazangian Lana Kazangian CHB	AGT-0010459-7 BL# UASUNGLOS001626 CONT# UACU8308424
2014-9834	12/16/2014	FDA/OMPT/CDER/ORP/DIDP/	Uday Shetty	IPCA, INDORE, INDIA; SILVASSA, INDIA - 483 01/01/2014 - 12/14/2014

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	01/16/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Drug Regulations	
2014-9835	12/16/2014 01/16/2015	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/NE-FO/NYK- DO/NYK-DCB/	Lana Kazangian Lana Kazangian CHB	AGT-0008500-2 BL# SAFM752756044 CONT# PONU0413020
2014-9836	12/16/2014 01/16/2015	FDA/OGROP/ORO/CE-FO/MIN- DO/MIN-CB/	Jamie Berger Spectrum Plastics Group	SPECTRUM PLASTICS GROUP, MINNEAPOLIS, MN - EIR 08/18/2014 - 08/20/2014
2014-9837	12/16/2014 01/16/2015	FDA/OGROP/ORO/NE-FO/NYK- DO/NYK-DCB/	Eleanor DaCosta United States Pharmacopeial Convention (USP)	CBP Entry Number 417-0282777-9; CBP Line Number 1; FDA Line Number 1; Refusal Date 7/12/2012 - LAB RECS
2014-9838	12/16/2014 01/16/2015	FDA/OMPT/CDRH/OCER/DFOI/	Anthony Pavel Morgan, Lewis & Bockius LLP	K003909
2014-9839	12/16/2014 01/16/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K132429
2014-9840	12/16/2014 01/16/2015	FDA/OC/OES/DFOI/	Nathaniel August Mangrove Partners	AHRQ, CISNET COST EFFECTIVENESS STUDY 12/15/2012 - 12/15/2014
2014-9841	12/16/2014 01/16/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anubhav agarwal CREDIT SUISSE	IPCA LABORATORIES, SILVASSA, INDIA - 483 12/07/2014 - 12/15/2014
2014-9842	12/16/2014 01/16/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rakhi Agg Agg, Rakhi	IPCA LABORATORIES, SILVASSA, INDIA - 483 12/07/2014 - 12/15/2014
2014-9843	12/16/2014 01/16/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Thomas Ayala Grant & Eisenhofer P.A.	ZOFRAN - APPROVALS, STUDIES, AERS ETC
2014-9844	12/16/2014 01/16/2015	FDA/OMPT/CDRH/OCER/DFOI/	JOSEPH WALKER Walker, Joseph	COMPLAINTS MADE ABOUT TREATMENT CENTERS PROMOTING HYPERBARIC OXYGEN FOR CLINICAL USES NOT CLEARED BY FDA 12/31/2010 - 12/15/2014
2014-9845	12/16/2014	FDA/OC/OES/DFOI/		FOI DAILY LOG 12/1-6/14

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	01/16/2015		FOI Services, Inc.	
2014-9846	12/16/2014 01/16/2015	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 121-6/14
2014-9847	12/16/2014 01/16/2015	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD Center for Regulatory Services,Inc.	FOI DAILY LOG 12-1-5/14
2014-9848	12/16/2014 01/16/2015	FDA/OC/OES/DFOI/	DEBRA LL COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 12/1-5/14
2014-9849	12/16/2014 01/16/2015	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 12/1-5/14
2014-9850	12/16/2014 01/16/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 12/1-5/14
2014-9851	12/16/2014 01/16/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 12/1-6/14
2014-9852	12/16/2014 01/16/2015	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 12/1-5/14
2014-9853	12/16/2014 01/16/2015	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 12/1-5/14
2014-9854	12/16/2014 01/16/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 12/1-5/14
2014-9855	12/16/2014 01/16/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	J ALEX WATKINS CAPITELLI & WICKER	GOLD BOND BODY POWDER REGULAR STRENGTH - AERS
2014-9856	12/16/2014 01/16/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	J ALEX WATKINS CAPITELLI & WICKER	GOLD BOND BODY POWDER EXTRA STRENGTH - AERS
2014-9857	12/16/2014 01/16/2015	FDA/OGROP/ORP/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KATHLEELN R HENRY Hyman, Phelps & McNamara P.C.	EMED TECHNOLOGIES CORP - VERSARATE FLOW CONTROLLER LTRS, EMAILS, CORR 1/14 TO PRESENT

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/		
2014-9858	12/16/2014 01/16/2015	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	KATHLEEN R HENRY Hyman, Phelps & McNamara P.C.	EMED TECHNOLOGIES CORP - INFUSET FLOW CONTROLLER EXTENSION SET LTRS, EMAILS, MEMOS, ETC 1/14 TO PRESENT, EIRS, 483'S 1/12 TO PRESENT
2014-9859	12/16/2014 01/16/2015	FDA/OMPT/CDRH/OCER/DFOI/	CHANCE WELDON MEYERSON LAW FIRM PC	MEDTRONIC - NEUROSTIMULATORS MODEL NUMBERS 37702, 37711, 37713, 510KS, PMAS, RPTS, ETC
2014-9860	12/16/2014 01/16/2015	FDA/OMPT/CDRH/OCER/DFOI/	CHANCE WELDON MEYERSON LAW FIRM PC	ST JUDE MEDICAL - EON OR EON IMINI IMPLANTABLE PULSE GENERATORS 510KS, PMAS, RPTS, ETC
2014-9861	12/16/2014 01/16/2015	FDA/OMPT/CDRH/OCER/DFOI/	WILLIAM ZINNANTI WILLIAM J ZINNANTI MD PHD	K930511 - DECISION LTR
2014-9862	12/16/2014 01/16/2015	FDA/OC/OES/DFOI/	CECIL M FERGUSON FERGUSON #272193, CECIL M	FORMS TO MAKE FOI REQUEST
2014-9863	12/16/2014 01/16/2015	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	ONIMIPOD - INVESTIGATION
2014-9864	12/16/2014 01/16/2015	FDA/OC/OES/DFOI/	M BRENNEN BOZE RYMER MOORE JACKSON ETA	SPECIALTY COMPOUNDING PHARMACY - RECS
2014-9865	12/16/2014 01/16/2015	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/ORO/DIOP/	DONALD N BLUE ZETETIC INC	ALL SHIPMENTS REGULATED BY US FDA 12/1-15/14
2014-9866	12/16/2014 01/16/2015	FDA/OFVM/CFSAN/OCD/EOS/	MICHAEL M GABA HOLLAND AND KNIGHT	MIRA WINERY LLC - OCEAN-AGED WINES INVESTIGATION
2014-9867	12/16/2014 01/16/2015	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDRH/OCER/DFOI/	AMARJIT JOWANDHA JOWANDHA, AMARJIT	AMARJIT JOWANDHA - RECS 4/1/13 TO 1/31/14
2014-9868	12/16/2014 01/16/2015	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	Avital Barlev Alpha-Bio Tec. Ltd	BIOMET 3I DENTAL IMPLANT RECALL Z-1458-2014 04/01/2014 - 12/01/2014
2014-9869	12/16/2014 01/16/2015	FDA/OC/OES/DFOI/	Christine Kim UC BERKELEY	NEUTROGENA COSMETIC PRODUCTS 01/01/2013 - 12/15/2014
2014-9870	12/17/2014 01/20/2015	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	Jennifer L. Counts PROCTER & GAMBLE	Retail Sample Testing and Results of Pampers Baby Wipes - Sample Number 888892
2014-9871	12/17/2014 01/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ann Fishman, Esq. Ann Fishman, Esq.	New Drug Application and Attachments and Supplementary Information for Synthroid

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2014-9872	12/17/2014 01/20/2015	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	Chemistry review memoranda and any releasable data relating to dietary exposure to silver in several FCN
2014-9873	12/17/2014 01/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	Russ Garrison VerAvanti Inc.	K842481
2014-9874	12/17/2014 01/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	Russ Garrison VerAvanti Inc.	K001408
2014-9875	12/17/2014 01/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	Russ Garrison VerAvanti Inc.	K911090
2014-9876	12/17/2014 01/20/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Allison Bratzel Robert W. Baird & Co.	MAKENA - AERS
2014-9877	12/17/2014 01/20/2015	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Robert P. Tomaselli RPT Medical Products Consulting Inc	ATRIUM INNOVATIONS, PITTSBURGH, PA - EIR 09/01/2012 - 01/01/2013
2014-9878	12/17/2014 01/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	Russ Garrison VerAvanti Inc.	K951721
2014-9879	12/17/2014 01/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	Russ Garrison VerAvanti Inc.	K952638
2014-9880	12/17/2014 01/20/2015	FDA/OC/OCC/	Michelle Dickinson Michelle Dickinson	BTG - SUBPOENA RE LC BEAD 01/01/2014 - 12/15/2014
2014-9881	12/17/2014 01/20/2015	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	JEFF BAILLON FOX 9 NEWS	DR STEPHEN OLSON, UINIV OF MINNESOTA - BIORESEARCH MONITORING INQUIRY, SITE VISIT 10/14, 11/14
2014-9882	12/17/2014 01/20/2015	FDA/OMPT/CTP/OD/	JEFFREY A BURD BURD, JEFFREY A	RAW CONE NATURAL UNREFINED ROLLING PAPERS - INVESTIGATION RECS
2014-9883	12/17/2014 01/20/2015	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/ FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OGROP/ORACE-FO/MIN-	ADAM KREMR SHUR-GREEN FARMS LLC	HERITAGE ENVIRONMENTAL, HERITAGE INTERACTIVE, GA WINTNER & SON CO, ETC - 483S

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		DO/MIN-CB/		
2014-9884	12/17/2014 01/20/2015	OC/ORO/ OC/ORO/	MARK PRINZ Registrar Corp	LIST OF FIRMS THAT RECEIVED NOTICES OF INSP
2014-9885	12/17/2014 01/20/2015	OC/ORO/ OC/ORO/	CATHERINE CARMANY SPARKLING CITY RECORDS	SPECIALTY COMPOUNDING LLC, CEDAR PARK, TX - RECS
2014-9886	12/17/2014 01/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	DOUGLAS E CHABOT DECOF DECOF & BARRY	STRYKER ORTHOPAEDICS - LFIT ANATOMIC V40 FEMORAL HEAD 510K, CORR
2014-9887	12/17/2014 01/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	DOUGLAS E CHABOT DECOF DECOF & BARRY	STRYKER ORTHOPAEDICS - TRIDENT X3 0 DEGREE POLYETHYLENE INSERT 510K, CORR
2014-9888	12/17/2014 01/20/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	DOUGLAS E CHABOT DECOF DECOF & BARRY	STRYKER ORTHOPAEDICS - TRIDENT PSL HA CLUSTER ACETABULAR SHELL 510K, CORR
2014-9889	12/17/2014 01/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	DOUGLAS E CHABOT DECOF DECOF & BARRY	STRYKER ORTHOPAEDICS - ACCOLADE TMZF PLUS 127 NECK ANGLE V40 HIP STEM 510K, CORR
2014-9890	12/17/2014 01/20/2015	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	LUCY LU DFEC ENTERPRISE INC	NATURE HONEY ENTRY #9HX-5500134-8, ENTRY #CFS-7500429-3
2014-9891	12/17/2014 01/20/2015	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	LUCY LU DFEC ENTERPRISE INC	NATURE HONEY ENTRY #9HX-5500138-9, ENTRY #CFS-7500417-8
2014-9892	12/17/2014 01/20/2015	FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORO/SE-FO/SJN-DO/SJN-CB/	HENRY F BAYARD COLE, SCOTT & KISSANE	ST JUDE - PM2210; GUIDANT - ATRIAL LEAD; GUIDANT - VENTRICULAR LEAD RPTS, INVESTIGATION RECS, RECALLS, ETC
2014-9893	12/17/2014 01/20/2015	OC/ORO/OCI/ OC/ORO/OCI/	Doe J	INDIVIDUAL RECS
2014-9894	12/17/2014 01/20/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN H KOZMIN Kozmin, John H	LITHIUM CARBONATE - LBLG, AERS, MFR NAME, ETC
2014-9895	12/17/2014 01/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	MARK C TANNENBAUM MARK C TENENBAUM ATTY	OMNI LIFE SCIENCE - APEX SURGICAL MODULAR FEMORAL NECK WITH PLUG, APEX SURGICAL POROUS FEMORAL STEM, APEX SURGICAL FEMORAL HEAD APRVL

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				RECS
2014-9896	12/17/2014 01/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	REBECCA L DANDEKER MORGAN LEWIS & BOCKIUS LLP	HETERO DRUGS LTD, MANDAL, VISAKHAPATNAM, INDIA - EIRS 1/1/10 TO 9/28/14
2014-9897	12/17/2014 01/20/2015	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	REBECCA L DANDEKER MORGAN LEWIS & BOCKIUS LLP	SONNEBORN INC, PETROLIA, PA - 483, EIR 6/1/14-8/1/14
2014-9898	12/17/2014 01/20/2015	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Padmini Sahoo Immucor GTI Diagnostics, Inc.	ONE LAMBDA, INC - 483 12/15/2009 - 12/15/2014
2014-9899	12/17/2014 01/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lauren Welling Phillips Law Firm	NDA 202439; XARELTO INVESTIGATION, TESTING, ANALYSIS ETC
2014-9900	12/17/2014 01/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ryan Smith Janus Capital Group ATTN: RYAN SMITH	EEMT - AERS
2014-9901	12/17/2014 01/20/2015	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	Ann Glavan Chronicle of the Horse	ALTECH ANIMAL FEED, LAKELAND ANIMAL NUTRITION - INVESTIGATION RECS 10/01/2013 - 12/16/2014
2014-9902	12/17/2014 01/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Olena Izhak University of Helsinki (FINLAND)	ANDA APPROVAL LETTERS
2014-9903	12/17/2014 01/20/2015	FDA/OC/OES/DFOI/ FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/ FDA/OC/OES/DFOI/	Martha Folan MERIT MEDICAL SYSTEMS INC	K93490, K943739, K93004; MERIT MEDICAL SYSTEMS, INC, GALWAY, IRELAND, SOUTH JORDAN, UT, MALVERN, PA - EIR
2014-9904	12/17/2014	FDA/OMPT/CDER/GRP/DIDP/	Ryan Smith	IMBRUVICA - AERS

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	01/20/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Janus Capital Group ATTN: RYAN SMITH	
2014-9905	12/17/2014 01/20/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FICHA TECNICA DE MIRALAX - (NDA) 020698 TECNOFARMA	NDA 020698
2014-9906	12/18/2014 01/21/2015	FDA/OMPT/CDRH/OCER/DFOI/	David Livingston Katecho, Inc	K020288
2014-9907	12/18/2014 01/21/2015	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Lisa Gordon Hospira, Inc.	HOSPIRA, INC, CLAYTON, NC - EIR JUNE 2013
2014-9908	12/18/2014 01/21/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K130921
2014-9909	12/18/2014 01/21/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Thomas Mathies Thomas Mathies	POZEN, INC - COMMUNICATIONS REGARDING INSPECTION OF A FOREIGN MANUFACTURING FACILITY 09/01/2014 - 12/17/2014
2014-9910	12/18/2014 01/21/2015	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	Abhishek Gurnani Amin Talati & Upadhye, LLC	AYUSH HERBS, INC - EIR 01/01/2010 - 12/17/2014
2014-9911	12/18/2014 01/21/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Stephanie Garcia Hospira, Inc.	HOSPIRA LISCATE SPA, ITALTY - EIR 05/05/2014 - 12/17/2014
2014-9912	12/18/2014 01/21/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DDM/	Amanda Goodwin Eisai Inc.	Gastroenterology Regulatory Endpoints and the Advancement of Therapeutics (GREAT II) Workshop held in MD on October 21 - 22, 2013 - TRANSCRIPT
2014-9913	12/18/2014 01/21/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K133790
2014-9914	12/18/2014 01/21/2015	FDA/OMPT/CDRH/OCER/DFOI/	Imran Karim Imran Karim	K141567, K140931, K141242 ETC
2014-9915	12/18/2014	FDA/OMPT/CDRH/OCER/DFOI/	ChengI Chuang	K140933

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	01/21/2015		ChengI Chuang	
2014-9916	12/18/2014 01/21/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ravi Chandran Signature Pharmaceuticals, LLC.	ANDA 076413, ANDA 077211 - COVER LETTER, APPROVAL LETTER, RECALL LETTER ETC
2014-9917	12/18/2014 01/21/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jennifer Ensign Jennifer Ensign	NDA 205613
2014-9918	12/18/2014 01/21/2015	OC/ORO/ OC/ORO/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	David McKinney David McKinney	CONSUMER COMPLAINT 139502 - RECS
2014-9919	12/18/2014 01/21/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	JMA Consulting JMA Consulting	K123731
2014-9920	12/18/2014 01/21/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	REBECCA SHAMES-SCHULZ Hogan Lovells, ILP	T-STAT OXIMETER - K04684
2014-9921	12/18/2014 01/21/2015	FDA/OMPT/CDRH/OCER/DFOI/	ANNAMARIE BONDI-STODDARD PEGALIS & ERICKSON LLC	SYNTHES GMBH - STERNAL ZIPFIX WITH NEEDLE STERILE/5 PACK TESTING, MDRS
2014-9922	12/18/2014 01/21/2015	FDA/OMPT/CDRH/OCER/DFOI/	EDWARD LEMAHIEU WALT MEDICAL PRODUCT SERVICES & STAFFING INC	K130689, K033981
2014-9923	12/18/2014 01/21/2015	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	MOHAMED BARAKAT PRIME PACKAGING INC	PRIME PACKAGING INC, MIAMI, FL - EIR 7/11/04
2014-9924	12/18/2014 01/21/2015	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	CYNTHIA BROWN LSU HEALTHCARE NETWORK	LOUISIANA STATE UNIV HEALTH SCIENCE CENTER DEPARTMENT OF RHEUMATOLOGY, NEW ORLEANS, LA - 483 OR WARNING LTR 8/04 TO 12/04
2014-9925	12/18/2014 01/21/2015	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	JOHN NAIZBY MARCARELLI-NAIZBY LAW FIRM	YALE NEW HAVEN HOSP NEONATAL UNIV - SOLGAR ABC DOPHILUS CONTAMINATED ABC COPHILIUS POWER RECS
2014-9926	12/18/2014	FDA/OC/OES/DFOI/	M BRENNEN BOZE	SUBPOENA

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	01/21/2015		RYMER MOORE JACKSON ETA	
2014-9927	12/18/2014 01/21/2015	FDA/OC/OES/DFOI/	CAROLINE M KELLY MORRISON MAHONEY LLP	NEW ENGLAND COMPOUNDING CENTER (AMERIDOSE) - EIRS, AUDITS, EVALUATIONS, ETC 9/05 TO PRESENT
2014-9928	12/18/2014 01/21/2015	FDA/OC/OES/DFOI/	COURTNEY CROSBY CROSBY, COURTNEY	ACTOS (PIGOLITAZOLE) - RPTS
2014-9929	12/18/2014 01/21/2015	OC/CVM/OCD/	Vicki Selzer KindredBio	NADA 141147
2014-9930	12/18/2014 01/21/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mahidhar Chinta Micro Labs USA, Inc	NDA 020064
2014-9931	12/18/2014 02/23/2015	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	Mehdi Muradi Ofogh Darou Pars PJS	RB MANUFACTURING LLC, SALT LAKE CITY, UT - EIR 06/01/2014 - 12/18/2014
2014-9932	12/18/2014 01/21/2015	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Ralph Aguila RALPH AGUILA	EDGE SYSTEMS CORP - EIR 05/17/2010 - 05/25/2010
2014-9933	12/19/2014 01/22/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K130143
2014-9934	12/19/2014 01/22/2015	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	JOSEPH WALKER Walker, Joseph	OXYHEALTH LLC - WARNING LETTER RECS 08/01/2013 - 04/30/2014
2014-9935	12/19/2014 01/22/2015	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Marie Evangelisto Doyle Teva Pharmaceuticals	VERTELLUS HEALTH AND SPECIALTY PRODUCTS, ZEELAND, MI - EIR 01/01/2012 - 12/17/2014
2014-9936	12/19/2014 01/22/2015	FDA/OMPT/CDRH/OCER/DFOI/	Joseph Mark (via Sean Spence) NICO Corporation	K955168 K000470 Q131322
2014-9937	12/19/2014 01/22/2015	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Arrastia Capote Partners Arrastia Capote Partners	SONAR PRODUCTS, INC, CARLSTADT, NJ - 483
2014-9938	12/19/2014 01/22/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K123459
2014-9939	12/19/2014 01/22/2015	FDA/OMPT/CDRH/OCER/DFOI/	Dionicia Reblando TRI-STAR CONSULTING	K082848, K111119, K100889 ETC
2014-9940	12/19/2014 01/22/2015	FDA/OMPT/CDRH/OCER/DFOI/	William Plishker IGI Technologies	K010336
2014-9941	12/19/2014	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson	K032104

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	01/22/2015		FOI Services, Inc.	
2014-9942	12/19/2014 01/22/2015	FDA/OMPT/CDRH/OCER/DFOI/	William Plishker IGI Technologies	K071964
2014-9943	12/19/2014 01/22/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sarah Harr Rasmussen Willis Dickey & Moore, LLC	1998 ORANGE BOOK
2014-9944	12/19/2014 01/26/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Rachel Johnson FOI Services, Inc.	BLA 125432
2014-9945	12/19/2014 01/26/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Rachel Johnson FOI Services, Inc.	BLA 125413
2014-9946	12/19/2014 01/22/2015	FDA/OMPT/CDRH/OCER/DFOI/	William Plishker IGI Technologies	K041521
2014-9947	12/19/2014 01/22/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sarah Harr Rasmussen Willis Dickey & Moore, LLC	2012 ORANGE BOOK
2014-9948	12/19/2014 01/22/2015	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Alex Branoff TELEFLEX MEDICAL	ACE-MEDICAL CO - EIR 01/01/2013 - 12/18/2014
2014-9949	12/19/2014 01/22/2015	FDA/OMPT/CDRH/OCER/DFOI/	Jennifer Kinney Halo Medical Technologies	THE PROMETHEUS GROUP - CPT 1400805 09/23/2014 - 12/18/2014

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2014-9950	12/19/2014 01/22/2015	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Alexandra Ajmo UAS Labs	UAS LABS, WAUSAU, WI - EIR 01/01/2010 - 12/18/2014
2014-9951	12/19/2014 01/22/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	ZIMMER 510K RE KINEMATIC DISTAL REFERENCING GUIDE, KINEMATIC SURGICAL TECHNIQUE FOR PERSONA KNEE SYSTEM
2014-9952	12/19/2014 01/22/2015	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Alexandra Ajmo Protec	PROTEC LABORATORY, QUITMAN, TX - EIR 01/01/2010 - 12/18/2014
2014-9953	12/19/2014 01/22/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Roderick Walker QUINTILES TRANSNATIONAL CORP	DR MANUEL LAVADOS, SANTIAGO, CHILE - EIR, 483 01/01/2010 - 12/31/2010
2014-9954	12/19/2014 01/22/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Melvin Reichman Lankenau Institute for Medical Research	MEGLUMINE - SUMMARY DATA RE SAFETY AND BIOAVAILABILITY
2014-9955	12/19/2014 01/22/2015	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	TOXICITY OF DIETHYLENE GLYCOL DIBENZOATE, DIPROPYLENE GLYCOL DIBENZOATE, PROPYLENE GLYCOL DIBENZOAT ETC
2014-9956	12/19/2014 01/22/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	INGRID HOOS HORIZON PHARMA INC	RAYOS (PREDNISONE) NDA 02-020 APRVL, MEDICAL RVW, SUMMARY RVW
2014-9957	12/19/2014 01/29/2015	OC/ORAE/ OC/ORAE/ FDA/OGROP/ORAE/ORO/DIOP/	LINDA ROTHFIELD Pier 1 Imports	LIST OF IMPORT ALERTS
2014-9958	12/19/2014 01/22/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MEREDITH BERGER GLOBAL HEALTH JUSTICE PARTNERSHIP	SOVALDI (SOFOSBUVIR) APRVL
2014-9959	12/19/2014 01/22/2015	FDA/OC/OES/DFOI/	DERAFFAELE 376709, JOSEPH	LIST OF APPROVED DRUGS LATER FOUND WITH AER
2014-9960	12/22/2014 01/23/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ibrutinib - Individual Case Reports Ken Tong	IMBRUVICA - ICR 1056496, 10565010, 10565019, ETC

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		FDA/OMPT/CDER/GRP/DIDP/		
2014-9961	12/22/2014 01/23/2015	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	Mohit Bhat Kline & Company, Inc.	MEDTRONIC, NORTHRIDGE, CA; MEDTRONIC, PR; TANDEM, SAN DIEGO, CA ETC - EIR, EXHIBITS 01/01/2009 - 12/19/2014
2014-9962	12/22/2014 01/23/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Idelalisib - Individual Case Report Ken Tong	ZYDELIG - ICR 10561655, 10563217, 10564235 ETC
2014-9963	12/22/2014 01/23/2015	FDA/OC/OES/DFOI/	Vik Bajnath ARTHREX INC.	ADVERSE EVENT REPORTER INFORMATION
2014-9964	12/22/2014 01/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	Trishia Dwyer GE Healthcare	K131252
2014-9965	12/22/2014 01/23/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Thomas A. Marciniak Thomas A. Marciniak, M.D.	NDA 021526 S 004
2014-9966	12/22/2014 01/23/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CherylN Boutan EAST JEFFERSON GENERAL HOSPITAL	ROCEPHIN IV PUSH - AERS
2014-9967	12/22/2014 01/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	K133521 Elucid Bioimaging Inc.	K133521
2014-9968	12/22/2014 01/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	K141480 Elucid Bioimaging Inc.	K141480
2014-9969	12/22/2014 01/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	K103480 Elucid Bioimaging Inc.	K103480
2014-9970	12/22/2014	FDA/OMPT/CDRH/OCER/DFOI/	K142037	K142037

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	01/23/2015		Elucid Bioimaging Inc.	
2014-9971	12/22/2014 01/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	K121517 Elucid Bioimaging Inc.	K121517
2014-9972	12/22/2014 01/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	K062386 Elucid Bioimaging Inc.	K062386
2014-9973	12/22/2014 01/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	K063877 Elucid Bioimaging Inc.	K063877
2014-9974	12/22/2014 01/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	K033374 Elucid Bioimaging Inc.	K033374
2014-9975	12/22/2014 01/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	K131447 Elucid Bioimaging Inc.	K131447
2014-9976	12/22/2014 01/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	K121916 Elucid Bioimaging Inc.	K121916
2014-9977	12/22/2014 01/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	K121213 Elucid Bioimaging Inc.	K121213
2014-9978	12/22/2014 01/23/2015	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Susan Greenbowe bluebird bio	DR STEPHAN A GRUPP, PHILADELPHIA, PA - 483, CORR 01/01/2005 - 12/29/2010
2014-9979	12/22/2014 01/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	JMA Consulting JMA Consulting	K111250
2014-9980	12/22/2014 01/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	JMA Consulting JMA Consulting	K101769
2014-9981	12/22/2014 01/23/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Christine Scifert Memphis Regulatory Consulting, LLC	K071876, K111266, K112794, ETC
2014-9982	12/22/2014 01/23/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Robert Di Tullio Di Tullio Consulting, Inc.	NANOSTRING TECHNOLOGIES, INC - CORR RE MARKETING, ADVERTISING AND PROMOTION PRACTICES FOR THE NANOSTRING TECHNOLOGIES NCOUNTER ELEMENTS GENERAL PURPOSE REAGENTS BY OIR
2014-9983	12/22/2014 01/23/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joshua Malamud Hyman, Phelps & McNamara P.C.	DETERMINATION BY FDA THAT THE FIRST COMPANY TO SUBMIT AN ANDA FOR ESOMEPRAZOLE MAGNESIUM DELAYED-RELEASE CAPSULES, 20 MG AND 40 MG CONTAINING A PARAGRAPH IV CERTIFICATION FOREITED OR LOST ELIGIBILITY FOR 180 DAY EXCLUSIVITY ETC

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2014-9984	12/22/2014 01/23/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Nicole Pinto Elanco, Division Eli Lilly Canada Inc.	JOHNSON AND JOHNSON APDC, MUMBAI, INDIA - EIR MAY 2014
2014-9985	12/22/2014 01/23/2015	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Brian Laskowski Hospira, Inc.	HOSPIRA, AUSTIN, TX - EIR MAY 2014
2014-9986	12/22/2014 01/23/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	JUSTIN A BOYD,CADLIA PHARMACEUTICALS LTD, ANKIESHWAR,L GUJARAT STATE, INDIA , - 483S 3/24-28/14
2014-9987	12/22/2014 01/23/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	OLEKSANDRA V STASYSHYN MD PHD, LVIV, UKRAINE - 483S 1/21-25/13
2014-9988	12/22/2014 01/23/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	DOREL SANDESC MD, TIMISOARA, ROMANIA - 483S 10/28/13-11/1/13
2014-9989	12/22/2014 01/23/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	HIKMA PHARMACEUTICAL LTD, JORDAN, PORTUGAL - 483S 3/20-28/14
2014-9990	12/22/2014 01/23/2015	FDA/OC/OES/	ANNA EDNEY BLOOMBERG NEWS	MTG WITH APPLE - MINS 12/12/13 TO PRESENT
2014-9991	12/22/2014 01/23/2015	FDA/OFVM/CFSAN/OCD/EOS/	WILBUR JOHNSON JR COMMITMENT & CREDIBILITY	PYRUS MALUS (APPLE) FRUIT METABOLISM EXTRACT, PYRUS MALUS (APPLE) BARK EXTRACT, PYRUS MALUS (APPLE) CARPEL POWDER, ETC - MEWTABOLISM/BIOAVL, DERMAL PENETRATION, TOXICITY
2014-9992	12/22/2014 01/23/2015	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	JACK A SHULMAN SHULMAN, JACK A	TRIARRCO INDUSTRIES, PATTERSON, NJ, ARCHON VITAMIN CORP, IRVINGTON, NJ, GARY NULL & ASSOC, NYC, NY - RECALL, INVESTIGATION, WARNING COMPLIANCE, ETC 12/09 TO PRESENT

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2014-9993	12/22/2014 01/23/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Erin Stewart, MD Stanford University Hospital and Clinics - Department of Pulmonary and Critical Care Medicine	METHYLPHENIDATE - AERS
2014-9994	12/22/2014 01/23/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Saion Mukherjee Nomura Financial Advisory & Securities (India) Private Limited	IMATINIB MESYLATE - TENTATIVE APPROVAL LETERS TO SUN PHARMA INDUSTRIES 11/01/2009 - 11/01/2014
2014-9995	12/22/2014 01/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	Tomophase TOMOPHASE CORP	TOMOPHASE 510K SUBMISSION
2014-9996	12/22/2014 01/23/2015	FDA/OC/OES/DFOI/	Elliott Graham SQA-Learning Foundation	FY 2014 483 UNDER 7348.001, 7348.808, 7348.808A ETC
2014-9997	12/22/2014 01/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	C CLAGETT claggett 27008-086, c	FMC BUTNER - LINEAR ACCELERATOR LICENSING & OPERATION OVER-RADIATION, MEAS OF REPAIRS, ETC
2014-9998	12/22/2014 01/23/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID L SIBERSTEIN Valeant Pharmaceuticals North America LLC	MEDICIS- PREDNISOLONE SODIUM PHOSPHATE ORAL SOL ANDA 75-250 SUBMMISSION
2014-9999	12/23/2014 01/26/2015	FDA/OC/OES/DFOI/	Doe J	AER
2014-10000	12/23/2014 01/26/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HURLEY, WENEEKE	LINZESS - AER
2014-10001	12/23/2014 01/26/2015	FDA/OGROP/ORO/CE-FO/PHI-DO/PHI-CB/	REBECCA L. DANDEKER MORGAN LEWIS & BOCKIUS LLP	SONNEBORN INC, PETROLIA, PA - EIR 6/1/14-8/1/14
2014-10002	12/23/2014 01/26/2015	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	GILMORE #344879, PERRY	STEM CELL RECS
2014-10003	12/24/2014 01/27/2015	FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/	Eric A Fernandez Vice News	Guayaquil-based Star Company, S.A., Crimasa Criaderos De Mariscos, S.A., Gialmar-Productos Alimentares S.A. etc - Warning Letter, Inspection Records, Emails

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2014-10004	12/24/2014 01/27/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Edward Kobus Invado Pharmaceuticals	K062795
2014-10005	12/24/2014 01/27/2015	FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/	Lynn Keefe - ref#FDA1413555 Keefe, Lynn	BRACCO DIAGNOSTICS, PRINCETON, NJ - EIR, 483 04/01/2014 - 06/30/2014
2014-10006	12/24/2014 01/27/2015	OC/ORACE/ORM/ OC/ORACE/ORM/	Genevieve Stevens Nivagen Pharmaceuticals, Inc.	LIST OF PHARMACEUTICAL INSPECTIONS LAST THREE YEARS
2014-10007	12/24/2014 01/27/2015	FDA/OGROP/ORACE-FO/NOL- DO/NOL-CB/	David Windish Newtyn Management	BIOMIMETIC THERAPEUTICS, WRIGHT MEDICAL - INSPECTION RECS 01/01/2010 - 12/22/2014
2014-10008	12/24/2014 01/27/2015	FDA/OMPT/CDRH/OCER/DFOI/	Wayne Billings Fellers, Snider, Blankenship, Bailey & Tippens, P.C.	CORIN CORMET ADVANCED HIP RESURFACING SYSTEM - MANUFACTURING STANDARDS
2014-10009	12/24/2014 01/27/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K112605
2014-10010	12/24/2014 01/27/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K080595
2014-10011	12/24/2014 01/27/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rahul Jeewani IIFL Institutional Equities	IPCA LABS, INDIA - 483 12/08/2014 - 12/17/2014
2014-10012	12/24/2014 01/27/2015	FDA/OMPT/CDRH/OCER/DFOI/	Pat Palmer Powers Medical Devices (Pat Palmer, CEO)	K010388
2014-10013	12/24/2014 01/27/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K141681
2014-10014	12/24/2014 01/27/2015	FDA/OMPT/CDRH/OCER/DFOI/	Kathy Remsen Medtronic Sofamor Danek USA	K000073
2014-10015	12/24/2014 01/27/2015	OC/ORACE/ OC/ORACE/ OC/ORACE/ORM/ OC/ORACE/ORM/	David Mangione Govzilla, Inc.	LISTING OF INSPECTIONS 03/15/2014 - 12/22/2014
2014-10016	12/24/2014 01/27/2015	FDA/OMPT/CDRH/OCER/DFOI/	Kathy Remsen Medtronic Sofamor Danek USA	K112231
2014-10017	12/24/2014 01/27/2015	FDA/OMPT/CDRH/OCER/DFOI/	Kathy Remsen Medtronic Sofamor Danek USA	K102566

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2014-10018	12/24/2014 01/27/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Scott Dalton Eli Lilly and Company - Global Patient Safety	MEDWATCH 139521
2014-10019	12/24/2014 01/27/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anna Edney BLOOMBERG NEWS	GVK BIOSCIENCES, INDIA - 483
2014-10020	12/24/2014 01/27/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	G. Srinivas Zydus Pharmaceuticals USA Inc.	ALBENZA - NDA
2014-10021	12/24/2014 01/27/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sireesha Alla InnoPharma Licensing LLC	NDA 021038 S020
2014-10022	12/24/2014 01/27/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ADITYA KHEMKA AMBIT CAPITAL PVT LTD	IPCA LBARATORIES, INDIA - EIR 2014
2014-10023	12/24/2014 01/27/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Laurent Harvey ACASTI PHARMA INC	NDA 205060
2014-10024	12/24/2014 01/27/2015	OC/CVM/OCD/	Angie Richardson Mark Anderson & Associates, Inc.	INAD I-008476
2014-10025	12/24/2014 01/27/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Chirag Talati Kotak Securities	APPROVAL LETTERS ANDA 78043 78466 65392 ETC
2014-10026	12/24/2014 01/27/2015	FDA/OC/OES/	Rachel Johnson FOI Services, Inc.	Materials Submitted by Organogenesis for 01/16/2014 Meeting with FDA
2014-10027	12/24/2014	FDA/OMPT/CDRH/OCER/DFOI/	Larissa D'Andrea	K143244

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	01/27/2015		ResMed Corp.	
2014-10028	12/24/2014 01/27/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	RAM KAMATH CANARA ASSOCIATES INC.	NDA 020649
2014-10029	12/24/2014 01/27/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joe Malca Malca, Joseph	ANDA 075896, ANDA 075998
2014-10030	12/24/2014 01/27/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	RAM KAMATH CANARA ASSOCIATES INC.	NDA 020379
2014-10031	12/24/2014 01/27/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Peter R. Breggin, MD Center for the Study of Empathic Therapy	VENLAFAXINE - AERS
2014-10032	12/24/2014 01/27/2015	FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/ORA/ OC/ORA/	Doe J	INDIVIDUAL RECS
2014-10033	12/29/2014 01/28/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Chirag Talati Kotak Securities	AUROBINDO PHARMA, TARO - EIR, 483 01/01/2010 - 12/24/2014
2014-10034	12/29/2014 01/28/2015	FDA/OMPT/CDRH/OCER/DFOI/	Andrew Stolper Eagan Avenatti	KIMBERLY-CLARK MICROCOOL SURGICAL GOWNS, SURGICAL DRAPES - FORM 3500, 3500A, 3500B 01/22/2011 - 12/22/2014
2014-10035	12/29/2014 02/26/2015	FDA/OGROP/ORA/SW-FO/DEN- DO/DEN-CB/	Tara Azadi Schidd Company	RECKITT BENCKISER, SALT LAKE CITY, UT - 483 01/01/2014 - 10/14/2015

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2014-10036	12/29/2014 01/28/2015	FDA/OMPT/CDRH/OCER/DFOI/	Mia Hunt Medtronic, Inc.	BIOTRONIK - MOST RECENT ANNUAL REPORT FOR IMPLANTABLE CARDIOVERTER DEFIBRILLATORS 12/01/2012 - 12/24/2014
2014-10037	12/29/2014 01/28/2015	FDA/OMPT/CDRH/OCER/DFOI/	Mia Hunt Medtronic, Inc.	BIOTRONIK - MOST RECENT ANNUAL REPORT FOR LEADS 12/01/2012 - 12/24/2014
2014-10038	12/29/2014 01/28/2015	FDA/OMPT/CDRH/OCER/DFOI/	Jack Meyerson Meyerson, Jack	P050053
2014-10039	12/29/2014 01/28/2015	FDA/OMPT/CDRH/OCER/DFOI/	Mia Hunt Medtronic, Inc.	ST JUDE MEDICAL MOST RECENT ANNUAL REPORT SUBMITTED FOR LEADS 12/01/2012 - 12/24/2014
2014-10040	12/29/2014 01/28/2015	FDA/OMPT/CDRH/OCER/DFOI/	Debra Franck Boston Children's Hospital	K942583, K971048, K040415 ETC
2014-10041	12/29/2014 01/28/2015	FDA/OMPT/CDRH/OCER/DFOI/	Mia Hunt Medtronic, Inc.	BOSTON SCIENTIFIC MOST RECENT ANNUAL REPORT FOR LEADS 12/01/2012 - 12/24/2014
2014-10042	12/29/2014 01/28/2015	FDA/OMPT/CDRH/OCER/DFOI/	Mia Hunt Medtronic, Inc.	ST JUDE MEDICAL MOST RECENT ANNUAL REPORT FOR IMPLANTABLE CARDIOVERTER DEFIBRILLATORS 12/01/2012 - 12/24/2014
2014-10043	12/29/2014 01/28/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joseph Malca Malca, Joseph	ANDA 075998 CHEMISTRY REVIEW
2014-10044	12/29/2014 01/28/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Tom Leusner Prirista, Inc.	SHIRE HUMAN GENETIC THERAPIES - BIOLOGICAL DEVIATION REPORTS
2014-10045	12/29/2014 01/28/2015	FDA/OMPT/CDRH/OCER/DFOI/	Mia Hunt Medtronic, Inc.	BOSTON SCIENTIFIC MOST RECENT ANNUAL REPORT FOR IMPLANTABLE CARDIOVERTER DEFIBRILLATORS 12/01/2012 - 12/24/2014
2014-10046	12/29/2014 01/28/2015	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Tom Leusner Prirista, Inc.	AMGEN, WEST GREENWICH, RI - EIR, INVESTIGATOR NOTES 07/20/2014 - 08/20/2014
2014-10047	12/30/2014 01/29/2015	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	JoNel Aleccia The Seattle Times	HAPPY APPLES OF WASHINGTON, MO - CORR WITH FDA 10/01/2014 - 12/26/2014
2014-10048	12/30/2014 01/29/2015	FDA/OMPT/CDRH/OCER/DFOI/	Tirunelveli Ramalingam OCT Medical Imaging Inc	K113008, K112997, K102599 ETC

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2014-10049	12/30/2014 01/29/2015	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	MW5029909
2014-10050	12/30/2014 01/29/2015	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	Padmini Sahoo Immucor GTI Diagnostics, Inc.	BLOOD CENTER OF WISCONSIN - 483 MOST RECENT
2014-10051	12/30/2014 01/29/2015	FDA/OFVM/CFSAN/OCD/EOS/	Chuck Cathcart North Star Coating	FCN 1240, 818, 297 TOXICOLOGY RECS
2014-10052	12/30/2014 01/29/2015	FDA/OFVM/CFSAN/OCD/EOS/	Chuck Cathcart North Star Coating	FCN 1239, 823, 300 - CHEMISTRY, TOXICOLOGY RECS
2014-10053	12/31/2014 01/30/2015	FDA/OC/OES/DFOI/	Kari Twaite BEVERIDGE & DIAMOND PC	CFSAN FOIA REQUESTS 11/25/2014 - 12/30/2014
2014-10054	12/31/2014 01/30/2015	FDA/OFVM/CFSAN/OCD/EOS/	James Wood Woodland Gardens LLC	SYNSEPALUM DULCIFICUM FRUIT, MIRACULIN - NON APPROVAL RECS 01/02/1974 - 12/31/1974
2014-10055	12/31/2014 01/30/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K091760
2014-10056	12/31/2014 01/30/2015	FDA/OMPT/CDRH/OCER/DFOI/	Sweta Patel BIO-RAD LABORATORIES, INC.	K993107
2014-10057	12/31/2014 01/30/2015	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Valerie Staffey MMJ Labs	MMJ LABS, ATLANTA, GA - EIR 05/01/2014 - 12/30/2014
2014-10058	12/31/2014 01/30/2015	FDA/OMPT/CDRH/OCER/DFOI/	K132148 Withings	K132148
2014-10059	12/31/2014 01/30/2015	FDA/OFVM/CFSAN/OCD/EOS/	Chris Lahiff McDermott Will & Emery LLP	Any Reportable Food Reports related to caramel apples filed by Safeway, Happy Apples, Bidart Brother, Pacific Coast Fruit and California Snack Foods
2015-1	01/02/2015 03/13/2015	FDA/OC/OES/DFOI/	David Mangione Govzilla, Inc.	483 RELEASED 09/18/2014 - 12/22/2014
2015-2	01/02/2015 02/02/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ADITYA KHEMKA AMBIT CAPITAL PVT LTD	SUN PHARMA, HALOL, INDIA; CADILA HEALTHCARE, ANKHALESHWAR, INDIA - WARNING LETTER, IMPORT ALERT 01/01/2014 - 12/26/2014
2015-3	01/02/2015 02/02/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	William Cady, PharmD QUALITY RESEARCH SERVICES	ANDA 200675 - SUMMARY OF REVIEW COMMENTS
2015-4	01/02/2015	FDA/OMPT/CDRH/OCER/DFOI/	Russ Garrison	K050808

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	02/02/2015		VerAvanti Inc.	
2015-5	01/02/2015 02/02/2015	FDA/OMPT/CDRH/OCER/DFOI/	Amy Clendening-Wheeler Quest Medical, Inc.	K053106
2015-6	01/02/2015 02/02/2015	FDA/OMPT/CDRH/OCER/DFOI/	Anita Sapper Anita Sapper	DEEP BRAIN STIMULATION TO TREAT SKIN PICKING DISORDER - ADVERSE EVENTS 01/01/1995 - 01/01/2015
2015-7	01/02/2015 02/02/2015	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	Tracey Weidner Mitra Law Group, LLC	2014-7882 UNREDACTED
2015-8	01/02/2015 02/02/2015	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OFVM/CFSAN/OCD/EOS/	Thomas A. Cohn NBTY, Inc., parent company of Solgar, Inc.	ABC DOPHILUS FROM SOLGAR - SAMPLE PHOTOGRAPHS YALE UNIVERSITY
2015-9	01/02/2015 02/02/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K071202
2015-10	01/02/2015 02/02/2015	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	Karol Ann Hoffman AvKARE Inc	AVKARE, PULASKI, TN - REQUEST FOR INSPECTION JUNE 2014
2015-11	01/02/2015 02/02/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Genevieve Stevens Nivagen Pharmaceuticals, Inc.	ANDA 040745
2015-12	01/02/2015 02/02/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	G. Srinivas Zydus Pharmaceuticals USA Inc.	LASIX NDA 016273- APPROVAL PACKAGE
2015-13	01/02/2015 02/02/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ADITYA KHEMKA AMBIT CAPITAL PVT LTD	NATCO PHARMA, STRIDES ARCOLAB - 483, EIR 01/01/2014 - 12/31/2014
2015-14	01/02/2015 02/02/2015	OC/ORPA/ OC/ORPA/ FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	Sara K. Justice Justice, Sara K	SAMPE 870515 - TESTING RESULTS
2015-15	01/02/2015 02/02/2015	FDA/OMPT/CDRH/OCER/DFOI/	Amarjit Jowandha Sony Electronics Inc.	K122167

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2015-16	01/02/2015 02/02/2015	FDA/OC/OES/DDM/	Lisa Capote Arrastia Capote Partners	2007P-0322
2015-17	01/02/2015 02/02/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nina M. Cerasi Baxter, Baker, Sidle, Conn & Jones, P.A.	HUMIRA - AERS
2015-18	01/02/2015 02/02/2015	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SE-FO/ATL- DO/ATL-CB/	Theron Gober EndoChoice, Inc.	Consumer Complaint 137959
2015-19	01/02/2015 02/02/2015	FDA/OC/OES/DFOI/	William Sietsema NeoStem	DENDREON - PRE-APPROVAL EIR, 483 01/01/2007 - 12/31/2014
2015-20	01/02/2015 02/02/2015	FDA/OMPT/CDRH/OCER/DFOI/	Lynn Shepler MD JD Tick-borne Disease Legal Project/Lynn Shepler MD	BIOMERIEUX VIDAS LYME - APPROVAL RECS SEPARATED BY SEX OF SUBJECT 01/01/2000 - 01/01/2015
2015-21	01/02/2015 02/02/2015	FDA/OFVM/CFSAN/OCD/EOS/	Mark Prinz Registrar Corp	MANKO NATURAL FLAVOURS & EXTRACTS, BELOORBAYIR BIOTECH LTD, BAYIR EXTRACTS PVT LTD ETC - 483 MOST RECENT
2015-22	01/02/2015 02/02/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jade Tabony Gradient Corporation	HALOPERIDOL - REFERENCE LIST FOR SEVENTEEN PLACEBO-CONTROLLED STUDIES IN BOX WARNING
2015-23	01/02/2015 02/02/2015	FDA/OMPT/CDRH/OCER/DFOI/	Huiyou Zhu TrioWave Technologies	K083580, K090042, K120500 ETC
2015-24	01/02/2015 02/02/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	UNIVERSITY OF MINNESOTA - REQUESTS TO CDER 01/01/2008 - 01/01/2015
2015-25	01/02/2015 02/02/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kiran Awate THE OHIO STATE UNIVERSITY	ORANGE BOOK DATA FILES FOR EXPIRED PATENTS
2015-26	01/02/2015 02/02/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Marie Link REMS Logic, LLC	Number of REMS Drug Error Reports (by drug) - from 2005 through 2013

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2015-27	01/05/2015 02/03/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PAIGE STRADLEY MERCHANT & GOULD	ZOMETA NDA 21-386 - MEDICAL RVW PART 1 AND PART 2
2015-28	01/05/2015 02/03/2015	FDA/OFVM/CFSAN/OCD/EOS/	DARRYL YOUNG X04261 YOUNG X04261, DARRYL	FDA FOOD CODE MANUAL 2014
2015-29	01/05/2015 02/03/2015	FDA/OGROP/ORO/PA-FO/SEA-DO/SEA-CB/	CITOLI, MERRY	NSPIRED FOODS - ALMOND BUTTER RECALL RECS
2015-30	01/05/2015 02/03/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	S ALBERT EDWARDS PHARM D S ALBERT EDWARDS PHARM D	A H ROBINS - SKELAXIN (METAXALONE) NDA 13-217 APRVL LTR
2015-31	01/05/2015 02/03/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	DIANE M HARPER MD MPH MS UNIV OF LOUISVILLE SCHOOL OF MEDICINE	GARDASIL 9 - STATISTICAL RVW AND EVALUATION, CLNCL RVW
2015-32	01/05/2015 02/03/2015	FDA/OMPT/CDRH/OCER/DFOI/	MICHELLE S CHAN JOANNE R WERNER LAW OFC	JOERNS HEALTHCARE - HOSPITAL ELECTRIC BED MDR 3041143
2015-33	01/05/2015 02/03/2015	FDA/OC/OES/DFOI/	David Mangione Govzilla, Inc.	LIST OF FDA INVESTIGATORS WHO ARE NATIONAL EXPERTS
2015-34	01/05/2015 02/03/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mark Mathieu PAREXEL	IND SUBMISSIONS TO CDER IN 2014; BREAKDOWN OF ACTIVE IND WORKLOADS BY DIVISION ETC
2015-35	01/05/2015 02/03/2015	FDA/OFVM/CFSAN/OCD/EOS/	ERIC F GREENBERG ERIC F GREENBERG PC	BASF CORP - FCN 1285
2015-36	01/05/2015 02/03/2015	FDA/OFVM/CFSAN/OCD/EOS/	ERIC F GREENBERG ERIC F GREENBERG PC	NALCO - FCN 1277
2015-37	01/05/2015 02/03/2015	FDA/OGROP/ORO/CE-FO/CHI-DO/CHI-CB/	Pamela Larsen Marathon Pharmaceuticals, LLC	MARATHON PHARMACEUTICALS, LLC, DEERFIELD, IL - EIR 1/30/13
2015-38	01/05/2015 02/03/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Neha Manpuria J.P. Morgan India Pvt Ltd	SUN PHARMACEUTICAL, INDIA - 483 09/01/2014 - 09/30/2014

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2015-39	01/05/2015 02/03/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	ISR 3760332
2015-40	01/05/2015 02/03/2015	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/NWJ- DO/NWJ-CB/	Doe J	INDIVIDUAL RECS
2015-41	01/05/2015 02/03/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	A Ercument Cocek CARNEGIE MELLON UNIVERSITY	HUMAN DRUGS - AERS
2015-42	01/05/2015 02/03/2015	FDA/OMPT/CDRH/OCER/DFOI/	Mark Harris The Economist, IEEE Spectrum, New Scientist	MICROSOFT BAND - APPROVAL RECS 01/02/2014 - 01/03/2015
2015-43	01/05/2015 02/03/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joe Malone Joe Malone	BIRTH CONTROL DRUGS - AERS DATA
2015-44	01/05/2015 02/03/2015	FDA/OGROP/ORO/CE-FO/CIN- DO/CIN-CB/	NICK DIBERADINIS VWR International LLC	NATIONAL BIOCHEMICALS CORP - INSPS 6/24-26/96, 7/8/96; 2/22-24,28,29/00, 3/2/00 RECS
2015-45	01/05/2015 02/03/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Dedi Gilad Tyto Care	K132560, K102893, K041934 ETC
2015-46	01/05/2015 02/03/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Abhay Shanbhag Abhay Shanbhag	SRI KRISHNA PHARMACEUTICALS, HYDERABAD, INDIA - 483 08/01/2014 - 12/20/2014
2015-47	01/05/2015 02/03/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Allison Magwire (Tarantino) ARIAD Pharmaceuticals, Inc.	ICLUSIG - AERS, NARRATIVES
2015-48	01/05/2015	FDA/OGROP/ORO/CE-FO/BLT-	Ann Marie Brooks	EXPERIMENTAL PATHOLOGY LABORATORY, STERLING, VA

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	02/03/2015	DO/BLT-CB/	Zoetis	- 482, 483, EIR 12/22/2011 - 12/31/2014
2015-49	01/05/2015 02/03/2015	FDA/OC/OES/DFOI/	RANDY BANKS #B-17963 BANKS #B-17963, RANDY	ACTIONS TAKEN AGAINST ANY US COMPANY, CORPORATION, OR BUSINESS FOR VIOLATIONS OF ANY SECTION OF THE COSMETIC LABELING ACT 1/1/14-12/20/14, CMLPNTS, ETC
2015-50	01/05/2015 02/03/2015	FDA/OMPT/CDRH/OCER/DFOI/	ROBERT LEE ABBOTT MEDICAL OPTICS INC	VICTUS FEMTOSECOND LASER PLATFORM K140615
2015-51	01/05/2015 02/03/2015	FDA/OC/OES/DFOI/	Doe J	NAGASAKI FALLOUT - RECS
2015-52	01/05/2015 02/03/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LUIS ECHEVERRIA ECHEVERRIA, LUIS	DEPAKOTE - BLACK BOX WARNINGS, AERS
2015-53	01/05/2015 02/03/2015	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	M ELIZABETH BIERMAN MORGAN LEWIS & BOCKIUS LLP	SMITH & NEPHEW, ST PETERSBURG, FL - EIR 11/13
2015-54	01/05/2015 02/03/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SANFORD W BIGELOW PHD VANGUARD GLOBAL ASSOCIATES	MEGLUMINE (N-METHYLGLUCAMINE) - TECHNICAL, SAFETY, AND TOXICOLOGICAL RECS
2015-55	01/05/2015 02/03/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	2014-9023
2015-56	01/05/2015 02/03/2015	FDA/OMPT/CDRH/OCER/DFOI/	BILL BRODBECK STERIS CORP	TSO3 - STERIZONE STERILIZER K141163
2015-57	01/05/2015 02/03/2015	FDA/OMPT/CDRH/OCER/DFOI/	David Windish Newtyn Management	NUMBER OF PMA SUBMISSIONS, NUMBER OF PMA SUBMISSIONS RECEIVING APPROVABLE LETTER, ETC 01/01/2011 - 06/30/2014
2015-58	01/05/2015 02/03/2015	FDA/OMPT/CDRH/OCER/DFOI/	Melissa Thompson, Contract QSM Genchem Genchem, Inc.	K040971
2015-59	01/05/2015 02/03/2015	FDA/OMPT/CDRH/OCER/DFOI/	Melissa Thompson, Contract QSM Genchem Genchem, Inc.	K040975
2015-60	01/05/2015 02/03/2015	FDA/OMPT/CDRH/OCER/DFOI/	Melissa Thompson, Contract QSM Genchem Genchem, Inc.	K040974
2015-61	01/05/2015	FDA/OMPT/CDRH/OCER/DFOI/	Melissa Thompson, Contract QSM	K040973

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	02/03/2015		Genchem Genchem, Inc.	
2015-62	01/05/2015 02/03/2015	FDA/OMPT/CDRH/OCER/DFOI/	Melissa Thompson, Contract QSM Genchem Genchem, Inc.	K040972
2015-63	01/05/2015 02/03/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOE MALONE MALONE, JOE	ORTHO EVRA, NUVARING, IMPLANON, ETC - NUMBER OF PERSCRIPTIONS FILLED 5/01 TO 11/14
2015-64	01/05/2015 02/03/2015	FDA/OC/OES/DFOI/	CHRIS SZECHENYI ON POINT INVESTIGATIONS	POZEN INC - PA8140, PA32540 LTRS, EMAILS, COMM 3/27/13 TO 11/16/14
2015-65	01/05/2015 02/03/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID LOHMAN MILLENNIUM MANAGEMENT LLC	LANNETT CO - FEDERAL INVESTIGATION INTO POSSIBLE VIOLATIONS OF THE SHERMAN ACT
2015-66	01/05/2015 02/03/2015	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	DARREN YOUNG ALCON RESEARCH LTD	ALCON RESEARCH LTD, LAKE FOREST, CA - EIR 9/10-16/14
2015-67	01/05/2015 02/03/2015	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	DARREN YOUNG ALCON RESEARCH LTD	ALCON LENSX INC, ALISO VIEJO, CA - EIR 1/27/14-2/10/14
2015-68	01/05/2015 02/03/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	A LUKE SMITH RADICE LAW FIRM	RANBAXY - NEXIUM ANDA 77-830; TEVA - NEXIUM ANDA 78-003; DR REDDY'S - NEXIUM ANDA 78-279 FDA DECISION TO REVOKE APRVL
2015-69	01/05/2015 02/03/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	A LUKE SMITH RADICE LAW FIRM	RANBAXY - FDA DECISION TO REVOKE GENERIC NEXIUM
2015-70	01/05/2015 02/03/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	A LUKE SMITH RADICE LAW FIRM	GENERIC NEXIUM - ANTITRUST LAWSUITS COMM
2015-71	01/05/2015 02/03/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DR FLORIAN NAUDET MF PHD CENTRE HOSPITALIER UNIVERSITAIRE DE RENNES	NALMEFENE - CLNCL TRIAL RECS

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2015-72	01/06/2015 02/04/2015	FDA/OMPT/CDRH/OCER/DFOI/	Mauricio S. Umana Safis Solutions LLC	K874867
2015-73	01/06/2015 02/04/2015	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/DET- DO/DET-CB/	caroline nguyen N/A	CC 137532
2015-74	01/06/2015 02/04/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Mauricio S. Umana Safis Solutions LLC	K930530, K930530C
2015-75	01/06/2015 02/04/2015	FDA/OMPT/CDRH/OCER/DFOI/	Mauricio S. Umana Safis Solutions LLC	K910081, K910081/A
2015-76	01/06/2015 02/04/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mark Machado Machado, Mark	NDA 20357
2015-77	01/06/2015 02/04/2015	OC/CVM/OCD/	Sandeep Manchanda Ark Sciences, Inc.	INAD 83491, NADA 141-217 - PIVOTAL STUDY DATA
2015-78	01/06/2015 02/04/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Pembrolizumab - All AEs Ken Tong	KEYTRUDA - AERS 12/01/2014 - 12/31/2014
2015-79	01/06/2015 02/04/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ibrutinib - All AEs Ken Tong	IMBRUVICA - AERS
2015-80	01/06/2015 02/04/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Idelalisib - All AE's Ken Tong	ZYDELIG - AERS 12/01/2014 - 12/31/2014
2015-81	01/06/2015 02/04/2015	FDA/OMPT/OSMP/OOPD/	H. Greg Thomas codaDOSE, Inc.	GRALISE - ORPHAN DRUG DESIGNATION CORR 11/01/2010 - 11/30/2010
2015-82	01/06/2015	FDA/OMPT/CDER/ORP/DIDP/	Pallavi Ail	DRUG MANUFACTURING FACILITIES IN INDIA - EIR 01/01/2012 - 12/31/2013

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	02/04/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	The Financial Express	
2015-83	01/06/2015 02/04/2015	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Jeremy Johnson Traditional medicinals	SADDLE CREEK CORPORATION - INSPECTION RECS, RECALL RECS, REPORTABLE FOOD REGISTRY ETC 01/05/2012 - 01/05/2015
2015-84	01/06/2015 02/04/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Howard Pomeranz, MD, PhD North Shore Long Island Jewish Health System	CIALIS - AERS
2015-85	01/06/2015 02/04/2015	FDA/OMPT/CDRH/OCER/DFOI/	Mauricio S. Umana Safis Solutions LLC	K943250 SUMMARY
2015-86	01/06/2015 02/04/2015	FDA/OMPT/CDRH/OCER/DFOI/	Mauricio S. Umana Safis Solutions LLC	K002154
2015-87	01/06/2015 02/04/2015	FDA/OMPT/CDRH/OCER/DFOI/	Mauricio S. Umana Safis Solutions LLC	K002154 SUMMARY
2015-88	01/06/2015 02/04/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jesse McLean Toronto Star	DR REDDY LABS, INDIA - 483 01/05/2012 - 01/05/2015
2015-89	01/06/2015 02/04/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Emily Mathieu Toronto Star	INDUSTRIAS QUIMICAS FALCON, MEXICO - 483 01/05/2012 - 01/05/2015
2015-90	01/06/2015 02/04/2015	FDA/OMPT/CDRH/OCER/DFOI/	Mauricio S. Umana Safis Solutions LLC	K941911 SUMMARY
2015-91	01/06/2015 02/04/2015	FDA/OMPT/CDRH/OCER/DFOI/	Mauricio S. Umana Safis Solutions LLC	K891773 SUMMARY
2015-92	01/06/2015 02/04/2015	FDA/OMPT/CDRH/OCER/DFOI/	Mauricio S. Umana Safis Solutions LLC	K001515
2015-93	01/06/2015 02/04/2015	FDA/OMPT/CDRH/OCER/DFOI/	Mauricio S. Umana Safis Solutions LLC	K960496 SUMMARY
2015-94	01/06/2015	OC/ORA/	Maya Foa	PENTOBARBITAL SODIUM POWDER, SOLUTION - IMPORT

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	02/04/2015	OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORO/CE-FO/DET- DO/DET-CB/ FDA/OC/OES/DFOI/	Reprieve US	DATA 01/05/2014 - 01/05/2015
2015-95	01/06/2015 02/04/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Howard Pomeranz, MD, PhD North Shore LIJ Health System	VERDENAFIL, LEVITRA - AERS Date Range: 08/01/2003 - 01/01/2015
2015-96	01/06/2015 02/04/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Chirag Talati Kotak Securities	ANDA 203286
2015-97	01/06/2015 02/04/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Howard Pomeranz, MD North Shore LIJ Health System	AVANAFIL, STENDRA - AERS 04/01/2012 - 01/01/2015
2015-98	01/06/2015 02/04/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Orna Oz Oz, Orna	K132560
2015-99	01/06/2015 02/04/2015	FDA/OMPT/CDRH/OCER/DFOI/	Melissa Thompson, Contract QSM Genchem Genchem, Inc.	K040976
2015-100	01/06/2015 02/04/2015	FDA/OMPT/CDRH/OCER/DFOI/	Melissa Thompson, Contract QSM Genchem Genchem, Inc.	K040977
2015-101	01/06/2015 02/04/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K082491

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2015-102	01/06/2015 02/04/2015	FDA/OGROP/ORR/SE-FO/NOL-DO/NOL-CB/	Meaghan Meyer Maplehurst Bakeries, LLC	CREATIVE OCCASIONS, INC, NASHVILLE, TN - INSPECTIONS, COMPLAINTS 01/01/2013 - 01/06/2015
2015-103	01/06/2015 02/04/2015	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2014-9430
2015-104	01/07/2015 02/05/2015	FDA/OMPT/CDRH/OCER/DFOI/	Melissa Thompson, Contract QSM Genchem Genchem, Inc.	K965134
2015-105	01/07/2015 02/05/2015	FDA/OMPT/CDRH/OCER/DFOI/	Melissa Thompson, Contract QSM Genchem Genchem, Inc.	K955936
2015-106	01/07/2015 02/05/2015	FDA/OMPT/CDRH/OCER/DFOI/	Melissa Thompson, Contract QSM Genchem Genchem, Inc.	K090283
2015-107	01/07/2015 02/05/2015	OC/CVM/OCD/	Barron Dickinson Searcy Denney Scarola Barnhart Shipley	RECS RE MEETING BETWEEN TEVA AND FDA 08/26/10
2015-108	01/07/2015 02/05/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Robert Wolfangel CERTUS INTERNATIONAL INC	CARDIOLITE - APPROVAL PACKAGE
2015-109	01/07/2015 02/05/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Walter Brittle FDA COMPLIANCE HELP DESK, INC	K063458
2015-110	01/07/2015 02/05/2015	FDA/OGROP/ORR/SE-FO/NOL-DO/NOL-CB/	Cheryl Spencer Forman Perry Watkins Krutz & Tardy LLP	GULF COAST COLD STORAGE A1, PASCAGOULA, MS - PHOTO, VIDEO ETC RE FIRE AND CLEANUP EFFORTS 12/10/2013 - 12/10/2014
2015-111	01/07/2015 02/05/2015	FDA/OGROP/ORR/PA-FO/SEA-DO/SEA-CB/	JoNel Aleccia The Seattle Times	LSG SKY CHEFS INC, SEATTLE, WA - 483 01/01/2014 - 01/06/2015
2015-112	01/07/2015 02/05/2015	FDA/OMPT/CDRH/OCER/DFOI/	Walter Brittle FDA COMPLIANCE HELP DESK, INC	K111393
2015-113	01/07/2015 02/05/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Moumita Rawal G&W Laboratories, Inc.	ANDA 062531, ANDA 062307, ANDA 062427, ETC - SBA

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2015-114	01/07/2015 02/05/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Eric White MISSION PHARMACAL COMPANY/PRESIDENT	NDA 19569
2015-115	01/07/2015 02/05/2015	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	GRANDFATHERED TOBACCO PRODUCT STATUS DETERMINATION FOR NATURAL AMERICAN SPIRIT PRODUCTS
2015-116	01/07/2015 02/05/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kartik Mehta ICICI Securities	SUN PHARMACEUTICALS - 483 UPDATE RECS 09/17/2014 - 01/07/2015
2015-117	01/07/2015 02/05/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	510K RELEASED DECEMBER 2014
2015-118	01/07/2015 02/05/2015	FDA/OMPT/CDRH/OCER/DFOI/	Orna Oz Oz, Orna	K083903
2015-119	01/07/2015 02/05/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Michelle Urban Iron Mountain	All registered drug and device manufacturers with addresses, contact information, and the number of annual anatomic pathology tests per year
2015-120	01/07/2015 02/05/2015	FDA/OMPT/CDRH/OCER/DFOI/	Shilpa Prem Epstein Becker and Green, P.C.	K132560, K102893, K041934 ETC
2015-121	01/07/2015 02/05/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Alexandra Boone Miller Weisbrod, LLP	NDA 202439, NDA 022406
2015-122	01/07/2015 02/05/2015	FDA/OMPT/CDRH/OCER/DFOI/	Manuel Reboso Rossman, Baumberger, Reboso & Spier, PA	Any and all complaints received by Intuitive Surgical, Inc., or the FDA pertaining to electrical arcing related to the use of the da Vinci Surgical System
2015-123	01/07/2015 02/05/2015	FDA/OGROP/ORACE-FO/BLT- DO/BLT-CB/	Dominick DiPaolo Dominick DiPaolo	ACTAVIS, OWINGS, MILLS, MD - 483 01/01/2013 - 01/01/2015
2015-124	01/07/2015	FDA/OMPT/CDRH/OCER/DFOI/	Manuel Reboso	FDA Form 3419 or electronic equivalent, and all attachments

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	02/05/2015		Rossman, Baumberger, Reboso & Spier, PA	thereto, of any user facility related to a da Vinci Surgical System manufactured by Intuitive Surgical, Inc
2015-125	01/07/2015 02/05/2015	FDA/OMPT/CDRH/OCER/DFOI/	Manuel Reboso Rossman, Baumberger, Reboso & Spier, PA	FDA Form 3500A or electronic equivalent, and all attachments thereto, of any user facility related to a da Vinci Surgical System manufactured by Intuitive Surgical, Inc
2015-126	01/07/2015 02/05/2015	OC/ORO/ORM/ OC/ORO/ORM/	Eric Schulman liberty national	LIST OF REGULATED FOOD AND ANIMAL FEED FACILITES IN IDAHO COUNTIES 01/01/2014 - 01/05/2015
2015-127	01/07/2015 02/05/2015	FDA/OMPT/CDRH/OCER/DFOI/	Orna Oz Oz, Orna	K041934
2015-128	01/07/2015 02/05/2015	FDA/OMPT/CDRH/OCER/DFOI/	Orna Oz Oz, Orna	K102893
2015-129	01/07/2015 02/05/2015	FDA/OMPT/CDRH/OCER/DFOI/	Orna Oz Oz, Orna	K050159
2015-130	01/07/2015 02/05/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dr Girish Bakhru HSBC Securities and Capital Markets	DR REDDY, SRIKAKULAM, INDIA - 483 11/03/2014 - 11/28/2014
2015-131	01/07/2015 02/05/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anita Fauchier Cempra Pharmaceuticals (Anita Fauchier)	ERCROS SA, MADRID, SPAIN - 483 12/01/2014 - 01/07/2015
2015-132	01/08/2015 02/06/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Brandon Beagle PhD PFC Devp./New Alliance Pharma	NDA 020091
2015-133	01/08/2015 02/06/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	mark julian mark julian	K103113
2015-134	01/08/2015 02/06/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Saritha JNTU	AXIS CLINICALS LIMITED - EIR 08/06/2013 - 08/08/2013
2015-135	01/08/2015 02/06/2015	FDA/OMPT/CDRH/OCER/DFOI/	Manuel Reboso Rossman, Baumberger, Reboso & Spier, PA	INTUITIVE SURGICAL, INC DA VINCI SURGICAL SYSTEM - FORM 3500A, INCDate Range: 01/01/2007 - 12/31/2014

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2015-136	01/08/2015 02/06/2015	FDA/OMPT/CDRH/OCER/DFOI/	Alon Mozes Neocis Inc	K030685, K112679
2015-137	01/08/2015 02/06/2015	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Susan Marra MARRA, SUSAN	ETHOX INTERNATIONAL - EIR, 483 01/01/2010 - 03/31/2010
2015-138	01/08/2015 02/06/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Vicki Whatsitt NATURAL PRODUCTS ASSOCIATION	Clinical data for galantamine and/or galanthamine submitted in conjunction with API submissions for Nivalin, Razadyne, Razadyne ER, Reminyl, and Lycoremine
2015-139	01/08/2015 02/06/2015	FDA/OMPT/CDRH/OCER/DFOI/	Tom Wilemon The Tennessean	Names and the locations of the dialysis centers in Tennessee that received recalled lots of Fresenius Naturalyte Liquid Bicarbonate Concentrate.
2015-140	01/08/2015 02/06/2015	OC/CVM/OCD/	Kelly Beers (US Agent for Huvepharma AD) Huvepharma, Inc.	NADA 065-252
2015-141	01/08/2015 02/06/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	mary moschos mary moschos	CYCLOSPORINE - LETTERS, COMPLAINTS
2015-142	01/08/2015 02/06/2015	FDA/OC/OES/DFOI/	Sean Kane SAFETY RESEARCH & STRATEGIES INC	FOIA LOG 01/01/2013 - 01/01/2015
2015-143	01/08/2015 02/06/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Carl Lauter MD WILLIAM BEAUMONT HOSPITAL	NATAIZUMAB - AERS
2015-144	01/08/2015 02/06/2015	FDA/OC/OES/DDM/	Donald A. Ecklund Carella, Byrne	58 FR 2852 - COMMENTS 01/01/1991 - 01/12/1993
2015-145	01/08/2015 02/06/2015	FDA/OC/OES/DFOI/	TUCKER 940992, LORNE	ASBESTOS REMEDIATION
2015-146	01/08/2015 02/06/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MANOJ GARG MERRILL LYNCH	DR REDDYS LABS, VIZAG SEZ PLANT, ANDHRA PRADESH, INDIA - 483
2015-147	01/08/2015	FDA/OMPT/CDER/GRP/DIDP/	Bharat Celly	CADILA HEALTHCARE LTD MORAIYA - 483 08/25/2014 - 09/10/2014

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	02/06/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Research Delta	
2015-148	01/08/2015 02/06/2015	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRIAN COKE NG NG, BRIAN COKE	JANSSEN RESEARCH & DEVELOPMENT LLC LTR 2/6/13 CERTIFIED
2015-149	01/08/2015 02/06/2015	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	RANDALL, JASON	LONZA - 483, CO RESP, CLOSE OUT LTR
2015-150	01/08/2015 02/06/2015	FDA/OFVM/CFSAN/OCD/EOS/	ARLENE MORALES BURDOCK GROUP	PROTOTHECA MORIFORMIS - REGULATORY STATUS, CONSUMPTION, SAFETY
2015-151	01/08/2015 02/06/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GUIOVITZ, JUDY	FORTEO - AER
2015-152	01/08/2015 02/06/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHIASMA LTD	SANDOSTATIN (OCTREOTIDE); SOMATULINE (LANREOTIDE) - AER
2015-153	01/08/2015 02/06/2015	OC/CVM/OCD/ OC/ORA/ OC/ORA/ FDA/OGROP/ORA/CE-FO/BLT- DO/BLT-CB/ FDA/OGROP/ORA/CE-FO/CHI- DO/CHI-CB/ FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/ FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SEA- DO/SEA-CB/ FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	RYAN T. KEARNEY COZEN O'CONNOR	CHICKEN JERKY PET TREATS - INVESTIGATION, TESTING FOR ANTI-VIRAL DRUGS 10/13 TO PRESENT

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		FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/		
2015-154	01/08/2015 02/06/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	AMAURY SANCHEZ NOVEN PHARMACEUTICALS INC	MYLAN TECHNOLOGIES - ESTRADIOL TRANSDERMAL SYS (ANDA 01-675)
2015-155	01/08/2015 02/06/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SAMPSON LEE DR REDDYS LABORATORIES INC	FORREST LAB INC - CARAFATE NDA 09-183 SBA
2015-156	01/08/2015 02/06/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	FALCONER MD, ERICK	LIST OF RECIPIENTS OF ALERT LTRS REGARDING BOTOX 2009 TO 2014
2015-157	01/08/2015 02/06/2015	FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	NICHOLAS J. PAROLISI JR LITCHFIELD CAVO LLP	WONTON FOODS INC - MUNG BEAN SPROUTS SALMONELLA ENTERITIDIS OUTBREAK INVESTIGATION RECS, CORR, RPTS, ETC
2015-158	01/08/2015 02/06/2015	FDA/OC/OES/DFOI/	Doe J	ELECTROMETER - INVESTIGATION
2015-159	01/08/2015 02/06/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KIM HENDERSON SANOFI PASTEUR	ACTISITE (TETRACYCLINE HCL) NDA 50-653 SBA, RVWS
2015-160	01/08/2015 02/06/2015	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANNE WEISMANN CITIZENS FOR RESPONSIBILITY & ETHICS IN WASHINGTON	FINANCIAL RPTS FILED BY FDA FOR PARTICIPATION ON ADVISORY COMMITTEES FOR DRUGS, VACCINES, DVCS 1/09 TO 12/1/14

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		FDA/OMPT/CDRH/OCER/DFOI/		
2015-161	01/09/2015 02/09/2015	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-2196
2015-162	01/09/2015 02/09/2015	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-3277
2015-163	01/09/2015 02/09/2015	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-822
2015-164	01/09/2015 02/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Brandon Beagle PhD PFC Devp./New Alliance Pharma	NDA 021191
2015-165	01/09/2015 02/09/2015	FDA/OMPT/CDRH/OCER/DFOI/	Jennifer Jackson Straumann USA, LLC	K141450
2015-166	01/09/2015 02/09/2015	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Helen Lysy PPD	PPD DEVELOPMENT, LLC, RICHMOND, VA - EIR 05/21/2012 - 05/25/2012
2015-167	01/09/2015 02/09/2015	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Matt Stirling PPD	PPD DEVELOPMENT LLC, RICHMOND, CA - EIR 05/21/2012 - 05/25/2012
2015-168	01/09/2015 02/09/2015	FDA/OMPT/CDRH/OCER/DFOI/	Mauricio S. Umana Safis Solutions LLC	K023905
2015-169	01/09/2015 02/09/2015	FDA/OMPT/CDRH/OCER/DFOI/	Mauricio S. Umana Safis Solutions LLC	K033256
2015-170	01/09/2015 02/09/2015	FDA/OMPT/CDRH/OCER/DFOI/	K133237 CANOPY MEDICAL INC	K133237
2015-171	01/09/2015 02/09/2015	FDA/OMPT/CDRH/OCER/DFOI/	Mauricio S. Umana Safis Solutions LLC	K083704
2015-172	01/09/2015 02/09/2015	FDA/OMPT/CDRH/OCER/DFOI/	Mauricio S. Umana Safis Solutions LLC	K081480
2015-173	01/09/2015 02/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 206627 EXCLUSIVITY SUMMARY
2015-174	01/09/2015 02/09/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Mauricio S. Umana Safis Solutions LLC	K053434

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2015-175	01/09/2015 02/09/2015	FDA/OMPT/CDRH/OCER/DFOI/	Shreya Mehta STANFORD UNIVERSITY	P920023
2015-176	01/09/2015 02/09/2015	FDA/OMPT/CDRH/OCER/DFOI/	Shreya Mehta STANFORD UNIVERSITY	K130651
2015-177	01/09/2015 02/09/2015	FDA/OMPT/CDRH/OCER/DFOI/	Mauricio S. Umana Safis Solutions LLC	K002154
2015-178	01/09/2015 02/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bocar Guisse SANDOZ CANADA INC.	ANDA 022396
2015-179	01/09/2015 02/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Saion Mukherjee Nomura Financial Advisory & Securities (India) Private Limited	DMF 17922, 18348, 18387, ETC
2015-180	01/09/2015 02/09/2015	FDA/OMPT/CDRH/OCER/DFOI/	Mauricio S. Umana Safis Solutions LLC	K103698
2015-181	01/09/2015 02/09/2015	FDA/OMPT/CDRH/OCER/DFOI/	Mauricio S. Umana Safis Solutions LLC	K141158
2015-182	01/09/2015 02/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ibrutinib - Individual Case Report Ken Tong	IMBRUVICA - AERS
2015-183	01/09/2015 02/25/2015	FDA/OGROP/ORACE-FO/BLT- DO/BLT-CB/ FDA/OGROP/ORASW-FO/DEN- DO/DEN-CB/ FDA/OGROP/ORASW-FO/KAN- DO/KAN-CB/	DESMONNE A BENNETT BRYAN CAVE LLP	PREMIUM PET HEALTH, DENVER, CO; SIOUX CITY, IA; SMITHFIELD, VA, ETC - INVESTIGATIONS, EVALUATIONS, VIOLATIONS, ETC
2015-184	01/09/2015 02/09/2015	FDA/OGROP/ORASW-FO/KAN- DO/KAN-CB/	NANCY KABODLIAN ABBHEY SPANIER LLP	RESER'S FINE FOODS INC, TOPEKA, KS - INSPS LAST 10 YRS, LISTERIA MONOCYTOGENES FINDINGS, VIOLATIONS, ETC
2015-185	01/09/2015 02/09/2015	FDA/OMPT/CDRH/OCER/DFOI/	REBECCA SHAMES-SCHUTZ Hogan Lovells, ILP	RAYSEARCH LABS - RAYSTATION K140187
2015-186	01/09/2015 02/09/2015	FDA/OGROP/ORACE-FO/PHI- DO/PHI-CB/	ELENA HOWELL Hogan Lovells, ILP	CASTLE CHEESE INC, SLIPPERY ROCK, PA - CMLPNT 4/26/12, RESP TO 483, CORR, ETC

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2015-187	01/09/2015 02/09/2015	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	ELENA HOWELL Hogan Lovells, ILP	CASTLE CHEESE INC, SLIPPERY ROCK, PA - RESP TO WARNING LTR 7/11/13
2015-188	01/09/2015 02/09/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	FURADANTIN NDA 9-175 - APRVL LTR, LBLG, MEDICAL RVW, ETC
2015-189	01/09/2015 02/09/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHRISTOPHER TOOMBS PHD FARADAY PHARMACEUTICALS	IODOPEN SODIUM IODIDE INJ - NONCLNCL ANIMAL TOXICOLOGY DATA, HUMAN CLNCL TRIAL SAFETY DATA, FORMULATION AND STABILITY
2015-190	01/09/2015 02/09/2015	FDA/OMPT/CDRH/OCER/DFOI/	Kristen Berger Regulatory & Quality Solutions LLC	MEDICAL DEVICE COMPANIES REGISTERED IN MA, NJ, OH, PA - NAME, ADDRESS, SPECIALTY
2015-191	01/09/2015 02/09/2015	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ian Flawn Orpana Ian Flawn Orpana	NDA 20472
2015-192	01/09/2015 02/09/2015	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jonathan Marcus ROBINS KAPLAN ET AL	SUPREP - ISR
2015-193	01/09/2015 02/09/2015	OC/ORACE/ORM/ OC/ORACE/ORM/ FDA/OFVM/CFSAN/OCD/EOS/	Mark Prinz Registrar Corp	REGISTERED FOREIGN FOOD FACILITIES BY COUNTRY - NAME, NUMBER OF FOOD FACILITIES Date Range: 12/31/2014 - 12/31/2014
2015-194	01/12/2015 02/10/2015	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	Daily logs regarding Tysabri, Antegren, etc.
2015-195	01/12/2015 02/10/2015	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	FCN 1475
2015-196	01/12/2015 02/10/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michelle Crawford MOUNT SINAI HOSPITAL	DEFERASIROX - AERES

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		FDA/OMPT/CDER/GRP/DIDP/		
2015-197	01/12/2015 02/10/2015	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Santiago Hernandez Soft Gel Technologies Inc,	SOFT GEL TECHNOLOGIES, LOS ANGELES, CA - EIR 01/01/2011 - 01/09/2015
2015-198	01/12/2015 02/10/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lauren Farruggia Hyman, Phelps & McNamara, P.C.	Letter dated September 28, 2012 from Martin Shimer, Branch Chief, Regulatory Support Branch, Office of Generic Drugs, concerning 180-Day Exclusivity for Valsartan Tablets
2015-199	01/12/2015 02/10/2015	FDA/OC/OES/DFOI/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Manuel Reboso Rossman, Baumberger, Reboso & Spier, PA	INTUITIVE SURGICAL, INC - CORR, WARNING LETTERS RE DA VINCE SURGICAL SYSTEM 01/01/2007 - 12/31/2014
2015-200	01/12/2015 02/10/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Anubhav Aggarwal CREDIT SUISSE	SUN PHARMA, HALOL, INDIA - EIR 09/08/2014 - 01/01/2015
2015-201	01/12/2015 02/10/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K091515
2015-202	01/12/2015 02/10/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K132785
2015-203	01/12/2015 02/10/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	GILEAD SCIENCES - CORR WITH DIVISION OF ANTI VIRAL PRODUCTS 01/01/2001 - 02/10/2007
2015-204	01/12/2015 02/10/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K142310
2015-205	01/12/2015 02/10/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	SABRIL - REMS
2015-206	01/12/2015 02/17/2015	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Trudy R. Papson Regulatory Consultants Group	APOLLO ENSOSURGERY, AUSTIN, TX - 483, EIR, COLLECTION REPORT 01/02/2014 - 01/01/2015
2015-207	01/12/2015 02/10/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Somi Ekwealor STRYKER ENDOSCOPY	K024291

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		FDA/OC/OES/DFOI/		
2015-208	01/12/2015 02/10/2015	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Rachel Johnson FOI Services, Inc.	SCANTIBODIES, SANTEE, CA - 483
2015-209	01/12/2015 02/10/2015	FDA/OC/OES/DFOI/	DAVIS 1403883, MINYARD	2014 ANNUAL RPT; USDA ARCHIVE INDEX, USDA DRUG SAFETY RPT, ETC
2015-210	01/12/2015 02/10/2015	FDA/OMPT/CDRH/OCER/DFOI/	Anekwe, Peter	EMIT-ST DRUG DETECTION SYS - DRUG ABUSE PROFICIENCY TESTING SURVEY 1972 TO 1981
2015-211	01/12/2015 02/10/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	COLESTIPOL HCL NDA 77-510 - APRVL, LBLG, CHEMISTRY RVW, ETC
2015-212	01/12/2015 02/10/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	NIMBEX NDA 20-551 - CHEMISTRY RVW
2015-213	01/12/2015 02/10/2015	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	Joseph F. Bermudez Wilson Elser Moskowitz Edelman & Dicker, LLP	UNITED 1 INTERNATIONAL LABORATORIES LLC AKA GLOBAL INTERNATIONAL, LLC - INVESTIGATION RECS, AUDITS 01/01/2010 - 01/09/2015
2015-214	01/12/2015 02/10/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michelle Elizabeth Legiec Eagle Pharmaceuticals, Inc.	ZYDUS BSV PHARMA PVT PTD, GUJARAT, INDIA - 483, EIR SUMMARY 01/01/2014 - 01/31/2014
2015-215	01/12/2015 02/10/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Fran Silverman truthinadvertising.org	TESTIM, TESTOPEL, ANDROGEL ETC - AERS
2015-216	01/12/2015 02/10/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Alberto Rossi UNIVERSITY OF MARYLAND	AERS - DATE PUBLISHED ON FDA WEBSITE 01/01/2004 - 01/09/2015
2015-217	01/12/2015 02/10/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARY ANN ALBERTAZZIE MYLAN INC	EPIPEN - ISR 95007481, 95007781, 96969991

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		FDA/OMPT/CDER/GRP/DIDP/		
2015-218	01/12/2015 02/10/2015	FDA/OC/OES/DFOI/	Briana Cahill none	NUT BUTTER RECALL AUGUST 2014 08/19/2014 - 01/09/2015
2015-219	01/12/2015 02/10/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	B&H Consulting Services, Inc., Sandy Lee B&H Consulting Services, Inc.	DR REDDY LABORATORY, SRIKAKULAM, INDIA - 483 01/01/2014 - 12/31/2014
2015-220	01/12/2015 02/10/2015	FDA/OMPT/CDRH/OCER/DFOI/	Andrew Tucker Xintek Inc.	K083344
2015-221	01/12/2015 02/10/2015	FDA/OC/OES/DFOI/	Keller and Heckman LLP	2014-P-0259 DRAFT 0003, 0004, 0005 ETC
2015-222	01/12/2015 02/10/2015	FDA/OC/OES/DFOI/	JFF	FDA 2014-N-1243-0001, FDA 2010-P-0559
2015-223	01/12/2015 02/10/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Peter R. Breggin, MD Center for the Study of Empathic Therapy	SERTRALINE - 5 YEAR AERS SUMMARY
2015-224	01/12/2015 02/10/2015	FDA/OC/OES/DFOI/	WILSON SOSINI GOODRICH & ROSATI	2014-N-1491, 2014-D-1167, 2014-D-0902
2015-225	01/12/2015 02/10/2015	FDA/OC/OES/DFOI/	COVINGTON & BURLING LLP	FDA-1975-N-0012
2015-226	01/12/2015 02/10/2015	FDA/OC/OES/DFOI/	SOLITTA JONES SAME DAY PROCESS	FDA-0009-N-0361
2015-227	01/12/2015 02/10/2015	FDA/OC/OES/DFOI/	BRYAN KOENIG FDA NEWS	FDA-2014-N-1741-0001
2015-228	01/12/2015 02/10/2015	FDA/OC/OES/DFOI/	BRYAN KOENIG FDA NEWS	FDA-2014-N-1491-0001
2015-229	01/12/2015 02/10/2015	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/	DONALD BLUE ZETETIC INC	SHIPMENTS REGULATED BY FDA 12/15-31/14
2015-230	01/12/2015 02/10/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELAINE CHANG GLANCY BINKOW & GOLDBERG LLP	PROVECTUS BIOPHARMACEUTICALS INC - DOCS

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2015-231	01/12/2015 02/10/2015	FDA/OMPT/CDRH/OCER/DFOI/	ROSEMARY HARRY DEVICE FOUNDATIONS INC	OVESCO ENDOSCOPY AG - OVER-THE-SCOPE CLIP SYS SET K101428
2015-232	01/13/2015 02/11/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lokesh Dayal CLEVELAND CLINIC FOUNDATION	TESTOSTERONE SUPPLEMENTS - AGGREGATED DATA OF VENOUS BLOOD CLOT EVENTS 01/01/2010 - 12/31/2014
2015-233	01/13/2015 02/11/2015	FDA/OFVM/CFSAN/OCD/EOS/	Restaurants buy from the New Yung Wah Trading Co. Epoch Times	New Yung Wah Trading Co. - CUSTOMER LIST 01/02/2014 - 12/31/2014
2015-234	01/13/2015 02/11/2015	FDA/OMPT/CDRH/OCER/DFOI/	Lee Hartley Lee Hartley	K141399
2015-235	01/13/2015 02/11/2015	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	Chirag Talati Kotak Securities	DIVI LABS - EIR, 483 01/01/2010 - 01/12/2015
2015-236	01/13/2015 02/11/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Vaibhav Dusad Morgan Stanley	DEFICIENCY LETTER TO DR REDDY'S LABORATORIES, INDIA RE: NEXIUM; COMPLETE RESPONSE LETTER AND BIOEQUIVALENCE DEFICIENCY ON NEXIUM ISSUED TO DR REDDY'S LABORATORIES
2015-237	01/13/2015 02/11/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Iva Klemick Amerigen Pharmaceuticals inc	RYTARY - SBA
2015-238	01/13/2015 02/11/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Houria Khelifati SANDOZ CANADA INC.	NDA 204300
2015-239	01/13/2015 02/11/2015	FDA/OGROP/ORACE-FO/LOS-DO/LOS-CB/	Mary Clare Jalonick The Associated Press	BIDART BROS - 483 01/01/2005 - 01/15/2015

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		FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/		
2015-240	01/13/2015 02/11/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Santana McMurrey/Zoloff ARNOLD & ITKIN LLP	Any and all documents related to the FDA's March 18, 2014 request for review of the epidemiological studies of pregnant women exposed to sertraline
2015-241	01/13/2015 02/11/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Peter Mione CutisPharma, Inc.	NATIONAL THERAPY PRODUCTS, INC, ONTARIO, CANADA - EIR, 483, RESPONSES 01/01/2007 - 12/31/2012
2015-242	01/13/2015 02/11/2015	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Jim Austin Arizona Nutritional Supplements	WELLMILL LLC DBA VITAMIX - 483 05/01/2014 - 05/31/2014
2015-243	01/13/2015 02/11/2015	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Rachel Johnson FOI Services, Inc.	ALERE, SAN DIEGO, CA - 483 05/05/2014 - 06/09/2014
2015-244	01/13/2015 02/11/2015	FDA/OMPT/CDRH/OCER/DFOI/	Lynn Lueders Smiths Medical Inc.	K141389
2015-245	01/13/2015 02/11/2015	FDA/OMPT/CDRH/OCER/DFOI/	Lynn Lueders Smiths Medical, Inc.	K141102
2015-246	01/13/2015 02/11/2015	FDA/OC/OES/DFOI/	Ly Nguyen AUBURN UNIVERSITY	DATA RE INSPECTIONS FOR FOOD, DRUGS, COSMETICS 01/01/2000 - 01/02/2014
2015-247	01/13/2015 02/11/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kathleen Helm-Bychowski Leydig, Voit and Mayer, Ltd	NDA 205060
2015-248	01/13/2015 02/11/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOIA REQUESTS CLOSED 2014
2015-249	01/13/2015 02/11/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 12/1-31/2014
2015-250	01/13/2015 02/11/2015	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-2945
2015-251	01/13/2015 02/11/2015	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-3378

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2015-252	01/13/2015 02/11/2015	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-3259
2015-253	01/13/2015 02/11/2015	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-8643
2015-254	01/13/2015 02/11/2015	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-3361
2015-255	01/13/2015 02/11/2015	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-3361
2015-256	01/13/2015 02/11/2015	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-3361
2015-257	01/13/2015 02/11/2015	FDA/OMPT/CDRH/OCER/DFOI/	DANIEL ZANG INNOVATION CONSULTING SERVICES INC	HUMAN BIOSCIENCES INC, OAK GROVE, MN - SKINWTEMP II K122325; BIOCORE INC, TOPEKA, KS - SKINTEMP MODIFICATION K925545; BIOCORE INC, TOPEKA, KS - SKINTEMP K913023, ETC
2015-258	01/13/2015 02/11/2015	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/ORA/OCI/ OC/ORA/OCI/	W MATTHEW NAKAJIMA O'CONNOR ACCIANI ET AL	DR MULLAI, HEMATOLOGY & ONCOLOGY CENTER, SOMERSET, KY - UNAPPROVED & IMPROPERLY LABELED CHEMOTHERAPY DRUGS INVESTIGATION RECS LAST 5 YRS
2015-259	01/13/2015 02/11/2015	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	WAYNE SADOWSKI NOVARTIS PHARMACEUTICAL CORP	DR ROBERT SCHLOSSMAN, BOSTON MA 6/16-23/14; DR KEITH ROBINSON, OAKLAND PARK, FL 6/23/14-7/3/14 - EIRS, 483S, 482S, ETC
2015-260	01/13/2015 02/11/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN D'ANGELO PRAGMA	PRAGAMA PHARMS - DESYREL(TRAZODONE HCL) TABS 50 MG, 100 MG, 150 MG, 300 MG NDA 18-207 APRVD APPL
2015-261	01/13/2015 02/11/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ADAM WARD WARD #1026408, ADAM	WELLBUTRON, VISCRILL - AERS

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		FDA/OMPT/CDER/GRP/DIDP/		
2015-262	01/13/2015 02/11/2015	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANI BYRNE Jamieson Laboratories Ltd.	JAMIESON - RECS (INCLUDING FDA 3500, 3500A, 3500B) 9/3/14-12/31/14
2015-263	01/13/2015 02/11/2015	FDA/OMPT/CDRH/OCER/DFOI/	Peter Bacas Drop Diagnostics	K141520
2015-264	01/13/2015 02/11/2015	FDA/OMPT/CDRH/OCER/DFOI/	Larissa DAndrea ResMed Corp.	K142554
2015-265	01/13/2015 02/11/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Olena Izhak University of Helsinki (FINLAND)	ANDA APPROVAL LETTERS
2015-266	01/13/2015 02/11/2015	FDA/OC/OES/DFOI/	AMIR DAVARI DAVARI, AMIR	MONSANTO, DOW, DUPONT - FOOD SAFETY & GMO BREAKDOWN ON STAFF
2015-267	01/13/2015 02/11/2015	FDA/OC/OES/DFOI/	ELENA HOWELL Hogan Lovells, ILP	2014-9798
2015-268	01/13/2015 02/11/2015	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SE-FO/SJN- DO/SJN-CB/	SAMANTHA MYERS ROANOKE CLAIMS SERVICES	PRP TRADING CORP - ENTRY #D05-01247080 NOTICES
2015-269	01/13/2015 02/11/2015	FDA/OC/OES/DFOI/	VICTOR MONTGOMERY MONTGOMERY, VICTOR	CV FOR HIRED INDIVIDUAL
2015-270	01/13/2015 02/11/2015	FDA/OC/OES/DFOI/	ADAM WARD WARD #1026408, ADAM	EFFEXOR - AERS
2015-271	01/13/2015 02/11/2015	FDA/OC/OES/DFOI/	ELENA HOWELL HOGAN LOVELLS LLP	2014-7023
2015-272	01/13/2015 02/11/2015	FDA/OFVM/CFSAN/OCD/EOS/	RATNA M SUDHA UNIQUE BIOTECH LTD	UNIQUE BIOTECH LTD - BACILLUS COAGULANS UNIQUE 1S2 GRN 526 COMMENTS
2015-273	01/13/2015 02/11/2015	FDA/OC/OES/DFOI/	AMIE N VANELLA FAEGRE BAKER DANIELS	SIMPLY THICK, SIMPLY THICK LLC - FOIA REQUESTS 10/30/14 TO PRESENT
2015-274	01/14/2015	FDA/OMPT/CDRH/OCER/DFOI/	Liane LaRochelle	K140439

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	02/12/2015		DEKA R&D	
2015-275	01/14/2015 02/12/2015	FDA/OMPT/CDRH/OCER/DFOI/	Jing Gu W.H.P.M, INC.	K132167
2015-276	01/14/2015 02/12/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Laura Granite (on behalf of Jerry Prince) THE JOHNS HOPKINS UNIVERSITY	K113202, K062525, K032347 ETC
2015-277	01/14/2015 02/12/2015	FDA/OMPT/CDRH/OCER/DFOI/	Steven Hershman LifeMap Solutions	K133951, K140638, K121609, ETC
2015-278	01/14/2015 02/12/2015	FDA/OMPT/CDRH/OCER/DFOI/	Will Clifton Procyrion	ABIOMED IMPELLA - 510K, PMA, DATA ETC 01/01/2008 - 12/31/2014
2015-279	01/14/2015 02/12/2015	OC/ORO/ OC/ORO/	Kris Shubert Essential Pharmacy Compounding	ESSENTIAL PHARMACY COMPOUNDING - CLOSEOUT LETTER 01/01/2005 - 01/01/2015
2015-280	01/14/2015 02/12/2015	FDA/OGROP/ORO/CE-FO/NWJ-DO/NWJ-CB/	Marsha Ajhar Smith, Gambrell & Russell, LLP	FANTIS FOODS INC - INSPECTIONS, VIOLATIONS, FINES 01/01/2009 - 01/13/2015
2015-281	01/14/2015 02/12/2015	FDA/OGROP/ORO/CE-FO/NWJ-DO/NWJ-CB/	Michael T. Price Brooks Wilkins Sharkey & Turco PLLC	PHARMACEUTICALS INNOVATIONS, INC - 483, AMENDMENTS, HRA ETC (CERTIFIED) 04/01/2011 - 05/01/2013
2015-282	01/14/2015 02/12/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joe Malone Joe Malone	BIRTH CONTROL DRUGS - ADVERSE EVENTS
2015-283	01/14/2015 02/12/2015	FDA/OMPT/CDRH/OCER/DFOI/	Jing Gu W.H.P.M, INC.	K132167
2015-284	01/14/2015 02/12/2015	FDA/OO/OFBA/OAGS/	Rose Santos FOIA GROUP INC	FDARFP1130645 - WINNING PROPOSALS
2015-285	01/14/2015 02/12/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	B&H Consulting Services, Inc.; Sandy Lee B&H Consulting Services, Inc.	DELPHARM LILLE SAS, FRANCE; PIRAMAL HEALTHCARE - PHARMA SOLUTIONS, ENGLAND - 483
2015-286	01/14/2015 02/12/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELAINE JANKE EMERGENT BIOSOLUTIONS	VARIZIG - ISRS 10458399, 10446763

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2015-287	01/14/2015 02/12/2015	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/	DONALD N BLUE ZETETIC INC	SHIPMENTS REGULATED BY THE FDA 1/1-15/15
2015-288	01/14/2015 02/12/2015	FDA/OC/OES/DFOI/ OC/ORO/ORM/ OC/ORO/ORM/	GAIL LESSICK LACHMAN CONSULTANT SERVICES INC	DRUG COMPANIES, MEDICAL DVC MFRS, BLOOD ESTABLISHMENTS, ETC - FOREIGN AND DOMESTIC INSPS 9/14 TO 12/14
2015-289	01/14/2015 02/12/2015	FDA/OFVM/CFSAN/OCD/EOS/	VISAGINE VIJAYAKULASINGAM IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 176429,176524, 177048, ETC
2015-290	01/14/2015 02/12/2015	FDA/OMPT/CDRH/OCER/DFOI/	JUDY F GORDON DVM CLINREG CONSULTING SERVICES INC	GLAUKOS ISTENT TRABECULAR MICRO-BYPASS STENT SYS P080030/S012
2015-291	01/14/2015 02/12/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	BIOFER SPA, MEDOLIA, ITALY - 483 1/31/14-2/4/14
2015-292	01/14/2015 02/12/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	SHARP GLOBAL LTD, GUJRANWALA TOWN, NEW DELHI, INDIA - 483 3/14
2015-293	01/14/2015 02/12/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	NOVACYL WUXI PHARMACEUTICAL CO LTD, JIANGSU, CHINA - 483 10/14-18/13
2015-294	01/14/2015 02/12/2015	FDA/OGROP/ORO/CE-FO/BLT- DO/BLT-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	PAUL D MINTZ MD, CHARLOTTESVILLE, VA - EIR, 483, CO RESP 2/24/14-3/28/14
2015-295	01/14/2015 02/12/2015	FDA/OGROP/ORO/CE-FO/NWJ- DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	MCNEIL-PPC INC, SKILLMAN, NJ - EIR, 483, CO RESP 3/21/13-4/10/13
2015-296	01/14/2015 02/12/2015	FDA/OGROP/ORO/CE-FO/CIN- DO/CIN-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	PI PHARMA INC, CAMPTON, KY - EIR, 483, CO RESP 2/10-19/14
2015-297	01/14/2015 02/12/2015	FDA/OGROP/ORO/NE-FO/NYK- DO/NYK-DCB/	WALTER E CHALKLEY THOMSON REUTERS	NEW HOPE FERTILITY CENTER, NEW YORK, NY - EIR, 483, CO RESP 8/26/14-9/15/14

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			(SCIENTIFIC) SAS	
2015-298	01/14/2015 02/12/2015	FDA/OMPT/CDRH/OCER/DFOI/	(Mr.) Taro Kanai MIC Internationa Corp.	K080079, K120035, K042455
2015-299	01/14/2015 02/12/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Peter Gerold Gerold, Peter J	ADENOSCAN AERS
2015-300	01/14/2015 02/12/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Bret Andre EyeReg Consulting, Inc.	K001962, K002099
2015-301	01/14/2015 02/12/2015	FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	TEXAS APPLIED BIOMEDICAL SERVICES, HOUSTON, TX - EIR, 483, CO RESP 4/16-25/12
2015-302	01/14/2015 02/12/2015	FDA/OGROP/ORACE-FO/DET- DO/DET-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	APPLIED LABORATORIES INC, CLOUMBUS, IN - EIR, 483, CO RESP 2/11-18/14
2015-303	01/14/2015 02/12/2015	FDA/OGROP/ORACE-FO/DET- DO/DET-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	CENTURY PHARMACEUTICALS INC, INDIANAPOLIS, IN - EIR, 483, CO RESP 1/13-14/14
2015-304	01/14/2015 02/12/2015	FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	LABORATORY SERCICE, CARTERET, NJ - EIR, 483, CO RESP 2/27/14-3/5/14
2015-305	01/14/2015 02/12/2015	FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	LABORATORY SERCICE, CARTERET, NJ - EIR, 483, CO RESP 2/27/14-3/5/14
2015-306	01/14/2015 02/12/2015	FDA/OGROP/ORASW-FO/DEN- DO/DEN-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	ISAAC TAWII MD, ALBUQUERQUE, NM - EIR, 483, CO RESP 11/19/13-12/5/13
2015-307	01/14/2015 02/12/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lalit Kumar Nomura Financial Advisory & Securities (India) Private Limited	ANDA 203286 COMPLETE RESPONSE
2015-308	01/14/2015 02/12/2015	FDA/OGROP/ORACE-FO/CHI- DO/CHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	FRESENIUS KABI USA LLC, MELROSE PARK, IL - EIR, 483, CO RESP 9/25/13-12/11/13
2015-309	01/14/2015	FDA/OGROP/ORASE-FO/SJN-	WALTER E CHALKLEY	DELIZ PHARMACEUTICAL CORP, CAROLINA, PR - EIR, 483,

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	02/12/2015	DO/SJN-CB/	THOMSON REUTERS (SCIENTIFIC) SAS	CO RESP 3/3-6/14
2015-310	01/14/2015 02/12/2015	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	SHELLY D SENDERS MD, SOUTH EUCLID, OH - EIR, 483, CO RESP 1/16-23/14
2015-311	01/14/2015 02/12/2015	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	NOSTRUM LABORATORIES INC, KANSAS CITY, MO - EIR, 483, CO RESP 2/10-19/14
2015-312	01/14/2015 02/12/2015	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	IVF PHOENIX, SCOTTSDALE, AZ - EIR, 483, CO RESP 2/1-5/10
2015-313	01/14/2015 02/12/2015	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	EMANUEL CALENOFF MD, DALLAS, TX - EIR, 483, CO RESP 5/19-22/14
2015-314	01/14/2015 02/12/2015	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	KEITH AQUA, BOYNTON BEACH, FL - EIR, 483, CO RESP 2/3/14-3/17/14
2015-315	01/14/2015 02/12/2015	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	BAXTER HEALTHCARE CORP, MARION, NC - EIR, 483, CO RESP 1/15-24/14
2015-316	01/14/2015 02/12/2015	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	NORMAN KALMIN MD, SAN ANTONIO, TX - EIR, 483, CO RESP 11/7-9/11
2015-317	01/14/2015 02/12/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	IMPAX LABORATORIES (TAIWAN) INC, JHUNAN, MIAO-LI COUNTY, TAIWAN - 483 7/21-26/14
2015-318	01/14/2015 02/12/2015	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OPP/OP/	EMILIA C LONARDO PHD GROCERY MANUFACTURERS ASSOCIATION	DKT 1994P-0036
2015-319	01/15/2015	FDA/OC/OES/DFOI/	Jaime Vassallo	2014-9888

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	02/13/2015		LexisNexis CourtLink Document Retrieval	
2015-320	01/15/2015 02/13/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K091034
2015-321	01/15/2015 02/13/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K133443
2015-322	01/15/2015 02/13/2015	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2013-5283
2015-323	01/15/2015 02/13/2015	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2012-4524
2015-324	01/15/2015 02/13/2015	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	David Puryear Han Feng Inc	ENTRY NUMBER 413-9018678-6
2015-325	01/15/2015 02/13/2015	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2014-1008
2015-326	01/15/2015 02/13/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Saion Mukherjee Nomura Financial Advisory & Securities (India) Private Limited	The initial ANDA submissions (letters) by Dr Reddy's Laboratories between 01 Jan 2014 to 31 Dec 2014
2015-327	01/15/2015 02/13/2015	FDA/OMPT/CDRH/OCER/DFOI/	Jennifer Edwards Wicker, Smith, O'Hara, McCoy & Ford, P.A.	All product literature and product specifications regarding the ConforMIS Total Knee Replacement implant
2015-328	01/15/2015 02/13/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Saion Mukherjee Nomura Financial Advisory & Securities (India) Private Limited	The Manufacturing Site indicated by Dr Reddy's for its DMF filing for ESOMEPRAZOLE MAGNESIUM TRIHYDRATE. The DMF number is 25858.
2015-329	01/15/2015 02/13/2015	FDA/OMPT/CDRH/OCER/DFOI/	Michelle Chan for Karen Spelleccacy Law Office of Joanne R. Werner	MAUDE REPORT
2015-330	01/15/2015 02/13/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	ROSSMAX INTERNATIONAL, TAIWAN, CHINA - EIR, 483
2015-331	01/15/2015	FDA/OMPT/CDRH/OCER/DFOI/	James Wong	MEDTRONIC MINIMED PARADIGM INSULIN INFUSION SETS

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	02/13/2015		HARMAN LAW LLC	- MAUDE RECS
2015-332	01/15/2015 02/13/2015	FDA/OFVM/CFSAN/OCD/EOS/	Mark Prinz Registrar Corp	FOREIGN FOOD FACILITIES REGISTERED AS OF 1/12/15
2015-333	01/15/2015 02/13/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ayesha Adil The Weinberg Group	NDA 203629 SBA
2015-334	01/15/2015 02/13/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joy Wise Joy Wise	PROLIA, FOXAMAX - AERS
2015-335	01/15/2015 02/13/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MICHAEL MONTAVON MICHAEL C MONTAVON PC	MEDIMERGENT LLC - RESEARCH COLLABORATION AGREEMENT (RCA) RECS
2015-336	01/15/2015 02/13/2015	FDA/OMPT/CDRH/OCER/DFOI/	ANTHONY PIOTRKOWSKI STERIS CORP	GETINGE 633HC STREAM STERILIZER AIR GLIDE SYS - K120532
2015-337	01/15/2015 02/13/2015	FDA/OFVM/CFSAN/OCD/EOS/	R LYNN YOUNG MILK REGULATORY CONSULTANTS, LLC	WESTINGHOUSE ELECTRIC CORP - FAP 5M1592
2015-338	01/15/2015 02/13/2015	FDA/OMPT/CDRH/OCER/DFOI/	PARLATO, MICHAEL	DENVER PLEURAL - PERITONEAL SHUNT K842139
2015-339	01/15/2015 02/13/2015	FDA/OMPT/CDRH/OCER/DFOI/	SUSIE S. CHEN KARL STORZ ENDOSCOPY AMERICA INC	OLYMPUS CORP OF THE AMERICAS, OLYMPUS MEDICAL SYSTEMS CORP - NARROW BAND IMAGING 510K
2015-340	01/15/2015 02/13/2015	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	CHRIS WULF SUN SPROUTS	SUN SPROUTS - PRDUCT SPLS 878359, 878360, 878361, 878362 12/22/14
2015-341	01/15/2015 02/13/2015	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	DONALD N. BLUE ZETETIC INC	MEDICORP LTD - OTC BLOOD GLUCOSE TEST - ENTRY NO MH9-0087497-4
2015-342	01/15/2015 02/13/2015	FDA/OMPT/CDRH/OCER/DFOI/	SUSANNE SCROGGIN PULLMAN & COMLEY LLC	BRIDGEPORT HOSPITAL, BRIDGEPORT, CT - MDRS 1/08 TO PRESENT
2015-343	01/15/2015	FDA/OMPT/CDER/ORP/DIDP/	Kiran Awate	DRUG ESTABLISHMENTS CURRENT REGISTRATION SITE

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	02/13/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	THE OHIO STATE UNIVERSITY	01/01/2000 - 01/01/2009
2015-344	01/15/2015 02/13/2015	OC/ORA/ORM/ OC/ORA/ORM/	Craig A. Garmendia FLORIDA INTERNATIONAL UNIVERSITY/UNIVERSITY OUTREACH	LIST OF BIMO INSPECTIONS 10/01/2013 - 09/30/2014
2015-345	01/15/2015 02/13/2015	FDA/OMPT/CDRH/OCER/DFOI/	Celso Duran COVIDIEN	K133578
2015-346	01/15/2015 02/13/2015	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	Dr. Paul Knoepfler UC DAVIS SCHOOL OF MEDICINE	KRISTEN COMELLA, SHARON MCQUILLAN, AGELESS REGENERATIVE, STEMLOGIX - 482, 483, CORR ETC 01/03/2012 - 01/14/2015
2015-347	01/15/2015 02/13/2015	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OFVM/CFSAN/OCD/EOS/	CYNTHIA LIEBERMAN Keller and Heckman LLP	PNC NOS 1317, 1398
2015-348	01/15/2015 02/13/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	SF-1019 WAS LABELED UNABLE TO CONTINUE - RECS
2015-349	01/16/2015 02/17/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	HEALTH & LIFE, JIANGSU, CHINA - EIR, 483
2015-350	01/16/2015 02/17/2015	FDA/OMPT/CDRH/OCER/DFOI/	Susan Sorrells Grifols Inc,	NOEL MCELVANEY, DUBLIN, IRELAND - 483 04/13/2014 - 05/08/2014
2015-351	01/16/2015 02/17/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-7048
2015-352	01/16/2015 02/17/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-7059
2015-353	01/16/2015 02/17/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-7062
2015-354	01/16/2015 02/17/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-7734
2015-355	01/16/2015 02/17/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Anurag patel Dr. Reddy's Laboratories Inc.	NDA 203159 GENERIC BE GUIDANCE

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2015-356	01/16/2015 02/17/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Trish Douglas PFIZER	XALATAN - SBA
2015-357	01/16/2015 02/17/2015	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	Ben Smart Smart, Ben	NATURE'S PRODUCT INC, SUNRISE, FL - EIR, 483, CORR ETC 06/01/2007 - 12/21/2014
2015-358	01/16/2015 02/17/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Margaret Sestrom / Diana Morgan PFIZER	MELATONIN, WARFARIN - DDI RECS
2015-359	01/16/2015 02/17/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-7044
2015-360	01/16/2015 02/17/2015	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	Shannon Petersen RADIANT RESEARCH	RADIANT RESEARCH, CINCINNATI, OH - EIR 12/01/2013 - 07/31/2014
2015-361	01/16/2015 02/17/2015	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	Donald Barrett Donald C. Barrett, P.A.	LYNN PEAVEY COMPANY - WARNING LETTER RECS
2015-362	01/16/2015 02/17/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kiran Awate THE OHIO STATE UNIVERSITY	NDA DATA 01/04/1990 - 01/15/2015
2015-363	01/16/2015 02/17/2015	FDA/OMPT/CDRH/OCER/DFOI/	Jesse Mendelson Avalere Health	GUDID DATABASE FOR INFUSION PUMPS
2015-364	01/16/2015 02/17/2015	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Nicola Hubert OASIS Medical Inc.	OASIS MEDICAL INC - EIR 04/11/2014 - 09/30/2014
2015-365	01/16/2015 02/17/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jeanie Ward Jeanie Ward	POLYETHYLENE GLYCOL - ADVERSE EVENTS
2015-366	01/16/2015 02/17/2015	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	Shannon Petersen RADIANT RESEARCH	RADIANT RESEARCH, CINCINNATI, ON - EIR 02/01/2014 - 12/31/2014
2015-367	01/16/2015 02/17/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Andrew Finkelstein Susquehanna Financial Group	ANDA AWAITING OGD ACTION

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2015-368	01/16/2015 02/17/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WILLIAM MCINTYRE LUPIN PHARMACEUTICALS INC	KERYX BIOPHARMS - AURYXIA (FERRIC CITRATE) TABS 210 MG NDA 205-874 SBA
2015-369	01/16/2015 02/17/2015	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/ FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/	DAVID A GRANT PAYNE & FEARS	GEMSA ENTERPRISES LLC, ITALCAL TRADING CO, EMILIO VISCOMI, ETC - INVESTIGATION RECS 1/1/10 TO PRESENT
2015-370	01/16/2015 02/17/2015	OC/ORA/ORM/ OC/ORA/ORM/	LESLIE RAMSEY FDA NEWS	LISTING OF 483'S NOTICES FOR PHARMACEUTICAL, BIOLOGICS & MEDICAL DEVICE MFG, CLNCL TRIAL FACILITIES IN US & OUTSIDE US 12/1-31/14
2015-371	01/16/2015 02/17/2015	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/CE-FO/BLT- DO/BLT-CB/	Doe J	IPB300 BATH LIFT - CMLPNT
2015-372	01/20/2015 02/18/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Scott Hodes Scott Hodes, Attorney at Law	Any documents that list the compounding pharmacies in the United States that compounded large quantities (ten (10) or more vials per week) of hydroxyprogesterone caproate (17P) for the past six (6) months from the date of the search for responsive records
2015-373	01/20/2015 02/18/2015	FDA/OFVM/CFSAN/OCD/EOS/	Carlos Andres Donado CarboUA	DIMETHYLDIALKYLAMMONIUM IN SUGAR MILLS FOR PRODUCTION OF WHITE SUGAR
2015-374	01/20/2015 02/18/2015	FDA/OFVM/CFSAN/OCD/EOS/	Erin Tesch TECHNOLOGY SCIENCES GROUP INC	SILVER ACETATE STUDY RECS
2015-375	01/20/2015 02/18/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Brian Cercek Macquarie CAF LLC	DRUGS FILED UNDER NDA GRANTED PRIORITY REVIEW STATUS 01/01/1992 - 12/31/2014
2015-376	01/20/2015 02/18/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mona Bahouth JOHNS HOPKINS HOSPITAL	ALTEPLASE - AERS

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		FDA/OMPT/CDER/GRP/DIDP/		
2015-377	01/20/2015 02/18/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Mary Gustafson PPTA	TABLES OF FINAL CONCLUSIONS PLASMA DONOR FATALITIES FY 2013, 2014
2015-378	01/20/2015 02/18/2015	FDA/OGROP/ORR/SE-FO/FLA- DO/FLA-CB/	Doe J	ALOE MAN INTERNATIONAL CORP, ALOE MAN INC - INSPECTION REPORTS, WARNING LETTER RESPONSE 01/16/2009 - 01/16/2015
2015-379	01/20/2015 02/18/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Donna Bitzelberger Venable, LLP	NDA 20782, 21168 S004 - APPROVAL LETTER (CERTIFIED)
2015-380	01/20/2015 02/18/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Donna Bitzelberger Venable, LLP	NDA 21168 S012 - APPROVAL LETTER (CERTIFIED)
2015-381	01/20/2015 02/18/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	9797153, 9805305, 9921411 ETC
2015-382	01/20/2015 02/18/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	9922370, 10024182 - MEDWATCH, SOURCE DOCUMENTS, DIRECT REPORTS
2015-383	01/20/2015 02/18/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	9959011, 9796988, 9880454 ETC - DIRECT REPORTS, MEDWATCH REPORTS, ANY SOURCE DOCUMENTS
2015-384	01/20/2015 02/18/2015	FDA/OGROP/ORR/SE-FO/FLA- DO/FLA-CB/	Mehul Govani P & L Development, LLC	TEVA BRANDED PHARMACEUTICAL PRODUCTS R & D, MIAMI, FL - 483 01/01/2005 - 01/16/2015
2015-385	01/20/2015 02/18/2015	FDA/OMPT/CDRH/OCER/DFOI/	Tiffany Suekama LC Therapeutics	K142120, K133017
2015-386	01/20/2015 02/18/2015	FDA/OMPT/CDRH/OCER/DFOI/	Andrew M. Purdy Joseph Saveri Law Firm, Inc.	EMKINETICS, INC - RECS SUBMITTED BY OR PERTAINING TO CE MARK AND 510K CLEARANCE 07/01/2011 - 06/30/2013
2015-387	01/20/2015 02/18/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Geoff Marcek International Biophysics	K991864

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			Corporation	
2015-388	01/20/2015 02/18/2015	FDA/OC/OL/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	CORR RE APLIGRAP, DERMAGRAF, EPIFIX, ETC
2015-389	01/20/2015 02/18/2015	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Stephen Fowler Celerion, Inc.	CELERION, INC, TEMPE, AZ - EIR 08/13/2013 - 08/22/2013
2015-390	01/20/2015 02/25/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORA/ OC/ORA/ FDA/OGROP/ORA/ORO/DIOP/	Jackie Warhollick Fanwood Chemical Inc	TRICLOSAN NOTICE OF ARRIVALS
2015-391	01/20/2015 02/18/2015	FDA/OMPT/CDRH/OCER/DFOI/	Jennifer F. Bryan DT Ward PC	K090421
2015-392	01/20/2015 02/18/2015	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Nancy Duplisea Boston Ivf	BOSTON IVF, SOUTH PORTLAND, ME - EIR 01/01/2013 - 01/01/2015
2015-393	01/20/2015 02/18/2015	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OC/OES/DFOI/	Gary Black Gary Black	HI TECH PHARMACEUTICALS, NORCROSS, GA - WARNINGS, EVIDENCE, NOTIFICATION
2015-394	01/20/2015 02/18/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Lloyd Olson Society for Technology in Anesthesia	K043299
2015-395	01/20/2015 02/18/2015	FDA/OMPT/CDRH/OCER/DFOI/	Stacy Kluesner Ethicon	K003431
2015-396	01/20/2015 02/18/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Donna Bitzelberger Venable, LLP	NDA 18723 S020, NDA 19680 S008 - APPROVAL LETTER

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2015-397	01/20/2015 02/18/2015	FDA/OMPT/CDRH/OCER/DFOI/	Julia Helgeson STRYKER CORPORATION	K141668
2015-398	01/20/2015 02/18/2015	FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/	Stephen Fowler Celerion, Inc.	CELERION, LINCOLN, NE - EIR 06/20/2011 - 06/24/2011
2015-399	01/20/2015 02/18/2015	FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/	Stephen Fowler Celerion, Inc.	CELERION, LINCOLN, NE - EIR 06/29/2010 - 07/02/2010
2015-400	01/20/2015 02/18/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Marc C. Sanchez, Esq. Contract In-House Counsel and Consultants, LLC	K050174, K060846
2015-401	01/20/2015 02/18/2015	FDA/OMPT/CDRH/OCER/DFOI/	Dinesh Puppala Suneris, Inc.	K140313
2015-402	01/20/2015 02/18/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michele Sinoway LACHMAN CONSULTANT SERVICES INC	NDA 019188 SBA
2015-403	01/20/2015 02/18/2015	FDA/OMPT/CDRH/OCER/DFOI/	Dinesh Puppala Suneris, Inc.	K122886
2015-404	01/20/2015 02/18/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Saion Mukherjee Nomura Financial Advisory & Securities (India) Private Limited	CADILA HEALTHCARE - 483 07/02/2014 - 10/31/2014
2015-405	01/20/2015 02/18/2015	FDA/OGROP/ORR/CE-FO/CIN-DO/CIN-CB/	Lori Wright WIL RESEARCH LABS LLC	WIL RESEARCH, ASHLAND, OH - EIR 05/05/1986 - 05/23/1986
2015-406	01/20/2015 02/18/2015	FDA/OMPT/CDRH/OCER/DFOI/	Avital Merl BECTON DICKINSON	K143189
2015-407	01/20/2015 02/18/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	THIERRY FILLOUX TRISKEL INTEGRATED SERVICES	CAMPTOSAR NDA 20-571
2015-408	01/20/2015 02/18/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SCOTT J. WEIR UNIVERSITY OF KANSAS MEDICAL CENTER	ETHACRYNIC ACID NDA 16-092 LBLG, APRVL LTR, MOR, ETC

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2015-409	01/20/2015 02/18/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DEAN RYAN Taylor Wessing LLP	TAXOL (PACLITAXEL) LBLG
2015-410	01/20/2015 02/18/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PAIGE STRADLEY MERCHANT & GOULD	ZOMETA NDA 21-386 ALL VERSIONS
2015-411	01/20/2015 02/18/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GERARD RYAN PARKER & WAICHMAN ATTYS	MIRENA POST MARKETING SURVEILLANCE STUDY IN JAPAN IDENTIFIER NCT01414140 - CORR, ATTACHMENTS, ENCLOSURES, ETC
2015-412	01/20/2015 02/18/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Doe J	INDIVIDUAL RECS
2015-413	01/20/2015 02/18/2015	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/	DONALD BLUE ZETETIC INC	ALL SHIPMENTS REGUALTED BY FDA 1/1-15/15
2015-414	01/20/2015 02/18/2015	FDA/OGROP/ORO/CE-FO/CIN- DO/CIN-CB/	DONALD BLUE ZETETIC INC	ENTRY NO UPS-1716242-3
2015-415	01/20/2015 02/18/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KATE REYNOLDS ROCKY MOUNTAIN POISON & DRUG CENTER	ISRS 6892196, 6983996, 6984134 ETC
2015-416	01/20/2015 02/18/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KATE REYNOLDS ROCKY MOUNTAIN POISON & DRUG CENTER	FAERS 78721474, 90524889, 93634437
2015-417	01/20/2015 02/18/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KATE REYNOLDS ROCKY MOUNTAIN POISON & DRUG CENTER	FAERS 7872147, 8444988, 8784430 ETC
2015-418	01/20/2015 02/18/2015	FDA/OGROP/ORO/NE-FO/NYK- DO/NYK-DCB/	LESLIE A. RAMSEY FDA NEWS	LABORATORIO MAGNACHEM INTL - RESP TO 483'S

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2015-419	01/20/2015 02/18/2015	FDA/OC/OES/DFOI/	DAVID A. ERNST DAVIS WRIGHT TREMAINE LLP	YOSEMITE HANTAVIRUS OUTBREAK 2012 CDC RECS
2015-420	01/21/2015 02/19/2015	FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/	Jason Werner Werner, Jason B	SEVENTH WAVE LABORATORIES, CHESTERFIELD, MO - EIR 09/27/2013 - 01/16/2015
2015-421	01/21/2015 02/19/2015	FDA/OC/OES/DFOI/	Rachael McGuire Rachael McGuire	Clinical Investigator Inspection Reports (CLIL) and FDA Form 483s
2015-422	01/21/2015 02/19/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lisa Girion LOS ANGELES TIMES	LETTER FROM FDA TO PURDUE PHARMA RE OXYCONTIN OCT 1994
2015-423	01/21/2015 02/19/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bruce Johnson Bruce Johnson	JETREA - AERS
2015-424	01/21/2015 02/19/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mark Keeton Hutchinson Regional Medical Center	MEGESTROL ACETATE - AERS
2015-425	01/21/2015 02/19/2015	FDA/OMPT/CDRH/OCER/DFOI/	Tessa Hopsicker ConMed Corporation	K033333
2015-426	01/21/2015 02/19/2015	FDA/OFVM/CFSAN/OCD/EOS/	Marisa Rihner TOXICOLOGY REGULATORY SERVICES	FAP 9A3441
2015-427	01/21/2015 02/19/2015	FDA/OGROP/ORR/PA-FO/SAN-DO/SAN-CB/	Annette Kenser BAYER HEALTHCARE	YOUNG VETERINARY RESEARCH SERVICES, TURLOCK, CA - 483 02/19/2013 - 03/18/2013
2015-428	01/21/2015 02/19/2015	FDA/OFVM/CFSAN/OCD/EOS/	Marisa Rihner Toxicology Regulatory Services Inc.	FAP 6A4763
2015-429	01/21/2015 02/19/2015	FDA/OMPT/CDRH/OCER/DFOI/	Joseph M Ascenzi JMA Consulting	K874106

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2015-430	01/21/2015 02/19/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Brian J. Elbaum Law Offices of Brian J. Elbaum	ALLI, XENICAL - AERS
2015-431	01/21/2015 02/19/2015	FDA/OMPT/CDRH/OCER/DFOI/	Andrea Fruetel INSITU TECHNOLOGIES INC	K041269
2015-432	01/21/2015 02/19/2015	FDA/OMPT/CDRH/OCER/DFOI/	Judith Rosen Zimmer Trabecular Metal Technology, Inc	K053340
2015-433	01/21/2015 02/19/2015	FDA/OFVM/CFSAN/OCD/EOS/	Michael Landa not applicable	FINAL REPORT OF CFSAN NUTRITION REVIEW 12/01/2014 - 12/31/2014
2015-434	01/21/2015 02/19/2015	FDA/OMPT/CDRH/OCER/DFOI/	Beth Luoma DuVal & Associates, P.A.	K945594, K951085, K940208 ETC
2015-435	01/21/2015 02/19/2015	FDA/OFVM/CFSAN/OCD/EOS/	Laura Anderson Arkema Inc.	FCN 56, 345
2015-436	01/21/2015 02/19/2015	FDA/OMPT/CDRH/OCER/DFOI/	Larissa DAndrea RESMED CORP	K140580
2015-437	01/21/2015 02/19/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Vincent P. Andolina AuroMedics Pharma LLC	APOTEX PHARMACHEM INC, ONTARIO, CANADA - 483 10/01/2014 - 01/20/2015
2015-438	01/21/2015 02/19/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ayesha Adil The Weinberg Group	NDA 021196 - SBA
2015-439	01/21/2015 02/19/2015	FDA/OMPT/CDRH/OCER/DFOI/	Tessa Hopsicker ConMed Corporation	K102082
2015-440	01/21/2015 02/19/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Chris Beyer Beyer, Christopher	NEOSTIGMINE METHYLSULFATE - APPROVAL POSTING DATE
2015-441	01/21/2015 02/19/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Joseph M Ascenzi JMA Consulting	K024148

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2015-442	01/21/2015 02/19/2015	FDA/OMPT/CDRH/OCER/DFOI/	Tessa Hopsicker ConMed Corporation	K091495
2015-443	01/21/2015 02/19/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Joseph M Ascenzi JMA Consulting	K030802
2015-444	01/21/2015 02/19/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Su Zhang DUKE UNIVERSITY	prescription drug list published in the annual version of orange book from 2000 to 2013
2015-445	01/21/2015 02/19/2015	FDA/OMPT/CDRH/OCER/DFOI/	Tessa Hopsicker ConMed Corporation	K040129
2015-446	01/21/2015 02/19/2015	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	Bertha Sorfleet Cloverhill Pastry-Vend, LLC	CLOVERHILL PASTRY-VEND, CHICAGO, IL - 483 04/22/2014 - 04/22/2014
2015-447	01/21/2015 02/19/2015	FDA/OC/OES/DFOI/	Walid Gardezi Walid Gardezi	STAAR SURGICAL - INSPECTION REPORTS 1/1/2013 - 1/20/2015
2015-448	01/21/2015 02/19/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Tessa Hopsicker ConMed Corporation	K063677
2015-449	01/21/2015 02/19/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lisa Girion LOS ANGELES TIMES	NDA 202880
2015-450	01/21/2015 02/19/2015	FDA/OMPT/CDRH/OCER/DFOI/	Tessa Hopsicker ConMed Corporation	K970052
2015-451	01/21/2015 02/19/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Tessa Hopsicker ConMed Corporation	K041606
2015-452	01/21/2015 02/19/2015	FDA/OGROP/ORACE-FO/FLA-DO/FLA-CB/	William Diaz-Garcia Blount Law, PL	SOLARA, INC - INVESTIGATION RECS 01/01/2012 - 12/31/2014
2015-453	01/21/2015 02/19/2015	OC/ORACE-FO/ OC/ORACE-FO/ FDA/OMPT/CTP/OD/	Lisa Isgett Counter Tools	LIST OF TOBACCO RETAILERS IN VIRGINIA 01/01/2012 - 01/31/2015
2015-454	01/21/2015 02/19/2015	OC/ORACE-FO/ OC/ORACE-FO/ FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Mark Prinz Registrar Corp	ENTRY 231-8131584-1

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2015-455	01/21/2015 02/19/2015	FDA/OO/OHR/	DAVARI, AMIR	MARGARET HAMBURG, ELIZABETH DICKINSON, MARTINA VAMADO, ETC - CV
2015-456	01/21/2015 02/19/2015	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	LESLIE RAMSEY FDA NEWS	FISHER DIAGNOSTICS, MIDDLETOWN, VA - 483S 12/1-31/14
2015-457	01/21/2015 02/19/2015	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	LESLIE RAMSEY FDA NEWS	JM HUBER CORP, QUINCY, IL - 483S 12/1-31/14
2015-458	01/21/2015 02/19/2015	FDA/OGROP/ORACE-FO/CINDO/CIN-CB/	LESLIE RAMSEY FDA NEWS	SYNAPSE BIOMEDICAL INC, OBERLIN, OH; THERMEDX LLC, SOLON, OH; RAM PRECISION INDUSTRIES, CENTERVILLE, OH, ETC - 483S 12/1-31/14
2015-459	01/21/2015 02/19/2015	FDA/OGROP/ORASW-FO/DALDO/DAL-CB/	LESLIE RAMSEY FDA NEWS	CARDIOVASCULAR SYSTEMS INC, HOUSTON, TX; RIGHT VALUE DRUG STORES INC, HURST, TX; AMERICAN SPECIALTY PHARMACY, PLANO, TX, ETC - 483S 12/1-31/14
2015-460	01/21/2015 02/19/2015	FDA/OGROP/ORASW-FO/DENDO/DEN-CB/	LESLIE RAMSEY FDA NEWS	ZYTO TECHNOLOGIES INC, LINDON, UT; CYCLOTRON RADIOCHEMISTRY LAB (HUNTSMAN CANCER INSTITUTE), SALT LAKE CITY, UT; BAXTER CORPORATION ENGLEWOOD, ENGLEWOOD, CO - 483S 12/1-31/14
2015-461	01/21/2015 02/19/2015	FDA/OGROP/ORACE-FO/DETDO/DET-CB/	LESLIE RAMSEY FDA NEWS	FREEMAN MANUFACTURING CO, STURGIS, MI; KREMERS URBAN PHARMACEUTICALS INC, SEYMOUR, IN; MEDICAL MINDS LLC, ALLENDALE, MI, ETC - 483S 12/1-31/14
2015-462	01/21/2015 02/19/2015	FDA/OGROP/ORASE-FO/FLADO/FLA-CB/	LESLIE RAMSEY FDA NEWS	EUSA GLOBAL LLC (DBA ECLERIS USA), MEDLEY, FL; FEN DENTAL MANUFACTURING INC - 483S 12/1-31/14
2015-463	01/21/2015 02/19/2015	FDA/OGROP/ORASW-FO/KANDOKAN-CB/	LESLIE RAMSEY FDA NEWS	ERFOSAFE PRODUCTS LLC (DBA PRISM MEDICAL), MARYLAND HEIGHTS, MO; ORTHOTIC & PROSTHETICS ONE INC, WATERLOO, IA - 483S 12/1-31/14
2015-464	01/21/2015 02/19/2015	FDA/OGROP/ORAPA-FO/LOSDO/LOS-CB/	LESLIE RAMSEY FDA NEWS	MAST BIOSURGERY USA INC, SAN DIEGO, CA; NEW WORLD MEDICAL INC, RANCHO CUCAMONGA, CA; WATSON LABORATORIES INC, CORONA, CA, ETC - 483S 12/1-31/14
2015-465	01/21/2015 02/19/2015	FDA/OGROP/ORACE-FO/MINDO/MIN-CB/	LESLIE RAMSEY FDA NEWS	ALLIANCE PACKAGING GROUP INC, SAUKVILLE, WI; HOOF HEALTH LLC (DBA HOOF EFFECTS), HELENVILLE, WI; EPIC SYSTEMS CORP, VERONA, WI - 483S 12/1-31/14
2015-466	01/21/2015 02/19/2015	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	LESLIE RAMSEY FDA NEWS	JS DENTAL MANUFACTURING INC, RIDGEFIELD, CT; COOPERSURGICAL INC, TRUMBULL, CT - 483S 12/1-31/14
2015-467	01/21/2015 02/19/2015	FDA/OGROP/ORACE-FO/NWJDO/NWJ-CB/	LESLIE RAMSEY FDA NEWS	BASF CORP, WASHINGTON, NJ; SOMA LABS INC, MIDDLESEX, NJ; ACCRIVA DIAGNOSTICS, EDISON, NJ, ETC - 483S 12/1-31/14
2015-468	01/21/2015 02/19/2015	FDA/OGROP/ORASE-FO/NOLDO/NOL-CB/	LESLIE RAMSEY FDA NEWS	VINTAGE PHARMACEUTICALS LLC (DBA QUALITEST PHARMS), HUNTSVILLE, AL - 483S 12/1-31/14
2015-469	01/21/2015	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	LESLIE RAMSEY	BLUE OCEAN MEDICAL PRODUCTS LLC, ROCHESTER, NY - 483S 12/1-31/14

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	02/19/2015		FDA NEWS	
2015-470	01/21/2015 02/19/2015	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	LESLIE RAMSEY FDA NEWS	KVK-TECH INC, NEWTOWN, PA - 483S 12/1-31/14
2015-471	01/21/2015 02/19/2015	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	LESLIE RAMSEY FDA NEWS	IRIDEX CORP, MOUNTAIN VIEW, CA; PACIFIC IMPLANT INC, RIO DELL, CA; BIOCHECK INC, FOSTER CITY, CA, ETC - 483S 12/1-31/14
2015-472	01/21/2015 02/19/2015	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	LESLIE RAMSEY FDA NEWS	ESSILOR INDUSTRIES, PONCE, PR - 483S 12/1-31/14
2015-473	01/21/2015 02/19/2015	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	LESLIE RAMSEY FDA NEWS	LIFEPORT INC, WOODLAND, WA; PEDIGO PRODUCTS INC, VANCOUVER, WA; MEDIANA USA INC, REDMOND, WA, ETC - 483S 12/1-31/14
2015-474	01/21/2015 02/19/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LESLIE RAMSEY FDA NEWS	CADILA HEALTHCARE LTD INDIA, AHMEDABAD, INDIA; F HOFFMAN-LA ROCHE LTD, KAISERAUGST, SWITZERLAND; IDT BIOLOGIKA GMBH, DESSAU-ROSSLAU, GERMANY - 483S 12/1-31/14
2015-475	01/21/2015 02/19/2015	FDA/OMPT/CDRH/OCER/DFOI/	LESLIE RAMSEY FDA NEWS	BMC MEDICAL CO LTD, BEIJING, CHINA; SCICAN LTD, TORONTO, CANADA; PEROUSE MEDICAL, IRGNY, FRANCE, ETC - 483S 12/1-31/14
2015-476	01/21/2015 02/19/2015	FDA/OC/OES/DFOI/	Greg Overstreet GO Printing Inc.	PAYMENT MADE BY FDA TO GPO 06/01/2007 - 05/31/2012
2015-477	01/22/2015 02/20/2015	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Rachel Johnson FOI Services, Inc.	TOBACCO INSPECTION RECS SEPT TO DEC 2014
2015-478	01/22/2015 02/20/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	post-market commitment_psu THE PENNSYLVANIA STATE UNIVERSITY	POST MARKET STUDIES
2015-479	01/22/2015 02/20/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-5904
2015-480	01/22/2015	FDA/OC/OES/DFOI/	Jo Hogan	2014-5918

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	02/20/2015		FOI Services, Inc.	
2015-481	01/22/2015 02/20/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-5749
2015-482	01/22/2015 02/20/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-7824
2015-483	01/22/2015 02/20/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-7827
2015-484	01/22/2015 02/20/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-7828
2015-485	01/22/2015 02/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	Daniel Burnett TheraNova LLC	K924436
2015-486	01/22/2015 02/20/2015	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Rachel Johnson FOI Services, Inc.	NESTLE PURINA PETCARE, ALLENTOWN, PA - INSPECTION RECS
2015-487	01/22/2015 02/20/2015	FDA/OFVM/CFSAN/OCD/EOS/	Paul Hughes SEALED AIR CORPORATION	FCN 140
2015-488	01/22/2015 02/20/2015	FDA/OFVM/CFSAN/OCD/EOS/	Paul Hughes SEALED AIR CORPORATION	FCN 880
2015-489	01/22/2015 02/20/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-7051
2015-490	01/22/2015 02/20/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-7055
2015-491	01/22/2015 02/20/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-7063
2015-492	01/22/2015 02/20/2015	FDA/OC/OES/DDM/ FDA/OMPT/CDRH/OCER/DFOI/	Beth Luoma DuVal & Associates, PA	TRANSCRIPTS FROM CLASSIFICATION PANEL MEETINGS - GFD DERMATONE
2015-493	01/22/2015 02/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K140719
2015-494	01/22/2015 02/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K120093
2015-495	01/22/2015 02/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	Gregory W. Sachs Sachs & Associates, Inc.	CPT 1400805
2015-496	01/22/2015 02/20/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Avital Barlev Alpha-Bio Tec. Ltd	NIBEC CO LTD, KOREA - INSPECTION REPORTS 01/01/2010 - 01/01/2015

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/		
2015-497	01/22/2015 02/20/2015	FDA/OFVM/CFSAN/OCD/EOS/	Richard Warburton CHEMDAQ INC	LOW ACID CANNED FOOD DATA 2014
2015-498	01/22/2015 02/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joe Malone Joe Malone	BIRTH CONTROL DRUGS - AERS
2015-499	01/22/2015 02/20/2015	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	Janet Moye'-sister and representative to Peter S. Jones Janet Moye'	DR BRIAN PEARLMAN, ATLANTA MEDICAL CENTER - INSPECTION RECS 07/01/2012 - 02/23/2013
2015-500	01/22/2015 02/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K041242
2015-501	01/22/2015 02/20/2015	OC/CVM/OCD/	Gary L. Stec Harvey Kruse, PC	LASALOCID IN GREASE - SAMPLE ANALYSIS, REPORTS 07/01/2014 - 01/21/2015
2015-502	01/22/2015 02/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	S. Albert Edwards S. Albert Edwards, Pharm.D., LTD	SKELAXIN - SIDE EFFECT STUDIES 01/01/1968 - 01/21/2015
2015-503	01/22/2015 02/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joe Malone Joe Malone	BIRTH CONTROL DRUGS - AERS
2015-504	01/22/2015 02/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Maria Johnson University of Maryland, Baltimore School of Medicine, Department of Psychiatry	IND 45228
2015-505	01/22/2015 02/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K030834
2015-506	01/22/2015 02/20/2015	FDA/OGROP/ORR/PA-FO/SAN-DO/SAN-CB/	Eric French PERRIGO COMPANY	GILEAD SCIENCES, INC, FOSTER CITY, CA - 483 OCT 2013
2015-507	01/22/2015	FDA/OMPT/CDER/GRP/DIDP/	JACOB BERINO #08846-082	SUBOXONE, RITALIN, SUDAFED, ETC - MFG PROCESS

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	02/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BERINO #08846-082, JACOB	
2015-508	01/22/2015 02/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JACOB BERINO #08846-082 BERINO #08846-082, JACOB	ORANGE BOOK
2015-509	01/22/2015 02/20/2015	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/ FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KARIE FUGATE Fugate, Karie	DEXAMETHASONE SODIUM PHOSPHATE INJ, SODIUM BICARBONATE INJ - RECALL RECS
2015-510	01/22/2015 02/20/2015	FDA/OFVM/CFSAN/OCD/EOS/	KEVIN S FRIES COSMETIC INGREDIENT REVIEW	VOLUNTARY COSMETIC REGISTRATION PROGRAM (VCRP) SPREADSHEET
2015-511	01/22/2015 02/20/2015	FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/ FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/ FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	ROBERT KING FDA NEWS	STREM CHEMICALS INC, NEWBURYPORT, MA; RHODES TECHNOLOGIES, COVENTRY, RI; MASS BIOLOGICS, BOSTON, MA, ETC - 483 RESPS
2015-512	01/22/2015 02/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Leslie E. Gerwin PRINCETON UNIVERSITY	INVOKANA - AERS
2015-513	01/22/2015 02/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tushar Manudhane Indianivesh securities	INDOCO REMEDIES LIMITED - 483 05/10/2013 - 01/08/2015
2015-514	01/22/2015 02/20/2015	FDA/OC/OES/DFOI/	Trish Gavankar Rock food Allergies Consulting	CUMIN RECALL - MANUFACTURER, SUPPLIER 12/01/2014 - 01/21/2015
2015-515	01/22/2015 02/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	CINDY TORNA COCHRAN FIRM SOUTH	AMBULATORY DIAGNOSTIC CENTER INC - MAMMOGRAPHY QUALITY STANDARDS ACT RECS

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			FLORIDA	
2015-516	01/22/2015 02/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	JACQUELINE J CHAN K&L Gates LLP	K140022 - CORR, MINS, ATTACHMENTS, ETC
2015-517	01/22/2015 02/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	JACQUELINE J CHAN K&L Gates LLP	K122132 - CORR, MINS, ATTACHMENTS, ETC
2015-518	01/22/2015 02/20/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	JACQUELINE J CHAN K&L Gates LLP	K063692 - CORR, MINS, ATTACHMENTS, ETC
2015-519	01/22/2015 02/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	JACQUELINE J CHAN K&L Gates LLP	K133276 - CORR, MINS, ATTACHMENTS, ETC
2015-520	01/22/2015 02/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	JACQUELINE J CHAN K&L Gates LLP	K130852 - CORR, MINS, ATTACHMENTS, ETC
2015-521	01/22/2015 02/20/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/OSMP/OOPD/	A LUKE SMITH RADICE LAW FIRM	SYNACTHEN (TETRACOSACTIDE) - IND OR NDA RECS
2015-522	01/22/2015 02/20/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	A LUKE SMITH RADICE LAW FIRM	HP ACTHAR GEL (REPOSITORY CORTICOTROPIN INJ)/ACTH - SAFETY OR EFFICACY RECS
2015-523	01/22/2015 02/20/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	A LUKE SMITH RADICE LAW FIRM	ACTHAR GEL-SYNTHETIC NDA 17-861 - SBA
2015-524	01/22/2015 02/20/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHRISTINE LIVOTI DEERFIELD INSTITUTE	GILDEAD SCIENCES - HARVONI (SOFOSBUVIR, LEDIPASVIR) AERS, MEDICATION ERRORS
2015-525	01/22/2015 02/20/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHRISTINE LIVOTI DEERFIELD INSTITUTE	GILEAD SCIENCES - SOVALDI (SOFOSBUVIR) AERS, MEDICATION ERRORS
2015-526	01/22/2015	FDA/OMPT/CDER/ORP/DIDP/	CHRISTINE LIVOTI	ABBVIE - PAK (DASABUVIR SODIUM, OMBITASVIR,

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	02/20/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DEERFIELD INSTITUTE	PARITPREVIR, RITONAVIR) AERS, MEDICATION ERRORS
2015-527	01/22/2015 02/20/2015	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	VICTORIA SCOTT Hemispherx Biopharma, Inc	HEMISPHERX BIOPHARMA INC, NEW BRUNSWICK, NJ - INSP 11/19/14 MEMO
2015-528	01/22/2015 02/20/2015	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	ANN ALBOLOTE RITEDOSE CORP	RITEDOSE CORP, COLUMBIA, SC - EIR 9/8-30/10
2015-529	01/22/2015 02/20/2015	FDA/OC/OES/DFOI/	GERALD STEEL Steel, Gerald	2011-1940
2015-530	01/22/2015 02/20/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CAROL CHITTENDEN Empire State Consumer Project, Inc	PEG 3550 - AERS, RECS
2015-531	01/22/2015 02/20/2015	OC/ORACE/ORM/ OC/ORACE/ORM/	SASHA GRAY THOMSON REUTERS	FOREIGN AND DOMESTIC DRUG INSPS 3/14 TO 12/14
2015-532	01/23/2015 02/23/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Leslie E. Gerwin PRINCETON UNIVERSITY	FARXIGA - AERS
2015-533	01/23/2015 02/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	Eben Gordon Inari Medical	K140151
2015-534	01/23/2015 02/23/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Brittney M Wilson Hare Wynn Newell & Newton, LLP	MEDTRONIC INSULIN PUMPS - AERS 01/01/2005 - 01/22/2015
2015-535	01/23/2015 02/23/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Adam Smith KemPharm, Inc.	NDA 019892
2015-536	01/23/2015 02/23/2015	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Rachel Johnson FOI Services, Inc.	AMERICAN SUGAR REFINING, BALTIMORE, MD - EIR, 483
2015-537	01/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	Corey Jaseph	K131799

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	02/23/2015		Ultradent Products, Inc.	
2015-538	01/23/2015 02/23/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ibrutinib - Individual Case Report Ken Tong	IMBRUVICA - 10621827,10622185, 10622410, ETC
2015-539	01/23/2015 02/23/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Idelalisib - Individual Case Reports Ken Tong	ZYDELIG - AERS
2015-540	01/23/2015 02/23/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Pembrolizumab - Individual Case Report Ken Tong	KEYTRUDA - AERS
2015-541	01/23/2015 02/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	Takahiro Haruyama Globizz Corp.	K120922
2015-542	01/23/2015 02/23/2015	FDA/OFVM/CFSAN/OCD/EOS/	Garry Wiltshire The Dow Chemical Company	FCN 1356
2015-543	01/23/2015 02/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	Priyangi Perera Pro-Lab Diagnostics	K141220
2015-544	01/23/2015 02/23/2015	FDA/OFVM/CFSAN/OCD/EOS/	Derek Drechsel Cardno ChemRisk	MONSTER - ADVERSE EVENTS 01/01/1997 - 12/31/2014
2015-545	01/23/2015 02/23/2015	FDA/OFVM/CFSAN/OCD/EOS/	Derek Drechsel Cardno ChemRisk	5HOUR, 5 HOUR, FIVE HOUR, ETC - ADVERSE EVENTS 01/01/1997 - 12/31/2014
2015-546	01/23/2015 02/23/2015	FDA/OFVM/CFSAN/OCD/EOS/	Derek Drechsel Cardno ChemRisk	NOS - ADVERSE EVENTS 01/01/1997 - 12/31/2014
2015-547	01/23/2015 02/23/2015	FDA/OFVM/CFSAN/OCD/EOS/	Derek Drechsel Cardno ChemRisk	AMP - ADVERSE EVENTS 01/01/1997 - 12/31/2014
2015-548	01/23/2015 02/23/2015	FDA/OFVM/CFSAN/OCD/EOS/	Derek Drechsel Cardno ChemRisk	FULL THROTTLE, FULLTHROTTLE - ADVERSE EVENTS 01/01/1997 - 12/31/2014
2015-549	01/23/2015 02/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K141771
2015-550	01/23/2015 02/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K130010

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2015-551	01/23/2015 02/23/2015	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Kirsten Clingman Kirsten Clingman	CELLTEX THERAPEUTICS CORPORATION, HOUSTON, TX - INSPECTION REPORTS, RESPONSES
2015-552	01/23/2015 02/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K122474
2015-553	01/23/2015 02/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K130349
2015-554	01/23/2015 02/23/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MR PAUL CAVENEY Beatson Clark Ltd	DRUG MASTER FILE 10500
2015-555	01/23/2015 02/23/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michelle Elizabeth Legiec Eagle Pharmaceuticals, Inc.	ZYDUS BSV PHARMA PVT LTD, INDIA - EIR 01/01/2014 - 01/31/2014
2015-556	01/23/2015 02/23/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jennifer Baird University of Pittsburgh Medical Center (UPMC)	IND VX-770
2015-557	01/23/2015 02/23/2015	FDA/OGROP/ORASW-FO/DET-DO/DET-CB/	Darcy Cox, MBA, MT(ASCP), Laboratory Manager Aleda E. Lutz VA Medical Center	ALEDA E LUTZ VA MEDICAL CENTER, SAGINAW, MI - INSPECTION REPORT FOR BLOOD BANK LABORATORY 08/15/2013 - 08/16/2013
2015-558	01/23/2015 02/23/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DDM/	Daniel Kolitz N/A	Any and all transcripts of Psychopharmacologic Drugs Advisory Committee and Drug Safety and Risk Management Advisory meetings related to NDA 11-522 and SLI-381 (Adderall and Adderall XR)
2015-559	01/23/2015 02/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K131153
2015-560	01/23/2015 02/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K142168
2015-561	01/23/2015 02/23/2015	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	Tobacco listings & registrations 08/01/2014 to present
2015-562	01/23/2015	FDA/OFVM/CFSAN/OCD/EOS/	Derek Drechsel	ROCK STAR, ROCKSTAR - ADVERSE EVENTS 01/01/1997 - 12/31/2013

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	02/23/2015		Cardno ChemRisk	
2015-563	01/23/2015 02/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	Katron Owens (Convatec) CONVATEC	K862935
2015-564	01/23/2015 02/23/2015	FDA/OFVM/CFSAN/OCD/EOS/	Derek Drechsel Cardno ChemRisk	RED BULL, REDBULL - ADVERSE EVENTS 01/01/1997 - 12/31/2014
2015-565	01/23/2015 02/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K132882
2015-566	01/23/2015 02/23/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anurag patel DR REDDYS LABORATORIES INC	NDA 017426
2015-567	01/23/2015 02/23/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Peter Murphy BIOPHARM INSIGHT	ELOCTATE - AERS
2015-568	01/23/2015 02/23/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Peter Murphy BIOPHARM INSIGHT	ZONTIVITY - AERS
2015-569	01/23/2015 02/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	Joseph Neev Femto-Sec Tech Inc.	K101006
2015-570	01/23/2015 02/23/2015	OC/ORO/ OC/ORO/	Austin Gore Austin Gore	DR MOHAN IYER - AVASTIN LAB RESULTS
2015-571	01/23/2015 02/23/2015	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/	Jamie Stanton Jamie Stanton	COMPLAINT RECS
2015-572	01/23/2015 02/23/2015	FDA/OFVM/CFSAN/OCD/EOS/	Garry Wiltshire The Dow Chemical Company	FCN 1502
2015-573	01/23/2015 02/23/2015	FDA/OGROP/ORO/SW-FO/DEN- DO/DEN-CB/	RAYAN MERKLEY PHYSICIANS COMMITTEE FOR RESPONSIBLE MEDICINE	CARE RESEARCH LLC, FORT COLLINS, CO - COMPLIANCE WITH GOOD LABORATORY PRACTICES EIRS, COMM , PHOTOGRAPHS, ETC 1/10 TO PRESENT

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2015-574	01/23/2015 02/23/2015	FDA/OC/OES/DDM/	ENCARNACION SUAREZ UPSHER-SMITH LABORATORIES INC	A/C ANESTHETIC & LIFE SUPPORT COMMITTEE MEETING 12/1-2/86
2015-575	01/23/2015 02/23/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JENNIFER LECUYER MEDICURE	AGGRASTAT (TIROFIBAN HCL) - AERS
2015-576	01/23/2015 02/23/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	BAYER - ALEVE PM (DIPHENHYDRAMINE HCL NAPROXEN SODIUM) NDA 205-352 RVWS
2015-577	01/23/2015 02/23/2015	FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/	W PATRICK NOONAN W PATRICK NOONAN	MICRO QUALITY LABS, BURBANK, CA - EIRS, 482S, 483S, ETC
2015-578	01/23/2015 02/23/2015	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/	DONALD N BLUE ZETETIC INC	SHIPMENTS REGULATED BY THE US FDA 1/15-31/15
2015-579	01/23/2015 02/23/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JULIA ZHU AMGEN INC.	PROLIA, XGEVA (DENOS UMAB AMG 162 HUMAN MONOCLONAL ANTIBODY TO RAK LIGAND) BLA 125320/5,6 - APRVL LTR, RVWS
2015-580	01/23/2015 02/23/2015	OC/ORO/ OC/ORO/ OC/ORO/OCI/ OC/ORO/OCI/	D SKYLAR ROSENBLOOM FISHMAN HAYGOOD PHELPS ET AL	FRANKLIN PHARMACY, RUSSELLVILLE, AL - AFFIDAVIT 8/8/12
2015-581	01/23/2015 02/23/2015	FDA/OC/OES/DFOI/	BRANDON M SCHWARTZ SCHWARTZ LAW FIRM	DELETED RECS
2015-582	01/26/2015 02/24/2015	OC/ORO/ OC/ORO/	PATRICK M LAVETTE DAVENPORT LAVETTE & CLECKER PC	MEDS IV LLC - TOTAL PARENTERAL NUTRITION SOL MARCESCENS BACTERIA RECS, INVESTIGATION, REGISTRATION, ETC
2015-583	01/26/2015 02/24/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LESLIE GALDSTONE RESTAINO ESQ Validus Pharmaceuticals	LOPRESSOR HCT (METOPROLOL TARTRATE, HYDROCHLOROTHIZIDE) TABS NDA 18-303 - RECALLS, SAFETY ALERTS, MARKET WITHDRAWALS 1/07 TO PRESENT
2015-584	01/26/2015	FDA/OMPT/CDER/ORP/DIDP/	KATHLEEN R HENRY	CHILDREN'S FEXOFENADINE HCL ALLERGY, CHILDREN'S

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	02/24/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Hyman, Phelps & McNamara P.C.	FEXOFENADINE HCL HIVES ANDA 203-330 - APRVL LTR 11/18/14
2015-585	01/26/2015 02/27/2015	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/ORO/DIOP/ FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORA/SW-FO/SWID/SWID-CB/	BENJAMIN L ENGLAND ESQ BENJAMIN L ENGLAND & ASSOCIATES LLC	ZHEJIANG LUDAO, TAIZHOU LUDAO - IMPORT ENTRY 1/13 TO PRESENT
2015-586	01/26/2015 02/24/2015	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	PATRICK J CAULFIELD GRUNFELD DESIDERIO LEBOWITZ ET AL	ENTRY # 9ES-0019509-7 - LAB TEST RESULTS AND ANALYSIS
2015-587	01/26/2015 02/24/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LAWRENCE F TRACEY TRACEY & FOX	PFIZER - ZOLOFT (SERTALINE) CORR, MTG MINS REGARDING DRUG LBLG SECTION 8.1
2015-588	01/26/2015 02/24/2015	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	RAM K SHRIVASTAVA MD EASTSIDE COMPREHENSIVE MEDICAL CENTER LLC	EASTSIDE COMPREHENSIVE MEDICAL SERVICES, NEW YORK, NY - AUDIT RPT 9/86
2015-589	01/26/2015 02/24/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRIAN J ELBAUM BRIAN J ELBAUM LAW OFCS	XENICAL - AERS
2015-590	01/26/2015 02/24/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/ORO/DIOP/	MANOJ GARG MERRILL LYNCH	IPCA LABORATORIES LTD, RATLAM (MADYA PRADESH), INDIA - IMPORT ALERT
2015-591	01/26/2015	FDA/OMPT/CDER/GRP/DIDP/	Barron F. Dickinson	APOTEX HOLDINGS, INC - EXHIBITS

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2015-592	01/26/2015 02/24/2015	OC/CVM/OCD/	K Smedley Center for Regulatory Services, Inc.	FAP 2259
2015-593	01/26/2015 02/24/2015	FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/	Chastity Rodriguez Rodriguez, Chastity	FORT WORTH EYE BANK - WARNING LETTER, 483 01/23/2012 - 01/23/2015
2015-594	01/26/2015 02/24/2015	FDA/OMPT/CDRH/OCER/DFOI/	W A Olson Center for Regulatory Services, Inc.	P050027 TABLE OF CONTENTS
2015-595	01/26/2015 02/24/2015	FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/	Maritza Ward HealthTronics	HEALTHTRONICS, AUSTIN, TX - EIR (CERTIFIED) 10/01/2011 - 10/31/2011
2015-596	01/26/2015 02/24/2015	FDA/OMPT/CDRH/OCER/DFOI/	Amanda Haider Smiths Medical ASD, Inc.	K113207
2015-597	01/26/2015 02/24/2015	FDA/OMPT/CDRH/OCER/DFOI/	K071513 Elucid Bioimaging Inc.	K071513
2015-598	01/26/2015 02/24/2015	FDA/OMPT/CDRH/OCER/DFOI/	K083227 Elucid Bioimaging Inc.	K083227
2015-599	01/26/2015 02/24/2015	FDA/OMPT/CDRH/OCER/DFOI/	K022013 Elucid Bioimaging Inc.	K022013
2015-600	01/26/2015 02/24/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Zachary Mider BLOOMBERG NEWS	VIVITROL ADVERSE EVENTS 100284791 99977791 99255091 ETC
2015-601	01/26/2015 02/24/2015	FDA/OMPT/CDRH/OCER/DFOI/	Brian Gall Teleflex, Inc	K970596
2015-602	01/26/2015 02/24/2015	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	Carol Muniz RTI Surgical, Inc	UNIVERSITY OF MIAMI TISSUE BANK - 483 11/20/2012 - 01/01/2015
2015-603	01/26/2015 02/24/2015	OC/ORR/ OC/ORR/ FDA/OGROP/ORR/CE-FO/DET-DO/DET-CB/	Karl K. Wust Karl Wust	SAMPLE 720483 - COLLECTION, LAB REPORT
2015-604	01/26/2015	FDA/OGROP/ORR/PA-FO/SAN-	Chastity Rodriguez	NEVADA DONOR NETWORK - WARNING LETTER, 483

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	02/24/2015	DO/SAN-CB/	Rodriguez, Chastity	01/23/2012 - 01/23/2015
2015-605	01/26/2015 02/24/2015	FDA/OMPT/CDRH/OCER/DFOI/	JUDY F GORDON DVM CLINREG CONSULTING SERVICES INC	EKOSONIC MACH 4 ENDOVASCULAR DVC, EKOSONIC CONTROL UNIT K140151
2015-606	01/26/2015 02/24/2015	FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/	Jeanine Gouveia Aerie Pharmaceuticals Inc.	DR DAVID I WIRTA, EYE RESEARCH FOUNDATION, NEWPORT BEACH, CA - INSPECTION RECS 01/01/2011 - 01/23/2015
2015-607	01/26/2015 02/24/2015	FDA/OGROP/ORANE-FO/NYK- DO/NYK-DCB/	Jeanine Gouveia Aerie Pharmaceuticals Inc.	DR HOWARD I SCHENKER, ROCHESTER OPHTHALMOLOGICAL GROUP PC, ROCHESTER, NY - INSPECTION REC 08/18/2014 - 08/22/2014
2015-608	01/26/2015 02/24/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	PPI DRUGS, ACID BLOCKING DRUGS - AERS
2015-609	01/26/2015 02/24/2015	FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/	Chastity Rodriguez Rodriguez, Chastity	GREAT PLAINS LION EYE BANK - WARNING LETTER, 483 01/23/2012 - 01/23/2015
2015-610	01/26/2015 02/24/2015	FDA/OMPT/CDRH/OCER/DFOI/	Vera De La Cruz UT MD Anderson Cancer Center	510K for BIOELECTRICAL IMPEDANCE ANALYZER - SE LETTER
2015-611	01/26/2015 02/24/2015	FDA/OGROP/ORASE-FO/NOL- DO/NOL-CB/	Chastity Rodriguez Rodriguez, Chastity	EAST TENNESSEE LIONS EYE BANK, INC - WARNING LETTER, 483 01/23/2012 - 01/23/2015
2015-612	01/26/2015 02/24/2015	FDA/OC/OES/DFOI/	ANDRE ANTROBUS ANTROBUS #13A2171, ANDRE	HISTORY AND ENCYCLOPEDIA ON DRUGS, LAGAUDIA PAPERS, VICTOR LICATA HISTORY, ETC
2015-613	01/26/2015 02/24/2015	FDA/OMPT/CDRH/OCER/DFOI/	Andrew Gillam Infant Guard, LLC	SASH AND BASSINETTE - DEVICE DETERMINATION RECS
2015-614	01/26/2015 02/24/2015	FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/	Chastity Rodriguez Rodriguez, Chastity	LIONS EYE BANK OF TEXAS - WARNING LETTER, 483 01/23/2012 - 01/23/2015
2015-615	01/26/2015 02/24/2015	FDA/OO/OHR/	Kelly Stern Kelly Stern	VETERINARY MEDICAL OFFICER GS-701-13 FDA-DH-14- 1070239-GP
2015-616	01/26/2015 02/24/2015	FDA/OO/OHR/	Kelly Stern Kelly Stern	VETERINARY MEDICAL OFFICER GS-701-13 FDA-DH-14- 1228253-GP
2015-617	01/26/2015 02/24/2015	FDA/OFVM/CFSAN/OCD/EOS/	Jessie Hellmann CHICAGO TRIBUNE	PURE POWDERED CAFFEINE - NUMBER OF DEATHS, ADVERSE EVENTS IN US 01/01/2014 - 01/23/2015
2015-618	01/26/2015 02/24/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K072370
2015-619	01/26/2015	FDA/OMPT/CDER/GRP/DIDP/	Arthur Levinson	CVS SpectraVite Multivitamin Adult 50+ - AERS

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	02/24/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	Arthur Levinson	
2015-620	01/26/2015 02/24/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Susan Overgard Teva Pharmaceuticals	GVK BioSciences Private Ltd., - EIR, 483
2015-621	01/26/2015 02/24/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Linh Chu - Post marketing pharmacovigilance data for Viadur Intarcia Therapeutics, Inc	Post-marketing pharmacovigilance data for Viadur ALZA Corporation Application No.: 21-088. Approval Date: 3/3/2000
2015-622	01/26/2015 02/24/2015	FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/	Chastity Rodriguez Rodriguez, Chastity	NORTHWEST LOUISIANA EYE BANK - WARNING LETTER, 483 01/23/2012 - 01/23/2015
2015-623	01/26/2015 02/24/2015	FDA/OGROP/ORA/CE-FO/CIN- DO/CIN-CB/	Chastity Rodriguez Rodriguez, Chastity	CINCINNATI EYE BANK - WARNING LETTER, 483 01/23/2012 - 01/23/2015
2015-624	01/26/2015 02/24/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Becky Hartman Teva Pharmaceuticals	ADUSAVE - AERS
2015-625	01/26/2015 02/24/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Glen Kelley kaleo pharmaceutical	NDA 019890 SBA
2015-626	01/26/2015 02/24/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Becky Hartman Teva Pharmaceuticals	TBO-FILGRASTIM - AERS
2015-627	01/26/2015 02/24/2015	FDA/OGROP/ORA/CE-FO/CIN- DO/CIN-CB/	Chastity Rodriguez Rodriguez, Chastity	CINCINNATI EYE BANK FOR SIGHT RESTORATION - WARNING LETTER, 483 01/23/2012 - 01/23/2015
2015-628	01/26/2015 02/24/2015	FDA/OMPT/CDRH/OCER/DFOI/	Abraham Gitterman Arnold & Porter, LLP	BIG SKY DIAGNOSTIC IMAGING - MQSA ACCREDITATION, REVOCATION 01/01/2012 - 01/23/2015
2015-629	01/26/2015	FDA/OGROP/ORA/SW-FO/KAN-	Chastity Rodriguez	LIONS EYE BANK OF NEBRASKA - WARNING LETTER, 483

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	02/24/2015	DO/KAN-CB/	Rodriguez, Chastity	01/23/2012 - 01/23/2015
2015-630	01/26/2015 02/24/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ernesto Alamo PATTERSON BELKNAP WEBB & TYLER	CIPRO - REVIEWS, RECS RE PERIPHERAL NEUROPATHY
2015-631	01/26/2015 02/24/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Becky Hartman Teva Pharmaceuticals	QNASL - AERS
2015-632	01/26/2015 02/24/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	David Tukey EverPoint Asset Management	ASTELLAS, XTANDI, ZYTIGA ETC - AERS
2015-633	01/26/2015 02/24/2015	FDA/OGROP/ORANE-FO/NYK- DO/NYK-DCB/	Chastity Rodriguez Rodriguez, Chastity	UPSTATE NEW YORK TRANSPLANT SERVICES - WARNING LETTER, 483 01/23/2012 - 01/23/2015
2015-634	01/26/2015 02/24/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joe Malone Joe Malone	HORMONAL CONTRACEPTIVES - AERS
2015-635	01/26/2015 02/24/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Becky Hartman Teva Pharmaceuticals	QUARTETTE - AERS
2015-636	01/26/2015 02/24/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Howard D. Pomeranz, MD NorthShore LIJ Health System	AMIODARONE - AERS
2015-637	01/26/2015 02/24/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Becky Hartman Teva Pharmaceuticals	SYNRIBO - AERS
2015-638	01/26/2015 02/24/2015	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	THRESHOLD OF REGULATION EXEMPTION 2014-001

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2015-639	01/26/2015 02/24/2015	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Chastity Rodriguez Rodriguez, Chastity	LONE STAR LIONS EYE BANK - WARNING LETTER, 483 01/23/2012 - 01/23/2015
2015-640	01/26/2015 02/24/2015	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	Chastity Rodriguez Rodriguez, Chastity	MISSISSIPPI LIONS EYE BANK - WARNING LETTER, 483 01/23/2012 - 01/23/2015
2015-641	01/26/2015 02/24/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Becky Hartman Teva Pharmaceuticals	ARGATROBAN - AERS
2015-642	01/26/2015 02/24/2015	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Teri Dubeck Teri Dubeck	MENVEO VACCINE - ALLERGIC REACTIONS
2015-643	01/26/2015 02/24/2015	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Teri dubeck Teri Dubeck	MEACTRA VACCINE - ALLERGIC REACTIONS
2015-644	01/26/2015 02/24/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kristine DeVoge Kristine DeVoge	ISENTRESS - AERS
2015-645	01/26/2015 02/24/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	ADITYA KHEMKA AMBIT CAPITAL PVT. LTD.	THE IMPORT ALERT LETTER SENT TO IPCA LABORATORIES FOR RATLAM FACILITY, INDIA
2015-646	01/26/2015 02/24/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Eric White MISSION PHARMACAL COMPANY/PRESIDENT	ANDA A202044
2015-647	01/26/2015 02/24/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Eric White MISSION PHARMACAL COMPANY/PRESIDENT	ANDA A201172
2015-648	01/26/2015 02/24/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Eric White MISSION PHARMACAL COMPANY/PRESIDENT	ANDA 202489

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2015-649	01/26/2015 02/24/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Saion Mukherjee Nomura Financial Advisory & Securities (India) Private Limited	DR REDDY - RESPONSE TO 483
2015-650	01/26/2015 02/24/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mike Perez Safer America	ADDERAL - AERS
2015-651	01/26/2015 02/24/2015	OC/ORR/ORM/ OC/ORR/ORM/	David Mangione Govzilla, Inc.	LIST OF INSPECTIONS 03/15/2014 - 01/25/2015
2015-652	01/26/2015 02/24/2015	FDA/OGROP/ORR/CE-FO/DET- DO/DET-CB/	David Mangione Govzilla, Inc.	BAXTER PHARMACEUTICAL SOLUTIONS, LLC, BLOOMINGTON, IN - 483, EIR 10/20/2014 - 10/24/2014
2015-653	01/26/2015 02/24/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	David Mangione Govzilla, Inc.	CANGENE CORPORATION, WINNIPEG, CANADA - EIR, 483 07/09/2014 - 07/18/2014
2015-654	01/26/2015 02/24/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	David Mangione Govzilla, Inc.	BOEHRINGER INGELHEIM RCV, GMBH, AUSTRIA - EIR, 483 11/03/2014 - 11/11/2014
2015-655	01/27/2015 02/25/2015	FDA/OGROP/ORR/SW-FO/DAL- DO/DAL-CB/	Danielle Jester LifeShare Blood Centers	LIFESHARE BLOOD CENTERS, BEAUMONT, TEX; LIFESHARE BLOOD CENTERS, TEXARKANA, TX - EIR 05/31/2015 - 11/02/2015
2015-656	01/27/2015 02/25/2015	FDA/OMPT/CDRH/OCER/DFOI/ FOI Services, Inc.	Rachel Johnson FOI Services, Inc.	CHEEN HOUNG ENTERPRISE, TAIWAN - EIR 08/05-08/2013
2015-657	01/27/2015 02/25/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Peter Murphy BIOPHARM INSIGHT	STALLERGENES ORALAIR - AERS
2015-658	01/27/2015 02/25/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Andrea Demakas ADVERSEEVENTS INC	HARVONI, SOVALDI, XIGDUO XR - AERS

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		FDA/OMPT/CDER/GRP/DIDP/		
2015-659	01/27/2015 02/25/2015	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Danielle Jester LifeShare Blood Centers	LIFESHARE BLOOD CENTERS - EIR 01/03/2013 - 07/31/2014
2015-660	01/27/2015 02/25/2015	FDA/OO/OHR/	Adam Kennedy N/A	FDA-ORA-15-DE-1226627EW, FDA-ORA-15-MP-1226649WW
2015-661	01/27/2015 02/25/2015	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	Danielle Jester LifeShare Blood Centers	BLOOD CENTERS, SHREVEPORT, LA - EIR 01/01/2011 - 12/31/2015
2015-662	01/27/2015 02/25/2015	FDA/OMPT/CDRH/OCER/DFOI/	Brian J Petersen Podimetrics, Inc.	K080816, K081162
2015-663	01/27/2015 02/25/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Beth Luoma DuVal & Associates, PA	K100272, K012349
2015-664	01/27/2015 02/25/2015	FDA/OMPT/CDRH/OCER/DFOI/	Mauricio S. Umana Safis Solutions LLC	K110179
2015-665	01/27/2015 02/25/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jaya Ayyagari DR REDDYS LABORATORIES INC	ANDA 064134 SBA
2015-666	01/27/2015 02/25/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Scott Hodes Scott A. Hodes, Attorney at Law	17-alpha HYDROXYPROGESTERONE CAPROATE COMPOUNDED IN US
2015-667	01/27/2015 02/25/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jaya Ayyagari Jaya Ayyagari	NDA 050592 SBA
2015-668	01/27/2015 02/25/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Leonardo Pereira European programme in Pharmacovigilance and Pharmacoepidemiology	FAERS DATA
2015-669	01/27/2015 02/25/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/	Adria Liu Lagis Enterprise Co., Ltd.	K930933

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2015-670	01/27/2015 02/25/2015	FDA/OC/OES/DDM/	Paul Latkany, M.D. Paul Latkany, M.D.	GANCICLOVIR, VALGANCICLOVIR, FOSCARNET ETC - ADV COMM NOTES, TRANSCRIPTS 01/01/1985 - 01/01/2002
2015-671	01/27/2015 02/25/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ADITYA KHEMKA AMBIT CAPITAL PVT LTD	AUCTUS PHARMA, GRANULE INDIA FACILITIES - 483, WARNING LETTER, IMPORT ALERT ETC : 01/01/2008 - 01/01/2015
2015-672	01/28/2015 02/26/2015	FDA/OC/OES/DFOI/	Paul Knoepfler UC DAVIS SCHOOL OF MEDICINE	CELLTEX THERAPEUTICS OF TEXAS - LIST OF PREVIOUS REQUESTS
2015-673	01/28/2015 02/26/2015	FDA/OC/OES/DFOI/	Paul Knoepfler UC DAVIS SCHOOL OF MEDICINE	23 AND ME - LIST OF PREVIOUS FOIA REQUESTS
2015-674	01/28/2015 02/26/2015	FDA/OC/OES/DFOI/	Paul Knoepfler UC DAVIS SCHOOL OF MEDICINE	CYTORI THERAPEUTICS - PREVIOUS FOIA REQUESTS 01/03/2013 - 01/20/2015
2015-675	01/28/2015 02/26/2015	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	Heather Baierl Nature's Way Product	CORBION CARAVAN, LENEXA, KS - EIR, 483, RESPONSES ETC 01/01/2010 - 01/27/2015
2015-676	01/28/2015 02/26/2015	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	Todd Bailey Premier Biotech, Inc	COMPLAINT FOR FORENSIC USE ONLY - PREMIER BIOTECH 01/01/2014 - 01/11/2015
2015-677	01/28/2015 02/26/2015	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lewis Slack MAVERICK CAPITAL	PHARMACYCLICS, INC, SUNNYVALE, CA - CORR 07/01/2014 - 01/27/2015
2015-678	01/28/2015 02/26/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ayesha Adil The Weinberg Group	NDA 203629 LABEL
2015-679	01/28/2015 02/26/2015	FDA/OC/OES/DFOI/	Kari L. Twaite BEVERIDGE & DIAMOND PC	LIST OF CFSAN FOIA REQUESTS 01/01/2015 - 01/27/2015

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2015-680	01/28/2015 02/26/2015	FDA/OMPT/CDRH/OCER/DFOI/	Cato Research Ltd. Cato Research Ltd.	K133538
2015-681	01/28/2015 02/26/2015	FDA/OMPT/CDRH/OCER/DFOI/	Natan Pheil Norfolk Medical Products, Inc.	K863721
2015-682	01/28/2015 02/26/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Erin Stewart, MD Stanford University Hospital and Clinics - Department of Pulmonary and Critical Care Medicine	3427653 3595565 3634908 ETC
2015-683	01/28/2015 02/26/2015	FDA/OO/OFBA/OAGS/	Mike Appleman Coast to Coast Computer Products Inc.	PURCHASE CARD HOLDER LIST
2015-684	01/28/2015 02/26/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K091207
2015-685	01/28/2015 02/26/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K090288
2015-686	01/28/2015 02/26/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 13025 CHEMISTRY SECTION
2015-687	01/28/2015 02/26/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Renata Kovalski Kythera Biopharaceuticals	ALMAC PHARMA SERVICES, CB - EIR 04/01/2013 - 05/31/2013
2015-688	01/28/2015 02/26/2015	FDA/OGROP/ORR/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/	Leslie Paul Perrigo - Corporate Quality Compliance	AARON INDUSTRIES, LYNWOOD, CA; WESTBURY, NY - 483, EIR 03/01/2012 - 01/27/2015
2015-689	01/28/2015 02/26/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gene Hall Gene Hall	IND RECS
2015-690	01/28/2015 02/26/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gene Hall Gene Hall	Investigational new drug applications for participants in the NIH Biomedical test materials program

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		FDA/OMPT/CDER/GRP/DIDP/		
2015-691	01/28/2015 02/26/2015	FDA/OC/OES/DDM/ OC/CVM/OCD/	Zachary Marker CENTER FOR FOOD SAFETY	NITARSONE - DRUG EXPERIENCE REPORTS, COMMUNICATIONS WITH SPONSORS, ETC
2015-692	01/28/2015 02/26/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-9827 - REQUEST LETTER
2015-693	01/28/2015 02/26/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-10032 - REQUEST LETTER
2015-694	01/28/2015 02/26/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-9406 - REQUEST LETTER
2015-695	01/28/2015 02/26/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-9617 - REQUEST LETTER
2015-696	01/28/2015 02/26/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-9654 - REQUEST LETTER
2015-697	01/28/2015 02/26/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-9796 - REQUEST LETTER
2015-698	01/28/2015 02/26/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-9796 - REQUEST LETTER
2015-699	01/28/2015 02/26/2015	OC/ORO/ OC/ORO/ OC/ORO/ORM/ OC/ORO/ORM/ FDA/OGROP/ORO/ORO/DIOP/	CHLOE BIRD PCCA	MANUFACTURER ID CODES FOR ALL FOREIGN & DOSESTIC 10/5/05
2015-700	01/28/2015 02/26/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHLOE BIRD PCCA	NDC NUMBERS ISSUED TO US FOREIGN DRUG COMPANIES
2015-701	01/28/2015 02/26/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/CVM/OCD/	REBECCA L. DANDEKER MORGAN LEWIS & BOCKIUS LLP	YICHANG SANXIA PHARMACEUTICAL CO LTD, HUBEI PROVINCE PR CHINA - EIR 1/1/14 TO 12/31/14
2015-702	01/28/2015 02/26/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	IMBRUVICA (IBRUTINIB) NDA 02-552 - RVWS

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	(SCIENTIFIC) SAS	
2015-703	01/28/2015 02/26/2015	OC/ORP/ OC/ORP/ FDA/OGROP/ORP/ORO/DIOP/ FDA/OMPT/CDRH/OCER/DFOI/	BENJAMIN L.ENGLAND, Esq. BENJAMIN L ENGLAND & ASSOCIATES LLC	PETITION TO REMOVE VIVIDA SA CC FROM IMPORT ALERT 89-08 - CORR (UNREDACTED)
2015-704	01/28/2015 02/26/2015	FDA/OMPT/CDRH/OCER/DFOI/	Jahan Azizi Heart Sync Inc.	MW5039125
2015-705	01/28/2015 02/26/2015	FDA/OGROP/ORP/CE-FO/PHI- DO/PHI-CB/	David Mangione Govzilla, Inc.	MERCK SHARPE & DOHME CORP, WEST POINT, PA - 483, EIR 09/12/2014 - 09/12/2014
2015-706	01/28/2015 02/26/2015	FDA/OGROP/ORP/SE-FO/NOL- DO/NOL-CB/	Abhishek Gurnani Amin Talati & Upadhye, LLC	CENTRIX PHARMACEUTICALS, BIRMINGHAM, AL - INSPECTION RECS, APPROVAL RECS 01/03/1995 - 01/27/2015
2015-707	01/28/2015 02/26/2015	FDA/OGROP/ORP/NE-FO/NYK- DO/NYK-DCB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Abhishek Gurnani Amin Talati & Upadhye, LLC	SYNTHO PHARMACEUTICALS, FARMINGDALE, NY - INSPECTION RECS, APPROVAL RECS 01/03/1995 - 01/27/2015
2015-708	01/28/2015 02/26/2015	FDA/OGROP/ORP/SE-FO/NOL- DO/NOL-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Abhishek Gurnani Amin Talati & Upadhye, LLC	CREEKWOOD PHARMACEUTICALS, BIRMINGHAM, AL - INSPECTION RECS, APPROVAL RECS 01/03/1995 - 01/27/2015
2015-709	01/28/2015 02/26/2015	FDA/OGROP/ORP/CE-FO/NWJ- DO/NWJ-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Abhishek Gurnani Amin Talati & Upadhye, LLC	AMNEAL PHARMACEUTICALS, PATERSON, NJ - INSPECTION RECS, APPROVAL RECS 01/03/1995 - 01/27/2015
2015-710	01/28/2015 02/26/2015	FDA/OGROP/ORP/NE-FO/NWE- DO/NWE-CB/ FDA/OGROP/ORP/SE-FO/FLA- DO/FLA-CB/	Abhishek Gurnani Amin Talati & Upadhye, LLC	BRECKENRIDGE PHARMACEUTICALS, BOCA RATON, FL; BERLIN, CT - INSPECTION RECS, APPROVAL RECS 01/03/1995 - 01/27/15

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2015-711	01/28/2015 02/26/2015	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	Abhishek Gurnani Amin Talati & Upadhye, LLC	SYNTHO PHARMACEUTICALS - EIR AUGUST 2013
2015-712	01/29/2015 02/27/2015	FDA/OMPT/CDRH/OCER/DFOI/	CASSANDRA KEW COMMINS HENDRIKS PTY LTD	DEPUY - LCS DUOFIX FEMORAL INSERT KNEE REPLACEMENT COMPONENT CORR, PRTS, MEMOS, ETC
2015-713	01/29/2015 02/27/2015	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OES/DDM/	MARK MCAFEE Organic Pastures Dairy Company	RAW BUTTER - BAN ON INTERSTATE SHIPMENT RECS
2015-714	01/29/2015 02/27/2015	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	SHERI O COVINGTON K&L Gates LLP	ASTHMA INC CLINICAL RSEARCH CENTER, SEATTLE, WA - EIR 11/17/14-12/17/14
2015-715	01/29/2015 02/27/2015	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	VIRGINIA NG Seafood Products Association	SANTA BARBARA SMOKEHOUSE, SANTA BARBARA, CA - EIR 8/14 TO 9.14
2015-716	01/29/2015 02/27/2015	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	SAMANTHA MYERS ROANOKE CLAIMS SERVICES	PERUSA INC - ENTRY #MH900947259 NOTICES FOR REQUEST OF INFORMATION (CF28), NOTICE OF ACTION, CBP REDELIVER NOTICES, ETC
2015-717	01/29/2015 02/27/2015	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	MARK DOERR GIBSON DUNN & CRUTCHER LLP	DOCTOR'S DATA INC, ST CHARLES, IL - CORR, CMLNPTS, INVESTIGATIONS, ETC
2015-718	01/29/2015 02/27/2015	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	PATRICK KELLY CONWAY HOMER & CHIN-CAPLAN PC	INIDIVIDUAL RECS
2015-719	01/29/2015 02/27/2015	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	Doe J	INDIVIDUAL RECS
2015-720	01/29/2015 02/27/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	JOANN BROWN WILLIAMS MERIWETHER AND THARP LLC	DERMA=FLEX QS HIGH VISCOSITY TISSUE ADHESIVE K101276

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2015-721	01/29/2015 02/27/2015	OC/ORR/ORM/ OC/ORR/ORM/	RAY THOMPSON THOMPSON, RAY	GMP, GLP, GCP INSPS 8/1/14 TO 1/15/15
2015-722	01/29/2015 02/27/2015	FDA/OMPT/CDRH/OCER/DFOI/	ALAN G MINSK ARNALL GOLDEN GREGORY LLP	BD VACUTAINER PLUS PLASTIC URINE C & S TUBES AND KITS K102420
2015-723	01/29/2015 02/27/2015	FDA/OMPT/CDRH/OCER/DFOI/	ALAN G MINSK ARNALL GOLDEN GREGORY LLP	BD VACUTAINER RAPID SERUM TUBE PLUE BLOD COLLECTION TUBE K091292
2015-724	01/29/2015 02/27/2015	OC/CVM/OCD/	Joyce Cox Joyce Cox	MOMETAMAX - DEAFNESS IN DOGS
2015-725	01/29/2015 02/27/2015	OC/ORR/OCI/ OC/ORR/OCI/	Marin Kurti RUTGERS UNIVERSITY	NUMBER OF OCI CASES RE SALE OF UNTAXED, COUNTERFEIT CIGARETTES IN NY; SEIZURE STATISTICS
2015-726	01/29/2015 02/27/2015	FDA/OMPT/CDRH/OCER/DFOI/	Qserve Group US, Inc Qserve Group US, Inc.	K120080
2015-727	01/29/2015 02/27/2015	FDA/OMPT/CDRH/OCER/DFOI/	Qserve Group US, Inc. Qserve Group US, Inc.	K131870
2015-728	01/29/2015 02/27/2015	FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/	Jane Bentley Alcon Laboratories, Inc.	ALCON LABORATORIES, INC, FORT WORTH, TX - EIR 07/14/2014 - 07/24/2014
2015-729	01/30/2015 03/02/2015	FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDRH/OCER/DFOI/	SARAH F. BLANKSTEIN ROPES & GRAY LLP	SUNQUEST INFORMATION SYSTEMS, ARIZONA & UK - 483'S SINCE 2009
2015-730	01/30/2015 03/02/2015	FDA/OGROP/ORR/CE-FO/MIN-DO/MIN-CB/	SARAH F BLANKSTEIN ROPES & GRAY LLP	MERGE HEALTHCARE INC, WI - 483'S SINCE 2009
2015-731	01/30/2015 03/02/2015	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	SARAH F BLANKSTEIN ROPES & GRAY LLP	SCC SOFT COMPUTER, FL - 483'S SINCE 2009
2015-732	01/30/2015 03/02/2015	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	SARAH F BLANKSTEIN ROPES & GRAY LLP	DATA INNOVATIONS INC - BK120051
2015-733	01/30/2015 03/02/2015	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	SARAH F BLANKSTEIN ROPES & GRAY LLP	SANGUIN INTL INC - BK090061
2015-734	01/30/2015 03/02/2015	FDA/OGROP/ORR/CE-FO/CHI-DO/CHI-CB/	SARAH F BLANKSTEIN ROPES & GRAY LLP	SYSMEX CORP, JAPAN, MUNDELEIN, IL, LINCOLNSHIRE, IL - 483'S SINCE 2009
2015-735	01/30/2015 03/02/2015	FDA/OMPT/CDRH/OCER/DFOI/	SARAH F. BLANKSTEIN ROPES & GRAY LLP	ROCHE DIAGNOSTICS, GRAZ STEIERMARK, AUSTRIA; MANNHEIM BADEN - WURTTENBERG, GERMANY; ROTKREUZ ZUG, SWITZERLAND - 483'S SINCE 2009

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2015-736	01/30/2015 03/02/2015	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	SARAH F BLANKSTEIN ROPES & GRAY LLP	SIEMENS HEALTHCARE DIAGNOSTICS INC, MALVERN, PA; TARRYTOWN NY; NEWARK, DE; NORWOOD, MA - 483'S SINCE 2009
2015-737	01/30/2015 03/02/2015	FDA/OMPT/CDRH/OCER/DFOI/	SARAH F BLANKSTEIN ROPES & GRAY LLP	MISYS HEALTHCARE SYS - BK040065
2015-738	01/30/2015 03/02/2015	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	SARAH F. BLANKSTEIN ROPES & GRAY LLP	MEDICAL INFORMATION TECHNOLOGY, MA; GA; MI - 483'S SINCE 2009
2015-739	01/30/2015 03/02/2015	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	SARAH F BLANKSTEIN ROPES & GRAY LLP	GE MEDICAL SYS INFORMATION TECHNOLOGIES, EL PASO, TX; MILWAUKEE, WI - 483'S SINCE 2009
2015-740	01/30/2015 03/02/2015	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	GREGG GIZA ThermaSolutions, Inc.	EIGHT MEDICAL, BLOOMINGTON, IN - EIR MOST RECENT
2015-741	01/30/2015 03/02/2015	FDA/OC/OES/DFOI/	RON NIXON NEW YORK TIMES	MAIL FROM LAW ENFORCEMENT 2001 TO 2012
2015-742	01/30/2015 03/02/2015	FDA/OC/OES/DFOI/	LEONARDI PH D, RONALD	2010-63
2015-743	02/02/2015 03/03/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	David Mangione Govzilla, Inc.	LONZA AG, SWITZERLAND - EIR 08/29/2014 - 08/29/2014
2015-744	02/02/2015 03/03/2015	OC/ORACE-FO/ OC/ORACE-FO/	Maryann Gribbin Faith & Royale Consulting	INSPECTIONS OF PHARMACEUTICAL CHEMISTRY AND MICROBIOLOGY LABS, TRAINING FOR FIELD AND CENTERS ON DATA INTEGRITY ETC 01/02/2014 - 01/28/2015
2015-745	02/02/2015 03/03/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Maha Katabi Sectoral Asset Management	XTANDI - AERS

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2015-746	02/02/2015 03/03/2015	FDA/OMPT/CDRH/OCER/DFOI/	Jane Bentley Alcon Laboratories, Inc.	CIBA VISION ASIAN MANUFACTURING AND LOGISTICS PTE LTD, SINGAPORE - EIR 06/23/2014 - 06/26/2014
2015-747	02/02/2015 03/19/2015	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Amy N. Plewke The Deters Lawfirm, P.S.C.	PUREGEN, ALPHATEC SPINE - PARCELL LABORATORIES - REPORTS, RECALLS, WARNINGS ETC (CERTIFIED) 01/01/2005 - 01/29/2015
2015-748	02/02/2015 03/03/2015	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Liziel Concepcion Allergan Liziel Concepcion	DR ELLEN MARMUR, NEW YORK, NY - 483, EIR 12/29/2014 - 01/08/2015
2015-749	02/02/2015 03/03/2015	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Robert Wolfangel Certus International Inc.	NDA 017630
2015-750	02/02/2015 03/03/2015	FDA/OMPT/CDRH/OCER/DFOI/	Robert A. Yokel ALKYMOS, Inc.	K120150
2015-751	02/02/2015 03/03/2015	FDA/OMPT/CDRH/OCER/DFOI/	Bruce Robie Robie Device Group, LLC	K974020
2015-752	02/02/2015 03/03/2015	FDA/OMPT/CDRH/OCER/DFOI/	Bruce Robie Robie Device Group, LLC	K790238
2015-753	02/02/2015 03/03/2015	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Theresa Ritter NDA Partners	NDA 19698
2015-754	02/02/2015 03/03/2015	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Terrence Weatherspoon International Brotherhood Teamsters	Blood Establishment Registration Database
2015-755	02/02/2015 03/03/2015	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Manon Vranderick Duchesnay Inc.	NEOPHARM LABS INC, CANADA - EIR 01/01/2012 - 01/01/2015
2015-756	02/02/2015 03/03/2015	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Manon Vranderick Duchesnay Inc.	SGS LIFE SCIENCE SERVICES, CANADA - EIR 01/01/2012 - 01/01/2015
2015-757	02/02/2015	FDA/OMPT/CDER/ERP/DIDP/	ADITYA KHEMKA	IPCA - IMPORT ALERT RATLAM API FACILITY

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	03/03/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	AMBIT CAPITAL	
2015-758	02/02/2015 03/03/2015	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Amy N. Plewke The Deters Lawfirm, P.S.C.	ATIQ ABUBAKAR DURRANI, MD - REPORTS, WARNING LETTERS ETC 01/01/2005 - 01/29/2015
2015-759	02/02/2015 03/03/2015	FDA/OMPT/CDRH/OCER/DFOI/	Priscilla Caro Priscilla Caro	K140464
2015-760	02/02/2015 03/03/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Smith BioTex, Inc.	K991139
2015-761	02/02/2015 03/03/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 002918
2015-762	02/02/2015 03/03/2015	FDA/OMPT/CDRH/OCER/DFOI/	Bruce Robie Robie Device Group, LLC	K781444
2015-763	02/02/2015 03/03/2015	FDA/OMPT/CDRH/OCER/DFOI/	Bruce Robie Robie Device Group, LLC	K791009
2015-764	02/02/2015 03/03/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	NDA 22574 S 001
2015-765	02/02/2015 03/03/2015	FDA/OC/OES/DFOI/	Lisa Dunbar VLP Law Group LLP	FOIA LOG 2013, 2014
2015-766	02/02/2015 03/03/2015	FDA/OMPT/CDRH/OCER/DFOI/	Jordan Kim Bio Focus Co., Ltd.	K053452
2015-767	02/02/2015 03/03/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	REVIEW OF LIDEGAARD REANALYSIS
2015-768	02/02/2015 03/03/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	NDA 21-098/S022 NDA 21-676/S012 NDA 22-532/S004 ETC

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2015-769	02/02/2015 03/03/2015	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/	Chris Noonan HealthGuidance, Inc.	MILLENNIUM PRODUCTS DBA KOMBUCHA, SYNERGY - INVESTIGATIONS, PROCEEDINGS 01/01/2013 - 01/30/2015
2015-770	02/02/2015 03/03/2015	FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	John Kristensen Kristensen Weisberg, LLP	COMM BETWEEN FDA AND SAN ANTONIO COMMUNITY HOSPITAL, UPLAND, CA RE ACTINOMYCS, BACTERIA 02/26/2014 - 01/29/2015
2015-771	02/02/2015 03/03/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Smith BioTex, Inc.	K021494
2015-772	02/02/2015 03/03/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	NDA 22-532 S1
2015-773	02/02/2015 03/03/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rebecca Dandeker Morgan, Lewis & Bockius LLP	XELLIA PHARMACEUTICALS LTD, HUNGARY - EIR 01/01/2014 - 01/01/2015
2015-774	02/02/2015 03/03/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rebecca Dandeker Morgan, Lewis & Bockius LLP	XELLIA PHARMACEUTICALS LTD, HUNGARY - EIR SUMMARY, 483 01/01/2014 - 01/01/2015
2015-775	02/02/2015 03/03/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Stephen Saye InDevR, Inc.	FDA/CBER PROTOCOL FOR SINGLE RADIAL IMMUNODIFFUSION
2015-776	02/02/2015 03/03/2015	FDA/OMPT/CDRH/OCER/DFOI/	Kevin Cosgrove Kaplan Fox & Kilsheimer, LLP	COMMUNICATIONS BETWEEN FDA AND VENAXIS, INC RE 510K 01/01/2015 - 01/29/2015
2015-777	02/02/2015 03/03/2015	FDA/OO/OHR/	Kelly Stern Kelly Stern	FDA-DH-14-1070239-GP
2015-778	02/02/2015 03/03/2015	FDA/OO/OHR/	Kelly Stern Kelly Stern	FDA-DH-14-1228253-GP
2015-779	02/02/2015 03/03/2015	FDA/OGROP/ORACE-FO/CHI- DO/CHI-CB/	Kate Dylewsky BORN FREE USA	PANTHERA LEO - INSPECTION RECS 01/01/2004 - 01/28/2015

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2015-780	02/02/2015 03/03/2015	FDA/OC/OL/	Gary Ruskin U.S. Right to Know	CORR WITH CONGRESS RE SODA, SODA POP, SWEETENED BEVERAGES ETC - 1/1/12 TO PRESENT
2015-781	02/02/2015 03/03/2015	FDA/OC/OL/	Gary Ruskin U.S. Right to Know	CORR WITH CONGRESS RE GROCERY MANUFACTURERS ASSOCIATION, SNACK FOOD ASSOCIATION, CALORIE CONTROL COUNCIL ETC - 1/1/12 TO PRESENT
2015-782	02/02/2015 03/03/2015	FDA/OC/OL/	Gary Ruskin U.S. Right to Know	CORR WITH CONGRESS RE MONSANTO, SYNGENTA, BAYER CROPSOURCE ETC - 1/1/12 TO PRESENT
2015-783	02/02/2015 03/03/2015	FDA/OC/OL/	Gary Ruskin U.S. Right to Know	CORR WITH CONGRESS RE AGRICULTURAL PESTICIDE OR HERBICIDE ETC - 1/1/12 TO PRESENT
2015-784	02/02/2015 03/03/2015	FDA/OC/OL/	Gary Ruskin U.S. Right to Know	CORR WITH CONGRESS RE ARTIFICIAL SWEETENERS, ADVANTAME, ASPARTAME ETC - 1/1/12 TO PRESENT
2015-785	02/02/2015 03/03/2015	FDA/OC/OL/	Gary Ruskin U.S. Right to Know	CORR WITH CONGRESS RE ADDED SUGAR, HIGH FRUCTOSE CORN SYRUP, HFCS - 1/1/12 TO PRESENT
2015-786	02/02/2015 03/03/2015	FDA/OC/OL/	Gary Ruskin U.S. Right to Know	CORR WITH CONGRESS RE GMO ETC - 1/1/12 TO PRESENT
2015-787	02/02/2015 03/03/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-7414
2015-788	02/02/2015 03/03/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-7050
2015-789	02/02/2015 03/03/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-6806
2015-790	02/02/2015 03/03/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2012-8218
2015-791	02/02/2015 03/03/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2012-7000
2015-792	02/02/2015 03/03/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2013-7000
2015-793	02/02/2015 03/03/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-8272
2015-794	02/02/2015 03/03/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Jo Hogan FOI Services, Inc.	2014-5129

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2015-795	02/02/2015 03/03/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-3480
2015-796	02/02/2015 03/03/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2013-657
2015-797	02/02/2015 03/03/2015	FDA/OC/OES/ FDA/OFVM/CFSAN/OCD/EOS/	Gary Ruskin U.S. Right to Know	GLYSOPHATE IN FOOD, ADVERSE HEALTH EFFECTS, TESTING
2015-798	02/02/2015 03/03/2015	FDA/OC/OES/ FDA/OFVM/CFSAN/OCD/EOS/	Gary Ruskin U.S. Right to Know	GMOS IN FOOD, ADVERSE HEALTH EFFECTS, SAFETY TESTING
2015-799	02/02/2015 03/03/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Smith BioTex, Inc.	K891688
2015-800	02/02/2015 03/03/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Smith BioTex, Inc.	K001083
2015-801	02/02/2015 03/03/2015	FDA/OMPT/CDRH/OCER/DFOI/	sandra witt sandra witt	CPT 1300573
2015-802	02/02/2015 03/03/2015	OC/CVM/OCD/	TOM D'ERRICO D'ERRICO, TOM	INFLAMMATORY CYTOKINES IN BEEF - RECS
2015-803	02/02/2015 03/03/2015	FDA/OFVM/CFSAN/OCD/EOS/	CHARLENE NOVAK HALL & EVANS LLC	E COLI OUTBREAK IN DENVER - RPT 4/16/14
2015-804	02/02/2015 03/03/2015	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	SARAH F BLANKSTEIN ROPES & GRAY LLP	GE HEALTHCARE, BARRINGTON, IL - 483S 2009 TO PRESENT
2015-805	02/02/2015 03/03/2015	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	SARAH F BLANKSTEIN ROPES & GRAY LLP	GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES INC - CENTRICITY ULTRA LABORATORY MEDICINE BK050018
2015-806	02/02/2015 03/03/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	A LUKE SMITH RADICE LAW FIRM	IVAX, TEVA - NEXIUM (ESOMEPRAZOLE MAGNESIUM) APRVL RECS
2015-807	02/02/2015 03/03/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ALEX ORTIZ ORTIZ 310400067, ALEX	MK-9 PEPPER MACE FOGGER - SAFETY RECS

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2015-808	02/02/2015 03/03/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Casey Swetlik Casey Swetlik	VENLAFAXINE - AERS
2015-809	02/02/2015 03/03/2015	FDA/OMPT/CDRH/OCER/DFOI/	Anthony Le Poincare Medical	K123369
2015-810	02/02/2015 03/03/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	COURTNEY J CROSBY CROSBY, COURTNEY J	ACTOS (PIOGLIAZONE) - REPRODUCTIVE CANCER RECS
2015-811	02/02/2015 03/03/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rahul Jeewani IIFL Cap	CADILA HEALTHCARE LIMITED - 483 12/01/2014 - 12/12/2014
2015-812	02/02/2015 03/03/2015	OC/ORA/ OC/ORA/ FDA/OGROP/ORPA/FO/LOS- DO/LOS-CB/	Doe J	COMPLAINT 137942
2015-813	02/02/2015 03/03/2015	FDA/OMPT/CDRH/OCER/DFOI/	Marc C. Sanchez, Esq. Contract In-House Counsel and Consultants, LLC	K091757, K122744
2015-814	02/02/2015 03/03/2015	FDA/OC/OES/DFOI/	Nathaniel August Mangrove Partners	CMS STUDY
2015-815	02/02/2015 03/03/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CAROL CHITTENDEN Empire State Consumer Project, Inc	PEG 3350 - AERS
2015-816	02/02/2015 03/03/2015	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	CPT1400952
2015-817	02/02/2015 03/03/2015	FDA/OMPT/CDRH/OCER/DFOI/	Mike Houchin Law Offices of Ronald Marron	FIFTY SHADES OF GREY COME ALIVE PLEASURE GEL, LOVE HONEY - RECS, 510K 01/01/2010 - 01/30/2015
2015-818	02/02/2015 03/03/2015	FDA/OGROP/ORASW-FO/KAN- DO/KAN-CB/ FDA/OMPT/CDER/ORP/DIDP/	SARAH F BLANKSTEIN ROPES & GRAY LLP	CERNER CORP, KANSAS CITY, MO; INDIA; CANADA - 483S 2009 TO PRESENT

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2015-819	02/02/2015 03/03/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K974187
2015-820	02/02/2015 03/03/2015	FDA/OGROP/ORAP/PA-FO/SEA-DO/SEA-CB/	Rindy Griffith Preg O'Donnell & Gillett	SNOQUALMIE GOURMET ICE CREAM, SNOHOMISH, WA - LAB RESULTS, COLLECTION REPORTS, CORR ETC 12/01/2012 - 12/30/2014
2015-821	02/02/2015 03/03/2015	FDA/OMPT/CDRH/OCER/DFOI/	ERIC EGGERS 510KONSULT LLC	DE NOVO - DEXCOM SHARE DIRECT SECONDARY DISPLAYS RECLASSIFICATION ORDER, DECISION SUMMARY
2015-822	02/02/2015 03/03/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	EDWARD JOHN ALLERA BUCHANAN INGERSOLL & ROONEY PC	INVERSINE (MECAMYLAMINE HCL) NDA 10-251 - APRVL RECS, DESI RVVS
2015-823	02/02/2015 03/03/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MANOJ GARG MERRILL LYNCH	IPCA LABORATORIES LTD, RATLAM (MADYA PRADESH), INDIA - IMPORT ALERT
2015-824	02/02/2015 03/03/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GARY J MCGARITY MCGARITY, GARY J	SCHERING LABORATORIES - NORMODYNE INJ (LABETOLOL) NDA 18-686 PHARMACOKINETICS RECS
2015-825	02/02/2015 03/03/2015	FDA/OMPT/CDRH/OCER/DFOI/	DAVID RESPIRE MEDICAL	RESPIRE BLUE SERIES K111207; RESPIRE PINK SERIES K131138
2015-826	02/02/2015 03/03/2015	FDA/OC/OES/DDM/	HERBERT GERSTENZANG Gerstenzang, Herbert	OTC VOLUME 070168, 070126, 070099, ETC
2015-827	02/02/2015 03/03/2015	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	INDIVIDUAL RECS
2015-828	02/02/2015 03/03/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DEAN RYAN Taylor Wessing LLP	TAXOL, TAXOTERE (DOCETAXEL) - AUTHORIZATION LABELS
2015-829	02/02/2015	FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY	ENDO PHARMS - AVEED (TESTOSTERONE UNDECANOATE) NDA 22-219 - ARPVL RECS

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	03/03/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	THOMSON REUTERS (SCIENTIFIC) SAS	
2015-830	02/02/2015 03/03/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DIANNE LIN Lin X09327, Dianne	LUPRON INJ, MICRO-DOSE FLAIRE LUPRON INJ - AERS
2015-831	02/02/2015 03/03/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DIANNE LIN Lin X09327, Dianne	HUMAN CHORIONIC GONADOTROPIN (HCG) INJ - AERS
2015-832	02/02/2015 03/03/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DIANNE LIN Lin X09327, Dianne	REPRONEX, PERGONAL INJ - AERS
2015-833	02/02/2015 03/03/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DIANNE LIN Lin X09327, Dianne	GONAL F INJ - AERS
2015-834	02/02/2015 03/03/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DIANNE LIN Lin X09327, Dianne	ESTROGEN/ESTRADIOL INJ, VIVELLE ESTRADERM PATCHES - AERS
2015-835	02/02/2015 03/03/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DIANNE LIN Lin X09327, Dianne	MEDROL TABS - AERS
2015-836	02/02/2015 03/03/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DIANNE LIN Lin X09327, Dianne	PROGESTERONE IN OIL, INJ, LOZENGES, SUPPOSITORIES - AERS
2015-837	02/03/2015 03/04/2015	FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/	Nicole Oliynyk ARIAD PHARMACEUTICALS INC	ARIAD PHARMACEUTICALS, CAMBRIDGE, MA - EIR 09/01/2014 - 01/30/2015

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2015-838	02/03/2015 03/09/2015	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	Susan Apito Susan Apito	AROMATHERAPY UNITED - COMPLAINTS, WARNING LETTER RECS
2015-839	02/03/2015 03/04/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Anubhav Aggarwal CREDIT SUISSE	CADILA HEALTHCARE LIMITED INDIA - 483 12/01/2014 - 12/07/2014
2015-840	02/03/2015 03/04/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rahul Jeewani IIFL Cap	CADILA HEALTHCARE LIMITED, INDIA - 483 08/28/2014 - 09/05/2014
2015-841	02/03/2015 03/04/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K133665
2015-842	02/03/2015 03/04/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Joseph M Ascenzi JMA Consulting	K991938
2015-843	02/03/2015 03/04/2015	FDA/OMPT/CDRH/OCER/DFOI/	Anthony Le Poincare Medical	K141769
2015-844	02/03/2015 03/04/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Anthony Le Poincare Medical	K141453
2015-845	02/03/2015 03/04/2015	FDA/OMPT/CDRH/OCER/DFOI/	Anthony Le Poincare Medical	K093857
2015-846	02/03/2015 03/04/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K141456
2015-847	02/03/2015 03/04/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K133573
2015-848	02/03/2015 03/04/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K133444
2015-849	02/03/2015 03/04/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dennis W. Raisch UNIVERSITY OF NEW MEXICO	BENDAMUSTINE - AERS

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2015-850	02/03/2015 03/04/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dennis W. Raisch UNIVERSITY OF NEW MEXICO	BENDAMUSTINE - AERS
2015-851	02/03/2015 03/04/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Martin Kwok MASSACHUSETTS COLLEGE OF PHARMACY	I GAUGIN TRIAL - START DATE
2015-852	02/03/2015 03/04/2015	FDA/OMPT/CDRH/OCER/DFOI/	Laser pointer report SHENZHEN WOWTOU TECH CO., LIMITED	CHENZHEN WOWTOU TECH CO LIMITED - LASER POINTER REPORT 08/01/2014 - 02/01/2015
2015-853	02/03/2015 03/04/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Chirag Talati Kotak Securities	DR REDDY'S, ZYDUS CADILA - 483 01/01/2014 - 12/31/2014
2015-854	02/03/2015 03/04/2015	FDA/OGROP/ORASW-FO/KAN- DO/KAN-CB/	Joe McCann Joe McCann	RELIABLE PHARMACEUTICALS, ST LOUIS, MO - 483 03/02/2010 - 02/02/2015
2015-855	02/03/2015 03/04/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-8455
2015-856	02/03/2015 03/04/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-8392
2015-857	02/03/2015 03/04/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-7238
2015-858	02/03/2015 03/04/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-8301
2015-859	02/03/2015 03/04/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Lauren Farruggia Hyman, Phelps & McNamara P.C.	K033761, K042231, K083091 ETC
2015-860	02/03/2015 03/04/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-3411
2015-861	02/03/2015 03/04/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2013-149
2015-862	02/03/2015 03/04/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-8644

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2015-863	02/03/2015 03/04/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-8537
2015-864	02/03/2015 03/04/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-7842
2015-865	02/03/2015 03/04/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nishith Sanghvi CIMB Securities (India) Pvt Ltd	ZYDUS PHARMA - 483 09/02/2014 - 02/02/2015
2015-866	02/03/2015 03/04/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 1/1-31/2015
2015-867	02/03/2015 03/04/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-7821
2015-868	02/03/2015 03/04/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	A list of all FOIA requests closed 1/1-31/2015
2015-869	02/03/2015 03/04/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	G. Srinivas Zydus Pharmaceuticals USA Inc.	NDA 020503
2015-870	02/03/2015 03/04/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sally Yang Cote Orphan, LLC	CORTEF - NDA, CORR, SBA LETTER
2015-871	02/03/2015 03/04/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Marvin Miller MD Marvin Miller Md	CITALOPRAM - AERS 08/24/2011 - 12/31/2014
2015-872	02/03/2015 03/04/2015	FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	NATHAN BASS, UNIV OF CALIFORNIA, SAN FRANCISCO, CA - EIRS, 483S, CO RESP 4/28/14-5/9/14
2015-873	02/03/2015 03/04/2015	FDA/OGROP/ORO/SW-FO/DEN-DO/DEN-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	VILAVICIENCIO ALAN T, BOULDER, CO - EIRS, 483S, CO RESP 5/21-6/05/14
2015-874	02/03/2015 03/04/2015	FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/	WALTER E CHALKLEY THOMSON REUTERS	MARK POLHEMUS, SUNY MEDICAL UNIV, SYRACUSE,, NY - EIRS, 483S, CO RESP 5/28/14-6/11/14

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			(SCIENTIFIC) SAS	
2015-875	02/03/2015 03/04/2015	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	WALTER E CHALKLEY THOMSON REUTERS	AIRGAS USA LLC, EAST GREENWICH, RI - EIRS, 483S, CO RESP 2/26/14
2015-876	02/03/2015 03/04/2015	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	ALAN NIEDERMAN MD, FT LAUDERDALE, FL - EIRS, 483S, CO RESP 9/15-10/16/09
2015-877	02/03/2015 03/04/2015	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	GHANDI SAADEH MD, NORFOLK, VA - EIRS, 483S, CO RESP
2015-878	02/03/2015 03/04/2015	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	PRAXAIR DISTRIBUTION INC, HILLSIDE, IL - EIRS, 483S, CO RESP 12/03-04/13
2015-879	02/03/2015 03/04/2015	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	JUNE JACOBS LABS LLC, MOONACHIE, NJ - EIRS, 483S, CO RESP 1/08-14/14
2015-880	02/03/2015 03/04/2015	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	THOMSON REUTERS THOMSON REUTERS	OCTAPHAMA PLASMA, YPSILANTI, MI - EIRS, 483S, CO RESP 2/03-06/14
2015-881	02/03/2015 03/04/2015	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	BELCHER PHARMACEUTICALS LLC, LARGO, FL - EIRS, 483S, CO RESP 1/15/14-2/3/14
2015-882	02/03/2015 03/04/2015	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	WALTER E CHALKLEY THOMSON REUTERS	DR MAHENDRA SANAPATI, EVANSVILLE, IN - EIRS, 483S, CO RESP 1/22/14-2/6/14
2015-883	02/03/2015 03/04/2015	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	WALTER E CHALKLEY THOMSON REUTERS	LYNE LABORATORIES INC, BROCKTON, MA - EIRS, 483S, CO RESP 1/27/14-2/13/14
2015-884	02/03/2015 03/04/2015	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	WALTER E CHALKLEY THOMSON REUTERS	PAXAIR INC, RIVER ROUGE, MI - EIRS, 483S, CO RESP 9/25/13
2015-885	02/03/2015 03/04/2015	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	BROWER ENTERPRISES, CANTON, SD - EIRS, 483S, CO RESP 12/04-07/12
2015-886	02/03/2015 03/04/2015	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	WALTER E CHALKLEY THOMSON REUTERS	GENZYME (SANOFI CO), CAMBRIDGE, MA - EIRS, 483S, CO RESP 9/20-30/13
2015-887	02/03/2015 03/04/2015	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	WALTER E CHALKLEY THOMSON REUTERS	PACIFIC COAST TISSUE BANK, LOS ANGELES, CA - EIRS, 483S, CO RESP 4/24-66/19/12

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2015-888	02/03/2015 03/04/2015	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	SYNERGY ORTHOPAEDIC SYSTEMS INC, SACRAMENTO, CA - EIRS, 483S, CO RESP 8/08-13/12
2015-889	02/03/2015 03/04/2015	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	FENWAL INTERNATIONAL INC, MARICAO, PR - EIRS, 483S, CO RESP 4/25/13
2015-890	02/03/2015 03/04/2015	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	PRIME ENTERPRISES INC, HIALEAH, FL - EIRS, 483S, CO RESP 11/27/12 TO 1/03/13
2015-891	02/03/2015 03/04/2015	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	WALTER E CHALKLEY THOMSON REUTERS	FRANCIS W PRICE JR MD, INDIANAPOLIS, IN - EIRS, 483S, CO RESP 1/08-17/14
2015-892	02/03/2015 03/04/2015	FDA/OC/OES/	REMINGTON NEVIN MUCKROCK NEWS	MEFLOQUINE MTG 11/11/13 - OFFICE OF THE COMMISSIONER AGENDAS, PRESENTATIONS, INTERNAL MO, ETC, 7/12 TO 7/13
2015-893	02/03/2015 03/04/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DR REMINGTON NEVIN MUCKROCK NEWS	MEFLOQUINE MTG 1/11/13 - GENERIC DRUGS AGENDAS, PRESENTATIONS, INTERNAL MO, ETC 7/12 TO 7/13
2015-894	02/03/2015 03/04/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DR REMINGTON NEVIN MUCKROCK NEWS	MEFLOQUINE MTG 1/11/13 - SURVEILLANCE & EPIDEMIOLOGY AGENDAS, PRESENTATIONS, INTERNAL MO, ETC 7/12 TO 7/13
2015-895	02/03/2015 03/04/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DR REMINGTON NEVIN MUCKROCK NEWS	MEFLOQUINE MTG 1/11/13 - ANTIMICROBIAL PRODS AGENDAS, PRESENTATIONS, INTERNAL MO, ETC 7/12 TO 7/13
2015-896	02/03/2015 03/04/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	ENTYVIO - AERS
2015-897	02/03/2015 03/04/2015	OC/ORARM/ OC/ORARM/	LESLIE RAMSEY FDA NEWS	PHARMECEUTICAL, BIOLOGICS, MEDICAL DVC MFG, CLNCL TRIAL FACILITIES IN & OUTSIDE THE US - 483'S 1/1-31/15
2015-898	02/03/2015 03/04/2015	FDA/OMPT/CTP/OD/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN LUIS BUSEKRUS BUSEKRUS, LUIS JOHN	ELECTONIC CIGARETTES - BACKUP DETAILS, TEST RESULTS, SPREADSHEETS, ETC 4/22/14

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2015-899	02/03/2015 03/04/2015	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	RYAN MERKLEY PHYSICIANS COMMITTEE FOR RESPONSIBLE MEDICINE	CARE RESEARCH LLC, FORT COLLINS, CO - EIRS, COMM, PHOTOGRAPHS, ETC 1/10 TO PRESENT
2015-900	02/03/2015 03/04/2015	FDA/OMPT/CDRH/OCER/DFOI/	GEORGE J MARCEL SERENE MEDICAL	ACI INC - GFX NERVE ABLATION SYS K063753; BIO FORM MEDICAL INC - MODIFICATION TO GFX NERVE ABATION SYS K081729
2015-901	02/03/2015 03/04/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LEONARDO PEREIRA PEREIRA, LEONARDO	ACTEMRA (TOCILIZUMAB) - AERS
2015-902	02/03/2015 03/04/2015	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	BRENDA COOK - PHETE-EL COOK - PEHTE-EL, BRENDA	CASTLEBERRY FOOD CO - 483S, LAB RPORTS, EXHIBIT 6A-B AFFIDAVITS, ETC 7/17/07-8/10/07
2015-903	02/04/2015 03/05/2015	FDA/OC/OES/DFOI/	George Samuel De la Rosa Law Firm	INTUITIVE SURGICAL - PREVIOUSLY RELEASED RECS 01/01/2009 - 01/29/2015
2015-904	02/04/2015 03/05/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Ryan Lockhart University Stem Cell Center	ANTRIA - APPROVAL RECS
2015-905	02/04/2015 03/05/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kenneth I Barron, MD Florida Hospital Orlando	METHYLERGONOVINE - AERS
2015-906	02/04/2015 03/05/2015	FDA/OMPT/CDRH/OCER/DFOI/	Anna Wexler Anna Wexler	TDCS - MEDICAL DEVICE ANALYSIS SENT TO CAL DEPARTMENT OF PUBLIC HEALTH 10/01/2012 - 06/08/2013
2015-907	02/04/2015 03/05/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Allison Magwire ARIAD Pharmaceuticals, Inc.	ICLUSIG - AERS
2015-908	02/04/2015 03/05/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Marshall Hayward, Ph.D., on behalf of EffRx Pharmaceuticals Marshall Hayward Associates LLC	NDA 202344

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2015-909	02/04/2015 03/05/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Donna L DeRoos DeRoos, Donna L	ANASTROZOLE - AERS
2015-910	02/04/2015 03/05/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sally Yang Cote Orphan, LLC	NDA 009866
2015-911	02/04/2015 03/05/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Will Nefzger William D. Nefzger PLLC	MIRENA, SKYLA, JADELLE ETC - AERS
2015-912	02/04/2015 03/05/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORACE-FO/MIN- DO/MIN-CB/ FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORACE-FO/PHI- DO/PHI-CB/ FDA/OGROP/ORACE-FO/NWE- DO/NWE-CB/ FDA/OGROP/ORACE-FO/NYK- DO/NYK-DCB/	Rend Al-Mondhiry COUNCIL FOR RESPONSIBLE NUTRITION	SOLGAR ABC DOPHILUS POWDER - TESTS, ANALYSES, INTEPRETATIONS 09/01/2014 - 02/03/2015
2015-913	02/04/2015 03/05/2015	FDA/OC/OES/DDM/	Lauren L. Haertlein Arnold & Porter LLP	DKT 00N-1396 - INDEX TO COMMENTS
2015-914	02/04/2015 03/05/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Saion Mukherjee Nomura Financial Advisory & Securities (India) Private Limited	LUPIN LTD, INDIA - 483 12/01/2014 - 02/03/2015
2015-915	02/04/2015 03/05/2015	FDA/OGROP/ORACE-FO/KAN- DO/KAN-CB/	Gregg Albus Perrigo Animal Health	VIRBAC CORP, BRIDGETON, MO - 483 01/03/2013 - 02/03/2015

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2015-916	02/04/2015 03/05/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Abdur Rashid BioQ-IRB inc	ANDA A078668
2015-917	02/04/2015 03/05/2015	FDA/OMPT/CDRH/OCER/DFOI/	Jonathan Sackner-Bernstein jonathan sackner-bernstein	P950037, P950037/S28, P840068 - SSED
2015-918	02/04/2015 03/05/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shin Kang WELLS FARGO	TECFIDERA, SOVALDI, HARVONI ETC - AERS
2015-919	02/04/2015 03/05/2015	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	Alexandra Ajmo LIFE EXTENSION	SUN PAC MANUFACTURING, TAMPA, FL - EIR 01/01/2010 - 02/03/2015
2015-920	02/04/2015 03/05/2015	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/ OC/ORA/ OC/ORA/	Brandon Henry RBC	BIOMIMETICS/WRIGHT MEDICAL - 483 01/25/2015 - 01/28/2015
2015-921	02/04/2015 03/05/2015	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/ OC/ORA/ OC/ORA/	Neil Lanteigne Neil Lanteigne	BIOMIMETICS/WRIGHT MEDICAL - 483 01/01/2015 - 02/03/2015
2015-922	02/04/2015 03/05/2015	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	Alexandra Ajmo LIFE EXTENSION	ALASKA SPRING PHARMACEUTICALS INC, WESTBURY, NY - EIR 01/01/2011 - 02/03/2015
2015-923	02/04/2015 03/05/2015	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/ FDA/OMPT/CDRH/OCER/DFOI/ OC/ORA/ OC/ORA/	Neetu Dhaliwal VISIUM ASSET MANAGEMENT LLC	BIOMIMETIC/WRIGHT MEDICAL - 483 10/24/2014 - 02/02/2015; APPROVABLE LETTER
2015-924	02/04/2015 03/05/2015	FDA/OMPT/CDRH/OCER/DFOI/	Beth Stanford GALDERMA LABORATORIES INC	Q-MED AB, SWEDEN - EIR 07/13/2006 - 09/26/2006
2015-925	02/04/2015 03/05/2015	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	Matthew Poselwait Applied Laboratories, Inc.	APPLIED LABORATORIES, INC. - EIR 01/01/2014 - 12/31/2014
2015-926	02/04/2015 03/05/2015	FDA/OMPT/CDRH/OCER/DFOI/	Mark Urness GE Healthcare	DEVICE EVENT KEY 4124583 ETC
2015-927	02/04/2015	FDA/OMPT/CDER/GRP/DIDP/	Karen Marshall	SANDOZ GMBH BIOPHARMACEUTICALS, AUSTRIA - 483,

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	03/05/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tarsa Therapeutics, Inc.	EIR 01/02/2014 - 12/31/2014
2015-928	02/04/2015 03/05/2015	FDA/OMPT/CDRH/OCER/DFOI/	Kevin Ackermann Medela AG	K113276
2015-929	02/04/2015 03/05/2015	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	Alexandra ajmo LIFE EXTENSION	CSB NUTRITION CORPORATION, SPANISH FORK, UT - 01/01/2010 - 02/03/2015
2015-930	02/04/2015 03/05/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CAROLINE STOUT ECOR1 CAPITAL LLC	PHARMACYCLICS INC - IMBRUVICA (IBRUTINIB) AERS
2015-931	02/04/2015 03/05/2015	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	RACHAEL MCGUIRE Partners.org	EASTERN RESEARCH INC, HIALEAH, FL 1/8/14; OHIO STATE UNIV/NISONGER CTR , COLUMBUS, OH; 4/25/14 UNIV OF FLORIDA HEALTH SCIENCE CENTER SHANDS JACKSONVILLE, JACKSONVILLE, FL 1/13/14, ETC EIRS, 483S

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		FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/		
2015-932	02/04/2015 03/05/2015	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	CHRIS SZECHENYI ONE POINT INVESTIGATIONS	OVASCIENCE - UNTITLED LTR 9/6/13
2015-933	02/04/2015 03/05/2015	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	RYAN MERKLEY PHYSICIANS COMMITTEE FOR RESPONSIBLE MEDICINE	CARE RESEARCH LLC OF FORT COLLINS, CO - EIRS, EXHIBITS, ATTACHMENTS 8/22/12
2015-934	02/04/2015 03/05/2015	FDA/OFVM/CFSAN/OCD/EOS/	MITZI NG CLARK Keller and Heckman LLP	FCN 1472 - RVW MEMO
2015-935	02/04/2015 03/05/2015	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	DAVID JARVIS Jarvis, David	PRODUCT QUEST MANUFACTURING INC, DAYTONA BEACH, FL - INSPS, VIOLATIONS
2015-936	02/04/2015 03/05/2015	FDA/OO/OHR/	AMIR DAVARI DAVARI, AMIR	MARGARET HAMBURG, ELIZABETH DICKINSON, MICHAEL R TAYLOR, ETC - CV
2015-937	02/04/2015 03/05/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHARLA HELTON MD HELTON, SHARLA	BOTOX, BOTOX COSMETIC - AERS
2015-938	02/04/2015 03/05/2015	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	PRAXAIR INC, TONAWANDA, NY - EIR, 483, CO RESP 7/2914-8/8/14
2015-939	02/04/2015 03/05/2015	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	TREYMED INC, SUSSEX, WI - EIR, 483, CO RESP 10/7-21/14
2015-940	02/04/2015 03/05/2015	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	WEST-WARD PHARMACEUTICAL CORP, EATONTOWN, NJ - EIR, 483, CO RESP 2/4-26/14
2015-941	02/04/2015 03/05/2015	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	HODI FRANCK, DANA-FARBER CANCER INSTITUTE, BOSTON, MA - EIR, 483, CO RESP 8/30/10
2015-942	02/04/2015	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	WALTER E CHALKLEY	LOUISE A TABER MD, PHOENIX, AZ - EIR, 483, CO RESP 7/7-18/14

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	03/05/2015		THOMSON REUTERS	
2015-943	02/04/2015 03/05/2015	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	MIDWEST MEDICAL HOLDINGS LLC (DBA MIDWEST MEDICAL SERVICE), MOUNDS VIEW, MN - EIR, 483, CO RESP 1/22-23/14
2015-944	02/04/2015 03/13/2015	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	WALTER E CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	JHP PHARMACEUTICALS LLC, ROCHESTER, MI - EIR, 483, CO RESP 2/3-10/14
2015-945	02/04/2015 03/05/2015	FDA/OC/OES/DFOI/	Craig Bijou WELLS FARGO SECURITIES	MEDICAL DEVICE COMPANIES - 483 01/01/2015 - 01/31/2015
2015-946	02/05/2015 03/06/2015	FDA/OC/OES/DFOI/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	PATRICIA REGENYE Celgene Corporation	ADVANCED RESEARCH INSTITUTE, OGDEN,UT- 483 4/08 TO 1/15
2015-947	02/05/2015 03/06/2015	FDA/OC/OES/DFOI/	PATRICIA REGENYE Celgene Corporation	NEW RIVER VALLEY RESEARCH INSTITUTE, CHRISTIANSBURG, VA - 483 1/12 TO 1/15
2015-948	02/05/2015 03/06/2015	FDA/OC/OES/DFOI/	PATRICIA REGENYE Celgene Corporation	EAST BAY BERM MED GROUP, FREMONT CA - 483 7/10 TO 1/15
2015-949	02/05/2015 03/06/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/CVM/OCD/	REBECCA DANDEKER Morgan, Lewis & Bockius LLP	YICHANG SANXIA PHARMACEUTICAL CO, YICHANG CITY, HUBEI PROVINCE, PR CHINA - EIR 1/11 TO 1/31/11
2015-950	02/05/2015 03/06/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shannon Pickering Shannon Pickering	REMICADE - AERS 01/01/2010 - 01/01/2015
2015-951	02/05/2015 03/06/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/CVM/OCD/	REBECCA DANDEKER Morgan, Lewis & Bockius LLP	YICHANG SANXIA PHARMACEUTICAL CO LTD, YICHANG CITY, HUBEI PROVINCE, PR CHINA - 483 1/11 TO 12/31/11
2015-952	02/05/2015 03/06/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	REBECCA DANDEKER Morgan, Lewis & Bockius LLP	YICHANG SANXIA PHARMACEUTICAL CO LTD, YICHANG CITY, HUBEI PROVINCE, PR CHINA - 483 1/14 TO 1/31/14

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		OC/CVM/OCD/		
2015-953	02/05/2015 03/06/2015	FDA/OFVM/CFSAN/OCD/EOS/	Lila Razmara ANDREWS THORNTON	SYNEPHRINE - REPORTS, MEMO, CORR ETC 01/01/2011 - 02/03/2015
2015-954	02/05/2015 03/06/2015	FDA/OMPT/CDRH/OCER/DFOI/	Deborah Sheffield Sheffield Consulting	K140845
2015-955	02/05/2015 03/06/2015	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	bill smithson SMITHS MEDICAL ASD INC	SMITHS MEDICAL ASD INC - EIR 08/01/2013 - 02/02/2015
2015-956	02/05/2015 03/06/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	ELUXADOLINE - APPROVAL STATUS
2015-957	02/05/2015 03/06/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHERRY CONDIE XGEN PHARMACEUTICALS	SANDOZ - OXACILLIN ANDA 61-490 APRVD ARTWORK FOR THE SECONDARY PACKAGING
2015-958	02/05/2015 03/06/2015	FDA/OMPT/CTP/OD/	Ben Fenner Fredericks Peebles & Morgan LLP	Shinnecock Cigarette Products
2015-959	02/05/2015 03/06/2015	FDA/OMPT/CDRH/OCER/DFOI/	Suzana Otano BIOMET	K141420
2015-960	02/05/2015 03/06/2015	FDA/OGROP/ORACE-FO/PHIDO/PHI-CB/	SHERYL LOGUE DENENBERG TUFFLEY PLLC	EMPIRE KOSHER POULRTY, HARRISBURG, PA - 10/18/13 INVESTIGATON
2015-961	02/05/2015 03/06/2015	OC/ORACE/ OC/ORACE/ FDA/OGROP/ORACE-FO/SEADO/SEA-CB/	KAREN PRESTON NORTHWEST PEDIATRIC EYE CARE	SPL 731693
2015-962	02/05/2015 03/06/2015	FDA/OMPT/CDRH/OCER/DFOI/	Karen Ascetta TOXCEL	SPORICIDIN STERILIZING AND DISINFECTING SOLUTION - AERS
2015-963	02/05/2015 03/06/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jaya Ayyagari Dr.Reddys Laboratories Inc	NDA 010515 SBA
2015-964	02/05/2015 03/06/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Eckhard Milsmann Diapharm GmbH & Co. KG	HEMELN PHARMACEUTICLAS GMBH, GERMANY - 483 07/01/2014 - 07/31/2014

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2015-965	02/05/2015 03/06/2015	FDA/OMPT/CDRH/OCER/DFOI/	Angela Hume Sullivan, Mountjoy, Stainback & Miller	MEDTRONIC SYNCHROMED II - PMA, POST APPROVAL STUDIES, 510K ETC
2015-966	02/05/2015 03/06/2015	FDA/OC/OL/	Vicki Whitsitt NATURAL PRODUCTS ASSOCIATION	CORR SUBMITTED BY SEN DURBIN, BLUMENTHAL REQUESTING NATIONWIDE INVESTIGATION INTO DIETARY SUPPLEMENTS 02/02/2015 - PRESENT
2015-967	02/05/2015 03/06/2015	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/ OC/ORA/ OC/ORA/	HENRY, BRANDON	BIOMIMETICS (WRIGHT CO) 483
2015-968	02/05/2015 03/06/2015	FDA/OMPT/CDRH/OCER/DFOI/	RANIL FERNANDO BIO SCREEN TESTING SERVICES INC	BIOFILM - ASTROGLIDE SENSUAL STRAWBERRY K140590; TRIGG LABORATORIES INC - WET PLATINUM PERSONAL LUBRICANT K30012
2015-969	02/05/2015 03/06/2015	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	SHADY JOULANI NIXON PEABODY LLP	TOTAL SWEETENERS INC, PLAINES, IL - RECS
2015-970	02/05/2015 03/06/2015	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ OC/CVM/OCD/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Ashley Parker Rate My Horse PRO	ADM EQUINE FEED INVESTIGATION - EMAILS, SAMPLES, ETC 08/01/2014 - 02/28/2015
2015-971	02/05/2015 03/06/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WARD #1026408, ADAM	ORTHO MCNEIL PHARMA INC RISPERDAL - AER
2015-972	02/05/2015 03/06/2015	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Focus Laboratories FOCUS Laboratories	TOZAL SAMPLE 728891
2015-973	02/05/2015 03/06/2015	FDA/OMPT/CDRH/OCER/DFOI/	Laura Coffey Donohue Brown Mathewson & Smyth, LLC	MW5014928
2015-974	02/05/2015 03/06/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Saion Mukherjee Nomura Financial Advisory & Securities (India) Private Limited	TENTATIVE APPROVAL LETTERS - ANDA 090961, ANDA 203499

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		FDA/OMPT/CDER/GRP/DIDP/		
2015-975	02/05/2015 03/06/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Andrea Demakas ADVERSEEVENTS INC	VICTOZA, MINASTRIN 24 FE, EPOGEN/PROCRIT ETC - AERS
2015-976	02/05/2015 03/06/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BERINO 08846082, JACOB	ORGANON - SUSTANON 250 CHEMICAL STRUCTURE, SYNTHESIS, PHARMACOLOGY, ETC
2015-977	02/05/2015 03/06/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	LINDANE - AERS
2015-978	02/05/2015 03/06/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Sandy Liu Industrial technology and research institute, Sandy Liu	K130874
2015-979	02/05/2015 03/06/2015	FDA/OMPT/CDRH/OCER/DFOI/	Katrin Schmidt Brainlab AG	BRAINLAB AG, GERMANY - EIR 06/21/2013 - 02/04/2015
2015-980	02/05/2015 03/06/2015	FDA/OFVM/CFSAN/OCD/EOS/	Emyr Peregrine Symphony Environmental Ltd.	FCN1169
2015-981	02/05/2015 03/06/2015	FDA/OC/OES/DFOI/	DAVIS 30180, MINYARD	ANNUAL PERFORMANCE RPT 2014
2015-982	02/05/2015 05/28/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Brandon Beagle PhD PFC Development/New Alliance	IND BB-6195
2015-983	02/05/2015 03/06/2015	FDA/OFVM/CFSAN/OCD/EOS/	Lila Razmara ANDREWS THORNTON	SYNEPHRINE - AERS, MEDWATCH 01/01/2011 - 02/03/2015

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2015-984	02/05/2015 03/06/2015	FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	WALID, GARDEZI	STAAR SURGICAL, MONROVIA, CA - EIRS 2/14 TO 3/14, 11/14 TO 12/14; COMM 11/14 TO 12/14
2015-985	02/05/2015 03/06/2015	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Doe J	INDIVIDUAL RECS
2015-986	02/05/2015 03/06/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	STEFAN ELLIS PEPPER HAMILTON LLP	PROZAC NDA 18-936 - RVWS, CORR
2015-987	02/05/2015 03/06/2015	FDA/OC/OES/DDM/	ALEXANDRA MAYS VENABLE LLP	DCK 2014N-0168
2015-988	02/05/2015 03/06/2015	FDA/OFVM/CFSAN/OCD/EOS/	VISAGINE VIJAYAKULASINGAM IOVATE HEALTH SCIENCES INTERNATIONAL INC	IOVATE - HYDROXYCUT; SMARTBURN; RAPIDSLIM ETC CAERS
2015-989	02/05/2015 03/06/2015	FDA/OMPT/CDRH/OCER/DFOI/	JOSHUA HILL BUTLER SNOW LLP	SERIOUS COMPLICATIONS ASSOCIATED WITH TRANSVAGINAL PLACEMENT OF SURGICAL MESH IN REPAIR OF PELVIC ORGAN PROLAPSE & STRESS URINARY INCONTINENCE; CONSIDERATIONS ABOUT SURGICAL MESH FOR SUI (CERTIFIED)
2015-990	02/05/2015 03/06/2015	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 12/22-26/14
2015-991	02/05/2015 03/06/2015	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 12/29/14-1/2/15
2015-992	02/05/2015 03/06/2015	FDA/OC/OES/DFOI/	LESLIE RAMSEY FDA NEWS	DAILY LOG 12/22-26/14
2015-993	02/05/2015 03/06/2015	FDA/OC/OES/DFOI/	LESLIE RAMSEY FDA NEWS	DAILY LOG 12/29/14-1/2/15
2015-994	02/05/2015 03/06/2015	FDA/OC/OES/DFOI/	FDA NEWS	DAILY LOG 12/22-27/14
2015-995	02/05/2015 03/06/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 12/29/14 -1/3/15
2015-996	02/05/2015 03/06/2015	FDA/OC/OES/DFOI/	DEBRA L. COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 12/19/14-1/2/15
2015-997	02/05/2015 03/06/2015	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION	DAILY LOG 12/29/14-1/2/15

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			SOURCE	
2015-998	02/05/2015 03/06/2015	FDA/OC/OES/DFOI/	GLADYS TONKIN Center for Regulatory Services, Inc.	DAILY LOG 12/29/14-1/2/15
2015-999	02/05/2015 03/06/2015	FDA/OC/OES/DFOI/	LAUREN BARR JH BARR & ASSOCIATES LLC	DAILY LOG 12/29/14-1/2/15
2015-1000	02/06/2015 03/09/2015	FDA/OMPT/CDRH/OCER/DFOI/	Tiffany Suekama LC Therapeutics	P100046, K031247, K110117 ETC
2015-1001	02/06/2015 03/09/2015	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	SE0003298
2015-1002	02/06/2015 03/09/2015	FDA/OMPT/CDRH/OCER/DFOI/	John Garinger Tissue Regeneration Systems, Inc.	K123633
2015-1003	02/06/2015 03/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Idelalisib - All AE's Ken Tong	ZYDELIG - AERS
2015-1004	02/06/2015 03/09/2015	FDA/OMPT/CDRH/OCER/DFOI/	Walter Brittle FDA COMPLIANCE HELP DESK, INC	DEN080011, K081406
2015-1005	02/06/2015 03/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joe Zhu YoungTech Pharmaceuticals, Inc.	ANDA 075753
2015-1006	02/06/2015 03/09/2015	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	SE0001698
2015-1007	02/06/2015 03/09/2015	FDA/OMPT/CTP/OD/	Carla Scarmazzi, FDA & Life Sciences Specialist KING & SPALDING	SE0004001
2015-1008	02/06/2015 03/09/2015	FDA/OMPT/CDRH/OCER/DFOI/	Dane Thomas Stark Medical	K140366
2015-1009	02/06/2015 03/09/2015	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	SE0001697
2015-1010	02/06/2015 03/09/2015	FDA/OMPT/CDRH/OCER/DFOI/	Barbara L. Smith W. L. Gore & Associates, Inc.	K123128
2015-1011	02/06/2015	FDA/OMPT/CDRH/OCER/DFOI/	Corrine Herlinger	K061248

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	03/09/2015		BLUE BELT TECHNOLOGIES INC	
2015-1012	02/06/2015 03/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Brandon Beagle PhD PFC Development/New Alliance	IND 41653
2015-1013	02/06/2015 03/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 22320
2015-1014	02/06/2015 03/09/2015	FDA/OMPT/CDRH/OCER/DFOI/	Valerie Defiesta-Ng EXPERIEN GROUP LLC	K071733
2015-1015	02/06/2015 03/09/2015	FDA/OMPT/CDRH/OCER/DFOI/	Chris Henza Regulatory Compliance Associates, Inc.	K071573
2015-1016	02/06/2015 03/09/2015	FDA/OMPT/CDRH/OCER/DFOI/	Agfa HealthCare CAVANAGH, JAMES	K140271
2015-1017	02/06/2015 03/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ibrutinib - All AE's Ken Tong	IMBRUVICA - AERS
2015-1018	02/06/2015 03/09/2015	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	SE0003297
2015-1019	02/06/2015 03/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ying Chun Li Hospira Healthcare Corporation	METOCLOPRAMIDE - SBA
2015-1020	02/06/2015 03/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Pembrolizumab - All AE's Ken Tong	KEYTRUDA - AERS
2015-1021	02/06/2015 03/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kurt Wiehle Wiehle, Kurt	NDA 022535 ORPHAN DESIGNATION

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/OSMP/OOPD/		
2015-1022	02/06/2015 03/09/2015	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	SE0003299
2015-1023	02/06/2015 03/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	5,129 Drugs Marketed Without an Approved NDA/ANDA
2015-1024	02/06/2015 03/09/2015	FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/	Heather Baierl Nature's Way Product	ASPIRE PHARMACEUTICALS, SOMERSET, NJ - EIR 02/01/2010 - 02/05/2015
2015-1025	02/06/2015 03/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lindsey De Lott, MD UNIVERSITY OF MICHIGAN	BETASERON - PHASE III CLINICAL TRIAL DATA
2015-1026	02/06/2015 03/09/2015	FDA/OMPT/OSMP/OOPD/	Kurt Wiehle Wiehle, Kurt	NDA 205832 ORPHAN DESIGNATION
2015-1027	02/06/2015 03/09/2015	OC/ORACE/ OC/ORACE/ FDA/OGROP/ORACE-FO/CHI- DO/CHI-CB/	Gia Robertson Woodland Foods Ltd	REFUSAL OF ADMISSION ENTRY G33-0172430-5
2015-1028	02/06/2015 03/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Saion Mukherjee Nomura Financial Advisory & Securities (India) Private Limited	DMF 23564; DMF 23596 - MANUFACTURING FACILITIES
2015-1029	02/06/2015 03/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Saion Mukherjee Nomura Financial Advisory & Securities (India) Private Limited	ANDA 078936
2015-1030	02/06/2015 03/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Abhishek Sharma IIFL Cap	LUPIN LIMITED - 483 01/01/2015 - 01/31/2015
2015-1031	02/06/2015	FDA/OMPT/CDRH/OCER/DFOI/	nissim shaked	K132028

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	03/09/2015		Nissim Shaked	
2015-1032	02/06/2015 03/09/2015	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Melissa Daggerhart Segal Institute for Clinical Research	DR SEGAL - FOLLOW UP LETTER 01/03/2013 - 02/05/2015
2015-1033	02/06/2015 03/09/2015	FDA/OGROP/ORR/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORR/CE-FO/DET-DO/DET-CB/ FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/	Linda Bowen SANOFI	MERRELL RESEARCH CENTER, MERRELL NATIONAL LABORATORIES, RICHARDSON MERRELL, CINCINNATI, OH ETC - INSPECTION RECS
2015-1034	02/06/2015 03/09/2015	FDA/OGROP/ORR/CE-FO/NWJ-DO/NWJ-CB/	John Walsh James Alexander Corporation	ATLANTIC SCALE, INC - RECALL RECS 08/01/2013 - 02/05/2015
2015-1035	02/06/2015 03/09/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 12/8-13/14
2015-1036	02/06/2015 03/09/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 12/15-20/14
2015-1037	02/06/2015 03/09/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 12/22-27/14
2015-1038	02/06/2015 03/09/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 12/29/14 TO1/3/15
2015-1039	02/06/2015 03/09/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 12/8-13/14
2015-1040	02/06/2015 03/09/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 12/15-20/14
2015-1041	02/06/2015 03/09/2015	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 12/15-19/14
2015-1042	02/06/2015 03/09/2015	FDA/OC/OES/DFOI/	LESLIE RAMSEY FDA NEWS	FOI DAILY LOG 12/15-19/14
2015-1043	02/06/2015 03/09/2015	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD Center for Regulatory Services,Inc.	FOI DAILY LOG 12/15-19/14
2015-1044	02/06/2015	FDA/OC/OES/DFOI/	WILLIAM A OSLON PHD	FOI DAILY LOG 12/22-26/14

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	03/09/2015		Center for Regulatory Services,Inc.	
2015-1045	02/06/2015 03/09/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 12/15-19/14
2015-1046	02/06/2015 03/09/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 12/22-26/14
2015-1047	02/06/2015 03/09/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 12/9/14 TO 1/02/15
2015-1048	02/06/2015 03/09/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 12/15-19/14
2015-1049	02/06/2015 03/09/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 12/22-26/14
2015-1050	02/06/2015 03/09/2015	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 12/15-19/14
2015-1051	02/06/2015 03/09/2015	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 12/22-26/14
2015-1052	02/06/2015 03/09/2015	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 12/29/14 TO 1/2/15
2015-1053	02/06/2015 03/09/2015	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 12/15-19/14
2015-1054	02/06/2015 03/09/2015	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 12/22-26/14
2015-1055	02/06/2015 03/09/2015	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 12/15-19/14
2015-1056	02/06/2015 03/09/2015	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 12/22-26/14
2015-1057	02/06/2015 03/09/2015	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 12/29/14 TO 1/2/15
2015-1058	02/06/2015 03/09/2015	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 12/15-19/14

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2015-1059	02/06/2015 03/09/2015	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 12/22-16/14
2015-1060	02/06/2015 03/09/2015	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SE-FO/SJN-DO/SJN-CB/	Doe J	LBLG CLAIMS FOR PET CARE PRODS - COMPLNTS
2015-1061	02/06/2015 03/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Peter Loftus THE WALL STREET JOURNAL	BASF, GERMANY - 483
2015-1062	02/06/2015 03/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rene Siewczynski arznei-telegramm, A.T.I. Arzneimittelinformation Berlin GmbH	MONUROL - MEDICAL REVIEW
2015-1063	02/06/2015 03/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	lease send me a pdf or copy of the medical revie Rene Siewczynski arznei-telegramm, A.T.I. Arzneimittelinformation Berlin GmbH	METROCREAM MEDICAL REVIEW
2015-1064	02/06/2015 03/09/2015	FDA/OGROP/ORO/PA-FO/SEA-DO/SEA-CB/	Rachel Johnson FOI Services, Inc.	WLSEA1301 - COMPANY RESPONSE
2015-1065	02/06/2015 03/09/2015	FDA/OMPT/CDRH/OCER/DFOI/	TOM QUINN QUINN, TOM	CPT1400875 - NOTES, SUMM, COMM , ETC
2015-1066	02/06/2015 03/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DR SCHULLER SCHULLER, DR	DRUG EFFICACY LIST
2015-1067	02/06/2015 03/09/2015	FDA/OC/OES/DFOI/	Grace Davies Grace Davies c/o Tilton & Dunn PLLP	ETHICON ENDO-SURGERY, INC - EIR, 483 01/01/2003 - 02/03/2015
2015-1068	02/06/2015 03/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WENDY M BEHAN CASEY GERRY SCHENK ET AL	SANOFI - MULTAQ (DRONEDARONE) AERS,, COMM, MEMO

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2015-1069	02/06/2015 03/09/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	CHARLEA SEIFE NEW YORK UNIV ARTS & SCIENCE	UNREDACTED NIPOE, NOOH, WARNING LTR DTD AFTER 1/98
2015-1070	02/06/2015 03/09/2015	FDA/OC/OES/DFOI/ FDA/OGROP/ORACE-FO/PHI- DO/PHI-CB/	ANNE M HULL HUTTON & HUTTON	NUTECK DISPOSABLE INC - SIMPLY RIGHT WIPES RECALL, CORR, LAB STUDIES, ETC
2015-1071	02/06/2015 03/09/2015	OC/ORA/ OC/ORA/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORASE-FO/ATL- DO/ATL-CB/ FDA/OGROP/ORASE-FO/ATL- DO/ATL-CB/	BROOKE SCHUMM III SCHUMM III, BROOKE	ATLANTA CENTER FOR NUTRIENT ANALYSIS (ACNA) - VITAMIN A, B12,C, ETC TESTING PROTOCOLS
2015-1072	02/06/2015 03/09/2015	FDA/OC/OES/DFOI/	JOANNE E MATUSKO NastLaw, LLC	BAYER CORP, JANSSEN RESEARCH & DEVELOPMENT ENTITIES - XARELTO APRVL APPL, PERMITS, PROCEDURE MANUALS, ETC
2015-1073	02/09/2015 03/10/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lauren Cutler Gilead Sciences, Inc.	BLA 103532/5175 SBA
2015-1074	02/09/2015 03/10/2015	FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/	Arthur Phillips UNITE HERE	FLYING FOOD GROUP, LOS ANGELES, CA; HARBOR CITY, CA; BURLINGAME, CA ETC - INSPECTION RECS
2015-1075	02/09/2015 04/02/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ OC/ORA/ORM/ OC/ORA/ORM/	Kendall Taggart Buzzfeed News	DATA DICTIONARY FOR INSPECTIONS OF HUMAN CELL AND TISSUE ESTABLISHMENTS 01/01/2010 - 02/01/2015
2015-1076	02/09/2015 03/10/2015	FDA/OMPT/CDRH/OCER/DFOI/	Elisabetta Bianchini quipu	K033266
2015-1077	02/09/2015 03/10/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K123999
2015-1078	02/09/2015	FDA/OMPT/CDER/ORP/DIDP/	Mary K. Blasy	REVANCE THERAPEUTICS, MEDICIS PHARMACEUTICAL CORPORATION - CORR RE RT001 01/01/2000 - 02/06/2015

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	03/10/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mary K. Blasy	
2015-1079	02/09/2015 03/10/2015	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2014-9541
2015-1080	02/09/2015 03/10/2015	OC/CVM/OCD/	Kelly Beers (US Agent for Huvepharma AD) Huvepharma, Inc.	FDA APPROVED METHOD TO ASSAY RACTOPAMINE IN TYPE B AND C SWINE AND TURKEY FEEDS
2015-1081	02/09/2015 03/10/2015	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2014-9792
2015-1082	02/09/2015 03/10/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	B&H Consulting Services, Inc. B&H Consulting Services, Inc.	APOTEX RESEARCH PRIVATE LIMITED, INDIA - 483 11/17/2014 - 02/06/2015
2015-1083	02/09/2015 03/10/2015	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Rachel Johnson FOI Services, Inc.	MEAD JOHNSON NUTRITION, EVANSVILLE, IN; MEAD JOHNSON NUTRITIONALS, ZEELAND, MI; ETC - 483, EIR 09/01/2014 TO PRESENT
2015-1084	02/09/2015 03/10/2015	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Rachel Johnson FOI Services, Inc.	BREATHABLE FOODS - CORR RE WARNING LETTER 03/05/2012
2015-1085	02/09/2015 03/10/2015	FDA/OMPT/CDRH/OCER/DFOI/	Jing Gu W.H.P.M., Inc.	K060463
2015-1086	02/09/2015 03/10/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Paola Teegarden Kinex Pharmaceuticals Inc.	NDA 020262 S 000 ETC
2015-1087	02/09/2015 03/10/2015	FDA/OMPT/CDRH/OCER/DFOI/	Stephen McKelvey Zimmer, Inc.	K110895
2015-1088	02/09/2015 03/10/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Zory Shaposhnik Kythera Biopharmaceuticals, Inc	NDA 018669
2015-1089	02/09/2015	FDA/OGROP/ORA/CE-FO/CIN-	Rachel Johnson	DANNON, MINSTER, OH, PBM NUTRITIONALS, COVINGTON,

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	03/10/2015	DO/CIN-CB/	FOI Services, Inc.	OH - EIR, 483 483 09/01/2014 TO PRESENT
2015-1090	02/09/2015 03/10/2015	FDA/OMPT/CDRH/OCER/DFOI/	Stephanie Dominguez Applied Medical	K123444
2015-1091	02/09/2015 03/10/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Henry Song KDL Pharma	ANDA 077263
2015-1092	02/09/2015 03/10/2015	FDA/OGROP/ORAP/PA-FO/SEA-DO/SEA-CB/	Cherie Tregoning Aseptico, Inc.	ASEPTICO, WOODINVILLE, WA - EIR 09/01/2009 - 09/04/2009
2015-1093	02/09/2015 03/10/2015	FDA/OMPT/CDRH/OCER/DFOI/	Simon Fitzer Biocomposites Ltd	BIOCOMPOSITE - EIR, CLOSEOUT LETTER 02/04/2013 - 02/04/2015
2015-1094	02/09/2015 03/10/2015	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	BRETT A CARTER ESQ BENSON ERTOLDO BAKER ET AL	STRYKER, HOWMEDICA - GLOBAL MODULAR REPLACEMENT SYS (GMRS), MODULAR ROTATING HINGE KNEE (MRHK) FEMORAL COMPONENT MDRS, MEMOS, WARNING LTRS, ETC
2015-1095	02/09/2015 03/10/2015	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JEANIE WARD WARD, JEANIE	POLYETHYLENE GLYCOL 3350 - AERS 1998 TO PRESENT, CORR 6/13/84
2015-1096	02/09/2015 03/10/2015	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	CISPLATIN, PLATINOL, THIMEROSAL - AERS; FLU VACCINE - VACCINE INJURY TABLE 2013-2014, ETC
2015-1097	02/09/2015 03/10/2015	FDA/OFVM/CFSAN/OCD/EOS/	JOAN SYLVAIN BAUGHAN Keller and Heckman LLP	FCN 912
2015-1098	02/09/2015 03/10/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHRISTOPHER L SCHNIEDERS WAGSTAFF & CARTMELL LLP	XARELTO (RIVAROXABAN) NDA 22-406, NDA 202-439 - CORR, AERS, MOR, ETC
2015-1099	02/09/2015 03/10/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ADAM L SLATER MAZIE SLATER KATZ ET AL	DAIICHI SANKYO INC, FOREST LABORATORIES INC, ETC - BENICAR, AZOR, TRIBENZOR, ETC EIRS, CORR, AERS, ETC

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2015-1100	02/09/2015 03/10/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MICHAEL R COHEN RPH MS SCD INSTITUTE FOR SAFE MEDICATION PRACTICES	MEDWATCH RPTS CODED AS MEDICATION ERRORS 12/14 TO 1/15
2015-1101	02/09/2015 03/10/2015	FDA/OC/OES/DFOI/	PATRICIA L REGENYE Celgene Corporation	KURT LESH, COLORADO SPRINGS FAMILY PRACTICE, COLORADO SPRINGS, CO - 483S 5/09 TO PRESENT
2015-1102	02/09/2015 03/10/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	DAVID L BENNINGHOFF MD BENNINGHOFF MD, DAVID	SIPULEUCEL-T - NCT00065442 STUDY
2015-1103	02/10/2015 03/11/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PATRICK HRUBY HRUBY, PATRICK	ROCHE - TORADOL (KETOROLAC) IND SAFETY RPTS, AERS, TOXICOLOGY RECS, ETC
2015-1104	02/10/2015 03/11/2015	FDA/OFVM/CFSAN/OCD/EOS/	SHARON L LYERLY WATKINS LOURIE ROLL & CHANCE PC	HYDROXYCUT - CAERS 112830, 113122, 116215, ETC
2015-1105	02/10/2015 03/11/2015	FDA/OFVM/CFSAN/OCD/EOS/	LAURA MACCLEERY CENTER FOR SCIENCE IN THE PUBLIC INTEREST	EXPOSURE ESTIMATE FOR FD&C COLORS FOR THE US POPULATION - PRODUCT IDENTITY
2015-1106	02/10/2015 03/31/2015	FDA/OC/OES/ FDA/OFVM/CFSAN/OCD/EOS/	LAURA MACCLEERY CENTER FOR SCIENCE IN THE PUBLIC INTEREST	POWDERED CAFFEINE - SALE OR DISTRIBUTION PHONE LOGS, LTRS, NOTES, ETC
2015-1107	02/10/2015 03/11/2015	FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECS
2015-1108	02/10/2015 03/11/2015	FDA/OGROP/ORR/SE-FO/FLA- DO/FLA-CB/ FDA/OC/OES/DFOI/	DAVID JARVIS Jarvis, David	PRODUCT QUEST MANUFACTURING INC, DAYTONA BEACH, FL - INSP RECS
2015-1109	02/10/2015 03/11/2015	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	REPUBLIC TOBACCO - CORR WITH FDA
2015-1110	02/10/2015 03/11/2015	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	REPUBLIC TOBACCO - CORR WITH FDA
2015-1111	02/10/2015 03/11/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	CORGARD (NADOLOL) NDA 18-063 APRVL LTR, LBLG, MOR, ETC

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2015-1112	02/10/2015 03/11/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Helbert Rondon UNIVERSITY OF PITTSBURGH	SAMSCA - AERS
2015-1113	02/10/2015 03/11/2015	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/	Doe J	RECS RE COMPLAINT 139980
2015-1114	02/10/2015 03/11/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Leslie Dixon St. David's	VANCOMYCIN - AERS
2015-1115	02/10/2015 03/11/2015	FDA/OMPT/CDRH/OCER/DFOI/	Mike Johnson Mike Johnson	TRAVATAN DOSING AID - PATHWAY TO MARKET 01/01/2005 - 12/31/2011
2015-1116	02/10/2015 03/11/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Monique Lantz BRIDGE CLINICAL RESEARCH	NDA 201917
2015-1117	02/10/2015 03/11/2015	FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/	Rebekah Cafrelli Rebekah Cafrelli	HERSHEY MEDICAL CENTER BLOOD BANK - EIR 12/10/2014 - 12/10/2014
2015-1118	02/10/2015 03/11/2015	FDA/OMPT/OSMP/OOPD/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Yamil Hernandez Cerium Pharmaceuticals, Inc.	NDA 022181 - SBA, ORPHAN DRUG DESIGNATION
2015-1119	02/10/2015 03/11/2015	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	James Rogers Valinor Management	INSYS THERAPEUTICS - INSPECTION RECS, AERS 01/02/2011 - 02/09/2015
2015-1120	02/10/2015	FDA/OMPT/CTP/OD/	Rachel Johnson	SILVERFOILTUBES - CORR WITH FDA

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	03/11/2015		FOI Services, Inc.	
2015-1121	02/10/2015 03/11/2015	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/	mirolsav vlk wake spol. s r.o.	WOUND BE GONE - IMPORT ALERT
2015-1122	02/10/2015 03/11/2015	OC/ORO/ OC/ORO/ FDA/OC/OES/DFOI/ OC/ORO/ORM/ OC/ORO/ORM/	Josh Long Informa / Natural Products Insider	DIETARY SUPPLEMENTS - INSPECTION DATA
2015-1123	02/10/2015 03/11/2015	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	DR JONATHAN SAMET - COMMUNICATIONS WITH FDA CTP JUNE 20, 2014 TO PRESENT
2015-1124	02/10/2015 03/11/2015	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	HOUSE OF OLIVER TWIST A/S - CORR WITH FDA
2015-1125	02/10/2015 03/11/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 205874
2015-1126	02/10/2015 03/11/2015	FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/	Larry Evers Florida Farm Bureau General Insurance Company	REPTILE INDUSTRIES - SALMONELLA OUTBREAK, INVESTIGATIVE REPORTS, MEDICAL REPORTS 05/01/2014 - 08/31/2014
2015-1127	02/10/2015 03/11/2015	FDA/OMPT/CDRH/OCER/DFOI/	Cara Neil OPEN MINDS	ANTHROTRONIX INC DANA 510K
2015-1128	02/10/2015 03/11/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tom Blackwell National Post	DR REDDY'S LABORATORIES, INDIA; IPCA LABORATORIES, INDIA - 483 01/01/2014 - 02/10/2015
2015-1129	02/10/2015 03/11/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sara Wexler Koblitz Fish and Richardson P.C.	ANDA 076373
2015-1130	02/10/2015 03/11/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jennifer Newberger Hyman, Phelps & McNamara P.C.	BIOEQUIVALENCE REQUIREMENTS FOR INHALED NITRIC OXIDE

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		FDA/OMPT/CDER/GRP/DIDP/		
2015-1131	02/10/2015 03/11/2015	FDA/OMPT/CDRH/OCER/DFOI/	Steve Miller AIR LIQUIDE HEALTHCARE AMERICA CORP	K080966
2015-1132	02/10/2015 03/11/2015	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	HOUSE OF OLIVER TWIST A/S - CORR WITH FDA
2015-1133	02/10/2015 03/11/2015	FDA/OGROP/ORASW-FO/DEN- DO/DEN-CB/	Dr. Edward Cutler Cutler, Edward	XLEAR - 483 01/01/2000 - 02/09/2015
2015-1134	02/10/2015 03/11/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	PAREXEL, BERLIN, GERMANY - EIR, 483
2015-1135	02/10/2015 03/11/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Julia Clarkson GOLDMAN SACHS	CLOZAPINE - DEATHS
2015-1136	02/10/2015 03/11/2015	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	S&M BRANDS - CORR WITH FDA
2015-1137	02/10/2015 03/11/2015	FDA/OMPT/CTP/OD/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	REPUBLIC TOBACCO - CORR WITH FDA
2015-1138	02/10/2015 03/11/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Darlene Rosario Dance Biopharm Inc	NDA 022472
2015-1139	02/10/2015 03/11/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	ALBENZA (ALBENDAZOLE) NDA 20-666 APRVL LTR, LBLG, MOR, ETC
2015-1140	02/10/2015 03/11/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	LOTENSIN HCT (BENAZEPRIL HCL, HYDROCHLOROTHIAZIDE) NDA 20-033 APRVL LTR, LBLG, MOR, ETC
2015-1141	02/10/2015	FDA/OMPT/CDER/GRP/DIDP/	CHARLES CELESTE	CHLORPROMAZINE HCL NDA 80-439 - APRVL LTR, LBLG, MOR, ETC

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	03/11/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	EAS CONSULTING GROUP LLC	
2015-1142	02/10/2015 03/11/2015	FDA/OGROP/OIP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES SEIFE NEW YORK UNIV ARTS & SCIENCE	GVK BIOSCIENCES, HYDERABAD - EIRS, 483S, COMM, ETC 9/14 TO PRESENT
2015-1143	02/10/2015 03/11/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES SEIFE NEW YORK UNIV ARTS & SCIENCE	CETERO RESEARCH - RESP TO UNTITLED LTR 7/26/11
2015-1144	02/10/2015 03/11/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES SEIFE NEW YORK UNIV ARTS & SCIENCE	GENERIC FIRMS THAT MARKETED 81 PRODUCTS AFFECTED BY CETERO FRAUD - BIEQV STUDIES
2015-1145	02/10/2015 03/11/2015	FDA/OMPT/CDRH/OCER/DFOI/	EDWARD KOBUS Invado Pharmaceuticals	K093642
2015-1146	02/10/2015 03/11/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DANIELLE BRADLEY ROCHELLE MCCULLOUGH LLP	GLAXOSMITHKLINE - LAMICTAL SAFETY UPDATE RPT, AERS
2015-1147	02/11/2015 03/12/2015	FDA/OMPT/CDRH/OCER/DFOI/	Anna Longwell Longwell and Associates	K141742
2015-1148	02/11/2015 03/12/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K132750
2015-1149	02/11/2015 03/12/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ayesh Adil The Weinberg Group	NDA 021446 S10
2015-1150	02/11/2015 03/12/2015	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2014-8655

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2015-1151	02/11/2015 03/12/2015	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2014-3330
2015-1152	02/11/2015 03/12/2015	FDA/OGROP/ORR/CE-FO/NWJ-DO/NWJ-CB/	John Walsh James Alexander Corporation	NATUREX, SOUTH HACKENSACK, NJ - EIR, 483 RECALL 09/01/2013 - 02/10/2015
2015-1153	02/11/2015 03/12/2015	FDA/OC/OES/DFOI/	Patrice Doyle Doyle, Patrice	HARD CANDY CAT MAKEUP KIT - AERS 01/01/2010 - 02/01/2015
2015-1154	02/11/2015 03/12/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sally Yang Cote Orphan, LLC	CORTEF - SUPPLEMENTAL NDA, CORR, SUPPLEMENTAL APPROVAL 01/01/1973 - 01/01/1979
2015-1155	02/11/2015 03/12/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sally Yang Cote Orphan, LLC	NDA 008697
2015-1156	02/11/2015 03/12/2015	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2014-9433
2015-1157	02/11/2015 03/12/2015	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2013-5597
2015-1158	02/11/2015 03/12/2015	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2014-9359
2015-1159	02/11/2015 03/12/2015	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2014-1940
2015-1160	02/11/2015 03/12/2015	OC/ORR/ORM/ OC/ORR/ORM/	Casi Lumbr Bain & Co.	STERIS ISOMEDIX, STERIGENICS - LIST OF 483 01/01/2012 - 02/10/2015
2015-1161	02/11/2015 03/12/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K124006
2015-1162	02/11/2015 03/12/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ayesha Adil The Weinberg Group	NDA 021427

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2015-1163	02/11/2015 03/12/2015	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/	Rachel Johnson FOI Services, Inc.	AUGMENT BONE GRAFT PREAPPROVAL INSPECTION - 483, CORR
2015-1164	02/11/2015 03/12/2015	FDA/OC/OES/DDM/	Rachel Johnson FOI Services, Inc.	General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee background materials for 12/01/2011 meeting
2015-1165	02/11/2015 03/12/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Brenda Goodman WebMD	ALL FOR CAUSE INSPECTION REQUESTS MADE TO FDA OSI 01/01/2010 - 02/01/2015
2015-1166	02/11/2015 03/12/2015	FDA/OMPT/CDRH/OCER/DFOI/	Gregory Foster Alliance Labs	K093585
2015-1167	02/11/2015 03/12/2015	FDA/OFVM/CFSAN/OCD/EOS/	Daria Church Clariant Corporation	FAP 2B4297
2015-1168	02/11/2015 03/12/2015	FDA/OGROP/ORO/CE-FO/MIN- DO/MIN-CB/	Kyle Maloney - WR Medical Electronics WR Medical Electronics	WR MEDICAL, MAPLEWOOD, MN - EIR 04/01/2014 - 05/31/2014
2015-1169	02/11/2015 03/12/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K123955
2015-1170	02/11/2015 03/12/2015	FDA/OGROP/ORO/CE-FO/MIN- DO/MIN-CB/	Ann Holden STANDARD PROCESS INC.	STANDARD PROCESS, PALMYRA, WI - EIR 01/01/2012 - 02/10/2015
2015-1171	02/11/2015 03/12/2015	FDA/OGROP/ORO/SW-FO/KAN- DO/KAN-CB/	Janice Wittgrove sanofi-aventis U.S. LLC	SANOFI, ST LOUIS - EIR 02/04/2014 - 02/10/2015
2015-1172	02/11/2015 03/12/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Monique Lantz BRIDGE CLINICAL RESEARCH	NDA 103964
2015-1173	02/11/2015 03/12/2015	FDA/OMPT/CDRH/OCER/DFOI/	Shankar Venkateswaran HEARTWARE INC	HEARTWARE INC - HVAD CLINICAL DATA
2015-1174	02/11/2015 03/12/2015	FDA/OC/OES/DDM/	Donna Bitzelberger Venable, LLP	ADVISORY COMMITTEE MEETING MATERIALS - DNP REVIEW OF NEURODEVELOPMENTAL DELAYS WITH PRENATAL VALPROIC ACID EXPORSURE (CERTIFIED) 06/01/2009 - 06/30/2009
2015-1175	02/11/2015	FDA/OC/OES/DFOI/		INDIVIDUAL RECS

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	03/12/2015		Doe J	
2015-1176	02/11/2015 03/12/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 1/26-30/15
2015-1177	02/11/2015 03/12/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 1/19-23/15
2015-1178	02/11/2015 03/12/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 1/12-16/15
2015-1179	02/11/2015 03/12/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 1/05-09/15
2015-1180	02/11/2015 03/12/2015	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 1/12-16/15
2015-1181	02/11/2015 03/12/2015	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 1/5-9/15
2015-1182	02/11/2015 03/12/2015	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 1/19-23/15
2015-1183	02/11/2015 03/12/2015	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 1/12-16/15
2015-1184	02/11/2015 03/12/2015	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 1/26-30/15
2015-1185	02/11/2015 03/12/2015	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 1/19-23/15
2015-1186	02/11/2015 03/12/2015	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 1/15-9/15
2015-1187	02/11/2015 03/12/2015	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 1/26-30/15
2015-1188	02/11/2015 03/12/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 1/5-10/15
2015-1189	02/11/2015 03/12/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 1/19-24/15
2015-1190	02/11/2015	FDA/OC/OES/DFOI/		CLOSED FOIA REQUESTS 1/12-17/15

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	03/12/2015		FOI Services, Inc.	
2015-1191	02/11/2015 03/12/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 1/26-31/15
2015-1192	02/11/2015 03/12/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	LAURA A HALPER HALPER GROUP	ORALIEF OTC TOOTHPASTE FOR SENSITIVE TEETH - K080228; ORALIEF THERAPY FOR SENSITWIVE TEETH - K040858
2015-1193	02/11/2015 03/12/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KRISTEN H STRAIN VENABLE LLP	EUGENE EMERGENCY PHYSICIANS PC, EUGENE, OR, ANN M COOLEY MD, PEACEHEALTH SACRED HEART MEDICAL CENTER AT RIVERBEND, SPRINGFIELD, OR, PEACEHEALTH SACRED HEART MEDICAL CENTER HOSP UNIV DISTRICT, EUGENE, OR - METOCOLPRAMID, REGLAN INJ, METOCLOPRAMIDE INJ BOXED WARNINGS COMM, DEAR DOCTOR LTRS, ETC (CERTIFIED)
2015-1194	02/11/2015 03/12/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KRISTEN H STRAIN VENABLE LLP	BAXTER HEALTHCARE CORP - METOCLOPRAMIDE, REGLAN INJ, METOCLOPRAMIDE INJ RISK OF LONG-TERM OR HIGH-DOSE BOXED WARING COMM, DEAR DOCTOR LTRS, ETC (CERTIFIED)
2015-1195	02/11/2015 03/12/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELENA HOWELL HOGAN LOVELLS US LLP	MYLAN PHARMA - ESOMEPRAZOLE MAGNESIUM NDA 78-936; TENTATIVE APRVL LTR 2/14/15
2015-1196	02/11/2015 03/12/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SUSAN TODD WEST-WARD PHARMACEUTICAL CORP	LIST OF DRUG PRODS THAT ARE STILL ON THE MARKET W/O ANDA OR NDA APRVL
2015-1197	02/11/2015 03/12/2015	FDA/OMPT/CDRH/OCER/DFOI/	Request to the FDA for a copy of the inspection report Medimaging Integrated Solution Inc.	MEDIMAGING INTEGRATED SOLUTION INC - EIR 08/18/2014 - 02/11/2015
2015-1198	02/11/2015 03/12/2015	OC/CVM/OCD/	Lisa Winebarger COMPASSION OVER KILLING	PET FOOD SLAUGHTER RECS
2015-1199	02/11/2015 03/12/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Vaibhav Dusad Morgan Stanley	AUROBINDO PHARMA UNIT IV, INDIA - 483 09/02/2014 - 09/30/2014
2015-1200	02/11/2015	FDA/OGROP/ORAP/PA-FO/SEA-	BRUCE MILLIKEN	OREGON AESTHETIC TECNOLOGIES DBA ANSR -

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	03/12/2015	DO/SEA-CB/	MILLIKEN, BRUCE	WARNING LTR 9/14/12 REMAINDER OF CORR
2015-1201	02/11/2015 03/12/2015	FDA/OC/OES/DFOI/ FDA/OO/OHR/	Doe J	INDIVIDUAL RECS
2015-1202	02/11/2015 03/12/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Marie Link REMS Logic, LLC	REMS DRUG ERROR REPORTS BY DRUG 01/01/2005 - 12/31/2013
2015-1203	02/11/2015 03/12/2015	FDA/OMPT/CDRH/OCER/DFOI/	Carrie Poppy Oh No, Ross and Carrie	Flex-Belt FDA clearance
2015-1204	02/11/2015 03/12/2015	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	WM P WINKLER WINKLER, WM P	B F MAZZEO FRUITE & PRODUCE INC, NORTHFIELD, NJ - EIRS, ENFORCEMENT ACTIONS
2015-1205	02/11/2015 03/12/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	David Kim Partner Fund Management	DR REDDY'S LABORATORIES - 483 11/01/2014 - 02/11/2015
2015-1206	02/11/2015 03/12/2015	FDA/OC/OES/DDM/	RYAN VIKAN NEASE CO LLC	ENVIRO TECH CHEMICAL SERVICES INC - DKT 96F-0076
2015-1207	02/11/2015 03/16/2015	FDA/OC/OCC/ FDA/OC/OES/ OC/CVM/OCD/	TIFFANY FINCK-HAYNES FRIENDS OF THE EARTH US	RELEASE OF GENETICALLY ENGINEERED OR MODIFIED BEES - RECS, RELATING TO INVESTIGATIONAL NEW ANIMAL DRUG, SUPPORT, RDNA CONSTRUCT, ETC
2015-1208	02/11/2015 03/12/2015	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	PATRICIA SCHNOOR CAPILLUS LLC	SPL 756801, 756802 - RPT
2015-1209	02/11/2015 03/12/2015	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	ANTONIO VESPARI LIBERTY MUTUAL	BIDART BROTHERS APPLE PACKING, SHAFTER, CA, HAPPY APPLE CO, OROSI, CA - RECALL LISTERIA PATHOGEN SAFETY INSP, CMLPLNT LTRS, CONSUMER INTERVIEWS, ETC
2015-1210	02/12/2015 03/13/2015	FDA/OMPT/CDRH/OCER/DFOI/	Anita Zacherl OSTEOMED CORP	K051093
2015-1211	02/12/2015 03/13/2015	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document	2014-9843

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			Retrieval	
2015-1212	02/12/2015 03/13/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michael DeMeuse UPSHER-SMITH LABORATORIES INC	ANDA 076648
2015-1213	02/12/2015 03/13/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Rebecca Posten PrevaLeaf	K810310
2015-1214	02/12/2015 03/13/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Chase Southern TLG Capital Investments LLC	OHR PHARMACEUTICAL END-OF-PHASE II MEETING MINUTES 09/01/2014 - 10/15/2014
2015-1215	02/12/2015 03/13/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michael DeMeuse UPSHER-SMITH LABORATORIES INC	ANDA 077066
2015-1216	02/12/2015 03/13/2015	FDA/OMPT/CDRH/OCER/DFOI/	Melissa Thompson Carolina Liquid Chemistries, Corp.	K870233
2015-1217	02/12/2015 03/13/2015	FDA/OMPT/CDRH/OCER/DFOI/	Melissa Thompson Carolina Liquid Chemistries, Corp.	K973634
2015-1218	02/12/2015 03/13/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	A. LUKE SMITH RADICE LAW FIRM	MINOCYCLINE HYDROCHLORIDE (LUPIN) ANDA 91-424 APRVL
2015-1219	02/12/2015 03/13/2015	FDA/OMPT/CDRH/OCER/DFOI/	Anna Longwell Longwell and Associates	K122474
2015-1220	02/12/2015 03/13/2015	FDA/OMPT/CDRH/OCER/DFOI/	Matthew Ofstie MWO Enterprises LLC d/b/a BeachWheeler	K954261
2015-1221	02/12/2015 03/13/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	A LUKE SMITH RADICE LAW FIRM	MINOCYCLINE HYDROCHLORIDE (AUROBINDO) ANDA 02- 261 APRVL

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2015-1222	02/12/2015 03/13/2015	FDA/OMPT/CDRH/OCER/DFOI/	Anna Longwell Longwell and Associates	K131153
2015-1223	02/12/2015 03/13/2015	FDA/OMPT/CDRH/OCER/DFOI/	Anna Longwell Longwell and Associates	K121478
2015-1224	02/12/2015 03/13/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	A LUKE SMITH RADICE LAW FIRM	MINOCYCLINE HYDROCHLORIDE (MYLAN) ANDA 01-467 APRVL
2015-1225	02/12/2015 03/13/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Susan Cusack, VP Regulatory Affairs Innocoll Technologies	NDA 022496
2015-1226	02/12/2015 03/13/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	A LUKE SMITH RADICE LAW FIRM	MINOCYCLINE HYDROCHLORIDE (RANBAXY) ANDA 91-118 APRVL
2015-1227	02/12/2015 03/13/2015	FDA/OMPT/CTP/OD/	Robert M. Spiller, Jr. Robert M. Spiller, Jr.	CIVIL MONEY PENALTIES PURSUANT TO TOBACCO CONTROL ACT
2015-1228	02/12/2015 03/13/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	A LUKE SMITH RADICE LAW FIRM	MINOCYCLINE HYDROCHLORIDE (SANDOZ) ANDA 90-422 APRVL
2015-1229	02/12/2015 03/13/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	A LUKE SMITH RADICE LAW FIRM	MINOCYCLINE HYDROCHLORIDE (MYLAN) ANDA 03-443 APRVL
2015-1230	02/12/2015 03/13/2015	FDA/OC/OES/DFOI/	Vik Bajnath ARTHREX INC.	MW5039853 - FACILITY NAME, CONTACT
2015-1231	02/12/2015 03/13/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Felecia Jones CHEMICAL INFORMATION SERVICES, INC.,	ORANGE BOOK - APPROVALS, DELETIONS, CHANGES ETC 01/01/2014 - 02/12/2015
2015-1232	02/12/2015	FDA/OMPT/CDER/ORP/DIDP/	A LUKE SMITH	MINOCYCLINE HYDROCHLORIDE (MYLAN) ANDA 90-911

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	03/13/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RADICE LAW FIRM	APRVL
2015-1233	02/12/2015 03/13/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	A LUKE SMITH RADICE LAW FIRM	MINOCYCLINE HYDROCHLORIDE (BARR) ANDA 65-485 APRVL
2015-1234	02/12/2015 03/13/2015	FDA/OC/OES/DFOI/	Vik Bajnath ARTHREX INC.	MW5040174 - FACILITY, CONTACT
2015-1235	02/12/2015 03/13/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Neha Manpuria J.P. Morgan India Pvt Ltd	DR REDDY, INDIA - 483 11/01/2014 - 02/01/2015
2015-1236	02/12/2015 03/13/2015	FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/	Peggy Meder Skin, A Medical Spa	VALEANT PHARMACEUTICALS INTERNATIONAL - WARNING LETTER, RESPONSE 09/14/2014 - 02/11/2015
2015-1237	02/12/2015 03/13/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kevin Su YALE SCHOOL OF MEDICINE	REVIEW DOCUMENTS FOR 12 CANCER DRUGS
2015-1238	02/12/2015 03/13/2015	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2014-9889
2015-1239	02/12/2015 03/13/2015	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2014-9886
2015-1240	02/12/2015 03/13/2015	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2014-3496
2015-1241	02/12/2015 03/13/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	A LUKE SMITH RADICE LAW FIRM	MINOCYCLINE HYDROCHLORIDE (IMPAX) ANDA 90-024 APRVL
2015-1242	02/12/2015 03/13/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-415 - REQUEST LETTER ONLY

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2015-1243	02/12/2015 03/13/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-682 - REQUEST LETTER ONLY
2015-1244	02/12/2015 03/13/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-41 - REQUEST LETTER ONLY
2015-1245	02/12/2015 03/13/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-509 - REQUEST LETTER ONLY
2015-1246	02/12/2015 03/13/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-63 - REQUEST LETTER ONLY
2015-1247	02/12/2015 03/13/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-43 - REQUEST LETTER ONLY
2015-1248	02/12/2015 03/13/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-78 - REQUEST LETTER ONLY
2015-1249	02/12/2015 03/13/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-39 - REQUEST LETTER ONLY
2015-1250	02/12/2015 03/13/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-334 - REQUEST LETTER ONLY
2015-1251	02/12/2015 03/13/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-31 - REQUEST LETTER ONLY
2015-1252	02/12/2015 03/13/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-540 - REQUEST LETTER ONLY
2015-1253	02/12/2015 03/13/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-503 - REQUEST LETTER ONLY
2015-1254	02/12/2015 03/13/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-498 - REQUEST LETTER ONLY
2015-1255	02/12/2015 03/13/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-568 - REQUEST LETTER ONLY
2015-1256	02/12/2015 03/13/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-644 - REQUEST LETTER ONLY
2015-1257	02/12/2015 03/13/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-689 - REQUEST LETTER ONLY
2015-1258	02/12/2015 03/13/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-704 - REQUEST LETTER ONLY
2015-1259	02/12/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2015-705 - REQUEST LETTER ONLY

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	03/13/2015		MERCK & CO., INC.	
2015-1260	02/12/2015 03/13/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CEFZIL NDA 50664 and 50665 harmonic Pharma	NDA 50664, 50665
2015-1261	02/12/2015 03/13/2015	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	CRAIG BIJOU EQUITY RESEARCH	BIOLOGICS THERAPEUTICS, OCALA, FL 1/22/15; SCORPION MEDICAL, OCALA, FL 1/22/15; EDGE BIOLOGICALS, MEMPHIS, TN 1/29/15 - INSP
2015-1262	02/12/2015 03/13/2015	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	MARK W. McBRAYER Crenshaw, Dupree & Milam, LLP	MINSA CORP, MULESHOE, TX - INSP 4/17/13, CERTIFICATE OF FREE SALE & SANITATION APRVL
2015-1263	02/12/2015 03/13/2015	FDA/OMPT/CDRH/OCER/DFOI/	JEFF GRIZZEL FDA NEWS	REGISTRATION LIST FOR FRAMEWORK FOR REGULATORY OVERSIGHT OF LABORATORY DEVELOPED TESTS WORKSHOP 1/8-9/15
2015-1264	02/12/2015 03/13/2015	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	PATTI WALLER Marler Clark Law Firm	LISTERIA OUTBREAK OCTOBER - DECEMBER 2014
2015-1265	02/12/2015 03/13/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHLOE BIRD PCCA	PROFESSIONAL COMPOUNDING CTX OF AMERICA, HOUSTON, TX; OLAINFARM JSC, OLAINES NOVADS, LATVIA - EIR
2015-1266	02/12/2015 03/13/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARTIN BINNES Luthi & Co.	ANTIHPERTENSIVE - CLNCL SUMMARY
2015-1267	02/12/2015 03/13/2015	FDA/OO/OFBA/OAGS/	Lauree Valverde Lauree Valverde	HHSF223201000054I - CONTRACT, MODIFICATIONS, TASK ORDERS
2015-1268	02/12/2015 03/13/2015	FDA/OO/OFBA/OAGS/	Lauree Valverde Lauree Valverde	FDA-14-1131234, FDA-SOL-13-1118990 - SOLICITATION RECS, CONTRACTS
2015-1269	02/12/2015 03/13/2015	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	RENEE L. BRANT HALICZER PETTIS & SCHWAMM	ST LUCIE MEDICAL CTR - INVESTIGATION 2008 TO PRESENT
2015-1270	02/12/2015	FDA/OGROP/ORA/SE-FO/FLA-	RENEE L BRANT	INTERGRATED REGIONAL LABS LLP - INVESTIGATION 2008

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	03/13/2015	DO/FLA-CB/	HALICZER PETTIS & SCHWAMM	TO PRESENT
2015-1271	02/12/2015 03/13/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	INDIVIDUAL RECS
2015-1272	02/12/2015 03/13/2015	FDA/OC/OES/DFOI/	Doe J	ABBOTT LABS, CASA GRANDE - POWERED FORMULA NVESTIGATION 9/23/11; GAIN T EAGLE WAREHOUSE - SIMILAC INVESTIGATION 9/30/11
2015-1273	02/12/2015 03/13/2015	FDA/OC/OES/DFOI/	Owen V Grace Medical Center Watson, Caraway, Midkiff & Lunningham	STRYER NEPTUNE - RECS PREVIOUSLY RELEASED UNDER FOIA 05/01/2006 - 02/05/2015
2015-1274	02/12/2015 03/13/2015	FDA/OGROP/ORAC/CE-FO/DET-DO/DET-CB/	AUTUMN L BORTON PFIZER INC	PAR STERILE PRODUCTS LLC, ROCHESTER, MI - EIR 11/2014
2015-1275	02/13/2015 03/16/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	LIST OF CURRENT REQUESTS
2015-1276	02/13/2015 03/16/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LESLIE RAMSEY FDA NEWS	LASBORATORIES BOIRON, MESSIMY, FRANCE, KYOWA HAKKO KOGYO CO LTD, SAKAI-CITY OSAKA, JAPAN, LUPIN LTD, INDORE, INDIA - 483S 1/1-31/15
2015-1277	02/13/2015 03/16/2015	FDA/OMPT/CDRH/OCER/DFOI/	LESLIE RAMSEY FDA NEWS	SEDATELEC, IRIGNY, FRANCE, ALCON LABORATORIES IRELAND LTD, CORK, IRELAND, GUANGZHOU T K MEDICAL INSTRUMENT CO LTD, GUANGXZZHOU CITY, CHINA, ETC - 483S 1/1-31/15
2015-1278	02/13/2015 03/16/2015	FDA/OGROP/ORAC/CE-FO/BLT-DO/BLT-CB/	LESLIE RAMSEY FDA NEWS	WOOD'S PHARMACY INC, BOONES MILL, VA - 483S 1/1-31/15
2015-1279	02/13/2015 03/16/2015	FDA/OGROP/ORAC/CE-FO/CIN-DO/CIN-CB/	LESLIE RAMSEY FDA NEWS	GREAT LAKES NEUROTECHNOLOGIES INC, VALLEY VIEW, OH, INTEGRATED MEDICAL SYSTEMS INTERNATIONAL INC, STOW, OH, ELECTRO CAP INTERNATIONAL INC, EATON, OH, ETC - 483S 1/1-31/15
2015-1280	02/13/2015 03/16/2015	FDA/OGROP/ORAC/SW-FO/DAL-DO/DAL-CB/	LESLIE FDA NEWS	UNIVERSITY OF TEXAS MD ANDERSON CANCER CENTER, HOUSTON, TX - EIRS 1/1-31/15
2015-1281	02/13/2015 03/16/2015	FDA/OGROP/ORAC/SW-FO/DEN-DO/DEN-CB/	LESLIE RAMSEY FDA NEWS	DYNATRONICS CORP, SALT LAKE CITY, UT - 483S 1/1-31/15
2015-1282	02/13/2015 03/16/2015	FDA/OGROP/ORAC/SW-FO/KAN-DO/KAN-CB/	LESLIE RAMSEY FDA NEWS	WEXFORD LABS INC, KIRKWOOD, MO, MALLINCKRODT INC, MARYLAND HEIGHTS, MO, TRIAD ISOTOPES INC, KANSAS CITY, MO - 483S 1/1-31/15

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2015-1283	02/13/2015 03/16/2015	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	LESLIE RAMSEY FDA NEWS	BREWER COMPANY LLC, MENOMONEE FALLS, WI, LIFE TECHNOLOGIES CORP, BROWN DEER, WI, BELL INTERNATIONAL LABORATORIES INC, MINNEAPOLIS, MN - 483S 1/1-31/15
2015-1284	02/13/2015 03/16/2015	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	LESLIE RAMSEY FDA NEWS	CAMBRIDGE ISOTOPE LABORATORIES INC, TEWKSBURY, MA - 483S 1/1-31/15
2015-1285	02/13/2015 03/16/2015	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	LESLIE RAMSEY FDA NEWS	ARTEGRAFT INC, NORTH BRUNSWICK, NJ - 483S 1/1-31/15
2015-1286	02/13/2015 03/16/2015	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	LESLIE RAMSEY FDA NEWS	BIG RIVER ENGINEERING & MANUFACTURING, MEMPHIS, TN, MRP, LLC (AMUSA), NASHVILLE, TN, ISCREEN VISION INC, CORDOVA, TN, ETC - 483S 1/1-31/15
2015-1287	02/13/2015 03/16/2015	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	LESLIE RAMSEY FDA NEWS	ORTHO BIOLOGICS LLC, MANATI, PR, AMGEN MANUFACTURING LTD, JUNCOS, PR, EDWARDS LIFESCIENCES TECHNOLOGY SARL, ANASCO, PR - 483S 1/1-31/15
2015-1288	02/13/2015 03/16/2015	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	LESLIE RAMSEY FDA NEWS	COMFORT ACRYLICS INC, CAMAS, WA, OR SPECIFIC INC, VANCOUVER, WA, VENTRIPOINT INC, BELLEVUE, WA, ETC - 483S 1/1-31/15
2015-1289	02/13/2015 03/16/2015	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	LESLIE RAMSEY FDA NEWS	SMALL WORLD TRADING COMPANY INC, SAN RAFAEL, CA, BENTEC MEDICAL INC, WOODLAND, CA - 483S 1/1-31/15
2015-1290	02/13/2015 03/16/2015	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	LESLIE RAMSEY FDA NEWS	ABBEY COLOR INC, PHILADELPHIA, PA, PHARMACEUTICAL MANUFACTURING RESEARCH SERVICES INC (PMRS), HORSHAM, PA - 483S 1/1-31/15
2015-1291	02/13/2015 03/16/2015	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	LESLIE RAMSEY FDA NEWS	FISHER WALLACE LABS, NEW YORK, NY, SCIEGEN PHARMACEUTICALS INC, HAUPPAUGE, NY, TIME-CAP LABORATORIES INC, FARMINGDALE, NY, ETC - 4383S 1/1-31/15
2015-1292	02/13/2015 03/16/2015	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	LESLIE RAMSEY FDA NEWS	BARD PERIPHERAL VASCULAR INC, TEMPE, AZ, PHARMACEUTICA NORTH AMERICA, GLENDALE, CA, PYRAMID LABORATORIES INC, COSTA MESA, CA, ETC - 483S 1/1-31/15
2015-1293	02/13/2015 03/16/2015	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	LESLIE RAMSEY FDA NEWS	TARMAC PRODUCTS INC, MIAMI GARDENS, FL , SMITH & NEPHEW INC, SAINT PETERSBURG, FL, SOFT COMPUTER CONSULTANTS INC, CLEARWATER, FL, ETC - 483S 1/1-31/15
2015-1294	02/13/2015 03/16/2015	FDA/OFVM/CFSAN/OCD/EOS/	Scott Burya Akzo Nobel Coatings Inc	FCN 256
2015-1295	02/13/2015 03/16/2015	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	ANTHONY M CARR GALIHDER DEROBERETIS WAXMAN ATTY	STANDER INC (STANDER, STANDERS, STANDERS INC) - BED RAILS OR MOBILITY AIDS CMLPNTS, RECALLS, INVESTIGATION, ETC

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2015-1296	02/13/2015 03/16/2015	FDA/OC/OES/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Misha Angrist Misha Angrist, PhD	FABRAZYME SHORTAGE - INTERNAL DELIBERATIONS, CORR
2015-1297	02/13/2015 03/16/2015	FDA/OC/OES/DDM/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Misha Angrist Misha Angrist, PhD	REPLAGAL - BRIEFING MATERIALS, CORR
2015-1298	02/13/2015 03/16/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	NDA 21-098/S022, NDA 21-676/S012, NDA 22-532/S004 ETC
2015-1299	02/13/2015 03/16/2015	FDA/OMPT/CDRH/OCER/DFOI/	J. Alan Fuehrer Pyrotecnico FX	21 CFR 1040.11(c) VARIANCES - LIST OF NAMES, ADDRESSES, TERMINATIONS
2015-1300	02/13/2015 03/16/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORASW-FO/KAN- DO/KAN-CB/	Jennifer L Counts PROCTER & GAMBLE	SAMPLE 888891
2015-1301	02/13/2015 03/16/2015	FDA/OMPT/CDRH/OCER/DFOI/	KIM FONDA CORDIS CORPORATION	K081996, K102519, K112522, ETC
2015-1302	02/13/2015 03/16/2015	FDA/OMPT/CDRH/OCER/DFOI/	Phyllis A. Clark Phyllis A. Clark	VACUUM ASSISTED DELIVERY - AERS
2015-1303	02/13/2015 03/16/2015	FDA/OFVM/CFSAN/OCD/EOS/	Scott Burya Akzo Nobel Coatings Inc	FCN 1353
2015-1304	02/13/2015 03/16/2015	FDA/OMPT/CDRH/OCER/DFOI/	Larissa DAndrea RESMED CORP	K131982
2015-1305	02/13/2015 03/16/2015	FDA/OMPT/CDRH/OCER/DFOI/	Larissa DAndrea RESMED CORP	K130077

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2015-1306	02/13/2015 03/16/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ADITYA KHEMKA AMBIT CAPITAL	IPCA LABS - EIR 10/01/2014 - 02/13/2015
2015-1307	02/13/2015 03/16/2015	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	Rona Murphy ULTRADENT PRODUCTS INC	ULTRADENT PRODUCTS INC, SOUTH JORDAN, UT - EIR 10/01/2014 - 02/12/2015
2015-1308	02/13/2015 03/16/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Robert Bexton Aristotle Capital Management	HOSPIRA, INC, INDIA - 483 01/01/2015 - 02/12/2015
2015-1309	02/13/2015 03/16/2015	FDA/OC/OES/DDM/	Lisa Thompson LeClairRyan, PC	DKT FDA-2013-P-0219
2015-1310	02/13/2015 03/16/2015	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OC/OES/DFOI/ OC/ORA/ OC/ORA/	RENE MARSH CNN	All documents related to the loss of A2LA accreditation on September 19, 2014 of FDAs Northeast Regional lab in Jamaica, New York.
2015-1311	02/13/2015 03/16/2015	FDA/OMPT/CDRH/OCER/DFOI/	Martin Espinosa Beaumont Health System	K961837
2015-1312	02/13/2015 03/16/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sony Chandi Shrestha London Metropolitan University	Sitagliptin, Sitagliptin+Metformin - AERS
2015-1313	02/13/2015 03/16/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Takahiro Haruyama Globizz Corp.	K033448
2015-1314	02/13/2015 03/16/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jennifer Newberger Hyman, Phelps & McNamara P.C.	PRAXAIR - CORR RE BIOEQUIVALENCE REQUIREMENTS FOR GENERIC INHALED NITRIC OXIDE
2015-1315	02/13/2015 03/16/2015	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/ORO/DIOP/	DONALD N BLUE ZETETIC	SHIPMENTS REGULATED BY THE US FDA 2/1-15/15
2015-1316	02/13/2015	FDA/OC/OES/	SHELDON T BRADSHAW	MENTHOL CIGARETTE STUDIES

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	03/16/2015	FDA/OMPT/CTP/OD/	HUNTON & WILLIAMS LLP	
2015-1317	02/17/2015 03/17/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Darlene O'Banion Revance Therapeutics	BLA 103000
2015-1318	02/17/2015 03/17/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sara Green ARIAD Pharmaceuticals, Inc	NDA 021588 S 042 - SBA
2015-1319	02/17/2015 03/17/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Peter R. Breggin, MD Center for the Study of Empathic Therapy	XANAX - SAFETY REVIEW, EVALUATION 3/24/89
2015-1320	02/17/2015 03/17/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Peter R. Breggin, MD Center for the Study of Empathic Therapy	ALPRAZOLAM, TRIAZOLOBENZODIAZEPINES - TWO PAPERS
2015-1321	02/17/2015 03/17/2015	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Shengyang Wu Shengyang WU	STEPHEN W LASTIG - WARNING LETTER RECS 01/01/2000 - 02/25/2005
2015-1322	02/17/2015 03/17/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Peter R. Breggin, MD Center for the Study of Empathic Therapy	ALPRAZOLAM - AERS
2015-1323	02/17/2015 03/17/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jaya Ayyagari Dr. Reddy's Laboratories Inc.	ANDA 074612
2015-1324	02/17/2015 03/17/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Daniel Kolitz N/A	METHYPATCH - REVIEWS, LETTERS ETC RE REJECTED NDA
2015-1325	02/17/2015 03/17/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mark Pohl Pharmaceutical Patent Attorneys,	Alembic Pharmaceuticals, Ltd., MacLeods Pharmaceuticals Ltd. - name and address of US Agent ;

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LLC	
2015-1326	02/17/2015 03/17/2015	FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDRH/OCER/DFOI/	Chastity Rodriguez Rodriguez, Chastity	AL CHI MI A SRL, PONTE S NICOLO, ITALY - 483S, WARNING LTRS LAST 3 YRS
2015-1327	02/17/2015 03/17/2015	FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/	Jennifer Jines YOUNG DENTAL MANUFACTURING	MEDICAL PRODUCTS LABORATORIES, INC. - WARNING LETTER DOCUMENTATION
2015-1328	02/17/2015 03/17/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sara Green ARIAD Pharmaceuticals, Inc	NDA 022068 S 020
2015-1329	02/17/2015 03/17/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dennis W. Raisch UNIVERSITY OF NEW MEXICO	Voriconazole - FAERS
2015-1330	02/17/2015 03/17/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dennis W. Raisch UNIVERSITY OF NEW MEXICO	FLUOROSIS - AERS
2015-1331	02/17/2015 03/17/2015	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	Scott Fawcett Carroll Quality Consult, Inc.	LITTLE TEA CUP CORP, SUNRISE, FL - EIR 12/03/2013 - 12/19/2013
2015-1332	02/17/2015 03/17/2015	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	Kyle Bailey Steri-Pharma. LLC	STERI-PHARMA, SYRACUSE, NY - EIR 10/06/2014 - 10/10/2014
2015-1333	02/17/2015 03/17/2015	FDA/OMPT/CDRH/OCER/DFOI/	Elaine Larkin Philips Rspironics	K133057
2015-1334	02/17/2015 03/17/2015	FDA/OMPT/CDRH/OCER/DFOI/	Elaine Larkin PHILIPS RESPIRONICS	K121891
2015-1335	02/17/2015 03/17/2015	OC/ORA/OCI/ OC/ORA/OCI/	Strategic Research LLC / Thomas Dubocq, manager Strategic Research LLC Thomas Dubocq, manager	MITCHELL GHEN, INSTITUTE OF CELLULAR MEDICINE - INVESTIGATION RECS 01/01/2000 - 01/01/2015
2015-1336	02/17/2015	FDA/OMPT/CDRH/OCER/DFOI/	Alan Neil	K833549, K923378

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	03/17/2015		ASN Associates, Inc	
2015-1337	02/17/2015 03/17/2015	OC/ORO/ORM/ OC/ORO/ORM/	David Mangione Govzilla, Inc.	LIST OF INSPECTIONS 03/15/2014 - 02/15/2015
2015-1338	02/18/2015 03/18/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Amy N. Plewke Deters Lawfirm	PUREGEN APPROVAL 2013
2015-1339	02/18/2015 03/18/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Amy N. Plewke Deters Lawfirm	PUREGEN APPROVAL 2012
2015-1340	02/18/2015 03/18/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jane Talkington OKLAHOMA STATE UNIVERSITY	PURTOX - CLINICAL TRIAL PHASE 3 FINDINGS, RESULTS
2015-1341	02/18/2015 03/18/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Peter R. Breggin, MD Peter R. Breggin, MD	SERTRALINE - AERS
2015-1342	02/18/2015 03/18/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michele Sinoway LACHMAN CONSULTANT SERVICES, INC.	NDA 000552
2015-1343	02/18/2015 03/18/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michele Sinoway LACHMAN CONSULTANT SERVICES, INC.	NDA 013132
2015-1344	02/18/2015 03/18/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michele Sinoway LACHMAN CONSULTANT SERVICES, INC.	NDA 014694
2015-1345	02/18/2015 03/18/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michele Sinoway LACHMAN CONSULTANT SERVICES, INC.	NDA 012674
2015-1346	02/18/2015 03/18/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michele Sinoway LACHMAN CONSULTANT	NDA 012675

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SERVICES, INC.	
2015-1347	02/18/2015 03/18/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michele Sinoway LACHMAN CONSULTANT SERVICES, INC.	NDA 020430
2015-1348	02/18/2015 03/18/2015	FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Pamela Anderson NOVATION LLC	ATRIUM, MAQUET - 483 01/01/2010 - 02/16/2015
2015-1349	02/18/2015 03/18/2015	FDA/OGROP/ORAPA-FO/SAN- DO/SAN-CB/	Jacob Beckel, CEO of AnazaoHealth Corporation AnazaoHealth Corporation	ANAZAOHEALTH CORPORATION, LAS VEGAS, NV - EIR 01/20/2015 - 01/30/2015
2015-1350	02/18/2015 03/18/2015	FDA/OFVM/CFSAN/OCD/EOS/	James H. Botkin BOTKINCHEMIE	FCN 519
2015-1351	02/18/2015 03/18/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Smith BioTex, Inc.	K120816
2015-1352	02/18/2015 03/18/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Smith BioTex, Inc.	K103008
2015-1353	02/18/2015 03/18/2015	FDA/OGROP/ORANE-FO/NYK- DO/NYK-DCB/	Michael Kolb Mainetti, Mainetti & O'Connor, PC	BEECH-NUT NUTRITION COMPANY, TOWN OF FLORIDA, NY - INVESTIGATION RECS 01/01/2014 - 02/17/2015
2015-1354	02/18/2015 03/18/2015	OC/ORA/ OC/ORA/ FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/	Deborah Hines - Hines Nut Company	HINES NUT COMPANY SALMONELLA TESTING OF WALNUTS 02/01/2015 - 02/17/2015
2015-1355	02/18/2015 03/18/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michele Sinoway LACHMAN CONSULTANT SERVICES, INC.	NDA 013304
2015-1356	02/18/2015 03/18/2015	FDA/OFVM/CFSAN/OCD/EOS/	Aprahamian Apravo	AMERICAN HYALURONIC ACID MANUFACTURERS, SUPPLIERS 02/17/2014 - 02/17/2015
2015-1357	02/18/2015 03/18/2015	FDA/OFVM/CFSAN/OCD/EOS/	Mark McAndrew TAFT STETTINIUS & HOLLISTER	GREEN VIBRANCE, VIBRANT CLEANSE, VIBRANT HEALTH ETC - ADVERSE EVENTS

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2015-1358	02/18/2015 03/18/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Smith BioTex, Inc.	K092666
2015-1359	02/18/2015 03/18/2015	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Wendy Lockwood Banka Wendy Lockwood Banka	ATTACHMENTS TO EMAIL SENT FROM STATE OF MICHIGAN TO FDA DETROIT DISTRICT 08/01/2014 - 02/17/2015
2015-1360	02/18/2015 03/18/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-8690
2015-1361	02/18/2015 03/18/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-9978
2015-1362	02/18/2015 03/18/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-10005
2015-1363	02/18/2015 03/18/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-389
2015-1364	02/18/2015 03/18/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Morgan Rettig LATHAM & WATKINS LLP	EXPAREL, BUPIVACAINE - AERS
2015-1365	02/18/2015 03/18/2015	FDA/OFVM/CFSAN/OCD/EOS/	Gaurav Attri Kline & company Inc.	FCN 732
2015-1366	02/18/2015 03/18/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 205122
2015-1367	02/18/2015 03/18/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Morgan Rettig LATHAM & WATKINS LLP	EXPAREL - AERS
2015-1368	02/18/2015 03/18/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sandy Suh Exeltis	NDA 020038, NDA 019897
2015-1369	02/18/2015 03/18/2015	FDA/OMPT/CDRH/OCER/DFOI/	Kathryn A Jayne, Director RAQA OxySure Systems, Inc.	K052396
2015-1370	02/18/2015	FDA/OMPT/CDER/GRP/DIDP/	Darcey Pipinich	AZITHROMYCIN - AERS

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	03/18/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CROWLEY FLECK, PLLP	
2015-1371	02/18/2015 03/18/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Morgan Rettig LATHAM & WATKINS LLP	EXPAREL - WRITTEN SUBMISSIONS TO FDA OFFICE OF PRESCRIPTION DRUG PROMOTION 10/28/2011 - 02/17/2015
2015-1372	02/18/2015 03/18/2015	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	Jacob Beckel, CEO of AnazaoHealth Corporation AnazaoHealth Corporation	ANAZAOHEALTH CORPORATION, TAMPA, FL - EIR 02/19/2013 - 02/22/2013
2015-1373	02/18/2015 03/18/2015	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	David Woods Panoramic Corporation	PANORAMIC CORPORATION, FOR WAYNE, IN - 483 01/01/2009 - 12/31/2009
2015-1374	02/18/2015 03/18/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FDA Approval Letter of ANDA 078970 (Lupin) Chirag Shah	ANDA 078970
2015-1375	02/18/2015 03/18/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tushar Manudhane Indianivesh securities	WOCKHARDT LTD, CHIKAHLTHANA - 483 01/01/2015 - 02/18/2015
2015-1376	02/18/2015 03/18/2015	FDA/OMPT/CDRH/OCER/DFOI/	Edward Kobus Invado Pharmaceuticals	K093642
2015-1377	02/18/2015 03/18/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Anubhav Aggarwal CREDIT SUISSE	LUPIN, INDIA - 483 01/12/2015 - 01/23/2015
2015-1378	02/18/2015 03/18/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Elizabeth Bonanno Elizabeth Bonanno	PROZAC - APPROVAL RECS
2015-1379	02/18/2015 03/18/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Karen Marshall Tarsa Therapeutica	SGS CANADA, INC - EIR 06/19/2014 - 06/20/2014

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		FDA/OMPT/CDER/ORP/DIDP/		
2015-1380	02/18/2015 03/18/2015	FDA/OMPT/CDRH/OCER/DFOI/	Susan C. Kelly DTWard PC	K051007
2015-1381	02/18/2015 03/18/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KATABI PhD., MAHA	XTANDI (ENZALUTAMIDE) - AER
2015-1382	02/18/2015 03/18/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN D'ANGELO PRAGMA	PRAGMA PHARMACEUTICALS -DESYREL (TRAZODONE HYDROCHLORIDE) NDA 18-207
2015-1383	02/18/2015 03/18/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PAMELA SHEPPARD TARO PHARMACEUTICALS USA INC	ANCHEN PHARMS - CLONIDINE HYDROCHLORIDE SBA, MED RVW, CHEM RVW, LBLG
2015-1384	02/18/2015 03/18/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PAMELA SHEPPARD TARO PHARMACEUTICALS USA INC	ANCHEN PHARMS - CLONIDINE HYDROCHLORIDE ANDA 02-983 SBA, MEDICAL RVW, CHEMISTRY RVW, LBLG
2015-1385	02/18/2015 03/18/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WILLIAM McINTYRE, PhD. LUPIN PHARMACEUTICALS INC	ZETIA (EZITIMIBE) NDA 21-445 RX & OTC DRUG PRODUCT PATENT & EXCLUSIVITY LIST MONTHLY SUPPLEMENTS 5/06 TO 10/06
2015-1386	02/18/2015 03/18/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WILLIAM McINTYRE, Ph.D. LUPIN PHARMACEUTICALS INC	KERYX BIOPHARMS - AURYXIA (FERRIC CITRATE) NDA 205-874 SBA, RWV
2015-1387	02/18/2015 03/18/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID B. DeSIVER ROGAK AND GIBBONS LLP	FDA DRUG BULLETIN APR 1982 VOL 12 NO 1 - (CERTIFIED)
2015-1388	02/18/2015 03/18/2015	FDA/OFVM/CFSAN/OCD/EOS/	NATIONAL CORPORATE	PREMARKET BIOTECHNOLOGY NOTIFICATION FOR MON 87411 CORN W/DOUBLE STRANDED RNA

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			RESEARCH	
2015-1389	02/18/2015 03/18/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	McKENZIE CATO Hyman, Phelps & McNamara, P.C.	QUIMICA FARMACEUTICA BAYER SA, LA FERGUERA, AUSTURIAS, SPAIN - 483 6/14; SHANDONG XINHUA PHARMACEUTICAL CO LTD, ZIBO, CHINA - 483 4/14
2015-1390	02/18/2015 03/18/2015	OC/CVM/OCD/	FATIMA ASLAM Keller and Heckman, LLP	MANUAL OF THE ASSOCIATION OF AMERICAN FEED CONTROL OFFICIALS -INGREDIENT DEFINITION 36.15 - DOCS
2015-1391	02/18/2015 03/18/2015	FDA/OC/OES/DFOI/	MARGARET B. KWOKA UNIVERSITY OF DENVER STURM COLLEGE OF LAW	LIST OF REQUESTERS WHO APPEALED DENIALS 2013
2015-1392	02/18/2015 03/18/2015	FDA/OC/OES/DFOI/	MARGARET B. KWOKA UNIVERSITY OF DENVER STURM COLLEGE OF LAW	RESULT OF ALL FOIA REQUESTS 2013
2015-1393	02/18/2015 03/18/2015	FDA/OFVM/CFSAN/OCD/EOS/	XIN TAO Hogan Lovells, ILP	ALCRESTA INC - FCN 001498 TOXICOLOGY
2015-1394	02/19/2015 03/19/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Elaine Chang GLANCY BINKOW & GOLDBERG LLP	SUBSYS - AERS
2015-1395	02/19/2015 03/19/2015	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Matthew Bilbo Grato Holdings, Inc.	GRATO HOLDINGS, WOODBINE, IA - EIR 03/01/2011 - 08/31/2013
2015-1396	02/19/2015 03/19/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Casey Sadler GLANCY BINKOW & GOLDBERG LLP	SAREPTA - GUIDANCE, COMMUNICATIONS RE TIMELINE OF NDA ETC 11/01/2013 - 02/18/2015
2015-1397	02/19/2015 03/19/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	idelalisib - ICSR Ken Tong	ZYDELIG - AERS
2015-1398	02/19/2015 03/19/2015	OC/ORAS/ OC/ORAS/	American Pharmaceutical Ingredients, LLC American Pharmaceutical Ingredients, LLC	MEDISCA, PLATTSBURGH, NY; LETCO MEDICAL, DECATUR, AL; PROFESSIONAL COMPOUNDING CENTERS OF AMERICA, HOUSTON, TX - EIR, 483 02/18/2014 - 02/18/2015
2015-1399	02/19/2015	FDA/OFVM/CFSAN/OCD/EOS/	Ben Wieder	5 HOUR ENERGY - PRODUCT COMPLAINTS, ADVERSE

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	03/19/2015		THE CENTER FOR PUBLIC INTEGRITY	HEALTH EVENTS 10/24/2012 - 02/18/2015
2015-1400	02/19/2015 03/19/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ibrutinib - ICSR Ken Tong	IBRUTINIB - CASE REPORTS
2015-1401	02/19/2015 03/19/2015	FDA/OMPT/CDRH/OCER/DFOI/	Kimberly Bulls TECHLAB, Inc.	K032222
2015-1402	02/19/2015 03/19/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Carol Griffin The Clorox Company	EUROFINS LANCASTER LABORATORIES - QAP 10/01/2012 - 02/18/2015
2015-1403	02/19/2015 03/19/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Andrea Larson UNIVERSITY OF WISCONSIN-MADISON	PEDIATRIC APPROVAL RECS
2015-1404	02/19/2015 03/19/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	david gortler MG Pharmacy	LOVALO - MEDICAL REVIEW
2015-1405	02/19/2015 03/19/2015	OC/CVM/OCD/	LUCAS A WESTBY NELSON MULLINS RILEY & SCARBOROUGH LLP	MERIAL LTD - NEXGARD (AFOXOLANER) CHEWABLE TABS FOR DOGS NADA 141-406 AERS, LBLG, INVESTIGATIONS, ETC
2015-1406	02/19/2015 03/19/2015	FDA/OFVM/CFSAN/OCD/EOS/	TSE-LING FONG MD Keck School of Medicine, University of Southern California	EXTREME PRODUCTS GROUP - TRI-METHYL XTREME CAERS
2015-1407	02/19/2015 03/19/2015	FDA/OMPT/CDRH/OCER/DFOI/	HORTENSE ALLISON ETHICON ENDO SURGERY INC	STRYKER SUSTAINABILITY SOLUTIONS - REPROCESSED HARMONIC ACB SHEARS WITHOUT ADAPTIVE TECHNOLOGY K133672
2015-1408	02/19/2015 03/19/2015	FDA/OFVM/CFSAN/OCD/EOS/	MARISA C MALECK GIBSON DUNN & CRUTCHER LLP	BARBARA O SCHNEEMAN LTR 4/14/06 (CERTIFIED)
2015-1409	02/19/2015 03/19/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHRISTOPHER L SCHEIDERS WAGSTAFF & CARTMELL LLP	CLOMID AND CLOMIPHENE CITRATE NDA 16-131 - LBLG 2/1/67 TO PRESENT

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2015-1410	02/19/2015 03/19/2015	FDA/OMPT/CDRH/OCER/DFOI/	DR ALVARO BETANCUR BOCA DENTAL SUPPLY LLC	K091292
2015-1411	02/19/2015 03/19/2015	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CAROLINE STOUT ECOR1 CAPITAL LLC	GILENYA (FINGOLIMOD) - AERS 1/1/13 TO PRESENT
2015-1412	02/19/2015 03/19/2015	FDA/OC/OES/DFOI/	CAROLINE STOUT ECOR1 CAPITAL LLC	IMBRUVICA (IBRUTINIB) - FOI REQUESTS 1/1/10 TO PRESENT
2015-1413	02/19/2015 03/19/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KATHLEEN PORUPSKI PORUPSKI, KATHLEEN	SUN PHARMACEUTICALS, HALOL - 483S 9/14 TO PRESENT
2015-1414	02/19/2015 03/19/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	GISELLE CAMPANARO bioCSL	VAERS 554258-1
2015-1415	02/20/2015 03/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	APURVA N GOKHALE NxStage Medical, Inc.	TABLO CONSOLE - K140866
2015-1416	02/20/2015 03/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	APURAVA N GOKHALE NxStage Medical, Inc.	TABLO CARTRIDGE- K140841
2015-1417	02/20/2015 03/20/2015	FDA/OC/OL/	BRODY MULLINS WALL STREET JOURNAL	SEN PRAND PAUL - CORR 1/11 TO PRESENT
2015-1418	02/20/2015 04/15/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	MARTIN RUBENSTEIN HOWARD M FILE ESQ PC	SANOFE - FLUZONE VAERS (CERTIFIED)
2015-1419	02/20/2015 03/20/2015	FDA/OFVM/CFSAN/OCD/EOS/	BOBBY SCHOCHET OLSSON FRANK WEEDA TERMAN BODE MATZ	DARK CHOCOLATE PRODS CONTAINING MILK - FDA CONSUMER UPDATE STUDY 2/15
2015-1420	02/20/2015 03/20/2015	FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/	BRUCE STURGEON ETEX CORP	ETEX CORP - EIRS 9/29/10, 2/15/13, 8/19/14
2015-1421	02/20/2015 03/20/2015	FDA/OGROP/ORANE-FO/NYK- DO/NYK-DCB/	LORI REARDON MARSHALL DENNEHEY WARNIER ET AL	MONGIELLO ITALIAN CHEESE SPECIALTIES INC - WARNING LTR NYK-2014-17 RESP, INSPS 7/22-24,26/13, 8/13/13, ANALYSIS, ETC
2015-1422	02/20/2015	FDA/OMPT/CDER/ORP/DIDP/	A LUKE SMITH	ANDA 201-173 - APRVL LTR

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	03/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	RADICE LAW FIRM	
2015-1423	02/20/2015 03/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MCKENZIE CATO Hyman Phelps and McNamara PC	VELOXIS PHARMACEUTICALS INC - ENVARUSUS XR (TACROLIMUS ER TABS) NDA 206-406; ASTELLAS PHARMA US INC - ASTAGRAF XL (TACROLIMUS EX CAPSULES) NDA 204-096 APRVL
2015-1424	02/20/2015 03/20/2015	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CAROLINE STOUT ECOR1 CAPITAL LLC	LINZESS (ILINCLOTIDE) - AERS 1/13 TO PRESENT
2015-1425	02/20/2015 03/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN S BAKER IV LIGHTFOOT FRANKLIN & WHITE LLC	TESTOPEL - FOLLOW UP RPTS
2015-1426	02/20/2015 03/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHRISOPHER L SCHNIEDERS WAGSTAFF & CARTMELL LLP	CLOMID, CLOMIPHENE CITRATE - NDA 16-131 LBLG 1/67 TO PRESENT
2015-1427	02/20/2015 03/20/2015	FDA/OC/OES/DFOI/	Jean Xiao Graduate Student, Jean Xiao	INSPECTION DATA
2015-1428	02/20/2015 03/20/2015	FDA/OC/OES/DFOI/	Jean Xiao Graduate Student, Jean Xiao	INSPECTION, APPLICATION, APPROVAL DATA
2015-1429	02/20/2015 03/20/2015	FDA/OFVM/CFSAN/OCD/EOS/	Mark Prinz Registrar Corp	FOOD SHIPMENT CONSIGNEES
2015-1430	02/20/2015 03/20/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PennState_PostMarketStudy PENNSYLVANIA STATE UNIVERSITY	DATASET FOR POSTMARKET REQUIREMENTS NDA/BLA 01/01/1992 - 02/01/2015
2015-1431	02/20/2015	FDA/OMPT/CDER/GRP/DIDP/	Laura A. Bischoff	DR SURESH GUPTA, DAYTON, OH - NIDPOE, CORR 01/01/2008 - 02/19/2015

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	03/20/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAYTON DAILY NEWS	
2015-1432	02/20/2015 03/20/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Charlie Fair UGA College of Pharmacy	DALBAVANCIN, TEDIZOLID, ORITAVANCIN - MEDWATCH REPORTS 05/03/2014 - 02/19/2015
2015-1433	02/20/2015 03/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	Mark Pohl Pharmaceutical Patent Attorneys, LLC	SILVER NITRATE CAUSTIC STICKS - AERS
2015-1434	02/20/2015 03/20/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	William Kethman CONSUMER	K121609
2015-1435	02/20/2015 03/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	Steven C Zekowski, MD none	CPT1400353
2015-1436	02/20/2015 03/20/2015	FDA/OC/OES/DFOI/	Carla Scarmazzi KING & SPALDING	FOIA REQUESTS FROM FORSTA AP-FONDEN, DANSKE INVEST MANAGEMENT A/S; BLACKROCK ETC 01/01/2005 - 06/30/2013
2015-1437	02/20/2015 03/20/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michelle Boudin WCNC-TV	FLUOROQUINOLONE DRUGS - AERS
2015-1438	02/20/2015 03/20/2015	FDA/OC/OES/DFOI/	Carla Scarmazzi KING & SPALDING	ST JUDE MEDICAL - FOIA REQUESTS FOR 483
2015-1439	02/20/2015 03/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	William Kethman CONSUMER	K070375
2015-1440	02/20/2015 03/20/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Assaf Gur ClearCut Medical Ltd.	K083510
2015-1441	02/20/2015 03/20/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Neetu Dhaliwal VISIUM ASSET MANAGEMENT LLC	ANIKA THERAPEUTICS CINGAL TRIAL DATA
2015-1442	02/20/2015 03/20/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Pembrolizumab - ICSR Ken Tong	KEYTRUDA - AERS

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2015-1443	02/20/2015 03/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	Ken Burns Telemed Solutions	K110693 PERFORMANCE TESTING DATA
2015-1444	02/20/2015 03/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	Ken Burns Telemed Solutions	K132437 PERFORMANCE TESTING DATA
2015-1445	02/20/2015 03/20/2015	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	Amerx Health Care Corp. Arrastia Capote Partners	KOVA LABORATORIES - COMPLAINTS
2015-1446	02/20/2015 03/20/2015	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	Amerx Health Care Corp. Arrastia Capote Partners	AMERX HEALTH CARE CORP - CONSUMER COMPLAINTS 01/01/2013 - 01/01/2014
2015-1447	02/20/2015 03/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	Amerx Health Care Corp. Arrastia Capote Partners	K971918
2015-1448	02/20/2015 03/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	Bradley Lampe NSF International	FCN 823, 1239
2015-1449	02/20/2015 03/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	Ken Burns Telemed Solutions	K003940 PEROFRMANCE TESTING DATA
2015-1450	02/20/2015 03/20/2015	FDA/OC/OES/DFOI/	Carla Scarmazzi KING & SPALDING	FOIA LOG ST JUDE MEDICAL
2015-1451	02/20/2015 03/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	INDIVIDUAL RECS
2015-1452	02/20/2015 03/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Molly Rapp Fresenius Kabi USA LLC	NDA 050450 SBA
2015-1453	02/20/2015 03/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Molly Rapp Fresenius Kabi USA LLC	ANDA 064144 SBA
2015-1454	02/20/2015 03/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Molly Rapp Fresenius Kabi USA LLC	NDA 020068 SBA

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		FDA/OMPT/CDER/GRP/DIDP/		
2015-1455	02/20/2015 03/20/2015	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	TERUMO CARDIOVASCULAR SYSTEMS CORPORATION, ANN ARBOR, MI - EIR, 483, RESPONSE 01/01/2014 - 02/28/2014
2015-1456	02/20/2015 03/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dr Girish Bakhr HSBC Securities and Capital Markets	LUPIN, GOA, INDIA - 483 01/05/2015 - 01/30/2015
2015-1457	02/20/2015 03/20/2015	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	HILL-ROM, INC, BATESVILLE, IN - EIR, 483, RESPONSE 01/01/2014 - 01/31/2014
2015-1458	02/20/2015 03/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Emily Field Field, Emily P	MALLINKRODT, KUDCO - AERS CITED IN PRESS RELEASE
2015-1459	02/20/2015 03/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michele Sinoway LACHMAN CONSULTANT SERVICES, INC.	NDA 020430, NDA 012675, NDA 012674 ETC
2015-1460	02/23/2015 03/23/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Moumita Rawal G&W Laboratories Inc.	NDA 016199, NDA 017351 SBA
2015-1461	02/23/2015 03/23/2015	OC/ORACE/ OC/ORACE/	Carla Scarmazzi KING & SPALDING	RECS RE DATE AND TIME OF ST JUDE MEDICAL 483 POSTED
2015-1462	02/23/2015 03/23/2015	FDA/OC/OES/DFOI/	Alexandra Scranton Women's Voices for the Earth	YEARLY STATISTICS FOR ADVERSE EVENTS BY PRODUCT TYPE
2015-1463	02/23/2015 03/23/2015	FDA/OFVM/CFSAN/OCD/EOS/	Flavia de Almeida Flavia de Almeida	Wazzoodles ProSoft PUL fabric COMPLIANCE WITH FDA REGULATIONS
2015-1464	02/23/2015 03/23/2015	FDA/OFVM/CFSAN/OCD/EOS/	Jason Bagley truthinadvertising.org	PREVAGEN - AERS
2015-1465	02/23/2015 03/23/2015	FDA/OFVM/CFSAN/OCD/EOS/	Jason Bagley truthinadvertising.org	PREVAGEN - AERS
2015-1466	02/23/2015	FDA/OMPT/CBER/OCOD/DDOM/	Rachel Johnson	BK8200020

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	03/23/2015	ALFB/	FOI Services, Inc.	
2015-1467	02/23/2015 03/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	sharon begley REUTERS	FDA CORR WITH MANUFACTURERS OF DUODENOSCOPES 01/01/2009 - 02/20/2015
2015-1468	02/23/2015 03/23/2015	FDA/OFVM/CFSAN/OCD/EOS/	Anahad O'Connor NEW YORK TIMES	EMAIL BETWEEN DANIEL FABRICANT AND KENNETH SPAETH RE PURITY HEALTH FIRST 03/03/2013 - 07/31/2013
2015-1469	02/23/2015 03/23/2015	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Jason Bagley truthinadvertising.org	CORR BETWEEN FDA AND QUINCY BIOSCIENCE RE PREVAGEN
2015-1470	02/23/2015 03/23/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	ANDA 91422 BIOEQUIVALENCE REVIEWS
2015-1471	02/23/2015 03/23/2015	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	Paige Stradley MERCHANT & GOULD	2015-27 (CERTIFIED)
2015-1472	02/23/2015 03/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	David Mott Parkell, Inc.	K110661
2015-1473	02/23/2015 03/23/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/	Rachel Majerczak Nalco, An Ecolab Company	FAP8A4598 / PMN000018
2015-1474	02/23/2015 03/23/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 80472
2015-1475	02/23/2015 03/23/2015	FDA/OFVM/CFSAN/OCD/EOS/	Lewis Perdue Wine Industry Insight	STUDIES AND DATA RE SAFETY OF CORKS USED AS CLOSURES FOR FOOD AND BEVERAGES; CORR; OPINIONS ETC 01/01/2013 - 02/20/2014
2015-1476	02/23/2015 03/23/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 205613

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		FDA/OMPT/CDER/GRP/DIDP/		
2015-1477	02/23/2015 03/23/2015	FDA/OGROP/ORAC/CE-FO/PHI-DO/PHI-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	GORDON SCHNELL Constantine Cannon	MERCK, WEST POINT, PA - MUMPS VACCINE EFFICACY, MUMPS OUTBREAK RECS 2005 TO PRESENT; 483 8/6/01, ETC
2015-1478	02/23/2015 03/23/2015	FDA/OFVM/CFSAN/OCD/EOS/	VISAGINE VIJAYAKULASINGAM IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 181758
2015-1479	02/23/2015 03/23/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JAMES R JOHNSON Hogan Lovells, ILP	NYDRAZID NDA 08-392, NICONYL NDA 08-486, ISONIAZID NDA 08-499, ETC
2015-1480	02/23/2015 03/23/2015	OC/ORAC/ OC/ORAC/ FDA/OGROP/ORAC/SE-FO/FLA-DO/FLA-CB/	SEBASTIAN DE ANDRACA ALFA INTERNATIONAL SEAFOOD INC	ENTRY #RD8-0021189-1 - ANALYTICAL RECS
2015-1481	02/23/2015 03/23/2015	OC/ORAC/ OC/ORAC/ FDA/OGROP/ORAC/SE-FO/FLA-DO/FLA-CB/	SEBASTIAN DE ANDRACA ALFA INTERNATIONAL SEAFOOD INC	ENTRY #RD8-0021185-9 - ANALYTICAL RECS
2015-1482	02/23/2015 03/23/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	AUDREY ALIBRANTI EGAN ETHYPHARM USA CORP	AFINITOR (EVEROLIMUS) TABS 22-234 - SBA
2015-1483	02/23/2015 03/23/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KATHY JUNGEMAN JUNGEMAN, KATHY	BOTOX - AERS
2015-1484	02/24/2015 03/24/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	David L. Felts N/A	TEMAZEPAM AERS

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2015-1485	02/24/2015 03/24/2015	FDA/OMPT/CDRH/OCER/DFOI/	Dean Bruhn-Ding CVRx, Inc.	HDE HG130007
2015-1486	02/24/2015 03/24/2015	FDA/OO/OFBA/OAGS/	Scarlet Eakins RELI Group, Inc.	8A CONTRACTS FOR RELI GROUP DATA
2015-1487	02/24/2015 03/24/2015	FDA/OMPT/CDRH/OCER/DFOI/	Eileen Fick GE Healthcare	GE HEALTHCARE JAPAN - EIR 11/26/2012 - 11/26/2012
2015-1488	02/24/2015 03/24/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Alok Dalal CLSA India Pvt Ltd	LUPIN LTD, INDIA 01/01/2015 - 01/31/2015
2015-1489	02/24/2015 03/24/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joshua Cohen Amylyx Pharmaceuticals Inc	NONCLINICAL SAFETY OF BUPHENYL
2015-1490	02/24/2015 03/24/2015	FDA/OMPT/CDRH/OCER/DFOI/	John Urtz Stryker Orthobiologics	K113871
2015-1491	02/24/2015 03/24/2015	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Charlesworth Charlesworth Rae	CHILDREN'S NATIONAL MEDICAL CENTER - CORR, AUDIT 01/01/2009 - 02/23/2015
2015-1492	02/24/2015 03/24/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Vaibhav Dusad Morgan Stanley	LUPIN, INDIA - 483 01/01/2015 - 02/03/2015
2015-1493	02/24/2015 03/24/2015	FDA/OMPT/CDRH/OCER/DFOI/	Michael Weiss Carroll & Weiss LLP	DUODENOSCOPES - MDR, ENGINEERING ASSESSMENT REFERENCED

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2015-1494	02/24/2015 03/24/2015	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	Chris Letter Odom & Des Roches, LLP	WATSON/ACTAVIS, SALT LAKE CITY, UT - EIR, 483 01/01/2010 - 12/31/2012
2015-1495	02/24/2015 03/24/2015	OC/CVM/OCD/	Genna Reed Food & Water Watch	CVM RECS RE OXITEC APPROVAL 01/01/2009 - 02/23/2015
2015-1496	02/24/2015 03/24/2015	FDA/OMPT/CDRH/OCER/DFOI/	Mohit Bhat Kline & company Inc.	JABIL CIRCUIT AUSTRIA GMBH - EIR 01/01/2011 - 02/23/2015
2015-1497	02/24/2015 03/24/2015	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Jason Bagley truthinadvertising.org	CORR BETWEEN FDA AND QUINCY BIOSCIENCE RE PREVAGEN
2015-1498	02/24/2015 03/24/2015	FDA/OMPT/CDRH/OCER/DFOI/	Valerie Giambanco STRYKER ORTHOPAEDICS	K130167
2015-1499	02/24/2015 03/24/2015	FDA/OMPT/CDRH/OCER/DFOI/	Dean Bruhn-Ding CVRx, Inc.	IDE G060182
2015-1500	02/24/2015 03/24/2015	FDA/OMPT/CDRH/OCER/DFOI/	Dean Bruhn-Ding CVRx, Inc.	IDE G090001
2015-1501	02/24/2015 03/24/2015	FDA/OMPT/CDRH/OCER/DFOI/	Dean Bruhn-Ding CVRx, Inc.	IDE G120137
2015-1502	02/24/2015 03/24/2015	FDA/OMPT/CDRH/OCER/DFOI/	Dean Bruhn-Ding CVRx, Inc.	IDE G120010
2015-1503	02/24/2015 03/24/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Guri Stark CorTechs Labs Inc.	FREESURFER - RECS RE CLINICAL DRUG TRIALS
2015-1504	02/24/2015 03/24/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	TIZANDINE, ZANAFLEX, CIPRO - AERS
2015-1505	02/24/2015 03/24/2015	FDA/OMPT/CDRH/OCER/DFOI/	Kristi Ashton STRYKER INSTRUMENTS	KIVA - 510K
2015-1506	02/24/2015 03/24/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Olena Izhak University of Helsinki (FINLAND)	ANDA APPROVAL LETTERS

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2015-1507	02/24/2015 03/24/2015	FDA/OMPT/CDRH/OCER/DFOI/	Dean Bruhn-Ding CVRx, Inc.	IDE G140145
2015-1508	02/24/2015 03/24/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lalit Kumar Nomura Securities	LUPIN, INDIA - 483 01/01/2015 - 02/22/2015
2015-1509	02/24/2015 03/24/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ADITYA KHEMKA AMBIT CAPITAL	LUPIN LTD - 483 01/01/2015 - 02/23/2015; IPCA - STATUS UPDATE; SCHEDULED DATE OF INSPECTION IPCA RATLAM API
2015-1510	02/24/2015 03/24/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Chirag Talati Kotak Securities	LUPIN, INDIA - 483 01/01/2015 - 02/23/2015
2015-1511	02/24/2015 03/24/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ADITYA KHEMKA AMBIT CAPITAL	GDUFA ANNUAL REPORT
2015-1512	02/24/2015 03/24/2015	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	Day-Lee Foods, Inc Joseph Huertas	DAY-LEE FOODS, INC, SANTA FE SPRINGS, CA - REALL RECS, COMPLIANCE 12/01/2010 - 02/22/2015
2015-1513	02/24/2015 03/24/2015	FDA/OMPT/CDRH/OCER/DFOI/	Beth Luoma DuVal & Associates, PA	K942530, K131146
2015-1514	02/24/2015 03/24/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bharat Celly Research Delta	LUPIN, INDIA - 483 12/16/2014 - 01/23/2015
2015-1515	02/24/2015 03/24/2015	FDA/OMPT/CDRH/OCER/DFOI/	David Stark STANFORD UNIVERSITY	MAMMOGRAM DATA 01/01/2012 - 01/02/2014
2015-1516	02/24/2015 04/09/2015	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/ OC/ORAP/	Jonathan Singer Miles & Stockbridge, P.C.	GMP RELATED PRODUCT COMPLAINTS RE MONSTER ENERGY DRINKS FOR LAST TEN YEARS, INSPECTIONS, CITATIONS ETC

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		OC/ORR/		
2015-1517	02/24/2015 03/24/2015	FDA/OGROP/ORR/CE-FO/NWJ-DO/NWJ-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	SANOVI US, BRIDGEWATER, NJ - 483, EIR, RESPONSE 07/01/2014 - 07/31/2014;
2015-1518	02/24/2015 03/24/2015	FDA/OGROP/ORR/SE-FO/NOL-DO/NOL-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	PROVIDENCE HOSPITAL IRB, MOBILE, AL - 483, EIR, RESPONSE 05/01/2014 - 06/30/2014
2015-1519	02/24/2015 03/24/2015	FDA/OGROP/ORR/NE-FO/NWE-DO/NWE-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	BIOGEN IDEC, INC, CAMBRIDGE, MA - 483, EIR, RESPONSE 6/24/14-7/3/14
2015-1520	02/24/2015 03/24/2015	FDA/OGROP/ORR/SE-FO/SJN-DO/SJN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	PFIZER PHARMACEUTICALS, VEGA BAJA, PR - 483, EIR, RESPONSE 03/01/2014 - 03/31/2014
2015-1521	02/24/2015 03/24/2015	FDA/OGROP/ORR/PA-FO/SEA-DO/SEA-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	GILEAD SCIENCES, INC, SEATTLE, WA - 483, EIR, RESPONSE 01/01/2014 - 03/31/2014
2015-1522	02/24/2015 03/24/2015	FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	MEDTRONIC, INC, WEST DES MOINES, IA - 483, EIR, RESPONSE 02/01/2012 - 02/29/2012
2015-1523	02/24/2015 03/24/2015	FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	ALLERGAN, INC, IRVINE, CA - 483, EIR, RESPONSE 03/01/2014 - 03/31/2014
2015-1524	02/24/2015 03/24/2015	FDA/OGROP/ORR/CE-FO/CHI-DO/CHI-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	ABBOTT LABORATORIES, ABBOTT PARK, IL - 483, EIR, RESPONSE 08/01/2013 - 08/31/2013
2015-1525	02/24/2015 03/24/2015	FDA/OGROP/ORR/NE-FO/NYK-DO/NYK-DCB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	JOHN P BILEZIKIAN, MD, NEW YORK, NY - 483, EIR, RESPONSE 03/01/2014 - 04/30/2014
2015-1526	02/24/2015 03/24/2015	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	BAXTER HEALTHCARE CORPORATION, LARGO, FL - 483, EIR, RESPONSE 05/01/2014 - 05/31/2014
2015-1527	02/24/2015 03/24/2015	FDA/OGROP/ORR/CE-FO/DET-DO/DET-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	ZIMMER, INC, WARSAW, IN - 483, EIR, RESPONSE 02/01/2014 - 02/28/2014
2015-1528	02/24/2015 03/24/2015	FDA/OGROP/ORR/CE-FO/MIN-DO/MIN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	BOSTON SCIENTIFIC CRM CORP, SAINT PAUL, MN - 483, EIR, RESPONSE 08/01/2013 - 11/30/2013

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2015-1529	02/24/2015 03/24/2015	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	COVIDIENT LP, NORTH HAVEN, CT - 483, EIR, RESPONSE 01/01/2012 - 02/29/2012
2015-1530	02/24/2015 03/24/2015	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	VERICHEM LABORATORIES INC, PROVIDENCE, RI - 483, EIR, RESPONSE 10/01/2014 - 11/30/2014
2015-1531	02/24/2015 03/24/2015	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	MUSE, DEREK, MD - 483, EIR, RESPONSE 07/01/2014 - 07/31/2014
2015-1532	02/24/2015 03/24/2015	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	BEN VENUE LABORATORIES INC, BEDFORD, OH - 483, EIR, RESPONSE 06/01/2014 - 06/30/2014
2015-1533	02/24/2015 03/24/2015	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	GUSTAV R ELES, DO, PITTSBURGH, PA - 483, EIR, RESPONSE 02/01/2007 - 03/31/2007
2015-1534	02/24/2015 03/30/2015	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	THOMAS P DAVIS, MD - 483, EIR, DETROIT, MI - 11/01/2006 - 12/31/2006
2015-1535	02/24/2015 03/24/2015	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	WILSON T ASFORA, MD, SIOUX FALLS, SD - 483, EIR, RESPONSE 11/01/2007 - 12/31/2007
2015-1536	02/24/2015 03/24/2015	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	STAAR SURGICAL COMPANY, MONROVIA, CA - 483, EIR, RESPONSE 02/01/2007 - 03/31/2007
2015-1537	02/24/2015 03/24/2015	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	BRIDGES R MCINTYRE, MD, SHREVEPORT, LA - 483, EIR, RESPONSE 03/01/2007 - 03/31/2007
2015-1538	02/24/2015 03/24/2015	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	AKORN, INC, DECATUR, IL - EIR, 483, RESPONSE 04/01/2013 - 05/31/2013
2015-1539	02/24/2015 03/24/2015	FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 1/5-9/15
2015-1540	02/24/2015 03/24/2015	FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	foi daily log 1/12-16/15

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2015-1541	02/24/2015 03/24/2015	FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 1/19-23/15
2015-1542	02/24/2015 03/24/2015	FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 1/26-30/15
2015-1543	02/24/2015 03/24/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 1/12-17/15
2015-1544	02/24/2015 03/24/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 1/19-24/15
2015-1545	02/24/2015 03/24/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 1/26-31/15
2015-1546	02/24/2015 03/24/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 1/5-10/15
2015-1547	02/24/2015 03/24/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 1/5-9/15
2015-1548	02/24/2015 03/24/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 1/12-16/15
2015-1549	02/24/2015 03/24/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Hans Platteeuw Chamaeleo Pharma bvba	NDA 10-010 APPROVAL, LABELING DATA
2015-1550	02/24/2015 03/24/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 1/19-23/15
2015-1551	02/24/2015 03/24/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 1/26-30/15
2015-1552	02/24/2015 03/24/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	MELHSEN, JESPER, DENMARK - EIR, 483, RESPONSE 01/01/2014 - 07/31/2014
2015-1553	02/24/2015 03/24/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kirit Gogri Quant Capital	LUPIN LTD, INDIA - 483 01/01/2015 - 01/31/2015

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2015-1554	02/24/2015 03/24/2015	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 1/5-9/15
2015-1555	02/24/2015 03/24/2015	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/BLT- DO/BLT-CB/	Doe J	INDIVIDUAL RECS
2015-1556	02/24/2015 03/24/2015	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 1/1-16/15
2015-1557	02/24/2015 03/24/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Uday Shetty Drug Regulations	LUPIN, INDIA - 483 11/01/2014 - 02/24/2015
2015-1558	02/24/2015 03/24/2015	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 1/19-23/15
2015-1559	02/24/2015 03/24/2015	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 1/26-30/15
2015-1560	02/24/2015 03/24/2015	FDA/OGROP/ORO/SE-FO/ATL- DO/ATL-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	CAROLINA SURGICAL SOLUTIONS, LLC, FLORENCE, SC - EIR, 483, RESPONSE 05/01/2014 - 05/31/2014
2015-1561	02/24/2015 03/24/2015	FDA/OGROP/ORO/CE-FO/PHI- DO/PHI-CB/	Chalkley Walter THOMSON REUTERS (SCIENTIFIC) SAS	MERCK & CO, AMBLER, PA - EIR, 483, RESPONSE 09/01/2013 - 09/30/2013
2015-1562	02/24/2015 03/24/2015	FDA/OC/OES/DFOI/	LESLIE RAMSEY FDA NEWS	FOI DAILY LOG 1/5-9/15
2015-1563	02/24/2015 03/24/2015	FDA/OC/OES/DFOI/	LESLIE RAMSEY FDA NEWS	FOI DAILY LOG 1/12-16/15
2015-1564	02/24/2015 03/24/2015	FDA/OGROP/ORO/SW-FO/DAL- DO/DAL-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	SILIMED, INC, DALLAS, TX - EIR, 483, RESPONSE 01/01/2007 - 01/31/2007
2015-1565	02/24/2015 03/24/2015	FDA/OC/OES/DFOI/	LESLIE RAMSEY FDA NEWS	FOI DAILY LOG 1/9-23/15
2015-1566	02/24/2015	FDA/OC/OES/DFOI/	LESLIE RAMSEY	FOI DAILY LOG 1/26-30/15

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	03/24/2015		FDA NEWS	
2015-1567	02/24/2015 03/24/2015	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 1/5-9/15
2015-1568	02/24/2015 03/24/2015	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 1/12-16/15
2015-1569	02/24/2015 03/24/2015	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 1/19-23/15
2015-1570	02/24/2015 03/24/2015	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 1/26-30/15
2015-1571	02/24/2015 03/24/2015	FDA/OC/OES/DFOI/	GLADYS B TONKIN Center for Regulatory Services,Inc.	FOI DAILY LOG 1/5-9/15
2015-1572	02/24/2015 03/24/2015	FDA/OC/OES/DFOI/	GLADYS B TONKIN Center for Regulatory Services,Inc.	FOI DAILY LOG 1/12-16/15
2015-1573	02/24/2015 03/24/2015	FDA/OC/OES/DFOI/	GLADYS B TONKIN Center for Regulatory Services, Inc.	FOI DAILY LOG 1/19-23/15
2015-1574	02/24/2015 03/24/2015	FDA/OC/OES/DFOI/	GLADYS B TONKIN Center for Regulatory Services, Inc.	FOI DAILY LOG 1/26-30/15
2015-1575	02/25/2015 03/25/2015	FDA/OMPT/CDRH/OCER/DFOI/	Anissa Lloyd ARJOHUNTLEIGH	K881917
2015-1576	02/25/2015 03/25/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	KRATOM - AERS
2015-1577	02/25/2015 03/25/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	ZEMBRIN - AERS
2015-1578	02/25/2015	FDA/OMPT/CDRH/OCER/DFOI/	Kirk Pope	PMA 030042

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	03/25/2015		POPE MCGLAMRY ET AL ATTYS	
2015-1579	02/25/2015 03/25/2015	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OC/OES/DFOI/	Wendy Lockwood Banka Wendy Banka	L PERRIGO CO, ALLEGAN, MI - 483 08/11/2014 - 09/04/2014
2015-1580	02/25/2015 03/25/2015	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Dustin Block IPD Analytics, LLC	ANDA 078936 TENTATIVE APPROVAL LETTER
2015-1581	02/25/2015 03/25/2015	FDA/OMPT/CDRH/OCER/DFOI/	Evelyn De La Vega BAUSCH AND LOMB	P980040/S041
2015-1582	02/25/2015 03/25/2015	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Chloe Bird Professional Compounding Centers of America (PCCA)	IPCA LABORATORIES - 483, WARNING LETTER 01/01/2011 - 02/24/2015
2015-1583	02/25/2015 03/25/2015	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Wendy Lockwood Banka Wendy Banka	SHUR-GREEN FARMS, ANSONIA, OH - 483 10/03/2014 - 11/19/2014
2015-1584	02/25/2015 03/25/2015	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OC/OES/DFOI/	Wendy Lockwood Banka Wendy Banka	CAYMAN CHEMICAL COMPANY, ANN ARBOR, MI - 483 11/17/2014 - 11/19/2014
2015-1585	02/25/2015 03/25/2015	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	LUNDBECK, TEESSIDE, ENGLAND - 483
2015-1586	02/25/2015 03/25/2015	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	OTSUKA PHARMACEUTICAL CO LTD, TOKUSHIMA WAJIKI FATORY, NAKA GUN, TOKUSHIMA PREFECTURE, JAPAN - EIR 6/9-17/14
2015-1587	02/25/2015 03/25/2015	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	OTSUKA PARMACEUTICAL CO LTD, SECOND TOKUSHIMA FACTORY, EBISUNO HIRAISHI, KAWAUCHI-CHO TOKUSHIMA, JAPAN - EIR 6/18-26/14
2015-1588	02/25/2015 03/25/2015	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	OTSUKA PHARMACEUTICAL CO LTD, ITANO FACTORY, ITANO-JUN, TOKUSHIMA PREFECTURE, JAPAN - EIR 3/17-20/14

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		FDA/OMPT/CDER/GRP/DIDP/		
2015-1589	02/25/2015 03/25/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	OTSUKA PHARMACEUTICAL CO LTD, TOKUSHIMA, WAJIKI FACTORY, NAKA-GUN, TOKUSHIMA PREFECTURE, JAPAN - EIR 7/11-19/12
2015-1590	02/25/2015 03/25/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHALRES CELESTE EAS CONSULTING GROUP LLC	OTSUKA SAGA FACTORY, OTSUKA PHARMACEUTICAL CO LTD, SAGA PREFECTURE, JAPAN - EIR 12/1-5/14
2015-1591	02/25/2015 03/25/2015	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	ELENA HOWELL CLARK Hogan Lovells, ILP	CASLTE CHEESE INC, SLIPPERY ROCK, PA - EIR CMPNT 11/14/12-12/11/12
2015-1592	02/25/2015 03/25/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELENA HOWELL CLARK HOGAN LOVELLS US LLP	PAR PHARMACEUTIAL - COLCHICINE ANDA 03-976 APRVL
2015-1593	02/25/2015 03/25/2015	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	ELENA HOWELL CLARK Hogan Lovells, ILP	CASTLE CHEESE INC, SLIPPERY ROCK, PA - CO RESP 11/14/12-12/11/12
2015-1594	02/25/2015 03/25/2015	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	SEBASTIAN De ANDRACA ALFA INTERNATIONAL SEAFOOD INC	ENTRY NO RDB-0021189-1
2015-1595	02/25/2015 03/25/2015	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	SEBASTIAN De ANDRACA ALFA INTERNATIONAL SEAFOOD INC	ENTRY NO RD8-0021185-9
2015-1596	02/25/2015 03/25/2015	FDA/OC/OES/DFOI/	BETSY CHESSLER MORRISON & FOERSTER LLP	LIST OF REQUESTS FROM NOVADAQ FOR 510K
2015-1597	02/25/2015 03/25/2015	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	WILBUR JOHNSON, JR. COSMETIC INGREDIENT REVIEW	FIBROIN, HYDROLYZED FIBROIN, HYDROLYZED SERICIN - BIOEQUIV , TOXICITY
2015-1598	02/25/2015	FDA/OMPT/CDER/GRP/DIDP/	PETER KOHN	SUN PHARMACEUTICAL INDUSTIRES LTD - NIASPAN ANDA

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	03/25/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FARUQI & FARUQI LLP	200-484 APRVL
2015-1599	02/25/2015 03/25/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PETER KOHN FARUQI & FARUQI LLP	LUPIN LTD - NIASPAN ANDA 90-446 BIOEQUIV, CHEMISTY RVW
2015-1600	02/25/2015 03/25/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PETER KOHN FARUQI & FARUQI LLP	SUN PHARMACEUTICAL INDUSTRIES LTD - NIASPAN ANDA 201-273 BIOEQUIV, CHEMISTRY RVW
2015-1601	02/25/2015 03/25/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PETER KOHN FARUQI & FARUQI LLP	LUPIN LTD - NIASPAN ANDA 90-892
2015-1602	02/25/2015 03/25/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PETER KOHN FARUQI & FARUQI LLP	SUN PHARMACEUTICAL INC - NIASPAN ANDA 200-484 BIOEQUIV, CHEMISTRY RVW
2015-1603	02/25/2015 03/25/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JESSICA WARREN INTERCEPT PHARMACEUTICALS INC	PIRAMAL HEALTHCARE UK LTD, NORTHUMBERLAND, ENGLAND - EIR 10/14
2015-1604	02/25/2015 03/25/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	DOUGLAS N. BLUE II ZETETIC INC	PREMIUM LIPIL POWERED MILK - ENTRY NO 300-5257008-1
2015-1605	02/25/2015 03/25/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bhagwan Chaudhary Sunidhi Securities and Finance Ltd	LUPIN LTD, INDIA - 483 01/12/2015 - 01/23/2015

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2015-1606	02/25/2015 03/25/2015	FDA/OMPT/CDRH/OCER/DFOI/	PHMB Brightwake Ltd	K101882
2015-1607	02/25/2015 03/25/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jaya Ayyagari Dr. Reddy's Laboratories Inc.	ANDA 204051 TENTATIVE APPROVAL LETTER
2015-1608	02/25/2015 03/25/2015	FDA/OMPT/CDRH/OCER/DFOI/	P060028 / The Mentor MemoryShape Core Study (10-year data) Melon Oy	MENTOR BREAST IMPLANT MEMORYSHAPE CORE STUDY TEN YEAR DATA
2015-1609	02/25/2015 03/25/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mikel Alberdi Pharmaceutical Development Group, Inc.	BONINE - MEDWATCH REPORT
2015-1610	02/25/2015 03/25/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sarah Wong-Goodrich BGB Group	PML REPORT NOVARTIS
2015-1611	02/25/2015 03/25/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	DRSP-CONTAINING COCs - STUDY REPORTS, ETC
2015-1612	02/25/2015 03/25/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jim Hunt The Dunn Group Inc.	HUMIRA - CLINICAL TRIAL PROTOCOL, INFORMED CONSENT FORM
2015-1613	02/25/2015 03/25/2015	FDA/OGROP/ORACE-FO/BLT- DO/BLT-CB/	Nathan Horrell UNITE HERE	FLYING FOOD GROUP, STERLING, VA - AGREEMENTS, INSPECTIONS, ETC 01/01/2014 - 02/24/2015
2015-1614	02/25/2015 03/25/2015	FDA/OC/OES/DFOI/	Jeanette Schramm Rochester Institute of Technology - Mechanical Engineering	LABELING OF ORGANIC PRODUCTS
2015-1615	02/25/2015 03/25/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nick Garcia OAKLAND UNIVERSITY	BELVIQ - CLINICAL TRIAL DATA SETS

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		FDA/OMPT/CDER/ORP/DIDP/		
2015-1616	02/25/2015 03/25/2015	FDA/OC/OES/DFOI/	BECKY COOSEMAN BROWN & CROUPPEN PC	ZOLL MANUFACTURING CORP, PITTSBURGH, PA - LIFEVEST EIR, 483, WARNING LTR 2002 TO PRESENT
2015-1617	02/25/2015 03/25/2015	OC/ORA/ORM/ OC/ORA/ORM/	Mark Prinz Registrar Corp	INSPECTIONS LIST 10/01/2011 - 09/30/2014
2015-1618	02/25/2015 03/25/2015	FDA/OGROP/ORA/CE-FO/BLT- DO/BLT-CB/ FDA/OGROP/ORA/CE-FO/CIN- DO/CIN-CB/ FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/ FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/ FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/ FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/ FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/ FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/ OC/ORA/ OC/ORA/	Rachel Johnson FOI Services, Inc.	TOBACCO INSPECTION RECS
2015-1619	02/25/2015 03/25/2015	OC/ORA/OCI/ OC/ORA/OCI/	Paul J. Linden Wood, Herron & Evans, L.L.P.	ARREST WARRANT
2015-1620	02/25/2015 03/25/2015	OC/ORA/OCI/ OC/ORA/OCI/	Paul J. Linden Wood, Herron & Evans, L.L.P.	ARREST WARRANT
2015-1621	02/25/2015 03/25/2015	FDA/OC/OES/DFOI/	Zachary Brennan WRBM	LIST OF 483S FOR DRUG FIRMS 1/1/15 TO PRESENT
2015-1622	02/26/2015 03/26/2015	FDA/OC/OES/DDM/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	DKT FDA-2013-P-0048
2015-1623	02/26/2015 03/26/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Smith BioTex, Inc.	K043371
2015-1624	02/26/2015 03/26/2015	FDA/OC/OEXA/OMA/ FDA/OFVM/CFSAN/OCD/EOS/	Matthew Mosk ABC NEWS	RECS RE ABC NEWS REQUEST FOR INFORMATION RE SHRIMP IMPORTS 02/19/2015 - 02/25/2015

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2015-1625	02/26/2015 03/26/2015	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2014-5312
2015-1626	02/26/2015 03/26/2015	OC/ORR/ORM/ OC/ORR/ORM/	Eyal Maor MAOR, ALON	LIST OF INSPECTIONS 02/04/2008 - 02/25/2015
2015-1627	02/26/2015 03/26/2015	FDA/OC/OES/DFOI/	Kari L. Twaite BEVERIDGE & DIAMOND PC	CFSAN FOIA REQUESTS 01/27/2015 - 02/25/2015
2015-1628	02/26/2015 03/26/2015	FDA/OFVM/CFSAN/OCD/EOS/	Eleanor DaCosta United States Pharmacopeial Convention (USP)	BLACK COHOSH - AERS
2015-1629	02/26/2015 03/26/2015	FDA/OC/OES/DFOI/	Form 483 on Wockhardt Limited's Waluz Facility India ICFAI University	WOCKHARDT LIMITED, INDIA - 483 11/01/2014 - 01/31/2015
2015-1630	02/26/2015 03/26/2015	FDA/OC/OES/DFOI/	Dr Girish Bakhru HSBC Securities and Capital Markets	WOCKHARDT, INDIA - 483 01/01/2015 - 02/26/2015
2015-1631	02/26/2015 03/26/2015	FDA/OC/OES/DFOI/	Uday Shetty Drug Regulations	WOCKHARDT, INDIA - 483 10/02/2014 - 02/26/2015
2015-1632	02/26/2015 03/26/2015	FDA/OC/OES/DFOI/	Ashish Rathi Spark Capital India (Private) Advisors Ltd	WOCKHARDT, INDIA - 483 01/01/2015 - 02/28/2015
2015-1633	02/26/2015 03/26/2015	FDA/OC/OES/DFOI/	Ali Afnan Ali Afnan	WOCKHARDT, INDIA - 483 02/02/2015 - 02/26/2015
2015-1634	02/26/2015 03/26/2015	FDA/OC/OES/DFOI/	RAKESH NAYUDU BESI GROUP NOVO BANCO	LUPIN, INDORE, INDIA - 483
2015-1635	02/26/2015 03/26/2015	FDA/OC/OES/DFOI/	SEAN P. KRISPINSKY LATHAM & WATKINS LLP	SUGAR SWEETENED BEVERAGES - AER, MRKG, ETC
2015-1636	02/27/2015 03/27/2015	FDA/OC/OES/DFOI/	Kathryn Biszko GREENBERG TRAURIG LLP	K001149 RECS PREVIOUSLY RELEASED
2015-1637	02/27/2015 03/27/2015	FDA/OMPT/CDRH/OCER/DFOI/	Kathryn Biszko GREENBERG TRAURIG LLP	K052392, K092807, K094056 ETC
2015-1638	02/27/2015 03/27/2015	FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORR/PA-FO/SAN-DO/SAN-CB/	Ben Smart Smart, Ben	INITIATIVE FOODS, SANGER, CA - EIR, 483, CORR 01/01/2004 - 02/26/2015

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2015-1639	02/27/2015 03/27/2015	FDA/OMPT/CDRH/OCER/DFOI/	Sun Choi ADVANCED STERILIZATION PRODUCTS	K031012
2015-1640	02/27/2015 03/27/2015	FDA/OMPT/CDRH/OCER/DFOI/	Hila Debby Given Imaging	K130945
2015-1641	02/27/2015 03/27/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ROBERT MAHONEY MAHONEY, ROBERT	ZOFRAN (ONDANSTRERON) - AERS
2015-1642	02/27/2015 03/27/2015	FDA/OC/OES/ FDA/OMPT/CDRH/OCER/DFOI/	PETER EISLER USA TODAY	DUODENOSCOPES - DISINFECTION DIFFICULTIES, SPREAD OF INFECTIONS CORR 1/10 TO PRESENT
2015-1643	02/27/2015 03/27/2015	FDA/OFVM/CFSAN/OCD/EOS/	JANET M FLAHERTY Abbott Nutrition	HONEST CO - ORGANIC PREMIUM FORMULA RECS
2015-1644	02/27/2015 03/27/2015	FDA/OMPT/CDRH/OCER/DFOI/	ROBERT H GREGG DDS MILLENNIUM DENTAL TECHNOLOGIES INC	BIOLASE INC (BIOL) - WATERLASE IPLUS ER,CR,YSGG CMLPNTS, MISBRANDING RECS
2015-1645	02/27/2015 03/27/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	JESSICA ANDREW DEWSNUP KING & OLSEN	COOK INC - MIRAFLEX HIGH FLOW MICROCATHETER K080737, MIRAFLEX MICROCATHETER K060224, CANTATA MICROCATHETER K101450, ETC
2015-1646	02/27/2015 03/27/2015	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	LESLIE A RAMSEY FDA NEWS	GILEAD SCIENCES - 483 5/14/14
2015-1647	02/27/2015 03/27/2015	FDA/OGROP/ORAP/NE-FO/NYK-DO/NYK-DCB/	MANOJ GARG DSP Merrill Lynch	TARO PHARMACEUTICALS, HAWTHORNE, NY - 483 12/9-19/14
2015-1648	02/27/2015 03/27/2015	OC/ORAP/ORM/ OC/ORAP/ORM/	KIM C CAPONE PORZIO LIFE SCIENCES	PRESCRIPTION DRUG MAKRETING ACT (PDMA) LIST OF INSPS 2010 TO PRESENT
2015-1649	02/27/2015 03/27/2015	FDA/OMPT/CDRH/OCER/DFOI/	PATRICIA A GROOMS MCKEEN & ASSOCIATES PC	AMBIT PUMP - MDRS 2013
2015-1650	02/27/2015 03/27/2015	FDA/OC/OES/ FDA/OC/OL/	JEREMY BERNS BERNS, JEREMY	MARCO RUBIO - CORR, CMLPNTS, RPTS, ETC 2000 TO PRESENT
2015-1651	03/02/2015 03/30/2015	FDA/OC/OES/DFOI/	James Wong HARMAN LAW LLC	MEDTRONIC MINIMED - PREVIOUSLY RELEASED RECORDS 06/01/2009 - 02/18/2015
2015-1652	03/02/2015 03/30/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Wendy Ou Kaiyuan Hengtai Chemical Co., Ltd.	KAIYUAN HENGTAI CHEMICAL CO, LTD, CHINA - EIR 09/22/2014 - 02/24/2015

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		FDA/OMPT/CDER/GRP/DIDP/		
2015-1653	03/02/2015 03/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 203441/S2
2015-1654	03/02/2015 03/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Erin Duffy Erin Duffy	ZOFRAN - AERS
2015-1655	03/02/2015 03/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michael DeMeuse UPSHER-SMITH LABORATORIES INC	ANDA 074700 SBA
2015-1656	03/02/2015 03/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michael DeMeuse UPSHER-SMITH LABORATORIES INC	ANDA 074225 SBA
2015-1657	03/02/2015 03/30/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Carly Rodriguez Research Excellence to Stop TB Resistance (RESIST-TB)	LIST OF DRUG APPROVED FOR EXPANDED USE
2015-1658	03/02/2015 03/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dr Girish Bakhru HSBC Securities and Capital Markets	CADILA HEALTHCARE, INDIA - 483 01/01/2015 - 02/05/2015
2015-1659	03/02/2015 03/30/2015	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	John Tozzi Bloomberg Businessweek	ENGINEERING ASSESSMENT RE ERCP DUODENOSCOPES, REVIEWS OF REPROCESSING DATA, CORR ETC
2015-1660	03/02/2015 03/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shawn Wellman Cabell Huntington Hospital	DEXMEDETOMIDINE - AERS

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2015-1661	03/02/2015 03/30/2015	FDA/OC/OES/DFOI/	David Heath THE CENTER FOR PUBLIC INTEGRITY	NRDC - SETTLEMENT RECORDS
2015-1662	03/02/2015 03/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Morgan Rettig LATHAM & WATKINS LLP	EXPAREL REPORTS
2015-1663	03/02/2015 03/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Samer Shkoukani BIOPHARM INSIGHT	BIOMARIN PHARM VIMIZIM BLA 125460 MEDWATCH REPORT
2015-1664	03/02/2015 03/30/2015	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OCC/	Takeo Matsumoto Umeda Sogo Law Office	PHARMACEUTICALS INNOVATIONS - REPORTS, WARNINGS, LEGAL PROCEEDINGS ETC
2015-1665	03/02/2015 03/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	G. Srinivas Zydus Pharmaceuticals USA Inc.	NDA 203312
2015-1666	03/02/2015 03/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ali Afnan Ali Afnan	MYLAN, BANGALORE, INDIA - 483 02/01/2015 - 02/27/2015
2015-1667	03/02/2015 03/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Samer Shkoukani BIOPHARM INSIGHT	MALLINCKRODT INC XARTEMIS XR NDA 204031 MEDWATCH REPORTS
2015-1668	03/02/2015 03/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Samer Shkoukani BIOPHARM INSIGHT	CUBIST PHARMS INC SIVEXTRO TEDIZOLID PHOSPHATE NDA 205435 MEDWATCH REPORTS
2015-1669	03/02/2015 03/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	G. Srinivas Zydus Pharmaceuticals USA Inc.	ANDA 076684

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		FDA/OMPT/CDER/GRP/DIDP/		
2015-1670	03/02/2015 03/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Samer Shkoukani BIOPHARM INSIGHT	DURATA THERAPS INTL DALVANCE DALBAVANCIN HYDROCHLORIDE NDA 021883 MEDWATCH REPORTS
2015-1671	03/02/2015 03/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	G. Srinivas Zydus Pharmaceuticals USA Inc.	ANDA 077857
2015-1672	03/02/2015 03/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	G. Srinivas Zydus Pharmaceuticals USA Inc.	ANDA 076726
2015-1673	03/02/2015 03/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Samer Shkoukani BIOPHARM INSIGHT	DENDO PHARMS INC AVEED (TESTOSTERONE UNDECANOATE) MEDWATCH REPORTS
2015-1674	03/02/2015 03/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Samer Shkoukani BIOPHARM INSIGHT	UPSHER SMITH CYRAMZA (RAMUCIRUMAB) (BLA 125477) MEDWATCH REPORTS
2015-1675	03/02/2015 03/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jennifer Schumacher The Invus Group	XIAFLEX - FAERS
2015-1676	03/02/2015 03/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Samer Shkoukani BIOPHARM INSIGHT	NOVARTIS PHARMS CORP ZYKADIA (CERITINIB) (NDA 205755) MEDWATCH REPORTS
2015-1677	03/02/2015 03/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Andrea Demakas ADVERSEEVENTS INC	ELIQUIS, HARVONI, SOVALDI, ETC - AERS

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2015-1678	03/02/2015 03/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Samer Shkoukani BIOPHARM INSIGHT	ALPROLIX - MEDWATCH REPORTS
2015-1679	03/02/2015 03/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	G. Srinivas Zydus Pharmaceuticals USA Inc.	NDA 020340
2015-1680	03/02/2015 03/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Samer Shkoukani BIOPHARM INSIGHT	BLA 125496 MEDWATCH REPORTS
2015-1681	03/02/2015 03/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	David Tukey EverPoint Asset Management	Special Protocol Assessment for NewLink Genetics Phase 3 trial of its HyperAcute therapy (algenpantucel-L) for resected pancreatic cancer
2015-1682	03/02/2015 03/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	G. Srinivas Zydus Pharmaceuticals USA Inc.	NDA 019183
2015-1683	03/02/2015 03/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Samer Shkoukani BIOPHARM INSIGHT	UPSHER SMITH NDA 204399 MEDWATCH REPORTS
2015-1684	03/02/2015 03/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Liz King Oxford Pharmascience	NDA 018685 SBA
2015-1685	03/02/2015 03/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Samer Shkoukani BIOPHARM INSIGHT	AMYLIN PHARMS LLC MYALEPT (METRELEPTIN) (BLA 125390) MEDWATCH REPORTS

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		FDA/OMPT/CDER/GRP/DIDP/		
2015-1686	03/02/2015 03/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michele Sinoway LACHMAN CONSULTANT SERVICES, INC.	YUNG SHIN PHARMACEUTICAL INDUSTRY CO, LTD, TAIWAN - 483
2015-1687	03/02/2015 03/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Gay Parsons Janssen Inc.	METHLYLPHENIDATE - ADVERSE EVENT ANALYSIS
2015-1688	03/02/2015 03/30/2015	FDA/OMPT/CDRH/OCER/DFOI/	Dale Davison NextStep Arthropedix	K112802
2015-1689	03/02/2015 03/30/2015	FDA/OMPT/CDRH/OCER/DFOI/	Dale Davison NextStep Arthropedix	K132312
2015-1690	03/02/2015 03/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Gay Parsons Janssen Inc.	Drug stability and Dissolution data for generic methylphenidate hydrochloride ER
2015-1691	03/02/2015 03/30/2015	FDA/OMPT/CDRH/OCER/DFOI/	Dale Davison NextStep Arthropedix	K122158
2015-1692	03/02/2015 03/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Gay Parsons Janssen Inc.	GENERIC METHYLPHENIDATE - AERS
2015-1693	03/02/2015 03/30/2015	FDA/OMPT/CDRH/OCER/DFOI/	Alexander Braun Henderson BraunSolutions	K091158
2015-1694	03/02/2015 03/30/2015	FDA/OMPT/CDRH/OCER/DFOI/	Heather Neely Neely, Heather	K142940
2015-1695	03/02/2015 03/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 22271
2015-1696	03/02/2015 03/30/2015	FDA/OMPT/CDRH/OCER/DFOI/	Nick Radachi Edlen Imaging	K072134

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2015-1697	03/02/2015 03/30/2015	FDA/OMPT/CDRH/OCER/DFOI/	Dave Harvey Medical Connections Ltd	COR14000556
2015-1698	03/02/2015 03/30/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 206088
2015-1699	03/02/2015 03/30/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nishith Sanghvi CIMB Securities	WOCKHARDT - INSPECTIONS LAST SIX MONTHS
2015-1700	03/02/2015 03/30/2015	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Rebecca Dandeker Morgan, Lewis & Bockius LLP	FOCUS LABORATORIES INC, NORTH LITTLE ROCK, AR - 483, EIR SUMMARIES 08/01/2013 - 11/01/2013
2015-1701	03/02/2015 03/30/2015	FDA/OMPT/CDRH/OCER/DFOI/	Kristine Tucker Tornier Inc.	K131559
2015-1702	03/02/2015 03/30/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSSAN/OCD/EOS/	Jaap D. Kluijthoof Stepan Lipid Nutrition	GRN 000449 - FDA CORR WITH LONZA RE MEETINGS
2015-1703	03/02/2015 03/30/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Robert Bexton Aristotle Capital Management	HOSPIRA HEALTHCARE INDIA PRIVATE LIMITED - 483 02/15/2015 - 02/25/2015
2015-1704	03/02/2015 03/30/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Robert Stone TOWER LABORATORIES LTD	SHENZHEN ORIENTAL PHARMACEUTICAL CO, CHINA - EIR 03/01/2014 - 03/30/2014
2015-1705	03/02/2015 03/30/2015	FDA/OMPT/OSMP/OOPD/	Todd Phillips Cardinal Health Regulatory Sciences	CODADOSE, INC - ORPHAN DRUG DESIGNATION REQUEST
2015-1706	03/02/2015 03/30/2015	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Rebecca Dandeker Morgan, Lewis & Bockius LLP	FOCUS LABORATORIES, NORTH LITTLE ROCK, AR - EIR 08/01/2013 - 11/01/2013
2015-1707	03/02/2015	FDA/OMPT/CDRH/OCER/DFOI/	Kristine Tucker	K130126

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	03/30/2015		Tornier Inc.	
2015-1708	03/02/2015 03/30/2015	FDA/OMPT/CDRH/OCER/DFOI/	Kristine Tucker Tornier Inc.	K131129
2015-1709	03/02/2015 03/30/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ADITYA KHEMKA AMBIT CAPITAL PVT. LTD.	CIPLA LIMITED FACILITIES - 483, IMPORT ALERTS, WARNING LETTERS 02/01/2013 - 02/28/2015
2015-1710	03/02/2015 03/30/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ADITYA KHEMKA AMBIT CAPITAL PVT. LTD.	ZYDYUS CADILA - 483 09/02/2014 - 02/28/2015
2015-1711	03/02/2015 03/30/2015	FDA/OMPT/CDRH/OCER/DFOI/	John Beasley MedTech Review, LLC	MW5038594 COMM WITH FDA
2015-1712	03/02/2015 03/30/2015	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORA/ OC/ORA/	jane talkington OKLAHOMA STATE UNIVERSITY	RECS DESCRIBING WHY FDA FUNDED 11 LABORATORIES TO CONDUCT A MOUSE LD STUDY
2015-1713	03/02/2015 03/30/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Allison Magwire ARIAD Pharmaceuticals, Inc	ICLUSIG - AERS
2015-1714	03/02/2015 03/30/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ADITYA KHEMKA AMBIT CAPITAL PVT. LTD.	ZYDUS CADILA - 483 10/01/2014 - 03/02/2015
2015-1715	03/02/2015 03/30/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Aram Sethian Quad Capital	HOSPIRA, INDIA - 483 07/01/2014 - 03/02/2015
2015-1716	03/02/2015 03/30/2015	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	TOBACCO MEDWATCH REPORTS
2015-1717	03/02/2015 03/30/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Margaret Sestrom on behalf of Nhu Tran PFIZER	NDA 20599

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		FDA/OMPT/CDER/GRP/DIDP/		
2015-1718	03/02/2015 03/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	COHEN, MIRIAM	PROMETHAZINE - AER
2015-1719	03/02/2015 03/30/2015	FDA/OC/OES/DDM/	WHITTELSEY, FRANCES	DCK 94P-0420; FDA 2008-P-0309-0001/CP - CITIZEN PETITIONS
2015-1720	03/02/2015 03/30/2015	FDA/OMPT/CDRH/OCER/DFOI/	R.O. DEAN COMPLIANCE SYSTEMS INTERNATIONAL LLC	TSO3 STERIZONE VP4 STERILIZER K141163
2015-1721	03/02/2015 03/30/2015	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	JENNA LIPKA OPTIM LLC	OPTIM LLC, STURBRIDGE, MA - EIR 1/29/13 - 2/7/13
2015-1722	03/02/2015 03/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WILLIAM J. REGAN NAVIDEA	LYMPHOSEEK NDA 202-207 - AERS RESP LTR 4/1/14
2015-1723	03/02/2015 03/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MANOJ GARG MERRILL LYNCH	LUPIN, INDORE MADHYA, PRADESH, INDIA - 483 1/12-23/15
2015-1724	03/02/2015 03/30/2015	FDA/OC/OES/DFOI/	JAMES WONG HARMAN LAW LLC	MEDTRONIC MINIMED INC, NORTHRIDGE, CA 12/16/13; VILLALBA, PR 5/15/14; HUMACAO, PR 5/13/11 ETC - 483, EIR, CO RESP
2015-1725	03/02/2015 03/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LIN X09327, DIANNE	FOLIC ACID - AER
2015-1726	03/02/2015 03/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LIN X09327, DIANNE	FENTANYL IV - AER
2015-1727	03/02/2015 03/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LIN X09327, DIANNE	DOXYCYCLINE TETRACYCLINE - AER

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		FDA/OMPT/CDER/GRP/DIDP/		
2015-1728	03/02/2015 03/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LIN X09327, DIANNE	HEPARIN INJ- AER
2015-1729	03/02/2015 03/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LIN X09327, DIANNE	DESOGEN - AER
2015-1730	03/02/2015 03/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LIN X09327, DIANNE	GLUCOPHAGE METFORMIN - AER
2015-1731	03/02/2015 03/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LIN X09327, DIANNE	PRE NATAL VITAMINS - AER
2015-1732	03/02/2015 03/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LIN X09327, DIANNE	BABY ASPIRIN - AER
2015-1733	03/02/2015 03/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WILLIAM McINTYRE, Ph.D. LUPIN PHARMACEUTICALS INC	OTSUKA - ABILIFY (ARIPIRAZOLE) NDA 21-436 - FORM 3542
2015-1734	03/02/2015 03/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JAMES FAUCETT, M.A, M.S NORTHWEST CLINICAL RESEARCH CTR	ARICEPT (DONEZIPIL HYDROCHLORIDE NDA 20-690 - STATISICAL RVW
2015-1735	03/02/2015 03/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELENA HOWELL CLARK Hogan Lovells, ILP	SANDOZ INC - LEVOLEUCOVORIN CALCIUM ANDA 203-563 TENTATIVE APRVL LTR

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2015-1736	03/02/2015 03/30/2015	FDA/OFVM/CFSAN/OCD/EOS/	ZIA C. OATLEY GIBSON DUNN & CRUTCHER LLP	LTRS, EMAILS BY F EDWARD SCARBOROUGH CONCERNING WHETHER A FOOD MFR CAN MAKE A STATEMENT ABOUT A NUTRIENT ON A FOOD PACKAGE LABEL
2015-1737	03/02/2015 03/30/2015	FDA/OMPT/CDRH/OCER/DFOI/	KAREN FOSHAY Al Jazeera America	OLYMPUS MEDICAL SYSTEM - Q180V ENDOSCOPE - 510K, APRVL, CORR SINCE 2010
2015-1738	03/02/2015 03/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DOUGLAS N. BLUE, II ZETETIC INC	IMATINIB MESYLATE - ANDA
2015-1739	03/03/2015 03/31/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sandy Suh Exeltis	NDA 018205 SBA
2015-1740	03/03/2015 03/31/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ALL FOIA REQUESTS CLOSED FEB 2015
2015-1741	03/03/2015 03/31/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	sandy suh Exeltis	NDA 17455 SBA
2015-1742	03/03/2015 03/31/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shea Shaver REILLY POZNER LLP	ZOFRAN - CORR WITH SPONSOR RE BIRTH DEFECTS ETC 01/01/1985 - 03/02/2015
2015-1743	03/03/2015 03/31/2015	FDA/OC/OES/DFOI/	David Heath THE CENTER FOR PUBLIC INTEGRITY	FOIA REQUESTS FILED BY SUSANNE RUST OR MEG KISSINGER OF MILWAUKEE JOURNAL SENTINEL, RESPONSES 01/01/2008 - 01/01/2010
2015-1744	03/03/2015 03/31/2015	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	BTS Research BTS Research	TOX PATH SPECIALISTS, LLC, FREDERICK, MD - EIR, 483 RESPONSE 07/14/2013 - 03/31/2015
2015-1745	03/03/2015 03/31/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sandy Suh Exeltis	NDA 017408
2015-1746	03/03/2015	FDA/OMPT/CDER/GRP/DIDP/	Ellen Hirst	HOSPIRA HEALTHCARE INDIA PRIVATE LIMITED - 483 02/15/2015 - 02/26/2015

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2015-1747	03/03/2015 03/31/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 2/1-28/2015
2015-1748	03/03/2015 03/31/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Molly Rapp Fresenius Kabi USA LLC	HOSPIRA HEALTHCARE INDIA PRIVATE LIMITED - 483 02/01/2015 - 02/28/2015
2015-1749	03/03/2015 03/31/2015	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	MANUFACTURERS AND IMPORTERS OF TOBACCO PRODUCTS FOR WHICH A USER FEE WAS RECEIVED IN FIRST QUARTER OF 2015 ETC
2015-1750	03/03/2015 03/31/2015	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	REPORTS OF HEALTH OR SAFETY ISSUES WITH TOBACCO PRODUCTS 10/9/14 TO PRESENT
2015-1751	03/03/2015 03/31/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Darlene O'Banion Revance Therapeutics	BLA 103000
2015-1752	03/03/2015 03/31/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	510K RELEASED FEB 2015
2015-1753	03/03/2015 03/31/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ADITYA KHEMKA AMBIT CAPITAL PVT. LTD.	AUROBINDO PHARMA - 483 09/02/2014 - 03/31/2015
2015-1754	03/03/2015 03/31/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	yangchw First People's Hospital of Chongqing	ANDA 074346
2015-1755	03/03/2015 03/31/2015	FDA/OMPT/CDRH/OCER/DFOI/	SORIN C. POPA Imperial College London	TRANSVASCULAR INC - CATHETER MODEL TA-XP-001 K031920
2015-1756	03/03/2015 03/31/2015	FDA/OC/OES/DFOI/	KENNETH L LEVINSON BALABAN LEVINSON & COSTIGAN PC	FRESCA FOODS INC, SUNLAND INC - PEANUT PRODS RECALL RECS, CORR, NOTICES, ETC
2015-1757	03/03/2015	FDA/OMPT/CDER/GRP/DIDP/	ELIZABETH C FUHRMANN	DEPAKOTE NDA 18-723, NDA 19-680 - MEDICATION

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2015-1758	03/03/2015 03/31/2015	FDA/OC/OL/	JACK GILLUM ASSOCIATED PRESS	SEN RAND PAUL - CORR LOGS 1/11 TO PRESENT
2015-1759	03/03/2015 03/31/2015	FDA/OMPT/CDRH/OCER/DFOI/	ERIC EGGERS 510KONSULT LLC	MEDTRONIC - DUET EXTERNAL DRAINAGE RECLASSIFICATION ORDER, DECISION SUMMARY FOR DE NOVO DEN120017
2015-1760	03/03/2015 03/31/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KATHLEEN R HENRY Hyman Phelps and McNamara PC	SUN PHARMA GLOBAL - ZOLEDRONIC ACID ANDA 204-051 TENTATIVE APRVL LTR 7/3/14
2015-1761	03/03/2015 03/31/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KATHLEEN R HENRY Hyman Phelps and McNamara PC	SUN PHARMA GLOBAL - ZOLEDRONIC ACID ANDA 204-138 TENTATIVE APRVL LTR 7/22/14
2015-1762	03/03/2015 03/31/2015	FDA/OMPT/OSMP/OOPD/	SHAUNA FARR-JONES QB3	BIOMEDICAL FRONTIERS INC - 40SD02 ORPHAN PROD DESIGNATION
2015-1763	03/03/2015 03/31/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 2/16-20/15
2015-1764	03/03/2015 03/31/2015	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 2/16-20/15
2015-1765	03/03/2015 03/31/2015	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 2/16-20/15
2015-1766	03/03/2015 03/31/2015	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD Center for Regulatory Services, Inc.	FOI DAILY LOG 2/16-20/15
2015-1767	03/03/2015 03/31/2015	FDA/OC/OES/DFOI/	LESLIE RAMSEY FDA NEWS	FOI DAILY LOG 2/16-20/15
2015-1768	03/03/2015 03/31/2015	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 2/16-20/15
2015-1769	03/03/2015 03/31/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 2/16-20/15

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2015-1770	03/03/2015 03/31/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 2/9-13/15
2015-1771	03/03/2015 03/31/2015	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 2/9-13/15
2015-1772	03/03/2015 03/31/2015	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 2/9-13/15
2015-1773	03/03/2015 03/31/2015	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD Center for Regulatory Services, Inc.	FOI DAILY LOG 2/9-13/15
2015-1774	03/03/2015 03/31/2015	FDA/OC/OES/DFOI/	LESLIE RAMSEY FDA NEWS	FOI DAILY LOG 2/9-13/15
2015-1775	03/03/2015 03/31/2015	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 2/9-13/15
2015-1776	03/03/2015 03/31/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 2/9-13/15
2015-1777	03/03/2015 03/31/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 2/2-6/15
2015-1778	03/03/2015 03/31/2015	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 2/2-6/15
2015-1779	03/03/2015 03/31/2015	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 2/2-6/15
2015-1780	03/03/2015 03/31/2015	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD Center for Regulatory Services, Inc.	FOI DAILY LOG 2/2-6/15
2015-1781	03/03/2015 03/31/2015	FDA/OC/OES/DFOI/	LESLIE RAMSEY FDA NEWS	FOI DAILY LOG 2/2-6/15
2015-1782	03/03/2015 03/31/2015	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 2/2-6/15
2015-1783	03/03/2015 03/31/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 2/2-6/15
2015-1784	03/04/2015 04/01/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 203257

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2015-1785	03/04/2015 04/01/2015	FDA/OMPT/CDRH/OCER/DFOI/	Tadeusz Pyz Pyz, Tadeusz	AQUAMID - SUBMISSION RE AGENT
2015-1786	03/04/2015 04/01/2015	FDA/OMPT/OSMP/OOPD/	Sheldon Garrison Promentis	CANNIBIDIOL - ORPHAN PRODUCT DESIGNATION RECS
2015-1787	03/04/2015 04/01/2015	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	Wendy Lees NORTHWEST COSMETIC LABS LLC	DERMAZONE SOLUTIONS, ST PETERSBURG, FL - EIR, 483, WARNING LETTER 01/01/2010 - 03/01/2015
2015-1788	03/04/2015 04/01/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Douglas Jacobs, MD Douglas Jacobs, M.D.	ZOLOFT - HOMICIDE EVENTS
2015-1789	03/04/2015 04/01/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lauren Farruggia Hyman Phelps and McNamara PC	ANDA 201894
2015-1790	03/04/2015 04/01/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lauren Farruggia Hyman Phelps and McNamara PC	ANDA 201578
2015-1791	03/04/2015 04/01/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jaya Ayyagari Dr. Reddys Laboratories Inc	AARTI DRUGS LIMITED, INDIA - 483 AUGUST 2014
2015-1792	03/04/2015 04/01/2015	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Keli J. Renoud UTMB at Galveston	UTMB Blood Donor Center - 483 MARCH 2014
2015-1793	03/04/2015 04/01/2015	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Wendy Lees NORTHWEST COSMETIC LABS LLC	AWARE PRODUCTS, CHATSWORTH, CA - EIR, 483, WARNING LETTERS 01/01/2010 - 03/01/2015
2015-1794	03/04/2015 04/01/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lauren Farruggia Hyman Phelps and McNamara PC	ANDA 203005

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2015-1795	03/04/2015 04/01/2015	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Yu Shi The Rosen Law Firm, P.A.	MACRILEN - SPA, NDA, CORR ETC
2015-1796	03/04/2015 04/01/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lauren Farruggia Hyman Phelps and McNamara PC	NDA 076258
2015-1797	03/04/2015 04/01/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	DRSP-CONTAINING COC - FINAL STUDY REPORT RECS
2015-1798	03/04/2015 04/01/2015	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Christine Burns Discovery Laboratories, Inc.	DISCOVERY - REDACTED EIRS 09/01/2007 - 06/01/2008
2015-1799	03/04/2015 04/01/2015	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Taylor Hermes University of Kiel - Taylor Hermes, doctoral candidate	AMERICAN NATUROPATHIC RESEARCH INSTITUTE, NATUROPATHIC ONCOLOGY RESEARCH INSTITUTE - REGISTRATION, 482, 483 ETC 01/01/2005 - 03/03/2015
2015-1800	03/04/2015 04/01/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lauren Farruggia Hyman Phelps and McNamara PC	ANDA 203005
2015-1801	03/04/2015 04/01/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 2/2-7/15
2015-1802	03/04/2015 04/01/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 2/9-14/15
2015-1803	03/04/2015 04/01/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 2/16-21/15
2015-1804	03/04/2015 04/01/2015	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 2/2-6/15
2015-1805	03/04/2015	FDA/OC/OES/DFOI/	DEBI COHEN	CLOSED FOIA REQUESTS 2/9-13/15

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	04/01/2015		WOLTERS KLUWER LAW & BUSINESS	
2015-1806	03/04/2015 04/01/2015	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 2/16-20/15
2015-1807	03/04/2015 04/01/2015	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 2/2-6/15
2015-1808	03/04/2015 04/01/2015	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 2/9-13/15
2015-1809	03/04/2015 04/01/2015	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 2/16-20/15
2015-1810	03/04/2015 04/01/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 2/2-6/15
2015-1811	03/04/2015 04/01/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 2/9-13/15
2015-1812	03/04/2015 04/01/2015	FDA/OC/OES/DFOI/	LLAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 2/16-20/15
2015-1813	03/04/2015 04/01/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	AMANDA WILLS RABBAT GOODWIN PROCTOR	NOVARTIS PHARMACEUTICAL CORP - CLEEVEC (IMATINIB MESYLATE) CAPS NDA 21-335 PHARMACOLOGY/ TOX RVW, CLNCL & BIOPHARMACUTICS RVW, INTERNAL PROCEDURES FOR PUBLISHING NDA
2015-1814	03/04/2015 04/01/2015	FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/	Doe J	RESTLESS LEG SYSNDROME - PROD FDA APPRVD
2015-1815	03/04/2015 04/01/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	STEFAN ELLIS PEPPER HAMILTON LLP	PROZAC NDA 18-936 - CORR, COMM, DRAFTS, ETC
2015-1816	03/04/2015 04/01/2015	FDA/OGROP/ORO/CE-FO/DET-DO/DET-CB/ FDA/OGROP/ORO/CE-FO/DET-DO/DET-CB/	Doe J	CS PLASMAL DANLIEL - INVESTIGATION 6/14
2015-1817	03/04/2015 04/01/2015	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	CPT1400619
2015-1818	03/04/2015	FDA/OMPT/CDER/ORP/DIDP/	David Krugler	NIZORAL - COMMUNICATIONS BETWEEN FDA AND MANUFACTURERS 07/01/2013 - 02/01/2014

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	04/01/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CK&F	
2015-1819	03/04/2015 04/01/2015	FDA/OMPT/OSMP/OOPD/	Sheldon Garrison Promentis	INTRAVENOUS CARBAMAZEPINE - ORPHAN DESIGNATION RECS
2015-1820	03/04/2015 04/01/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Judith Hill Intertek Health Sciences Inc.	VEDOLUZIMAB, ENTYVIO, 125476 - APPROVAL RECS
2015-1821	03/04/2015 04/01/2015	FDA/OMPT/CDRH/OCER/DFOI/	Justin Pessa DAVOL INC	K141560
2015-1822	03/05/2015 04/02/2015	FDA/OGROP/ORAP/PA-FO/LOS- DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Diana G. Moregon Jackson Lewis, P.C.	CONTINENTAL DENTAL CERAMICS - CORR, INVESTIGATIONS, MEMO ETC
2015-1823	03/05/2015 04/02/2015	FDA/OFVM/CFSAN/OCD/EOS/	Akshay Sachdev EASTMAN CHEMICAL COMPANY	ACCERA, INC - WARNING LETTER RECS 12/03/2013 - 03/04/2015
2015-1824	03/05/2015 04/02/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	David Holzwarth Johnson & Johnson Vision Care, Inc.	NDA 18033 S017, S018
2015-1825	03/05/2015 04/02/2015	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2015-1068
2015-1826	03/05/2015 04/02/2015	FDA/OMPT/CDRH/OCER/DFOI/	Susan Gray Susan Gray	K050016
2015-1827	03/05/2015 04/02/2015	FDA/OMPT/CDRH/OCER/DFOI/	Susan Gray Susan Gray	K993678
2015-1828	03/05/2015 04/02/2015	FDA/OFVM/CFSAN/OCD/EOS/	Ben Wieder CENTER FOR PUBLIC INTEGRITY	5 HOUR ENERGY - CAERS 02/19/2014 - 03/04/2015
2015-1829	03/05/2015 04/02/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Melissa Thompson LeClairRyan, PC	COUNCIL ON RADIONUCLIDES, RADIOPHARMACEUTICALS TO CAROL BENNETT 04/29/2014 - 06/30/2014

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2015-1830	03/05/2015 04/02/2015	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	Michael Howard Michael Howard	STEPHEN C OLSON, MD, UNIVERSITY OF MINNESOTA - INVESTIGATION RESULTS
2015-1831	03/05/2015 04/02/2015	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Rockline Industries ROCKLINE INDUSTRIES	PACON MANUFACTURING, SOMERSET, NJ - 483, EIR 01/01/2012 - 03/01/2015
2015-1832	03/05/2015 04/02/2015	FDA/OMPT/CDRH/OCER/DFOI/	Margaret Klippel STRYKER ORTHOPAEDICS	K142787
2015-1833	03/05/2015 04/02/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Smith BioTex, Inc.	K0123338
2015-1834	03/05/2015 04/02/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Smith BioTex, Inc.	K090001
2015-1835	03/05/2015 04/02/2015	FDA/OC/OES/DFOI/	Erik Prentice Prentice, Erik	THERANOS DEVICE APPROVALS
2015-1836	03/05/2015 04/02/2015	FDA/OC/OES/DFOI/	Doe J	INTAS PHARMACEUTICALS, INDIA - INSPECTIONS
2015-1837	03/06/2015 04/03/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sarah Karlin [no person],	NEW DRAFT LABELING LANGUAGE SENT TO TESTOSTERONE DRUG SPONSORS 02/01/2015 - 03/31/2015
2015-1838	03/06/2015 04/03/2015	FDA/OFVM/CFSAN/OCD/EOS/	Scott Thenell THENELL & ASSOCIATES LLC	OKANAGAN SPECIALTY FRUITS, CANADA - EMAILS, DATA, ETC SENT TO CFSAN 01/01/2005 - 03/05/2015
2015-1839	03/06/2015 04/03/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Idelalisib - All AE's Ken Tong	ZYDELIG - AERS
2015-1840	03/06/2015 04/03/2015	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	Libby Smith KCNC-TV NEWS 4	PURINA, DENVER, CO - 483 01/01/2014 - 12/31/2014
2015-1841	03/06/2015 04/03/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Pembrolizumab - All AE's Ken Tong	KEYTRUDA - AERS
2015-1842	03/06/2015	OC/ORA/OCI/	Richard E. Widup, Jr.	OCI 2014-NYN-701-0431 LAB REPORT

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	04/03/2015	OC/ORA/OCI/	MEAD JOHNSON NUTRITIONALS	
2015-1843	03/06/2015 04/03/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ibrutinib - All AE's Ken Tong	IBRUTINIB - AERS
2015-1844	03/06/2015 04/03/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K002465
2015-1845	03/06/2015 04/03/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	G. Srinivas Zydus Pharmaceuticals USA Inc.	SBA 019141
2015-1846	03/06/2015 04/03/2015	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Skye Resendes Law Offices of Ronald A. Marron	ALPHA CF, BOERICKE & TAFEL - REPORTS, COMM
2015-1847	03/06/2015 04/03/2015	FDA/OMPT/CDRH/OCER/DFOI/	Devyani Nanduri Devyani Nanduri	K093565
2015-1848	03/06/2015 04/03/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	G. Srinivas Zydus Pharmaceuticals USA Inc.	NDA 019137 SBA
2015-1849	03/06/2015 04/03/2015	FDA/OMPT/OSMP/OOPD/	Rachel Johnson FOI Services, Inc.	DEUTERTRABENAZINE - ORPHAN DESIGNATION LETTERS
2015-1850	03/06/2015 04/03/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K023135
2015-1851	03/06/2015 04/03/2015	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/ORO/DIOP/ FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/ FDA/OMPT/CDER/ORP/DIDP/	Maya Foa REPRIEVE	SODIUM THIOPENTAL, THIOPENTAL SODIUM POWDER AND SOLUTION -IMPORT RECS 01/01/2014 - 03/06/2015

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2015-1852	03/06/2015 04/03/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Matthew Humbaugh Harbor Spring Capital	ANDA RE LEVOTHYROXINE SODIUM 01/01/2014 - 03/05/2015
2015-1853	03/09/2015 04/06/2015	FDA/OFVM/CFSAN/OCD/EOS/	David Heath THE CENTER FOR PUBLIC INTEGRITY	CORR BETWEEN FDA, CENTER FOR FOOD SAFETY, AND JUSTIN TEEGUARDEN, STEVE HENTGES, AMERICAN CHEMISTRY COUNCIL 01/01/2010 - 03/01/2015
2015-1854	03/09/2015 04/06/2015	FDA/OMPT/CDRH/OCER/DFOI/	Brian Orwat STRYKER MEDICAL	WHEELCHAIR ELEVATOR DEVICE, POWERED PATIENT TRANSPORT DEVICE - EXEMPTION RECS
2015-1855	03/09/2015 04/06/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Rachel Johnson FOI Services, Inc.	TOLOSA HUNT - HEPLISAV BLA 125-428 CAVERNOUS SINUS SYNDROME CASE STUDY DV2-HBV-16 EVALUATION
2015-1856	03/09/2015 04/06/2015	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/MIN-DO/MIN-CB/	Eva Berg Eva Berg	COMPLAINT 131002
2015-1857	03/09/2015 04/06/2015	FDA/OMPT/CDRH/OCER/DFOI/	Valerie Defiesta-Ng EXPERIEN GROUP LLC	K132931
2015-1858	03/09/2015 04/06/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K022140.
2015-1859	03/09/2015 04/06/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rob M Hagopian MEDICA CORPORATION	K132121
2015-1860	03/09/2015 04/06/2015	FDA/OO/OHR/	Todd Walls Todd Walls	SUCCESSFUL CANDIDATES FOR POSITION OF CONSUMER SAFETY OFFICER - ONE EXAMPLE OF CV FOR GS-07, GS-09, GS-11, GS-12, GS-13 01/06/2013 - 03/03/2015
2015-1861	03/09/2015 04/06/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	ADCENTRIS - AERS

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2015-1862	03/09/2015 04/06/2015	FDA/OMPT/CDRH/OCER/DFOI/	Travis Bendele Bendele Engineering	K120552
2015-1863	03/09/2015 04/06/2015	FDA/OMPT/CDRH/OCER/DFOI/	Travis Bendele Bendele Engineering	K111250
2015-1864	03/09/2015 04/06/2015	FDA/OMPT/CDRH/OCER/DFOI/	Travis Bendele Bendele Engineering	K093642
2015-1865	03/09/2015 04/06/2015	FDA/OMPT/CDRH/OCER/DFOI/	Travis Bendele Bendele Engineering	K091718
2015-1866	03/09/2015 04/06/2015	FDA/OMPT/CDRH/OCER/DFOI/	Mark McGlothlin Apex Medical Technologies, Inc.	K052396
2015-1867	03/09/2015 04/06/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Teresa Reed Teresa Reed	ZOFRAN - AERS
2015-1868	03/09/2015 04/06/2015	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	SILVERFOILTURBES SE RECS
2015-1869	03/09/2015 04/06/2015	FDA/OMPT/CDRH/OCER/DFOI/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	K123653
2015-1870	03/09/2015 04/06/2015	FDA/OMPT/CDRH/OCER/DFOI/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	K14481
2015-1871	03/09/2015 04/06/2015	FDA/OMPT/CDRH/OCER/DFOI/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	K143155
2015-1872	03/09/2015 05/11/2015	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	CTP EXPANDED CONFLICT OF INTEREST CRITERIA, REVIEW/SCREENING OF TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE MEMBERS SINCE JAN 2015
2015-1873	03/09/2015 04/06/2015	FDA/OMPT/CDRH/OCER/DFOI/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	BLA 125160 S 213
2015-1874	03/09/2015 04/06/2015	FDA/OMPT/CDRH/OCER/DFOI/	Nathan Williams personal	K070598
2015-1875	03/09/2015 04/06/2015	FDA/OMPT/CDRH/OCER/DFOI/	Nathan Williams personal	K133520

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2015-1876	03/09/2015 04/06/2015	FDA/OMPT/CDRH/OCER/DFOI/	THERESA A APPELBAUM Padberg, Corrigan & Appelbaum	MEDTRAD INC, INDIANOLA, PA - AVANTA FLUID MANAGEMENT INJ SYS (CERTIFIED)
2015-1877	03/09/2015 04/06/2015	FDA/OC/OES/DFOI/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	PATRICIA L REGENYE Celgene Corporation	ALAMO MED RES, ERIC LAWITSZ, SAN ANTONIO, TX - 483S 5/10 TO PRESENT
2015-1878	03/09/2015 04/06/2015	FDA/OC/OES/DFOI/ FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	PATRICIA L REGENYE Celgene Corporation	ROBERT HERRING, NASHVILLE, TN - 483S 6/09 TO L PRESENT
2015-1879	03/09/2015 04/06/2015	FDA/OC/OES/DFOI/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	PATRICIA L LREGENYE Celgene Corporation	STANFORD UNIV, KRISTEN GANJOO, STANFORD, CA - 483S 4/08 TO PRESENT
2015-1880	03/09/2015 04/06/2015	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PATRICIA L REGENYE Celgene Corporation	CHU RANGUEIL/ SERV DE NEPHROLOGIE TRANSPLANTATION D-ORGANE, TOULOUSE, FRANCE - 483S 12/09 TO PRESENT
2015-1881	03/09/2015 04/06/2015	FDA/OC/OES/DFOI/ FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	PATRICIA L REGENYE Celgene Corporation	NORTHWESTER UNIV, LEO GORDON, CHICAGO, IL - 483S 3/01 TO PRESENT
2015-1882	03/09/2015 04/06/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	JUSTIN CHOU Walkup, Melodia, Kelly and Schoenberger	TFS MANUFACTURING PTY LTD, NORTH PLYMPTON, SOUTH AUSTRALILA - TISSUE FIXATION SYS K0540418
2015-1883	03/09/2015 04/06/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WILLIAM MCINTRE LUPIN PHARMACEUTICALS INC	FRESENIUS KABI - DIPRIVAN (PROPOFOL) INJ EMUISSION NDA 19-627 FORM 3542
2015-1884	03/09/2015 04/06/2015	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	CLASS ONE MEDICAL DVC - CMPNT
2015-1885	03/09/2015 04/06/2015	FDA/OMPT/CDRH/OCER/DFOI/	SUSAN D GOLDSTEIN-FALK MDI CONSULTANTS INC	LIVECOR - LIVECOR HEART MONITOR K142743, LIVECOR HEAT MONITOR OTC K130921
2015-1886	03/09/2015 04/06/2015	FDA/OMPT/CDRH/OCER/DFOI/	MARILYNN WHITNEY COVINGTON BURLING LLP	CIANNA MEDICAL - SGS TUSSUE MARKER & SYS DVC K141318
2015-1887	03/09/2015 04/06/2015	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	WAYNE SADOWSKI NOVARTIS PHARMACEUTICAL CORP	DR GREGORY L BEATTY, PHILADELPHIA, PA 10/29-11/6/14; DR NOELLE V FREY, PHILADELPHIA 11/3-12/14; DR MARCELA MAUS, OPHILADELPHIA, PA 11/12-17/14, - EIRS, 483S, CO RESP ETC

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2015-1888	03/09/2015 04/06/2015	FDA/OGROP/ORR/SE-FO/NOL-DO/NOL-CB/	JOHN BAUGH EMILIA RESOURCES LLC	PHARMA PAC LLC, DEKALB, MS - EIRS 1118/13-12/06/13
2015-1889	03/09/2015 04/06/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JAY S TRIVEDI PATRIN PHARMA INC	HELSINN HEALTHCARE - PALONOSETRON HCL CAPS ORAL (ALOXI) NDA 22-233 SBS
2015-1890	03/09/2015 04/06/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LAKEITH AMIR-SHARIF LAMIR-SHARIF #150596, LAKEITH	TEGRETOL, GEODON, DILANTIN, ETC - AERS
2015-1891	03/09/2015 04/06/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KATHLEEN R HENRY Hyman Phelps and McNamara PC	DOMPERIDONE - SBA
2015-1892	03/09/2015 04/06/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	STEFAN ELLIS PEPPER HAMILTON LLP	PROZAC (FLUOXITINE) NDA 18-936 - CORR, DRAFTS, RVWS, ETC
2015-1893	03/09/2015 04/06/2015	FDA/OC/OES/DFOI/	Lauren Miller N/A	PURINA - COMPLAINTS, TESTING, ETC 03/01/2011 - 03/03/2015
2015-1894	03/09/2015 04/06/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Katherine Eban FORTUNE MAGAZINE	MIKE GAVINI, PETER BAKER - INSPECTIONS IN INDIA 01/01/1999 - 12/31/2014
2015-1895	03/09/2015 04/06/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bhagwan Chaudhary Sunidhi Securities & Finance Ltd	SHILPA MEDICARE LTD, INDIA - 483 03/02/2015 - 03/07/2015
2015-1896	03/09/2015 04/06/2015	FDA/OGROP/ORR/CE-FO/MIN-DO/MIN-CB/	Martin Lueders Lueders, Martin J	EXPRESS DIAGNOSTICS INTERNATIONAL, INC - EIR, COMM, MEETING ETC 06/01/2014 - 03/06/2015
2015-1897	03/09/2015 04/06/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	IPCA, INDIA - 483

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		FDA/OMPT/CDER/GRP/DIDP/		
2015-1898	03/09/2015 04/06/2015	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	Chastity Rodriguez Rodriguez, Chastity	PRAZAIR DISTRIBUTION INC, SOUTHEAST LLC - WARNING LETTER, 483 03/06/2012 - 03/06/2015
2015-1899	03/09/2015 04/06/2015	FDA/OMPT/CDRH/OCER/DFOI/	Mor Buchshtav Medinol Ltd.	K110134
2015-1900	03/09/2015 04/06/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	David Mangione Govzilla, Inc.	EUROGENTEC, BELGIUM - EIR, 483 12/19/2014 - 12/19/2014
2015-1901	03/09/2015 04/06/2015	FDA/OFVM/CFSAN/OCD/EOS/	Tom Alexander INDIVIDUAL	MIRACULIN, MIRACLE FRUIT, SYNSEPALUM DULCIFICUM - RECS RE FOOD ADDITIVE DENIAL, GRAS RECS 06/01/1974 - 12/31/1977;
2015-1902	03/09/2015 04/06/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MOHAMMED ABDULLAH ALNEMER King Saud bin Abdulaziz University for Health sciences (KSAU-HS)	VINBLASTINE - CASE REPORTS
2015-1903	03/09/2015 04/06/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Glenn Brandys Kim Orr Barristers	TOLBUTAMIDE, PROBENECID, SACCHARIN ETC - APPLICATIONS, FORMULAS, APPROVALS ETC 01/01/1967 - 12/31/1982
2015-1904	03/09/2015 04/06/2015	FDA/OFVM/CFSAN/OCD/EOS/	Scott Thenell THENELL & ASSOCIATES LLC	FOOD SAFETY AND NUTRITIONAL ASSESSMENT OF GENETICALLY ENGINEERED SUGAR BEET EVENT H7-1
2015-1905	03/09/2015 04/06/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Zainab Jafar Zainab Jafar	CHANTIX - AERS
2015-1906	03/09/2015 04/06/2015	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	CPT 1400960
2015-1907	03/09/2015 04/06/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michael Telliard Horizon Pharma Inc.	DIVI LABORATORIES, INDIA - EIR 05/01/2014 - 07/06/2014
2015-1908	03/09/2015 04/06/2015	OC/ORR/ OC/ORR/	WILLIAM WEST SEEGRILLER SEEGRILLER LAW FIRM	KELLOGG'S - MINI--WHEATS RECALL DUE TO METAL MESH CONTAMINATION

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2015-1909	03/09/2015 04/06/2015	FDA/OC/OES/DFOI/	KAREN NUNEZ NUNEZ, KAREN	PROCESS THAT GOES THROUGH WHEN A COSMETIC PROD IS BEING TESTED
2015-1910	03/09/2015 04/06/2015	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/	Doe J	MARUCHAN NOODLES - CMLNT
2015-1911	03/09/2015 04/06/2015	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	CHARLES CELESTE EAS CONSULTING GROUP LLC	TURMERIC UKON CAPS ENTRY# U52-0788484-7 - ANALYTICAL W/S, TESTING METHODS
2015-1912	03/09/2015 04/06/2015	FDA/OO/OFBA/OAGS/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JAYNE O'DONNELL USA TODAY	HHSF2232010000081
2015-1913	03/09/2015 04/06/2015	OC/ORO/ORM/ OC/ORO/ORM/	GAIL LESSICK LACHMAN CONSULTANT SERVICES, INC.	FORIGIN & DOMESTIC DRUG COMPANIES, MEDICAL DVC MFRS, BLOOD ESTABLISHMENTS, ETC - INSPS 1/1-31/15
2015-1914	03/09/2015 04/06/2015	FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/ OC/ORO/ OC/ORO/	Doe J	CMLNT
2015-1915	03/09/2015 04/06/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michael Telliard Horizon Pharma Inc.	DR REDDY'S LABORATORIES, INDIA - 483 01/26/2015 - 02/20/2015
2015-1916	03/09/2015 04/06/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sarah Wong-Goodrich BGB Group	GILENYA - AERS
2015-1917	03/09/2015	FDA/OMPT/CDER/ORP/DIDP/	Sue Sutter	BLA 125553

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	04/06/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	[no person],	
2015-1918	03/10/2015 04/07/2015	FDA/OMPT/CDRH/OCER/DFOI/	Joanne Doroshow Center for Justice & Democracy at New York Law School	2012 DIALYSATE CONCENTRATES, ALKALI DOSING ERRORS WITH HEMODIALYSIS SAFETY COMMUNICATION
2015-1919	03/10/2015 04/07/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John Fauber MILWAUKEE JOURNAL SENTINEL	VYVANSE - BRIEFING RECS, MEDICAL REVIEWS 01/01/2013 - 03/07/2015
2015-1920	03/10/2015 04/07/2015	OC/ORAOE/ OC/ORAOE/ OC/ORAOE/ OC/ORAOE/ FDA/OMPT/CDRH/OCER/DFOI/	Jean Xiao Vanderbilt Law and Economics Program	MEDICAL DEVICE RECALL DATA
2015-1921	03/10/2015 04/07/2015	OC/ORAOE/ OC/ORAOE/ OC/ORAOE/ OC/ORAOE/	Jean Xiao Vanderbilt University, Graduate Student	DRUG RECALL DATA
2015-1922	03/10/2015 04/07/2015	OC/ORAOE/ OC/ORAOE/	Jean Xiao, Graduate Student VANDERBILT UNIVERSITY	INSPECTIONS DATA
2015-1923	03/10/2015 04/07/2015	FDA/OMPT/CDRH/OCER/DFOI/	Jean Xiao, Graduate Student Vanderbilt Law and Economics Program	MEDICAL DEVICE RECALL REPORT FY2003, FY2012 DATA SPREADSHEET
2015-1924	03/10/2015 04/07/2015	OC/ORAOE/ OC/ORAOE/ OC/ORAOE/ OC/ORAOE/	Jean Xiao, Graduate Student VANDERBILT UNIVERSITY	MEDICAL DEVICE RECALLS BEFORE 2002
2015-1925	03/10/2015 04/07/2015	FDA/OC/OES/DFOI/	Lara Simmons Chester Packaging	2000 WARNING LETTER TO CHESTER LABS, INC, CINCINNATI, OH
2015-1926	03/10/2015 04/07/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Peter R. Breggin, MD Peter R. Breggin, MD	BUPROPION PRODUCTS - AERS

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2015-1927	03/10/2015 04/07/2015	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	VAAGE - FOIA REQUESTS
2015-1928	03/10/2015 04/07/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Thomas Harvey Dynport Vaccine Company LLC, a CSC Company	STAFF MANUAL GUIDE 4850.7
2015-1929	03/10/2015 04/07/2015	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	INFUSE - FOIA REQUESTS
2015-1930	03/10/2015 04/07/2015	FDA/OGROP/ORR/SE-FO/FLA- DO/FLA-CB/	Jeanine Gouveia Aerie Pharmaceuticals Inc.	BAUSH & LOMB, TAMPLA, FL - 483 03/04/2015 - 03/06/2015
2015-1931	03/10/2015 04/07/2015	FDA/OC/OES/DFOI/	Nathan Jensen MMK Capital Group LLC	LIST OF FOIA REQUESTS SUBMITTED 01/01/2014 - 12/31/2014
2015-1932	03/10/2015 04/07/2015	FDA/OMPT/CDRH/OCER/DFOI/	Terri Wallace Polymed Therapeutics, Inc.	K103277
2015-1933	03/10/2015 04/07/2015	OC/ORR/ OC/ORR/	Evan Stulberger WNBC-TV	FOOD ALLERGY ADVISORY LABEL COMPLAINTS 01/01/2012 - 03/09/2015
2015-1934	03/10/2015 04/07/2015	FDA/OMPT/CDRH/OCER/DFOI/	Terri Wallace Polymed Therapeutics, Inc.	K133968
2015-1935	03/10/2015 04/07/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 205552 S 2
2015-1936	03/10/2015 04/07/2015	FDA/OGROP/ORR/CE-FO/PHI- DO/PHI-CB/	Rockline Industries ROCKLINE INDUSTRIES	NUTEK DISPOSABLES, ELHATTAN, PA - EIR 10/01/2014
2015-1937	03/10/2015 04/07/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sarah Wong-Goodrich BGB Group	GILENYA - AERS
2015-1938	03/10/2015 04/07/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	MICHAEL MANCINELLI CONWAY HOMER & CHIN- CAPLAN PC	INDIVIDUAL RECS
2015-1939	03/10/2015 04/07/2015	FDA/OMPT/CDRH/OCER/DFOI/ OC/ORR/OCI/	BONNA SMITH BOND BOND, BONNA SMITH	DR MARCELLO PIETRANTONI - CASE #2012-CIO-713-0124

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		OC/ORO/OCI/		
2015-1940	03/10/2015 04/07/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WILLIAM MCINTYRE PHD LUPIN PHARMACEUTICALS INC	FRESENIUS KABI - DIPRIVAN (PROPOFOL) NDA 19-627 FORM 3542
2015-1941	03/10/2015 04/07/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JIM FAUCETT NORTHWEST CLINICAL RESEARCH CTR	NAMZARIC (MEMANTINE HCL ER) NDA 206-439 SBA
2015-1942	03/10/2015 04/07/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JACQUELINE J CHAN K&L Gates LLP	WOCKHARDT - FEXOFENADINE ANDA 79-112 CORR, MTG MINS, APRVL LTRS, ETC
2015-1943	03/10/2015 04/07/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	IAN M SACK DAVIS & FERBER LLP	REGANEX - STUDIES, TESTINGS, BLACK BOX WARNINGS, ETC
2015-1944	03/10/2015 04/07/2015	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/ OC/ORO/	JANET M FLAHERTY Abbott Nutrition	INFANT FORMULA MFRS IN OR OUTSIDE THE US 1/1/13 TO 3/5/15
2015-1945	03/10/2015 04/07/2015	FDA/OGROP/ORO/NE-FO/NWE- DO/NWE-CB/	PAUL B CALLAHAN CHARLES RIVER LABS	CHARLES RIVER LABORATORIES INC, WILMINGTON, MA - EIR 5/29/14
2015-1946	03/10/2015 04/07/2015	FDA/OC/OES/DFOI/	JOANNE E MATUSKO NastLaw, LLC	GLAXOSMITHKLINE - ZOFTRAN INVESTIGATIONS, RPTS, STUDIES, ETC 1/87 TO 12/06
2015-1947	03/10/2015 04/07/2015	FDA/OC/OES/DFOI/	JOANNE E MATUSKO NastLaw, LLC	ONDANSETRON - PROCEDURE MANUALS, APRVL RECS, INSPS, ETC 12/06 TO PRESENT
2015-1948	03/10/2015 04/07/2015	FDA/OMPT/CDRH/OCER/DFOI/	RON BOWMAN OPTICAL INTEGRITY INC	MICROQUART MEDICAL INC - QUADRALASE ADJUSTABLE SIDE-FIRING LASER FIBER K952974
2015-1949	03/10/2015 04/07/2015	FDA/OC/OES/DFOI/	MARY LYONS KAYE SCHOLER LLP	FOI DAILY LOG 6/13 TO PRESENT
2015-1950	03/10/2015 04/07/2015	FDA/OC/OES/ FDA/OC/OL/	KRYSTAL L RAMIREZ RAMIREZ, KRYSTAL L	MICHAEL PENCE - RPTS, CMLNPTS, INVESTIGATIONS, ETC 1991 TO PRESENT
2015-1951	03/10/2015	FDA/OC/OES/	TYLER KOTKIN	PIYUSH "BOBBY" JINDAL - CMLNPTS, RPTS,

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	04/07/2015	FDA/OC/OL/	KOTKIN, TYLER	INVESTIGATIONS, ETC 1996 TO PRESENT
2015-1952	03/10/2015 04/07/2015	FDA/OC/OES/ FDA/OC/OL/	CLAIRE VINOCUR VINOCUR, CLAIRE	JOHN KASICH - CMLPNTS, RPTS, INVESTIGATIONS, ETC 1983 TO PRESENT
2015-1953	03/10/2015 04/07/2015	FDA/OC/OES/ FDA/OC/OL/	KELLY ROBERT ROBERTS, KELLY	RANDAL "RAND" PAUL - CMLPNTS, RPTS, INVESTIGATIONS, ETC 1990 TO PRESENT
2015-1954	03/10/2015 04/07/2015	FDA/OC/OES/ FDA/OC/OL/	ERIC BENNETT BENNETT, ERIC	JAMES RICHARD "RICK" PERRY - CMLPNTS, RPTS, INVESTIGATIONS, ETC 1972 TO 2015
2015-1955	03/10/2015 04/07/2015	FDA/OC/OES/ FDA/OC/OL/	PATRICK STRANIX STRANIX, PATRICK	JOHN ELLIS "JEB" BUSH - CMLPNTS, RPTS, INVESTIGATIONS, ETC 1974 TO 2015
2015-1956	03/10/2015 04/07/2015	FDA/OC/OES/ FDA/OC/OL/	ERIC BENNETT BENNETT, ERIC	RAFAEL EDWARD "TED" CRUZ - CMLPNTS, RPTS, INVESTIGATIONS, ETC 1995 TO PRESENT
2015-1957	03/10/2015 04/07/2015	FDA/OC/OES/ FDA/OC/OL/	MICHAEL KANE KANE, MICHAEL	CHRISTOPHER "CHRIS" J CHRISTIE - CMLPNTS, RPTS, INVESTIGATIONS, ETC 1987 TO PRESENT
2015-1958	03/10/2015 04/07/2015	FDA/OC/OES/DFOI/	BRYAN KOENIG FDA NEWS	DKT 2014D-1891-001
2015-1959	03/10/2015 04/07/2015	FDA/OC/OES/DFOI/	SPENCER FOGEL VENABLE LLP	1995G-GRAS-0009
2015-1960	03/10/2015 04/07/2015	FDA/OC/OES/DFOI/	RANDY CHAVEZ REGENESIS BIOMEDICAL INC	DKT 2012N-0378
2015-1961	03/10/2015 04/07/2015	FDA/OC/OES/DFOI/	CHRIS CELESTE EAS CONSULTING GROUP LLC	42 FR 38608-38615
2015-1962	03/10/2015 04/07/2015	FDA/OC/OES/DFOI/	CHRIS CELESTE EAS CONSULTING GROUP LLC	43 FR 146641-14644; 49 FR 5608-5614; 50 FR 49535-49537
2015-1963	03/10/2015 04/07/2015	FDA/OC/OES/DFOI/	NATALIE SANDERS LATHAM WATKINS LLP	DKT 2014N-1051
2015-1964	03/10/2015 04/07/2015	FDA/OC/OES/DFOI/	CARLA DARMACCY DARMACCY, CARLA	DKT 2014D-1692
2015-1965	03/10/2015 04/07/2015	FDA/OC/OES/DFOI/	IVAN YOTOV LATHAM WATKINS LLP	DKT 2014N-1051
2015-1966	03/10/2015 04/07/2015	FDA/OC/OES/DFOI/	HERBERT GERSENZANE GERSENZANE, HERBERT	OTC VOLS 070099, 070126, 070168
2015-1967	03/10/2015 04/07/2015	FDA/OFVM/CFSAN/OCD/EOS/	JOSEPH N STROBLE BRADLEY ARANT BOULT	SYNGENTA SEEDS INC - MAIZE EVENT MIR162, BNF 113, BNF 128, ETC RECS

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			CUMMINGS LLP	
2015-1968	03/10/2015 04/07/2015	FDA/OC/OES/DFOI/	CHRIS TURNER SWANKIN & TURNER	DKT 2012P-0904
2015-1969	03/11/2015 04/08/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Wonsun Chung LAB	CAS MEDICAL SYSTEMS, INC FORE-SIGHT ELITE ABSOLUTE TISSUE MONITOR 510K RECS
2015-1970	03/11/2015 04/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Colleen Dominguez SAGE CHEMICALS	MIGRANAL NDA 20148 - CMC
2015-1971	03/11/2015 04/08/2015	FDA/OMPT/CDRH/OCER/DFOI/	Wonsun Chung LAB	FORE-SIGHT CEREBRAL OXIMETE MONITOR MC-2000 510K RECS
2015-1972	03/11/2015 04/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Observation report on Waluj plant of Wockhardt Ltd. Baljit Securities Pvt. Ltd.	WOCKHARDT LTD, INDIA - 483 02/01/2015 - 02/28/2015
2015-1973	03/11/2015 04/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Emily Krulewitz The Weinberg Group	NDA 050605 S 17 SBA
2015-1974	03/11/2015 04/08/2015	FDA/OMPT/CDRH/OCER/DFOI/	Laura Anderson Slate Magazine	K871358
2015-1975	03/11/2015 04/08/2015	FDA/OMPT/CDRH/OCER/DFOI/	Laura Anderson Slate Magazine	K902936
2015-1976	03/11/2015 04/08/2015	FDA/OMPT/CDRH/OCER/DFOI/	Laura Anderson Slate Magazine	K922688
2015-1977	03/11/2015 04/08/2015	FDA/OMPT/CDRH/OCER/DFOI/	Laura Anderson Slate Magazine	K942697
2015-1978	03/11/2015 04/08/2015	FDA/OMPT/CDRH/OCER/DFOI/	Laura Anderson Slate Magazine	K955672
2015-1979	03/11/2015 04/08/2015	FDA/OMPT/CDRH/OCER/DFOI/	Laura Anderson Slate Magazine	K011480
2015-1980	03/11/2015 04/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michele Sinoway LACHMAN CONSULTANT	NDA 12885

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SERVICES, INC.	
2015-1981	03/11/2015 04/08/2015	FDA/OMPT/CDRH/OCER/DFOI/	Laura Anderson Slate Magazine	K122219
2015-1982	03/11/2015 04/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Morgan Rettig LATHAM WATKINS LLP	SUBMISSION TO THE FDA OFFICE OF PRESCRIPTION DRUG PROMOTION RE EXPAREL 11/28/2011 - 03/10/2015
2015-1983	03/11/2015 04/08/2015	FDA/OMPT/CDRH/OCER/DFOI/	Kate Leslie Hamilton Thorne, Inc.	K141434
2015-1984	03/11/2015 04/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tushar Manudhane Indianivesh securities	SHILPA MEDICARE LTD, INDIA - 483 01/01/2015 - 03/09/2015
2015-1985	03/11/2015 04/08/2015	FDA/OC/OES/DFOI/	Paige Stradley MERCHANT & GOULD	ONCOLOGIC DRUGS ADVISORY COMMITTEE - 1/31/02 TRANSCRIPT (CERTIFIED)
2015-1986	03/11/2015 04/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	Paige Stradley MERCHANT & GOULD	ONCOLOGIC DRUGS ADVISORY COMMITTEE FINAL AGENDA 1/31/02
2015-1987	03/11/2015 04/08/2015	FDA/OMPT/CDRH/OCER/DFOI/	Adam Wasch Wasch Law LLP	K091875
2015-1988	03/11/2015 04/08/2015	FDA/OMPT/CDRH/OCER/DFOI/	Amerx Health Care Corp. Arrastia Capote Partners	K112666
2015-1989	03/11/2015 04/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mehmet Ozcan The University of Oklahoma Dept of Anesthesiology	PROPOFOL - AERS
2015-1990	03/11/2015 04/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Harshitha Talluri Appco Pharmaceutical Corporation	ANDA 075074 SBA

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2015-1991	03/11/2015 04/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Daniel Bernier Hospira, Inc.	CELLTRION - 483 01/01/2015 - 03/10/2016
2015-1992	03/11/2015 04/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Cristina Ghenoiu COWEN AND COMPANY	TECFIDERA LABEL CHANGES
2015-1993	03/11/2015 04/08/2015	FDA/OMPT/CDRH/OCER/DFOI/	Timothy Schweizer Medical Componets, Inc	MEDICAL COMPONENTS, INC - 483 01/01/2012 - 12/30/2012
2015-1994	03/11/2015 04/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Hee Chul Chang Daewoong America Inc.	EMEND - STABILITY TEST INFORMATION 03/25/2002 - 09/28/2012
2015-1995	03/11/2015 04/08/2015	FDA/OMPT/CDRH/OCER/DFOI/	Laura Anderson Slate Magazine	K901202
2015-1996	03/11/2015 04/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ann Agnor BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.	BLA 125527 S-000
2015-1997	03/11/2015 04/08/2015	FDA/OMPT/CDRH/OCER/DFOI/	chris hannan Remote Diagnostic Technologies Ltd.	K142915
2015-1998	03/11/2015 04/08/2015	FDA/OMPT/CDRH/OCER/DFOI/	Brian Gall Teleflex, Inc	K994074
2015-1999	03/11/2015 04/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kuamra Sekar MICRO LABS USA INC	ANDA 090874 SBA
2015-2000	03/11/2015 04/08/2015	OC/ORA/ OC/ORA/	Alison J Cherney CEO Ionia Pharmacy	IONIA PHARMACY - COMPLAINTS, LAB RESULTS 01/01/2015 - 03/10/2015
2015-2001	03/11/2015 04/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 71961

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2015-2002	03/11/2015 04/08/2015	FDA/OGROP/ORR/CE-FO/PHI-DO/PHI-CB/	Strides Pharma Inc Strides Pharma Inc.	SIGNAPHARM LABORATORIES, LLC, BENSALEM, PA - EIR 01/01/2014 - 03/10/2015
2015-2003	03/11/2015 04/08/2015	FDA/OMPT/CDRH/OCER/DFOI/	PATRICIA SCHNOOR CAPILLUS LLC	CAPPILLUS LLC - K143199
2015-2004	03/11/2015 04/08/2015	FDA/OMPT/CDRH/OCER/DFOI/	ANDRREW M GAMMILL DINSMORE & SHOHL LLP	OCULAR SYSTEMS INC - ENDOSERTER K090626
2015-2005	03/11/2015 04/08/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHERYL SSOKOL SSOKOL, SHERYL	INTAS - 483 2013
2015-2006	03/11/2015 04/08/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MICHAEL R COHEN INSTITUTE FOR SAFE MEDICATION PRACTICES	MEDWATCH RPTS CODED AS MEDICATION ERRORS 2/1-28/15
2015-2007	03/11/2015 04/08/2015	FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/	LESLIE RAMSEY FDA NEWS	GILEAD SCIENCES - 483 5/16/14
2015-2008	03/11/2015 04/08/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/ORR/ OC/ORR/	MAJORIE CHALFANT RN JD THE NURSE ATTORNEY PA	FRANCK'S PHARMACY/FRANCK'S COMPOUNDING LAB - BRILLIANT BLUE G (BBG) INJ, PRESERVATIVE-FEE; TRIAMCINOLONE INJ, PRESERVATIVE-FREE COMPOUNDED RECS
2015-2009	03/11/2015 04/08/2015	FDA/OC/OES/DFOI/ FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/	PATRICIA L REGENYE Celgene Corporation	ROBERT AMAETO, BAYLOR COLL MED/SEC GENITOURINARY ONCOLOGY, HOUSTON TX \- 4813S 8/25 TO PRESENT
2015-2010	03/11/2015 04/08/2015	FDA/OC/OES/ FDA/OMPT/CDRH/OCER/DFOI/	MICHAEL A CAROME MD PUBLIC CITIZEN	MASIMO CORP - PULSE OXIMETER SUPPORT STUDY INVESTIGATION RECS
2015-2011	03/11/2015 04/08/2015	FDA/OFVM/CFSAN/OCD/EOS/	DAVID HEATH CENTER FOR PUBLIC INTEGRITY	TEEGUARDEN JG, TWADDLE N, CHURCHWELL MI, ETC - BISHENOL A 24-HR HUMAN URINE & SERUM PROFILES; CHURCHWELL MI, CAMACHO L, VANLANDINGHAM, MM, ETC - COMPARISON OF LIFE-STAGE DEPENDENT INTERNAL DOSIMETRY FOR BISHENOL A, ETHINYL ESTRADIOL, ETC
2015-2012	03/11/2015	FDA/OFVM/CFSAN/OCD/EOS/	MICHELLE C JACKSON	DEHYDROPEIANDROSTENEDIONE (DHEA) - CAERS 1/10 TO

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	04/08/2015		VENABLE LLP	PRESENT
2015-2013	03/11/2015 04/08/2015	FDA/OMPT/OSMP/OCF/	MCKENZIE CATO Hyman, Phelps & McNamara P.C.	REQUESTS FOR DESIGNATION SUBMISSIONS AND DECISION REGARDING DRUG-ELUTING EMBOLIZATION BEADS, RADIATION-CONTAINING GLASS BEADS FOR CANCER TREATMENT, DRUG/BIOLOGIC EMBOLIZATION AGENTS, ETC
2015-2014	03/11/2015 04/08/2015	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDRH/OCER/DFOI/	WILLIAM C IVISON ESQ ADCOCK & MORRISON PLLC	CONAIR CORP, STAMFORD, CT - WARNING LTR RESPS, CMLPNTS, 483 5/31/13, ETC
2015-2015	03/11/2015 04/08/2015	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Doe J	CISPLATIN (CISPLATINUM), MERCURY (THIMEROSAL) - VAERS, FLU SHOTS VACCINE INFORMATION STATEMENT, ETC
2015-2016	03/11/2015 04/08/2015	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	K MICHELLE VASSALLO LINCARE INC	BBMK ENTERPRISES LLC, OXYCARE INC, MIDDLESEX HOME CARE & SUPPLIES INC, ETC - EIRS, 483S, WARNING LTRS 1/98 TO PRESENT
2015-2017	03/11/2015 04/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JACKIE HERNDON ZAREMBA BROWNELL & BROWN PLLC	KLONOPIN (CLONAZEPAM) - RECS (CERTIFIED)
2015-2018	03/11/2015 04/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	JOHNSON & JOHNSON, JANSSEN RESEARCH AND DEVELOPMENT - RISPERDAL AERS
2015-2019	03/11/2015 04/08/2015	FDA/OC/OES/DFOI/	DARNELL MCBRISE #356444 McBride, Darnell	CELEXA (CITALOPRAM) - RECS
2015-2020	03/11/2015 04/08/2015	FDA/OMPT/CDRH/OCER/DFOI/	Arrastia Capote Partners Arrastia Capote Partners	K123910
2015-2021	03/11/2015 04/08/2015	OC/ORO/ OC/ORO/	Alison J Cherney CEO Ionia Pharmacy	DR ROBERT LUPO, TAMPA, FL - COMPLAINT, TEST RESULTS 01/01/2015 - 03/09/2015
2015-2022	03/11/2015 04/08/2015	FDA/OFVM/CFSAN/OCD/EOS/	TSE-LING FONG MD UNIV OF CALIFORNIA KECK SCHOOL OF MEDICINE	TRIMETHY XTREME - DEMOGRAPHICS, PAST MEDICAL HISTORY, DATE OF ONSET OF SYMPTOMS, ETC

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2015-2023	03/11/2015 04/08/2015	FDA/OMPT/CDRH/OCER/DFOI/	Lyric Xia Shenzhen Hlongmed Biotech Co.,Ltd	K123806
2015-2024	03/11/2015 04/08/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	ISUPREL - APPROVAL RECS
2015-2025	03/11/2015 04/08/2015	FDA/OMPT/CDRH/OCER/DFOI/	Medical device 510K document- K092886 Shenzhen Hlongmed Biotech Co.,Ltd	K092886
2015-2026	03/11/2015 04/08/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ketaki Gokhale BLOOMBERG NEWS	WOCKHARDT LTD, INDIA - 483 02/01/2014 - 03/31/2015
2015-2027	03/11/2015 04/08/2015	OC/ORO/ORM/ OC/ORO/ORM/	LESLIE RAMSEY FDA NEWS	PHARMACEUTICALS, BIOLOGICS, MEDICAL DVC MFG, CLNCL TRIAL FACILITIES IN AND OUTSIDE THE US - 483S 2/1-28/15
2015-2028	03/11/2015 04/08/2015	FDA/OGROP/ORO/PA-FO/SEA-DO/SEA-CB/	Bharat Celly Research Delta	JUBILANT HOLLISTER, SPOKANE, WA - 483 11/01/2014 - 12/16/2014
2015-2029	03/11/2015 04/08/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/OSMP/OCP/	MCKENZIE CATO Hyman, Phelps & McNamara P.C.	NORDION INTERNATIONAL INC - THERASPHERE ADMINISTATION SYS REQUEST FOR DESIGNATION, HUMANITARION DVC EXEMPTION
2015-2030	03/11/2015 04/08/2015	FDA/OMPT/CDRH/OCER/DFOI/	Amerx Health Care Corp. Amerx Health Care Corporation	K092086
2015-2031	03/12/2015 04/09/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-1582
2015-2032	03/12/2015 04/09/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Robert Damon Robert Damon	SUGAMMADEX - AERS
2015-2033	03/12/2015 04/09/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-295
2015-2034	03/12/2015 04/09/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-302

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2015-2035	03/12/2015 04/09/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-303
2015-2036	03/12/2015 04/09/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-405
2015-2037	03/12/2015 04/09/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-506
2015-2038	03/12/2015 04/09/2015	FDA/OMPT/CDRH/OCER/DFOI/	Edward Kobus Invado Pharmaceuticals	K093642, K091718
2015-2039	03/12/2015 04/09/2015	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	STAR SCIENTIFIC, INC - REVIEW RECS FOR SE0000282, SE0000283, SE0000284, ETC
2015-2040	03/12/2015 04/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Robert Mahoney Robert Mahoney	ZOFRAN - AERS
2015-2041	03/12/2015 04/09/2015	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	JASH INTERNATIONAL, INC - REVIEW RECORDS RE SE0003441, SE0003442, SE0003443, ETC
2015-2042	03/12/2015 04/09/2015	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Allie Robinson Gibson Bristol Herald Courier	WEST HOPE DAIRY, LLC, SALTVILLE, VA - CORR WITH FDA, RESPONSE TO WARNING LETTER 02/03/2015 - 03/11/2015
2015-2043	03/12/2015 04/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Siobhan Innes-Gawn TULANE UNIVERSITY	ANDA 091211 078355 077686 ETC APPROVAL LETTERS
2015-2044	03/12/2015 04/30/2015	FDA/OMPT/CTP/OD/	Stacy Ehrlich Kleinfeld Kaplan and Becker LLP	LIST OF ALL PRODUCTS FOR WHICH CTP ISSUED GRANDFATHER DETERMINATIONS 03/01/2011 - 03/31/2015
2015-2045	03/12/2015 04/09/2015	FDA/OMPT/OSMP/OOPD/	Dr. Oliver Wingerter YES Pharma Services GmbH	TESTOSTERONE UNDECANOATE - ORPHAN DRUG DESIGNATION RECS
2015-2046	03/12/2015 05/14/2015	FDA/OC/OES/DFOI/ FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/ FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORACE-FO/DET-	SCHARBERG, DAVID L	INSP PERFORMED AT ANY FACILITY PERFORMING GLP NON CLNCL/BIOANALYTICAL TESTING 1/13 TO 12/131/13

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		DO/DET-CB/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/		
2015-2047	03/12/2015 04/09/2015	FDA/OMPT/CDRH/OCER/DFOI/	YURIDIA SANTOYO LG MEDICAL DESIGN LLC	MINDRAY DS USA INC - AS3700 ANESTHESIA DVC SYS - CERTIFICATES TO FOREIGN GOVERNMENT
2015-2048	03/12/2015 04/09/2015	FDA/OMPT/CDRH/OCER/DFOI/	ERIK PRENTICE PROACTIVE WORLDWIDE	THERANOS DVC TESTING PROCESS - RECS
2015-2049	03/12/2015 04/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PATRICIA L. REYGENYE Celgene Corporation	GUILIA BIANCHI, SC MEDICINA ONCOLOGICA, MILANO, ITALY - 483 7/13 TO PRESENT
2015-2050	03/12/2015 04/09/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	STRAIN, JEANNE	BAXTER HEALTHCARE - OSPA VACCINE CORP CLNCL TRIAL
2015-2051	03/12/2015 04/09/2015	FDA/OMPT/CDRH/OCER/DFOI/	J.P. SAWYER SAWYER LAW FIRM INC	BERLIN HEART INC - BERLIN HEART OUTFLOW ARTERIAL FLOW CANNULA MDR 4216597
2015-2052	03/12/2015	FDA/OMPT/CDRH/OCER/DFOI/	HORTENSE ALLISON MSC, RAC	STRYKER SUSTAINABILITY SOLUTIONS - REPROCESSED IIRMONIC ACE SHEARS W/O ADAPTIVE TISSUE

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	04/09/2015		ETHICON ENDO SURGERY INC	TECHNOLOGY K133672
2015-2053	03/13/2015 04/10/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rhona Baniqued Greenleaf Health	ZARXIO SUMMARY AND REVIEW 01/01/2015 - 04/30/2015
2015-2054	03/13/2015 04/10/2015	FDA/OMPT/CDRH/OCER/DFOI/	Mark Charest Ironwood Pharmaceuticals, Inc.	K011471
2015-2055	03/13/2015 05/21/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	John Chapman Stem Cell Partners LLC	BK130079
2015-2056	03/13/2015 04/10/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/OSMP/OOPD/	Rachel Johnson FOI Services, Inc.	TETRABENAZINE - ORPHAN DRUG DESIGNATION
2015-2057	03/13/2015 04/10/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ayesha Adil The Weinberg Group	ZARXIO - SBA
2015-2058	03/13/2015 04/10/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Christine Peterson REXAHN PHARMACEUTICALS INC	NDA 20-449 PEDIATRIC STUDY RECS
2015-2059	03/13/2015 04/10/2015	OC/ORA/ OC/ORA/	Amar Eldaher American Pharmaceutical Ingredients, LLC	MEDISCA INC, PLATTSBURGH, NY; LETCO MEDICAL, DECATUR, AL; PROFESSIONAL COMPOUNDING CENTERS OF AMERICA, HOUSTON, TX - EIR, 483 01/01/2012 - 03/12/2015
2015-2060	03/13/2015 04/10/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	C Eve J Kimball All About Children Pediatric Partners PC	TUBERSOL - AERS
2015-2061	03/13/2015 04/10/2015	FDA/OMPT/OSMP/OOPD/	Rachel Johnson FOI Services, Inc.	TETRABENAZINE - ORPHAN DESIGNATION FOR HUNTINTON'S 12/11/97

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2015-2062	03/13/2015 04/10/2015	FDA/OMPT/OSMP/OOPD/	Rachel Johnson FOI Services, Inc.	TETRABENAZINE - ORPHAN DESIGNATION FOR TOURETTE'S
2015-2063	03/13/2015 04/10/2015	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Christopher Ott not applicable	YOUNG PHARMACEUTICALS, WETHERSFIELD, CT - EIR, 483 01/01/2010 - 03/12/2015
2015-2064	03/13/2015 04/10/2015	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	Le-Van Nguyen Allergen Research Corporation	PATHEON PUERTO RICO, INC, MANATI, PR - EIR 2013, 2014 06/01/2013 - 09/30/2014
2015-2065	03/13/2015 04/10/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shahid Ahmed Nexus Pharmaceuticals Inc	CENEXI LABORATORIES THISSEN, BELGIUM - EIR 03/27/2014 - 04/15/2014;
2015-2066	03/13/2015 04/10/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bobby W. Sandage, Jr., Ph.D. St. Louis College of Pharmacy	AVEED - AERS
2015-2067	03/13/2015 04/10/2015	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	KIM C CAPONE PORZIO LIFE SCIENCES	MEDECOR PHARMA LLC, BATON ROUGE, LA - EIRS, 483S 12/4/14
2015-2068	03/13/2015 04/10/2015	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	KIM C CAPONE PORZIO LIFE SCIENCES	JAYMAC PHARMACEUTICALS LLC, SUNSET, LA - EIRS, 483S 4/21/14
2015-2069	03/13/2015 04/10/2015	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	AURELIA BROWNRIDGE SALTER LABS	BEEVERS MANUFACTURING & SUPPLY INC, BEEVERS MEDICAL SOLUTIONS, MCMINNVILLE, OR - EIRS 6/24/14-7/7/14
2015-2070	03/13/2015 04/10/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LESLIE FRANZ FRANZ, LESLIE	INVOKANA - AERS
2015-2071	03/13/2015 04/10/2015	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	PATRICIA L REGENYE Celgene Corporation	AJAY GOPAL, SEATTLE CA CARE ALLIANCE, SEATTLE, WA - 483S 4/11 TO PRESENT
2015-2072	03/13/2015 04/10/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANIL K HLTESHI SPECTRUM PHARMACEUTICALS INC	FUSLLEV (LEVOLEUCOVORIN) - NDA 20-140/S002, FUSLLEV (LEVOLEUCOVORIN CALCIUM) - NDA 20-140/S11 UNREDATED RVWS
2015-2073	03/13/2015 04/10/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MADHU DAN HARIHARAN PATRIN PHARMA INC	PERRIGO ISRAEL - FLUCINOLONE ACETONIDE ANDA 20-2847 SBA

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		FDA/OMPT/CDER/GRP/DIDP/		
2015-2074	03/13/2015 04/10/2015	FDA/OC/OES/DDM/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHELSEA PALCHER HOGAN LOVELLS LLP	DKT FDA-2014-P-1615
2015-2075	03/13/2015 04/10/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHELSEA PALCHER HOGAN LOVELLS LLP	SANDOZ INC - LEVOLEUCOVORIN CALCIUM ANDA 20-563 RVWS
2015-2076	03/13/2015 04/10/2015	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OFVM/CFSAN/OCD/EOS/	ARLENE MORALES BURDOCK GROUP	GRN 137
2015-2077	03/13/2015 04/10/2015	FDA/OC/OES/DDM/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHELSEA PALCHER HOGAN LOVELLS LLP	DKT FDA-2014-P-1649
2015-2078	03/13/2015 04/10/2015	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OFVM/CFSAN/OCD/EOS/	WILL BLOCK LIFE ENHANCEMENT MAGAZINE	METHODS FOR DETERMINING THE TOTAL LAMOUNT OF VITAMIN C IN A DIETARY SUPPL
2015-2079	03/13/2015 04/10/2015	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OFVM/CFSAN/OCD/EOS/	VISAGINE VIJAYAKULASINGAM IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS - 181758, 182431, 182803, ETC -
2015-2080	03/13/2015 04/10/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MINYARD DAVIS DAVIS 30180, MINYARD	FY 2013 PDUFA PERFORMANCE RPTS
2015-2081	03/13/2015 04/10/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Samer Shkoukani BIOPHARM INSIGHT	NDA 205677 MEDWATCH REPORTS
2015-2082	03/13/2015 04/10/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Samer Shkoukani BIOPHARM INSIGHT	NDA 204569 MEDWATCH REPORTS

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2015-2083	03/13/2015 04/10/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Samer Shkoukani BIOPHARM INSIGHT	NDA 203567 MEDWATCH REPORTS
2015-2084	03/13/2015 04/10/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Samer Shkoukani BIOPHARM INSIGHT	NDA 205122 MEDWATCH REPORTS
2015-2085	03/13/2015 04/10/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Samer Shkoukani BIOPHARM INSIGHT	NDA 206256 MEDWATCH REPORTS
2015-2086	03/13/2015 04/10/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Samer Shkoukani BIOPHARM INSIGHT	NDA 205858 MEDWATCH REPORTS
2015-2087	03/13/2015 04/10/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Samer Shkoukani BIOPHARM INSIGHT	NDA 202293 MEDWATCH REPORTS
2015-2088	03/13/2015 04/10/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Samer Shkoukani BIOPHARM INSIGHT	NDA 205437 MEDWATCH REPORTS
2015-2089	03/13/2015 04/10/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Samer Shkoukani BIOPHARM INSIGHT	RAGWITEK - MEDWATCH REPORTS
2015-2090	03/13/2015	OC/ORP/		INDIVIDUAL RECS

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	04/10/2015	OC/ORA/ FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	Doe J	
2015-2091	03/13/2015 04/10/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Samer Shkoukani BIOPHARM INSIGHT	BLA 125431 MEDWATCH REPORTS
2015-2092	03/13/2015 04/10/2015	FDA/OMPT/CDRH/OCER/DFOI/	Jens Quistgaard Jens Quistgaard	K800101
2015-2093	03/13/2015 04/10/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Samer Shkoukani BIOPHARM INSIGHT	BLA 125476 MEDWATCH REPORTS
2015-2094	03/13/2015 04/10/2015	FDA/OC/OES/DDM/	Ryan O'Callaghan Phil Triolo and Associates	DKT 80N-0042
2015-2095	03/13/2015 04/10/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Wonsun Chung LAB	ETG-4000 Optical Topography System 510K
2015-2096	03/16/2015 05/27/2015	OC/ORR/ OC/ORR/	Carla Scarmazzi KING & SPALDING	RECS RE POSTING OF ST JUDE MEDICAL OR PACESETTER, SYLMAR, CA OR ARECIBO, PR 01/01/2009 - 06/30/2014
2015-2097	03/16/2015 04/13/2015	FDA/OC/OES/ FDA/OFVM/CFSAN/OCD/EOS/	MIKAELA BUFANO CBS NEWS	All records in connection with the TBB's consultation with the FDA regarding arsenic levels in wine discovered through the TTB's Alcohol Beverage Sampling Program
2015-2098	03/16/2015 04/13/2015	FDA/OGROP/ORR/SW-FO/DEN-DO/DEN-CB/	Curtis Walcker VRP Manufacturing, LLC	BIOSYNTRX - 483, EIR 09/05/2014 - 03/13/2015
2015-2099	03/16/2015 04/13/2015	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	COR14000106
2015-2100	03/16/2015 04/13/2015	FDA/OGROP/ORR/CE-FO/MIN-DO/MIN-CB/	Tim Murphy MOTHER JONES	BARTON PUBLISHING, SOUTH DAKOTA - CONSUMER COMPLAINTS 01/01/2008 - 03/13/2015
2015-2101	03/16/2015 04/13/2015	FDA/OMPT/CDRH/OCER/DFOI/	Mary Ryan LATHAM & WATKINS	K042259
2015-2102	03/16/2015 04/13/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Peter R. Breggin, MD Peter R. Breggin, MD	QUETIAPINE - AERS

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2015-2103	03/16/2015 04/13/2015	FDA/OMPT/CDRH/OCER/DFOI/	Jay Kotecha HIV Research Volunteer Project Inform	HIV TEST MEDIAN DATA
2015-2104	03/16/2015 04/13/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K092239
2015-2105	03/16/2015 04/13/2015	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	AMAR ELDAHER American Pharmaceutical Ingredients, LLC	MEDISCA INC, PLATTSBURGH, NY - 483 01/01/2012 - 01/01/2014
2015-2106	03/16/2015 04/13/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K101791
2015-2107	03/16/2015 04/16/2015	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	TERUMO, BCT INC, LAKEWOOD, CO - EIR, 483, RESPONSE 04/01/2014 - 05/31/2014
2015-2108	03/16/2015 04/13/2015	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Walter Whalkley THOMSON REUTERS (SCIENTIFIC) SAS	SIEMENS HEALTHCARE, NEWARK, DE - 483, EIR, RESPONSE 12/01/2011 - 02/29/2012
2015-2109	03/16/2015 04/13/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	Zimmer 483, EIR and correspondence May 2013 Mercredita, PR
2015-2110	03/16/2015 04/13/2015	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	ZIMMER MANUFACTURING BV, PR - 483, EIR, RESPONSE 03/01/2013 - 05/31/2013
2015-2111	03/16/2015 04/13/2015	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	STRYKER INSTRUMENTS, PORTAGE, MI - 483, EIR, RESPONSE 10/01/2012 - 11/30/2012
2015-2112	03/16/2015 04/14/2015	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	BRACCO DIAGNOSTIC INC, MONROE TOWNSHIP, NJ - 483, EIR, RESPONSE 05/01/2013 - 06/30/2013
2015-2113	03/16/2015 04/13/2015	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Walter chalkley THOMSON REUTERS (SCIENTIFIC) SAS	LINDE, LLC, KITTELY, ME - 483, EIR, RESPONSE 11/01/2013 - 11/30/2013

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2015-2114	03/16/2015 04/13/2015	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	ABBVIE BIOTECHNOLOGY, LTD, BARCELONETA, PR - 483, EIR, RESPONSE 07/01/2014 - 07/31/2014
2015-2115	03/16/2015 04/13/2015	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	GE HEALTHCARE LIFE SCIENCES, PRINCETON, NJ - 483, EIR, RESPONSE 07/01/2014 - 07/31/2014
2015-2116	03/16/2015 04/13/2015	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Walter chalkley THOMSON REUTERS (SCIENTIFIC) SAS	JAZZ PHARMACEUTICALS, INC, PALO ALTO, CA - 483, EIR, RESPONSE 03/01/2014 - 04/30/2014
2015-2117	03/16/2015 04/13/2015	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	HODGSON, KIM, MD, SPRINGFIELD, IL - 483, EIR, RESPONSE 06/01/2014 - 06/30/2014
2015-2118	03/16/2015 04/13/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	ELWOOD, RICHARD K, MD, VANCOUVER, CANADA - 483, EIR, RESPONSE 04/01/2014 - 04/30/2014
2015-2119	03/16/2015 04/13/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	NOVACYL, LTD, THAILAND - 483, EIR, RESPONSE 04/01/2014 - 04/30/2014
2015-2120	03/16/2015 04/13/2015	FDA/OFVM/CFSAN/OCD/EOS/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	KONINKLIJKE KAASFABRIEK, NETHERLANDS - 483, EIR, RESPONSE 08/01/2013 - 08/31/2013
2015-2121	03/16/2015 04/13/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 205053
2015-2122	03/16/2015 04/13/2015	FDA/OMPT/CDRH/OCER/DFOI/	Stephanie Blair Medline Industries, Inc.	K133077
2015-2123	03/16/2015 04/13/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ashish Rathi Spark Capital India (Private) Advisors Ltd	WOCKHARDT LIMITED, INDIA - 483 02/01/2015 - 03/16/2015

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2015-2124	03/16/2015 04/13/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ashish Rathi Spark Capital India (Private) Advisors Ltd	AUROBINDO PHARMA, INDIA - 483 02/01/2015 - 03/16/2015
2015-2125	03/16/2015 04/13/2015	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	Clarice J. Letizia, Esq. Letizia Law Firm	SCANTIBODIES BIOLOGICS, INC - 483, AFFIDAVITS, NOTES ETC 01/02/2013 - 12/31/2014
2015-2126	03/16/2015 04/13/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jeffrey A. Wolfson Strides Arcolab Limited	ONCO THERAPIES LIMITED, MYLAN LABORATORIES LIMITED, INDIA - 483 12/01/2013 - 03/13/2015
2015-2127	03/16/2015 04/13/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	charu sharma DermPathe Pharmaceuticals	NDA 050756, NDA 050703, ANDA 080198 ETC - SBA
2015-2128	03/16/2015 04/13/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Thomas V. Ayala Grant & Eisenhofer P.A.	ZOFTRAN, KYTRIL, ANZEMET, ETC - APPROVAL PACKAGES, REVIEWS, ADVERSE EVENTS ETC
2015-2129	03/16/2015 04/13/2015	FDA/OFVM/CFSAN/OCD/EOS/	Peter F. Goggi Tea Association of the U.S.A., Inc.	TEA ASSIGNMENT COMMUNICATIONS, RESULTS 02/01/2015 - 03/13/2015
2015-2130	03/16/2015 04/13/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Andrea Demakas ADVERSEEVENTS INC	VICTOZA, TRULICITY, TANZEUM - AERS
2015-2131	03/16/2015 04/13/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bhagwan Chaudhary National Institute of securities Markets	AUROBINDO, INDIA - 483 03/09/2015 - 03/14/2015
2015-2132	03/16/2015 04/13/2015	OC/ORA/ORM/ OC/ORA/ORM/	David Mangione Govzilla, Inc.	LISTING OF INSPECTIONS 03/15/2014 - 03/15/2015

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2015-2133	03/16/2015 04/24/2015	FDA/OC/OES/DFOI/	David Mangione Govzilla, Inc.	483 ISSUED AFTER 1/1/10 AND RELEASED UNDER FOIA SINCE 12/22/14
2015-2134	03/16/2015 04/13/2015	FDA/OMPT/CDRH/OCER/DFOI/	Dr. Diane Sudduth Imangel Consulting	PMA P010030 S034
2015-2135	03/16/2015 04/13/2015	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	ADVANCED BIONICS VENDOR B RELIABILITY OR FAILURE 01/01/2004 - 03/15/2015
2015-2136	03/16/2015 04/13/2015	FDA/OC/OES/DFOI/	Doe J	COCHLEAR, MED-EL, ADVANCED BIONICS - WARNING LETTERS, INSPECTION REPORTS, ADVERSE EVENTS ETC 03/01/2005 - 03/02/2015
2015-2137	03/16/2015 04/13/2015	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	W PATRICK NOONAN	XTC GET WET VISAGE PR USA, CARLSBAD, CA - 482, 483, CO RESP, ETC LAST FIVE YEARS
2015-2138	03/16/2015 04/13/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WILLIAM McINTYRE, Ph.D. LUPIN PHARMACEUTICALS INC	PERRIGO ISRAEL- CLOBETASOL PROPIONATE SHAMPOO ANDA -90-974 RVW, SBA
2015-2139	03/16/2015 04/13/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WILLIAM McINTYRE, Ph.D. LUPIN PHARMACEUTICALS INC	ACTAVIS MID ATLANTIC - CLOBETASOL PROPIONATE SHAMPOO ANDA 78-854 SBA, RVW
2015-2140	03/16/2015 04/13/2015	FDA/OC/OES/DFOI/	LEE D COPE Peters, Murdaugh, Parker, Eltzroth & Detrick	TB INFECTION, GREENWOOD COUNTY, SC 1/11 TO PRESENT
2015-2141	03/16/2015 04/13/2015	FDA/OO/OFBA/OAGS/	AMANDA GARCIA DELL FINANCIAL SERVICES	WARRANT OF AUTHORITY SHERRY SOLODKOVA (CONTRACTING OFFICER)
2015-2142	03/16/2015 04/13/2015	FDA/OC/OES/DFOI/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	JAMES LOVE KNOWLEDGE ECOLOGY INTERNATIONAL	RECS RELATED TO PATENT BARRIERS REGARDING THE DEVELOPMENT OF NEW VACCINES & DRUGS
2015-2143	03/16/2015 04/13/2015	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	THOMPSON, RAY	PATHEON PUERTO RICO, MANATI, PR; TAPI PUERTO RICO INC, HUMACAO, PR; TAPI PUERTO RICO, GUAYAMA, PR - 483
2015-2144	03/16/2015 04/13/2015	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	THOMPSON, RAY	BIOSCRIP INFUSION SERVICES OF NY, NEW HYDE PARK, NY 9/10-19/14; FRESENIUS KABI USA, GRAND ISLAND, NY 10/20-24/14; BRISTOL MYERS SQUIBB CO INC, EAST SYRACUSE, NY 9/23-25/14 - 483
2015-2145	03/16/2015	FDA/OGROP/ORACE-FO/NWJ-		ACINO PRODUCTS LLC, HAMILTON, NJ 8/7-19/14; ACUPAC

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	04/13/2015	DO/NWJ-CB/	THOMPSON, RAY	PACKAGING INC, MAHWAH, NJ 10/16-27/14; AMARIN PHARMA INC, BEDMINSTER, NJ 8/19 -9/9/14 - 483
2015-2146	03/17/2015 04/14/2015	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Steven M. Jodlowski Robbins Geller Rudman & Dowd LLP	OREXIGEN THERAPEUTICS, INC - CORR WITH FDA 02/23/2015 - 03/10/2015
2015-2147	03/17/2015 04/14/2015	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Mohit Bhat Kline & company Inc.	ASANTE SOLUTIONS, SUNNYVALE, CA - EIR 01/01/2012 - 03/16/2015
2015-2148	03/17/2015 04/14/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Charles Haines MCKINSEY & CO.	EFAVIRENZ, LAMIVUDINE, TENOFOVIR COMBINATION ETC - EXCLUSIVITY CLAIMS
2015-2149	03/17/2015 04/14/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K012480
2015-2150	03/17/2015 04/14/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 203312
2015-2151	03/17/2015 04/14/2015	FDA/OMPT/CDRH/OCER/DFOI/	Mey Saied DePuy Synthes Spine	K970748
2015-2152	03/17/2015 04/14/2015	FDA/OMPT/CDRH/OCER/DFOI/	James P. Curran Fulcrum Safety Solutions, Inc.	AB LASER RESISTOR TRIMMING SYSTEM NEUMAN MICRO TECHNOLOGIES - ACCESSION NUMBER 01/01/1996 - 03/16/2015
2015-2153	03/17/2015 04/14/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Donna Stauffer TELA Bio, Inc.	K082176
2015-2154	03/17/2015 04/14/2015	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	Amber Schofield Ultradent Products Inc.	ULTRADENT PRODUCTS INC, SOUTH JORDAN, UT - EIR 11/01/2013 - 03/17/2014
2015-2155	03/17/2015 04/14/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Chirag Talati Kotak Securities	MYLAN/STRIDES, INDIA - 483 03/01/2014 - 03/17/2015
2015-2156	03/17/2015	FDA/OMPT/CDRH/OCER/DFOI/	Terry Kim	K120454 - LABELING, IFU

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	04/14/2015		BIO PROTECH, INC.	
2015-2157	03/17/2015 04/14/2015	FDA/OC/OES/DDM/	Carolina Wirth, Esq. ReCellerate Inc.	FDA-1998-E-1268
2015-2158	03/17/2015 04/14/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KATE REYNOLDS MPH ROCKY MOUNTAIN POISON & DRUG CENTER	ACETAMINOPHEN PREPARATIONS - ISRS 8681751, 898823, 919231, ETC
2015-2159	03/17/2015 04/14/2015	FDA/OMPT/CDRH/OCER/DFOI/	LELAND H BELEW ANDRUS ANDERSON LLP	ADVANCED NEUROMODULATION SYSTEMS INC -TRIPOLE 16 LAMITODE PADDLE LEAD INSTRUCTION MANUALS, DIRECTIOINS FOR USE, CLINICIANS' MANUALS, ETC
2015-2160	03/17/2015 04/14/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SHOBHA REDDY CHAGAN DR REDDY'S LABORATORIES INC	ATON - SYPRINE (TRIENTINE HCL) NDA 19-194 SBA
2015-2161	03/17/2015 04/14/2015	FDA/OC/OES/DFOI/	Vik Bajnath ARTHREX INC.	MW5040532 REPORTER CONTACT
2015-2162	03/17/2015 04/14/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Elinore Mercer Cote Orphan Consulting	ANDA 085982
2015-2163	03/17/2015 04/14/2015	FDA/OMPT/OSMP/OOPD/	Elinore Mercer Cote Orphan Consulting	CERAMIDE TRIHEXOSIDASE/ALPHA-GALACTOSIDASE A - ORPHAN DESIGNATION RECS
2015-2164	03/17/2015 04/14/2015	OC/CVM/OCD/	TODD A HARRISON VENABLE LLP	VETOQUINOL - ANIMAL PRODS CMLPTS
2015-2165	03/18/2015 04/15/2015	FDA/OC/OES/DFOI/	Jeanne Lenzer, associate editor, The BMJ, New York Little, Brown and The BMJ	CYBERONICS VAGUS NERVE STIMULATOR - PREVIOUSLY RELEASED RECS 01/01/1990 - 03/16/2015
2015-2166	03/18/2015 04/15/2015	FDA/OMPT/CDRH/OCER/DFOI/	Scott Blood NinePoint Medical	K123421
2015-2167	03/18/2015 04/15/2015	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2015-1273
2015-2168	03/18/2015 04/15/2015	FDA/OMPT/CDRH/OCER/DFOI/	John Rizos Abbott Laboratories, Inc	K121214

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2015-2169	03/18/2015 04/15/2015	FDA/OMPT/CDRH/OCER/DFOI/	Dolan Mills Gyrus ACMI, Inc.	K941407
2015-2170	03/18/2015 04/15/2015	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORA/ OC/ORA/ OC/ORA/ORM/ OC/ORA/ORM/	Lindsay Mitchell Tri-Cor Flexible Packaging Inc.	LIST OF SEAFOOD PACKING FACILITIES 03/17/2014 - 03/17/2015
2015-2171	03/18/2015 04/15/2015	FDA/OC/OES/DFOI/	Eyal Maor Expenion	DRUGS, DEVICES - 483S
2015-2172	03/18/2015 04/15/2015	FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/	Peter Ganavazos MEDTRONIC	MEDTRONIC LOGISTICS, MEMPHIS, TN - EIR 11/04/2013 - 03/17/2015
2015-2173	03/18/2015 04/15/2015	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Harshitha Talluri Appco Pharmaceutical Corporation	ETODOLAC - LABEL RECS
2015-2174	03/18/2015 04/15/2015	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Valeria Povolotsky R-Pharm	MEKINIST/TRAMETINIB - INVESTIGATOR BROCHURE 01/01/2012 - 05/31/2015
2015-2175	03/18/2015 04/15/2015	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	FOIA Request, Investigators brochure for Zelboraf, vemurafen R-Pharm	ZELBORAF/VENURAMFENIB - INVESTIGATOR BROCHURE 01/01/2010 - 03/30/2010
2015-2176	03/18/2015 04/15/2015	OC/ORA/ORM/ OC/ORA/ORM/	Mark Prinz Registrar Corp	LIST OF FOREIGN FOOD FACILITIES RECEIVING 483 IN CONNECTION WITH INSPECTIONS 11/01/2014 - 02/28/2015
2015-2177	03/18/2015 04/15/2015	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Sushrut Waikar Sushrut Waikar	MANNITOL NDA 013684 APPROVAL RECS
2015-2178	03/18/2015 04/15/2015	FDA/OMPT/CDRH/OCER/DFOI/	John Rizos Abbott Laboratories, Inc	K121790
2015-2179	03/18/2015 04/15/2015	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Matt Valenti AntiCancer, Inc.	TAIHO ONCOLOGY - DATA FROM CLINICAL STUDIES AND PRECLINICAL STUDIES IN SUPPORT OF ROLLING NDA 01/01/2008 - 03/17/2015

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2015-2180	03/18/2015 04/15/2015	FDA/OC/OES/DFOI/	Jean Xiao Graduate Student, Jean Xiao	FAERS DATA
2015-2181	03/18/2015 04/15/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Doe J	RHOGAM - AERS
2015-2182	03/18/2015 04/15/2015	FDA/OFVM/CFSAN/OCD/EOS/	Bradley Lampe NSF International	FCN 1458 - CHEMISTRY, TOXICOLOGY MEMOS
2015-2183	03/18/2015 04/15/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Alexander Dersovitz Surveyor Capital	AMAG PHARMACEUTICALS - RECS RE MAKENA 01/01/2013 - 03/17/2015
2015-2184	03/18/2015 04/15/2015	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2015-1641
2015-2185	03/18/2015 04/15/2015	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2015-76
2015-2186	03/18/2015 04/15/2015	FDA/OMPT/CDRH/OCER/DFOI/	Chris Henza Regulatory Compliance Associates, Inc.	K072696
2015-2187	03/18/2015 04/15/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Harshitha Talluri Appco Pharmaceuticals Corporation	CLARITHROMYCIN - SBA
2015-2188	03/18/2015 04/15/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Luca Chinello Luca Chinello	MMR II VACCINE - CLINICAL TRIALS, STUDIES
2015-2189	03/18/2015 04/15/2015	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/	Mark Prinz Registrar Corp	IMPORT REFUSAL DATA

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2015-2190	03/18/2015 04/15/2015	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	RAY THOMPSON THOMPSON, RAY	3M HEALTHCARE BUSINESS, SAINT PAUL, MN 12/9-15/14, ALLIANCE PACKAGING GROUP INC, SAUKVILLE, WI 12/2-4/14, COVANCE LABORATORIES INC, MADISON, WI, 10/21/14-11/3/14, ETC - 483S
2015-2191	03/18/2015 04/15/2015	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	RAY THOMPSON THOMPSON, RAY	QUALITEST PHARMS, HUNTSVILLE, AL 7/28/14-8/11/14. VINTAGE PHARMACEUTICALS LLC, DBA QUALITEST, HUNTSVILLE, AL 12/15-19/14 483S
2015-2192	03/18/2015 04/15/2015	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	RAY THOMPSON THOMPSON, RAY	B & G LABS INC, SAINT LOUIS, MO 10/29/14-11/7/14, MERIDIAN MEDICAL TECHNOLOGIES (PFIZER CO), BRENTWOOD, MO 10/14/14-11/25/14, CATALENT CTS, LLC, KANSAS CITY, MO 10/27/14-11/10/14, ETC - 483S
2015-2193	03/18/2015 04/15/2015	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	RAY THOMPSON THOMPSON, RAY	MERIT MEDICAL SYSTEMS INC, CHESTER, VA, 8/27/14-9/16/14: MICROAIRE SURGICAL INSTRUMENTS LLC, CHARLOTTESVILLE, VA 8/11/14-22/14 - 483S
2015-2194	03/18/2015 04/15/2015	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	RAY THOMPSON THOMPSON, RAY	NAVAJO MANUFACTURING CO, DENVER, CO 8/11-22/14, CONMED ELECTROSURGERY, CENTENNIAL, CO 10/22/14-11/18/14, BAXTER CORPORATION ENGLEWOOD, ENGLWOOD, CO 12/12-19/14, ETC - 483S
2015-2195	03/18/2015 04/15/2015	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	RAY THOMPSON THOMPSON, RAY	ALLERGY LABORATORIES INC, OKLALHOMA CITY, OK 9/16/14-10/17/14, OXYSURE SYSTEMS INC, FRISCO, TX 9/3/14-10/3/14, CYBERONICS INC, HOUSTON, TX 8/11-22/14, ETC - 483S
2015-2196	03/18/2015 04/15/2015	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	RAY THOMPSON THOMPSON, RAY	CELSUS LALBORATORIES INC, CINCINNATI, OH 11/5-14/14, NORMAN NOBLE INC, HIGHLAND HEIGHTS, OH 9/15-30/14, STERIS CORP, MENTOR, OH 7/14/14-9/19/14, ETC - 483S
2015-2197	03/18/2015 04/15/2015	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	RAY THOMPSON THOMPSON, RAY	ABB VIE INC, NORTH CHICAGO 9/8-12/14, HYDROX LABS, ELGIN, IL 6/30/14-9/4/14, SMITHS MEDICAL CO, VERNON HILLS, IL 10/28/14-11/12/14, ETC - 483S
2015-2198	03/18/2015 04/15/2015	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	RAY THOMPSON THOMPSON, RAY	ENCOMPASS PHARMACEUTICAL SERVICES INC, NORCROSS, GA 11/10-13/14, REMINGTON MEDICAL INC, ALPHARETTA, GA 11/17-24/14, PATHEON MANUFACTURING SERVICES LLC, GREENVILLE, NC 9/9-12/14, ETC - 483S
2015-2199	03/18/2015 04/15/2015	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	RAY THOMPSON THOMPSON, RAY	BELCHER PHARMACEUTICALS LLC, LARGO, FL 11/17-21/14, KRAMER LABORATORIES INC, MIAMI, FL 9/29/14-10/14/14, TARMAC PRODUCTS INC, MIAMI GARDENS, FL 11/4/14-1/8/15, ETC - 483S
2015-2200	03/18/2015 04/15/2015	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	RAY THOMPSON THOMPSON, RAY	ACRA PAC INC (KIK CUSTOM PRODS), ELKHART, IN 11/3-21/14, KREMERS URBAN PHARMACEUTICALS INC, SEYMOUR, IN 12/1-16/14, CAYMAN CHEMICAL COMPANY INC, ANN ARBOR, MI 11/17-19/14, ETC - 483S
2015-2201	03/18/2015 04/15/2015	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	RAY THOMPSON THOMPSON, RAY	BARD PERIPHERAL VASCULALR INC, TEMPE, AZ 11/18/14-1/5/14, INTERNATIONAL MEDICATIONS SYSTEMS LTD,

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		FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/		8/27/14-9/12/14, PRIMA PHARM INC, SAN DIEGO, CA 10/21-14-11/3/14, ETC - 483S
2015-2202	03/18/2015 04/15/2015	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	RAY THOMPSON THOMPSON, RAY	ABCO LABORATORIES INC, FAIRFIELD, CA 10/20/14-11/4/14, CARLSBAD TECHNOLOGY INC, CARLSBAD, CA 10/21/14-11/21/14, PYRAMID LABORATORIES INC CARLSBAD, CA, 1/5-15/15, ETC - 483S
2015-2203	03/18/2015 04/15/2015	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	RAY THOMPSON THOMPSON, RAY	ASTRA ZENECA PHARMACEUTICALS LP, NEWARK, DE 8/20-27/14, KONSYL PHARMACEUTICALS INC, EASTON, MD 11/17-21/14, JANSSEN BIOTECH INC, MALVERN, PA 9/15-24/14, ETC - 483S
2015-2204	03/18/2015 04/15/2015	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	RAY THOMPSON THOMPSON, RAY	PFIZER INC, GROTON LABS, GROTON, CT 9/16-30/14, INNOTEQ INC, STRATFORD, CT 9/9-25/14, GENZYME CORP 9/8-25/14, FRAMING HAM, MA, ETC - 483S
2015-2205	03/18/2015 04/15/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	RAY THOMPSON THOMPSON, RAY	BAXTER HEALTHCARE SA (TRAVENOL), CASTLEBAR, IRELAND 10/6-14/14, GE HEALTHCARE, CARRIGTOHILL, COUNTY COR, IRELAND 9/8-15/14, ALCON LABORATORIES IRELAND LTD, CORK, IRELAND, 1/12-15/2015, ETC - 483S
2015-2206	03/18/2015 04/15/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RAY THOMPSON THOMPSON, RAY	CADLILA HEALTHCARE LTD, AHMEDABAD CITY, INDIA\ 8/28/14-9/5/14, IPCA LABORATORIES, LTD, SILVASA (D & NH), INDIA 12/11-19/14, SANDOZ PRIVATE LTD, NAVI MUMBAI, INDIA, 8/12-28/14, ETC - 483S
2015-2207	03/18/2015 04/15/2015	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	MARGE WYSZYNSKI RR DONNELLEY	HOSPIRA, MCPHERSON, KS - EIR, 483 MOST RECENT
2015-2208	03/18/2015 04/15/2015	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	MARGE WYSZYNSKI RR DONNELLEY	MADISON POLYMERIC, BRANFORD, CT - EIR, 483 1/15
2015-2209	03/18/2015 04/15/2015	FDA/OMPT/CDRH/OCER/DFOI/	MARGE WYSZYNSKI RR DONNELLEY	PAJUNK GMBH MEDIXZINTECHNOLOGIE, GEISINGER, GERMANY - EIR, 483, 1/13
2015-2210	03/18/2015 04/15/2015	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	MARGE WYSZYNSKI RR DONNELLEY	HOSPIRA, ROCKY MOUNT, NC - EIR, 483, MOST RECENT
2015-2211	03/18/2015 04/15/2015	FDA/OC/OES/DFOI/	JULIE MEWISSEN INCHECK INC	INDIVIDUAL RECS
2015-2212	03/18/2015 04/15/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRADFORD L JEFFERSON BRADFORD L JEFFERSON PA	AVASTIN - AERS

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2015-2213	03/18/2015 04/15/2015	FDA/OC/OES/DFOI/	GENEVIEVE HENRY THOMSON REUTERS (SCIENTIFIC) SAS	FOI DAILY LOG 2014
2015-2214	03/18/2015 04/15/2015	FDA/OC/OCC/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	CAROLINE STOUT ECOR1 CAPITAL LLC	NATIONAL INSTITUTE OF HEALTH - HUMAN GENE TRANSFER PROTOCOL #1404-1304 9/10/14 EXPENDITURE OF TIME & MONEY IN RESEARCHING, DRAFTING & PROMULGATING THE DISCUSSION, COMM, POWERPOINT PRESENTATION
2015-2215	03/18/2015 04/15/2015	FDA/OC/OES/ FDA/OC/OES/DDM/ FDA/OC/OES/DFOI/ FDA/OC/OL/ FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/ FDA/OMPT/CDRH/OCER/DFOI/ OC/ORA/OCI/ OC/ORA/OCI/	PETER KAUFMAN PANISH SHEA & BOYLE LLP	OLYMPUS - ENDOSCOPES TJF-Q180V, TJFQI809 & TJF-160VR DUODENOSCOPES - RECS
2015-2216	03/18/2015 04/15/2015	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	SIEMENS HEALTHCARE DIAGNOSTICS, INC, EAST WALPOLE, MA - EIR, 483, RESPONSE 10/01/2011 - 01/31/2012
2015-2217	03/18/2015 04/15/2015	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	SMITH & NEPHEW, SAINT PETERSBURG, FL - EIR, 483, RESPONSE 11/01/2013 - 11/30/2013
2015-2218	03/18/2015 04/15/2015	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	PHILIPS HEALTHCARE, SAN DIEGO, CA - EIR, 483, RESPONSE 07/01/2013 - 07/31/2013
2015-2219	03/18/2015 04/15/2015	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	BAXTER HEALTHCARE CORP, ROUND LAKE, IL - EIR, 483, RESPONSE 07/01/2013 - 07/31/2013
2015-2220	03/18/2015 04/15/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mark Prinz Registrar Corp	LIST OF DRUG ESTABLISHMENTS THAT LIST REGISTRAR CORP AS US AGENT OR REGISTRANT CONTACT IN THEIR REGISTRATION, LABELER CODE, OR SELF-IDENTIFICATION SPL SUBMISSIONS

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		FDA/OMPT/CDER/GRP/DIDP/		
2015-2221	03/18/2015 04/15/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Anna Edney BLOOMBERG NEWS	GVK BIOSCIENCES, CLINOGENT - CORR, INSPECTIONS, COMM 01/04/2007 - 03/17/2015
2015-2222	03/18/2015 04/15/2015	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	TERUMO CARDIOVASCULAR SYSTEMS CORPORATION, ANN ARBOR, MI - EIR, 483, RESPONSE 09/01/2012 - 09/30/2012
2015-2223	03/18/2015 04/15/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tushar Manudhane Indianivesh securities	WOCKHARDT LIMITED, INDIA - 483 01/01/2015 - 03/18/2015
2015-2224	03/18/2015 04/15/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ADITYA KHEMKA AMBIT CAPITAL PVT. LTD.	AUROBINDO PHARMA UNIT IV, UNIT VII, INDIA - 483, CLASSIFICATION 03/18/2015 - 09/01/2014
2015-2225	03/18/2015 04/15/2015	FDA/OMPT/CDRH/OCER/DFOI/	Marc C. Sanchez, Esq. Contract In-House Counsel Consl. LLC	NOTICES TO AMAZON RE LISTING, MARKETING, OR SELLING PERSONAL LUBRICANTS WITHOUT APPROVAL 01/01/2015 - 03/15/2015
2015-2226	03/18/2015 04/15/2015	FDA/OC/OES/DFOI/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	DAILY LOG 2014
2015-2227	03/18/2015 04/15/2015	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	Dr. Wolfgang Huhn Viforpharma	LUITPOLD PHARMACEUTICALS, SHIRLEY, NY - EIR 04/01/2014 - 12/31/2014
2015-2228	03/18/2015 04/15/2015	FDA/OMPT/CDRH/OCER/DFOI/	Correne Ramy DEPUY ORTHOPAEDICS INC	MASTER FILE MAF-610
2015-2229	03/18/2015 04/15/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Vaibhav Dusad Morgan Stanley	AUROBINDO PHARMA, INDIA - 483 09/08/2014 - 03/18/2015
2015-2230	03/18/2015 04/15/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bharat Celly Research Delta	WOCKHARDT, INDIA - 483 10/21/2014 - 03/18/2015

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2015-2231	03/18/2015 04/15/2015	FDA/OMPT/CDRH/OCER/DFOI/	Bttiker Urs Hautarzt Bubenberg	QUANTA - WARNING LETTER RECS 10/01/2013 - 03/01/2015
2015-2232	03/19/2015 04/16/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Moumita Rawal G&W Laboratories Inc.	ANDA A072041 SBA
2015-2233	03/19/2015 04/16/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Gary Conger Gary Conger	K011880
2015-2234	03/19/2015 04/16/2015	FDA/OMPT/CDRH/OCER/DFOI/	Bonnie Wu VCI	K141167
2015-2235	03/19/2015 04/16/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michael Rice Marathon Pharmaceuticals, LLC	ACTHAR GEL LETTER AND ATTACHMENTS
2015-2236	03/19/2015 04/16/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Larry Stoll Pedicis Research	RX LIQUID SALICYLIC ACID - SBA 01/01/1980 - 01/01/1995
2015-2237	03/19/2015 04/16/2015	OC/CVM/OCD/	Susan Thixton Susan Thixton/Association for Truth in Pet Food	PRIMAL PET FOOD - CONSUMER COMPLAINT, ADVERSE EVENTS 06/01/2014 - 03/16/2015
2015-2238	03/19/2015 05/01/2015	FDA/OGROP/ORR/CE-FO/DET- DO/DET-CB/	Wendy Lockwood Banka Wendy Lockwood Banka	EMAIL BETWEEN FDA DETROIT DISTRICT AND VARIOUS OTHERS 08/01/2014 - 03/18/2015
2015-2239	03/19/2015 04/16/2015	OC/ORR/ORM/ OC/ORR/ORM/	Gary Hugel ASI FOOD SAFETY CONSULTANTS	LIST OF FOOD WAREHOUSES AND DISTRIBUTION CENTERS 01/01/2010 - 04/30/2014
2015-2240	03/19/2015 04/16/2015	FDA/OO/OFBA/OAGS/	Rose Santos FOIA GROUP INC	HHSF223201110005B
2015-2241	03/19/2015 04/16/2015	FDA/OMPT/CDRH/OCER/DFOI/	Melissa Thompson, Contract QSM Genchem GENCHEM	K040973
2015-2242	03/19/2015	FDA/OMPT/CDER/ORP/DIDP/	Andrea Glinka Przybysz	VALPROIC ACID - REVIEWS

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	04/16/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TUCKER ELLIS LLP	
2015-2243	03/19/2015 04/16/2015	FDA/OMPT/CDRH/OCER/DFOI/	ANDREW M. GAMMILL DINSMORE & SHOHL LLP	SEEING MACHINES LTD - TRUE FIELD ANALYZER K063310
2015-2244	03/19/2015 04/16/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JAIN, POOJA	DESI DOCUMENTS
2015-2245	03/19/2015 04/16/2015	OC/CVM/OCD/	ARLENE MORALES BURDOCK GROUP	SCHIZPCHYTRIUM ILNANICUM - SAFETY INFO, USES IN POULTRY ETC
2015-2246	03/19/2015 04/16/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	NEIL, BULLOCH	TAKEDA PHARMACEUTIAL - COLCRYS APRVL
2015-2247	03/19/2015 04/16/2015	FDA/OFVM/CFSAN/OCD/EOS/	ALEXANDRA SIFFERLIN TIME	COSMETICS - AER 2005 TO PRESENT
2015-2248	03/19/2015 04/16/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DDM/	KAITLIN A. CANTY DAY PITNEY LLP	MEDICAL DVCS ADVISORY COMMITTEE MTG 2/27/15
2015-2249	03/19/2015 04/16/2015	FDA/OC/OES/	NORMAN GOLDFARB JOURNAL OF CLINICAL RESEARCH BEST PRACTICES	ANSWERS & QUESTIONS MADE TO GCP@OC.FDA.GOV IN 2012
2015-2250	03/19/2015 04/16/2015	FDA/OC/OES/DFOI/	AMIE VANELLA FAEGRE BAKER DANIELS	SIMPLY THICK REQUESTS 1/5/15 TO PRESENT
2015-2251	03/19/2015 04/16/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	JEFF FELDHAUS M SQUARED ASSOCIATES INC	K904422, K934261,0K942299
2015-2252	03/19/2015 04/16/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SASHA GRAY THOMSON REUTERS	TEVA PHARMACEUTICALS - TERAZOSIN NDA 74-651; ABBOTT LABS - PROPOFOL NDA 74-704; TEVA CANADA - FAMOTIDINE NDA 74-687 ETC TENTATIVE APRVL

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2015-2253	03/20/2015 04/17/2015	FDA/OMPT/CDRH/OCER/DFOI/	Toshio Murata NIDEK INC	K133476 K140451 K140450
2015-2254	03/20/2015 04/17/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Christopher Michael Small Peking University	NUMBER OF EMPLOYEES IN EACH OFFICE IN CDER
2015-2255	03/20/2015 04/17/2015	FDA/OMPT/OSMP/OOPD/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	TEMODAR, TEMODAL - COMPLETE RESPONSE LETTERS RE ORPHAN DESIGNATIONS
2015-2256	03/20/2015 04/17/2015	FDA/OMPT/OSMP/OOPD/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ZOLINZA - COMPLETE RESPONSE LETTER RE ORPHAN DESIGNATION
2015-2257	03/20/2015 04/17/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Elinore Mercer Cote Orphan Consulting	ANDA 085981
2015-2258	03/20/2015 04/17/2015	FDA/OMPT/CDRH/OCER/DFOI/	Deborah Bradley Deborah Bradley	K081593
2015-2259	03/20/2015 04/17/2015	FDA/OMPT/OSMP/OOPD/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	COMPLETE RESPONSE - COMPLETE RESPONSE RE ORPHAN DESIGNATION
2015-2260	03/20/2015 04/17/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ron Carnal Teva Pharmaceuticals	BLA 103780 S 5121 SBA
2015-2261	03/20/2015 04/17/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dustin Block IPD Analytics, LLC	ANDA 040486 - EFFECTIVE APPROVAL LETTER; NDA 205636 - TENTATIVE APPROVAL LETTER
2015-2262	03/20/2015 04/17/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ron Carnal Teva Pharmaceuticals	NDA 20622 S089
2015-2263	03/20/2015 04/17/2015	FDA/OMPT/CDRH/OCER/DFOI/	Deborah Bradley Deborah Bradley	K053451
2015-2264	03/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	Jeffrey Feldhaus	K904421

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	04/17/2015		M SQUARED ASSOCIATES INC	
2015-2265	03/20/2015 04/17/2015	FDA/OFVM/CFSAN/OCD/EOS/	#110038 GRASP SVP DEUTSCHLAND AG	GRAS 3G0026 GRAS 0G0363, GRAS 5G0415 ETC
2015-2266	03/20/2015 04/17/2015	FDA/OO/OFBA/OAGS/	Cheryl Denman Denman, Cheryl	FDA-15-223-SOL-1142466
2015-2267	03/20/2015 04/17/2015	FDA/OMPT/OSMP/OOPD/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	VIINTAFOLIDE - COMPLETE RESPONSE RE ORPHAN DESIGNATION
2015-2268	03/20/2015 04/17/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jim Intrater Columbus Nova, LLC	MERCK TOXICOLOGY REPORT
2015-2269	03/20/2015 04/17/2015	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORASW-FO/SWID/SWID-CB/	Luis Chavarria Supaso International LLC	GR PRODUCE, MCALLEN, TX - EIR, SAMPLES, ETC
2015-2270	03/20/2015 04/17/2015	FDA/OMPT/CDRH/OCER/DFOI/	270-60400 Montgomery, Rennie & Jonson	K874656, K941870, K932199 ETC
2015-2271	03/20/2015 04/17/2015	FDA/OMPT/OSMP/OOPD/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	KEYTRUDA - COMPLETE RESPONSE LETTER RE ORPHAN DESIGNATION
2015-2272	03/20/2015 04/17/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Robert H. Schiffman LifeGlobal Group, LLC	FUJIAN FUKANG PHARMACEUTICAL CO, LTD - EIR 03/28/2014 - 03/28/2014
2015-2273	03/20/2015 04/17/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dheeresh Pathak Dheeresh Pathak	WOCKHARDT, INDIA - 483 01/01/2015 - 03/19/2015
2015-2274	03/20/2015 04/17/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Emily Krulewitz The Weinberg Group	NDA 019842 - SBA, MEDICAL REVIEW
2015-2275	03/20/2015 04/17/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Cathy Dreifort Dreifort, Cathy	HARVONI - AERS

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		FDA/OMPT/CDER/GRP/DIDP/		
2015-2276	03/20/2015 04/17/2015	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	Wendy Lees NORTHWEST COSMETIC LABS LLC	COLOR DESIGN LABORATORY, NORTHRIGGE, CA - EIR, 483, WARNING LETTER 0/01/2010 - 03/01/2015
2015-2277	03/20/2015 04/17/2015	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	Wendy Lees NORTHWEST COSMETIC LABS LLC	WEST COAST COSMETICS, CHATSWORTH, CA - EIR, 483, WARNING LETTER 01/01/2010 - 03/01/2015
2015-2278	03/20/2015 04/17/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Julia Queen Julia Queen	ACETYLCYSTEINE 10% OPTH SOLN - AERS
2015-2279	03/20/2015 04/17/2015	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORAP/CE-FO/MIN-DO/MIN-CB/	Eric Hall Healthy Ventures, LLC	ZULA - INVESTIGATION OF COMPLAINT, HACCP REGULATION 03/15/2014 - 03/15/2015
2015-2280	03/20/2015 04/17/2015	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	Staci Ellis MEI Pharma, Inc.	DR GARY SCHILLER, UCLA MEDICAL CENTER, LOS ANGELES, CA - 483, EIR, RESPONSES 09/01/2001 - 11/30/2011
2015-2281	03/20/2015 04/17/2015	FDA/OMPT/OSMP/OOPD/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	COMPLETE RESPONSE POSACONAZOLE -COMPLETE RESPONSE LETTER RE ORPHAN DESIGNATION
2015-2282	03/20/2015 04/17/2015	FDA/OMPT/OSMP/OOPD/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	8-4-(1-aminocyclobutyl)phenyl-9-phenyl-1,2,4-triazolo3,4-f1,6naph-thyrin-3(2H)-one mono-hydrochloride - COMPLETE RESPONSE LETTER RE ORPHAN DESIGNATION 9/3/2009
2015-2283	03/20/2015 04/17/2015	FDA/OGROP/ORAP/CE-FO/NWJ-DO/NWJ-CB/	Donald E. Kraft Diagnostica Stago Inc.	DIAGNOSTICA STAGO, INC, MOUNT OLIVE, NJ; PARSIPPANY, NJ - INVESTIGATOR DIARIES 10/22/2013 - 11/29/2013
2015-2284	03/20/2015 04/17/2015	FDA/OMPT/OSMP/OOPD/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	LETERMIVIR - COMPLETE RESPONSE LETTER RE ORPHAN DESIGNATION 12/12/2011
2015-2285	03/20/2015 04/17/2015	FDA/OMPT/OSMP/OOPD/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	DINACICLIB - COMPLETE RESPONSE LETTER RE ORPHAN DESIGNATION 8/25/2011
2015-2286	03/20/2015 04/17/2015	FDA/OMPT/CDRH/OCER/DFOI/	Joe Forte Expansion Medical	K143314
2015-2287	03/20/2015 04/17/2015	FDA/OMPT/CDRH/OCER/DFOI/	Jake Scheiterlein Sodium Systems llc	K102456
2015-2288	03/20/2015 04/17/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Smith BioTex, Inc.	K071246
2015-2289	03/20/2015	FDA/OMPT/CDER/GRP/DIDP/	Morgan Tichy/Tori Cunningham	HARVONI - AERS

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	04/17/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	VA Eastern Kansas Healthcare System	
2015-2290	03/20/2015 04/17/2015	FDA/OMPT/CDRH/OCER/DFOI/	Chen Barak ESCALA Medical Ltd.	K120831
2015-2291	03/20/2015 04/17/2015	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	Wendy Lees NORTHWEST COSMETIC LABS LLC	SPATZ LABS, OXNARD, CA - EIR, 483, WARNING LETTER 01/01/2012 - 03/01/2015
2015-2292	03/20/2015 04/17/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	T. J. Jesky Stude's, LLC	ANDA 079217 001; ANDA 079217 002; ANDA 079217 003 - SBA
2015-2293	03/23/2015 04/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	Vered Nitzan Biogaming Ltd.	K130847
2015-2294	03/23/2015 04/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mark Pregenzer Ronald Reagan UCLA Medical Center	NDC 61703-0243-53 DATE PRODUCT DISCONTINUED
2015-2295	03/23/2015 04/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	John Zulkey Hinkhouse Williams Walsh LLP	WRIGHT MEDICAL TECHNOLOGY - RECS RE NUMBER OF POSTMARKET SURVEILLANCE STUDIES 01/03/2011 - 03/19/2015
2015-2296	03/23/2015 04/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Josh Levine XTL Biopharmaceuticals, Ltd.	IND 070484
2015-2297	03/23/2015 04/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	Michelle Roeding Avinger	K883346
2015-2298	03/23/2015 04/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	G. Srinivas Zydus Pharmaceuticals USA Inc.	NDA 018760
2015-2299	03/23/2015 04/20/2015	FDA/OGROP/ORAP/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Millan Bederu CONSUMERS' RESEARCH MAGAZINE	23ANDME - CLOSE OUT LETTER RECS 09/13/2012 - 03/25/2014

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2015-2300	03/23/2015 04/20/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-6520
2015-2301	03/23/2015 04/20/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-6754
2015-2302	03/23/2015 04/20/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-5542
2015-2303	03/23/2015 04/20/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-7630
2015-2304	03/23/2015 04/20/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-7627
2015-2305	03/23/2015 04/20/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-3503
2015-2306	03/23/2015 04/20/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-7826
2015-2307	03/23/2015 04/20/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-7098
2015-2308	03/23/2015 04/20/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-6735
2015-2309	03/23/2015 04/20/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-7839
2015-2310	03/23/2015 04/20/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-7830
2015-2311	03/23/2015 04/20/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-5872
2015-2312	03/23/2015 04/20/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-6381
2015-2313	03/23/2015 04/20/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-3516
2015-2314	03/23/2015 04/20/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-2698
2015-2315	03/23/2015 04/20/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Hogan Lovells US LLP HOGAN LOVELLS US LLP	K053655
2015-2316	03/23/2015	FDA/OC/OES/DFOI/	Jo Hogan	2014-3539

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	04/20/2015		FOI Services, Inc.	
2015-2317	03/23/2015 04/20/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-3131
2015-2318	03/23/2015 04/20/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-3839
2015-2319	03/23/2015 04/20/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-4986
2015-2320	03/23/2015 04/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	William Maher Addiction Technologies Co.	K820622
2015-2321	03/23/2015 04/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rebecca Dandeker Morgan, Lewis & Bockius LLP	SHANDONG FREDO BIOPHARM CO LTD, CHINA - EIR 01/01/2013 - 01/31/2015
2015-2322	03/23/2015 04/20/2015	FDA/OFVM/CFSAN/OCD/EOS/	Jennifer Hastings General Mills- QRO	GENERAL MILLS, BRAZIL - EIR, 483, RESPONSE 02/08/2014 - 03/20/2015
2015-2323	03/23/2015 04/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 10515 S 23, 24, 31
2015-2324	03/23/2015 04/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	Konstantin Valtchev, M.D. Conkin Surgical Instruments Ltd	K954311
2015-2325	03/23/2015 04/20/2015	FDA/OFVM/CFSAN/OCD/EOS/	Scott Thenell THENELL & ASSOCIATES LLC	GRAS 5G0046
2015-2326	03/23/2015 04/20/2015	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	LESLIE RAMSEY FDA NEWS	GENZYME CORP, FRAMINGHAM, MA; APLICARE INC, MERIDEN, CT; VERICHEM LABORATORIES INC, PROVIDENCE, RI, ETC - 483S 11/1-30/14
2015-2327	03/23/2015 04/20/2015	FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/	LESLIE RAMSEY FDA NEWS	COATING PLACE INC, VERONA, WI; ANYBATTERY INC, ROSEMOUNT, MN - 483S 11/1-30/14
2015-2328	03/23/2015 04/20/2015	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	LESLIE RAMSEY FDA NEWS	BACHEM AMERICAS INC, TORRANCE, CA; CARLSBAD TECHNOLOGY INC, CARLSBAD, CA; PRIMA PHARM UNC, SAN DIEGO, CA, ETC - 483S 11/1-30/14
2015-2329	03/23/2015 04/20/2015	FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/	LESLIE RAMSEY FDA NEWS	B & G LABS INC, SAINT LOUIS, MO; MERIDIAN MEDICAL TECHNOLOGIES (PFIZER CO), BRENTWOOD, MO; CATALENT CTS LLC, KANSAS CITY, MO - 483S 11/1-30/14
2015-2330	03/23/2015	FDA/OGROP/ORA/SE-FO/FLA-	LESLIE RAMSEY	ENCOMPAS UNLIMITED INC, SARASOTA, FL; BELCHER

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	04/20/2015	DO/FLA-CB/	FDA NEWS	PHARMACEUTICALS LLC, LARGO, FL; INOVO INC, LEIGH ACRES, FL, ETC - 483S 11/1-30/14
2015-2331	03/23/2015 04/20/2015	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OC/OES/DFOI/	LESLIE RAMSEY FDA NEWS	NEOTERIC COSMETICS INC, DENVER, CO; CONMED ELECTROSURGERY, CENTERNNIAL, CO - 483S 11/1-30/14
2015-2332	03/23/2015 04/20/2015	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ OC/ORASW-FO/DAL-DO/DAL-CB/ OC/ORASW-FO/DAL-DO/DAL-CB/	LESLIE RAMSEY FDA NEWS	NELSON ENVIRONMENTAL TECHNOLOGIES INC, STAFFORDX, TX; WALGREENS INFUSION SERVICES, HOUSTON, TX - 483S 11/1-30/14
2015-2333	03/23/2015 04/20/2015	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	LESLIE RAMSEY FDA NEWS	APTALIS PHARMATECH INC, VANDALIA, OH; CELSUS LABORATORIES INC, CINCINNATI, OH; GOLDEN TOUCH LLC, BENTON, KY - 483S 11/1-30/14
2015-2334	03/23/2015 04/20/2015	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	LESLIE RAMSEY FDA NEWS	JONES MEDICAL INSTRUMENT CO, OAK BROOK, IL; SMITHS MEDICAL CO, VERNON HILLS, IL;; EDWARD HINES VA HOSPITAL PATHOLOGY & LABORATORY, HINES, IL, ETC - 483S 11/1-30/14
2015-2335	03/23/2015 04/20/2015	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	LESLIE RAMSEY FDA NEWS	PREVENTIVE TECHNOLOGIES INC, INDIAN TRAIL, NC; PHARMA TECH INDUSTRIES, ROYSTON, GA; REMINGTON MEDICAL INC, ALPHARETTA, GA - 483S 11/1-30/14
2015-2336	03/23/2015 04/20/2015	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	LESLIE RAMSEY FDA NEWS	NEWTON LABORATORIES INC, CONYERS, GA; SUNNEX INC, CHARLOTTE, NC - 483S 2/1-28/15
2015-2337	03/23/2015 04/20/2015	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	LESLIE RAMSEY FDA NEWS	BLUE NATURALS LLC, CHARLOTTESVILLE, VA - 483 2/1-28/15
2015-2338	03/23/2015 04/20/2015	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	LESLIE RAMSEY FDA NEWS	THERAPEUTIC PROTEINS INTERNATIONAL LLC, CHICAGO, IL; SUNSTAR AMERICIAN INC, ELGIN, IL - 483S 2/1-28/15
2015-2339	03/23/2015 04/20/2015	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	LESLIE RAMSEY FDA NEWS	SPOONAMORE DRUG CO INC, LOUISVILLE, KY; NEUROWAVE SYSTEMS INC, CLEVELAND HEIGHTS, OH; CLEVELAND MEDICAL DEVICES INC, CLEVELAND, OH - 483S 2/1-28/15
2015-2340	03/23/2015 04/20/2015	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	LESLIE RAMSEY FDA NEWS	DENTAL REPUBLIC, DALLAS, TX; TRILLIANT SURGICAL LTD, HOUSTON, TX; CHEMOLEE LAB CORP, IRVING, TX, ETC - 483S 2/1-28/15
2015-2341	03/23/2015 04/20/2015	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	LESLIE RAMSEY FDA NEWS	FOREVERGREEN INTERNATIONAL LLC, PLEASANT GROVE, CO; CEA MEDICAL MANUFACTURING INC, COLORADO SPRINGS, CO; AMGEN INC, LONGMONT, ETC - 483S 2/1-28/15
2015-2342	03/23/2015 04/20/2015	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	LESLIE RAMSEY FDA NEWS	BATTLE CREEK EQUIPEMNT, CO, FREMONT, IN; APPLIED LABORATORIES INC, COLUMUS, IN; TRI-MED INC (ADVANCED CARE INFUSION-SHELBY)L, SHELBY

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				TOWNSHIP, MI - 483S 2/1-28/15
2015-2343	03/23/2015 04/20/2015	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	LESLIE RAMSEY FDA NEWS	RIVERSIDE WATER TECHNOLOGY INC (CULLIGAN OF PERRYVILLE), PERRYVILLE, MO; MEDICAL SOLUTIONS INTERNATIONAL INC, MERRIAM, KS; LONG PHARMACEUTICALS LLC, FENTON, MO - 483S 2/1-28/15
2015-2344	03/23/2015 04/20/2015	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	LESLIE RAMSEY FDA NEWS	VERTEBRAL TECHNOLOGIES, INC, MINNETONKA, MN; WILSON-HURD MFG CO INC, BERLIN, WI; QIG GROUP LLC, BLAINE, MN, ETC - 483S 2/1-28/15
2015-2345	03/23/2015 04/20/2015	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	LESLIE RAMSEY FDA NEWS	GARDNER DENVER THOMAS INC, MONROE, LA; TEGRA MEDICAL LLC, HERNANDOS, MS - 483S 2/1-28/15
2015-2346	03/23/2015 04/20/2015	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	LESLIE RAMSEY FDA NEWS	IBA MOLECULAR NORTH AMERICA INC, COLONIE, NY; C P HEALTH PRODUCTS INC, HAUPPAUGE, NY - 483S 2/1-28/15
2015-2347	03/23/2015 04/20/2015	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	LESLIE RAMSEY FDA NEWS	DEXTA CORP, NAPA, CA; SOMERSAULT ORTHOPEDICS INC, PLEASANTON, CA - 483S 2/1-28/15
2015-2348	03/23/2015 04/20/2015	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	LESLIE RAMSEY FDA NEWS	BAXTER HEALTHCARE OF PUERTO RICO, GUAYAMA, PR - 483 2/1-28/15
2015-2349	03/23/2015 04/20/2015	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	LESLIE RAMSEY FDA NEWS	SPEN TECH INC, REDMOND, WA; GENESIS NORTHWEST INC, PORTLAND, OR; THORN FORD DENTAL LABORATORY LLC, BOTHELL, WA, ETC - 483S 2/1-28/15
2015-2350	03/23/2015 04/20/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LESLIE RAMSEY FDA NEWS	EMCURE PHARMAEUTICAL LTD, HINJWADI, PUNE, INDIA; HOSPIRA HEALTHCARE INDIA PVT LTD, SRIPERUMBUDUR, INDIA.; PRIME EUROPEAN THERAPEUTICALS SPA (EUTICALS SPA), ROZZANI, ITALY - 483S 2/1-28/15
2015-2351	03/23/2015 04/20/2015	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	LESLIE RAMSEY FDA NEWS	DPT LAKEWOOD LLC, LAKEWOOD, NJ; INOPAK LTD, RINGWOOD, NJ; CMIC CMO USA CORP, CRANBURY, NJ, ETC - 483S 2/1-28/15
2015-2352	03/23/2015 04/20/2015	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	LESLIE RAMSEY FDA NEWS	BREG INC, CARLSBA, CA; STAAR SURGUICAL CO, MONROVIA, CA; SPEC ENGINEERING CO, VAN NUYS, CA, ETC - 483S 2/1-28/15
2015-2353	03/23/2015 04/20/2015	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	LESLIE RAMSEY FDA NEWS	INFUPHARMA LLC (PRESIDENT PHARMACY), HOLLYWOOD, FL; THE ANSPACH EFFORT INC, PALM BEACH GARDENS, FL; PRODUCT QUEST MANUFACTURING LLC, HOLLY HILL, FL, ETC - 483S 2/1-28/15
2015-2354	03/23/2015 04/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	LESLIE RAMSEY FDA NEWS	APK TECHNOLOGY CO LTD, SHENZHEN CITY, CHINA; APEX MEDICAL (KUNSHAN) CORP, KUNSHAN, CHINA; TECRES SPA, SOMMACAMPAGNA, ITALY, ETC - 483S 2/1-28/15
2015-2355	03/23/2015 04/20/2015	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/	Ralph Crowder Crowder, Ralph	HP ACTHAR

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2015-2356	03/23/2015 04/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 78992
2015-2357	03/23/2015 04/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 71961 S1, S2, S3, S4
2015-2358	03/23/2015 04/20/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-6366
2015-2359	03/23/2015 04/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	Brian Gall Teleflex, Inc	K840239
2015-2360	03/23/2015 04/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K983436
2015-2361	03/24/2015 05/22/2015	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORAN/FO/NYK- DO/NYK-DCB/ FDA/OGROP/ORAN/ORO/DIOP/ OC/ORAN/ OC/ORAN/	SHUKUN WANG BEIJING NEWS	YINLU FOOD GROUP CO LTD - IMPORT REFUSAL RECS
2015-2362	03/24/2015 04/21/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	MIRALAX, POLYETHYLENE GLYCOL 3350 - AERS
2015-2363	03/24/2015 04/21/2015	FDA/OGROP/ORAN/PA-FO/LOS- DO/LOS-CB/	Rachel Johnson FOI Services, Inc.	PYRAMID, COSTA MESA, CA - INVESTIGATOR DIARIES 01/05-15/2015
2015-2364	03/24/2015 04/21/2015	FDA/OGROP/ORAN/PA-FO/LOS- DO/LOS-CB/	yi zhou Zhou, Yi	PYRAMID LABORATORIES - RESPONSE TO 483 01/01/2015 - 03/12/2015
2015-2365	03/24/2015 04/21/2015	FDA/OGROP/ORAN/PA-FO/LOS- DO/LOS-CB/	Rachel Johnson FOI Services, Inc.	PYRAMID, COSTA MESA, CA - EIR, CORR 01/05-15/2015

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2015-2366	03/24/2015 04/21/2015	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Wendy Lockwood Banka Wendy Lockwood Banka	ZOETIS LLC, LINCOLN, NE - 483 01/01/2015 - 01/31/2015
2015-2367	03/24/2015 04/21/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rebecca Dandeker Morgan, Lewis & Bockius LLP	FREDA BIOPHARM CO LTD - 483, EIR SUMMARIES 01/01/2013 - 01/31/2015
2015-2368	03/24/2015 04/21/2015	FDA/OFVM/CFSAN/OCD/EOS/	Mark Prinz Registrar Corp	SPREADSHEET LISTING COMPANIES THAT HAVE COMPLETED THE DHHS/FDA MENU AND VENDING MACHINE LABELING VOLUNTARY REGISTRATION
2015-2369	03/24/2015 04/21/2015	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sophiya Das UNIVERSITY OF HOUSTON	NDA, BLA APPROVAL TIMES 01/01/2009 - 02/28/2015
2015-2370	03/24/2015 04/21/2015	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Andrew Finkelstein Susquehanna Financial Group	QUALITEST, CHARLOTTE, NC - 483, WARNING LETTER 07/01/2014 - PRESENT
2015-2371	03/24/2015 04/21/2015	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	Andrew Finkelstein Susquehanna Financial Group	QUALITEST, HUNTSVILLE, AL - 483, WARNING LETTER 07/01/2014 TO PRESENT
2015-2372	03/24/2015 04/21/2015	FDA/OFVM/CFSAN/OCD/EOS/	Mark Prinz Registrar Corp	NUTRITIONAL LABELING OF STANDARD MENU ITEMS IN RESTAURANTS ETC - SPREADSHEET OF ENTITIES SUBJECT TO RULE
2015-2373	03/24/2015 04/21/2015	FDA/OMPT/CDRH/OCER/DFOI/	SICAT GmbH & Co. KG SICAT GmbH & Co. KG	K111066, K102909
2015-2374	03/24/2015 04/21/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Paul D Cohn Wintermute Biomedical	MRSA, STAPH, ACNE, FUNGAL ET - EXPENSES FOR OTC TOPICALS, RX 01/01/2011 - 03/15/2015
2015-2375	03/24/2015 04/21/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michele Sinoway LACHMAN CONSULTANT SERVICES, INC.	CDER FTE CEILING, FTE ONBOARD PLUS EOD CHART; CDER FTE CEILING SPLIT CHART
2015-2376	03/24/2015 04/21/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Emily Schmall THE ASSOCIATED PRESS	CHIMERIX - CORR RE EMERGENCY APPROVAL OF BRINCIDOFOVIR IN EBOLA PATIENT

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2015-2377	03/24/2015 04/21/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sara Xiao Hisun Pharmaceuticals USA, Inc.	DAUNORUBICIN HYDROCHLORIDE INJECTION SOLUTION - RLD LABELS
2015-2378	03/24/2015 04/21/2015	FDA/OMPT/CDRH/OCER/DFOI/	Millan Bederu CONSUMERS' RESEARCH MAGAZINE	23ANDME 510K WITHDRAWAL, WARNING LETTER - OPINION, INFORMATION LETTERS, EMAILS ETC Date Range 11/22/2013 - 03/20/2015
2015-2379	03/24/2015 04/21/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	G. Srinivas Zydus Pharmaceuticals USA Inc.	ANDA 202640 SBA
2015-2380	03/24/2015 04/21/2015	FDA/OMPT/CDRH/OCER/DFOI/	Anthony T. Pavel MORGAN, LEWIS & BOCKIUS	K120972, K013061, K062818
2015-2381	03/24/2015 04/21/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	G. Srinivas Zydus Pharmaceuticals USA Inc.	ANDA 200294 SBA
2015-2382	03/24/2015 04/21/2015	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	David Gregoire Algorihme Pharma	PRACS, FARGO, ND - EIR 09/01/2011 - 12/31/2012
2015-2383	03/24/2015 04/21/2015	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Lynn Keefe Keefe, Lynn	BRACCO DIAGNOSTICS INC, MONROE TOWNSHIP, NJ - 483 05/01/2014 - 06/30/2014
2015-2384	03/24/2015 04/21/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Natoya Burke B. BRAUN MEDICAL INC	NDA 006488
2015-2385	03/24/2015 04/21/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Natoya Burke B.Braun	NDA 018692
2015-2386	03/24/2015 04/21/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Natoya Burke B.Braun	ANDA 083914

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2015-2387	03/24/2015 04/21/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jintan Jintan Liu	NUMBER OF EMPLOYEES AND STAFF IN CDER
2015-2388	03/24/2015 04/21/2015	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SE-FO/NOL-DO/NOL-CB/	SAMANTHA MYERS ROANOKE CLAIMS SERVICES	KINCAID ENTERPRISES INC - ENTRY #EAQ00001631 CF 28, CF29, CBP REDELIVER NOTICES,E TC
2015-2389	03/24/2015 04/21/2015	FDA/OC/OES/DFOI/	PETER KAUFMAN PANISH SHEA & BOYLE LLP	2003-6609, 2009-3077, 2012-5361, 2015-1737
2015-2390	03/24/2015 04/21/2015	FDA/OMPT/CDRH/OCER/DFOI/	JEROME LEW JEROME LEW	TPS - HDE SUBMISSION, APPROVAL ORDER, SAFETY SUMMARY ETC
2015-2391	03/24/2015 04/21/2015	FDA/OC/OES/DFOI/	RAFI MASLATON CRESULTS CONSULTING	HOSPIRA INC, AUSTIN, TX - 483S 2009 TO 2015
2015-2392	03/24/2015 04/21/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHRIS HENDEL CONSUMER REPORTS	SPRAY-ON SINSCREENS - AERS 2010 TO PRESENT
2015-2393	03/24/2015 04/21/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOE AUGUSTINE KSTP-TV LLC	FLUOROQUINOLONES - PHARMACOVIGILANCE RVWS 4/17/13 TO PRESENT
2015-2394	03/24/2015 04/21/2015	FDA/OC/OES/DFOI/	Tod Cooperman - Request for copy of FOIA #2015-1122 CONSUMERLAB.COM	2015-1122
2015-2395	03/24/2015 04/21/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Prasanna Gore, PhD PharmaCompany, Inc	PRODUCT SPECIFIC RECOMMENDATIONS FOR GENERIC DRUG DEVELOPMENT 01/01/2014 - 03/23/2015
2015-2396	03/24/2015 04/21/2015	OC/ORO/ OC/ORO/ OC/ORO/ORM/ OC/ORO/ORM/	Sara R Jordan Center for Public Administration & Policy, Virginia Tech	ENFORCEMENT REPORTS - CORRECTED VERSIONS 01/01/2004 - 05/07/2012

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2015-2397	03/24/2015 04/21/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	G. Srinivas Zydus Pharmaceuticals USA Inc.	ANDA 200294 SBA
2015-2398	03/24/2015 04/21/2015	FDA/OMPT/CDRH/OCER/DFOI/	John Arne Forte Automation Systems, Inc.	K142006
2015-2399	03/24/2015 04/21/2015	FDA/OFVM/CFSAN/OCD/EOS/	QUIANA A MONTGOMERY Keller and Heckman LLP	NATURAL RESOURCES DEFENSE COUNCIL - PERFLUOROALKYL ETHYL IN FOOD CONTACT APPLICATIONS
2015-2400	03/24/2015 04/21/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gary Dixon Dixon, Gary W	PIRAMAL HEALTHCARE, UK - EIR 10/13/2014 - 10/17/2014
2015-2401	03/24/2015 04/21/2015	FDA/OMPT/CDRH/OCER/DFOI/	JEFF FELDHAUS M SQUARED ASSOCIATES INC	CANDELA LCS K926464 - SS&E, SE LTR
2015-2402	03/24/2015 04/21/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jean Xiao, Graduate Student Vanderbilt Law and Econ Program	PARAGRAPH IV CERTIFICATIONS 1986 TO 2004
2015-2403	03/24/2015 04/21/2015	FDA/OC/OES/DFOI/	Lauren Appel LeClairRyan, PC	COMPLAINT RECORDS, COMMUNICATIONS
2015-2404	03/24/2015 04/21/2015	OC/CVM/OCD/ FDA/OFVM/CFSAN/OCD/EOS/	Craig Pullman CONSUMER	MONSANTO - WHOLESOMENESS STUDIES CITED IN BNF 000001
2015-2405	03/24/2015 04/21/2015	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/	DONALD N BLUE ZETETIC INC	SHIPMENTS REGULATED BY FDA 3/1-15/15
2015-2406	03/24/2015 04/21/2015	FDA/OC/OES/DFOI/	Kari L. Twaite BEVERIDGE & DIAMOND PC	FOIA REQUESTS TO CFSAN 02/25/2015 - 03/23/2015
2015-2407	03/24/2015 04/21/2015	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/NE-FO/NYK- DO/NYK-DCB/	SAMANTHA MYERS ROANOKE CLAIMS SERVICES	OMSHEEL LLC - ENTRY #18500562535 CF28, CF29, NOTICE OF ACTION, ETC
2015-2408	03/24/2015 04/21/2015	FDA/OGROP/ORO/CE-FO/DET- DO/DET-CB/	Wendy Lockwood Banka Wendy Lockwood Banka	ZOETIS, KALAMAZOO, MI - 483 04/01/2014 - 04/30/2014

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2015-2409	03/24/2015 04/21/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jean Xiao, graduate student Vanderbilt Law and Economics Program	ORANGE BOOK DATA
2015-2410	03/24/2015 04/21/2015	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	LESLIE RAMSEY FDA NEWS	ASH STEVENS INC, RIVERVIEW, MI. BIOPRO INC, PORT HURON, MI, OSSUR AMERICAS INC, ALBION, MI, ETC - 483S 11/1-30/14
2015-2411	03/24/2015 04/21/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ashish Rathi Spark Capital India (Private) Advisors Ltd	AUROBINDO PHARMA - 483 03/01/2014 - 03/01/2015
2015-2412	03/24/2015 04/21/2015	FDA/OMPT/CDRH/OCER/DFOI/	LESLIE RAMSEY FDA NEWS	LAC MAC LTD, LONDON, CANADA, STORZ MEDICAL AG, TAGERWILEN, SWITZERLAND, DORO INC, OTTAWA, CANADA, ETC - 483S 11/1-30/14
2015-2413	03/24/2015 04/21/2015	FDA/OMPT/CDRH/OCER/DFOI/	Mike Johnson Mike Johnson	TRAVALERT - PATHWAY, DATE OF APPROVAL
2015-2414	03/24/2015 04/21/2015	FDA/OC/OES/DFOI/	RAYMOND NESBITT #M00998 Nesbitt, Raymond	LISINOPRIL, DIVALPROEX, REMERON, ETC - RECS
2015-2415	03/24/2015 04/21/2015	OC/ORACE/OCI/ OC/ORACE/OCI/	CHANDLER FREDERICK FREDERICK, CHANDLER	GOOGLE INC - CRIMINAL INVESTIGATION RECS; TIMOTHY ARMSTRONG, NIKESH ARORA, DENNIS WOODSIDE, ETC - SETTLEMENT AGREEMENT 8/11
2015-2416	03/24/2015 04/21/2015	FDA/OMPT/CDRH/OCER/DFOI/	RICHARD M ORMSBEE MAR COR PURIFICATION	VIVONIC GMBH - AQUABPLUS, AQUABPLUS B2, AQUABPLUS HF, ETC K133829
2015-2417	03/24/2015 04/21/2015	FDA/OMPT/CDRH/OCER/DFOI/	RICHARD M ORMSBEE MAR COR PURIFICATION	LAUER MEMBRAN WASSERTECHNIK GMBH - AQUABOSS ECORO I, ECORO I HT, ECORO II, ETC K124059
2015-2418	03/24/2015 04/21/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GLORIA DEALBA DEALBA, GLORIA	SOLWAY - TORA (PHENTERMINE HCL) 8MG ANDA 84-035 CLNCL STUDIES, APRVL LTR
2015-2419	03/24/2015 04/21/2015	FDA/OMPT/CDRH/OCER/DFOI/	JASON B WYNBERG MD JBW7 INNOVATIONS LLC	COOK LAWSON RETROGRADE NEPHROSTOMY KIT K833762
2015-2420	03/24/2015 04/21/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RACHEL M SHARE DRINKER BIDDLE & REATH LLP	RISPERIDONE NDA 20-272 VOLS 127-135

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		FDA/OMPT/CDER/GRP/DIDP/		
2015-2421	03/24/2015 04/21/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	RAY THOMPSON THOMPSON, RAY	CATALENT PHARMA SOLUTIONS LTD, SWINDON, WILTSHIRE, UK 9/8-12/14; PATHEON UK LTD, SWINDON, UK 9/4-12/14; ROSEMONT PHARMACEUTICALS LTD, LEEDS, UK, 12/8-12/14, ETC - 483S
2015-2422	03/24/2015 04/21/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	RAY THOMPSON THOMPSON, RAY	SANOFI CHIMIE, SISTERON CEDEX, FRANCE 12/8-12/14; FERRING GMBH, KIEL, GERMANY 11/3-11/14; SANDOZ GMBH, KUNDL, AUSTRIA 9/8-16/14, ETC - 483S
2015-2423	03/24/2015 04/21/2015	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	LESLIE RAMSEY FDA NEWS	PARAMOUNT COSMETICS INC, CLIFTON, NJ; MTI PRECISION PRODUCTS LLC, LAKEWOOD, NJ; SONAR PRODUCTS INC, CARLSTADT, NJ, ETC - 483S 11/1-30/14
2015-2424	03/24/2015 04/21/2015	FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/	LESLIE RAMSEY FDA NEWS	J STRICKLAND AND CO, OLIVE BRANCH, MS; COASTAL MEDS LLC, BILOXI, MS - 483S 11/1-30/14
2015-2425	03/24/2015 04/21/2015	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	LESLIE RAMSEY FDA NEWS	NOVUM MEDICAL PRODUCTS CO, CLARENCE, NY - 483S 11/1-30/14
2015-2426	03/24/2015 04/21/2015	FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/	LESLIE RAMSEY FDA NEWS	CUSTOM ULTRASONICS INC, IVYLAND, PA; SIGMA PHARM LABORATORIES LLC, BENSLEM, PA - 483S 11/1-30/14
2015-2427	03/24/2015 04/21/2015	FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	LESLIE RAMSEY FDA NEWS	ABCO LABORATORIES INC, FAIRFIELD, CA; CONCENTRIC MEDICAL INC, MOUNTAIN VIEW, CA; UNITED BIO RESEARCH INC, SAN JOSE, CA - 483S 11/1-30/14
2015-2428	03/24/2015 04/21/2015	FDA/OGROP/ORA/SE-FO/SJN- DO/SJN-CB/	LESLIE RAMSEY FDA NEWS	TAPI PUERTO RICO INC, HUMACAO, PR - 483S 11/1-30/14
2015-2429	03/24/2015 04/21/2015	FDA/OGROP/ORA/PA-FO/SEA- DO/SEA-CB/	LESLIE RAMSEY FDA NEWS	ELECTRODE STORE INC, BUCKLEY, WA; CONTROLTEK INC, VANCOUVER, WA; GALENA BIOPHARMA INC, PORTLAND, OR - 483S 11/1-30/14
2015-2430	03/24/2015 04/21/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LESLIE RAMSEY FDA NEWS	APOTEX PHARMACHEM INC, BRANTFORD, CANADA; WYETH LEDERLE SRL, CATANIA, ITALY; DR REDDY'S LABORATORIES LTD CTO VI, SRIKAKULAM DISTRICT, INDIA - 483S 11/1-30/14
2015-2431	03/25/2015 04/22/2015	FDA/OMPT/CDRH/OCER/DFOI/	Russell Rudin Fanestra	K123229
2015-2432	03/25/2015	FDA/OC/OL/	Sheila Kaplan	LIST OF CORR WITH CONGRESS 03/01/2010 - 03/01/2015

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	04/22/2015		Edmond J. Safra Center for Ethics, Harvard Law	
2015-2433	03/25/2015 04/22/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Sporer DENTSPLY International Inc.	K120134 K120053
2015-2434	03/25/2015 04/22/2015	FDA/OMPT/CDRH/OCER/DFOI/	Ed Chomas OxyHeal Medical Systems, Inc.	K031649
2015-2435	03/25/2015 04/22/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FRATTI, JOHN	LEVAQUIN; CIPRO; AVELOX - AER
2015-2436	03/25/2015 04/22/2015	FDA/OC/OES/DFOI/	CAROLLO, RUSSELL	FOI REQUESTS 4/1/14 TO PRESENT
2015-2437	03/25/2015 04/22/2015	FDA/OC/OES/DFOI/	STEPHANIE O'CONNOR Douglas & London, P.C.	JOINT MGT OF THE ADVISORY COMMITTEE FOR REPRODUCTIVE HEALTH DRUGS; DRUG SAFETY & RISK MGMT ADVISORY COMMITTEE - TRANSCRIPT, MINUTES 12/8/11 CERTIFIED
2015-2438	03/25/2015 04/22/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DETZEL, ROBERT	BUPRENORPHINE - AER
2015-2439	03/25/2015 04/22/2015	FDA/OMPT/CDRH/OCER/DFOI/	ALAN G. MINSK ARNALL GOLDEN GREGORY LLP	THERMACARE HEAT WRAP K953442 - CORR
2015-2440	03/25/2015 04/22/2015	FDA/OGROP/ORR/CE-FO/CIN-DO/CIN-CB/	CHRIS LAMOND THORN RUN PARTNERS	LITTLE RIVER ICE CO LLC, CADIZ, KENTUCKY - EIR
2015-2441	03/25/2015 04/22/2015	FDA/OMPT/CDRH/OCER/DFOI/	ELIZABETH BRITTON COTTLE FIRM	ST JUDE MEDICAL INC - PENTA SPINAL STIMULATOR PADDLE IMPLANT PMA, MDR
2015-2442	03/25/2015 04/22/2015	FDA/OFVM/CFSAN/OCD/EOS/	Mark Prinz Registrar Corp	NALMA, SA - EIR, ATTACHMENTS MOST RECENT
2015-2443	03/25/2015 06/04/2015	FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	ST JUDE MEDICAL, INC, PLANO, TX - 483, EIR, RESPONSE 05/01/2014 - 05/31/2014

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2015-2444	03/25/2015 04/22/2015	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	Chalkley Walter THOMSON REUTERS (SCIENTIFIC) SAS	CALCAGNO, JOHN, GRESHAM, OR - 483, EIR, RESPONSE 10/01/2014 - 10/31/2014
2015-2445	03/25/2015 04/22/2015	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	MEDTRONIC PUERTO RICO OPERATIONS CO, VILLALBA, PR - 483, EIR, RESPONSE 05/01/2014 - 05/31/2014
2015-2446	03/25/2015 04/22/2015	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	MARTIN YUDOVICH, HOUSTON, TX - 483, EIR, RESPONSE 10/01/2014 - 10/31/2014
2015-2447	03/25/2015 04/22/2015	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	DENTSPLY ORTHOLAB INC, RACINE, WI - 483, EIR, RESPONSE 04/01/2014 - 04/30/2014
2015-2448	03/25/2015 04/22/2015	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	2015-886
2015-2449	03/25/2015 04/22/2015	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	AMYLIN OHIO, LLC, WEST CHESTER, OH - 483, EIR, RESPONSE 07/01/2014 - 07/31/2014
2015-2450	03/25/2015 04/22/2015	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	ALLERGAN, GOLETA, GA - 483, EIR, RESPONSE 08/01/2012 - 08/31/2012
2015-2451	03/25/2015 04/22/2015	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	BIOMARIN PHARMACEUTICAL, INC, NOVATO, CA - 483, EIR, RESPONSE 04/01/2014 - 04/30/2014
2015-2452	03/25/2015 04/22/2015	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DIANNE L. CHAMBERS HOGAN LOVELLS LLP	2015-1908
2015-2453	03/25/2015 04/22/2015	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	ONE BLOOD INC, LANTANA, FL - EIR, 483, RESPONSE 07/01/2013 - 07/31/2013
2015-2454	03/25/2015 04/22/2015	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	SUN PHARMACEUTICAL INDUSTRIES, DETROIT, MI - EIR, 483, RESPONSE 02/01/2013 - 05/31/2013
2015-2455	03/25/2015 04/22/2015	FDA/OFVM/CFSAN/OCD/EOS/	QUIANA A. MONTGOMERY Keller and Heckman LLP	AGGLOMERATED STOPPERS - ANALYTICAL DATA, STUDIES FOR ALCOHOLIC BEVERAGES; CORR
2015-2456	03/25/2015 04/22/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	eleanor mayer not applicable	BLA 125291 S 136 - SBA

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		FDA/OMPT/CDER/ORP/DIDP/		
2015-2457	03/25/2015 04/22/2015	FDA/OMPT/CDRH/OCER/DFOI/	LINDSEY A. SEESKIN RAPOPORT	CONVATEC INC - FLEXI SEAL CONTROL FECAL MGMT SYS RECALL, CMLPLNTS, MDRS
2015-2458	03/25/2015 04/22/2015	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	BIO-RAD LABORATORIES, REDMOND, WA - EIR, 483, RESPONSE 04/01/2014 - 04/30/2014
2015-2459	03/25/2015 04/22/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-1459 - REQUEST LETTER ONLY
2015-2460	03/25/2015 04/22/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-1477 - REQUEST LETTERS ONLY
2015-2461	03/25/2015 04/22/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-1451 - REQUEST LETTERS ONLY
2015-2462	03/25/2015 04/22/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-1561 - REQUEST LETTERS ONLY
2015-2463	03/25/2015 04/22/2015	FDA/OC/OES/DFOI/	CAROLINE STOUT ECOR1 CAPITAL LLC	SOLVALDI (SOFOSBUVIR) REQUEST LOG 1/1/10 TO PRESENT
2015-2464	03/25/2015 04/22/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-1020 - REQUEST LETTER ONLY
2015-2465	03/25/2015 04/22/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-1271 - REQUEST LETTER ONLY
2015-2466	03/25/2015 04/22/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-1442 - REQUEST LETTERS ONLY
2015-2467	03/25/2015 04/22/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-1312 - REQUEST LETTER ONLY
2015-2468	03/25/2015 04/22/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-824 - REQUEST LETTER ONLY
2015-2469	03/25/2015 04/22/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-827 - REQUEST LETTER ONLY
2015-2470	03/25/2015 04/22/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-950 - REQUEST LETTER ONLY
2015-2471	03/25/2015 04/22/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-976 - REQUEST LETTER ONLY
2015-2472	03/25/2015	FDA/OMPT/CDER/ORP/DIDP/	T.J. JESKY	INSYS THERAP ANDA 78-501 001, 78-501 002, 78-501 003 SBA

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	04/22/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	STUDES LLC	
2015-2473	03/25/2015 04/22/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-985 - REQUEST LETTER ONLY
2015-2474	03/25/2015 04/22/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-1342, 1344, 1345, 1346, 1347, 1355 - REQUEST LETTERS ONLY
2015-2475	03/25/2015 04/22/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-1385 - REQUEST LETTERS ONLY
2015-2476	03/25/2015 04/22/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-1432 - REQUEST LETTERS ONLY
2015-2477	03/25/2015 04/22/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-1414 - REQUEST LETTERS ONLY
2015-2478	03/25/2015 04/22/2015	OC/ORO/ORM/ OC/ORO/ORM/	TIMOTHY BEATTY UNIV OF CALIFORNIA DAVIS	EGG, PRODUCE, DAIRY PRODUCERS - TESTING DATA, COMPLIANCE INFO, ENFORCEMENT INFO, RECALL 1990-2014
2015-2479	03/25/2015 04/22/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SAMUEL M. WARD BARRACK RODOS & BACINE	OREXIGEN THERAPEUTICS INC - CONTRAVE (NALTREXONE HCI, BUPROPION HCI) CORR
2015-2480	03/25/2015 04/22/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SASHA GRAY THOMSON REUTERS	TEVA PHARMACEUTICALS - TERZOSIN HYDROCHLORIDE; ABBOTT LABORATORIES - PROPOFOL; TEVA CANADA - FAMOTIDINE ETC - APRVL
2015-2481	03/26/2015 04/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	Cole Dowden Fay Kaplan Law	SUBMISSIONS MADE BY DEVICE MANUFACTURERS OF POWER MORCELLATOR DEVICES REGARDING FDA REVIEW OF CANCEROUS TUMOR RISK FOR UTERINE FIBROID PROCEDURES 03/01/2013 - 12/31/2013
2015-2482	03/26/2015 04/23/2015	FDA/OGROP/ORO/ORO/DIOP/	Lakshmi Hiriyannaiah personal	IMPORT DATA 01/01/2013 - 03/31/2015
2015-2483	03/26/2015 04/23/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/	Robert Pyrtle Pyrtle, Robert	SCANTIBODIES BIOLOGICS INC - 483
2015-2484	03/26/2015	FDA/OGROP/ORO/SE-FO/FLA- DO/FLA-CB/	Julie Nowak	LUIS SANCHEZ-RAMOS, UF HEALTH SCIENCE CENTER UNIVERSITY, JACKSONVILLE, FL - 483 02/09/1998 -

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	04/23/2015		University of Florida College of Medicine - Jacksonville	02/09/1998
2015-2485	03/26/2015 04/23/2015	FDA/OC/OES/ OC/CVM/OCD/	Justine Nguyen Beveridge & diamond, P.C.	REQUESTS REGARDING REGULATORY STATUS OF GENOME-EDITED ANIMAL; RECS RE REGULATORY STATUS OF GENOME-EDITED ANIMAL INCLUDING RESPONSE TO REQUESTS
2015-2486	03/26/2015 04/23/2015	OC/CVM/OCD/	Patience O'Dowd O'Dowd, Mary E	INADA FOR PORCINE ZONA PELLUCIDA
2015-2487	03/26/2015 04/23/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gina Elton Teva Pharmaceuticals	TEVA PHARMACEUTICALS, KFAR SABA, ISRAEL - EIR 12/01/2013 - 12/31/2013
2015-2488	03/26/2015 04/23/2015	OC/CVM/OCD/ OC/ORO/ OC/ORO/	Susan Thixton Susan Thixton/Association for Truth in Pet Food	BENEFUL - ADVERSE EVENTS, CONSUMER COMPLAINTS 03/18/2014 - 03/24/2015
2015-2489	03/26/2015 04/23/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 202880
2015-2490	03/26/2015 04/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K021606
2015-2491	03/26/2015 04/23/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gina Elton Teva Pharmaceuticals	TEVA PHARMACEUTICALS, BEER SHEVA, ISRAEL - EIR 07/01/2014 - 07/31/2014
2015-2492	03/26/2015 04/23/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Shreya Agarwal NEW YORK UNIVERSITY	VIOXX - APPROVAL, APPLICATION, CORR 01/01/1999 - 12/31/2002
2015-2493	03/26/2015 04/23/2015	FDA/OC/OES/DFOI/	Carla Morrow LLOYD, Inc.	LLOYD, INC - FOIA REQUESTS 01/01/2012 - 03/25/2015
2015-2494	03/26/2015 05/14/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Shreya Agarwal NEW YORK UNIVERSITY	GARDASIL - APPROVAL LETTER, EMAILS, APPLICATION 01/03/2005 - 12/27/2010
2015-2495	03/26/2015	FDA/OMPT/CDER/ORP/DIDP/	Kerri O'Brien	LEVAQUIN, CIPRO, AVELOX - AERS 03/25/2010 - 03/25/2015

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	04/23/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WRIC-TV	
2015-2496	03/26/2015 04/23/2015	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2013-2250
2015-2497	03/26/2015 04/23/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 206627
2015-2498	03/26/2015 04/23/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Xavier A. Adame DPT Laboratories, Ltd	CONFAB LABORATORIES INC - PROFILE CLASS CODES
2015-2499	03/26/2015 04/23/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Xavier A. adame DPT Laboratories, Ltd	DPT LAKEWOOD - PROFILE CLASS CODES 12/01/2001 - 03/01/2015
2015-2500	03/26/2015 04/23/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Janet Ehlert Shionogi Inc.	DORIPENEM, DORIBAX - AERS
2015-2501	03/26/2015 04/23/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Samuel P. Vitello Triumvirate Environmental, Inc.	K950897, K950898, K001337
2015-2502	03/26/2015 04/23/2015	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	DAVID J MARTIN MEYERS RODBELL & ROSENBAUM PA	HARBOR HOUSE SEAFOOD, SEAFORD, DE - EIRS, 483S 7/1/10
2015-2503	03/26/2015 04/23/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rakesh Padigala EASTERN MICHIGAN UNIVERSITY	LIPITOR COUNTERFEIT DRUG CASE RECS

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		FDA/OMPT/CDER/GRP/DIDP/ OC/ORA/OCI/ OC/ORA/OCI/		
2015-2504	03/26/2015 04/23/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/ORA/OCI/ OC/ORA/OCI/	Rakesh Padigala EASTERN MICHIGAN UNIVERSITY	VIAGRA COUNTERFEIT DRUG RECS
2015-2505	03/26/2015 04/23/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jennifer Peppe Jennifer Peppe	SHIRE DEVELOPLMENT LLC CLINICAL HOLD LETTER SPD602, SSP-004184
2015-2506	03/26/2015 04/23/2015	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/	Doe J	PULMONETICS SYSTEMS, CAREFUSION LTV 1150 VENTILATOR - INVESTIGATION RECS 01/27/2014 - 04/30/2014
2015-2507	03/26/2015 04/23/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	IAN MASHAL BLOOM TREE	INSYS THERAPEUTICS - LAZANDA, ABSTRAL & FENTORA SUMMARY STATISTICS
2015-2508	03/26/2015 04/23/2015	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lauren Sulik Wilson Elser Moskowitz Edelman & Dicker, LLP	ADVANCE PHARMACEUTICAL, INC - RECALL RECS LOT 13A026
2015-2509	03/26/2015 04/23/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MATT KILOUGH KILLOUGH, MATT	SEROQUEL - AERS
2015-2510	03/26/2015 04/23/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PATRICIA L REGENYE Celgene Corporation	THOMAS ELLIOTT, DIABETES CLINIC & RESEARCH, VANCOUVER, CANADA - 483S 11/13 TO PRESENT

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2015-2511	03/26/2015 04/23/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michele Crawley Cipla USA, Inc.	ANDA 085635 DEPO-TESTOSTERONE (TESTOSTERONE CYPIONATE)
2015-2512	03/26/2015 04/23/2015	FDA/OO/OHR/	Dr. Thomas V. Montgomery, III Dr. Thomas V. Montgomery, III	FDA-CDRH-15-MP-1255935LK SELECTED APPLICANTS
2015-2513	03/26/2015 04/23/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WILLIAM J REGAN NAVIDEA	NAVIDEA BIOPHARMACEUTICALS - LYMPHOSEEK NDA 20-2207 SAFETY RPT 7/1/14-9/30/14
2015-2514	03/26/2015 04/23/2015	OC/CVM/OCD/	butch kukanich Butch Kukanich, Kansas State University	NADA 030-438, SUPPLEMENTS; NADA 030-525, SUPPLEMENTS
2015-2515	03/26/2015 04/23/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SHARLA CORNELSON HELTON HELTON, SHARLA CORNELSO	ALLERGAN INC, SMITH-KETTLEWELL EYE RESEARCH INSTITUTE - OCLINUM 1987 TO 1997
2015-2516	03/26/2015 04/23/2015	FDA/OC/OES/DFOI/	HAROLD LEE TINEYBEY TINEYBEY LQ2Y552Y, HAROLD LEE	MECHANICALLY SEPARATED CHICKEN - RECS
2015-2517	03/26/2015 04/23/2015	FDA/OC/OES/DFOI/	LUIS MURGULA BUMBLE BEE SEAFOODS	CMLPNT
2015-2518	03/26/2015 04/23/2015	OC/CVM/OCD/	SANDHYA RANI KOSURI BELCHER PHARMACEUTICALS INC	BELCHER PHARMACEUTICALS LLC - RIMADYL CHEWABLE TABS NADA 141-111 QUALITATIVE FORMULA, SCIENTIFIC DISCUSSION
2015-2519	03/26/2015 04/23/2015	FDA/OO/OHR/	KELLY MCCONAGHY MCCONAGHY, KELLY	VACANCY ANNOUNCEMENT FDA-CDER-14-DE-1164921DM RESEARCH TOXICOLOGIST GS-0415-13 - APPL PKG
2015-2520	03/26/2015 04/23/2015	FDA/OFVM/CFSAN/OCD/EOS/	Scott Burya akzonobel	FCN 415
2015-2521	03/26/2015 04/23/2015	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	Mehul Govani P & L Development LLC	P&L DEVELOPMENT, LLC, LYNWOOD, CA - EIR 01/01/2014 - 12/31/2014
2015-2522	03/27/2015	FDA/OMPT/CDER/ORP/DIDP/	Curtis Hamilton	ZHEJIANG TIANAI AURISCO PHARMACEUTICAL CO - 483,

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	04/24/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ECI Pharmaceuticals, LLC	EIR, RESPONSE 11/12/2013 - 11/15/2013
2015-2523	03/27/2015 04/24/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Hee Chul Chang Daewoong America Inc.	ANDA 90999
2015-2524	03/27/2015 04/24/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jean Xiao, Graduate Student Vanderbilt Law and Econ Program	NDA, ANDA SPREADSHEETS
2015-2525	03/27/2015 04/24/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jean Xiao, Graduate Student Vanderbilt Law and Econ Program	LIST OF PARAGRAPH I, II, AND III CERTIFICATIONS
2015-2526	03/27/2015 04/24/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/	Xavier A. adame DPT Laboratories, Ltd	DPT LABORATORIES, SAN ANTONIO, TX - PROFILE CLASS CODES
2015-2527	03/27/2015 04/24/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jean Xiao, Graduate Student Vanderbilt Law and Econ Program	INACTIVE INGREDIENT DATA
2015-2528	03/27/2015 04/24/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Debra Sweitzer Kythera Biopharmaceuticals, Inc.	EXPANSIA, DIVI'S LABORATORIES LTD, INDIA - EIR SUMMARY 01/01/2009 - 03/25/2015
2015-2529	03/27/2015 04/24/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jean Xiao, Graduate Student Vanderbilt Law and Econ Program	ANDA, NDA APPLICATION DATES

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2015-2530	03/27/2015 04/24/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dianna Carter Request File Number 2015-1504 Carter, Dianna E	TIZANIDINE CASE REPORTS
2015-2531	03/27/2015 04/24/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Gina Elton Teva Pharmaceuticals	TEVA PHARMACEUTICALS, KFAR SABA, ISRAEL - EIR (CERTIFIED) 12/01/2013 - 12/31/2013
2015-2532	03/27/2015 04/24/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sylvia Lamm Sylvia Lamm	ZYCLARA - AERS
2015-2533	03/27/2015 04/24/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	William M. Troetel, Ph.D., LLC William M Troetel, Ph.D., LLC, RAC	APTUIT, OXFORD, ENGLAND; VERONA, ITALY - 483, EIR, RESPONSE ETC 01/22/2005 - 03/25/2015
2015-2534	03/27/2015 04/24/2015	FDA/OGROP/ORA/SW-FO/DEN- DO/DEN-CB/	KENNETH L LEVINSON BALABAN LEVINSON & COSTIGAN PC	FRESCA FOODS - RECALL RECS
2015-2535	03/27/2015 04/24/2015	FDA/OFVM/CFSAN/OCD/EOS/	QUIANA A MONTGOMERY Keller and Heckman LLP	DOW CHEMICAL CO - FCN 1357
2015-2536	03/27/2015 04/24/2015	FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/ FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	DOUGLAS N BLUE ZETETIC INC	BABY FORMULA ENTRY #AV3-0041796-9
2015-2537	03/27/2015 04/24/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	COULTER JONES MEDPAGE TODAY	OPANA ER, ACETAMINOPHEN, VENLAFAXINE HCL, ETC - ISR 6545759; DMEROL, FENTORA, CYMBALTA, ETC - ISR 5321794
2015-2538	03/27/2015 04/24/2015	FDA/OMPT/CDRH/OCER/DFOI/	LAURA A HALPER PHD HALPER GROUP	EZ-ALIGN DENTAL APPLIANCE K121396
2015-2539	03/27/2015 04/24/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOEL BREWER BREWER, JOEL	COMPASSIONATE USE PROTOCOL PN104 (TRIACETYLRIDINE)

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2015-2540	03/27/2015 04/24/2015	FDA/OMPT/CDRH/OCER/DFOI/	Kathy Remsen MEDTRONIC SOFAMOR DANEK	K940973
2015-2541	03/27/2015 04/24/2015	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	REGINA K LAMPTEY ABM	INDIVIDUAL RECS
2015-2542	03/27/2015 04/24/2015	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	Rachel Johnson FOI Services, Inc.	ALLIED HEALTHCARE, STUYVESANT FALLS, NY - 483 NY 12/09-11/2013
2015-2543	03/27/2015 04/24/2015	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2014-9081
2015-2544	03/27/2015 04/24/2015	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	Carla Morrow LLOYD, Inc.	VIRBAC CORPORATION, ST LOUIS, MO - 483 09/01/2014 - 03/20/2015
2015-2545	03/27/2015 04/24/2015	FDA/OC/OES/DFOI/	Doe J	OBAMACARE - RECS
2015-2546	03/27/2015 04/24/2015	FDA/OFVM/CFSAN/OCD/EOS/	Qiuqi Luan Shandong University of Fiance and Economics	LIST OF NEW DIETARY INGREDIENT NOTICE OF GYNOSTEMMA PENTAPHYLLUM AND POLLEN PINI
2015-2547	03/27/2015 04/24/2015	FDA/OMPT/CTP/OD/	Jo Stedall Clearly Nova Ltd	FICTIONAL CIGARETTE, TILXA CIGARETTES, MERCHER CIGARETTES ETC
2015-2548	03/27/2015 04/24/2015	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Ken Faenza BRG Group	NESTLE, MODESTO, CA - 483 04/01/2013 - 04/01/2015
2015-2549	03/27/2015 04/24/2015	FDA/OFVM/CFSAN/OCD/EOS/	Don Boudreaux Boudreaux and Associates	FCN 45
2015-2550	03/27/2015 04/24/2015	FDA/OFVM/CFSAN/OCD/EOS/	Takahiro Haruyama Globizz Corp.	FCN 415
2015-2551	03/27/2015 04/24/2015	FDA/OC/OCC/ FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	INDIVIDUAL RECS 02/01/2014 - 03/26/2015
2015-2552	03/30/2015 04/27/2015	FDA/OC/OES/DFOI/	Chad Morris Chad Morris	FORM 483 FOIA REQUESTS LAST TWO YEARS
2015-2553	03/30/2015	FDA/OO/OHR/		INDIVIDUAL RECS

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	04/27/2015	OC/ORO/OCI/ OC/ORO/OCI/ OC/ORO/OCI/ OC/ORO/OCI/	Doe J	
2015-2554	03/30/2015 05/11/2015	FDA/OFVM/CFSAN/OCD/EOS/	Bryn Austin and Flora Or HARVARD SCHOOL OF PUBLIC HEALTH	DIETARY SUPPLEMENTS FOR SEXUAL ENHANCEMENT, BODY BUILDING, AND WEIGHT LOSS - ADVERSE EVENTS
2015-2555	03/30/2015 04/27/2015	FDA/OMPT/CDRH/OCER/DFOI/	Esie Cabral COVIDIEN	510K CLEARANCE LETTER FOR IVA SEALS
2015-2556	03/30/2015 04/27/2015	FDA/OGROP/ORO/SE-FO/NOL-DO/NOL-CB/	James Davis AMERICAN RED CROSS	CALDWELL TRACE, BIRMINGHAM, AL - EIR 04/28/2014 - 05/02/2014
2015-2557	03/30/2015 04/27/2015	FDA/OMPT/CDRH/OCER/DFOI/	Kurt W. Greve DeHay & Elliston	DEPUY PFC SIGMA KNEE PROSTHESIS, FEMORAL STEM ADAPTERS - 510K, AERS, RECS RE DESIGN, SAFETY ETC 01/01/1995 - 03/31/2015
2015-2558	03/30/2015 04/27/2015	FDA/OC/OES/DFOI/ FDA/OGROP/ORO/CE-FO/CIN-DO/CIN-CB/	Carla Scarmazzi, FDA Specialist KING & SPALDING	2014-5838
2015-2559	03/30/2015 05/11/2015	FDA/OGROP/ORO/SW-FO/DEN-DO/DEN-CB/	PDH Hansen, Paul	DOTERRA INTERNATIONAL LLC, PLEASANT GROVE, UT - INSPECTION RECS
2015-2560	03/30/2015 04/27/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K070173
2015-2561	03/30/2015 04/27/2015	FDA/OGROP/ORO/NE-FO/NWE-DO/NWE-CB/	Bob Buckley Aegerion Pharmaceuticals, Inc.	AEGERION PHARMACEUTICALS, INC, CAMBRIDGE, MA - EIR 08/21/2012 - 12/31/2012
2015-2562	03/30/2015 04/27/2015	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/	Kim Aylesworth GERBER PRODUCTS COMPANY	GERBER, FORT SMITH. AR - MICROBIOLOGICAL RESULTS 12/03/2014 - 12/04/2014
2015-2563	03/30/2015 04/27/2015	FDA/OFVM/CFSAN/OCD/EOS/	William Haun Collectis Plant Sciences	SIMPLOT PLANT SCIENCES, BIOTECHNOLOGY CONSULTATION AGENCY RESPONSE LETTER GENETICALLY ENGINEERED POTATOES - RECORDS RE CONSULTATION 01/01/2012 - 03/27/2015
2015-2564	03/30/2015 04/27/2015	FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	Jeanine Gouveia Aerie Pharmaceuticals Inc.	CATALENT PHARMA SOLUTIONS, MORRISVILLE, NC 03/16/2015 - 03/20/2015
2015-2565	03/30/2015	FDA/OGROP/ORO/SE-FO/FLA-	Mickie Anderson	LUSSIER DAIRY, HAWTHORNE, FL - INSPECTIONS,

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	04/27/2015	DO/FLA-CB/	GAINESVILLE SUN	ACTIONS, RESPONSE ETC 12/01/2014 - 03/26/2015
2015-2566	03/30/2015 04/27/2015	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	S B Loar S B Loar	DPT LAKEWOOD, INC, LAKEWOOD, NJ - EIR, 483 01/01/2014 - 03/27/2015
2015-2567	03/30/2015 04/27/2015	FDA/OMPT/CDRH/OCER/DFOI/	Kumar Akhil narang Medical Limited	K150121, K143394, K 143025 ETC
2015-2568	03/30/2015 04/27/2015	FDA/OC/OES/DDM/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Miles Orton Hughes Hubbard & Reed LLP	ENDOCRINOLOGIC AND METABOLIC DRUGS ADVISORY COMMITTEE MEETING - TRANSCRIPT, MINUTES, BACKGROUND DOCS ETC 02/04/1987 - 09/14/1987
2015-2569	03/30/2015 04/27/2015	FDA/OC/OES/DDM/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Miles Orton Hughes Hubbard & Reed LLP	ENDOCRINOLOGIC AND METABOLIC DRUGS ADVISORY COMMITTEE MEETING - TRANSCRIPT, MINUTES, BACKGROUND ETC 03/06/1994 - 01/14/1995
2015-2570	03/30/2015 04/27/2015	FDA/OMPT/CDRH/OCER/DFOI/	CHAR;LES CELESTE EAS CONSULTING GROUP LLC	K945835
2015-2571	03/30/2015 04/27/2015	FDA/OMPT/CDRH/OCER/DFOI/	JERRY LI GIMDX INC	K981013, K013971, K023075
2015-2572	03/30/2015 04/27/2015	FDA/OC/OL/	PETER OLSEN-PHILLIPS MUCKROCK NEWS	CONGRESSMAN VERNON BUCHANAN - CORR 1/1/14 TO 3/25/15
2015-2573	03/30/2015 04/27/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	CYMBALTA - AER
2015-2574	03/30/2015 04/27/2015	FDA/OFVM/CFSAN/OCD/EOS/	McMILLEN, ABBIE	FDA TO ASSESS ROSK OF SALMONELLOSIS ASSOCIATED W/EATING TREE NUTS - STUDY RECS 2013
2015-2575	03/30/2015 04/27/2015	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	RICHARD H. WOODS LEVIN PAPANTONIO ET AL	SMITH & NEPHEW - GENESIS II KNEE SYS MODEL 71420182 MDRS
2015-2576	03/30/2015 04/27/2015	FDA/OC/OES/DFOI/	KIM HENDERSON SANOFI PASTEUR	MERCK & CO INC - ZOSTAVAX APRVL, STATISTICAL RVW, CLNCL RVW
2015-2577	03/30/2015 04/27/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SIDNEY M. WOLFE, MD PUBLIC CITIZEN	VYNVANSE NDA 21-977/S-036/S-037 SUPPLEMENTARY APRVL RECS

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2015-2578	03/30/2015 04/27/2015	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	COURTNEY L. ENGELKE COLSON HICKS EIDSON LAW FIRM	BOSTON SCIENTIFIC - ZERO TIP NITINOL STONE RETRIEVAL BASKET 510K, PMA, RECALLS, MDRS
2015-2579	03/31/2015 04/28/2015	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Kelly Carver Texas Star Nut & Food Company, Inc	NATURE'S EATS NATURAL MACADAMIA NUTS - TEST RESULTS
2015-2580	03/31/2015 04/28/2015	FDA/OMPT/CDRH/OCER/DFOI/	Yuqing Pan Stanford University Department of Communication	INTUITIVE SURGICAL - ADVERSE EVENTS
2015-2581	03/31/2015 04/28/2015	FDA/OMPT/CDRH/OCER/DFOI/	Ji Hyun Kim JI KIM	P000025 S079, P000025 S063
2015-2582	03/31/2015 04/28/2015	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	shreya agarwal NEW YORK UNIVERSITY	GARDASIL - PURCHASE BY GOVERNMENT 05/01/2006 - 03/29/2015
2015-2583	03/31/2015 04/28/2015	FDA/OO/OHR/	Dr. thomas V. Montgomery, III Dr. Thomas V. Montgomery, III	FDA-CDRH-15-MP-1255935LK - CV, SF-50
2015-2584	03/31/2015 04/28/2015	FDA/OFVM/CFSAN/OCD/EOS/	Todd Jacobs SENSIENT COLORS LLC	Appendix A Certified Color Additive Assignment FPB 92-5
2015-2585	03/31/2015 04/28/2015	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	David Borasky COPERNICUS GROUP IRB	COPERNICUS GROUP IRB - EIR 09/16/2014 - 03/30/2015
2015-2586	03/31/2015 04/28/2015	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/ORO/DIOP/ FDA/OC/OCC/ FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	Import Alert 54-15
2015-2587	03/31/2015 04/28/2015	FDA/OMPT/CDRH/OCER/DFOI/	Lisa Giaquinto B. Braun Medical Inc.	K133147
2015-2588	03/31/2015 04/28/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Amir-Khan, Nazmin	FDA MEMO FROM JOHN PETERS REGARDING TRACKED SAFETY ISSUE 1349 METHYLPHANIDATE ER SUMMARY & CONCLUSIONS

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2015-2589	04/01/2015 04/29/2015	FDA/OMPT/CDRH/OCER/DFOI/	MEY SAIED DEPUY SYNTHES TRUMA	SMITH & NEPHEW INC - SPATIALFRAME VERSION 4.1 K110069
2015-2590	04/01/2015 04/29/2015	FDA/OMPT/CDRH/OCER/DFOI/	MEY SAIED DEPUY SYNTHES TRUMA	SMITH & NEPHEW INC - TYLOR SPATIAL FRAME K970748
2015-2591	04/01/2015 04/29/2015	FDA/OMPT/CDRH/OCER/DFOI/	MEY SAIED DEPUY SYNTHES TRUMA	SMITH & NEPHEW INC - CIRCULAR FIXATION K093047
2015-2592	04/01/2015 04/29/2015	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	SANDI SIMPSON Sterigenics	FTSI-FOOD TECHNOLOGY SERVICES INC - EIRS 3/4-16/13
2015-2593	04/01/2015 04/29/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LAYNE HILTON KANNER & WHITELEY LLC	ACTAVIS LABORATORIES INC - ANDA 07-7302; TEVA PHARMACEUTICAL INDUSTRIES LTD - ANDA 07-7488 APRVL
2015-2594	04/01/2015 04/29/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SOMA RAJU HETERO USA INC	PRAZQUANTEL (BILTRICADE) TABS 600 MG - NDA 18-714 CHEMISTRY RVW, BIOEQV RVW, CORR
2015-2595	04/01/2015 04/29/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Philip Serafino BLOOMBERG NEWS	AB SCIENCE SA, PARIS, FRANCE - INSPECTIONS OF CLINICAL TRIALS 01/01/2010 - 03/26/2015
2015-2596	04/01/2015 04/29/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca Dandeker Morgan, Lewis & Bockius LLP	Date Range: 01/01/2013 - 01/31/2015; I request the following: Any and all 483 Inspectional Observation(s) and Establishment Inspection Report SUMMARIES related to any FDA inspection(s) of Virupaksha Organics Pvt. Ltd., F-10, I.D.A., Gandhi Nagar, Balanagar, Hyderabad 500 037, Andhra, India, between the dates of January 1, 2013 and January 31, 2015. Please see attached request letter.
2015-2597	04/01/2015 04/29/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca Dandeker Morgan, Lewis & Bockius LLP	VIRUPAKSHA ORGANICS, INDIA - 483, EIR SUMMARY 01/01/2013 - 01/31/2015
2015-2598	04/01/2015 04/29/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca Dandeker Morgan, Lewis & Bockius LLP	VIRUPAKSHA ORGANICS, INDIA - EIR 01/03/2013 - 01/31/2015

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2015-2599	04/01/2015 04/29/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID E COOLEY David E Cooley	ENBREL - AERS
2015-2600	04/01/2015 04/29/2015	FDA/OMPT/CDRH/OCER/DFOI/	Marcus Susen Koch Parafinczuk & Wolf	CONCEPTUS INC, BAYER CORP - 483, CAPA, VIOLATIONS, ETC RE ESSURE 01/03/2002 - 03/26/2015
2015-2601	04/01/2015 04/29/2015	FDA/OC/OES/DFOI/	CAROLLO RUSSELL CAROLLO, RUSSELL	2014-1247, 2014-1316, 2014-1332, ETC
2015-2602	04/01/2015 04/29/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OES/DDM/	Jeff Della Valle LONZA INC	L-CARNITINE - STRUCTURE/FUNCTION CLAIMS 03/26/2005 - 03/26/2015
2015-2603	04/01/2015 04/29/2015	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ADAM MARCUS GASTROENTEROLOGY & ENDOSCOPY NEWS	PROPOFOL - AERS 2013, 2014, 2015
2015-2604	04/01/2015 04/29/2015	FDA/OC/OES/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Zachary Marker CENTER FOR FOOD SAFETY	NANISILVA - ALL RECS, COMMUNICATIONS, CONSULTATIONS 01/01/2013 - 03/27/2015
2015-2605	04/01/2015 04/29/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-7403
2015-2606	04/01/2015 04/29/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-7056
2015-2607	04/01/2015 04/29/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-7058
2015-2608	04/01/2015 04/29/2015	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	ELLEN RELKIN WEITZ & LUXEMBERG PC	ZIMMER - ZIMMER PERSONA PERSONALIZED KNEE SYSTEM MDRS, 510KS, PMAS, ETC

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		FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OC/OES/DFOI/		
2015-2609	04/01/2015 04/29/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-7060
2015-2610	04/01/2015 04/29/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-5778
2015-2611	04/01/2015 04/29/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-5860
2015-2612	04/01/2015 04/29/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2013-7269
2015-2613	04/01/2015 04/29/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2013-7130
2015-2614	04/01/2015 04/29/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-5553
2015-2615	04/01/2015 04/29/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Robinson Kroll Associates	NDA 17871
2015-2616	04/01/2015 04/29/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sailaja Machiraju Paragon BioTeck, Inc.	NDA 206289
2015-2617	04/01/2015 04/29/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jim Steffey STEFFEY, E.F.	COUMADIN - AERS 03/26/2014 - 03/26/2015
2015-2618	04/01/2015 04/29/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Alex Johnson Johnson, Alex	ELTOPRAZINE - IND
2015-2619	04/01/2015	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	Nick Coltrain	SIXDOG INVESTMENT, LLC, DBA SIXDOGS FARMS, WELLINGTON, CO - WARNING LETTER RECS 04/28/2014 -

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	04/29/2015		Fort Collins Coloradoan	03/27/2015
2015-2620	04/01/2015 04/29/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nazmin Amir-Khan Amir-Khan, Nazmin	OCTOBER 2014 FDA MEMO FROM JOHN PETERS MD RE TRACKED SAFETY ISSUE 1349 METHYLPHENIDATE ER SUMMARY AND CONCLUSIONS
2015-2621	04/01/2015 04/29/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ian Bryson McEldrew Young	NDA 018723 LABEL RECS
2015-2622	04/01/2015 04/29/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Barbara Wiggins MEDICAL UNIVERSITY OF SOUTH CAROLINA	HEPATITIS C DRUGS - NINE CASE REPORTS
2015-2623	04/01/2015 04/29/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 18680 S60
2015-2624	04/01/2015 04/29/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dr. Uday Shetty Drug Regulations	EMCURE PHARMACEUTICALS, INDIA - 483 01/01/2014 - 03/27/2015
2015-2625	04/01/2015 04/29/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-5179
2015-2626	04/01/2015 04/29/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anna Edney BLOOMBERG NEWS	OPDIVO - AERS
2015-2627	04/01/2015 04/29/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2012-2336
2015-2628	04/01/2015 04/29/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-3401
2015-2629	04/01/2015 04/29/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-4784

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2015-2630	04/01/2015 04/29/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2012-8873
2015-2631	04/01/2015 04/29/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Glenn Brandys Kim Orr Barristers	TOLBUTAMIDE, PROBENECID, SACCHARIN ETC - APPLICATIONS, PROCESSES, APPROVALS ETC
2015-2632	04/01/2015 04/29/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Elliot Favus, MD FAVUS INSTITUTIONAL RESEARCH LLC	EXPAREL - AERS
2015-2633	04/01/2015 04/29/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Brittany Torbert California Western School of Law	REGULATION OF PHASE IV CLINICAL STUDIES AND PHARMACOGENOMICS
2015-2634	04/01/2015 04/29/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michele Sinoway LACHMAN CONSULTANT SERVICES, INC.	NDA 20430
2015-2635	04/01/2015 04/29/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	G. Srinivas Zydus Pharmaceuticals USA Inc.	ELASE-CHLOROMYCETIN SBA
2015-2636	04/01/2015 04/29/2015	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	Johnny Childers ADM ALLIANCE NUTRITION INC	ADM ALLIANCE NUTRITION, CORDELE, GA - 483 2/31/2014 - 01/13/2015
2015-2637	04/01/2015 04/29/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Elliot Favus, MD FAVUS INSTITUTIONAL RESEARCH LLC	AFREZZA - REVIEW AND APPROVAL RECS 01/01/2014 - 03/30/2015
2015-2638	04/01/2015 04/29/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Lee Chan-Hui BESCON CO., LTD.	K001962
2015-2639	04/01/2015 04/29/2015	FDA/OMPT/CDRH/OCER/DFOI/	Lee Chan-Hui BESCON CO., LTD.	K002099

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2015-2640	04/01/2015 04/29/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Monica Reckless Salix Pharmaceuticals, Inc.	NDA 205613 - SBA
2015-2641	04/01/2015 04/29/2015	FDA/OMPT/CDRH/OCER/DFOI/	Dennis McLaughlin Philips	K142697
2015-2642	04/01/2015 04/29/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K130545
2015-2643	04/01/2015 04/29/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K141399
2015-2644	04/01/2015 04/29/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K142432
2015-2645	04/02/2015 04/30/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RHONDA J RICE MURRAY & MURRAY	CLOZARIL (CLOZAPINE) - AERS
2015-2646	04/02/2015 04/30/2015	FDA/OC/OES/DFOI/	ELLIOT FAVUS MD FAVUS INSTITUTIONAL RESEARCH LLC	FOI DAILY LOG 9/1/14 TO 3/31/15
2015-2647	04/02/2015 04/30/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TAMMY ROSE GENENTECH INC	EYLEA (AFILIBERCEPT) INJ BLA 125387/48 - SBA
2015-2648	04/02/2015 04/30/2015	FDA/OMPT/CDRH/OCER/DFOI/	HANK STUTE STUTE, HANK .	PARAGON VISION SCIENCES - Cmplnt CPT1200119
2015-2649	04/02/2015 04/30/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARK STARRETT STARRETT, MARK	CIRPOFLOXIN, LEVAQUIN - Cmplnts 2012-2014
2015-2650	04/02/2015 04/30/2015	FDA/OGROP/ORP/SE-FO/ATL- DO/ATL-CB/	SUSAN SIMMONS XYTEX CRYO INTERNATIONAL	XYTEX CORP, ATLANTA, GA - EIR 2/28/11
2015-2651	04/02/2015 04/30/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	ANDREW M GAMMILL DINSMORE & SHOHL LLP	CARL ZEISS INC - HUMPHREY FIELD ANALYZER K954167; CARL SEISS MEDITEC INC - GUIDED PROGRESSION ANALYSIS ON THE HUMPHREY FIELD ANALYZER II AND II-I

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				SERIES K093213
2015-2652	04/02/2015 04/30/2015	FDA/OMPT/CDRH/OCER/DFOI/	ANDREW M GAMMILL DINSMORE & SHOHL LLP	MEDTRONIC XOMED INC - TONO-PEN AVIA TONOMETER AND OCU-SHIELD TIP COVER K053430; MENTOR OPHTHALMICS INC - MENTOR TONO-PEN 3 K964312
2015-2653	04/02/2015 05/18/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Doe J	INDIVIDUAL RECS - VAERS
2015-2654	04/02/2015 04/30/2015	FDA/OC/OES/DDM/	Sara Anderson, Esq. ASHCRAFT & GEREL, LLP	DKT 77N-0094, C1, VOLUME 4, DKT 77N-0094, LET17, VOLUME 60 ETC CERTIFIED
2015-2655	04/02/2015 04/30/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dennis Raisch, Ph.D. University of New Mexico College of Pharmacy	SIMVASTATIN - AERS
2015-2656	04/02/2015 04/30/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	GLAND PHARMA, INDIA - 483
2015-2657	04/02/2015 04/30/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dennis Raisch, Ph.D. Univeristy of New Mexico College of Pharmacy	PRAVASTATIN - AERS
2015-2658	04/02/2015 04/30/2015	FDA/OGROP/ORACE-FO/MIN- DO/MIN-CB/	Eric Young Young, Eric	ST JUDE MEDICAL, INC, MINNETONKA, MN - INSPECTION RECS 01/01/2008 - 12/31/2010
2015-2659	04/02/2015 04/30/2015	FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/	Eric Young Young, Eric	ADVANCED NEUROMODULATION SYSTEMS, INC, PLANO, TX - INSPECTION RECS 01/01/2009 - 12/31/2010;
2015-2660	04/02/2015 04/30/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Andrew Hull Hyman, Phelps & McNamara, P.C.	NDA 020746 S 21 OTC LABELING UNREDACTED
2015-2661	04/02/2015 04/30/2015	FDA/OFVM/CFSAN/OCD/EOS/	Michael (Mike) Esterl WALL STREET JOURNAL	MONSTER, RED BULL, ROCKSTAR, ETC - AERS 10/24/2012 - 03/31/2015
2015-2662	04/02/2015 04/30/2015	FDA/OGROP/ORASE-FO/NOL- DO/NOL-CB/	Ricardo de Lemos de Lemos, Ricardo A	IMMUNOTEK BIOCENTERS - EIR 01/05/2012 - 03/30/2015
2015-2663	04/02/2015 04/30/2015	OC/ORO/ORM/ OC/ORO/ORM/	Andrew Sobera Kent State University	LIST OF FOOD PROCESSING AND PHARMACEUTICAL INSPECTIONS 01/01/2013 - 03/31/2015

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2015-2664	04/02/2015 04/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Steven Benkert NEW YORK PRESBYTERIAN HOSPITAL	BENZONATE ORAL CAPSULES - LITERATURE CITATIONS FOR PHASE THREE CLINICAL TRIALS
2015-2665	04/02/2015 04/30/2015	FDA/OMPT/CDRH/OCER/DFOI/	Shri Kant Tiwari MDC TESTING AND CERTIFICATIONS	K141825, K150009, K142418, ETC
2015-2666	04/02/2015 04/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jean Xiao, Graduate Student Vanderbilt Law and Economics Program	ANDA SPREADSHEET
2015-2667	04/02/2015 04/30/2015	FDA/OMPT/CDRH/OCER/DFOI/	Angie Zhang Otto bock healthcare LP	522 STUDY ORDER PS140001 ARGO MEDICAL TECHNOLOGIES, INC.
2015-2668	04/02/2015 04/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	GLAND PHARMA, INDIA - 483 07/29/2013 - 08/05/2013; 12/27/2010 - 01/07/2011; 03/24/2006 - 04/01/2006
2015-2669	04/02/2015 04/30/2015	FDA/OFVM/CFSAN/OCD/EOS/	Samuel Harreschou UC BERKELEY	LEAD, MERCURY, ARSENIC, ETC - STANDARDS FOR FOOD, BEVERAGES, AND DRINKING WATER
2015-2670	04/02/2015 04/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dennis Raisch, Ph.D. Univeristy of Mexico College of Pharmacy	ROUVASTATIN - AERS
2015-2671	04/02/2015 04/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Su Zhang DUKE UNIVERSITY	ANNUAL REPORT SUBMITTED BY NDA APPLICANTS TO FDA RE LABELING CHANGES
2015-2672	04/02/2015 04/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ryan Bailey Keck Graduate Institute	VERTEPORFIN - EFFICACY, SAFETY, FORMULATIONS ETC
2015-2673	04/02/2015 04/30/2015	FDA/OMPT/CDRH/OCER/DFOI/	Brian Sawin Brian Sawin	K001773, K001334, K032232 ETC

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2015-2674	04/02/2015 04/30/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dennis Rasich, Ph.D. University of New Mexico College of Pharmacy	FLUVASTATIN - AERS
2015-2675	04/02/2015 04/30/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dennis Raisch, Ph.D. University of New Mexico College of Pharmacy	ATORVASTATIN - AERS
2015-2676	04/02/2015 04/30/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dennis Raisch, Ph.D. University of New Mexico College of Pharmacy	LOVASTATIN - AERS
2015-2677	04/02/2015 04/30/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jackie Callaway WFTS TV	FLUROQUIONLONES - AERS
2015-2678	04/02/2015 04/30/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	David Tukey EverPoint Asset Management	SAFETY DATA FROM CYSTIC FIBROSIS PATIENTS TAKING KALYDECO, LUMACAFITOR, VX-661 ETC 01/01/2011 - 03/31/2015
2015-2679	04/02/2015 04/30/2015	FDA/OC/OES/DFOI/	Chad Terhune LOS ANGELES TIMES	AUTOMATED ENDOSCOPE REPROCESSORS - CONSENT DECREES, RECALLS, 483 ETC 01/01/2006 - 01/01/2015
2015-2680	04/02/2015 04/30/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dennis Raisch, Ph.D. Univeristy of New Mexico College of Pharmacy	PITAVASTATIN - AERS
2015-2681	04/02/2015 04/30/2015	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORO/CE-FO/PHI-DO/PHI-CB/	Nina Borg Kitten Rescue	RACHEL RAY NUTRISH CAT FOOD INV858657, INV858658, INV878138 TEST RESULTS
2015-2682	04/02/2015 04/30/2015	FDA/OMPT/CDRH/OCER/DFOI/	Kirsten Franco LIFESCAN INC	K141929

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2015-2683	04/02/2015 04/30/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K880450
2015-2684	04/02/2015 04/30/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mikhail Martchenko Keck Graduate Institute	NDA 019806
2015-2685	04/02/2015 04/30/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	T. J. Jesky Stude's, LLC	ANDA 078292 SBA
2015-2686	04/02/2015 04/30/2015	FDA/OMPT/CDRH/OCER/DFOI/	Brad Hewett Mike Kelly Law Group, LLC	RHEOS HIGH BLOOD PRESSURE PIVOTAL TRIAL, CVRX RHEOS BAROREFLEX HYPERTENSION THERAPY SYSTEM - APPROVAL, CORR, EMAIL ETC 01/01/2001 - 03/26/2015
2015-2687	04/02/2015 04/30/2015	FDA/OMPT/CDRH/OCER/DFOI/	Devyani Nanduri Theranova, LLC	K070582
2015-2688	04/02/2015 04/30/2015	FDA/OMPT/CDRH/OCER/DFOI/	Devyani Nanduri Theranova, LLC	K042709
2015-2689	04/02/2015 04/30/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K941578
2015-2690	04/02/2015 04/30/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K023805
2015-2691	04/02/2015 04/30/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 203976 TENTATIVE APPROVAL LETTER
2015-2692	04/02/2015 04/30/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K861401
2015-2693	04/02/2015 04/30/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K933048
2015-2694	04/02/2015 04/30/2015	FDA/OGROP/ORAC/CE-FO/CHI-DO/CHI-CB/	Mark Silverberg Akorn, Inc.	AKORN, DECATUR, IL - EIR 05/01/2014 - 12/31/2014
2015-2695	04/03/2015 05/01/2015	FDA/OMPT/CDRH/OCER/DFOI/	Jeff Stevens Jeff Stevens	K131044
2015-2696	04/03/2015	FDA/OMPT/CDRH/OCER/DFOI/	Kurdea Lyon	K070793

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	05/01/2015		Stryker AG	
2015-2697	04/03/2015 05/01/2015	OC/CVM/OCD/	Sandy O Merial Inc	NADA 097037 FOIA SUMMARY
2015-2698	04/03/2015 05/01/2015	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	James Whitehead Reliable Biopharmaceutical Corporation	RELIABLE BIOPHARMACEUTICAL CORPORATION - EIR 01/14/2013 - 01/25/2013
2015-2699	04/03/2015 05/01/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K113351
2015-2700	04/03/2015 05/01/2015	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Marie Evangelisto Doyle Teva Pharmaceuticals	SHARP CORPORATION, CONSHOHOCKEN, PA - EIR 05/01/2012 - 08/31/2012
2015-2701	04/03/2015 05/01/2015	FDA/OMPT/CDRH/OCER/DFOI/	Ivan Monso MONSON, BETTY	INVO BIOSCIENCE INVOCELL - APPROVAL RECS
2015-2702	04/03/2015 05/01/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Prof. Dr. Martin Dugas University of Münster, Germany	NCT00123487 - CFR
2015-2703	04/03/2015 05/01/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jaime Vassallo LexisNexis CourtLink	ANALYSIS OR REANALYSIS BY OFFICE OF PHARMACOVIGILANCE AND EPIPEMIOLOGY OR OFFICE OF SURVEILLANCE AND EPIDEMIOLOGY OR OFFICE OF DRUG SAFETY
2015-2704	04/03/2015 05/01/2015	OC/CVM/OCD/	Ashley Parker Rate My Horse PRO	Laboratory Information Bulletin (LIB) #4424
2015-2705	04/03/2015 05/01/2015	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Judi-Lynn Reidinger, Assoc. Dir. Tech Services and QA Breckenridge Pharmceutical, Inc.	Deltex Pharmceuticals Recall Termination Letter - RES 58065
2015-2706	04/03/2015 05/01/2015	FDA/OMPT/CDRH/OCER/DFOI/	John Hyte H&S Manufacturing Services	K822068 APPROVAL LETTER
2015-2707	04/03/2015 05/01/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	John Hyte H&S Manufacturing Services	K770002
2015-2708	04/03/2015 05/01/2015	FDA/OMPT/CDRH/OCER/DFOI/	Aegis Regulatory Inc. AEGIS REGULATORY INC	K051681

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2015-2709	04/03/2015 05/01/2015	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/CHI-DO/CHI-CB/	Doe J	COMPLAINT RECS
2015-2710	04/03/2015 05/01/2015	FDA/OMPT/CDRH/OCER/DFOI/	Gnarvana, Inc. Gnarvana, Inc.	C-PULSE HEART ASSIST DEVICE - CLINICAL TRIAL RECS
2015-2711	04/03/2015 05/01/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 3/1-31/2015
2015-2712	04/03/2015 05/01/2015	FDA/OGROP/ORO/CE-FO/PHI-DO/PHI-CB/	Marie Evangelisto Doyle Teva Pharmaceuticals	SHARP CORPORATION, CONSHONOCKEN, PA - EIR 05/01/2012 - 08/31/2012
2015-2713	04/03/2015 05/01/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	A list of all FOIA requests closed 3/1-31/2015
2015-2714	04/03/2015 05/01/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dave Milton Coker, Schickel, Sorenson, Posgay, Camerlengo & Iracki, P.A.	DRUG MASTER FILE 14760
2015-2715	04/03/2015 05/01/2015	FDA/OGROP/ORO/SW-FO/KAN-DO/KAN-CB/	Adam Cox Sparhawk Laboratories Inc.	SPARHAWK LABORATORIES, CHEMDEX - EIR 02/02/2015 - 02/12/2015
2015-2716	04/07/2015 05/05/2015	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/SEA-DO/SEA-CB/	Carey Gough WNCN NEWS	MIRACLE MINERAL SUPPLEMENT, MASTER MINERAL SUPPLEMENT, MMS ETC - CONSUMER COMPLAINTS, MEDWATCH ETC 01/01/2005 - 04/02/2015
2015-2717	04/07/2015 05/05/2015	FDA/OC/OES/DDM/	Yuthama Kusumpa Kusumpa, Yuthama	GMP ADVISORY COMMITTEE - TRANSCRIPT, AGENDA, DATA ETC 08/22/1995 - 09/15/1995
2015-2718	04/07/2015 05/05/2015	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RC2 Pharmaceutical Patent Attorneys, LLC	INDIGO CARMINE - AERS
2015-2719	04/07/2015 05/05/2015	FDA/OGROP/ORO/CE-FO/CIN-DO/CIN-CB/	John Decker Zoetis	WIL RESEARCH COMPANY, ASHLAND, OH - EIR, 483, 482 03/27/2011 - 03/31/2015
2015-2720	04/07/2015 05/05/2015	FDA/OGROP/ORO/PA-FO/SEA-DO/SEA-CB/	Marc C. Sanchez, Esq. Contract In-House Counsel and	OMEGA TECH LABS, LLC, GDMI, INC - WARNING LETTER RESPONSES, CORR, ETC

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		FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Consultants, LLC	
2015-2721	04/07/2015 05/05/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Olena Izhak University of Helsinki (FINLAND)	ANDA APPROVAL LETTERS
2015-2722	04/07/2015 05/05/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dawn Ionescu MASSACHUSETTS GENERAL HOSPITAL	KETAMINE - APPROVED DOSING
2015-2723	04/07/2015 05/05/2015	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Douglas Silveira Pacira Pharmaceuticals, Inc.	PACIRA PHARMACEUTICALS, SAN DIEGO, CA - EIR 02/03/2014 - 02/10/2014
2015-2724	04/07/2015 05/05/2015	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	Kurt Lesh, M.D. RADIANT RESEARCH	KURT LESH - EIR 06/01/2009 - 06/30/2009
2015-2725	04/07/2015 05/05/2015	FDA/OMPT/CDRH/OCER/DFOI/	Angela Blackwell Viax Dental Technologies	K132182
2015-2726	04/07/2015 05/05/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rebecca Dandeker Morgan, Lewis & Bockius LLP	HETERO LABS, INDIA - EIR 09/01/2014 - 10/01/2014
2015-2727	04/07/2015 05/05/2015	FDA/OFVM/CFSAN/OCD/EOS/	Jim Huang Bemis Company, Inc.	FCN 1434
2015-2728	04/07/2015 05/05/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rebecca Dandeker Morgan, Lewis & Bockius LLP	HERERO LABS, INDIA - 483, EIR SUMMARIES 09/01/2014 - 10/01/2014
2015-2729	04/07/2015 05/05/2015	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Interfashion Cosmetics Interfashion Cosmetics	INTERFASHION COSMETICS, TETERBORO, NJ - EIR 02/05/2009 - 02/25/2009
2015-2730	04/07/2015 05/05/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Colleen Johns Sancilio and Company, Inc.	NDA 017643, NDA 020248 - SBA
2015-2731	04/07/2015	FDA/OC/OES/DDM/	Michele Sinoway	RIVASTIGMINE - DRAFT GUIDANCE 02/05/2010 - 11/29/2010

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	05/05/2015		LACHMAN CONSULTANT SERVICES, INC.	
2015-2732	04/07/2015 05/05/2015	OC/CVM/OCD/ OC/ORO/ OC/ORO/	Dale Giali Dale Giali	PURINA BENEFUL DOG FOOD COMPLAINTS 01/01/2011 - 04/02/2015
2015-2733	04/07/2015 05/05/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Allene Dodge Allene M Dodge, Regulatory Affairs Consultant, LLC	CYTOMEL NDA 010379 APPROVAL RECS
2015-2734	04/07/2015 05/26/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Valerie Slater Mercy Hospital Joplin	HUMAN CELL AND TISSUE ESTABLISHMENT REGISTRATIONS ACCELERATED BIOLOGICS, CR BARD, BIOMET ETC
2015-2735	04/07/2015 05/05/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anthony Bongiorno Anthony Bongiorno	BOTOX - APPROVAL RECS RE HYPERHIDROSIS
2015-2736	04/07/2015 05/05/2015	FDA/OC/OES/DFOI/ OC/CVM/OCD/ OC/ORO/ OC/ORO/	Dale Giali Dale Giali	DOG FOOD COMPLAINTS 01/01/2011 - 04/02/2015
2015-2737	04/07/2015 05/05/2015	FDA/OFVM/CFSAN/OCD/EOS/	John F. Naizby MARCARELLI-NAIZBY LAW FIRM	SOLGAR INC ABC DOPHILUS MOLK OUTBREAK - CFSAN CORE INVESTIGATIONS RECS 07/03/2014 - 04/03/2015
2015-2738	04/07/2015 05/05/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sarah Wong-Goodrich BGB Group	CASE REPORT 10800144
2015-2739	04/07/2015 05/05/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Erin Kelm Fuld + Company	ODYSSA PHARMA, BELGIUM - EIR 09/01/2014 - 09/30/2014
2015-2740	04/07/2015 05/05/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joe Malone Joe Malone	MIRENA - DETAILED ADVERSE EVENT REPORT 01/03/2001 - 04/03/2015

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2015-2741	04/07/2015 05/05/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Douglas Jacobs, M.D. Professional Psychiatric Associates	ZOLOFT 7299275, 7415583, 7419942, ETC
2015-2742	04/07/2015 05/05/2015	FDA/OMPT/CDRH/OCER/DFOI/	cyrus j amato d.d.s. amato craniofacial engineering	K000580
2015-2743	04/07/2015 05/05/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Kristy Smith Rawls McNelis + Mitchell	INDIVIDUAL RECS
2015-2744	04/07/2015 05/05/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dustin Block IPD Analytics, LLC	ANDA 204299 TENTATIVE APPROVAL LETTER
2015-2745	04/07/2015 05/05/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Judy Alexander AVANIR PHARMACEUTICALS INC	NUEDEXTA - AERS
2015-2746	04/07/2015 05/05/2015	FDA/OMPT/CDRH/OCER/DFOI/	Jeff Stevens Jeff Stevens	K131287
2015-2747	04/07/2015 05/05/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jaime Vassallo LexisNexis CourtLink	COPAXONE - AERS
2015-2748	04/07/2015 05/05/2015	FDA/OMPT/CDRH/OCER/DFOI/	John Slate TearFilm Innovations, Inc.	K093937, K112704, K133127 ETC
2015-2749	04/07/2015 05/11/2015	FDA/OGROP/ORACE-FO/PHI- DO/PHI-CB/ FDA/OGROP/ORACE-FO/PHI- DO/PHI-CB/	Chad Terhune LOS ANGELES TIMES	CUSTOM ULTRASONICS - INSPECTIONS, RESPONSES 01/01/2007 - 01/01/2015
2015-2750	04/07/2015 05/05/2015	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	ASHCRAFT & GEREL - FOIA REQUESTS 2007-2014
2015-2751	04/07/2015 05/05/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARIA KEELAN GAMBRO RENAL PRODUCTS	POHOXILLUM RENAL REPLACEMENT SOL NDA 207-026 - SBA

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		FDA/OC/OES/DFOI/		
2015-2752	04/07/2015 05/05/2015	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Doe J	6.5X45 POLYAXIAL SCREW - LOT #501259; 7.2X40 POLYADIXIAL SCREW - L9OT #101 266; 65MM SPONAL ROD, ETC - LOT 500972, 103126 RECS
2015-2753	04/07/2015 05/05/2015	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PETER S REICHERTZ SHEPPARD MULLIN ET AL	LUITPOLD PHARMACEUTICALS INC - INJECTAFER FERRIC CARBOXYLMALTOSE INJ NDA 203-565 VAERS 7/25/13
2015-2754	04/07/2015 05/05/2015	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PETER S REICHERTZ SHEPPARD MULLIN ET AL	AMAG PHARMACEUTICALS INC - FERAHEME FERUMOXYTOL INJ NDA 22-180 VAERS 4/1/14
2015-2755	04/07/2015 05/05/2015	FDA/OO/OHR/	JOHN E SHEILDS JOHN E SHIELDS	INDIVIDUAL RECS
2015-2756	04/07/2015 06/09/2015	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OC/OCC/	HELEN LERNER MD LERNER MD, HELEN	MERCK - SHINGLES VACCINE VAER, MEMO, CONGRESSIONAL TESTIMONIES, ETC
2015-2757	04/07/2015 05/05/2015	FDA/OC/OES/DDM/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BILL MCPIKE MUCKROCK NEWS	DKT 2011P-0671
2015-2758	04/07/2015 06/02/2015	FDA/OFVM/CFSAN/OCD/EOS/	QUIANA A MONTGOMERY Keller and Heckman LLP	DANISCO A/S -FCN #750, 812, 1126
2015-2759	04/07/2015 05/05/2015	FDA/OFVM/CFSAN/OCD/EOS/	CARMEN DEBORD WESTLAW COURT EXPRESS	AN ASSESSMENT OF RISK ASSOCIATED WITH THE HUMAN CONSUMPTION OF SOME SPECIES OF FISH CONTAMINATED WITH POLYCHLORINATED BIPHENEYLS (PCB'S) 1979
2015-2760	04/07/2015 05/05/2015	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CAROLINE FLEETWOOD SIDLEY AUSTIN LLP	MALLINCKRODT - GABLOFEN (BACLOFEN) INJ NDA 22-462 APPRVL PKG UNREDACTED

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2015-2761	04/07/2015 05/05/2015	FDA/OC/OES/DDM/	MEGAN L CLAYTON PHD MPH CLAYTON, MEGAN L	DKT 2011N-0921
2015-2762	04/07/2015 05/05/2015	FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/	MICHAEL LANDA LANDA, MICHAEL	ARSENIC IN RICE - ANALYSES, RISK ASSESSMENTS 9/13
2015-2763	04/07/2015 05/05/2015	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/ORO/DIOP/	DONALD N BLUE ZETETIC INC	SHIPMENTS REGULATED BY THE FDA 2/16-28/15
2015-2764	04/07/2015 05/05/2015	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/ORO/DIOP/	DONALD N BLUE ZETETIC INC	SHIPMENTS REGULATED BY THE FDA 3/16-31/15
2015-2765	04/07/2015 05/05/2015	FDA/OC/OCC/ FDA/OC/OES/ OC/CVM/OCD/	CARTER DILLARD ANIMAL LEGAL DEFENSE FUND	CATTLEMEN'S BEEF BOARD, NATIONAL PORK BOARD, DAIRY MANAGEMENT INC, ETC - RPTS, MEMOS, OBJECTIVES, ETC
2015-2766	04/07/2015 05/05/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARK A HAMMEROID GIDEON COOPER & ESSARY	ACTAVIS - FENTANYL AERS
2015-2767	04/07/2015 05/05/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	MEREDITH ELKINS PUBLIC RESPONSIBILITY IN MEDICINE AND RESEARCH	LIST OF INDIVIDUALS ASSOCIATED WITH RESEARCH INSTITUTIONS, PHARMACEUTICAL, BIOTECHNOLOGY AND DVC COMPANIES, ETC
2015-2768	04/07/2015 05/05/2015	FDA/OC/OES/DFOI/	ROSA YARBROUGH YARBROUGH, ROSA	DRUGS - AERS
2015-2769	04/07/2015 05/05/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TAMMY ROSE GENENTECH INC	LUCENTIS (RANIBIZUMAB INJ) - SBA
2015-2770	04/07/2015	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	ROBERT V PRONGAY	ACELRX PHARMACEUTICAL INC - EIR, 483 6/14

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	05/05/2015		GLANCY BINKOW & GOLDBERG LLP	
2015-2771	04/08/2015 05/06/2015	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Rachel Johnson FOI Services, Inc.	US FLUE CURED TOBACCO GROWERS, TIMBERLAKE, NC; LORILLARD TOBACCO, GREENSBORO, NC; SANTA FE NATURAL TOBACCO, OXFORD, NC - INVESTIGATOR DIARIES
2015-2772	04/08/2015 05/06/2015	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Rachel Johnson FOI Services, Inc.	KENTUCKY CUT RAG, LEXINGTON, KY; TANTUS TOBACCO, RUSSELL SPRINGS, KY; GF VAUGHAN TOBACCO, LEXINGTON, KY - 483, WARNING LETTERS, ASSIGNMENTS ETC
2015-2773	04/08/2015 05/06/2015	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Rachel Johnson FOI Services, Inc.	DOMESTIC TOBACCO, LANCASTER, PA, ROCKTENN, CONVERTING COMPANY, MARLTON, NJ; SOUTHERN CROSS TOBACCO, MOUNTAIN TOP, PA - INVESTIGATOR DIARIES
2015-2774	04/08/2015 05/06/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-3357
2015-2775	04/08/2015 05/06/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-3358
2015-2776	04/08/2015 05/06/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-3353
2015-2777	04/08/2015 05/06/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-3362
2015-2778	04/08/2015 05/06/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-3375
2015-2779	04/08/2015 05/06/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-3351
2015-2780	04/08/2015 05/06/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-3345
2015-2781	04/08/2015 05/06/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-3364
2015-2782	04/08/2015 05/06/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-3321
2015-2783	04/08/2015 05/06/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-3366

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2015-2784	04/08/2015 05/06/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-2213
2015-2785	04/08/2015 05/06/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-3367
2015-2786	04/08/2015 05/06/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-2211
2015-2787	04/08/2015 05/06/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-3374
2015-2788	04/08/2015 05/06/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-3368
2015-2789	04/08/2015 05/06/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-3373
2015-2790	04/08/2015 05/06/2015	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Rachel Johnson FOI Services, Inc.	ROCKTENN, DES MOINES, IA; SWISHER INTERNATIONAL WHEELING, WV; STARION, CHASE CITY, VA - EIR, 483, WARNING LETTER ETC
2015-2791	04/08/2015 05/06/2015	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	Rachel Johnson FOI Services, Inc.	CONCEPTS/PREMIERE PACKAGING, MEMPHIS, TN; DOSAL TOBACCO, OPA LOCKA, FL; VIRGINIA CAROLINA COMPANY ETC - INVESTIGATOR DIARIES
2015-2792	04/08/2015 05/06/2015	OC/CVM/OCD/	Rachel Johnson FOI Services, Inc.	NADA 139075
2015-2793	04/08/2015 05/06/2015	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Rachel Johnson FOI Services, Inc.	NORTH CAROLINA FILTER, WILSON, NC; ALLIANCE ONCE SPECIALTY PRODUCTS, WILSON, NC; TOBACCO RAG, PROCESSORS, WILSON, NC - INVESTIGATOR DIARIES
2015-2794	04/08/2015 05/06/2015	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Rachel Johnson FOI Services, Inc.	NORTH CAROLINA FILTER, WILSON, NC; ALLIANCE ONE SPECIALTY PRODUCTS, WILSON, NC; TOBACCO RAG PROCESSORS, WILSON, NC - EIR, 483, WARNING LETTER ETC
2015-2795	04/08/2015 05/06/2015	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Rachel Johnson FOI Services, Inc.	DOMESTIC TOBACCO, LANCASTER, PA; ROCKTENN CONVERTING COMPANY, MARLTON, NJ; SOUTHERN CROSS TOBACCO, MOUNTAIN TOP, PA ETC - EIR, 483, WARNING LETTER, ETC

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2015-2796	04/08/2015 05/06/2015	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Rachel Johnson FOI Services, Inc.	KENTUCKY CUT RAGE, LEXINGTON, KY;TANTUS TOBACCO, RUSSELL SPRINGS, KY; GF VAUGHAN TOBACCO, LEXINGTON, KY - EIR, 483, WARNING LETTER ETC
2015-2797	04/08/2015 05/06/2015	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Rachel Johnson FOI Services, Inc.	ROCKTENN, DES MOINES, IA; SWISHER INTERNATIONAL, WHEELING, WV; STARION, CHASE CITY, VA; ETC - EIR, 483, WARNING LETTER ETC
2015-2798	04/08/2015 05/06/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Health Sci Funding Pharmaceutical Patent Attorneys, LLC	CHETOVIS, PSICOSTERONE, DIANDRONE - NDA,, AERS
2015-2799	04/08/2015 05/06/2015	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	Rachel Johnson FOI Services, Inc.	CRESCENT CONCEPTS/PREMIERE PACKAGING, MEMPHIS, TN; DOSAL TOBACCO, OPA LOCKA, FL; VIRGINIA CAROLINA COMPANY - EIR, 483, WARNING LETTERS ETC
2015-2800	04/08/2015 05/06/2015	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Rachel Johnson FOI Services, Inc.	US FLUE CURED TOBACCO GROWERS, TIMBERLAKE, NC; LORILLARD TOBACCO, GREENSBORO, NC; SANTA FE NATURAL TOBACCO, OXFORD, NC - EIR, 483, WARNING LETTER ETC
2015-2801	04/08/2015 05/06/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Erin Kelm Fuld + Company	ODYSSEA PHARMA - EIR AUGUST 22, 2014
2015-2802	04/08/2015 05/06/2015	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	Joseph Sener Hospira, Inc.	HOSPIRA, LAKE FOREST, IL - EIR 01/01/2014 - 04/06/2015
2015-2803	04/08/2015 05/06/2015	FDA/OMPT/CDRH/OCER/DFOI/	Jenette Bennett CENORIN LLC	K880683
2015-2804	04/08/2015 05/06/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Anurag Patel DR. REDDY'S LABORATORIES INC	NDA 206229 SBA
2015-2805	04/08/2015	OC/CVM/OCD/	Rachel Johnson	NADA 096298

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	05/06/2015		FOI Services, Inc.	
2015-2806	04/08/2015 05/06/2015	FDA/OC/OES/DFOI/	RUSSELL CARROLLO CAROLLO, RUSSELL	2014-5592
2015-2807	04/08/2015 05/06/2015	FDA/OFVM/CFSAN/OCD/EOS/	DANIEL HUISEBERG Baker Botts	SIMILAC - SUPPLEMENTATION EARLY SHIELD FORMULATION, MFG PROCESS & QUALITY FACTORS OF NORMAL PHYSICAL GROWTH & SUFFICIENT BIOLOGICAL QUALITY OF PROTEIN COMPONENT 10/1/12 TO 10/1/13
2015-2808	04/08/2015 05/06/2015	FDA/OFVM/CFSAN/OCD/EOS/	DANIEL HUISEBERG Baker Botts	SIMILAC EARLY SHIELD - FORMULATION, MFG PROCESSES & QUALITY FACTORS OF NORMAL PHYSICAL GROWTH & SUFFICIENT BIOLOGICAL QUALITY OF PROTEIN COMPONENTS 12/1/07 TO 7/1/08
2015-2809	04/08/2015 05/06/2015	FDA/OFVM/CFSAN/OCD/EOS/	DANIEL HUISEBERG Baker Botts	SIMILAC ADVANCE OPTIGRO STAGE 1 - FORMULATION, MFG PROCESSES & QUALITY FACTORS OF NORMAL PHYSICAL GROWTH & SUFFICIENT BIOLOGICAL QUALITY OF PROTEIN 6/1/13 TO 1/1/14
2015-2810	04/09/2015 05/07/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Earl Goehring THE DEGGE GROUP, LTD.	CASES WITH PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY
2015-2811	04/09/2015 07/08/2015	FDA/OMPT/CTP/OD/	Dorothy Kulik Dorothy Kulik	AGENCY RECORDS THAT LIST ANY AND ALL CHEMICALS ADDED TO TOBACCO PRODUCTS THAT ARE CURRENTLY IN USE BY ANY AND ALL TOBACCO COMPANIES
2015-2812	04/09/2015 05/07/2015	FDA/OFVM/CFSAN/OCD/EOS/	Mark Prinz Registrar Corp	AGRO HIDRO E.I.R.L., PERU; SU ZHOU HOUSSY DRINKS CO, LTD, CHINA; SHAKTI APIFOODS PVT LTD, INDIA ETC - 483
2015-2813	04/09/2015 05/07/2015	OC/ORO/ OC/ORO/ OC/ORO/ORM/ OC/ORO/ORM/	Mark Prinz Registrar Corp	SPREADSHEET OF FIRMS THAT ISSUED A RECALL, MARKET WITHDRAWAL OR SAFETY ALERT 10/01/2011 - 03/31/2015
2015-2814	04/09/2015 05/07/2015	OC/CVM/OCD/	Peggy Jones American Peat Technology	CVM RECS THAT SUPPORT THE 2014 OFFICIAL PUBLICATION DEFINITION OF REED-SAGE PEAT AS ANIMAL FEED INGREDIENT
2015-2815	04/09/2015 05/07/2015	FDA/OGROP/ORO/NE-FO/NYK- DO/NYK-DCB/	GINA ROEBKE LNK INTERNATIONAL, INC,	PL DEVELOPMENTS, WESTBURY, NY - 483, EIR 01/01/2011 - 01/01/2015
2015-2816	04/09/2015 05/07/2015	OC/CVM/OCD/	John G. Dillard OLSSON FRANK WEEDA	FORM 2481 MOST RECENT VERSION

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			TERMAN MATZ PC	
2015-2817	04/09/2015 05/07/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	10083238 ; 10213779 ; 10227236 ; ETC
2015-2818	04/09/2015 05/07/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	10052145; 10057916 ; 10058020 ; ETC
2015-2819	04/09/2015 05/07/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	10065250 ; 10067727 ; 10102273
2015-2820	04/09/2015 05/07/2015	FDA/OFVM/CFSAN/OCD/EOS/	Micihael Bernsein Michael Bernstein	DARK CHOCOLATE TEST DATA
2015-2821	04/09/2015 05/15/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	nancy haskin-leblanc nancy haskins-leblanc	VACCINES GIVEN TO CHILDREN - INGREDIENTS 09/01/1994 - 09/01/2005
2015-2822	04/09/2015 05/07/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dennis W Raisch UNIVERSITY OF NEW MEXICO	IRBUTINIB - AERS
2015-2823	04/09/2015 05/07/2015	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/ FDA/OGROP/ORO/PA-FO/SAN- DO/SAN-CB/ FDA/OGROP/ORO/CE-FO/CIN- DO/CIN-CB/	Lewis O. Unglesby Unglesby, Lewis	WALLCUR, LLC - LAB RESULTS 12/01/2014 - 04/01/2015

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2015-2824	04/09/2015 05/07/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Kinnari Shah MEDIVATORS INC	K920025
2015-2825	04/09/2015 05/07/2015	FDA/OGROP/ORA/CE-FO/BLT- DO/BLT-CB/	John Walsh James Alexander Corporation	ESSENTA POROUS TECHNOLOGIES, COLONIAL HEIGHTS, VA - 483, EIR, RECALLS 03/01/2013 - 04/06/2015
2015-2826	04/09/2015 05/07/2015	OC/ORA/ OC/ORA/ OC/ORA/ORM/ OC/ORA/ORM/	Mark Prinz Mark Prinz	WARNING LETTER SPREADSHEET
2015-2827	04/09/2015 05/07/2015	OC/CVM/OCD/	Kenny Chu Virbac Australia Pty Ltd	NADA: 140-915 LABELING
2015-2828	04/09/2015 05/07/2015	FDA/OFVM/CFSAN/OCD/EOS/	William Olson Center for Regulatory Services, Inc.	FCN 24
2015-2829	04/09/2015 05/07/2015	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	Zetetic, Inc. ZETETIC INC	ENTRY AV3-0041771-2
2015-2830	04/09/2015 05/07/2015	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	Zetetic, Inc. Zetetic, Inc.	ENTRY AV0040929-7
2015-2831	04/09/2015 05/07/2015	FDA/OMPT/OSMP/OOPD/	Joshua Malamud Hyman, Phelps & McNamara P.C.	RYANODEX - ORPHAN DESIGNATION RECS
2015-2832	04/09/2015 05/07/2015	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	Zetetic, Inc. Zetetic, Inc.	ENTRY FY6-2008519-8
2015-2833	04/09/2015 05/07/2015	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	Zetetic, Inc. Zetetic, Inc.	ENTRY AV3-0040984-2
2015-2834	04/09/2015 05/07/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Cynthia Katsempris ACTAVIS INC	IZBA - SBA

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2015-2835	04/09/2015 05/07/2015	FDA/OMPT/CDRH/OCER/DFOI/	Brit Baird EKOS Corporation	K082981
2015-2836	04/09/2015 05/07/2015	FDA/OMPT/CDRH/OCER/DFOI/	CONGRESSMAN SEAN P DUFFY DUFFY, SEAN P.	INDIVIDUAL RECS
2015-2837	04/09/2015 05/07/2015	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	ROGER J DONAHUE JR GIARRUSO NORTON COOLEY & MCGLONE PC	UNO FOODS INC, BROCKTON, MA - RPTS, NOTES, MEMOS, INSPS, ETC
2015-2838	04/09/2015 05/21/2015	FDA/OFVM/CFSAN/OCD/EOS/	DAVID B FERNANDES JR BARON & BUDD PC	PHARMAVITE LLC, NATURE MADE - HERBAL SUPPLEMENTS TRANS, NOTES, INVESTIGATIONS, ETC
2015-2839	04/09/2015 05/07/2015	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	RACHEL LOWERY UNIV OF MISSISSIPPI MEDICAL CENTER	GANITUMAB IND 120449
2015-2840	04/09/2015 05/07/2015	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KIMBERLY PHILLIPS MABEL GARDERE WYNNE SEWELL LLP	PERCHLORATE - WHITE PAPERS, FACT SHEETS, RPTS, ETC
2015-2841	04/09/2015 05/07/2015	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	ANNA C SWEENEY ESQ SADAKA ASSOCIATES LLC	2014-6191 - ITEM #8 RECS
2015-2842	04/09/2015 05/07/2015	FDA/OMPT/OSMP/OOPD/	JEFF LILLARD LILLAARD, JEFF	KV PHARMACEUTICAL CO - PREVENTION OF PRETERM BIRTH IN SINGLETON PREGNANCIES ORPHAN DRUG DESIGNATION 1/25/07
2015-2843	04/09/2015 05/07/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SIDNEY M WOLFE MD PUBLIC CITIZEN	EDOXABAN NDA 206-316 - MOR
2015-2844	04/09/2015 05/07/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	STEVEN K HUNTER HUNTER & LYNCH	ENBREL - AERS
2015-2845	04/09/2015	FDA/OMPT/CDER/GRP/DIDP/	MARTA ANDREA GODECKI	TEVA PHARMACEUTICALS USA - COPAXONE NDA 02-0622/S088,S089,S090 APRVL RECS

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	05/07/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MORRISON & FOERSTER LLP	
2015-2846	04/09/2015 05/07/2015	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	MARGE WYSZYNSKI RR DONNELLEY	SPECTRA MEDICAL DEVICES, WILMINGTON, MA - EIR, 483 MOST RECENT
2015-2847	04/09/2015 05/07/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID L ROSEN FOLEY & LARDNER LLP	SUN PHARMA GLOBAL - LIPODOX ANDA 203-263 RVWS, ANALYSIS, MEMOS, ETC
2015-2848	04/09/2015 05/07/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID L ROSEN FOLEY & LARDNER LLP	SUN PHARMA - LIPOSOMAL DOXORUBICIN ANDA 203-263 SBA
2015-2849	04/09/2015 05/07/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID L ROSEN FOLEY & LARDNER LLP	SUN PHARMA GLOBAL - LIPODOX IMPORTATION RVWS, MEMOS, ANALYSIS, ETC
2015-2850	04/09/2015 05/07/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	HARVONI - AERS
2015-2851	04/09/2015 05/07/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DIANNE LIN X09327 LIN X09327, DIANNE	BABY ASPIRIN - AERS
2015-2852	04/09/2015 05/07/2015	FDA/OFVM/CFSAN/OCD/EOS/	ANI BYRNE Jamieson Laboratories	JAMIESON - FORM FDA 3500, 3500A, 3500B
2015-2853	04/09/2015 05/07/2015	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	HELEN ANDERSON doterra	DOTERRA - FORMA FDA 463A (ATTACHMENT 6 TO EIR)
2015-2854	04/09/2015 05/07/2015	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	LAURA A HALPER PHD HALPER GROUP	IDEAL IMPLANT INC, DALLAS, TX - EIRS, 483S 2/25/13-3/1/13
2015-2855	04/09/2015 05/07/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SUZANNE M GOLDBERG GOLDBERG, SUZANNE M	VYVANSE NDA 21-977/S036.S037 - AERS

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2015-2856	04/09/2015 05/07/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	CYMBALTA - AERS
2015-2857	04/09/2015 05/07/2015	FDA/OMPT/CDRH/OCER/DFOI/	SUSAN D GOLDSTEIN-FALK MDI CONSULTANTS INC	FORA CARE - K110044; OMRON - K042506; A&D ENGINEERING INC - K012472
2015-2858	04/09/2015 05/07/2015	OC/ORR/ORM/ OC/ORR/ORM/	LESLIE RAMSEY FDA NEWS	PHARMACEUTICAL, BIOLOGICS, MEDICAL DVC MFG AND CLNCL TRIAL FACILITIES IN AND OUTSIDE THE US - 483S 3/1-31/15
2015-2859	04/09/2015 05/07/2015	FDA/OC/OES/DFOI/	ELLIOT FAVUS MD FAVUS INSTITUTIONAL RESEARCH LLC	2015-2528, 2015-2463, 2015-2261, ETC
2015-2860	04/09/2015 05/07/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	2015-1068
2015-2861	04/09/2015 05/07/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	2015-886
2015-2862	04/09/2015 05/07/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HANNAH SCHWARZCHILD HAGENS BERMAN SOBOL SHAPIRO LLP	ANDA 91-422 - ROUTING SHEETS, APRVL LTRS
2015-2863	04/09/2015 05/07/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HANNAH SCHWARZCHILD HAGENS BERMAN SOBOL SHAPIRO LLP	ANDA 91-149 - ROUTING SHEETS, APRVL LTRS
2015-2864	04/09/2015 05/07/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HANNAH SCHWARZCHILD HAGENS BERMAN SOBOL SHAPIRO LLP	ANDA 203-326 - ROUTING SHEETS, APRVL LTRS
2015-2865	04/09/2015 05/07/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HANNAH SCHWARZCHILD HAGENS BERMAN SOBOL SHAPIRO LLP	ANDA 203-136 - ROUTING SHEETS, APRVL LTRS

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2015-2866	04/13/2015 05/11/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Allison Magwire ARIAD Pharmaceuticals, Inc.	ICLUSIG - AERS
2015-2867	04/13/2015 05/11/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mikhail Martchenko Keck Graduate Institute	INDOMETHACIN RECS
2015-2868	04/13/2015 05/11/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mikhail Martchenko Keck Graduate Institute	INDOMETHACIN - APPROVAL RECS
2015-2869	04/13/2015 05/11/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Martchenko Keck Graduate Institute	ALPRAZOLAM APPROVAL RECS
2015-2870	04/13/2015 05/11/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	MICROSORT - CLASSIFICATION RECS
2015-2871	04/13/2015 05/11/2015	FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/	Tony Farmer Farmer, Tony	INDIVIDUAL RECS
2015-2872	04/13/2015 05/11/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ramzi Abadou Kahn Swick & Foti, LLC	OREXIGEN - COMM, AGREEMENTS WITH FDA RE CONTRAVENE 06/01/2014 - 04/06/2015
2015-2873	04/13/2015 05/11/2015	FDA/OFVM/CFSAN/OCD/EOS/	Lila Razmara ANDREWS THORNTON	HYDROXYCUT SX-7 - REPORTS, MEMOS, CORR ETC 01/01/2011 - 04/07/2015
2015-2874	04/13/2015 05/11/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Robert Bauchwitz M.D., Ph.D. Robert Bauchwitz M.D., Ph.D.	RO4917523 STUDY RECS
2015-2875	04/13/2015 05/11/2015	FDA/OMPT/CDRH/OCER/DFOI/	International Trade Group, Inc. International Trade Group, Inc	K130802
2015-2876	04/13/2015	FDA/OMPT/CDER/ORP/DIDP/	Sumithra Ramachandran	ANDA 080819

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	05/11/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Keck Graduate Institute of Applied Life Sciences	
2015-2877	04/13/2015 05/11/2015	FDA/OMPT/CDRH/OCER/DFOI/	Deborah Bradley Deborah Bradley	K123822
2015-2878	04/13/2015 05/11/2015	OC/CVM/OCD/	Banu Ramachandran Citron Pharma, LLC	NADA 055-099 - FOIA SUMMARY
2015-2879	04/13/2015 05/26/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Peter Loftus THE WALL STREET JOURNAL	SANOFI, TORONTO, CANADA - 483, EIR, CORR 01/05/2012 - 04/07/2015
2015-2880	04/13/2015 05/11/2015	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	GUARANA - COLA REVIEW, LABEL APPROVALS ETC
2015-2881	04/13/2015 05/11/2015	FDA/OGROP/ORASE-FO/SJN- DO/SJN-CB/	Walter chalkley THOMSON REUTERS (SCIENTIFIC) SAS	INTEGRA NEUROSCIENCES PR, INC, ANASCO, PR - 483, EIR, RESPONSE 11/01/2013 - 12/01/2013
2015-2882	04/13/2015 05/11/2015	FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	PHARMACEUTICAL INNOVATIONS, INC, NEWARK, NJ - 483, EIR, RESPONSE 02/01/2012 - 03/01/2012
2015-2883	04/13/2015 05/11/2015	FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/	Walter chalkley THOMSON REUTERS (SCIENTIFIC) SAS	MCNEIL-PPC, INC, SKILLMAN, NJ - 483, EIR, RESPONSE 04/01/2013 - 05/01/2013
2015-2884	04/13/2015 05/11/2015	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OFVM/CFSAN/OCD/EOS/	Lila Razmara ANDREWS THORNTON	HYDROYCUT SX-7 - AERS, MEDWATCH
2015-2885	04/13/2015 05/11/2015	FDA/OGROP/ORASE-FO/SJN- DO/SJN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	COOPER VISION CARIBBEAN CORP, JUAN DIAZ, PR - 483, EIR, RESPONSE 12/01/2013 - 01/31/2014
2015-2886	04/13/2015 05/11/2015	FDA/OGROP/ORASE-FO/ATL- DO/ATL-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	CR BARD, INC, UROLOGICAL DIVISION, COVINGTON, GA - 483, EIR, RESPONSE 07/01/2012 - 07/31/2012
2015-2887	04/13/2015 06/08/2015	FDA/OGROP/ORASW-FO/DEN- DO/DEN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	COVIDIENT, PLC, BOULDER, CO - 483, EIR, RESPONSE 05/01/2014 - 06/30/2014
2015-2888	04/13/2015 05/11/2015	FDA/OGROP/ORAPA-FO/SEA- DO/SEA-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	ADVANCED RENAL TECHNOLOGIES, INC, BELLEVUE, WA - 483, EIR, RESPONSE 03/01/2014 - 04/01/2014
2015-2889	04/13/2015	FDA/OGROP/ORACE-FO/BLT- DO/BLT-CB/	Walter Chalkley	KEVIN B FRICKA, MD, ALEXANDRIA, VA - 483, EIR, RESPONSE 02/01/2014 - 02/28/2014

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	05/11/2015		THOMSON REUTERS (SCIENTIFIC) SAS	
2015-2890	04/13/2015 05/11/2015	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	BECTON DICKINSON AND COMPANY, COLUMBUS, NE - 483, EIR, RESPONSE 09/01/2013 - 09/30/2013
2015-2891	04/13/2015 05/11/2015	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	3M UNITEK CORPORATION, MONRAVIA, CA - 483, EIR, RESPONSE 03/01/2014 - 03/31/2014
2015-2892	04/13/2015 05/11/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K081238
2015-2893	04/13/2015 05/11/2015	FDA/OMPT/CDRH/OCER/DFOI/	Dave Hernon SonaCare Medical, LLC	K100786
2015-2894	04/13/2015 05/11/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K122982
2015-2895	04/13/2015 05/11/2015	FDA/OMPT/CDRH/OCER/DFOI/	Gary Syring Quality and Regulatory Associates, LLC	K042616
2015-2896	04/13/2015 05/11/2015	FDA/OMPT/CDRH/OCER/DFOI/	Valerie Defiesta-Ng EXPERIEN GROUP LLC	K952737
2015-2897	04/13/2015 05/11/2015	FDA/OMPT/CDRH/OCER/DFOI/	Stacci Cronk C. R. Bard, Inc.	K141139
2015-2898	04/13/2015 05/11/2015	FDA/OMPT/CDRH/OCER/DFOI/	K081151 Compumedics Neuvo Quality and Regulatory Associates, LLC	K081151
2015-2899	04/13/2015 05/11/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 205053
2015-2900	04/13/2015 05/11/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	HARVONI - AERS
2015-2901	04/13/2015 05/11/2015	FDA/OMPT/CDRH/OCER/DFOI/	Dave Hernon SonaCare Medical, LLC	K141785

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2015-2902	04/13/2015 05/11/2015	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	Xcelience, LLC Tampa, FL EIR and 483 TARIS Biomedical	XCELIENCE, TAMPA, FL - EIR, 483 12/01/2008 - 01/30/2009
2015-2903	04/13/2015 05/11/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Steven Richards Richards, Steven	PACLITAXEL - AERS
2015-2904	04/13/2015 05/11/2015	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	Adam Steinbaugh Adam Steinbaugh	ROCA LABS, INC., ROCA LABS PHARMACEUTICALS, ROCA LABS USA - COMPLAINTS, REFUSAL, INSPECTION ETC 01/01/2009 - 04/15/2015
2015-2905	04/13/2015 05/11/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Suchitra Ramachandran Keck Graduate Institute	PENICILLIN G SODIUM ANDA 065068
2015-2906	04/13/2015 05/11/2015	FDA/OGROP/ORR/CE-FO/BLT-DO/BLT-CB/	Steve Rogers Zoetis Inc.	BIORELIANCE CORPORATION, ROCKVILLE, MD - 482, 483, EIR 01/01/2011 - 04/08/2015
2015-2907	04/13/2015 05/11/2015	FDA/OGROP/ORR/CE-FO/CIN-DO/CIN-CB/	Steve Rogers Zoetis Inc.	WIL RESEARCH, ASHLAND, OH - 482, 483, EIR 03/01/2011 - 04/08/2015
2015-2908	04/13/2015 05/11/2015	FDA/OMPT/CDRH/OCER/DFOI/	Brit Baird EKOS Corporation	P900056 S026
2015-2909	04/13/2015 05/11/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bobbie Coles-Brown Sun Pharmaceutical Industries, Inc.	ANDA 202348
2015-2910	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	Fabian Struck University of Passau, Bavaria, Germany	CORDIS CORPORATION - WARNING LETTERS 01/01/2004 - 12/31/2004
2015-2911	04/13/2015 05/11/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/CVM/OCD/	Kellie Garrett CHEMICAL INFORMATION SERVICES, INC.,	2nd Quarter DMF file (Excel format) 2nd Quarter VMF file (PDF format)
2015-2912	04/13/2015 05/11/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Gay Parsons, Janssen Inc Janssen Inc.	GENERIC METHYLPHENIDATE HYDROCHLORIDE ER - ADVERSE EVENTS EXCEL, CVS FORMAT 12/28/2012 - 02/27/2015

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2015-2913	04/13/2015 05/11/2015	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	MPI RESEARCH, INC, MATTAWAN, MI - 483, EIR, RESPONSE 08/01/2012 - 08/31/2012
2015-2914	04/13/2015 05/11/2015	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	SRI INTERNATIONAL, MENLO PARK, CA - 483, EIR, RESPONSE 02/01/2012 - 02/28/2012
2015-2915	04/13/2015 05/11/2015	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	CHARLES RIVER PATHOLOGY ASSOCIATES, CHICAGO, IL - 483, EIR, RESPONSE 06/01/2012 - 07/30/2012
2015-2916	04/13/2015 06/08/2015	FDA/OC/OCC/ FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	LOVELACE RESPIRATORY RESEARCH INSTITUTE, ALBUQUERQUE, NM - 483, EIR, RESPONSE 03/01/2012 - 03/31/2012
2015-2917	04/13/2015 05/11/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Alan Zarembo LOS ANGELES TIMES	CORR FROM UCLA OR DR GARY SMALL TO FDA RE WARNING LETTER 01/01/2015 - 04/08/2015
2015-2918	04/13/2015 05/11/2015	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	PHARMANET USA, PRINCETON, NJ - 483, EIR, RESPONSE 08/01/2012 - 09/30/2012
2015-2919	04/13/2015 05/11/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Misha Angrist Misha Angrist, PhD	REPLAGAL - RECS RE EXPANDED ACCESS, COMPASSIONATE USE 06/16/2009 - 03/01/2012
2015-2920	04/13/2015 05/11/2015	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	COVANCE LABORATORIES, INC, CHANDLER, AZ - 483, EIR, RESPONSE 06/01/2012 - 07/30/2012
2015-2921	04/13/2015 05/11/2015	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	David Mangione Govzilla, Inc.	CONAGR FOODS, AFFTON, MO - EIR 01/27/2014 - 09/24/2014
2015-2922	04/13/2015 05/11/2015	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	US ARMY MEDICAL RESEARCH INSTITUTE OF INFECTIOUS DISEASES, FORT DETRICK, MD - 483, EIR, RESPONSE 03/01/2012 - 03/30/2012
2015-2923	04/13/2015 05/11/2015	FDA/OFVM/CFSAN/OCD/EOS/	Don Boudreaux Boudreaux and Associates	FCN 178

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2015-2924	04/13/2015 05/11/2015	FDA/OMPT/CDRH/OCER/DFOI/	Justin Baker Arteriocyte, Inc.	K063517
2015-2925	04/13/2015 05/11/2015	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	RICERCA BIOSCIENCES, LLC, CONCORD, NH - 483, EIR, RESPONSE 04/01/2012 - 04/30/2012
2015-2926	04/13/2015 05/11/2015	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	PPD DEVELOPMENT, LP, RICHMOND, VA - 483, EIR, RESPONSE 02/01/2012 - 02/28/2012
2015-2927	04/13/2015 05/11/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Beryl Li UC Berkeley-Student	ORTHO EVRA - AERS
2015-2928	04/13/2015 05/11/2015	FDA/OFVM/CFSAN/OCD/EOS/	Don Boudreaux Boudreaux and Associates	FCN 475
2015-2929	04/13/2015 05/11/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	LURPON - AERS
2015-2930	04/13/2015 05/11/2015	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	EXELIXIS, SOUTH SAN FRANCISCO, CA - 483, EIR, RESPONSE 09/01/2012 - 09/30/2012
2015-2931	04/13/2015 05/11/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/ORA/ OC/ORA/ FDA/OGROP/ORA/ORO/DIOP/ OC/ORA/OCI/ OC/ORA/OCI/	Tom Blackwell National Post	CORR SENT TO CANADA DRUGS LTD, WINNIPEG, MANITOBA, CANADA RE EXPORT OF PRESCRIPTION MEDICATION TO THE US 03/01/2012 - 04/08/2015
2015-2932	04/13/2015 05/11/2015	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	kimberly hudson personal use	RECALL Z-0006-04 RECS
2015-2933	04/13/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson	K012677

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	05/11/2015		FOI Services, Inc.	
2015-2934	04/13/2015 05/11/2015	FDA/OMPT/CDRH/OCER/DFOI/	Scott Ericsson Androscore Corporation	K100341
2015-2935	04/13/2015 05/11/2015	FDA/OMPT/CDRH/OCER/DFOI/	Siemens Medical Solutions USA, Inc. Siemens Medical Solutions USA, Inc.	K133705
2015-2936	04/13/2015 05/11/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K111773
2015-2937	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink	2014-3015
2015-2938	04/13/2015 05/11/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca Dandeker Morgan, Lewis & Bockius LLP	ANDA 090379 SBA
2015-2939	04/13/2015 05/11/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Blake Goodner Bridger Healthcare	DMF 1201, DMF 17157, DMF 18963 ETC
2015-2940	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	Elliot Favus, MD FAVUS INSTITUTIONAL RESEARCH LLC	2015-2528, 2015-2463, 2015-2261 ETC
2015-2941	04/13/2015 05/11/2015	FDA/OGROP/ORR/CE-FO/DET-DO/DET-CB/	Blake Goodner Bridger Healthcare	MONOSOL RX, PORTAGE, INDIANA - 483, WARNING LETTER, RESPONSES 01/03/2013 - 04/09/2015
2015-2942	04/13/2015 05/11/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K041867
2015-2943	04/13/2015 05/11/2015	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	JP Douglas PARIS ENTERPRISES	BK140191
2015-2944	04/13/2015 06/03/2015	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	JPDOUGLAS PARIS ENTERPRISES	BK130065
2015-2945	04/13/2015 05/11/2015	FDA/OMPT/CDRH/OCER/DFOI/	Alex Johnson Inter Med / Vista Dental Products	K110582
2015-2946	04/13/2015 05/11/2015	FDA/OMPT/CDRH/OCER/DFOI/	Alex Johnson Inter Med / Vista Dental Products	K123468

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2015-2947	04/13/2015 05/11/2015	FDA/OMPT/CDRH/OCER/DFOI/	Alex Johnson Inter Med / Vista Dental Products	K130163
2015-2948	04/13/2015 05/11/2015	FDA/OMPT/CDRH/OCER/DFOI/	Leigh Spotten KARL STORZ Endoscopy-America, Inc.	K142024
2015-2949	04/13/2015 05/11/2015	FDA/OMPT/CDRH/OCER/DFOI/	Leigh Spotten KARL STORZ Endoscopy-America, Inc.	FK140337
2015-2950	04/13/2015 05/11/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Dave Hernon SonaCare Medical, LLC	K081042
2015-2951	04/13/2015 05/11/2015	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	SHIRE HUMAN GENETIC THERAPIES, NORTH READING, MA - EIR, 483, RESPONSE 01/01/2014 - 01/31/2014
2015-2952	04/13/2015 05/11/2015	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	FOREST RESEARCH INSTITUTE, FARMINGDALE, NY - EIR, 483, RESPONSE 03/01/2012 - 04/30/2012
2015-2953	04/13/2015 05/11/2015	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	ALBANY MOLECULAR RESEARCH, ALBANY, NY - EIR, 483, RESPONSE 12/01/2013 - 12/31/2013
2015-2954	04/13/2015 05/11/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORA/ OC/ORA/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Doe J	DILANTIN - COMPLAINT RECS
2015-2955	04/13/2015 05/11/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Felix P. Martinson MALLINCKRODT	WACKER CHEMIE AG MUNICH, GERMANY; PHARMAZELL, CHENNAI, INDIA - 483, EIR LAST FIVE YEARS
2015-2956	04/13/2015 05/11/2015	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Robert Cole USA CONTAINER CO., INC.	USA CONTAINER CO, INC, HILLSBOROUGH, NJ - EIR 01/03/2012 - 01/05/2015
2015-2957	04/13/2015 05/11/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	FDA minutes with Seattle Genetics regarding the AETHERA study, from 01/01/2014 to the present

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2015-2958	04/13/2015 05/11/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	FDA meeting minutes with Teva Pharmaceuticals discussing generic EpiPen from 01/01/2014 to the present
2015-2959	04/13/2015 05/11/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Holly Wedding Myself (consumer)	DASETTA - AERS
2015-2960	04/13/2015 05/11/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	FDA meeting minutes with Prosensa (now BioMarin) discussing drisapersen from 01/01/2014 to the present
2015-2961	04/13/2015 05/11/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	FDA meeting minutes with Sarepta Therapeutics discussing Eteplirsen 10/01/2014 to the present
2015-2962	04/13/2015 05/11/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	03/2015 meeting minutes between FDA & Amicus
2015-2963	04/13/2015 05/11/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	FDA meeting minutes with Alkermes discussing ALKS 9070 from 01/01/2014 to the present
2015-2964	04/13/2015 05/11/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	FDA meeting minutes with industry discussing HP Acthar Gel (respository corticotropin gel) from 01/01/2012 to the present
2015-2965	04/13/2015 05/11/2015	FDA/OMPT/CDRH/OCER/DFOI/	Ryan McKeegan Ryan McKeegan	LIST OF FDA CLEARED OR APPROVED VERTEBRAL BODY REPLACEMENT DEVICES FOR USE IN THE CERVICAL SPINE 04/04/2001 - 04/09/2015
2015-2966	04/13/2015	FDA/OMPT/CDER/ORP/DIDP/	Daniel Bernier	PFIZER, AUSTRALIA - 483 11/01/2014 - 04/09/2015

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	05/11/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Hospira, Inc.	
2015-2967	04/13/2015 05/11/2015	FDA/OFVM/CFSAN/OCD/EOS/	Linda Loretz PERSONAL CARE PRODUCTS COUNCIL	COSMETIC VOLUNTARY REGISTRATION PROGRAM - INGREDIENT DATA
2015-2968	04/13/2015 05/11/2015	FDA/OMPT/CDRH/OCER/DFOI/	Chris Alder Chris Alder	ACELRX PHARMACEUTICALS ZALVISO - COMMUNICATIONS WITH FDA RE DEVICE PORTION 03/01/2014 - 07/31/2014
2015-2969	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-2991
2015-2970	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-4430
2015-2971	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-4497
2015-2972	04/13/2015 05/11/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Katherine Kaempchen Forward Pharma Gmbh- Katherine Kaempchen	TECFIDERA - AERS
2015-2973	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-4460
2015-2974	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-4605
2015-2975	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-4255
2015-2976	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-4297
2015-2977	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-4291
2015-2978	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-4289
2015-2979	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-4298
2015-2980	04/13/2015	FDA/OC/OES/DFOI/	Jo Hogan	2014-4824

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	05/11/2015		FOI Services, Inc.	
2015-2981	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-4302
2015-2982	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-4315
2015-2983	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-4830
2015-2984	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-4917
2015-2985	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-4867
2015-2986	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-4847
2015-2987	04/13/2015 05/11/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Roddy Boyd Southern Investigative Reporting Foundation	SUBSYS - AERS
2015-2988	04/13/2015 05/11/2015	FDA/OGROP/ORACE-FO/PHI- DO/PHI-CB/	Sherita hall TissueGene, Inc	WUXI APPTec, PHILADELPHIA, PA - EIR 12/17/2002 - 04/10/2015
2015-2989	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	GLADYS B TONKIN Center for Regulatory Services, Inc.	FOI DAILY LOG 3/16-20/15
2015-2990	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	GLADYS B TONKIN Center for Regulatory Services, Inc.	FOI DAILY LOG 3/2-6/16
2015-2991	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	GLADYS B TONKIN Center for Regulatory Services, Inc.	FOI DAILY LOG 3/9-13/15
2015-2992	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	GLADYS B TONKIN Center for Regulatory Services, Inc.	FOI DAILY LOG 3/23-27/15
2015-2993	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 2/23-27/15
2015-2994	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 3/16-20/15
2015-2995	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 3/2-6/15

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2015-2996	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 3/9-13/15
2015-2997	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 3/23-27/15
2015-2998	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 3/2-6/15
2015-2999	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 3/9/13/15
2015-3000	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 3/16-20/15
2015-3001	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 2/23-27/15
2015-3002	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	DEBI L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 3/23-27/15
2015-3003	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 3/16-20/15
2015-3004	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 3/2-6/15
2015-3005	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 3/9-13/15
2015-3006	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	DEBI L COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 2/23-27/15
2015-3007	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	DEBI L COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 3/2-6/15
2015-3008	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	DEBI L COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 3/9-13/15
2015-3009	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	DEBI L COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 3/16-20/15

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2015-3010	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	DEBI L COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 3/23-27/15
2015-3011	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 2/23-28/15
2015-3012	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 3/16-21/15
2015-3013	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 3/2-7/15
2015-3014	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 3/9-14/15
2015-3015	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 2/23-28/15
2015-3016	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 3/2-7/15
2015-3017	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 3/9-14/15
2015-3018	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 3/16-21/15
2015-3019	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 3/23-28/15
2015-3020	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 2/23-27/15
2015-3021	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 3/2-6/15
2015-3022	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 3/9-13/15
2015-3023	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 3/16-20/15
2015-3024	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 3/23-27/15
2015-3025	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 3/23-27/15

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2015-3026	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 3/16-20/15
2015-3027	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 3/2-6/15
2015-3028	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 3/9-13/15
2015-3029	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	LESLIE RAMSEY FDA NEWS	FOI DAILY LOG 3/23-27/15
2015-3030	04/13/2015 05/11/2015	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	SHAFIEL A. KARIM LAW OFFICE OF SHAFIEL A KARIM	DIETARY SUPPLEMENT FIRMS - CGMP INSP RPTS 1/10 TO 3/15; JINHER INC, CHINO, CA 3/26/14, KABCO PHARMACEUTICALS INC, AMITYVILLE, NY 11/26/13, ROBINSON PHARMA INC, SANTA ANA, CA 11/1813, ETC - 483S
2015-3031	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	LESLIE RAMSEY FDA NEWS	FOI DAILY LOG 3/16-20/15
2015-3032	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	LESLIE RAMSEY FDA NEWS	FOI DAILY LOG 3/2-6/15
2015-3033	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	LESLIE RAMSEY FDA NEWS	FOI DAILY LOG 3/9-13/15
2015-3034	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 3/23-27/15
2015-3035	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 3/16-20/15
2015-3036	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 3/2-6/15
2015-3037	04/13/2015 05/11/2015	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 3/9-13/15
2015-3038	04/13/2015 05/11/2015	OC/ORO/ OC/ORO/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	LUIS MURGUIA BUMBLE BEE SEAFOODS	CMLPNT 139589
2015-3039	04/13/2015 05/11/2015	FDA/OMPT/CDRH/OCER/DFOI/	ADAM SIMON CERORA INC	ZOOM 100DC K082886; NEUROFAST MONITORING SYS MODEL NS 201 K092477; SWAY BALANCE K121590, ETC

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2015-3040	04/13/2015 05/11/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HANNAH SCHWARZSCHILD HAGENS BERMAN LLP	ANDA 203-136, ANDA 091-422 APRVL
2015-3041	04/13/2015 05/11/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GREGORY J. GREBE HAGENS BERMAN LLP	DURAMORPH (MORPHINE SULFATE) NDA 18-565
2015-3042	04/13/2015 05/11/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GREGORY J. GREBE LAW OFFICES OF GREGORY J GREBE	DURAMORPH (MORPHINE SULFATE) NDA 18-565
2015-3043	04/13/2015 05/11/2015	FDA/OMPT/CDRH/OCER/DFOI/	KA SAUNDRA L. HOSEA Saalfeld Shad Stokes Inclan Stoudemire & Stone, PA	MAUDE Cmplnt MW5017940
2015-3044	04/13/2015 05/11/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SCIRONE, MARIA	PROLIA - AER
2015-3045	04/13/2015 05/11/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MICHAEL R. COHEN INSTITUTE FOR SAFE MEDICATION PRACTICES	MEDWATCH MEDICATION ERRORS 3/2015
2015-3046	04/13/2015 05/11/2015	OC/CVM/OCD/	KENNY CHU Virbac Australia Pty Ltd	SAFEHEART - LBLG
2015-3047	04/13/2015 05/11/2015	FDA/OMPT/CDRH/OCER/DFOI/	ARUN J. MOHAN Richards Layton & Finger P.A.	MAXWELL ENERGY PRODUCTS DIVISION (SIERRA) - BROADBAND EMI FILTER DESIGNS FOR HUMAN IMPLANTABLE PACEMAKERS & DEFIBRILLATORS THAT PROVIDE IMMUNITY TO CELLULAR PHONES & OTHER EMITTERS PRESENTATION RECS 9/10/96
2015-3048	04/13/2015 05/11/2015	FDA/OGROP/ORP/SW-FO/KAN- DO/KAN-CB/	K. MICHELLE VASSALLO LINCARE INC	PROVIDER PLUS INC, MI OR KS - 483, EIR, WARNING LTRS 1/98 TO PRESENT
2015-3049	04/13/2015 05/11/2015	FDA/OGROP/ORP/NE-FO/NWE- DO/NWE-CB/ FDA/OGROP/ORP/NE-FO/NYK-	K. MICHELLE VASSALLO LINCARE INC	QMES, LLC, CT, MA, NH, NY, RI - 483, EIR, WARNING LTRS 1/98 TO PRESENT

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		DO/NYK-DCB/		
2015-3050	04/14/2015 05/12/2015	FDA/OGROP/ORPA-FO/LOS-DO/LOS-CB/	Skye Resendes Law Offices of Ronald A. Marron	NATURE'S WAY - INSPECTION REPORTS, WARNING LETTERS
2015-3051	04/14/2015 05/12/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Nitesh Darji Phibro Animal Health Corporation	HANGZOU MINSHENG PHARMACEUTICAL GROUP, CHINA; HANGZOU MINSHENG PHARMACEUTICAL CO LT, CHINA - EIR 06/01/2002 - 12/31/2004
2015-3052	04/14/2015 05/12/2015	FDA/OGROP/ORPA-FO/SAN-DO/SAN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	NAZ, AFTAB, MADERA, CA - EIR, 483, RESPONSE 10/01/2014 - 10/30/2014
2015-3053	04/14/2015 05/12/2015	FDA/OMPT/CDRH/OCER/DFOI/	Reid Glass Reid Glass, Attorney At Law	INTERNATIONAL DIVERSIFIED PRODUCTS, INC, LAWRENCE R. KOH, INMOTIONSPINEBOARD - 510K, REGISTRATION RECS, APPROVAL DATE ETC
2015-3054	04/14/2015 05/12/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Leah Fitzgerald Swedish Medical Center, Leah Fitzgerald	DOMPERIDONE IND
2015-3055	04/14/2015 05/12/2015	FDA/OGROP/ORPA-FO/SAN-DO/SAN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	MEDIMMUNE VACCINES, INC, SANTA CLARA, CA - EIR, 483, RESPONSE 01/01/2014 - 01/31/2014
2015-3056	04/14/2015 05/12/2015	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	SUNOVION PHARMACEUTICALS, MARLBOROUGH, MA - EIR, 483, RESPONSE 05/01/2013 - 05/30/2013
2015-3057	04/14/2015 05/12/2015	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	EXXON MOBIL CHEMICAL COMPANY, BATON ROUGE, LA - EIR, 483, RESPONSE 04/01/2013 - 04/30/2013
2015-3058	04/14/2015 05/12/2015	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	ABBVIE, LTD, BARCELONETA, PR - EIR, 483, RESPONSE 05/01/2014 - 05/30/2014
2015-3059	04/14/2015 05/12/2015	FDA/OGROP/ORPA-FO/SAN-DO/SAN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	GENERITECH CORPORATION, FRESNO, CA - EIR, 483, RESPONSE 04/01/2013 - 04/30/2013
2015-3060	04/14/2015 05/12/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Walter Chalkley THOMSON REUTERS	HISAMITSU PHARMACEUTICAL, TOSU, JAPAN - EIR, 483, RESPONSE 04/01/2014 - 04/30/2014

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2015-3061	04/14/2015 05/12/2015	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Sherita Hall TissueGene, Inc	WUXI APPTTEC INC, PHILADELPHIA, PA - EIR, 483, RESPONSE 12/17/2002 - 04/10/2015
2015-3062	04/14/2015 05/12/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joshua Malamud Hyman, Phelps & McNamara P.C.	ARROW GENERICS LTD, STEVENAGE, UK; ARROW PHARMA LTD, MALTA; COBALT PHARMACEUTICALS, CANADA ETC - 483
2015-3063	04/14/2015 05/12/2015	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Fran Silverman truthinadvertising.org	HI-TECH PHARMACEUTICAL, JARED WHEAT - CORR WITH FDA 01/01/2000 - 04/10/2015
2015-3064	04/14/2015 05/12/2015	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	TOLMAR, INC, FORT COLLINS, CO - EIR, 483, RESPONSE 01/01/2014 - 01/31/2014
2015-3065	04/14/2015 05/12/2015	FDA/OFVM/CFSAN/OCD/EOS/	Fran Silverman truthinadvertising.org	THERMO-RX ETC - AERS 01/01/2010 - 04/10/2015
2015-3066	04/14/2015 05/12/2015	FDA/OFVM/CFSAN/OCD/EOS/	Fran Silverman truthinadvertising.org	ATTENTION LINK, BETA-STIM, GREEN COFFEE BEAN EXTRACT ETC - AERS
2015-3067	04/14/2015 05/12/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Samit Deb Pharmaceutics International, Inc.	PHARMACEUTICS INTERNATIONAL, INC BUPRENORPHINE HYDROCHLORIDE - NDA 018401 TERMINALLY STERILIZED PRODUCT
2015-3068	04/14/2015 05/12/2015	OC/ORAE/ OC/ORAE/ FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Heleni Suydam SANDS & ASSOCIATES	ETHICON ENDO-SURGERY, ETHICON SURGICAL STAPLERS, RELOADS - COMPLAINTS 01/01/2008 - 12/31/2014
2015-3069	04/14/2015 05/12/2015	OC/ORAE/ OC/ORAE/	Kelly D Johnson Monty & Ramirez LLP	DV1-0155421-5 - SEIZURE RECS, CORR, ETC
2015-3070	04/14/2015 05/12/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Nav Persaud UNIVERSITY OF TORONTO	DOXYLAMINE-PYRODOXINE, BENEDICTIN - PEER REVIEW GROUP RECS 01/12/1956 - 04/12/2015

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2015-3071	04/14/2015 05/12/2015	FDA/OFVM/CFSAN/OCD/EOS/	Micheal Mathews Micheal Mathews	BEBIDA BEVERAGE COMPANY - WARNING LETTER RESPONSE, CORR 01/01/2015 - 04/10/2015
2015-3072	04/14/2015 05/12/2015	FDA/OMPT/CDRH/OCER/DFOI/	Marisa Testa Thema s.r.l.	K102776
2015-3073	04/14/2015 05/12/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Andrea Demakas ADVERSEEVENTS INC	XARELTO, PRADAXA, HARVONI ETC - AERS
2015-3074	04/14/2015 05/12/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Andrew Vaino Eudysmic Capital	LAMPRENE - APPROVAL RECS 01/01/1985 - 04/13/2015
2015-3075	04/14/2015 05/12/2015	FDA/OMPT/CDRH/OCER/DFOI/	Plamena Entcheva-Dimitrov, PhD Preferred Clinical Research, LLC	K132520, K053625, K120894
2015-3076	04/14/2015 05/12/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Danielle Crotty HUNTINGTON HOSPITAL	APIXABAN - AERS
2015-3077	04/14/2015 05/12/2015	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OFVM/CFSAN/OCD/EOS/	H MICHAEL O'BRIEN WILSON ELSEER MOSKOWITZ EDELMAN & DICKER LLP	E COLI OUTBREAK, MA - INVESTIGATION RECS 5/13 TO 6/13
2015-3078	04/14/2015 06/05/2015	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	ANDREAS PIGNI REGEN LAB SA	ESTAR TECHNOLOGIES LTD -TROPOCELLS AUTOLOGOUS PLATELET PREPARATION KIT BK110035
2015-3079	04/14/2015 05/12/2015	FDA/OMPT/CDRH/OCER/DFOI/	DAWN S BROWN ALFRED I DUPONT HOSPITAL FOR CHILDREN	SOMEDIC SALES AB (SOMEDIC AB) - FDA ESTABLISHMENT REGISTRATION NUMBER 8030907
2015-3080	04/14/2015 05/12/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	DARLENE CRISP CRISP, DARLENE	L HIP TOTAL ARTHROPLASTY - Cmplnts, Recalls
2015-3081	04/14/2015 05/12/2015	FDA/OMPT/OSMP/OOPD/	MICHAEL KROLL PRAXISKLINIK	THIOLA (TIOPRONIN) - ORPHAN DRUG APRVL
2015-3082	04/14/2015	FDA/OO/OHR/	KELLY MCCONAGHY	VACANCY ANOUNCEMENT - INTERDISCIPLINARY SCIENTIST FDA-ORA-14-MP-1120616-DY APPLICATION

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	05/13/2015		Alpha Medical Instruments	
2015-3092	04/15/2015 05/13/2015	FDA/OMPT/CDRH/OCER/DFOI/	Dr. William Bennett Bennett, William	K133164
2015-3093	04/15/2015 05/13/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Richard Klemm ORBIMED ADVISORS LLC	ORENITRAM - AERS
2015-3094	04/15/2015 05/13/2015	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	List of FOIA Requests made by Baum Hedlund
2015-3095	04/15/2015 05/13/2015	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/	David McKinney David McKinney	NUSCIENCE CORPORATION, LANCASTER, CA - RECS SINCE OCT 2013 12/01/2014 - 04/13/2015
2015-3096	04/15/2015 05/13/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dr. Joseph J. Zambon Joseph J. Zambon DDS, PhD	LAMOTRIGINE - AERS
2015-3097	04/15/2015 05/13/2015	FDA/OGROP/ORACE-FO/DET- DO/DET-CB/ FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/	Rachel Johnson FOI Services, Inc.	POST FOODS - EIR, 483, RESPONSES 2014
2015-3098	04/15/2015 05/13/2015	FDA/OGROP/ORAPA-FO/SAN- DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Rebeca Ballard Absolute Research, LLC	INDEPENDENT REVIEW CONSULTING - INSPECTION REPORTS, EXHIBITS, RESPONSE ETC 04/01/2010 - 04/13/2015
2015-3099	04/15/2015 05/13/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Erin Kelm Fuld + Company	GP PHARM PLANT - 483 01/01/2015 - 04/30/2015
2015-3100	04/15/2015 05/13/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	RECS RE FDA ADVISORY RE FORMATION OF GLASS LAMELLAE IN CERTAIN INJECTABLE DRUGS
2015-3101	04/15/2015 05/13/2015	FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/	Rebecca Ballard Absolute Research, LLC	TENEO IRB, TULSA, OK - INSPECTION REPORT, WARNING LETTER, RESPONSE ETC 11/01/2009 - 04/13/2015
2015-3102	04/15/2015	FDA/OMPT/CDER/ORP/DIDP/	Pratik Pangaonkar	CANDESARTAN CILEXIL ANDA 078702

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	05/13/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Keck Graduate Institute of Applied Lifesciences	
2015-3103	04/15/2015 05/13/2015	FDA/OMPT/CDRH/OCER/DFOI/	Jason Adams Nightscout Foundation	DEXCOM SUBMISSION DOCUMENT FOR DEXCOM SHARE DIRECT SECONDARY DISPLAYS 12/01/2014 - 02/01/2015
2015-3104	04/15/2015 05/13/2015	FDA/OGROP/ORAC/CE-FO/CHIDO/CHI-CB/	Stephanie Wasielewski CORPAK MedSystems	CORPAK MEDSYSTEMS - EIR 2014
2015-3105	04/15/2015 05/13/2015	FDA/OMPT/CDRH/OCER/DFOI/	Samuel P. Vitello Triumvirate Environmental, Inc.	K112774
2015-3106	04/15/2015 05/13/2015	OC/ORAC/ORM/ OC/ORAC/ORM/	Melanie Figueroa UNIVERSITY OF PUERTO RICO MEDICAL	LIST OF INSPECTIONS FOR FOOD, DRUG COMPANIES IN COSTA RICA, DOMINIC REPUBLIC, CHILE, ARGENTINA, AND BRAZIL
2015-3107	04/15/2015 05/13/2015	FDA/OGROP/ORAC/CE-FO/BLT-DO/BLT-CB/	James Andrew Carmichael Hunter-Holmes McGuire Veterans Affairs Medical Center	HUNTER HOLMES MCGUIRE VETERANS AFFAIRS MEDICAL CENTER, NORTH CHESTERFIELD, VA - INSPECTION RECS 02/03/2015 - 04/14/2015
2015-3108	04/15/2015 05/13/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Robert Bexton Aristotle Capital Management	SUN PHARMACEUTICALS INDUSTRIES LIMITED - 483 12/31/2012 - 04/15/2015
2015-3109	04/15/2015 05/13/2015	FDA/OMPT/CDRH/OCER/DFOI/	Carla Scarmazzi, FDA Specialist KING & SPALDING	K141399
2015-3110	04/15/2015 05/13/2015	FDA/OGROP/ORAC/SW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Alexander Panetta The Canadian Press	HEALTH MANAGEMENT ASSOCIATES - REPORT INTO TAINTED BLOOD 01/01/1983 - 01/01/1986
2015-3111	04/15/2015 05/13/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sarah Lynch Schachter, Hendy & Johnson PSC	PFIZER, PHARMACIA AND UPJOHN - COMM WITH FDA RE ADDING THE RISK OF BLOOD CLOTS TO LABEL FOR DEPO-TESTOSTERONE 01/01/2014 - 02/01/2016
2015-3112	04/15/2015 05/13/2015	FDA/OGROP/ORAC/SW-FO/DEN-DO/DEN-CB/	Leanne Acklin Leanne Acklin	YOUNG LIVING, LEHI, UT; DOTERRA INTERNATIONAL, PLEASANT GROVE, UT - WARNING LETTER RECS; 09/01/2014 - 04/14/2015
2015-3113	04/15/2015 05/13/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sarah Lynch Schachter, Hendy & Johnson PSC	ACTIENT PHARMACEUTICALS, AUXILIUM PHARMACEUTICALS, ENDO PHARMACEUTICALS - CORR WITH FDA RE RISK OF BLOOD CLOTS TO LABEL FOR TESTOPEL 01/01/2014 - 02/01/2016

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		FDA/OMPT/CDER/GRP/DIDP/		
2015-3114	04/15/2015 05/13/2015	FDA/OGROP/ORR/PA-FO/SAN-DO/SAN-CB/	Lily Huang Lily Huang	KAN HERBS, SANTA CRUZ, CA - EIR 01/01/2011 - 12/31/2014
2015-3115	04/16/2015 05/14/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Cecilia Dahlgren Swedish Orphan Biovitrum AB (publ)	BLA 125319/62
2015-3116	04/16/2015 05/14/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sarah Lynch Schachter, Hendy & Johnson PSC	ELI LILLY - CORR WITH FDA RE ADDING RISK OF BLOOD CLOTS IN THE VEINS TO LABELING FOR AXIRON
2015-3117	04/16/2015 05/14/2015	FDA/OFVM/CFSAN/OCD/EOS/	Tim Murphy MOTHER JONES	PROPECTIN, VITAPRO - COMPLAINTS 03/11/2011 - 04/14/2015
2015-3118	04/16/2015 05/14/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sarah Lynch Schachter, Hendy & Johnson PSC	ENDOPHARMACEUTICALS - CORR WITH FDA RE ADDING RISK OF BLOOD CLOTS IN THE VEINS TO LABELING FOR FORTESTA
2015-3119	04/16/2015 05/14/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sarah Lynch Schachter, Hendy & Johnson PSC	ACTAVIS - CORR WITH FDA RE ADDING RISK OF BLOOD CLOTS IN THE VEINS TO LABELING FOR ANDRODERM
2015-3120	04/16/2015 05/14/2015	FDA/OMPT/CDRH/OCER/DFOI/	Holly Rockweiler Holly Rockweiler Consulting	K130978
2015-3121	04/16/2015 05/14/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sarah Lynch Schachter, Hendy & Johnson PSC	ENDO PHARMACEUTICALS - CORR WITH FDA RE ADDING RISK OF BLOOD CLOTS IN THE VEINS TO LABELING FOR DELATESTRYL
2015-3122	04/16/2015 05/14/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sarah Lynch Schachter, Hendy & Johnson PSC	AUXILLIUM, ENDO PHARMACEUTICALS - CORR RE LABELING CHANGES FOR TESTIM
2015-3123	04/16/2015 05/14/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sarah Lynch Schachter, Hendy & Johnson PSC	ABBOTT, ABBVIE - CORR WITH FDA RE ADDING RISK OF BLOOD CLOTS IN THE VEINS TO LABELING FOR ANDROGEL ETC

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2015-3124	04/16/2015 05/14/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sarah Lynch Schachter, Hendy & Johnson PSC	AUXILIUM PHARMACEUTICALS,. ENDO PHARMACEUTICALS - CORR WITH FDA RE ADDING RISK OF BLOOD CLOTS IN THE VEINS TO LABELING FOR STRIANT ETC
2015-3125	04/16/2015 05/14/2015	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink	2015-2128
2015-3126	04/16/2015 05/14/2015	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	GRN 526
2015-3127	04/16/2015 05/14/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sonja Loar Sonja Loar Consulting	NDA 018677 SBA
2015-3128	04/16/2015 05/14/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Melissa Hipolit WTVR-TV	PROPECIA - AERS
2015-3129	04/16/2015 05/14/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HARESH DODIA MANAS CLINICAL RESEARCH PVT LTD	ANDA 079135 BIOPHARMACEUTICAL REVIEW
2015-3130	04/16/2015 05/14/2015	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink	2014-6187
2015-3131	04/16/2015 05/14/2015	OC/CVM/OCD/	Banu Ramachandran Citron Pharma, LLC	NADA 055-099 - CLINICAL DATA, SUMMARY, COMMUNICATIONS, NAME CHANGE RECS
2015-3132	04/16/2015 05/14/2015	FDA/OMPT/CDRH/OCER/DFOI/	DeROYAL Industried DEROYAL INDUSTRIES, INC.	K112458
2015-3133	04/16/2015 05/14/2015	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink	2015-1946
2015-3134	04/16/2015 05/14/2015	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink	2015-1867
2015-3135	04/16/2015	FDA/OC/OES/DFOI/	Jaime Vassallo	2015-1742

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	05/14/2015		LexisNexis CourtLink	
2015-3136	04/16/2015 05/14/2015	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink	2015-1654
2015-3137	04/16/2015 05/14/2015	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Robert Pyrtle Access Biologicals-Robert Pyrtle	SCANTIBODIES LABORATORIES INC - 483 05/24/2013 - 05/24/2013
2015-3138	04/16/2015 05/14/2015	FDA/OGROP/ORASE-FO/FLADO/FLA-CB/	David Morrison Vitamin Shoppe	NUTRIFORCE NUTRITION, MIAMI, FL - EIR 01/01/2015 - 04/15/2015
2015-3139	04/16/2015 05/14/2015	FDA/OMPT/CTP/OD/	ERIC S ROSEN ESQ KELLEY & UUSTAL PLC	PHILIP MORRIS USA INC, RJ REYNOLDS TOBACCO CO, LORILLARD TOBACCO CO, AND/OR LIGGETT GROUP LLC - TOBACCO CONTROL ACT VIOLATION RECS
2015-3140	04/16/2015 05/14/2015	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORASE-FO/FLADO/FLA-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	WAYNE SADOWSKI NOVARTIS PHARMACEUTICAL CORP	EUGENE LU MD, LITTLE ROCK, AR 5/12-21/09; MATTHEW J GUY MD, ROCKAWAY PARK, NY 8/2/04-12/8/04; PATRICK J DALEY, TULSA, OK 7/19/02-9/6/02, ETC - INPS
2015-3141	04/16/2015 05/14/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARTA GODECKI MORRISON & FOERSTER LLP	TEVA PHARMACEUTICALS USA - COPAXONE NDA 02-0622/S089,S090 APRVL RECS
2015-3142	04/16/2015 05/14/2015	FDA/OMPT/CDRH/OCER/DFOI/	GAYLE M BLATT CASEY GERRY SCHENK ET AL	CLINTON RIVER MEDICAL PRODUCTS LLC - TAILWIND WHEELCHAIR RPTS
2015-3143	04/16/2015 05/14/2015	FDA/OMPT/CDRH/OCER/DFOI/	CHARLES CELESTE EAS CONSULTING GROUP LLC	K984413
2015-3144	04/16/2015 05/14/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jane Talkington Oklahoma State Universtiy	OCULINUM - APPLICATIONS 01/01/1977 - 12/31/1989
2015-3145	04/16/2015 05/14/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dennis J. Cotter MTPPI	NDA103234 RAW DATA, DATA DICTIONARY

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2015-3146	04/16/2015 05/14/2015	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Doe J	DR HO - COMPLIANCE FOLLOW UP RECS 03/05/2015 - 04/14/2015
2015-3147	04/16/2015 05/14/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bradley Sullivan, PhD THE UNIVERSITY OF KANSAS	DEFERASIROX - CLINICAL, PRECLINICAL DEVELOPMENT
2015-3148	04/16/2015 05/14/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Brett Gaspers Objective Insights, Inc.	DOMPERIDONE - NUMBER OF EXPANDED ACCESS IND APPLICATIONS 01/01/2005 - 12/31/2014
2015-3149	04/16/2015 05/14/2015	FDA/OFVM/CFSAN/OCD/EOS/	Daniel Paul Moore Berezka Brew	CHAGA MUSHROOM - NDA, GRAS 04/01/1990 - 04/15/2015
2015-3150	04/16/2015 06/18/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Elihu Young OpSaniTx	GENITRIX - PRE-IND RECS 04/01/2004 - 04/15/2015
2015-3151	04/16/2015 05/14/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Adam Grossman Praedicat, Inc.	LEGACY AERS DATA 01/01/1990 - 12/31/2003
2015-3152	04/16/2015 05/14/2015	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	William Olson Center for Regulatory Services, Inc.	FIRST PRIORITY, ELGIN, IL - EIR, 483 01/01/2009 - 04/15/2015
2015-3153	04/16/2015 05/14/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/CVM/OCD/	William Olson Center for Regulatory Services, Inc.	MTC, ONTARIO, CANADA - EIR, 483 01/01/2009 - 04/15/2015
2015-3154	04/16/2015 05/14/2015	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink	2015-1947

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2015-3155	04/16/2015 05/14/2015	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink	2015-1926
2015-3156	04/16/2015 05/14/2015	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink	2015-2040
2015-3157	04/16/2015 05/14/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tushar Manudhane Indianivesh securities	INDOCO REMEDIES LTD, PARALGANGA, INDAI - 483 03/01/2015 - 04/15/2015
2015-3158	04/16/2015 05/14/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	charu sharma DermPathe Pharmaceuticals	NDA 020629, NDA 021478
2015-3159	04/16/2015 05/14/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Andreas Wesley Canadian Broadcasting Corporation	PATHEON, WHITBY, ONTARIO - 483, EIR 01/19/2009 - 04/15/2015
2015-3160	04/16/2015 05/14/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Chirag Talati Kotak Securities	AJANTA PHARMA - EIR, 483 LAST FIVE YEARS
2015-3161	04/16/2015 05/14/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SEAN HUMPHREY DOW PHARMACEUTICAL SCIENCES	DOW PHARMACEUTICAL SCIENCES - JUBLIA (EFINACONAZOLE) TOPICAL SOL NDA 203-567 MEDICAL, CLNCL PHARMACOLOGY BIOPHARMACEUTICS RVWS
2015-3162	04/16/2015 05/14/2015	FDA/OMPT/CDRH/OCER/DFOI/	KEITH A LAZERE MCALOON & FRIEDMAN	ELLIQUENCE LLC - GRASPING FORCEPS CMLNTS, ACCIDENT RPTS
2015-3163	04/16/2015 05/14/2015	FDA/OGROP/ORA/PA-FO/SEA- DO/SEA-CB/	PETER R JOHNSON TASTY BAKE INC	RECALL F-1884-2013 - RECS
2015-3164	04/16/2015 05/14/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/ORO/DIOP/	Zetetic, Inc. ZETETIC INC	FDA ENTRY DOCUMENTATION REQUEST: ALL DOCUMENTATION APR 01, 2015 - APR 15, 2015

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2015-3165	04/16/2015 05/14/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	MINUTES OF MEETINGS WITH FDA RE HP ACTHAR GEL
2015-3166	04/16/2015 05/14/2015	FDA/OC/OCC/ FDA/OC/OES/ FDA/OC/OL/ FDA/OMPT/CDRH/OCER/DFOI/	RUSSELL CAROLLO CAROLLO, RUSSELL	AMERICAN CLINICAL LABORATORY ASSOCIATION (ACLA), QUEST DIAGNOSTICS, LABORATORY CORPORATION OF AMERICA (LABCORP) - LABORATORY-DEVELOPED TESTS CONGRESSIONAL CORR, EMAILS, CMLPNTS, ETC
2015-3167	04/16/2015 05/14/2015	FDA/OMPT/CDRH/OCER/DFOI/	CHARLES CELESTE EAS CONSULTING GROUP LLC	K102478
2015-3168	04/16/2015 05/14/2015	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	THOMAS WEI Wei, Thomas	AMERICAN LABORATORIES INC, OMAHA, NE - EIRS, 483S 3/29/10, 5/2/11, 11/19/12
2015-3169	04/16/2015 05/14/2015	OC/ORASW-FO/ OC/ORASW-FO/	SASHA GRAY THOMSON REUTERS	FOREIGN AND DOMESTIC DRUG INSPS 10/14 TO 3/15
2015-3170	04/17/2015 05/15/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	chelsea molnar Chelsea Molnar	SDVALDI, RIBAVIRIN - AERS
2015-3171	04/17/2015 05/15/2015	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-2341
2015-3172	04/17/2015 05/15/2015	FDA/OMPT/CDRH/OCER/DFOI/	Daniel Schreck Law Office of G. Oliver Koppell & Associates	WICHITA FUSION NAIL - AERS, INVESTIGATIONS 01/01/1990 - 04/15/2015
2015-3173	04/17/2015 05/15/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID E. COOLEY COOLEY, DAVID E	CASE 10330990
2015-3174	04/17/2015 05/15/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	CALCIUM GLUCONATE IV - AERS
2015-3175	04/17/2015 05/15/2015	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-1723

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2015-3176	04/17/2015 05/15/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-1291
2015-3177	04/17/2015 05/15/2015	FDA/OMPT/CDRH/OCER/DFOI/	Amerx Healthcare Corp Amerx Healthcare Corp	K092086
2015-3178	04/17/2015 05/15/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	Debra Pagan Kreindler & Kreindler, LLP	MERZ - REPORTS, SUMMARIES RE RECALL OF RADIESSE 01/01/2010 - 04/16/2015
2015-3179	04/17/2015 05/15/2015	OC/CVM/OCD/	Kathleen Galliher IAMS Dog Food	IAMS DOG FOOD - SPECIE OF SALMONELLA AUGUST 2013
2015-3180	04/17/2015 05/15/2015	OC/ORA/ORM/ OC/ORA/ORM/	David Mangione Govzilla, Inc.	LIST OF INSPECTIONS 03/14/2015 - 04/15/2015
2015-3181	04/17/2015 05/15/2015	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	Richard Pecora PECORA CONSULTING LLC	899704, 899705 LAB RECS
2015-3182	04/17/2015 05/15/2015	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Lisa Robertson Rawls McNelis + Mitchell	VAERS RECS
2015-3183	04/17/2015 05/15/2015	FDA/OO/OHR/	Laurence K. Hill, J.D. Hill, Laurence K	EEO COMPLAINTS CDRH AND CDER OFFICE OF COMPLIANCE 04/16/2005 - 04/16/2015
2015-3184	04/17/2015 05/15/2015	FDA/OMPT/CDRH/OCER/DFOI/	James Luker Sun Nuclear Corporation	TRADE COMPLAINT RESULTS 04/12/2013 - 04/16/2015
2015-3185	04/17/2015 05/15/2015	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	Timothy E. Field Mortara Instrument, Inc.	MORTARA INSTRUMENT, INC, MILWAUKEE, WI - EIR 08/01/2013 - 10/01/2013
2015-3186	04/17/2015 05/15/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	john e. fitzpatrick Odom & Des Roches, LLP	ANDA 091149, ANDA 203136, ANDA 203326
2015-3187	04/17/2015 05/15/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ADITYA KHEMKA AMBIT CAPITAL PVT LTD	TORRENT PHARMA INDRAD, INDIA - 483 03/01/2015 - 04/16/2015

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2015-3188	04/17/2015 05/15/2015	FDA/OC/OES/DFOI/	Katherine Pierson Katherine Pierson	PROPOSED REGULATION OF ELECTRONIC CIGARETTES
2015-3189	04/17/2015 05/15/2015	FDA/OO/OHR/	Joe Palazzolo THE WALL STREET JOURNAL	EMPLOYEES HIRED SINCE 01/01/10 FOR POSITIONS THAT REQUIRE A LAW DEGREE AND WHOSE DUTIES INCLUDE INVESTIGATING OR PROSECUTING AGENCY ENFORCEMENT ACTIONS
2015-3190	04/17/2015 05/15/2015	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Brian Sims Indiana Botanic Gardens, Inc.	INDIANA BOTANIC GARDENS, INC., HOBART, IN - EIR 08/01/2009 - 08/31/2009
2015-3191	04/17/2015 05/15/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sonja Loar Sonja Loar Consulting	NDA 018651 SBA
2015-3192	04/17/2015 05/15/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jesse McLean Toronto Star	LEO PHARM A/S, MUSTAFA NEVZAT ILAC SANAYII AS, NOBILUS ENT ETC - 483
2015-3193	04/17/2015 05/15/2015	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	DON PERITZ JR NBC 5 KXAS-TV	BLUE BELL CREAMERIES, , TX, AR, OK - EIRS 1/113 TO 4/13/15
2015-3194	04/17/2015 07/01/2015	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OFVM/CFSAN/OCD/EOS/	TYLER G MERCER LUBEL VOYLES LLP	WAWONA PACKING CO - LISTERIA MONOCYTOGENES RECALL IN PEACHES, NECTARINES, PLUMS, PLUOTS TEST RESULTS, STUDIES, RPTS, ETC 7/19/14
2015-3195	04/17/2015 05/15/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	Doe J	TERAZOSIN - AERS
2015-3196	04/17/2015 05/15/2015	FDA/OGROP/ORAIORO/DIOP/ OC/ORAI/ OC/ORAI/ FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BENJAMIN L ENGLAND BENJAMIN L ENGLAND & ASSOCIATES LLC	LABORATORI DERIVATI ORGANICI, MILANO, ITALY, VERCELLI, ITALY - HEPARAN SULFATE DECISION TO REFUSE ENTRIES BSS-0000370-9, BSS-0000369-1 & ADD TO IMPORT ALERT 66-66 CORR UNREDACTED

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2015-3197	04/20/2015 05/18/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Roger Zhang STANFORD UNIVERSITY	IND 071384
2015-3198	04/20/2015 05/18/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nathan Beaver FOLEY & LARDNER LLP	AUROBINDO PHARMA CEFIXIME - SBA
2015-3199	04/20/2015 05/18/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	AJ Walker NBC CONNECTICUT NEWS	FLUOROQUINOLONE ANTIBACTERIAL DRUGS - AERS
2015-3200	04/20/2015 05/18/2015	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	ALTRIA CLIENT SERVICES, PHILIP MORRIS USA INC, US SMOKELESS TOBACCO BRANDS INC - FILINGS RE INTENT TO ADVERTISE OR LABEL CIGARETTES OR SMOKELESS TOBACCO
2015-3201	04/20/2015 05/18/2015	FDA/OC/OES/DDM/	Rowena D. Devlin Bayer HealthCare Pharmaceuticals	INDA REWERITE - FEDERAL REGISTER ANNOUNCEMENT WITH PREAMBLE 01/01/1985 - 12/31/1987
2015-3202	04/20/2015 05/18/2015	FDA/OMPT/CDRH/OCER/DFOI/	Iris van Uitert Finapres Medical Systems B.V.	K014063
2015-3203	04/20/2015 05/18/2015	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	Marc Randazza Randazza Legal Group	ROCA LABS, INC, ROCA LABS NUTRACUETICALS, ROCA LABS USA - COMPLAINTS, APPLICATIONS, IMPORT REFUSALS ETC 01/01/2010 - 04/16/2015
2015-3204	04/20/2015 05/18/2015	FDA/OMPT/CDRH/OCER/DFOI/	Dr. William Bennett Bennett, William	K003015
2015-3205	04/20/2015 05/18/2015	FDA/OGROP/ORR/CE-FO/CHI-DO/CHI-CB/	Daniel Bernier TITAN CORP	THERAPEUTIC PROTEINS INTERNATIONAL, LLC - 483 12/01/2014 - 03/31/2015
2015-3206	04/20/2015 05/18/2015	FDA/OMPT/CDRH/OCER/DFOI/	Dr. William Bennett Bennett, William	K036726
2015-3207	04/20/2015 05/18/2015	FDA/OGROP/ORR/CE-FO/MIN-DO/MIN-CB/	Susan Du City Pages	DR STEPHEN OLSON - INSPECTION REPORT 10/01/2014 - 04/17/2015
2015-3208	04/20/2015 05/18/2015	FDA/OFVM/CFSAN/OCD/EOS/	Michael J. O'Flaherty OLSSON FRANK WEEDA TERMAN MATZ PC	WRITE UPS REFERENCED IN LETTER FROM FELICIA BILLINGSLEA, CFSAN
2015-3209	04/20/2015	FDA/OMPT/CTP/OD/	Kevin Schmidt	COMMUNICATIONS BETWEEN CTP PRESS OFFICERS AND

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	05/18/2015	FDA/OC/OCC/	Kevin Schmidt	SABRINA TAVERNISE, MATT RICHTEL, MICHAEL FELDERBAUM 04/01/2014 - 04/17/2015
2015-3210	04/20/2015 05/18/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jane Talkington OKLAHOMA STATE UNIVERSITY	IND ANNUAL REPORTS ON OCULINUM 01/01/1977 - 12/31/1989
2015-3211	04/20/2015 05/18/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Steve Gupta Physicians for Integrity in medical Research Inc.	DALIRESP - POST MARKET REPORT 01/01/2012 - 06/30/2014
2015-3212	04/20/2015 05/18/2015	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink	2014-76
2015-3213	04/20/2015 05/18/2015	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	ERIC NICKERSON MONOSOL RX LLC	MONOSOL RX LLC, PORTAGE, IN - EIR 3/30 - 4/3/15
2015-3214	04/20/2015 05/18/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	CRAIG M. SILVERMAN PETER G ANGELOS LAW OFC	RIVAROXABAN (XARELTO) NDA, APRVL
2015-3215	04/20/2015 05/18/2015	FDA/OFVM/CFSAN/OCD/EOS/	SHARON L. LYERLY WATKINS LOURIE ROLL & CHANCE PC	HYDROXYCUT HARDCORE CAPSULES 160492; HYDROXYCUT REGUALR RAPID RELEASE CAPLETS 160495; HYDROXYCUT (EPHEDRA FREE) REGULAR RELEASE CAPLETS 160498
2015-3216	04/20/2015 05/18/2015	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	CMPLNT 209951007
2015-3217	04/20/2015 05/18/2015	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Doe J	CMPLNT CC139385
2015-3218	04/20/2015 06/12/2015	FDA/OMPT/CTP/OD/	GARY BRINKMAN RINKE NOONAN	DCK FDA-2015-H-0950

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2015-3219	04/20/2015 05/18/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	KIM HENDERSON SANOFI PASTEUR	MERCK & CO - ZOSTAVAX SBA, CLNCL RVW, STATISTICAL RVW
2015-3220	04/20/2015 05/18/2015	FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECS
2015-3221	04/20/2015 05/18/2015	FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECS
2015-3222	04/20/2015 05/18/2015	FDA/OMPT/CDRH/OCER/DFOI/	ANDREAS PIGNI REGENLAB	ECLIPSE AESTHETICS LLC - ECLIPSE PRP REGISTRATION 3009032449
2015-3223	04/20/2015 05/18/2015	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MYRON LEVIN FAIRWARNING	ASBESTOS IN TALC - RPTS
2015-3224	04/20/2015 05/18/2015	FDA/OMPT/OSMP/OOPD/	LILLARD, JEFF	ORPHAN DESIGNATION TREATMENT OF PEDIATRIC CROHNS DISEASE 10-19-2006
2015-3225	04/21/2015 05/19/2015	FDA/OMPT/CDRH/OCER/DFOI/	KATHIE O'CONNELL AMERICAN MEDICAL SYSTEMS INC	AMERICAN MEDICAL SYSTEMS (INNOVAQUATZ) - SUREFLEX FIBER K994010
2015-3226	04/21/2015 05/19/2015	OC/ORO/ORM/ OC/ORO/ORM/	Columba McGuire Columba McGuire	LIST OF FOOD MANUFACTURING COMPANIES, FOOD PROCESSING COMPANIES, FOOD DISTRIBUTION COMPANIES IN USA ETC 01/01/2014 - 04/17/2015
2015-3227	04/21/2015 05/19/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Gregory A Broderick MD Gregory A Broderick MD	SILDENAFIL - AERS
2015-3228	04/21/2015 05/19/2015	FDA/OGROP/ORO/PA-FO/SEA- DO/SEA-CB/	Samm Blumenshine Airline Support Inc.	AIRLINE SUPPORT, INC, LSG SKYCHEF, ANCHORAGE, AK - 483 01/01/2010 - 04/15/2015
2015-3229	04/21/2015 05/19/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sarah Lynch Schachter, Hendy & Johnson PSC	ABBOTT PHARMACEUTICALS, ABBVIE, ACTAVIS ETC - JUNE 2014 LABELING CHANGE ADDING RISK OF BLOOD CLOTS IN THE VEINS TO THE LABELING FOR ANDRODERM, ANDROGEL, AXIRON ETC
2015-3230	04/21/2015 05/19/2015	FDA/OMPT/CDRH/OCER/DFOI/	Angelika Scherp BUSINESS SUPPORT INTERNATIONAL	K944656

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2015-3231	04/21/2015 05/19/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WILLIAM H CARTER MD CARTER, WILLIAM H	METHADONE - AERS
2015-3232	04/21/2015 05/19/2015	FDA/OGROP/ORAC/CE-FO/CHI-DO/CHI-CB/	Felix P. Martinson MALLINCKRODT	CSL BEHRING, BRADLEY, IL - EIR 07/01/2014 - 04/20/2015
2015-3233	04/21/2015 05/19/2015	FDA/OMPT/CDRH/OCER/DFOI/	Alicia Nakonetschny, President Custom Ultrasonics Inc.	K983017
2015-3234	04/21/2015 05/19/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Phil Graf Nano Terra, Inc.	DMF 015490
2015-3235	04/21/2015 05/19/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ayesha Adil The Weinberg Group	NDA 21330 S013
2015-3236	04/21/2015 05/19/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Olena Izhak University of Helsinki (FINLAND)	8 ANDA APPROVAL LETTERS
2015-3237	04/21/2015 05/19/2015	FDA/OGROP/ORAC/SW-FO/DAL-DO/DAL-CB/	Theresa Empey Empey , Theresa	SAMPLE RESULTS 894620
2015-3238	04/21/2015 05/19/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BARBARA A BINZAK BLUMENFELD BUCHANAN INGERSOLL & ROONEY PC	ORIENT BIO INC, REPUBLIC OF KOREA - CYCLOSPORINE FOR FORMS 1571, 1572 COVER SHEETS
2015-3239	04/21/2015 05/19/2015	FDA/OC/OES/DDM/	GAIL A BALL BALL LEGAL FIRM PC	WYETH - EFFEXOR ER, PSYCHOPAHMACOLOGICAL DRUGS A/C 9/20/91 -WHY DISCONTINUATION OF THIS FORMULATION, MINS
2015-3240	04/21/2015 05/19/2015	FDA/OMPT/OSMP/OOPD/	BABRIELE BLUMBERG MD BLUMBERG MD, GABRIELE	THIOLA (TIOPRONIN) - ORPHAN DSRUGS APRVL LTR
2015-3241	04/21/2015 05/19/2015	FDA/OGROP/ORAC/NE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDRH/OCER/DFOI/	IRIS HEWLETT HEWLETT, IRIS	LORAD M-IV MAMMOGRAPHY SYS CLASS 11 RECALL #Z-0148-04, #Z0149-04 - MFG REQUIREMENTS

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2015-3242	04/22/2015 05/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jamie Artale MARTHA JEFFERSON HOSPITAL	CODEINE - AERS
2015-3243	04/22/2015 05/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	Stephen Braaksma Simplex Scientific	K031964
2015-3244	04/22/2015 05/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	Amy Anstead GRAS ASSOCIATES LLC	FAP 3B4373
2015-3245	04/22/2015 05/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	Stephen Braaksma Simplex Scientific	K073630
2015-3246	04/22/2015 05/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sara Freund Sara Freund, Northwestern University	PIRACETAM - IND, CLINICAL TRIAL DATA, ETC
2015-3247	04/22/2015 05/20/2015	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	Joshua Ferguson Abrams Cohen & Associates	ELITE MEDICAL SUPPLY, WEST SENECA, NEW YORK - 483 08/01/2014 - 08/31/2014
2015-3248	04/22/2015 05/20/2015	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink	2015-1409
2015-3249	04/22/2015 05/20/2015	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink	2015-2740
2015-3250	04/22/2015 05/20/2015	FDA/OC/OES/DDM/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mathieu CHARVERIAT THERANEXUS	MEFLOQUINE (LARIAM) - SAFETY LABELING CHANGES, SBA, ADVISORY COMMITTEE MEETING MINUTES ETC
2015-3251	04/22/2015 05/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Karl Gallegos Karl Gallegos, MD	FERUMOXITOL - AERS
2015-3252	04/22/2015	FDA/OMPT/CDER/GRP/DIDP/	William M. Troetel, Ph.D., LLC	APTUIT, UK; APTUIT LTD, ITALY - EIR 01/22/2005 - 03/25/2015

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	05/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	William M. Troetel, Ph.D., LLC	
2015-3253	04/22/2015 05/20/2015	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	Jarusha Bonitz Pharmaceutics International, Inc.	PHARMACEUTICS INTERNATIONAL, INC, COCKEYSVILLE, MD - EIR 08/27/2013 - 09/13/2013
2015-3254	04/22/2015 05/20/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Julie Bassett Medtronic Spine and Biologics	K093438
2015-3255	04/22/2015 05/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	Jane Talkington jane talkington	BOTOX - AERS
2015-3256	04/22/2015 05/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Connie VanderMeulen Connie VanderMeulen	PROLIA - AERS LINE LISTING
2015-3257	04/22/2015 05/20/2015	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	Luke Weissler HUSCH BLACKWELL LLP	DR ASHOK KADAMBI, MD; FORT WAYNE ENDOCRINOLOGY; BELLE SANTE MEDICAL SPA - CORR, COMPLAINTS, INVESTIGATIONS ETC 04/01/2005 - 04/21/2015
2015-3258	04/22/2015 05/20/2015	FDA/OC/OES/DFOI/	Ken Reid Washington Information Source Co.	REQUESTS FOR 483, EIR SINCE 7/1/2014
2015-3259	04/22/2015 05/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	Abhijit Rajan NeoLight LLC	K070180
2015-3260	04/22/2015 05/20/2015	FDA/OC/OES/DFOI/	MARGARET B KWOKA UNIV OF DENVER STURM COLLEGE OF LAW	2013-999, 2013-6827, 2013-6949, ETC
2015-3261	04/22/2015 05/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CINZIA BUSSOLATI CHIESI FARMACEUTICI SPA	3M PHARMS - QVAR (BECLOMETHASONE DIPROPIONATE) INHALATION AEROSOL NDA 20-911 MEDICAL RVWS

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		FDA/OMPT/CDER/GRP/DIDP/		
2015-3262	04/22/2015 05/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARK A HAMMERVOLD GIDEON COOPER & ESSARY	ACTAVIS - FENTANYL AERS
2015-3263	04/22/2015 05/20/2015	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	M ELIZABETH BIERMAN MORGAN LEWIS & BOCKIUS LLP	SMITH & NEPHEW, ST PETERSBURG, FL - EIR 11/13
2015-3264	04/22/2015 05/20/2015	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	PATRICIA L REGENYE Celgene Corporation	HAGOP KANTARJIAN, UNIV OF TEXAS MD ANDERSON CANCER CTR, HOUSTON, TX - 483S 9/11 TO PRESENT
2015-3265	04/22/2015 05/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	DMF 6371
2015-3266	04/22/2015 05/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	PURDUE PHARMA, CANADA - 483, EIR, RESPONSE 09/01/2013 - 09/30/2013
2015-3267	04/22/2015 05/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	TERUMO CORP, JAPAN - 483, EIR, RESPONSE 04/01/2014 - 04/30/2014
2015-3268	04/22/2015 05/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	Eric Mellon Eric Mellon	K102915, K111862
2015-3269	04/22/2015 05/20/2015	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	SHARON L MALCOM MALCOM, SHARON L	CMPLNT #140551
2015-3270	04/22/2015 05/20/2015	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	Claire Bailey-Mayers Reckitt Benckiser Group	FUNGI-NAIL BRAND, FUNGI-NAIL BRAND ANTI-FUNGAL TREATMENT SYSTEM - WARNING LETTER RECS
2015-3271	04/22/2015 05/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	ROBERT READ, MD, UK - EIR, 483, RESPONSE 08/01/2014 - 08/31/2014

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2015-3272	04/22/2015 05/20/2015	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	CAREFUSION 2200, INC, MANNFORD, OK - EIR, 483, RESPONSE 06/01/2014 - 06/30/2014
2015-3273	04/22/2015 05/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	sarah hoskins sarah hoskins	TECFIDERA - AERS
2015-3274	04/23/2015 05/21/2015	FDA/OMPT/CDRH/OCER/DFOI/	Jenette Bennett Cenorin, LLC	K922789
2015-3275	04/23/2015 05/21/2015	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ OC/ORAS/ OC/ORAS/ FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	Claudia Grisales AUSTIN AMERICAN-STATESMAN	BLUE BELL - INSPECTION REPORTS 01/01/2010 - 04/22/2015
2015-3276	04/23/2015 05/21/2015	FDA/OFVM/CFSAN/OCD/EOS/	Lisa Bartley kabc-tv	MIRACLE MINERAL SUPPLMENT - AERS 04/01/2009 - 04/22/2015
2015-3277	04/23/2015 05/21/2015	FDA/OMPT/CDRH/OCER/DFOI/	Paul Michael Vuksich Law Office of Paul Michael Vuksich	IMAGING3, BURBANK, CA - 510K DENIAL RECS 10/20/2010 - 04/22/2015
2015-3278	04/23/2015 05/21/2015	OC/ORAS/ OC/ORAS/ FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Lauren Sweeney KPRC-TV	BLUE BELL CREAMERIES, BRENHAM, TX, BROKEN ARROW, OK; ALABAMA - 483 01/01/2015 - 04/20/2015
2015-3279	04/23/2015 05/21/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joshua A. Klarfeld ULMER & BERNE LLP	LEXAPRO - UNREDACTED MEMO, REVIEW
2015-3280	04/23/2015 05/21/2015	OC/ORAS/ OC/ORAS/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Lauren Sweeney KPRC-TV	BLUE BELL CREAMERIES, BROKEN ARROW, OK - INSPECTION RECS 01/01/2009 - 01/01/2013
2015-3281	04/23/2015 05/21/2015	OC/ORAS/ OC/ORAS/	Jeff Rotkin ROTKIN, JEFFREY	COMPLAINT 137032

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		FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/		
2015-3282	04/23/2015 05/21/2015	FDA/OMPT/CDRH/OCER/DFOI/	Linda Kariya Nihon Kohden America, Inc.	K131973
2015-3283	04/23/2015 05/21/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	J Mason Weeda Mason Weeda	K100066
2015-3284	04/23/2015 05/21/2015	FDA/OMPT/CDRH/OCER/DFOI/	Patrick Morrison ACON Labortories Inc	K092910
2015-3285	04/23/2015 05/21/2015	FDA/OMPT/CDRH/OCER/DFOI/	Patrick Morrison ACON LABORATORIES INC	K110212
2015-3286	04/23/2015 05/21/2015	FDA/OMPT/CDRH/OCER/DFOI/	Kathrine Aaberg Medtronic Neuromodulation	P960009 Annual Report 002 Amendment 004
2015-3287	04/23/2015 05/21/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anurag patel Dr. Reddy's Laboratories Inc.	NDA 205060 - SBA
2015-3288	04/23/2015 05/21/2015	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	W. PATRICK NOONAN W PATRICK NOONAN	21 CFR PART 20 - CORR, CO RESP, 483, EIR 2010 TO 2015
2015-3289	04/23/2015 05/21/2015	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	KEVIN M. KEENAN WHEELER UPHAM	LASALOCID CONTANIMATION - ANIMAL FEED RTP 8/2014 TO 9/2014
2015-3290	04/23/2015 05/21/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ARNOLD KING Cadian Capital	PACIRA PHARMACEUTICALS INC - WARNING LTR, CORR, CRECS RELATED TO WARNING LTR, ETC
2015-3291	04/23/2015 05/21/2015	OC/ORAOCI/ OC/ORAOCI/	MYRON LEVIN FAIRWARNING	FILE 2010-AST-713-0290
2015-3292	04/23/2015 05/21/2015	FDA/OMPT/CDRH/OCER/DFOI/	ANU GAUR MICROLINE SURGICAL	MICRO SURGICAL INC - EG-383OUT W/HITACHI SCANNER EUB-525 K031789; EG-383OUT W/HITACHI SCANNER EUB-5500/8500; EG-387OUTK W/HITACHI SCANNER HV-900 K090197
2015-3293	04/23/2015 05/21/2015	FDA/OC/OES/DFOI/	CAROLLO, RUSSELL	2014-7819, 2014-8195, 2014-8723, 2015-1282
2015-3294	04/23/2015	FDA/OC/OES/DFOI/		2002-4427, 2006-11050, 2007-4393

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	05/21/2015		CAROLLO, RUSSELL	
2015-3295	04/23/2015 05/21/2015	OC/ORA/ OC/ORA/ FDA/OGROP/ORPA-FO/LOS-DO/LOS-CB/	PATRICK D. RIDDLE LAW OFFICES OF PATRICK D RIDDLE PC	TRADER JOES SALMONELLA CONTAMINATION OF WALNUTS LOT NO GU4345, GU4346, GU4349 ETC
2015-3296	04/23/2015 05/21/2015	FDA/OMPT/CDRH/OCER/DFOI/	KRISTIN TODARO KAUFMAN BERGEEST & RYAN LLP	INNOVATIVE PRODUCTS UNLIMITED INC - IPU SHOWER TRANSPORT GURNEY MODEL TSG500 RECALL, MAUDE PRT CERTIFIED
2015-3297	04/23/2015 05/21/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHELSEA A. PALCHER HOGAN LOVELLS LLP	DELALUTIN (HYDROXYPROGESTERONE CAPROATE) APRVD LBLG
2015-3298	04/23/2015 05/21/2015	FDA/OMPT/CTP/OD/	SHELDON T. BRADSHAW HUNTON & WILLIAMS LLP	STUDY REGARDING TASTE PERCEPTIONS IN TOBACCO USE, EFFECTS OF MENTHOL
2015-3299	04/23/2015 05/21/2015	OC/CVM/OCD/ OC/ORA/ OC/ORA/	DR RANDALL SINGER UNIVERSITY OF MINNESOTA	PFGE PATTERN JF6X01.0045, JF6X01.0258, JF6X01.0326 ETC 1996 TO PRESENT
2015-3300	04/23/2015 06/11/2015	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	JIM HERING PAKIS GIOTES ET AL	OBIM FRESH CUT FRUIT CO LLC, FORT WORTH, TX - DOCS 6/1/05 - 5/1/12 CERTIFIED COPIES
2015-3301	04/23/2015 05/21/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OO/OHR/	BRENDA SEIDMAN SEIDMAN REGULATORY TOXICOLOGY LLC	RESUMES OF PEOPLE WHO HAVE INVOLVEMENT IN BIOCOMPATIBILITY TOXICOLOGY OR RISK ASSESSMENT
2015-3302	04/23/2015 05/21/2015	FDA/OMPT/CDRH/OCER/DFOI/	Cook, Dennis	AEROBIKA OSCILLATING POSITIVE EXPIRATORY PRESSURE DVC K123400
2015-3303	04/23/2015 05/21/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	COULTER JONES MEDPAGE TODAY	GENERVON BIOPHARMACEUTICALS LLC - DRUG TRIALS
2015-3304	04/23/2015 05/21/2015	FDA/OGROP/ORAPPA-FO/LOS-DO/LOS-CB/	GAMBLE, LILLIE	GODS GARDEN PHARMACY - CLOSE OUT LTR
2015-3305	04/24/2015 05/22/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michele Sinoway LACHMAN CONSULTANT SERVICES, INC.	NDA 020430

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2015-3306	04/24/2015 05/22/2015	FDA/OO/OHR/	Yasemin Kasim Luebke Yasemin Kasim Luebke	FDA-CTP-15-RG-1367576JCH, FDA-CTP-14-RG-1139104KL, FDA-CTP-15-DE-1318963JJ
2015-3307	04/24/2015 05/22/2015	FDA/OMPT/CDRH/OCER/DFOI/	Paul Dryden ProMedic, Inc.	K023579
2015-3308	04/24/2015 05/22/2015	FDA/OMPT/CDRH/OCER/DFOI/	Asa Sundstrm Wellspect HealthCare, a division of Dentsply IH AB	K143182, K023254
2015-3309	04/24/2015 05/22/2015	FDA/OC/OES/DFOI/	Gina Ecolino Beveridge & diamond, P.C.	LIST OF CFSAN FOIA REQUESTS 03/24/2015 - 04/23/2015
2015-3310	04/24/2015 05/22/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	YUNHSHIN PHARMACEUTICAL, TAIWANN - EIR, 483
2015-3311	04/24/2015 05/22/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	COULTER JONES MEDPAGE TODAY	GENERVON BIOPHARMACEUTICALS LLC - GM604 STATISTICAL RPTS, RAW DATA, SUPPORTING RECS
2015-3312	04/24/2015 05/22/2015	FDA/OMPT/CDRH/OCER/DFOI/	LUCY BUSTAMANTE ABC TV WVEC 13	BAYER HEALTH CARE - ESSURE CONTRACEPTIVE MDRS
2015-3313	04/24/2015 05/22/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Peter Loftus THE WALL STREET JOURNAL	SANOFI, TORONTO, CANADA - RESPONSE TO 2012 WARNING LETTER
2015-3314	04/24/2015 05/22/2015	FDA/OMPT/CDRH/OCER/DFOI/	Vizma Carver Carver Global Health Group LLC	SSED CLINICAL TRIAL META FROM OFFICE OF COMPLIANCE 01/01/1980 - 04/22/2015
2015-3315	04/24/2015 05/22/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Richard E.Musty Independent Scholar	ANALYSES OF CANNABIDIOL AVAILABLE FOR PURCHASE ONLINE 02/22/2015 - 04/22/2015
2015-3316	04/24/2015 05/22/2015	FDA/OMPT/CDRH/OCER/DFOI/	Sharalee Grosman Elite Massagers, LLC.	ELITE MESSAGERS - MDR RECS 12/31/2014 - 03/12/2015
2015-3317	04/24/2015 05/22/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	T. Christian Miller PROPUBLICA	5212969, 5216751, 5217088 ETC

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2015-3318	04/24/2015 05/22/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Suchitra Ramachandran Keck Graduate Institute	NDA 008693
2015-3319	04/24/2015 05/22/2015	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Dan Fannon Polysciences Inc	POLYSCIENCES, INC, WARRINGTON, PA - EIR 06/01/2010 - 06/30/2010
2015-3320	04/24/2015 05/22/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	William Olson Center for Regulatory Services, Inc.	ZHEJIANG HISUN PHARMACEUTICAL, CHINA - EIR, 483 01/01/2009 - 04/23/2015
2015-3321	04/24/2015 05/22/2015	FDA/OMPT/CDRH/OCER/DFOI/	Vivian Cao ALFA SCIENTIFIC DESIGNS INC	K091168
2015-3322	04/24/2015 05/22/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Janet Arrowsmith Arrowsmith Consulting LLC	MAPP 6020.7 OFFICE OF NEW DRUGS FOREIGN LANGUAGE LABELING
2015-3323	04/24/2015 05/22/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ayesha Adil The Weinberg Group	GLATOPA ANDA 090218 BIOEQUIVALENCE REVIEW
2015-3324	04/24/2015 05/22/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	T. Christian Miller PROPUBLICA	5285150, 5285150, 5395627, ETC
2015-3325	04/24/2015 05/22/2015	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Walter chalkley THOMSON REUTERS (SCIENTIFIC) SAS	GALENA BIOPHARMA, INC. DISCOVERY BAY, CA - EIR, 483, RESPONSE 11/01/2014 - 11/30/2014
2015-3326	04/24/2015 05/22/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ben Newton United BioSource Corporation	7109375 7248251 7278230 ETC
2015-3327	04/24/2015 05/22/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anderea Sweet Sweet, Andrea	22083 NDA SUPP 16

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2015-3328	04/24/2015 05/22/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dave Milton Coker, Schickel, Sorenson, Posgay, Camerlengo & Iracki, P.A.	DMF 14760 AERS
2015-3329	04/24/2015 05/22/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	David Baker David Baker	VYVANSE, ADDERALL XR, CONCERTA ETC - AERS
2015-3330	04/24/2015 05/22/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Roberta Trepal Roberta Trepal	SEROQUEL - AERS
2015-3331	04/24/2015 05/22/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sherman Mark Carter Carter, Sherman M	5741038, 5830129, 5903311 ETC
2015-3332	04/24/2015 05/22/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	T. Christian Miller PROPUBLICA	ISR - INTIAL AND FOLLOW-UP SERIOUS AERS
2015-3333	04/24/2015 05/22/2015	FDA/OMPT/CDRH/OCER/DFOI/	KA SAUDRA L HOSEA Saalfeld Shad Stokes Inclan Stoudemire & Stone, PA	MW5017940
2015-3334	04/24/2015 05/22/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	PATRICK KELLY CONWAY HOMER & CHIN- CAPLAN PC	INDIVIDUAL RECS
2015-3335	04/24/2015 05/22/2015	FDA/OFVM/CFSAN/OCD/EOS/	TSE-LING FANG MC Keck School of Medicine, University of Southern California	SUPER TREN V, TREN V - CAERS
2015-3336	04/24/2015 05/22/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/	STEPHEN SOPER E-94630 SOPER E-94630, STEPHEN	FLU SHOTS, TETANUS/WHOOPING COUGH VACCINE INJURY TABLE

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2015-3337	04/24/2015 05/22/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	RICHARD A OETHEIMER GOODWIN PROCTER LLP	DELALUTIN (HYDROXYPROGESTERONE CAPROATE) DNA 10-347, NDA 16-911 - LBLG IN EFFECT WHEN FDA WITHDREW APRVL
2015-3338	04/24/2015 05/22/2015	FDA/OC/OES/DFOI/	Jamie Antonioli Dwight Eschliman Photography	FDA 79-2115 FDA CONSUMER MAGAZINE
2015-3339	04/27/2015 05/26/2015	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	LISLIE RAMSEY FDA NEWS	OUTCOME SOLUTIONS LLC; MOCKSVILLE, NC; 7 OAKS PHARMACEUTICAL CORP, EASLEY; SC; ATLANTA HEALTHCARE SERVICES, ATLANTA, GA, ETC - 483S 3/1-31/15
2015-3340	04/27/2015 05/26/2015	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	LESLIE RAMSEY FDA NEWS	HOME ACCESS HEALTH CORP (HAHC), HOFFMAN ESTATES, IL; ASTRON DENTAL CORP, LAKE ZURICH, IL - 483S 3/1-31/15
2015-3341	04/27/2015 05/26/2015	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	LESLIE RAMSEY FDA NEWS	DR PHARMACY INC, MIDLAND, TX; THE APOTHECARY SHOPPE LLC, TULSA, OK; WEXLER SURGICAL INC, HOUSTON, TX - 483S 3/1-31/15
2015-3342	04/27/2015 05/26/2015	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	LESLIE RAMSEY FDA NEWS	VENTLAB LLC, GRAND RAPIDS, MI; INDUSTRIAL WOODWORKING CORP, ZEELAND, MI; COOK INC, BLOOMINGTON, IN, ETC - 483S 3/1-31/15
2015-3343	04/27/2015 05/26/2015	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	LESLIE RAMSEY FDA NEWS	GLOBAL SURGICAL, SAINT LOUIS, MO; MERIDIAN MEDICAL TECHNOLOGIES (PIFZER CO), BRENTWOOD, MO; CARE-TECH LABORATORIES INC, SAINT LOUIS, MO, ETC - 483S 3/1-31/15
2015-3344	04/27/2015 05/26/2015	FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	LESLIE RAMSEY FDA NEWS	WARNER CHILCOTT COMPANY LLC, FAJARDO, PR; FENWAL INTERNATIONAL INC, MARICAO, PR - 483S 3/1-31/15
2015-3345	04/27/2015 05/26/2015	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	LESLIE RAMSEY FDA NEWS	THE SEABERG COMPANY INC (SAM MEDICAL PRODS), WILSONVILLE, OR; OCULAR INSTRUMENTS INC, BELLLEVUE, WA; GENZYME (SANOFI CO), LYNNWOOD, WA, ETC - 483S 3/1-31/15
2015-3346	04/27/2015 05/26/2015	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	LESLIE RAMSEY FDA NEWS	OCTAPHAMA PHARMAZEUTIKI PRODUKTIONS GMBH, VIENNA, AUSTRIA - 483S 3/1-31/15
2015-3347	04/27/2015 05/26/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LESLIE RAMSEY FDA NEWS	AUROBINDO PHARMA LTD - UNIT 9, HATINOORA, MEDAK, HYDERABAD, INDIA; DR REDDY'S LABORATORIES LTD, VISAKHAPATNAM, INDIA; DANIPHARM A/S, NIBE, DENMAR - 483S 3/1-31/15

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		FDA/OMPT/CDER/GRP/DIDP/		
2015-3348	04/27/2015 05/26/2015	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	LESLIE RAMSEY FDA NEWS	LGO MEDICAL LLC, FRANKLIN, WI; CPR RSQ ASIST INC, FRANKLIN, WI - 483S 3/1-31/15
2015-3349	04/27/2015 05/26/2015	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	LESLIE RAMSEY FDA NEWS	KEYSTONE LABORATORIES INC, MEMPHIS, TN; DERoyal INDUSTRIES INC, POWELL, TN - 483S 3/1-31/15
2015-3350	04/27/2015 05/26/2015	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	LESLIE RAMSEY FDA NEWS	STRYKER HOWMEDICA OSTEONICS CORP, MAHWAH, NJ; KOBO PRODUCTS INC, S PLAINFIELD, NJ; BURPEE MATERIALS TECHNOLOGY LLC, EATONTOWN, NJ - 483S 3/1-31/15
2015-3351	04/27/2015 05/26/2015	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	LESLIE RAMSEY FDA NEWS	B BRAUN MEDICAL, IRVINE, CA; AFFINITY MEDICAL TECHNOLOGIES LLC, COSTA MESA, CA; IONIA PHARMACY, TUSTIN, CA, ETC - 483S 3/1-31/15
2015-3352	04/27/2015 05/26/2015	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	LESLIE RAMSEY FDA NEWS	BURKLOW PHARMACY, MILTON, FL; BAUSCH & LOMB INC, TAMPA, FL; POWERS MEDICAL DEVICES LLC, DELRAY BEACH, FL, ETC - 483S 3/1-31/15
2015-3353	04/27/2015 05/26/2015	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	LESLIE RAMSEY FDA NEWS	SOPHONO INC, BOULDER, CO; MESA LABORATORIES, INC, LAKEWOOD, CO; INTERNATIONAL MEDICAL DEVELOPMENT CORP, HUNTSVILLE, UT, ETC - 483S 3/1-31/15
2015-3354	04/27/2015 05/26/2015	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	LESLIE RAMSEY FDA NEWS	RADIOMETER AMERICA INC, WESTLAKE, OH; SMITHS MEDICAL ASD INC, DUBLIN, OH; QUALITY ELECTRODYNAMICS LLC, MAYFIELD VILLAGE, OH, ETC - 483S 3/1-31/15
2015-3355	04/27/2015 05/26/2015	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	LESLIE RAMSEY FDA NEWS	HUNTER HOLMES MCGUIRE VETERNAS ADMIN MEDICAL CENTER, RICHMOND, VA; C B FLEET CO INC, LYNCHBURG, VA; THE WELLNESS PHARMACY LLC, WINCHESTER, VA, ETC - 483S 3/1-31/15
2015-3356	04/27/2015 05/26/2015	FDA/OMPT/CDRH/OCER/DFOI/	LESLIE RAMSEY FDA NEWS	CORIN LTD, CIRENCESTER, UK; BREAS MEDICAL AB, MOLNLYCKE, SWEDEN; CONTEC MEDICAL SYSTEMS CO LTD, QINHUAGDAO, CHINA, ETC - 483S 3/1-31/15
2015-3357	04/27/2015 05/26/2015	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	LESLIE RAMSEY FDA NEWS	OCULAR THERAPEUTICX INC, BEDFORD, MA; THERAPUTIX; MEVION MEDICAL SYSTEMS INC, LITTLETON, MA; FAIRA LTD (SHEFFIELD PHARMS), NEW LONDON, CT, ETC - 483S 3/1-31/15
2015-3358	04/27/2015 05/26/2015	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	LESLIE RAMSEY FDA NEWS	FRESENIUS KABI USA LLC, GRAND ISLAND, NY; FALLON WELLNESS PHARMACY LLC, LATHAM, NY; NORTECH LABS, FARMINGDALE, NY, ETC - 483 3/1-31/15
2015-3359	04/27/2015 05/26/2015	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	LESLIE RAMSEY FDA NEWS	AESCLAP IMPLANT SYSTEMS LLC, BREINGSVILLE, PA; BIOSPECTRA INC, ROSETO, PA; ZOLL MANUFACTURING CORP, PITTSBURGH, PA, ETC -483S 3/1-31/15
2015-3360	04/27/2015	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	LESLIE RAMSEY	RAPID DIAGNOSTICS (MP BIOMEDICALS LLC), BURLINGAME, CA; BECKMAN COULTER INC, WEST

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	05/26/2015		FDA NEWS	SACRAMENTO, CA; DREAM SYSTEMS LLC, ROSEVILLE, CA, ETC - 483S 3/1-31/15
2015-3361	04/27/2015 05/26/2015	FDA/OMPT/CDRH/OCER/DFOI/	DOMINIC GREEN M SQUARED ASSOCIATES INC	MASIMO SET RAD-5 PULSE OXIMETER - K033296; NBM 200MP PULSE OXIDIMETRY DVC - K091564
2015-3362	04/27/2015 05/26/2015	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MORGAN WEST WEST, MOLRGAN	DIPEXIMUM PHARMACEUTICALS INC - EIRS, 483S, WARNING LTRS, ETC
2015-3363	04/27/2015 05/26/2015	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MORGAN WEST WEST, MOLRGAN	AGENUS INC - EIRS, 483S, WARNING LTRS, ETC
2015-3364	04/27/2015 05/26/2015	FDA/OFVM/CFSAN/OCD/EOS/OC/ORA/ OC/ORA/ OC/ORA/ORM/ OC/ORA/ORM/	RICHARD LARDNER AP ASSOCIATED PRESS	DIETARY SUPPLEMENTS - CARES, EIRS 4/1/10 TO 4/1
2015-3365	04/27/2015 05/26/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WILLIAM MCINTYRE LUPIN PHARMACEUTICALS INC	FOUGERA - BESTAMETHASONE DIPROPIONATE OINTMENT NDA 19-141 SBA
2015-3366	04/27/2015 05/26/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KATE REYNOLDS ROCKY MOUNTAIN POISON & DRUG CENTER	ACETAMINOPHEN - ISR 4208507, 657U1460, 7U507205, ETC
2015-3367	04/27/2015 05/26/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SUSAN R GROSS BERNARD M GROSS LAW OFCS	NYMOX PHARMACEUTICAL CORP - NX02-0017, NX02-0018 DELAY IN RESULTS, CERTIFICATIONS
2015-3368	04/27/2015	FDA/OMPT/CDER/GRP/DIDP/		EMORY UNIV, GILEAD SCIENCES INC - EMTRIVA

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2015-3369	04/27/2015 05/26/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John Kiley APC Pharmaceuticals, LLC	HISUN PHARMACEUTICALS, PRC - 483 03/01/2015 - 03/30/2015
2015-3370	04/27/2015 05/26/2015	FDA/OMPT/CDRH/OCER/DFOI/	Catherine Campbell BioMarin Pharmaceuticals	K102961 TESTING DATA
2015-3371	04/27/2015 05/26/2015	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/ FDA/OGROP/ORACE-FO/CINDO/CIN-CB/ FDA/OGROP/ORACE-FO/MINDO/MIN-CB/ FDA/OGROP/ORACE-FO/ATLDO/ATL-CB/ FDA/OGROP/ORACE-FO/NOLDO/NOL-CB/ FDA/OGROP/ORACE-FO/KANDO/KAN-CB/	Rachel Johnson FOI Services, Inc.	TOBACCO INSPECTIONS JAN TO MAR 2015 - EIR
2015-3372	04/27/2015 05/27/2015	FDA/OGROP/ORACE-FO/DETDO/DET-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Gillam, James MAGLIO, MURRILL	ZIMMER - CORR WITH FDA RE Z-1266-2015
2015-3373	04/27/2015 05/26/2015	FDA/OMPT/CDRH/OCER/DFOI/	William Plishker IGI Technologies	K071063
2015-3374	04/27/2015 05/26/2015	FDA/OMPT/CDRH/OCER/DFOI/	Mikael Eriksson Sooma Oy	K133033
2015-3375	04/27/2015 05/26/2015	FDA/OC/OES/DFOI/	Cody Gillians Mayer Brown LLP	MASIMO CORP - RECS PREVIOUSLY RELEASED UNDER FOIA, REQUEST LETTERS
2015-3376	04/27/2015 05/26/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Catherine Campbell BioMarin Pharmaceuticals	DEPOCYT - APPROVAL RECS

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2015-3377	04/27/2015 05/26/2015	FDA/OMPT/CDRH/OCER/DFOI/	William Plishker IGI Technologies	K101979
2015-3378	04/27/2015 05/26/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Brenda Goodman WebMD	OPANA ER - AERS, EMAILS
2015-3379	04/27/2015 05/26/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dave Milton Coker, Schickel, Sorenson, Posgay, Camerlengo & Iracki, P.A.	SANDOZ INC METHOTREXATE PRODUCTS - QUALITY DEFECT REPORTS
2015-3380	04/27/2015 05/26/2015	FDA/OGROP/ORAN/NE-FO/NWE-DO/NWE-CB/	Rachel Johnson FOI Services, Inc.	SIMENENS HEALTHCARE, NORWOOD, MA - INSPECTION RECS
2015-3381	04/27/2015 05/26/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	SIEMENS ADIOLOGISCHE TECHNIK, GERMANY - INSPECTION RECS
2015-3382	04/27/2015 05/26/2015	FDA/OMPT/OSMP/OCF/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Catherine Campbell BioMarin Pharmaceuticals	LIST OF ALL DRUG-DEVICE AND BIOLOGIC-DEVICE COMBINATION PRODUCTS APPROVED 01/01/2003 - 04/24/2015
2015-3383	04/27/2015 05/26/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	T. Christian Miller PROPUBLICA	5285150, 5395627, 5429211, ETC
2015-3384	04/27/2015 05/26/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dennis W. Raisch UNIVERSITY OF NEW MEXICO	IBRUTINIB - AERS
2015-3385	04/27/2015 05/26/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	CELECOXIB - AERS

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		FDA/OMPT/CDER/GRP/DIDP/		
2015-3386	04/27/2015 05/26/2015	FDA/OO/OFBA/OAGS/ FDA/OC/OES/DFOI/	Suzanne M Corbett CORBETT, BETH D	HHSF 22320110350M PAYMENT RECS
2015-3387	04/27/2015 05/26/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K101314
2015-3388	04/27/2015 05/26/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K101786
2015-3389	04/27/2015 05/26/2015	FDA/OMPT/CDRH/OCER/DFOI/	Vivian Cao ALFA SCIENTIFIC DESIGNS INC	K133534
2015-3390	04/27/2015 05/26/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	G. Srinivas Zydus Pharmaceuticals USA Inc.	DEMECLOCYCLINE HYDROCHLORIDE ANDA 065425 SBA
2015-3391	04/27/2015 05/26/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	G. Srinivas Zydus Pharmaceuticals USA Inc.	AMITRIPTYLINE HYDROCHLORIDE FDA ANDA 085966 SBA
2015-3392	04/27/2015 05/26/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	G. Srinivas Zydus Pharmaceuticals USA Inc.	NDA 006035 SBA
2015-3393	04/27/2015 05/26/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Melissa Truffa AbbVie	SOFOSBUVIR, SPIRONOLACTONE - AERS
2015-3394	04/27/2015 05/26/2015	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Edward Donnelly Edward Donnelly	ZOLL MANUFACTURING, LIFEVEST, PITTSBURGH, PA - 483 02/01/2015 - 04/30/2015
2015-3395	04/27/2015 05/26/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Laura Shumaker Ross Medical Corporation	K102350
2015-3396	04/27/2015 05/26/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	SUZHOU FLEXTRONICS TECHNOLOGY, CHINA - INSPECTION RECS
2015-3397	04/27/2015 05/26/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	ABBOTT, GERMANY - EIR

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/		
2015-3398	04/27/2015 05/26/2015	FDA/OGROP/ORAC/CE-FO/CIN-DO/CIN-CB/	JD Malone The Columbus Dispatch	JENI'S SPLENDID ICE CREAMS, COLUMBUS, OH - 483
2015-3399	04/27/2015 05/26/2015	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OO/OFBA/OAGS/	Suzanne M Corbett CORBETT, SUZANNE	VENDOR SUBMITTALS AND PAYMENTS TO FRANKLIN REGIONAL COUNCIL OF GOVERNMENTS FOR PARTICIPATING IN FDA FOOD PROGRAM STANDARDS ETC 04/01/2010 - 12/31/2014
2015-3400	04/27/2015 05/26/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Travounda Foster Avalere Health	GUDID DATA SET
2015-3401	04/27/2015 05/26/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dr. Matthew Burns Northshore University Health System	DEPO-MEDTROL - PAGE 4 OF SAFETY SECTION OF THE FDA INFORMATION
2015-3402	04/27/2015 05/26/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	G. Srinivas Zydus Pharmaceuticals USA Inc.	NDA 205636 SBA
2015-3403	04/27/2015 05/26/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Zerlina Santillanes Pharm.D. Optima Health	ACTHAR GEL - AERS
2015-3404	04/27/2015 05/26/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-2089 - REQUEST LETTER ONLY
2015-3405	04/27/2015 05/26/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-2188 - REQUEST LETTER ONLY
2015-3406	04/27/2015 05/26/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-2268 - REQUEST LETTER ONLY
2015-3407	04/27/2015 05/26/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-2414 - REQUEST LETTER ONLY

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2015-3408	04/27/2015 05/26/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-2435 - REQUEST LETTER ONLY
2015-3409	04/27/2015 05/26/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-2492 - REQUEST LETTER ONLY
2015-3410	04/27/2015 05/26/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-2494 - REQUEST LETTER ONLY
2015-3411	04/27/2015 05/26/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-2495 - REQUEST LETTER ONLY
2015-3412	04/27/2015 05/26/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-2551 - REQUEST LETTER ONLY
2015-3413	04/27/2015 05/26/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-2082 - REQUEST LETTER ONLY
2015-3414	04/27/2015 05/26/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-1841 - REQUEST LETTER ONLY
2015-3415	04/27/2015 05/26/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-1677 - REQUEST LETTER ONLY
2015-3416	04/27/2015 05/26/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-1668 - REQUEST LETTER ONLY
2015-3417	04/27/2015 05/26/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-1994 - REQUEST LETTER ONLY
2015-3418	04/27/2015 05/26/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-2032 - REQUEST LETTER ONLY
2015-3419	04/27/2015 05/26/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-1714 - COMPLETE RESPONSE
2015-3420	04/28/2015 05/27/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OO/OHR/	Doe J	INDIVIDUAL RECS
2015-3421	04/28/2015 05/27/2015	FDA/OO/OFBA/OAGS/	Suzanne M Corbett CORBETT, SUZANNE	HHSF 2230110350M
2015-3422	04/28/2015 05/27/2015	FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/	Nathan Koppikar TPG Public Equity Partners	FRESHPET - CONSUMER COMPLAINT RECS, INSPECTION RECS 01/01/2011 - 04/24/2015
2015-3423	04/28/2015 05/27/2015	FDA/OGROP/ORAPA-FO/SEA- DO/SEA-CB/	Marek Wolter, PhD Quality Works, Inc.	GALENA BIOPHARMA, INC, PORTLAND, OR - 483, EIR, RESPONSE ETC 11/01/2014 - 12/31/2014
2015-3424	04/28/2015	FDA/OMPT/CDER/ORP/DIDP/	Jon Kluff	INSYS THERAPEUTICS - SUBSYS AERS

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	05/27/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Atika Capital Management	
2015-3425	04/28/2015 05/27/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jay gillenwater GILLENWATER, J	ELIQUIS - AERS
2015-3426	04/28/2015 05/27/2015	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SW-FO/DAL- DO/DAL-CB/ FDA/OGROP/ORO/CE-FO/CIN- DO/CIN-CB/ FDA/OGROP/ORO/SE-FO/NOL- DO/NOL-CB/	Mary Clare Jalonick ASSOCIATED PRESS	BLUE BELL, JENI'S ICE CREAM - INSPECTION RECS 04/29/2005 - 04/27/2015
2015-3427	04/28/2015 05/27/2015	FDA/OGROP/ORO/SE-FO/NOL- DO/NOL-CB/	Rachel Johnson FOI Services, Inc.	AMERICAN SNUFF, CLARKSVILLE, TN - INSPECTION RECS
2015-3428	04/28/2015 05/27/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	HOSPIRA, VICTORIA, AUSTRALIA - EIR, 483
2015-3429	04/28/2015 05/27/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jon Kluff Atika Capital Management	FENTORA - AERS
2015-3430	04/28/2015 05/27/2015	FDA/OGROP/ORO/PA-FO/SAN- DO/SAN-CB/	Doe J	INDIVIDUAL RECS
2015-3431	04/28/2015 05/27/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Doe J	INDIVIDUAL RECS
2015-3432	04/28/2015 05/27/2015	FDA/OGROP/ORO/CE-FO/NWJ- DO/NWJ-CB/	Theresa Fazio TARIS Biomedical	MUTCHLER INC PHARMACEUTICAL INGREDIENTS, HARRINGTON PARK, NJ 01/01/2012 - 04/27/2015
2015-3433	04/28/2015 05/27/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ann Pullen NOVO NORDISK	NDA 206538

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		FDA/OMPT/CDER/GRP/DIDP/		
2015-3434	04/28/2015 05/27/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Terry Lo ROCHE	APTIMA HRHPV CLEAR TRIAL DATA
2015-3435	04/28/2015 05/27/2015	FDA/OMPT/CDRH/OCER/DFOI/	Tove Kjaer Origio A/S	K122982
2015-3436	04/28/2015 05/27/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Erin R. Fox University of Utah Health Care	EMCURE - GMP INSPECTION REPORTS 01/02/2014 - 04/27/2015
2015-3437	04/28/2015 05/27/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kenneth Zaremba Niedweske Barber Hager	IND 109278
2015-3438	04/28/2015 05/27/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ann Pullen NOVO NORDISK	NDA N022472
2015-3439	04/28/2015 05/27/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joshua Malamud Hyman, Phelps & McNamara P.C.	FDA MEMO RE DISPOSITION OF 180-DAY EXCLUSIVITY FOR LAMOTRIGINE ORALLY DISINTEGRATING TABLETS ANDA 200828
2015-3440	04/28/2015 05/27/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mary Margaret Schneider dld lawyers -mary margaret schneider	BRENTUXIMAB VEDOTIN (ADCENTRIS) - AERS
2015-3441	04/28/2015 05/27/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jon Kluff Atika Capital Management	ACTIQ - AERS
2015-3442	04/28/2015	FDA/OMPT/CDER/GRP/DIDP/	KIM C CAPONE	DELALUTIN (HYDROXYPROGESTERONE CAPROATE) INJ

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	05/27/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/	PORZIO BROMBERG & NEWMAN PC	NDA 10-347, NDA 16-911 - LBLG
2015-3443	04/28/2015 05/27/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Doe J	INDIVIDUAL RECS - VAERS
2015-3444	04/28/2015 05/27/2015	FDA/OC/OES/DFOI/	JEFF BAKER BAKER #32292, JEFF	EFFERDENT DENTURE CLEANSING TABS, PERCARDIA - ALERTS, WARNINGS, NOTIFICATIONS, ETC
2015-3445	04/28/2015 05/27/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JEAN VACCA VACCA, JEAN	COLLOIDAL SILVER - AERS
2015-3446	04/28/2015 05/27/2015	FDA/OMPT/CDRH/OCER/DFOI/	NeuroSave, Inc. NeuroSave, Inc.	K070112
2015-3447	04/28/2015 05/27/2015	FDA/OMPT/CDRH/OCER/DFOI/	David Depman Parselan	K133355
2015-3448	04/28/2015 05/27/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	BRACCO SUISSE, SWITZERLAND - EIR
2015-3449	04/28/2015 05/27/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rahul Jeewani IIFL Capital	INTAS PHARAMCEUTICALS - 483 04/01/2015 - 04/20/2015
2015-3450	04/28/2015 05/27/2015	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/CE-FO/CHI- DO/CHI-CB/	GERALDINE GRIFFITH GRIFFTH, GERALDINE	CMPLNT #140748
2015-3451	04/28/2015 05/27/2015	FDA/OC/OES/DFOI/	JOHN F JOHNSON III FDAIMPORTS.COM LLC	2014-690 - DELETED RECS
2015-3452	04/28/2015 05/27/2015	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID SUTTON SUTTON, DAVID	ADVANCE PHARMACEUTICAL INC - RUGBY IRON SUPPLEMENT FERROUS SULFATE, ENTERIC ASPIRIN RECALL RECS

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		FDA/OMPT/CDER/GRP/DIDP/		
2015-3453	04/28/2015 05/27/2015	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MORGAN WEST WEST, MORGAN	OCATA THERAPEUTICS INC - EIRS, 483S, WARNING LTRS, ETC
2015-3454	04/28/2015 05/27/2015	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MORGAN WEST WEST, MORGAN	ADVANCED CELL TECHNOLOGY INC - EIRS, 483S, WARNING LTRS, ETC
2015-3455	04/28/2015 05/27/2015	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MORGAN WEST WEST, MORGAN	TG THERAPEUTICS INC - EIRS, 483S, WARNING LTRS, ETC
2015-3456	04/28/2015 05/27/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Mitchell Johnson IntriCon Corp	K072008, K081444
2015-3457	04/28/2015 05/27/2015	FDA/OMPT/CDRH/OCER/DFOI/	Michele Chin-Purcell BioSig Technologies	K134044
2015-3458	04/29/2015 05/28/2015	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	SINCLAIR RESEARCH CENTER, AUXVASSE, MO - 483, EIR, ETC
2015-3459	04/29/2015 05/28/2015	FDA/OFVM/CFSAN/OCD/EOS/	Michael Landa CONSUMER	MEETINGS BETWEEN OFVN OR CFSAN AND FOOD INDUSTRY AND TRADE GROUPS RE: PARTIALLY HYDROGENATED OILS, ARSENIC 01/05/2015 - 04/27/2015
2015-3460	04/29/2015 05/28/2015	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	Doe J	INDIVIDUAL RECS
2015-3461	04/29/2015 05/28/2015	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	JAIME GONZALEZ CREATIVE TESTING SOLUTIONS	CREATIVE TESTING SOLUTIONS, ST PETERSBURG, FL - EIR 08/01/2014 - 08/31/2014

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2015-3462	04/29/2015 05/28/2015	FDA/OMPT/CDRH/OCER/DFOI/	Alex Bock Alex Bock	K122550
2015-3463	04/29/2015 05/28/2015	FDA/OFVM/CFSAN/OCD/EOS/	Emily Johns MIAMI UNIVERSITY	AMMONIUM HYDROXIDE IN FOOD
2015-3464	04/29/2015 05/28/2015	FDA/OMPT/CDRH/OCER/DFOI/	Alex Bock Alex Bock	K964325
2015-3465	04/29/2015 05/28/2015	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Rachel Johnson FOI Services, Inc.	KNEX WORLDWIDE, CHARLOTTE, NC; TENOWO, LINCOLNTON, NC; RJ REYNOLDS, WINSTON-SALEM, NC ETC - EIR, 483, ETC
2015-3466	04/29/2015 05/28/2015	FDA/OMPT/CDRH/OCER/DFOI/	Eric Gunther Precision Biopsy LLC	K133948
2015-3467	04/29/2015 05/28/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rob Leary Simply Solutions LLC	LIST OF PERSONAL LUBRICANT MANUFACTURERS IN NUC CATEGORY CONTACTED BY FDA 01/01/2014 - 04/27/2015
2015-3468	04/29/2015 05/28/2015	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OCC/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Robert Blaskiewicz Robert Blaskiewicz	BURZYNSKI RESEARCH INSTITUTE, STAFFORD, TX - INSPECTION RECS 01/01/2015 - 04/03/2015
2015-3469	04/29/2015 05/28/2015	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2015-2732
2015-3470	04/29/2015 05/28/2015	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2015-2732
2015-3471	04/29/2015 05/28/2015	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2013-2804
2015-3472	04/29/2015 05/28/2015	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2015-2488
2015-3473	04/29/2015 05/28/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-1517
2015-3474	04/29/2015 05/28/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-1521

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2015-3475	04/29/2015 05/28/2015	FDA/OO/OFBA/OAGS/	Brett Benson Leadership Directories, Inc.	PURCHASE CARD, CREDIT CARD HOLDERS
2015-3476	04/29/2015 05/28/2015	FDA/OMPT/CDRH/OCER/DFOI/	Laura Shumaker Ross Medical Corporation	K133997
2015-3477	04/30/2015 05/29/2015	FDA/OMPT/CDRH/OCER/DFOI/	Alex Bock Alex Bock	K131681
2015-3478	04/30/2015 05/29/2015	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	PERNIX, HOUSTON, TX - 483
2015-3479	04/30/2015 05/29/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K142282
2015-3480	04/30/2015 06/10/2015	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Steve Drzick MPI Research, Inc.	MPI RESEARCH, INC, MATTAWAN, MI - EIR REDACTED 08/01/2012 - 04/29/2015
2015-3481	04/30/2015 05/29/2015	FDA/OFVM/CFSAN/OCD/EOS/	Paul Hughes SEALED AIR CORPORATION	FCN 360
2015-3482	04/30/2015 05/29/2015	FDA/OFVM/CFSAN/OCD/EOS/	Jessica P. O'Connell COVINGTON & BURLING	CORR BETWEEN BETWEEN CFSAN, OVFM AND PUBLIC RE KIND LLC, KIND BRAND PRODUCTS 01/01/2012 - 04/30/2015
2015-3483	04/30/2015 05/29/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Rebecca Ballard Absolute Research LLC	RECS RE CBER-02-010
2015-3484	04/30/2015 05/29/2015	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Rebecca Ballard Absolute Research LLC	ALI R REZAI, MD, CLEVELAND, OH - WARNING LETTER RECS 07/01/2008 - 12/01/2009
2015-3485	04/30/2015 05/29/2015	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Margaret Groves, JD, CRA, CCRP, CHRC Duke University Ethics and Compliance Office	DR THOMAS ORTEL, DURHAM, NC - CLOSE OUT LETTER
2015-3486	04/30/2015 05/29/2015	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OMPT/CDRH/OCER/DFOI/	ROBERT E. GODOSKY GODOSKY & GENTILE PC	SYNOVIS MICRO COMPANIES ALLIANCE INC - GEM MICROVASCULAR ANASTOMOTIC COUPLER CMLPLNTS
2015-3487	04/30/2015 05/29/2015	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	DAVID J. MARTIN MEYERS RODBELL & ROSENBAUM PA	HARBOR HOUSE SEAFOOD - EIR, EXHIBITS, ATTACHEMMENTS
2015-3488	04/30/2015 05/29/2015	FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECS
2015-3489	04/30/2015 05/29/2015	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	TREVOR L. BRADLEY CETRULO LLP	KAZ INC - VICKS VAPORIZER MODEL V150 AER, RECALLS 1/1970

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		FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORANE-FO/NYK- DO/NYK-DCB/		
2015-3490	05/01/2015 06/01/2015	FDA/OC/OES/DFOI/	KELLEN OWINGS FDA NEWS	WOCKHARD'S CHIKALTHANA PLANT - 483'S
2015-3491	05/01/2015 06/01/2015	FDA/OC/OES/DFOI/	CAROLLO RUSSELL CAROLLO, RUSSELL	2012-2656, 2012-2510, 2012-927, ETC
2015-3492	05/01/2015 06/01/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	CRAIG M SILVERMAN PETER ANGELOS LAW OFC	XARELTO -FOIA REQUESTS
2015-3493	05/01/2015 06/01/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GREGORY J BREBE LAW OFFICES GREGORY J GREBE	MORPHINE SULFATE - ISR 8762180, 9015676, 9995001, ETC
2015-3494	05/01/2015 06/01/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GREGORY J GREBE LAW OFFICES GREGORY J GREBE	SURAMORPH (MORPHINE SULFATE) - NDA 18-565 SBA
2015-3495	05/01/2015 06/01/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHRIS CELESTE EAS CONSULTING GROUP LLC	CYANOCOBOLAMIN INJ - ANDA 80-737 APRVL LTR, LBLG, CHEMISTRY RVW, ETC
2015-3496	05/01/2015 06/01/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHRIS CELESTE EAS CONSULTING GROUP LLC	VIBISONE - CYANOCOBOLAMIN INJ - ANDA 80-557 APRVL LTR, LBLG, CHEMISTRY RVW, ETC
2015-3497	05/01/2015 06/01/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHRIS CELESTE EAS CONSULTING GROUP LLC	CYANOCOBOLAMIN INJ - ANDA 87-967 APRVL LTR, LBLG, CHMISTRY RVW, ETC
2015-3498	05/01/2015	FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/	LESLIE RAMSEY	TURNCO TOOL & INSTRUMENT INC, GEORGETOWN, TX - 483 3/28/14

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	06/01/2015		FDA NEWS	
2015-3499	05/01/2015 06/01/2015	FDA/OMPT/CDRH/OCER/DFOI/	QUIANA A MONTGOMERY Keller and Heckman LLP	23ANDME PERSONAL GENOME SERVICE - CARRIER SCREENING TEST FOR BLOOM SYNDROME ORIGINAL REQUEST, ATTACHMENTS, SUBMISSIONS, ETC
2015-3500	05/01/2015 06/01/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	LUCINDA TODD HILL-ROM	MAERSK MEDICAL LTD - K004028
2015-3501	05/01/2015 06/01/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	REENA HARJAI APCER Pharma Solutions, Inc	ANGIOMAX (BIVALIRUDIN) - AERS
2015-3502	05/01/2015 06/01/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GARY J MCGARITY Gary J McGarity, PharmD	AMBIEN (ZOLPIDEM) - AERS
2015-3503	05/01/2015 06/01/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	PAR PHARMACEUTICAL INC, SPRING VALLEY, NY - CHOLESTYRAMINE POWDER PACT CMLPNTS
2015-3504	05/01/2015 06/01/2015	OC/ORA/ OC/ORA/ FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/	BARBARA J SMITH LAW OFC KEVIN R SCUDDER	SLEEP SCIENCE PARTNERS INC (THE PURE SLEEP CO) - CMLPNT 139586
2015-3505	05/01/2015 06/01/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	A LUKE SMITH RADICE LAW FIRM	PAR PHARMACUTICAL INC - DEXLANSOPRAZOLE ANDA 202-294 ROUTING SUMMARY, APRVL LTR
2015-3506	05/01/2015 06/01/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID HOFFMEISTER Wilson Sonsini Goodrich & Rosati	PERRIGO - SCOPOLAMINE TRANSDERMAL THERAPEUTIC SYS ANDA 78-883; ACTAVIS - LIDOCAINE PATCH ANDA 200-675 APRVL PKG
2015-3507	05/01/2015 06/01/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DANIEL KAPLAN SPORTS BUSINESS JOURNAL	DR GRAY SMALL, DR JORGE BARRIO - INVESTIGATION CMPNT, CORR 2/15

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2015-3508	05/01/2015 06/01/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-2207
2015-3509	05/01/2015 06/01/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-2007
2015-3510	05/01/2015 06/01/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-1753
2015-3511	05/01/2015 06/01/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	AMANDA WILLIS RABBAT GOODWIN PROCTER LLP	NOVARTIS PHARMACEUTICALS CORP - GLEEVEC (IMATINIB MESYLATE) CAPS NDA 21-335 WEB POSTINGS REQUEST FORMS PERTAINING TO APRVL PKG, COMM WITH APPLICANT, STANDARD OPERATING PROCEDURES, ETC
2015-3512	05/01/2015 06/01/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-1710
2015-3513	05/01/2015 06/01/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-1524
2015-3514	05/01/2015 06/01/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-1647
2015-3515	05/01/2015 06/01/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-886
2015-3516	05/01/2015 06/01/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-2522
2015-3517	05/01/2015 06/01/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-2533
2015-3518	05/01/2015 06/01/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-883
2015-3519	05/01/2015 06/01/2015	FDA/OGROP/ORO/SW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORO/CE-FO/DET-DO/DET-CB/	DAVID E LONG LEITNER WILLIAMS ET AL	NUTRA BALANCE, INDIANAPOLIS, IN - EIRS, RESULTS, ENFORCEMENT RPTS 6/13 TO 6/14
2015-3520	05/01/2015 06/01/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-2491
2015-3521	05/01/2015 06/01/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 202971 S 3

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2015-3522	05/01/2015 06/01/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tim Ziegenfuss G&W Laboratories, Inc.	NDA 050600 SBA
2015-3523	05/01/2015 06/01/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	BLA 125057/062
2015-3524	05/01/2015 06/01/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Marion Coe UNIVERSITY OF KENTUCKY	NDA 18276
2015-3525	05/01/2015 06/01/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Paola Teegarden Kinex Pharmaceuticals Inc.	ANDA 076131 S 000
2015-3526	05/01/2015 06/01/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	BOROSILICATE VIALS - DELAMINATION, LAMELLAE, DATA, REPORTS ETC
2015-3527	05/01/2015 06/01/2015	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/BLT- DO/BLT-CB/	Doe J	DIET COKE - CMLPNT 140139
2015-3528	05/01/2015 06/01/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jaya Ayyagari Dr. Reddy's Laboratories Inc.	ANDA 090218 SBA
2015-3529	05/01/2015 06/01/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jennifer Miller Eli Lilly and Company - Global Patient Safety	NDA 206538
2015-3530	05/01/2015	FDA/OMPT/CDER/ORP/DIDP/	Joshua Malamud	ARROW PHARMACEUTICALS LTD, AUSTRALIA - INSPECTION RECS JUNE 2008

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	06/01/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Hyman, Phelps & McNamara P.C.	
2015-3531	05/01/2015 06/01/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Brenda Goodman WebMD	OSE reviews related to oxymorphone (Opana ER) and the medical complication thrombotic microangiopathy (TMA)
2015-3532	05/01/2015 06/01/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Samip Patel Samip Patel - Inox Consulting Services	WOCKHARDT LIMITED, INDIA - EIR, 483 09/02/2014 - 04/28/2015
2015-3533	05/01/2015 06/01/2015	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	Lisa Abel YSI Incorporated	YSI INCORPORATED, YELLOW SPRINGS, OH - EIR 03/01/2014 - 12/31/2014
2015-3534	05/01/2015 06/01/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH	SBA 202608
2015-3535	05/01/2015 06/01/2015	FDA/OFVM/CFSAN/OCD/EOS/	Stephen Heim Steve Heim	Process Validation study submitted to FDA for HPP- High Hydrostatic Pressure Processing for packaged as Pouched or Cup Applesauce
2015-3536	05/01/2015 06/01/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jeanine Gouveia Aerie Pharmaceuticals Inc.	NDA 21214 S 6, S 7 - SBA
2015-3537	05/01/2015 06/01/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kimberly Edgerton Synthon Pharmaceuticals	ANDA 90218
2015-3538	05/01/2015 06/01/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sander Sanchez Seattle Children's Hospital Research Foundation	AUVI-Q, EPIPEN, EPIPEN JR - ADRENALICK STABILITY
2015-3539	05/01/2015 06/01/2015	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Margaret Groves, JD, CRA, CCRP, CHRC	ASHWIN PATKAR, DURHAM, NC - CLOSE OUT LETTER

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			Duke University Ethics and Compliance Office	
2015-3540	05/01/2015 06/03/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SE-FO/FLA- DO/FLA-CB/	Nadine Ritter Global Biotech Experts, LLC	BIOTEST - WARNING LETTER, CLOSE OUT LETTERS 01/01/2005 - 04/01/2015
2015-3541	05/01/2015 06/01/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sumithra Ramachandran Keck Graduate Institute of Applied Life Sciences	ANDA 062349
2015-3542	05/01/2015 06/01/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Stephen Hayward Ag Conexus, Inc.	ONDANSETRON - AERS
2015-3543	05/01/2015 06/01/2015	OC/ORO/ OC/ORO/	Robert Hirst INTERNATIONAL BOTTLED WATER ASSOCIATION	DELEGATION AGREEMENT BETWEEN FDA AND COMMONWEALTH OF PENNSYLVANIA FOR ENFORCEMENT OF FSMA 01/01/2011 - 04/30/2015
2015-3544	05/01/2015 06/01/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michele Sinoway LACHMAN CONSULTANT SERVICES, INC.	NDA 20430, NDA 000552, NDA 013304 ETC - CMC SUPPLEMENT UNREDACTED
2015-3545	05/01/2015 06/01/2015	FDA/OFVM/CFSAN/OCD/EOS/	Marjorie Grimm Faces By Design	FACT SHEET RE TATTOOS 01/01/1995 - 01/01/1996
2015-3546	05/01/2015 06/01/2015	FDA/OMPT/CDRH/OCER/DFOI/	Mara Macdonald CytoVale	DEN140019
2015-3547	05/01/2015 06/01/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 4/1-30/2015
2015-3548	05/01/2015 06/01/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	CLOSED FOIA REQUESTS 4/1-30/2015
2015-3549	05/01/2015 06/01/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Doe J	VAERS RECS
2015-3550	05/01/2015	FDA/OMPT/CDRH/OCER/DFOI/	Anngela Beaudoin	ESSURE FIVE YEAR REVIEW

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	06/01/2015		Anngela Beaudoin	
2015-3551	05/01/2015 06/01/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jacqueline DeMarco DeMarco, Jacqueline	ZOFRAN - AERS
2015-3552	05/01/2015 06/01/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michel Smogur UPPC	HALOPERIDOL NON INJECTABLE - MONOGRAPH
2015-3553	05/01/2015 06/01/2015	FDA/OMPT/CDRH/OCER/DFOI/	Noah Roth ICON CLINICAL RESEARCH	K090224
2015-3554	05/01/2015 06/01/2015	OC/ORA/ OC/ORA/ FDA/OGROP/ORACE-FO/CIN- DO/CIN-CB/	Donald N. Blue ZETETIC INC	AEK-0186764-4
2015-3555	05/01/2015 06/01/2015	FDA/OFVM/CFSAN/OCD/EOS/	SCOTT BURYA AkzoNobel Packaging Coatings	DOW CHEMICAL CO - FCN 1095 MALEIC ANHYDRIDE GRAFED POLYROYLENE
2015-3556	05/01/2015 06/01/2015	FDA/OC/OPP/OP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Rachel Johnson FOI Services, Inc.	MTG BETWEEN FDA AND ORGANOGENESIS - EMAIL, MINUTES, PRESENTATIONS
2015-3557	05/01/2015 06/01/2015	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	THIRD TRILATERAL MEETING ON TOBACCO AND REGULATION - AGENDA, ROSTER, NOTES ETC
2015-3558	05/04/2015 06/02/2015	FDA/OMPT/CDRH/OCER/DFOI/	Christopher Thomas Donner SI-TECHNOLOGY, LLC	K150017, K150714
2015-3559	05/04/2015 06/02/2015	FDA/OMPT/CDRH/OCER/DFOI/	Michele Chin-Purcell BioSig Technologies	K110878
2015-3560	05/04/2015 06/02/2015	FDA/OMPT/CDRH/OCER/DFOI/	Larissa D'Andrea RESMED CORP	K143646
2015-3561	05/04/2015 06/02/2015	FDA/OMPT/CDRH/OCER/DFOI/	Larissa D'Andrea RESMED CORP	K140575
2015-3562	05/04/2015 06/02/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K960777
2015-3563	05/04/2015 06/02/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K100049

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2015-3564	05/04/2015 06/02/2015	OC/ORA/ OC/ORA/ FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/	Mark Collette HOUSTON CHRONICLE	BLUE BELL CREAMERIES - 483 01/01/2005 - 05/01/2015
2015-3565	05/04/2015 06/02/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ben Newton United BioSource Corporation	FDA AERS 8967754 9186133 9314001 9513408 9513490
2015-3566	05/04/2015 06/02/2015	FDA/OMPT/CDRH/OCER/DFOI/	Larissa D'Andrea RESMED CORP	K140980
2015-3567	05/04/2015 06/02/2015	FDA/OMPT/CDRH/OCER/DFOI/	Larissa D'Andrea RESMED CORP	K142988
2015-3568	05/04/2015 06/02/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Andrea Demakas ADVERSEEVENTS INC	ALIMTA, AVASTIN, GILOTRIF ETC - AERS 10/01/2014 - 05/01/2015
2015-3569	05/04/2015 06/02/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Linh Chu Intarcia Therapeutics, Inc	NDA 21919, NDA: 22200 GENOTOXICITY STUDIES
2015-3570	05/04/2015 06/02/2015	FDA/OMPT/CDRH/OCER/DFOI/	JACQUELINE A. HAUGE MEDTRONIC	MAGUET CARDIOPULMONARY SET - JOSTRA HLM TUBING SET K053025
2015-3571	05/04/2015 06/02/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PATRICIA L. REGENYE Celgene Corporation	IVAN BUNGANIC, GASTROENTEROLO AMBULANCIA MUCO, PRESOV, SVK - 483 9/12 TO 4/15
2015-3572	05/04/2015 06/02/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHONG-XAIN PAN, MD, Ph.D. UNIVERSITY OF CALIFORNIA DAVIS	NICLOSAMIDE - PHARMACOLOGY, TOXICOLOGY STUDY
2015-3573	05/04/2015 06/02/2015	FDA/OC/OES/DFOI/	Zuniga, P	CATARACTS, ALTERNATIVE AND CONVENTIONAL TREATMENTS FOR CATARACTS AND CATARACT LENS REPLACEMENT SURGERY
2015-3574	05/04/2015	FDA/OMPT/CDER/GRP/DIDP/	DAVID L. ROSEN, B.S. PHARM.,	FRESENIUS KABI USA - XYLOCAINE (LIDOCAINE HCL) NDA

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	06/02/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JD FOLEY & LARDNER LLP	06-488 APRVL RECS
2015-3575	05/04/2015 06/02/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BAHRIJCZUK, TAYLOR	NEXPLANON; IMPLANON - AERS
2015-3576	05/04/2015 06/02/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARINA ASHER MORRISON MAHONEY LLP	BIOLOGENE LLC - IND 108281 MTG MINS, CORR, RPTS, ETC
2015-3577	05/04/2015 06/02/2015	FDA/OMPT/CDRH/OCER/DFOI/	LORI A. FITTON ANGIODYNAMICS INC	DIOMED INC - EVLT KIT D15 PLUS & D30 PLUS DLODE LASERS K023543
2015-3578	05/04/2015 06/02/2015	OC/CVM/OCD/	JENNIFER C. PRATT Esq. JENNIFER C PRATT PLLC	PROHEART 6 - CMLPTS, RECALL RECS, APRVL, ETC
2015-3579	05/05/2015 06/03/2015	FDA/OO/OHR/ FDA/OC/OES/DFOI/	CHRISTAL BABLES WRITTEN DEPOSITION SERVICE LLC	INDIVIDUAL RECS
2015-3580	05/05/2015 06/03/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PATRICIA ANDERSON MAPI USA INC	RESERPINE TABS NDA 98-859, CHLORPROMAZINE HCI TABS NDA 85-331 - RECS
2015-3581	05/05/2015 06/03/2015	FDA/OGROP/OIP/	LINDSAY MERRIFIELD HARRISON PENSA LLP	HOFFMANN-LA ROCHE - ACCUTANE RECS
2015-3582	05/05/2015 06/03/2015	FDA/OC/OES/DFOI/	RUSSELL CAROLLO CAROLLO, RUSSELL	2012-2656, 2012-2510, 2012-927, ETC
2015-3583	05/05/2015 06/03/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PETER S REICHERTZ SHEPPARD MULLIN RICHTER & HAMPTON, LLP	PARENTERAL IRON AND ANAPHYLACTOID - MINI-SENTINEL ASSESMENT PROTOCOL FINAL RPT
2015-3584	05/05/2015 06/03/2015	OC/ORO/ OC/ORO/ OC/ORO/ORM/	Fabian Struck University of Passau, Bavaria, Germany	WARNING LETTER CLOSEOUT DATES

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		OC/ORR/ORM/		
2015-3585	05/05/2015 06/03/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Brad Schonhoff Willow Run Advisors, LLC	PATHEON, MONZA, ITALY - 483, WARNING LETTERS 01/01/2013 - 04/30/2015
2015-3586	05/05/2015 06/03/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Smith BioTex, Inc.	K021176
2015-3587	05/05/2015 06/03/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Smith BioTex, Inc.	K093223
2015-3588	05/05/2015 06/03/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Smith BioTex, Inc.	K081151
2015-3589	05/05/2015 06/03/2015	FDA/OC/OES/DFOI/ FDA/OGROP/ORA/PA-FO/SEA- DO/SEA-CB/	KEN REID WASHINGTON INFORMATION SOURCE	2014-10001, 2014-10005, 2014-10022, ETC
2015-3590	05/05/2015 06/03/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	David Mangione Govzilla, Inc.	CANGENE, WINNIPEG, CANADA - 483, EIR 01/26/2015 - 02/03/2015
2015-3591	05/05/2015 06/03/2015	FDA/OGROP/ORA/CE-FO/CHI- DO/CHI-CB/	Christy Anton Rush University Medical Center	DEMETRIUS LOPES, MD - EIR 01/01/2003 - 01/01/2004
2015-3592	05/05/2015 06/03/2015	FDA/OC/OES/DFOI/ FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/	PETER EISLER USA TODAY	CUSTOM ULTRASONICS - CEASE AND DESIST ORDER 9/12; 483S 5/26/10, 1/26/12/ 11/8/12
2015-3593	05/05/2015 06/03/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Chris LaVallee Precision Health Economics	ORANGE BOOK DATA 01/01/2000 - 05/01/2015
2015-3594	05/05/2015 06/03/2015	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 4/13-17/15
2015-3595	05/05/2015 06/03/2015	FDA/OC/OES/ FDA/OFVM/CFSAN/OCD/EOS/ OC/CVM/OCD/	Dan Vergano Buzzfeed News	COMMUNICATIONS AND DATA SHARED BETWEEN FDA AND EPA UNDER MOU RE PESTICIDES AND TOXIC SUBSTANCES 03/03/2015 - 05/01/2015
2015-3596	05/05/2015	FDA/OC/OES/DFOI/	DAVID MCFARLAND	CLOSED FOI REQUEST 4/13-17/15

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	06/03/2015		FDA REVIEW/FDA WEBVIEW	
2015-3597	05/05/2015 06/03/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED ROI REQUESTS 4/13-17/15
2015-3598	05/05/2015 06/03/2015	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 4/6-10/15
2015-3599	05/05/2015 06/03/2015	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOI REQUESTS 4/6-10/15
2015-3600	05/05/2015 06/03/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 4/6-10/15
2015-3601	05/05/2015 06/03/2015	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 3/30/15-4/3/15
2015-3602	05/05/2015 06/03/2015	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOI REQUESTS 3/30/15-4/3/15
2015-3603	05/05/2015 06/03/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 3/30/15-4/3/15
2015-3604	05/05/2015 06/03/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 3/30/15-4/3/15
2015-3605	05/05/2015 06/03/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 4/6-10/15
2015-3606	05/05/2015 06/03/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 4/13-17/15
2015-3607	05/05/2015 06/03/2015	FDA/OMPT/CTP/OD/	Caitlyn Ozier King & Spalding LLP	TRADE COMPLAINT RECS 14F00017 7/9/2014, 14G00004 7/9/2014 14G00005 7/9/2014, ETC
2015-3608	05/05/2015 06/03/2015	FDA/OMPT/CDRH/OCER/DFOI/	Christopher Thomas Donner SI-TECHNOLOGY, LLC	K112595
2015-3609	05/05/2015 06/03/2015	FDA/OMPT/CDRH/OCER/DFOI/	Christopher Thomas Donner SI-TECHNOLOGY, LLC	K122226, K111479, K103072
2015-3610	05/05/2015 06/03/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mukteeshwar Riconpharma LLC	ORANGE BOOK ANNUAL 34TH EDITION
2015-3611	05/05/2015	FDA/OMPT/CDER/ORP/DIDP/	Prasanna Gore, PhD	NDA 206229

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	06/03/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PharmaCompany, Inc	
2015-3612	05/05/2015 06/03/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	T. Christian Miller PROPUBLICA	FERTILITY DRUGS AERS
2015-3613	05/05/2015 06/03/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anne Spengler UNIVERSITY OF WASHINGTON MEDICAL CENTER	KADCYLA - AERS
2015-3614	05/05/2015 06/03/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	T. Christian Miller PROPUBLICA	ISR 5500699, 6115627, 6121983, ETC
2015-3615	05/05/2015 06/03/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Smith BioTex, Inc.	K955841
2015-3616	05/05/2015 06/03/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Smith BioTex, Inc.	K000068
2015-3617	05/05/2015 06/03/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Smith BioTex, Inc.	K003175
2015-3618	05/05/2015 06/03/2015	FDA/OGROP/ORACE-FO/MIN- DO/MIN-CB/	Karen Campo DreamPak, LLC	DREAMPAK, LCC, NEW BERLIN, WI - EIR 03/09/2015 - 03/10/2015
2015-3619	05/05/2015 06/03/2015	FDA/OGROP/ORACE-FO/CHI- DO/CHI-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Eugene P Schmittgens Jr Schmittgens Jr, Eugene P	ROBOTIC ASSISTED SURGERIES AT ADVOCATE SOUTH SURBAN HOSPITAL, HAZEL CREST, IL - INCIDENT REPORTS 01/01/2014 - 05/04/2015
2015-3620	05/05/2015 06/03/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Smith BioTex, Inc.	K072201
2015-3621	05/05/2015 06/03/2015	FDA/OMPT/CDRH/OCER/DFOI/	Liran Oren UNIVERSITY OF CINCINNATI	K140929
2015-3622	05/05/2015 06/03/2015	FDA/OGROP/ORACE-FO/ATL- DO/ATL-CB/	David Mangione Govzilla, Inc.	CATALENT PHARMA SOLUTIONS, LLC, MORRISVILLE, NC - 483, EIR 03/16/2015 - 03/20/2015
2015-3623	05/05/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Smith	K033052

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	06/03/2015		BioTex, Inc.	
2015-3624	05/05/2015 06/03/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Smith BioTex, Inc.	K051085
2015-3625	05/05/2015 06/03/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Smith BioTex, Inc.	K040194
2015-3626	05/05/2015 06/03/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	G. Srinivas Zydus Pharmaceuticals USA Inc.	ANDA 074132, ANDA 074234, ANDA 073553 SBA
2015-3627	05/06/2015 06/04/2015	FDA/OMPT/CDRH/OCER/DFOI/	Bret Andre EyeReg Consulting Inc.	K143280
2015-3628	05/06/2015 06/04/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Natalie Jimenez CBS NEWS	DROSPIRENONE-BASED BIRTH CONTROL PILLS, PROGESTIN-BASED BIRTH CONTROL PILLS - AERS
2015-3629	05/06/2015 06/04/2015	FDA/OMPT/CDRH/OCER/DFOI/	Kathy Remsen MEDTRONIC SOFAMOR DANEK	K142203
2015-3630	05/06/2015 06/04/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Kathy Remsen MEDTRONIC SOFAMOR DANEK	K031482
2015-3631	05/06/2015 06/04/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ann Agnor BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.	BLA 125477/S-007
2015-3632	05/06/2015 06/04/2015	FDA/OGROP/ORAP/PA-FO/SEA- DO/SEA-CB/	Jennifer Baker Oregon Nurses Association	PUGET SOUND BLOOD CENTER - 483, CORR 01/01/2014 - 05/05/2015
2015-3633	05/06/2015 06/04/2015	FDA/OGROP/ORAP/CE-FO/CHI- DO/CHI-CB/	Gerd Kochendoerfer DEPOMED INC	MORTON GROVE PHARMACEUTICALS, MORTON GROVE, IL - EIR 03/26/2014 - 05/05/2015
2015-3634	05/06/2015 06/04/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Allison Magwire ARIAD Pharmaceuticals, Inc.	ICLUSIG - AERS
2015-3635	05/06/2015 06/04/2015	FDA/OGROP/ORAP/SE-FO/SJN- DO/SJN-CB/	Alexander Foster Arnall Golden Gregory LLP (on	CUSTOMED - MEETING MINUTES, NOTES 03/12/2015 - 04/17/2015

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			behalf of Customed, Inc.)	
2015-3636	05/06/2015 06/04/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TOM TUDUJ TUDUJ M05570, TOM	FORFIVO XL - AERS
2015-3637	05/06/2015 06/04/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TOM TUDUJ TUDUJ M05570, TOM	ADVAIR - AERS
2015-3638	05/06/2015 06/04/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TOM TUDUJ TUDUJ M05570, TOM	AVANDIA - AERS
2015-3639	05/06/2015 06/04/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TOM TUDUJ TUDUJ M05570, TOM	PAXIL CR - AERS
2015-3640	05/06/2015 06/04/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TOM TUDUJ TUDUJ M05570, TOM	PAXIL - AERS
2015-3641	05/06/2015 06/04/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TOM TUDUJ TUDUJ M05570, TOM	ZOLPIDEM - AERS
2015-3642	05/06/2015 06/04/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TOM TUDUJ TUDUJ M05570, TOM	PROPRANOLOL - AERS
2015-3643	05/06/2015 06/04/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TOM TUDUJ TUDUJ M05570, TOM	AMBIEN - AERS

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2015-3644	05/06/2015 06/04/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TOM TUDUJ TUDUJ M05570, TOM	AMBIEN CR - AERS
2015-3645	05/06/2015 06/04/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TOM TUDUJ TUDUJ M05570, TOM	BUPROPION - AERS
2015-3646	05/06/2015 06/04/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TOM TUDUJ TUDUJ M05570, TOM	WELLBUTRIN - AERS
2015-3647	05/06/2015 06/04/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TOM TUDUJ TUDUJ M05570, TOM	WELLBUTRIN SR - AERS
2015-3648	05/06/2015 06/04/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TOM TUDUJ TUDUJ M05570, TOM	WELLBUTRIN XL
2015-3649	05/06/2015 06/04/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TOM TUDUJ TUDUJ M05570, TOM	ST JOHN'S WORT - AERS
2015-3650	05/06/2015 06/04/2015	FDA/OMPT/CDRH/OCER/DFOI/	COLLEN M DURRAN Fresenius Medical Care North America	DEKA RESEARCH & DEVELOPMENT CORP, MANCHESTER NH - AMIA AUTOMATED PD SYS K124018
2015-3651	05/06/2015 06/04/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TAMI T MARTIN SUPERNUS PHARMACEUTICALS INC	TOPAMAX (TOPIRAMATE) - ISRS 4502937-1, 6120398-6, 7161594-9, ETC
2015-3652	05/06/2015 06/04/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/	STEPHEN SOPER SOPER E-94630, STEPHEN	AFLURIA, ERBITUX - PROD MOLNOGRAPH, AERS 2/12/13 TO 2/13/15

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2015-3653	05/06/2015 06/04/2015	FDA/OGROP/ORAC/FO/CIN- DO/CIN-CB/	JEFFREY E STEVENSON STEVENSON, JEFFREY E	UNCLE JESTER'S FINE FOODS LLC - EIRS 3/15 TO 4/15
2015-3654	05/06/2015 06/04/2015	FDA/OGROP/ORAC/FO/NWJ- DO/NWJ-CB/	PATRICIA R CARLEY LAW OFC PATRICIA R CARLEY LLC	CORE PHARMA LLC, MIDDLESEX, NJ - MSDS SHEETS, ACCIDENTS, INVESTIGATIONS, ETC 2014, 2015
2015-3655	05/06/2015 06/04/2015	FDA/OFVM/CFSAN/OCD/EOS/	VISAGINE VIJAYAKULASINGAM IOVATE HEALTH SCIENCES INTERNATIONAL INC	IOVATE, HYDROXYCUT, SMARTBURN, ETC - CAERS 2/3/15 TO PRESENT
2015-3656	05/06/2015 06/04/2015	OC/CVM/OCD/	CRAIG PULLMAN PULLMAN, CRAIG	MOLNSANTO'S SEPTEMBER 2 SUBMISSION PAGE 49
2015-3657	05/06/2015 06/04/2015	FDA/OFVM/CFSAN/OCD/EOS/	ELIZABETH SWEIS INTERTEK REGULATORY SERVICES	FRAUNHOFER INSTITUT VERFAHRENSTECHNIK UND VERPACKUNG (LUIGI BANDERA SPA) - POLYETHYLENE TEREPHTHALATE (PET) FCN 119
2015-3658	05/06/2015 06/04/2015	FDA/OMPT/CDRH/OCER/DFOI/	Paul Liu TaiDoc Technology Corp.	CPT1400457, GEN1400371, CPT1400361
2015-3659	05/06/2015 06/04/2015	FDA/OGROP/ORAC/SE-FO/NOL- DO/NOL-CB/ FDA/OGROP/ORAC/SW-FO/KAN- DO/KAN-CB/	Jennifer Hastings General Mills- QRO	GENERAL MILLS, CARLISLE, IA; MURFREESBORO, TN - EIR, 483, ETC
2015-3660	05/06/2015 06/04/2015	OC/ORAC/ OC/ORAC/ FDA/OGROP/ORAC/ORO/DIOP/	Zetetic, Inc. ZETETIC INC	IMPORT DATA 4/16/15 - 4/30/15
2015-3661	05/06/2015 06/04/2015	FDA/OMPT/CDRH/OCER/DFOI/	Talariant Talariant	K063304
2015-3662	05/06/2015 06/04/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jenny E. Blau MD Blau, Jenny E	CANAGLIFLOZIN, DAPAGLIFLOZIN, EMPAGLIFLOZIN - AERS
2015-3663	05/06/2015 06/04/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-9550
2015-3664	05/07/2015 06/05/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2015-312

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2015-3665	05/07/2015 06/05/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2015-1455
2015-3666	05/07/2015 06/05/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-5840
2015-3667	05/07/2015 06/05/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-7820
2015-3668	05/07/2015 06/05/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-9024
2015-3669	05/07/2015 06/05/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2012-4168
2015-3670	05/07/2015 06/05/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2012-4230
2015-3671	05/07/2015 06/05/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2013-10022
2015-3672	05/07/2015 06/05/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-2190
2015-3673	05/07/2015 06/05/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-5803
2015-3674	05/07/2015 06/05/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-4624
2015-3675	05/07/2015 06/05/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-8639
2015-3676	05/07/2015 06/05/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-8640
2015-3677	05/07/2015 06/05/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-8475
2015-3678	05/07/2015 06/05/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-5549
2015-3679	05/07/2015 06/05/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2012-2028
2015-3680	05/07/2015 06/05/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-8210
2015-3681	05/07/2015	FDA/OC/OES/DFOI/	Jo Hogan	2015-877

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	06/05/2015		FOI Services, Inc.	
2015-3682	05/07/2015 06/05/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2015-984
2015-3683	05/07/2015 06/05/2015	FDA/OC/OES/DFOI/	Jo Hogan FOI Services, Inc.	2014-9023
2015-3684	05/07/2015 06/05/2015	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/	Steve Schone Endevr Inc	ENTRY 277-0143296-8
2015-3685	05/07/2015 06/05/2015	FDA/OMPT/CDRH/OCER/DFOI/	Christine Scifert Memphis Regulatory Consulting, LLC	K864492
2015-3686	05/07/2015 06/05/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Andrea Demakas ADVERSEEVENTS INC	LANOXIN - AERS
2015-3687	05/07/2015 06/05/2015	FDA/OGROP/ORO/NE-FO/NWE- DO/NWE-CB/	Rachel Johnson FOI Services, Inc.	ASSOCIATES OF CAPE COD, EAST FALMOUTH, MA - EIR, 43
2015-3688	05/07/2015 06/05/2015	FDA/OGROP/ORO/SE-FO/FLA- DO/FLA-CB/	Gina Peralta Precision Research Organization LLC	CIRO REYES, MD, MIAMI LAKES, FL - 483 03/24/2015 - 05/05/2015
2015-3689	05/07/2015 06/05/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	KRATOM, MITRAGYNA, VIVAZEN - AERS
2015-3690	05/07/2015 06/05/2015	OC/ORO/ OC/ORO/ OC/ORO/ORM/ OC/ORO/ORM/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Fabian Struck University of Passau, Bavaria, Germany	CLOSE OUT LETTER DATA 01/01/2004 - 09/01/2009

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		FDA/OMPT/CDRH/OCER/DFOI/		
2015-3691	05/07/2015 06/05/2015	FDA/OC/OES/DFOI/	Davide Mancini EATALIA Fine Foods LLC	BELGIAN CONDIMENT SAUCES
2015-3692	05/07/2015 06/05/2015	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Allen Allen	FLUORIDE RECS
2015-3693	05/07/2015 06/05/2015	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/CIN-DO/CIN-CB/	Doe J	INDIVIDUAL RECS
2015-3694	05/07/2015 06/05/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lucy Crosby Greenville Health System	PACIRA PHARMACEUTICALS - RESPONSE LETTER, ACKNOWLEDGEMENT OF RESPONSE 09/23/2014 - 05/06/2015
2015-3695	05/07/2015 06/05/2015	FDA/OMPT/CDRH/OCER/DFOI/	Mahesh Agarwal Medionics International Inc.	MEDIONICS INTERNATIONAL, CANADA - EIR 06/22/2009 - 06/25/2009
2015-3696	05/07/2015 06/05/2015	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sajjan Aryal Accucaps Industries Limited	API MANUFACTURER EIR 07/01/2012 - 05/06/2015
2015-3697	05/07/2015 06/05/2015	FDA/OMPT/CDRH/OCER/DFOI/	John Tozzi Bloomberg Businessweek	FDA ACTION RELATED TO PRODUCTS DETERMINED TO BE MEDICAL DEVICES THAT ARE BEING MARKETED WITHOUT 510K 01/01/2010 - 05/07/2015
2015-3698	05/07/2015 06/05/2015	FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	Neil Wallace Neil Wallace	DR JESSE ANDREW STOFF - 483 01/01/1980 - 12/31/2000
2015-3699	05/07/2015 06/05/2015	FDA/OMPT/CDRH/OCER/DFOI/	Varun Bhardwaj Varun Bhardwaj	EARGO, INC - APPROVAL RECS 01/01/2013 - 05/06/2015
2015-3700	05/07/2015 06/05/2015	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/ FDA/OGROP/ORO/CE-FO/NWJ-	Matthew Wagner Diserio Martin O'Connor & Castiglioni, LLP	TIMITE AND SONS, TIMITE AND SONS BEAUTY SUPPLY, WORLD BEAUTY SUPPLY ETC - FDA IMPORT NOTICES ETC 01/01/2008 - 05/06/2015

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		DO/NWJ-CB/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/		
2015-3701	05/07/2015 06/05/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Daria MARI POLICHEM SA	ANDA 077623
2015-3702	05/07/2015 06/05/2015	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	AGILUX LABORATORIES, WORCESTER, MA - EIR, 483, RESPONSE 07/01/2013 - 07/31/2013
2015-3703	05/07/2015 06/05/2015	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	INTERTEK USA, INC, SAN DIEGO, CA - EIR, 483, RESPONSE 09/01/2012 - 09/30/2012
2015-3704	05/07/2015 06/05/2015	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	CHANTEST CORPORATION, CLEVELAND, OH - EIR, 483, RESPONSE 06/01/2013 - 06/30/2013
2015-3705	05/07/2015 06/05/2015	FDA/OMPT/CDRH/OCER/DFOI/	francesco dell'antonio quanta system spa	K111303, K111851
2015-3706	05/07/2015 06/05/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Elisabeth Prager AOP ORPHAN PHARMACEUTICALS AG	NDA 20-333/S-013 FDA ASSESSMENT OF 2 YEAR RAT STUDY
2015-3707	05/07/2015 06/05/2015	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	TEXAS BIOMEDICAL RESEARCH INSTITUTE, SAN ANTONIO, TX - EIR, 483, RESPONSE 09/01/2012 - 09/30/2012
2015-3708	05/07/2015 06/05/2015	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	TOXIKON CORP, BEDFORD, MA - EIR, 483, RESPONSE 09/01/2013 - 09/30/2013
2015-3709	05/07/2015 06/05/2015	FDA/OC/OES/	MITCH GOLDSMITH, M.A. PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS	PRESENTATIONS BY THE FOUNDATION FOR BIOMEDICAL RESEARCH OR THE NATIONAL ASSOC FOR BIOMEDICAL RESEARCH - 1/1/10 TO PRESENT
2015-3710	05/07/2015 06/05/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	ALLERGAN, INC, IRVINE, CA - EIR, 483, RESPONSE 03/01/2013 - 03/31/2013

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/		
2015-3711	05/07/2015 06/05/2015	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	BATTELLE MEMORIAL INSTITUTE, COLUMBUS, OH - EIR, 483, RESPONSE 10/01/2012 - 10/31/2012
2015-3712	05/07/2015 06/05/2015	FDA/OFVM/CFSAN/OCD/EOS/	ELIZABETH SWEIS INTERTEK	RIKEN VITAMIN CO LTD - ETHOXYLATED ALCOHOLS FCN 1313 CHEMISTRY AND TOXICOLOGY RVW MEMO, CORR, FORM 3480, ETC
2015-3713	05/07/2015 06/05/2015	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	COVANCE LABORATORIES, GREENFIELD, IN - EIR, 483, RESPONSE 06/01/2014 - 06/30/2014
2015-3714	05/07/2015 06/05/2015	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	HOFFMAN LA ROCHE, NUTLEY, NJ - EIR, 483, RESPONSE 05/01/2013 - 05/31/2013
2015-3715	05/07/2015 06/05/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	PITISUTTIHUM PUNNEE MD, BANGKOK, THAILAND - EIR, 483, RESPONSE 05/01/2014 - 05/31/2014
2015-3716	05/07/2015 06/05/2015	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	DYAX CORP, BURLINGTON, MA - EIR, 483, RESPONSE 08/01/2014 - 08/31/2014
2015-3717	05/07/2015 06/05/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	David Mangione Govzilla, Inc.	CANGENE CORPORATION, CANADA - EIR, 483, RESPONSE 07/09/2014 - 07/18/2014
2015-3718	05/07/2015 06/05/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	VALEANT PHARMACEUTICALS INTERNATIONAL, CANADA - EIR, 483, RESPONSE 09/01/2013 - 09/30/2013
2015-3719	05/07/2015 06/05/2015	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	Walter Chalkley THOMSON REUTERS	EMERGENT BIODEFENSE, LANSING, MI - EIR, 483, RESPONSE 11/01/2013 - 11/30/2013

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			(SCIENTIFIC) SAS	
2015-3720	05/07/2015 06/05/2015	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	CSL BEHRING, BRADLEY, IL - EIR, 483, RESPONSE 07/01/2014 - 07/31/2014
2015-3721	05/07/2015 06/05/2015	FDA/OMPT/CDRH/OCER/DFOI/	Freddie Lee Epic International (Thailand) Co., Ltd.	K910007
2015-3722	05/07/2015 06/05/2015	FDA/OFVM/CFSAN/OCD/EOS/	GARY J. BURIN, Ph.D., DABT TECHNOLOGY SERVICES GROUP INC	FCN 0277
2015-3723	05/07/2015 06/05/2015	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	CORDEN PHARMA COLORADO, BOULDER, CO - EIR, 483, RESPONSE 06/01/2013 - 06/30/2013
2015-3724	05/07/2015 06/05/2015	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	BRISTOL MYERS SQUIBB, DEVENS, MA - EIR, 483, RESPONSE 06/01/2013 - 06/30/2013
2015-3725	05/07/2015 06/05/2015	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	CARDINAL HEALTH LLC, LAS VEGAS, NV - EIR, 483, RESPONSE 11/01/2013 - 11/30/2013
2015-3726	05/07/2015 06/05/2015	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	GILEAD SCIENCES, INC, FOSTER CITY, CA - EIR, 483, RESPONSE 09/23/2013 - 10/10/2013
2015-3727	05/07/2015 06/05/2015	FDA/OGROP/ORACE-FO/PHIDO/PHI-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	PREMIER RESEARCH INTERNATIONAL, PHILADELPHIA, PA - EIR, 483, RESPONSE 02/01/2012 - 02/29/2012
2015-3728	05/07/2015 06/05/2015	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	CANGENE BIOPHARMA, INC DBA EMERGENT BIOSOLUTIONS, BALTIMORE, MD - EIR, 483, RESPONSE 03/31/2014 - 04/09/2014
2015-3729	05/07/2015 06/05/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	David Gorelick University of Maryland, Baltimore School of Medicine Clinical Neurobehavioral Center	IND 45228
2015-3730	05/07/2015 06/05/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JORGE ALEMANY SPHERIUM BIOMED	CILASTATIN - FORMULATION, PRECLINICAL INFORMATION, BIOAVAILABILITY ETC

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		FDA/OMPT/CDER/GRP/DIDP/		
2015-3731	05/07/2015 06/05/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Emily Krulewitz The Weinberg Group	TUZISTRA XR APPROVAL RECS
2015-3732	05/07/2015 06/05/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Marc Elia BRIDGER CAPITAL LLC	ADVETRIS, KYNAMRO, HETLIOZ, ETC - AERS
2015-3733	05/07/2015 06/05/2015	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Barron F. Dickinson Searcy Denney Scarola Barnhart & Shipley, P.A.	TEVA PARENTERAL MEDICINES, IRVINE, CA - EIR, EXHIBITS, ATTACHMENTS, ETC 01/07/2009 - 01/01/2010
2015-3734	05/07/2015 06/05/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	VICTORIA SCOTT HEMISPHEREX BIOPHARMA INC	LONZA BIOLOGICS - IMMOBILIZED MONOCLONAL ANTIBODY DMF 18596
2015-3735	05/07/2015 06/05/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BERNARD M. GROSS, PC BERNARD M GROSS LAW OFCS	NYMOX PHARMACEUTICAL CORP - NX02-0017; NX02-0018
2015-3736	05/07/2015 06/05/2015	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDRH/OCER/DFOI/	MICHELLE A. RAMIREZ SIDLEY AUSTIN LLP	FUJIFILM CORP - DUODENOSCOPES 483'S, WARNING LTRS, FOREIGN & DOMESTIC SINCE 1/1/15
2015-3737	05/07/2015 06/05/2015	FDA/OMPT/CDRH/OCER/DFOI/	MICHELLE A. RAMIREZ SIDLEY AUSTIN LLP	PENTAX MEDICAL, HOYA CORP - DUODENOSCOPES MEDWATCH, CMLPNTS SINCE 7/96
2015-3738	05/07/2015 06/05/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LYNAE CHANG BOSCOGEN INC	SYN TECH PHARM, TAINAN COUNTY, TAIWAN - EIR 1/26-29/15
2015-3739	05/07/2015 06/05/2015	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OMPT/CDRH/OCER/DFOI/	ADAM M. EPSTEIN MAZIE SLATER KATZ ET AL	CORDIS CORP - OPTEASE VENA CAVA FILTER; RETRIEVAL CATHETER; PERMANENT VENA CAVA FILTER & INTRODUCTION KIT

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2015-3740	05/07/2015 06/05/2015	FDA/OGROP/ORPA/PA-FO/LOS-DO/LOS-CB/	PATRICK D. RIDDLE LAW OFFICES OF PATRICK D RIDDLE PC	TRADER JOES - RAW WALNUTS SALMONELLA RECALL
2015-3741	05/07/2015 06/05/2015	FDA/OMPT/CDRH/OCER/DFOI/	JACQUELINE J. CHAN K and L Gates LLP	OLYMPUS MEDICAL SYS CORP - DUODENOSCOPES WARNING LTRS, 483'S FOREIGN & DOMESTIC SINCE 1/1/15
2015-3742	05/07/2015 06/05/2015	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Gregory Gogo, Esq.	DKT MER-L-1112-13
2015-3743	05/07/2015 06/05/2015	FDA/OGROP/ORPA/PA-FO/LOS-DO/LOS-CB/	Doe J	SPINAL SOLUTUONS, LONG BEACH, CA - COSIGNEES
2015-3744	05/07/2015 06/05/2015	OC/ORA/ OC/ORA/ FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	JONATHAN BERMAN JONES DAY	JENIS SPLENDID ICE CREAMS - SPL 2673
2015-3745	05/08/2015 06/08/2015	FDA/OMPT/CDRH/OCER/DFOI/	Darren Dorman Siemens Medical Solutions USA, Inc.	K090318
2015-3746	05/08/2015 06/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	ANDA 200630 TENTATIVE APPROVAL LETTER, LABELING
2015-3747	05/08/2015 06/08/2015	FDA/OMPT/CDRH/OCER/DFOI/	Dirk Loeckx icomatrix	K140828
2015-3748	05/08/2015 06/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	ANDA 203976 LABELING, PACKAGE INSERT
2015-3749	05/08/2015 06/08/2015	FDA/OMPT/CDRH/OCER/DFOI/	Elizabeth Torre Reckitt Benckiser Group	K150615 SUMMARY
2015-3750	05/08/2015 06/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	David E Watson ELI LILLY & CO	OFEV - PHARMACOLOGY REVIEW

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2015-3751	05/08/2015 06/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Peter R. Breggin Center for the Study of Empathic Therapy	PERPHENAZINE - AERS
2015-3752	05/08/2015 06/08/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Andrey Godes Multi Radiance Medical	K093547
2015-3753	05/08/2015 06/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Chris Cole Pike Photocopy, Inc.	COUNTERFEIT BOTOX - AERS, TOXICOLOGY
2015-3754	05/08/2015 06/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Steve J. Polich Steve J. Polich	PATANASE - AERS
2015-3755	05/08/2015 06/08/2015	FDA/OGROP/ORR/SW-FO/DEN- DO/DEN-CB/	Marc C. Sanchez, Esq. Contract In-House Counsel Consl. LLC	DERMA PEN WARNING LETTER RECS 03/16/2015 - 03/31/2015
2015-3756	05/08/2015 06/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID BAKER BAKER, DAVID	STRATTERA - AERS
2015-3757	05/08/2015 06/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BILLY COCHRAN COCHRAN V-04815, BILLY	IBUPROFEN, ACETAMINOPHEN, PROZOSIN, ETC - MEDICATION GUIDE, PRESCRIPTION PROTOCOLS, DURATION LIMITS
2015-3758	05/08/2015 06/08/2015	FDA/OC/OES/DDM/ FDA/OMPT/CTP/OD/	MARK E GREENWOLD CAMPAIGN FOR TOBACCO- FREE KIDS	PRODUCT QUANTITY CHANGE SUBSTANTIAL EQUIVALENCE RPTS, DKT 2011D-0147
2015-3759	05/08/2015 06/08/2015	FDA/OFVM/CFSAN/OCD/EOS/	ANI BYRNE Jamieson Laboratories	CAERS 183160

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2015-3760	05/08/2015 06/08/2015	FDA/OFVM/CFSAN/OCD/EOS/	TOM NASH MUCKROCK NEWS	4-METHYLIMIDAZOLE IN SODA - RPTS 2014 TO PRESENT
2015-3761	05/08/2015 06/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	INDIVIDUAL RECS
2015-3762	05/08/2015 06/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JEAN VACCA VACCA, JEAN	COLLOIDAL SILVER - RPT
2015-3763	05/08/2015 06/08/2015	FDA/OMPT/CDRH/OCER/DFOI/	JESSICA TERRANOVA A STEP AHEAD PROSTHETICS	OTTOBOCK C-LEG 4 MICROPROCESSOR CONTROLLED PROSTHETIC KNEE - IP TESTING, LIQUID INGRESS PROTECTION TESTING, IMMERSION TESTING, ETC
2015-3764	05/08/2015 06/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MATTHEW O GREENBERG Blizzard & Nabers, LLP	GLAXOSMITHKLINE PLC, NOVARTIS AG, NOVARTIS PHARMACEUTICAL COR - ZOFAN (ONDANSETRON) RVWS, AERS, COMM, ETC 1991 TO 2015
2015-3765	05/08/2015 06/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MATTHEW O GREENBERG Blizzard & Nabers, LLP	FOREST PHARMS, FOREST LABS - CELEXA (CITALOPRAM), LEXAPRO (ESCITALOPRAM) RVWS, AERS, COMM, ETC 2009 TO 2015
2015-3766	05/08/2015 06/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	CYANOCOBOLAMIN INJ ANDA 87-969 - CHEMISTRY RVW
2015-3767	05/08/2015 06/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	VIBISONE (CYANOCOBOLAMIN) INJ ANDA 80-557 - CHEMISTRY RVW
2015-3768	05/08/2015 06/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	CYANOCOBOLAMIN INJ ANDA 80-737 - CHEMISTRY RVW
2015-3769	05/08/2015	FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE	OTSUKA PHARMACEUTICAL CO LTD, SAGA PREFECTURE,

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	06/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	EAS CONSULTING GROUP LLC	JAPAN - EIR 12/1-5/14
2015-3770	05/08/2015 06/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	OTSUKA PHARMACEUTICAL CO LTD, NAKA-GUN, TOKUSHIMA PREFECTURE, JAPAN - EIR 6/9-17/14
2015-3771	05/08/2015 06/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	OTSUKA PHARMACEUTICAL CO LTD, EBISUNO HIRAISHI, KAWAUCHI-CHO, TOKUSHIMA, JAPAN - EIR 6/18-26/14
2015-3772	05/08/2015 06/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	OTSUKA PHARMACEUTICAL CO LTD, ITANO-GUN, TOKUSHIMA PREFECTURE, JAPAN - EIR 3/17-20/14
2015-3773	05/08/2015 06/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	LUNDBECK, TEESSIDE, ENGLAND, UK - EIR MOST RECENT
2015-3774	05/08/2015 06/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	ALUMINOSILICARE GLASS IN PARENTERAL APPLICATIONS - CORR, MINS, REGULATORY OPINIONS 1/10 TO PRESENT
2015-3775	05/08/2015 06/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	STEVANTO GROUP - ALUMINOSILICATE GLASS CORR, MINS, REGULATORY OPINIONS, ETC
2015-3776	05/08/2015 06/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	OMPI PHARMA - ALUMINOSILICARE GLASS CORR, MINS, REGULATORY OPINIONS, ETC
2015-3777	05/08/2015 06/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	CORNING - ALUMINOSILICATE GLASS CORR, MINS, REGULAOTRY OPINIONS, ETC

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		FDA/OMPT/CDER/ORM/DIDP/ FDA/OMPT/CDER/ORM/DIDP/		
2015-3778	05/08/2015 06/08/2015	OC/ORA/ORM/ OC/ORA/ORM/	Eyal Maor FDAAWARE	LIST OF INSPECTIONS 02/17/2015 - 05/15/2015
2015-3779	05/08/2015 06/08/2015	FDA/OC/OES/DDM/	Gabriele Papenkort Federal Instistution for Drugs and Medical Devices - Library	DRAFT GUIDANCE HEART VALVES - INVESTIGATIONAL DEVICE EXEMPTIONS AND PREMARKET APPROVAL APPLICATIONS 02/20/2010 - 04/27/2015
2015-3780	05/08/2015 06/08/2015	FDA/OMPT/CDER/ORM/DIDP/ FDA/OMPT/CDER/ORM/DIDP/ FDA/OMPT/CDER/ORM/DIDP/ FDA/OMPT/CDER/ORM/DIDP/	Chintan Dave Food and Drug information: Drug Shortages	DRUG SHORTAGE DATA 01/01/2008 - 12/31/2013;
2015-3781	05/08/2015 06/08/2015	FDA/OMPT/CDER/ORM/DIDP/ FDA/OMPT/CDER/ORM/DIDP/ FDA/OMPT/CDER/ORM/DIDP/ FDA/OMPT/CDER/ORM/DIDP/	MIRIAM COHEN COHEN, MIRIAM	PROMETHAZINE - OUTCOME OF THE DRUG EFFICACY SAFETY IMPLEMENTATION (DESI) RVWS
2015-3782	05/08/2015 06/08/2015	FDA/OC/OES/DFOI/	Jeremy Gerrard Food Engineering Magazine	BLUE BELL CREAMERIES
2015-3783	05/08/2015 06/08/2015	FDA/OC/OES/DFOI/	Jeremy Gerrard BNP Media, Food Engineering Magazine	BLUE BELL CREAMERIES
2015-3784	05/11/2015 06/09/2015	FDA/OC/OES/DFOI/	MARYLINN WHITNEY COVINGTON BURLING LLP	DKT 1998P-0547
2015-3785	05/11/2015 06/09/2015	FDA/OC/OES/DFOI/	JESSICA GRINSPAM FDA NEWS	DKT 2013N-0500
2015-3786	05/11/2015 06/09/2015	FDA/OC/OES/DFOI/	SHIRLEY DAN DAN, SHIRLEY	DKT 2015P-0091
2015-3787	05/11/2015 06/09/2015	FDA/OC/OES/DFOI/	SARAH ABRAMSON VENABLE LLP	DKT 1975-0184
2015-3788	05/11/2015 06/09/2015	FDA/OC/OES/DFOI/	JACQUELINE PROSCIA Wilson Sonsini Goodrich & Rosati	DKT 2013N-0500
2015-3789	05/11/2015 06/09/2015	FDA/OC/OES/DFOI/	PAUL DELEO AMERICAN CLEANING INSTITUTE	1975N-0183
2015-3790	05/11/2015	FDA/OC/OES/DFOI/	HATHRYN MERRITT	DKT 2011N-0920, 2011N-0921

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	06/09/2015		National Sustainable Agriculture Coalition	
2015-3791	05/11/2015 06/09/2015	FDA/OC/OES/DFOI/	ZACHARY MORGAN MERCURY PUBLIC AFFAIRS	DKT 2007N-0363-0040
2015-3792	05/11/2015 06/09/2015	FDA/OC/OES/DFOI/	TATIANA DA SILVA KPW LAW	DKT 2015P-0569
2015-3793	05/11/2015 06/09/2015	FDA/OC/OES/DFOI/	JACQUELINE PROSCIA Wilson Sonsini Goodrich & Rosati	DKT 2011N-0830, 2007N-0363, 2013N-0500
2015-3794	05/11/2015 06/09/2015	FDA/OC/OES/DFOI/	CHRIS CELESTE EAS CONSULTING GROUP LLC	DKT 2003N-0196, 2005N-0453, 20060-0314, ETC
2015-3795	05/11/2015 06/09/2015	FDA/OC/OES/DFOI/	CHRIST CELESTE EAS CONSULTING GROUP LLC	FEDERAL REGISTER VOL 50 N062 PG 12821-12825
2015-3796	05/11/2015 06/09/2015	FDA/OC/OES/DFOI/	SARAH ABRAMSON VENABLE LLP	DKT 75N-0184
2015-3797	05/11/2015 06/09/2015	FDA/OC/OES/DFOI/	XZACHARY MORGAN MERCURY PUBLIC AFFAIRS	DKT 2007N-0363-0040
2015-3798	05/11/2015 06/09/2015	FDA/OC/OES/DFOI/	BRYNN KOENIG FDA NEWS	DKT 2014N-1168-0029
2015-3799	05/11/2015 06/09/2015	FDA/OC/OES/DFOI/	CATHY KOMENDA LATHAM & WATKINS	DKT 2014N-1051
2015-3800	05/11/2015 06/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KATE REYNOLDS ROCKY MOUNTAIN POISON DRUG CTR	COUGH & COLD PREPARATIONS - ISRS 91691343, 94455812, 96810154, ETC
2015-3801	05/11/2015 06/09/2015	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/ FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	JUSTIN ANG Hound Partners	IMPAX LABS, HAYWARD, CA, MIAOLI COUNTY 350, TAIWAN - EIRS
2015-3802	05/11/2015	OC/ORA/	MANDIE TRIMBLE	JENI'S SPLENDID ICE CREAMS - EIRS 1/1/10 TO 5/8/15

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	06/09/2015	OC/ORO/ FDA/OGROP/ORO/CE-FO/CIN- DO/CIN-CB/	89.7 NPR NEWS	
2015-3803	05/11/2015 06/09/2015	OC/ORO/ORM/ OC/ORO/ORM/	LESLIE RAMSEY FDA NEWS	LIST OF 483S FOR PHARMACEUTICAL, BIOLOGICS & MEDICAL DVC MFG & CLNCL TRIAL FACILITIES IN THE US & OUTSIDE THE US 4/1-30/15
2015-3804	05/11/2015 06/09/2015	FDA/OC/OL/	DALE J GLALI Mayer Brown LLP	SENATOR RICHARD DURBIN OR SENATOR DIANE FEINSTEIN - RESP LTR 3/11/15
2015-3805	05/11/2015 06/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	sandy suh Exeltis	NDA 016954
2015-3806	05/11/2015 06/09/2015	FDA/OGROP/ORO/SW-FO/KAN- DO/KAN-CB/	James Peach Precision Biologic Inc.	BIO-MEDICAL INC, OVERLAND PARK, KS - EIR, INVESTIGATOR NOTES, 483 03/01/1994 - 10/31/2012
2015-3807	05/11/2015 06/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	sandy suh Exeltis	NDA 017031
2015-3808	05/11/2015 06/09/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mary Stipancic Pharma Medica Research Inc.	PHARMA MEDICA RESEARCH INC, CANADA - EIR 03/16/2015 - 03/27/2015
2015-3809	05/11/2015 06/09/2015	FDA/OMPT/CDRH/OCER/DFOI/	(Mr.) Taro Kanai MIC International Corp.	K091935
2015-3810	05/11/2015 06/09/2015	FDA/OC/OES/DFOI/	David Mangione Govzilla, Inc.	LIST OF FOIA REQUESTS LAST 12 MONTHS
2015-3811	05/11/2015 06/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	David Mangione Govzilla, Inc.	CANGENE CORPORATION, CANADA - EIR 02/03/2015 - 02/03/2015
2015-3812	05/11/2015 06/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Peter R. Breggin Center for the Study of Empathic Therapy	GUIDANCE RECS FOR PHARMACEUTICAL COMPANIES RE TESTING NEW DRUGS FOR TREATMENT OF SCHIZOPHRENIA OR PSYCHOSIS IN CHILDREN AND ADULTS 01/01/2000 - 01/01/2015

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		FDA/OMPT/CDER/GRP/DIDP/		
2015-3813	05/11/2015 06/09/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jeffrey Shaman, Ph.D. Coriell Life Sciences	ADR DATA 01/01/2012 - 12/31/2014
2015-3814	05/11/2015 06/09/2015	FDA/OMPT/CDRH/OCER/DFOI/	David Livingston Katecho, Inc	K110825
2015-3815	05/11/2015 06/09/2015	FDA/OMPT/CDRH/OCER/DFOI/	Meditherm Med2000 K003332 Vikas Khurana	K003332, MEDITHERM RESPONSE TO WARNING LETTER
2015-3816	05/11/2015 06/09/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jaya Ayyagari Dr. Reddy's Laboratories Inc.	NDA 017422
2015-3817	05/11/2015 06/09/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Kristin Bergeson MEDIVATORS INC	K09056
2015-3818	05/11/2015 06/09/2015	FDA/OMPT/CDRH/OCER/DFOI/	Kristin Bergeson MEDIVATORS INC	K123546
2015-3819	05/11/2015 06/09/2015	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	CTP GRANDFATHER DETERMINATIONS LIST 03/01/2011 - 03/31/2015
2015-3820	05/11/2015 06/09/2015	OC/ORR/ OC/ORR/ OC/ORR/ORM/ OC/ORR/ORM/ FDA/OMPT/CDRH/OCER/DFOI/	Comeron Ghobadi SAINT JOSEPH HOSPITAL	CLASS I MEDICAL DEVICE RECALLS 11/1/2002
2015-3821	05/11/2015 06/09/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 17469
2015-3822	05/11/2015 06/09/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 12107
2015-3823	05/11/2015	FDA/OMPT/CDRH/OCER/DFOI/	Christopher Thomas Donner	K122538

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	06/09/2015		SI-TECHNOLOGY, LLC	
2015-3824	05/11/2015 06/09/2015	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	Monica Willits Stray Dog Cafe	CORR BETWEEN FDA AND MY CHAI RE WARNING LETTER VIOLATIONS 11/07/2014 - 05/08/2015
2015-3825	05/11/2015 06/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	melody chang chang, melody	DOCETAXEL, TAXOTERE - AERS
2015-3826	05/11/2015 06/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Xiaonan Gao Keck Graduate Institute	NDA 021336, NDA 021708
2015-3827	05/11/2015 06/09/2015	FDA/OFVM/CFSAN/OCD/EOS/	Merle Zimmermann AMERICAN HERBAL PRODUCTS ASSOCIATION	DIETARY SUPPLEMENT AERS 07/01/2013 - 12/31/2014
2015-3828	05/11/2015 06/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Chris Cole Pike Photocopy, Inc.	COUNTERFEIT BOTOX - AERS, TOXICOLOGICAL EFFECTS
2015-3829	05/11/2015 06/09/2015	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Mark Collette HOUSTON CHRONICLE	BLUE BELL CREAMERIES - LAB RESULTS, ENVIRONMENTAL ASSESSMENTS, ETC 02/01/2015 - 05/08/2015
2015-3830	05/11/2015 06/09/2015	FDA/OC/OES/DFOI/	Holly Ennis Ennis & Ennis, P.A.	ESSURE - APPROVAL RECS
2015-3831	05/11/2015 06/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ryan Dunnegan Kennedy Capital Management	ZIOPTAN - SBA
2015-3832	05/12/2015 06/10/2015	FDA/OC/OES/DDM/ FDA/OMPT/CDRH/OCER/DFOI/	STEPHEN A SEACH ESQ SEACH LAW OFCS	DORNIER MEDICAL SYSTEMS INC - LITHOTRIPTERS SS&E
2015-3833	05/12/2015 06/10/2015	FDA/OC/OES/DFOI/	Doe J	SODIUM PERBORATE MONOHYDRATE, POTASSIUM MONOPERSULFATE WARNINGS, RPTS, CONSUMER ALERTS, ETC
2015-3834	05/12/2015	FDA/OMPT/CDER/ORP/DIDP/	PAUL B CALLAHAN	EUROFINS MEDINET, BREDA, THE NETHERLANDS - EIR 11/3-7/08 (REDACTED)

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	06/10/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES RIVER LABS	
2015-3835	05/12/2015 06/10/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PETER S REICHERTZ SHEPPARD MULLIN RICHTER & HAMPTON, LLP	NOVARTIS - SANOREX (MAZINDOL) NDA 17-247 PI
2015-3836	05/12/2015 06/10/2015	OC/ORA/ OC/ORA/	SHARON BIERMANN BIERMANN, SHARON	METHODS FOR CONDUCTING RECALL EFFECTIVENESS CHECKS
2015-3837	05/12/2015 06/10/2015	FDA/OMPT/CDRH/OCER/DFOI/	RIKKI MITCHELL KGUN-TV	BAYER HEALTHCARE PHARMACEUTICALS INC - ESSURE INVESTIGATION RESULTS 3/26/15
2015-3838	05/12/2015 06/10/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	FORTEO - AERS
2015-3839	05/12/2015 06/10/2015	FDA/OMPT/CDRH/OCER/DFOI/	MARTIN O'CONNOR GERMAINE LABORATORIES INC	SHEATHING TECHNOLOGIES INC - SHEATHES STERILE ULTRASOUND GEL K130041
2015-3840	05/12/2015 06/10/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	RANTIDINE - RECS, RISK FACTORS
2015-3841	05/12/2015 06/10/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K132031
2015-3842	05/12/2015 06/10/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Katherine Nami Yoon UNIVERSITY OF PITTSBURGH	POST MARKET REQUIREMENTS AND COMMITMENT DATA SINCE 1970
2015-3843	05/12/2015 06/10/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Lois Chandler CARDIUM THERAPEUTICS	BB-IND 7471

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2015-3844	05/12/2015 06/10/2015	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Amar Eldaher American Pharmaceutical Ingredients, LLC	AMERICAN PHARAMCEUTICAL INGREDIENTS, LLC, WATERFORD, MI - 483, EIR 01/01/2015 - 05/05/2015
2015-3845	05/12/2015 06/10/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jesse McLean Toronto Star	SMITHKLINE BEECHAM, CORK, IRELAND; HOSPIRA HEALTHCARE INDIA; WYETH LEDERLE, ITALY ETC - 483
2015-3846	05/12/2015 06/10/2015	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ OC/ORARM/ OC/ORARM/	Michael Lindenberger THE DALLAS MORNING NEWS	LIST OF FOOD SAFETY INSPECTIONS IN TEXAS, LISTERIA RECS, BLUE BELL CORR 01/01/2012 - 05/10/2015
2015-3847	05/12/2015 06/10/2015	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	Doe J	INDIVIDUAL RECS
2015-3848	05/12/2015 06/10/2015	FDA/OFVM/CFSAN/OCD/EOS/	Garry M. Wiltshire The Dow Chemical Company	FCN 1505
2015-3849	05/12/2015 06/10/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Freddie Lee Epic International (Thailand) Co., Ltd.	K944692
2015-3850	05/12/2015 06/10/2015	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2013-5575, 2013-7111, 2014-8117
2015-3851	05/12/2015 06/10/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-3128 - REQUEST LETTER ONLY
2015-3852	05/12/2015 06/10/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-2821 - REQUEST LETTER ONLY
2015-3853	05/12/2015 06/10/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-3170 - REQUEST LETTER ONLY
2015-3854	05/12/2015 06/10/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-2756 - REQUEST LETTER ONLY
2015-3855	05/12/2015 06/10/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-3182 - REQUEST LETTER ONLY
2015-3856	05/12/2015 06/10/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-2743 - REQUEST LETTER ONLY

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2015-3857	05/12/2015 06/10/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-3219 - REQUEST LETTER ONLY
2015-3858	05/12/2015 06/10/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-2675 - REQUEST LETTER ONLY
2015-3859	05/12/2015 06/10/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-3305 - REQUEST LETTER ONLY
2015-3860	05/12/2015 06/10/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-2655 - REQUEST LETTER ONLY
2015-3861	05/12/2015 06/10/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-3332 - REQUEST LETTER ONLY
2015-3862	05/12/2015 06/10/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-2653 - REQUEST LETTER ONLY
2015-3863	05/12/2015 06/10/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-3431 - REQUEST LETTER ONLY
2015-3864	05/12/2015 06/10/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-2634 - REQUEST LETTER ONLY
2015-3865	05/12/2015 06/10/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-3336 - REQUEST LETTER ONLY
2015-3866	05/12/2015 06/10/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-2622 - REQUEST LETTER ONLY
2015-3867	05/12/2015 06/10/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-3443 - REQUEST LETTER ONLY
2015-3868	05/13/2015 06/11/2015	FDA/OMPT/CDRH/OCER/DFOI/	Kathleen Bostwick Medication Control Systems, LLC	DEN060002/K051338, K150174
2015-3869	05/13/2015 06/11/2015	FDA/OMPT/CDRH/OCER/DFOI/	Dr. Diane Sudduth Imangel Consulting	K140306, K130943
2015-3870	05/13/2015 06/11/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Becky Hartman Teva Pharmaceuticals	PROAIR RESPCLICK 205636 AERS
2015-3871	05/13/2015 06/11/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Becky Hartman Teva Pharmaceuticals	SYNRIBO AERS

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		FDA/OMPT/CDER/ORP/DIDP/		
2015-3872	05/13/2015 06/11/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Becky Hartman Teva Pharmaceuticals	QUARTETTE - AERS
2015-3873	05/13/2015 06/11/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michele Sinoway LACHMAN CONSULTANT SERVICES, INC.	NDA 021008 S030
2015-3874	05/13/2015 06/11/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Becky Hartman Teva Pharmaceuticals	QNASL - AERS
2015-3875	05/13/2015 06/11/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michele Sinoway LACHMAN CONSULTANT SERVICES INC	NDA 021008 S030
2015-3876	05/13/2015 06/11/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Becky Hartman Teva Pharmaceuticals	ADASUVE - AERS
2015-3877	05/13/2015 06/11/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Becky Hartman Teva Pharmaceuticals	TBO-FILGRASTIM - AERS
2015-3878	05/13/2015 06/11/2015	FDA/OGROP/ORP/SE-FO/SJN-DO/SJN-CB/	Caleb Marker Ridout Lyon + Ottoson LLP	AMGEN, JUNCOS, PUERTO RICO - INSPECTION RECS, WARNING LETTERS 10/01/2013 - 05/01/2015
2015-3879	05/13/2015 06/11/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	SENZA SYSTEM PMA
2015-3880	05/13/2015 06/11/2015	OC/ORP/ OC/ORP/ FDA/OGROP/ORP/SW-FO/DAL-DO/DAL-CB/	Jesse Newman THE WALL STREET JOURNAL	BLUE BELL CREAMERIES - INSPECTION RECS 01/01/2012 - 05/12/2015

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		FDA/OGROP/ORR/SE-FO/NOL-DO/NOL-CB/		
2015-3881	05/13/2015 06/11/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Becky Hartman Teva Pharmaceuticals	ARGATROBAN - AERS
2015-3882	05/13/2015 06/11/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mark Prinz Registrar Corp	DMF SPREADSHEET
2015-3883	05/13/2015 06/11/2015	FDA/OMPT/CDRH/OCER/DFOI/	MARILYNN WHITNEY COVINGTON & BURLING LLP	NEOMEDIX CORP - WARNING LTR, CO RESP 2/2/14
2015-3884	05/13/2015 06/11/2015	OC/ORR/ OC/ORR/ FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/	RYAN OSTERHOLM PRITZKER OLSEN	BLU BELL CREAMERIES - LISTERIA OUTBREAK
2015-3885	05/13/2015 06/11/2015	FDA/OMPT/CDRH/OCER/DFOI/	SEAMUS O'CONNOR NATUS MANUFACTURING LTD	NATUS MANUFATURING LTD - EIR 1/20-23/14
2015-3886	05/13/2015 06/11/2015	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OO/OHR/	Doe J	INDIVIDUAL RECS
2015-3887	05/13/2015 06/11/2015	OC/ORR/ORM/ OC/ORR/ORM/	KIMBERLY SYRE ATTENTION TO DETAIL	DRUG, BIOLOGIC, MEDICAL DVC, DIETARY SUPPLEMENTS - ADDRESS DATABASE
2015-3888	05/13/2015 06/11/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LYNN W. MEHLER HOGAN LOVELLS LLP	ROXANE LABORATORIES INC - REMS FOR ALOSETRON PRODUCTS
2015-3889	05/13/2015 06/11/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Doe J	INDIVIDUAL RECS
2015-3890	05/13/2015 06/11/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	MICHAEL S. OLIN MICHAEL S OLIN PA	INTRA LOCK INTL BK110053
2015-3891	05/13/2015 06/11/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARK A. HAMMERVOLD GIDEON COOPER & ESSARY	CASE NOS 4184938, 5671663, 6034579

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		FDA/OMPT/CDER/GRP/DIDP/		
2015-3892	05/13/2015 06/11/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DIANA J. KEIR NAIR & LEVIN PC	DELALUTIN - AERS, STUDIES, CMLPNTS, ETC
2015-3893	05/13/2015 06/11/2015	FDA/OC/OES/DFOI/	KEVIN P. WAGNER FAEGRE BAKER DANIELS	GUIDANT ANCURE ENDOGRAFT SYS - RECALL, CORR, INVESTIGATION RECS, ETC
2015-3894	05/14/2015 06/12/2015	FDA/OMPT/CDRH/OCER/DFOI/	RachaelHagan EMORY UNIVERSITY	K080650
2015-3895	05/14/2015 06/12/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	barry pressman PureTek Corporation	ANDA 088042, ANDA 74514 APPROVAL LETTERS
2015-3896	05/14/2015 06/12/2015	FDA/OMPT/CDRH/OCER/DFOI/	Jonathan Hayman N/A	K123985
2015-3897	05/14/2015 06/12/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Stephen Doogan Real Life Sciences	HUMIRA, ENBREL - AERS
2015-3898	05/14/2015 06/12/2015	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Helena Champion Drug Quality Assurance, LLC	ADVANCED COSMETIC RESEARCH LABORATORIES, CHATTSWORTH, CA - EIR, 483, WARNING LETTER 01/01/2011 - 05/12/2015
2015-3899	05/14/2015 06/12/2015	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink	2015-3223
2015-3900	05/14/2015 06/12/2015	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Justin Wales Carlton Fields Jordan Burt	DERMAMEDICS LLC - RECALL RECS ETC
2015-3901	05/14/2015 06/12/2015	OC/ORA/ORM/ OC/ORA/ORM/ OC/CVM/OCD/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Wendy Kowal Wendy Kowal	LIST OF FIRMS APPROVED FOR COLLECTION OF PMSG

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		FDA/OMPT/CDER/ORP/DIDP/		
2015-3902	05/14/2015 06/12/2015	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	LESLIE RAMSEY FDA NEWS	CORTEX MANUFACTURING INC, LAKE STEVENS, WA; DENTAL ALLIANCE HOLDINGS LLC, ALBANY, OR; SPIRATION INC, REDMOND, WA, ETC - 483S 4/1-30/15
2015-3903	05/14/2015 06/12/2015	FDA/OMPT/CDRH/OCER/DFOI/	LESLIE RAMSEY FDA NEWS	COASTAL CONTACTS INC, VANCOUVER, CANADA; ORTHOHEM LTD, NOTTINGHAM, UK; WU'S TECH CO LTD, HSIN-CHU, TAIWAN, ETC - 483S 4/1-30/15
2015-3904	05/14/2015 06/12/2015	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	LESLIE RAMSEY FDA NEWS	ROCKWELL MEDICAL INC, WIXOM, MI; MONOSOL RX LLC, PORTAGE, IN; PROGRESSIVE DYNAMICS INC, MARSHALL, MI, ETC - 483S 4/1-30/15
2015-3905	05/14/2015 06/12/2015	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	LESLIE RAMSEY FDA NEWS	ARSTASIS INC, FREMONT, CA; SILK ROAD MEDICAL INC, SUNNYVALE, CA; OCUMETRICS INC, MOUNTAIN VIEW, CA, ETC - 483S 4/1-30/15
2015-3906	05/14/2015 06/12/2015	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	LESLIE RAMSEY FDA NEWS	TRIAD ISOTOPES, MACON, GA; ETHICON INC, CORNELIA, GA - 483S 4/1-30/15
2015-3907	05/14/2015 06/12/2015	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	LESLIE RAMSEY FDA NEWS	MAXIM BIOMEDICAL INC, ROCKVILLE, MD; LC TECHNOLOGIES INC, FAIRFAX, VA; HAWKNAD MANUFACTURING INDUSTRIES INC. ALEXANDRIA, VA - 483S 4/1-30/15
2015-3908	05/14/2015 06/12/2015	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	LESLIE RAMSEY FDA NEWS	ORGAN RECOVERY SYSTEMS INC, ITASCA, IL - 483S 4/1-30/15
2015-3909	05/14/2015 06/12/2015	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	LESLIE RAMSEY FDA NEWS	B & P INDUSTRIAL INC, TULSA, OK; GRESKO PRODUCTS INC, STAFFORD, TX; ELITE MASSAGERS LLC, RICHARDSON, TX, ETC - 483S 4/1-30/15
2015-3910	05/14/2015 06/12/2015	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	LESLIE RAMSEY FDA NEWS	TRONOX, GREEN RIVER, WY; OTTO BOCK HEALTHCARE, SALT LAKE CITY, UT; BROWN'S COMPUNDING CENTER INC, ENGLEWOOD, CO - 483S 4/1-30/15
2015-3911	05/14/2015 06/12/2015	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	LESLIE RAMSEY FDA NEWS	CFS DENTAL INC, HIALEAH, FL; ULTROID TECHNOLOGIES INC, TAMPA, FL; GENICO INC, WINTER PARK, FL, ETC - 4/1-30/15
2015-3912	05/14/2015 06/12/2015	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	LESLIE RAMSEY FDA NEWS	PETNET SOLUTIONS INC, OVERLAND PARK, KS; HOSPIRA INC, MCPHERSON, KS; WEEKS & LEO CO INC, ETC - 483S 4/1-30/15
2015-3913	05/14/2015 06/12/2015	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	LESLIE RAMSEY FDA NEWS	PRECISION COMPOUNDING CENTERS LLC, BREA, CA; TMJ SOLUTIONS INC, VENTURA, CA; AVRIO BIOPHARMACEUTICALS LLC, IRVINE, CA, ETC - 483S 4/1-30/15
2015-3914	05/14/2015 06/12/2015	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	LESLIE RAMSEY FDA NEWS	ALLESEE ORTHODONTIC INC, STURTEVANT, WI; FAGRON INC, ST PAUL, MN - 483S 4/1-30/15
2015-3915	05/14/2015	FDA/OGROP/ORASE-FO/NOL-	LESLIE RAMSEY	HOLLYWOG LLC, CHATTANOOGA, TN; SANMINA INC,

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	06/12/2015	DO/NOL-CB/	FDA NEWS	HUNTSVILLE, AL; MAX MOBILITY LLC, ANTIOCH, TN - 483S 4/1-30/15
2015-3916	05/14/2015 06/12/2015	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	LESLIE RAMSEY FDA NEWS	BROOKFIELD MEDICAL/SURGICAL SUPPLY INC, BROOKFIELD, CT; INFRARED X INC, BURLINGTON, MA; POLYCARBON INDUSTRIES INC, NEWBURYPORT, MA - 483S 4/1-30/15
2015-3917	05/14/2015 06/12/2015	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	LESLIE RAMSEY FDA NEWS	ALTAIRE PHARMACEUTICALS INC, AQUEBOGUE, NY; RTF MANUFACTURING CO LLC, HUDSON, NY; PURINEPHARMA LLC, MASSENA, NY - 483S 4/1-30/15
2015-3918	05/14/2015 06/12/2015	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	LESLIE RAMSEY FDA NEWS	CUSTOM ULTRASONICS INC, IVYLAND, PA; POLYSCIENCES INC, WARRINGTON, PA - 483S 4/1-30/15
2015-3919	05/14/2015 06/12/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LESLIE RAMSEY FDA NEWS	AMGEN TECHNOLOGY IRELAND, DON LAOGHAIRE, IRELAND; LUPIN LTD, AURANGBAD, INDIA; PFIZER PHARMACEUTICALS LTD, DALIAN, CHINA - 483S 4/1-30/15
2015-3920	05/14/2015 06/12/2015	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	LESLIE RAMSEY FDA NEWS	SONAR PRODUCTS INC, CARLSTADT, NJ; DERMACEUTICAL LABORATORIES LLC, TETERBORO, NJ; THERAKOS INC, BRIDGEWATER, NJ, ETC - 483S 4/1-30/15
2015-3921	05/15/2015 06/15/2015	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	POST FOODS WARNING LETTER RESPONSE 03/10/2015
2015-3922	05/15/2015 06/15/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Wanda Sullivan Covance Labs	NDA 21484 PROTOCOLS
2015-3923	05/15/2015 06/15/2015	FDA/OFVM/CFSAN/OCD/EOS/	Nathan Mayer Nathan Mayer	BABY FORMULA - LIST OF PRODUCERS 05/12/2000 - 05/12/2015
2015-3924	05/15/2015 06/15/2015	OC/ORA/ OC/ORA/ OC/CVM/OCD/	Wendy Kowal Wendy Kowal	LIST OF EXPORTERS WHO DELIVER PMSG TO US
2015-3925	05/15/2015 06/15/2015	FDA/OFVM/CFSAN/OCD/EOS/	Willie Clayton SAINT LOUIS UNIVERSITY HEALTH SCIENCES CENTER	SURVEY TOOL USED TO COLLECT DATA FOR FDA HEALTH AND DIET SURVEY
2015-3926	05/15/2015 06/15/2015	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	CPT1400711
2015-3927	05/15/2015 06/15/2015	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Raymond Murray The Gillette Company	GILLETTE COMPANY, ANDOVER, MA - EIR 01/23/2014 - 06/30/2014

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2015-3928	05/15/2015 06/15/2015	FDA/OMPT/CDRH/OCER/DFOI/	Marci L. Waddle Salim-Beasley, LLC	ESSURE - ADVERSE EVENTS
2015-3929	05/15/2015 06/15/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	G. Srinivas Zydus Pharmaceuticals USA Inc.	NDA 018716
2015-3930	05/15/2015 06/15/2015	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Carla Nolden AMERICAN RED CROSS	AMERICAN RED CROSS GEORGIA LOCATIONS - EIR 06/02/2010 - 03/19/2015
2015-3931	05/15/2015 07/02/2015	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Helena Champion Drug Quality Assurance, LLC	NAPP TECHNOLOGIES INC - EIR, 483, WARNING LETTER 01/01/2011 - 05/13/2015
2015-3932	05/15/2015 06/15/2015	FDA/OO/OFBA/OAGS/	Rachel Johnson FOI Services, Inc.	FDA CONTRACTS WITH DUNS & BRADSTREET 01/01/2005 to 05/30/2015
2015-3933	05/15/2015 06/15/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Helena Champion Drug Quality Assurance, LLC	JAGSONPAL PHARMACEUTICALS LIMITED, INDIA - 483, EIR, WARNING LETTER 01/01/2011 - 05/31/2015
2015-3934	05/15/2015 06/15/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	SIMPONI - AERS
2015-3935	05/15/2015 06/15/2015	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Deborah Currllin Volcano Corporation	VOLCANO CORPORATION, RANCHO CORDOVA, CA - EIR 10/01/2012 - 06/28/2013
2015-3936	05/15/2015 06/15/2015	FDA/OMPT/CDRH/OCER/DFOI/	Joel Barr Stericycle, Inc.	K063722
2015-3937	05/15/2015 06/15/2015	FDA/OMPT/CDRH/OCER/DFOI/	Eliza Lemons Brain Sentinel	K864690
2015-3938	05/15/2015 06/15/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sibet Freides Sibet Freides	OXTELLAR XR - AERS
2015-3939	05/15/2015 06/15/2015	OC/ORA/ OC/ORA/	Rachel Johnson FOI Services, Inc.	BLUE BELL CREAMERIES INSPECTION RECS

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		FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/		
2015-3940	05/15/2015 06/15/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachelle Fitzgerald ConMed Corporation	K122462
2015-3941	05/15/2015 06/15/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachelle Fitzgerald ConMed Corporation	K926104
2015-3942	05/15/2015 06/15/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K102452
2015-3943	05/15/2015 06/15/2015	FDA/OMPT/CDRH/OCER/DFOI/	Anna Lisa Somera Briteseed, LLC	K072932, K082870, K032315
2015-3944	05/15/2015 06/15/2015	FDA/OMPT/CDRH/OCER/DFOI/	Madeline Tormoen Tormoen, Madeline	INDIVIDUAL RECS
2015-3945	05/15/2015 06/15/2015	FDA/OMPT/CDRH/OCER/DFOI/	Julie Hall Butler, Vines and Babb, PLLC	MEDWATCH REPORT
2015-3946	05/15/2015 06/15/2015	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	G. Srinivas Zydus Pharmaceuticals USA Inc.	ANDA 075113
2015-3947	05/15/2015 06/15/2015	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Jean Kieselburg The Patient Advocate	PREGABALIN - MEDWATCH REPORTS OR OTHER PRE OR POST MARKET REPORTS; AERS
2015-3948	05/15/2015 06/15/2015	FDA/OMPT/CDRH/OCER/DFOI/	Holly Kelly Ennis, Esq. Ennis & Ennis, P.A.	ESSURE - PMA
2015-3949	05/15/2015 06/15/2015	FDA/OMPT/CDRH/OCER/DFOI/	NATALIE HICHAK TELEFLEX MEDICAL	TELEFLEX MEDICAL, NORRISVILLE, NC - NEEDESCOPIC RESPOSABLE DVC SYS K132232; MINI-LAP BIPOLAR ELECTROCAUTERY DVC K113597; ARVIKI LAPAROSCOPIC ASPIRATION STRUMENT K102274, ETC
2015-3950	05/15/2015 06/15/2015	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	JENNY E BLAU NATIONAL INSTITUTES OF HEALTH DEPT OF HEALTH HUMAN SERVICES	SITAGLPTIN, SAXAGLIPTIN, LINAGLIPTIN, ETC - AERS 10/06, 7/06, 7/09, 2011 TO PRESENT, 2013 TO PRESENT
2015-3951	05/15/2015 06/15/2015	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	BENJAMIN L ENGLAND BENJAMIN L ENGLAND & ASSOCIATES LLC	LIST OF ALL BULK INGREDIENT DRUG PRODS SUBMITTED BY DOMESTIC & FOREIGN ESTABLISHMENTS 1/11 TO PRESENT

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2015-3952	05/15/2015 06/15/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DIANA J KEIR NAIR & LEVIN PC	DELALUTIN (17-HYDROXY PROGESTERONE CAPROATE INJ) - AERS
2015-3953	05/15/2015 06/15/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	COURTNEY CROSBY CROSBY, COURTNEY	BENICAR - AERS, LIST OF DRUGS BEING RECALLED
2015-3954	05/15/2015 06/15/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LYNN W MEHLER HOGAN LOVELLS LLP	ROXANE LABORATORIES INC - ALOSETRON MEMO TO SUPPORT DECISION TO APRVD & WAIVE REQUIREMENTS
2015-3955	05/15/2015 06/15/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jonathan Thwaite University of St. Gallen, Switzerland	ORANGE BOOK WEB LINK
2015-3956	05/15/2015 06/15/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Olena Izhak University of Helsinki (FINLAND)	ANDA APPROVAL LETTERS
2015-3957	05/15/2015 06/15/2015	OC/CVM/OCD/	michael Fry Zoetis Inc.	NADA 141-042 FOIA SUMMARY
2015-3958	05/15/2015 06/15/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dr. Pipasha Biswas Symogen Ltd	SOLIRIS - AERS
2015-3959	05/15/2015 06/15/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	AMANDA PHIPPS RESEARCH INVESTMENT INC	STAFF MANUAL GUIDE 8/31/76
2015-3960	05/15/2015	FDA/OMPT/CDER/ORP/DIDP/	Thea Piltzecker	CANNABIDIOL TRIAL SUBMISSION RECS 01/01/2013 -

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	06/15/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Partisan Pictures	01/01/2015
2015-3961	05/15/2015 06/15/2015	FDA/OFVM/CFSAN/OCD/EOS/	James A. Boiani Epstein Becker Green	DMAA CAERS
2015-3962	05/15/2015 06/15/2015	FDA/OMPT/CDRH/OCER/DFOI/	Mark Harris IEEE Spectrum	GOOGLE INC - COMMUNICATIONS WITH RE DEVELOPMENT OF CONTACT LENSES WITH INTEGRATED ELECTRONIC ELEMENTS 01/01/2013 - 05/13/2015
2015-3963	05/15/2015 06/15/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LILIAM RODRIGUEZ IVARZ LILIAM RODRGUEZ IVARZ LAW OFC	AVELOX (MOXIFLOXACIN) - AERS
2015-3964	05/15/2015 06/15/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	William Cady, PharmD QUALITY RESEARCH SERVICES	ANDA 075074 PHARMACOKINETIC REVIEW
2015-3965	05/15/2015 06/15/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Silvia Schaffer The Reardon Law Firm	MEDROXYPROGESTERONE ACETATE - AERS
2015-3966	05/15/2015 06/15/2015	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	VICTOR I GREEN KCAS LLC	KCAS LLC BIOANALYTICAL FACILITY, SHAWNEE, KS - EIRS 8/25/14, 9/2/14
2015-3967	05/15/2015 06/15/2015	FDA/OGROP/ORASW-FO/LOS-DO/LOS-CB/	DAWN HAAKE NUVASIVE INC	NU VASIVE INC, SAN DIEGO, CA - EIR 2/14
2015-3968	05/15/2015 06/15/2015	FDA/OMPT/CTP/OD/	WILLIAM J MCGOWAN SILVER MCGOWAN & SILVER PC	US FLUE CURED TOBACCO GROWER - KENTUCKY RED, SILVER, GOLD, BLUE, GREEN TOBACCO SUSTASNIAL EQUIVALENCE RPTS
2015-3969	05/15/2015 06/15/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORASW/OCI/ OC/ORASW/OCI/	RUSSELL CAROLLO CAROLLO, RUSSELL	SYNACTHEN (SYNACTHEN DEPOT) - ACTH EIRS, 483S, WARNING LTRS, ETC
2015-3970	05/15/2015	FDA/OO/OFBA/OAGS/	PAMELA LIPSCOMB	DR REUBEN MATALON - RESP OF P;HENYLKETONURIA TO TETRAHYDROBIOTERN (BH4) PROJECT GRANT APPL

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	06/15/2015	FDA/OO/OFBA/OAGS/	ARENT FOX LLP	5R01FD002006-1 THROUGH 5401FD002006-03-2005
2015-3971	05/15/2015 06/26/2015	FDA/OFVM/CFSAN/OCD/EOS/	LAURA MACCLEERY CENTER FOR SCIENCE IN PUBLIC INTEREST	SILICON DIOXIDE - GRN 298; ACACIA OR GUM ARABIC - GRN 48; LACTOBACILLUS - GRN 463, 409,324, ETC
2015-3972	05/15/2015 06/15/2015	FDA/OFVM/CFSAN/OCD/EOS/	LAURA MACCLEERY CENTER FOR SCIENCE IN PUBLIC INTEREST	MARLOW FOODS LTD - QUORN-BRAND MEAT SUBSTITUTE CMLPLNTS 5/1-8/15
2015-3973	05/15/2015 06/23/2015	FDA/OFVM/CFSAN/OCD/EOS/	LAUREN MACCLEERY CENTER FOR SCIENCE IN PUBLIC INTEREST	PETITIONS FOR EXEMPTION FOR PREEMPTION
2015-3974	05/15/2015 06/15/2015	FDA/OC/OES/DFOI/	READE WILSON ENVIROMENTAL WORKING GROUP	ASBESTOS - SOURCING OF TALC, TESTING SURVEY, CUMM 2000 TO PRESENT, 2009 TO 2010
2015-3975	05/18/2015 06/16/2015	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	TERESA A CURTIN ESQ WEITZ & LUXEMBERG PC	2014-344, 2009-10122, 2014- 8613, ETC
2015-3976	05/18/2015 06/16/2015	FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/	LISA RONAYNE RONAYNE, LISA	90 MEATS DEPOT & LATINO FOOD DISTRIBUTORS, SPRINGFILED, MA - HEALTH, SAFETY & SANITARY INSPS, VIOLATIONS, CMLPLNTS LAST 15-20 YRS
2015-3977	05/18/2015 06/16/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/ORAN/ OC/ORAN/ FDA/OGROP/ORANE-FO/FLA- DO/FLA-CB/	SUSAN FUENTES FUENTES, SUSAN	ALLERGAN - RESTASIS (CYCLOSPORINE) RPT
2015-3978	05/18/2015 06/16/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CINDY SHEARER UNIV OF MISSOURI SCHOOL OFLAW LIBRARY	ORANGE BOOK 1986, 2001-2003
2015-3979	05/18/2015 06/16/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	SHREYA AGARWAL NEW YORK UNIVERSITY	MERCK & CO INC - GARDASIL HPV VACCINE NUMBER OF CMLPLNTS UNTL 3/15
2015-3980	05/18/2015 06/16/2015	OC/ORAN/ORM/ OC/ORAN/ORM/	GAIL LESSICK LACHMAN CONSULTANT SERVICES, INC.	DRUG COMPANIES, MEDICAL DVC MFRS, BLOOD ESTABLISHMENTS, ETC - FOREIGN AND DOMESTIC INSPS 2/15 TO 3/15
2015-3981	05/18/2015	FDA/OMPT/CDER/GRP/DIDP/	Nelson Rivera	MYLAN, INDIA - 483 12/01/2014 - 03/01/2015

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	06/16/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	RIVERA, NELSON	
2015-3982	05/18/2015 06/16/2015	FDA/OFVM/CFSAN/OCD/EOS/	Coby Beckers DSM Information Services	FOOD ADVISORY COMMITTEE MEETING TRANSCRIPT 2/24/03
2015-3983	05/18/2015 06/16/2015	FDA/OFVM/CFSAN/OCD/EOS/	Wendy Lane Wendy Lane	MONSTER ENERGY ADVERSE EVENTS
2015-3984	05/18/2015 06/16/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K091780
2015-3985	05/18/2015 06/16/2015	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	David Gilbert David Gilbert	REAL SCIENTIFIC HEMP OIL - LAB RESULTS
2015-3986	05/18/2015 06/16/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K120301
2015-3987	05/18/2015 06/16/2015	OC/ORA/OCI/ OC/ORA/OCI/	karen robinson-jacobs DALLAS MORNING NEWS	BLUE BELL CREAMERIES - OCI INVESTIGATION RECS 01/01/2010 - 05/15/2015
2015-3988	05/18/2015 06/16/2015	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/ORO/DIOP/	Zetetic, Inc. ZETETIC INC	FDA ENTRY RECS 5/1/15 TO 5/15/15
2015-3989	05/18/2015 06/16/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Margaret Sestrom on behalf of Alicia Holsey PFIZER	BLA 103795 - SBA S-1004
2015-3990	05/18/2015 06/16/2015	FDA/OMPT/CDRH/OCER/DFOI/	Kelli Dryer STRYKER SUSTAINABILITY SOLUTIONS	K133853
2015-3991	05/18/2015 06/16/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	INDIVIDUAL RECS
2015-3992	05/18/2015 06/16/2015	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	karen robinson jacobs dallas morning news	BLUE BELL CREAMERIES - ENVIRONMENTAL TESTING 01/01/2010 - 05/15/2015
2015-3993	05/18/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson	K120298

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	06/16/2015		FOI Services, Inc.	
2015-3994	05/18/2015 06/16/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K091781
2015-3995	05/18/2015 06/16/2015	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Majerczak Nalco, An Ecolab Company	FAP3B3696
2015-3996	05/18/2015 06/16/2015	FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/	Marc C. Sanchez, Esq. Contract In-House Counsel Consl. LLC	ECLIPSE AESTHETICS - 483, RESPONSE, CLOSE OUT ETC 02/01/2014 - 01/31/2015
2015-3997	05/18/2015 06/16/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lauren Welling Sanders Phillips Grossman	XARELTO - APPLICATION, INVESTIGATION, TESTING ETC
2015-3998	05/18/2015 06/16/2015	OC/ORR/ORM/ OC/ORR/ORM/	Jacqueline Pitts Pitts, Jacqueline	QUALITY ASSURANCE LABORATORIES FOR FOOD ANALYSIS
2015-3999	05/18/2015 06/16/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Melissa Truffa AbbVie	10175042, 10175158, 10355704, ETC
2015-4000	05/18/2015 06/16/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K120296
2015-4001	05/18/2015 06/16/2015	FDA/OC/OES/DFOI/	Robert Forner Hydrite Chemical Co	DOMESTIC FOOD FACILITY REGISTRATION
2015-4002	05/18/2015 06/16/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Melissa Truffa AbbVie	10069989, 10283699, 10353121 ETC
2015-4003	05/18/2015 06/16/2015	FDA/OC/OES/DFOI/	Jesse Newman THE WALL STREET JOURNAL	ICE CREAM INSPECTIONS 01/01/2010 - 05/15/2015
2015-4004	05/19/2015 06/17/2015	FDA/OMPT/CDRH/OCER/DFOI/	STEPHANIESIMMONS JOHNSON GRAFFE ET AL	OLYMPUS - DUODENOSCOPE MDRS
2015-4005	05/19/2015 06/17/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MANOJ GARG MERRILL LYNCH	DR REDDY'S LABS, ANDHRA PRADESH, INDIA - FTO 7 ORAL SOLID INJ FROMULATIONS 483

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		FDA/OMPT/CDER/GRP/DIDP/		
2015-4006	05/19/2015 06/17/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MATTHEW MINGUS LAW OFC STEVEN R ANDREWS PA	JANSSEN PIIARMS - LEVAQUIN (LEVOFLOXACIN) NDA 020-634/.004,012.013, ETC LABELS CERTIFIED
2015-4007	05/19/2015 06/17/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DON J MIZERK HUSCH BLACKWELL LLP	FRESENIUS KABI USA - AZITHROMYCIN INJ NDA 65-179 12/13/05; PILVA HERVATSKA DOLO- AZITHROMYCIN INJ NDA 65-265 1/18/07; HOSPIRA - AZITHROMYCIN INJ NDA 65-500 6/26/09, ETC APRVL LTRS
2015-4008	05/19/2015 06/17/2015	FDA/OFVM/CFSAN/OCD/EOS/	QUIANA A MONTGOMERY Keller and Heckman LLP	QUALITAS HEALTH - ALMEGA PL OMEGA-3 OIL NEW DIETARY INGREDIENT NOTIFICATION (NDIN)
2015-4009	05/19/2015 06/17/2015	FDA/OFVM/CFSAN/OCD/EOS/	QUIANA A MONTGOMERY Keller and Heckman LLP	BIS (2,2,6,6-TETRAMETHYL-4-PIPERIDINYL SEBACATE TINUVIN.770) - TOXICOLOGY RVWS
2015-4010	05/19/2015 06/17/2015	OC/ORA/OCI/ OC/ORA/OCI/	LAUREN APPEL LECLAIR RYAN	INTEGRATED RESOURCES INC OR BIOGEN IDEC - MR LEI YIIN'S COMM 1/1/11-12/31/11
2015-4011	05/19/2015 06/17/2015	FDA/OC/OES/DFOI/ OC/CVM/OCD/	KATHLEEN GALLIHER GALLIHER, KATHLEEN	IAMS DOG FOOD - SALMONELLA OUTBREAK RECS 8/13
2015-4012	05/19/2015 06/17/2015	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	Jane Byrne William Reed Business Media	SHUR GREEN FARMS - WARNING LETTER RESPONSE TO APRIL 2015 WARNING LETTER
2015-4013	05/19/2015 06/17/2015	FDA/OMPT/CDRH/OCER/DFOI/	Devyani Nanduri Theranova, LLC	K003289, K022287, K063442 ETC
2015-4014	05/19/2015 06/17/2015	FDA/OMPT/CDRH/OCER/DFOI/	Brian Overstreet ADVERSEEVENTS INC	FRESH MEDICAL LABORATORIES - REVIEW LETTERS 02/01/2015 - 02/28/2015
2015-4015	05/19/2015 06/17/2015	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Emily Rand CBS NEWS	BLUE BELL CREAMERIES - COMMUNICATIONS WITH FDA 01/01/2015 - 05/18/2015
2015-4016	05/19/2015 06/17/2015	FDA/OMPT/CDRH/OCER/DFOI/	Holly Rockweiler Holly Rockweiler Consulting	K133895
2015-4017	05/19/2015 06/17/2015	FDA/OMPT/OSMP/OOPD/	Maryse Brulotte Vestan, Inc.	LYMPHOSEEK - ORPHAN DRUG DESIGNATION RECS
2015-4018	05/19/2015 06/17/2015	FDA/OMPT/CDRH/OCER/DFOI/	Devyani Nanduri Theranova, LLC	K041771, K060963, K070201 ETC

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2015-4019	05/19/2015 06/17/2015	FDA/OMPT/CDRH/OCER/DFOI/	illumireg employee illumireg inc.	K061515
2015-4020	05/19/2015 06/17/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mike Ratcliffe EMC Analytics Group	NATCO PHARMA LTD, HYDERABAD, INDIA - 483 07/01/2014 - 12/31/2014
2015-4021	05/19/2015 06/17/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	G. Srinivas Zydus Pharmaceuticals USA Inc.	NDA 018687 SBA
2015-4022	05/19/2015 06/17/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Mauricio de la Garza Mauricio de la Garza	TELESTA TEHRAPEUTICS INC - MEETING MINUTES RE BLA MCNA 01/19/2014 - 05/18/2015
2015-4023	05/19/2015 06/17/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Carol Rea Flynn Gerresheimer Glass Inc	DMF 9543
2015-4024	05/19/2015 06/17/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	David Risinger Morgan Stanley	COMM BETWEEN FDA AND MALLINCKRODT RE METHYLPHENIDATE EXTENDED RELEASE AND CONCERTA
2015-4025	05/19/2015 06/17/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Steven Woloshin The Dartmouth Institute for Health Policy and Clinical Practice	APPROVAL RECS PREVIOUSLY RELEASED
2015-4026	05/19/2015 06/17/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Marc Elia BRIDGER CAPITAL LLC	COMPASSIONATE USE, INVESTIGATOR-SPONSORED OR PHYSICIAN-SPONSORED SINGLE PATIENT IND REQUESTS FOR USE OF BANKED TCELL THERAPIES FROM MEMORIAL SLOAN KETTERING

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2015-4027	05/19/2015 06/17/2015	OC/ORO/ORM/ OC/ORO/ORM/	David Mangione Govzilla, Inc.	LIST OF INSPECTIONS 03/15/2014 - 05/19/2015
2015-4028	05/20/2015 06/18/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jaymeth Maddox SCILUCENT LLC	HERAEUS PRECIOUS METALS GMBH & CO HG, IDT BIOLOGIKA - EIR, 483, COVER LETTER
2015-4029	05/20/2015 06/23/2015	FDA/OGROP/ORO/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORO/CE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORO/SW-FO/DEN-DO/DEN-CB/	Ryan Woods PRA Health Sciences	PRA HEALTH SCIENCES, CRI LIFETREE - EIR 11/15/2004 - 09/04/2014
2015-4030	05/20/2015 06/18/2015	FDA/OC/OES/DFOI/	Lisa Lilley Lisa Lilley	ESSENTIAL OILS
2015-4031	05/20/2015 06/18/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Patrick White Patrick White	MAXALT - AERS
2015-4032	05/20/2015 06/18/2015	FDA/OFVM/CFSAN/OCD/EOS/	Kristy Appelhans Herbalife International of America Inc	HERBALIFE - AERS
2015-4033	05/20/2015 06/18/2015	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink	2015-3551
2015-4034	05/20/2015 06/18/2015	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/PHI-DO/PHI-CB/	Nathan Koppikar TPG Public Equity Partners	FRESHPET - CONSUMER COMPLAINTS 01/01/2015 - 05/19/2015
2015-4035	05/20/2015 06/18/2015	FDA/OMPT/CDRH/OCER/DFOI/	Jeff Hendrickson Hendrickson, Jeff	BECTON DICKINSON GRAY TOP VACUTAINER 367001 APPROVAL RECS 05/01/1960 - 05/19/2015
2015-4036	05/20/2015 06/18/2015	FDA/OMPT/CDRH/OCER/DFOI/	CODY GILLIAMS MAYOR BROWN	MASIMO - CLEARANCE OF THEIR PRODS 2000 TO PRESENT
2015-4037	05/20/2015 06/18/2015	FDA/OMPT/CDRH/OCER/DFOI/	Copy of the 510(k)documents that we have submitted to FDA Solco Biomedical Co., Ltd.	K060702 K102458 K101818 ETC
2015-4038	05/20/2015	OC/ORO/	Allison Conway	SAMPLE RESULTS

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	06/18/2015	OC/ORA/ FDA/OGROP/ORPA-FO/LOS-DO/LOS-CB/	Allison Conway	
2015-4039	05/20/2015 06/18/2015	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	JANICE G DUBBER MONTGOMERY MCCrackEN WALKER ET AL	OTSUKA PHARMACEUTICAL & DEVELOPMENT & COMMERCIALIZATION INC - EIRS, 483S, COMM, ETC 3/6,7,10,11,13,14 ,18/14
2015-4040	05/20/2015 06/18/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	ABBY LAWLOR LAWLOR, ABBY	BEAT BIO THERAPUTICS - BB-412 THERAPY TREATMENT IND APPL, RVW, APRVL, ETC
2015-4041	05/20/2015 06/18/2015	FDA/OFVM/CFSAN/OCD/EOS/	KIERAN P DWYER DORSEY & WHITNEY LLP	USE OR EVALUATION OF THE LABEL DECAFFEINATD ON COFFEE OR TEA PRODS POLICY, COMM, RPTS, ETC
2015-4042	05/20/2015 06/18/2015	FDA/OC/OES/DFOI/	Doe J	ASPARTAME - HIPAA STATE OF MAINE RULES & REGULATIONS
2015-4043	05/20/2015 06/18/2015	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Peter Mione CutisPharma, Inc.	CUTISPHARMA - EIR 01/01/2014 - 05/20/2015
2015-4044	05/20/2015 06/18/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Adrienne Rothstein AbbVie	CROSS DISCIPLINE TEAM LEADER AND DIVISION OF PHARMACOVIGILANCE - MEMOS RE LABELING CHANGE FOR OLYSIO 01/01/2014 - 05/20/2015
2015-4045	05/21/2015 06/19/2015	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Doe J	INDIVIDUAL RECS
2015-4046	05/21/2015 06/19/2015	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDRH/OCER/DFOI/	DEAN KANTIS Life After Lasik	PROCEDURES FOR THE ISSUANCE OF A PUBLIC HEALTH ADVISORY
2015-4047	05/21/2015 06/19/2015	OC/CVM/OCD/	CAROLIN EWERS CFCS - CONSULT GMBH	MAXIMUM AMOUNT OF PERMETHRIN ALLOWED IN FDA-APRVD ANTI-FELA/TICK MEDICATION FOR CATS
2015-4048	05/21/2015 06/19/2015	FDA/OC/OES/DFOI/	Emily Rand CBS NEWS	BLUE BELL CREAMERIES, BROKEN ARROW, OK; BLUE BELL CREAMERIES BRENHEM, TX - INSPECTION RECS 01/01/2010 - 05/19/2015
2015-4049	05/21/2015 06/19/2015	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Kelly Beers (US Agent for Huvepharma AD) Huvepharma, Inc.	HUVEPHARMA INC, ST LOUIS, MO - EIR 02/14/2013 - 07/02/2014
2015-4050	05/21/2015	FDA/OMPT/CDER/ORP/DIDP/	Andrew Thibault	FAERS SEROQUEL CASES

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	06/19/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Andrew Thibault	
2015-4051	05/21/2015 06/19/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jaya Ayyagari Dr. Reddy's Laboratories Inc.	ANDA 073403
2015-4052	05/21/2015 06/19/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Adrienne Rothstein AbbVie	10647564, 10736427, 10741259 ETC
2015-4053	05/21/2015 06/19/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jaya Ayyagari Dr. Reddy's Laboratories Inc.	ANDA 062653
2015-4054	05/21/2015 06/19/2015	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Santiago Hernandez Soft Gel Technologies, Inc.	VITA KEY PACKAGING, INC, RIVERSIDE, CA - 482, 483 01/01/2014 - 05/20/2015
2015-4055	05/21/2015 06/19/2015	OC/CVM/OCD/	Dale Giali Dale Giali	PETNET REPORTS RE PURINA BENEFUL 01/01/2011 - 05/20/2015
2015-4056	05/21/2015 06/19/2015	FDA/OMPT/CDRH/OCER/DFOI/	Nickie Power Elekta Limited	K111862
2015-4057	05/21/2015 06/19/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Simhepfailfatal AbbVie	10175042, 10175158, 10355704, ETC
2015-4058	05/21/2015 06/19/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Olive O'Driscoll MEDIC, CIT	K133921, K103595, K082188
2015-4059	05/21/2015 06/19/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Abhishek Sharma IIFL Cap	CLARIS INJECTABLES LIMITED, INDIA - 483 03/01/2015 - 05/15/2015
2015-4060	05/21/2015	FDA/OGROP/ORA/CE-FO/CIN-	Christine Capati	KEVIN BLACK, ROBERT BONWETSCH, PHILIP BOURGEOIS,

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	06/19/2015	DO/CIN-CB/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ACADIA Pharmaceuticals Inc.	ETC - 483, EIR, RESPONSE ETC
2015-4061	05/21/2015 06/19/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Shin Kang HCR Partners	XTANDI AERS
2015-4062	05/21/2015 06/19/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Emilio Mallo DLD Lawyers - Emilio Mallo	ADVERSE EVENT
2015-4063	05/21/2015	FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16)	DMF 4181

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	06/19/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MERCK & CO., INC.	
2015-4064	05/21/2015 06/19/2015	FDA/OMPT/CDRH/OCER/DFOI/	Siemens Medical Solutions USA, Inc. Siemens Medical Solutions USA, Inc.	K142098
2015-4065	05/21/2015 06/19/2015	OC/ORa/OCI/ OC/ORa/OCI/	Mark Supple Mark Supple	GUIDANT/BOSTON SCIENTIFIC DEFECTIVE IMPLANTABLE CARDIAC DEFIBRILLATORS - OCI INVESTIGATION RECS 05/02/2005 - 12/30/2011
2015-4066	05/21/2015 06/19/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Adrienne Rothstein AbbVie	10069989, 10283699, 10353121, ETC
2015-4067	05/21/2015 06/19/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 204516
2015-4068	05/21/2015 06/19/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	David Baker David Baker	STRATTERA - AERS
2015-4069	05/21/2015 06/19/2015	FDA/OMPT/OSMP/OOPD/	Banu Ramachandran Citron Pharma, LLC	DROXIDOPA - ORPHAN DESIGNATION RECS
2015-4070	05/22/2015 06/22/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHANTAL LAVIGNE LAVIGNE, CHANTAL	CHIMERIX - BRINCIDOFOVIR CORR
2015-4071	05/22/2015 06/22/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	PREDNISONE - Cmplnt
2015-4072	05/22/2015 06/22/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OGROP/ORa/CE-FO/BLT-	DEAN GRESHAM GRESHAM PC ATTY AT LAW	FAIRFAX CRYOBANK, CRYOGENIC LABORATORIES INC, GENETICS & IVF INSTITUTE INC - INSPS, INVESTIGATIONS, WARNINGS, ETC

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		DO/BLT-CB/		
2015-4073	05/22/2015 06/22/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	NEIL EULIANO ETECT INC	RAISIN PERSONAL MONITOR K093976; PROTEUS PATCH INCLUDING INGESTIBLE SENSOR K133263, K131524, K131009
2015-4074	05/22/2015 06/22/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	EPANOVA NDA 205-060 - APRVL RECS
2015-4075	05/22/2015 06/22/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	INDIVIDUAL RECS - Cmplnts to CDER
2015-4076	05/22/2015 06/22/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	LEVAQUIN NDA 21-721, NDA 20-635, NDA 20-634; QUIXIN, LEVOFLOXACIN - AERS 6/5/12 TO PRESENT
2015-4077	05/22/2015 06/22/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	LEVOFLOXACIN, QUIXIN, LEVAQUIN NDA 21-721, NDA 20-635, NDA 20-634 - AERS 11/1/97 TO 6/14/12
2015-4078	05/22/2015 06/22/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	NATALIA RESIAK KALAS MIT SCHOOL OF MANAGEMENT	GEMTASIBINE - NDA, IND
2015-4079	05/22/2015 06/22/2015	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	CHARLENE NOVAK HALL & EVANS LLC	DENVER METRO AREA E COLI OUTBREAK - INVESTIGATION RECS
2015-4080	05/22/2015 06/22/2015	FDA/OC/OCC/ FDA/OC/OES/ OC/CVM/OCD/	JOHN H DONBOLI DEL MAR LAW GROUP LLP	PET FOOD LBLG - ENFORCEMENT ACTIONS, VIOLATIONS, CORR, ETC 6/14 TO PRESENT
2015-4081	05/22/2015 06/22/2015	FDA/OC/OES/DDM/	TED G MEADOWS BEASLEY ALLEN ET AL	DKTS 1994P-0420, FDA-2008-0309-0001/CP
2015-4082	05/22/2015 06/22/2015	FDA/OGROP/ORAS/SE-FO/ATL-DO/ATL-CB/	ANA MARIA ABREU MD PHD VELEZ, ANA MARIA ABREU	DR DENNIS MARCUS, MEDICAL COLLEGE OF GEORGIA, ATLANTA, GA - EIRS, 483S, CORR 2005 TO 2011

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2015-4083	05/22/2015 06/22/2015	FDA/OC/OES/DFOI/	KATHLEEN DOHERTY USC SOL PRICE SCHOOL OF PUBLIC POLICY	TITLE, PROFESSIONAL INSTITUTIONAL AFFILIATIONS OF TEMPORARY AND PERMANENT A/C MEMBERS 1997 TO 2014
2015-4084	05/22/2015 06/22/2015	FDA/OFVM/CFSAN/OCD/EOS/	JAMES HARTTEN ARENT FOX LLP	COCA COLA CO - SAFETY OF CAFFEINE CORR, CO RESP 8/1/13
2015-4085	05/22/2015 06/22/2015	FDA/OFVM/CFSAN/OCD/EOS/	JAMES HARTTEN ARENT FOX LLP	PEPSICO - SAFETY OF CAFFEINE CORR, CO RESP 8/1/13
2015-4086	05/22/2015 06/22/2015	FDA/OFVM/CFSAN/OCD/EOS/	JAMES HARTTEN ARENT FOX LLP	MONSTER BEVERAGE CO - SAFETY OF CAFFEINE CORR, CO RESP 6/24/13
2015-4087	05/22/2015 06/22/2015	FDA/OFVM/CFSAN/OCD/EOS/	JAMES HARTTEN ARENT FOX LLP	KRAFT FOODS GROUP INC - SAFETY OF CAFFEINE CORR, CO RESP 8/5/13
2015-4088	05/22/2015 06/22/2015	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	MICHAEL MANCINELLI CONWAY HOMER & CHIN-CAPLAN PC	INDIVIDUAL RECS
2015-4089	05/22/2015 06/22/2015	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	PATRICK KELLY CONWAY HOMER & CHIN-CAPLAN PC	INDIVIDUAL RECS
2015-4090	05/22/2015 06/22/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Andrew Thibault Andrew Thibault	MYSLEE, FLUOXETINE, VYVANSE ETC - AERS
2015-4091	05/22/2015 06/22/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Andrew Thibault Andrew Thibault	RISPERDAL, ZOLPIDEM TARTRATE, CYAMEMAZINE ETC - AERS
2015-4092	05/22/2015 06/22/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mary Blasy - PN-Eleven Biotherapeutics Robbins Geller Rudman & Dowd LLP	EBI-005 IND RECS
2015-4093	05/22/2015 06/22/2015	FDA/OGROP/ORO/SW-FO/DEN-DO/DEN-CB/	Derek Moon LSG Sky Chefs	CHELSEA FOOD SERVICES, DENVER, CO - 483 01/03/2013 - 01/15/2015
2015-4094	05/22/2015 06/22/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lauren Welling Sanders Phillips Grossman	NEW ORAL ANTICOAGULANTS - TESTING, INVESTIGATION, ANALYSIS ETC

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		FDA/OMPT/CDER/GRP/DIDP/		
2015-4095	05/22/2015 06/22/2015	FDA/OFVM/CFSAN/OCD/EOS/	Gina Ecolino Beveridge & Diamond, PC	LIST OF CFSAN FOIA REQUESTS SINCE 4/24/15
2015-4096	05/22/2015 06/22/2015	OC/OROA/ OC/OROA/ FDA/OGROP/ORO/SW-FO/DAL- DO/DAL-CB/	Mark Collette HOUSTON CHRONICLE	BLUE BELL - CORRECTIVE ACTION, AFFIDAVIT, RESPONSE TO 483 07/23/2009 - 05/21/2015
2015-4097	05/22/2015 06/22/2015	OC/CVM/OCD/	Sandra O'Kelley Merial Inc	NADA 139-877 TOTALON, NADA 140-844 TRAMISOL
2015-4098	05/22/2015 06/22/2015	FDA/OMPT/CDRH/OCER/DFOI/	Robin Azzam CITY COLLEGE OF NEW YORK	K143531, K992911
2015-4099	05/22/2015 06/22/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	doranne stanton doranne stanton	BLA/STN 101246
2015-4100	05/22/2015 06/22/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Padmini Sahoo Immucor GTI Diagnostics, Inc.	BK140141 SUMMARY
2015-4101	05/22/2015 06/22/2015	FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/	Andrew Khouri LOS ANGELES TIMES	MASIMO CORP, IRVINE - EIR, 483, RESPONSE 01/01/2013 - 05/21/2015
2015-4102	05/22/2015 06/22/2015	FDA/OC/OES/DFOI/	Steve Ellman Steve Ellman	Transcript of Gastroenterology and Urology Devices Panel Meeting May 14-15, 2015
2015-4103	05/22/2015 06/22/2015	FDA/OMPT/CDRH/OCER/DFOI/	Weaver Gaines OBMedical	K101801
2015-4104	05/22/2015 06/22/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 21299
2015-4105	05/22/2015 06/22/2015	FDA/OFVM/CFSAN/OCD/EOS/	Kate Ehrenberger Miles & Stockbridge PC	MONSTER ENERGY DRINK REPORTS
2015-4106	05/22/2015 06/22/2015	OC/CVM/OCD/	Beth Briczinski NATIONAL MILK PRODUCERS FEDERATION	REPORT RE CHEMICAL CONTAMINANTS IN DOMESTICALLY PRODUCED ANIMAL DERIVED FOOD

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2015-4107	05/27/2015 06/24/2015	FDA/OO/OFBA/OAGS/	FGI#46763 FOIA GROUP INC	HHSF2232012100271
2015-4108	05/26/2015 06/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	JIM SPENCER MINNEAPOLIS STAR TRIBUNE	MEDTRONIC - INFUSE BONE GRAFT EXEMPTION RPT COMM, MEMOS, CORR
2015-4109	05/26/2015 06/23/2015	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	LAUREN PENISI SULLIVAN PAPAIN BLOCK ET AL	UNION SQUARE MEDICAL IMAGING & MANNOGRAPHY - INVESTIGASTION, INSP RECS
2015-4110	05/26/2015 06/23/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENTON D TEELING Menn Law Firm LTD.	WALGREENS, COUNCIL BLUFFS, IA - USED SYRINGE IN A BOTTLE OF WAL-MUCIL INVESTIGATION, COMM
2015-4111	05/26/2015 06/23/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANTHONY M MAFFIA III SANDOZ INC	SANDOZ - GLATOPA (GLATIRAMER ACETATE INJ) ANDA 090-218 RECS
2015-4112	05/26/2015 06/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	Emily Bartkowicz Akerman LLP	CARDIOPULMONARY BYPASS OXYGENATOR - REG AUTHORSHIP, GUIDANCE AUTHORSHIP, 6 HOUR LIMIT
2015-4113	05/26/2015 06/23/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Zachary Petrone HIGHSIDE CAPITAL MANAGEMENT	DONNATAL - LIST OF DRUGS, COMPANIES THAT REQUESTED HEARINGS, LIST OF COHORT DRUGS REMOVED FROM MARKET, LIST OF DRUGS THAT HAVE HAD A HEARING ETC
2015-4114	05/26/2015 06/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	Alexis Arquilliere Withings	K011291
2015-4115	05/26/2015 06/23/2015	FDA/OO/OHR/	Tyler Grigery Tyler Grigery	OCI IT POSITION DESCRIPTIONS GS-14
2015-4116	05/26/2015 06/23/2015	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/ OC/ORO/	DAVID HEATH CENTER FOR PUBLIC INTEGRITY	BISPHENOL A - RECORD LAYOUTS, DICTIONARTIES, LOOKUP TABLES, ETC
2015-4117	05/26/2015 06/23/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sara Cotter UBS AG	DKA, SGLT2 - AERS
2015-4118	05/26/2015 06/23/2015	FDA/OFVM/CFSAN/OCD/EOS/	JAMES HARTTEN ARENT FOX LLP	ROCKSTAR INC - SAFETY OF CAFFEINE LTR, CO RESP 6/24/13

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2015-4119	05/26/2015 06/23/2015	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Georgia Hatzis ULMER & BERNE LLP	MASTERS PHARMACEUTICALS, FAIRFIELD, OH; WAYNE CORONA - FINES, AGREEMENTS, INVESTIGATIONS 01/11/2007 - 05/22/2015
2015-4120	05/26/2015 06/23/2015	FDA/OFVM/CFSAN/OCD/EOS/	JAMES HARTTEN ARENT FOX LLP	JELLY BELLY CANDY CO - SAFETY OF CAFFEINE LTR, CO RESP 6/24/13
2015-4121	05/26/2015 06/23/2015	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	CXL-USA, LLC, ROCKVILLE, MD - EIR, 483, RESPONSE 8/18/14
2015-4122	05/26/2015 06/23/2015	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	WIL RESEARCH, HILLSBOROUGH, NC - EIR, 483, RESPONSE 02/01/2013 - 03/07/2013
2015-4123	05/26/2015 06/23/2015	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	JANSSEN RESEARCH & DEVELOPMENT, RADNOR, PA - EIR, 483, RESPONSE 08/05/2013 - 08/09/2013
2015-4124	05/26/2015 06/23/2015	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	AMERICAN NATIONAL RED CROSS, TOLEDO, OH - EIR, 483, RESPONSE 08/01/2014 - 08/29/2014
2015-4125	05/26/2015 06/23/2015	FDA/OC/OCS/NCTR/OCD/ OC/ORA/ OC/ORA/	DAVID HEATH CENTER FOR PUBLIC INTEGRITY	PACIFIC NORTHWEST NATIONAL LABORATORY - JUSTIN TEEGUARDEN, RUDY GUNAWAN, SESHS HANSON-DRURY, ETC LTRS, EMAILS, ATTACHMENTS 1/10 TO PRESENT; NCTR, NIEHS STAFF, LITTLE ROCK, AR - CLARITY PROGRAM WITH PRINCIPAL INVESTIGATORS RECORDINGS, TRANS, AGENDAS 2/29/12 TO 3/1/12
2015-4126	05/26/2015 06/23/2015	FDA/OO/OHR/	Tyler Grigery Tyler Grigery	OCI INTELLIGENCE RESEARCH SPECIALIST, INVESTIGATIVE ANALYST GS-14 POSITION DESCRIPTIONS 05/01/2014 - 05/22/2015
2015-4127	05/26/2015 06/23/2015	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	JOSEPH A KWNETUS, MD, FLOWOOD, MS - EIR, 483, RESPONSE 03/01/2013 - 03/18/2013
2015-4128	05/26/2015 06/23/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Wendy Kowal Wendy Kowal	PMSG - LIST OF APPROVED COMPANIES TO IMPORT
2015-4129	05/26/2015 06/23/2015	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/ FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORASE-FO/ATL-	Jesse McLean Toronto Star	AKORN, ALZA, BAXTER ETC - 483

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		DO/ATL-CB/ FDA/OGROP/ORR/SE-FO/SJN-DO/SJN-CB/		
2015-4130	05/26/2015 06/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K992762
2015-4131	05/26/2015 06/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	Elijah Walker Dreamscape Medical	K111680, K120371, K120372 ETC
2015-4132	05/26/2015 06/23/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Christopher McCartney, MD Center for Research in Reproduction- University of Virginia	IND 64125, 64126 FORM 1572
2015-4133	05/26/2015 07/09/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	ANNA KLUKOWSKA, WARSAW, POLAND - EIR, 483, RESPONSE 09/01/2014 - 09/30/2014
2015-4134	05/26/2015 06/23/2015	OC/ORR/ OC/ORR/ FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/	Mark Collette HOUSTON CHRONICLE	BLUE BELL CREAMERIES - COMPLAINTS THAT PROMPTED INPSECTIONS 01/01/2005 - 05/22/2015
2015-4135	05/26/2015 06/23/2015	FDA/OGROP/ORR/CE-FO/CIN-DO/CIN-CB/	Wendy Banka Wendy Banka	SHUR-GREEN FARMS, ANSONIA, OH - RESPONSE TO WARNING LETTER 04/24/2015 - 05/24/2015
2015-4136	05/26/2015 06/23/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	NOVACYL, THAILAND - EIR, 483, RESPONSE 04/01/2014 - 04/30/2014
2015-4137	05/26/2015 06/23/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Walter Chalkley THOMSON REUTERS	CIPA LIMITED, INDIA - EIR, 483, RESPONSE 6/23/15
2015-4138	05/26/2015 06/23/2015	FDA/OGROP/ORR/NE-FO/NWE-DO/NWE-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	ALEXION PHARMACEUTICALS - EIR, 483, RESPONSE 09/01/2014 - 09/30/2014

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2015-4139	05/26/2015 06/23/2015	FDA/OGROP/ORА/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	NEPHRON PHARMACEUTICALS CORP, ORLANDO, FL - EIR, 483, RESPONSE 02/01/2014 - 02/28/2014
2015-4140	05/26/2015 06/23/2015	FDA/OGROP/ORА/CE-FO/BLT-DO/BLT-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	TOX PATH SPECIALISTS, FREDERICK, MD - EIR, 483, RESPONSE 07/01/2013 - 07/31/2013
2015-4141	05/26/2015 06/23/2015	FDA/OGROP/ORА/CE-FO/NWJ-DO/NWJ-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	PRODUCT SAFETY LABS, DAYTON, NJ - EIR, 483, RESPONSE 08/26/2013 - 09/11/2013
2015-4142	05/27/2015 06/24/2015	OC/ORА/ OC/ORА/ FDA/OGROP/ORА/SE-FO/NOL-DO/NOL-CB/	JOAN BRADY CRAWDADDYS CAJUN & CREOLE CUISINE	CMPNT 140447
2015-4143	05/27/2015 06/24/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Chris Havanas GOJO Industries Inc.	NDA 019258
2015-4144	05/27/2015 06/24/2015	FDA/OGROP/ORА/SW-FO/DEN-DO/DEN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	TANDEM LABS, SALT LAKE CITY, UT - EIR, 483, RESPONSE 05/13/2013 - 05/17/2013
2015-4145	05/27/2015 06/24/2015	FDA/OGROP/ORА/SE-FO/FLA-DO/FLA-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	STEPHEN W. WELDEN, MD, LUTZ, FL - EIR, 483, RESPONSE 12/01/2014 - 01/08/2015
2015-4146	05/27/2015 06/24/2015	FDA/OGROP/ORА/CE-FO/NWJ-DO/NWJ-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	HUNTINGDON LIFE SCIENCES, EAST MILLSTONE, NJ - EIR, 483, RESPONSE 08/22/2014 - 09/12/2014
2015-4147	05/27/2015 06/24/2015	FDA/OGROP/ORА/SE-FO/SJN-DO/SJN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	BAXTER HEALTHCARE CORPORATION, JAYUYA, PR - EIR, 483, RESPONSE 01/15/2014 - 02/11/2014
2015-4148	05/27/2015 06/24/2015	FDA/OGROP/ORА/CE-FO/BLT-DO/BLT-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	UNIVERSITY OF MARYLAND SCHOOL OF MEDICINE, BALTIMORE, MD - EIR, 483, RESPONSE 12/01/2012 - 12/31/2012
2015-4149	05/27/2015 06/24/2015	FDA/OGROP/ORА/CE-FO/DET-DO/DET-CB/	Gael Tisack TERUMO CARDIOVASCULAR SYSTEMS CORP	TERUMO CARDIOVASCULAR SYSTEMS, ANN ARBOR, MI - EIR 01/01/2014 - 05/22/2015
2015-4150	05/27/2015	FDA/OGROP/ORА/CE-FO/CIN-	Wendy Banka	SHUR-GREEN FARMS, LLC - RESPONSE TO 483 12/15/2014

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	06/24/2015	DO/CIN-CB/	Wendy Banka	- 12/16/2014
2015-4151	05/27/2015 06/24/2015	FDA/OMPT/CDRH/OCER/DFOI/	Lew Jerome Lew Jerome	MEDTRONIC - LETTERS REFERENCING MEDICAL DEVICES OR SPINAL IMPLANTS FOR INTENDED USE OF VERTEBRAL BODY REPLACEMENT DETERMINED NSE 01/01/2000 - 05/23/2015
2015-4152	05/27/2015 06/24/2015	FDA/OFVM/CFSAN/OCD/EOS/	Daria Church Clariant Corporation	FCN 54
2015-4153	05/27/2015 06/24/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Steve Hemphill Steve Hemphill	Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act
2015-4154	05/27/2015 06/24/2015	OC/ORA/ OC/ORA/ FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/	PATTI WALLER Marler Clark Law Firm	BLUE BELL ICECREAM - LISTERIA INVESTIGATION
2015-4155	05/27/2015 06/24/2015	FDA/OGROP/ORR/CE-FO/CIN-DO/CIN-CB/	Rosemary Parker MLive Media Group	SHUR-GREEN - 483, LETTERS, RESPONSES 11/19/2014 - 05/25/2015
2015-4156	05/27/2015 06/24/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Sarah Fitzgerald HILL-ROM	K011693, K061317, K091246
2015-4157	05/27/2015 06/24/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Zahra Mohammadi UNIVERSITY OF PENNSYLVANIA	NATIONAL DRUG CODE PRODUCT LIST 12/31/1996 - 12/31/2014
2015-4158	05/27/2015 06/24/2015	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink	2013-4738
2015-4159	05/27/2015 06/24/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	ANDA 200652
2015-4160	05/27/2015 06/24/2015	FDA/OGROP/ORR/CE-FO/CIN-DO/CIN-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Georgia Hatzis ULMER & BERNE LLP	MASTERS PHARMACEUTICALS, INC, WAYNE CORONA - INVESTIGATION RECS ETC

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		OC/ORO/OCI/ OC/ORO/OCI/		
2015-4161	05/27/2015 06/24/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Steven Brill Steven Brill	RISPERDONE - NDA, ANDA APPROVAL, NONAPPROVABLE LETTERS
2015-4162	05/27/2015 06/24/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Andrea Demakas ADVERSEEVENTS INC	OBIZUR, KITABIS PAK, BLINCYTO, ETC - AERS
2015-4163	05/27/2015 06/24/2015	FDA/OMPT/CDRH/OCER/DFOI/	Winkie Wong KARL STORZ Endoscopy-America, Inc.	K033437
2015-4164	05/27/2015 06/24/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Thomas Minich Lonza Inc.	DISHMAN PHARMACEUTICALS AND CHEMICALS LTD - EIR, 483 04/26/2013 - 09/09/2013
2015-4165	05/27/2015 06/24/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kalub Hahne Cook Research Incorporated	NDA 21321 UNREDACTED CHEMISTRY REVIEWS
2015-4166	05/27/2015 06/24/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ashish Rathi Spark Capital India (Private) Advisors Ltd	WOCKHARDT LIMITED, INDIA - 483 05/01/2015 - 05/27/2015
2015-4167	05/27/2015 06/24/2015	FDA/OMPT/CDRH/OCER/DFOI/	shani Duet medical	K132698
2015-4168	05/27/2015 06/24/2015	FDA/OMPT/CDRH/OCER/DFOI/	shani Duet medical	K093845
2015-4169	05/27/2015 06/24/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Erin Stewart Stanford University Hospital and Clinics - Department of Pulmonary and Critical Care Medicine	CASE REPORTS 3427653 3595565 3634908 ETC

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2015-4170	05/27/2015 06/24/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Freddie Lee Epic International (Thailand) Co., Ltd.	K933652
2015-4171	05/27/2015 06/24/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DDM/	ANGELIN C. ARCIGA CROFTSCOPE LTD	FLOURIDE DENTIFRICE DRUG PRODUCTS - TESTING PROCEDURES
2015-4172	05/27/2015 06/24/2015	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	PAUL W. TRIPP LINCARE INC	AMERICAN HOME PATIENT INC - 483, EIR, WARNING LTR 1/12 TO PRESENT
2015-4173	05/27/2015 06/24/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KASIA KOSACKA LEGATE & ASSOCIATES LLP	CELEXA - APRVL, EFFICACY RVWS, AER, CMLPNTS,
2015-4174	05/27/2015 06/24/2015	FDA/OC/OES/DFOI/	AMIE N. VANELLA FAEGRE BAKER DANIELS	SIMPLY THICK - FOI REQUESTS 3/12/15 TO PRESENT
2015-4175	05/27/2015 06/24/2015	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	RONAYNE, LISA	NEBRASKALAND, BRONX, NY - CMLPNTS SINCE 2000
2015-4176	05/27/2015 06/24/2015	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	RONAYNE, LISA	LATINO FOOD DISTRIBUTORS, WEST SPRINGFIELD, MA - CMLPNTS SINCE 2000
2015-4177	05/27/2015 06/24/2015	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JENNIFER NGUYEN MARKER GROUP INC	INDIVIDUAL RECS
2015-4178	05/27/2015	FDA/OMPT/CDER/ORP/DIDP/	KASIA KOSACKA	DUCHESNAY INC - DICLECTIN APRVL, RVWS, AER

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	06/24/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LEGATE & ASSOCIATES LLP	
2015-4179	05/28/2015 06/25/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K110268
2015-4180	05/28/2015 06/25/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K133987
2015-4181	05/28/2015 06/25/2015	FDA/OMPT/CDRH/OCER/DFOI/	Vijay Kumar AeskuNY, Inc	K150155
2015-4182	05/28/2015 06/25/2015	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/DET- DO/DET-CB/	CC #137532 caroline nguyen	CONSUMER COMPLAINT 137532 RECS
2015-4183	05/28/2015 06/25/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K061201
2015-4184	05/28/2015 06/25/2015	FDA/OMPT/CDRH/OCER/DFOI/	John Nanos Kevo Medical	K133333
2015-4185	05/28/2015 06/25/2015	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/	William Beadle- 2 KH International, Inc.	VINCULOS AGRICOLAS E.I.R.L. IMPORT ALERT RECS 04/01/2015 - 05/24/2015
2015-4186	05/28/2015 06/25/2015	FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/	Brandon Henry RBC	PYRAMID LABORATORIES - 483 04/29/2015 - 05/31/2015
2015-4187	05/28/2015 06/25/2015	FDA/OMPT/CDRH/OCER/DFOI/	W Standifer Virtual Design	K133125
2015-4188	05/28/2015 06/25/2015	FDA/OGROP/ORO/CE-FO/DET- DO/DET-CB/	Kelly Reed PD Pharmatech, LLC	jJLM PHARMACTECH, LLC - EIR 11/13/2012 - 12/31/2012
2015-4189	05/28/2015 06/25/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K131700
2015-4190	05/28/2015 06/25/2015	FDA/OMPT/CDRH/OCER/DFOI/	BYRON B MILLER MALONEY LAW GROUP PLLC	NAVILYST MEDICAL - NAMIC FLUID DELIVERY SET; MEDRAD - MARK V PROVIS POWER INJ MDRS
2015-4191	05/28/2015 06/25/2015	FDA/OGROP/ORO/SE-FO/FLA- DO/FLA-CB/	JONATHAN W EMORD EMORD & ASSOCIATES, P.C.	CLR ROASTERS LLC, MIAMI, FL - INSP RECS 5/19/15
2015-4192	05/28/2015	FDA/OFVM/CFSAN/OCD/EOS/	JAMES HARTTEN	ROCKSTAR INC - SAFETY OF CAFFEINE CORR, CO RESP 6/13

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	06/25/2015		ARENT FOX LLP	
2015-4193	05/28/2015 06/25/2015	FDA/OMPT/CDRH/OCER/DFOI/	JEFFREY M SENGER SIDLEY AUSTIN LLP	ZIMMER INC - TOTAL HIP PROSTHESIS INAPPROPRIATE PROMOTIONAL CLAIM Cmplnts 11/14/14
2015-4194	05/28/2015 06/25/2015	OC/ORO/ORM/ OC/ORO/ORM/	GAIL LESSICK LACHMAN CONSULTANT SERVICES INC	DRUG COMPANIES, MEDICAL DVC MFRS, BLOOD ESTABLISHMENTS, ETC - DOMESTIC AND FOREIGN INSPS 4/1-30/15
2015-4195	05/28/2015 06/25/2015	FDA/OC/OES/DFOI/	LIZA GROSS GROSS, LIZA	BISPHENOL A, PHTHALATES, FLAME RETARDANTS, ETC - FOI REQUESTS 2008 TO PRESENT
2015-4196	05/28/2015 06/25/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JENNY BLAU MD Blau, Jenny E	CANAGLIFOZIN - RPTS 1/1/13 TO 1/2/14
2015-4197	05/28/2015 06/25/2015	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	ALLERGAN - 410 COHESIVE GEL BREAST IMPLANTS LIST OF PLASTIC SURGEONS CHOSEN FOR FDA STUDIES
2015-4198	05/28/2015 06/25/2015	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/NE-FO/NWE-DO/NWE-CB/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/	J. Fenton Williams Complaint CC141071 J. Fenton Williams	RESPONSE TO CONSUMER COMPLAINT
2015-4199	05/28/2015 06/25/2015	FDA/OMPT/OSMP/OOPD/	Robert Unger GeneSegues, Inc.	NAVIDEA BIOPHARMACEUTICALS, INC - ORPHAN PRODUCTS RECS RE LYMPHOSEEK 05/01/2014 - 10/31/2014
2015-4200	05/28/2015 06/25/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Wonsun Chung Wonsun Chung	K080377, K120949
2015-4201	06/01/2015 06/29/2015	FDA/OMPT/CDRH/OCER/DFOI/	Michael Imprevento Breit Drescher Imprevento, P. C.	ETHICO ENDO-SURGERY SUTUE ASSISTANT - APPROVAL RECS 12/12/1987 - 05/26/2015
2015-4202	06/01/2015 06/29/2015	FDA/OMPT/CDRH/OCER/DFOI/	Byron Miller Maloney Law Group, P.L.L.C.	NAVILYS MEDICAL NAMIC FLUID DELIVERY SET, MEDRAD MARK V PROVIS POWER INJECTOR - INVESTIGATION, RECALL, MALFUNCTION RECS 3/11/2010 - 05/26/2015
2015-4203	06/01/2015 06/29/2015	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	TPSAC CONFLICT OF INTEREST RECS
2015-4204	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	Claire Fitterer Claire Fitterer	INTUITIVE SURGICAL - 510K RECS
2015-4205	06/01/2015	FDA/OMPT/CDER/ORP/DIDP/	Michele Sinoway	ZHEJIANG HISUN PHARMA CO, CHINA - 483 03/01/2015 -

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	06/29/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lachman Consultants	03/30/2015
2015-4206	06/01/2015 06/29/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dustin Block IPD Analytics, LLC	ANDA 202298
2015-4207	06/01/2015 06/29/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nicholas Oo Invus Group	XIAFLEX - AERS
2015-4208	06/01/2015 06/29/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRITTANY LA HOXIE & ASSOCIATES LLC	PFIZER -LYRICA (PREGABALIN) RESP LTR 12/09;; NON APPROVABLE LTR 8/04;; RESP LTR OR NON-APPROVABLE LTRS 1/00 TO PRESENT
2015-4209	06/01/2015 06/29/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JEFFREY A CODERRE ORA	BAUSCH & LOMB - LUMINESSE BRIMONIDINE TARTARATE OPHTHALMIC SOL NDA 208-144 ISR 369082, 3445488, 3778011, ETC
2015-4210	06/01/2015 06/29/2015	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OC/OES/DFOI/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	JESSE C FERRANTELLA OGLETREE DEAKINS	SCANTIBODIES LABORATORY INC, SCANTIBODIES CLINICAL LABORATORY INC, SCANTIBODIES BIOLOGICS INC - INSP/AUDITS, EIRS, 483S, ETC 1/1/13 TO 12/31/14
2015-4211	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	MANEESH SETHI BEHAVIORAL TECHNOLOGY GROUP INC	K820622, K790738
2015-4212	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP MAPI GROUP	BIAXIN (CLARITEHROMYCIN) - LONG TERM TOXICITY STUDIES
2015-4213	06/01/2015 06/29/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Wonsun Chung Wonsun Chung	K080769
2015-4214	06/01/2015 06/29/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Pam Larson Medigene, Inc.	CMP PHARMA GMBH & CO KG, GERMANY - EIR 09/01/2013 - 09/30/2014

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		FDA/OMPT/CDER/GRP/DIDP/		
2015-4215	06/01/2015 06/29/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	John Marshall, MD, PhD UNIVERSITY OF VIRGINIA	IND 64125, 64126 FORM 1572
2015-4216	06/01/2015 06/29/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Therese Timmons, PhD Bellicum Pharmaceuticals, Inc.	APPENDIX M, CLINICAL PROTOCOL FOR #0712-886, #1010-1071, #1207-1176, #1312-1281
2015-4217	06/01/2015 06/29/2015	FDA/OMPT/CDRH/OCER/DFOI/	Kerri LaPlaca LaPlaca, Kerri	K142564
2015-4218	06/01/2015 06/29/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Steven J. Stanwyck The Stanwyck Firm	DRUG ACCESS - RECS RE CEASE AND DESIST, EAP ETC 01/01/2010 - 07/31/2015
2015-4219	06/01/2015 06/29/2015	FDA/OGROP/ORAC/CE-FO/CHI-DO/CHI-CB/	Demetrius Lopes Rush University Medical Center	DR DEMETRIUS LOPES - 483 01/01/2001 - 01/01/2011
2015-4220	06/01/2015 06/29/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ryan Hoerger Ryan Hoerger	LIST OF QIDP-DESIGNATED DRUG APPLICATIONS
2015-4221	06/01/2015 06/29/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Karol LaCroix GlaxoSmithKline	7241182 7250072 6642518 ETC
2015-4222	06/01/2015 06/29/2015	FDA/OC/OES/ FDA/OFVM/CFSAN/OCD/EOS/	Alan Judd Atlanta Journal-Constitution	MEETINGS BETWEEN FDA AND COCA-COLA, CORR 01/01/2005 - 04/30/2015
2015-4223	06/01/2015 06/29/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jason Birri ARIAD Pharmaceuticals, Inc.	PENN PHARMACEUTICAL SERVICES LTD, UK - EIR 11/01/2014 - 05/28/2015

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		FDA/OMPT/CDRH/OCER/DFOI/		
2015-4224	06/01/2015 06/29/2015	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Sally Hawkins ABC News Nightline	HILLANDALE FARMS, PENNSYLVANIA, OHIO, IOWA - 483 07/01/2010 - 05/25/2015
2015-4225	06/01/2015 06/29/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/CVM/OCD/	Ann Luecking United Compounding Management	LIST OF DRUGS ON DO NOT COMPOUND LIST
2015-4226	06/01/2015 06/29/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dheeresh Pathak Dheeresh Pathak	WOCKHARDT - 483 ISSUED MAY 2015
2015-4227	06/01/2015 06/29/2015	OC/ORACE/ OC/ORACE/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Doe J	SAMPLE RESULTS
2015-4228	06/01/2015 06/29/2015	FDA/OFVM/CFSAN/OCD/EOS/	Vrinda Devani Vrinda Devani	MUCUNA PRURIENS - AERS
2015-4229	06/01/2015 06/29/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Charles Snow Hyman, Phelps & McNamara P.C.	FORM FDA 3542 FOR NDA 20571
2015-4230	06/01/2015 06/29/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Claudine Homolash Homolash, Claudine Q	FARXIGA - AERS
2015-4231	06/01/2015	FDA/OMPT/CDER/ORP/DIDP/	Dr Girish Bakhr	CLARIS LIFE SCIENCES, INDIA - 483 05/01/2015 - 05/15/2015

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	06/29/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HSBC	
2015-4232	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 5/1-31/2015
2015-4233	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	A list of all FOIA requests closed 5/1-31/2015
2015-4234	06/01/2015 06/29/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jennifer Miller Eli Lilly and Company - Global Patient Safety	NDA 205747
2015-4235	06/01/2015 06/29/2015	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAP/PA-FO/SAN-DO/SAN-CB/	Kyle Harvey KBAK-TV Eyewitness News	HOUCHIN COMMUNITY BLOOD BANK, BAKERSFIELD, CA - EIR 01/01/2013 - 06/01/2015
2015-4236	06/01/2015 06/29/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Jack T Krauser JACK T KRAUSER	K143022, K100985, K093321 ETC
2015-4237	06/01/2015 06/29/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dianne Karlowicz Dianne Karlowicz	AERS DATA
2015-4238	06/01/2015 06/29/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rich Bellino belldevmedical llc	K142919
2015-4239	06/01/2015 06/29/2015	FDA/OMPT/CDRH/OCER/DFOI/	Alan Chivers SRA Developments Ltd	K925699
2015-4240	06/01/2015 06/29/2015	FDA/OMPT/CDRH/OCER/DFOI/	Jack T Krauser JACK T KRAUSER	K974280, K961381, K961382 ETC
2015-4241	06/01/2015 06/29/2015	FDA/OMPT/CDRH/OCER/DFOI/	Alan Chivers SRA Developments Ltd	K971861
2015-4242	06/01/2015 06/29/2015	FDA/OGROP/ORAP/CE-FO/NWJ-DO/NWJ-CB/	Diane Arpino Mindray DS USA, Inc.	MINDRAY DS USA, INC, MAHWAH, NJ - EIR 06/01/2012 - 03/10/2015
2015-4243	06/01/2015 06/29/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Alan Chivers SRA Developments Ltd	K132612

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/		
2015-4244	06/01/2015 06/29/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dr. Uday Shetty Drug Regulations	WOCKHARDT, INDIA - 483 01/01/2015 - 05/29/2015
2015-4245	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 5/4-9/15
2015-4246	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 5/11-16/15
2015-4247	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA LOG 5/18-23/15
2015-4248	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSD FOIA REQUESTS 5/11-15/15
2015-4249	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	JO HAGAN FOI Services, Inc.	FOI DAILY LOG 4/20-25/15
2015-4250	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	JO HOGAN FOI Services, Inc.	FOI DAILY LOG 4/27/15-5/2/15
2015-4251	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 5/4-8/15
2015-4252	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 5/11-15/15
2015-4253	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 5/18-22/15
2015-4254	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 4/20-24/15
2015-4255	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 4/27/15-5/1/15
2015-4256	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION	FOI DAILY LOG 4/20-24/15

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			SOURCE	
2015-4257	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 4/27/15-5/1/115
2015-4258	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	GLADYS B TONKIN Center for Regulatory Services, Inc.	FOI DAILY LOG 4/20-24/15
2015-4259	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	GLADLYS B TONKIN Center for Regulatory Services, Inc.	FOI DAILY LOG 4/27/15-5./1/15
2015-4260	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 5/4-8/15
2015-4261	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 5/11-15/15
2015-4262	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 5/18-22/15
2015-4263	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 4/20-24/15
2015-4264	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 4/27/15-5/1/15
2015-4265	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 4/27/15-5/1/15
2015-4266	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 5/4-8/15
2015-4267	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 5/18-22/15
2015-4268	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	LESLIE RAMSEY FDA NEWS	FOI DAILY LOG 4/20-24/15
2015-4269	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI REQUESTS 4/20-24/15
2015-4270	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	JO HOGAN FOI Services, Inc.	FOI DAILY LOG 5/4-9/15
2015-4271	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	JO HOGAN FOI Services, Inc.	FOI DAILY LOG 5/11-16/15
2015-4272	06/01/2015	FDA/OC/OES/DFOI/	JO HOGAN	FOI DAILY LOG R5/18-23/15

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	06/29/2015		FOI Services, Inc.	
2015-4273	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	JO HOGAN FOI Services, Inc.	FOI DAILY LOG 4/20-25/15
2015-4274	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	JOI HOGAN FOI Services, Inc.	FOI DAILY LOG 4/27/15-5/2/15
2015-4275	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	GLADYS B TONKIN Center for Regulatory Services, Inc.	FOI DAILY LOG 5/4-8/15
2015-4276	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	GLADYS B TONKIN Center for Regulatory Services, Inc.	FOI DAILY LOG 5/11-15/15
2015-4277	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	GLADYS B TONKIN Center for Regulatory Services, Inc.	FOI DAILY LOG 5/18-22/15
2015-4278	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 5/4-8/15
2015-4279	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 5/11-15/15
2015-4280	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 5/18-22/15
2015-4281	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 4/27/15-5/1/15
2015-4282	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 5/4-8/15
2015-4283	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 5/11-15/15
2015-4284	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 5/18-22/15
2015-4285	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	LESLIE RAMSEY FDA NEWS	FOI DAILY LOG 4/27/15-5/1/15
2015-4286	06/01/2015	FDA/OC/OES/DFOI/	LESLIE RAMSEY	FOI DAILY LOG 5/4-8/15

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	06/29/2015		FDA NEWS	
2015-4287	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	LESLIE RAMSEY FDA NEWS	FOI DAILY LOG 5/11-15/15
2015-4288	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	LESLIE RAMSEY FDA NEWS	FOI DAILY LOG 5/18-22/15
2015-4289	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 5/4-8/15
2015-4290	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 5/11-15/15
2015-4291	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOIG 5/18-22/15
2015-4292	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 4/20-24/15
2015-4293	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 4/27/15-5/1/15
2015-4294	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 4/27/15-5/1/15
2015-4295	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 5//4-8/15
2015-4296	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG R5/11-15/15
2015-4297	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 5/18-22/15
2015-4298	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	DAVIDF MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 4/20-24/15
2015-4299	06/01/2015 06/29/2015	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 4.20-24/15
2015-4300	06/02/2015 06/30/2015	FDA/OMPT/CDRH/OCER/DFOI/	Andrew Rubenstein Andrew Rubenstein	COOK UROLOGICAL INC, KARL STORZ, FEMRX/JOHNSON & JOHNSON - POWER MORECELLATOR 510K, ADVERSE EVETNS 01/01/1991 - 05/31/2015
2015-4301	06/02/2015 06/30/2015	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Lisa Robertson Rawls McNelis + Mitchell	VAERS RECS
2015-4302	06/02/2015	FDA/OC/OES/DFOI/	Cat Ferguson	FOIA LOG 01/01/2006 - 06/30/2015

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	06/30/2015		BuzzFeed, Inc.	
2015-4303	06/02/2015 06/30/2015	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	Charles Snow Hyman, Phelps & McNamara P.C.	ZARBEE'S INC - WARNING LETTER RECS, LABELING RECS
2015-4304	06/02/2015 06/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dr Leonard Lionnet, PhD Dr Leonard Lionnet	TOTAL NUMBER OF FORMS 2253 RECEIVED BY OPDP BY YEAR 2012-2014
2015-4305	06/02/2015 06/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Yang Yu Yang Yu	CEMPRA PHARMACEUTICAL INC CEM-101 - AERS
2015-4306	06/02/2015 06/30/2015	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Charles Snow Hyman, Phelps & McNamara P.C.	ZARBEE'S - COMMUNICATIONS WITH FDA RE WARNING LETTER, LABELING
2015-4307	06/02/2015 06/30/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-2719
2015-4308	06/02/2015 06/30/2015	FDA/OFVM/CFSAN/OCD/EOS/	Brenda Goodman WebMD	REPORTS OF UNDECLARED ALLERGENS IN FOODS 01/01/2013 - 05/29/2015
2015-4309	06/02/2015 06/30/2015	OC/ORAS/ OC/ORAS/ OC/ORAS/ORM/ OC/ORAS/ORM/	Oliver Yu Zymergi LLC	LIST OF INSPECTIONAL OBSERVATIONS DATA 01/01/2005 - 05/30/2015
2015-4310	06/02/2015 06/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Zeba Siddiqui THOMSON REUTERS	SUN PHARMACEUTICALS INDUSTRIES LTD - CORR WITH FDA 01/02/2014 - 06/01/2015

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2015-4311	06/02/2015 06/30/2015	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink	2015-3974
2015-4312	06/02/2015 06/30/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Andrea Demakas ADVERSEEVENTS INC	EVOTAZ (ATAZANAVIR, COBICISTAT), GLYXAMBI (EMPAGLIFLOZIN, LINAGLIPTIN), ETC AERS
2015-4313	06/02/2015 06/30/2015	FDA/OMPT/CDRH/OCER/DFOI/	Bill Hyatt Stryker Neurovascular	K142458
2015-4314	06/02/2015 06/30/2015	FDA/OMPT/CDRH/OCER/DFOI/	Ellis Liu Carroll and Weiss LLP	510K SUBMISSIONS FOR AUTOMATED ENDOSCOPE REPROCESSORS REFERENCED IN FDA EXECUTIVE SUMMARY 01/01/2009 - 05/31/2015
2015-4315	06/02/2015 06/30/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-2801
2015-4316	06/02/2015 06/30/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-2883
2015-4317	06/02/2015 06/30/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-3266
2015-4318	06/02/2015 06/30/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-2890
2015-4319	06/02/2015 06/30/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-2913
2015-4320	06/02/2015 06/30/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-2920
2015-4321	06/02/2015 06/30/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-2694
2015-4322	06/02/2015 06/30/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-315
2015-4323	06/02/2015 06/30/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-1520
2015-4324	06/02/2015 06/30/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-2966
2015-4325	06/02/2015 06/30/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-1526
2015-4326	06/02/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2015-2698

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	06/30/2015		MERCK & CO., INC.	
2015-4327	06/02/2015 06/30/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-1744
2015-4328	06/02/2015 06/30/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-2116
2015-4329	06/02/2015 06/30/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-2114
2015-4330	06/02/2015 06/30/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-2566
2015-4331	06/02/2015 06/30/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-2204
2015-4332	06/02/2015 06/30/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-2203
2015-4333	06/02/2015 06/30/2015	FDA/OC/OCC/ FDA/OC/OES/ FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/ OC/ORO/	TINA SIGURDSON ENVIRONMENTAL WORKING GROUP	FEDERAL TRADE COMMISSION (FTC), DEPT OF AGRRICULTURE (USDA), COSMETIC MFRS, ETC - USE OF GREEN MARKETING TERMS TO DESCRIBE COSMETICS CMLNPTS, RECS LAST 5 YRS
2015-4334	06/02/2015 06/30/2015	FDA/OC/OES/ FDA/OC/OES/DDM/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	READE WILSON EWG ACTION FUND	ASBESTOS CONTAMINATION OF COSMETICS, FOOD, AND DRUGS THAT CONTAIN TALC - RECS, CORR 2000 TO PRESENT
2015-4335	06/02/2015 06/30/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CINDY SHEARER UNIV OF MISSOURI SCHOOL OFLAW LIBRARY	ORANGE BOOK 1985; ORANGE BOOK SUPPLEMENTS 1985- 2013
2015-4336	06/02/2015 06/30/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JAMIE BELCASTRO RPH BELMORA LLC	GRAHAM CHEMICAL - LIDOCAINE 5% OINTMENT ANDA 80- 210

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2015-4337	06/02/2015 06/30/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	IRENE E HUDSON FISH & RICHARDSON PC	DASABUVIR IND 101-636 - CORR, RECS
2015-4338	06/02/2015 06/30/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	IREBE E HUDSON FISH & RICHARDSON PC	VIEKIRA PAK NDA 206-619 - CLNCL TRIALS SIMULATIONS, CORR, APRVL RECS, ETC
2015-4339	06/02/2015 06/30/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	IRENE E HUDSON FISH & RICHARDSON PC	OMBITASVIR IND 108-434, NDA 206-619 - EXPOSURE-EFFICACY MODELING, EXPOSURE-RESPONSE ANALYSES, CORR, ETC
2015-4340	06/02/2015 06/30/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	IRENE E HUDSON FISH & RICHARDSON PC	PARITAPREVIR INDA 103-526 - CLNCL TRIAL SIMULATIONS, EXPOSIURE-RESPONSE ANALYSES, EXPOSURE-EFFICACT MODELING CORR, ETC
2015-4341	06/02/2015 06/30/2015	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SW-FO/KAN-DO/KAN-CB/	Doe J	INDIVIDUAL RECS
2015-4342	06/02/2015 06/30/2015	FDA/OGROP/OIP/	Zeba Siddiqui THOMSON REUTERS	FDA CORR WITH INDIA MINISTRY OF HEALTH AND FAMILY WELFARE 01/02/2014 - 06/02/2015
2015-4343	06/02/2015 06/30/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Allison Chen HARVEST CONSULTING CORP	K093477
2015-4344	06/02/2015 06/30/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ALEXANDRE HUNEAU CENTRE HOSPITALIER UNIVERSITAIRE DE RENNES	NALMEFENE, NALTREXONE, BACLOFEN, ETC - CLNCL TRIAL RECS
2015-4345	06/02/2015 06/30/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mark Prinz Registrar Corp	DRUG MASTER FILE SPREADSHEET
2015-4346	06/02/2015	FDA/OMPT/CDRH/OCER/DFOI/	Ellis Liu	ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATOGRAPHY ENDOSCOPES

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	06/30/2015		Carroll and Weiss LLP	REFERENCED IN EXECUTIVE SUMMARY - MDR
2015-4347	06/02/2015 06/30/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	HARVONI - MEDWATCH REPORTS
2015-4348	06/02/2015 06/30/2015	FDA/OC/OES/DFOI/	David Puryear Han Feng Inc	2015-324 CERTIFIED
2015-4349	06/02/2015 06/30/2015	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/	Lakshmi Hiriyannaiah personal	IMPORT DATA
2015-4350	06/02/2015 06/30/2015	FDA/OMPT/CTP/OD/	Lisa Isgett Counter Tools	LIST OF TOBACCO RETAILERS IN MINNESOTA
2015-4351	06/02/2015 06/30/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Allison Magwire Ariad Pharmaceuticals, Inc. (C/O Allison Magwire)	ICLUSIG - AERS
2015-4352	06/02/2015 06/30/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joshua Malamud Hyman, Phelps & McNamara P.C.	TECFIDERA - 5 YEAR NEW CHEMICAL ENTITY EXCLUSIVITY RECS
2015-4353	06/02/2015 06/30/2015	FDA/OMPT/CTP/OD/	Tisha Thompson Jacobs Tobacco Company	JACOBS TOBACCO COMPANY - SE REPORTS
2015-4354	06/02/2015 06/30/2015	FDA/OC/OES/ FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/	Liza Gross Liza Gross	CORR FROM WEINBERG GROUP RE PHTHALATES OR BPA; CORR FROM JOHN KYTE, BURSON MARSTELLAR RE PHTHALATES OR BPA; CORR FROM SOCIETY OF PLASTICS INDUSTRY MEMBERS RE PHTHALATES OR BPA
2015-4355	06/02/2015 06/30/2015	FDA/OGROP/ORO/CE-FO/NWJ-DO/NWJ-CB/	Nelson Yang, J.D. CONVENTUS BIOMEDICAL SOLUTIONS INC	DR VESOLE, HACKENSACK, NJ - 483, EIR
2015-4356	06/02/2015 06/30/2015	FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	ANA MARIA ABREU VELEZ MD PHD VELEZ, ANA MARIA ABREU	DR DENNIS MARCUS, MEDICAL COLLEGE OF GEORGIA, ATLANTA, GA - EIRS, 483S, CORR 2005 TO 2011
2015-4357	06/02/2015 06/30/2015	OC/ORO/ORM/ OC/ORO/ORM/	RAY THOMPSON THOMPSON, RAY	GMP, GLP, GCP INSPS 1/16/15-5/1/15
2015-4358	06/02/2015	FDA/OMPT/CDER/ORP/DIDP/	PAULA HARVEY	HEPARIN - AERS 2014

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	06/30/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	HARVEY, PAULA	
2015-4359	06/02/2015 06/30/2015	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	PATRICIA L REGENYE Celgene Corporation	JOHN GOFF, GASTROENTEROLOGY ASSOC PC, DENVER, CO - 483S 4/06 TO PRESENT
2015-4360	06/02/2015 06/30/2015	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	PATRICIA L REGENYE Celgene Corporation	KURT LESH, COLORADO SPRINGS FAMILY PRACTICE, COLORADO SPRINGS, CO - 483S 5/09 TO PRESENT
2015-4361	06/02/2015 06/30/2015	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	PATRICIA L REGENYE Celgene Corporation	LAWRENCE WRUBLE, MEMPHIS GASTROENTEROLOGY GROUP, MEMPHIS, TN - 483S 2/06 TO PRESENT
2015-4362	06/02/2015 06/30/2015	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OC/OES/DFOI/	PATRICIA L REGENYE Celgene Corporation	ROBERT PROVENZANO, ST JOHN HOSPITAL & MEDICAL CENTER, DETROIT, MI - 483S 4/08 TO PRESENT
2015-4363	06/02/2015 06/30/2015	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	PATRICIA L REGENYE Celgene Corporation	MARK RINGOLD, NEW RIVER VALLEY RESEARCH INSTITUTE, CHRISTIANSBURG, VA - 483S 1/12 TO PRESENT
2015-4364	06/02/2015 06/30/2015	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	PATRICIA L REGENYE Celgene Corporation	SUZANNE GAZDA, INTEGRA CLINICAL RESEARCH, SAN ANTONIO, TX - 483S 10/05 TO PRESENT
2015-4365	06/02/2015 06/30/2015	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	PATRICIA L REGENYE Celgene Corporation	MARIO JUAREZ, PANACEA CLINICAL RESEARCH, SAN ANTONIO, TX - 483S 6/14 TO PRESENT
2015-4366	06/02/2015 06/30/2015	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	PATRICIA L REGENYE Celgene Corporation	JOHN LOWE, ADVANCED RESEARCH INSTITUTE, OGDEN, UT - 483S 4/08 TO PRESENT
2015-4367	06/02/2015 06/30/2015	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	PATRICIA L REGENYE Celgene Corporation	DOUGLAS YOUNG, NORTHERN CALIFORNIA RES CORP, SACRAMENTO, CA - 483S 7/06 TO PRESENT
2015-4368	06/02/2015 06/30/2015	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	PATRICIA L REGENYE Celgene Corporation	GERALD PIERONE, TREASURE COAST INFECT DISEASE CONSULTS, VERO BEACH, FL - 483S 6/01 TO PRESENT
2015-4369	06/02/2015 06/30/2015	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	PATRICIA L REGENYE Celgene Corporation	SUNIL DHAWAN, EAST BAY DERM MED GRP, FREMONT, CA - 483S 7/10 TO PRESENT
2015-4370	06/02/2015 06/30/2015	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	PATRICIA L REGENYE Celgene Corporation	ANDREW SCHREIBER, NG, IRVINE, CA - 483S 6/12 TO PRESENT
2015-4371	06/02/2015	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	PATRICIA L REGENYE	MOUSTAFA MOUSTAFA, SOUTH CAROLINA NEPHROLOGY & HYPERTENSION CENTER, ORANGEBURG, SC - 483S 8/10

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	06/30/2015		Celgene Corporation	TO PRESENT
2015-4372	06/02/2015 06/30/2015	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OC/OES/DFOI/	PATRICIA L REGENYE Celgene Corporation	MAHENDRA SANAPATI, ADVANCED PAIN CARE CLINIC, EVANSVILLE, IN - 483S 1/14 TO PRESENT
2015-4373	06/02/2015 06/30/2015	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	PATRICIA L REGENYE Celgene Corporation	BETH SAFIRSTEIN, MD CLINICAL, HALLANDALE BEACH, FL - 483S 5/09 TO PRESENT
2015-4374	06/02/2015 06/30/2015	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	PATRICIA L REGENYE Celgene Corporation	GIGI LEFEBVRE, MERIDIEN RESEARCH, ST PETERSBURG, FL - 483S 6/11 TO PRESENT
2015-4375	06/02/2015 06/30/2015	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	PATRICIA L REGENYE Celgene Corporation	ROY FREEMAN, DEACONESS HOSPITAL, BOSTON, MA - 483S 8/95 TO PRESENT
2015-4376	06/03/2015 07/10/2015	FDA/OC/OES/DFOI/	Eyal Maor FDAAWARE	RESPONSE TO 483 - RECS PREVIOUSLY RELEASED UNDER FOIA 01/01/2014 - 06/01/2015
2015-4377	06/03/2015 07/01/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dorothea Pratt Dorothea Pratt	VIVITROL, NALTREXONE - AERS
2015-4378	06/03/2015 07/01/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Emily Krulewitz The Weinberg Group	NDA 21-196/S-005 MEDICAL REVIEW
2015-4379	06/03/2015 07/01/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lisa Zimmerman Pozen, Inc	SHANDONG XINHUA PHARMACEUTICAL CO LTD, SHANDONG, CHINA - EIR 03/24/2014 - 04/04/2014
2015-4380	06/03/2015 07/01/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kevin Patel Cowen and Co.	COPAXONE - SBA
2015-4381	06/03/2015 07/01/2015	FDA/OMPT/CDRH/OCER/DFOI/	Dede Fauconnet Dede Fauconnet	K143536
2015-4382	06/03/2015 07/01/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Cathy Slagle Stuart & Branigin	NORCO - APPROVED LABELING (CERTIFIED) 01/01/2008 - 03/01/2010

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		FDA/OMPT/CDER/GRP/DIDP/		
2015-4383	06/03/2015 07/01/2015	FDA/OMPT/CDRH/OCER/DFOI/	Scott Kokones CardioSolv, Inc.	K131158
2015-4384	06/03/2015 07/01/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	ANDA 200652, 91149, 91422 - REMS NOTIFICATION LETTERS
2015-4385	06/03/2015 07/01/2015	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	ZAC COLLINS BIOLOGIC THERAPIES	NDH MEDICAL INC, SAINT PETERSBURG, FL - EIR MOST RECENT
2015-4386	06/03/2015 07/01/2015	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	PHILIP MARTELLO NOVA BIOMEDICAL	NOVA BIOMEDICAL CORP, BILLERICA, MA - EIR 7/6-17/13
2015-4387	06/03/2015 07/01/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SOPER E-94630, STEPHEN	AFLURIA; PLATINOL - AERS
2015-4388	06/03/2015 07/01/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CINDY SHEARRER UNIV OF MISSOURI SCHOOL OF LAW LIBRARY	LIST OF GRANTS OF NCE SINCE ENACTMENT OF HATCH WAXMAN
2015-4389	06/03/2015 07/01/2015	FDA/OFVM/CFSAN/OCD/EOS/	GARY J. BURIN, Ph.D., DABT TECHNOLOGY SCIENCES GROUP INC	FCN 0561
2015-4390	06/03/2015 07/01/2015	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	STEPHEN RUGGERO WAYMOUTH FARMS INC	RECALL F-2314-2015
2015-4391	06/03/2015 07/01/2015	FDA/OC/OES/DFOI/	Nadine Ritter Global Biotech Experts, LLC	BIOTEST PHARMACEUTICALS - WARNING LETTER 01/01/2013 - 05/26/2015
2015-4392	06/03/2015 07/01/2015	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	MALCOLM B. WISEHEART III, Esq. MALCOLM B WISEHEART III PLLC	FLORIDA BOTTLING INC; LAKEWOOD ORGANIC; LAKEWOOD JUICES - INVESTIGATIONS, INSP, CMLPLNTS SINCE 2012
2015-4393	06/03/2015 07/01/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	RACHEL OLLAR ENTRICAN WELLS ANDERSON & RACE LLC	FOSAMAX - FEMUR FRACTURES

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2015-4394	06/03/2015 07/01/2015	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OMPT/CDRH/OCER/DFOI/	MARILYN J. RAMOS SILVER GOLUB & TEITELL	DKT 3:13-CV-01094
2015-4395	06/03/2015 07/01/2015	FDA/OO/OFBA/OAGS/	PERRY, BRUCE	1ZIAHDOOO257-08, 1ZIAHD008931-02; 1ZIACOO20003-06 ETC
2015-4396	06/03/2015 07/01/2015	FDA/OC/OES/DDM/	DOMINIC SCHILLER EQUIPPED 4 LIMITED	DKT 00D-1392
2015-4397	06/03/2015 07/01/2015	FDA/OFVM/CFSAN/OCD/EOS/	STEVEN J. MOSER, Esq. STEVEN J MOSER PC	SIROB IMPORTS, INC, LINDENHURST, NY - INSP, EIR, FOOD EXPORT CERT
2015-4398	06/03/2015 07/01/2015	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	DAVID LUKE NHS LABS	PALMER NATURAL PRODUCTS - 483
2015-4399	06/03/2015 07/01/2015	FDA/OFVM/CFSAN/OCD/EOS/	MICHAEL KLEIN USA RICE	ARSENIC IN RICE & RICE PRODUCTS RISK ASSESSMENT - DRAFT RPT CORR, STUDIES, RESEARCH, ETC
2015-4400	06/03/2015 07/01/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LOGAN HAINE-ROBERTS JACKSON & CAMPBELL	CVS HEALTH CORP AER, MEDWATCH
2015-4401	06/03/2015 07/01/2015	FDA/OFVM/CFSAN/OCD/EOS/	BENJAMIN L ENGLAND & ASSOCIATES LLC	ACCERA INC - WARNING LTR 1/14
2015-4402	06/03/2015 07/01/2015	FDA/OFVM/CFSAN/OCD/EOS/	JON M. SETOGUCHI ATKINSON ANDELSON LOYA ETAL	YS HEALTH - WARNING LTRS, INSP, 483, SINCE 2010
2015-4403	06/03/2015 07/01/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	CHEE HUAT KOH EPIC MEDICAL PTE LTD	K933652
2015-4404	06/03/2015 07/01/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DR. REENA HARJAI APCER Pharma Solutions, Inc	CASE 3740975, 3877826, 3925288, ETC
2015-4405	06/03/2015 07/01/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ALEXANDER J. VAROND Hyman Phelps and McNamara PC	SARAPIN (SARRACENIA PURPUREA) LBLG
2015-4406	06/03/2015	FDA/OFVM/CFSAN/OCD/EOS/	KATHRYN C. SKAGGS	FOX RIVER FIBER - NOL SUBMISSION, CORR

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	07/01/2015		Keller and Heckman LLP	
2015-4407	06/03/2015 07/01/2015	FDA/OC/OES/DDM/	DENNIS C. GUCCIARDO HOGAN LOVELLS LLP	DKT 019-0343
2015-4408	06/03/2015 07/01/2015	FDA/OMPT/CDRH/OCER/DFOI/	DENNIS C. GUCCIARDO HOGAN LOVELLS LLP	SMITH & NEPHEW ORTHOPAEDICS - BIRMINGHAM HIP RESURFACING (BHR) SYS P040033/S001,S002,S003 ETC APRVL RECS
2015-4409	06/03/2015 07/01/2015	FDA/OMPT/CDRH/OCER/DFOI/	DENNIS C. GUCCIARDO HOGAN LOVELLS LLP	CORIN USA - CORMET HIP RESURFACING SYS P050016/S001,S002,S003, ETC APRVL RECS
2015-4410	06/03/2015 07/01/2015	FDA/OMPT/CDRH/OCER/DFOI/	DENNIS C. GUCCIARDO HOGAN LOVELLS LLP	MICROPORT ORTHOPEDICS INC - CONSERVE PLUS TOTAL RESURFACING HIP SYS APRVL, P030042/S002, S003, S004
2015-4411	06/03/2015 07/01/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DR. FARON FARIBA The Patient Advocate	LYRICA (PREGABALIN) - AER SINCE 1996
2015-4412	06/03/2015 07/01/2015	FDA/OFVM/CFSAN/OCD/EOS/	GARY J. BURIN, Ph.D., DABT TECHNOLOGY SCIENCES GROUP INC	FCN 0728
2015-4413	06/04/2015 07/02/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Toni Schmittling University of Michigan - Michael Smietana	DRUG SHORTAGE RECS 01/01/1965 - 05/28/2015
2015-4414	06/04/2015 07/02/2015	FDA/OMPT/CDRH/OCER/DFOI/	Ellis Liu Carroll and Weiss LLP	PENTAX MEDICAL, PENTAX PRECISION INSTRUMENTS ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATOGRAPHY - 510K 01/01/2010 - 05/31/2015
2015-4415	06/04/2015 07/02/2015	FDA/OMPT/CDRH/OCER/DFOI/	Ellis Liu Carroll and Weiss LLP	MEDIVATORS REPROCESSING SYSTEMS AUTOMATIC ENDOSCOPE REPROCESSOR - 510K 01/01/2010 - 05/31/2015
2015-4416	06/04/2015 07/02/2015	FDA/OMPT/CDRH/OCER/DFOI/	Ellis Liu Carroll and Weiss LLP	FUJIFILM, FUJI MEDICAL SYSTEM USA INC, FUJINON, INC - ENDOSCOPE MDR 01/01/2010 - 05/31/2015
2015-4417	06/04/2015 07/02/2015	FDA/OMPT/CDRH/OCER/DFOI/	Ellis Liu Carroll and Weiss LLP	DUODENOSCOPE 510K REFERENCED IN FDA EXECUTIVE SUMMARY 01/01/2009 - 05/31/2015
2015-4418	06/04/2015 07/02/2015	FDA/OMPT/CDRH/OCER/DFOI/	Ellis Liu Carroll and Weiss LLP	CUSTOM ULTRASONICS - AUTOMATIC ENDOSCOPE REPROCESSOR 510K 01/01/2010 - 05/31/2015
2015-4419	06/04/2015 07/02/2015	FDA/OMPT/CDRH/OCER/DFOI/	Ellis Liu Carroll and Weiss LLP	AUTOMATED ENDOSCOPE REPROCESSORS REFERENCED IN FDA EXECUTIVE SUMMARY - MDR

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2015-4420	06/04/2015 07/02/2015	FDA/OMPT/CDRH/OCER/DFOI/	Ellis Liu Carroll and Weiss LLP	FUJIFILM, FUJI MEDICAL SYSTEMS USA USA, FUJINON ENDOSCOPE - 510K
2015-4421	06/04/2015 07/02/2015	FDA/OMPT/CDRH/OCER/DFOI/	Ellis Liu Carroll and Weiss LLP	PENTAX MEDICAL, PENTAX PRECISION INSTRUMENTS - MDR SUMMARIES 01/01/2010 - 05/31/2015
2015-4422	06/04/2015 07/02/2015	FDA/OMPT/CDRH/OCER/DFOI/	Ellis Liu Carroll and Weiss LLP	MEDIVATORS REPROCESSING SYSTEMS AUTOMATIC ENDOSCOPE REPROCESSOR - MDR 01/01/2010 - 05/31/2015
2015-4423	06/04/2015 07/02/2015	FDA/OMPT/CDRH/OCER/DFOI/	Ellis Liu Carroll and Weiss LLP	CUSTOM ULTRASONICS - AUTOMATIC ENDOSCOPE REPROCESSOR MDR 01/01/2010 - 05/31/2015
2015-4424	06/04/2015 07/02/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anne Chiaramello GEORGE WASHINGTON UNIVERSITY MEDICAL CENTER	IND 47776
2015-4425	06/04/2015 07/02/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Charles Snow Hyman, Phelps & McNamara P.C.	ANDA 203967 APPROVAL LETTER
2015-4426	06/04/2015 07/02/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	shin kang HCRP	FLUOROURACIL - AERS
2015-4427	06/04/2015 07/02/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	STEVEN BRILL Steven Brill	NDA 20272
2015-4428	06/04/2015 07/02/2015	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Blake Goodner Bridger Healthcare	HOSPIRA, MCPHERSON, KS - 483, WARNING LETTERS, RESPONSE LETTERS 01/02/2014 - 06/03/2015
2015-4429	06/04/2015 07/02/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	2015-3644
2015-4430	06/04/2015 07/02/2015	FDA/OMPT/CDRH/OCER/DFOI/	LELAND H BELEW ANDRUS ANDERSON LLP	ST JUDE MEDICAL INC OR ADVANCED NEUROMODULATION SYSTEMS INC - ANS'S TRIPOLE 16 LAMITRODE PADDLE LEAD P010032/S026 APRVL, LBLG CHANGES
2015-4431	06/04/2015 07/02/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	IRENE E HUDSON FISH & RICHARDSON PC	VIEKIRA PAK - NDA 206-619, PARITAPREVIR 103-526, OMBITASIVIR 108-434 CLNCL TRIAL SIMULATIONS, APRVL,

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		CORR RELATED TO EXPOSURE-EFFICACY MODELING; EXPOSURE-RESP AFTER 1/08 & PRIOR TO 12/21/14
2015-4432	06/04/2015 07/02/2015	FDA/OGROP/ORP/PA-FO/LOS- DO/LOS-CB/	ANIL K HITESHI SPECTRUM PHARMACEUTICALS INC	SPECTRUM PHARMACEUTICALS INC, IRVINE, CA - EIRS 3/13-18/14
2015-4433	06/04/2015 07/02/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	COULTER JONES MEDPAGE TODAY	PRADAXA; JANSSEN- RIVAROXABAN 20 MG; DABIGATRAN, ISR 10271037, ETC
2015-4434	06/04/2015 07/02/2015	OC/ORP/ OC/ORP/ FDA/OGROP/ORP/ORO/DIOP/	Zetetic, Inc. Zetetic, Inc.	FDA ENTRY DOCUMENTATION REQUEST ALL DOCUMENTATION MAY 16, 2015 - MAY 31, 2015
2015-4435	06/04/2015 07/02/2015	FDA/OMPT/CDRH/OCER/DFOI/	Sanae Morita TSK Laboratory, Japan	K123300
2015-4436	06/04/2015 07/02/2015	FDA/OMPT/CDRH/OCER/DFOI/	Sanae Morita TSK Laboratory, Japan	K140516
2015-4437	06/04/2015 07/02/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GARY ORR ORR, GARY	ABBOTT LABS, ABBOTT PARK, IL - SYNTHROID VARIATION IN STRENGHT FROME ON TAB TO ANOTHER
2015-4438	06/04/2015 07/02/2015	FDA/OMPT/CDRH/OCER/DFOI/	Jean LaDouceur Jean LaDouceur	K140497
2015-4439	06/04/2015 07/02/2015	FDA/OMPT/CDRH/OCER/DFOI/	Jean LaDouceur Jean LaDouceur	K113811
2015-4440	06/04/2015 07/02/2015	FDA/OMPT/CDRH/OCER/DFOI/	Amelia R Striegel COVIDIEN	K141785
2015-4441	06/04/2015 07/02/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GARY, ORR ORR, GARY	MYLAN PHARMACEUTICALS INC, CANONSBURG, PA - LEVOTHYROXINE (LEVOTHYROXINE SODIUM) VARIATION IN STRENGTH FROM ONE TAB TO ANOTHER
2015-4442	06/04/2015 07/02/2015	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Aparajita Khatri Ceramisphere Pty Ltd	LIST OF PHARMACEUTICAL AND FOOD PRODUCTS WITH SILICA APPROVED BY FDA FOR HUMAN USE, CLINICAL TRIALS 06/04/2015 - 06/18/2015

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2015-4443	06/04/2015 07/02/2015	FDA/OGROP/ORAL/SE-FO/ATL-DO/ATL-CB/	Shawn Henegar Shawn Henegar	CAROLINA BIOLOGICAL SUPPLY COMPANY, BURLINGTON, NC - ANIMAL PURCHASES 09/01/2014 - 05/30/2015
2015-4444	06/04/2015 07/02/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	MEMO RE WAIVER OF REQUIREMENT FOR SINGLE, SHARED REMS PROGRAM
2015-4445	06/04/2015 07/02/2015	FDA/OC/OES/ FDA/OC/OL/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GREGORY B COLLINS KERCSMAR & FELTUS PLLC	DESIGNER ANABOLIC STEROID CONTROL ACT OF 2014 - COMM, EMAILS
2015-4446	06/04/2015 07/02/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Andrew M. Nason Sterne Kessler Goldstein & Fox PLLC	UNSATURATED KETONE IMPURITIES IN OPIOIDS
2015-4447	06/04/2015 07/02/2015	FDA/OGROP/ORAL/SW-FO/DAL-DO/DAL-CB/	Mary Lynn The Windward Company	STILLMEADOW, INC, DALLAS, TX - EIR 04/23/2013 - 06/05/2013
2015-4448	06/04/2015 07/02/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	John Walsh James Alexander Corporation	WENNG DRUCK GMBH - EIR, 483, RECALL 06/01/2012 - 06/03/2015
2015-4449	06/04/2015 07/02/2015	FDA/OFVM/CFSAN/OCD/EOS/	JOSEPH LAWLOR HAYNES AND BOONE, LLP	L'OREAL USA MELA-D PIGMENT CONTROL - COMM WITH EMPLOYEES, AGENTS, REPRESENTATIVES, WARNING LTR 2/12/15
2015-4450	06/04/2015 07/02/2015	FDA/OGROP/ORAL/NE-FO/NWE-DO/NWE-CB/	CYNTHIA BURNS NEW WAVE SEAFOOD INC.	NEW WAVE SEAFOOD INC, STAMFORD, CT - EIR
2015-4451	06/04/2015 07/02/2015	OC/ORAL/ OC/ORAL/ OC/ORAL/ORM/ OC/ORAL/ORM/	Merle Zimmermann AMERICAN HERBAL PRODUCTS ASSOCIATION	GMP INSPECTION LIST RE COMPLIANCE WITH 21 CFR 111 01/01/2014 - 12/31/2014
2015-4452	06/04/2015	FDA/OFVM/CFSAN/OCD/EOS/	Edward Launay	DELAWARE INLAND BAYS - SHELLFISH SANITARY AND

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	07/02/2015		Environmental Resources, Inc. (ERI)	SHORELINE SURVEYS, CORR 01/01/2011 - 06/01/2015
2015-4453	06/04/2015 07/02/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OCC/	John R. Manthei Manthei, John R	EXPAREL - IND RECS
2015-4454	06/04/2015 07/02/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Terrence Clark Nexcyon Pharmaceuticals, Inc.	NDA 016750
2015-4455	06/04/2015 07/02/2015	FDA/OGROP/ORAC/CE-FO/NWJ-DO/NWJ-CB/	Ismail EICHagea International Trading Pharmaceutical Labs (ITPL)	G&W LABORATORIES, SOUTH PLAINFIELD, NJ - 483, EIR TWO MOST RECENT 06/01/2010 - 06/03/2015
2015-4456	06/04/2015 07/02/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Paul Brakeman Paul Brakeman c/o University of California, San Francisco	ANDA 203005
2015-4457	06/04/2015 07/02/2015	FDA/OMPT/CDRH/OCER/DFOI/	Amelia R Striegel COVIDIEN	K100786
2015-4458	06/05/2015 07/06/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JENNIFER RICHNAFSKY SCHULTE, ROTH & ZABEL LLP	PACIRA PHARMS - EXPAREL APRVL MTG MINS 3/15, 4/15
2015-4459	06/05/2015 07/06/2015	FDA/OC/OES/DFOI/	JOHN C ROBERTS JR Wilson Sonsini Goodrich & Rosati, P.C.	CHELSEA THERAPEUTICS INTERNATIONAL LTD - NORTHERA (DROXIDROPS) NDA 203-202 FOI REQUESTS MADE BY ROMAN ZAK OR FARUQI & FARUQI LLP 3/29/12 TO 3/29/15
2015-4460	06/05/2015 07/06/2015	FDA/OC/OES/DFOI/	RICHARD L GIAMPA ESQ RICHARD L GIAMPA ESQ PC	CERTIFIED RECS
2015-4461	06/05/2015 07/06/2015	FDA/OMPT/CDRH/OCER/DFOI/	TERRENCE E SULLIVAN GYRUS ACMI INC	APPLIED MEDICAL RESOURCES - VOYANT OPEN SEALER-DIVIDER DVC K143517
2015-4462	06/05/2015 07/06/2015	FDA/OC/OEXA/OMA/	HARRY HAMMITT ACCESS REPORTS INC	DOONESBURY CARTOON STRIP PARODY OF GOVERNEMNT EMMPLOYEES OR POLICIES 10/70 TO PRESENT

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2015-4463	06/05/2015 07/06/2015	FDA/OFVM/CFSAN/OCD/EOS/	QUIANA A MONTGOMERY Keller and Heckman LLP	TEH FONG MIN - OPTICAL BRIGHTENERS IN FOOD CONTACT PAPER NO OBJECTION LTRS
2015-4464	06/05/2015 07/06/2015	FDA/OFVM/CFSAN/OCD/EOS/	LAURA MACCLEERY CENTER FOR SCIENCE IN THE PUBLIC INTEREST	EXPERIMENTAL STUDY ON CONSUMER RESPONSES TO NUTRITION FACTS LABELS WITH VARIOUS FOOTNOTE FORMATS AND DECALARATION OF ADDED SUGARS - QUESTIONNAIRE, SURVEYS, FOCUS GROUPS ETC 4/13 TO PRESENT
2015-4465	06/05/2015 07/06/2015	FDA/OFVM/CFSAN/OCD/EOS/	LAURA MACCLEERY CENTER FOR SCIENCE IN THE PUBLIC INTEREST	PARTIALLY HYDROGENATED OIL (PHO) - FOOD ADDITIVE PETITIONS 1/15 TO PRESENT
2015-4466	06/05/2015 07/06/2015	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LISA F HARRINGTON Hyman, Phelps & McNamara P.C.	LEVONORGESTREL/ETHINYL ESTRADIOL TABS ANDA 201-088 - APRVL LTR
2015-4467	06/05/2015 07/06/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LISA F HARRINGTON Hyman, Phelps & McNamara P.C.	AZITHROMYCIN ORAL SOL ANDA 65-488 - APRVL LTR
2015-4468	06/05/2015 07/06/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LISA F HARRINGTON Hyman, Phelps & McNamara P.C.	AZITHROMYCIN TABS ANDA 65-400 - APRVL LTR
2015-4469	06/05/2015 07/06/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHARLES D SNOW Hyman, Phelps & McNamara P.C.	ESCITALOPRAM OXALATE SOL ANDA 203-967 - APRVL LTR
2015-4470	06/05/2015 07/06/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHARLES D SNOW Hyman, Phelps & McNamara P.C.	BUPROPION HCL ER TABS ANDA 202-304 - APRVL LTR
2015-4471	06/05/2015 07/06/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHARLES D SNOW Hyman, Phelps & McNamara P.C.	RISENDRONATE SODIUM DELAYED-RELEASE TABS ANDA 203-217 - APRVL LTR

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2015-4472	06/05/2015 07/06/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES D SNOW Hyman, Phelps & McNamara P.C.	ACITRETIN CAPS ANDA 204-633 - APRVL LTR
2015-4473	06/05/2015 07/06/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES D SNOW Hyman, Phelps & McNamara P.C.	LEVITIRACITAM ER TABS ANDA 203-468 - APRVL LTR
2015-4474	06/05/2015 07/06/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES D SNOW Hyman, Phelps & McNamara P.C.	METHOTREXATE SODIUM TABS ANDA 201-749 - APRVL LTR
2015-4475	06/05/2015 07/06/2015	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LISA F HARRINGTON Hyman, Phelps & McNamara P.C.	BICALUTAMIDE TABS ANDA 200-274 - APRVL LTR
2015-4476	06/05/2015 07/06/2015	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LISA F HARRINGTON Hyman, Phelps & McNamara P.C.	DESOGESTREL/ETHINYL ESTRADIOL TABS ANDA 202-085 - APRVL LTR
2015-4477	06/05/2015 07/06/2015	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LISA F HARRINGTON Hyman, Phelps & McNamara P.C.	GLIPIZIDE ER TABS ANDA 202-298 - APRVL LTR
2015-4478	06/05/2015 07/06/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	STEPEN SOPER SOPER E-94630, STEPHEN	AFLURIA - VAERS 2012-2013
2015-4479	06/05/2015 07/06/2015	FDA/OC/OES/DFOI/	GRAEME LADDS PHARSAFER ASSOCIATES LTD	PHARMACEUTICAL COMPANIES, CROs - PHARMACOVIGILANCE AND GCP INSP RPTS 1/14 TO 5/15
2015-4480	06/08/2015 07/07/2015	FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/	Cindy Hill Professional Liability Insurance	AURORA PRODUCTS - INSPECTION REPORTS 01/01/2015 - 06/02/2015

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			Services, Inc.	
2015-4481	06/08/2015 07/07/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Margaret Sestrom on behalf of Azzura Ravizza PFIZER	FAERS REPORTS
2015-4482	06/08/2015 07/07/2015	OC/ORR/ORM/ OC/ORR/ORM/	Eyal Maor FDAAWARE	INSPECTION LIST 01/01/2008 - 06/01/2015
2015-4483	06/08/2015 07/07/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Amanda Ramaker Reinhart Boerner Van Dueren	PURTOX IND 012042, BOTULINUM TOXIN, MENTOR CORPORATION, MENTOR WORLDWIDE, ETC
2015-4484	06/08/2015 07/07/2015	FDA/OGROP/ORR/CE-FO/BLT-DO/BLT-CB/	Erica Tauriello Wentworth Douglass Hospital	NCI - CIRB, EMMES CORP - EIR 01/01/2015 - 06/06/2015
2015-4485	06/08/2015 07/07/2015	FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Linda Vicary Law Offices of Marshall Silberberg	SYNERGY HEALTH CONCEPTS 05/01/2012 - 06/03/2013
2015-4486	06/08/2015 07/07/2015	FDA/OC/OL/	Ian Mandel Ian Mandel	CORR FROM HILLARY CLINTON 01/03/2001 - 01/21/2009
2015-4487	06/08/2015 07/07/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Linda Bowen SANOFI	SCINOPHARM TAIWAN, LTD - 483
2015-4488	06/08/2015 07/07/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Linda Bowen SANOFI	SCINOPHARM TAIWAN, LTD - EIR
2015-4489	06/08/2015 07/07/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Betty Swem Swem, Betty L	HOSPIRA LIDOCAINE 2% - AERS
2015-4490	06/08/2015 07/07/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	David Mangione Govzilla, Inc.	LONZA AG, SWITZERLAND - EIR, 483 03/31/2015 - 03/31/2015

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2015-4491	06/08/2015 07/07/2015	FDA/OGROP/ORPA-FO/LOS-DO/LOS-CB/ FDA/OC/OES/DFOI/	David Windish Newtyn Management	PYRAMID LABORATORIES - INSPECTION RECS PREVIOUSLY RELEASED 01/01/2000 - 06/03/2015
2015-4492	06/08/2015 07/07/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Betty Swem Swem, Betty L	INDIVIDUAL RECS
2015-4493	06/08/2015 07/07/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Maya Mahue ONYX PHARMACEUTICALS	IXAZOMIB - AERS
2015-4494	06/08/2015 07/07/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Younjung Yuk DENTIUM USA	K122295
2015-4495	06/08/2015 07/07/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Charles Snow Hyman, Phelps & McNamara P.C.	ANDA 201066 APPROVAL LETTER
2015-4496	06/08/2015 07/07/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Charles Snow Hyman, Phelps & McNamara P.C.	ANDA 090041 APPROVAL LETTER
2015-4497	06/08/2015 07/07/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Charles Snow Hyman, Phelps & McNamara P.C.	ANDA 202048 APPROVAL LETTER
2015-4498	06/08/2015 07/07/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Charles Snow Hyman, Phelps & McNamara P.C.	ANDA 203104 APPROVAL LETTER

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2015-4499	06/08/2015 07/07/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 8578
2015-4500	06/08/2015 07/07/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Raquel Herrera Comoglio Raquel Herrera Comoglio	METHIMAZOLE ISCR AND LIVER INJURY
2015-4501	06/08/2015 07/07/2015	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	David Mangione Govzilla, Inc.	HOSPIRA, INC, MCPHERSON, KS - 483, EIR 04/03/2015 - 04/03/2015
2015-4502	06/08/2015 07/07/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jessica Ramich ALBANY MEDICAL CENTER	PHENYLEPHRINE - RECS RE CONCENTRATION 01/01/2011 - 06/05/2015
2015-4503	06/08/2015 07/07/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Charles Snow Hyman, Phelps & McNamara P.C.	ANDA 091676 APPROVAL LETTER
2015-4504	06/08/2015 07/07/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Charles Snow Hyman, Phelps & McNamara P.C.	ANDA 202937
2015-4505	06/08/2015 07/07/2015	FDA/OMPT/CDRH/OCER/DFOI/	Jenette Bennett CENORIN LLC	K983068, K950566, K953645
2015-4506	06/08/2015 07/07/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Charles Snow Hyman, Phelps & McNamara P.C.	ANDA 202525 APPROVAL LETTER
2015-4507	06/08/2015 07/07/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Charles Snow Hyman, Phelps & McNamara P.C.	ANDA 203112 APPROVAL LETTER

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		FDA/OMPT/CDER/GRP/DIDP/		
2015-4508	06/08/2015 07/07/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Charles Snow Hyman, Phelps & McNamara P.C.	ANDA 204603 APPROVAL LETTER
2015-4509	06/08/2015 07/07/2015	FDA/OC/OES/DFOI/	Walid Gardezi Walid Gardezi	PATHEON MANUFACTURING SERVICES LLC, ETC - INPSECTION RECS PREVIOUSLY RELEASED 05/30/2010 - 05/30/2015
2015-4510	06/08/2015 07/07/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Charles Snow Hyman, Phelps & McNamara P.C.	ANDA 202610
2015-4511	06/08/2015 07/07/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Charles Snow Hyman, Phelps & McNamara P.C.	ANDA 203916 APPROVAL LETTER
2015-4512	06/08/2015 07/07/2015	FDA/OFVM/CFSAN/OCD/EOS/	Merle Zimmermann AMERICAN HERBAL PRODUCTS ASSOCIATION	CANNABIS, CANNABIDIOL - DIETARY SUPPLEMENT ADVERSE EVENTS
2015-4513	06/08/2015 07/07/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Charles Snow Hyman, Phelps & McNamara P.C.	ANDA 203691 APPROVAL LETTER
2015-4514	06/08/2015 07/07/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Charles Snow Hyman, Phelps & McNamara P.C.	NDA 203929 APPROVAL LETTER
2015-4515	06/08/2015 07/07/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Charles Snow Hyman, Phelps & McNamara P.C.	ANDA 077006 APPROVAL LETTER
2015-4516	06/08/2015 07/07/2015	FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/	Doe J	AUREX LABORATORIES, EAST WINDSOR, NJ - INVESTIGATION RECS 02/01/2015 - 06/04/2015
2015-4517	06/08/2015	FDA/OGROP/ORACE-FO/KAN-	Leslie Wootten	GREYHOUNDS ARE OUR BUSINESS - EIR 10/01/2013 -

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	07/07/2015	DO/KAN-CB/	Leslie Wootten	12/01/2013
2015-4518	06/08/2015 07/07/2015	FDA/OMPT/CDRH/OCER/DFOI/	David Jackson SnoreHero, llc	K112205
2015-4519	06/08/2015 07/07/2015	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Rachel Johnson FOI Services, Inc.	INVENTURE FOODS, JEFFERSON, GA - EIR, 483, RESPONSE
2015-4520	06/08/2015 07/07/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Charles Snow Hyman, Phelps & McNamara P.C.	ANDA 077301 APPROVAL LETTER
2015-4521	06/08/2015 07/07/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Charles Snow Hyman, Phelps & McNamara P.C.	ANDA 091190 APPROVAL LETTER
2015-4522	06/08/2015 07/07/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Charles Snow Hyman, Phelps & McNamara P.C.	ANDA 091635 APPROVAL LETTER
2015-4523	06/08/2015 07/07/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Charles Snow Hyman, Phelps & McNamara P.C.	ANDA 203534 APPROVAL LETTER
2015-4524	06/08/2015 07/07/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Charles Snow Hyman, Phelps & McNamara P.C.	ANDA 203991 APPROVAL LETTER
2015-4525	06/08/2015 07/07/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rhona Shanker Z & B Enterprises, Inc.	K090367, K141946, K142105
2015-4526	06/08/2015 07/07/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Charles Snow Hyman, Phelps & McNamara P.C.	ANDA 090621 APPROVAL LETTER
2015-4527	06/08/2015 07/07/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Charles Snow Hyman, Phelps & McNamara P.C.	ANDA 090453 APPROVAL LETTER

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2015-4528	06/08/2015 07/07/2015	FDA/OMPT/CDRH/OCER/DFOI/	Caio Formenti Kip Petroff Associates (c/o Mathis & Donheiser, P.C.)	PMA 040033, K5002996, K061243 ETC
2015-4529	06/08/2015 07/07/2015	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/	Jesse Newman THE WALL STREET JOURNAL	BLUE BELL CREAMERIES - CORR WITH FDA, LAB RESULTS 01/01/2015 - 06/08/2015
2015-4530	06/08/2015 07/07/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Charles P Cannata Charles P Cannata	MASTERPHARM PHARMACY - RECS RE APPROVAL TO COMPOUND MEDICATION FOR CLINICAL TRIALS 03/06/2011 - 06/04/2015
2015-4531	06/08/2015 07/07/2015	FDA/OFVM/CFSAN/OCD/EOS/	Ling Tao CORNELL UNIVERSITY	NANNOCHLOROPSIS - INVESTIGATIONAL FOOD ADDITIVE, FOOD USE AUTHORIZATIONS, FOOD ADDITIVE PETITION, ETC
2015-4532	06/09/2015 07/08/2015	FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	PATRICIA L REGENYE Celgene Corporation	BRUCE SALZBERG, ATLANTA GASTROENTEROLOGY ASSOCIATES, A TLANTA, GA - 483'S 11/08 TO PRESENT
2015-4533	06/09/2015 07/08/2015	FDA/OGROP/ORO/SE-FO/NOL-DO/NOL-CB/	PATRICIA L REGENYE Celgene Corporation	ZIAD YOUNES, GASTROENTEROL CTR MIDSOUTH, MEMPHIS, TN - 483'S 12/06 TO PRESENT
2015-4534	06/09/2015 07/08/2015	FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	PATRICIA L REGENYE Celgene Corporation	DOUGLAS WOLF, ATLANTA GASTROENTEROLOGY ASSOCIATES LLC, ATLANTA, GA - 483'S 10/07 TO PRESENT
2015-4535	06/09/2015 07/08/2015	FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/ FDA/OC/OES/DFOI/	PATRICIA L REGENYE Celgene Corporation	KENNETH BROWN, DIGESTIVE HLTH ASSOC TEXAS, PLANO, TX - 483'S 9/10 TO PRESENT
2015-4536	06/09/2015 07/08/2015	FDA/OC/OES/DFOI/	JOHN ROBERTS Wilson Sonsini Goodrich & Rosati, P.C.	2013-323, 2014-1612, 2014-4237
2015-4537	06/09/2015 07/08/2015	OC/ORO/ORM/ OC/ORO/ORM/	LESLIE RAMSEY FDA NEWS	LIST OF 483'S FOR PHARMACEUTICAL, BIOLOGICS & MEDICAL DVC MFG & CLNCL TRTIAL FACILITIES BOTH IN THE US & OUTSIDE THE US 5/1-31/15
2015-4538	06/09/2015 07/08/2015	FDA/OFVM/CFSAN/OCD/EOS/	RENATA NORONHA IOVATE HEALTH SCIENCES INTERNATIONAL INC	IRS 182803, 183304, 182912 - CAERS

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2015-4539	06/09/2015 07/08/2015	FDA/OMPT/CDRH/OCER/DFOI/	JOHN MARTINEZ MARTINEZ, JOHN	QUELL - K130919
2015-4540	06/09/2015 07/08/2015	FDA/OMPT/CDRH/OCER/DFOI/	LEROY L HAMILTON HAMILTON PHD, LEROY L	EXPLANATION OF FIELDS ADDED TO THE CLASSIFICATION DATABASE FILE, NAMELY PHYSICALSTATE, TECHNICALMETHOD, TARGETAREA, IMPLANT FLAG & LIFE SUSTAIN SUPPORT FLAG
2015-4541	06/09/2015 07/08/2015	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	WAYNE SADOWSKI NOVARTIS PHARMACEUTICAL CORP	DR KEITH ROBINSON, OAKLAND PARK, FL - EIR, 482, 4836/23/14-7/3/14
2015-4542	06/09/2015 07/08/2015	FDA/OGROP/ORR/CE-FO/PHI-DO/PHI-CB/	ANNE M HULL HUTTON & HUTTON	NUTECK DISPOSABLES INC - SIMPLY RIGHT WIPES RECALL, CORR, LAB STUDIES, ETC
2015-4543	06/09/2015 07/08/2015	FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/	ZACHARY T FAIRES BROWN & JAMES	BAILY INTERNATIONAL (SPICE KING), ST LOUIS, MO - RECALL OF AFOREMENTIONED SPICE KING PRODS INVESTIGATION NOTES, RECORDED STATEMENTS, PHOTOGRAPHS, ETC 4/26/11
2015-4544	06/09/2015 07/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TERRI M SMITH FELDMAN SHEPHERD ET AL	ISR 3794682, 6099237, 6355270, ETC
2015-4545	06/09/2015 07/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SABERI RANA Valeant Pharmaceuticals North America LLC	BRIMONIDINE TARTATE - ISR 4157759, 6750362, 8023104, ETC
2015-4546	06/09/2015 07/08/2015	FDA/OMPT/OSMP/OOPD/	KATHLEEN R HENRY Hyman, Phelps & McNamara P.C.	ABB VIE INC, NORTH CHICAGO, IL - DUODOPA (LEVODOPA & CARBIDOPA NDA 203-952 CORR,ORPHAN DRUGS DESIGNATION & APRVL
2015-4547	06/09/2015 07/08/2015	FDA/OMPT/CDRH/OCER/DFOI/ OC/ORR/ OC/ORR/ FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/	W PATRICK NOONAN W PATRICK NOONAN	WESTRIDGE LABS, SANTA ANA, CA -I-D GLIDE EIR, 483, 482, ETC
2015-4548	06/09/2015 07/08/2015	OC/ORR/ORM/ OC/ORR/ORM/	ELLIOTT GRAHAM QA LEARNING FOUNDATION	IN VIVO BIOEQUIVALENCE 7348.001; GLP (NONCLINICAL LABS) 7348.808; GLP (NONCLINICAL LABS) EPA DATA AUDIT INSP 7348.808A, ETC 483S 2013
2015-4549	06/09/2015 07/08/2015	FDA/OFVM/CFSAN/OCD/EOS/	LAURA MACCLEERY CENTER FOR SCIENCE IN PUBLIC INT	JOLT, ROCKSTAR, 5 HOUR ENERGY DRINKS, ETC - CAERS, MEDICAL RPTS, MEMOS, ETC 1/13 TO PRESENT

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2015-4550	06/09/2015 07/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	TECFIDERA (DIMETHYL FUMARATE) 240 MG - IS THERE ANY DATA ON PATIENTS THAT DISCONTUNUE TECFIDERAL UNTIL LYMPHOPENIA IS RESOLVED & RESTARTED AGAIN?; DO THEY HAVE THE SAME AERS EFFECT OF LOW LYMPHOCYTES?; HAVE THERE BEEN MALIGNANCIES RPORTED ON OTHER PATIENTS WITH LYMPHOPENIA WHILE TAKING TECFIDERA & IN SKIN CANCERS?
2015-4551	06/09/2015 07/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kelly Sioris SafetyCall International, PLLC	SODIUM SULFACETAMIDE - AERS
2015-4552	06/09/2015 07/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	Merle Zimmermann American Herbal Products Association	CANNABIS, CANNABIDIOL IN IND, MARKETED DRUGS - AERS
2015-4553	06/09/2015 07/08/2015	FDA/OGROP/ORAP/PA-FO/SEA-DO/SEA-CB/	Maura Martin Airgas USA, LLC	AIRGAS, TACOMA, WA - EIR 01/05/2015 - 01/17/2015
2015-4554	06/09/2015 07/08/2015	FDA/OGROP/ORAP/PA-FO/SEA-DO/SEA-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Rachel Johnson FOI Services, Inc.	CMC BIOLOGICS, BOTHELL, WA - EIR, 483
2015-4555	06/09/2015 07/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Maggie Tsavaris Maggie Tsavaris	PREMPRO - LABEL, PACKAGE INSERT, CHANGES ETC 01/01/2005 - 12/31/2013
2015-4556	06/09/2015 07/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Maggie Tsavaris Maggie Tsavaris	ESTRADIOL/NORETHINDRONE - SBA, LABELS, PACKAGE INSERTS ETC 04/01/2008 - 05/15/2013
2015-4557	06/09/2015 07/08/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K143531
2015-4558	06/09/2015 07/08/2015	FDA/OO/OHR/	Kimberly Wigglesworth Kimberly Wigglesworth	FDA-ORA-15-DE-1345224-KBH - APPLICATION, CV OF SUCCESSFUL CANDIDATE
2015-4559	06/09/2015 07/08/2015	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	Steve Kradjian Conventus Biomedical Solutions,	THE ANGELES CLINIC, SANTA MONICA, CA - 483, EIR, CORR 01/01/2010 - 05/26/2015

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			Inc.	
2015-4560	06/09/2015 07/08/2015	OC/ORO/ OC/ORO/	Eunice Lim Eunice Lim	BENEFUL - PRODUCT TESTING RESULTS 01/01/2011 - 06/05/2015
2015-4561	06/09/2015 07/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Carly Rodriguez Research Excellence to Stop TB Resistance (RESIST-TB)	LIST OF DRUGS APPROVED FOR EXPANDED ACCESS USES
2015-4562	06/09/2015 07/08/2015	FDA/OMPT/CDRH/OCER/DFOI/	Thesi Roestel iRT Systems GmbH	K062817
2015-4563	06/09/2015 07/08/2015	FDA/OGROP/ORO/PA-FO/SEA-DO/SEA-CB/	Kevin Fettes Kevin Fettes	GALENA BIOPHARMA INC, PORTLAND, OR - 483 11/17/2014 - 11/21/2014
2015-4564	06/09/2015 07/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dustin Block IPD Analytics, LLC	ANDA 091620
2015-4565	06/09/2015 07/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nicholas Temming Leventhal & Puga	DEPO MEDROL - AERS
2015-4566	06/09/2015 07/08/2015	FDA/OMPT/CDRH/OCER/DFOI/	Thesi Roestel iRT Systems GmbH	K072374
2015-4567	06/09/2015 07/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Neil Bapodra LifeSci Capital	bb2121 BCMA CAR-T IND RECS
2015-4568	06/09/2015 07/08/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Cheryl Scalzo Wilkes & McHugh, P.A.	ANDA 062349, 062512, 062517, ETC - LABELING
2015-4569	06/09/2015 07/08/2015	OC/CVM/OCD/	Elizabeth Bliss Elizabeth Bliss	PREVICOX - AERS

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2015-4570	06/09/2015 07/08/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shaun Daugherty Coles Barton LLP	PRILOCAINE - AERS
2015-4571	06/09/2015 07/08/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	P080027
2015-4572	06/09/2015 07/08/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Amelia R Striegel COVIDIEN	K081042
2015-4573	06/09/2015 07/08/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Cynthia Katsempris ACTAVIS	NDA 021537/S-008
2015-4574	06/09/2015 07/08/2015	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	Amar Eldaher American Pharmaceutical Ingredients, LLC	JUBILANT HOLLISTERSTIER, SPOKANE, WA - 483, WARNING LETTER 01/08/2012 - 06/08/2015
2015-4575	06/09/2015 07/08/2015	OC/CVM/OCD/	Curtis R. Youngs, PhD IOWA STATE UNIVERSITY	NADA 108-901 FOIA SUMMARY
2015-4576	06/09/2015 07/08/2015	OC/ORA/OCI/ OC/ORA/OCI/	Eric Litke Gannett Wisconsin Media	DOOR COUNTY, WISCONSIN - PARAMEDICS INVESTIGATION 01/01/2014 - 06/05/2015
2015-4577	06/09/2015 07/08/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Andrew Finkelstein Susquehanna Financial Group	AKORN, INDIA - 483 01/01/2014 - 06/09/2015
2015-4578	06/09/2015 07/08/2015	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Mark Collette HOUSTON CHRONICLE	COMM BETWEEN FDA, SOUTH CAROLINA, AND CDC RE POSITIVE LISTERIA TESTS ON BLUE BELL ICE CREAM 01/01/2015 - 06/05/2015
2015-4579	06/09/2015 07/08/2015	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Mark Gardner DuVal & Associates, P.A.	RODAN AND FIELDS - UNTITLED LETTERS, WARNING LETTERS, ENFORCEMENT ACTIONS 06/01/2011 - 06/01/2015
2015-4580	06/09/2015 07/08/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Amy N. Plewke Deters Lawfirm	MEDWATCH REPORTS

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2015-4581	06/09/2015 07/08/2015	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ OC/OR/ OC/OR/	Moishe Friedman Atlantix Commodities	REFRIG-IT WAREHOUSE, KEARNY, NJ - PINE NUT RECS 03/01/2015 - 06/08/2015
2015-4582	06/09/2015 07/08/2015	OC/CVM/OCD/	Beth Marchitelli, DVM Beth Marchitelli, DVM	BEUTHANASIA D - SAFETY STUDIES
2015-4583	06/09/2015 07/08/2015	OC/OR/ OC/OR/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORASW-FO/SWID/SWID-CB/	Guadalupe del Razo La Italiana, S.A. de C.V.	118-1108244-2-001-004 LAB REPORT
2015-4584	06/09/2015 07/08/2015	FDA/OMPT/CDRH/OCER/DFOI/	Brett A. Eckstein CANNON & DUNPHY SC ATTYS	INDIVIDUAL RECS
2015-4585	06/09/2015 07/08/2015	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Stephen Grimes Mercia Pharma, Inc.	CBER SOP 000333 POTENCY DETERMINATION OF INACTIVATED INFLUENZA VIRUS VACCINE BY THE SINGLE RADIAL IMMUNODIFFUSION; TEMPLATE SRID TRIVALENT CALCULATIONS
2015-4586	06/10/2015 07/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/OR/ OC/OR/ FDA/OGROP/ORA/ORO/DIOP/	JON M SANDS FEDERAL PUBLIC DEFENDER ARIZONA	THIOPENTAL SODIUM, PANCURONIUM, POTASSIUM CHLORIDE - IMPORTATION RECS
2015-4587	06/10/2015 07/09/2015	OC/OR/ OC/OR/ FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	SARA REARDON NATURE	CMPLNT REGARDING CONTAMINATION AND POOR QUALITY CONTROL AT THE NIH PHARMACEUTICAL DEVELOPMENT SERVICE
2015-4588	06/10/2015 07/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LAUREN A FARRUGGIA Hyman, Phelps & McNamara P.C.	DRUG LIST - FOI REQUESTS 2014-493, 2014-1703
2015-4589	06/10/2015 07/09/2015	FDA/OC/OES/DFOI/	BRAD RACINO MUCKROCK NEWS	FDA RECORD RETENTION SCHEDULE

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2015-4590	06/10/2015 07/09/2015	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	Jeanne Gouveia Aerie Pharmaceuticals Inc.	BAUSCH & LOMB, TAMPA, FL - 483 03/04/2015 - 03/06/2015
2015-4591	06/10/2015 07/09/2015	FDA/OMPT/CDRH/OCER/DFOI/	James Boiani Epstein Becker Green	MEDICAL DEVICE RECALL DATA 10/01/2012 - 06/01/2015
2015-4592	06/10/2015 07/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Data Integrity Sophia Wang	DATA INTEGRITY REQUIREMENT FOR CHINESE PHARMACEUTICAL FIRMS
2015-4593	06/10/2015 07/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	ANDA APPROVAL LETTERS
2015-4594	06/10/2015 07/09/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	P120032
2015-4595	06/10/2015 07/09/2015	FDA/OGROP/ORR/CE-FO/CHI-DO/CHI-CB/ FDA/OGROP/ORR/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORR/NE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/	Seth Payer United Food and Commercial Workers	ADVANCEPIERRE FOODS, ENID, OK, ETC - 483
2015-4596	06/10/2015 07/09/2015	FDA/OO/OHR/	Joy Lazaroff et al FDA ERG Group	MD-715
2015-4597	06/10/2015 07/09/2015	FDA/OGROP/ORR/SW-FO/DEN-DO/DEN-CB/	Justin Prochnow GREENBERG TRAURIG	DOTERRA - COMPLAINTS, RESPONSE TO 483 01/01/2015 - 06/08/2015
2015-4598	06/10/2015 07/09/2015	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	Zetetic, Inc. Zetetic, Inc.	FDA ENTRY DOCUMENTATION REQUEST AM1-0196057-4
2015-4599	06/10/2015 07/09/2015	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	Zetetic, Inc. Zetetic, Inc.	FDA ENTRY DOCUMENTATION REQUEST AM1-0195722-4
2015-4600	06/10/2015 07/09/2015	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	Zetetic, Inc. Zetetic, Inc.	FDA ENTRY DOCUMENTATION REQUEST AM1-0195202-7
2015-4601	06/10/2015	FDA/OGROP/ORR/SE-FO/FLA-	Zetetic, Inc.	FDA ENTRY DOCUMENTATION REQUEST AM1-0195155-7

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	07/09/2015	DO/FLA-CB/	Zetetic, Inc.	
2015-4602	06/10/2015 07/09/2015	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	Zetetic, Inc. Zetetic, Inc.	FDA ENTRY DOCUMENTATION REQUEST AM1-0194717-5
2015-4603	06/10/2015 07/09/2015	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	Zetetic, Inc. Zetetic, Inc.	FDA ENTRY DOCUMENTATION REQUEST AM1-0193799-4
2015-4604	06/10/2015 07/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Barry Pressman PureTek Corporation	ANDA 077863 SBA
2015-4605	06/10/2015 07/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	10280030, 10335010, 10343763, ETC
2015-4606	06/10/2015 07/09/2015	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORR/CE-FO/CIN-DO/CIN-CB/	Seth Payer United Food and Commercial Workers	ADVANCEPIERRE FOODS - LETTERS, COMMUNICATIONS 01/01/2010 - 06/01/2015
2015-4607	06/10/2015 07/09/2015	FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/	Alexandra Ajmo LIFE EXTENSION	CAPTEK SOFTGEL INTERNATIONAL, CERRITOS, CA - EIR 01/01/2008 - 06/09/2015
2015-4608	06/10/2015 07/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Randall Brown Randall Brown, MD	RECS RE USE OF PLANT DNA MADE BY APPLIED DNA SCIENCES, ETC 06/01/2014 - 06/09/2015
2015-4609	06/10/2015 07/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ashish Rathi Spark Capital India (Private) Advisors Ltd	GLENMARK PHARMACEUTICALS LIMITED, INDIA - 483 01/01/2015 - 05/27/2015
2015-4610	06/10/2015 07/09/2015	FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/	Alexandra Ajmo LIFE EXTENSION	J&D LABORATORIES, VISTA, CA - EIR 01/01/2010 - 06/09/2015
2015-4611	06/10/2015 07/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	HIKMA, PORTUGAL - 483 2003 TO PRESENT
2015-4612	06/10/2015	OC/ORR/	Brittany Quinn	ENTRY 916-2702957-1 TEST RESULTS

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	07/09/2015	OC/ORA/ FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	MEDLINE INDUSTRIES INC	
2015-4613	06/10/2015 07/09/2015	FDA/OC/OEXA/OMA/	Michael Joyce SAUL EWING LLP	EMAIL SENT BY JEFF VENTURA TO ASSOCIATED PRESS RE NEBREASKA ATEMPTS TO IMPORT LETHAL INJECTION DRUGS TO US, OTHER CORR 05/29/2015 - 06/09/2015
2015-4614	06/10/2015 07/09/2015	FDA/OO/OHR/	Joy Lazaroff et al FDA ERG Group	FDA SCORES FOR EMPLOYEE VIEWPOINT SURVEY, FEDERAL EQUAL OPPORTUNITY RECRUITMENT PROGRAM, DISABLED VETERANS AFFIRMATIVE ACTION PROGRAM PLANS SUBMITTED TO OPM ETC
2015-4615	06/10/2015 07/09/2015	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Alexandra Ajmo LIFE EXTENSION	DEERLAND ENZYMES, KENNESAW, GA - EIR 01/01/2010 - 06/09/2015
2015-4616	06/10/2015 07/09/2015	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Alexandra Ajmo LIFE EXTENSION	FLORIDA SUPPLEMENTS, HOLLYWOOD, FL - EIR
2015-4617	06/10/2015 07/09/2015	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	Alexandra Ajmo LIFE EXTENSION	A-PLUS SECURE PACKAGING, LAVERGNE, TN - EIR 01/01/2010 - 06/09/2015
2015-4618	06/10/2015 07/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Shin Kang HCRP	ZYTIGA - AERS
2015-4619	06/10/2015 07/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	VOLTAREN GEL - AERS
2015-4620	06/10/2015 07/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Valerie Ahmuty TherapeuticsMD	ANDA 205256
2015-4621	06/10/2015 07/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	REPORTS FOR 10356808 DIFICID
2015-4622	06/10/2015 07/09/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	REPORTS FOR 10284699, 10289533, 10290402, 10301457, ETC DULERA

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		FDA/OMPT/CDER/ORP/DIDP/		
2015-4623	06/10/2015 07/09/2015	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	Zetetic, Inc. Zetetic, Inc.	FDA ENTRY DOCUMENTATION REQUEST AM1-0193582-4
2015-4624	06/10/2015 07/09/2015	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	Zetetic, Inc. Zetetic, Inc.	FDA ENTRY DOCUMENTATION REQUEST AM1-0193234-2
2015-4625	06/11/2015 07/10/2015	OC/CVM/OCD/	David Yandell ELANCO ANIMAL HEALTH	NADA's 141-276 141-280 141-278 ETC TYPE C BLUEBIRD LABELING
2015-4626	06/11/2015 07/10/2015	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	Zetetic, Inc. Zetetic, Inc.	FDA ENTRY DOCUMENTATION REQUEST AM1-0192671-6
2015-4627	06/11/2015 07/10/2015	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	Zetetic, Inc. Zetetic, Inc.	FDA ENTRY DOCUMENTATION REQUEST AM1-0192412-5
2015-4628	06/11/2015 07/10/2015	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	Zetetic, Inc. Zetetic, Inc.	FDA ENTRY DOCUMENTATION REQUEST AM1-0192020-6
2015-4629	06/11/2015 07/10/2015	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	Zetetic, Inc. Zetetic, Inc.	FDA ENTRY DOCUMENTATION REQUEST AM1-0191873-9
2015-4630	06/11/2015 07/10/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Robert Garris, Pharm.D., MPH Teva Pharmaceuticals	SANDOZ INC - RESC SUBMITTED FOR GLATIRAMER ACETATE INJECTION 20 MG/ML
2015-4631	06/11/2015 07/10/2015	FDA/OGROP/ORR/SE-FO/SJN-DO/SJN-CB/	Walter Chalkley THOMSON REUTERS	AMGEN MANUFACTURING LIMITED, JUNCOS, PR - EIR, 483, RESPONSE 01/01/2015 - 01/23/2015
2015-4632	06/11/2015 07/10/2015	FDA/OGROP/ORR/PA-FO/SAN-DO/SAN-CB/	Walter Chalkley THOMSON REUTERS	SANTA CLARA VALLEY MEDICAL CENTER IRB, SAN JOSE, CA - EIR, 483, RESPONSE 08/01/2014 - 09/19/2014
2015-4633	06/11/2015 07/10/2015	FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/	Walter Chalkley THOMSON REUTERS	DR NICOLAS SHONKA, OMAHA, NE - EIR, 483, RESPONSE 06/01/2014 - 06/20/2014
2015-4634	06/11/2015 07/10/2015	FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/	Walter Chalkley THOMSON REUTERS	OCTAPHARMA PLASMA, INC, OMAHAM, NE - EIR, 483, RESPONSE 12/01/2014 - 01/08/2015
2015-4635	06/11/2015 07/10/2015	FDA/OGROP/ORR/CE-FO/NWJ-DO/NWJ-CB/	Walter Chalkley THOMSON REUTERS	MERCK SHARP & DOHME, RAHWAY, NJ - EIR, 483, RESPONSE 05/01/2014 - 05/19/2014
2015-4636	06/11/2015 07/10/2015	FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/	Walter Chalkley THOMSON REUTERS	ST JOHN HEALTH SYSTEM IRB, TULSA, OK - EIR, 483, RESPONSE 12/01/2014 - 01/09/2015
2015-4637	06/11/2015 07/10/2015	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	Walter Chalkley THOMSON REUTERS	BIOTEST PHARMACEUTICALS, CORP, BOCA RATON, FL - EIR, 483, RESPONSE 07/01/2014 - 08/14/2014

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2015-4638	06/11/2015 07/10/2015	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Walter Chalkley THOMSON REUTERS	LONZA BIOLOGICS, PORTSMOUTH, NH - EIR, 483, RESPONSE 01/01/2015 - 02/10/2015
2015-4639	06/11/2015 07/10/2015	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Walter Chalkley THOMSON REUTERS	VERTEX PHARMACEUTICALS, BOSTON, MA - EIR, 483, RESPONSE 10/01/2014 - 10/16/2014
2015-4640	06/11/2015 07/10/2015	OC/ORAN/ OC/ORAN/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Brenda Van Goethem Nature's Way Product	COMPLAINT 141514
2015-4641	06/11/2015 07/10/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jean Xiao, Graduate Student Vanderbilt Law and Economics Program	ORANGE BOOK ELECTRONIC ZIPPED FILES
2015-4642	06/11/2015 07/10/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Walter Chalkley THOMSON REUTERS	TOMASZ SZCZPANSKI, POLAND - EIR, 483, RESPONSE 09/08/2014 - 09/11/2014
2015-4643	06/11/2015 07/10/2015	FDA/OC/OES/DFOI/	Tao Li UNIVERSITY OF WARWICK	FOIA LOG 01/01/2014 - 05/31/2015
2015-4644	06/11/2015 07/10/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Walter Chalkley THOMSON REUTERS	PATHEON INC, CANADA - EIR, 483, RESPONSE 01/01/2015 - 01/31/2015
2015-4645	06/11/2015 07/10/2015	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Walter Chalkley THOMSON REUTERS	BATTELLE MEMORIAL INSTITUTE, COLUMBUS, OH - EIR, 483, RESPONSE 03/01/2014 - 04/04/2014
2015-4646	06/11/2015 07/10/2015	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Walter Chalkley THOMSON REUTERS	CHARLES RIVER, NV - EIR, 483, RESPONSE 07/01/2012 - 07/25/2012
2015-4647	06/11/2015 07/10/2015	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Walter Chalkley THOMSON REUTERS	ALVARO OCAMPO, MIAMI, FL - EIR, 483, RESPONSE 06/01/2014 - 07/07/2014
2015-4648	06/11/2015 07/10/2015	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Walter Chalkley THOMSON REUTERS	BOEHRINGER INGELHEIM ROXANE, COLUMBUS, OH - EIR, 483, RESPONSE 06/01/2014 - 06/26/2014
2015-4649	06/11/2015 07/10/2015	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Walter Chalkley THOMSON REUTERS	CEUTICAL LABORATORIES, INC, FARMERS BRANCH, TX - EIR, 483, RESPONSE 02/01/2014 - 06/24/2014

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2015-4650	06/11/2015 07/10/2015	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Walter Chalkley THOMSON REUTERS	GILEAD SCIENCES, SAN DIMAS, CA - EIR, 483, RESPONSE 05/07/2014 - 05/16/2014
2015-4651	06/11/2015 07/10/2015	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	Jim Austin Arizona Nutritional Supplements	HERON BOTANICALS, INC, KINGSTON, WA - EIR, 483, RESPONSE 09/01/2014 - 09/30/2014
2015-4652	06/11/2015 07/10/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Paul MacDonald Nova Biomedical Corporation	K041478
2015-4653	06/11/2015 07/10/2015	FDA/OMPT/CDRH/OCER/DFOI/	Leonardo Neumeyer Leonardo Neumeyer	K142672
2015-4654	06/11/2015 07/10/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jenna Durney EIRGEN PHARMA LTD	ANDA 202179
2015-4655	06/11/2015 07/10/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Aileen Chen, MD, PhD University of Miami Miller School of Medicine	SUBCUTANEOUS DIPHENHYDRAMINE - AERS, LABELING CHANGE RECS PRESERVATIVES, CARRIER INGREDIENTS
2015-4656	06/11/2015 07/10/2015	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Zetetic, Inc. Zetetic, Inc.	FDA ENTRY DOCUMENTATION REQUEST AM1-0196964-1
2015-4657	06/11/2015 07/10/2015	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Zetetic, Inc. Zetetic, Inc.	FDA ENTRY DOCUMENTATION REQUEST AM1-0196398-2
2015-4658	06/11/2015 07/10/2015	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Zetetic, Inc. Zetetic, Inc.	FDA ENTRY DOCUMENTATION REQUEST AM1-0196469-1
2015-4659	06/11/2015 07/10/2015	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Zetetic, Inc. Zetetic, Inc.	FDA ENTRY DOCUMENTATION REQUEST AM1-0196308-1
2015-4660	06/11/2015 07/10/2015	FDA/OC/OES/DFOI/	YIFRAH, YORAM	DAILY LOG SINCE 2006
2015-4661	06/11/2015 07/10/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	MONICA RICHARDSON CSL BEHRING	BLA 125582
2015-4662	06/11/2015 07/10/2015	FDA/OMPT/CDRH/OCER/DFOI/	Jarvis, David	MDR 2031966-2015-00022
2015-4663	06/11/2015 07/10/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	EDWARD A. STEELE EAS CONSULTING GROUP LLC	CORR BETWEEN FDA & OMPI PHARMA REGARDING GLASS TUBING 1/10 TO PRESENT

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2015-4664	06/11/2015 07/10/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	EDWARD A. STEELE EAS CONSULTING GROUP LLC	CORR BETWEEN FDA & STEVANATO GROUP REGARDING GLASS TUBING 1/10 TO PRESENT
2015-4665	06/11/2015 07/10/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	EDWARD A. STEELE EAS CONSULTING GROUP LLC	CORR BETWEEN FDA & CORNING REGARDING GLASS TUBING 1/10 TO PRESENT
2015-4666	06/11/2015 07/10/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID W. HANNUM SANDERS LAW FIRM LLC	GLAXO SMITH KLINE - ZOFAN (ONDANSETRON) NDA 20-0007
2015-4667	06/11/2015 07/10/2015	FDA/OC/OES/DDM/	Lin X09327, Dianne	REPRODUCTIVE DRUG TRANSCRIPTS
2015-4668	06/11/2015 07/10/2015	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	DUNTON, DOTANN	CMPLNT 137847
2015-4669	06/11/2015 07/10/2015	FDA/OO/OHR/	PARKER D. KASMER LIGHTFOOT FRANKLIN & WHITE LLC	DR. MICHAEL CAROME RECS
2015-4670	06/11/2015 07/10/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HARVEY, AMANDA	NATIONAL FORMULARY
2015-4671	06/11/2015 07/10/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GARY L. WILSON ROBINS KAPLAN ET AL	ABILIFY (ARIPIRAZOLE) - AERS 3/14, LBLG THAT MENTIONS GAMBLING AS A WARNING
2015-4672	06/12/2015 07/13/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 5/25-30/15
2015-4673	06/12/2015 07/13/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 5/25-30/15

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2015-4674	06/12/2015 07/13/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 5/25-29/15
2015-4675	06/12/2015 07/13/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 5/225-28/15
2015-4676	06/12/2015 07/13/2015	FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 5/25-29/15
2015-4677	06/12/2015 07/13/2015	FDA/OC/OES/DFOI/	DEBI L COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 5/25-29/15
2015-4678	06/12/2015 07/13/2015	FDA/OC/OES/DFOI/	LESLIE RAMSEY FDA NEWS	FOI DIALY LOG 5/25-29/15
2015-4679	06/12/2015 07/13/2015	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 5/25-29/15
2015-4680	06/12/2015 07/13/2015	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 5/25-29/15
2015-4681	06/12/2015 07/13/2015	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 5/25-29/15
2015-4682	06/12/2015 07/13/2015	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD Center for Regulatory Services, Inc.	FOI DAILY LOG 5/25-29/15
2015-4683	06/12/2015 07/13/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MCKENZIE CATO Hyman, Phelps & McNamara P.C.	CORR CONFIRMING WHETHER OR NOT THE APRVL OF PARASAL (AMINOSALICYLIC ACID), PARSAL SODIUM (AMINSALICYLATE SODIUM) NDA 6-811 HAS BEEN WITHDRAWN
2015-4684	06/12/2015 07/13/2015	OC/ORO/ OC/ORO/	EMILY MAYER ARMSTRONG TEASDALE LLP	SOUTHERN ILLINOIS MEDICAL SERVICES (LOGAN PRIMARY CARE), HERRIN, IL - METHYLPREDNISONE ACETATE (MPA) AERS 2011 TO PRESENT; MAIN STREET FAMILY PHARMACY, NEWBERN, TN - METHYLPREDNISONE ACETATE (MPA) INJ INVESTIGATIONS 2011 TO PRESENT
2015-4685	06/12/2015 07/13/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K133578
2015-4686	06/12/2015 07/13/2015	FDA/OMPT/CDRH/OCER/DFOI/	April Clanton Precision Dynamics Corp (PDC)	K073262
2015-4687	06/12/2015	FDA/OMPT/CDRH/OCER/DFOI/	LeeAnn Lauricella	CPT1400952

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	07/13/2015		LeeAnn Lauricella	
2015-4688	06/12/2015 07/13/2015	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Blake Goodner Bridger Healthcare	INSULET CORPORATION - 483, RESPONSE, WARNING LETTERS 01/05/2012 - 06/11/2015
2015-4689	06/12/2015 07/13/2015	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Zetetic, Inc. Zetetic, Inc.	FDA ENTRY DOCUMENTATION REQUEST (REFUSAL) AM1-0192966-0
2015-4690	06/12/2015 07/13/2015	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Zetetic, Inc. Zetetic, Inc.	FDA ENTRY DOCUMENTATION REQUEST AM1-0198191-9
2015-4691	06/12/2015 07/13/2015	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Zetetic, Inc. Zetetic, Inc.	FDA ENTRY DOCUMENTATION REQUEST AM1-0192803-5
2015-4692	06/12/2015 07/13/2015	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Zetetic, Inc. Zetetic, Inc.	FDA ENTRY DOCUMENTATION REQUEST (REFUSAL) AM1-0196649-8
2015-4693	06/12/2015 07/13/2015	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Zetetic, Inc. Zetetic, Inc.	FDA ENTRY DOCUMENTATION REQUEST (REFUSAL)AM1-0191769-9
2015-4694	06/12/2015 07/13/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Leslie Gerwin PRINCETON UNIVERSITY	INVOKANA - AERS
2015-4695	06/12/2015 07/13/2015	FDA/OMPT/CDRH/OCER/DFOI/	Oculus Innovative Science Inc. Malgorzata Jankowski	K090725
2015-4696	06/12/2015 07/13/2015	FDA/OMPT/CDRH/OCER/DFOI/	Tessa Hopsicker ConMed Corporation	K123601
2015-4697	06/12/2015 07/13/2015	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Blake Goodner Bridger Healthcare	INSULET CORPORATION, BILLERICA, MA - 483, RESPONSE, WARNING LETTERS 01/01/2012 - 06/11/2015
2015-4698	06/12/2015 07/13/2015	FDA/OMPT/CDRH/OCER/DFOI/	Tessa Hopsicker ConMed Corporation	K142973
2015-4699	06/12/2015 07/13/2015	FDA/OMPT/CDRH/OCER/DFOI/	Tessa Hopsicker ConMed Corporation	K132809
2015-4700	06/12/2015 07/13/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Charles Snow Hyman, Phelps & McNamara P.C.	NDA 022272 S14
2015-4701	06/12/2015 07/13/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Altaire Altaire Pharmaceuticals, Inc.	NDA 203510 SUPPLEMENTS

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2015-4702	06/12/2015 07/13/2015	FDA/OC/OES/DFOI/	Tania Shapiro-Barr DYKEMA GOSSETT PLLC	BLUE BELL CREAMERIES ICE CREAM RECS
2015-4703	06/12/2015 07/13/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Lauren Farruggia Hyman, Phelps & McNamara, P.C.	K000748
2015-4704	06/12/2015 07/13/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Cindy Cui Pacira Pharmaceuticals, Inc.	CYKLOKAPRON NDA 019281 APPROVAL REVIEWS
2015-4705	06/12/2015 07/13/2015	FDA/OMPT/CDRH/OCER/DFOI/	Lauren Farruggia Hyman, Phelps & McNamara, P.C.	K020659
2015-4706	06/15/2015 07/14/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	COMPLAINT FOLLOW UP RECORDS
2015-4707	06/15/2015 07/14/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	INDIVIDUAL RECS
2015-4708	06/15/2015 07/14/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Curt Thomas lodiTech.com	CROWN LABS - SUBMISSION FOR USE OF POTASSIUM IODIDE AS API FOR RADIATION TREATMENT 01/01/2015 - 06/12/2015
2015-4709	06/15/2015 07/14/2015	FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Andrew Finkelstein Susquehanna Financial Group	IMPAX LABS, HAYWARD, CA; TAIWAN - 483 01/01/2015 - 12/31/2015
2015-4710	06/15/2015 07/14/2015	FDA/OMPT/CDRH/OCER/DFOI/	RICK CALABRESE SARTORIUS STEDIM NORTH AMERICA INC	SARTORIUS MINISART K844504, K851816, K851817, ETC
2015-4711	06/15/2015	FDA/OMPT/CDER/GRP/DIDP/	S DREW BARNETT	CORR BTWN FDA AND WAL-MART PHARMACIES TO

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	07/14/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BELT & BRUNER PC	PROVIDE MEDICATION GUIDES TO ITS PHARMACY PATIENTS, INVESTIGATIONS, RPTS, INSPS, ETC
2015-4712	06/15/2015 07/14/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	POTASSIUM MONO PERSULFATE COMPUND, TETRA SODIUM EDTA HYDRATE, SODIUM SULFATE ANHYDROUS, ETC - RECS
2015-4713	06/15/2015 07/14/2015	FDA/OMPT/CDRH/OCER/DFOI/	JACQUELINE J CHAN K&L Gates LLP	OLYMPUS MEDICAL SYSTEMS CORP - EIRS, 483S, WARNING LTRS, ETC 1/15 TO PRESENT
2015-4714	06/15/2015 07/14/2015	FDA/OMPT/CDRH/OCER/DFOI/	JACQUELINE J CHAN K&L Gates LLP	HOYA CORP, PENTAX LIFE CARE DIVISION - EIRS, 483S, WARNING LTRS, ETC 1/15 TO PRESENT
2015-4715	06/15/2015 07/14/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WILLIAM MCINTYRE PHD LUPIN PHARMACEUTICALS INC	ACTAVIS MID ATLANTIC - CLOBETASOL PROPIONATE SHAMPOO ANDA 78-854 SBA, PHARMACOLOGY AND BIOPHARMACEUTICS RVWS
2015-4716	06/15/2015 07/14/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WILLIAM MCINTYRE PHD LUPIN PHARMACEUTICALS INC	GLAXOSMITHKLINE - CEFTIN (CEFUROXIME AXETIL) FOR ORAL SUSPENSION NDA 50-672 SBA, RVWS
2015-4717	06/15/2015 07/14/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WILLIAM MCINTYRE PHD LUPIN PHARMACEUTICALS INC	PERRIGO ISRAEL - CLOBETASOL PROPIONATE SHAMPOO ANDA 90-974 PHARMACOLOGY AND BIOPHARMACEUTICS RVWS, SBA
2015-4718	06/15/2015 07/14/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WILLIAM MCINTYRE PHD LUPIN PHARMACEUTICALS INC	GLAXOSMITHKLINE - CEFTIN (CEFUROXIME AXETIL) NDA 50-605 SBA, RVWS

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2015-4719	06/15/2015 07/14/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-4021 - REQUEST LETTER ONLY
2015-4720	06/15/2015 07/14/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-4031 - REQUEST LETTER ONLY
2015-4721	06/15/2015 07/14/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-4002 - REQUEST LETTER ONLY
2015-4722	06/15/2015 07/14/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-4052 - REQUEST LETTER ONLY
2015-4723	06/15/2015 07/14/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-4057 - REQUEST LETTER ONLY
2015-4724	06/15/2015 07/14/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-4066 - REQUEST LETTER ONLY
2015-4725	06/15/2015 07/14/2015	FDA/OC/OES/DFOI/	RUSSELL CAROLLO CAROLLO, RUSSELL	2009-4213
2015-4726	06/15/2015 07/14/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-4169 - REQUEST LETTER ONLY
2015-4727	06/15/2015 07/14/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-4177 - REQUEST LETTER ONLY
2015-4728	06/15/2015 07/14/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-4075 - REQUEST LETTER ONLY
2015-4729	06/15/2015 07/14/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-3999 - REQUEST LETTER ONLY
2015-4730	06/15/2015 07/14/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-3979 - REQUEST LETTER ONLY
2015-4731	06/15/2015 07/14/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-3544 - REQUEST LETTER ONLY
2015-4732	06/15/2015 07/14/2015	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OMPT/CDRH/OCER/DFOI/	DANIELLE SHIRLEY NASH & FRANCISKATO LAW FIRM	ZIMMER INC - PERSONA KEE SYS, PERSONA TRABECULAR METAL TIBIAL PLATE CLNCL TRIALS, RECALL NOTICES, CORR, ETC
2015-4733	06/15/2015 07/14/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-3612 - REQUEST LETTER ONLY
2015-4734	06/15/2015 07/14/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-3991 - REQUEST LETTER ONLY

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2015-4735	06/15/2015 07/14/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-3614 - REQUEST LETTER ONLY
2015-4736	06/15/2015 07/14/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-3963 - REQUEST LETTER ONLY
2015-4737	06/15/2015 07/14/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-3565 - REQUEST LETTER ONLY
2015-4738	06/15/2015 07/14/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-3950 - REQUEST LETTER ONLY
2015-4739	06/15/2015 07/14/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-3934 - REQUEST LETTER ONLY
2015-4740	06/15/2015 07/14/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-3761 - REQUEST LETTER ONLY
2015-4741	06/15/2015 07/14/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-3575 - REQUEST LETTER ONLY
2015-4742	06/15/2015 07/14/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-3549 - REQUEST LETTER ONLY
2015-4743	06/15/2015 07/14/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CINDY BEDIENT BEDIENT, CINDY	PREDNISONE - AERS
2015-4744	06/15/2015 07/14/2015	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	Chastity Rodriguez Rodriguez, Chastity	VRL LABORATORIES, CENTENNIAL, CO - WARNING LETTERS, 483 06/11/2012 - 06/11/2015
2015-4745	06/15/2015 07/14/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	charu sharma DermPathe Pharmaceuticals	ANDA 070730, NDA 020541, N016131 ETC
2015-4746	06/15/2015 07/14/2015	FDA/OFVM/CFSSAN/OCD/EOS/ FDA/OC/OPP/OP/	Emilia Lonardo, PhD GROCERY MANUFACTURERS ASSOCIATION	RAW DATA USED IN REGULATORY IMPACT ANALYSIS FOR 2003 FINAL RULE 01/01/1998 - 01/01/2004
2015-4747	06/15/2015 07/15/2015	FDA/OC/OES/DFOI/ FDA/OC/OES/	John Cotter AMERICAN BRIDGE	EMAILS TO/FROM Jeb@jeb.org, Jeb@myflorida.com, fl.governor@eog.state.fl.us ETC AND FDA OC -
2015-4748	06/15/2015 07/14/2015	FDA/OGROP/ORASW-FO/LOS-DO/LOS-CB/	BRENDON HENRY RBC CAPITAL MARKETS	PYRAMID LABS - AUGMENT (PDFG-BB+BETA TCP) 483, CO RESP 6/15

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2015-4749	06/15/2015 07/14/2015	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD Center for Regulatory Services, Inc.	FOI DIALY LOG 6/1-5/15
2015-4750	06/15/2015 07/14/2015	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 6/1-5/15
2015-4751	06/15/2015 07/14/2015	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 6/1-5/15
2015-4752	06/15/2015 07/14/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kevin Cosgrove Kaplan Fox & Kilsheimer, LLP	PUMA BIOTECHNOLOGY - COMMUNICATIONS WITH FDA RE NDA FOR PB272 01/01/2014 - 05/13/2015
2015-4753	06/15/2015 07/14/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Karol LaCroix GlaxoSmithKline	7241182 7250072 6642518 ETC
2015-4754	06/15/2015 07/14/2015	FDA/OC/OES/DFOI/	LESLIE RAMSEY FDA NEWS	FOI DAILY LOG 6/1-5/15
2015-4755	06/15/2015 07/14/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jaya Ayyagari Dr. Reddy's Laboratories Inc.	NDA 020165 SUPP 011 TO 019 SBA
2015-4756	06/15/2015 07/14/2015	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 6/1-5/25
2015-4757	06/15/2015 07/14/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DDM/	Rachel Johnson FOI Services, Inc.	10/23/2009 LETTER FROM FDA TO AXXIN, VETROP & HARKRIDER RE 5 YEAR NCE EXCLUSIVITY FOR VYVANSE
2015-4758	06/15/2015 07/14/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OCC/	Rachel Johnson FOI Services, Inc.	VASCEPA - EXCLUSIVITY RECS

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2015-4759	06/15/2015 07/14/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 6/1-5/15
2015-4760	06/15/2015 07/14/2015	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink	2015-4081
2015-4761	06/15/2015 07/14/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 6-1-5/15
2015-4762	06/15/2015 07/14/2015	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 6/1-5/15
2015-4763	06/15/2015 07/14/2015	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 6/1-5/15
2015-4764	06/15/2015 07/14/2015	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 6/1-5/15
2015-4765	06/15/2015 07/14/2015	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOI REQUESTS 6/1-5/15
2015-4766	06/15/2015 07/14/2015	FDA/OMPT/CDRH/OCER/DFOI/	Julie Pasto Acumed LLC	RECS RE MW5041780
2015-4767	06/15/2015 07/14/2015	FDA/OMPT/CDRH/OCER/DFOI/	Armine Badalyan Antarma LLC	K140415
2015-4768	06/15/2015 07/14/2015	FDA/OMPT/CDRH/OCER/DFOI/	(Mr.) Taro Kanai MIC International Corp.	K050273
2015-4769	06/15/2015 07/14/2015	FDA/OMPT/CDRH/OCER/DFOI/	Armine Badalyan Antarma LLC	K003028, K072076
2015-4770	06/15/2015 07/14/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Leslie Gerwin PRINCETON UNIVERSITY	FARXIGA AERS
2015-4771	06/15/2015 07/14/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Leslie Gerwin PRINCETON UNIVERSITY	GLYXAMBI AERS
2015-4772	06/15/2015 07/14/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Leslie Gerwin PRINCETON UNIVERSITY	JARDIANCE AERS

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2015-4773	06/15/2015 07/14/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Leslie Gerwin PRINCETON UNIVERSITY	INVOKANAMET AERS
2015-4774	06/15/2015 07/14/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Leslie Gerwin PRINCETON UNIVERSITY	XIGDUO XR AERS
2015-4775	06/16/2015 07/15/2015	FDA/OGROP/ORAN/NE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORAN/SE-FO/ATL-DO/ATL-CB/	Rachel Johnson FOI Services, Inc.	TOBACCO 483
2015-4776	06/16/2015 07/15/2015	FDA/OC/OES/DFOI/	Jake McDowell The Weinberg Group Inc.	FOIA DAILY LOG 02/28/2014 - 06/15/2015
2015-4777	06/16/2015 07/15/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	AMO MANUFACTURING, SPAIN - EIR 6/09-12/14
2015-4778	06/16/2015 07/15/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Leslie Dixon Leslie Dixon	ALTEPLASE PACKAGE INSERT WORDING CHANGE 01/01/2012 - 04/01/2015
2015-4779	06/16/2015 07/15/2015	FDA/OGROP/ORAN/PA-FO/LOS-DO/LOS-CB/	Martha Mendoza ASSOCIATED PRESS	H & T SEAFOOD - WARNING LETTERS, INVESTIGATIONS, ETC 06/11/2010 - 06/12/2015
2015-4780	06/16/2015 07/15/2015	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Lauren Davis Frith & Ellerman Law Firm, PC	DIN/Unit # W0876 14 013911
2015-4781	06/16/2015 07/15/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gina Elton Teva Pharmaceuticals	TEVA PHARMACEUTICALS, BEER SHEVA, ISRAEL - EIR 07/01/2014 - 07/31/2014
2015-4782	06/16/2015 07/15/2015	FDA/OFVM/CFSAN/OCD/EOS/	Rend Al-Mondhiry COUNCIL FOR RESPONSIBLE NUTRITION	SOLGAR ABC DOPHILUS POWDER - TESTING RESULTS 09/01/2014 - 06/15/2015
2015-4783	06/16/2015	FDA/OMPT/CDRH/OCER/DFOI/	Ted Deacon	EDWARDS LIFE SCIENCES INC AROTIC CATHETER EL1001

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	07/15/2015		Wilcoxon Callaham	- CORRECTIVE ACTIONS, ADVERSE LIFE SCIENCES INC 01/01/2009 - 06/15/2015
2015-4784	06/16/2015 07/15/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nishith Sanghvi CIMB Securities	WOCKHARDT - 483 10/02/2014 - 06/15/2015
2015-4785	06/16/2015 07/15/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Charles Snow Hyman, Phelps & McNamara P.C.	ANDA 200222 FDA MEMO DETERMINATION THAT 180 DAY EXCLUSIVITY WAS NOT FORFEITED
2015-4786	06/16/2015 07/15/2015	FDA/OC/OES/DDM/	Massimo Calabresi TIME MAGAZINE	DKT FDA-2012-P-0895, DKT FDA-2012-P-0895-0001, ETC
2015-4787	06/16/2015 07/15/2015	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	Brandon Henry RBC	PYRAMID LABORATORIES - 483, RESPONSE 03/12/2015 - 06/12/2015
2015-4788	06/16/2015 07/15/2015	FDA/OMPT/CDRH/OCER/DFOI/	CMS case #411274 Cheen Houg Enterprise Co., Ltd.	CHEEN HOUNG ENTERPRISE CO, LTD - EIR 08/10/2015 - 11/01/2014
2015-4789	06/16/2015 07/15/2015	FDA/OC/OEXA/OMA/	Matthew Mosk ABC NEWS	COMM REGARDING POTENTIAL ABC NEWS COVERAGE OF FOOD SAFETY MATTERS 04/01/2015 - 06/15/2015
2015-4790	06/16/2015 07/15/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Zhejiang Hisun Pharmaceutical Co., Ltd FORM 483 TDV	ZHEJIANG HISUN PHARMACEUTICALS CO, LTD, CHINA - 483 02/01/2015 - 04/30/2015
2015-4791	06/16/2015 07/15/2015	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/ORO/DIOP/	Martin Ponce de Leon Blumar Usa, LLC.	BLUMAR USA LLC, CHILE - IMPORT ALERT RECS 07/21/2014 - 07/21/2014
2015-4792	06/16/2015 07/15/2015	FDA/OMPT/CDRH/OCER/DFOI/	Sarah Smith Bodyport Inc.	SCANADU SCOUT DEVICE - 510K, PRESALE CAMPAIGN OF INVESTIGATIONAL USE
2015-4793	06/16/2015 07/15/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Jack T Krauser Jack T Krauser	K131345
2015-4794	06/16/2015 07/15/2015	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	Rachel Johnson FOI Services, Inc.	MEDICAL OPTICS, SANTA ANA, CA - EIR 07/29/2013 - 08/01/2013
2015-4795	06/16/2015 07/15/2015	FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/ FDA/OMPT/CDER/ORP/DIDP/	Dustin Block IPD Analytics, LLC	ANDA 091555 EFFECTIVE APPROVAL LETTER

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2015-4796	06/16/2015 07/15/2015	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Alexandra Ajmo LIFE EXTENSION	RELIANCE VITAMINS, EDISON, NJ - EIR 01/01/2010 - 06/15/2015
2015-4797	06/16/2015 07/15/2015	FDA/OC/OES/DFOI/	Alberto Rossi University of Maryland, College Park	FOIA LOGS ALL AVAILABLE
2015-4798	06/16/2015 07/15/2015	FDA/OMPT/CDRH/OCER/DFOI/	Ruby Chiang Aeon Astron Europe B.V.	K112568
2015-4799	06/16/2015 07/15/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	JOSEPH LAWLOR HAYNES AND BOONE, LLP	SINCLAIR - K024367
2015-4800	06/16/2015 07/15/2015	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	JAMES LINON LINON PHD, JAMES	TEVA PHARMACEUTICALS USA INC, MEXICO, MO - EIRS, 483S, CORRECTIVE PLANS OF ACTION, ETC 3/5/15
2015-4801	06/16/2015 07/15/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHELDON T BRADSHAW HUNTON & WILLIAMS LLP	ROXANE - ALOSETRON HCL TABS ANDA 200-652 DECISION TO WAIVE THE REQUIREMENTS FOR A SINGLE SHARD SYS REMS PROGRAM MEMO 4/30/15: BUPREONPRPHINE-CONTAINING TRANSMUCOSAL PRODS ANDA EXTENSION OF SINGLE SHARED SYS REMS WAIVER MEMO 2/19/15
2015-4802	06/16/2015 07/15/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	R JOHN POCH KANE FUNK & POCH PC	VIAGRA - APRVL 3/27/98
2015-4803	06/17/2015 07/16/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-3919
2015-4804	06/17/2015 07/16/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	G. Srinivas Zydus Pharmaceuticals USA Inc.	FORTESTA NDA 021463 SBA
2015-4805	06/17/2015 07/16/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K983314
2015-4806	06/17/2015 07/16/2015	FDA/OMPT/CDRH/OCER/DFOI/	Theresa Coleman Sartorius Stedim North America Inc.	K851818
2015-4807	06/17/2015	FDA/OMPT/CDRH/OCER/DFOI/	Theresa Coleman	K851817

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	07/16/2015		Sartorius Stedim North America Inc.	
2015-4808	06/17/2015 07/16/2015	FDA/OMPT/CDRH/OCER/DFOI/	Theresa Coleman SARTORIUS STEDIM NORTH AMERICA INC	K851816
2015-4809	06/17/2015 07/16/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Theresa Coleman Sartorius Stedim North America Inc.	K844504
2015-4810	06/17/2015 07/16/2015	FDA/OMPT/CDRH/OCER/DFOI/	Bryan Mercer Enuresis Associates	CPT1400894, CPT1400892 RECS
2015-4811	06/17/2015 07/16/2015	FDA/OMPT/CDRH/OCER/DFOI/	Brian Brockway VivaQuant, LLC	K955015
2015-4812	06/17/2015 07/16/2015	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jordan Guzzardo Cmw Media	RECS RE FDA DECISION TO EXCLUDE CANNABIDIOL FROM DIETARY SUPPLEMENT CATEGORIZATION
2015-4813	06/17/2015 07/16/2015	FDA/OMPT/CDRH/OCER/DFOI/	Jim Klett TheraSigma, LLC	K100117
2015-4814	06/17/2015 07/16/2015	OC/ORO/ORM/ OC/ORO/ORM/	David Mangione Govzilla, Inc.	LIST OF INSPECTIONS 03/15/2014 - 06/15/2015
2015-4815	06/17/2015 07/16/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K140920
2015-4816	06/17/2015 07/16/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANDA 77-990 Zolpiden Tartrate Tablets USP 5mg&10mg ADE Rep Carlsbad Technology, Inc.	ZOLPIDEM - AERS REPORT
2015-4817	06/17/2015 07/16/2015	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/	Zetetic, Inc. Zetetic, Inc.	FDA ENTRY DOCUMENTATION REQUEST ALL DOCUMENTATION JUNE 01, 2015 TO JUNE 15, 2015
2015-4818	06/17/2015 07/16/2015	FDA/OMPT/CDRH/OCER/DFOI/	Chris Felabom Felabom, Chris	K110686

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2015-4819	06/17/2015 07/16/2015	FDA/OMPT/CDRH/OCER/DFOI/	Shepard G. Bentley Bentley Biomedical Consulting, LLC	K133868
2015-4820	06/17/2015 07/16/2015	FDA/OMPT/CDRH/OCER/DFOI/	Freddie Lee Epic International (Thailand) Co., Ltd.	K052217
2015-4821	06/17/2015 07/16/2015	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Anna Parker Request Archive	INTERCEPT BLOOD SYSTEM RECS
2015-4822	06/17/2015 07/16/2015	FDA/OC/OES/DFOI/	David Mangione Govzilla, Inc.	483 RELEASED SINCE 3/15/15
2015-4823	06/17/2015 07/16/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Thomas A. Hope UNIVERSITY OF CALIFORNIA, SAN FRANCISCO	FERUMOXYTOL - DEATH REPORTS
2015-4824	06/17/2015 07/16/2015	FDA/OFVM/CFSAN/OCD/EOS/	Amie Vanella Faegre Baker Daniels LLP	FCN 685 ETC
2015-4825	06/17/2015 07/16/2015	FDA/OMPT/CDRH/OCER/DFOI/	Jim Klett TheraSigma, LLC	K093138
2015-4826	06/17/2015 07/16/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Andrew Ellis Andrew Ellis	INTELENCE - AERS
2015-4827	06/17/2015 07/16/2015	FDA/OMPT/CDRH/OCER/DFOI/	Jim Klett TheraSigma, LLC	SHENZHEN DONGDIXIN TECHNOLOGY - INSPECTION RECS 06/01/2010 - 06/16/2015
2015-4828	06/17/2015 07/16/2015	FDA/OO/OFBA/OAGS/	Laura Kolaczowski Laura Kolaczowski	PATIENTS LIKE ME - CONTRACT WITH FDA RE DATA AND ANALYSIS EVALUATION 04/13/2015 - 06/01/2015
2015-4829	06/17/2015 07/16/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ron Regan WEWS-TV	LEVAQUIN, LEVOFLOXACIN - AERS 01/01/2010 - 06/10/2015
2015-4830	06/17/2015 07/16/2015	FDA/OGROP/ORO/CE-FO/PHI-DO/PHI-CB/	Blake Goodner Bridger Healthcare	LANNETT COMPANY, PHILADELPHIA, PA - 483, WARNING LETTERS, RESPONSE LETTERS 01/02/2014 - 06/16/2015
2015-4831	06/17/2015 07/16/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ron Regan WEWS-TV	LEVAQUIN/LEVOFLOXACIN - DEATHS

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2015-4832	06/17/2015 07/16/2015	FDA/OGROP/ORAC/CE-FO/MIN-DO/MIN-CB/	Peter Nye Minerva Surgical, Inc.	VESTA, INC, FRANKLIN, WI - 483 05/01/2014 - 08/01/2015
2015-4833	06/17/2015 07/16/2015	FDA/OMPT/CDRH/OCER/DFOI/	Freddie Lee Epic International (Thailand) Co., Ltd.	K041414
2015-4834	06/17/2015 07/16/2015	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Michaela F. Roberts VENABLE LLP	MERCK & CO, INC, WEST POINT, PA - 8/6/01 INSPECTION RECS, SUPPLEMENTAL BIOLOGICS LICENSE APPLICATION SUBMITTED 1/29/04 STN 101069, APPROVAL RECS RE PROTOCOL 007 ETC
2015-4835	06/17/2015 07/16/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K140284
2015-4836	06/17/2015 07/16/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K042674
2015-4837	06/17/2015 07/16/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K083423
2015-4838	06/17/2015 07/16/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K012313
2015-4839	06/17/2015 07/16/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K030982
2015-4840	06/17/2015 07/16/2015	FDA/OMPT/CDRH/OCER/DFOI/	TASHA MARCIEL Tasha Marciel	SUNQUEST PRO 26SX WOLFF BED OPERATING MANUAL
2015-4841	06/17/2015 07/16/2015	FDA/OMPT/CDRH/OCER/DFOI/	Ian Sheffield Bridger Healthcare	INSULET CORPORATION AERS
2015-4842	06/17/2015 07/16/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Mor Buchshtav Medinol Ltd.	K101530, K062750
2015-4843	06/17/2015 07/16/2015	FDA/OMPT/CDRH/OCER/DFOI/	David Grosso FISHER DIAGNOSTICS	K000781
2015-4844	06/17/2015 07/16/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tushar Manudhane Indianivesh securities	WOCKHARDT WALUJ, INDIA - 483 05/01/2015 - 06/16/2015
2015-4845	06/17/2015	FDA/OFVM/CFSAN/OCD/EOS/	Mark Prinz	MURACA SRL, ITALY; DELLEPIANE SAN LUIS SA, ARGENTINA; SHANGHAI PASSIONO INTERNATIONAL CO,

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	07/16/2015		Registrar Corp	LT, CHINA ETC - 483
2015-4846	06/17/2015 07/16/2015	FDA/OC/OES/DFOI/ FDA/OGROP/ORR/SE-FO/NOL-DO/NOL-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nicodemo Fiorentino Nicodemo Fiorentino	PRESCRIPTION DRUG MARKETING ACT - 483, WARNING LETTER 01/03/2013 - 06/16/2015
2015-4847	06/17/2015 07/16/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-2802
2015-4848	06/17/2015 07/16/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-2879
2015-4849	06/17/2015 07/16/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-2882
2015-4850	06/17/2015 07/16/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-2906
2015-4851	06/17/2015 07/16/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-2914
2015-4852	06/17/2015 07/16/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-2915
2015-4853	06/17/2015 07/16/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-2918
2015-4854	06/17/2015 07/16/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-2922
2015-4855	06/17/2015 07/16/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-2930
2015-4856	06/17/2015 07/16/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-2951
2015-4857	06/17/2015 07/16/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-2953
2015-4858	06/17/2015 07/16/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-3056
2015-4859	06/17/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2015-3423

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	07/16/2015		MERCK & CO., INC.	
2015-4860	06/17/2015 07/16/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-3710
2015-4861	06/17/2015 07/16/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-3713
2015-4862	06/17/2015 07/16/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-3723
2015-4863	06/17/2015 07/16/2015	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-2770
2015-4864	06/17/2015 07/16/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Elizabeth Carney Elizabeth Carney	FLURALANER, AFOXOLANER - AERS
2015-4865	06/17/2015 07/16/2015	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	M. ELIZABETH BIERMAN MORGAN LEWIS & BOCKIUS LLP	SMITH & NEPHEW, ST PETERSBURG, FL - EIR, 483 12/14/14 TO 1/13 /15
2015-4866	06/17/2015 07/16/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN D'ANDELO PRAGMA	DESRVEL (TRAZODONE HYDROCHLORIDE) NDA 18-207
2015-4867	06/17/2015 07/16/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	RICHARD E. MUSTY, Ph.D. UNIVERSITY OF VERMONT	ANALYSES OF CANNABIDIOL PRODUCTS
2015-4868	06/17/2015 07/16/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	EMILIO MALLO DLD Lawyers - Emilio Mallo	INDIVIDUAL RECS
2015-4869	06/17/2015 07/16/2015	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORR/ OC/ORR/ FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	JAMES E. LOZIER DICKINSON & WRIGHT PLLC	INVENTURE FOODS INC - LISTERIA MONOCYTOGENES RECALL 6/14 TO PRESENT
2015-4870	06/17/2015	FDA/OFVM/CFSAN/OCD/EOS/	ALISA A. KARLSONS	FCN 1458

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	07/16/2015		Keller and Heckman, LLP	
2015-4871	06/17/2015 07/16/2015	FDA/OMPT/CTP/OD/	MARC J. SCHEINESON, Esq. ALSTON & BIRD LLP	GRANDFATHER DETERMINATION LETTER OF PORDUCT SOLD 2/15/07
2015-4872	06/18/2015 07/17/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	ACS DOBFAR, SWITZERLAND - 483
2015-4873	06/18/2015 07/17/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K050404
2015-4874	06/18/2015 07/17/2015	FDA/OMPT/CDRH/OCER/DFOI/	Colleen Durran Fresenius Medical Care North America	K110823, K072983
2015-4875	06/18/2015 07/17/2015	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SW-FO/KAN-DO/KAN-CB/	Jennifer DeSotel Active Biomaterials	SAMPLE RESULTS 900935
2015-4876	06/18/2015 07/17/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	myriam armant myriam armant	ELISA METHODOLOGY USED IN THE STUDY OF ADVERSE REACTIONS
2015-4877	06/18/2015 07/17/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anne Muehe STANFORD UNIVERSITY	FERAHEME - AERS
2015-4878	06/18/2015 07/17/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	ACS DOBFAR, ITALY - 483
2015-4879	06/18/2015 07/17/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K122132
2015-4880	06/18/2015 07/17/2015	OC/ORO/ORM/ OC/ORO/ORM/	John V. Gray THE OHIO STATE UNIVERSITY	DRUG MANUFACTURING PLANT DATA 01/01/2000 - 12/31/2014
2015-4881	06/18/2015 07/17/2015	FDA/OGROP/ORO/SE-FO/NOL-DO/NOL-CB/	Cari Gerbracht Sunless Inc.	NORVELL SKIN SOLUTIONS, ALEXANDRIA, TN - 483, RECALLS, WARNING LETTERS 05/05/2015 - 06/17/2015

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2015-4882	06/18/2015 07/17/2015	FDA/OMPT/CDRH/OCER/DFOI/	Amerx Health Care Corp Amerx Health Care Corp.	K002136
2015-4883	06/18/2015 07/17/2015	FDA/OGROP/ORR/SW-FO/DEN-DO/DEN-CB/	Bill Young Sterigenics	NELSON LABORATORIES, SALT LAKE CITY, UT - WARNING LETTER, 483, EIR 01/20/2012 - 05/18/2015
2015-4884	06/18/2015 07/17/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K090993
2015-4885	06/18/2015 07/17/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	ACS DOBFAR, ITALY - 483
2015-4886	06/18/2015 07/17/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORR/SE-FO/SJN-DO/SJN-CB/	Rachel Johnson FOI Services, Inc.	TEVA API PUERTO RICO - 483
2015-4887	06/18/2015 07/17/2015	FDA/OGROP/ORR/NE-FO/NYK-DO/NYK-DCB/	Rachel Johnson FOI Services, Inc.	WG CRITICAL CARE, HAMILTON, NY - 483
2015-4888	06/18/2015 07/17/2015	FDA/OMPT/CDRH/OCER/DFOI/	MASSIMILIANO VIOTTI KRISTAL SRL	K902075
2015-4889	06/18/2015 07/17/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	SCINOPHARM, TAIWAN - 2012 483
2015-4890	06/18/2015 07/17/2015	FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/	Monica King Halyard Health	AVENT TUSCON, AZ - EIR 11/01/2014 - 12/01/2014
2015-4891	06/18/2015 07/17/2015	OC/ORR/ OC/ORR/	Evi International Group, LLC FEI: 3010083524 Evi International Group, LLC	ORGANIC SPROUTED CHIA SEEDS POWDER - INVESTIGATION, REPORTS, LAB ANALYSIS ETC 04/02/2014 - 09/30/2014
2015-4892	06/18/2015 07/17/2015	FDA/OGROP/ORR/NE-FO/NWE-DO/NWE-CB/	Amanda P. Rawson DePuy Mitek, Raynham, MA	MITEK, RAYNHAM, MA - EIR 01/01/2013 - 12/31/2013
2015-4893	06/18/2015 07/17/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	K040237

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/		
2015-4894	06/18/2015 07/17/2015	FDA/OFVM/CFSAN/OCD/EOS/	Anna Edney BLOOMBERG NEWS	FOOD ADDITIVE PETITIONS RE PARTIALLY HYDROGENATED OILS OR TRANS FATS SUBMITTED BY GROCERY MANUFACTURERS ASSOCIATION 01/01/2015 - 06/17/2015
2015-4895	06/18/2015 07/17/2015	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Rachel Johnson FOI Services, Inc.	AMRI, NY, MA - 483
2015-4896	06/18/2015 07/17/2015	FDA/OFVM/CFSAN/OCD/EOS/	Wendy McCombie Lewis & Harrison LLC	FCN 1471
2015-4897	06/18/2015 07/17/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	BIOCON, INDIA - 483
2015-4898	06/18/2015 07/17/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	HISUN, CHINA - 483
2015-4899	06/18/2015 07/17/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Anurag patel Dr. Reddy's Laboratories Inc.	NDA 205060 SBA
2015-4900	06/18/2015 07/17/2015	OC/CVM/OCD/	Yvonne Lim Rhone Ma Malaysia Sdn Bhd	CLOPIDOL - TARGET ANIMAL AND HUMAN FOOD SAFETY INFORMATION
2015-4901	06/18/2015 07/17/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	XELLIA, HUNGARY, DENMARK - 483
2015-4902	06/18/2015 07/17/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Robert Stone TOWER LABORATORIES LTD	MALLADI DRUGS & PHARMACEUTICALS, INDIA - EIR 09/10/2012 - 09/14/2012

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2015-4903	06/18/2015 07/17/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rod Walker Quintiles	DR SUNIL VERNA, SUNNYBROOK HEALTH SCIENCES CENTER, ODETTE CANCER CENTRE, CANADA - 483 01/01/2012 - 12/31/2012
2015-4904	06/18/2015 07/17/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rahul Jeewani IIFL Institutional Equities	GLENMARK PHARMACEUTICALS LIMITED, INDIA - 483 02/16/2015 - 02/27/2015
2015-4905	06/18/2015 07/17/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rahul Jeewani IIFL Institutional Equities	GLENMARK PHARMACEUTICALS LIMITED, INDIA - 483 05/18/2015 - 05/29/2015
2015-4906	06/18/2015 07/17/2015	FDA/OC/OES/DFOI/	MARTIN CORIA DEM MEDICAL SYSTEMS	K041111
2015-4907	06/18/2015 07/17/2015	FDA/OC/OES/DFOI/	MARTIN CORIA DEM MEDICAL SYSTEMS	K082331
2015-4908	06/18/2015 07/17/2015	FDA/OC/OES/DFOI/	MARTIN CORIA DEM MEDICAL SYSTEMS	K043030
2015-4909	06/18/2015 07/17/2015	FDA/OC/OES/DFOI/	MARTIN CORIA DEM MEDICAL SYSTEMS	K041111 MAGNETON C SYS
2015-4910	06/18/2015 07/17/2015	FDA/OC/OES/DFOI/	MARTIN CORIA DEM MEDICAL SYSTEMS	K992135 EXCITE MR SYS
2015-4911	06/18/2015 07/17/2015	FDA/OC/OES/DFOI/	MARTIN CORIA DEM MEDICAL SYSTEMS	K043112 SIGNA PROFILE EXCITE MR SYS
2015-4912	06/18/2015 07/17/2015	FDA/OC/OES/DFOI/	MARTIN CORIA DEM MEDICAL SYSTEMS	K033168 GE O.2T SIGNA PROFILE MAGNETIC RESONANCE SYS
2015-4913	06/18/2015 07/17/2015	FDA/OMPT/CDRH/OCER/DFOI/	MICHELLE A. RAMIREZ SIDLEY AUSTIN LLP	FUJIFILM - DUODENOSCOPES WARNING LTRS, 483S, EIR, CO RESP SINCE 1/15
2015-4914	06/18/2015 07/17/2015	FDA/OGROP/ORO/ORO/DIOP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JENNIFER M. MORENO UNIVERSITY OF CALIFORNIA BERKELEY	THIOPENTAL, PANCURONIUM - RECS 1/14 TO 1/1/16

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2015-4915	06/18/2015 07/17/2015	FDA/OC/OES/ FDA/OGROP/OIP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORA/ OC/ORA/	SCOTT PARKER REPUBLICAN NATIONAL COMMITTEE	FINAL CLARIFICATION 6/17
2015-4916	06/18/2015 07/17/2015	FDA/OC/OES/DFOI/	GRAEME LADDS PHARSAFER HOUSE	PHARMACOVIGILANCE - 483S
2015-4917	06/18/2015 07/17/2015	OC/ORA/ OC/ORA/	LUIS ECHEVERRIA Evi International Group, LLC	ORGANIC SPROUTED CHIA SEEDS POWDER - SALMONELLA OUTBREAK
2015-4918	06/18/2015 07/17/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DON J. MIZERK HUSCH BLACKWELL LLP	ACRYLATES COPOLYMER - APRVL
2015-4919	06/18/2015 07/17/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BARBARA A. BINZAK BLUMENFELD BUCHANAN INGERSOLL & ROONEY PC	DIGOXIN SBA ANDA 78-556, 76-363, 77-002
2015-4920	06/18/2015 07/17/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID HOFFMEISTER WILSON SONSINI ET AL	GLAXO SMITH KLEIN NDA 21-077/S-51, CO RESP
2015-4921	06/18/2015 07/17/2015	OC/ORA/OCI/ OC/ORA/OCI/	SEAN THOMAS HIGGINS, Esq. ANDREWS THORNTON	CASE 3:13-MJ-00750-BK
2015-4922	06/18/2015 07/17/2015	FDA/OC/OES/DFOI/	SHEPARD 155575, RICKY	AMLOPIPINE, ASCEND, CARLSBAD T, ZYGENERICS, DOXAZOSIN MESYLATE - AER
2015-4923	06/18/2015 07/17/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	KAY MITCHEN Natural Immunogenics Corp.	ASAP WOUND DRESSING GEL K082333; ELTA SILVER ANTIMICROBIAL WOUND GEL K071703; ACRYDERM SILVER ANTIMICROBIAL WOUND GEL K011994
2015-4924	06/18/2015 07/17/2015	FDA/OMPT/CDRH/OCER/DFOI/	STEVE ANDRUS AWARENESS TECHNOLOGY INC	K864696, K853607, K875066 ETC
2015-4925	06/18/2015	FDA/OGROP/ORA/CE-FO/DET-	MATTHEW POSELWAIT	APPLIED LABS INC - EIR 2/20/15

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	07/17/2015	DO/DET-CB/	APPLIED LABORATORIES INC	
2015-4926	06/19/2015 07/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	Charvi Shetty Charvi Shetty	K150137
2015-4927	06/19/2015 07/20/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Andrea Demakas ADVERSEEVENTS INC	MEVACOR, LIPITOR, CRESTOR ETC - AERS
2015-4928	06/19/2015 07/20/2015	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Walter Chalkley THOMSON REUTERS	AIRGAS USA, LLC, CHESHIRE, CT - EIR, 483, RESPONSE
2015-4929	06/19/2015 07/20/2015	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Walter Chalkley THOMSON REUTERS	ALKERMES, INC, WILMINGTON, OH - EIR, 483, RESPONSE
2015-4930	06/19/2015 07/20/2015	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Walter Chalkley THOMSON REUTERS	MERCK SHARP & DOHME CORP, ELKTON, VA - EIR, 483, RESPONSE
2015-4931	06/19/2015 07/20/2015	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	Walter Chalkley THOMSON REUTERS	LINCARE, BREMERTON, WA - EIR, 483, RESPONSE
2015-4932	06/19/2015 07/20/2015	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Daniel Bernier Hospira, Inc.	DR ANANT DESI, GRANADA HILLS, CA - 483 02/01/2015 - 05/31/2015
2015-4933	06/19/2015 07/20/2015	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Daniel Bernier Hospira, Inc.	DR STEVEN ZEIG, PEMBROKE PINES, FL - EIR, 483, RESPONSE 02/01/2015 - 05/31/2015
2015-4934	06/19/2015 07/20/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 21107
2015-4935	06/19/2015 07/20/2015	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Daniel Bernier Hospira, Inc.	DR MOHAMED EL-SHAHAWY, LOS ANGELES, CA - 483 02/01/2015 - 05/31/2015
2015-4936	06/19/2015 07/20/2015	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	Daniel Bernier Hospira, Inc.	DR PAUL CRAWFORD, EVERGREEN PARK, IL - 483 02/01/2015 - 05/31/2015
2015-4937	06/19/2015 07/20/2015	FDA/OC/OES/DFOI/	Jon Schirado, Regulatory Affairs Manager Sivantos, Inc.	MDR RECS
2015-4938	06/19/2015 07/20/2015	OC/ORA/ OC/ORA/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Michael C Valdez Andrews & Thornton	ENTRY WBO-0028489-7

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		FDA/OGROP/ORASW-FO/SWID/SWID-CB/		
2015-4939	06/19/2015 07/20/2015	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Kenneth Wexler BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.	CATALENT MORRISVILLE, NC - EIR, 483 03/02/2015 - 06/18/2015
2015-4940	06/19/2015 07/20/2015	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Wendy Kowal Wendy Kowal	CENTRAL BIOMEDIA, IRWIN, MO; LENEXA, KA - 483 01/01/2013 - 06/18/2015
2015-4941	06/19/2015 07/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	EMAILS RE SINGLE SHARED REMS FOR ALOSETRON HCI
2015-4942	06/19/2015 07/20/2015	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Daniel Bernier Hospira, Inc.	DR WARREN SHAPIRO, BROOKLYN, NY - 483 02/01/2015 - 05/31/2015
2015-4943	06/19/2015 07/20/2015	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Daniel Bernier Hospira, Inc.	DR KAMAL V. GANDHI, GRANADA HILLS, CA - 483 02/01/2014 - 05/31/2015
2015-4944	06/19/2015 07/20/2015	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	Daniel Bernier Hospira, Inc.	DR SATYA P. AHUJA, EVERGREEN, IL - 483 06/01/2014 - 09/30/2014
2015-4945	06/19/2015 07/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Walter Chalkley THOMSON REUTERS	DR MARIA ELENA SANTOLAYA DE PABLO, CHILA - 483 08/11/2014 - 08/22/2014
2015-4946	06/19/2015 07/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Walter Chalkley THOMSON REUTERS	JOINN LABORATORIES, CHINA - 483
2015-4947	06/19/2015 07/20/2015	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Walter Chalkley THOMSON REUTERS	AMERICAN NATIONAL RED CROSS, EAU CLAIRE, WI - EIR, 483, RESPONSE
2015-4948	06/19/2015 07/20/2015	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Walter Chalkley THOMSON REUTERS	LLOYD INC OF IOWA, SHENANDOAH, IA - EIR, 483, RESPONSE 03/18/2013 - 04/16/2013
2015-4949	06/19/2015 07/20/2015	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	LESLIE RAMSEY FDA NEWS	MCNEIL CONSUMER HEALTHCARE, INC (DIV OF MCNEIL-PPC, FORT WASHINGTON, PA; AIR LIQUIDE HEALTHCARE AMERICA CORP, PLUMSTEADVILLE, PA; GURADIAN ANGEL PRODUCTS INC, HUNTINGTON VALLEY, PA - 483S 5/1-

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2015-4950	06/19/2015 07/20/2015	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	LESLIE RAMSEY FDA NEWS	MEDIMMUNE UK LTD, LIVERPOOL, UK - 483S 5/1-31/15
2015-4951	06/19/2015 07/20/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LESLIE RAMSEY FDA NEWS	SMITHKLINE BEECHAMAN (COR) LTD, CORK, IRELAND; NOSCH LABS PRIVATE LTD, VELIMINEDU, INDIA; DIPHARMA FRANCIS SRI, BARNZATE, ITALY - 483S 5/1-31/15
2015-4952	06/19/2015 07/20/2015	FDA/OGROP/ORAP/PA-FO/SEA- DO/SEA-CB/	LESLIE RAMSEY FDA NEWS	MONTANA COMPOUNDING PHARMACY, MISSOULA, MT; INDEPENDENT NUTRITION CENTERS INC, EUGENE, OR - 483S 5/1-31/15
2015-4953	06/19/2015 07/20/2015	FDA/OGROP/ORAP/SE-FO/SJN- DO/SJN-CB/	LESLIE RAMSEY FDA NEWS	BAXTER HEALTHCARE CORP, JAYUYA, PR - 483S 5/1-31/15
2015-4954	06/19/2015 07/20/2015	FDA/OGROP/ORAP/SE-FO/NOL- DO/NOL-CB/	LESLIE RAMSEY FDA NEWS	MS SURGICAL INC, MEMPHIS, TN; THE COMPOUNDING PHARMACY OF AMERICA, KNOXVILLE, TN; THE WELLNESS CENTER PHARMACY INC (DESIGNER DRUGS), CHATTANOOGO, TN, ETC - 483S 5/1-31/15
2015-4955	06/19/2015 07/20/2015	FDA/OGROP/ORAP/CE-FO/NWJ- DO/NWJ-CB/	LESLIE RAMSEY FDA NEWS	MIRROR PHARMACEUTICALS LLC, FAIRFIELD, NJ; ZIMMER TRABECULAR METAL TECHNOLOGY INC, PARSIPPANY, NJ; IBA MOLECULAR NORTH AMERICA, TOTOWA, NJ, ETC - 483S 5/1-31/15
2015-4956	06/19/2015 07/20/2015	FDA/OGROP/ORAP/NE-FO/NWE- DO/NWE-CB/	LESLIE RAMSEY FDA NEWS	NEUROMETRIX INC, WOBURN, MA; CARDINAL HEALTH, EAST HARTFOR, CT; AUTUMN HARP, ESSEX JUNCTION, VT - 483S 5/1-31/15
2015-4957	06/19/2015 07/20/2015	FDA/OGROP/ORAP/CE-FO/MIN- DO/MIN-CB/ FDA/OGROP/ORAP/SW-FO/KAN- DO/KAN-CB/ FDA/OGROP/ORAP/CE-FO/MIN- DO/MIN-CB/	LESLIE RAMSEY FDA NEWS	ALPHA SOURCE INC, MILWAUKEE, WI; MEDIVATORS INC, PLYMOUTH, MN; MODERN PRODUCTS INC, MEQUON, WI, ETC - 483S 5/1-31/15
2015-4958	06/19/2015 07/20/2015	FDA/OGROP/ORAP/SW-FO/KAN- DO/KAN-CB/	LESLIE RAMSEY FDA NEWS	NESHER PHARMACESUTICALS (USA), LLC, BRIDGETON, SAINT LOUIS, MO;/ GRAIN PROCESSING CORP, MUSCATINE, IA; ESSENTIAL PHARMACY COMPOUNDING, OMAHA, NE, ETC - 483S 5/1-31/15
2015-4959	06/19/2015 07/20/2015	FDA/OGROP/ORAP/CE-FO/DET- DO/DET-CB/	LESLIE RAMSEY FDA NEWS	MAATERIALISE USA, LLC, PLYMOUTH, MI; CARDINAL HEALTH, MSU PET SITE, EAST LANSING, MI; INNOVATIVE SURGICAL SOLUTIONS LLC (SENTIO LLC), WIXOM, MI - 483S 5/1-31/15
2015-4960	06/19/2015 07/20/2015	FDA/OGROP/ORAP/SW-FO/DEN- DO/DEN-CB/	LESLIE RAMSEY FDA NEWS	SYNTHESES (USA), LLC, MONUMENT, CO; ABL MEDICAL, LLC, AMERICAN FORK, UT; EMERGE MEDICAL INC, DENVER, CO

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		FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/		- 483S 5/1-31/15
2015-4961	06/19/2015 07/20/2015	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	LESLIE RAMSEY FDA NEWS	APNEICARE LLC, WORTHINGTON, OH;/ 3D AND COMPANY, CINCINNATI, OH; KILTEX CORP, AKRON, OH, ETC - 483S 5/1-31/15
2015-4962	06/19/2015 07/20/2015	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	LESLIE RAMSEY FDA NEWS	CAREFUSION 220P0 INC, VERMON HILLS, IL; HOSPIRA INC, LAKE FOREST, IL; CENTRAL ILLIONIS COMPOUNDING INC (PRECKSHOT PROFESSIONA), PEORIA HESIGHTS, IL, ETC - 483S 5/1-31/15
2015-4963	06/19/2015 07/20/2015	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	LESLIE RAMSEY FDA NEWS	AFTON SCIENTIFIC LLC, CHARLOTTESVILLE, VA; AG ESSENCE INC, RICHMOND, VA - 483S 5/1-31/15
2015-4964	06/19/2015 07/20/2015	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	LESLIE RAMSEY FDA NEWS	OUTCOME SOLUTIONS LLC, MOCKSVILLE, NC; 7 OAKS PHARMACEUTICAL CORP, EASLEY, SC; ATLANTA HEALTHCARE SERVICES, ATLANTA, GA, ETC - 483S 5/1-31/15
2015-4965	06/19/2015 07/20/2015	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	LESLIE RAMSEY FDA NEWS	DECIMAL INC, SANDFORD, FL; LD TECHNOLOGY LLC, MIAMI, FL; UNILENS CORP, USA, SEMINOLE, FL, ETC - 483S 5/1-31/15
2015-4966	06/19/2015 07/20/2015	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	LESLIE RAMSEY FDA NEWS	SPECIALITY COMPOUNDING LLC, CEDAR PARK, TX; HOME INTENSIVE CARE PHARMACY LLC, SAN ANTONIO, TX; NEUROLUMEN LLC, OKLAHOMA CITY, OK, ETC, 483S 5/1-31/15
2015-4967	06/19/2015 07/20/2015	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	LESLIE RAMSEY FDA NEWS	VISTA BIOLOGICALS CORP, CARLSBAD, CA; AMERICAN IMEX, IRVINE, CA; AJINOMOTO ALTHEA INC, SAN DIEGO, CA, ETC - 483S 5/1-31/15
2015-4968	06/19/2015 07/20/2015	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	LESLIE RAMSEY FDA NEWS	MEDICAL TECHNOLOGY PRODUCTS INC, RONKONKOMA, NY; CHARTWELL PHARMS, CONGERS, NY; NEW PRODUCT DEVELOPMENT INC, EAST SYRACUSE, NY, ETC - 483S 5/1-31/15
2015-4969	06/19/2015 07/20/2015	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	LESLIE RAMSEY FDA NEWS	HELIO USA INC, SAN JOSE, CA; THE QUEEN'S MEDICAL CENTER, HONOLULU, HI; ALEXZA PHARMACEUTICALS INC, MOUNTAIN VIEW, CA, ETC - 483S 5/1-31/15
2015-4970	06/19/2015 07/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	LESLIE RAMSEY FDA NEWS	STERILIN LYF, NEWPORT, UK; FUJIFILM, ASHIGARAKAMI GUN, JAPAN; MEWD-EL ELEKTROMEDIZINISCHE GERATE GMMBH, INNSBRUCK, AUSTRIA, ETC - 483S 5/1-31/15
2015-4971	06/19/2015 07/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	CT ELNISTE - FOLLOW UP
2015-4972	06/19/2015	FDA/OMPT/CDRH/OCER/DFOI/	CHRIS SZSECHENYI	VENAXIS INC - APPY1 DIAGNOSTIC TEST APPL FOR APRVL, PMA APRVL, 510k CLEARANCE, ETC

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	07/20/2015		ON POINT INVESTIGATIONS	
2015-4973	06/19/2015 07/20/2015	FDA/OGROP/ORPA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	SERAN HIGGINS ANDREWS & THORNTON	USP LABS LLC - EIRS, 483S; SK LABORATORIES INC - EIRS, 483S
2015-4974	06/19/2015 07/20/2015	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	LeAnn Seidl-Kollmer Nature's Way Product	INTEGRITY NUTRACEUTICALS, SPRING HILL, TN - EIR, 483 10/01/2012 - 06/18/2015
2015-4975	06/19/2015 07/20/2015	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Walter Chalkley THOMSON REUTERS	RICONPHARMA, LLC, DENVILLE, NJ - EIR, 483, RESPONSE 01/20/2015 - 01/21/2015
2015-4976	06/19/2015 07/20/2015	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Walter Chalkley THOMSON REUTERS	TGA SCIENCES, MEDFORD, MA - EIR, 483, RESPONSE
2015-4977	06/19/2015 07/20/2015	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Walter Chalkley THOMSON REUTERS	STEVEN ROHRBECK, HIGH POINT, NC - EIR, 483, RESPONSE 04/15/2013 - 05/06/2013
2015-4978	06/19/2015 07/20/2015	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	Walter Chalkley THOMSON REUTERS	LOVELACE RESPIRATORY RESEARCH INSTITUTE, ALBUQUERQUE, NM - EIR, 483, RESPONSE 02/25/2013 - 03/13/2013
2015-4979	06/19/2015 07/20/2015	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Walter Chalkley THOMSON REUTERS	ZOETIS P & U, LLC., KALAMAZOO, MI - EIR, 483, RESPONSE 04/07/2014 - 04/17/2014
2015-4980	06/19/2015 07/20/2015	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Walter chalkley THOMSON REUTERS	MERCK SHARP & DHOME, RAHWAY, NJ - EIR, 483, RESPONSE
2015-4981	06/19/2015 07/20/2015	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Walter Chalkley THOMSON REUTERS	WYETH BIOPHARMA DIVISION OF WYETH PHARMACEUTICALS, ANDOVER, MA - EIR, 483, RESPONSE 02/01/2014 - 02/28/2014
2015-4982	06/19/2015 07/20/2015	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	DJ Summers Alaska Journal of Commerce	BLOOD BANK OF ALASKA - LIST OF CITATIONS 01/01/1994 - 06/17/2015
2015-4983	06/19/2015 07/20/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kenalog-40 NDA 014901 Summary Based on Approval Alpha Pharma Services LLC	NDA 014901 SBA
2015-4984	06/19/2015 07/20/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	ANDA 200652 SINGLE SHARED REMS
2015-4985	06/19/2015 07/20/2015	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Daniel Bernier Hospira, Inc.	DR RAFFI R MINASIAN, GLENDALE, CA - 483 02/01/2015 - 05/31/2015

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2015-4986	06/19/2015 07/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	Megan Dickey MEDIVATORS INC	K992893, K992868
2015-4987	06/19/2015 07/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	Walter Chalkley THOMSON REUTERS	CSL PLASMA INC, MESQUITE, TX - EIR, 483, RESPONSE 01/07/2015 - 01/09/2015
2015-4988	06/19/2015 07/20/2015	FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/	Walter Chalkley THOMSON REUTERS	LAURENCE H BELKOFF, BALA CYNWYD, PA - EIR, 483, RESPONSE 02/05/2015 - 02/12/2015
2015-4989	06/19/2015 07/20/2015	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	Walter Chalkley THOMSON REUTERS	BRACCO DIAGNOSTICS, MONROE TOWNSHIP, NJ - EIR, 483, RESPONSE 05/01/2014 - 05/30/2014
2015-4990	06/19/2015 07/20/2015	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	Walter Chalkley THOMSON REUTERS	ACTAVIS LABORATORIES, FL, INC, DAVIE, FL - EIR, 483, RESPONSE 12/01/2013 - 12/20/2013
2015-4991	06/19/2015 07/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Glen Kelley kale, Inc.	NDA 020459 SBA
2015-4992	06/19/2015 07/20/2015	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	Walter Chalkley THOMSON REUTERS	B. BRAUN MEDICAL, INC, IRVINE, CA - EIR, 483, RESPONSE 01/23/2014 - 02/13/2014
2015-4993	06/19/2015 07/20/2015	OC/CVM/OCD/	Beth Marchitelli, DVM Beth Marchitelli, DVM	NADA 128-967, NADA 100-809 FOIA SUMMARY
2015-4994	06/19/2015 07/20/2015	FDA/OGROP/ORA/CE-FO/CHI- DO/CHI-CB/	Daniel Bernier Hospira, Inc.	HOSPIRA, LAKE FOREST, IL - 483 02/01/2015 - 05/31/2015
2015-4995	06/19/2015 07/20/2015	FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/	Wendy Banka Wendy Banka	RESTAURANT RECYCLING SERVICES, LLC, FREMONT, MI - 483 08/01/2014 - 06/18/2015
2015-4996	06/19/2015 07/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michelle Elizabeth Legiec Eagle Pharmaceuticals, Inc.	CIPLA, INDIA, ZYDUS, INDIA - EIR, 483 04/08/2015 - 04/17/2015
2015-4997	06/19/2015 07/20/2015	FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/	Wendy Banka Wendy Banka	HERBRUCK POULTRY RANCH, SARANAC, MI - 483 08/01/2014 - 06/18/2015

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2015-4998	06/19/2015 07/20/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Lars Aagaard Smart Tech Imaging	K943272
2015-4999	06/19/2015 07/20/2015	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	Wendy Banka Wendy Banka	SIETSMA FARM FEED, LCC, HOWARD CITY, MI - 483 08/11/2014 - 06/18/2015
2015-5000	06/19/2015 07/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 206406 FINAL THREE YEAR EXCLUSIVITY
2015-5001	06/19/2015 07/20/2015	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OC/OES/DFOI/	Wendy Banka Wendy Banka	PFIZER, INC, ROCHESTER, MI - 483 08/01/2014 - 08/30/2014
2015-5002	06/19/2015 07/20/2015	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Liane LaRochelle DEKA Research and Development Corp.	INSULET CORPORATION, BILLERICA, MA - EIR 03/10/2015 - 03/28/2015
2015-5003	06/19/2015 07/20/2015	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Edward Seefeldt Edward Seefeldt	POPCORN INDIANA - INSPECTION REPORT 12/23/2013 - 05/30/2015
2015-5004	06/19/2015 07/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	Christopher Oxx Parker Waichman, LLP	INFUSE BONE GRAFT - LABELING RECS 01/01/2000 - 06/18/2015
2015-5005	06/19/2015 07/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	MEMOS TO ANDA HOLDERS OF BUPRENORPHINE-CONTAINING TRANSMUCOSAL PRODUCTS REGARDING SINGLE-SHARED REMS
2015-5006	06/19/2015 07/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	Freddie Lee Epic International (Thailand) Co., Ltd.	K812442
2015-5007	06/19/2015 07/20/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Chirag Talati Kotak Securities	ANDA 078340, NDA 079179
2015-5008	06/19/2015 07/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	Freddie Lee Epic International (Thailand) Co., Ltd.	K844401
2015-5009	06/19/2015 07/20/2015	FDA/OMPT/CDRH/OCER/DFOI/	Lyric Xia Shenzhen Hlongmed Biotech Co.,Ltd	K090802, K060187

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2015-5010	06/22/2015 07/21/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FAUZE RIBAS RIBAS, FAUZE	SB-73 - APRVL RECS
2015-5011	06/22/2015 07/21/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JENNIFER RICHNAFSKY SCHULTE, ROTH & ZABEL LLP	DIGOXIN, URSODIOL, ACETAZOLAMMIDE, ETC - RECS
2015-5012	06/22/2015 07/21/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angel Lau Robbins Geller Rudman and Dowd	COMMUNICATIONS BETWEEN FDA MEDICAL REVIEWERS AND AERIE PHARMACEUTICALS RE RHOPRESSA 07/01/2014 - 06/19/2015
2015-5013	06/22/2015 07/21/2015	FDA/OMPT/CDRH/OCER/DFOI/	Michael D Lurie MacDonald Law Group LLC	GUIDANT ACS HI-TORQUE HEAVYWEIGHT GUIDE WIRE WITH HYDROCOAT - RECS RE DESIGN AND MANUFACTURE (K982083) 01/01/1998 - 06/19/2015
2015-5014	06/22/2015 07/21/2015	FDA/OMPT/CDRH/OCER/DFOI/	Meghal Khakhar Baylis Medical Company Inc.	K142480
2015-5015	06/22/2015 07/21/2015	FDA/OFVM/CFSAN/OCD/EOS/	Maureen Kozuch The Dow Chemical Company	GRAS AFFIRMATION PETITION 2G0280
2015-5016	06/22/2015 07/21/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Frederick Weiss IGI laboratories, Inc	NDA 018933
2015-5017	06/22/2015 07/21/2015	FDA/OMPT/CDRH/OCER/DFOI/	Casey Ming Bacterin International, Inc.	DCI DONOR SERVICES REFICIO PUTTY - 510K 01/01/2000 - 06/19/2015
2015-5018	06/22/2015 07/21/2015	FDA/OMPT/CDRH/OCER/DFOI/	Meghal Khakhar Baylis Medical Company Inc.	K990284
2015-5019	06/22/2015 07/21/2015	FDA/OGROP/ORR/SW-FO/DEN-DO/DEN-CB/	Wendy Banka Wendy Banka	ANALYSIS OF LASALOCID RESIDUES IN GREASE AND FAT USING LIQUID CHROMATOGRAPHY MASS SPECTROMETRY - SAMPLE DATA
2015-5020	06/22/2015 07/21/2015	FDA/OMPT/CDRH/OCER/DFOI/	Meghal Khakhar Baylis Medical Company Inc.	K051670
2015-5021	06/22/2015 07/21/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jennifer dwards WICKER SMITH ET AL	SOLUMEDROL, METHYLPREDNISOLONE - AERS, RECALLS 01/01/2004 - 06/19/2015

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2015-5022	06/22/2015 07/21/2015	FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECS
2015-5023	06/22/2015 07/21/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	Thomas Chimera Thomas Chimera	THENTIX - RECS RE BAN FROM SALE IN US
2015-5024	06/22/2015 07/21/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Morgan Rettig LATHAM & WATKINS	NDA 022496 SBA
2015-5025	06/22/2015 07/21/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Mauna Kea Technologies Mauna Kea Technologies	K111377
2015-5026	06/22/2015 07/21/2015	FDA/OMPT/CDRH/OCER/DFOI/	James Makous Makous, James	K142432
2015-5027	06/22/2015 07/21/2015	FDA/OFVM/CFSAN/OCD/EOS/	Jason Bagley truthinadvertising.org	THRIVE - AERS
2015-5028	06/22/2015 07/21/2015	FDA/OMPT/CDRH/OCER/DFOI/	RHONDA BAKER DEBEVEV DEBEVEC LAW FIRM LLC	ETHICON - PROXIMATE PPH HEMORRHOIDAL CIRCULAR STAPLER K030411, K030925, K051301, ETC RECALL RECS
2015-5029	06/22/2015 07/21/2015	FDA/OMPT/CDRH/OCER/DFOI/	Meghal Khakhar Baylis Medical Company Inc.	K073326 REVIEW NOTES
2015-5030	06/22/2015 07/21/2015	FDA/OC/OES/DFOI/	DIANNE L CHAMBERS HOGAN LOVELLS US LLP	2015-4464
2015-5031	06/22/2015 07/21/2015	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAP/PA-FO/SAN-DO/SAN-CB/	Saumya Valookaran ApoPharma Inc.	AMPAC FINE CHEMICALS LLC, RANCHO CORDOVA, CA - 483 JAN 2015
2015-5032	06/22/2015 07/21/2015	FDA/OGROP/ORAP/NE-FO/NWE-DO/NWE-CB/	Kimberly Peck Kimberly Peck	SHIRE, CAMBRIDGE, MA - EIR 06/03/2013 - 11/29/2013
2015-5033	06/22/2015 07/21/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Edgar R. Gonzalez, PharmD Capital Pharmacy Consultants	OFLOXACIN 0.3% - AERS, TONICITY, PH 01/01/2006 - 12/31/2011

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		FDA/OMPT/CDER/GRP/DIDP/		
2015-5034	06/22/2015 07/21/2015	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	AUTUMN L BORTON PFIZER INC	PFIZER, HANNIBAL, MISSOURI - EIR 2012
2015-5035	06/22/2015 07/21/2015	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Kimberly Peck Kimberly Peck	SHIRE HGT, LEXINGTON, MA - EIR 05/06/2013 - 11/29/2013
2015-5036	06/22/2015 07/21/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Celeste Wheeler Kleinfeld, Kaplan & Becker LLP	ANDA 090218
2015-5037	06/22/2015 07/21/2015	FDA/OMPT/CDRH/OCER/DFOI/	Meghal Khakhar Baylis Medical Company Inc.	K010265
2015-5038	06/22/2015 07/21/2015	FDA/OMPT/CDRH/OCER/DFOI/	Tushar Ranchod BroadSpot Imaging Corporation	K102859
2015-5039	06/22/2015 07/21/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Abhay Shanbhag Abhay Shanbhag	MEGA FINE PHARMA PRIVATE LTD, INDIA - 483 04/01/2015 - 06/13/2015
2015-5040	06/22/2015 07/21/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dr. Samba Reddy TEXAS A&M UNIVERSITY	GANAXOLONE IND RECS
2015-5041	06/22/2015 07/21/2015	OC/ORA/ OC/ORA/	Jeremy Lefkovits Lefkovits, Jeremy	VONNIE'S GREENS - COMPLAINT 140664
2015-5042	06/22/2015 07/21/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Freddie Lee Epic International (Thailand) Co., Ltd.	K042228
2015-5043	06/22/2015 07/21/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Vanessa Silva EMS S/A	NDA 020622, ANDA 090218
2015-5044	06/22/2015 07/21/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GEORGIANNA HARRIS ALKERMES INC	OTSUKA PHARMACEUTICAL CO LTD - ABILIFY NDA 202-971/S003 SBA

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		FDA/OMPT/CDER/GRP/DIDP/		
2015-5045	06/22/2015 07/21/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Olena Izhak University of Helsinki (FINLAND)	ANDA APPROVAL LETTERS
2015-5046	06/22/2015 07/21/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GEORGIANNA HARRIS ALKERMES INC	VELOXIA PHARMS - ENVARUSUS XR (TACROLIMUS) TABS NDA 206-406 3 YR EXCLUSIVITY DECISION
2015-5047	06/22/2015 07/21/2015	FDA/OMPT/CDRH/OCER/DFOI/	ROBERT O CROWDER PHD PENTAIR FLOW & FILTRATION SOLUTIONS	PALL BIOMEDICAL PRODUCTS CO - BLOOD TRANSFUSION MICROFILTER K960993
2015-5048	06/22/2015 07/21/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	COLLINS #327692, MARKIES	PSYCHEDELIC AND MIND ALTERING SUBSTANCES - RECS
2015-5049	06/22/2015 07/21/2015	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	LARS AAGAARD Smart Tech Imaging	K943272
2015-5050	06/22/2015 07/21/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Gregory Jacot Ithos Global, Inc.	FULL LIST OF HUMAN DRUG SUBSTANCES REFERENCED IN CFR TITLE 21 I a
2015-5051	06/23/2015 07/22/2015	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	WALT KANE NEWS 12 NEW JERSEY	TURKANA FOOD, KENILWORTH, NJ - INSP 3/31/15 TO 6/18/15
2015-5052	06/23/2015 07/22/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	RONNIE MOORE TOURO COLLEGE OF PHARMACY	DICLOFENAC SODIUM ANDA
2015-5053	06/23/2015 07/22/2015	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	SCOTT D. MANCUSO MURA & STORM	ELITE MEDICAL SUPPLY, NY - INSP 8/8-14/14, INVESTIGATIONS
2015-5054	06/23/2015 07/22/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PARKER D. KASMER GOODWIN PROCTER LLP	VELOXIS PHARMACEUTICALS - ENVARUSUS XR NDA 06-406

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2015-5055	06/23/2015 07/22/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PARKER D. KASMER GOODWIN PROCTER LLP	OTSUKA PHARMACEUTICAL COMPANY LTD - ABILIFY MAINTENA KIT (ARIPRAZOLE) NDA 02-971/S-003 SBA
2015-5056	06/24/2015 07/23/2015	FDA/OC/OES/DFOI/	Gina Ecolino Beveridge & diamond, P.C.	CFSAN FOIA REQUESTS 05/22/2015 - 06/22/2015
2015-5057	06/24/2015 07/23/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sara Langsenkamp Purdue University	MIRENA REPORT 68420195
2015-5058	06/24/2015 07/23/2015	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Richard Newitter Leerink Partners	PYRAMID LABORATORIES - 483 05/22/2015 - 06/08/2015
2015-5059	06/24/2015 07/23/2015	FDA/OFVM/CFSAN/OCD/EOS/	Brianna Schehr DSM Biomedical	COLOR ADDITIVE PETITION FOR CHROMIUM-COBALT-ALUMINUM OXIDE
2015-5060	06/24/2015 07/23/2015	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Louis Lubitz American Marine Ingredients	CAPTEK SOFTGEL INTERNATIONAL, CERRITOS, CA - 483 11/01/2014 - 02/28/2015
2015-5061	06/24/2015 07/23/2015	OC/ORA/ OC/ORA/	Jessica Purdy AmeriVap Systems	LIST OF ICE CREAM MANUFACTURERS 01/01/2015 - 06/22/2015
2015-5062	06/24/2015 07/23/2015	FDA/OC/OES/DDM/	Carmen Debord WESTLAW COURT EXPRESS	PROPOSED TEMPLATE FOR PACKAGE INSERTS FOR IMMUNOHISTOCHEMISTRY PRODUCTS 01/01/1994 - 12/29/1994
2015-5063	06/24/2015 07/23/2015	FDA/OFVM/CFSAN/OCD/EOS/	Michael M. Landa Michael Landa	RECS RE PACE AND SCOPE OF IMPLEMENTATION OF FACTS UP FRONT NUTRITION KEYS, COMPLIANCE WITH FACTS UP FRONT PROGRAM RULES, EVALUATION OF FACTS UP FRONT SYSTEM ETC
2015-5064	06/24/2015 07/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	P140025
2015-5065	06/24/2015 07/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	James Makous Makous, James	K141399
2015-5066	06/24/2015 07/23/2015	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	William Jones Medicago	CBER STATISTICAL PLAN FOR POTENCY TESTING OF INFLUENZA VACCINES BY SRID METHOD
2015-5067	06/24/2015 07/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	James Makous Makous, James	K960728 K883780 K860158 ETC
2015-5068	06/24/2015	FDA/OMPT/CDRH/OCER/DFOI/	Kim Campbell	K813324

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	07/23/2015		TELEFLEX MEDICAL	
2015-5069	06/24/2015 07/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K022241
2015-5070	06/24/2015 07/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K011702
2015-5071	06/24/2015 07/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K061166
2015-5072	06/24/2015 07/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K061892
2015-5073	06/24/2015 07/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K120479
2015-5074	06/24/2015 07/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K122048
2015-5075	06/24/2015 07/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K140300
2015-5076	06/24/2015 07/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K131143
2015-5077	06/24/2015 07/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K133169
2015-5078	06/24/2015 07/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K101587
2015-5079	06/24/2015 07/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K091499
2015-5080	06/24/2015 07/23/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gay Parsons Janssen Inc. Canada	ANDA 091695
2015-5081	06/24/2015 07/23/2015	FDA/OFVM/CFSAN/OCD/EOS/	Brianna Schehr DSM Biomedical	CAP 8C0253
2015-5082	06/24/2015 07/23/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gay Parsons Janssen Inc. Canada	ANDA 091695

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2015-5083	06/24/2015 07/23/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	DMF 6371
2015-5084	06/24/2015 07/23/2015	OC/ORA/ OC/ORA/	Jessica Collier, Esq. Wilson Elser Moskowitz Edelman & Dicker, LLP	2012 REMOVAL OF KOREAN CERTIFIED SHIPPERS OF MOLLUSCAN SHELLFISH FROM THE INTERSTATE CERTIFIED SHELLFISH SHIPPERS LIST
2015-5085	06/24/2015 07/23/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Qiang Zheng Center for Pharmaceutical Information and Engineering Research	ANDA APPROVED SINCE 2002 FILING DATE
2015-5086	06/24/2015 07/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	Kim N. Nguyen Nguyen, Kim	MOGEN, MOGEN-TYPE CIRCUMCISION CLAMPS - MAUDE REPORTS; MISDOM-FRANK CIRCUMCISION CLAMPS - ALL RECS
2015-5087	06/24/2015 07/23/2015	FDA/OFVM/CFSAN/OCD/EOS/	David C. Bernard, Brian T. Carr & Associates Brian T. Carr & Associates	SVC MANUFACTURING, INC, PROPEL ZERO POWDER - INGREDIENTS, COMPLAINTS, ETC 08/06/2002 - 06/23/2015
2015-5088	06/24/2015 07/23/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dave Milton Coker, Schickel, Sorenson, Posgay, Camerlengo & Iracki, P.A.	METHOTREXATE - AERS
2015-5089	06/24/2015 07/23/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dave Milton Coker, Schickel, Sorenson, Posgay, Camerlengo & Iracki, P.A.	METHOTREXATE - PROBLEM REPORTS
2015-5090	06/24/2015 07/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	Copy of the 510(k)documents that we have submitted to FDA Solco Biomedical Co., Ltd.	K050471 K060702 K082453 ETC
2015-5091	06/24/2015 07/23/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Erin Kelm Fuld and Company	GP PHARM, SPAIN - EIR 01/01/2015 - 01/31/2015
2015-5092	06/24/2015 07/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	Ellen Denham Bradshaw & Associates, P.C.	PINNACLE COMPLETE ACETABULAR HIP SYSTEM - IDE G050078
2015-5093	06/24/2015	FDA/OFVM/CFSAN/OCD/EOS/	Brianna Schehr	CAP 3C0176

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	07/23/2015		DSM Biomedical	
2015-5094	06/24/2015 07/23/2015	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	John Walsh James Alexander Corporation	MICROBIOLOGICAL CONSULTANTS, INC, HUNTINGTON, WV - EIR, 483, RECALL 06/01/2014 - 06/23/2015
2015-5095	06/24/2015 07/23/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ke Dong Center for Pharmaceutical Information and Engineering Research	PFIZER PHARMACEUTICALS LTD, CHINA; ZHEJIANG HISUN PHARMACEUTICAL CO, LTD, CHINA - 483
2015-5096	06/24/2015 07/23/2015	FDA/OO/OFBA/OAGS/	Sarah Boehm IQ Solutions, Inc.	FDA - C-31034-SB "CVM Database and Web Support"
2015-5097	06/24/2015 07/23/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dustin Block IPD Analytics, LLC	ANDA 091602
2015-5098	06/24/2015 07/23/2015	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	John Walsh James Alexander Corporation	AVANTOR PERFORMANCE MATERIALS, PHILLIPSBURG, NH - EIR, 483, RECALL RECS 06/01/2011 - 06/23/2015
2015-5099	06/24/2015 07/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	Gary Syring Quality & Regulatory Assoc. LLC	K003154
2015-5100	06/24/2015 07/23/2015	FDA/OC/OES/DFOI/	Walter Chalkley THOMSON REUTERS	FOIA DAILY LOG JAN THROUGH APRIL 2015
2015-5101	06/24/2015 07/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	Nolan Sardesai VasoInnovations, Inc.	K070423, K092503, K111837 ETC
2015-5102	06/24/2015 07/23/2015	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Brandon Henry RBC	PYRAMID LABORATORIES - RESPONSE TO 483
2015-5103	06/24/2015 07/23/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TUDUI M05570, TOM	WELLBUTRIN - AER
2015-5104	06/24/2015 07/23/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TUDUI M05570, TOM	AMBIEN - AER
2015-5105	06/24/2015 07/23/2015	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TUDUI M05570, TOM	PROPANOL - AER

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2015-5106	06/24/2015 07/23/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TUDUI M05570, TOM	AMBIEN CR AER
2015-5107	06/24/2015 07/23/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TUDUI M05570, TOM	WELLBUTRIN XL - AER
2015-5108	06/24/2015 07/23/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TUDUI M05570, TOM	ST JOHNS WORT - AER
2015-5109	06/24/2015 07/23/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	ZOLPIDEM, PROPINOL, WELLBUTRIN XL - CLNCL TRIALS
2015-5110	06/24/2015 07/23/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	G. Srinivas Zydus Pharmaceuticals USA Inc.	NDA 19322, NDA 19323
2015-5111	06/24/2015 07/23/2015	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	G. Srinivas Zydus Pharmaceuticals USA Inc.	ANDA 074248
2015-5112	06/24/2015 07/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K072404
2015-5113	06/24/2015 07/23/2015	FDA/OMPT/CDRH/OCER/DFOI/	MEYER, FRANK	DEDEPUY - SB CHARITE III INTERVERTEBAL DISC SPACER FDA INVESTIGATION
2015-5114	06/24/2015 07/23/2015	FDA/OC/OES/DFOI/	McCLOUD E72855, EARL	LIST OF RECALLED DRUGS

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2016-1	01/04/2016 02/02/2016	FDA/OC/OES/ FDA/OPPLA/OL/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCE/DID/	John Tozzi Bloomberg Businessweek	VARIOUS MEETING MINUTES 01/01/2015 - 12/01/2015
2016-2	01/04/2016 02/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Abhishek Sharma IIFL Cap	HOSPIRA HEALTHCARE INDIA PRIVATE LIMITED, INDIA - 483 11/01/2013 - 12/31/2013
2016-3	01/04/2016 02/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Abhishek Sharma IIFL Cap	SIPCOT, INDIA - 483 09/01/2012 - 10/31/2012
2016-4	01/04/2016 02/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Abhishek Sharma IIFL Cap	HOSPIRA HEALTHCARE SIPCOT- 483 01/01/2015 - 02/24/2015
2016-5	01/04/2016 02/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gregory Renza JEFFERIES & CO	KALYDECO, ORKAMBI, JAKAFI ETC - AERS
2016-6	01/04/2016 02/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Chi Ho Marciniak Chi Ho Marciniak	NDA 022307, S008, NDA 022433, S 015
2016-7	01/04/2016 02/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sharon Brown Sharon Brown	VALTESSA- AERS
2016-8	01/04/2016 02/02/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Elliott Millenson Elliott Millenson	DIRECT ACCESS DIAGNOSTICS - RECS RE CALL 09/15/1994 - 02/28/1995

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		FDA/OC/OES/		
2016-9	01/04/2016 02/02/2016	FDA/OC/OES/DFOI/	K Campbell Kristy Campbell	K990461
2016-10	01/04/2016 02/02/2016	FDA/OC/OES/DFOI/	K Campbell Kristy Campbell	K982946
2016-11	01/04/2016 02/02/2016	FDA/OC/OES/DFOI/	K Campbell Kristy Campbell	K982256
2016-12	01/04/2016 02/02/2016	FDA/OC/OES/DFOI/	K Campbell Kristy Campbell	K050770
2016-13	01/04/2016 02/02/2016	FDA/OC/OES/DFOI/	K Campbell Kristy Campbell	K033039
2016-14	01/04/2016 02/02/2016	FDA/OC/OES/DFOI/	K Campbell Kristy Campbell	K023098
2016-15	01/04/2016 02/02/2016	FDA/OC/OES/DFOI/	K Campbell Kristy Campbell	K020862
2016-16	01/04/2016 02/02/2016	FDA/OC/OES/DFOI/	K Campbell Kristy Campbell	K014091
2016-17	01/04/2016 02/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lura Morgan Lura Morgan	MYCOCIDE - AERS
2016-18	01/04/2016 02/02/2016	FDA/OMPT/CDRH/OCE/DID/	Shruti Jayakumar ZELTIQ Aesthetics, Inc.	K151179
2016-19	01/04/2016 02/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dennis Chirico Chirico, Dennis P	DILTIAZEM XR, CARDIZEM - AERS
2016-20	01/04/2016 02/02/2016	FDA/OGROP/OIP/	Zeba Siddiqui THOMSON REUTERS	CORR BETWEEN FDA AND INDIA MINISTRY OF HEALTH AND FAMILY WELFARE 01/02/2014 - 12/28/2015
2016-21	01/04/2016 02/02/2016	FDA/OFVM/CFSAN/OCD/EOS/	Wendy Banka Wendy Banka	SPREADSHEET OF PRODUCTS REPORTED TO REPORTABLE FOOD REGISTRY 01/01/2014 - 12/28/2015
2016-22	01/04/2016 02/02/2016	FDA/OMPT/OSMP/OOPD/	Michael Burr iVeena	RIBOFLAVIN OPHTHALMIC SOLUTION & ULTRAVIOLET - ORPHAN DESIGNATION RECS 09/03/2010 - 09/05/2011

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2016-23	01/04/2016 02/02/2016	FDA/OGROP/OIP/	Zeba Siddiqui THOMSON REUTERS	MEMORANDUM OF UNDERSTANDING ON MEDICAL PRODUCTS WITH INDIA - RECS RE FOLLOW UP ACTIONS 01/01/2014 - 12/28/2015
2016-24	01/04/2016 02/02/2016	OC/ORO/ OC/ORO/	Houston Byrd Houston Byrd	GENERAL MILLS - COMPLAINTS RE FOREIGN OBJECTS 01/01/2000 - 12/01/2001
2016-25	01/04/2016 02/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Veeranna Lolla Strides Pharma Inc.	ANDA 071196 SBA
2016-26	01/04/2016 02/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Veeranna Lolla Strides Pharma Inc.	ANDA 062298 SBA
2016-27	01/04/2016 02/02/2016	FDA/OPPLA/OL/	Elliott Millenson Elliott Millenson	RECS RE FRANK YOUNG TESTIMONY RE HIV HOME TESTS 02/01/1989 - 04/30/1989
2016-28	01/04/2016 02/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gail Chirico Chirico, Dennis P	CARDURA, DOXASOSIN - AERS
2016-29	01/04/2016 02/02/2016	FDA/OMPT/CDRH/OCE/DID/	Anna Hwang Acclarent, Inc.	K133573 K141456 K133665
2016-30	01/04/2016 02/02/2016	FDA/OC/OES/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Elliott Millenson Elliott Millenson	RECS RE MEETINGS BETWEEN UHL CORPORATION AND OFFICE OF COMMISSIONER RE REQUEST FOR AN EVIDENTIARY HEARING 08/01/1992 - 02/21/1993
2016-31	01/04/2016 02/02/2016	FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDRH/OCE/DID/	Jonathan S. Wallack BONNETT FAIRBOURN ET AL	CUTERA INCORPORATED CLASS II MEDICAL DEVICE TRUSCULPT - LICENSING RECS, AUDITS, RECALLS, ETC 12/01/2000 - 12/29/2015
2016-32	01/04/2016 02/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Brenna Kelly SAUL EWING LLP	DRUG INFO EMAIL - IDENTITY OF SENDER
2016-33	01/04/2016 03/18/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	David J. Goldsmith Labaton Sucharow LLP	CELLADON MYDICAR - COMMUNICATIONS AND MEETING MINUTES RE FAST TRACK DESIGNATION AND CBER BREAKTHROUGH THERAPY DESIGNATION ETC 01/01/2010 - 04/26/2015

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2016-34	01/04/2016 02/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	William Vaughn McCall MEDICAL COLLEGE OF GEORGIA	CASE REPORTS 6309807 ETC
2016-35	01/04/2016 02/02/2016	FDA/OMPT/CDRH/OCE/DID/ FDA/OMPT/OSMP/OOPD/	Marc C. Sanchez, Esq. Contract In-House Counsel & Consl. LLC	Office of Device Evaluation or Similar CDRH Division communications, submissions or related documents for classification or approval of the Symmetry Surgical C-Assist Clamp and Retractor
2016-36	01/04/2016 02/02/2016	FDA/OMPT/CDRH/OCE/DID/	Julia Helgeson STRYKER INSTRUMENTS	K150682
2016-37	01/04/2016 02/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Andy Washkowitz venBio LLC	MGCD265 AERS
2016-38	01/04/2016 02/02/2016	FDA/OMPT/CDRH/OCE/DID/	Scott Goldman Hyman, Phelps & McNamara P.C.	K052003
2016-39	01/04/2016 02/02/2016	FDA/OMPT/CDRH/OCE/DID/	Kathryn Thomas Kathryn Thomas	RECS BETWEEN FDA AND 23ANDME RE CUSTOMER POSTS 11/01/2013 - 11/30/2015
2016-40	01/04/2016 02/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Nabin K C Nabin K C	LYMPHOMA AS ADVERSE EVENT REPORTED ON INFLIXIMAB
2016-41	01/04/2016 02/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dr Ulrich Korell PharmaKorell GmbH	MYLAN LABORATORIES LTD, INDIA - EIR 04/01/2015 - 12/31/2015
2016-42	01/04/2016 02/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sungji Koo Blume Donelly	5-FU AERS
2016-43	01/04/2016 02/02/2016	FDA/OC/OES/DFOI/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Rachel Johnson FOI Services, Inc.	RECS RE 2014-10026
2016-44	01/04/2016	FDA/OC/OES/DFOI/	Rachel Johnson	RECS RE 2014-9742

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	03/28/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	FOI Services, Inc.	
2016-45	01/04/2016 02/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	VAUGHN SNIDER Snider, Vaughn	DILANTIN - AERS
2016-46	01/04/2016 02/02/2016	OC/ORA/ OC/ORA/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	PATTI WALLER MARLER CLARK LLP, PS	INDIVIDUAL RECS
2016-47	01/04/2016 02/02/2016	OC/ORA/OCI/ OC/ORA/OCI/	ANGIE SALVATIERRA US LEGAL SUPPORT INC	OCI CASE NUMBER 2009-LAC-715-0060
2016-48	01/04/2016 02/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BED ADLIN Leafly News	GUIDANCE PROVIDED BY THE FDA TO THE DEA REGARDING POTENTIAL RESCHEDULING OF CANNABIS/MARIJUANA OR ITS DERIVATIVES UNDER THE CONTROLLED SUBSTANCES ACT
2016-49	01/04/2016 02/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WILLIAM MCINTYRE PHD LUPIN PHARMACEUTICALS INC	AUROBINDO - CEFIXIME FOR ORAL SUSPENSION ANDA 204-835 APRVL RECS
2016-50	01/04/2016 02/02/2016	FDA/OMPT/CDRH/OCE/DID/	BERYL C D LIPTON MUCKROCK	FREE MERCURY IN AMALGAM TRITURATORS MW4002086
2016-51	01/04/2016 02/02/2016	FDA/OMPT/CDRH/OCE/DID/	BERYL C D LIPTON MUCKROCK	KERR CORP - MW4002087
2016-52	01/04/2016 02/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAWN M CHITTY TORRENT PHARMA INC	MYCOLOG II CREAM (NYSTATIN AND TRIAMCINOCLOLONE ACETONIDE) ANDA 60-576 - SBA
2016-53	01/04/2016 02/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAWN M CHITTY TORRENT PHARMA INC	MYCOSTATIN CREAM (NYSTATIN) ANDA 60-575 - SBA
2016-54	01/04/2016 02/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAWN M CHITTY TORRENT PHARMA INC	MYCOLOG OINTMENT (NYSTATIN AND TRIAMCINOLONE ACETONIDE) ANDA 60-572 - SBA

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2016-55	01/04/2016 02/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAWN M CHITTY TORRENT PHARMA INC	NYSTATIN AND TRIAMCINOLONE ACETONIDE CREAM ANDA 62-606 - SBA
2016-56	01/04/2016 02/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	NICHOLAS A SRADER SRADER 143218, NICHOLAS	PPI - AERS
2016-57	01/04/2016 02/02/2016	FDA/OGROP/ORO/SW-FO/KAN- DO/KAN-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID PARKS MD CENTRAL WEST CLINICAL RESEARCH INC	CENTRAL WEST CLINICAL RESEARCH INC, ST LOUIS, MO - AUDIT 5/7-15/14
2016-58	01/04/2016 02/02/2016	FDA/OMPT/CDRH/OCE/DID/	MICHAELL A HUBER DDS UT HEALTH SCIENCE CENTER SAN ANTONIO	PERIRX LLC - SALIMARK TEST FOR ORA CANCER FDA OVERSIGHT
2016-59	01/04/2016 02/02/2016	FDA/OMPT/CDRH/OCE/DID/	MICHAELL A HUBER DDS UT HEALTH SCIENCE CENTER SAN ANTONIO	ESPYOC - FDA OVERSIGHT
2016-60	01/04/2016 02/02/2016	FDA/OC/OES/DFOI/	BERYL C D LIPTON MUCKROCK	DENTAL AMALGAMS - RISKS, RPTS, USEFULNESS, ETC
2016-61	01/04/2016 02/02/2016	FDA/OMPT/CDRH/OCE/DID/	BERYL C D LIPTON MUCKROCK	KERR CORP - MAUDE RPT 1815757-1999-00001
2016-62	01/04/2016 02/02/2016	FDA/OMPT/CDRH/OCE/DID/	BERYL C D LIPTON MUCKROCK	DENTAL AMALGAM - MDRS 2003 TO 2015
2016-63	01/05/2016 02/03/2016	FDA/OMPT/CDRH/OCE/DID/	Andrew Yokopovich HAMPTON & RAWLINGS	PRAXAIR VANTAGE GRAB 'N CO OXM-AEGNGVNTG - MEMOS, MEDWATCH REPORTS, ETC 01/01/2006 - 12/01/2015
2016-64	01/05/2016 03/29/2016	FDA/OC/OES/DFOI/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Rachel Johnson FOI Services, Inc.	2015-3556 RECS
2016-65	01/05/2016	FDA/OC/OES/DFOI/	Andrew Yokopovich	CORR, NOTES, EMAILS BETWEEN FDA AND SCOTT

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	02/03/2016	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OMPT/CDRH/OCE/DID/	HAMPTON & RAWLINGS	FETZER, MEDWATCH REPORTS, RECALLS, TESTING RE WESTERN/SCOTT FETZER OXYTOTE ETC
2016-66	01/05/2016 02/03/2016	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Peter Marchese Peter Marchese	YOUNG PHARMACEUTICALS, WETHERSFIELD, CT - ATTEMPTED SITE INSPECTION RECS 01/01/2010 - 12/30/2015
2016-67	01/05/2016 02/03/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Brenda Goodman WebMD	DICLEGIS - FORM 2253 07/01/2015 - 09/01/2015
2016-68	01/05/2016 02/03/2016	FDA/OMPT/CDRH/OCE/DID/ OC/ORA/ OC/ORA/	NeJame Law, PA/Stephen Calvacca, Esq. NeJame Law, PA	no!no! Pro Hair Removal Device - COMPLAINTS, APPROVAL RECS 12/01/1990 - 12/31/2015
2016-69	01/05/2016 02/03/2016	FDA/OC/OES/DFOI/	Vince H Suneja Vince Suneja	CADILA HEALTHCARE - WARNING LETTERS 01/01/2015 - 12/31/2015
2016-70	01/05/2016 02/03/2016	FDA/OMPT/CDRH/OCE/DID/	Sue Darcey Informa Business Information/	THE COOK GROUP - MEETING MINUTES, SUMMARIES, EMAIL 11/03/2015 - 12/31/2015
2016-71	01/05/2016 02/03/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dheeresh Pathak Dheeresh Pathak	INDOCO REMEDIES, INDIA - 483 05/01/2015 - 09/30/2015
2016-72	01/05/2016 02/03/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bryan Krumm Bryan Krumm	FDA RECOMMENDATION TO DEA RE CANNABIS RESCHEDULING PETITIONS FILED BY BRYAN KRUMM, STATE OF WASHINGTON, STATE OF RHODE ISLAND
2016-73	01/05/2016 02/03/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOSEPH WALKER Walker, Joseph	REPATHA, PRALUENT - CASE REPORT
2016-74	01/05/2016 02/03/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Vince H. Suneja Vince H Suneja	ORCHID PHARMA LTD, INDIA - EIR 01/01/2015 - 12/31/2015
2016-75	01/05/2016	FDA/OMPT/CDER/GRP/DIDP/	Prutha Desai	SHASON PHARMACEUTICALS LIMITED, INDIA - EIR 01/03/2013 - 12/31/2015

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	02/03/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	P & L Development, LLC	
2016-76	01/05/2016 02/03/2016	FDA/OC/OES/ FDA/OPPLA/OL/ FDA/OMPT/CDRH/OCE/DID/	Sue Darcey [no person],	MEETING BETWEEN SENATE STAFFERS AND FDA OFFICIALS RE IN VITRO DIAGNOSTICS - EMAILS, SUMMARIES, MINUTES 08/06/2015 - 10/06/2015
2016-77	01/05/2016 02/03/2016	FDA/OMPT/CDRH/OCE/DID/	Kip Petroff Kip Petroff Law Office (c/o Mathis & Donheiser)	K071160
2016-78	01/05/2016 02/03/2016	OC/ORR/ORM/ OC/ORR/ORM/	Glen Potvin Quintiles	LIST OF DRUG, DEVICE 482 12/01/2015 - 12/31/2015
2016-79	01/05/2016 02/03/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Olena Izhak University of Pennsylvania, Wharton School, Finance Department	8 ANDA APPROVAL LETTERS
2016-80	01/05/2016 02/12/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Tasha Kerr, BSN, RN Baxalta	ELOCTATE - SAFETY DATA FROM PRE-AUTHORIZATION AND POST-APPROVAL SAFETY REPORTS
2016-81	01/06/2016 02/04/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 12/1-31/2015
2016-82	01/06/2016 02/04/2016	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2015-9116 INTERNAL CORR
2016-83	01/06/2016 02/04/2016	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	RECS RE 2015-9125
2016-84	01/06/2016 02/04/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Timothy Bassett Pura Vida Investments	PRALUENT - AERS
2016-85	01/06/2016 02/04/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	LIST OF CLOSED FOIA REQUESTS 1/1/2015 TO 12/31/2015
2016-86	01/06/2016	FDA/OMPT/CDER/ORP/DIDP/	Qiang Zheng	CSPC ZHONGNUP PHARM CO LTD, CHINA; HISUN PFIZER

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	02/04/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Peking University	PHARMACEUTICALS, CHINA; SHANGHAI DESANO CHEMICAL PHARMCEUTICAL, CHINA ETC - 483
2016-87	01/06/2016 02/04/2016	FDA/OC/OES/DFOI/	Amanda Schauer Smart Reviews LLC	THERMACOOL SMARTTOUCH BI-DIRECTIONAL HEART CATHETER - MAUDE REPORTS 01/01/2007 - 01/04/2016
2016-88	01/06/2016 02/04/2016	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	Fran Silverman truthinadvertising.org	IT WORKS AKA CRAZY WRAP THING, BRADENTON, FL - AERS, INSPECTIONS, CORR 01/01/2010 - 01/04/2016
2016-89	01/06/2016 02/04/2016	FDA/OMPT/CDRH/OCE/DID/	Anita Dalrymple Biomerics LLC	K823701
2016-90	01/06/2016 02/04/2016	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	ALLER, ROBERT	DR. HARRIS LEWIN, UNIV OF CALIFORNIA AT DAVIS - LETTERS 2012, 2013
2016-91	01/06/2016 02/04/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ted Keller CFA EverPoint Asset Management	CASE REPORTS 11230723 11633431 11776673 ETC
2016-92	01/06/2016 02/04/2016	FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/	Martin Lueders Martin Lueders	EXPRESS DIAGNOSTICS INT'L, INC - INSPECTION RECS 06/01/2014 - 01/04/2016
2016-93	01/06/2016 02/04/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michael Metschl ORBIMED ADVISORS LLC	CASE REPORTS 11230723 11342154 11633431 ETC
2016-94	01/06/2016 02/04/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	David Lebowitz Morgan Stanley	REPATHA - AERS
2016-95	01/06/2016 02/04/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Qiang Zheng Center for Pharmaceutical Information and Engineering Research	HISUN PFIZER PHARMACEUTICALS CO, CHINA; BRIGHTGENE PHARMACEUTICALS CO, LTD, CHINA; SUNSHINE LAKE PHARMA, CHINA - 483 04/01/2015 - 11/30/2015
2016-96	01/06/2016 02/04/2016	OC/CVM/OCD/	Elizabeth Carney, DVM Elizabeth Carney, DVM	AFOXOLANER, FLURALANER - ADE COMPREHENSIVE CLINICAL DETAIL REPORT LISTING

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2016-97	01/06/2016 02/04/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JENNIFER A. DAVIDSON Kleinfeld Kaplan and Becker LLP	OTIPRIO NDA 20-7986 APRVL
2016-98	01/06/2016 02/04/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dale Usner Statistics and Data Corporation	NDA 050555
2016-99	01/06/2016 02/04/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Zach Piper FT Options, LLC	PRALUENT - AERS
2016-100	01/06/2016 04/05/2016	FDA/OPPLA/OL/ FDA/OC/OES/ FDA/OFVM/CFSAN/OCD/EOS/	Candice Choi ASSOCIATED PRESS	EMAIL, RECS RE LEGISLATION REQUIRING RESTAURANT CHAINS AND VENDING MACHINES TO POST CALORIE COUNTS ON MENUS 01/01/2008 - 01/04/2016
2016-101	01/06/2016 02/04/2016	FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECS
2016-102	01/06/2016 02/04/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	William B Hinshaw Markle & Hinshaw Gynecology	Statistical Review and Evaluation - Clinical Studies Document Date: September 4, 1998 Document Number: NDA 20-560 SE8-015 Document Authors: Bruce Schneider (HFD-510) Anthony Mucci (HFD-715) Studies under Review: The Clinical Fracture Study, and the combined Clinical Fracture/Vertebral Fracture Studies, from the Fracture Intervention Trials (FIT)
2016-103	01/06/2016 02/04/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	David Lebowitz Morgan Stanley	PRALUENT - AERS
2016-104	01/06/2016 02/04/2016	OC/ORO/ OC/ORO/ OC/ORO/ORM/ OC/ORO/ORM/	Kris Christian FDAZILLA	LIST OF INSPECTIONS 12/02/2015 - 01/04/2016
2016-105	01/06/2016 02/04/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mark Mathieu PAREXEL International Corporation	DRUG, BIOLOGICS SUBMISSIONS, APPROVALS 2015

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2016-106	01/06/2016 02/04/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Matthew Herper FORBES	PRALUENT, REPATHA - AERS
2016-107	01/06/2016 02/04/2016	FDA/OMPT/CDRH/OCE/DID/	Nancy Phan Globizz Corporation	K102092 K102923
2016-108	01/06/2016 02/04/2016	FDA/OC/OES/DFOI/	David Lebowitz Morgan Stanley	FOIA REQUESTS RE ORKAMBI, REPATHA, PRALUENT
2016-109	01/06/2016 02/04/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ke Dong Center for Pharmaceutical Information and Engineering Research	FILING DATE FOR ANDA SINCE 1991
2016-110	01/06/2016 02/04/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Zheng Zhao Center for Pharmaceutical Information and Engineering Research	ZHENGJIANG MEDICINE CO LTD, CHINA, QILU TIANHE PHARMACEUTICAL CO, CHINA; SHANGHAI DESANO CHEMICAL PHARMACEUTICAL CO LTD, CHINA - 483 01/01/2015 - 12/31/2015
2016-111	01/06/2016 02/04/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jaime Vassallo LexisNexis CourtLink	GLATOPA, GLATIRAMER ACETATE, COPAXONE - AERS
2016-112	01/06/2016 02/04/2016	FDA/OC/OES/DFOI/	Matthew Herper FORBES	2015-10250
2016-113	01/06/2016 02/04/2016	OC/ORO/ORM/ OC/ORO/ORM/	Merle Zimmermann (ext. 106) AMERICAN HERBAL PRODUCTS ASSOCIATION	LISTING OF GMP INSPECTIONS UNDER PART 111 IN 2015
2016-114	01/06/2016 03/08/2016	FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORO/PA-FO/SAN- DO/SAN-CB/	Kris Christian FDAZILLA	ALLERGAN INC, CAMPBELL, CA - 483, EIR, RESPONSE 04/06/2015 - 04/20/2015
2016-115	01/06/2016 02/04/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kris Christian FDAZILLA	SMITHKLINE BEECHAM LIMITED, UK - 483, EIR, RESPONSE 07/02/2015 - 07/10/2015

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-116	01/06/2016 02/04/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANNE SABINE ZOLLER AURIS MEDICAL	OTIPRIO NDA 20-7986 APRVL
2016-117	01/06/2016 02/04/2016	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	Michele Milone Michele Milone	INDIVIDUAL RECS
2016-118	01/06/2016 02/04/2016	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	MICHAEL J. GILBERT DECHERT LLP	AAI PHARMA SERVICES CORP; CAMBRIDGE MAJOR LABS - 483, WARNING LTRS, CORR 2010 TO PRESENT
2016-119	01/06/2016 02/04/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Daven Mody Impax Laboratories, Inc.	NDA 017481 SBA
2016-120	01/06/2016 02/04/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jaya Ayyagari Dr. Reddy's Laboratories Inc.	NDA 008845 SBA
2016-121	01/06/2016 02/04/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Biren Amin JEFFERIES & CO	REPATHA, PRALUENT - AERS
2016-122	01/06/2016 02/04/2016	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/ORO/DIOP/	Zetetic, Inc. Zetetic, Inc.	FDA ENTRY DOCUMENTATION REQUEST ALL DOCUMENTATION 12/16/2015 - 12/31/2015
2016-123	01/06/2016 02/04/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	FLOURIDE - AER

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-124	01/06/2016 02/04/2016	FDA/OC/OES/DDM/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CAROLLO, RUSSELL	ARMOUR PHARMACEUTICALS INC - ACTHAR GEL SYNTHETIC - RECS
2016-125	01/06/2016 02/04/2016	FDA/OFVM/CFSSAN/OCD/EOS/ FDA/OC/OES/DDM/	DANIEL L. CAJIGAS CLINICIANS SUPPLEMENT CONSULTANTS	RPT 955-0316, 955-0316 - CERTIFIED
2016-126	01/06/2016 02/04/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	RUBIN, KEN	APOTEX - FERRIPROX NDA 021-825 RVWS
2016-127	01/06/2016 02/04/2016	FDA/OC/OES/DFOI/	Doe J	OPINION LETTER ON 12/2/15
2016-128	01/06/2016 02/04/2016	FDA/OC/OES/DFOI/	SEAN DUNAGAN JUDICIAL WATCH	CDC EMERGENCY OPERATIONS CENTER - IMMIGRANTS RECS 6/14 TO PRESENT
2016-129	01/06/2016 02/04/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHRISTOPHER McDANIEL Buzzfeed News	HARRIS PHARMA - EXECUTION DRUGS RECS
2016-130	01/06/2016 02/04/2016	FDA/OGROP/ORR/CE-FO/DET-DO/DET-CB/ FDA/OC/OES/DFOI/	LYNDSEY TELFORD TELEGRAPH MEDIA GROUP	DEPUY ORTHOPAEDICS - WARSAW, IN - INSP 5/11 - 6/11
2016-131	01/07/2016 02/05/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TIM LENONS LEMONS, TIM	SEROQUEL, RESPERADAL, BUPRION - CLNCL STUDIES, AERS
2016-132	01/07/2016 02/05/2016	FDA/OMPT/CDRH/OCE/DID/ OC/ORR/ OC/ORR/ FDA/OGROP/ORR/NE-FO/NYK-DO/NYK-DCB/	CHRISTOPHER T BASILO GIBBONS PC	CARESTREAM HEALTH INC - POINT-OF-CARE MODEL 260 AND MODEL 360 COMPUTED RADIOLOGY PLATE SCANNER CMLPNTS 1/05 TO PRESENT
2016-133	01/07/2016	FDA/OGROP/ORR/PA-FO/LOS-	MICHAEL D LEVIN	FORMULATION TECHNOLOGY INC, OAKDALE, CA - EIRS,

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	04/06/2016	DO/LOS-CB/ FDA/OGROP/ORAP/PA-FO/SAN-DO/SAN-CB/	HEALTH BUSINESS STRATEGIES	483S, WARNING LTRS, ETC 1/1/05 TO 12/15/15
2016-134	01/07/2016 02/05/2016	FDA/OMPT/CDRH/OCE/DID/	SUE DARCEY The Gray Sheet	ADVAMED - RX REGULATORY REFORMS MTG MINS, SUMMARIES, EMAILS, ETC 11/19/15
2016-135	01/07/2016 02/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Parker Cane Parker Cane	NDA 022396
2016-136	01/07/2016 02/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mary McKenzie PFIZER INC	NDA 022396
2016-137	01/07/2016 02/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Genevieve Stevens Nivagen Pharmaceuticals, Inc.	ANDA 71961
2016-138	01/07/2016 02/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	DIGOZIN (LANOXIN) - AERS
2016-139	01/07/2016 02/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Hannah Cane Hannah Cane	NDA 022396
2016-140	01/07/2016 02/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jaya Ayyagari Dr. Reddy's Laboratories Inc.	NDA 008453 SBA
2016-141	01/07/2016 02/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DONALD D BACON BACON, DONALD D	KETAMINE - APRVL RECS

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2016-142	01/07/2016 02/05/2016	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	Heather Sinn Agilent Technologies INC	AGILENT TECHNOLOGIES, BOULDER, CO - EIR AUGUST 2015
2016-143	01/07/2016 02/05/2016	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink	2015-6842
2016-144	01/07/2016 02/05/2016	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOI REQUESTS 12/14-18/15
2016-145	01/07/2016 02/05/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 12/14-18/15
2016-146	01/07/2016 02/05/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 12/14-18/15
2016-147	01/07/2016 02/05/2016	FDA/OC/OCC/ OC/ORAOCI/ OC/ORAOCI/	Jill Bonnin LegitScript LLC	RAM KAMATH - RECS RE DEFERRED PROSECUTION/DISMISSAL AGREEMENT RE USA V. CANADADRUGS.COM LTD PARTNERSHIP ET AL 01/01/2011 - 01/05/2016
2016-148	01/07/2016 02/05/2016	FDA/OFVM/CFSAN/OCD/EOS/	Merle Zimmermann (ext 106) AMERICAN HERBAL PRODUCTS ASSOCIATION	DIETARY SUPPLEMENTS - AERS 01/01/2015 - 12/31/2015
2016-149	01/07/2016 02/05/2016	FDA/OMPT/CDRH/OCE/DID/	Jason J. Velligan Meyers & Flowers, LLC	PMA 060038
2016-150	01/07/2016 02/05/2016	FDA/OFVM/CFSAN/OCD/EOS/	Anjelica Q. Nguyen Burg Simpson Eldredge Hersh & Jardine, PC	p-Phenylenediamine ETC - AERS
2016-151	01/07/2016 02/05/2016	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Kris Christian FDAZILLA	AMGEN, INC, THOUSAND OAKS, CA - 483, EIR, 483 RESPONSE 05/04/2015 - 05/22/2015
2016-152	01/07/2016 02/05/2016	FDA/OO/OHR/	Doe J	INDIVIDUAL RECS
2016-153	01/07/2016 02/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Clark Hammond Wallace Jordan Ratliff & Brandt LLC	DRUG APPLICATIONS, DATA SUBMITTED FOR APPROVAL OF ZONEGRAN FOR USE IN CHILDREN 01/01/2002 - 01/05/2016
2016-154	01/07/2016 02/05/2016	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	MARGARET NG MARGARET NG, CAPTEK SOFTGEL INTERNATIONAL	CAPTEK SOFTGEL INTERNATIONAL, CERRITOS, CA - EIR 06/01/2015 - 01/05/2016

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2016-155	01/07/2016 02/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Katherine Eban Katherine Eban	RECS RE GDUFA REGULATORY SCIENCE RESEARCH PROGRAM 01/01/2013 - 01/05/2016
2016-156	01/07/2016 02/05/2016	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Kris Christian FDAZILLA	BIOGEN US CORPORATION, RESEARCH TRIANGLE PARK, NC - 483, EIR, 483 RESPONSE 11/30/2015 - 12/10/2015
2016-157	01/07/2016 02/05/2016	FDA/OFVM/CFSAN/OCD/EOS/	Anjelica Q. Nguyen Burg Simpson Eldredge Hersh & Jardine, PC	JUST FOR MEN HAIR PRODUCTS - AERS
2016-158	01/07/2016 02/05/2016	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OC/OES/DFOI/	Elizabeth Luoma DuVal & Associates, P.A.	REPRO-MED SYSTEMS, INC - EIR 06/09/2015 - 06/09/2015
2016-159	01/07/2016 02/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	SUBSYS - FAER
2016-160	01/07/2016 02/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Prashant Modi Lambda Therapeutic Research	Access to LCMSMS/ELISA generated PK data of Herceptin by ROCHE
2016-161	01/07/2016 02/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	PROMACTA - AERS
2016-162	01/07/2016 02/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	KYPROLIS - AERS
2016-163	01/07/2016 02/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michael Metschl ORBIMED ADVISORS LLC	PRALUENT - CASE REPORTS 11230723 11633431 11776673 ETC
2016-164	01/07/2016 02/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Akash Tewari Evercore ISI	GLATOPA, COPAXONE - AERS

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2016-165	01/07/2016 02/05/2016	FDA/OMPT/CDRH/OCE/DID/	David Skorohod, Accurate Medical Accurate Medical Therapeutics Ltd.	K110459 K121677
2016-166	01/07/2016 02/05/2016	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 12/14-18/15
2016-167	01/07/2016 02/05/2016	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOI REQUESTS 12/21-25/15
2016-168	01/07/2016 02/05/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 12/21-25/15
2016-169	01/07/2016 02/05/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 12/21-25/15
2016-170	01/07/2016 02/05/2016	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOI REQUESTS 12/28/15-1/1/16
2016-171	01/07/2016 02/05/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 12/28/15-1/1/16
2016-172	01/07/2016 02/05/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 12/28/15-1/1/16
2016-173	01/07/2016 02/05/2016	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 12/28/15-1/1/16
2016-174	01/07/2016 02/05/2016	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOI REQUESTS 12/7-11/15
2016-175	01/07/2016 02/05/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 12/7-11/15
2016-176	01/07/2016 02/05/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 12/7-11/15
2016-177	01/07/2016 02/05/2016	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 12/21-25/15
2016-178	01/07/2016 02/05/2016	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 12/7-11/15
2016-179	01/08/2016	FDA/OC/OES/DFOI/	DEBI COHEN	CKISED FIUA REQUESTS 12/14-18/15

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	02/08/2016		WOLTERS KLUWER LAW & BUSINESS	
2016-180	01/08/2016 02/08/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 12/7-11/15
2016-181	01/08/2016 02/08/2016	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 12/14-18/15
2016-182	01/08/2016 02/08/2016	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 12/7-11/15
2016-183	01/08/2016 02/08/2016	FDA/OC/OES/DFOI/	WILLIAM A OLSON Center for Regulator Services, Inc	FOI DAILY LOG 12/14-18/15
2016-184	01/08/2016 02/08/2016	FDA/OC/OES/DFOI/	WILLIAM A OLSON Center for Regulator Services, Inc	FOI DAILY LOG 12/7-11/15
2016-185	01/08/2016 02/08/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 12/14-18/15
2016-186	01/08/2016 02/08/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 12/7-11/15
2016-187	01/08/2016 02/08/2016	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 12/14-18/15
2016-188	01/08/2016 02/08/2016	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 12/7-11/15
2016-189	01/08/2016 02/08/2016	FDA/OC/OES/DFOI/	LESLIE RAMSEY FDA NEWS	FOI DAILY LOG 12/14-18/15
2016-190	01/08/2016 02/08/2016	FDA/OC/OES/DFOI/	LESLIE RAMSEY FDA NEWS	FOI DAILY LOG 12/7-11/15
2016-191	01/08/2016 02/08/2016	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 12-21-15/15
2016-192	01/08/2016 02/08/2016	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 12-14-18/15
2016-193	01/08/2016 02/08/2016	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 12/7-11/15
2016-194	01/08/2016	FDA/OMPT/CDRH/OCE/DID/	BRENDA LIGORSKY	BIS MONITOR - MDRS

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	02/08/2016		CARROLL KELLY ET AL	
2016-195	01/08/2016 02/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDRH/OCE/DID/	STEPHAN D BLANDIN Romanucci & Blandin	HARVARD APPARATUS REGENERATIVE TECHNOLOGY INC - IND, APRVL LTRS, SUBMISSIONS
2016-196	01/08/2016 02/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID J NORTHRUP NORTHRUP V13733, DAVID J	PROZAC, ZOLOFT - LBLG, APRVL DATE; LSIT OF PUBERTY BLOCKERS
2016-197	01/08/2016 02/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GUILLAUME BUELL LABATON SUCHAROW	BIOGEN INC - TECFIDERA (DIMETHYL FUMARATE) ALERT, COMM, SAFETY LBLG CHANGE 4/14 TO 12/14, 3/13, ETC
2016-198	01/08/2016 02/08/2016	FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/ FDA/OMPT/CDRH/OCE/DID/	CHRISTOPHER SZECHENYI ON POINT INVESTIGATIONS	CONFORMIS, WILMINGTON, MA - INSPS, CTRS, REGISTRATION PAPER, COMM 2014, 2015
2016-199	01/08/2016 02/08/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	BRANDON MENARD MENARD C2-211, BRANDON	GUIDELINE FOR COLLECTION OF BLOOD OR BLOOD PRODS FROM DONORS WITH POSITIVE TESTS FOR INFECTIOUS DISEASE MARKERS (HIGH RISK DONORS) 1989; WORKSHOP ON BEHAVIOR-BASED DONOR DEFERRAL IN TH NAT ERA 2006, ETC
2016-200	01/08/2016 02/08/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Michael Mee Flagship VentureLabs	OVASCIENCE - UNTITLED LETTER SEPTEMBER 2013
2016-201	01/08/2016 02/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Andrews Thornton- Sean Thomas Higgins Andrews & Thornton	BRAVELLE - AERS
2016-202	01/08/2016 02/08/2016	FDA/OMPT/CDRH/OCE/DID/	Patty Veazey Patty Veazey	LATEST FDA MEDICAL DEVICE TRACKING GUIDANCE FOR INDUSTRY AND FDA; TRACKING ORDER FOR INTERIOR VENA CAVA FILTER MEDICAL DEVICES
2016-203	01/08/2016 02/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	janice m anderson md forbes family medicine	BUPRENORPHINE - AERS

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-204	01/08/2016 02/08/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Michael Mee Flagship VentureLabs	OVASCIENCE, INC - COMMUNICATIONS WITH FDA 08/01/2013 - 01/06/2016
2016-205	01/08/2016 02/08/2016	FDA/OFVM/CFSAN/OCD/EOS/	Sanjay Karnik Amin Talati & Upadhye, LLC	NONPRESCRIPTION DIETARY SUPPLEMENTS BY BPI SPORTS, LLC - AERS 01/01/2006 - 12/31/2015
2016-206	01/08/2016 02/08/2016	FDA/OMPT/OSMP/OOPD/	Charles Snow Hyman, Phelps & McNamara P.C.	RAVICTI - ORPHAN DRUG DESIGNATION RECS
2016-207	01/08/2016 02/08/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Janine Tschupp FALCON RESEARCH	ACTHAR CASE REPORTS 11235973 11244367 11245232 ETC
2016-208	01/08/2016 02/08/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Janine Tschupp FALCON RESEARCH	ACTHAR - FAERS SUMMARY REPORT
2016-209	01/08/2016 02/08/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Janine Tschupp FALCON RESEARCH	CASE REPORTS 1080202411129487 10970454ETC
2016-210	01/08/2016 02/08/2016	FDA/OC/OES/DFOI/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Tick-Borne Disease Legal Project Tick-borne Disease Legal Project/Lynn Shepler MD	SmithKline Beecham human Lyme Vaccine recs
2016-211	01/08/2016 02/08/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	BLA 125057 S 394
2016-212	01/08/2016 02/08/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	EPOETIN ALFA - FAERS
2016-213	01/08/2016 02/08/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kris Christian FDAZILLA	QILU TIAHNE PHARMACEUTICAL CO LTD - 483, EIR, RESPONSE 05/26/2015 - 06/02/2015

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-214	01/08/2016 02/08/2016	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Billy Peard PEARD, BILLY	CHANG FARM, CHANG & SONS ENTERPRISES, INC, WHATELY, MA - FOOD SAFETY INVESTIGATIONS, CORR 01/02/2007 - 05/01/2012
2016-215	01/08/2016 02/08/2016	FDA/OMPT/CDRH/OCE/DID/	Doris Walter Instrumentation Industries, Inc.	K140919
2016-216	01/08/2016 02/08/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jeffrey Lazar Jeffrey Lazar	EXPAREL PHARM/TOX REVIEW
2016-217	01/08/2016 02/08/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jeffrey Lazar Jeffrey Lazar	EXPAREL - PHARM/TOX REVIEW
2016-218	01/08/2016 02/08/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ayesha Adil The Weinberg Group	ANDA 090218
2016-219	01/08/2016 02/08/2016	FDA/OMPT/CTP/OD/	Desmond Jenson Tobacco Control Legal Consortium	All records and communications associated with Potential Tobacco Violation Report ID 15D00013
2016-220	01/08/2016 02/08/2016	FDA/OC/OES/	Steven Hentges AMERICAN CHEMISTRY COUNCIL	Written communications from the FDA Office of the Chief Scientist to the California Office of Environmental Health Hazard Assessment (OEHHA) related to chemicals and Proposition 65 01/01/2015 - 12/31/2015
2016-221	01/08/2016 02/08/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Fred Defesche REGCON Solutions LLC	NDA 018101 SBA
2016-222	01/08/2016 03/16/2016	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Kris Christian FDAZILLA	SUN PHARMACEUTICAL INDUSTRIES, INC - 483, EIR, RESPONSE 06/01/2015 - 07/15/2015
2016-223	01/08/2016 02/08/2016	FDA/OFVM/CFSAN/OCD/EOS/	Megan Favignano Columbia Tribune	REFLUX SOLUTIONS, MARCI-KIDS, INFANT REFLUX SOLUTIONS ETC - AERS, VIOLATION RECS 12/01/2011 - 01/07/2016

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2016-224	01/08/2016 02/08/2016	FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/	Holly Meade Holly Meade	PHARMA MEDICA RESEARCH, SAINT CHARLES, MO - 483 09/21/2015 - 09/25/2015
2016-225	01/08/2016 02/08/2016	FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/	Paul Knoepfler Paul Knoepfler/UC Davis School of Medicine	IRVINE STEM CELL TREATMENT CENTER - 483 01/02/2015 - 01/01/2016
2016-226	01/08/2016 02/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mohammed Yousffi Fresenius Kabi USA, LLC	CIPLA, LTD - EIR, 483 02/02/2015 - 01/07/2016
2016-227	01/11/2016 02/09/2016	FDA/OGROP/ORR/SW-FO/DEN-DO/DEN-CB/	Mark Kohl Ophthotech	AGILENT, BOULDER, CO - EIR 01/01/2015 - 01/07/2016
2016-228	01/11/2016 02/09/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bharat Celly Research Delta Advisors	SUN PHARMA, HALOL, INDIA - 483 05/01/2015 - 06/30/2015
2016-229	01/11/2016 02/09/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Woodward Heather The Medical Center of Aurora	DOFETILIDE - AERS
2016-230	01/11/2016 02/09/2016	FDA/OC/OES/DDM/ FDA/OFVM/CFSAN/OCD/EOS/	Laura McWilliams EXPONENT	FAP, CORR FROM DEAN FOODS, WHITE WAVE FOODS, FAP 3A4801, FDA-2013-N-0888
2016-231	01/11/2016 02/09/2016	FDA/OMPT/CDRH/OCE/DID/	David Holmes David Holmes	K151025
2016-232	01/11/2016 02/09/2016	FDA/OFVM/CFSAN/OCD/EOS/	Judy Negley The Valspar Corporation	FCN 1213
2016-233	01/11/2016 02/09/2016	FDA/OMPT/CDRH/OCE/DID/ FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCE/DID/ FDA/OC/OES/DFOI/	Michael Gusel Topcon Medical Systems, Inc.	K113066 K143086
2016-234	01/11/2016 03/11/2016	FDA/OGROP/ORR/PA-FO/SAN-DO/SAN-CB/	Kris Christian FDAZILLA	GENETECH, INC, SOUTH SAN FRANCISCO, CA - 483, EIR, RESPONSE 02/04/2014 - 02/21/2014
2016-235	01/11/2016 02/09/2016	FDA/OFVM/CFSAN/OCD/EOS/	Judy Negley The Valspar Corporation	FCN 1212

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2016-236	01/11/2016 02/09/2016	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Kris Christian FDAZILLA	MYLAN PHARMACEUTICALS INC, MORGANTOWN, WV - 483, EIR, RESPONSE 04/13/2015 - 04/24/2015
2016-237	01/11/2016 02/09/2016	FDA/OO/OHR/	Michal Leah Kanovsky Michal Leah Kanovsky	VINCENT TOLINO, STEPHANIE COLLINS - SF-50S 01/06/2006 - 01/07/2016
2016-238	01/11/2016 02/09/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kris Christian FDAZILLA	PFIZER MANUFACTURING BELGIUM NV - 483, EIR, RESPONSE 06/22/2015 - 06/30/2015
2016-239	01/11/2016 02/09/2016	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Kris Christian FDAZILLA	GENENTECH INC, OCEANSIDE, CA - 483, EIR, RESPONSE 05/11/2015 - 05/21/2015
2016-240	01/11/2016 02/09/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Anurag patel Dr. Reddy's Laboratories Inc.	NDA 022185 SBA
2016-241	01/11/2016 02/09/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Katherine Kaempchen Forward Pharma Gmbh- Katherine Kaempchen	FUMARIC ACID ESTERS - AERS
2016-242	01/11/2016 02/09/2016	FDA/OMPT/CDRH/OCE/DID/	Kris Christian FDAZILLA	BATRIK MEDICAL MFG INC, CANADA - 483, EIR, RESPONSE 07/13/2015 - 07/16/2015
2016-243	01/11/2016 02/09/2016	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	TOBACCO PRODUCT AERS NOV-DEC 2015
2016-244	01/11/2016 02/09/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kris Christian FDAZILLA	FARMABIOS, SPA, ITALY - 483, EIR, RESPONSE 10/19/2015 - 10/23/2015
2016-245	01/11/2016 03/01/2016	FDA/OFVM/CFSAN/OCD/EOS/	Maureen E. Kozuch The Dow Chemical Company	FCN 955
2016-246	01/11/2016 02/09/2016	FDA/OMPT/CDRH/OCE/DID/	Brandon Walker Innovasis	K103369 K081395 K082252 ASTM TEST REPORTS

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2016-247	01/11/2016 02/09/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Becky Hartman Teva Pharmaceuticals	SYNRIBO - AERS
2016-248	01/11/2016 02/09/2016	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	CTP REVIEWER GUIDE SUBSTANTIAL EQUIVALENCE REPORTS
2016-249	01/11/2016 02/09/2016	FDA/OO/OHR/	Thomas V. Montgomery, III Thomas V. Montgomery, III, Ed.D.	HHS-FDA-CDER-MP-15-1465961
2016-250	01/11/2016 02/09/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Barbra King Barbra King	LISINOPRIL - AERS
2016-251	01/11/2016 02/09/2016	FDA/OFVM/CFSAN/OCD/EOS/	Matt Timberlake Timberlake Ventures, Inc.	PRIORITY BASED ASSESSMENT OF FOOD ADDITIVES DATABASE
2016-252	01/11/2016 02/09/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Becky Hartman Teva Pharmaceuticals	PRO-AIR RESPI CLICK ALBUTEROL SULFATE INHALATION POWDER - AERS
2016-253	01/11/2016 02/09/2016	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	Monica King Halyard Health	HALYARD, LINWOOD, NC - EIR 06/01/2013 - 06/30/2013
2016-254	01/11/2016 02/09/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Becky Hartman Teva Pharmaceuticals	QUARTETTE - AERS
2016-255	01/11/2016 02/09/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Becky Hartman Teva Pharmaceuticals	ADASUVE - AERS
2016-256	01/11/2016 02/09/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Becky Hartman Teva Pharmaceuticals	ZECUITY - AERS
2016-257	01/11/2016	FDA/OFVM/CFSAN/OCD/EOS/		FAP 4M4428

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	02/29/2016		BENJAMIN L ENGLAND & ASSOCIATES LLC	
2016-258	01/11/2016 02/09/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	AIRIS PHARMA PVT LTD	ALEMBIC PHARMACEUTICALS LTD, GUJARAT, INDIA - EIR
2016-259	01/11/2016 02/09/2016	FDA/OC/OES/DFOI/	JACKSON 303-792, WILLIAM	RESOURCES FOR EX FELONS
2016-260	01/11/2016 02/09/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MELISSA L. ENGLISH SMITH GILDEA ET AL	NIEHS NDAs MADE IN 1992 FOR SUCCIMER USE
2016-261	01/11/2016 02/09/2016	OC/CVM/OCD/ FDA/OFVM/CFSAN/OCD/EOS/	SEAN HIGGINS, Esq. Andrews & Thornton	OXY EILTE PRO SUPER THERMO - INVESTIGATIONS, RPTS
2016-262	01/11/2016 02/09/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DANIEL WOLFE OPEN SOCIETY FOUNDATIONS	VIVITROL - AERS
2016-263	01/12/2016 02/10/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joshua Cain Esq. Appalachian Law PLLC	DEPAKOE, DIVALPROEX SODIUM - AERS
2016-264	01/12/2016 02/10/2016	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	Paul Knoepfler Paul Knoepfler UC Davis	STEMEDICA - INSPECTIONS, CORR, ETC 01/04/2013 - 01/08/2016
2016-265	01/12/2016 02/10/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Scott Hodes Scott A. Hodes, Attorney at Law	OSIRIS AGREEMENT RE GRAFIX 10/01/2013 - 11/01/2013
2016-266	01/12/2016 02/10/2016	FDA/OC/OES/DFOI/ FDA/OGROP/ORAP/NE-FO/NWE-DO/NWE-CB/	Evan Anderson Evan Anderson	JUDGE ROTENBERG EDUCATIONAL CENTER, CANTON, MA - WARNING LETTER, CORR ETC
2016-267	01/12/2016 02/10/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OC/OCC/	Rachel Johnson FOI Services, Inc.	ORGANOGENESIS, ARENT FOX - RECS RE MEETING WITH FDA 11/6/2015
2016-268	01/12/2016 02/10/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Janine Tschupp FALCON RESEARCH	ISR 115018012 113834861 109626151

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2016-269	01/12/2016 03/02/2016	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Scott A. Hodes Scott A. Hodes, Attorney at Law	MIMEDX - CORR WITH FDA, WARNING LETTERS, 483 10/01/2013 - 01/08/2016
2016-270	01/12/2016 02/10/2016	FDA/OC/OES/DFOI/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Theresa Fiorito, MD Hasbro Children's Hospital/Warren Alpert Medical School of Brown University	TRUMEMBA AERS
2016-271	01/12/2016 02/10/2016	FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Paul Knoepfler Paul Knoepfler/ UC Davis	CELLTEX - INSPECTION RECS, CORR 01/03/2014 - 01/08/2016
2016-272	01/12/2016 02/16/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Ben Heikali Faruqi & Faruqi, LLP	LIONS EYE INSTITUTE, AVALANCHE BIOTECHNOLOGIES, INC - STUDY RECS
2016-273	01/12/2016 02/10/2016	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	LIST OF COMPLIANCE CHECK INSPECTION VIOLATIONS FOR TOBACCO PRODUCT RETAILERS
2016-274	01/12/2016 02/10/2016	FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/	Paul Knoepfler Paul Knoepfler UC Davis	STEMGENEX, LA JOLLA, CA - INSPECTION RECS, CORR 01/03/2014 - 01/08/2016
2016-275	01/12/2016 02/10/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Srikant Dash Srikant Dash	INFLIXIMAB, ADALIMUMAB, ETC - AERS
2016-276	01/12/2016 02/10/2016	FDA/OPPLA/OL/	Sheila Kaplan STAT (Boston Globe Media)	CORR BETWEEN SENATORS OF HELP COMMITTEE AND DR ROBERT CALIFF RE NOMINATION 11/17/2015 - 12/30/2015
2016-277	01/12/2016 02/10/2016	FDA/OGROP/ORR/SE-FO/NOL-DO/NOL-CB/	Joe Kihm Joe Kihm	RECS RE FDA WARNING LETTER TO DEWMAR INTERNATIONAL BRAND MANAGEMENT 03/01/2013 - 01/10/2016
2016-278	01/12/2016 02/10/2016	FDA/OMPT/CDRH/OCE/DID/	Neel Tanna Neel Tanna	SORIN, CYBERONICS, LIVANOVA - INSPECTION RECS, WARNING LETTERS, CORR RE PERCEVAL APPROVALS 01/01/2014 - 01/08/2016
2016-279	01/12/2016	FDA/OMPT/CDER/ORP/DIDP/	Jane Talkington	BOTOX CASE REPORT 6263865

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	02/10/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	OKLAHOMA STATE UNIVERSITY	
2016-280	01/12/2016 02/10/2016	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Paul Knoepfler Paul Knoepfler/ UC Davis	CELL SURGICAL NETWORK, MARK BERMAN, ELLIOT LANDER - CORR WITH STEM CELL CLINICS 01/02/2014 - 01/09/2016
2016-281	01/12/2016 02/10/2016	FDA/OMPT/CDRH/OCE/DID/	Carol Vierling C L VIERLING, LLC	K092227
2016-282	01/12/2016 02/10/2016	FDA/OMPT/CDRH/OCE/DID/ FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCE/DID/ FDA/OC/OES/DFOI/	Sandeep Samudre Eastern Virginia Eye Institute	K090626, K121579
2016-283	01/12/2016 02/10/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tanya Akimova Saptalis Pharmaceuticals LLC	NDA 017426 SBA, NDA 017010 SBA, ANDA 063305 SBA
2016-284	01/12/2016 02/10/2016	FDA/OGROP/ORA/CE-FO/CIN- DO/CIN-CB/	Steve Rogers Zoetis Inc.	RICERCA, CONCORD, OH - 483, 482, EIR 06/01/2010 - 01/11/2016
2016-285	01/12/2016 02/10/2016	FDA/OGROP/ORA/SW-FO/DEN- DO/DEN-CB/	Steve Rogers Zoetis Inc.	MICROBIAL RESEARCH INC, FORT COLLINS, CO - 482, 483, EIR 01/01/2013 - 01/11/2016
2016-286	01/12/2016 02/10/2016	FDA/OMPT/CDRH/OCE/DID/	ERIC THORN NAT'L ASSOC OF DENTAL LABS	DENTAL DVCS - IMPORTER ESTABISHMENT REGISTRATION & DVC LISTING
2016-287	01/12/2016 02/10/2016	FDA/OMPT/CDRH/OCE/DID/	THOMAS WM ARBON BEN C MARTIN LAW OFC	CR BARD INC, BARD PERIPHERAL VASCULAR INC OR IMPRA - RECOVERY FILTER SYS K022236, K031328, CORR, TESTING, ETC
2016-288	01/12/2016 02/10/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/ORA/ OC/ORA/	WU SHENG TIANJIN TIANYAO PHARMACEUTICALS CO LTD	HYDROGEN CYANIDES - 523-1096587-4, 523-1096603-2 TEST METHODOLOGY, INSTRUMENTATION, ACTUAL LEVELS, ETC
2016-289	01/12/2016 02/10/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	AUDREY ALIBRANTI EGAN ETHYPHARM USA CORP	BUPRENOPHINE HCL INJ 0.3 ANDA 206-586 - CMC RVW

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2016-290	01/12/2016 02/10/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PAUL KARCH PHENOMENEX	DRUG ESTABLISHMENTS REGISTERED COMPANY 2015
2016-291	01/12/2016 02/10/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BENJAMIN L ENGLAND BENJAMIN L ENGLAND & ASSOCIATES LLC	API/BULK INGREDIENT DRUG LISTING SUBMITTED BY BOTH DOMESTIC & FOREIGN ESTABLISHMENTS 1/11 TO PRESENT
2016-292	01/12/2016 02/10/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ROBERTTO C RIVERA RIVERA #AS-2743, ROBERTO C	RISPERDAL - AERS
2016-293	01/12/2016 02/10/2016	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	DAVID ANDERSON WARD ANDERSON PORRITT & BILA	SHUR-GREEN FARMS - SALE OF LASCADOIL TO CERTAIN ANIMAL FEED OUTLETS EIRS 10/314-11/19/14
2016-294	01/12/2016 02/10/2016	FDA/OFVM/CFSAN/OCD/EOS/	DIANNE L CHAMBERS Hogan Lovells, ILP	HAMPTON CREEK FOODS INC - RESP TO WARNING LTR 8/12/15
2016-295	01/12/2016 02/10/2016	FDA/OFVM/CFSAN/OCD/EOS/	ROBERT ALTKORN INTERTEK	SOLVAY SPECIALTY POLYMERS USA LLC - FCN 83
2016-296	01/12/2016 02/10/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	DENISE RIEKER SANOFI PASTEUR	SANOFI PASTEUR LTD, TORONTO, CANADA - 483S 7/21/15-8/10/15
2016-297	01/12/2016 02/10/2016	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LISA BARTLEY EYEWITNESS NEWS INVESTIGATIVE PROUCESR	MIRACLE MINERAL SOL OR MMS -CARES 4/23/15 TO PRESENT
2016-298	01/12/2016 02/10/2016	OC/ORACE/ORM/ OC/ORACE/ORM/	LESLIE RAMSEY FDA NEWS	PHARMACEUSTICAL, BIOLOGICS, MEDICAL DVC MFG, CLNCL TRIAL FACILITIES IN & OUSIDE THE US - 483S 12/1-31/15
2016-299	01/12/2016 05/02/2016	FDA/OFVM/CFSAN/OCD/EOS/	CHRISTINE BOUCHERON UNILEVER	LITHOL RUBINE B (D&C 7 CA LAKE) CI 15850:1; LITHOL RUBINE BN (D&C RED 6) CI 15850; BORDAUX RED B (D&C RED 34 LAKE) CI 15880, ETC - SAFETY RECS

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2016-300	01/12/2016 02/10/2016	FDA/OMPT/CDRH/OCE/DID/	Logan Greenberg Unglesby & Williams, LLC	ESSURE - AERS
2016-301	01/12/2016 02/10/2016	FDA/OMPT/CDRH/OCE/DID/	Nahbee Jong TheraNova LLC	K150386
2016-302	01/12/2016 02/10/2016	FDA/OMPT/CDRH/OCE/DID/	Gary W Enos Codonics Incorporated	CPT1500299
2016-303	01/12/2016 02/10/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-335
2016-304	01/12/2016 02/10/2016	FDA/OMPT/CDRH/OCE/DID/	Nola Benstog Health Line International Organization	K970644 K97066 UNREDACTED
2016-305	01/12/2016 02/10/2016	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/	ANNA MARIE PALMER-HARPER MILLER MILLING COMPANY LLC	SAMPLE RESULTS
2016-306	01/12/2016 02/10/2016	FDA/OGROP/ORO/NE-FO/NYK- DO/NYK-DCB/	Rachel Johnson FOI Services, Inc.	REPRO-MED/RMS MEDICAL, CHESTER, NY - EIR, 483
2016-307	01/12/2016 02/10/2016	FDA/OGROP/ORO/CE-FO/PHI- DO/PHI-CB/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	BIOSPECTRA, INC, BANGOR, PA - 483, EIR, CORR
2016-308	01/12/2016 02/10/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mike Koehler Mike Koehler	PEG 3350, POLYETHYLENE GLYCOL 3350, MIRALAX ETC - AERS
2016-309	01/12/2016 02/10/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Doe J	INDIVIDUAL RECS
2016-310	01/12/2016 02/10/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Priyasha Uppal Priyasha Uppal	DPP4 INHIBITORS - AERS
2016-311	01/13/2016 02/11/2016	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/CHI- DO/CHI-CB/	Doe J	INDIVIDUAL RECS
2016-312	01/13/2016	FDA/OMPT/CDRH/OCE/DID/	Dana Hayes on behalf of Douglas	K070090, K121795, CYTOPHIL IDE

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	02/11/2016		Lineberry, Esq. McNair Law Firm, P.A.	
2016-313	01/13/2016 02/11/2016	FDA/OGROP/ORPA/FO/LOS-DO/LOS-CB/ FDA/OGROP/ORPA/FO/SAN-DO/SAN-CB/	Kimi Best Kimi Best	SPROUTS MARKET, AVONDALE, AZ - WALNUT RECS 10/19/2015 - 01/11/2016
2016-314	01/13/2016 02/11/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Soby Fennell Renaissance Pharma, Inc.	ANDA 071961 SBA
2016-315	01/13/2016 02/11/2016	FDA/OMPT/CDRH/OCE/DID/	M. Kohlrutz European Pharma Group BV	K962956
2016-316	01/13/2016 02/11/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	David M. Petrick David Petrick	STUDY NUMBER 0110058 TO SUPPORT NDA 50791; STUDY NUMBER 21951 TO SUPPORT NDA 50791
2016-317	01/13/2016 02/11/2016	FDA/OGROP/ORASW/FO/KAN-DO/KAN-CB/ FDA/OGROP/ORACE/FO/NWJ-DO/NWJ-CB/	Ryan Woods PRA Health Sciences	PRA INTERNATIONAL EARLY DEVELOPMENT SERVICES, LENEXA, KS - EIR 03/01/2012 - 03/08/2012
2016-318	01/13/2016 02/11/2016	FDA/OGROP/ORACE/FO/NWJ-DO/NWJ-CB/	Ryan Woods PRA Health Sciences	CRI WORLDWIDE, CLEMENTON, NJ - EIR 07/07/2008 - 01/26/2009
2016-319	01/13/2016 02/11/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Vadim Kutsar Vadim Kutsar	NARROW THERAPEUTIC INDEX DRUG INDEX
2016-320	01/13/2016 02/11/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michael DeMeuse Michael DeMeuse	NDA 208019 SBA
2016-321	01/13/2016 02/11/2016	FDA/OGROP/ORASW/FO/DEN-DO/DEN-CB/	Steve Rogers Zoetis Inc.	COLORADO QUALITY RESEARCH, WELLINGTON, CO - 483, 482, EIR ETC 05/01/2013 - 01/11/2016
2016-322	01/13/2016 02/11/2016	FDA/OGROP/ORANE/FO/NYK-DO/NYK-DCB/ FDA/OMPT/CDRH/OCE/DID/	Elizabeth Luoma DuVal & Associates, P.A.	REPRO-MED/RMS MEDICAL COMPLAINT FOLLOW UP, INSPECTION RECS 06/01/015 - 01/11/2016

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2016-323	01/13/2016 02/11/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ed Pardon MERCHANT & GOULD	Form 3542 or Form 3542a submitted to the FDA by any NDA holder for NDA 201280 (linagliptin 5 mg tablets) in connection with US Patent No. 9,173,859 (CERTIFIED)
2016-324	01/13/2016 02/11/2016	FDA/OGROP/ORR/SE-FO/SJN-DO/SJN-CB/	JUDITH BERKAN BERKAN MENDEZ LAW OFC	CMPLNT 135146; MONSANTO CARIBE LLC, ISABELA, PR - INVESTIGATIONS, COMPLIANCE RPTS, RESEARCH, ETC 12/09 TO PRESENT; MON 54133, MON 54134
2016-325	01/13/2016 02/11/2016	FDA/OGROP/ORR/CE-FO/PHI-DO/PHI-CB/	MEGAN C LAMBERT K&L Gates LLP	CUSTOM ULTRASONICS - EIRS, 483S, WARNING LTRS, ETC 1/05 TO PRESENT
2016-326	01/13/2016 02/11/2016	FDA/OGROP/ORR/CE-FO/PHI-DO/PHI-CB/	THOMAS A LEONARD COZEN O'CONNOR	SUNOPTA GLOBAL ORGANIC INGREDIENTS INC, ALLENTOWN, PA - EIRS, CORR, ANALYSES, ETC 1/12 TO 1/15
2016-327	01/13/2016 02/11/2016	FDA/OGROP/ORR/SW-FO/DEN-DO/DEN-CB/	KEN REID WASHINGTON INFORMATION SOURCE	TERUMO, LAKEWOOD, CO - 483 RESPS 6/10/124-7/9/14
2016-328	01/13/2016 02/11/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ROMAN ROIK RUBRIC CAPITAL MANAGEMENT LLC	IRONWOOD PHARMACEUTICALS INC, ALLERGAN PLC - LINZESS (LINACLOTIDE); SUCAMPO PHARMACEUTICALS INC, TAKEDA PHARMACEUTICAL CO LTD - AMITIZA (LUBIPROSTONE) AERS
2016-329	01/13/2016 02/11/2016	OC/CVM/OCD/	Vickie Ramirez UNIVERSITY OF WASHINGTON	NARMS SAMPLING DATA FROM SLAUGHTERHOUSES, HARVEST FACILITIES AND LIVE ANIMALS IN WASHINGTON STATE 01/01/2009 - 12/31/2013
2016-330	01/13/2016 02/11/2016	OC/ORR/ORM/ OC/ORR/ORM/	Kris Christian FDAZILLA	LIST OF INSPECTION CITATIONS 01/11/2015 - 01/11/2016
2016-331	01/13/2016 02/24/2016	FDA/OC/OES/DFOI/	Kris Christian FDAZILLA	RELEASED 483, 483 RESPONSES, EIR SINCE 12/10/2015
2016-332	01/13/2016 02/11/2016	OC/ORR/ORM/ OC/ORR/ORM/	Eyal Maor FDAAWARE	LIST OF INSPECTIONS
2016-333	01/13/2016 02/11/2016	FDA/OMPT/CDRH/OCE/DID/	Patsy J trisler Patsy J Trisler	P900033 (Integra Wound Dressing) - Original PMA SSED
2016-334	01/13/2016 02/11/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Paola Teegarden Kinex Pharmaceuticals Inc.	NDA 020239 SUPPLEMENTS
2016-335	01/13/2016	FDA/OMPT/CDER/ORP/DIDP/	Paola Teegarden	NDA 019698 NDA 019645 SUPPLEMENTS

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	02/11/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kinex Pharmaceuticals Inc.	
2016-336	01/13/2016 02/11/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	REPORT FROM BOSTON SCIENTIFIC RE OPTIM
2016-337	01/13/2016 02/11/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Meera G Kumar SANOFI	PRALUENT - AERS
2016-338	01/13/2016 02/11/2016	FDA/OGROP/ORANE-FO/NYK- DO/NYK-DCB/	Steven Moser Steven Moser	NATURE'S VALUE, INC, CORAM, NY - INSPECTION RECS 11/01/2001 - 01/12/2016
2016-339	01/13/2016 02/11/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Patrick Kelly Conway, Homer & Chin-Caplan, PC	VAERS RECS
2016-340	01/13/2016 02/11/2016	OC/ORO/ OC/ORO/ FDA/OFVM/CFSAN/OCD/EOS/	Tom Bellamore California Avocado Commission	RECS RE MICROBIOLOGICAL SURVEILLANCE SAMPLING ACTIVITIES ON AVACADOS, SAMPLING ASSIGNMENTS 01/01/2014 - 01/31/2016
2016-341	01/13/2016 02/11/2016	FDA/OC/OES/DDM/ FDA/OFVM/CFSAN/OCD/EOS/	Daniel Fabricant NATURAL PRODUCTS ASSOCIATION	FAP 7M4768; SUPPORTING STUDIES FOR DETERMINATION TO ACCEPT CARBON DIOXIDE AS SAFE TO USE FOR LASER ETCHING FOR CITRUS FRUIT
2016-342	01/13/2016 02/11/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Patrick Kelly Conway, Homer & Chin-Caplan, PC	VAERS RECS
2016-343	01/13/2016 02/11/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Granules India Spark Capital Advisors (I) Private Limited	GRANULES, INDIA - 483 10/01/2015 - 12/03/2015
2016-344	01/14/2016 02/12/2016	FDA/OO/OFBA/OAGS/	Mohammad Elias RELI Group Inc.	SPREADSHEET OF 8A CONTRACTS 10/02/2014 - 01/12/2016
2016-345	01/14/2016 02/12/2016	FDA/OFVM/CFSAN/OCD/EOS/	P.J. Huffstutter Reuters News	LIST OF FOOD-BORNE ILLNESS CLUSTERS RELATED TO CHIPOTLE MEXICAN GRILL 2008 TO 2015
2016-346	01/14/2016 05/03/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	JOHN CHAPMAN, Ph.D. Stem Cell Partners LLC	GPS III MINI PLATELET CONCENTRATE SEPARATION KIT W/ACD-A BK070026
2016-347	01/14/2016	FDA/OGROP/ORAPA-FO/LOS-	Raul Arevalo	ONE LAMBDA, INC, CANOGA PARK, CA - EIR 09/01/2014 -

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	02/12/2016	DO/LOS-CB/	One Lambda Inc.	10/31/2014
2016-348	01/14/2016 02/12/2016	FDA/OGROP/ORR/SE-FO/NOL-DO/NOL-CB/	Katherine Eban FORTUNE MAGAZINE	K&K SEAFOOD, LOREAUVILLE, LA - EIR 01/01/2000 - 12/31/2000
2016-349	01/14/2016 02/12/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	ANI BYRNE Jamieson Laboratories	JAMIESON - FORM 3500 VOLUNTARY REPORTING 10/2015 TO 12/31/2015
2016-350	01/14/2016 02/12/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Brittany Freeman KMGH-TV	MIRENA, SKYLA, LILETTA - AERS
2016-351	01/14/2016 02/12/2016	FDA/OC/OES/DDM/	Jaime Vassallo LEXIS NEXIS COURTLINK INC	FDA Docket 2013-P-0048 CERTIFIED
2016-352	01/14/2016 02/12/2016	FDA/OC/OES/DFOI/	PATRICIA L. REGENYE Celgene Corporation	RICHARD FINN, UCLA JONSSON COMPREHENSIVE CTR, LOS ANGELES, CA - 483 9/19 TO 1/16
2016-353	01/14/2016 02/12/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Azza AbuDagga PUBLIC CITIZEN	BOTOX, MYOBLOC - MEDWATCH REPORTS
2016-354	01/14/2016 02/12/2016	FDA/OGROP/ORR/SE-FO/NOL-DO/NOL-CB/	Katherine Eban FORTUNE MAGAZINE	SHERMAN PHARMACEUTICALS, ABITA SPRINGS, LA - EIR, 483 01/01/1990 - 12/31/2000
2016-355	01/14/2016 02/12/2016	FDA/OFVM/CFSAN/OCD/EOS/	Madhu Soni, Ph.D. SONI & ASSOCIATES INC	RICE HULL FIBER - MEMOS, CORR, ETC 01/01/2013 - 01/12/2016
2016-356	01/14/2016 02/12/2016	FDA/OC/OES/DFOI/	PATRICIA L. REGENYE Celgene Corporation	RICHARD LARSON, UNIV CHICAGO MEDICAL CTR, CHICAGO, IL - 483 8/14 TO 1/16
2016-357	01/14/2016 02/12/2016	FDA/OC/OES/DFOI/	PATRICIA L. REGENYE Celgene Corporation	RUBEN MESA, SCOTTSDALE, AZ - 483 1/15 TO 1/16
2016-358	01/14/2016 02/12/2016	FDA/OMPT/CTP/OD/ OC/ORR/ OC/ORR/	Rachel Johnson FOI Services, Inc.	TOBACCO PRODUCT CUSTOMER COMPLAINTS LISTED IN FDA FACTS 9/14 TO 12/15
2016-359	01/14/2016 02/12/2016	OC/ORR/ OC/ORR/	Doe J	INDIVIDUAL RECS

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		FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/		
2016-360	01/14/2016 02/12/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	BLA 103951
2016-361	01/14/2016 02/12/2016	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Doe J	ALFALFA HAY INVESTIGATION RECS
2016-362	01/14/2016 02/12/2016	FDA/OPPLA/OL/	Scott Powers FloridaPolitics.com	LETTER FROM US REP ALAN GRAYSON TO FDA RE NARCAN 01/01/2015 - 12/01/2015
2016-363	01/14/2016 02/12/2016	FDA/OMPT/CDRH/OCE/DID/	Sandra Aprahamian MEDTRONIC MINIMED	K112370 K120314 K141273
2016-364	01/14/2016 02/12/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	INH (isoniazid) John L Davis	INH - AERS
2016-365	01/14/2016 02/12/2016	FDA/OMPT/CDRH/OCE/DID/	Sheila Walcoff Goldbug Strategies LLC	K150154
2016-366	01/14/2016 02/12/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Chris Thomas Carilion Health Care	LIST OF INACTIVE NDC NUMBERS 01/01/2015 - 01/01/2016
2016-367	01/14/2016 02/12/2016	FDA/OC/OES/DFOI/	Stefan Ellis PEPPER HAMILTON LLP	2015-769 CERTIFIED
2016-368	01/14/2016 02/12/2016		THOMAS R. RASK, III KELL ALTERMAN ET AL	MEDOLAC LABORATORIES - RECS
2016-369	01/14/2016 02/12/2016	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	TOBACCO RELATED PRODUCT AERS REPORTED TO CTP, FDA SAFETY REPORTING PORTAL, MEDWATCH PROGRAM, AERS SYSTEM 10/6/13 TO 2/28/14
2016-370	01/14/2016 02/12/2016	FDA/OMPT/CDRH/OCE/DID/	JING GU W.H.P.M., Inc.	K060463
2016-371	01/14/2016 02/12/2016	OC/ORO/ORM/ OC/ORO/ORM/	Tate Borcoman Tate Borcoman / Integrated Solutions	LIST OF INSPECTIONS 03/01/2015 - 01/13/2016

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2016-372	01/14/2016 02/12/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jaya Ayyagari Dr. Reddy's Laboratories Inc.	NDA 017989 SBA
2016-373	01/14/2016 02/12/2016	FDA/OFVM/CFSAN/OCD/EOS/	Mark Prinz Registrar Corp	FOREIGN FOOD FACILITIES LIST AS OF 12/31/15
2016-374	01/14/2016 02/12/2016	FDA/OMPT/CDRH/OCE/DID/ FDA/OGROP/ORR/SE-FO/FLA- DO/FLA-CB/	LEE FUGATE ZUCKERMAN SPAEDER LLP	ADVANCED ORTHOGONAL EQUIPMENT - PERCUSSION ADJUSTING INSTRUMENT RECS
2016-375	01/14/2016 02/12/2016	OC/ORR/ORM/ OC/ORR/ORM/	Mark Prinz Registrar Corp	LIST OF WARNING LETTERS 10/01/2011 - 12/31/2015
2016-376	01/14/2016 02/12/2016	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink	2016-67
2016-377	01/14/2016 02/12/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Michael Mancinelli, Paralegal Conway, Homer & Chin-Caplan, PC	INDIVIDUAL RECS
2016-378	01/14/2016 02/12/2016	FDA/OMPT/CDRH/OCE/DID/	Sandra Aprahamian MEDTRONIC MINIMED	K841772
2016-379	01/14/2016 02/12/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Benjamin Lampson DANA FARBER CANCER INSTITUTE	102873091 10287309 104406112 ETC
2016-380	01/14/2016 02/12/2016	FDA/OFVM/CFSAN/OCD/EOS/	Michael J. O'Flaherty OLSSON FRANK WEEDA TERMAN MATZ PC	RECS RE SINGLE-SERVE POWDERED INFANT FORMULAS, CAPSULE/POD CONTAINERS ETC RE NESTLE GERBER BABYNES SYSTEM 01/01/2014 - 01/13/2016
2016-381	01/14/2016 02/12/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Daniela Sinatra Centrix Pharmaceutical, Inc.	11240090 11369468 11423048 ETC
2016-382	01/14/2016 02/12/2016	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink	2015-7339
2016-383	01/14/2016 02/12/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Daniela Sinatra Centrix Pharmaceutical, Inc.	10939173 11015156 11043177 ETC

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-384	01/14/2016 02/12/2016	OC/ORP/ OC/ORP/	NEMA KOOHMARAIE INSTITUTE FOR ENVIRONMENTAL HEALTH INC	CHIPOLTE MEXICAN GRILL - SALMONELLA BAILDON 12/14 TO 2/15
2016-385	01/14/2016 02/12/2016	FDA/OC/OES/DFOI/	EDWARD MALNICK DAILY TELEGRAPH NEWSPAPER	DEPUY ORTHOPAEDICS INC - EIR 1/28/08 UNREDACTED
2016-386	01/14/2016 02/12/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARIA McCOLGAN ST CHRISTOPHER'S HOSPITAL	VICKS VAPORUB - AER
2016-387	01/14/2016 02/12/2016	FDA/OGROP/ORP/CE-FO/DET- DO/DET-CB/ FDA/OC/OES/DFOI/	LYNDSEY TELFORD TELEGRAPH MEDIA GROUP	DEPUY AND FDA CORRESPONDENCE - EIR 2011
2016-388	01/15/2016 02/16/2016	FDA/OMPT/CDRH/OCE/DID/	STACIE GEFFNER-ATLYA BECTON DICKINSON F331B	EQUASHIELD - CLOSED ANTINEOPLASTIC & HAZARDOUS DSRUG RCONSTITUTION & TRANFER SYS K15029
2016-389	01/15/2016 02/16/2016	FDA/OGROP/ORP/NE-FO/NYK- DO/NYK-DCB/	ONA SCANDURRA Country Life	NATURE'S VALUE, CORAM, NY - 483S 6/1/14 TO PRESENT
2016-390	01/15/2016 02/16/2016	OC/ORP/ OC/ORP/ OC/CVM/OCD/ FDA/OFVM/CFSAN/OCD/EOS/ OC/ORP/ OC/ORP/	AMANDA HUNGERFORD HUMANE SOCIETY	SUSPENSION OR TERMINATION OF OR CHANGES TO ANY & ALL FDA EGG FACILITY INSPS OR INSP PROGRAMS/PROCEDURES 1/1/15 TO PRESENT
2016-391	01/15/2016 02/16/2016	FDA/OO/OHR/ FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECS
2016-392	01/15/2016 02/16/2016	FDA/OC/OES/DFOI/	MYERS DOYLE MELANIE RUBINSKY JD LLM	OFF-LABEL & INVESTIGATIONAL USE OF MARKETED DRUGS, BIOLOGICS & MEDICAL DVC INFORMATION SHEET (CERTIFIED)
2016-393	01/15/2016 02/16/2016	OC/ORP/ORM/ OC/ORP/ORM/	ELLIOT GRAHAM SOCIETY OF QUALITY ASSURANCE	TURBO EIR LIST FI/13
2016-394	01/15/2016 02/16/2016	OC/ORP/ORM/ OC/ORP/ORM/	ELLIOTT GRAHAM SOCIETY OF QUALITY ASSURANCE	TURBO EIR LIST FI/14
2016-395	01/15/2016	FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson	NDA 208036

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	02/16/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	
2016-396	01/15/2016 02/16/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	07/25/1994 LETTER TO UPJOHN RE LABELING FOR DEPO-PROVERA, DEPO-TESTOSTERONE
2016-397	01/15/2016 02/16/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Daniela Sinatra Centrix Pharmaceutical, Inc.	10788278 10788476 10804824 ETC
2016-398	01/15/2016 02/16/2016	FDA/OMPT/CDRH/OCE/DID/	Lori Burns GLOBUS MEDICAL	K990214
2016-399	01/15/2016 02/16/2016	FDA/OMPT/CDRH/OCE/DID/	Lori Burns GLOBUS MEDICAL	K012937 K971675
2016-400	01/15/2016 02/16/2016	FDA/OMPT/CDRH/OCE/DID/	Andrew Jackson Crawford Healthcare Ltd	K080383 K121275 K123481
2016-401	01/15/2016 02/16/2016	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	Neil Toensmeier la colombe torrefaction	CONSUMER COMPLAINT 143802
2016-402	01/15/2016 02/16/2016	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	TOBACCO PRODUCT INJURY, AERS REPORTED TO CTP, FDA SAFETY REPOTING PORTAL, MEDWATCH ETC 11/1/15 TO 12/18/15
2016-403	01/15/2016 02/16/2016	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/ORO/DIOP/ FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	Zetetic, Inc. Zetetic, Inc.	FDA ENTRY DOCUMENTATION REQUEST (REFUSAL) 144-8840283-8
2016-404	01/15/2016 02/16/2016	FDA/OMPT/CDRH/OCE/DID/	Todd Landsman TEXAS A&M UNIVERSITY	K123696
2016-405	01/15/2016 03/31/2016	FDA/OMPT/CDRH/OCE/DID/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	James Petricek James Petricek	K142463 BK130060
2016-406	01/15/2016	FDA/OMPT/CBER/OCOD/DDOM/	Elliott J. Millenson	RECS RE HIV HOME TESTS

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	02/16/2016	ALFB/	Elliott Millenson	
2016-407	01/15/2016 02/16/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Elliott Millenson Elliott Millenson	RECS FROM RE HOME HIV TESTING AMONG WHITE HOUSE, HHS, FDA
2016-408	01/15/2016 02/16/2016	FDA/OGROP/ORR/SW-FO/DEN- DO/DEN-CB/ FDA/OMPT/CDRH/OCE/DID/	Darlene King Darlene King	COMMUNICATION BETWEEN FDA AND SORIN GROUP RE HEATER COOLER 3T DEVICES - 483, EIR, RESPONSE ETC 01/06/2006 - 01/13/2016
2016-409	01/15/2016 02/16/2016	OC/CVM/OCD/	Takeshi Toyoda Division of Pathology, National Institute of Health Sciences	NADA 128-549
2016-410	01/15/2016 02/16/2016	FDA/OFVM/CFSAN/OCD/EOS/	Marilynn Whitney COVINGTON & BURLING LLP	CERTIFICATE OF FREE SALE
2016-411	01/15/2016 02/16/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	MAXIMILIAN FERNANDEZ BAXALTA US INC	BLA 125566/0 SBA
2016-412	01/15/2016 02/16/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Genevieve Stevens Nivagen Pharmaceuticals, Inc.	NDA 017351
2016-413	01/15/2016 02/16/2016	FDA/OGROP/ORR/SE-FO/NOL- DO/NOL-CB/ FDA/OGROP/ORR/SE-FO/NOL- DO/NOL-CB/	Tanya Eberle Cartiva, Inc.	BIOMIMETIC THERAPEUTICS - 483 01/03/2014 - 01/01/2016
2016-414	01/15/2016 02/16/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	MAXIMILIAN FERNANDEZ BAXALTA US INC	BLA 125577/0 SBA
2016-415	01/15/2016 02/16/2016	FDA/OGROP/ORR/SW-FO/DAL- DO/DAL-CB/	Patricia Hillenmeyer AbbVie	OKLAHOMA UNIVERSITY HEALTH SCIENCES CENTER IRB, DR PAMELA ALLEN, OKLAHOMA, OK - EIR, 483, RESPONSE 01/01/2015 - 01/14/2016
2016-416	01/15/2016 02/16/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Zeba Siddiqui THOMSON REUTERS	WOCKHARDT LTD, INDIA - INDIA 01/01/2016 - 01/15/2016

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2016-417	01/15/2016 02/16/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Darshan Mehta ET Now	WOCKHARDT LTD, INDIA - 483 01/06/2016 - 01/14/2016
2016-418	01/15/2016 02/16/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Anjali Cordeiro BLOOMBERG NEWS	WOCKHARDT LTD, INDIA - 483 1/15/15 - 1/15/16
2016-419	01/15/2016 02/16/2016	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Walter Chalkley THOMSON REUTERS	IRVINE STEM CELL TREATMENT CENTER, NEWPORT BEACH, CA - EIR, 483, RESPONSE 07/27/2015 - 09/08/2015
2016-420	01/15/2016 02/16/2016	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	MANHATTAN REGENERATIVE MEDICINE MEDICAL GROUP, NEW YORK, NY - EIR, 483, RESPONSE 07/27/2015 - 09/19/2015
2016-421	01/15/2016 02/16/2016	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	MIAMI STEM CELL TREATMENT CENTER, BOCA RATON, FL - EIR, 483, RESPONSE 07/27/2015 - 09/11/2016
2016-422	01/15/2016 02/16/2016	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	MARK KUTNER, MIAMI, FL - EIR, 483, RESPONSE 05/12/2015 - 05/15/2015
2016-423	01/15/2016 02/16/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Walter Chalkley THOMSON REUTERS	DR REDDY LABORATORIES, LTD, INDIA - 483 02/26/2015 - 03/06/2015
2016-424	01/15/2016 02/16/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Walter Chalkley THOMSON REUTERS	ZHEJIANG HISUN PHARMACEUTICAL CO, LTD, CHINA - 483 03/02/2015 - 03/07/2015
2016-425	01/15/2016 02/16/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Walter Chalkley THOMSON REUTERS	CADILA HEALTHCARE LIMITED, INDIA - 483 08/28/2014 - 09/05/2014
2016-426	01/19/2016	FDA/OMPT/CDRH/OCE/DID/	KATHLEEN A MCGUINNESS	NOVA BIOMEDICAL CORP - NOVA STA PROFILE 5 K874832

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	02/17/2016		GOODWIN PROCTER LLP	
2016-427	01/19/2016 02/17/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAWN M CHITTY TORRENT PHARMA INC	GLAND PHARMA LTD, HYDERABAD, INDIA, ANDHRA PRADESH, INDIA, ETC - 482S, 483S MOST RECENT
2016-428	01/19/2016 02/17/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAWN M CHITTY TORRENT PHARMA INC	INDOCO REMEDIES LTD, GOA, INDIA; MAHARASHTRA, INDIA, ETC - 482S, 483S MOST RECENT
2016-429	01/19/2016 02/17/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MANOJ GARG DSP Merrill Lynch	WOCKHARDT, MAHARASHTRA, INDIA - 483 MOST RECENT
2016-430	01/19/2016 02/17/2016	OC/ORO/ORM/ OC/ORO/ORM/	GAIL LESSICK LACHMAN CONSULTANT SERVICES, INC.	DRUG COMPANIES, MEDICAL DVC MFRS, BLOOD ESTABLISHMENTS, ETC - DOMESTIC AND FOREIGN INSPS, 483S 10/1/15-12/31/15
2016-431	01/19/2016 02/17/2016	FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	LESLIE RAMSEY FDA NEWS	DLC LABORATORIES INC, PARAMOUNT, CA; ZEST ANCHORS LLC, ESCONDIDO, CA; GENLABS CORP, CHINO, CA, ETC - 483S 12/1-31/15
2016-432	01/19/2016 02/17/2016	FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/	LESLIE RAMSEY FDA NEWS	ALICIA DIAGNOSTICS INC, CHULUOTA, FL; US STEM CELL CLINIC LLC, SUNRISE, FL; ISOAID LLC, PORT RICHEY, FL, ETC - 483S 12/1-31/15
2016-433	01/19/2016 02/17/2016	FDA/OMPT/CDRH/OCE/DID/	LESLIE RAMSEY FDA NEWS	RAINBOW SPECIALTY & HEALTH PRODUCTS, MARKHAM, CANADA; SANOFI-AVENTIS DEUTSCHLAND GMBH, FRANKFURT AM MAIN, GERMANY; BLUE ORTHO, LA TRONCHE, FRANCE, ETC - 483S 12/1-31/15
2016-434	01/19/2016 02/17/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca Dandeker Morgan, Lewis & Bockius LLP	SUN PHARMACEUTICALS INDUSTRIES, INDIA - 483, EIR SUMMARIES 07/01/2013 - 09/30/2015
2016-435	01/19/2016 02/17/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-9970 - REQUEST LETTER ONLY
2016-436	01/19/2016 02/17/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-10000 - REQUEST LETTER ONLY
2016-437	01/19/2016 02/17/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LESLIE RAMSEY FDA NEWS	CRYSTAL CLAIRE COSMETICS INC, EAST YORK, CANADA; PATHEON INC-TORONTO REGION OPERATIONS,

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		MISSISSAUGA, CANADA; AVMOR, LAVAL, CANADA, ETC - 483S 12/-131/15
2016-438	01/19/2016 02/17/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-9927 - REQUEST LETTER ONLY
2016-439	01/19/2016 02/17/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-9891 - REQUEST LETTER ONLY
2016-440	01/19/2016 02/17/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-9941 - REQUEST LETTER ONLY
2016-441	01/19/2016 02/17/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-9909 - REQUEST LETTER ONLY
2016-442	01/19/2016 02/17/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-9964 - REQUEST LETTER ONLY
2016-443	01/19/2016 02/17/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-10183 - REQUEST LETTER ONLY
2016-444	01/19/2016 02/17/2016	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	LESLIE RAMSEY FDA NEWS	MAYO CLINIC PET RADIOCHEMISTRY FACILITY, ROCHESTER, MN; MORTON DRUG CO DBA MORTON LTC, NEENAH, WI - 483S 12/1-31/15
2016-445	01/19/2016 02/17/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-10248 - REQUEST LETTER ONLY
2016-446	01/19/2016 02/17/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-9885 - REQUEST LETTER ONLY
2016-447	01/19/2016 02/17/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-9840 - REQUEST LETTER ONLY
2016-448	01/19/2016 02/17/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-9770 - REQUEST LETTER ONLY
2016-449	01/19/2016 02/17/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-9967 - REQUEST LETTER ONLY
2016-450	01/19/2016 02/17/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-9574 - REQUEST LETTER ONLY
2016-451	01/19/2016 02/17/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-10265 - REQUEST LETTER ONLY
2016-452	01/19/2016 02/17/2016	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	LESLIE RAMSEY FDA NEWS	DERMAPAC INC, SHELTON, CT - 483S 12/1-31/5
2016-453	01/19/2016	FDA/OGROP/ORACE-FO/NWJ-	LESLIE RAMSEY	L'OREAL USA PRODUCTS INC, PISCATAWAY, NJ; HOVIONE

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	02/17/2016	DO/NWJ-CB/	FDA NEWS	LLC, EAST WINDSOR, NJ - 483S 12/1-31/15
2016-454	01/19/2016 02/17/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Priyasha Uppal Priyasha Uppal	DIPEPTIDYL PEPTIDASE-4 - AERS
2016-455	01/19/2016 02/17/2016	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	LESLIE RAMSEY FDA NEWS	NASHVILLE SURGICAL INSTRUMENTS LLC, SPRINGFIELD, TN - 483S 12/1-31/15
2016-456	01/19/2016 02/17/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Steve Gupta Physicians for Integrity in medical Research Inc.	DALIRESP - POST-MARKET DRUG SAFETY EVALUATION SUMMARIES 01/01/2014 - 12/31/2015
2016-457	01/19/2016 02/17/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rebecca Dandeker Morgan, Lewis & Bockius LLP	SUN PHARMACEUTICAL INDUSTRIES LIMITED, INDIA - EIR 07/01/2013 - 09/30/2015
2016-458	01/19/2016 02/17/2016	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	LESLIE RAMSEY FDA NEWS	ADVANCE PHARMACEUTICAL INC, HOLTSMVILLE, NY; MISONIX INC, FARMINGDALE, NY; BUFFALO DENTAL MANUFACTURING CO INC, ETC - 483S 12/1-31/15
2016-459	01/19/2016 02/17/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lisa Samuels PFIZER INC.	NDA 202324
2016-460	01/19/2016 02/17/2016	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	LESLIE RAMSEY FDA NEWS	G S COSMECEUTICAL USA INC, LIVERMORE, CA; CS BIO COMPANY - 483S 12/1-31/15
2016-461	01/19/2016 02/17/2016	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	LESLIE RAMSEY FDA NEWS	VANGUARD EMS INC, BEAVERTON, OR; SWEETSPOT DIABETES CARE INC, PORTLAND, CO - 483S 12/1-13/15
2016-462	01/19/2016 02/17/2016	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	LESLIE RAMSEY FDA NEWS	RENNER & CO, CARY, IL - 483S 12/1-31/15
2016-463	01/19/2016 02/17/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rebecca Dandeker Morgan, Lewis & Bockius LLP	SUN PHARMACEUTICALS INDUSTRIES LIMITED, INDIA - 483, EIR SUMMARIES 07/01/2013 - 09/30/2015
2016-464	01/19/2016 02/17/2016	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	LESLIE RAMSEY FDA NEWS	CAMCO CHEMICAL CO, FLORENCE, KY - 483S 12/1-31/15

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2016-465	01/19/2016 02/17/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca Dandeker Morgan, Lewis & Bockius LLP	SUN PHARMACEUTICAL INDUSTRIES LIMITED - EIR 07/01/2013 - 09/30/2015
2016-466	01/19/2016 02/17/2016	FDA/OMPT/CDRH/OCE/DID/	Mara Caler SALTER LABS	K912434
2016-467	01/19/2016 02/17/2016	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	RJ REYNOLDS ECLIPSE RECS
2016-468	01/19/2016 02/18/2016	FDA/OFVM/CFSAN/OCD/EOS/	Dave Newberry The Weston Firm	LETTERS TO MANUFACTURERS, MARKETERS, DISTRIBUTORS OF WEIGHT LOSS PRODUCTS CONTAINING GREEN COFFEE, GREEN COFFEE EXTRACT, OR CHLOROGENIC ACID 01/01/2012 - 01/01/2016
2016-469	01/19/2016 02/17/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tony Farmer Tony farmer	MERCOLA, MERCOLA.COM, JOSEPH MARCOLA - RECS RE DRUGS, WEBSITE 01/01/2010 - 01/12/2016
2016-470	01/19/2016 02/17/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Vince H Suneja Vince H Suneja	WOCKHARDT LIMITED, INDIA - 483 10/01/2015 - 01/15/2016
2016-471	01/19/2016 02/17/2016	FDA/OMPT/OSMP/OOPD/	Neha Thakkar Cote Orphan Consulting	JAPANESE ENCEPHALITIS VACCINE ORPHAN PRODUCT DESIGNATION RECS 01/01/2010 - 01/15/2016
2016-472	01/19/2016 02/17/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel johnson FOI Services, Inc.	K090141
2016-473	01/19/2016 02/17/2016	FDA/OMPT/CDRH/OCE/DID/	Lori Burns GLOBUS MEDICAL	K012937
2016-474	01/19/2016 02/17/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K101882
2016-475	01/19/2016 02/17/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K131286
2016-476	01/19/2016 02/17/2016	FDA/OMPT/CDRH/OCE/DID/	Lori Burns GLOBUS MEDICAL	K971675
2016-477	01/19/2016 02/17/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K130857

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2016-478	01/19/2016 02/17/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	REMS Modification Notification Letter for Lotronex
2016-479	01/19/2016 02/17/2016	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	John Thomas John Thomas	RECS RE DETENTION ORDER DO-0370
2016-480	01/19/2016 02/17/2016	OC/ORA/ OC/ORA/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	Brian Dolin Brian Dolin	SALMONELLA OUTBREAKS RE ALMOND BUTTER, HAIN CELESTIAL GROUP, COSTCO ETC 01/01/2012 - 01/15/2016
2016-481	01/19/2016 02/17/2016	FDA/OMPT/CDRH/OCE/DID/	Lori Burns Globus Medical	K000246
2016-482	01/19/2016 02/17/2016	FDA/OMPT/CDRH/OCE/DID/	Lori Burns GLOBUS MEDICAL	K974187
2016-483	01/19/2016 02/17/2016	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	Sylvia L. Johnson PharmaTech LLC	PHARMATECH LLC, DAVIE, FL - EIR 01/12/2012 - 01/24/2012
2016-484	01/19/2016 02/17/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	REMS Notification Modification Letter for Alosetron
2016-485	01/19/2016 02/17/2016	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Brenda Goodman WebMD	BIOTRIAL, NEWARK, NJ - INSPECTION RECS 01/01/2011 - 01/15/2015
2016-486	01/19/2016 02/17/2016	FDA/OFVM/CFSAN/OCD/EOS/	Marilynn Whitney COVINGTON & BURLING LLP	CERTIFICATES OF FREE SALE FOR DIETARY SUPPLEMENTS
2016-487	01/19/2016 02/17/2016	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	James William Woodlee Kleinfeld, Kaplan and Becker, LLP	EIR UNREDACTED NATIONAL TOBACCO CO DRESDEN, TN, LOUISVILLE, KY 01/01/2012 - 01/15/2016
2016-488	01/19/2016 02/17/2016	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Doe J	SHIGELLA FOOD POISONING PETER PAN CREAMY PEANUT BUTTER COMPLAINT 142373
2016-489	01/19/2016	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	LESLIE RAMSEY	AUSTIN PHARMA LLC, ROUND ROCK, TX; DOUGHERTY'S PHARMACY, DALLAS, TX - 483S 12/1-31/15

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	02/17/2016		FDA NEWS	
2016-490	01/19/2016 02/17/2016	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	Christopher Markos Markos, Christopher	ELORAC, INC, VERNON HILLS, IL - EIR 12/15/2014 - 01/14/2016
2016-491	01/19/2016 02/17/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 21107/S26 SUPPLEMENTAL APPROVAL RECS
2016-492	01/19/2016 02/17/2016	FDA/OMPT/CDRH/OCE/DID/ FDA/OC/OES/DFOI/	Diane Brinza Diane Brinza	K141865
2016-493	01/19/2016 02/17/2016	FDA/OMPT/CDRH/OCE/DID/	Sandeep Saboo Corinth MedTech, Inc	K042523
2016-494	01/19/2016 02/17/2016	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	LESLIE RAMSEY FDA NEWS	ADAPTA MEDICAL INC, COLORADO SPRINGS, CO; MYRIAD GENETICS LABORATORIES INC, SALT LAKE CITY, UT - 483S 12/1-31/15
2016-495	01/19/2016 02/17/2016	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCE/DID/	Amanda Dykeman ASHES NONPROFIT	Essure PMA PO20014 P020014/S001 P020014/S002 P020014/S003 ETC
2016-496	01/19/2016 02/17/2016	FDA/OMPT/CDRH/OCE/DID/	Karen E. Warden, PhD BackRoads Consulting Inc.	K131345
2016-497	01/19/2016 02/17/2016	FDA/OMPT/CDRH/OCE/DID/	Sandeep Saboo Corinth MedTech, Inc	K152092
2016-498	01/19/2016 02/17/2016	FDA/OMPT/CDRH/OCE/DID/	Sandeep Saboo Corinth MedTech, Inc	K133799
2016-499	01/19/2016 02/17/2016	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	LESLIE RAMSEY FDA NEWS	BIOMEDIX INC, BLOOMINGTON, IN; SUMMIT MFG & MACHINING INC, BREMEN, IN; HAVEN INNOVATION INC, GRAND HAVEN, MI - 483S 12/1-31/15
2016-500	01/19/2016 02/17/2016	FDA/OMPT/CDRH/OCE/DID/	Sara Chen Cardica, Inc.	K141952
2016-501	01/19/2016 02/17/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kim Grayson St Vincent's Hospital	DEXMEDETOMIDINE - AERS
2016-502	01/19/2016 02/17/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Leonardo Roque Pereira Erasmus/Bordeaux/Hertsfordshire Universities	SALES DATA FOR TOCILIZUMAB IN US 01/01/2010 - 09/30/2014

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-503	01/19/2016 02/17/2016	OC/ORA/ OC/ORA/ OC/ORA/ORM/ OC/ORA/ORM/	Kris Christian FDAZILLA	LIST OF INSPECTIONS 12/16/2015 - 01/18/2016
2016-504	01/19/2016 02/17/2016	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	LESLIE RAMSEY FDA NEWS	WINDER LABORATORIES LLC, WINDER, GA; EISAI INC, RESEARCH TRIANGLE PARK, NC; ABC COMPOUNDING COMPANY INC, ETC - 483S 12/1-31/15
2016-505	01/19/2016 02/17/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	G. Srinivas Zydus Pharmaceuticals USA Inc.	NDA 017830
2016-506	01/19/2016 02/17/2016	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	LESLIE RAMSEY FDA NEWS	MEDIFOCUS INC, COLUMBIA, MD; BARR LABORATORIES INC, FOREST, VA; AMERICAN ANTIBIOTICS INC, BALTIMORE, MD - 483S 12/1-31/15
2016-507	01/19/2016 02/17/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LESLIE RAMSEY FDA NEWS	LES IMPORTATIONS HERBASSANTE INC, SAINT-LAURENT, CANADA; MERCK SERONO SA AUBONNE, AUBONNE, SWITZERLAND; BOEHRINGER INGELHEIM PHARA GMBH & CO KG - 483S 12/1-31/15
2016-508	01/20/2016 02/18/2016	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	John Thomas John Thomas	RECS RE INSPECTIONS RESULTING IN, SUPPORTING FORFEITURE
2016-509	01/20/2016 02/18/2016	FDA/OC/OES/DFOI/	CHARLES SNOW Hyman Phelps and McNamara PC	DKT: 01P-0148 - COMMENTS FOR 2001 CITIZEN PETITION
2016-510	01/20/2016 02/18/2016	FDA/OC/OES/DFOI/	JENNIFER KANE AITRIA CLIENT SERVICE	FDA-2015N-2002
2016-511	01/20/2016 02/18/2016	FDA/OC/OES/DFOI/	MINDI MESSMER TERRA NOVA	FDA - 2021 N-0967U
2016-512	01/20/2016 02/18/2016	FDA/OC/OES/DFOI/	ROSS RENDELMAN HOGAN LOVELLS US LLP	FDA-1975N-0366, FDA-1975N-0337
2016-513	01/20/2016 02/18/2016	FDA/OC/OES/DFOI/	ROBERT GRAHAM PENCO INFO	GUIDANCE FOR INDUSTRY CHRONIC HEPITITIS CYP3A4 VIRUS INTETION
2016-514	01/20/2016 02/18/2016	FDA/OC/OES/DFOI/	SETH A MAILHD Michael Best and Friedrich LLP	DKT 20097F-0283

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2016-515	01/20/2016 02/18/2016	FDA/OC/OES/DFOI/	JOE CANTHUPE FDA NEWS	DKT 2015-03438 - COMMENTS
2016-516	01/20/2016 02/18/2016	FDA/OC/OES/DFOI/	KUSHI DESAI Earth Justice	FDA-2011N-0899 - COMMENTS
2016-517	01/20/2016 02/18/2016	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCE/DID/	ELLEN EPSTEIN COHEN ADLER COHEN ET AL ATTYS	JOHNSON & JOHNSON, ETHICON INC, ETHICON ENDO-SURGERY INC - SPREAD OR UPSTAGING OF UNSUSPECTED CANCER THROUGH MORCELLATION OF UTERINE TISSUE MDRS 12/13 TO PRESENT
2016-518	01/20/2016 02/18/2016	FDA/OC/OES/DFOI/	JAMES E GIRARDS GIRARDS LAW FIRM	ANULEX TECHNOLOGIES - XCLOSE TISSUE REPAIR DVC, XCLOSE-TRS WARNING LTRS, MDRS
2016-519	01/20/2016 02/18/2016	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	WAYNE SADOWSKI NOVARTIS PHARMACEUTICALS CORPORATION	DR ROBERT SCHLOSSMAN, BOSTON, VA - EIR, 483, 482, ETC 6/16-23/14
2016-520	01/20/2016 02/18/2016	OC/CVM/OCD/	Doe J	BAYER CORP, BAYER HEALTHCARE LLC, SHAWNEEM, KS - BAYTRIL (ENROFLAXACIN) AERS
2016-521	01/20/2016 02/18/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARKER GROUP INC	INDIVIDUAL RECS
2016-522	01/20/2016 02/18/2016	FDA/OC/OES/DFOI/ FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	MARYLEE MCRAE VON BRIESEN & PURTELL SC	STRYKER CORP - NEPTUNE 1 ROVER SILVER (120V) WASTE MANAGEMENT SYS RECALLS INSPS, MEMOS, ETC
2016-523	01/20/2016 02/18/2016	FDA/OC/OES/DDM/	qingzhen Zhang qingzhen, zhang	Guidance for Industry for the Submission of Chemistry Manufacturing and Controls Information for Synthetic Peptide Substances
2016-524	01/20/2016 02/18/2016	FDA/OMPT/CDRH/OCE/DID/	Adrienne Lenz Pathway Regulatory Consulting, LLC	K142552 K151954
2016-525	01/20/2016 02/18/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K020732
2016-526	01/20/2016 02/18/2016	OC/CVM/OCD/	Emily Sundman Emily Sundman	DIPYRONE OPINION
2016-527	01/20/2016 02/18/2016	FDA/OC/OES/DFOI/	Eyal Maor FDAAWARE	LIST OF 483S RELEASED UNDER FOIA 08/01/2015 - 12/15/2015
2016-528	01/20/2016 02/18/2016	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink	2015-9441

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2016-529	01/20/2016 02/18/2016	FDA/OMPT/CDRH/OCE/DID/	C-Reg Medical C-Reg Medical	K152041
2016-530	01/20/2016 02/18/2016	FDA/OMPT/CDRH/OCE/DID/	Lan Herrington Carol Cole Company	K141921 K010335
2016-531	01/20/2016 02/18/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ya Ping Lee Curtin University	PPI AERS
2016-532	01/20/2016 02/18/2016	FDA/OMPT/CDRH/OCE/DID/	Ryan Bouchard ORA, Inc	K150977
2016-533	01/20/2016 02/18/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bhagwan Chaudhary National Institute of Securities Markets , Navi Mumbai	WOCKHARDT LIMITED, INDIA - 483 01/01/2016 - 01/15/2016
2016-534	01/20/2016 02/18/2016	FDA/OMPT/CTP/OD/	Desmond Jenson Tobacco Control Legal Consortium	All records and communications associated with Potential Tobacco Violation Report ID 14L00001
2016-535	01/20/2016 02/18/2016	FDA/OFVM/CFSAN/OCD/EOS/	Murali K. Akkapeddi, Ph.D. Graham Packaging Co.	FCN 1045
2016-536	01/20/2016 02/18/2016	FDA/OMPT/CDRH/OCE/DID/	James Hurlman Dynarex Corporation	K112628
2016-537	01/20/2016 02/18/2016	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink	2015-9264
2016-538	01/20/2016 02/18/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K023778
2016-539	01/20/2016 02/18/2016	OC/ORP/ORM/ OC/ORP/ORM/	Eyal Maor FDA AWARE	LIST OF FEI NUMBERS
2016-540	01/21/2016 02/19/2016	FDA/OFVM/CFSAN/OCD/EOS/	Janet Balson RiceBran Technologies	RECS RE WARNING LETTER TO HARMLESS HARVEST THAILAND 11/13/2015.
2016-541	01/21/2016 02/19/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Vaibhav Dusad Morgan Stanley	WOCKHARDT INDIA - 483 01/02/2015 - 01/14/2016
2016-542	01/21/2016	FDA/OGROP/ORP/CE-FO/MIN-	Walter Chalkley	UNIVERSITY OF WISCONSIN SCHOOL OF MEDICINE AND

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	02/19/2016	DO/MIN-CB/	THOMSON REUTERS (SCIENTIFIC) SAS	PUBLIC HEALTH, MADISON, WI - EIR, 483, RESPONSE 01/20/2015 - 01/29/2015
2016-543	01/21/2016 02/19/2016	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	SONAR PRODUCTS, CARLSTADT, NJ - EIR, 483, RESPONSE 02/06/2014 - 03/18/2014
2016-544	01/21/2016 02/19/2016	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	PUGET SOUND BLOOD CENTER AND PROGRAM, RENTON, WA - EIR, 483, RESPONSE 10/14/2014 - 10/15/2014
2016-545	01/21/2016 02/19/2016	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	Walter Chalkley THOMSON REUTERS	JAU-SHIN LOU, M D, PORTLAND, OR - EIR, 483, RESPONSE 02/21/2012 - 02/29/2012
2016-546	01/21/2016 02/19/2016	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	LAWRENCE D. PETZ, MD, LOS ANGELES, CA - EIR, 483, RESPONSE 05/05/2014 - 05/21/2014
2016-547	01/21/2016 02/19/2016	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Walter Chalkley THOMSON REUTERS	LONG PHARMACEUTICALS, FENTON, MO - EIR, 483, RESPONSE 02/17/2015 - 02/26/2015
2016-548	01/21/2016 02/19/2016	FDA/OMPT/CDRH/OCE/DID/	Catherine A Williams, RAC Wako Life Sciences, Inc.	DEN040003 K032373
2016-549	01/21/2016 02/19/2016	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	Walter Chalkley THOMSON REUTERS	JAMES W BAKER, MD, LAKE OWSEGO, OR - EIR, 483, RESPONSE 09/04/2013 - 09/19/2013
2016-550	01/21/2016 02/19/2016	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Walter Chalkley THOMSON REUTERS	HUNTERDON MEDICAL CENTER BLOOD BANK, FLEMINGTON, NJ - EIR, 483, RESPONSE 07/18/2013 - 07/25/2013
2016-551	01/21/2016 02/19/2016	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Walter Chalkley THOMSON REUTERS	IBA MOLECULAR NORTH AMERICA, MORGANTOWN, WV - EIR, 483, RESPONSE 08/06/2012 - 08/16/2012
2016-552	01/21/2016 02/19/2016	FDA/OFVM/CFSAN/OCD/EOS/OC/CVM/OCD/	Jodi Miller ToxStrategies, Inc.	FAP METHYL ESTERS OF CONJUGATED LINOLEIC ACID
2016-553	01/21/2016 02/19/2016	FDA/OMPT/CDRH/OCE/DID/	Timothy Chuter University of California San Francisco- Division of Vascular and Endovascular Surgery	IDE G000265
2016-554	01/21/2016 02/19/2016	FDA/OMPT/CDRH/OCE/DID/	Robert Steins Product Make	K151070, K130581, K131905, ETC
2016-555	01/21/2016 02/19/2016	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Rachel Johnson FOI Services, Inc.	NEPHRON, WEST COLUMBIA, SC - EIR
2016-556	01/21/2016 02/19/2016	FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 207986

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2016-557	01/21/2016 02/19/2016	FDA/OFVM/CFSAN/OCD/EOS/	Bjornson Regulatory Consulting LLC Bjornson Regulatory Consulting LLC	FAP 1490 TOXICOLOGY
2016-558	01/21/2016 02/19/2016	FDA/OMPT/CDRH/OCE/DID/	Nahbee Jong TheraNova LLC	K150550
2016-559	01/21/2016 02/19/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	GLATOPA - AERS
2016-560	01/21/2016 02/19/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Kris Christian FDAZILLA	SANOFI PASTEUR SA, ETOILE, FRANCE - 483, EIR 9/25/2015
2016-561	01/21/2016 02/19/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MANOJ GARG MERRILL LYNCH	WOCKHARDT, MAHARASHTRA, INDIA - 483 1/16
2016-562	01/21/2016 05/05/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	JUSTIN SATHUE DebitRepair	LIFT OF BAN ON BLOOD DONATION
2016-563	01/21/2016 02/19/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JAMIE BELCASTRO BELMORA LLC	BELMORA LLC - MEDWATCH RPTS 2015
2016-564	01/21/2016 02/19/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	EFFIENT (PRASUGREL) AER
2016-565	01/21/2016 02/19/2016	FDA/OGROP/ORACE-FO/CIN- DO/CIN-CB/	GARY A. MAXIMIUK WHEELER UPHAM	SHUR GREEN FARMS LLC - 483 11/19/14
2016-566	01/21/2016 02/19/2016	FDA/OMPT/CDRH/OCE/DID/	ALLCHIN, TYLER	K093717; KK101734; K142603 ETC
2016-567	01/21/2016 02/19/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	FORTEO - AER

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2016-568	01/21/2016 02/19/2016	FDA/OC/OES/	NORMAN M. GOLDFARB JOURNAL OF CLINICAL RESEARCH BEST PRACTICES	ALL ANSWERS WITH RELEVANT QUESTIONS THAT THE FDA HAS PROVDDED THROUGH ITS GCPQUESTIONS@OC.FDA.GOV IN 2014
2016-569	01/21/2016 02/19/2016	FDA/OGROP/ORASW-FO/KAN- DO/KAN-CB/	SAVCHENKO, ANDY	DOG FOOD - REFUSED CARGO INSP RPT 10/28/15E THIS: ALL ANSWERS WITH RELEVANT QUESTIONS THAT THE FDA HAS PROVDDED THROUGH ITS GCPQUESTIONS@OC.FDA.GOV IN 2014
2016-570	01/21/2016 02/19/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Doe J	INDIVIDUAL RECS
2016-571	01/22/2016 02/22/2016	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 12/28/15-1/1/16
2016-572	01/22/2016 02/22/2016	FDA/OC/OES/DFOI/	LESLIE RAMSEY FDA NEWS	DAILY LOG 12/21-25/15
2016-573	01/22/2016 02/22/2016	FDA/OC/OES/DFOI/	LESLIE RAMSEY FDA NEWS	DAILY LOG 12/28/15-1/1/16
2016-574	01/22/2016 02/22/2016	FDA/OC/OES/DFOI/	DAVID GAROFALO WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 12/21-25/15
2016-575	01/22/2016 02/22/2016	FDA/OC/OES/DFOI/	DAVID GAROFALO WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 12/28/15-1/1/16
2016-576	01/22/2016 02/22/2016	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 12/21-25/15
2016-577	01/22/2016 02/22/2016	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 12/28/15-1/1/16
2016-578	01/22/2016 02/22/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 12/21-25/15
2016-579	01/22/2016 02/22/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 12/28/15-1/1/16
2016-580	01/22/2016 02/22/2016	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 12/21-25/15
2016-581	01/22/2016	FDA/OC/OES/DFOI/	LAUREN S. BARR	DAILY LOG 12/28/15-1/1/16

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	02/22/2016		JH BARR & ASSOCIATES LLC	
2016-582	01/22/2016 02/22/2016	FDA/OC/OES/DFOI/	WILLIAM A. OLSON, Ph.D. Center for Regulator Services, Inc	daily log 12/21-25/15
2016-583	01/22/2016 02/22/2016	FDA/OC/OES/DFOI/	WILLIAM A. OLSON, Ph.D. Center for Regulator Services, Inc	DAILY LOG 12/28/15-1/1/16
2016-584	01/22/2016 02/22/2016	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	Walter Chalkley THOMSON REUTERS	IPR PHARMACEUTICALS, CANOVANAS, PR - 483, EIR, RESPONSE 06/24/2013 - 07/29/2013
2016-585	01/22/2016 02/22/2016	FDA/OMPT/CDRH/OCE/DID/	Toni Clarke THOMSON REUTERS	K030736
2016-586	01/22/2016 02/22/2016	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	MASTERPHARM LLC, SOUTH RICHMOND HILL, NY - 483, EIR, RESPONSE 04/22/2015 - 05/06/2015
2016-587	01/22/2016 02/22/2016	FDA/OMPT/CTP/OD/	Will Woodlee Kleinfeld, Kaplan & Becker, LLP	A list of all tobacco products for which FDA has issued grandfathered status determinations
2016-588	01/22/2016 02/22/2016	FDA/OMPT/CDRH/OCE/DID/	Mikael Berglund NaturalCycles Nordic AB	K954183
2016-589	01/22/2016 02/22/2016	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Barbara Kowinsky COSMETIC LABORATORIES OF AMERICA	THIBIANT INTERNATIONAL EIR 01/01/2015 - 01/16/2016
2016-590	01/22/2016 02/22/2016	FDA/OFVM/CFSAN/OCD/EOS/OC/ORA/OC/ORA/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Tina Sigurdson ENVIRONMENTAL WORKING GROUP	WEN - AERS, CORR WITH GUTHY-RENKER LLC 01/01/2008 - 01/20/2016
2016-591	01/22/2016 02/22/2016	FDA/OMPT/OSMP/OOPD/	Jack Spira Sensidose	DUODOPA - ORPHAN PRODUCT RECS
2016-592	01/22/2016 02/22/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jeffrey A. Wolfson Strides Arcolab Limited	ONCO THERAPIES LIMITED, AGILA SPECIALTIES PRIVATE LIMITED - 483, EIR 01/01/2013 - 12/31/2015
2016-593	01/22/2016 02/22/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Meghan Daley Levi & Korsinsky LLP	TETRAPHASE PHARMACEUTICALS INC - CORR WITH FDA RE CLINICAL TRIALS FOR ERAVACYCLINE 09/01/2014 - 01/19/2016

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2016-594	01/22/2016 02/22/2016	FDA/OFVM/CFR/OC/EO/	Mark McAndrew TAFT STETTINIUS & HOLLISTER	PANOS BRANDS, PANOS HOLDINGS COMPANY, RY-CON SPECIALTY FOODS 01/01/2013 - 12/31/2015 - AERS, COMPLAINTS
2016-595	01/22/2016 02/22/2016	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Barbara Kowinsky COSMETIC LABORATORIES OF AMERICA	GORDON LABORATORIES, CARSON, CA - EIR 01/01/2015 - 01/15/2016
2016-596	01/22/2016 02/22/2016	FDA/OC/OES/DFOI/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Rachel Johnson FOI Services, Inc.	RECS RE 2015-9116
2016-597	01/22/2016 02/22/2016	FDA/OC/OES/DFOI/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Rachel Johnson FOI Services, Inc.	RECS RE 2015-9125
2016-598	01/22/2016 02/22/2016	FDA/OMPT/CTP/OD/	Will Woodlee Kleinfeld, Kaplan & Becker, LLP	SWISHER INTERNATIONAL INC - RESPONSE TO WARNING LETTER ETC 01/01/2015 - 01/20/2016
2016-599	01/22/2016 02/22/2016	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Lori Howell Howells, Drew	MAINE SHELLFISH GROWING AREA PROGRAM PEER REPORT 10/01/2012 - 09/30/2014
2016-600	01/22/2016 02/22/2016	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OMPT/CDRH/OCE/DID/	Carasusana Wall Zoll & Kranz, LLC	ZIMMER PERSONA PERSONALIZED KNEE SYSTEM - K121771, RECALL RECS
2016-601	01/22/2016 02/22/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tim Henkel VenatoRx Pharmaceuticals, Inc.	NDA 050580
2016-602	01/22/2016 02/22/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Douglas Kling Matinas BioPharma, Inc.	QIDP DESIGNATIONA REQUEST FROM ASTELLAS PHARMACEUTICALS FOR CRESEMBA
2016-603	01/22/2016 02/22/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jaya Lakshmi Ayyagari Dr. Reddy's Laboratories Inc.	ANDA 077007

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2016-604	01/22/2016 02/22/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tim Henkel VenatoRx Pharmaceuticals, Inc.	NDA 050621
2016-605	01/22/2016 02/22/2016	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/	Zetetic, Inc. Zetetic, Inc.	FDA ENTRY DOCUMENTATION REQUEST ALL DOCUMENTATION 01/01/2016 - 01/15/2016
2016-606	01/22/2016 02/22/2016	FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	Richard LeVasseur Kiel Laboratories, Inc.	KIEL LABORATORIES, INC, FLOWERY BRANCH, GA - EIR 07/29/2015 - 01/20/2016
2016-607	01/22/2016 02/22/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anand Shukla Nivagen Pharmaceuticals Inc.	NDA 207958
2016-608	01/22/2016 02/22/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anand Shukla Nivagen Pharmaceuticals, Inc.	NDA 017558
2016-609	01/22/2016 02/22/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anand Shukla Nivagen Pharmaceuticals, Inc.	NDA 011790
2016-610	01/22/2016 02/22/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anand Shukla Nivagen Pharmaceuticals Inc.	ANDA 064144
2016-611	01/22/2016 02/22/2016	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Majerczak Nalco an Ecolab Company	FCN 1486 CHEMISTRY, TOXICITY
2016-612	01/22/2016 02/22/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Reena Harjai APCER Life Sciences, Inc.	BARIUM SULFATE - AERS
2016-613	01/22/2016 02/22/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K982385

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2016-614	01/22/2016 02/22/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ulrika Berg-Andersson PolyPeptide Laboratories (Sweden) AB	NDA203255 CMC REVIEW
2016-615	01/22/2016 02/22/2016	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	Sara Makes Dynamic Pet Products, LLC	DYNAMIC PET PRODUCTS, LLC, WASHINGTON, MO - EIR, COMPLAINTS, ETC 01/01/2011 - 01/22/2016
2016-616	01/22/2016 02/22/2016	FDA/OMPT/CDRH/OCE/DID/	Elli Mletzko WaveLight GmbH	ERLANGEN, GERMANY - EIR 09/07/2015 - 09/11/2015
2016-617	01/22/2016 02/22/2016	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	Angie Rock BIOTRONIK, Angie Rock	PARKVIEW HEALTH INSTITUTIONAL REVIEW BOARD, FORT WAYNE, IND - EIR, FOLLOW UP COMMUNICATIONS 07/01/2015 - 12/01/2015
2016-618	01/22/2016 02/22/2016	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	Kimberly Light BioPro, Inc	BIOPRO, PORT HURON, MI - EIR 11/01/2014 - 01/21/2016
2016-619	01/22/2016 02/22/2016	FDA/OC/OES/DFOI/	Gina Ecolino Beveridge & Diamond, PC	CFSAN FOIA REQUESTS 12/31/2015 - 01/21/2016
2016-620	01/22/2016 02/22/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jaya Lakshmi Ayyagari Dr. Reddy's Laboratories Inc.	ANDA 090821 SBA
2016-621	01/22/2016 02/22/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K062259
2016-622	01/22/2016 02/22/2016	FDA/OMPT/CDRH/OCE/DID/	Vijaya Krishnamoorthy Moximed, Inc.	K003269 K033810
2016-623	01/22/2016 02/22/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K990276
2016-624	01/22/2016 03/14/2016	FDA/OFVM/CFSAN/OCD/EOS/	Heather McIntyre Mondelez Global LLC	BIHN DUONG KIHN CORPORATION, VIET NAM - EIR, 483 ETC 09/19/2011 - 09/20/2011
2016-625	01/22/2016 02/22/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jaya Lakshmi Ayyagari Dr. Reddy's Laboratories Inc.	ANDA 090711 SBA
2016-626	01/22/2016 02/22/2016	FDA/OMPT/CDRH/OCE/DID/	Ricky Widjaja Kico Knee Innovation Company	K140257 K110397 K131559 ETC
2016-627	01/25/2016	FDA/OGROP/ORA/SW-FO/KAN-	Ryan Woods	PRA INTERNATIONAL EDS LENEXA, KS - EIR REDACTED

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	02/23/2016	DO/KAN-CB/	PRA Health Sciences	03/01/2012 - 03/08/2012
2016-628	01/25/2016 02/23/2016	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	John Moore MORGAN & MORGAN	REPRODUCTIVE MEDICINE INSTITUTE IVF, LLC - INSPECTION REPORTS, CERTIFICATIONS, ETC 01/01/2011 - 01/21/2016
2016-629	01/25/2016 02/23/2016	FDA/OMPT/CDRH/OCE/DID/	Rose Pritchard Hamlin & Burton Liability Management	SHOWER CHAIR MEDICAL DEVICES AERS 01/01/2010 - 01/21/2016
2016-630	01/25/2016 03/14/2016	FDA/OC/OES/DFOI/	Eyal Maor FDAAWARE	PREVIOUSLY RELEASED 483 08/01/2015 - 12/15/2015
2016-631	01/25/2016 02/23/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jaya Lakshmi Ayyagari Dr. Reddy's Laboratories Inc.	ANDA 203690 SBA
2016-632	01/25/2016 02/23/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nora Lee Monash Health	TAMOXIFEN - AERS
2016-633	01/25/2016 02/23/2016	OC/ORR/ORM/ OC/ORR/ORM/	Meagan Randall Meagan Randall	LIST OF DEVICE INSPECTIONS 01/01/2015 - 12/31/2015
2016-634	01/25/2016 02/23/2016	OC/ORR/OCI/ OC/ORR/OCI/	Doe J	INDIVIDUAL RECS 02/25/2015 - 05/01/2015
2016-635	01/25/2016 02/23/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Quinn Lin EverPoint Asset Management	PRALUENT, REPATHA - AERS
2016-636	01/25/2016 02/23/2016	FDA/OMPT/CDRH/OCE/DID/	Richard de la Cruz Silver Lake Group Inc	LIST OF REGISTERED CLASS 1 SOFTWARE PRODUCTS, COMPANY, PRODUCT NAME
2016-637	01/25/2016 03/07/2016	FDA/OO/OFBA/OAGS/	Rose Santos FOIA GROUP INC	HHSF223201110003I
2016-638	01/25/2016 02/23/2016	FDA/OC/OES/DFOI/	Daniel Lemkuil Daniel Lemkuil	CBD OIL FROM CHARLOTTE'S WEB 01/01/2016 - 01/22/2016
2016-639	01/25/2016 02/23/2016	FDA/OMPT/CDRH/OCE/DID/	Gary Syring Quality and Regulatory Associates LLC	K043132

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2016-640	01/25/2016 02/23/2016	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	John Walsh James Alexander Corporation	ANACHEMIA CHEMICALS, INC, ROUSES POINT, NY - EIR, 483, RECALL 01/01/2012 - 01/22/2016
2016-641	01/25/2016 02/23/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Acuna-Narvaez Adaptive RC LLC	K081075
2016-642	01/25/2016 02/23/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angela Volpe IDT Australia Limited	ANDA 075943
2016-643	01/25/2016 02/23/2016	FDA/OMPT/CDRH/OCE/DID/	Ann Morrison Ann Morrison	DEPUY PINNACLE METAL-ON-METAL HIP IMPLANT - AERS 12/13/2000 - 12/31/2015
2016-644	01/25/2016 02/23/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ren Siewczynski arznei-telegramm, A.T.I. Arzneimittelinformation Berlin GmbH	MON-US-03 NDA 50717 CDER MEDICAL REVIEW
2016-645	01/25/2016 02/23/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tamar Wilner NEWSWEEK	BURZYNSKI - EARLIEST APPROVAL RE ANTINEOPLASTINS; FDA STATEMENT JUNE 2014 REGARDING REMOVAL OF FDA PARTIAL HOLD ON BURZYNSKI TRIALS; CURRENT RESTRICTIONS ON TRIALS
2016-646	01/25/2016 02/23/2016	FDA/OMPT/CTP/OD/	Mitch Neuhauser RAI Services Company	MEMO DRAFTED BY DR CHAD REISSIG 9/11/15 RE FDA REVIEW OF RJRT CAMEL CRUSH BOLD SUBSTANTIAL EQUIVALENCE REPORT, VANTAGE TECH 13 SE REPORT, PALL MALL DEEP SET FILTER MENTHOL SE REPORT
2016-647	01/25/2016 02/23/2016	FDA/OMPT/CDRH/OCE/DID/	Zsantee Tapley Dysart Law Firm, PC	LAP BAND ADJUSTABLE GASTRIC BANDING DEVICE - APPROVAL RECS
2016-648	01/25/2016 02/23/2016	OC/ORO/ORM/ OC/ORO/ORM/ FDA/OC/OES/DFOI/	Josh Long Natural Products INSIDER/Informa Exhibitions LLC	ATTACHED LETTER
2016-649	01/25/2016 02/23/2016	FDA/OFVM/CFSAN/OCD/EOS/	Jovan Miles Jovan Miles	LIST OF STATE REGISTERED FOOD ESTABLISHMENTS
2016-650	01/25/2016 02/23/2016	OC/ORO/ OC/ORO/	Thomas Wilverding Central Admixture Pharmacy Services, Inc	SAMPLE RESULTS
2016-651	01/25/2016 02/23/2016	OC/ORO/ OC/ORO/	Thomas Wilverding Central Admixture Pharmacy Services, Inc	MEMO ETC RE SAMPLING PROCEDURES FOR INSPECTION AND ENVIRONMENTAL SAMPLING OF COMPOUNDING PHARMACIES AND PRODUCERS OF STERILE PRODUCTS

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2016-652	01/25/2016 02/23/2016	FDA/OFVM/CFSAN/OCD/EOS/	Jovan Miles Jovan Miles	LIST OF MEDICAL FOOD AND DIETARY SUPPLEMENT MANUFACTURERS
2016-653	01/25/2016 09/14/2016	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/	Jeremy Singer-Vine Buzzfeed News	OASIS database and record layouts
2016-654	01/25/2016 02/23/2016	FDA/OMPT/CDRH/OCE/DID/	Gary Syring Quality and Regulatory Associates, LLC	K990565
2016-655	01/25/2016 02/23/2016	FDA/OMPT/CDRH/OCE/DID/	Gary Syring Quality and Regulatory Associates, LLC	K030611
2016-656	01/25/2016 02/23/2016	FDA/OMPT/CDRH/OCE/DID/	Gary Syring Quality and Regulatory Associates, LLC	K061996
2016-657	01/25/2016 02/23/2016	FDA/OC/OES/DFOI/	Joel Kurth The Detroit News	MEDICAL DEVICE ADVERSE EVENTS
2016-658	01/26/2016 02/24/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	VAERS DIRECT REPORTS, MEDWATCH REPORTS and ANY SOURCE DOCUMENTS for THE FOLLOWING ONE (1) CASE, VAERS ID 10823530 for Gardasil
2016-659	01/26/2016 02/24/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	VAERS DIRECT REPORTS, MEDWATCH REPORTS and ANY SOURCE DOCUMENTS for THE FOLLOWING ONE (1) CASE, VAERS ID 10880763 for GRASSTEK
2016-660	01/26/2016 02/24/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	DIRECT REPORTS, MEDWATCH REPORTS and ANY SOURCE DOCUMENTS 10729093; 10742251; 10759177; 10789092; 10878777 DULERA
2016-661	01/26/2016 02/24/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Raj a Agnihotram Fresenius Kabi USA, LLC	ANDA 078319
2016-662	01/26/2016	OC/CVM/OCD/	Susan Maze	NADA 131675

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	02/24/2016		MATHESON KEYS & KORDZIK PLLC	
2016-663	01/26/2016 02/24/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	DIRECT REPORTS, MEDWATCH REPORTS and ANY SOURCE DOCUMENTS 10784352; 10866464; 10883055; ETC
2016-664	01/26/2016 02/24/2016	FDA/OMPT/CDRH/OCE/DID/	Sweta Patel BIO-RAD LABORATORIES, INC.	K031539
2016-665	01/26/2016 02/24/2016	FDA/OMPT/CDRH/OCE/DID/	Brian Carter Black Duck Software, Inc.	REGISTRATION LIST FOR PUBLIC WORKSHOP COLLABORATIVE APPROACHES TO MEDICAL DEVICE CYBERSECURITY 01/20/2016
2016-666	01/26/2016 02/24/2016	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Matt Sanctis Springfield News-Sun	DOLE, SPRINGFIELD, OH - INSPECTION RECS 01/03/2011 - 01/15/2016
2016-667	01/26/2016 02/24/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	DIRECT REPORTS, MEDWATCH REPORTS and ANY SOURCE DOCUMENTS 10736257; 10742622; 10742622; ETC
2016-668	01/26/2016 02/24/2016	OC/ORACE/ OC/ORACE/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Nicole Dove Summit Medical	COMPLAINT 142208 RECS
2016-669	01/26/2016 02/24/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K140911
2016-670	01/26/2016 02/24/2016	FDA/OFVM/CFSAN/OCD/EOS/	Steve Myers Natural Products Insider	NDIN 881
2016-671	01/26/2016 02/24/2016	FDA/OO/OFBA/OAGS/	nicholas fleischer FLEISCHER, NICHOLAS M	U01FD005266
2016-672	01/26/2016 02/24/2016	FDA/OMPT/CDRH/OCE/DID/	Andrew Harvey Weill Cornell Medicine	K042065
2016-673	01/26/2016 02/24/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	DIRECT REPORTS, MEDWATCH REPORTS and ANY SOURCE DOCUMENTS 10789757; 10912896
2016-674	01/26/2016	FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16)	DIRECT REPORTS, MEDWATCH REPORTS SOURCE DOCUMENTS 10758225; 10758377

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	02/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MERCK & CO., INC.	
2016-675	01/26/2016 02/24/2016	FDA/OC/OES/DDM/	Andrea Hilbert CBS NEWS	Neurological Devices Panel Transcript 01/27/2011 - 01/28/2011
2016-676	01/26/2016 02/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	William Vaughn McCall MEDICAL COLLEGE OF GEORGIA	TEMAZEPAM, GUAZEPAM, ESTAZOLAM - AERS
2016-677	01/26/2016 02/24/2016	FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/	Eric Evans Orchard View Capital Advisors LP	DPT LABORATORIES, SAN ANTONIO, TX - 483, EIR 01/01/2010 - 01/25/2016
2016-678	01/26/2016 02/24/2016	FDA/OC/OES/DFOI/ FDA/OGROP/ORACE-FO/DET- DO/DET-CB/ FDA/OGROP/ORACE-FO/MIN- DO/MIN-CB/ FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORACE-FO/PHI- DO/PHI-CB/ FDA/OGROP/ORAPA-FO/SAN- DO/SAN-CB/ FDA/OGROP/ORASE-FO/NOL- DO/NOL-CB/ FDA/OGROP/ORASW-FO/KAN- DO/KAN-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCE/DID/	Logan Greenberg Unglesby & Williams LLC	BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER ESSURE INC ETC - 483, WARNING LETTERS 01/06/2012 - 01/22/2016
2016-679	01/26/2016 02/24/2016	OC/CVM/OCD/	Sandra O'Kelley Merial Inc	NADA 098-379
2016-680	01/26/2016 02/24/2016	FDA/OMPT/OSMP/OOPD/	Lynn E. Bayless Voyager Therapeutics, Inc.	DUOPA - ORPHAN DRUG DESIGNATION RECS

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2016-681	01/26/2016 02/24/2016	FDA/OMPT/CDRH/OCE/DID/	Margaret Klippel STRYKER ORTHOPAEDICS	P960047
2016-682	01/26/2016 02/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Patricia Lilagan Axar Pharmaceuticals, Inc.	NDA 021924
2016-683	01/26/2016 02/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Amy Stanton AMGEN INC.	HIKAK LTD, INDIA - 483, RESPONSE 09/10/2012 - 09/13/2012
2016-684	01/26/2016 02/24/2016	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Cartic Ramakrishnan IBM	PREVIOUSLY RELEASED ADVERSE EVENTS FOR DRUGS 12/29/2015 - 01/20/2016
2016-685	01/26/2016 02/24/2016	FDA/OMPT/CDRH/OCE/DID/	tony bartsh PARK WEST ASSET MANAGEMENT LLC	SIENTRA THIRD PARTY TESTING DATA AND REPORT 01/01/2012 - 12/31/2015
2016-686	01/26/2016 02/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Amy Stanton AMGEN INC.	HIKAL LTD, INDIA - 483, RESPONSE 03/01/2004 - 04/11/2014
2016-687	01/26/2016 02/24/2016	FDA/OMPT/CDRH/OCE/DID/	Jonathan Demchick Morgan Stanley Research	CORR BETWEEN FDA AND INTUITIVE SURGICAL, DLR, SRI INTERNATIONAL RE ROBOTICS DEVELOPMENTS AND APPROVALS 01/01/2014 - 01/25/2016
2016-688	01/27/2016 02/25/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-9596
2016-689	01/27/2016 02/25/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-9598
2016-690	01/27/2016 02/25/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-10118
2016-691	01/27/2016 02/25/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-9753
2016-692	01/27/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2015-9598

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	02/25/2016		MERCK & CO., INC.	
2016-693	01/27/2016 02/25/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-9756
2016-694	01/27/2016 02/25/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-10149
2016-695	01/27/2016 02/25/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-9864
2016-696	01/27/2016 02/25/2016	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	List of FOIA requests for Essure P020014
2016-697	01/27/2016 02/25/2016	OC/ORO/ OC/ORO/	Elsie Nolan WBZ-TV	NABISCO - CONSUMER COMPLAINTS RE STRONG CHEMICAL ODOR 01/01/2012 - 01/23/2016
2016-698	01/27/2016 02/25/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Katherine Eban Katherine Eban	INDUSTRIAS QUIMICAS FALCON DE MEXICO SA DE CV (DR REDDYS) - EIR 02/01/2010 - 01/06/2014
2016-699	01/27/2016 02/25/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/ OC/CVM/OCD/	Sandra O'Kelley Merial Inc	NADA 136742 CURATREM
2016-700	01/27/2016 02/25/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jane Talkington OKLAHOMA STATE UNIVERSITY	BOTOX REPORTS 8415511, 10663394, 10649147, ETC
2016-701	01/27/2016 02/25/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jane Talkington OKLAHOMA STATE UNIVERSITY	BOTOX REPORTS 41937754, 6110312, 7556274, ETC
2016-702	01/27/2016 02/25/2016	FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/	Charlyann Duffy RESPIRE MEDICAL	RESPIRE MEDICAL, BROOKLYN, NY - EIR 01/16/2014 - 01/16/2014
2016-703	01/27/2016 02/25/2016	FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/	Sylvia L.Johnson Regulatory Representative for PharmaTech	PHARMATECH LLC, DAVIE, FL- EIR UNREDACTED 01/12/2012 - 01/24/2012

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			PharmaTech LLC	
2016-704	01/27/2016 02/25/2016	FDA/OMPT/CDRH/OCE/DID/	Jaclyn Docs Acuitive Technologies	K140625
2016-705	01/27/2016 02/25/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K143513
2016-706	01/27/2016 02/25/2016	FDA/OMPT/CDRH/OCE/DID/	Jaclyn Docs Acuitive Technologies	K031712
2016-707	01/27/2016 02/25/2016	FDA/OMPT/CDRH/OCE/DID/	Jaclyn Docs Acuitive Technologies	K990291
2016-708	01/27/2016 02/25/2016	FDA/OMPT/CDRH/OCE/DID/	Jaclyn Docs Acuitive Technologies	K111077
2016-709	01/27/2016 02/25/2016	FDA/OMPT/CDRH/OCE/DID/	Jaclyn Docs Acuitive Technologies	K964970
2016-710	01/27/2016 02/25/2016	FDA/OMPT/CDRH/OCE/DID/	Jaclyn Docs Acuitive Technologies	K961608
2016-711	01/27/2016 02/25/2016	FDA/OMPT/CDRH/OCE/DID/	Jaclyn Docs Acuitive Technologies	K133950
2016-712	01/27/2016 02/25/2016	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Walter Mason GOODIER COSMETICS INC	GOODIER COSMETICS, DALLAS, TX - PHOTOS FROM INSPECTION 10/05/2015 - 10/08/2015
2016-713	01/27/2016 02/25/2016	FDA/OMPT/CDRH/OCE/DID/	Jaclyn Docs Acuitive Technologies	K050275
2016-714	01/27/2016 02/25/2016	FDA/OMPT/CDRH/OCE/DID/	Jaclyn Docs Acuitive Technologies	510(k) Submission: Takiron "Osteotrans-OT Pin"
2016-715	01/27/2016 02/25/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Erin Kelm Fuld + Company	BCN PEPTIDES - EIR JAN 2015
2016-716	01/27/2016 02/25/2016	FDA/OGROP/ORASW-FO/MIN-DO/MIN-CB/ FDA/OMPT/CDRH/OCE/DID/	J. Rodney Mills Baldor Electric Company	Z-1825-2015
2016-717	01/27/2016 02/25/2016	FDA/OFVM/CFSAN/OCD/EOS/ OC/CVM/OCD/	Carey Gillam U.S. Right to Know	RECS RECEIVED BY FDA FROM EPA, USDA, MONSANTO, RUTGERS RE TESTING FOOD OR GRAINS FOR GLYPHOSATE RESIDUES
2016-718	01/27/2016	FDA/OMPT/CBER/OCOD/DDOM/	Patrick Kelly	VAERS RECS

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	02/25/2016	ALFB/	Conway, Homer & Chin-Caplan, PC	
2016-719	01/27/2016 02/25/2016	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/MIN- DO/MIN-CB/	Doe J	INDIVIDUAL RECS
2016-720	01/27/2016 02/25/2016	FDA/OMPT/CDRH/OCE/DID/	Hidetoshi Kabeya TSK Laboratory, Japan	K073122
2016-721	01/27/2016 02/25/2016	FDA/OGROP/ORO/CE-FO/BLT- DO/BLT-CB/	Debashis Mohanty LUPIN PHARMACEUTICALS INC	LUPIN PHARMACEUTICALS, INC, BALTIMORE, MD - 483 01/03/2000 - 01/26/2016
2016-722	01/27/2016 02/25/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORO/ OC/ORO/	Rosemary Gibson THE HASTINGS CENTER	CDER ALERT RE POTENTIAL CONTAMINATION OF DRUG SHIPMENTS FROM EXPLOSIONS IN TIANJIN CITY - LIST OF 40 CONTAMINANTS IDENTIFIED AT BLAST SITE
2016-723	01/27/2016 02/25/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Benjamin Lampson DANA FARBER CANCER INSTITUTE	10470277, 10755274, 10793250, ETC
2016-724	01/27/2016 02/25/2016	FDA/OGROP/ORO/CE-FO/CIN- DO/CIN-CB/	Ana Panyko Halo Pharmaceutical, Inc.	AVANTOR PERFORMANCE MATERIALS, PARIS, KY - 483, RESPONSE 07/13/2015 - 07/20/2015
2016-725	01/28/2016 02/26/2016	FDA/OGROP/ORO/SE-FO/FLA- DO/FLA-CB/	Alexandra Ajmo LIFE EXTENSION	PURE SOURCE INC, MIAMI, FL - EIR 01/01/2013 - 01/27/2016s;
2016-726	01/28/2016 02/26/2016	FDA/OC/OES/DFOI/	Jaime Vassallo CourtLink Document Retrieval	2015-6590
2016-727	01/28/2016 02/26/2016	FDA/OC/OES/DFOI/	Jaime Vassallo CourtLink Document Retrieval	2016-522
2016-728	01/29/2016 02/29/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K101077
2016-729	01/29/2016 02/29/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K124031
2016-730	01/29/2016 02/29/2016	FDA/OFVM/CFSAN/OCD/EOS/	Simplot J.R. Simplot Company	BNF 000146 SCIENTIFIC MEMOS

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2016-731	01/29/2016 02/29/2016	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	Christopher Markos Markos, Christopher	SAGE PRODUCTS, LLC, CARY, IL - EIR 12/01/2013 - 01/31/2014
2016-732	01/29/2016 02/29/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K142310
2016-733	02/01/2016 03/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WILLIAM MCINTYRE PHD LUPIN PHARMACEUTICALS INC	GLAXOSMITHKLINE - BACTROBAN (MUPIROCIN CALCIUM) CREAM 2% NDA 50-746 SBA
2016-734	02/01/2016 03/01/2016	FDA/OMPT/OSMP/OOPD/	ELENA HOWELL Hogan Lovells, ILP	SANOFI-AVENTIS US INC - OFORTA (FLUDARABINE PHOSPHATE ORAL TABS ORPHAN DRUG DESIGNATION,CORR, FINAL DECISION MEMO, ETC
2016-735	02/01/2016 03/01/2016	FDA/OMPT/OSMP/OOPD/	ELENA HOWELL Hogan Lovells, ILP	RAXALTRA US INC - RIXUBIS (COAGULATION FACTOR IX RECOMBINANT) ORPHAN DRUG DESIGNATION, CORR, DECISION MEMO, ETC
2016-736	02/01/2016 03/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KATE REYNOLDS MPH ROCKY MOUNTAIN POISON & DRUG CENTER	ACETAMINOPHEN PREPARATIONS - ISRS 6959752, 6959806, 7418329, ETC
2016-737	02/01/2016 03/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KATE REYNOLDS MPH ROCKY MOUNTAIN POISON & DRUG CENTER	COUGH AND COLD PREPARATIONS - ISRS 9868992, 10067528, 10383034, ETC
2016-738	02/01/2016 03/01/2016	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	LARRY FREEDMAN CLARION BRANDS LLC	HUMCO HOLDING GROUP INC, TEXARKANA, TX - EIR, FDA RESP TO HUMCO'S RESP TO 483 6/25/15-7/1/15
2016-739	02/01/2016 03/01/2016	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OMPT/CDRH/OCE/DID/	CARRIE SHUFFLEBARGER THOMPSON HINE LLP	MEDSHARE INC, MEDICAL AESTHETICS SEMINARS LLC, JAMES FALLER, ETC - INVESTIGATIONS CORR, CMLPNTS, ETC 1/13 TO PRESENT
2016-740	02/01/2016 03/01/2016	FDA/OMPT/CDRH/OCE/DID/	MEGAN C LAMBERT K&L GATES	OLYMPUS DUODENOSCOPE MODEL TJF-Q180V K143153
2016-741	02/01/2016 03/01/2016	FDA/OC/OES/DFOI/	MITZI NG CLARK Keller and Heckman LLP	1-HYDROXYETHANE 1,1-DIPHOSPHONIC ACID - TOXICOLOGY, CHEMISTRY RVW MEMOS
2016-742	02/01/2016 03/01/2016	FDA/OMPT/CDRH/OCE/DID/	LILIANA CESAR DVM TRANSLATIONAL, TESTING AND TRAINING LABORATORIES INC	BOSTON SCIENTIFIC - BLAZER II XP CARDIAC ABLATION CATHETER P920047/S044; BLAZER II & BLAZER PRIME HTD CATHETERS P290047/S046
2016-743	02/01/2016	FDA/OMPT/CBER/OCOD/DDOM/	SCOTT M LASSMAN	HERPES ZOSTER, SHINGLES - GUIDANCE RELATED TO

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	03/10/2016	ALFB/	Kleinfeld, Kaplan & Becker LLP	DISEASE AWARENESS ADVERTISEMENTS, CORR, MTG MINS, ETC
2016-744	02/01/2016 03/01/2016	FDA/OMPT/CTP/OD/	JOHN TOZZI Bloomberg Businessweek	E-CIGARETTES - COMM BTWN FDA AND CDC
2016-745	02/01/2016 03/01/2016	FDA/OC/OES/DFOI/	ANTHONY A ORLANDI Branstetter, Stranch and Jennings, PLLC	MAIN STREET FAMILY PHARMACY LLC - INVESTIGATION, RECALL RECS 2013
2016-746	02/01/2016 04/06/2016	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAP/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	FRED A FREDERICK VERICLAIM INC	KAROUN DAIRIES INC - LISTERIOSIS OUTBREAK INVESTIGATION RECS, MTG ECS, CORR, ETC
2016-747	02/01/2016 03/01/2016	FDA/OMPT/CDRH/OCE/DID/	MURIEL CARRINGTON MERIDIAN BIOSCIENCE INC	ALERE SCARBOROUGH INC - ALERE I STREP A K141757
2016-748	02/01/2016 03/01/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OGROP/ORAP/SE-FO/NOL-DO/NOL-CB/	KURT R WEBER WEBER, KURT ROLAND	DCI DONOR SERVICES, TISSUE SERVICES DIV, NASHVILLE, TN - RECALL B-0240-16 RECS
2016-749	02/01/2016 03/31/2016	FDA/OC/OES/DDM/	BARRY JOSEPH JOSEPH, BARRY	DKT 1980N-0439
2016-750	02/01/2016 03/01/2016	OC/ORAP/OCI/ OC/ORAP/OCI/	Doe J	INDIVIDUAL RECS
2016-751	02/01/2016 03/04/2016	OC/ORAP/OCI/ OC/ORAP/OCI/	Doe J	INDIVIDUAL RECS
2016-752	02/01/2016 03/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angela Volpe IDT Australia Limited	ANDA 085370
2016-753	02/01/2016 03/01/2016	FDA/OMPT/CDRH/OCE/DID/	Ann Morrison Ann Morrison	2011 FDA report of Depuy Pinnacle Metal Liners made in Leeds,UK
2016-754	02/01/2016 03/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angela Volpe IDT Australia Limited	ANDA 087781

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2016-755	02/01/2016 03/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Prashanth Jayaram Prashanth Jayaram	XTANDI - AERS
2016-756	02/01/2016 03/01/2016	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kendrick Luse EverPoint Asset Management	TECFIDERA - AERS, FOIA REQUESTS
2016-757	02/01/2016 03/01/2016	FDA/OMPT/CDRH/OCE/DID/	Jane Bentley ALCON LABORATORIES	CIBA VISION GMBH, GERMANY - EIR 07/27/2015 - 07/30/2015
2016-758	02/01/2016 03/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anup Patel Alvogen Pine Brook LLC	NDA 207932
2016-759	02/01/2016 03/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jeffrey A. Wolfson Strides Arcolab Limited	ONCO THERAPIES LIMITED INDIA - 483 8/8/14 ETC
2016-760	02/01/2016 03/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kristi Smedley Center for Regulatory Services Inc.	HAUPT PHARMA, GMBM - EIR 2/1/14 TO PRESENT
2016-761	02/01/2016 03/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kristi Smedley Center for Regulatory Services Inc.	HAUPT PHARMA GHBH - 483 2/1/14 TO PRESENT
2016-762	02/01/2016 03/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RegCon Solutions LLC REGCON Solutions LLC	ANDA 090862
2016-763	02/01/2016 03/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Caitlin Dugdale Caitlin Dugdale	NIVOLUMAB - AERS

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2016-764	02/01/2016 03/01/2016	FDA/OMPT/CDRH/OCE/DID/	Jane Bentley ALCON LABORATORIES	WAVELIGHT GMBH, GERMANY - EIR 09/07/2015 - 09/11/2015
2016-765	02/01/2016 03/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCE/DID/	Jane Bentley ALCON LABORATORIES	ALCON LABORATORIES IRELAND LTD, IRELAND - EIR 01/12/2015 - 01/15/2015
2016-766	02/01/2016 03/01/2016	OC/CVM/OCD/	ED KANE PHD KANE PhD, ED	REMOVAL OF VITAMIN E FROM VITAMINS A AND D IN INJECTABLE PROD LABELS FOR LIVESTOCK
2016-767	02/01/2016 03/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Narratives for four mesenteric panniculitis cases NovoNordisk A/S	LIRAGLUTIDE 10979169; 9718932; 8884703; ETC
2016-768	02/01/2016 03/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCE/DID/	Roya Naghi Naghi, Roya	Botox, Restalyne, Belatore - ingredients
2016-769	02/01/2016 03/01/2016	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/	Patricia Jimenez REF: Entry # 900-0092759 / 900-0093601-4 Hagroex, S.A.	Empresas Villar LLC - LAB RESULTS, ETC
2016-770	02/01/2016 03/01/2016	FDA/OC/OCS/NCTR/OCD/	Doe J	INDIVIDUAL RECS
2016-771	02/01/2016 03/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Danlei Yan Cerenti Marketing Group	KRYSTEXXA POPULATION SIZE METHODOLOGY
2016-772	02/01/2016 03/01/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Ike Swetlitz STAT	Letter to Sponsors / Researchers - Human Cells Used in Therapy Involving the Transfer of Genetic Material By Means Other Than the Union of Gamete Nuclei - LIST OF RECIPIENTS
2016-773	02/01/2016	FDA/OMPT/CBER/OCOD/DDOM/	Ike Swetlitz	Letter to Sponsors / Researchers - Human Cells Used in Therapy

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	03/01/2016	ALFB/	STAT	Involving the Transfer of Genetic Material By Means Other Than the Union of Gamete Nuclei - RESPONSES
2016-774	02/01/2016 03/01/2016	FDA/OMPT/OSMP/OOPD/	STEPHANIE CHAN THERAVANCE BIOPHARMA US INC	NORTHERA (DROXIDOPA) NDA 203-202 - ORPHAN DRUG DESIGNATION
2016-775	02/01/2016 03/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Beth Regina Actavis LLC	NDA 019430
2016-776	02/01/2016 03/01/2016	FDA/OMPT/CDRH/OCE/DID/	Jaclyn Docs Acuitive Technologies	K07331
2016-777	02/01/2016 03/01/2016	FDA/OMPT/CDRH/OCE/DID/	Idan Geva Butterfly Medical	K130651
2016-778	02/01/2016 03/01/2016	FDA/OFVM/CFSAN/OCD/EOS/	Cathryn Sacra EAS Consulting Group, LLC	New Infant Formula Notification for Earth's Best Organic Formula with Iron New Infant Formula Notification for Earth's Best Sensitivity Organic Formula with Iron
2016-779	02/01/2016 03/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WILLIAM MCINTYRE PHD LUPIN PHARMACEUTICALS INC	GLAXOSMITHKLINE - BACTROBAN (MUPIROCIN) OINTMENT 2% DNA 50-591 SBA, NDA RVW
2016-780	02/01/2016 03/01/2016	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCE/DID/	William J Cahill Terumo Medical Corporation	CTP1500543, 2015-6608
2016-781	02/01/2016 03/01/2016	FDA/OMPT/CDRH/OCE/DID/	Gary Syring Quality and Regulatory Associates, LLC	K133348
2016-782	02/01/2016 03/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Brittany Freeman KMGH-TV	PARAGARD 7822842, 7836665, 8086542, ETC
2016-783	02/01/2016 03/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WILLIAM MCINTYRE PHD LUPIN PHARMACEUTICALS INC	GLAXOSMITHKLINE - BACTROBAN (MUPIROCIN CALCIUM) NASAN OINTMENT 2% NDA 50-703 SBA, NDA RVW
2016-784	02/01/2016 03/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Riley John Steptoe & Johnson LLP	POLOXALENE - AERS

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/CVM/OCD/		
2016-785	02/01/2016 03/01/2016	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/ FDA/OC/OES/DFOI/	LESLIE RAMSEY FDA NEWS	ILLUMINA INC, SAN DIEGO, CA 8/28/15, 11/18/03; HAYWARD, CA 5/18/07 - 483S
2016-786	02/01/2016 03/01/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tushar Manudhane Indianivesh securities	WOCKHARDT, SHENDRA INDIA - 483 11/03/2015 - 01/28/2016
2016-787	02/01/2016 03/01/2016	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	Anthony LaViola Pharmobedient Consulting, LLC	HI-TECH PHARMACAL, AMITYVILLE, NY - EIR 01/06/2012 - 01/28/2016
2016-788	02/01/2016 03/01/2016	FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/	LESLIE RAMSEY FDA NEWS	MOLDED PRODUCTS INC, HARLAN, IA - 483S 3/26/09, 2/14/13
2016-789	02/01/2016 03/01/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dr. Eckhard Milsmann Dr. Eckhard Milsmann	ZHEJIANG HISOAR PHARMACEUTICAL WAISHA - 483 07/01/2015 - 01/01/2016
2016-790	02/01/2016 03/01/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Robert Gilliam Decade Capital Management LLC	XIAFLEX - AERS
2016-791	02/01/2016 03/01/2016	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/ FDA/OC/OES/DFOI/	Paul Knoepfler Paul Knoepfler/UC Davis School of Medicine	MIAMI STEM CELL TREATMENT CENTER, THOMAS A GIONIS - INSPECTION CORR, 483 01/02/2015 - 01/28/2016
2016-792	02/01/2016 03/01/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MATTHEW TREVINO TREVINO, MATTHEW	RISPERDAL (RISPERIDONE) - AERS
2016-793	02/01/2016 03/01/2016	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	Tina Mehr, Esq. Marlin & Saltzman LLP	PRIVATE LABEL NUTRACEUTICALS LLC d/b/a MRITZMAYER LABORATORIES - INVESTIGATION RECS 01/02/2012 - 01/29/2016

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2016-794	02/02/2016 03/02/2016	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	ALAN KNUTSEN, CARDINAL GLENNON MEDICAL CENTER, ST LOUIS, MO - EIR, 483, RESPONSE 06/23/2015 - 06/29/2015
2016-795	02/02/2016 03/02/2016	OC/ORAS/ OC/ORAS/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	LEITER'S COMPOUNDING, SAN JOSE, CA - EIR, 483, RESPONSE 02/18/2014 - 03/06/2014
2016-796	02/02/2016 03/02/2016	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	KEYSTONE LABORATORIES, MEMPHIS, TN - EIR, 483, RESPONSE 08/12/2013 - 08/15/2013
2016-797	02/02/2016 03/02/2016	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	RICHARD K MCDAVID, JOHNSON CITY, TN - EIR, 483, RESPONSE 06/12/2013 - 06/20/2013
2016-798	02/02/2016 03/02/2016	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	WHITNEY LABS, ORMOND BEACH, FL - EIR, 483, RESPONSE 03/23/2015 - 03/31/2015
2016-799	02/02/2016 03/02/2016	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	PFIZER, NC, SANFORD, INC - EIR, 483, RESPONSE 07/15/2014 - 07/23/2014
2016-800	02/02/2016 03/02/2016	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	ABBVIE RESEARCH BIORESEARCH CENTER, WORCESTER, MA - EIR, 483, RESPONSE 06/01/2015 - 06/11/2015
2016-801	02/02/2016 03/02/2016	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Walter Chalkley THOMSON REUTERS	ACINO PRODUCTS, HAMILTON, NJ - EIR, 483, RESPONSE 01/01/2015 - 01/21/2015
2016-802	02/02/2016 03/02/2016	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	BIOMAT USA, JOLIET, IL - EIR, 483, RESPONSE 09/30/2014 - 01/29/2015
2016-803	02/02/2016 03/02/2016	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Walter Chalkley THOMSON REUTERS	IMPAX LABORATORIES, MIDDLESEX, NJ - EIR, 483, RESPONSE 05/05/2012 - 06/11/2012
2016-804	02/02/2016 03/02/2016	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	CISPHARMA, INC, CRANBURY, NJ - EIR, 483, RESPONSE 03/12/2012 - 04/23/2012
2016-805	02/02/2016 03/02/2016	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	EMEDICUS IRB, BEDFORD, MA - EIR, 483, RESPONSE 09/09/2013 - 09/11/2013
2016-806	02/02/2016 03/02/2016	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Walter Chalkley THOMSON REUTERS	CHARLES RIVER LABORATORIES, WILMINGTON, MA - EIR, 483, RESPONSE 05/29/2014 - 06/12/2014

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			(SCIENTIFIC) SAS	
2016-807	02/02/2016 03/02/2016	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	RICHARD S FINN, MD, LOS ANGELES, CA - EIR, 483, RESPONSE 09/02/2014 - 11/18/2014
2016-808	02/02/2016 03/02/2016	FDA/OMPT/CDRH/OCE/DID/	Sona Manickam MEDTRONIC	K880232
2016-809	02/02/2016 03/02/2016	FDA/OMPT/CDRH/OCE/DID/	Sona Manickam MEDTRONIC	K884309
2016-810	02/02/2016 03/02/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Winnie Aman Sunsey International	BK980027
2016-811	02/02/2016 03/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	pascal besman Pascal Besman	ORKAMBI - AERS
2016-812	02/02/2016 03/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sahil Doshi Saptalis Pharmaceuticals	ANDA 089049
2016-813	02/02/2016 03/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sahil Doshi Saptalis Pharmaceuticals	ANDA 087859
2016-814	02/02/2016 03/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sahil Doshi Saptalis Pharmaceuticals	ANDA 090590
2016-815	02/02/2016 03/02/2016	FDA/OMPT/CDRH/OCE/DID/	Liudmila Zakharova Lattice Biologics	K021792
2016-816	02/02/2016 03/02/2016	FDA/OMPT/CDRH/OCE/DID/ FDA/OC/OES/DFOI/	Chris Turitzin Wink Health Inc.	K002095
2016-817	02/02/2016 03/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	ANDA 200652 SUPPLEMENTAL APPROVAL LETTER

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-818	02/02/2016 03/02/2016	FDA/OMPT/CDRH/OCE/DID/	Amanda Altan Kimberly-Clark Corporation	K151413
2016-819	02/02/2016 03/02/2016	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	Patricia Hillenmeyer AbbVie	PRECISION RESEARCH CENTER, MIAMI LAKES, FL - EIR 03/02/2015 - 07/31/2015
2016-820	02/02/2016 03/02/2016	FDA/OFVM/CFSAN/OCD/EOS/	Dan Paznek ClorDiSys Solutions, Inc.,	FAP4A4408 FAP4A4415
2016-821	02/02/2016 03/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Paola Teegarden Kinex Pharmaceuticals Inc.	GRANISETRON - AERS
2016-822	02/02/2016 03/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ryan Smith Janus Capital Group ATTN: RYAN SMITH	REPATHA, PRALUENT - AERS
2016-823	02/02/2016 03/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joe McCann Slingshot Insights	SUBSYS - AERS
2016-824	02/03/2016 03/03/2016	FDA/OMPT/CDRH/OCE/DID/	Chia Chin Yin JMS Singapore Pte Ltd	JMS SINGAPORE PTE LTD - CLOSE OUT LETTER
2016-825	02/03/2016 03/03/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Abhijit Pangu, B&H Consulting Services, Inc. B&H Consulting Services, Inc.	VUAB PHARMA AS, CZECH REPUBLIC - 483, WARNING LETTER 06/01/2014 - 01/29/2016
2016-826	02/03/2016 03/03/2016	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	Brenda Rigsby Brenda Rigsby	LUNG INSTITUTE - COMPLAINTS, INSPECTION REPORTS 1/01/2014 - 01/29/2016
2016-827	02/03/2016 03/03/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Thomas Sims Baron & Budd, PC	COMMUNICATIONS BETWEEN FDA AND HEALTHCARE PHARMACEUTICALS RE PROPOSED LABEL CHANGE FOR AVELOX 10/01/2003 - 07/31/2004

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-828	02/03/2016 03/03/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ana Koster Lewis & Harrison LLC	LIST OF ACTIVE PHARMACEUTICAL INGREDIENT/BULK INGREDIENT PRODUCTS LISTED WITH FDA FOR ACTIVE CONSTITUENT CHLOROXYLENOL
2016-829	02/03/2016 03/03/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Abhijit Pangu, B&H Consulting Services, Inc. B&H Consulting Services, Inc.	LUPIN LIMITED, INDIA - 483, WARNING LETTER 01/01/2012 - 01/29/2016
2016-830	02/03/2016 03/03/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Abhijit Pangu, B&H Consulting Services, Inc. B&H Consulting Services, Inc.	LUPIN LIMITED, INDIA - 483, WARNING LETTERS 01/01/2012 - 01/29/2016
2016-831	02/03/2016 03/03/2016	FDA/OMPT/CDRH/OCE/DID/	Chia Chin Yin JMS Singapore Pte Ltd	JMS SINGAPORE PTE LTD - EIR 2010
2016-832	02/03/2016 03/03/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Thomas Sims Baron & Budd, PC	COMMUNICATIONS BETWEEN FDA AND BAYER HEALTHCARE RE PROPOSED LABEL CHANGE FOR CIPRO 10/01/2003 - 07/31/2004
2016-833	02/03/2016 03/03/2016	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	Scott Fawcett Carroll Quality Consult, Inc.	I'M A LITTLE TEA CUP CORP, SUNRISE, FL - EIR 12/02/2013 - 04/30/2015
2016-834	02/03/2016 03/03/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Steve N. Caritis, MD Steve N. Caritis, MD	CYTOGAM DATA
2016-835	02/03/2016 03/03/2016	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	Information on 10 Natural American Spirit cigarette products
2016-836	02/03/2016 03/03/2016	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Steve Rogers Zoetis Inc.	XENOBIOTIC LABORATORIES COMPANY, PLAINSBORO, NJ - EIR, 483, 482 03/01/2012 - 01/29/2016
2016-837	02/03/2016 03/03/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kris Christian FDAZILLA	WOCKHARDT LIMITED, INDIA - 483, EIR
2016-838	02/03/2016 03/03/2016	OC/ORA/ORM/ OC/ORA/ORM/	Glen Potvin Quintiles	LIST OF INSPECTIONS DRUGS, BIOLOGICS, DEVICES 01/01/2016 - 01/29/2016

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2016-839	02/03/2016 03/03/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ravi Pamnani Ravi Pamnani	Pre-clinical and clinical data submitted for the approval of Canasa (mesalamine) suppositories
2016-840	02/03/2016 03/03/2016	FDA/OMPT/CDRH/OCE/DID/	Jon Anderson Jon Anderson	AMERICAN MEDICAL ISOTOPE CORPORATION RADIOGEL - CORR, MEETINGS
2016-841	02/03/2016 03/03/2016	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	THOMAS SMITH THOMAS SMITH	LIFEWORCS WELLNESS CENTER, DAVID I MINKOFF, MD, BODYHEALTH.COM LCC, CLEARWATER, FL - COMPLAINTS, INSPECTION RECS 02/2006 - 12/31/2015
2016-842	02/03/2016 03/03/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ravi Pamnani Ravi Pamnani	Pre-clinical and clinical data submitted to FDA for Uceris (budesonide) rectal foam, 2 mg
2016-843	02/03/2016 03/03/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tushar Manudhane Indianivesh securities	AUROBINDO PHARMA, INDIA - 483 01/01/2016 - 01/31/2016
2016-844	02/03/2016 03/03/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Prashant Nair Citigroup Global Markets Private Limited	AUROBINDO PHARM, WOCKHARDT, INDIA - 483 01/04/2016 - 02/01/2016
2016-845	02/03/2016 03/03/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Darshan Mehta ET Now	AUROBINDO PHARMA, INDIA - 483 01/24/2016 - 01/30/2016
2016-846	02/03/2016 03/03/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Hossein Dabiri Hossein Dabiri	DR JEREMY COLE - FORM 1572 01/31/2013 - 01/31/2016
2016-847	02/03/2016 03/03/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 1/1-31/2016
2016-848	02/03/2016 03/03/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	A list of all FOIA requests closed for 1/1-31/2016
2016-849	02/03/2016	FDA/OMPT/CDER/GRP/DIDP/	ANIL SACHDEVA	AMBISOME (AMPHOTERICIN B LIPOSOME) NDA 50-740

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	03/03/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MYLAN INC	
2016-850	02/03/2016 03/03/2016	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	YUNTAKARI WIHARYANTO TAKARI INTERNATIONAL INC	ENTRY NO 349-0973598-6
2016-851	02/03/2016 03/03/2016	FDA/OC/OES/DFOI/	DIANNE L. CHAMBERS Hogan Lovells, ILP	2016-488
2016-852	02/03/2016 03/03/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BEN CAREY NEW YORK TIMES	CORR FROM ELAN CZISLER 1/14 TO PRESENT
2016-853	02/03/2016 03/03/2016	FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/	EDWARD MALNICK DAILY TELEGRAPH NEWSPAPER	EIR CORRESPONDENCE
2016-854	02/03/2016 03/03/2016	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JENNIFER ZACHARY COVINGTON BURLING LLP	CORR BETWEEN FDA & STANDARD HOMEOPATHIC COMPANY 9/8/10 TO PRESENT
2016-855	02/03/2016 03/03/2016	FDA/OC/OES/DFOI/	GEMKOW, CATHERINE	DYNAMIC PET HICKORY SMOKED REAL HAM BONES FOR DOG - CMLPNTS
2016-856	02/03/2016 03/03/2016	OC/ORA/OCI/ OC/ORA/OCI/	SAMANTHA PEDROZA TYLER ALLEN LAW FIRM	INDIVIDUAL RECS
2016-857	02/03/2016 03/03/2016	FDA/OO/OFBA/OAGS/ OC/ORA/OCI/ OC/ORA/OCI/	CAROLYN VERNOLA NISEN & ELLIOTT LLC	ACQUISITION OF CASE MGMT SOFTWARE OR SOFTWARE UPGRADES BY FDA'S OFFICE OF CRIMINAL INVESTIGATIONS - RECS
2016-858	02/03/2016 03/03/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	TROY CARTER MUCKROCK	EMAILS FROM HEINZ FELDMANN, NATIONAL INSTITUTE OF ALLERGY & INFECTIOUS DISEASES, ROCKY MOUNTAIN LABS 9/20/12-10/20/14
2016-859	02/03/2016 03/03/2016	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JODI L. NOFSINGER BERMAN & SIMMONS PA	INDIVIDUAL RECS

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2016-860	02/03/2016 03/03/2016	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/ORA/OCI/ OC/ORA/OCI/	KRISTEN L. BREMER MOORE TONKON TORP LLP	INDIVIDUAL RECS
2016-861	02/03/2016 03/03/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JAMIE BELCASTRO BELMORA LLC	FLANAX - AER
2016-862	02/03/2016 03/03/2016	FDA/OMPT/CDRH/OCE/DID/	KEVIN WALLS REGULATORY INSIGHTS, INC.	CFR 21 PMA
2016-863	02/03/2016 03/03/2016	FDA/OFVM/CFSAN/OCD/EOS/	KEVIN FRIES COSMETIC SAFETY REVIEW	VCRP DATA
2016-864	02/03/2016 03/03/2016	OC/CVM/OCD/	EMILY BARRELL COLORADO STATE UNIVERSITY	FENBENDAZOLE NDA 1977
2016-865	02/04/2016 03/04/2016	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	Keosha Barrett CSL Plasma Inc.	CSL PLASMA INC, MEMPHIS, TN - EIR 1/001/2015 - 01/31/2015
2016-866	02/04/2016 03/04/2016	FDA/OMPT/CDRH/OCE/DID/	Ashley Santos BOSTON SCIENTIFIC	K153088
2016-867	02/04/2016 03/04/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DDM/	Gaurang Gupte Gaurang Gupte	Transcript of Nov 24, 2015 Meeting of the Peripheral and Central Nervous Systems Drugs Advisory Committee
2016-868	02/04/2016 03/04/2016	FDA/OMPT/CDRH/OCE/DID/	Kevin Kleinfeld Fluoresprobe Sciences, LLC.	ARROWS CO, LTD, OSAKA, JAPAN - K871115

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2016-869	02/04/2016 03/04/2016	FDA/OMPT/CDRH/OCE/DID/	Robert H Gregg Institute for Advanced Laser Dentistry	CPT1401 029
2016-870	02/04/2016 03/04/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Erik Bjornson Baxalta US Inc.	BLA 125566/0 SBA
2016-871	02/04/2016 03/04/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jessica Wang NOVARTIS PHARMACEUTICALS CORPORATION	NDA 202570 XALKORI S 014
2016-872	02/04/2016 03/04/2016	FDA/OMPT/CDRH/OCE/DID/	Christopher Shakib Terrell, Hogan & Yegelwel, P.A.	P990074
2016-873	02/04/2016 03/04/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jackson DSouza DSouza, Jackson	WOCKHARDT LIMITED, INDIA - 483 12/01/2015 - 01/20/2016
2016-874	02/04/2016 03/04/2016	OC/ORR/ORM/ OC/ORR/ORM/	Kris Christian FDAZILLA	LIST OF INSPECTIONS 12/30/2015 - 02/01/2016
2016-875	02/04/2016 03/04/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tushar Manudhane Indianivesh securities	SUN PHARMACEUTICALS INDUSTRIES LIMITED - MINUTES OF MEETING WITH FDA 12/03/2015 - 02/01/2016
2016-876	02/04/2016 03/04/2016	FDA/OGROP/ORR/NE-FO/NWE-DO/NWE-CB/	Emily Rapp Patheon Biologics LLC	LONZA BIOLOGICS, PORTSMOUTH, NH - 483 01/01/2009 - 12/31/2013
2016-877	02/04/2016 03/04/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bhagwan Chaudhary National Institute of Securities Markets , Navi Mumbai	AUROBINDO PHARMA, INDIA - 483 01/18/2016 - 01/30/2016

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2016-878	02/04/2016 03/04/2016	FDA/OC/OES/DFOI/	Annie Ksadzhikeyan The Boesch Law Group	ULTIMATE FORMULATIONS INC DBA BEST FORMULATIONS, CITY OF INDUSTRY, CA 01/01/2010 - 02/01/2016
2016-879	02/04/2016 03/04/2016	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Jane Bentley ALCON LABORATORIES	ALCON LABS, LESAGE, WV - EIR 09/25/2012 - 09/26/2012
2016-880	02/04/2016 03/04/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	pascal besman Pascal Besman	INTERFERON GAMMA 1-B - AERS
2016-881	02/04/2016 03/04/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	BLA 125504/S1 & S2
2016-882	02/04/2016 03/04/2016	FDA/OMPT/CDRH/OCE/DID/	Joe Williams Inside Health Policy	GOLDBUG STRATEGIES LLC, SILVER SPRING, MD - MEETING SUMMARY, MATERIALS SHARED 12/18/2015 - 12/18/2015
2016-883	02/04/2016 03/04/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Nedra Lexow UNIVERSITY OF PENNSYLVANIA	METHYPHENIDATE - LABELS NOT AVAILABLE IN APPROVAL HISTORY 12/05/1955 - 08/08/2006
2016-884	02/04/2016 03/04/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lipocine Inc. Lipocine Inc.	TESTOSTERONE REPLACEMENT THERAPY - AERS
2016-885	02/04/2016 03/04/2016	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Jane Bentley ALCON LABORATORIES	ALCON LABS, HUNTINGTON, WV - EIR 02/24/2012 - 02/25/2012
2016-886	02/04/2016 03/04/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Eric Evans Orchard View Capital Advisors LP	PEXIGANAN - MINUTES, CORR, COMPLETE RESPONSE LETTER ETC 02/01/1999 - 02/01/2015
2016-887	02/04/2016 03/04/2016	FDA/OMPT/CDRH/OCE/DID/	Christy Mocny Christy Mocny	K130702
2016-888	02/04/2016 03/04/2016	FDA/OMPT/CDRH/OCE/DID/	Christy Mocny Christy Mocny	K133800

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2016-889	02/04/2016 03/04/2016	FDA/OMPT/CDRH/OCE/DID/	Andrew Valen Impladent Ltd	K100927
2016-890	02/04/2016 03/04/2016	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Nicholas King Rholen Fish, LLC	RECS RE LISTERIA OUTBREAK AT ROME PACKING/OCEAN'S CATCH, EAST PROVIDENCE, RI 01/01/2014 - 02/02/2016
2016-891	02/04/2016 03/04/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michele Sinoway LACHMAN CONSULTANT SERVICES, INC.	BUSHU PHARMACEUTICALS, KAWAGOE-SHI, JAPAN - 483 10/01/2013 - 12/31/2013
2016-892	02/04/2016 03/04/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 201923
2016-893	02/04/2016 03/04/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 22315/S9
2016-894	02/04/2016 03/04/2016	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OC/OES/DFOI/	CHRISTOPHER MORIARTY MOTLEY RICE LLC	HI-TECH PHARMACEUTICALS INC - INVESTIGATION RECS, FASTIN-XR, FASTIN RAPID RELEASE CORR, CMLNPTS, ETC
2016-895	02/04/2016 03/04/2016	FDA/OFVM/CFSAN/OCD/EOS/	SUFYAN ZAFAR MD IOVATE HEALTH SCIENCES INTERNATIONAL INC	HYDROXYCUT, SMARTBURN, CREATINE, ETC - CAERS
2016-896	02/04/2016 03/04/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHELSEA JERRY HOGAN LOVELLS LLP	EIGHT FACTOR ANALYSIS AND RECOMMENDATIONS FOR TRANSFERRING MARIJUANA OUT OF SCHEDULE I OF THE CONTROLLED SUBSTANCES ACT
2016-897	02/04/2016 03/04/2016	OC/ORAE/ OC/ORAE/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORASW-FO/SWID/SWID-CB/	WILLIAM J SENIOR ESQ BENJAMIN L ENGLAND & ASSOCIATES LLC	NARTEX LABORATORIES HOMEOPATICOS SA DE CV - BOS-0058183-8 LAB TEST
2016-898	02/04/2016	FDA/OMPT/CDER/GRP/DIDP/	DAVID M HOFFMEISTER	LIBERTY PHARMS - MILNACIPRAN HCL ANDA 205-071

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	03/04/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WILSON SONSINI ET AL	APRVL LTR
2016-899	02/04/2016 03/04/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RICK TAYLOR BAKER & MCKENZIE	ORANGE BOOK
2016-900	02/04/2016 03/04/2016	FDA/OFVM/CFSAN/OCD/EOS/	YVONNE M FLAHERTY LOCKRIDGE GRINDAL NAUEN PLLP	EGOPHARMA LLC, CONTROLLED LABS, EURPOA SPORTS PRODUCTS INC - BITTER ORANGE, CITRUS AURANTIUM, SYNEPHRINE NEW DIETARY INGREDIENT (NDI) RECS 2005 TO PRESENT
2016-901	02/04/2016 03/04/2016	FDA/OMPT/CDRH/OCE/DID/	NYROBIA FREEMAN CONMED LINVATEC CORP	DEPUY MITEK - HEALIX KNOTLESS ANCHOR K113534
2016-902	02/04/2016 03/04/2016	FDA/OMPT/CDRH/OCE/DID/	NYROBIA FREEMAN CONMED LINVATEC CORP	DEPUY MITEK - HEALIX KNOTLESS ANCHOR K112249
2016-903	02/04/2016 03/04/2016	FDA/OMPT/CDRH/OCE/DID/	NYROBIA FREEMAN CONMED LINVATEC CORP	ATHREX INC - ARTHREX SWIVELOCK ANCHORS K101823
2016-904	02/04/2016 03/04/2016	FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECS
2016-905	02/05/2016 03/07/2016	FDA/OFVM/CFSAN/OCD/EOS/	ANTHONY ROBERTS MUCKROCK	ALL NEW DIETARY INGREDIENT NOTIFICATIONS, SUBMISSIONS, RESPS 2006
2016-906	02/05/2016 03/07/2016	FDA/OFVM/CFSAN/OCD/EOS/	ANTHONY ROBERTS MUCKROCK	ALL NEW DIETARY INGREDIENT NOTIFICATIONS, SUBMISSIONS, RESPS 2002
2016-907	02/05/2016 03/07/2016	FDA/OFVM/CFSAN/OCD/EOS/	ANTHONY ROBERTS MUCKROCK	ALL NEW DIETARY INGREDIENT NOTIFICATIONS, SUBMISSIONS, RESPS 2003
2016-908	02/05/2016 03/07/2016	FDA/OFVM/CFSAN/OCD/EOS/	ANTHONY ROBERTS MUCKROCK	ALL NEW DIETARY INGREDIENT NOTIFICATIONS, SUBMISSIONS, RESPS 1999
2016-909	02/05/2016 03/07/2016	FDA/OC/OES/DFOI/	Arkady Gershteyn Arkady Gershteyn	MINI SENTINEL CSV FORMAT
2016-910	02/05/2016 03/07/2016	FDA/OFVM/CFSAN/OCD/EOS/	ANTHONY ROBERTS MUCKROCK	ALL NEW DIETARY INGREDIENT NOTIFICATIONS, SUBMISSIONS, RESPS
2016-911	02/05/2016 03/07/2016	FDA/OFVM/CFSAN/OCD/EOS/	Morgan Legel Morgan Legel	CHIPOTLE - CORE INVESTIGATION RECS 05/01/2015 - 02/01/2016
2016-912	02/05/2016	FDA/OFVM/CFSAN/OCD/EOS/	ANTHONY ROBERTS	ALL NEW DIETARY INGREDIENT NOTIFICATIONS,

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	03/07/2016		MUCKROCK	SUBMISSIONS, RESPS 1997
2016-913	02/05/2016 03/07/2016	FDA/OFVM/CFSAN/OCD/EOS/	ANTHONY ROBERTS MUCKROCK	ALL NEW DIETARY INGREDIENT NOTIFICATIONS, SUBMISSIONS, RESPS 1996
2016-914	02/05/2016 03/07/2016	FDA/OFVM/CFSAN/OCD/EOS/	ANTHONY ROBERTS MUCKROCK	ALL NEW DIETARY INGREDIENT NOTIFICATIONS, SUBMISSIONS, RESPS 2010
2016-915	02/05/2016 03/07/2016	FDA/OFVM/CFSAN/OCD/EOS/	ANTHONY ROBERTS MUCKROCK	ALL NEW DIETARY INGREDIENT NOTIFICATIONS, SUBMISSIONS, RESPS 2008
2016-916	02/05/2016 03/07/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jaya Subramaniam Econdisc Contracting Solutions LLC	INDOCO REMEDIES, INDIA - 483 01/01/2015 - 02/02/2016
2016-917	02/05/2016 03/07/2016	FDA/OFVM/CFSAN/OCD/EOS/	ANTHONY ROBERTS MUCKROCK	ALL NEW DIETARY INGREDIENT NOTIFICATIONS, SUBMISSIONS, RESPS 2007
2016-918	02/05/2016 03/14/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Sren Truelsen Pharmasphere Consulting	NOVO NORDISK, DENMARK - EIR, 483 10/01/2015 - 12/01/2015
2016-919	02/05/2016 03/07/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Eyal Maor FDAAWARE	DEXCEL PHARMA - 483, RECALL, WARNING LETTERS 02/01/2008 - 02/01/2016
2016-920	02/05/2016 03/07/2016	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	Mathew Fairfax Surgical Technology Laboratories, Inc	SURGICAL TECHNOLOGY LABORATORIES, INC, LUGOFF, SC - EIR 04/09/2014 - 01/25/2016
2016-921	02/05/2016 03/07/2016	FDA/OGROP/ORR/CE-FO/PHI-DO/PHI-CB/	Alexandra Ajmo LIFE EXTENSION	PHYTOGENX, INC, MORGANTOWN, PA - EIR 01/01/2012 - 02/02/2016
2016-922	02/05/2016 03/07/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sriram Nagarajan Sriram Nagarajan	CASE REPORTS 3001194 3025859 ETC
2016-923	02/05/2016 03/07/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jaya Subramaniam Econdisc Contracting Solutions LLC	AUROBINDO PHARMA, INDIA - 483 10/01/2015 - 02/02/2016

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2016-924	02/05/2016 03/07/2016	OC/ORP/ OC/ORP/ FDA/OGROP/ORP/ORO/DIOP/	Zetetic, Inc. Zetetic, Inc.	FDA ENTRY DOCUMENTATION REQUEST ALL DOCUMENTATION JAN 16, 2016 TO JAN 31, 2016
2016-925	02/05/2016 03/07/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Hajra Mazhar Hajra Mazhar (University of Ottawa, Faculty of Science, Department of Biology)	CASE REPORTS 8128477 112486761 4600400 ETC
2016-926	02/05/2016 03/07/2016	FDA/OFVM/CFSAN/OCD/EOS/	ANTHONY ROBERTS MUCKROCK	ALL NEW DIETARY INGREDIENT NOTIFICATIONS, SUBMISSIONS, RESPS 2001
2016-927	02/05/2016 03/07/2016	FDA/OFVM/CFSAN/OCD/EOS/	ANTHONY ROBERTS MUCKROCK	ALL NEW DIETARY INGREDIENT NOTIFICATIONS, SUBMISSIONS, RESPS 2009
2016-928	02/05/2016 03/07/2016	OC/ORP/ OC/ORP/ FDA/OGROP/ORP/ORO/DIOP/	Tyler Shannon Food & Water Watch	DATA RE FISHERY IMPORTS 01/01/2013 - 12/31/2015
2016-929	02/05/2016 03/07/2016	FDA/OFVM/CFSAN/OCD/EOS/	ANTHONY ROBERTS MUCKROCK	ALL NEW DIETARY INGREDIENT NOTIFICATIONS, SUBMISSIONS, RESPS 2011
2016-930	02/05/2016 03/07/2016	FDA/OFVM/CFSAN/OCD/EOS/	ANTHONY ROBERTS MUCKROCK	ALL NEW DIETARY INGREDIENT NOTIFICATIONS, SUBMISSIONS, RESPS 2012
2016-931	02/05/2016 03/07/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jaime Vassallo CourtLink Document Retrieval	GLATOPA, GLATIRAMER ACETATE, COPAXONE - AERS
2016-932	02/05/2016 03/07/2016	FDA/OFVM/CFSAN/OCD/EOS/	ANTHONY ROBERTS MUCKROCK	ALL NEW DIETARY INGREDIENT NOTIFICATIONS, SUBMISSIONS, RESPS 2013
2016-933	02/05/2016 03/07/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Douglas Sawyer Maine Medical Center	MESALALZINE, SUFASALAZINE - AERS
2016-934	02/05/2016 03/07/2016	FDA/OFVM/CFSAN/OCD/EOS/	ANTHONY ROBERTS MUCKROCK	ALL NEW DIETARY INGREDIENT NOTIFICATIONS, SUBMISSIONS, RESPS 2014
2016-935	02/05/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson	K980448

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	03/07/2016		FOI Services, Inc.	
2016-936	02/05/2016 03/07/2016	FDA/OFVM/CFSAN/OCD/EOS/	ANTHONY ROBERTS MUCKROCK	ALL NEW DIETARY INGREDIENT NOTIFICATIONS, SUBMISSIONS, RESPS 2015
2016-937	02/05/2016 03/07/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dheeresh Pathak Dheeresh Pathak	AUROBINDO PHARMA, INDIA - 483 01/01/2016 - 02/02/2016
2016-938	02/05/2016 03/07/2016	FDA/OFVM/CFSAN/OCD/EOS/	ANTHONY ROBERTS MUCKROCK	ALL NEW DIETARY INGREDIENT NOTIFICATIONS, SUBMISSIONS, RESPS 2005
2016-939	02/05/2016 03/07/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bhagwan Chaudhary National Institute of Securities Markets , Navi Mumbai	SHILPA MEDICARE LTD, INDIA - EIR 11/02/2015 - 02/02/2016
2016-940	02/05/2016 03/07/2016	FDA/OFVM/CFSAN/OCD/EOS/	ANTHONY ROBERTS MUCKROCK	ALL NEW DIETARY INGREDIENT NOTIFICATIONS, SUBMISSIONS, RESPS 2000
2016-941	02/05/2016 03/07/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Maurice Raycroft JEFFERIES & CO	NCT02117479 SPECIAL PROTOCOL ASSESSMENT
2016-942	02/05/2016 03/07/2016	OC/ORO/ OC/ORO/	JANET F. CANEDO FLAWLESS BEAUTY & SKIN	METHODS FOR CONDUCTING RECALL EFFECTIVENESS CHECKS
2016-943	02/05/2016 03/07/2016	FDA/OMPT/CDRH/OCE/DID/	Carolyn Johnson WASHINGTON POST	EMAILS FROM LTC DAVID SCHOEMAKER TO DR SALLY HOJVAT RE THERANOS, REGULATORY STRATEGY 06/01/2012 - 06/01/2013
2016-944	02/05/2016 03/07/2016	FDA/OGROP/ORO/CE-FO/PHI-DO/PHI-CB/	Christina Bernstein FOI Norian Synthes BB Medical Surgical	NORIAN SYNTHES, PA - 483 01/01/2001 - 12/31/2005
2016-945	02/05/2016 03/07/2016	FDA/OGROP/ORO/CE-FO/CIN-DO/CIN-CB/	Amie N. Vanella FAEGRE BAKER DANIELS	DOLE, SPRINGFIELD, OH - TESTING RECS RE SALAD LISTERIA OUTBREAK 09/01/2015 - 02/02/2016
2016-946	02/05/2016 03/07/2016	FDA/OFVM/CFSAN/OCD/EOS/	Laura McWilliams EXPONENT, INC.	CAP2C0297; CAP4C0300; CAP 5C0301
2016-947	02/05/2016 03/07/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Catherine Lindsay Catherine Lindsay	ACTION LETTERS RE NEW OPIOID DRUGS APPROVED WITHOUT ADVISORY COMMITTEE ETC 01/01/2013 - 02/02/2016

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2016-948	02/05/2016 03/07/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Donna Bitzelberger VENABLE LLP	APPROVAL LETTER - CERTIFIED
2016-949	02/05/2016 03/07/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Poornaa Venkatesan Jefferies India Pvt Ltd	AUROBINDO PHARMA, INDIA - 483 01/14/2016 - 02/02/2016
2016-950	02/05/2016 03/07/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHRISTINE N. SANG, MD BRIGHAM & WOMEN'S HOSPITAL	HALOTHANE APRVL 1958
2016-951	02/05/2016 03/07/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Donna Bitzelberger VENABLE LLP	APPROVAL LETTER - CERTIFIED
2016-952	02/05/2016 03/07/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCE/DID/	Brian Snyder Snyder & Wenner, P.C.	CALDERA - PACKAGE INSERT, APPROVAL RECS
2016-953	02/05/2016 03/07/2016	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Robert Lopez, RN, CRC, Quality Assurance Officer Alas Science Clinical Research	RUBIN H SAAVEDRA, MD, LAS VEGAS, NV - 483 04/01/2011 - 07/31/2011
2016-954	02/05/2016 03/07/2016	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	Carla Morrow LLOYD, Inc.	NEOGEN CORPORATION, LEXINGTON, KY - 483 01/01/2013 - 02/03/2016=
2016-955	02/05/2016 03/07/2016	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	HENRY F. BAYARD COLE SCOTT AND KISSANE	UNITED STATES BLOOD BANK INC - INVESTIGATION 7/1/14 TO PRESENT
2016-956	02/05/2016 03/07/2016	FDA/OMPT/CDRH/OCE/DID/	Christy Mocny Christy Mocny	K112728
2016-957	02/05/2016	FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson	BLA 125057 Supp 381

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	03/07/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FOI Services, Inc.	
2016-958	02/05/2016 03/07/2016	FDA/OMPT/CDRH/OCE/DID/	Christy Mocny Christy Mocny	K062716
2016-959	02/05/2016 03/07/2016	FDA/OMPT/CDRH/OCE/DID/	Zeinab Schwen Strategic Regulatory Consulting	K130393
2016-960	02/05/2016 03/07/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joshua Sharlin Joshua Sharlin	NDA 20449 WARNING LETTER CORR
2016-961	02/05/2016 03/21/2016	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	ABI DOCUMENT SUPPORT SERVICES	IMMUNOSCIENCE RECS
2016-962	02/05/2016 03/07/2016	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CDRH/OCE/DID/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Melissa Machado HAYNES AND BOONE, LLP	CORR BETWEEN FDA AND OXYSURE, 483 01/01/2008 - 02/02/2016
2016-963	02/05/2016 03/07/2016	FDA/OMPT/CDRH/OCE/DID/	Christy Mocny Christy Mocny	K052732
2016-964	02/05/2016 03/07/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 20845/S17
2016-965	02/05/2016 03/07/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dr Girish Bakhru HSBC	AUROBINDO PHARMA, INDIA - 483 01/01/2016 - 02/03/2016
2016-966	02/05/2016 03/07/2016	FDA/OMPT/CDRH/OCE/DID/	Christy Mocny Christy Mocny	K033448
2016-967	02/05/2016 03/07/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID M. HOFFMEISTER WILSON SONSINI ET AL	PURDUE PHARMA - FORM 3542 NDA 22-272

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-968	02/05/2016 03/07/2016	FDA/OMPT/CDRH/OCE/DID/	Christy Mocny Christy Mocny	K023830
2016-969	02/05/2016 03/07/2016	OC/ORR/ORM/ OC/ORR/ORM/	Kevin Nious NBC Bay Area News (KNTV)	REPRODUCTIVE TISSUE BANK VIOLATIONS 01/01/2015 - 02/02/2016
2016-970	02/05/2016 03/07/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DDM/	Cindy Hall Baum Hedlund	December 14, 2015 Endocrinologic and Metabolic Drugs Advisory Committee meeting transcript
2016-971	02/05/2016 03/07/2016	FDA/OGROP/ORR/SW-FO/DEN-DO/DEN-CB/	Rachel Johnson FOI Services, Inc.	INFINITY LABS, LITTLETON, CO - EIR
2016-972	02/05/2016 03/07/2016	FDA/OMPT/CDRH/OCE/DID/	Zeinab Schwen Strategic Regulatory Consulting	K081076
2016-973	02/05/2016 03/07/2016	FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/	Steve Kim Grifols Diagnostic Solutions Inc.	HOLOGIC INC, SAN DIEGO, CA - 483 01/11/2016 - 01/22/2016
2016-974	02/05/2016 03/07/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	INOMAX EXCLUSIVITY RECS
2016-975	02/05/2016 03/07/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Debra Webster CARDINAL HEALTH	NDA 206544, SUPPLEMENTAL PHARMACOLOGY/TOXICOLOGY REVIEW, FDA REVIEW OF IDT'S RESPONSE TO THE NONCLINICAL POST-MARKETING REQUIREMENTS
2016-976	02/05/2016 03/07/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 20845 FORMS 3542, 3542a
2016-977	02/05/2016 03/07/2016	FDA/OMPT/CDRH/OCE/DID/	Justin Baker Arteriocyte Inc.	K030774
2016-978	02/05/2016 03/07/2016	FDA/OGROP/ORR/NE-FO/NYK-DO/NYK-DCB/ FDA/OMPT/CDRH/OCE/DID/	JASON B. NEAL FISHER KANARIS PC	AIR SEP CORP - VISIONAIRE OXYGEN CONCENTRATOR INVESTIGATIONS CONSUMER RPTS, CMLPNTS, ETC

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2016-979	02/05/2016 03/07/2016	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ OC/ORA/ OC/ORA/	DONNA CHAMBERLIN LEWIS BRISBOIS ET AL	UNITED JUICE CORP - 2013 HEPATITIS A OUTBREAK
2016-980	02/08/2016 03/08/2016	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Chalkley Walter THOMSON REUTERS (SCIENTIFIC) SAS	VINTAGE PHARMACEUTICALS, CHARLOTTE, NC - EIR, 483, RESPONSE 01/14/2014 - 02/14/2014
2016-981	02/08/2016 03/08/2016	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	MOHAMED A EL-SHAHAWY, MD, LOS ANGELES, CA - EIR, 483, RESPONSE 02/05/2015 - 03/19/2015
2016-982	02/08/2016 03/08/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Colin Wilhelm UNIVERSITY OF NEVADA LAS VEGAS	NDA 019886 Approval Review Submitted 02/13/1990 Supplement Number 000; NDA 019726 Approval Review Submitted 12/29/1989 Supplement Number 000
2016-983	02/08/2016 03/08/2016	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2016-540
2016-984	02/08/2016 03/08/2016	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Reade Levinson The Stanford Daily	UNIVERSITY HEALTHCARE ALLIANCE, MENLO PARK, CA - INSPECTION RECS 02/10/2010 - 02/03/2016
2016-985	02/08/2016 03/08/2016	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	KIRKMAN LABORATORIES, INC, RENO, NV - EIR, 483, RESPONSE 06/03/2015 - 06/24/2015
2016-986	02/08/2016 03/08/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Walter Chalkley THOMSON REUTERS	SANDOZ INTERNATIONAL GMBH, GERMANY - 483 08/12/2014 - 08/28/2014
2016-987	02/08/2016 03/08/2016	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Walter Chalkley THOMSON REUTERS	AAI PHARMA ANALYTICAL SERVICES ST LOUIS INC, AFFTON, MO - EIR, 483, RESPONSE 01/12/2014 - 01/14/2014
2016-988	02/08/2016 03/08/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Walter chalkley THOMSON REUTERS (SCIENTIFIC) SAS	CADILA HEALTHARE LIMITED, INDIA - 483 12/01/2014 - 12/06/2014

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2016-989	02/08/2016 03/08/2016	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	ACINO PRODUCTS, HAMILTON, NJ - EIR, 483, RESPONSE 08/01/2014 - 08/19/2014
2016-990	02/08/2016 03/08/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	CHAN YAT HING MEDICINE FACTORY, HONG KONG - 483 07/06/2015 - 07/08/2015
2016-991	02/08/2016 03/08/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K052168
2016-992	02/08/2016 03/08/2016	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	MONMOUTH MEDICAL CENTER, LONG BRANCH, NJ - EIR, 483, RESPONSE 04/01/2015 - 04/20/2015
2016-993	02/08/2016 03/08/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K150550
2016-994	02/08/2016 03/08/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jaya Ayyagari Dr. Reddy's Laboratories Inc.	DMF 14309
2016-995	02/08/2016 03/08/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jaya Ayyagari Dr. Reddy's Laboratories Inc.	DMF 12341
2016-996	02/08/2016 03/08/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sule Karaman Sule Karaman	NDA 203568 KYNAMRO
2016-997	02/08/2016 03/08/2016	FDA/OMPT/CDRH/OCE/DID/	Brian Brockway Brian Brockway	K093141
2016-998	02/08/2016 03/08/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	BLA 125057 S 280
2016-999	02/08/2016 03/08/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Christina Chow Brookline Advisors	NDA 202439 CLINICAL PHARMCOLOGY REVIEW

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2016-1000	02/08/2016 03/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Meera G Kumar SANOFI	PRALUENT CASE REPORTS 11882162, 11863829, 11831413, ETC
2016-1001	02/08/2016 03/08/2016	FDA/OMPT/CDRH/OCE/DID/	Nahbee Jong TheraNova LLC	K153681
2016-1002	02/08/2016 03/08/2016	FDA/OMPT/CDRH/OCE/DID/	Serena Sanginthirath DJO, LLC	K982830
2016-1003	02/08/2016 03/08/2016	FDA/OC/OES/DFOI/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	FOIA LOG 09/01/2015 - 12/31/2015
2016-1004	02/08/2016 03/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jackson DSouza Jackson DSouza	CIPLA LTD, VERNA, GOA, INDIA - EIR 04/01/2015 - 02/04/2016
2016-1005	02/08/2016 03/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Susan Lee Susan Lee	NDA 9854
2016-1006	02/08/2016 03/08/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-5590
2016-1007	02/08/2016 03/08/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-5646
2016-1008	02/08/2016 03/08/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-5536
2016-1009	02/08/2016 03/08/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-5400
2016-1010	02/08/2016 03/08/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-5403
2016-1011	02/08/2016 03/08/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-5410

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2016-1012	02/08/2016 03/08/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-5411
2016-1013	02/08/2016 03/08/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-5468
2016-1014	02/08/2016 03/08/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-4981
2016-1015	02/08/2016 03/08/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-4981
2016-1016	02/08/2016 03/08/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-4973
2016-1017	02/08/2016 03/08/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-4977
2016-1018	02/08/2016 03/08/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-5002
2016-1019	02/08/2016 03/08/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-5053
2016-1020	02/08/2016 03/08/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-5379
2016-1021	02/08/2016 03/08/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-5399
2016-1022	02/08/2016 03/08/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-5402
2016-1023	02/08/2016 03/08/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-5440
2016-1024	02/08/2016 03/08/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-4589
2016-1025	02/08/2016 03/08/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-4649
2016-1026	02/08/2016 03/08/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-4928
2016-1027	02/08/2016 03/08/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-4930
2016-1028	02/08/2016	FDA/OC/OES/DFOI/		2015-4975

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	03/08/2016		FOI Services, Inc.	
2016-1029	02/08/2016 03/08/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-4976
2016-1030	02/08/2016 03/08/2016	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	InvaGen Pharmaceuticals, Inc. FDA form 483 from May 26, 2015 Vivek Agrawal, HDFC Securities	INVAGEN PHARMACEUTICALS, INC, HAUPPAUGE, NY - EIR, 483 05/01/2015 - 05/31/2015
2016-1031	02/08/2016 03/08/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Gregory Renza JEFFERIES & CO	ORKAMBI CASE REPORTS 11658937 11769562 11727591
2016-1032	02/08/2016 03/08/2016	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Amie N. Vanella Faegre Baker Daniels LLP	DOLE, SPRINGFIELD, OH - 483, EIR 01/01/2011 - 01/31/2016
2016-1033	02/08/2016 03/08/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	William Vaughn McCall MEDICAL COLLEGE OF GEORGIA	TEMAZEPAM - AERS
2016-1034	02/08/2016 03/08/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kumara Sekar KSS Consulting Inc	NDA 208143
2016-1035	02/08/2016 03/08/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jaya Ayyagari Dr. Reddy's Laboratories Inc.	ANDA 076726 SBA
2016-1036	02/08/2016 03/08/2016	OC/ORARM/ OC/ORARM/	Mark Prinz Registrar Corp	INSPECTION CLASSIFICATIONS LIST WITH FEI AND ADDRESS
2016-1037	02/08/2016 03/08/2016	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Seema Kanwal CAPSUGEL	PHARMACEUTICS INTERNATIONAL INC - 483 05/01/2015 - 05/31/2015
2016-1038	02/08/2016 03/08/2016	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Mark Alan Delaney BERMAN DEVALERIO ET AL	CORR WITH HEARTWARE INTERNATIONAL INC RE HVAD SYSTEMS 01/01/2014 - 01/15/2016

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		FDA/OMPT/CDRH/OCE/DID/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/		
2016-1039	02/08/2016 03/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Marie Mannino ROCHE PHARMACEUTICALS	SOLIRIS AERS REPORT 111966842, 97729699
2016-1040	02/08/2016 03/08/2016	FDA/OMPT/CDRH/OCE/DID/	DEAL, JEFFERY	XENEX DISINFECTIONS - INVESTIGATION 11/24/15
2016-1041	02/08/2016 03/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lupin Limited FDA form 483 from Jul 17, 2015 HDFC Securities	LUPIN LIMITED, INDIA - 483 07/01/2015 - 07/31/2015
2016-1042	02/08/2016 03/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nedra Lexow UNIVERSITY OF PENNSYLVANIA	NDA 010187 LABEL RECS
2016-1043	02/08/2016 03/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Cipla Limited FDA form 483 from Aug 07, 2015 HDFC Securities	CIPLA LIMITED, INDIA - 483 08/01/2015 - 08/26/2015
2016-1044	02/08/2016 03/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Paola Teegarden Kinex Pharmaceuticals Inc.	ANDA 078392, ANDA 077963, ANDA 077297ETC
2016-1045	02/08/2016 03/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Yumi Kim Hgstrm Yumi Kim Högström	CIPROFLOXACIN - AERS
2016-1046	02/09/2016 03/09/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Suzanne O'Shea NAVIGANT CONSULTING	BENTONITE ME BABY - TEST RESULTS, MEMOS, COMPLAINTS

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		OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/ FDA/OGROP/ORO/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORO/SW-FO/KAN-DO/KAN-CB/ FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/		
2016-1047	02/09/2016 03/09/2016	FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCE/DID/	Ian Sheffield Bridger Healthcare	CORR BETWEEN ST JUDE MEDICAL AND FDA RE MANUFACTURING ACTIVITIES AND QUALITY SYSTEMS REGULATIONS IN CARDIAC RHYTHM MANAGEMENT DIVISION 01/01/2014 - 02/06/2016
2016-1048	02/09/2016 03/09/2016	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	WARNING LETTER RECS
2016-1049	02/09/2016 03/09/2016	FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/ FDA/OMPT/CDRH/OCE/DID/	Ian Sheffield Bridger Healthcare	CORR BETWEEN ST JUDE MEDICAL AND FDA RE MANUFACTURING AND QUALITY SYSTEM REGULATIONS IN CARDIOMEMS DIVISION 01/01/2014 - 02/06/2016
2016-1050	02/09/2016 03/09/2016	FDA/OGROP/ORO/SE-FO/SJN-DO/SJN-CB/ FDA/OMPT/CDRH/OCE/DID/	Ian Sheffield Bridger Healthcare	CORR BETWEEN ST JUDE MEDICAL AND FDA RE MANUFACTURING AND QUALITY SYSTEM REGULATIONS AT ARECIBO, PR 01/01/2014 - 02/06/2016
2016-1051	02/09/2016 03/09/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Linda Bowen SANOFI	SCINOPHARM TAIWAN, LTD, TAIWAN - EIR 03/01/2015 - 04/01/2015
2016-1052	02/09/2016 03/09/2016	FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	Andy Jones Cory Watson, P.C.	RECS RE LEGIONELLA BACTERIA AT GLAXOSMITHKLINE ZEBULON, NC FACILITY 08/01/2015 - 08/31/2015
2016-1053	02/09/2016 03/09/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Inder Chaudhary, PhD G&W laboratories	Date Range: 02/04/2016 - 03/01/2016; CLINDAMYCIN LOTION - ANDA, SBA
2016-1054	02/09/2016 03/09/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Yumi Kim Hgstrm Yumi Kim Högström	CIPROFLOXACIN - AERS

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		FDA/OMPT/CDER/ORP/DIDP/		
2016-1055	02/09/2016 03/09/2016	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	TOBACCO ADVERSE EVENT RECS
2016-1056	02/09/2016 03/09/2016	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDRH/OCE/DID/	Ian Sheffield Bridger Healthcare	THORATEC CORPORATION - CORR WITH FDA RE MANUFACTURING AND QUALITY SYSTEM 01/01/2014 - 02/06/2016
2016-1057	02/09/2016 03/09/2016	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CDRH/OCE/DID/	Ian Sheffield Bridger Healthcare	ST JUDE MEDICAL - CORR WITH FDA RE MANUFACTURING AND QUALITY SYSTEM REGULATIONS AT NEUROMODULATION DIVISION 01/01/2014 - 02/06/2016
2016-1058	02/09/2016 03/09/2016	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	Kris Christian FDAZILLA	ABBVIE, INC, NORTH CHICAGO - 483, EIR, RESPONSE 07/13/2015 - 08/06/2015
2016-1059	02/09/2016 03/09/2016	FDA/OC/OES/DFOI/	Gregory Hankins Retirement Aspirations	NJ BUSINESSES ENROLLED IN SMALL BUSINESS HEALTH INSURANCE MARKETPLACE 10/01/2013 - 01/31/2016
2016-1060	02/09/2016 03/09/2016	FDA/OMPT/CDRH/OCE/DID/	Doe J	RAPID DIAGNOSTICS DIVISION OF MP BIOMEDICALS LLC, BURLINGAME, CA, MP BIOMEDICALS INDIA PVT LTD - MISREPRESENTATION OF CERTIFICATE TO FOREIGN GOVERNMENT (CFG)
2016-1061	02/09/2016 03/09/2016	FDA/OFVM/CFSAN/OCD/EOS/	MITZI NG CLARK Keller and Heckman LLP	1-HYDROXYETHANE 1,1-DIPHOSPHONIC ACID - CHEMISTRY, TOXICOLOGY RVWS
2016-1062	02/09/2016 03/09/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MADELINE CRANE MARKER GROUP INC	INDIVIDUAL RECS
2016-1063	02/09/2016 03/15/2016	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORASW-FO/SWID/SWID-CB/	BRENDAN T JARBOE FOLEY HOAG LLP	AMERICOLD, DALLAS, TX - AMMONIA LEAK RECS, CORR 6/9/15
2016-1064	02/09/2016 03/09/2016	FDA/OMPT/CDRH/OCE/DID/	Alli Katzen Hyman, Phelps & McNamara, P.C.	K152857
2016-1065	02/09/2016 03/09/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	P140031 PMA & IDE
2016-1066	02/09/2016 03/09/2016	FDA/OMPT/CDRH/OCE/DID/	Alli Katzen Hyman, Phelps & McNamara P.C.	K100099
2016-1067	02/09/2016 03/09/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID RICHARD WALKER JR WALKER LCDC#F188417, DAVID RICHARD	HALDOL, REMERON, AMBIEN, ETC - AERS

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2016-1068	02/09/2016 03/09/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lauren Vaks ETHYPHARM USA CORP	IVAX PHARMACEUTICALS INC - ESOMEPRAZOLE MAGNESIUM CAPS ANDA 78-003; DR REDDY'S LABORATORIES LTD - ESOMEPRAZOLE MAGNESIUM CAPS ANDA 78-279; MYLAN PHARMACEUTICALS INC - ESOMEPRAZOLE MAGNESIUM CAPS ANDA 78-936, ETC
2016-1069	02/09/2016 03/09/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID J NORTHRUP V13733 NORTHRUP V13733, DAVID J	PROZAC, TAGERTOL - LBLG
2016-1070	02/09/2016 03/09/2016	FDA/OMPT/CDRH/OCE/DID/	JAMES E GIRARDS GIRARDS LAW FIRM	ANULEX TECHNOLOGIES INC - XCLOSE TISSUE REPAIR SYS MDRS (CERTIFIED)
2016-1071	02/09/2016 03/09/2016	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	AMY T PERDOMO WEINBERG WHEELER ET AL	UNIV OF MIAMI TISSUE BANK, MIAMI, FL - INSP RECS 2012 TO PRESENT
2016-1072	02/09/2016 03/09/2016	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	AMY T PERDOMO WEINBERG WHEELER ET AL	INDIVIDUAL RECS
2016-1073	02/09/2016 03/09/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	EDWARD E MASTERSON #125382 MASTERSON #125382, EDWARD	TRILEPTAL, MALICTAL, PROZAC, ETC - RECS
2016-1074	02/09/2016 03/09/2016	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	ANDREA JOHNSON TRIGEN LABORATORIES LLC	TRIGEN LABORATORIES LLC, TAMPA, FL - EIR 5/6/14
2016-1075	02/09/2016 03/09/2016	FDA/OC/OES/DFOI/	DENNIS L ALBA 89560-012 ALBA 89560-012, DENNIS	SUCRALOSE - RECS
2016-1076	02/09/2016 03/09/2016	FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECS
2016-1077	02/09/2016 03/09/2016	FDA/OGROP/ORR/CE-FO/CHI-DO/CHI-CB/	Ms. Pat Hillenmeyer AbbVie	ABBVIE, NORTH CHICAGO, IL - EIR 09/01/2014 - 09/30/2014 necessary.;
2016-1078	02/09/2016 03/09/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	P130021/S14 PMA and IDE for P130021
2016-1079	02/09/2016 03/09/2016	FDA/OGROP/ORR/CE-FO/BLT-DO/BLT-CB/	Michael Kalish Walsh Colucci Lubeley & Walsh, P.C.	GOOD SEED, INC, SPRINGFIELD, VA - INSPECTION RECS, COMPLAINTS 12/31/2014 - 12/31/2015

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2016-1080	02/09/2016 03/09/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lisa Samuels PFIZER INC.	NDA holder address associated with each of the patents listed in the Orange Book that are included on the attached WORD document
2016-1081	02/09/2016 03/09/2016	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Carla Gillespie FoodPoisoningBulletin.com	DOLE, SPRINGFIELD, OH - INSPECTION RECS 01/01/2012 - 02/05/2016
2016-1082	02/09/2016 03/09/2016	FDA/OMPT/CDRH/OCE/DID/	Jason Nolan ROTHWELL, FIGG, ERNST & MANBECK, P.C.	US ENDODONTICS, LLC - REGISTRATION, APPROVAL RECS ETC 01/01/2010 - 02/05/2016
2016-1083	02/09/2016 03/09/2016	FDA/OFVM/CFSAN/OCD/EOS/	Amrit Bindra Amrit Bindra	2,3,4,5-Tetrachloro-6-cyanobenzoic acid, methyl ester reaction products with p-phenylenediamine and sodium methoxide (CAS reg. No. 106276806) for use only at levels not to exceed 1 percent by weight of polymers
2016-1084	02/09/2016 03/09/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Colleen Reisz, M.D. Colleen Reisz, MD	STATINS - AERS
2016-1085	02/09/2016 03/09/2016	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Dennis Hall Osmotica Pharmaceutical	SPRINGFIELD NEUROLOGY ASSOCIATES, SPRINGFIELD, VA; MERIDIEN RESEARCH, TAMPA, FL - EIR 10/26/2015 - 11/17/2015
2016-1086	02/09/2016 03/09/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Lynn Shepler Tick-Borne Legal Project	RECS RE DEVELOPMENT OF LYME DISEASE VACCINE PULLED FROM MARKET 01/01/1990 - 02/06/2016
2016-1087	02/09/2016 03/09/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Deborah Galt Fleet Laboratories	POLYETHYLENE GLYCOL 3350 WITHOUT ELECTROLYTES MEDWATCH FORMS 10/06/2006 - 02/04/2016
2016-1088	02/09/2016 03/09/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kris Christian FDAZILLA	ZHEIJIANG APELOA JIAYUAN PHARMACEUTICALS CO LTD, CHINA - 483 11/30/2015 - 12/04/2015
2016-1089	02/09/2016 03/09/2016	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Charlene Palmquist Anybattery, Inc.	ANYBATTERY, ROSEMOUNT, MN - INSPECTION REPORT 12/01/2015 - 12/31/2015
2016-1090	02/09/2016 03/09/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PFIZER PFIZER	THIOPLEX NDA 020058 S 10 SBA

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2016-1091	02/09/2016 03/09/2016	FDA/OMPT/CDRH/OCE/DID/	Sofia Hjortmo, Wellspect Healthcare Dentsply IH AB	K140310
2016-1092	02/09/2016 03/09/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Eric White MISSION PHARMACAL COMPANY/PRESIDENT	NDA N022424
2016-1093	02/09/2016 03/09/2016	OC/ORO/ORM/ OC/ORO/ORM/ FDA/OMPT/CDRH/OCE/DID/	Tate Borcoman Tate Borcoman / Integrated Solutions	LIST OF CDRH INSPECTIONS 01/01/2016 - 02/08/2016
2016-1094	02/09/2016 03/09/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dustin Block IPD Analytics, LLC	ANDA 073580 SUPP NDA
2016-1095	02/09/2016 03/09/2016	FDA/OGROP/ORO/CE-FO/CIN- DO/CIN-CB/ FDA/OGROP/ORO/CE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORO/CE-FO/PHI- DO/PHI-CB/ FDA/OGROP/ORO/NE-FO/NWE- DO/NWE-CB/ FDA/OGROP/ORO/NE-FO/NYK- DO/NYK-DCB/ FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORO/PA-FO/SAN- DO/SAN-CB/ FDA/OGROP/ORO/SE-FO/FLA- DO/FLA-CB/ FDA/OGROP/ORO/SW-FO/DAL- DO/DAL-CB/ FDA/OGROP/ORO/SW-FO/DEN- DO/DEN-CB/	Maddi Manos Antera Therapeutics	PACKAGING FIRMS VARIOUS RECORDS

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2016-1096	02/09/2016 03/09/2016	OC/ORO/ORM/ OC/ORO/ORM/ FDA/OC/OES/DFOI/	Chad Morris DDM, Inc.	INSPECTION RECS
2016-1097	02/09/2016 03/09/2016	FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	Michele Sinoway LACHMAN CONSULTANT SERVICES INC	EISAI, RESEARCH TRIANGLE PARK, NC - 483 12/10/2015 - 12/31/2015
2016-1098	02/10/2016 03/10/2016	FDA/OMPT/CDRH/OCE/DID/	SUSSMAN, MARVIN	MEDTRONIC - PS MEDICAL POLYURETHANE SHUNT K991502
2016-1099	02/10/2016 03/10/2016	FDA/OMPT/CDRH/OCE/DID/	SUSSMAN, MARVIN	RADIONICS INC - XDC EXTERNAL VENTRICULAR CATHETER K992379
2016-1100	02/10/2016 03/10/2016	FDA/OMPT/CDRH/OCE/DID/	SUSSMAN, MARVIN	NAVILYST MEDICAL INC - CATHETER INTRAVASCULAR THERAPEUTIC LONG TERM GREATER THAN 30 DAYS K121089
2016-1101	02/10/2016 03/10/2016	FDA/OMPT/CDRH/OCE/DID/	SUSSMAN, MARVIN	MEDTRONIC NEUROSURGERY - SHUNT CENTRAL NERVOUS SYS & COMPONENTS K110560
2016-1102	02/10/2016 03/10/2016	FDA/OMPT/CDRH/OCE/DID/	SUSSMAN, MARVIN	NAVILYST MEDICAL INC - CATHETER INTRAVASCULAR THERAPEUTIC LONG TERM GREATER THAN 30 DAYS K091261
2016-1103	02/10/2016 03/10/2016	FDA/OMPT/CDRH/OCE/DID/	SUSSMAN, MARVIN	R4 VASCULAR INC - ZEUS CT PICC 4 FR & FR SINGLE & DUAL LUMEN K083763
2016-1104	02/10/2016 03/10/2016	FDA/OMPT/CDRH/OCE/DID/	SUSSMAN, MARVIN	VYGON NEURO - SHUNT CENTRAL NERVOUS SYS & COMPONENTS K081942
2016-1105	02/10/2016 03/10/2016	FDA/OMPT/CDRH/OCE/DID/	SUSSMAN, MARVIN	COOK INC - SPECTRUM VENTRICULAR CATHETER K011812
2016-1106	02/10/2016 03/10/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MANOJ GARG MERRILL LYNCH	AUROBINDO PHARMA, TELANGANA, INDIA - 483
2016-1107	02/10/2016 03/10/2016	FDA/OFVM/CFSAN/OCD/EOS/	Smitha Stansbury KING & SPALDING	FDA RESPONSE TO CSPI 2013 LETTER TO DR MARY POOS RE LABELING OF TASTE MODIFIERS 01/01/2013 - 02/09/2016
2016-1108	02/10/2016 03/10/2016	FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	Francisco Marin SANDOZ	SANDOZ, WILSON, NC - EIR 08/13/2015 - 02/08/2016
2016-1109	02/10/2016 03/10/2016	FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	THOMAS F. SPENADER THEOCHEM LABORATORIES INC	THEOCHEM LABS - EIR, 483, WARNING LTRS 2010 - 2016

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2016-1110	02/10/2016 03/10/2016	OC/ORR/ORM/ OC/ORR/ORM/	LESLIE RAMSEY FDA NEWS	DVC & CLNCL TRIAL FACILITIES IN & OUT THE US - 483s 1/1-31/16
2016-1111	02/10/2016 03/10/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	BRILINTA - AER
2016-1112	02/10/2016 03/10/2016	FDA/OMPT/CDRH/OCE/DID/	Jonathan Demchick Morgan Stanley	CORR BETWEEN FDA AND SURGICAL ROBOTICS COMPANIES 01/01/2014 - 02/08/2016
2016-1113	02/10/2016 03/10/2016	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	Michele Sinoway LACHMAN CONSULTANT SERVICES INC	EISAI, RESEARCH TRIANGLE PARK, NC - 483 09/01/2013 - 09/30/2013
2016-1114	02/10/2016 03/10/2016	FDA/OGROP/ORA/SE-FO/SJN- DO/SJN-CB/	Wayne Thuna Drogueria de la Villa, Inc.	DROGUERIA DE LA VILLA, INC, ARECIBO, PR - FACILITY VISIT RECS 01/01/2010 - 12/31/2011
2016-1115	02/10/2016 03/10/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/ORR/ OC/ORR/ OC/ORR/ORO/DFS/ OC/ORR/ORO/DFS/ FDA/OGROP/ORA/ORO/DIOP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SIDNEY B. RUBENSTEIN, B.S. MEDIPHARM INTERNATIONAL CONSULTANTS LTD	TIANJIN DONGJIANG PORT RUIHAI INTL LOGISTICS CO - EXPLOSION INVESTIGATION 8/15
2016-1116	02/10/2016 03/10/2016	FDA/OC/OES/DDM/	John Rodakis N of One: Autisim Researcher Foundation	METARET ADVISORY COMMITTEE MEETING RECS 01/01/1998 - 12/31/1998
2016-1117	02/10/2016 03/10/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Eleanor DaCosta United States Pharmacopeial Convention (USP)	LACTOBACILLUS - AERS
2016-1118	02/10/2016	FDA/OMPT/CDER/GRP/DIDP/	Paola Teegarden	ANDA 078392 S011 ANDA 077963 S010 ETC

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	03/10/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kinex Pharmaceuticals Inc.	
2016-1119	02/10/2016 03/10/2016	FDA/OMPT/CDRH/OCE/DID/	AASEN, JAN MARIE	CAREFUSION - CLNCL TRAIL 2/25/10 - 10/13
2016-1120	02/10/2016 03/10/2016	FDA/OFVM/CFSAN/OCD/EOS/	Eleanor DaCosta United States Pharmacopeial Convention (USP)	OLIVE LEAF, OLIVE LEAF EXTRACT AERS
2016-1121	02/10/2016 03/10/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Cindy Banks Grifols Therapeutics, Inc	VAERS RECS
2016-1122	02/10/2016 03/10/2016	FDA/OFVM/CFSAN/OCD/EOS/	Eleanor DaCosta United States Pharmacopeial Convention (USP)	RED CLOVER ISOFLAVONE AGLYCONES - AERS
2016-1123	02/10/2016 03/10/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Maia Szalavitz Maia Szalavitz	VIVITROL - AERS
2016-1124	02/10/2016 03/10/2016	FDA/OMPT/CDRH/OCE/DID/	JING GU W.H.P.M., Inc.	K133343
2016-1125	02/10/2016 03/10/2016	OC/ORA/ OC/ORA/ FDA/OGROP/ORANE-FO/NYK- DO/NYK-DCB/	Christina John Sterling Seafood Corp STERLING SEAFOOD CORP	Front and Back of Duty Refund Check Copy Liquidation notice date of check cashing entry 594-0238532-8
2016-1126	02/10/2016 03/10/2016	OC/ORA/ OC/ORA/ FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/ FDA/OC/OCC/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/CVM/OCD/ OC/ORA/OCI/	James Creedon Van Every Creedon PLLC	WEATHERFORD COMPOUNDING PHARMACY LLC, WEATHERFORD, TX - INSPECTION RECS ETC 01/01/2010 - 02/09/2016

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		OC/ORa/OCI/		
2016-1127	02/10/2016 03/10/2016	FDA/OGROP/ORa/CE-FO/CHI-DO/CHI-CB/	Melissa Malapit Celgene Corporation	RICHARD LARSON UNIVERSITY CHICAGO MEDICAL CENTER, CHICAGO, IL - 483 08/01/2014 - 02/09/2016
2016-1128	02/10/2016 03/10/2016	FDA/OMPT/CDRH/OCE/DID/	Lauren Combs PREAT Corporation	K133791
2016-1129	02/10/2016 03/10/2016	FDA/OGROP/ORa/PA-FO/LOS-DO/LOS-CB/	Melissa Malapit Celgene Corporation	APINYA VUTIKULLIRD WEST COAST CLINICAL TRIALS, LLC, CYPRESS, CA - 483 11/3/10
2016-1130	02/10/2016 03/10/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joshua Sharlin Joshua Sharlin	SANOFI TAXOTERE - FDA COMMUNICATIONS RE LABELING 01/01/2013 - 02/09/2016
2016-1131	02/10/2016 03/10/2016	FDA/OGROP/ORa/PA-FO/LOS-DO/LOS-CB/	Melissa Malapit Celgene Corporation	RICHARD FINN, UCLA JONSSON COMPREHENSIVE CENTER, LOS ANGELES - 483 09/01/2014 - 02/09/2016
2016-1132	02/10/2016 03/10/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Colleen Reisz, M.D. Colleen Reisz, MD	ATORVASTATIN, SIMVISTATIN, ROSUVASTATIN ETC - AERS
2016-1133	02/10/2016 03/10/2016	OC/ORa/ OC/ORa/ FDA/OGROP/ORa/PA-FO/SEA-DO/SEA-CB/	JOHN F. JOHNSON, Esq. BENJAMIN L ENGLAND & ASSOCIATES LLC	ENTRY NO 572-23170978-6
2016-1134	02/10/2016 03/10/2016	FDA/OMPT/CDRH/OCE/DID/	LAURA B. KNOLL KNOLL LAW FIRM LLC	VANCARE INC - VANDER LIFT 11 MODEL B450 - CORR
2016-1135	02/10/2016 03/10/2016	FDA/OMPT/CDRH/OCE/DID/	KIM FONDA CONMED CORP	SURGIQUEST INC - 510K
2016-1136	02/10/2016 03/10/2016	FDA/OMPT/CTP/OD/	SUSAN JESMER NATIVE TRADING ASSOCIATES	NSE ORDERS RVWS
2016-1137	02/11/2016 03/11/2016	OC/ORa/ OC/ORa/ FDA/OGROP/ORa/SE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORa/NE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORa/CE-FO/NWJ-	Doe J	COMPLAINT RECS

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		DO/NWJ-CB/		
2016-1138	02/11/2016 03/11/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Paola Teegarden Kinex Pharmaceuticals Inc.	KETORALOC TROMETHAMINE, FENTANYL CITRATE - AERS
2016-1139	02/11/2016 03/11/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	NEXIUM AERS
2016-1140	02/11/2016 03/11/2016	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/DET-DO/DET-CB/	naik sea foods entry 799-3188672-0 STERLING SEAFOOD CORP	ENTRY 799-3188672-0 INVOICE, BILL OF LADING, NOTICE OF SAMPLING 10/01/2015 - 12/31/2015
2016-1141	02/11/2016 03/11/2016	OC/CVM/OCD/	Blaine Tolison WFTV 9	BRAVECTO - COMPLAINTS, FREQUENCY LIST, INVESTIGATION RECS 06/01/2014 - 01/01/2016
2016-1142	02/11/2016 03/11/2016	FDA/OC/OES/DFOI/ FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	Ryan Corbin Neuberger Law, LLC	HOSTESS BRANDS, LLC - WARNING LETTERS, UNTITLED LETTERS, COMPLAINTS, ETC 11/01/2011 - 02/09/2016
2016-1143	02/11/2016 03/11/2016	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/	Christina John Sterling Seafood Corp STERLING SEAFOOD CORP	ENTRY 594-0241090-2 - FRONT AND BACK OF DUTY REFUND CHECK COPY ISSUED; DATE CHECK WAS CASHED, NOTICE OF LIQUIDATION 11/01/2013 - 09/30/2015
2016-1144	02/11/2016 03/11/2016	FDA/OMPT/CDRH/OCE/DID/	DARREN REEVES DP DISTRIBUTION & CONSULTING, LLC	ALLEGIANCE HEALTHCARE CORP - CONVERTERS SPUNBONDED FLASHSPUN POLYOLEFIN GOWNS K982369
2016-1145	02/11/2016 03/11/2016	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/	Christina John Sterling Seafood Corp STERLING SEAFOOD CORP	ENTRY 594-0245287-0 - COPY OF DUTY REFUND CHECK ISSUES, DATA CASHED, NOTICE OF LIQUIDATION ENTRY 04/15/2014 - 08/31/2015
2016-1146	02/11/2016 03/11/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kris Christian FDAZILLA	NOVO NORDISK A/S, DENMARK - 483 10/19/2015 - 11/06/2015

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2016-1147	02/11/2016 03/11/2016	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Melissa Malapit Celgene Corporation	RUBEN MESA, SCOTTSDALE, AZ - 483 01/01/2015 - 02/09/2016
2016-1148	02/11/2016 03/11/2016	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDRH/OCE/DID/	Sonya Grant Zindel Sonya Zindel	LETTER FROM FDA TO STRYKER CORPORATION, HOWMEDICA OSTEONICS RE TRIDENT HEMISPHERAL, TRIDENT PSL CUPS
2016-1149	02/11/2016 03/11/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Meera G Kumar SANOFI	PRALUENT CASE REPORTS 11399356, 11440344, 11575325, ETC
2016-1150	02/11/2016 03/11/2016	FDA/OMPT/CDRH/OCE/DID/	Sonya Grant Zindel Sonya Zindel	TRIDENT ACETABULAR HIP IMPLANT COMPONENTS - MAUDE REPORTS 01/01/2002 - 07/07/2005
2016-1151	02/11/2016 03/11/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Felecia Jones CHEMICAL INFORMATION SERVICES, INC.,	LIST OF PDUFA ENTITIES
2016-1152	02/11/2016 03/11/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Olena Izhak University of Helsinki (FINLAND)	8 ANDA APPROVAL LETTERS
2016-1153	02/11/2016 03/11/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Krishna Kiran Spark Capital Advisors (I) Private Limited	AUROBINDO PHARMA, INDIA - 483 12/03/2015 - 02/09/2016
2016-1154	02/11/2016 03/11/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jigar Valia Ohm Group	AUROBINDO, INDIA - 483 01/01/2016 - 02/08/2016
2016-1155	02/11/2016 03/11/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/ORAO/OCI/ OC/ORAO/OCI/	Danielle Paquette WASHINGTON POST	CYTOTEC - AERS

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2016-1156	02/11/2016 03/11/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Stacie Wehling Scilucent, LLC	NDA 008720 SBA
2016-1157	02/11/2016 03/11/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Stacie Wehling Scilucent, LLC	NDA 008719 SBA
2016-1158	02/11/2016 03/11/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Carol Wasteney The Mentholatum Company	ASPERCREME LIDOCAINE PAIN RELIEVING CREAM - AERS
2016-1159	02/11/2016 03/11/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rahul Jeewani IIFL Capital	AUROBINDO, INDIA - 483 01/01/2016 - 02/10/2016
2016-1160	02/11/2016 03/11/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rahul Singh Solanki Edelweiss	AUROBINDO, INDIA - 483 01/01/2015 - 09/02/2016
2016-1161	02/11/2016 03/11/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LORI MILLER XTTRIUM LABORATORIES INC	NDA 19-422
2016-1162	02/11/2016 03/11/2016	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARIA E. CELIS Neville Peterson LLP	JO COSMETICS - EIR
2016-1163	02/11/2016 03/11/2016	FDA/OMPT/CDRH/OCE/DID/	LAUREN COMBS PREAT Corporation	K133791
2016-1164	02/11/2016 03/11/2016	FDA/OMPT/CDRH/OCE/DID/	McKENZIE CATO Hyman Phelps and McNamara PC	BRACCO INJENEERING - CT EXPRESS 3D CONTRAST MEDIA DELIVERY SYS BOTTLE SPIKE TYPE B DAY SET III HP PATIENT SET K151048

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2016-1165	02/11/2016 03/11/2016	FDA/OMPT/CDRH/OCE/DID/	JONAS EHINGER OSSTELL AB	TELLOS MEDICAL AB - TELLOS ISQ BUDDY K143445
2016-1166	02/11/2016 03/11/2016	FDA/OMPT/CDRH/OCE/DID/	JP McMENAMIN MDJD	AIRVO - 2 SERIES HUMIDIFIER K131895
2016-1167	02/12/2016 03/14/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K151981
2016-1168	02/12/2016 03/14/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Beth Glasgow GOJO Industries, Inc.	NDA 019422 SBA
2016-1169	02/12/2016 03/14/2016	FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	JOHN TOZZI BLOOMBERG BUSINESS NEWS	USP LABS - EIRS, 483S 2/7-21/12
2016-1170	02/12/2016 03/14/2016	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	EMILY KNAEBLE M25 INC	M2S, INC, WEST LEBANON, NH - EIRS 4/15/13
2016-1171	02/12/2016 03/14/2016	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	OPIDVO - AERS
2016-1172	02/12/2016 03/14/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	GLAXOSMITHKLINE - JALYN AERS
2016-1173	02/12/2016 03/14/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KATHY GAGRIC GAGRIC, KATHY	PFIZER - IBRANCE PALBOCIC LIB AERS
2016-1174	02/12/2016 03/14/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RYAN DEVORE DEVORE, RYAN	OPALESCENCE PF TOOTH WHITENING SUSTEM & GEL 10%-35% AERS

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2016-1175	02/12/2016 03/14/2016	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/CVM/OCD/	DEVORE, RYAN DEVORE, RYAN	JOHN MASTERS ORGANICS - ROSE & APRICOT HAIR MILK, SPEARMINT & MEDOWSWEET SCALP STIMULATING SHAMPOO, ETC - AERS, CAERS
2016-1176	02/12/2016 03/14/2016	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RYAN DEVORE DEVORE, RYAN	RODAN & FIELD - PROACTIV SKIN SMOOTHING EFOLIATOR, PORE TARGETING TREATMENT, COMPLEXION PERFECTING HYDRATOR, ETC AERS, CAERS
2016-1177	02/12/2016 03/14/2016	FDA/OFVM/CFSAN/OCD/EOS/	BRENDAN THOMPSON CUNEO GILBERT ET AL	APPLIED NUTRICEUTICALS, TOP SECRET, ICF INTERNATIONAL LLC, ETC - PICAMILON, BMPEA WARNING LTRS 11/30/15, 4/22/15
2016-1178	02/12/2016 03/14/2016	FDA/OFVM/CFSAN/OCD/EOS/	BRENDAN THOMPSON CUNEO GILBERT ET AL	GENERAL NUTRITON CORP - PICAMILON, BMPEA APPLICATION OF GNC FOR MKTG CLEARANCE OR APRVL, CLNCL TESTS, ANALYSES, ETC
2016-1179	02/12/2016 03/14/2016	OC/ORA/ OC/ORA/	ABBY J KAPLAN AVELLA OF DEER VALLEY INC	PACIFICO NATIONAL (AMEX PHARMACY), MELBOURNE, FL - EIRS, 483S, NOTES , ETC 1/22/16
2016-1180	02/12/2016 03/14/2016	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	TRICIA PIERCE PIERCE, TRICIA	NESTLE PURINA PETCARE - FRISKIES GRAVY SENSATIONS POUCH & POULTRY FAVORITES CAT FOOD RECS
2016-1181	02/12/2016 03/14/2016	FDA/OFVM/CFSAN/OCD/EOS/	LIDIA A BROWNELL UNIGEN	SCUTELLARIA BAICALENSES & ACACIA CATECHU (SENEGALIA CATECHU) - CAERS 9/10 TO 2/16
2016-1182	02/12/2016 03/14/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Theresa Fiorito, M.D. Hasbro Children's Hospital/Warren Alpert Medical School of Brown University	CLNCL TRIALS - B1971012 (TRUMEMBA) RECS
2016-1183	02/16/2016 03/15/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Meghan Jamison VERTEX PHARMACEUTICALS INC	DMF 24682
2016-1184	02/16/2016 03/15/2016	FDA/OGROP/ORACE-FO/ATL-DO/ATL-CB/	Melissa V. Malapit Celgene Corporation	BRUCE SALZBERG, ALTANTA GASTROENTEROLOGY ASSOCIATIES, ATLANTA, GA - 483 11/01/2008 - 02/12/2016

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2016-1185	02/16/2016 03/15/2016	FDA/OMPT/CDRH/OCE/DID/	Clark Braten DxNA,Ilc	K123955 K141520 K151917
2016-1186	02/16/2016 03/15/2016	FDA/OMPT/CDRH/OCE/DID/	Tobias Reichel Heraeus Medical GmbH	K073115
2016-1187	02/16/2016 03/15/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K142065
2016-1188	02/16/2016 03/15/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Daniela Sinatra Centrix Pharmaceutical, Inc.	COVARYX - 11369468 11423048 ETC
2016-1189	02/16/2016 03/15/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kathy Gagric GAGRIC, KATHY	IBRANCE PALBOCICLIB - AERS
2016-1190	02/16/2016 03/15/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Reena harjai APCER Life Sciences, Inc.	BARIUM SULFATE CASE LISTING
2016-1191	02/16/2016 03/15/2016	FDA/OMPT/CDRH/OCE/DID/	Karen E. Warden BackRoads Consulting Inc.	K813227
2016-1192	02/16/2016 03/15/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	Erik Gilbertson, MD SCRIPPS CLINIC	OTEZLA - AERS
2016-1193	02/16/2016 03/15/2016	OC/ORO/ORM/ OC/ORO/ORM/	Kris Christian FDAZILLA	LISTING OF INSPECTION DATA SINCE 02/08/2015
2016-1194	02/16/2016 03/15/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Duncan Turnbull Ramboll Environ US Corporation	FDA Staff Manual Guide 4750.7
2016-1195	02/16/2016 03/15/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	G. Srinivas Zydus Pharmaceuticals USA Inc.	NDA 011665 SBA, NDA 204737 SBA, NDA 203184

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2016-1196	02/16/2016 03/15/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Michael Mancinelli, Paralegal Conway, Homer & Chin-Caplan, PC	INDIVIDUAL RECS
2016-1197	02/16/2016 03/15/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Kristy Smith Rawls McNelis & Mitchell	INDIVIDUAL RECS
2016-1198	02/16/2016 03/15/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Doe J	INDIVIDUAL RECS
2016-1199	02/16/2016 03/15/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Kristy Smith Rawls McNelis & Mitchell	INDIVIDUAL RECS
2016-1200	02/16/2016 03/15/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angela Volpe IDT Australia Limited	ANDA 075943, 085370, 087781
2016-1201	02/16/2016 03/15/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tess Ceron KADMON CORPORATION, LLC	TRIENTINE HYDROCHLORIDE - AERS
2016-1202	02/16/2016 05/02/2016	FDA/OGROP/ORR/CE-FO/DET- DO/DET-CB/	Shoji Nagatani SymBio Pharmaceuticals, Ltd.	BIOANALYTICAL SYSTEMS, INC, WEST LAFAYETTE, IN - 483 01/01/2011 - 12/30/2012
2016-1203	02/16/2016 03/15/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Krishna Kiran Spark Capital Advisors (I) Private Limited	GRANULES INDIA LIMITED - 483 12/03/2015 - 01/21/2016
2016-1204	02/16/2016 03/15/2016	FDA/OMPT/CDRH/OCE/DID/	John Beasley MedTech Review, LLC	K130847
2016-1205	02/16/2016 03/15/2016	FDA/OGROP/ORR/CE-FO/PHI- DO/PHI-CB/	Abhishek K. Gurnani Amin Talati & Upadhye, LLC	NATURE'S WAY PUREWATER SYSTEMS, INC, PITTSBURGH, PA - 493, EIR 01/01/2010 - 02/10/2016
2016-1206	02/16/2016 03/15/2016	OC/ORR/ OC/ORR/	Foster Taft Foster Taft	NABISCO, GENERAL MILLS - COMPLAINT RECS 01/01/1993 - 06/30/2015
2016-1207	02/16/2016 03/15/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Kristy Smith Rawls McNelis & Mitchell	INDIVIDUAL RECS

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2016-1208	02/16/2016 03/15/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jeffrey A. Wolfson Strides Arcolab Limited	AGILA SPECIALTIES PRIVATE LIMITED, INDIA - EIR 01/01/2013 - 12/31/2015
2016-1209	02/16/2016 03/15/2016	FDA/OO/OHR/	Eyal Maor FDAAWARE	MONICA M. MCCLURE - CV
2016-1210	02/16/2016 03/15/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kris Christian FDAZILLA	SUN PHARMACEUTICAL INDUSTRIES LTD, INDIA - 483 10/10/2005 - 10/27/2005
2016-1211	02/16/2016 03/15/2016	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Jane Bentley ALCON LABORATORIES	ALCON RESEARCH LTD, FORT WORTH, TX - EIR 07/14/2014 - 07/24/2014
2016-1212	02/16/2016 03/15/2016	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Jane Bentley ALCON LABORATORIES	ALCON RESEARCH, LTD, FORT WORTH, TX - EIR 08/12/2013 - 08/20/2013
2016-1213	02/16/2016 03/15/2016	OC/ORA/OCI/ OC/ORA/OCI/	Elliott Millenson Elliott Millenson	OCI INVESTIGATION MEMO 08/01/1994 - 02/01/2016
2016-1214	02/16/2016 03/15/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Meghan Jamison VERTEX PHARMACEUTICALS INC	Drug Master File 24682
2016-1215	02/16/2016 03/15/2016	FDA/OC/OES/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	COMMUNICATIONS BETWEEN FDA AND PUBLIC CITIZEN RE PRESCRIPTION DRUG LABELING OR PRESCRIPTION DRUGS 1/1/12 TO PRESENT
2016-1216	02/16/2016 03/15/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Justin DiMartino Retrophin, Inc	ORGANON USA INC - LABELS, APPROVAL, WITHDRAWAL RECS NDA 009854 NDA 008975
2016-1217	02/16/2016 03/15/2016	FDA/OMPT/CDRH/OCE/DID/	Arielle Duhaime-Ross The Verge	LETTERS, EMAILS BETWEEN FDA AND PATHWAY GENOMICS CORPORATION 05/01/2010 - 11/11/2015
2016-1218	02/16/2016 03/15/2016	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	Dale Goodloe Grifols Biologics	JUAN CHEDIAK, MD ANGELO CRETICOS CANCER CENTER, CHICAGO, IL - 483 07/01/2001 - 12/31/2001

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2016-1219	02/16/2016 03/15/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	BLA 125554
2016-1220	02/16/2016 03/15/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kamesh Venugopal QSV Pharma LLC	ANDA 201537
2016-1221	02/16/2016 03/15/2016	FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/	John Walsh James Alexander Corporation	CORNING PHARMACEUTICALS GLASS, LLC, VINELAND, NJ - EIR, 483, RECALLS 02/01/2013 - 02/11/2016
2016-1222	02/16/2016 03/15/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Fredrik Hieronymus University of Gothenburg	NDA 018936 NDA 020031 NDA 020152
2016-1223	02/16/2016 03/15/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Elena Clark Hogan Lovells	NDA 021338/S-005
2016-1224	02/16/2016 03/15/2016	FDA/OMPT/CDRH/OCE/DID/	Arielle Duhaime-Ross The Verge	EMAILS, LETTERS BETWEEN FDA AND SURE GENOMICS 02/01/2016 - 04/01/2016
2016-1225	02/16/2016 03/15/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Suzanne Benedict TRACON Pharmaceuticals, Inc.	NDA 022465, SN010
2016-1226	02/16/2016 03/15/2016	OC/CVM/OCD/	Sandra O'Kelley Merial Inc	NADA 91-826 NADA 112-051
2016-1227	02/16/2016 03/15/2016	FDA/OMPT/CDRH/OCE/DID/	Kate Linebaugh THE WALL STREET JOURNAL	COMMUNICATIONS FROM FDA RE OPEN-SOURCED PROJECT BUILDING ARTIFICIAL PANCREAS SYSTEMS 01/03/2014 - 02/11/2016
2016-1228	02/16/2016 03/15/2016	FDA/OMPT/CDRH/OCE/DID/	Kate Linebaugh THE WALL STREET JOURNAL	RECS RE SUBMISSION AND APPROVAL OF DEXCOM SHARE, DEXCOM SHARE DIRECT SECONDARY DISPLAYS 08/01/2013 - 01/23/2015
2016-1229	02/16/2016 03/15/2016	FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/	Melissa Malapit Celgene Corporation	DAVID SIEFEL, HACKENSACK UNIVERSITY MEDICAL CENTER - 483 09/01/2015 - 02/11/2016

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2016-1230	02/16/2016 03/15/2016	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAP/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDRH/OCE/DID/	Arielle Duhaime-Ross The Verge	EMAIL,S LETTERS BETWEEN THERANOS INC AND FDA 08/01/2015 - 02/11/2016; INSPECTION REPORTS
2016-1231	02/16/2016 03/15/2016	FDA/OMPT/OSMP/OOPD/	Santosh Ramamurthy Cote Orphan LLC	Rare Pediatric Disease Designation Application Unituxin
2016-1232	02/16/2016 03/15/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K022236
2016-1233	02/16/2016 03/15/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 18892
2016-1234	02/16/2016 03/15/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Nicholas Oo The Invus Group / Attn: Nicholas Oo	XIAFLEX - AERS
2016-1235	02/16/2016 03/15/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ketan Agravat Unimark Remedies Limited Ahmedabad	DR REDDY'S LABORATORIES, INDIA - 483 11/01/2014 - 03/31/2015
2016-1236	02/16/2016 03/15/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Nicholas Oo The Invus Group / Attn: Nicholas Oo	TECFIDERA, GILENYA, AUBAGIO - AERS
2016-1237	02/16/2016 03/15/2016	FDA/OMPT/CDRH/OCE/DID/	Xu Wang Xu Wang	K090145 K130002
2016-1238	02/16/2016 03/15/2016	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	FCN 726
2016-1239	02/16/2016 03/15/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sheldon Garrison Promentis	NDA 13601
2016-1240	02/16/2016	FDA/OMPT/CDRH/OCE/DID/	Stephen Tilman	K023830

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	03/15/2016		Stephen Tilman	
2016-1241	02/16/2016 03/15/2016	FDA/OMPT/CDRH/OCE/DID/	ProMedic ProMedic LLC	K082982 K100528 K102525 ETC
2016-1242	02/17/2016 03/16/2016	FDA/OMPT/CDRH/OCE/DID/	Brad Blake Fellows & Blake, LLC	NUVASIVE NEUROMONITORING EQUIPMENT - APPROVAL RECS, EMAILS, NOTES, ETC
2016-1243	02/17/2016 03/16/2016	FDA/OFVM/CFSAN/OCD/EOS/	Jayme Poisson Toronto Star	E.D Smith Foods Ltd., Saputo Shashi Foods, Bee Maid Honey Ltd. CANADA - 483
2016-1244	02/17/2016 03/16/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Eric Steenstra Eric Steenstra	CANNABIDIOL - LETTERS, NOTES, MEMOS, ETC BETWEEN GW PHARMACEUTICALS
2016-1245	02/17/2016 03/16/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Cuccias FOIA Professional Services	EMAILS BETWEEN GW PHARMACEUTICALS AND FDA RE EPIDIOLEX 01/01/2013 - 01/01/2016
2016-1246	02/17/2016 03/16/2016	FDA/OC/OES/DFOI/	Rachel Cuccias FOIA Professional Services	FOIA log for GW Pharmaceuticals
2016-1247	02/17/2016 03/16/2016	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	John Moore MORGAN & MORGAN	REPRODUCTIVE MEDICINE INSTITUTE IVF, LLC - RESPONSE TO 483 ETC 01/01/2008 - 02/12/2016
2016-1248	02/17/2016 03/16/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Eastwood FOI 2016 Feb Eastwood Global Trade Inc.	List of the API products, with the relevant NDC numbers, of Foreign drug manufacturers 01/01/2010 - 02/12/2016
2016-1249	02/17/2016 03/16/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Maia Szalavitz freelance	VIVITROL - AERS
2016-1250	02/17/2016 03/16/2016	OC/ORR/ OC/ORR/ OC/ORR/ORM/ OC/ORR/ORM/	Laura Ybarra Laura Ybarra	FOOD RELATED RECALLS 2000 TO PRESENT
2016-1251	02/17/2016 03/16/2016	FDA/OGROP/ORR/PA-FO/SEA-DO/SEA-CB/	Michael Connett Fluoride Action Network	KIRKLAND LABORATORIES, INC - INSPECTION RECS 01/01/2014 - 02/12/2016

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2016-1252	02/17/2016 03/16/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Zonnenberg Parnassia Group	ANTIPSYCHOTIC DRUGS - REPORTS OF HYPOTHERMIA, 12/12/2000 - 12/02/2016
2016-1253	02/17/2016 03/16/2016	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Rachel Johnson FOI Services, Inc.	ACCESS BIO, SOMERSET, NJ - INSPECTION RECS
2016-1254	02/17/2016 03/16/2016	FDA/OMPT/CDRH/OCE/DID/	Adam Ettl Vascular Solutions, Inc.	PMA P810046 SUMMARY OF SAFETY AND EFFECTIVENESS
2016-1255	02/17/2016 03/16/2016	OC/ORA/ OC/ORA/	Toni Ann Booras Boston University News Service	CHIPOTLE - CONSUMER COMPLAINTS 01/01/2015 - 02/13/2016
2016-1256	02/17/2016 03/16/2016	FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/	Laura MacCleery Center for Science in the Public Interest	RECS RE WORKING GROUP EVALUATING SAFETY OF PHTHALATES PRIOR TO 2/12/16.
2016-1257	02/17/2016 03/16/2016	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	Shoji Nagatani SymBio Pharmaceuticals, Ltd.	CEPHALON, WEST CHESTER, PA - GLP INSPECTION REPORT 06/01/2012 - 12/31/2014
2016-1258	02/17/2016 03/16/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LUCITA SINGLETON SINGLETON, LUCITA	KEPPRA (LEVETIRACETAM) - AERS
2016-1259	02/17/2016 06/10/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	LUCITA SINGELTON SINGLETON, LUCITA	FLU VACCINE - VAERS
2016-1260	02/17/2016 03/16/2016	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	J ROBERT YEOMAN B&R COMPLIANCE ASSOCIATES LLC	TANGRAM COMPANY, LLC, HOLTSVILLE, NY - EIR 8/12 TO 12/15
2016-1261	02/17/2016 03/16/2016	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	J ROBERT YEOMAN B&R COMPLIANCE ASSOCIATES LLC	JOST CHEMICAL CO, ST LOUIS, MO - INSP EIRS 8/12 TO 12/15
2016-1262	02/17/2016 03/16/2016	FDA/OMPT/CDRH/OCE/DID/	SAMUEL NEFF MD AESCULAP INC	SHUNTCHECK - K040021
2016-1263	02/17/2016 03/16/2016	FDA/OMPT/CDRH/OCE/DID/	ALAN G MINSK ARNALL GOLDEN & GREGORY, LLP	ROCHE - NUCLEIC ACID-BASED (PCR) RAPID MYCOPLASMA TEST (MYCO TOOL) DETECTION KIT MARKETING AUTHORIZATION, APPRVL OR CLEARANCE
2016-1264	02/17/2016 03/16/2016	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/CE-FO/CIN-	STEPHEN T FOWLER Greenberg Traurig, LLP	DDN PHARMACEUTICAL LOGISTICS PROPELLING LIFE SCIENCE FACILITY, ONTARIO, CANADA - EIRS 9/10/09; CARDINAL HEALTH, GROVESPORT, OH - EIRS, SHIPPING

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		DO/CIN-CB/		RECEIPTS, PACKING LIST, DDN PICK SLIP
2016-1265	02/17/2016 03/16/2016	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	ANA MARIA ABREU VELEZ MD VELEZ, ANA MARIA ABREU	DR DENNIS MARCUS, MEDICAL COLLEGE OF GEORGIA, AUGUSTA, GA - EIRS, 483S, WARNING LTRS, ETC 2005 TO 2011
2016-1266	02/17/2016 03/16/2016	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	LAURA STORMS OLYMPUS CORPORATION OF THE AMERICAS	NEW YORK PRESBYTERIAN WEIL HOSPITAL (CORNELL MEDICAL CENTER) - EIRS, 483S, MINS, ETC
2016-1267	02/17/2016 03/16/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ALAN G MINSK ARNALL GOLDEN & GREGORY, LLP	LIFE TECHNOLOGIES CORP - MYCOSEQ MYCOPLASMA DETECTION SYS DMF #23784 4/30/10
2016-1268	02/17/2016 04/07/2016	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELYSE KINGERY DEGGE GROUP LTD	128534, 128538, 128933, ETC - CAERS
2016-1269	02/17/2016 03/16/2016	FDA/OC/OES/DFOI/	AHMED SEDDIK VETLIFE VETERINARY MEDICINES TRADING LLC	VETERINARY MEDICINE MANUFACTURING PLANTS, COMPANIES IN USA - RECS
2016-1270	02/17/2016 03/16/2016	FDA/OFVM/CFSAN/OCD/EOS/	SUSAN MATTHEES GENERAL MILLS	FRUIT, VEGETABLE COLOR ADDITIVES - CORR INTERPRETING 21 CFR 73.250, 72.260 - INFORMAL OPINION LTRS
2016-1271	02/17/2016 03/16/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	EMILY J WAGNER PIETRAGALLO BOSICK & GORDON	CEFTIN (CEFUROXIME) SYNDROME, CIPRO (CIPROFLOXACIN), KELFLEX (CEPHALEXIN) - STEVENS-JOHNSON SYNDROM & TOXIC EPIDERMAL NECROLYSIS AERS 1998 TO 2006
2016-1272	02/17/2016 03/16/2016	OC/ORAE/ OC/ORAE/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	YUNTAKARE WIHARYANTO TAKARI INTERNATIONAL INC	DANISA BUTTER COOKIES - ENTRY 349-0973598 RPT
2016-1273	02/17/2016 03/16/2016	OC/ORAE/ORM/ OC/ORAE/ORM/	JAYME POISSON Toronto Star	LIST OF CANADIAN FOOD COMPANIES THAT HAVE BEEN INSPECTED 1/1/05TO PRESENT; 483 ISSUED TO CANADIAN FOOD COMAPANIES THAT HAVE BEEN PREVIOUSLY RELEASED UNDER FOIA SINCE 1/1/05
2016-1274	02/17/2016 03/16/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID M HOFFMEISTER Wilson Sonsini Goodrich & Rosati	PURDUE PHARMA - OXYCONTIN NDA 22-72 FORM 3542

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2016-1275	02/17/2016 03/16/2016	FDA/OMPT/CDRH/OCE/DID/	Thomas C. Knott Benjamin L. England and Associates, LLC	K150409
2016-1276	02/17/2016 03/16/2016	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OC/OES/DFOI/	Christine Hopkins Kilgore & Kilgore, PLLC	ECLIPSE AESTHETICS LLC - WARNING LETTER, 483; REGENLAB AMERICA, INC - UNTITLED LETTER 04/19/2013 - 10/27/2015 (CERTIFIED)
2016-1277	02/17/2016 03/16/2016	OC/ORA/ORM/ OC/ORA/ORM/	Kris Christian FDAZILLA	LIST OF INSPECTIONS 01/13/2016 - 02/15/2016
2016-1278	02/17/2016 03/16/2016	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	John Walsh James Alexander Corporation	MOD PAC CORPORATION, BUFFALO, NY - EIR, 483, RECALLS 01/01/2013 - 02/15/2016
2016-1279	02/17/2016 03/16/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Benjamin Lampson DANA FARBER CANCER INSTITUTE	SAFETY REPORTS 10250309, 10946766, 10440611 ETC
2016-1280	02/17/2016 03/16/2016	FDA/OMPT/OSMP/OOPD/	Johan Frisk Johan Frisk	INBREATH AIRWAY TRANSPLANT SYSTEM HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC - CLINICAL RECS RE ORPHAN SUBMISSION 09/01/2013 - 02/15/2016
2016-1281	02/17/2016 03/16/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joseph Reo Bayer Consumer Healthcare	NDA 20428
2016-1282	02/17/2016 03/16/2016	FDA/OMPT/CDRH/OCE/DID/	Mariah Knight ACUMED	K063509
2016-1283	02/17/2016 03/16/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tushar Manudhane Indianivesh securities	NATCO PHARMA, INDIA - 483 12/01/2015 - 02/16/2016
2016-1284	02/18/2016 03/17/2016	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	LESLIE RAMSEY FDA NEWS	BC GROUP, ST CHARLES, MO - 483 1/29/16
2016-1285	02/18/2016	FDA/OGROP/ORA/SE-FO/FLA-	LESLIE RAMSEY	ERGOATIVES LLC, MIAMI, FL; AMERICAN CATHETER CORP,

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	03/17/2016	DO/FLA-CB/	FDA NEWS	STUART, FL - 483 1/1-31/16
2016-1286	02/18/2016 03/17/2016	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	LESLIE RAMSEY FDA NEWS	OXUS AMERICA INC, AUBURN HILLS, MI - 483 1/1-31/16
2016-1287	02/18/2016 03/17/2016	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	LESLIE RAMSEY FDA NEWS	SOMA ACCESS SYS LLC, ENGLEWOOD, CO; SPECTRANETICS, COLORADO SPRINGS, CO - 483 1/1-31/16
2016-1288	02/18/2016 03/17/2016	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	LESLIE RAMSEY FDA NEWS	RICHARD E COLGIN LTD, DALLAS, TX; SOVEREIGN PHARMACEUTICALS LLC, FORT WORTH, TX - 483 1/1-31/16
2016-1289	02/18/2016 03/17/2016	FDA/OMPT/CDRH/OCE/DID/	LESLE RAMSEY FDA NEWS	YANGZHOU QIONGHUA SPORTS GOODS CO LTD, YANGZHOU, CHINA; HINDUSTAN SYRINGES & MEDICAL DEVICES LTD, BALLABGARH, INDIA; MEDSORB DOMINICANA SA, SAN PEDRO DE MACORIS, DOMINICAN REPUBLIC - 483 1/1-31/16
2016-1290	02/18/2016 03/17/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LESLIE RAMSEY FDA NEWS	WOCKHARDT LTD, ANKLESHWAR, INDIA; ZHEJIANG APELOA JIAYUAN PHARMACEUTICAL CO LTD, DONGYANG, CHINA; ACTAVIS UK LTD, BARNSTAPLE, UK - 483 1/1-31/16
2016-1291	02/18/2016 03/17/2016	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	LESLIE RAMSEY FDA NEWS	BEST MEDICAL INTL INC, SPRINGFIELD, VA - 483 1/1-31/16
2016-1292	02/18/2016 03/17/2016	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	LESLIE RAMSEY FDA NEWS	DUKE UNIVERSITY MEDICAL CTR CAROLINAS CORD BLOOD, DURHAM, NC - 483 1/1-31/16
2016-1293	02/18/2016 03/17/2016	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	LESLIE RAMSEY FDA NEWS	ACUTE INNOVATIONS LLC - HILLSBORO, OR - 483 1/1-31/16
2016-1294	02/18/2016 03/17/2016	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	LESLIE RAMSEY FDA NEWS	AMGEN MANUFACTURING LTD, JUNCOS, PR - 483 1/1-31/16
2016-1295	02/18/2016 03/17/2016	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	LESLIE RAMSEY FDA NEWS	DAILYSIS MEDICAL SOLUTIONS LLC, LEWISBERRY, PA - 483 1/1-31/16
2016-1296	02/18/2016 03/17/2016	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	LESLIE RAMSEY FDA NEWS	NOVA HEALTH SYS INC, UTICA, NY; CR BARD INC, QUEENSBURY, NY; BROOKHAVEN NATIONAL LABS, UPTON, NY - 483 1/1-31/16
2016-1297	02/18/2016 03/17/2016	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	LESLIE RAMSEY FDA NEWS	KINETIC INSTRUMENTS INC, BETHEL, CT; RHODE ISLAND NOVELTY INC, FALL RIVER, MA - 483 1/1-31/16
2016-1298	02/18/2016 03/17/2016	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	LESLIE RAMSEY FDA NEWS	COSMETIC LABS OF AMERICA, CHATSWORTH, CA; RESPIRONICS CALIFORNIA INC, CARLSBAD, CA; BOSTON SCIENTIFIC NUEROMODULATION CORP, VALENCIA, CA - 483 1/1-31/16
2016-1299	02/18/2016	FDA/OMPT/CDER/GRP/DIDP/	Shilpa Medicare Limited	SHILPA MEDICARE, INDIA - 483 07/03/2015 - 10/16/2015

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	03/17/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Krishna Kiran, Spark Capital Advisors (I) Private Limited	
2016-1300	02/18/2016 03/17/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LESLIE RAMSEY FDA NEWS	PAN DRUGS LTD, VADODARA, INDIA; CHIFENG PHARMACEUTICAL CO LTD, CHIFENG, CHINA; NIPPON KAYAKU CO LTD, TAKASAKI, JAPAN - 483 1/1-31/16
2016-1301	02/18/2016 03/17/2016	FDA/OGROP/ORAC/CE-FO/DET- DO/DET-CB/ FDA/OO/OHR/ FDA/OC/OES/DFOI/	Linda S Jozefiak Linda Jozefiak	FDA-ORA-15-MD-1471274-WW INTERVIEW NOTES, REFERRALS, ETC
2016-1302	02/18/2016 03/17/2016	FDA/OFVM/CFSAN/OCD/EOS/	Nicole Leininger Nicole Leininger	LE-VEL THRIVE - AERS
2016-1303	02/18/2016 03/17/2016	FDA/OFVM/CFSAN/OCD/EOS/	Leslie Patton Technology Sciences Group, Inc.	FCN 935
2016-1304	02/18/2016 03/17/2016	OC/ORAC/ORM/ OC/ORAC/ORM/	ELLIOTT GRAHAM SOCIETY OF QUALITY ASSURANCE	EXCEL DATABASE 2015-2016
2016-1305	02/18/2016 03/17/2016	FDA/OC/OES/ FDA/OFVM/CFSAN/OCD/EOS/	DIANNE L. CHAMBERS Hogan Lovells, ILP	CORR TO CALIFORNIA OFFICE ENVIRONMENTAL HEALTH HAZZARD ASSESSMENT OF TOXICOLOGY OF BISPHENOL A (BPA)
2016-1306	02/18/2016 03/17/2016	FDA/OGROP/ORAC/SE-FO/FLA- DO/FLA-CB/	PATRICIA L. REGENYE CELEGENE CORP	RICHARD K VOGEL, INVIVO CORP, ORLANDO, FL - 483 8/15 - 1/16
2016-1307	02/18/2016 03/17/2016	FDA/OMPT/CDRH/OCE/DID/	SUSAN A. LONGACRE LONGACRE & ASSOCIATES	9/9/11 ADCOM MTNG TRANSCRIPT CERTIFIED
2016-1308	02/18/2016 03/17/2016	FDA/OMPT/CDRH/OCE/DID/	SUSAN A.LONGACRE LONGACRE & ASSOCIATES	9/8/11 ADCOM MTG TRASCRIPT CERTIFIED
2016-1309	02/18/2016 03/17/2016	FDA/OMPT/CDRH/OCE/DID/	SUSAN A. LONGACRE LONGACRE & ASSOCIATES	7/13/11 DVC ALERT CERTIFIED
2016-1310	02/18/2016 03/17/2016	FDA/OMPT/CDRH/OCE/DID/	SUSAN A. LONGACRE LONGACRE & ASSOCIATES	LETTER TO MARK G GOODWIN 1/3/12 CERTIFIED
2016-1311	02/18/2016 03/17/2016	FDA/OC/OES/DFOI/	SUSAN A LONGACRE LONGACRE & ASSOCIATES	NEWS RELEASE 1/4/16 CERTIFIED
2016-1312	02/18/2016	FDA/OMPT/CDRH/OCE/DID/	SUSAN A. LONGACRE	LETTER FROM BARD MEDICAL 1/13/12 CERTIFIED

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	03/17/2016		LONGACRE & ASSOCIATES	
2016-1313	02/18/2016 03/17/2016	FDA/OC/OES/DFOI/	Sally A. Stendardo Miroballi Durkin & Rudin, LLC	MAUDE REPORTS
2016-1314	02/18/2016 03/17/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ernesto Alamo PATTERSON BELKNAP WEBB & TYLER	NDA 019833
2016-1315	02/18/2016 03/17/2016	FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/	Richard Oakman XPO Logistics	NEBRASKA WAREHOUSE, OMAHA, NE - 483 01/01/2016 - 02/29/2016
2016-1316	02/18/2016 03/17/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dustin Block IPD Analytics, LLC	ANDA 203344 TENTATIVE APPROVAL LETTER
2016-1317	02/18/2016 03/17/2016	FDA/OMPT/CDRH/OCE/DID/	Cory Hatcher BeamReaders	K113543 K123519 K133320
2016-1318	02/18/2016 03/17/2016	FDA/OGROP/ORA/CE-FO/CHI- DO/CHI-CB/	Pat Hillenmeyer (Ms.) AbbVie	ABBVIE, NORTH CHICAGO, IL - EIR 09/08/2014 - 09/12/2014
2016-1319	02/18/2016 03/17/2016	OC/ORA/OCI/ OC/ORA/OCI/	Doe J	INDIVIDUAL RECS
2016-1320	02/18/2016 03/17/2016	FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	Roxanne Coulon Relypsa Inc	RELYPSA INC, REDWOOD CITY, CA - EIR FEB 2015
2016-1321	02/18/2016 03/17/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Reena Harjai APCER Life Sciences, Inc.	NDA 022249 S 19, 21
2016-1322	02/18/2016 03/17/2016	FDA/OC/OES/DFOI/	Peter Markland Peter Markland	WOCKHARDT, INDIA - 483 01/01/2015 - 02/16/2016
2016-1323	02/18/2016 03/17/2016	FDA/OMPT/CDRH/OCE/DID/	Christian G. H. Quass, Pajunk GmbH Medizintechnologie PAJUNK GMBH MEDIZINTECHNOLOGIE	K063233, K070179, K063697, ETC
2016-1324	02/18/2016 03/17/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sabella Scalise Sabella Scalise	BIO SILK MATERIALS IN DRUG INDUSTRY

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-1325	02/18/2016 03/17/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kris Christian FDAZILLA	SCM PHARMA TLD, UK - 483 10/28/2013 - 11/05/2013
2016-1326	02/18/2016 03/17/2016	FDA/OMPT/CDRH/OCE/DID/	Laurie Sang CR BARD INC	K123259 K112411
2016-1327	02/18/2016 03/17/2016	FDA/OFVM/CFSAN/OCD/EOS/	Priscilla Herpai DSM Biomedical	CAP FOR HIGH-PURITY BLACK FILED BY CABOT
2016-1328	02/18/2016 03/17/2016	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/	Zetetic, Inc. Zetetic, Inc.	FDA ENTRY DOCUMENTATION REQUEST ALL DOCUMENTATION FEB 01, 2016 FEB 15, 2016
2016-1329	02/18/2016 03/17/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Marion Scocca Merrimack Pharmaceuticals, Inc.	NDA 207793
2016-1330	02/18/2016 03/17/2016	FDA/OMPT/CDRH/OCE/DID/	Jonathan Bretz RSQM Associates, LLC	K813388
2016-1331	02/18/2016 03/17/2016	FDA/OMPT/CDRH/OCE/DID/ FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	FCN 1579
2016-1332	02/18/2016 03/17/2016	FDA/OMPT/CDRH/OCE/DID/	Nolan Sardesai VasolInnovations, Inc.	K142359
2016-1333	02/18/2016 03/17/2016	FDA/OMPT/CDRH/OCE/DID/	D. Preston Smith PottyMD, LLC	510K HOLLISTER INC PLASTIBELL
2016-1334	02/18/2016 03/17/2016	FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/	Alexandra Ajmo LIFE EXTENSION	DYNAMIC COSMETICS, POMPANO BEACH, FL - EIR 01/01/2011 - 02/17/2016
2016-1335	02/18/2016 03/17/2016	FDA/OGROP/ORO/CE-FO/CIN-DO/CIN-CB/	Amie N. Vanella Faegre Baker Daniels LLP	DOLE SPRINGFIELD, OH - TESTING DATA 01/01/2011 - 02/17/2016;
2016-1336	02/18/2016 03/17/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jacqueline Barrientos Chronic Lymphocytic Leukemia (CLL) Research and Treatment Program	CASE REPORTS 11092813, 11113980, 10777597 ETC
2016-1337	02/18/2016	FDA/OMPT/CDER/GRP/DIDP/	FOIA 18Feb16	NDA 018604 S 000 NDA 018604 S 015

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	03/17/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Acrux DDS Pty Ltd	
2016-1338	02/18/2016 03/17/2016	FDA/OMPT/CDRH/OCE/DID/	Nolan Sardesai VasoInnovations, Inc.	K152525 K142122
2016-1339	02/19/2016 04/05/2016	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDRH/OCE/DID/	JOHN NOONEN Geragos & Geragos, APC	INTUITIVE SURGICAL - DA VINCI ROBOTIC SURGICAL DVC RECALLS, WARNINGS 2008 TO PRESENT
2016-1340	02/19/2016 03/18/2016	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ FDA/OMPT/CDRH/OCE/DID/	CLARK P ROSENGARTEN POPE MCGLAMRY ET AL ATTYS	TELEFLEX INC, TELEFLEX MEDICAL INC, MORRISVILLE, NC; LAWTON GMBH & CO KG - MOGEN CIRCUMSICION CLAMP DESIGN, MANUFACTURE, DISTRIBUTION CORR, TRANS, SUMMARY, ETC
2016-1341	02/19/2016 03/18/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCE/DID/	JON RICHES GOLDWATER INSTITUTE	MEMORIAL SLOAN KETTERING CANCER CTR, NEW YORK, NY; MAYO CLINIC, ROCHESTER, NY; JOHNS HOPKINS HOSPITAL, BALTIMORE, MD, ETC - ACCESS SUBMISSIONS AND PROTOCOLS FY12 TO FY15
2016-1342	02/19/2016 03/25/2016	FDA/OC/OES/DDM/ FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OMPT/CDRH/OCE/DID/	TAKEENA THOMPSON COHEN & MALAD LLP	COOK MEDICAL INC, COOK INC - NESTER PLATINUM EMBOLISATION COIL, NESTER PLATINUM EMBOLIZATION MICROCOIL KR DVC K993455, K992121, K940982, ETC CORR, TRANS, MINS, ETC
2016-1343	02/19/2016 03/18/2016	FDA/OFVM/CFSAN/OCD/EOS/	JOANNA R DRAKE INTERNATIONAL ASSOCIATION OF COLOR MANUFACTURERS	WELCH FOOD INC - CAP 6C0124; GNT USA INC - CAP 6C0245; GRAPE SKIN EXTRACT - CAP
2016-1344	02/19/2016 03/18/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	DAVID MANN BARRY UNIVERSITY SCHOOL OF LAW	AN ASSESSMENT OF THIMEROSAL USE IN CHILDHOOD VACCINES; LESLIE K BALL, ROBERT BALL, R DOUGLAS PRATT OR WILLIAM EGAN CORR REFERENCING AUSTISM STUDIES CITING THIMEROSAL
2016-1345	02/19/2016 03/18/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PATRICK O'LEARY SIDLEY AUSTIN LLP	PURIFIED CORTOPIN GEL NDA 8-975 ANNUAL RPTS, LBLG, MEMOS, ETC
2016-1346	02/19/2016 03/18/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PATRICK O'LEARY SIDLEY AUSTIN LLP	ADRENOMONE NADA 008-760; ACTH GEL NADA 140-583 - LBLG, MEMOS, APRVL, WARNING LTRS, ETC

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/CVM/OCD/		
2016-1347	02/19/2016 03/18/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PATRICK O'LEARY SIDLEY AUSTIN LLP	REPOSITORY CORTICOTROPIN INJ NDA 10-831 ANNUAL RPTS, LBLG, MEMOS, ETC
2016-1348	02/19/2016 03/18/2016	FDA/OMPT/CDRH/OCE/DID/	Jason Nolan RFEM	EDGE ENDO, LLC - REGISTRATION, CERTIFICATION, APPROVAL RECS 02/01/2012 - 02/09/2016
2016-1349	02/19/2016 03/18/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joe McCann Slingshot Insights	CATALYST PHARMACEUTICALS - REFUSE TO FILE LETTER RE NDA
2016-1350	02/19/2016 03/18/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mark Prinz Registrar Corp	SPREADSHEET OF DMF ORIGINAL SUBMISSIONS 01/01/2015 - 12/31/2015
2016-1351	02/19/2016 03/18/2016	FDA/OFVM/CFSAN/OCD/EOS/	Maria de Ftima Poas Catholic University of Portugal - Faculty of Biotechnology	FCN 191 FCN 1505
2016-1352	02/19/2016 03/18/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PATRICK O'LEARY SIDLEY AUSTIN LLP	ACTH STERI-VIALS NDA 8-317 - ANNUAL RPTS, LBLG, MEMOS, ETC
2016-1353	02/19/2016 03/18/2016	FDA/OGROP/ORAP/FO/SAN-DO/SAN-CB/	Kris Christian FDAZILLA	BIOMARIN PHARMACEUTICAL, INC, NOVATO, CA - 483 04/08/2014 - 04/17/2014
2016-1354	02/19/2016 03/18/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PATRICK O'LEARY SIDLEY AUSTIN LLP	ACTHAR NDA 7-504 - ANNUAL RPTS, LBLG, MEMOS, ETC
2016-1355	02/19/2016 03/18/2016	FDA/OMPT/CDRH/OCE/DID/	Dave Oberhelman MedTek Lighting Corporation	K132643
2016-1356	02/19/2016	FDA/OMPT/CDER/GRP/DIDP/	PATRICK O'LEARY	REPOSITORY CORTICOTROPIN TUBEX INJ NDA 16-226 - ANNUAL RPTS, LBLG, MEMOS, ETC

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	03/18/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SIDLEY AUSTIN LLP	
2016-1357	02/19/2016 03/18/2016	FDA/OC/OES/DFOI/	Marilynn Whitney COVINGTON & BURLING LLP	2015-8544, 2013-7905, 2013-8650 ETC
2016-1358	02/19/2016 03/18/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dan Chiorean Odom & Des Roches, LLC	ANDA 076737 APPROVAL ROUTING SUMMARY
2016-1359	02/19/2016 03/18/2016	FDA/OMPT/CDRH/OCE/DID/	Jason Nolan RFEM	GUIDANCE ENDODONTICS, LLC - REGISTRATION, CERTIFICATION, APPROVAL RECS 01/02/2004 - 02/09/2016
2016-1360	02/19/2016 03/18/2016	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	Cathy Walker Aegerion Pharmaceuticals, Inc.	COVANCE, VIENNA, VA - EIR, 483 10/12/1994 - 11/12/1995
2016-1361	02/19/2016 03/18/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PATRICK O'LEARY SIDLEY AUSTIN LLP	CORTROPHIN-ZINC SUSPENSION NDA 9-854 - ANNUAL RPTS, LBLG, MEMOS, ETC
2016-1362	02/19/2016 03/18/2016	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	Cathy Walker Aegerion Pharmaceuticals, Inc.	COVANCE, VIENNA, VA - EIR, 483 08/05/1997 - 08/05/1998
2016-1363	02/19/2016 03/18/2016	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Alexandra Ajmo LIFE EXTENSION	BLISPAK ACQUISITION CORPORATION, WHIPPANY, NJ - EIR 01/01/2011 - 02/17/2016
2016-1364	02/19/2016 03/18/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Stacie Wehling Scilucnet, LLC	NDA 008719 NDA 008720
2016-1365	02/19/2016 03/18/2016	FDA/OMPT/CDRH/OCE/DID/	D. Preston Smith PottyMD, LLC	Olympic Circumstraint, Olympic Papoose Board 510K
2016-1366	02/19/2016 04/21/2016	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	Inbal Keret Atox Bio	PYRAMID LABORATORIES, COSTA MESA, CA - EIR; JUBILANT HOLLISTERSTIER, SPOKANE, WA - EIR, ETC 02/04/2013 - 12/30/2015
2016-1367	02/19/2016	FDA/OC/OES/	Molly McCrea	RECS RE GLYPHOSATE TESTING PLANS 01/01/2000 -

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	03/18/2016	FDA/OFVM/CFSAN/OCD/EOS/	KPIX NEWS	03/01/2016
2016-1368	02/19/2016 03/18/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PATRICK O'LEARY SIDLEY AUSTIN LLP	NDA 7-504, NDA 7-727, NDA 7-747, ETC - FOIA REQUESTS 1/1/11 TO 2/12/16, CORR, MEMOS
2016-1369	02/19/2016 03/18/2016	FDA/OMPT/CDRH/OCE/DID/	Derrick Bingham Owen, Gleaton, Egan, Jones & Sweeney, LLP	EXOFIN HIGH VISCOSITY TISSUE ADHESIVE - 510K 04/01/2011 - 02/17/2016
2016-1370	02/19/2016 03/18/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Cuccias FOIA Professional Services	EMAILS BETWEEN FDA AND GW PHARMACEUTICALS RE BREAKTHROUGH DESIGNATION 01/01/2013 - 01/01/2016
2016-1371	02/19/2016 03/18/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Melissa Spencer TRANSITION THERAPEUTICS INC	NDA 005929 SBA
2016-1372	02/19/2016 03/18/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PATRICK O'LEARY SIDLEY AUSTIN LLP	CORTICOTROPIN INJ ANDA 88-772 - ANNUAL RPTS, MEMOS, LBLG, ETC
2016-1373	02/19/2016 03/18/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca Acabchuk UNIVERSITY OF CONNECTICUT	BRINTELLIX - CLINICAL TRIAL RECS 02/15/2005 - 02/17/2016
2016-1374	02/19/2016 03/18/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PATRICK O'LEARY SIDLEY AUSTIN LLP	ANI PHARMACEUTICALS INC - NDA 8-975, NDA 9-854 MEMOS, CORR, MINS, ETC 1/1/11 TO 2/12/16
2016-1375	02/19/2016 03/18/2016	OC/ORA/ OC/ORA/	Elinor Murarova Advanced Infusion Solutions	ADVANCED INFUSION SOLUTIONS, BOND PHARMACY - EIR 09/01/2015 - 11/30/2015
2016-1376	02/19/2016 03/18/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Max Maccoby Butzel Long, P.C.	DILANTIN - SUPPLEMENTAL APPLICATION; FDA LETTERS TO PFIZER, CORR 01/03/2000 - 09/03/2007

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-1377	02/19/2016 03/18/2016	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	Ellie Clark Drink Eat Well	Lab analysis or results for sample 925630
2016-1378	02/19/2016 03/18/2016	FDA/OMPT/CDRH/OCE/DID/	Brian Janowski Biotech Navigators LLC	K0940954
2016-1379	02/19/2016 03/18/2016	FDA/OMPT/CDRH/OCE/DID/ FDA/OC/OES/DDM/	KELLY HAMILTON LADY LIGHT CREATIONS	VARIANCE RENEWAL APRVL LTR 2015-2016 FOR VAR 2014-V-1392
2016-1380	02/19/2016 03/18/2016	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	JEROME T LYNCH LYNCH, JEROME T	JOST CHEMICAL CO, ST LOUIS, MO - EIR 8/15
2016-1381	02/19/2016 03/18/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LINH PHAM MERCHANT LAW GROUP LLP	OXYCONTIN - LBLG FROM THE DATE OF THE DRUG RELEASE TO PRESENT
2016-1382	02/19/2016 03/18/2016	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	LINDSAY ABRAHAM WESTERN INSTITUTIONAL REVIEW BOARD	RAJESH C SACHDEO MD - EIRS, 482S, 483S, ETC 2011 TO PRESENT
2016-1383	02/19/2016 03/28/2016	FDA/OC/OES/DFOI/	GEORGE LABLANCHE LABLANCHE, GEORGE	HYDROXYCUT - INVESTIGATIONS, CONCLUSIONS
2016-1384	02/19/2016 03/18/2016	FDA/OMPT/CDRH/OCE/DID/	NANCY MACDONALD HEALTH POLICY ASSOCIATES INC	NAVILYST MEDICAL INC - BIOFLO MIDLINE CATHETER K150407
2016-1385	02/19/2016 03/18/2016	FDA/OC/OES/DFOI/	Borim Ryu Seoul National University College of Medicine	RANDOM CASE REPORTS
2016-1386	02/22/2016 03/21/2016	FDA/OMPT/CDRH/OCE/DID/	COLLEN CONROY OLSMAN MACKENZIE & WALLACE	EZ WAY SMART LIFET 600 LB CAPACITY - HOURGLASS SLING WITH MESH MATERIAL CMLPNTS
2016-1387	02/22/2016 03/21/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	JERRY MOORE MOORE, JERRY	SOBER-UP PILLS - AERS
2016-1388	02/22/2016	FDA/OC/OES/DFOI/	Kris Christian	REDACTED 483, RESPONSE, EIR RELEASED SINCE 1/7/16

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	03/29/2016		FDAZILLA	
2016-1389	02/22/2016 03/21/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCE/DID/	Kris Christian FDAZILLA	NOBEL PROCERA SERVICES INC., QUEBEC CANADA - 483 09/09/2013 - 09/12/2013
2016-1390	02/22/2016 03/21/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID J NORTHRUP NORTHRUP V13733, DAVID J	LEUPROLIDE ACETATE, HISTRELIN - LBLG
2016-1391	02/22/2016 03/21/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	Dr. John Clark RiskBenefits, LLC	MEDWATCH FORMS
2016-1392	02/22/2016 03/21/2016	FDA/OMPT/CDRH/OCE/DID/	Kris Christian FDAZILLA	MOOG MEDICAL DEVICES GROUP SRL, COSTA RICA - 483 09/16/2013 - 09/19/2013
2016-1393	02/22/2016 03/21/2016	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	Aaron Swanson PRO-TECH Design & Mfg, Inc.	PRO TECH DESIGN & MFG, INC, SANTA FE SPRINGS, CA - EIR 05/15/2014 - 02/18/2016
2016-1394	02/22/2016 03/21/2016	FDA/OMPT/CDRH/OCE/DID/	Kris Christian FDAZILLA	GLOBAL MED INC, TRENTON, CANADA - 483 09/03/2013 - 09/06/2013
2016-1395	02/22/2016 03/21/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Robert van Osdel Nexgen Pharma, Inc.	ANDA 201722
2016-1396	02/22/2016 03/21/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Hajra Mazhar Hajra Mazhar, University of Ottawa	SAFETY REPORTS 112486761; 4600400; 114765051; ETC
2016-1397	02/22/2016 03/21/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sheldon Garrison MATC	NDA 17366 SBA

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2016-1398	02/22/2016 03/21/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Susan Cusack Innocoll Inc.	NDA 22496 PHARM/TOX REVIEW
2016-1399	02/22/2016 03/21/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LAWRENCEW F TRACEY TRACEY & FOX	DIABETIC KETOACIDOSIS, INVOKANA, SGLT2 INIBITORS - SAFETY COMM, SAFETY ANNOUNCEMENT, LABEL CHANGE 5/15/15, 12/4/15
2016-1400	02/22/2016 03/21/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Susan Cusack Innocoll Inc.	NDA 19978 PHARM/TOX REVIEW
2016-1401	02/22/2016 03/21/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Susan Cusack Innocoll Inc.	NDA 18053 PHARM/TOX REVIEW
2016-1402	02/22/2016 03/21/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Susan Cusack Innocoll Inc.	NDA 16964 PHARM/TOX REVIEW
2016-1403	02/22/2016 03/21/2016	FDA/OMPT/CDRH/OCE/DID/	Jennifer Edouard BOSTON SCIENTIFIC	K092359
2016-1404	02/22/2016 03/21/2016	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Ryan D. Woods PRA Health Sciences	CRI WORLDWIDE FACILITY, CLEMENTON, NJ - 483 07/07/2008 - 07/21/2008
2016-1405	02/22/2016 03/21/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sheldon Garrison MATC	NDA 13601APPROVAL RECS
2016-1406	02/22/2016 03/21/2016	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	Julianne Van Norman Zimmerman Reed LLP	CASTLE CHEESE, INC, SLIPPERY ROCK, PA, INTERNATIONAL PACKING, LLC, UNIVERSAL CHEESE AND DRYING - INSPECTIONS RECS RE INVESTIGATION 01/01/2012 - 02/18/2016
2016-1407	02/22/2016 03/21/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kim Gilchrist GlaxoSmithKline Pharmaceutical	C HOLESTYRAMINE - NDA RECS

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Attn: Kim Gilchrist MD	
2016-1408	02/22/2016 03/21/2016	FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/	Laura MacCleery Center for Science in the Public Interest	ATTACHED RECS
2016-1409	02/22/2016 03/21/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Daniel Bernier PFIZER, INC.	TEVA PHARMACEUTICALS WORKS PRIVATE LIMITED, HUNGARY - 483 01/01/2016 - 02/15/2016
2016-1410	02/22/2016 03/21/2016	FDA/OC/OES/DFOI/	DAVID RICHARD WALKER JR. WALKER LCDC#F188417, DAVID RICHARD	BOSTON SCIENTIFIC - GREENFIELD FILTER, CBC FILTER RECALLS
2016-1411	02/22/2016 03/21/2016	FDA/OC/OES/DFOI/	Carl Malmstrom Wolf Haldenstein Adler Freeman & Herz LLC	CASTLE CHEESE REPORT 01/01/2013 - 02/19/2016
2016-1412	02/22/2016 03/21/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	kzeidner Amneal Pharmaceuticals	CANASA - APPROVAL RECS
2016-1413	02/22/2016 03/21/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K142516
2016-1414	02/22/2016 03/21/2016	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/	Colleen OBrien New York Apple Sales	Residue Tests: Sample # 887043 & 887044 Apples
2016-1415	02/22/2016 03/21/2016	FDA/OC/OES/DFOI/	Sherry Robinson LEXISNEXIS	VISX, INC - WARNING LETTER 1/16/2000
2016-1416	02/22/2016 03/21/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K140638
2016-1417	02/22/2016 03/21/2016	FDA/OMPT/CDRH/OCE/DID/	Al Van Houdt SPACELABS HEALTHCARE	K120406, K143714, K033275, ETC
2016-1418	02/22/2016 03/21/2016	FDA/OC/OES/DFOI/	BRUCE S LEWIS LEWIS, BRUCE S	EVALUATION OF THE HEALTH ASPECTS OF CARBON DIOXIDE AS A FOOD INGREDIANT 1979; PB-959/6 - RPTS
2016-1419	02/22/2016	FDA/OMPT/CDER/ORP/DIDP/	Daniel Bernier	TEVA PHARMACEUTICALS WORKS PRIVATE LIMITED, HUNGARY - 483 01/01/2016 - 02/19/2016

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	03/21/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PFIZER, INC.	
2016-1420	02/22/2016 03/30/2016	FDA/OFVM/CFSAN/OCD/EOS/	ERIC F GREENBERG ERIC F GREENBERG PC	NORTHWEST COATINGS - COPOLYMER OF MONOACRYOXYETHYL SUCCINATE (MAES), HEXAHYDROPHTHALATE (MAHP) FCN 642
2016-1421	02/22/2016 03/21/2016	FDA/OO/OHR/	Kendra Haar Perkins Coie, LLP	PERSONNEL RECS
2016-1422	02/22/2016 03/21/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jordan Schwartz Th Pew Charitable Trusts	ORANGE BOOK RECS
2016-1423	02/22/2016 03/21/2016	FDA/OMPT/CDRH/OCE/DID/	Al Van Houdt SPACELABS HEALTHCARE	K120406, K143714, K033275, ETC
2016-1424	02/22/2016 03/21/2016	FDA/OMPT/CDRH/OCE/DID/	Al Van Houdt SPACELABS HEALTHCARE	. K120406, K143714, K033275, ETC
2016-1425	02/22/2016 03/21/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Robert Struck Cancermedica LLC	IND of 4-hydroperoxycyclophosphamide (4-HC) for clinical treatment of neoplastic meningitis
2016-1426	02/22/2016 03/21/2016	FDA/OC/OES/DFOI/	Robert Struck Cancermedica LLC	IND of 4-hydroperoxycyclophosphamide (4-HC) for clinical treatment of neoplastic meningitis
2016-1427	02/22/2016 03/21/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Alec White HEALTHCOR MANAGEMENT LP	XIAFLEX - AERS
2016-1428	02/22/2016 03/21/2016	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	Arnie Sair Signature Brands, LLC	SIGNATURE BRANDS, LLC, OCALA, FL - EIR 10/01/2011 - 10/31/2011
2016-1429	02/22/2016 03/21/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Robert Struck Cancermedica LLC	IND of 4-hydroperoxycyclophosphamide (4-HC) for clinical treatment of neoplastic meningitis
2016-1430	02/22/2016 03/21/2016	FDA/OC/OES/DFOI/ FDA/OMPT/CTP/OD/	MICHAEL HOUCCCHIN RONALD A MARRON LAW OFC	SANTA FE NATURAL TOBACCO CO; AMERICAN SPIRIT CIGARETTES - FOIA REQUESTS, NON-EXEMPT RECS, ETC

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2016-1431	02/22/2016 03/21/2016	FDA/OC/OES/DFOI/	Brett Powers Brett Powers	RECS RE RECALL OF FRESENIUN NATURALYTE LIQUID BICARBONATE CONCENTRATE
2016-1432	02/22/2016 03/21/2016	FDA/OC/OES/DFOI/	Brett Powers Brett Powers	RECS RE RECALL OF FRESENIUN NATURALYTE LIQUID BICARBONATE CONCENTRATE
2016-1433	02/22/2016 03/21/2016	OC/CVM/OCD/	Kristi Smedley Center for Regulatory Services Inc.	OCLACITINIB - AERS SUMMARY IN DOGS
2016-1434	02/22/2016 03/21/2016	FDA/OC/OES/DFOI/	Kristi Smedley Center for Regulatory Services Inc.	OCLACITINIB - AERS SUMMARY IN DOGS
2016-1435	02/22/2016 03/21/2016	FDA/OC/OES/DFOI/	Kristi Smedley Center for Regulatory Services Inc.	OCLACITINIB - AERS SUMMARY IN DOGS
2016-1436	02/22/2016 03/21/2016	FDA/OC/OES/DFOI/	Kristi Smedley Center for Regulatory Services Inc.	OCLACITINIB - AERS SUMMARY IN DOGS
2016-1437	02/22/2016 03/21/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	David Lebowitz Morgan Stanley	ORKAMBI - AERS
2016-1438	02/22/2016 03/21/2016	FDA/OC/OES/DFOI/	David Lebowitz Morgan Stanley	ORKAMBI - AERS
2016-1439	02/22/2016 03/21/2016	OC/ORO/ OC/ORO/	LAWRENCE M ROSS HURWITZ & FINE PC	PINE PHARM, TONAWANDA, NY - EIR, 483, RESP TO 483, ETC 10/5-9/15
2016-1440	02/22/2016 03/21/2016	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/	RICHARD WOLESAGLE WOLESAGLE, RICHARD	CMPLNT 144293
2016-1441	02/23/2016 03/22/2016	FDA/OC/OES/DDM/ FDA/OMPT/CDRH/OCE/DID/	FERRUCIO A ROMERO ESQ FERRUCCIO A ROMERO ESQ LLC	HEARTWARE VENTICULAR ASSIST SYS 510K, RECALLS, LBLG, ETC
2016-1442	02/23/2016 03/22/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID HOFFMEISTER Wilson Sonsini Goodrich & Rosati, P.C.	ELI LILLY & CO - BASAGLAR (INSULIN GARGINE INJ) NDA 205-692 CORR, MTG MINS, MEMOS, ETC
2016-1443	02/23/2016 03/22/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TRICIA THOMPSON Thompson, Tricia	NATIONAL FOUNDATION FOR CELIAC AWARENESS (NFCA) - GLUTEN TESTING DATA

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-1444	02/23/2016 03/22/2016	FDA/OMPT/CDRH/OCE/DID/	COLLENT M DURRAN FRESENIUS MEDICAL CARE	GAMBRO RENAL PRODUCTS INC - K120333
2016-1445	02/23/2016 03/22/2016	FDA/OC/OES/DFOI/	SHERRY L ROBINSON LEXISNEXIS	VISX - WARNING LTR 12/02
2016-1446	02/23/2016 03/22/2016	FDA/OMPT/CDRH/OCE/DID/	EVAN P PHELPS OLSSON FRANK WEEDA TERMAN MATZ PC	UROMETRICS INC - NEVA SYSTEM PENILE TUMESCENCE MONITOR K980627
2016-1447	02/23/2016 03/22/2016	FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECS
2016-1448	02/23/2016 03/22/2016	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDRH/OCE/DID/ FDA/OMPT/CDRH/OCE/DID/	DAVID H STERNLIEB SHAPIRO & STERNLIEB LLC	BREAST CARE CTR, NEPTUNE, NJ; JERSEY SHORE IMAGING, NEPTUNE, NJ; JERSEY SHORE RADIOLOGY ASSOCIATES, NEPTUNE CITY, NJ, ETC - MQSA INSP RPTS 2000 TO PRESENT
2016-1449	02/23/2016 03/22/2016	FDA/OFVM/CFSAN/OCD/EOS/	TED WHITEHEAD DANNON CO	FDA FOOD RECALL DATABASE
2016-1450	02/23/2016 03/22/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PATRICIA WEITZEL RN WEITZEL, PATRICIA	HARVONI - AERS
2016-1451	02/23/2016 03/22/2016	FDA/OFVM/CFSAN/OCD/EOS/	DR SABINE VOGT BASF SE	FCN 1574
2016-1452	02/23/2016 03/22/2016	FDA/OFVM/CFSAN/OCD/EOS/	DR RUTH ZSCHIESCHE BASF SE	FCN 96
2016-1453	02/23/2016 03/22/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	EDWARD A STEELE EAS CONSULTING GROUP LLC	ACTAVIS LABS UT INC - URSODIOL CAPS NDA 19-594
2016-1454	02/23/2016 03/22/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	EDWARD A STEELE EAS CONSULTING GROUP LLC	SANDOZ - BUMETANIDE TABS ANDA 74-700
2016-1455	02/23/2016 03/22/2016	FDA/OFVM/CFSAN/OCD/EOS/	Fast Trac Auto Detailing Plus Abady Law Firm, P.C.	FAST TRAC AUTO DETAILING PLUS - CFSAN RESPONSE LETTER

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2016-1456	02/23/2016 03/22/2016	FDA/OC/OES/DFOI/	Wendy Banka Wendy Banka	EIR requested in 2015-7498 that was denied, including any exhibits or attachments
2016-1457	02/23/2016 03/22/2016	FDA/OC/OES/DFOI/	Wendy Banka Wendy Banka	EIR records requested in 2015-7497 that were denied, including any exhibits or attachments
2016-1458	02/23/2016 03/22/2016	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Wendy Banka Wendy Banka	EIR Exhibits and EIR Attachments for EIR dated 01/08/2015 for Kruger Commodities, Inc., of Hamilton, MI
2016-1459	02/23/2016 03/22/2016	FDA/OC/OES/DFOI/	Wendy Banka Wendy Banka	2015-501
2016-1460	02/23/2016 03/22/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	EDWARD A STEELE EAS CONSULTING GROUP LLC	USL PHARMA - CHLORPROMAZINE HCL TABS ANDA 84-114, ANDA 83-386, ANDA 84-115, ETC
2016-1461	02/23/2016 03/22/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joseph Gallagher eVenus Pharmaceutical Laboratories Inc.	ANDA 203869 APPROVAL LETTER CERTIFIED
2016-1462	02/23/2016 03/22/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joseph Gallagher eVenus Pharmaceutical Laboratories Inc.	ANDA 203793 APPROVAL LETTER CERTIFIED
2016-1463	02/23/2016 03/22/2016	FDA/OC/OES/DFOI/	Doe J	CHOCOLATE COVERED CASHEWS - CMLPNT
2016-1464	02/23/2016 03/22/2016	FDA/OFVM/CFSAN/OCD/EOS/	Todd Neeley DTN/The Progressive Farmer	RECS RE DEVELOPMENT OF METHODOLOGY TO BE USED FOR TESTING FOOD FOR RESIDUES OF GLYPHOSATE 01/01/2015 - 02/19/2016
2016-1465	02/23/2016 03/22/2016	FDA/OFVM/CFSAN/OCD/EOS/ OC/OR/ OC/OR/ FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAPA-FO/SAN-	Adam D. Wahlquist KIRTON MCCONKIE & POELMAN	RECS RE E.COLI OUTBREAK COSTCO CHICKEN SALAD 10/01/2015 - 02/19/2016

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		DO/SAN-CB/ FDA/OGROP/ORAP/PA-FO/SEA-DO/SEA-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/		
2016-1466	02/23/2016 03/22/2016	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/ORAP/ OC/ORAP/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Leif Reigstad HOUSTON PRESS	ADVERSE EVENTS, DIETARY SUPPLEMENT REPORTS ETC
2016-1467	02/23/2016 03/22/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rahul Solanki Edelweiss	COPAXONE - STAGE OF REVIEW 01/02/2015 - 02/18/2016
2016-1468	02/23/2016 03/22/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joseph Gallagher eVenus Pharmaceutical Laboratories Inc.	ANDA 090675 APPROVAL LETTER CERTIFIED
2016-1469	02/23/2016 03/22/2016	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORAP/ OC/ORAP/	Rend Al-Mondhiry COUNCIL FOR RESPONSIBLE NUTRITION	03/03/2014 - 02/19/2016 RECS RE DIETARY SUPPLEMENT RELATED TRAINING PROVIDED BY DANIEL FABRICANT AND COREY HILMAS
2016-1470	02/23/2016 03/22/2016	FDA/OC/OES/DFOI/	Carl Malmstrom Carl Malmstrom	CASTLE CHEESE REPORT
2016-1471	02/23/2016 03/22/2016	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OMPT/CDRH/OCE/DID/	Gael Tisack Terumo Cardiovascular Systems Corp.	LIVANOVA./SORIN, MUNICH, GERMANY; ARVADA, CO - 483 02/03/2015 - 02/07/2016
2016-1472	02/23/2016 03/22/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tushar Manudhane Indianivesh securities	ARACOLAB/STRIDES, BANGALORE, INDIA - 483 01/01/2016 - 02/20/2016

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-1473	02/23/2016 03/22/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Cathy Dreifort Dreifort, Cathy	HARVONI - AERS
2016-1474	02/23/2016 03/22/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rahul Solanki Edelweiss	SHILPA, INDIA - 483 09/01/2015 - 10/31/2015
2016-1475	02/23/2016 03/22/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Brett Vengroff ComplianceLogix	PHARSAFER ASSOCIATES LTD, UK - 483 09/30/2015 - 09/30/2015
2016-1476	02/23/2016 03/22/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Andrew Himsel Andrew Himsel	VISTOGARD APPROVAL RECS
2016-1477	02/23/2016 03/22/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Prasanna Sunthakar Grace Therapeutics LLC	NIMOTOP, NDA NDA 018869
2016-1478	02/23/2016 03/22/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	G. Srinivas Zydus Pharmaceuticals USA Inc.	ANDA 203184
2016-1479	02/23/2016 03/22/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 21436 S38
2016-1480	02/23/2016 03/22/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jigar Valia Ohm Group	WOCKHARDT, INDIA - 483 01/01/2016 - 01/15/2016

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2016-1481	02/23/2016 03/22/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Chingju Tseng TWi Pharmaceuticals, Inc.	FOSPHENYTOIN SODIUM NDA 020450
2016-1482	02/23/2016 03/22/2016	FDA/OC/OES/DFOI/	EMILY E RAND CBS NEWS	CASTLE CHEESE, SLIPPERY ROCK, PA - EIRS, 483S, COMM 1/12 TO PRESENT
2016-1483	02/24/2016 03/23/2016	FDA/OC/OES/DFOI/	Eyal Maor FDAAWARE	WARNING LETTER RESPONSES RELEASED UNDER FOIA 01/01/2008 - 12/31/2015
2016-1484	02/24/2016 03/23/2016	FDA/OMPT/CDRH/OCE/DID/	Gael Tisack Terumo Cardiovascular Group	MAQUET, GETINGE WORLDWIDE - 483 02/02/2015 - 02/19/2016
2016-1485	02/24/2016 03/23/2016	FDA/OC/OES/DFOI/	Jaime Vassallo CourtLink Document Retrieval	2013-7905
2016-1486	02/24/2016 03/23/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K141790
2016-1487	02/24/2016 03/23/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dheeresh pathak Dheeresh Pathak	STRIDES ARCOLAB, INDIA - 483 02/01/2016 - 02/24/2016
2016-1488	02/24/2016 03/23/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Marcin Mankowski TranScrip Partners	AVYCAZ AERS
2016-1489	02/24/2016 03/23/2016	FDA/OMPT/CDRH/OCE/DID/	Stephen Hayward Ag Conexus, Inc.	ESSURE - AERS
2016-1490	02/24/2016 03/23/2016	FDA/OGROP/ORO/PA-FO/SEA-DO/SEA-CB/	Melissa V. Malapit Celgene Corporation	JOHN PAGEL, FRED HUTCHINSON CANCER RESEARCH CENTER, SEATTLE, WA - 483 12/01/2009 - 02/23/2016
2016-1491	02/24/2016 03/23/2016	FDA/OFVM/CFSAN/OCD/EOS/	Renee Nelson Robert M Kerr Food & Ag Products Center	GRAS Notice Inventory #596 for Breadfruit Flour
2016-1492	02/24/2016 04/14/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Winnie Aman Sunsey International	BK840010
2016-1493	02/24/2016 04/14/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Winnie Aman Sunsey International	BK920027

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2016-1494	02/24/2016 04/14/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Winnie Aman Sunsey International	BK950049
2016-1495	02/24/2016 03/23/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	G. Srinivas Zydus Pharmaceuticals USA Inc.	NDA 017830
2016-1496	02/24/2016 03/23/2016	FDA/OMPT/OSMP/OOPD/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	DUOPA - ORPHAN DESIGNATION RECS
2016-1497	02/24/2016 03/23/2016	FDA/OMPT/CDRH/OCE/DID/	Sandeep Prabhu Saving Sara, Inc	K904267
2016-1498	02/24/2016 03/23/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sammy Alexander Sammy Alexander	CHANTIX - AERS
2016-1499	02/24/2016 03/23/2016	FDA/OC/OES/DFOI/	Jaime Vassallo CourtLink Document Retrieval	2013-8650
2016-1500	02/24/2016 03/23/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Leanne Usa Wockhardt USA LLC	ANDA 208031 ANDA 208037 ANDA 208066
2016-1501	02/24/2016 03/23/2016	FDA/OMPT/CDRH/OCE/DID/	Aishen Li UNIVERSITY OF MINNESOTA	MEDICAL DEVICE RECALL DATA
2016-1502	02/24/2016 03/23/2016	FDA/OGROP/ORACE-FO/MIN- DO/MIN-CB/	Ginger Glaser Monteris Medical	MONTERIS MEDICAL, PLYMOUTH, MN - EIR
2016-1503	02/24/2016 03/23/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Roxanne Coulon Relypsa Inc	DR ELENE GIODADZE, GEORGIA - EIR MARCH 2015
2016-1504	02/24/2016 03/23/2016	FDA/OC/OES/DFOI/ FDA/OGROP/ORANE-FO/NYK-	Lydia Mulvany BLOOMBERG NEWS	ICCO CHEESE, ORANGEBURG, NY - EIR, 483, CORR ETC 01/01/2011 - 02/23/2016

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		DO/NYK-DCB/		
2016-1505	02/24/2016 03/23/2016	OC/ORa/OCI/ OC/ORa/OCI/	Spencer R. Knapp The University of Vermont Medical Center	INVESTIGATION NOTIFICATION RECS
2016-1506	02/24/2016 03/23/2016	FDA/OGROP/ORa/CE-FO/PHI-DO/PHI-CB/	Lydia Mulvany BLOOMBERG NEWS	MICHELLE FARMS, SLIPPERY ROCK, PA - EIR, 483 02/01/2010 - 02/23/2016
2016-1507	02/24/2016 03/23/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Peter Harwin TAVISTOCK LIFE SCIENCES	LYNPARZA - AERS
2016-1508	02/24/2016 03/23/2016	FDA/OC/OES/DFOI/	Blake Kraus Blake Kraus	CHIPOTLE RECS
2016-1509	02/24/2016 03/23/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Douglas A. Daniels Douglas A. Daniels	LEVOTHYROXINE SODIUM - AERS
2016-1510	02/24/2016 03/23/2016	FDA/OMPT/CDRH/OCE/DID/	TIMOTHY G. LYNCH SWARTZ & LYNCH LLP	MEDLINE INDUSTRIES INC - HOMECARE BEDS & BEDRAILS MEDICAL DVC RECORDS 2003 TO PRESENT
2016-1511	02/24/2016 03/23/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORa/ OC/ORa/ FDA/OC/OES/DFOI/	ANGELA J. MASON COCHRAN FIRM	MAIN STREET FAMILY PHARMACY LLC, NEWBERN, TN - INVESTIGATION
2016-1512	02/24/2016 03/23/2016	FDA/OC/OES/DFOI/	GALKA, MAXWELL	FOI LOG
2016-1513	02/24/2016 03/23/2016	FDA/OGROP/ORa/NE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDRH/OCE/DID/	POWERS, BRETT	RECALL OF FRESENIUN NATURALYTE LIQUID BICARBONATE CONCETRATE
2016-1514	02/24/2016 03/23/2016	FDA/OFVM/CFSAN/OCD/EOS/	REED LAVOIE PHARMASAVE 325	REUMOFAN PLUS NATURAL DIETARY SUPPLEMENT - INVESTIGATION
2016-1515	02/24/2016 03/23/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRAIN C. TRINQUE, Ph.D., Esq. Lathrop & Gage LLP	OTSUKA - ABILIFY NDA 21-436/38

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2016-1516	02/24/2016 03/23/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DON J. MIZERK HUSCH BLACKWELL LLP	IMPAX LABS - ADDERALL XR NDA 76-852 APRVL
2016-1517	02/24/2016 03/23/2016	FDA/OMPT/CDRH/OCE/DID/	LORI A. CARR LORI A CARR INC	ZIMMER - TRABECULAR METAL ACETABULAR REVISION CAGE SYS K061226
2016-1518	02/24/2016 03/23/2016	FDA/OMPT/CDRH/OCE/DID/	LORI A. CARR LORI A CARR INC	ZIMMER - TRABECULAR METAL ACETABULAR REVISION SHELLS K050937
2016-1519	02/24/2016 03/23/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-383 - REQUEST LETTER ONLY
2016-1520	02/24/2016 03/23/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-379 - REQUEST LETTER ONLY
2016-1521	02/24/2016 03/23/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-34 - REQUEST LETTER ONLY
2016-1522	02/24/2016 03/23/2016	FDA/OC/OES/DFOI/	Jaime Vassallo CourtLink Document Retrieval	2015-8544
2016-1523	02/24/2016 03/23/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-308 - REQUEST LETTER ONLY
2016-1524	02/24/2016 03/23/2016	FDA/OC/OES/DFOI/	Jaime Vassallo CourtLink Document Retrieval	2015-9507
2016-1525	02/24/2016 03/23/2016	FDA/OC/OES/DFOI/	Jaime Vassallo CourtLink Document Retrieval	2016-782
2016-1526	02/24/2016 03/23/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-397 - REQUEST LETTER ONLY
2016-1527	02/24/2016 03/23/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-310 - REQUEST LETTER ONLY
2016-1528	02/24/2016 03/23/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-381 - REQUEST LETTER ONLY
2016-1529	02/24/2016 03/23/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-93 - REQUEST LETTER ONLY
2016-1530	02/24/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2016-309 - REQUEST LETTER ONLY

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	03/23/2016		MERCK & CO., INC.	
2016-1531	02/24/2016 03/23/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-275 - REQUEST LETTER ONLY
2016-1532	02/24/2016 03/23/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-91 - REQUEST LETTER ONLY
2016-1533	02/24/2016 03/23/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-40 - REQUEST LETTER ONLY
2016-1534	02/24/2016 03/23/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-268 - REQUEST LETTER ONLY
2016-1535	02/24/2016 03/23/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-209 - REQUEST LETTER ONLY
2016-1536	02/24/2016 03/23/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-570 - REQUEST LETTER ONLY
2016-1537	02/24/2016 03/23/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-102 - REQUEST LETTER ONLY
2016-1538	02/24/2016 03/23/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-454 - REQUEST LETTER ONLY
2016-1539	02/24/2016 03/23/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-521 - REQUEST LETTER ONLY
2016-1540	02/25/2016 03/24/2016	FDA/OC/OES/DFOI/	Amie N. Vanella Faegre Baker Daniels LLP	DOLE, SPRINGFIELD, OH - FOIA REQUESTS 09/01/2015 - 02/24/2016
2016-1541	02/25/2016 03/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Meg Morgen BAIRD LIGHTNER ET AL	ZEPATIER - AERS
2016-1542	02/25/2016 03/24/2016	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORASE-FO/ATLDO/ATL-CB/	Rachel Johnson FOI Services, Inc.	BAXTER INTERNATIONAL INC, MEDLINE INDUSTRIES - RECALL RECS
2016-1543	02/25/2016	FDA/OMPT/CDER/ORP/DIDP/	Roxanne Coulon	MERAB MAMATSASHVILI, TBILISI, GEORGIA - EIR APRIL

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	03/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Relypsa Inc	2015
2016-1544	02/25/2016 03/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Roxanne Coulon Relypsa Inc	ELENE GIORGADZE, TBILISI, GEORGIA - EIR APRIL 2015
2016-1545	02/25/2016 03/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Steve Lucas AuroMedics Pharma LLC	CHENG FONG CHEMICAL CO, TAOYUAN, TAIWAN - 483, EIR 04/05/2013 - 04/17/2013
2016-1546	02/25/2016 03/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Matthew Trachtenberg BECTON, DICKINSON AND COMPANY	CEQR PAQ PRESUBMISSIONS, Q-SUBS 01/01/2008 - 02/24/2016
2016-1547	02/25/2016 03/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	K143306
2016-1548	02/25/2016 03/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mehul Govani P&L Development, LLC	CF PHARMA LTD, BUDAPEST, HUNGARY - 483 01/01/2012 - 02/23/2016
2016-1549	02/25/2016 03/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Katherine Kaempchen Forward Pharma Gmbh- Katherine Kaempchen	CASE REPORTS 1134395; 111433938 ; ETC
2016-1550	02/25/2016 03/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Cuccias FOIA Professional Services	EMAILS BETWEEN KITE PHARMACEUTICAL AND FDA RE: TCR, NY-ESO-1, MAGE-A3, MAGE-A3/A6, HPV-16/E6 ETC 01/01/2015 - 12/31/2015
2016-1551	02/25/2016 03/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Cuccias FOIA Professional Services	CORR BETWEEN FDA AND KITE PHARMACEUTICAL RE: KTE-C19, EGFRvIII, ETC. 01/01/2015 - 12/31/2015

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-1552	02/25/2016 03/24/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Roxanne Coulon Relypsa Inc	TAMAZ SHABURISHVILI, TBILISI, GEORGIA - EIR MARCH 2015
2016-1553	02/25/2016 03/24/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Cuccias FOIA Professional Services	EMAILS BETWEEN KITE PHARMACEUTICAL AND FDA RE: SAFETY GUIDANCE, SAE, SAFETY CONCERN ETC 01/01/2015 - 12/31/2015
2016-1554	02/25/2016 03/24/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GARY L WILSON ROBINS KAPLAN LLC	ABILIFY (ARIPIRAZOLE) - COMM REGARDING WHETHER OR NOT TO INCLUDE A WARNING THAT MENTIONS GAMBLING AS A PRECAUTION, RISK, ETC
2016-1555	02/25/2016 05/09/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	LUCYNDA ADJEI-APPOH KAUFMAN BORGEEST & RYAN LLP	INDIVIDUAL RECS - VAERS
2016-1556	02/25/2016 03/24/2016	FDA/OMPT/CDRH/OCE/DID/	MEGAN C LAMBERT K&L GATES	MITSAR CO LTD - MITSAR EEG K143233
2016-1557	02/25/2016 03/24/2016	FDA/OMPT/CDRH/OCE/DID/	MEGAN C LAMBERT K&L GATES	HHSSYSTEMS LLC - QUANTITATIVE AUTONOMIC NERVOUS SYSTEM) QANS MONITORING SYS K142551
2016-1558	02/25/2016 03/24/2016	FDA/OGROP/ORANE-FO/NYK- DO/NYK-DCB/	LESLIE RAMSEY FDA NEWS	MOSS TUBES INC - RESP TO 483 11/12/15
2016-1559	02/25/2016 03/24/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DR NAOMI BRIGGS MASSACHUSETTS INSTITUTE OF TECHNOLOGY DEPT OF CHEMICAL ENGINEERING	MAPRIMED SA - NICARDIPINE HCL DMF 8919; MITSUBISHI CORP - NICARDIPINE HCL DMF 10702; NAVINTA LLC - NICARDIPINE HCL DMF 19773, ETC
2016-1560	02/25/2016 03/24/2016	FDA/OMPT/CDRH/OCE/DID/	JACQUELINE A HAUGE SPINEOLOGY INC	K100305
2016-1561	02/25/2016 03/24/2016	FDA/OC/OES/DFOI/	APOORV POTLIA MORIKAMI PARK ELEMENTARY SCHOOL	FOOD ALLERGIES - RECS
2016-1562	02/26/2016 03/25/2016	FDA/OC/OES/DFOI/ FDA/OGROP/ORACE-FO/DET- DO/DET-CB/	Wendy Banka Wendy Banka	Communications in 2015-6600 that were denied, including any exhibits or attachments

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2016-1563	02/26/2016 03/25/2016	FDA/OC/OES/DFOI/	Wendy Banka Wendy Banka	Communications in 2015-6261 that were denied, including any exhibits or attachments
2016-1564	02/26/2016 03/25/2016	FDA/OC/OES/DFOI/	Jaime Vassallo CourtLink Document Retrieval	2016-157
2016-1565	02/26/2016 03/25/2016	FDA/OC/OES/DFOI/	Jaime Vassallo CourtLink Document Retrieval	2016-1172
2016-1566	02/26/2016 03/25/2016	FDA/OC/OES/DFOI/	Jaime Vassallo CourtLink Document Retrieval	2016-1130
2016-1567	02/26/2016 03/25/2016	FDA/OC/OES/DFOI/	Jaime Vassallo CourtLink Document Retrieval	2014-8200
2016-1568	02/26/2016 03/25/2016	FDA/OMPT/OSMP/OOPD/	SHERI O COVINGTON K&L GATES	BEENA G SOOD MD., MS - AEROSOLIZED BERACHANT ORPAHN DRUG DESIGNATION
2016-1569	02/26/2016 03/25/2016	FDA/OMPT/OSMP/OOPD/	SHERI O COVINGTON K&L Gates LLP	BAYER HEALTHCARE PHARMACEUTICALS INC - CIPROFLAXACIN DRY POWDER ORPHAN DRUG DESIGNATION
2016-1570	02/26/2016 03/25/2016	FDA/OMPT/OSMP/OOPD/	SHERI O COVINGTON K&L Gates LLP	ARADIGM CORP - CIPROFLOXACIN ORPHAN DRUG DESIGNATION
2016-1571	02/26/2016 03/25/2016	FDA/OMPT/OSMP/OOPD/	SHERI O COVING TON K&L Gates LLP	BAYER HEALTHCARE PHARMACEUTICALS INC - CIPROFLAXACIN ORPHAN DRUG DESIGNATION
2016-1572	02/26/2016 03/25/2016	FDA/OMPT/OSMP/OOPD/	SHERI O COVINGTON K&L Gates LLP	DISCOVERY LABORATORIES INC - ORPHAN DRUG DESIGNATION
2016-1573	02/26/2016 03/25/2016	FDA/OMPT/OSMP/OOPD/	SHERI O COVINGTON K&L Gates LLP	FIBROCELL TECHNOLOGIES INC - AUTOLOGOUSGENETICALLY ORPHAN DRUG DESIGNATION
2016-1574	02/26/2016 03/25/2016	FDA/OMPT/OSMP/OOPD/	SHERI O COVINGTON K&L Gates LLP	RAPTOR INC - PROCYSBI (SYSTEMAINE ENTERIC COATED) NDA 203-389 ORPHAN DRUG DESIGNATION
2016-1575	02/26/2016 03/25/2016	FDA/OO/OFBA/OAGS/	KELLY WAINWRIGHT CHENHALLS STAFFING SERVICES INC	HHSF223201110031 - SOLICATION, ABSTRACT BID PKG, ETC
2016-1576	02/26/2016 03/25/2016	FDA/OC/OES/DFOI/	GINA E ECOLINO BEVERIDGE & DIAMOND PC	FOIA REQUESTS FILED WITH CFSAN 1/23/16 TO PRESENT
2016-1577	02/29/2016 03/28/2016	FDA/OC/OES/DFOI/	Tod Cooperman ConsumerLab.com, LLC	2015-1122
2016-1578	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-3101

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2016-1579	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2012-7275
2016-1580	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-3727
2016-1581	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-2801
2016-1582	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-2854
2016-1583	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-2955
2016-1584	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-3060
2016-1585	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2014-4719
2016-1586	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-3726
2016-1587	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-2219
2016-1588	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2014-9795
2016-1589	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2013-9788
2016-1590	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-4635
2016-1591	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-4559
2016-1592	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-4385
2016-1593	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-4133
2016-1594	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-4931
2016-1595	03/01/2016	FDA/OC/OES/DFOI/		2015-4386

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	03/29/2016		FOI Services, Inc.	
2016-1596	03/01/2016 03/29/2016	FDA/OFVM/CFSAN/OCD/EOS/	ALISSA D JIJON Keller and Heckman LLP	GRAS NOTICE GRN000449
2016-1597	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-4060
2016-1598	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2014-2485
2016-1599	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2013-8401
2016-1600	03/01/2016 03/29/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/ORO/ OC/ORO/	JOHN T LEPORE KATTEN MUCHIN ROSENMAN LLP	SUMMIT PHARMACY INC, PHOENIX, AZ - INSP, REGISTRATION, LICENSING, ETC
2016-1601	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-4632
2016-1602	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-4480
2016-1603	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-4309
2016-1604	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-2217
2016-1605	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-2222
2016-1606	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-2283
2016-1607	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-2371
2016-1608	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-2447
2016-1609	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-2449

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2016-1610	03/01/2016 03/29/2016	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	AUTUMN BORTON PFIZER INC	PFIZER, PEARL RIVER, NY - EIR 10/14
2016-1611	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	DAN CLEARY #M21234 CLEARY #M21234, DAN	MEDROL, MOTRIN, TYLENOL, ETC - AERS
2016-1612	03/01/2016 03/29/2016	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OFVM/CFSAN/OCD/EOS/	LU ZHAO BURDOCK GROUP	KONJAC, KONJAC FLOUR - REGULATORY STATUS, CONSUMPTION, SAFETY RECS, ETC
2016-1613	03/01/2016 03/29/2016	OC/CVM/OCD/	Doe J	BAYER HEALTHCARE ANIMAL HEALTH DIVISION - BAYTRILL CMLPNT
2016-1614	03/01/2016 03/29/2016	FDA/OMPT/CDRH/OCE/DID/	WANG YANG ANDON HEALTH CO LTD	KODON (TIANJIN) ELECTRONIC & ELECTRICAL APPARATUS CO LTD - KD-322 SEMI AUTOMATIC ELECTRONIC BLOOD PRESSURE MONITOR K052676
2016-1615	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-2715
2016-1616	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-6243
2016-1617	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-4989
2016-1618	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-5876
2016-1619	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2012-8625
2016-1620	03/01/2016 03/29/2016	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Barbara Chaney SEDGWICK LLP	SANTA CLARA WASTE WATER COMPANY, SANTA PAULA, CA - RECS RE EXPLOSION ETC 01/01/2011 - 02/22/2016;
2016-1621	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-5419
2016-1622	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-5333
2016-1623	03/01/2016 03/29/2016	FDA/OMPT/CDRH/OCE/DID/	Barbara Adrean EPIC Research & Diagnostics	VASOSCAN TM, 510K
2016-1624	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-4713
2016-1625	03/01/2016 03/29/2016	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/ OC/ORO/	Rachel Johnson FOI Services, Inc.	BIMBO BAKERIES - RECALL RECS; NESTLE WATERS NORTH AMERICA - RECALL RECS

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		FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/		
2016-1626	03/01/2016 03/29/2016	FDA/OMPT/CTP/OD/ OC/OR/ OC/OR/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Rachel Johnson FOI Services, Inc.	AMERICAN SNUFF COMPANY, LLC - RECALL RECS
2016-1627	03/01/2016 03/29/2016	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Rachel Johnson FOI Services, Inc.	BIMBO BAKERIES USA, NESTLE WATERS NORTH AMERICA EIR AUGUST 2015 TO FEBRUARY 2016
2016-1628	03/01/2016 03/29/2016	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	David Hodges, P.I. Fine Tooth Comb Investigations, Inc	DR DEBORAH BLANTON, MD, DUVAL COUNTY, FL - 483 05/01/2013 - 05/31/2013;
2016-1629	03/01/2016 03/29/2016	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	David Hodges, P.I. Fine Tooth Comb Investigations, Inc	LIVE THIN MEDICAL WEIGHT LOSS, JACKSONVILLE, FL - 483 05/01/2013 - 07/31/2013
2016-1630	03/01/2016 03/29/2016	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Rachel Johnson FOI Services, Inc.	JOSE MADRID SALSA - RECALL RECS F-2442-2015
2016-1631	03/01/2016 03/29/2016	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Rachel Johnson FOI Services, Inc.	HORMEL FOODS CORPORATION RECALL RECS F-0288-2016
2016-1632	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2012-8153
2016-1633	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-6266
2016-1634	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2013-9799
2016-1635	03/01/2016 03/29/2016	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OMPT/CDRH/OCE/DID/	Altom M. Maglio on behalf of James Gillam Maglio Christopher & Toale, PA	ZIMMER, INC - CORR WITH FDA RE Z-1266-2015
2016-1636	03/01/2016 03/29/2016	FDA/OFVM/CFSAN/OCD/EOS/	Lauren Somers Lauren Somers	GNC WOMEN'S ULTRA MEGA ENERGY & METABOLISM, GNC CLASOFT CHEW, GNC VITAMIN B-12 - AERS

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2016-1637	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-3714
2016-1638	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	Dominic Mercaldo Dominic Mercaldo	DOMOIC ACID LEVELS IN SEAFOOD
2016-1639	03/01/2016 03/29/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Carolyn Elmore Elmore Patent Law Group	NDA 021436 S 38 SBA
2016-1640	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	Edward Eagan PanAgora Asset Management	FOIA LOG 01/01/1999 - 12/31/2015
2016-1641	03/01/2016 03/29/2016	FDA/OMPT/CDRH/OCE/DID/	Doe J	MAUDE RECS
2016-1642	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2014-7043
2016-1643	03/01/2016 03/29/2016	FDA/OMPT/CDRH/OCE/DID/	Anders Nielsen AMBU A/S	BRONCHOSCOPE MAUDE REPORTS 2015
2016-1644	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2014-1648
2016-1645	03/01/2016 03/29/2016	FDA/OFVM/CFSAN/OCD/EOS/	Leslie Patton Technology Sciences Group, Inc.	FCN 1501
2016-1646	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2014-7243
2016-1647	03/01/2016 03/29/2016	FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/	Kyle Hach Raining Rose Inc.	RAINING ROSE INC, CEDAR RAPIDS, IA - EIR 06/08/2015 - 02/01/2016
2016-1648	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2013-2108
2016-1649	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2014-8305
2016-1650	03/01/2016 03/29/2016	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	Pharmatech LLC Stephen Angelos	PHARMATECH LLC, DAVIE, FL 33314 483
2016-1651	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2014-7206

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2016-1652	03/01/2016 03/29/2016	FDA/OMPT/OSMP/OOPD/	David Cyranoski NATURE	INBREATH AIRWAY TRANSPLANT SYSTEM ORPHAN PRODUCT RECS
2016-1653	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2014-3980
2016-1654	03/01/2016 03/29/2016	FDA/OMPT/CDRH/OCE/DID/	Rebecca Sporer DENTSPLY International Inc.	K141081
2016-1655	03/01/2016 03/29/2016	FDA/OMPT/CDRH/OCE/DID/	Estela Celi STRYKER CORPORATION	P050050, P050050/S001, P050050/S002, P050050/S007 ETC
2016-1656	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2014-4992
2016-1657	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2014-5292
2016-1658	03/01/2016 05/10/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Doe J	Complaint filed 6/18/16 regarding HPV Vaccine Advertising by the Michigan Department of Health and Human Services
2016-1659	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-2559
2016-1660	03/01/2016 03/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-2700
2016-1661	03/01/2016 03/29/2016	FDA/OGROP/ORAPA-FO/SAN- DO/SAN-CB/	Logan Greenberg Unglesby & Williams LLC	CONCEPTUS RECS RE FOLLOW UP INSPECTION Date Range: 01/01/2011 - 02/24/2016
2016-1662	03/01/2016 03/29/2016	FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/	Zaida Escalante Synergy Clinical Research Center	SYNERGY CLINICAL RESEARCH CENTER - EIR 03/10/2014 - 03/21/2014
2016-1663	03/01/2016 03/29/2016	OC/ORAP/ OC/ORAP/	Grace Parasmio Grace Parasmio	TESTING OF DARK CHOCOLATE 01/01/2013 - 02/24/2016
2016-1664	03/01/2016 03/29/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	James Harbour Gold Coast Medical Supply	API DATA
2016-1665	03/01/2016 03/29/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Marilynn Whitney COVINGTON & BURLING LLP	ANDA 091002
2016-1666	03/01/2016	FDA/OMPT/CDER/ORP/DIDP/	Marilynn Whitney	ANDA 091059

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	03/29/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	COVINGTON & BURLING LLP	
2016-1667	03/01/2016 03/29/2016	FDA/OMPT/CDRH/OCE/DID/	Tessa Hopsicker ConMed Corporation	K040981
2016-1668	03/01/2016 03/29/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Phuong Tran Acruz DDS Pty Ltd	ANDA 76-320 s 000; ANDA 76-290 s 000
2016-1669	03/01/2016 03/29/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Marilynn Whitney COVINGTON & BURLING LLP	ANDA 091059
2016-1670	03/01/2016 03/29/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Marilynn Whitney COVINGTON & BURLING LLP	ANDA 091002
2016-1671	03/02/2016 03/30/2016	FDA/OMPT/CDRH/OCE/DID/	Tessa Hopsicker ConMed Corporation	K052051
2016-1672	03/02/2016 03/30/2016	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/	ANNA MARIE PALMER-HARPER MILLER MILLING COMPANY LLC	SAMPLE RESULTS
2016-1673	03/02/2016 03/30/2016	FDA/OMPT/CDRH/OCE/DID/	Summer Harriff Summer Harriff	K082185, K092271, K110943, ETC
2016-1674	03/02/2016 03/30/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2014-5803
2016-1675	03/02/2016 03/30/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2013-8309
2016-1676	03/02/2016 03/30/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2014-3805
2016-1677	03/02/2016 03/30/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2014-5165

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2016-1678	03/02/2016 03/30/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2013-4355
2016-1679	03/02/2016 03/30/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2014-3352
2016-1680	03/02/2016 03/30/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2014-4505
2016-1681	03/02/2016 03/30/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2014-5777
2016-1682	03/02/2016 03/30/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2014-1639
2016-1683	03/02/2016 03/30/2016	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	FOI Services, Inc.	2014-5390
2016-1684	03/02/2016 03/30/2016	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	FOI Services, Inc.	2011-6353
2016-1685	03/02/2016 03/30/2016	FDA/OGROP/ORAN/NE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDRH/OCE/DID/	Becky Holmes Tepha, Inc.	ALLERGAN - WARNING LETTER RECS, EIR, 483 ETC 05/29/2015 - 02/15/2016
2016-1686	03/02/2016 03/30/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2012-7798
2016-1687	03/02/2016 03/30/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2014-5397
2016-1688	03/02/2016 03/30/2016	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	John Collorafi Law Offices of G. Oliver Koppell & Associates	DEPO-PROVERA - BLACK BOX LABEL; DEAR HEALTH CARE PROFESSIONAL LETTER 11/01/2004 - 12/01/2004
2016-1689	03/02/2016 03/30/2016	FDA/OGROP/ORAN/CE-FO/NWJ-DO/NWJ-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	GREGORY J TRACEY, MD, HOBOKEN, NJ - EIR, 483, RESPONSE 03/25/2015 - 04/15/2015
2016-1690	03/02/2016 03/30/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2014-5540
2016-1691	03/02/2016 03/30/2016	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Tushar Manudhane Indianivesh securities	INDOCO REMEDIES, INDIA - 483 05/01/2015 - 02/25/2016

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2016-1692	03/02/2016 03/30/2016	OC/ORO/ OC/ORO/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Flvia Lemos Ayres Bastos Paiva EMS Group	Regulatory guides of analytical validation of methodologies and GMP guides 02/25/2015 - 02/25/2016
2016-1693	03/02/2016 03/30/2016	OC/ORO/ OC/ORO/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Doe J	INDIVIDUAL RECS
2016-1694	03/02/2016 03/30/2016	FDA/OMPT/CDRH/OCE/DID/	Adrienne Nevola UNIVERSITY OF ARKANSAS FOR MEDICAL SCIENCES	CERTIFIED MAMMOGRAPHY FACILITIES BY STATE 01/01/2007 - 12/31/2013
2016-1695	03/02/2016 03/30/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gene Mack Ascendia Pharmaceuticals	CyDex; MDCO-157; PM 103 IND
2016-1696	03/02/2016 03/30/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Christina Chow Brookline Advisors	NDA 022406 NDA 202439 STUDY RECS
2016-1697	03/02/2016 03/30/2016	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	FOI Services, Inc.	2014-5626
2016-1698	03/02/2016 03/30/2016	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	Doe J	DIAGNAMICS, ENCINITAS, CA - INSPECTION RECS 12/11/2015 - 02/25/2016
2016-1699	03/02/2016 03/30/2016	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Alexandra Ajmo LIFE EXTENSION	MULTI-PAK PACKAGING, WEST CALDWELL, NJ - EIR 01/01/2011 - 02/25/2016
2016-1700	03/02/2016 03/30/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2014-5490

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2016-1701	03/02/2016 03/30/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2014-5478
2016-1702	03/02/2016 03/30/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anubhav Aggarwal CREDIT SUISSE	STRIDES ARCOLAB, INDIA - 483 02/15/2016 - 02/25/2016
2016-1703	03/02/2016 03/30/2016	FDA/OMPT/CDRH/OCE/DID/	Erik Robinson - Sintact Medical Systems Sintact Medical Systems	K831516
2016-1704	03/02/2016 03/30/2016	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDRH/OCE/DID/	Connie Garrison Tepha, Inc.	TEI BIOSCIENCES - WARNING LETTER RECS, EIR, RESPONSE 05/29/2015 - 02/15/2016
2016-1705	03/02/2016 03/30/2016	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDRH/OCE/DID/	Connie Garrison Tepha, Inc.	LIFECCELL - WARNING LETTER RECS, EIR, 483 ETC 06/01/2015 - 02/15/2016
2016-1706	03/02/2016 03/30/2016	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	Colleen OBrien New York Apple Sales	Pesticide Residue Test Results Sample # 920710
2016-1707	03/02/2016 03/30/2016	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OES/DDM/	Jaime Vassallo CourtLink Document Retrieval	Certified Documents: all publically available materials related to the FDA's April 1, 2014 Letter and denial of these petitions
2016-1708	03/02/2016 03/30/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	TEVA, ISRAEL - EIR
2016-1709	03/02/2016 03/30/2016	FDA/OC/OES/DFOI/	GARTEN 6481579, CHARLES	THALIDOMIDE - DATA
2016-1710	03/02/2016 03/30/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mark Prinz Registrar Corp	DMF CONTACT SPREADSHEET 01/01/2009 - 12/31/2009
2016-1711	03/02/2016 03/30/2016	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	Kristen Kim NYU SCHOOL OF MEDICINE	DR ALEXANDER NEUMEISTER - 483, EIR 06/17/2015 - 02/26/2016
2016-1712	03/02/2016	FDA/OMPT/CDRH/OCE/DID/	Michael Koczocik	MANUFACTURERS' LETTERS OF INTENT TO FILE FOR AUTOMATED EXTERNAL DEFIBRILLATORS 01/02/2004 -

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	03/30/2016		DEFIBTECH LLC	01/02/2015
2016-1713	03/02/2016 03/30/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	INDIVIDUAL RECS
2016-1714	03/02/2016 03/30/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	tTEVA, ONTARIO, CANADA - EIR
2016-1715	03/02/2016 03/30/2016	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORA/ OC/ORA/	Eric Steenstra Eric Steenstra	RECS RE ELECTRONIC SUBMISSION OF CONSUMER COMPLAINTS RE CANNABIDIOL 02/01/2014 - 02/26/2016
2016-1716	03/02/2016 03/30/2016	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	Carla Scarmazzi, FDA Specialist KING & SPALDING	ENOCHOICE, INC, ALPHARETTA, GA - INSPECTION RECS 9/8/14
2016-1717	03/02/2016 03/30/2016	FDA/OC/OES/DFOI/	WINDER 284821, EUGENE	VENDOR - REGULATIONS
2016-1718	03/02/2016 03/30/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	June Greaves June Greaves	PROPOXYPHENE - AERS
2016-1719	03/02/2016 03/30/2016	FDA/OC/OES/DFOI/	Jaime Vassallo CourtLink Document Retrieval	2016-1123
2016-1720	03/02/2016 03/30/2016	FDA/OMPT/CDRH/OCE/DID/	PATRICIA A. GROOMS MCKEEN & ASSOCIATES PC	AMBIT PUMP- 1722214-2013-0001
2016-1721	03/02/2016 03/30/2016	FDA/OMPT/CDRH/OCE/DID/	Ken Pilgrim EMERGO GROUP INC	K141757 CW150004 CR140261
2016-1722	03/02/2016 03/30/2016	FDA/OC/OES/DDM/	Marilynn Whitney COVINGTON & BURLING LLP	98P-0547
2016-1723	03/02/2016 03/30/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jeffrey Ishizuka MASSACHUSETTS GENERAL HOSPITAL	11010175, 10749318, 11078179, ETC
2016-1724	03/02/2016	FDA/OMPT/CDER/ORP/DIDP/	Laurel Benyo	NDA 007513 SBA

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	03/30/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PHARMAFORCE INC	
2016-1725	03/02/2016 03/30/2016	FDA/OMPT/CDRH/OCE/DID/	Dawn Burleson HyGleaCare	K003720
2016-1726	03/02/2016 03/30/2016	OC/ORP/ OC/ORP/ FDA/OGROP/ORP/NE-FO/NWE- DO/NWE-CB/	TESSA MAZZA PANEBELLE	SMPL 912143; 912142
2016-1727	03/02/2016 03/30/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PAUL B. CALLAHAN CHARLES RIVER	CHARLES RIVER LABS INC, BALLINA, IRELAND - EIR 1/25- 26/15 UNREDACTED
2016-1728	03/02/2016 03/30/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BROCK 08560-003, CARL BLAKE	MULTIDISCIPLINARY ASSOCIATION FOR PSYCHEDELIC STUDIES - MDMA (3,4- METHYLENEDIOXYMETHAPHETAMINE) STUDIES, DRUG TRIALS, ETC
2016-1729	03/03/2016 03/31/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-8922
2016-1730	03/03/2016 03/31/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-8922
2016-1731	03/03/2016 03/31/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-9755
2016-1732	03/03/2016 03/31/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORP/CE-FO/PHI- DO/PHI-CB/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-9892
2016-1733	03/03/2016 03/31/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-9913
2016-1734	03/03/2016 03/31/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 2/1-29/2016
2016-1735	03/03/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2015-9650

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	03/31/2016		MERCK & CO., INC.	
2016-1736	03/03/2016 03/31/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-10013
2016-1737	03/03/2016 03/31/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-9651
2016-1738	03/03/2016 03/31/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-10150
2016-1739	03/03/2016 03/31/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	A list of all FOIA requests closed for 2/1-29/2016
2016-1740	03/03/2016 03/31/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-9988
2016-1741	03/03/2016 03/31/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-560
2016-1742	03/03/2016 03/31/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-547
2016-1743	03/03/2016 03/31/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-238
2016-1744	03/03/2016 03/31/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-226
2016-1745	03/03/2016 03/31/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-9896
2016-1746	03/03/2016 03/31/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-224
2016-1747	03/03/2016 03/31/2016	FDA/OMPT/CDRH/OCE/DID/	Cornelia Damsky CDI Regulatory Consultants	K11071
2016-1748	03/03/2016 03/31/2016	FDA/OMPT/CDRH/OCE/DID/	Nancy Phan Globizz Corporation	K082891
2016-1749	03/03/2016 03/31/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nicholas Willoughby Nicholas Willoughby	ABILITY - AERS
2016-1750	03/03/2016 03/31/2016	FDA/OMPT/CDRH/OCE/DID/	Taly Lindner Resorbium	K133932

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2016-1751	03/03/2016 03/31/2016	FDA/OMPT/CDRH/OCE/DID/	John Plumb John Plumb	K053095 K072956 K080315 ETC
2016-1752	03/03/2016 03/31/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jim Simpson Jim Simpson	VALTREX - AERS
2016-1753	03/03/2016 03/31/2016	OC/ORO/OCI/ OC/ORO/OCI/	Doe J	CMPLNT
2016-1754	03/03/2016 03/31/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	HUIMAN BARNHART PHD DUKE CLINICAL RESEARCH INSTITUTE	CELEXA, LEXAPRO, OXYELITE, ETC - AERS
2016-1755	03/03/2016 03/31/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ERIC J ROTHSCHILD PEPPER HAMILTON LLP	AVANDIA NDA 21-071,S048,S049 - RVWS, MEMOS, DRAFTS, ETC
2016-1756	03/03/2016 03/31/2016	FDA/OMPT/CDRH/OCE/DID/	RON JEFFREY CAS MEDICAL SYSTEMS INC	ASPECT MEDICAL SYSTEMS - K040183
2016-1757	03/03/2016 03/31/2016	FDA/OC/OES/DFOI/	BOB BAILEY LEVEL GREEN LANDSCAPING	INDIVIDUAL RECS
2016-1758	03/03/2016 03/31/2016	FDA/OFVM/CFSAN/OCD/EOS/	MUCKROCK	NEW DIETARY INGREDIENT NOTIFICATIONS, SUBMISSIONS, FDA RESP 1995
2016-1759	03/03/2016 03/31/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANGIE MASON ROGAN PRODUCTIONS	RICHARDSON-MERRELL - KELVADON CLNCL STUDIES, APPLICATION 1/17/61; CORR WITH CHEMIE GRUNENTHAL 1/4/61,ETC
2016-1760	03/03/2016 03/31/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 1/11-15/16
2016-1761	03/03/2016 03/31/2016	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 1/11-15/16
2016-1762	03/03/2016	FDA/OC/OES/DFOI/	BABARA JONES	FOI DAILY LOG 1/11-15/16

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	03/31/2016		DOMINION GROUP INC	
2016-1763	03/03/2016 03/31/2016	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 1/11-15/16
2016-1764	03/03/2016 03/31/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 1/18-22/16
2016-1765	03/03/2016 03/31/2016	FDA/OC/OES/DFOI/	LESLIE RAMSEY FDA NEWS	FOI DAILY LOG 1/18-22/16
2016-1766	03/03/2016 03/31/2016	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD Center for Regulator Services, Inc	FOI DAILY LOG 1/18-22/16
2016-1767	03/03/2016 03/31/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 1/18-22/16
2016-1768	03/03/2016 03/31/2016	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 1/18-22/16
2016-1769	03/03/2016 03/31/2016	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 1/18-22/16
2016-1770	03/03/2016 03/31/2016	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 1/4-8/16
2016-1771	03/03/2016 03/31/2016	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOI REQUESTS 1/4-8/16
2016-1772	03/03/2016 03/31/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Katy Andrews Katy Andrews	FAERS CASE REPORTS 10566904, 10893160, 9265647 ETC
2016-1773	03/03/2016 03/31/2016	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/	Ric Kostick PURITY COSMETICS	PURITY COSMETICS, 100% PURE - CONSUMER COMPLAINTS 10/01/2011 - 02/27/2016
2016-1774	03/03/2016 03/31/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DDM/	Tim Henkel VenatoRx Pharmaceuticals, Inc.	ANTIVIRAL DRUGS ADVISORY COMMITTEE MEETING RECS 01/01/1998 - 12/31/2000

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2016-1775	03/03/2016 03/31/2016	FDA/OMPT/CDRH/OCE/DID/	Bret Andre EyeReg Consulting, Inc.	K001960
2016-1776	03/03/2016 03/31/2016	FDA/OMPT/CDRH/OCE/DID/	Bret Andre EyeReg Consulting, Inc.	K000795
2016-1777	03/03/2016 03/31/2016	OC/ORa/ORM/ OC/ORa/ORM/	Glen Potvin Quintiles	LISTOF INSPECTIONS 02/01/2016 - 02/29/2016
2016-1778	03/03/2016 03/31/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nancy Klett Cerium Pharmaceuticals, Inc.	NDA 008975 SBA
2016-1779	03/03/2016 03/31/2016	FDA/OC/OES/DFOI/	DEBI COEHN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 1/4-8/16
2016-1780	03/03/2016 03/31/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mike Koehler Mike Koehler	POLYETHYLENE GLYCOL, POLYETHYLENE GLYCOL 3350, MIRALAX ETC - AERS
2016-1781	03/03/2016 03/31/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nancy Klett Cerium Pharmaceuticals, Inc.	NDA 009854 SBA
2016-1782	03/03/2016 03/31/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 1/4-8/16
2016-1783	03/03/2016 03/31/2016	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 1/11-15/16
2016-1784	03/03/2016 03/31/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Matthew Loesch Matthew Loesch @ Tocqueville Asset Management	REFUSE TO FILE LETTERS SENT TO PTC THERAPEUTICS 02/01/2000 - 02/29/2016
2016-1785	03/03/2016 03/31/2016	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOI REQUESTS 1/11-15/16
2016-1786	03/03/2016 03/31/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joshua Kipnees Patterson Belknap Webb & Tyler LLP	TIBOTEC, JOHNSON & JOHNSON MEETING - NOTES, AGENDA, MEETING MINUTES 01/01/2006 - 07/31/2006

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2016-1787	03/03/2016 03/31/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 1/11-15/16
2016-1788	03/03/2016 03/31/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Robert Rabicoff Robert Rabicoff	TAXOTERE- LABELING ADDITION RECS 03/01/2015 - 02/28/2016
2016-1789	03/03/2016 03/31/2016	FDA/OMPT/CDRH/OCE/DID/	Janna Babson Davol Inc.	K040998
2016-1790	03/03/2016 03/31/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 1/11-15/16
2016-1791	03/03/2016 03/31/2016	FDA/OMPT/CDRH/OCE/DID/	Janna Babson Davol Inc.	K033671
2016-1792	03/03/2016 03/31/2016	FDA/OGROP/ORAN/NE-FO/NWE- DO/NWE-CB/	James Rogers Valinor Management	INSULET, BILLERICA, MA - 483 11/30/2015 - 12/11/2015
2016-1793	03/03/2016 03/31/2016	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 1/18-22/16
2016-1794	03/03/2016 03/31/2016	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOI REQUESTS 1/18-22/16
2016-1795	03/03/2016 03/31/2016	OC/ORAN/ORM/ OC/ORAN/ORM/	Kris Christian FDAZILLA	LIST OF INSPECTIONS 01/27/2016 - 02/29/2016
2016-1796	03/03/2016 03/31/2016	OC/ORAN/ORM/ OC/ORAN/ORM/	Tod Cooperman CONSUMERLAB.COM	DIETARY SUPPLEMENT INSPECTION LIST 01/01/2015 - 12/31/2015
2016-1797	03/03/2016 03/31/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Gay Parsons Janssen Inc.	10688062 9752158 9747610 ETC
2016-1798	03/03/2016 03/31/2016	FDA/OMPT/CDRH/OCE/DID/	CAREY GOUGH CBS NORTH CAROLINA	ESSURE - COMPLAINTS 01/01/2007 - 02/29/2016
2016-1799	03/03/2016 03/31/2016	OC/ORAN/ OC/ORAN/	Mark Collette HOUSTON CHRONICLE	BLUE BELL CREAMERIES - RESPONSE TO 483 MOST RECENT 08/25/2015 - 02/29/2016

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		FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/		
2016-1800	03/03/2016 03/31/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kevin A Phelan Kevin A Phelan LLC	NDA 020363
2016-1801	03/03/2016 03/31/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jaime Vassallo CourtLink Document Retrieval	GLATOPA, GLATIRAMER ACETATE, COPAXONE - AERS
2016-1802	03/03/2016 03/31/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	G. Srinivas Zydus Pharmaceuticals USA Inc.	JADENU - APPROVAL PACKAGE NDA 206910
2016-1803	03/03/2016 03/31/2016	FDA/OMPT/CDRH/OCE/DID/	Scott Wolf Aerin Medical Inc	K152958
2016-1804	03/03/2016 03/31/2016	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Armin Weidmann MorphoSys AG	JENNIFER R BROWN, MD, DANA FARBER CANCER INSTITUTE, BOSTON, MA - 483 05/01/2014 - 12/31/2015
2016-1805	03/03/2016 03/31/2016	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Pat Hillenmeyer (Ms.) AbbVie	EXPRESS SCRIPTS, MORGANTOWN, WV - EIR 04/30/2014 - 05/01/2014
2016-1806	03/03/2016 03/31/2016	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Pat Hillenmeyer (Ms.) AbbVie	EXPRESS SCRIPTS, MORGANTOWN, WV - EIR 04/16/2012 - 04/20/2012
2016-1807	03/03/2016 03/31/2016	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Pat Hillenmeyer (Ms.) AbbVie	EXPRESS SCRIPTS, MORGANTOWN, WV - EIR 11/18/2014 - 11/20/2014
2016-1808	03/03/2016 03/31/2016	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Pat Hillenmeyer (Ms.) AbbVie	EXPRESS SCRIPTS, KANSAS CITY, MO - EIR 02/17/2015 - 02/19/2015
2016-1809	03/03/2016 03/31/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 1/18-22/16
2016-1810	03/03/2016 03/31/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 1/18-22/16
2016-1811	03/03/2016	FDA/OMPT/CDER/ORP/DIDP/	bb. burgess	LIST OF CDER FOIA REQUESTS FROM 2013

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	03/31/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	b burgess	
2016-1812	03/03/2016 03/31/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Theresa King Breckenridge Pharmaceutical, Inc.	ANDA 062364 SBA
2016-1813	03/03/2016 03/31/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Theresa King Breckenridge Pharmaceutical, Inc.	ANDA 063305 SBA
2016-1814	03/03/2016 03/31/2016	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 1/25-29/16
2016-1815	03/03/2016 03/31/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jane Talkington OKLAHOMA STATE UNIVERSITY	BOTOX CASE REPORTS 3971497, 4054345, 4094118, ETC
2016-1816	03/03/2016 03/31/2016	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOI REQUESTS 1/25-29/16
2016-1817	03/03/2016 03/31/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 1/25-29/16
2016-1818	03/03/2016 03/31/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Harriet Ryan LOS ANGELES TIMES	PURDUE PHARMA - RECS SUBMITTED TO FDA RE OXYCONTIN 01/01/1985 - 03/01/2016
2016-1819	03/03/2016 03/31/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 1/25-29/16
2016-1820	03/03/2016 03/31/2016	FDA/OMPT/CDRH/OCE/DID/	Marie Gildea STRYKER INSTRUMENTS	K122494
2016-1821	03/03/2016 03/31/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gay Parsons Janssen Inc.	CASE REPORTS 10688062 9752158 9747610 ETC

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-1822	03/03/2016 03/31/2016	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 2/1-5/16
2016-1823	03/03/2016 03/31/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	G. Srinivas Zydus Pharmaceuticals USA Inc.	MEPHYTON - APPROVAL RECS NDA 010104
2016-1824	03/03/2016 03/31/2016	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOI REQUESTS 2/1-5/16
2016-1825	03/03/2016 03/31/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	G. Srinivas Zydus Pharmaceuticals USA Inc.	ACITRETIN APPROVAL RECS
2016-1826	03/03/2016 03/31/2016	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	John Walsh James Alexander Corporation	TMP TECHNOLOGIES, BUFFALO, NY - EIR, 483, RECALL 03/01/2013 - 03/01/2016
2016-1827	03/03/2016 03/31/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Harriet Ryan LOS ANGELES TIMES	NDA 20-553 CLINICAL TRIAL RECS
2016-1828	03/03/2016 03/31/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 2/1-5/16
2016-1829	03/03/2016 03/31/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 2/1-5/16
2016-1830	03/03/2016 03/31/2016	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 2/8-12/16
2016-1831	03/03/2016 03/31/2016	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOI REQUESTS 2/8-12/16
2016-1832	03/03/2016 03/31/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 2/8-12/16
2016-1833	03/03/2016 03/31/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 2/8-12/16
2016-1834	03/04/2016	FDA/OGROP/ORA/CE-FO/PHI-	Jeremy Creeger	K&L FEEDS INC, SELINGROVE, PA - EIR 01/01/2014 -

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	04/01/2016	DO/PHI-CB/	K&L Feeds Inc	02/01/2016
2016-1835	03/04/2016 04/01/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JULIE FERRARO KREINDLER & KREINDLER	PREVACID - AER
2016-1836	03/04/2016 04/01/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JULIE FERRARO KREINDLER & KREINDLER	ACIPHEX - AER
2016-1837	03/04/2016 04/01/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JULIE FERRARO KREINDLER & KREINDLER	PRILOSEC - AER
2016-1838	03/04/2016 05/27/2016	FDA/OFVM/CFSAN/OCD/EOS/	LUKAS KNIGHT MUCKROCK	KRATOM - RECS
2016-1839	03/04/2016 04/01/2016	FDA/OFVM/CFSAN/OCD/EOS/	ANTHONY ROBERTS MUCKROCK	ALL DIETARY SUBMISSIONS FOR 2004
2016-1840	03/04/2016 04/01/2016	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/ OC/ORO/ OC/ORO/ OC/ORO/	UNNI, MANOJ	CBD DISTRIBUTORS - WARNING LTRS 2/15 TO 2/16
2016-1841	03/04/2016 04/01/2016	FDA/OC/OES/DFOI/	Mattson, Leona Ellen	GABAPENTIN - AER
2016-1842	03/04/2016 04/01/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JULIE FERRARO KREINDLER & KREINDLER	NEXIUM - AER
2016-1843	03/04/2016 04/01/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANDREW D. PARKER PARKER ROSEN LLC	CCAM BIOTHERAPUTICS LTD - APRVL

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-1844	03/04/2016 04/01/2016	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	JOAN McCABE LIPOTRIAD LLC	NUTRA SCIENCE LABS - EIR, 483
2016-1845	03/04/2016 04/01/2016	FDA/OFVM/CFSAN/OCD/EOS/OC/ORAO/OC/ORAFDA/OC/OES/DFOI/	STEPHEN R. VAN ARSDALE Wegmans Food Markets Inc.	WEGMANS CLEANED & CUT PRODUCTS LISTERIA OUTBREAK - 7/30-10/8/15
2016-1846	03/04/2016 04/01/2016	OC/ORAO/OC/ORAFDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	LAW OFFICES OF ROBERT A BURNETT JR	CMLPNT 137330
2016-1847	03/04/2016 04/01/2016	FDA/OMPT/CDER/GRP/DIDP/FDA/OMPT/CDER/GRP/DIDP/FDA/OMPT/CDER/GRP/DIDP/FDA/OMPT/CDER/GRP/DIDP/	PATRICK O'LEARY SIDLEY AUSTIN LLP	ORTHANA KEMSIK FABRIK AS, KASTRUP, DENMARK; FREDERIKSBERG CHEMICAL LABS LTD, COPENHAGEN, DENMARK; MERCK SHARP & DOHME BV, OSS, NETHERLANDS - 483 1/1/11 TO PRESENT
2016-1848	03/04/2016 04/01/2016	FDA/OC/OES/DFOI/	DRAKE 00886-093, JOSEPH	SUBOXONE - USAGE, INGREDIENTS
2016-1849	03/04/2016 04/01/2016	FDA/OMPT/CDER/GRP/DIDP/FDA/OMPT/CDER/GRP/DIDP/FDA/OMPT/CDER/GRP/DIDP/FDA/OMPT/CDER/GRP/DIDP/	Kris Christian FDAZILLA	BOEHRINGER INGELHEIM PHARMA GHBH & CO KG, GERMANY - 483 11/09/2015 - 11/13/2015
2016-1850	03/04/2016 04/01/2016	FDA/OMPT/CDER/GRP/DIDP/FDA/OMPT/CDER/GRP/DIDP/FDA/OMPT/CDER/GRP/DIDP/FDA/OMPT/CDER/GRP/DIDP/	Kris Christian FDAZILLA	LONZA BIOLOGICS TUAS PTE LTD, SINGAPORE - 483 03/02/2015 - 03/10/2015
2016-1851	03/04/2016 04/01/2016	FDA/OFVM/CFSAN/OCD/EOS/OC/CVM/OCD/	Kristi Smedley Center for Regulator Services, Inc	All Correspondence regarding Algal Meal as provided by ADM or Synthetic Genomics Inc.
2016-1852	03/04/2016 04/01/2016	FDA/OFVM/CFSAN/OCD/EOS/OC/ORAO/OC/ORAFDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Jessica Sidman WASHINGTON CITY PAPER	RECS RE FIG AND OLIVE SALMONELLA OUTBREAK 09/01/2015 - 02/29/2016

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2016-1853	03/04/2016 04/01/2016	OC/CVM/OCD/	Jenni Chladek NORBROOK INC	Analytical Method information for Tissue Residue Studies for Cephapirin Benzathine
2016-1854	03/04/2016 04/01/2016	FDA/OGROP/ORR/SE-FO/SJN-DO/SJN-CB/	Kris Christian FDAZILLA	AMGEN MANUFACTURING LIMITED, JUNCOS, PR - 483 01/18/2016 - 01/22/2016
2016-1855	03/04/2016 04/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca Dandeker Morgan, Lewis & Bockius LLP	TARO PHARMACEUTICALS INDUSTRIES LTD, ISRAEL - EIR SUMMARY, 483 01/01/2015 - 01/01/2016
2016-1856	03/04/2016 04/01/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	TSVIA ERLICH NGIT PREMIUM CONSULTING	SARSTEDT INC - BK040080
2016-1857	03/04/2016 04/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca Dandeker Morgan, Lewis & Bockius LLP	TARO PHARMACEUTICAL INDUSTRIES LTD, ISRAEL - EIR 01/01/2015 - 01/01/2016
2016-1858	03/04/2016 04/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kris Christian FDAZILLA	TEVA PHARMACEUTICAL WORKD CO LTD, HUNGARY - 483 01/22/2016 - 01/29/2016
2016-1859	03/04/2016 04/01/2016	FDA/OMPT/CDRH/OCE/DID/	Kathleen M Wendel Wendel, Kathleen M	ROI CERVICAL CAGE - AERS
2016-1860	03/04/2016 04/01/2016	FDA/OC/OES/DFOI/	KENNETH B. FROMSON, Esq. FINKELSTEIN & PARTNERS	CERTIFIED RECS
2016-1861	03/04/2016 04/01/2016	OC/CVM/OCD/	Jenni Chladek NORBROOK INC	Analytical Method information for Tissue Residue Studies for cephalixin sodium
2016-1862	03/04/2016 04/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kris Christian FDAZILLA	SHANDONG LUKANG PHARMACEUTICAL CO LTD, CHINA - 483 01/11/2016 - 01/15/2016
2016-1863	03/04/2016 04/01/2016	FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/	Kris Christian FDAZILLA	ALLERGAN SALES, LLC, WACO, TX - 483 09/14/2015 - 10/08/2015
2016-1864	03/04/2016 04/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kris Christian FDAZILLA	CHAN YAT HING MEDICINE FACTORY, HONG KONG - 483 07/06/2015 - 07/08/2015

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-1865	03/04/2016 04/01/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kris Christian FDAZILLA	HAINAN POLY PHARM CO, LTD - EIR 01/18/2016 - 01/29/2016
2016-1866	03/04/2016 04/01/2016	OC/CVM/OCD/	Jenni Chladek NORBROOK INC	Analytical Method information for Tissue Residue Studies for tulathromycin
2016-1867	03/04/2016 04/01/2016	OC/CVM/OCD/	Jenni Chladek NORBROOK INC	Analytical Method information for Tissue Residue Studies for Fenbendazole Suspension
2016-1868	03/04/2016 04/01/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Annie Yeh Center laboratories Inc.	SYMMETREL MEDICAL REVIEWS
2016-1869	03/04/2016 04/01/2016	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2015-3830, 2015-8442 & 2015-8464
2016-1870	03/04/2016 04/01/2016	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	File Numbers 2013-2108, 2013-5142, 2013-7269, 2013-7381, 2013-7752, 2013-7769, and 2013-8343. Please see attached.;
2016-1871	03/07/2016 04/04/2016	FDA/OC/OES/DFOI/	LESLIE RAMSEY FDA NEWS	FOI DAILY LOG 1/25-29/16
2016-1872	03/07/2016 04/04/2016	FDA/OC/OES/DFOI/	LESLIE RAMSEY FDA NEWS	FOI DAILY LOG 2/1-5/16
2016-1873	03/07/2016 04/04/2016	FDA/OC/OES/DFOI/	LESLIE RAMSEY FDA NEWS	FOI DAILY LOG 2/8-12/16
2016-1874	03/07/2016 04/04/2016	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD Center for Regulator Services, Inc	FOI DAILY LOG 1/25-29/16
2016-1875	03/07/2016 04/04/2016	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD Center for Regulator Services, Inc	FOI DAILY LOG 2/1-5/16
2016-1876	03/07/2016 04/04/2016	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD Center for Regulator Services, Inc	FOI DAILY LOG 2/8-12/16
2016-1877	03/07/2016 04/04/2016	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 1/25-29/16
2016-1878	03/07/2016	FDA/OC/OES/DFOI/	KEN REID	FOI DAILY LOG 2/1-5/16

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	04/04/2016		WASHINGTON INFORMATION SOURCE	
2016-1879	03/07/2016 04/04/2016	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 2/8-12/16
2016-1880	03/07/2016 04/04/2016	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 1/25-29/16
2016-1881	03/07/2016 04/04/2016	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 2/1-5/16
2016-1882	03/07/2016 04/04/2016	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 2/8-12/16
2016-1883	03/07/2016 04/04/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 1/25-29/16
2016-1884	03/07/2016 04/04/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 2/1-5/16
2016-1885	03/07/2016 04/04/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 2/8-12/16
2016-1886	03/07/2016 04/04/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 1/25-29/16
2016-1887	03/07/2016 04/04/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 2/1-5/16
2016-1888	03/07/2016 04/04/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 2/8-12/16
2016-1889	03/07/2016 04/04/2016	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 1/25-29/16
2016-1890	03/07/2016 04/04/2016	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 2/1-5/16
2016-1891	03/07/2016 04/04/2016	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 2/8-12/16
2016-1892	03/07/2016 04/04/2016	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 1/8-22/16
2016-1893	03/07/2016	FDA/OC/OES/DFOI/	LAUREN S BARR	2016-1130

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	04/04/2016		JH BARR & ASSOCIATES LLC	
2016-1894	03/07/2016 04/04/2016	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Kris Christian FDAZILLA	COLDSTREEM LABORATORIES INC, LEXINGTON, KY - 483 04/08/2014 - 04/17/2014
2016-1895	03/07/2016 04/04/2016	FDA/OMPT/CDRH/OCE/DID/	David S. Grosso THERMO FISHER SCIENTIFIC	K925794
2016-1896	03/07/2016 04/04/2016	OC/ORACE/ OC/ORACE/ FDA/OGROP/ORACE/ORO/DIOP/	Zetetic, Inc. Zetetic, Inc.	FDA ENTRY DOCUMENTATION REQUEST ALL DOCUMENTATION FEB 16, 2016 FEB 29, 2016
2016-1897	03/07/2016 04/04/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Zachary Mietus The Weinberg Group	ANDA 070475 ANDA 071215
2016-1898	03/07/2016 04/04/2016	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Kris Christian FDAZILLA	GREGORY TRACEY, MD, HACKENSACK, NJ - 483 03/25/2015 - 04/15/2015
2016-1899	03/07/2016 04/04/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Charles Snow Hyman, Phelps & McNamara, P.C.	MESYLATE - DETERMINATIONS, MEMOS RE AGENCY DECISION TO AWARD MARKETING EXCLUSIVITY
2016-1900	03/07/2016 04/04/2016	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	Elizabeth Woeckner Citizens for Responsible Care & Research, Inc.	ILLINOISE COLLEGE OF MEDICINE IRB, PEORIA, IL - EIR, 483, RESPONSE 03/15/13
2016-1901	03/07/2016 04/04/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Thomas Rachel Thomas	NANOSCALE DEVICES - INSTRUMENTS USED, TESTING 01/01/2010 - 03/01/2016
2016-1902	03/07/2016 04/04/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CARLL BLAKE BROCK BROCK #08560-003, CARL BLAKE	MULTIDISCIPLINARY ASSOCIATION - PSYCHEDELIC STUDIES 3,4-METHYLENEDIAMINOMETHAMPHETAMINE (MDMA) AS THEY PERTAIN TO MICHAEL MTHOEFAR, RICK DOBLIN, STUDIES/TRIALS ON HUMANS
2016-1903	03/07/2016 04/04/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/CVM/OCD/	Rosalind Hafen B&H Consulting Services, Inc.	SEL BIOCHEM XINJIANG, CHINA - INSPECTION RECS 01/01/2014 - 03/02/2016
2016-1904	03/07/2016	OC/CVM/OCD/	Steven Clark, DVM	FDA Document: Finding of no significant impact and environmental assessment for the proposal to withdraw the

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	04/04/2016		Steven Clark, DVM	approvals of the NADA's for dimetridazole
2016-1905	03/07/2016 04/04/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Beth Regina Actavis LLC	NDA 019430 CORR, SUPPS
2016-1906	03/07/2016 04/04/2016	FDA/OMPT/CDRH/OCE/DID/	Scott Vincent Scott Vincent	INFUSYSTEM INFUSION PUMPS - AERS, CORR 01/01/2014 - 03/03/2016
2016-1907	03/07/2016 04/04/2016	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	Ryan D. Woods PRA Health Sciences	PRA HEALTH SCIENCES EARLY DEVELOPMENT SERVICES CRI LIFETREE RESEARCH - EIR, 482, CORR 11/15/2004 - 08/22/2013
2016-1908	03/07/2016 04/04/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K083845
2016-1909	03/07/2016 04/04/2016	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	John Walsh James Alexander Corporation	ROCHEM INTERNATIONAL, RONKONKOMA, NY - EIR, 483, RECALL 03/01/2012 - 03/03/2016
2016-1910	03/07/2016 04/04/2016	OC/ORASORM/ OC/ORASORM/	Meagan Randall Meagan Randall	DEVICE INSPECTION DATA
2016-1911	03/07/2016 04/04/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K083846
2016-1912	03/07/2016 04/04/2016	FDA/OMPT/CDRH/OCE/DID/	ECHO YU AB SCIEX	K100144 K122766
2016-1913	03/07/2016 04/04/2016	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Pat Hillenmeyer AbbVie	OKLAHOMA UNIVERSITY HEALTH SCIENCES, OKLAHOMA CITY, OK - EIR 06/01/2015 - 06/30/2015
2016-1914	03/07/2016 04/04/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michael S Sawaya Altaire Pharmaceuticals, Inc.	NDA 208135
2016-1915	03/07/2016 04/04/2016	FDA/OC/OES/DDM/	Saroja Gorantla AUROBINDO PHARMA USA INC	91P-0153/CP1
2016-1916	03/07/2016 04/04/2016	FDA/OMPT/CDRH/OCE/DID/	Lisa Anderson ConMed Corporation	K063367 K120151K120640
2016-1917	03/07/2016 04/04/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kristine Price Takeda Development Center Americas, Inc. Attn: Kristine Price	ALOGLIPTIN MEDWATCH REPORT

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2016-1918	03/07/2016 04/04/2016	FDA/OC/OES/DFOI/	Eleanor DaCosta United States Pharmacopeial Convention (USP)	CASTLE CHEESE, INC - INSPECTION RECS, LAB RECS 01/01/2012 - 02/29/2016
2016-1919	03/07/2016 04/04/2016	FDA/OFVM/CFSAN/OCD/EOS/	Dr. Ray Matulka BURDOCK GROUP	GRAS 306
2016-1920	03/07/2016 04/04/2016	FDA/OFVM/CFSAN/OCD/EOS/	Eleanor DaCosta United States Pharmacopeial Convention (USP)	KAVA - AERS
2016-1921	03/07/2016 04/04/2016	FDA/OFVM/CFSAN/OCD/EOS/	Eleanor DaCosta United States Pharmacopeial Convention (USP)	SCHISANDRA, CHINENSIS, SCHIZANDRA CHINENSIS AERS
2016-1922	03/07/2016 04/04/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Elda Tzoumaka CORCEPT THERAPEUTICS INC	DPV FAERS 10900304 4128921 5725464 ETC
2016-1923	03/07/2016 04/04/2016	FDA/OMPT/CDRH/OCE/DID/	Mark Prinz Registrar Corp	LISTING OF RADIATION EMITTING DEVICES REPORTED TO CDRH UNDER INITIATIAL RADIATION SAFETY REPORT 01/01/2013 - 02/29/2016
2016-1924	03/07/2016 04/04/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Benjamin Lampson DANA FARBER CANCER INSTITUTE	10470277, 10755274, 10793250, ETC
2016-1925	03/07/2016 04/04/2016	FDA/OGROP/ORASW-FO/DEN- DO/DEN-CB/	Deborah Samuel Deborah Samuel	DOTERRA INTERNATIONAL - WARNING LETTER RESPONSE 09/22/2014 - 01/01/2015
2016-1926	03/07/2016 04/04/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Pankajkumar U Patel Piramal Enterprises Limited	NIMBEX - CORR, MEDICAL REVIEW, CHEMISTRY REVIEW ETC
2016-1927	03/07/2016 04/04/2016	FDA/OMPT/CDRH/OCE/DID/	Scott DeShazo DeShazo & Nesbitt LLP	INDIVIDUAL RECS
2016-1928	03/07/2016 04/04/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K151307
2016-1929	03/07/2016 04/04/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	BLA 125057/S393

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-1930	03/07/2016 04/04/2016	FDA/OMPT/OSMP/OOPD/	GSK GSK Vaccines GmbH	MAKENA - ORPHAN DESIGNATION RECS
2016-1931	03/07/2016 04/04/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Paige Stradley MERCHANT & GOULD	NDA 022334 Form 3542, Form 3542a
2016-1932	03/07/2016 04/04/2016	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Manju Pamela Rajan -Clinical Operations Coordinator Prostate Cancer Clinical Trials Consortium, LLC	JOEL PINCUS, MD, WASHINGTON UNIVERSITY OF ST LOUIS - WARNING LETTER RESPONSE 09/20/2010
2016-1933	03/07/2016 04/04/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ira Schachar STANFORD UNIVERSITY	STORZ OPHTHALMICS CORPORATION NDA CHONDROITINASE
2016-1934	03/08/2016 04/05/2016	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ FDA/OMPT/CDRH/OCE/DID/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	THOMAS F GALLAGHER GALLAGHER KRICH APC	ALARIS MEDICAL SYSTEMS; CARDINAL HEALTH 303 INC; SISTEMAS MEDICOS ALARIS SA DE CV, TIJUANA, MEXICO, ETC - EIRS 483S 2010 TO 2014
2016-1935	03/08/2016 04/05/2016	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	Doe J	INDIVIDUAL RECS
2016-1936	03/08/2016 04/05/2016	FDA/OC/OES/DFOI/	CHAD MORRIS MORRIS, CHAD	483S 9/1/15 TO 2/29/15
2016-1937	03/08/2016 04/05/2016	FDA/OC/OES/DFOI/	ABRAHAM PAYTON AMERICAN BRIDGE 21ST CENTURY	FOIA REQUESTS THAT MENTION TRUMP 6/1/15 TO 3/2/16

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2016-1938	03/08/2016 04/05/2016	FDA/OFVM/CFSAN/OCD/EOS/	LISA P ALSOBROOK Keller and Heckman LLP	FCN 1265
2016-1939	03/08/2016 04/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID HOFFMEISTER Wilson Sonsini Goodrich & Rosati, P.C.	ACTAVIS (DEFERASIROX TABS) ANDA 203-560
2016-1940	03/08/2016 04/05/2016	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	K MICHELLE VASSALLO Lincare Holdings	SENTARA ENTERPRISES, SENTARA RMH MEDICAL CENTER, VA - EIRS, 483S, WARNING LTRS 1/99 TO PRESENT
2016-1941	03/08/2016 04/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	S ALBERT EDWARDS PHARM D S ALBERT EDWARDS PHARM D	SEPTODONT, DEPROCO - ARTICAIN (SEPTOCAINE) NDA 20-971 RECS, AERS
2016-1942	03/08/2016 04/05/2016	FDA/OMPT/CDRH/OCE/DID/	RACHEL THOMAS THOMAS, RACHEL	NANOSCALE DVCS - SAFETY AND WAYS OF DETECTION OR MEASURE THE PRESENCE AND EXCRETION
2016-1943	03/08/2016 04/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID HOFFMEISTER Wilson Sonsini Goodrich & Rosati, P.C.	SANOVI AVENTIS NDA 21-081 FOR PATENTS 7476652, 7713930, 7918833, ETC
2016-1944	03/08/2016 04/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SAMMY ALMASHAT MD PUBLIC CITIZEN	LUPRON, ZOLADEX, CLARITIN, ETC - FDA-GRANTED EXCLUSIVITIES THAT WERE ACTIVE AT ANY TIME FROM 2000 TO 2015
2016-1945	03/08/2016 04/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	A LUKE SMITH ESQ RADICE LAW FIRM	ANDA 76-378 - APRVL ROUTING SHEETS
2016-1946	03/08/2016 04/05/2016	FDA/OGROP/ORACE-SW-FO/DEN-DO/DEN-CB/	AMY M ALLEMAN KEATING WAGNER POLIDORI FREE PC	USA FOOD AND GAS, NORTHGLENN, CO - INSPS, CMLNPTS 2012
2016-1947	03/08/2016 04/05/2016	FDA/OMPT/CDRH/OCE/DID/	JENNIFER A DAVIDSON Kleinfeld, Kaplan & Becker LLP	SNS BIOSYSTEMS, SANTA MARIA, CA - MEDICAL DVC REGISTRATION 1985 TO 2016
2016-1948	03/08/2016 04/05/2016	OC/CVM/OCD/ OC/ORACE/	JEFFREY J JONES JONES DAY	SCOTT'S MIRACLE-GRO CO - WILD BIRD FOOD CLASS III RECALL 2008

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		OC/OR/ FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/		
2016-1949	03/08/2016 04/05/2016	FDA/OMPT/CDRH/OCE/DID/	Tim Allard Quanta Fluid Solutions Ltd.	K140866
2016-1950	03/08/2016 04/05/2016	FDA/OMPT/CDRH/OCE/DID/	John Bonasera Medrobotics	K943305, K960673, K90188
2016-1951	03/08/2016 04/05/2016	FDA/OFVM/CFSAN/OCD/EOS/	QUIANA A MONTGOMERY Keller and Heckman LLP	WYANDOTTE CHEMICALS CORP - FAMF #8
2016-1952	03/08/2016 04/05/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Lisa Robertson Rawls McNelis + Mitchell	INDIVIDUAL RECS
2016-1953	03/08/2016 04/05/2016	FDA/OMPT/CDRH/OCE/DID/	Cindy Stine Stine, Cindy L	RECS RE DIRECT ACCESS DIAGNOSTICS, JOHNSON & JOHNSON, HOME ACCESS HIV TESTING ETC 01/01/1990 - 12/31/2000
2016-1954	03/08/2016 04/05/2016	FDA/OMPT/CDRH/OCE/DID/	Thomas Berryman Thomas Berryman	K151413
2016-1955	03/08/2016 04/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Phenu Zachariah Phenu Zachariah	TYSABRI - AERS
2016-1956	03/08/2016 04/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAWSON REIMER MEDICURE PHARMA	AGGRASTAT (TIROFIBAN HCL) NDA 20-912, NDA 29-913 ORANGE BOOK LISTING
2016-1957	03/08/2016 04/05/2016	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/ FDA/OMPT/CDRH/OCE/DID/ OC/ORACE/OCI/ OC/ORACE/OCI/ OC/ORACE/OCI/ OC/ORACE/OCI/	Amber Maloney, Paralegal, for Attorney Lindsay A. Byrne Keating Jones Hughes, PC	OFF-LABEL MIRENA IUD- INVESTIGATION RECS 01/01/2006 - 03/04/2016
2016-1958	03/08/2016 04/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Maria Rahmany COLUMBIA UNIVERSITY	IND 64499 IND 70299 RECS, ORPHAN PRODUCT RECS

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/OSMP/OOPD/		
2016-1959	03/08/2016 04/05/2016	FDA/OMPT/CDRH/OCE/DID/	Charlotte Gasperlin BioSig Technologies, Inc.	K151911
2016-1960	03/08/2016 04/05/2016	FDA/OMPT/CDRH/OCE/DID/	Sartaj Kaur-Hurrle Evofem, Inc	K895640
2016-1961	03/08/2016 04/05/2016	FDA/OMPT/CDRH/OCE/DID/	Cari Reil Monaghan Medical Corporation	K143615
2016-1962	03/08/2016 04/05/2016	FDA/OFVM/CFSAN/OCD/EOS/ BURDOCK GROUP		SOYBEAN OIL WITH REDUCED PALMITIC AND LINOLENIC ACIDS AND INCREASED OLEIC ACID GRAS 306
2016-1963	03/08/2016 04/05/2016	OC/CVM/OCD/	Wendy Banka Wendy Banka	Any FSA Livestock Feed Safety Report for an Adverse Event reports in Michigan from August 1, 2014 through December 31, 2014
2016-1964	03/08/2016 04/05/2016	FDA/OMPT/CDRH/OCE/DID/	Carla Scarmazzi KING & SPALDING	ENOCHOICE, INC - TRADE COMPLAINTS 01/01/2014 - 03/04/2016
2016-1965	03/08/2016 04/05/2016	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	AMY ERICKSON HAGEN REPROTECH LTD	FERTILITY ANSWERS LLC, BATON ROUGE, LA 0 EIRS, 483S, WARNING LTRS, ETC 5/11 TO PRESENT
2016-1966	03/08/2016 04/05/2016	FDA/OMPT/CDRH/OCE/DID/	SUSAN D GOLDSTEIN-FALK MDI CONSULTANTS INC	ALIVECOR INC - ALIVECOR HEART MONITOR K140933
2016-1967	03/08/2016 04/05/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Gerald J. Orehostky Actinium Pharmaceuticals, Inc.	XOFIGO - SBA
2016-1968	03/08/2016 04/05/2016	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Ruel M. Garcia Arbor Pharmaceuticals LLC	RITEDOSE, COLUMBIA, SC - 483, EIR 01/01/2015 - 12/31/2015
2016-1969	03/08/2016 04/05/2016	FDA/OMPT/CDRH/OCE/DID/	Varun Saxena FierceMedicalDevices	REWALK ROBOTICS - RECS SINCE WARNING LETTER 09/30/2016 - 03/04/2016
2016-1970	03/08/2016 04/05/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Hajra Mazhar Hajra Mazhar University of Ottawa	AERS 3749511; 3888774; 4125770; ETC
2016-1971	03/08/2016 04/05/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kelly Burke MIDWESTERN UNIVERSITY	CANAGLIFOZIN - AERS DETAILED REPORT

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2016-1972	03/08/2016 04/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Raina Jain MEMORIAL SLOAN KETTERING CANCER CENTER	KEYTRUDA - SBA
2016-1973	03/08/2016 04/05/2016	FDA/OFVM/CFSAN/OCD/EOS/	STEPHEN MULLIN BUSH SPECIALTY VEHICLES INC	INTERSTATE CERTIFIED SHELLFISH SHIPPERS LIST
2016-1974	03/08/2016 04/05/2016	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCE/DID/ FDA/OGROP/ORAPA-FO/SAN- DO/SAN-CB/	Raquel Rutledge The Milwaukee Journal Sentinel	MW5059301 MW5059310 MW5059286 ETC; BECTON DICKINSON INSPECTION RECS 1/1/08 TO 3/7/16
2016-1975	03/08/2016 04/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Carl Minniti Rutgers Law School	ORANGE BOOK RECS
2016-1976	03/08/2016 04/05/2016	FDA/OMPT/CDRH/OCE/DID/	Tim Allard Quanta Fluid Solutions Ltd.	K050525 K041424 - PRESUBMISSION BRIEFING PACKAGE, IDE, 510K
2016-1977	03/08/2016 04/05/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Lisa Robertson Rawls McNelis + Mitchell	INDIVIDUAL RECS
2016-1978	03/08/2016 04/05/2016	FDA/OGROP/ORACE-FO/CHI- DO/CHI-CB/	John Walsh James Alexander Corporation	MASON CHEMICAL COMPANY, ARLINGTON HEIGHTS, IL - EIR, 483, RECALL RECS 03/01/2013 - 03/07/2016
2016-1979	03/08/2016 04/05/2016	FDA/OMPT/CDRH/OCE/DID/	Estela Celi Stryker Corporation- Trauma & Extremities Division	K870200; K021859; K061146 ETC
2016-1980	03/08/2016 04/05/2016	FDA/OMPT/CDRH/OCE/DID/	Linda Ruedy Silk Road Medical	P050019
2016-1981	03/08/2016 04/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/OSMP/OOPD/	Mary L. Bodzo Mary L. Bodzo	WRITTEN REQUESTS FOR NUSINERSEN APPROVAL IN US; CORR; EMAILS, ETC 01/01/2015 - 03/03/2016
2016-1982	03/08/2016 04/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Judy Norsigian OUR BODIES OURSELVES	MIRENA IUD - AERS

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2016-1983	03/08/2016 04/05/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	John Walsh James Alexander Corporation	CHANGZHOU SUNLIKGHT PHARMACEUTICAL - 483, EIR, RECALL RECS 03/01/2012 - 03/04/2016
2016-1984	03/08/2016 04/05/2016	FDA/OMPT/CDRH/OCE/DID/	Cindy Taylor TAYLOR, CYNTHIA A	FDA VALIDATION OF AERS OLYMPUS OER-PRO TJF-Q180V
2016-1985	03/08/2016 04/05/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jared Doster Vanderbilt University Law School	ORANGE BOOK RECS
2016-1986	03/08/2016 04/05/2016	FDA/OGROP/ORO/CE-FO/DET-DO/DET-CB/	Michael A Filoromo, III Katz, Marshall & Banks, LLP	MEAD JOHNSON NUTRITION, EVANSVILLE, IN - 483 01/01/2016 - 02/29/2016
2016-1987	03/09/2016 04/06/2016	FDA/OMPT/CDRH/OCE/DID/	David Marshall MARSHALL, DAVID	FDA approval of HIFU treatment for prostate cancer and the anticipated approval date of the CPT billing code for this procedure
2016-1988	03/09/2016 04/06/2016	FDA/OMPT/OSMP/OOPD/	Lisa Tarrison Schramp Mapi Life Sciences Canada	ORPHAN DRUG DESIGNATIONS FOR ORAL MUCOSITIS SINCE 2007
2016-1989	03/09/2016 04/06/2016	FDA/OC/OES/DFOI/ OC/ORO/ OC/ORO/	Andrea Leshak NY/NJ BAYKEEPER	FY 2012, FY 2013, FY 2014, and FY 2015 FDA Program Element Evaluation Reports for the State of New Jersey
2016-1990	03/09/2016 04/06/2016	FDA/OMPT/CDRH/OCE/DID/	John Tozzi BLOOMBERG NEWS	IT HAS COME TO OUR ATTENTION LETTERS
2016-1991	03/09/2016 04/06/2016	FDA/OFVM/CFSAN/OCD/EOS/	Chiara Di Lorenzo Università degli Studi di Milano	BOTANICALS - AERS
2016-1992	03/09/2016 04/06/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ben Zhao, Ph.D. Viatal Corp	ZHEJIANG MEDICINE CO LTD XIANCHANG PHARMACEUTICAL FACTORY - EIR 06/15/2015 - 03/07/2016
2016-1993	03/09/2016 04/06/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michelle Taylor ARIAD PHARMACEUTICALS INC	ICLUSIG AERS

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2016-1994	03/09/2016 04/06/2016	FDA/OMPT/CDRH/OCE/DID/	Bruce Hocking Acumed Medical Supplies Ltd.	CPT1500615
2016-1995	03/09/2016 04/06/2016	FDA/OMPT/CDRH/OCE/DID/	Philip Ross Gulf Coast Scientific	K130524
2016-1996	03/09/2016 04/06/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tom Glaser Think Investments LP	STRIDES SHASUN LTD, INDIA - 483 01/01/2015 - 03/08/2016
2016-1997	03/09/2016 04/06/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tom Glaser Think Investments LP	WOCKHARDT, INDIA - 483 01/01/2015 - 03/08/2016
2016-1998	03/09/2016 05/04/2016	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jason Bagley Truthinadvertising.org (TINA.org)	KYANI - AERS
2016-1999	03/09/2016 04/06/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Emily Krulewitz The Weinberg Group	ANDA 76648
2016-2000	03/09/2016 04/06/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Chandran Tiruvattar Alvogen Pine Brook LLC	ANDA 086069
2016-2001	03/09/2016 04/06/2016	FDA/OC/OES/DFOI/	Jaime Vassallo CourtLink Document Retrieval	2016-1410
2016-2002	03/09/2016 04/06/2016	FDA/OC/OES/DFOI/	Jaime Vassallo CourtLink Document Retrieval	2014-9195
2016-2003	03/09/2016 04/06/2016	FDA/OMPT/CTP/OD/	Desmond Jenson Tobacco Control Legal Consortium	15K00010 TOBACCO VIOLATION REPORT
2016-2004	03/09/2016 04/06/2016	FDA/OMPT/CDRH/OCE/DID/	James Barnes Turtle Beach Corporation	K150014 K132965 K111293 ETC

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2016-2005	03/10/2016 04/07/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 20762 S 49, 50, 51
2016-2006	03/10/2016 04/07/2016	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	John Walsh James Alexander Corporation	PACE ANALYTICAL LIFE SCIENCES , OAKDALE, MN- EIR, 483, RECALL RECS 03/01/2013 - 03/08/2016
2016-2007	03/10/2016 04/07/2016	FDA/OC/OES/DFOI/	Robert L. Dewey, Jr. Dewey, Jr., Robert L	2015-7373
2016-2008	03/10/2016 04/07/2016	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Anne Garstka TissueGene, Inc	WUXI APPTTEC, PHILADELPHIA, PA - EIR, 483, RESPONSE 12/17/2002 - 03/08/2016
2016-2009	03/10/2016 04/07/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ken Zeidner Amneal Pharmaceuticals	NDA 074220 SBA
2016-2010	03/10/2016 04/07/2016	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Anne Garstka TissueGene, Inc	LONZA, WALKERSVILLE, MD - EIR, 483, RESPONSE 12/17/2002 - 03/08/2016
2016-2011	03/10/2016 04/07/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ken Zeidner Amneal Pharmaceuticals	NDA 019323 SBA
2016-2012	03/10/2016 04/07/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Emily Krulewitz The Weinberg Group	ANDA 77066 SBA
2016-2013	03/10/2016 04/07/2016	FDA/OFVM/CFSAN/OCD/EOS/	Amanda C. Strauss Skadden, Arps, Slate, Meagher & Flom LLP	FOOD LABELING: USE OF THE TERM FRESH FOR FOODS PROCESSED WIHT ALTERNATIVE NONTHERMAL TECHNOLOGIES - NOTES, MINUTES 07/21/2000 - 07/21/2000
2016-2014	03/10/2016 04/07/2016	FDA/OFVM/CFSAN/OCD/EOS/	Erin Wurst DYKEMA GOSSETT PLLC	Trifluralin Data Submitted to the EPA.
2016-2015	03/10/2016 04/07/2016	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	Kris Christian FDAZILLA	NATIONAL PRODUCT SALES INC, SALT LAKE CITY, UT - 483 07/17/2001 - 07/17/2001
2016-2016	03/10/2016 04/07/2016	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Cindy Fasick Cindy Fasick	DR HUGO VARGAS, PHOENIX, AZ - 483 03/25/2009 - 03/25/2009

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2016-2017	03/10/2016 04/07/2016	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Melanie Burkhold Melanie Burkhold	DR STEPHEN MILLER, PALMETTO CARDIOLOGY, WALTERBORO, SC - EIR 05/01/2015 - 03/08/2016
2016-2018	03/10/2016 04/07/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Melanie Burkhold Melanie Burkhold	SAVAYSA - AERS
2016-2019	03/10/2016 04/07/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sarah Fink Fink, Sarah	INACTIVE INGREDIENT GUIDE 1/21/03
2016-2020	03/10/2016 04/07/2016	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	Kris Christian FDAZILLA	NATIONAL PRODUCT SALES, SALT LAKE CITY, UT - 483 09/03/2015 - 09/04/2015
2016-2021	03/10/2016 04/07/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Diana Rogers Diana Rogers	NDA 016807
2016-2022	03/10/2016 04/07/2016	FDA/OMPT/CDRH/OCE/DID/	John Rizos Abbott Laboratories, Inc	K160068
2016-2023	03/10/2016 06/23/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Laura Quinn GOODWIN PROCTER LLP	TISSUE REFERENCE GROUP RECOMMENDATIONS 01/01/2000 - 03/08/2016
2016-2024	03/10/2016 04/07/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Emily Krulewitz The Weinberg Group	ANDA 202250
2016-2025	03/10/2016 04/07/2016	OC/ORASE-FO/NOL-DO/NOL-CB/	Doe J	INDIVIDUAL RECS
2016-2026	03/10/2016 04/07/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 207071
2016-2027	03/10/2016	FDA/OMPT/CDER/GRP/DIDP/	RICHARD H WOODS	CENTOCOR ORTHO BIOTECH INC, JANSEN BIOTECH INC, JOHNSON & JOHNSON INC - STELARA (USTEKINUMAB) INJ

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	04/07/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LEVIN PAPANTONIO THOMAS ET AL	BLA 12561 CORR, LBLG, PROPOSALS, ETC
2016-2028	03/10/2016 04/07/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	INDIVIDUAL RECS
2016-2029	03/10/2016 04/07/2016	FDA/OMPT/CDRH/OCE/DID/	ASHLEY M ROTHE HUSCH BLACKWELL LLP	ALLERGAN - LAP-BAND CALIBRATION TUBE II MDR 2024601-2013-00528
2016-2030	03/10/2016 04/07/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	AMAURY SANCHEZ NOVEN PHARMACEUTICALS INC	MYLAN TECHNOLOGIES - LIDOCAINE PATCH ANDA 202-346 SBA, BIOEQV
2016-2031	03/10/2016 04/07/2016	FDA/OFVM/CFSAN/OCD/EOS/	NORA WEISER American Cheese Society	AMERICAN CHEESE SOCIETY (ACS) - MINS, AGENDA 2/11/16
2016-2032	03/10/2016 04/07/2016	FDA/OMPT/CDRH/OCE/DID/	BARBARA LOUISELL PAYNE MITCHELL LAW GROUP	SERI SURGICAL SCAFFOLD - CORR, APRVLS
2016-2033	03/10/2016 04/07/2016	FDA/OC/OES/DFOI/	BRANDON MENARD Menard AH8804, Brandon	GUIDANCE FOR INDUSTRY - PREVENTIVE MEASURES TO REDUCE THE POSSIBLE RISK OF TRANSMISSION OF CREUTZFELDT-JAKOB DISEASE 6/02
2016-2034	03/10/2016 04/07/2016	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORA/ OC/ORA/	NORA WEISER American Cheese Society	RAW MILK AND ARTISAN CHEESE - LISTERIA ENVIRONMENTAL SAMPLING PROGRAM, ERAW MILK CHEESE SAMPLING PROGRAM
2016-2035	03/10/2016 04/07/2016	FDA/OMPT/CDRH/OCE/DID/	LORI A CARR LORI A CARR INC	SMITH & NEPHEW INC - REDAPT POROUS ACETABULAR SHELL AND CEMENTED LINER K150790
2016-2036	03/10/2016 04/07/2016	FDA/OMPT/CDRH/OCE/DID/	LORI A COARR LORI A CARR INC	STRYKER - TITANIUM PL CAGE K152304
2016-2037	03/10/2016 04/07/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PAMELA SHEPPARD TARO PHARMACEUTICALS USA INC	PROMIUS PHARMA LLC - SERNIVO (BETAMETHASONE DIPROPIONATE) SPRAY NDA 208-079 SBA, MOR, LBLG, ETC
2016-2038	03/10/2016 04/07/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ROBERT J FEDERMAN MD UNIV OF MIAMI MILLER SCHOOL OF MEDICINE	EFLORNITHINE HCL (DFMO) IND 127229 - APPLICATION

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-2039	03/10/2016 04/07/2016	OC/ORA/ORM/ OC/ORA/ORM/	LESLIE RAMSEY FDA NEWS	PHARMACEUTICAL, BIOLOGICS, MEDICAL DVC MFG, CLNCL TRIAL FACILITIES IN AND OUTSIDE THE US - 483S 2/1-29/16
2016-2040	03/10/2016 04/07/2016	OC/ORA/ORM/ OC/ORA/ORM/	LESLIE RAMSEY FDA NEWS	PHARMACEUTICAL, BIOLOGICS, MEDICAL DVC MFG, CLNCL TRIAL FACILITIES IN AND OUTSIDE THE US - 483S 1/1-31/16
2016-2041	03/10/2016 04/07/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Chirag Talati Kotak Securities	CADILA PHARMACEUTICALS, INDIA - 483 01/01/2016 - 03/09/2016
2016-2042	03/10/2016 04/07/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bharat Celly Research Delta Advisors	NATCO PHARMACEUTICALS, INDIA - 483 01/20/2016 - 03/08/2016
2016-2043	03/10/2016 04/07/2016	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Eric Evans Orchard View Capital Advisors LP	OCULAR THERAPEUTIX, BEDFORD, MA - 483, EIR 01/01/2014 - 03/07/2015
2016-2044	03/10/2016 04/07/2016	FDA/OMPT/CDRH/OCE/DID/	Loren Taylor Loren Taylor	CPT 1600067
2016-2045	03/10/2016 04/07/2016	FDA/OMPT/CDRH/OCE/DID/	Estela Celi STRYKER CORPORATION	H010001 H980002
2016-2046	03/10/2016 04/07/2016	FDA/OMPT/CDRH/OCE/DID/	Laura Granite THE JOHNS HOPKINS UNIVERSITY	K113202; K143484; K152070 ETC
2016-2047	03/10/2016 04/07/2016	FDA/OMPT/CDRH/OCE/DID/	John Beasley MedTech Review, LLC	CPT1400117
2016-2048	03/10/2016 04/07/2016	FDA/OMPT/CDRH/OCE/DID/	Heta Shah Ethicon	K133821
2016-2049	03/10/2016 04/07/2016	FDA/OMPT/CDRH/OCE/DID/	Frank LaDuca Accriva Diagnostics	K041502 K150041
2016-2050	03/10/2016 04/07/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Christopher Digesu BRIGHAM AND WOMEN'S HOSPITAL	FERAHEME - AERS
2016-2051	03/10/2016	FDA/OMPT/CDRH/OCE/DID/	Estela Celi	P960053; P960053 ; P960053 etc

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	04/07/2016		STRYKER CORPORATION	
2016-2052	03/10/2016 04/07/2016	OC/CVM/OCD/	Sandy O'Kelley Merial Inc	BRAVECTO AERS
2016-2053	03/10/2016 05/20/2016	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	TISHCON - INSPECTION RECS ALL LOCATIONS
2016-2054	03/10/2016 04/07/2016	OC/ORACE/ OC/ORACE/	Leroy Clifton Leroy Clifton	LEITER PHARMACY, SAN JOSE, CA - INSPECTION RECS, TEST RESULTS 09/01/2014 - 03/01/2016
2016-2055	03/10/2016 04/07/2016	OC/CVM/OCD/	Sandy O'Kelley Merial Inc	TRIFEXIS AERS
2016-2056	03/10/2016 04/07/2016	FDA/OMPT/CDRH/OCE/DID/	Bettina N. Barth-King AngioDynamics, Inc.	Reminders from FDA Regarding Ruptured Vascular Access Devices from Power Injection - MAUDE REPORTS
2016-2057	03/10/2016 04/07/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Perry R. Staub, Jr. Taggart Morton, L.L.C.	Development and Commercialization Collaboration Agreement between Bristol-Myers Squibb Company ("BMS") and Otsuka Pharmaceutical Co., Ltd., ("Otsuka") from September 1999, with all attachments, amendments, and exhibits ETC
2016-2058	03/11/2016 04/08/2016	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Heather McIntyre Mondelez Global LLC	MONDELEZ CANADA INC, CANADA - EIR 11/17/2014 - 11/17/2014
2016-2059	03/11/2016 04/08/2016	FDA/OC/OES/DFOI/	Lydia Mulvany BLOOMBERG NEWS	FOIA REQUESTS 02/17/2016 - 03/10/2016
2016-2060	03/11/2016 04/08/2016	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Rachel Johnson FOI Services, Inc.	ABBOTT DIABETES CARE, ALAMEDA, CA - EIR 05/09-31/2013
2016-2061	03/11/2016 04/08/2016	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	Rachel Johnson FOI Services, Inc.	KNOLL/ABBVIE, JUYAYA, PR - 483 10/07-23/2015
2016-2062	03/11/2016 04/08/2016	FDA/OMPT/CDRH/OCE/DID/	Elizabeth Goldstein Fisher & Paykel Healthcare, Ltd.	K140279
2016-2063	03/11/2016	OC/ORACE/	Kelly Carver	NATURE'S EATS NATURAL PISTACHIOS, SAN ANTONIO, TX

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	04/08/2016	OC/ORO/ FDA/OGROP/ORO/SW-FO/DAL- DO/DAL-CB/	Texas Star Nut & Food Company, Inc	- TEST RESULTS 02/22/2016 - 03/25/2016
2016-2064	03/11/2016 04/08/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Neha Lodaya Drexel University	CHANTIX - AERS
2016-2065	03/11/2016 04/08/2016	FDA/OMPT/CDRH/OCE/DID/	David Grosso THERMO FISHER SCIENTIFIC	K955300
2016-2066	03/11/2016 04/08/2016	FDA/OC/OES/DFOI/	Kyle Heath Kyle Heath	OMNISCAN, MULTIHANCE, PROHANCE ETC - FOIA REQUESTS 01/01/2013 - 03/11/2016
2016-2067	03/11/2016 05/12/2016	FDA/OFVM/CFSAN/OCD/EOS/	Beatrice Maingi SAFE FOODS CORPORATION	FCN 1389 FCN 1465
2016-2068	03/11/2016 04/08/2016	FDA/OMPT/CDRH/OCE/DID/	Joseph M Ascenzi JMA Consulting	K111250
2016-2069	03/11/2016 04/08/2016	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/ FDA/OGROP/ORO/SE-FO/FLA- DO/FLA-CB/	Zetetic, Inc. Zetetic, Inc.	FDA ENTRY DOCUMENTATION REQUEST (REFUSAL) BVX- 0308465-4
2016-2070	03/11/2016 04/08/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Melissa V. Malapit Celgene Corporation	KEVIN SONG, VANCOUVER GENERAL HOSPITAL HEMATOLOGY - 483 11/01/2014 - 03/10/2016;
2016-2071	03/11/2016 04/08/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	ADVANCED MEDICAL OPTICS, UPPSALA, AB - EIR 03/16- 19/2009
2016-2072	03/11/2016 04/08/2016	FDA/OGROP/ORO/CE-FO/PHI- DO/PHI-CB/	Thomas Keilty Law Offices of Peter G. Angelos	F-2958-2015 - TEST RECORDS, INSPECTION RECS
2016-2073	03/11/2016 04/08/2016	FDA/OPPLA/OL/	Jonathan D. Salant NJ Advance Media/The Star- Ledger	CORR FROM CONGRESS RE APPROVAL OF ZOXYDOL, WARNING LABEL 01/01/2009 - 12/31/2015
2016-2074	03/11/2016	FDA/OC/OES/DFOI/	Kenneth A. Nazarian	ORTHOFIX - INSPECTION RECS, ADVERSE EVENTS

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	04/08/2016	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	BARNEY & KARAMANIS, LLP.	
2016-2075	03/11/2016 04/08/2016	OC/ORAS/ OC/ORAS/ FDA/OGROP/ORASORO/DIOP/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Zetetic, Inc. Zetetic, Inc.	FDA ENTRY DOCUMENTATION REQUEST (REFUSAL) BVX-0308716-0
2016-2076	03/11/2016 04/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Brooke Marvin Connelly Law Offices	ADVERSE DRUG REACTION RECS
2016-2077	03/11/2016 04/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Giovanna Scapin Giovanna Scapin	PENICILIN ANTIBIOTICS - AERS
2016-2078	03/11/2016 04/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Janice Rogers Janice Rogers	REMICADE AERS
2016-2079	03/11/2016 04/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Poornaa Venkatesan Jefferies India Pvt Ltd	INDIAN PHARMA COMPANIES - INSEPTION CLASSIFICATION
2016-2080	03/11/2016 04/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Poornaa Venkatesan Jefferies India Pvt Ltd	CIPLA, INDIA - 483 03/01/2015 - 03/09/2016
2016-2081	03/11/2016 04/08/2016	FDA/OGROP/ORASPA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDRH/OCE/DIDP/ FDA/OGROP/ORASPA-FO/SAN-DO/SAN-CB/	LESLIE RAMSEY FDA NEWS	EKSO BIONICS, RICHMOND, CA - 483 9/11/15
2016-2082	03/11/2016 04/08/2016	FDA/OFVM/CFSAN/OCD/EOS/	LUCA, ROBERT	GENETICALLY MODIFIED ORGANISMS ON THE BODY - EFFECTS

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2016-2083	03/11/2016 06/22/2016	OC/ORO/ OC/ORO/	TRACY D. JOHNSON-HALL, Ph.D. WILLIAM & MARY MASON SCHOOL OF BUSINESS	RECALL ENTERPRISE SYS RECORD
2016-2084	03/11/2016 04/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PALADINO SBI 590254B, BRIAN	SUBOXNE - AER
2016-2085	03/11/2016 04/08/2016	FDA/OGROP/ORO/SW-FO/DEN- DO/DEN-CB/	RAQUEL RUTLEDGE MILWAUKEE JOURNAL	BECTON DICKINSON MEDICAL SYS - 483
2016-2086	03/11/2016 04/13/2016	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORO/CE-FO/BLT- DO/BLT-CB/ FDA/OGROP/ORO/CE-FO/CIN- DO/CIN-CB/ FDA/OGROP/ORO/CE-FO/DET- DO/DET-CB/ FDA/OGROP/ORO/CE-FO/MIN- DO/MIN-CB/ FDA/OGROP/ORO/NE-FO/NYK- DO/NYK-DCB/ FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORO/PA-FO/SEA- DO/SEA-CB/ FDA/OGROP/ORO/SE-FO/ATL- DO/ATL-CB/ FDA/OGROP/ORO/SE-FO/FLA- DO/FLA-CB/ FDA/OGROP/ORO/SE-FO/NOL- DO/NOL-CB/ FDA/OGROP/ORO/SW-FO/DEN- DO/DEN-CB/ FDA/OGROP/ORO/SW-FO/KAN- DO/KAN-CB/	MYRNA A. ROMAIN Nestle Health Science	UAS LABS, MO; SHS NORTH AMERICA, BALTIMORE, MD; WYLDEWOOD CELLARS INC, KANSAS CITY, KS - WARNING LTR RESPONSES
2016-2087	03/11/2016 04/08/2016	FDA/OGROP/ORO/CE-FO/CIN- DO/CIN-CB/ FDA/OMPT/CDER/ORP/DIDP/	MICHAEL A. BUDKIE SAEN	CORR BETWEEN NATIONAL INSTITUTE ON ALLERGIES AND INFECTIOUS DISEASES & BATTELLE MEMORIAL INSTITUTE FACILITY - INSP SINCE 2013

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2016-2088	03/14/2016 04/11/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	EUGENE C BROOKS BROOKS LAW FIRM	NDA 20-971 CNCL INFORMATION AMENDMENT 7/6/15
2016-2089	03/14/2016 04/11/2016	FDA/OGROP/ORAC/CE-FO/PHI-DO/PHI-CB/	RAQUEL RUTLEDGE MILWAUKEE JOURNAL	GENTELL, BRISTOL, PA - 483 MOST RECENT
2016-2090	03/14/2016 04/11/2016	FDA/OGROP/ORAC/CE-FO/CHI-DO/CHI-CB/	John Walsh James Alexander Corporation	STEPAN CO, ELWOOD, IL - EIR, 483, RECALL RECS 03/01/2013 - 03/11/2016
2016-2091	03/14/2016 05/02/2016	OC/ORAC/ OC/ORAC/	Doe J	INDIVIDUAL RECS
2016-2092	03/14/2016 05/02/2016	OC/ORAC/ OC/ORAC/	Doe J	INDIVIDUAL RECS
2016-2093	03/14/2016 05/02/2016	OC/ORAC/ OC/ORAC/	Doe J	INDIVIDUAL RECS
2016-2094	03/14/2016 05/04/2016	FDA/OO/OHR/ OC/ORAC/ OC/ORAC/ FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECS
2016-2095	03/14/2016 05/02/2016	OC/ORAC/ OC/ORAC/	Doe J	INDIVIDUAL RECS
2016-2096	03/14/2016 05/02/2016	OC/ORAC/ OC/ORAC/	Doe J	INDIVIDUAL RECS
2016-2097	03/14/2016 05/02/2016	OC/ORAC/ OC/ORAC/	Doe J	INDIVIDUAL RECS
2016-2098	03/14/2016 05/02/2016	OC/ORAC/ OC/ORAC/	Doe J	INDIVIDUAL RECS
2016-2099	03/14/2016 05/02/2016	OC/ORAC/ OC/ORAC/	Doe J	INDIVIDUAL RECS
2016-2100	03/14/2016 05/02/2016	OC/ORAC/ OC/ORAC/	Doe J	INDIVIDUAL RECS

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2016-2101	03/14/2016 05/02/2016	OC/ORO/ OC/ORO/	Doe J	INDIVIDUAL RECS
2016-2102	03/14/2016 05/02/2016	OC/ORO/ OC/ORO/	Doe J	INDIVIDUAL RECS
2016-2103	03/14/2016 04/11/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michele Sinoway LACHMAN CONSULTANT SERVICES, INC.	ANDA 040626
2016-2104	03/14/2016 04/11/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michele Sinoway LACHMAN CONSULTANT SERVICES INC	ANDA 040626
2016-2105	03/14/2016 04/11/2016	FDA/OMPT/CDRH/OCE/DID/	Thomas Keilty Law Offices of Peter G. Angelos	K950339 K946147
2016-2106	03/14/2016 04/11/2016	FDA/OGROP/ORO/NE-FO/NYK- DO/NYK-DCB/	John Walsh James Alexander Corporation	PRIDE SOLVENTS & CHEMICAL CO, NY - EIR, 483, RECALLR ECS 03/01/2013 - 03/11/2016
2016-2107	03/14/2016 04/11/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michele Sinoway LACHMAN CONSULTANT SERVICES, INC.	ANDA 040586
2016-2108	03/14/2016 04/11/2016	FDA/OMPT/CDRH/OCE/DID/	Thao Le LSI Solutions	K121173
2016-2109	03/14/2016 04/11/2016	FDA/OMPT/CDRH/OCE/DID/	Markus Btler Medela AG	K130852
2016-2110	03/14/2016 04/11/2016	FDA/OMPT/CDRH/OCE/DID/	Markus Btler Medela AG	K100787
2016-2111	03/14/2016 04/11/2016	FDA/OMPT/CDRH/OCE/DID/	TMG-BMC d.o.o, TMG-BMC d.o.o.	K842262
2016-2112	03/14/2016 04/11/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michele Sinoway LACHMAN CONSULTANT SERVICES INC	ANDA 040586
2016-2113	03/14/2016	FDA/OC/OES/	Joseph Walker	RECS RE DR ROBERT CALIFF CONSULTING, BUSINESS, OR

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	04/11/2016		Walker, Joseph	FINANCIAL RELATIONSHIPS WITH INDUSTRY 01/03/2014 - 03/11/2016
2016-2114	03/14/2016 04/11/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Albert Chira Oregon State Psychiatric Hospital	NUMBER OF ACTIVE PATIENTS ON CLOZAPINE REGISTRY
2016-2115	03/14/2016 04/11/2016	FDA/OFVM/CFSAN/OCD/EOS/	Don Boudreaux Boudreaux and Associates	FCN 963
2016-2116	03/14/2016 04/11/2016	OC/ORR/ORM/ OC/ORR/ORM/	Eyal Maor FDA AWARE	LIST OF INSPECTIONS
2016-2117	03/14/2016 04/11/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	IPCA LABORATORIES, INDIA - 483 10/17/2014
2016-2118	03/14/2016 04/11/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Robert P. Bonin Jr Takeda Pharmaceuticals C/o Robert P. Bonin Jr	IDT BIOLOGIKA GMBH, GERMANY - 483, WARNING LETTER 01/04/2013 - 03/18/2016
2016-2119	03/14/2016 04/11/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	IPCA LABORATORIES, INDIA - 483 12/01/2014 - 12/19/2014
2016-2120	03/14/2016 04/11/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Poornaa Venkatesan Jefferies India Pvt Ltd	LUPIN, INDIA - 483 01/14/2015 - 03/14/2016
2016-2121	03/14/2016 04/11/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Walter Chalkley THOMSON REUTERS	IPCA LABORATORIES, INDIA - 483 07/14/2014 - 07/18/2014
2016-2122	03/14/2016 04/11/2016	FDA/OGROP/ORR/SW-FO/DAL- DO/DAL-CB/ FDA/OMPT/CDRH/OCE/DID/	Olga Marshall Haynes & Boone, LLP	OXYSURE RECALL - CORR WITH FDA, DOCUMENTATION RE EXPANSION OF RECALL 02/02/2016 - 03/11/2016
2016-2123	03/14/2016	FDA/OMPT/CDER/GRP/DIDP/	Hope Anderson	PLEGRIDY - AERS

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	04/11/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anderson, Hope	
2016-2124	03/14/2016 04/11/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kris Christian FDAZILLA	DISHMAN PHARMACEUTICALS AND CHEMICALS LTD, INDIA - 483 02/10/2015 - 02/13/2015
2016-2125	03/14/2016 04/11/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jianwei Xu Cambridge Solutions	PRALUENT - AERS
2016-2126	03/14/2016 04/11/2016	FDA/OMPT/CDRH/OCE/DID/	juraidi rey juraidi rey	Y90RadioGel HUMAN TESTING RECS
2016-2127	03/14/2016 04/11/2016	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	James Melton James Melton	JT NATURALS LLC, JOPLIN, MO - 483, RESPONSE, COMPLAINTS 08/04/2014 - 03/31/2016
2016-2128	03/14/2016 04/11/2016	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Pat Hillenmeyer (Ms.) AbbVie	NOVELLA CLINICAL, DURHAM, NC - EIR 01/01/2010 - 06/01/2010
2016-2129	03/15/2016 04/12/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRIDGET WALTON Sunovion Pharmaceuticals Inc.	LUPIN LTD - LURASIDONE HCL TABS ANDA 208-031; MSN LABORATORIES - LURASIDONE HCL TABS ANDA 208-037; EMCURE PHARMS LTD - LURASIDONE HCL TABS ANDA 208-058, ETC TENTATIVE APRVL LTRS
2016-2130	03/15/2016 04/12/2016	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	RAY THOMPSON THOMPSON, RAY	ABBOTT DIABETES CARE INC, ALAMEDA, CA 10/7-22/15; AFFYMETRIX INC, SANTA CLARA, CA 7/21-29/15; ABCO LABORATORIES INC, FAIRFIED, CA 9/15-25/15, ETC - 483S
2016-2131	03/15/2016 04/12/2016	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	RAY THOMPSON THOMPSON, RAY	ABBVIE INC, NORTH CHICAGO, IL 7/13/15-8/6/15; BAXTER HEALTHCARE CORP, ROUND LAKE, IL 5/27/15-6/19/15; DEL MEDICAL INC, BLOOMINGDALE, IL 7/8/15-9/23/15, ETC - 483S
2016-2132	03/15/2016 04/12/2016	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	RAY THOMPSON THOMPSON, RAY	CARDINAL HEALTH 414 LLC, PHOENIX, AZ 10/13-16/15; AMGEN INC, THOUSAND OIAKS, CA 5/4-22/15; ALERE SAN DIEGO INC, SAN DIEGO, CA 4/13/15-6/5/15, ETC - 483S
2016-2133	03/15/2016 04/12/2016	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	RAY THOMPSON THOMPSON, RAY	MCNEIL HEALTHCARE INC, WEST HAVEN, CT 8/10-13/15; ABBVIE RESEARCH BIORESEARCH CENTER, WORCESTER, MA 6/1-11/15; BIOGEN INC, CAMBRIDGE, MA 6/22-26/15, ETC - 483S
2016-2134	03/15/2016 04/12/2016	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	RAY THOMPSON THOMPSON, RAY	ASTELLAS PHARMA TECHNOLOGIES INC, NORMAN, OK 6/17-24/15; CAREFUSION 213 LLC, EL PASO, TX 6/17-25/15;

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				HEALTHRONICS INC, AUSTIN, TX 5/11-20/15, ETC - 483S
2016-2135	03/15/2016 04/12/2016	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	RAY THOMPSON THOMPSON, RAY	AKKORN INC, SOMERSET, NJ 5/19/15-6/5/15; ACTAVIS ELIZABETH LLC, ELIZABETH, NJ 7/29/15-8/27/15; GENESIS BPS LLC, RAMSEY, NJ 10/7-16/15, ETC - 483S
2016-2136	03/15/2016 04/12/2016	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	RAY THOMPSON THOMPSON, RAY	ADVANCED ORTHOPRO INC, INDIANAPOLIS, IN 7/27-30/15; BOSTON SCIENTIFIC CORP, SPENCER, IN 6/29/15-7/15/15; CLEAR IMAGE DEVICES LLC, ANN ARBOR, MI 8/4-20/15, ETC - 483S
2016-2137	03/15/2016 04/12/2016	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	RAY THOMPSON THOMPSON, RAY	ALLEGIAN HEALTH, DEER PARK, NY 5/12/15-6/2/15; EPIC PHARMA LLC, LAURELTON, NY 5/21/15-6/4/15; CMP INDUSTRIES LLC, ALBANY, NY 4/16/15-5/29/15; ETC - 483S
2016-2138	03/15/2016 04/12/2016	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	RAY THOMPSON THOMPSON, RAY	ABBOTT HEALTHCARE (PUERTO RICO) LTD, BARCELONETA, PR 10/20-29/15; JANSSEN ORTHO LLC, GURABO, PR 5/26-29/15; KNOLL LLC, JAYUYA, PR 10/7-23/15, ETC - 483S
2016-2139	03/15/2016 04/12/2016	OC/ORACE-FO/ORM/	RAY THOMPSON THOMPSON, RAY	GMP, GLP OR GCP INSPS 11/1/15-3/1/16
2016-2140	03/15/2016 04/12/2016	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	RAY THOMPSON THOMPSON, RAY	KIRKMAN LABORATORIES INC, LAKE OSWEGO, OR 6/3-24/15; MICROSURGICAL TECHNOLOGY INC, REDMOND, WA 10/5-16/15; EVERGREEN ORTHOPEDIC RESEARCH LAB LLC, KIRKLAND, WA 10/21-29/15 - 483S
2016-2141	03/15/2016 04/12/2016	FDA/OMPT/CDRH/OCE/DID/	Minoti Patel Microgenics Corporation part of Thermo Fisher Scientific	K980853
2016-2142	03/15/2016 04/12/2016	FDA/OMPT/CDRH/OCE/DID/	Heather Reed NinePoint Medical, Inc.	K140920
2016-2143	03/15/2016 04/12/2016	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	PAULA MORGAN NUVASIVE INC	NUVASIVE INC, GUAYNABO, PR - EIR 2/16
2016-2144	03/15/2016 04/12/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mikhail Martchenko Keck Graduate Institute	BITHIONOL - APPROVAL RECS
2016-2145	03/15/2016 04/12/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Laura R. Bobolts, PharmD, BCOP Oncology Analytics, Inc.	IRINOTECAN LIPOSOME INJECTION - APPROVAL RECS I
2016-2146	03/15/2016	OC/ORACE-FO/ORM/	Walter Chalkley	TOTAL PHARMACY SERVICES, HOUMA, LA - EIR, 483, RESPONSE 05/01/2013 - 05/22/13

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	04/12/2016	OC/ORO/ORM/ FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	THOMSON REUTERS (SCIENTIFIC) SAS	
2016-2147	03/15/2016 04/12/2016	FDA/OC/OES/ FDA/OFVM/CFSAN/OCD/EOS/	ROBERT A GOODIN GOODIN MACBRIDE SQUERI & DAY LLP	RISKS, BENEFITS, RISK MITIGATION PLANS THAT PRECEDED THE PUBLICATION OF THE GENOME OF C BOTULINUM STRAIN IBCA10-7060 12/14
2016-2148	03/15/2016 04/12/2016	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	JOEL S ROSS, MD, EATONTOWN, NJ - EIR, 483, RESPONSE 01/14/2014 - 01/30/2014
2016-2149	03/15/2016 04/12/2016	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Walter Chalkley THOMSON REUTERS	ANITA MERCADO, MD, ALHAMBRA, CA - EIR, 483, RESPONSE 06/15/2015 - 06/17/2015
2016-2150	03/15/2016 04/12/2016	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Kimberly Peck requesting EIR for Shire FDA inspection, SHIRE INC	SHIRE, LEXINGTON, MA - EIR 07/16/2012 - 08/31/2012
2016-2151	03/15/2016 04/12/2016	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	RICHARD P JUNGHANS, MD, PROVIDENCE, RI - EIR, 483, RESPONSE 04/01/2013 - 04/16/2013;
2016-2152	03/15/2016 04/12/2016	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Walter Chalkley THOMSON REUTERS	TRUMAN MILLING, MD, AUSTIN, TX - EIR, 483, RESPONSE 07/30/2012 - 08/06/2012
2016-2153	03/15/2016 04/12/2016	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Walter Chalkley THOMSON REUTERS	BAUTISTA MILAGROS, MD, QUEZON CITY, PHILIPPINES - 483 06/25/2012 - 06/29/2012
2016-2154	03/15/2016 04/12/2016	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	ANAZAOHEALTH CORPORATION, LAS VEGAS, NV - EIR, 483, RESPONSE 09/01/2014 - 09/23/2014
2016-2155	03/15/2016 04/12/2016	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	CHEMOLEE LAB CORPORATION, IRVING, TX - EIR, 483, RESPONSE 01/12/2015 - 02/13/2015
2016-2156	03/15/2016	FDA/OGROP/ORA/NE-FO/NYK-	Walter Chalkley	JAMAICA HOSPITAL IRB, JAMAICA HOSPITAL CENTER,

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	04/12/2016	DO/NYK-DCB/	THOMSON REUTERS (SCIENTIFIC) SAS	JAMAICA, NY - EIR, 483, RESPONSE 08/13/2015 - 08/20/2015
2016-2157	03/15/2016 04/12/2016	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Walter Chalkley THOMSON REUTERS	ACTAVIS, PLC, JERSEY CITY, NJ - EIR, 483, RESPONSE 01/22/2013 - 02/21/2013
2016-2158	03/15/2016 04/12/2016	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	CANGENE BIOPHARMA, INC DBA EMERGENT BIOSOLUTIONS, BALTIMORE, MD - EIR, 483, RESPONSE 08/01/2014 - 08/26/2014
2016-2159	03/15/2016 04/12/2016	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Walter Chalkley THOMSON REUTERS	ASTELLAS PHARMA TECHNOLOGIES, NORMAN, OK - EIR, 483, RESPONSE 06/17/2015 - 06/24/2015
2016-2160	03/15/2016 04/12/2016	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Pat Hillenmeyer (Ms.) AbbVie	ALBERTO A CHIAPPORI, MD, TAMPA, FL - EIR, 483 11/01/2012 - 05/01/2013
2016-2161	03/16/2016 04/13/2016	FDA/OMPT/CDRH/OCE/DID/	Heather Reed NinePoint Medical, Inc.	PMA P100005 - DEVICE COMPARISON, SUMMARY OF PERFORMANCE TESTING, ETC
2016-2162	03/16/2016 04/13/2016	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Humco Mercuroclear Recall Eugene Firsow	HUMCO RECALL RECS
2016-2163	03/16/2016 04/13/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ayan Deb Ayan Deb c/o Nomura Financial Advisory & Securities India Pvt Ltd	LUPIN - 483 12/01/2015 - 03/11/2016
2016-2164	03/16/2016 04/13/2016	FDA/OMPT/CDRH/OCE/DID/	Astrid Marx Heraeus Medical GmbH	K041363
2016-2165	03/16/2016 04/13/2016	FDA/OMPT/CDRH/OCE/DID/	Tsugumi Watabe Globizz Consulting	K030719
2016-2166	03/16/2016 04/13/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Prashant Nair Citigroup Global Markets Private Limited	LUPIN, GOA - 483 03/04/2016 - 03/14/2016
2016-2167	03/16/2016 04/13/2016	FDA/OMPT/CDRH/OCE/DID/	Tsugumi Watabe Globizz Corporation	K152311
2016-2168	03/16/2016 04/13/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	Eleanor DaCosta United States Pharmacopeial Convention (USP)	LACTOBACILLUS ACIDOPHILUS - AERS

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2016-2169	03/16/2016 04/13/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Krishna Kiran Konduri Spark Capital Advisors (I) Private Limited	GRANULES, INDIA - 483 12/03/2015 - 01/31/2016
2016-2170	03/16/2016 04/13/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jacques LeBoeuf Jacques LeBoeuf	WELLBUTRIN - ISR
2016-2171	03/16/2016 04/13/2016	FDA/OGROP/ORR/NE-FO/NYK-DO/NYK-DCB/	Alexandra Ajmo LIFE EXTENSION	GEMINI PHARMACEUTICALS, COMMACK, NY - EIR 01/01/2014 - 03/14/2016
2016-2172	03/16/2016 04/13/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K101887
2016-2173	03/16/2016 04/13/2016	FDA/OMPT/CDRH/OCE/DID/	Astrid Marx Heraeus Medical GmbH	K043260
2016-2174	03/16/2016 04/13/2016	FDA/OGROP/ORR/CE-FO/NWJ-DO/NWJ-CB/	Alexandra Ajmo LIFE EXTENSION	MANHATTAN DRUG COMPANY, HILLSIDE, NJ - EIR 01/01/2014 - 03/04/2016
2016-2175	03/16/2016 04/13/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Darshan Mehta ET Now	LUPIN, GOA - 483 03/01/2016 - 03/11/2016
2016-2176	03/16/2016 04/13/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Krishna Kiran Konduri Spark Capital Advisors (I) Private Limited	LUPIN, GOA - 483 01/01/2016 - 03/15/2016
2016-2177	03/16/2016 04/13/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Form 483 issued to Lupin's Goa facility AMBIT CAPITAL	LUPIN, GOA - 483 01/01/2016 - 03/15/2016
2016-2178	03/16/2016 04/13/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dr Girish Bakhru HSBC Securities and Capital Markets	LUPIN, GOA - 483 MARCH 2016
2016-2179	03/16/2016	FDA/OMPT/CDER/GRP/DIDP/	Rahul Jeewani	LUPIN LIMITED, GOA - 483 02/01/2016 - 03/15/2016

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	04/13/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	IIFL Capital	
2016-2180	03/16/2016 04/13/2016	FDA/OFVM/CFSAN/OCD/EOS/	Stacy Hung Seinoh Optical Co., Ltd	CAP 1C0291, CAP 1C0292
2016-2181	03/16/2016 04/13/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rahul Solanki Edelweiss	LUPIN LIMITED, GOA - 483 01/01/2016 - 03/14/2016
2016-2182	03/16/2016 04/13/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rahul Jeewani IIFL Capital	LUPIN LIMITED, GOA - 483 02/01/2016 - 03/14/2016
2016-2183	03/16/2016 04/13/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tushar Manudhane Indianivesh securities	LUPIN LIMITED, GOA - 483 03/01/2016 - 03/15/2016
2016-2184	03/16/2016 04/13/2016	FDA/OGROP/ORAN/NE-FO/NWE- DO/NWE-CB/	Michelle Elizabeth Legiec Eagle Pharmaceuticals, Inc.	AMRI BURLINGTON, MA - EIR 08/10/2015 - 08/19/2015
2016-2185	03/16/2016 04/13/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Vaibhav Dusad Morgan Stanley	LUPIN LIMITED, GOA - 483 02/01/2016 - 03/15/2016
2016-2186	03/16/2016 04/13/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jigar Valia Ohm Group	LUPIN LIMITED, GOA - 483 03/01/2016 - 03/12/2016
2016-2187	03/16/2016 04/13/2016	FDA/OMPT/CDRH/OCE/DID/	Leon Amariglio Lexington Medical, Inc.	K152421
2016-2188	03/16/2016 04/13/2016	FDA/OGROP/ORAN/SW-FO/DAL- DO/DAL-CB/	Pat Hillenmeyer (Ms.) AbbVie	US ONCOLOGY IRB, DALLAS, TX - EIR 02/01/2004 - 02/28/2004
2016-2189	03/16/2016 04/13/2016	FDA/OGROP/ORAN/NE-FO/NYK- DO/NYK-DCB/	Philipa Atta Medisca Inc.	MEDISCA, PLATTSBURGH, NY - EIR 02/17/2014 - 02/27/2014

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2016-2190	03/16/2016 04/13/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Chirag Talati Kotak Securities	LUPIN LIMITED, GOA - 483 01/01/2016 - 03/15/2016
2016-2191	03/16/2016 04/13/2016	OC/ORR/ORM/ OC/ORR/ORM/	Kris Christian FDAZILLA	LIST OF INSPECTIONS 02/10/2016 - 03/14/2016
2016-2192	03/16/2016 04/13/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Meg Morgen RW Baird	ZEPATIER - AERS
2016-2193	03/16/2016 04/13/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jeffrey R. Snyder BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.	NDA 21-395 CMC REVIEW COMMENTS
2016-2194	03/16/2016 04/13/2016	FDA/OMPT/CDRH/OCE/DID/	Tsugumi Watabe Globizz Corporation	K153080
2016-2195	03/16/2016 04/13/2016	FDA/OMPT/CDRH/OCE/DID/	Heather Reed NinePoint Medical, Inc.	K062789
2016-2196	03/16/2016 04/13/2016	FDA/OFVM/CFSAN/OCD/EOS/	JOAN SYLVAIN BAUGHAN Keller and Heckman LLP	ALCOHOLS TOXICOLOGY DATA C12-15; CASRN 68131-39-5
2016-2197	03/16/2016 04/13/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RAKESH NAYUDU HAITONG SECURITIES INDIA PRIVATE LIMITED	LUPIN, GOA - 483 3/7-11/16; 7/15
2016-2198	03/16/2016 04/13/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MANOJ GARG MERRILL LYNCH	LUPIN PHARMA, GOA, INDIA - 483 3/11/16
2016-2199	03/16/2016 04/13/2016	OC/ORR/ORM/ OC/ORR/ORM/	GAIL LESSICK LACHMAN CONSULTANT SERVICES INC	LIST OF INSP DOMESTIC & FOREIGN 1/1/16 TO 2/29/16
2016-2200	03/16/2016 04/13/2016	FDA/OMPT/CDRH/OCE/DID/	JOSHUA A. LEFKOVITZ PAIN MANAGEMENT TECHNOLOGIES	K896948

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2016-2201	03/16/2016 04/13/2016	FDA/OMPT/CDRH/OCE/DID/	DOTT ING SIMONE PREVICINI W & H STERILIZATION	W&H STERILIZATION - EIR 11/5-8/12
2016-2202	03/16/2016 04/13/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JULIE FERRARO KREINDLER & KREINDLER	NEXIUM 2001 TO PRESENT, PREVACID 1995 TO PRESENT, PRILOSEC 1989 TO PRESENT - GENERIC EQUIVALENCE
2016-2203	03/16/2016 04/13/2016	FDA/OMPT/CDRH/OCE/DID/	JAEWON JANG DIO MEDICAL CORP	DIO MEDICAL CO LTD - REXIOUS K111362, REX K121862, GALAXY K122872
2016-2204	03/16/2016 04/13/2016	FDA/OMPT/CDRH/OCE/DID/	JOHN M. STEELE RUNFT & STEELE LAW OFC	DEPUY - PEDICLE SCREWS TEST RESULTS, PREMARKET APRVL, MDRS, ETC
2016-2205	03/16/2016 04/13/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LARRY GLASS HAMILTON PHARMACEUTICALS	DMF 12951
2016-2206	03/16/2016 04/13/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SHERI O. COVINGTON K&L GATES	NITRATE OXIDE NDA 20-845/S014,017
2016-2207	03/17/2016 04/14/2016	FDA/OMPT/CDRH/OCE/DID/	Carroll Martin United States Endoscopy Group, Inc.	K102409
2016-2208	03/17/2016 04/14/2016	FDA/OMPT/CDRH/OCE/DID/	Vinnie Dang Vinnie Dang	MAF2557
2016-2209	03/17/2016 04/14/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kara Kenney WRTV-6	FLUOROQUINOLONES - AERS
2016-2210	03/17/2016 04/14/2016	FDA/OMPT/CDRH/OCE/DID/	Carroll Martin United States Endoscopy Group, Inc.	K102581
2016-2211	03/17/2016 04/14/2016	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/	Zetetic, Inc. Zetetic, Inc.	FDA ENTRY DOCUMENTATION REQUEST ALL DOCUMENTATION MAR 01, 2016 MAR 15, 2016
2016-2212	03/17/2016	FDA/OMPT/CDER/ORP/DIDP/	Sheldon Garrison	CETYLEV APPROVAL RECS

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	04/14/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MATC	
2016-2213	03/17/2016 04/14/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jill Buyon Jill P Buyon	IND 112,357
2016-2214	03/17/2016 04/14/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dheeresh Pathak Dheeresh Pathak	LUPIN, INDIA - 483 02/01/2016 - 03/14/2016
2016-2215	03/17/2016 04/14/2016	FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORO/PA-FO/SAN- DO/SAN-CB/	Olga M. Beato Grossman Roth Yaffa Cohen, P.A.	WESTERN MILLING, LLC, - 483, COMPLAINTS, WARNING LETTERS ETC 01/01/2015 - 03/16/2016
2016-2216	03/17/2016 04/14/2016	FDA/OMPT/CDRH/OCE/DID/	Tsugumi Watabe Globizz Corporation	K150977
2016-2217	03/17/2016 04/14/2016	FDA/OMPT/CDRH/OCE/DID/	Hyung Kim Sierra Medical International	K974521 K982816 K061373 ETC
2016-2218	03/17/2016 04/14/2016	FDA/OMPT/CDRH/OCE/DID/	Tsugumi Watabe Globizz Corporation	K984443
2016-2219	03/17/2016 04/14/2016	FDA/OMPT/CDRH/OCE/DID/	Tsugumi Watabe Globizz Corporation	K113129
2016-2220	03/17/2016 04/14/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Laurel Benyo PharmaForce Inc.	NDA 021945 S 007
2016-2221	03/17/2016 04/14/2016	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SE-FO/FLA- DO/FLA-CB/	PAIGE SAVITZ BEAVER STREET FISHERIES, INC.	SAMPLE 002-8161204-4 ANALYTICAL RESULTS
2016-2222	03/17/2016 04/14/2016	FDA/OMPT/CDRH/OCE/DID/	Heather Reed NinePoint Medical, Inc.	PMA P110014 - DEVICE COMPARISON, PERFORMANCE TESTING, ETC
2016-2223	03/17/2016	FDA/OMPT/CDRH/OCE/DID/	Terry Dagnon	K121447

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	04/14/2016		Dohmen Life Science Servcies	
2016-2224	03/17/2016 04/14/2016	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Barbara B. Overby, V-P Quality Improvement Wilkes Regional Medical Center	WIKLES REGIONAL MEDICAL CENTER, NORTH WILKESBORO, NC - EIR 02/01/2014 - 12/31/2014
2016-2225	03/17/2016 04/14/2016	FDA/OMPT/CDRH/OCE/DID/	Elizabeth Luoma DuVal & Associates, P.A.	K994262
2016-2226	03/17/2016 04/14/2016	FDA/OMPT/CDRH/OCE/DID/	Charles Snow Hyman, Phelps & McNamara, P.C.	513(G) REQUESTS, RESPONSES RE THYNC, THYNC VIBES, CORR ETC
2016-2227	03/17/2016 04/14/2016	FDA/OMPT/CDRH/OCE/DID/	Christopher Thomas Donner SI-TECHNOLOGY, LLC	K152304
2016-2228	03/17/2016 04/14/2016	FDA/OMPT/CDRH/OCE/DID/	Tsugumi Watabe Globizz Corporation	K101223
2016-2229	03/17/2016 04/14/2016	FDA/OMPT/CDRH/OCE/DID/	Jason Tsai, M.D. Jason Tsai, M.D.	PMA P930016 S019
2016-2230	03/17/2016 04/14/2016	FDA/OFVM/CFSAN/OCD/EOS/	Joshua Mattern Bodybuilding.com	BODYBUILDING.COM - AERS
2016-2231	03/17/2016 04/14/2016	FDA/OMPT/CTP/OD/	Anthony W. Lee Lee, Anthony	FEDERAL VIEWPOINT SURVEY RESULTS CTP OFFICE OF COMPLAINE AND ENFORCEMENT, OFFICE OF THE CENTER DIRECTOR, OFFICE OF MANAGEMENT ETC 2013, 2014, 2015
2016-2232	03/17/2016 04/14/2016	OC/ORAE/ OC/ORAE/ OC/ORAE/ORM/ OC/ORAE/ORM/	Kris Christian FDAZILLA	INSPECTION CITATIONS LIST 3/15/15 - 03/14/2016
2016-2233	03/17/2016 04/14/2016	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Jacqueline Gennuso Jacqueline Gennuso	MUSCULOSKELETAL TRANSPLANT FOUNDATION - RESPONSES TO WARNING LETTERS 01/01/2013 - 03/14/2016
2016-2234	03/17/2016 04/14/2016	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Jennifer LaBon Prime Enterprises, Inc.	PRIME ENTERPRISES, INC, MIAMI, FL - EIR 05/22/2015 - 06/08/2015
2016-2235	03/17/2016 04/14/2016	FDA/OMPT/CDRH/OCE/DID/	Marilynn Whitney COVINGTON & BURLING LLP	SMILECARECLUB - CORR WITH CDRH OFFICE OF COMPLIANCE, DENTAL DEVICES BRANCH 12/01/2015 - 03/14/2016
2016-2236	03/17/2016 04/14/2016	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Amanda Smith WKBN	INSPECTION OF EGG SHELL PRODUCTION FACILITIES IN OHIO 03/03/2015 - 03/14/2016
2016-2237	03/17/2016 04/14/2016	FDA/OMPT/CDRH/OCE/DID/	Michelle Roeding Natera	HITACHI ECHELON C - 510K 01/01/2005 - 03/16/2016

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2016-2238	03/17/2016 04/14/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Bentley Moyer Juno Therapeutics, Inc.	PRESENTATION BY MAURA O'LEARY TO RECOMBINANT DNA ADVISORY COMMITTEE 03/09/2016 - 03/09/2016
2016-2239	03/17/2016 04/14/2016	FDA/OGROP/ORANE-FO/NYK- DO/NYK-DCB/	Jennifer Kohn Crist Bros. Orchards, Inc.	INVESTIGATION RECS
2016-2240	03/17/2016 04/14/2016	FDA/OMPT/OSMP/OOPD/	Shreya Mehta ARIAD Pharmaceuticals, Inc.	ZYKADIA - ORPHAN DESIGNATION RECS
2016-2241	03/17/2016 04/14/2016	FDA/OMPT/CDRH/OCE/DID/	TMG-BMC d.o.o. TMG-BMC d.o.o.	NEUROGENIC TECHNOLOGIES - TECHNICAL FILE, INDICATIONS FOR USE, DEVICE DESCRIPTION ETC
2016-2242	03/17/2016 04/14/2016	FDA/OMPT/OSMP/OOPD/	Shreya Mehta ARIAD Pharmaceuticals, Inc.	ALECENSA - ORPHAN PRODUCT RECS
2016-2243	03/17/2016 04/14/2016	OC/ORA/ OC/ORA/ OC/CVM/OCD/	Jeffrey Meitrodt MINNEAPOLIS STAR TRIBUNE	ORA PET FOOD COMPLAINTS
2016-2244	03/17/2016 04/14/2016	FDA/OMPT/CDRH/OCE/DID/	Chirag Talati Kotak Securities	LUPIN, SUN PHARMA, ZYDUS ETC - 483 01/01/2015 - 03/15/2016
2016-2245	03/17/2016 04/14/2016	FDA/OGROP/ORASE-FO/NOL- DO/NOL-CB/	Wayne Risher The Commercial Appeal	KELLOG, MEMPHIS - INVESTIGATION RECS
2016-2246	03/18/2016 04/15/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/ORA/ OC/ORA/	JONATHAN L MARKS KATTEN MUCHIN ROSENMAN LLP	21ST CENTURY PHARMACY INC - OPERATION, REGISTRATION, COMPLIANCE, ETC
2016-2247	03/18/2016 04/15/2016	FDA/OC/OES/DFOI/	G HAROLD CHRISTIAN PAYMENT PROCESSING SERVICES LLC	SANDOZ INC - LIMITED PAYABILITY CANCELLATION CHECK RECS
2016-2248	03/18/2016 04/15/2016	FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/	ERIC MUSGROVE GLOBAL PACKAGING SYSTEMS	GLOBAL PACKAGING SYSTEMS INC, FORT WORTH, TX - EIR 2015
2016-2249	03/18/2016 04/20/2016	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORA/ OC/ORA/ FDA/OGROP/ORA/ORO/DIOP/	SUZANNE D JENSEN Kleinfeld, Kaplan & Becker LLP	GINSENG - IMPORT ALERT 99-05
2016-2250	03/18/2016	FDA/OMPT/CDER/GRP/DIDP/	ELENA CLARK	LUPIN LTD - LURASIDONE HCL TABS ANDA 208-031; MSN LABS - LURASIDONE HCL TABS ANDA 208-037; EMCURE

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	04/15/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Hogan Lovells, ILP	PHARMS LTD - LURASIDONE HCL TABS ANDA 208-058, ETC TENTATIVE APRVL LTRS
2016-2251	03/18/2016 04/15/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RICHARD H WOODS LEVIN PAPANTONIO THOMAS ET AL	CENTOCOR ORTHO BIOTECH INC, JANSEN BIOTECH INC, JOHNSON & JOHNSON INC - STELARA (USTEKINUMAB) INJ BLA 125261 LBLG CHANGES, SUBMISSIONS
2016-2252	03/18/2016 04/15/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RICHARD H WOODS LEVIN PAPANTONIO THOMAS ET AL	STELARA (USTEKINUMAB) BLA 125261, JAKAFI (RUXOLITINIB) NDA 202-192 - PERIODIC SAFETY UPDATE RPTS (PSUR); COSENTYX (SECUKINUMAB) BLA 125504, ETC - SAFETY ANALYSES
2016-2253	03/18/2016 04/15/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SUSAN TODD TELIGENT PHARMA INC	TARO - DIFLORASONE DIACETATE ANDA 75-508; FOUGERA PHARMS - DIFLORASONE DIACETATE ANDA 76- 263 SBA
2016-2254	03/18/2016 04/15/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WILLIAM A GARVIN BUCHANAN INGERSOLL & ROONEY PC	SYNTHO PAHRMACEUTICALS INC - PAYMENT OF USER FEES UNDER THE GENERIC DRUG USER FEE AMENDMENTS 0F 2012
2016-2255	03/18/2016 04/28/2016	FDA/OC/OES/DFOI/	Kris Christian FDAZILLA	483, EIR, RESPONSES RELEASED SINCE 2/22/16 02/11/2016 - 03/14/2016
2016-2256	03/18/2016 04/15/2016	FDA/OFVM/CFSAN/OCD/EOS/	Jared Whetstone Jared Whetstone	CHOCOLATE TOY SURPRISE COMBINATION - CORR WITH WITH FDA AND CANDY TREASURES LLC, FERRERO 01/01/2005 - 03/14/2016
2016-2257	03/18/2016 04/15/2016	FDA/OMPT/CDRH/OCE/DID/	Christian Behrenbruch Monash University	IDE REFUSE TO FILE NOTICES ONCOSIL MEDICAL LABORATORY 12/03/2015 - 03/01/2016
2016-2258	03/18/2016 04/15/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bharat Celly Research Delta Advisors	LUPIN, GOA, INDIA - 483 02/01/2016 - 03/14/2016
2016-2259	03/18/2016 04/15/2016	FDA/OMPT/CDRH/OCE/DID/ OC/ORO/ OC/ORO/	Nicholas Fleischer FLEISCHER, ALAN	RECS RE DEVELOPMENT OF BI0-RELEVANT IN-VITRO ASSAY TO DETERMINE LABILE IRON IN THE PARENTAL IRON COMPLEX PRODUCT 1U01FD004889-01
2016-2260	03/18/2016	FDA/OPPLA/OL/	Sam Falconer	SENATOR JOHN MCCAIN - CORR LOGS FEB 2012 TO

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	04/15/2016		Arizona Democratic Party	PRESENT
2016-2261	03/18/2016 04/15/2016	FDA/OO/OFBA/OAGS/	Nicholas Fleischer FLEISCHER, NICHOLAS M	HHSF223201310220C
2016-2262	03/18/2016 04/15/2016	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	Wayne Risher The Commercial Appeal	KELLOGG, MEMPHIS, TN - INSPECTION RECS 01/01/2011 - 03/15/2016
2016-2263	03/18/2016 04/15/2016	OC/ORAS/ORM/ OC/ORAS/ORM/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/CVM/OCD/	Wendy Kowal Wendy Kowal	LIST OF BIOLOGICAL CENTERS THAT DRAW EQUINE BLOOD, BIOLOGICAL CENTERS THAT PRODUCT EQUINE IGG SERUM PRODUCTS ETC
2016-2264	03/18/2016 04/15/2016	OC/ORAS/ OC/ORAS/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORAS/PA-FO/SAN-DO/SAN-CB/ FDA/OC/OCC/ FDA/OGROP/ORAS/SW-FO/DEN-DO/DEN-CB/	Sender Gruen GRUEN, CARL	CAN-C EYE DROPS, SUPPEMENTS - COMPLIANCE RECS 01/16/2005 - 03/16/2016
2016-2265	03/18/2016 04/15/2016	FDA/OC/OES/DFOI/	Kendall Taggart Kendall Taggart, BuzzFeed News	APPROVALS, DENIALS OF REQUESTS FOR OUTSIDE ACTIVITY GS-14 OR HIGHER 01/01/2010 - 03/16/2016
2016-2266	03/18/2016 05/23/2016	FDA/OGROP/ORAS/SW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORAS/SW-FO/DAL-DO/DAL-CB/	Joshua Riegelhaupt Baron Capital	NEOS THERAPEUTICS - 483 ETC 01/01/2015 - 03/16/2016

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2016-2267	03/18/2016 04/15/2016	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCE/DID/	Sofia Bruera PSB	K901508, K951508, MAUDE RPTS, ETC
2016-2268	03/18/2016 04/15/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John V. Gray THE OHIO STATE UNIVERSITY	FDA NDC, DECRS
2016-2269	03/18/2016 04/15/2016	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/	Kai Gao Seafood Expert West Inc	SALMON, POLLOCK - ENTRIES TO NY BEING SAMPLED BY FDA 02/01/2016 - 03/16/2016
2016-2270	03/18/2016 04/15/2016	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OFVM/CFSAN/OCD/EOS/	Martin Hoagland Nalco an Ecolab Company	FAP3B3696 000588-595, 000637-000644
2016-2271	03/18/2016 04/15/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ayesha Adil The Weinberg Group	NDA 020221 SBA
2016-2272	03/18/2016 04/15/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ronald F. Miszewski Ronald F. Miszewski	MONTELUKAST SODIUM, PSORIASIS, PSORIATIC ARTHRITIS - CORR BETWEEN MERCK AND FDA 01/01/1999 - 08/02/2012
2016-2273	03/18/2016 04/15/2016	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2015-8862
2016-2274	03/18/2016 04/15/2016	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2015-3482
2016-2275	03/18/2016 04/15/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nazmin Amir Actavis Laboratories FL, Inc.	NDA 20049 S27
2016-2276	03/18/2016 04/15/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nazmin Amir Actavis Laboratories FL, Inc.	NDA 20049 S15
2016-2277	03/18/2016 04/15/2016	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Pramod Dahibhate LUPIN LIMITED	LUPIN - LIST OF FOIA REQUESTS

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2016-2278	03/21/2016 04/18/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Hajra Mazhar Hajra Mazhar (University of Ottawa)	ISR 6867898; 6882788; 6902426; ETC
2016-2279	03/21/2016 04/18/2016	FDA/OFVM/CFSAN/OCD/EOS/	Kevin O. Gillies Kevin O. Gillies Consulting Services, LLC	FCN 1018
2016-2280	03/21/2016 04/18/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nazmin Amir Actavis Laboratories FL, Inc.	CARBAMAZEPINE ER TABLETS - SBA
2016-2281	03/21/2016 04/18/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LUIS DIESTRE IE BUSINESS SCHOOL	ELECTRONIC EDITIONS OF THE ORANGE BOOK 1995 - 2016
2016-2282	03/21/2016 04/18/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Walter Chalkley THOMSON REUTERS	EMCURE PHARMACEUTICALS LTD, INDIA - 483 01/27/2015 - 02/04/2015
2016-2283	03/21/2016 04/18/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Gina Mastro Simone Gina Mastro Simone	ZOSTAVAX - PACKAGE INSERT RECS
2016-2284	03/21/2016 04/18/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Gina Mastro Simone Mastro Simone, Gina	PREVNAR - PACKAGE INSERT RECS
2016-2285	03/21/2016 04/18/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bob Golding Daavlin Distributing	NDA/ADNAs, DMF RE : 8-Methoxypsoralen (Methoxsalen), 2,5,9-Trimethylpsorale (Trioxsalen), 5-Methoxypsoralen (Bergapten)

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-2286	03/21/2016 04/18/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Andrew Trepp Center Pond Management	NDA 008975 S 000-006, NDA 009854 S 000-012, NDA 022028 S 000-004
2016-2287	03/21/2016 04/18/2016	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Ginny Boynton Ginny Boynton	IMPAX, HAYWARD, CA - 483 01/01/2012 - 03/17/2016
2016-2288	03/21/2016 04/18/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jason M Kane UNIVERSITY OF CHICAGO	DEXMEDETOMIDINE - MEDWATCH, AERS
2016-2289	03/21/2016 04/18/2016	FDA/OFVM/CFSAN/OCD/EOS/	Anthony Connors Anthony Connors	BRUCE W KNELLER - CORR WITH FDA 01/01/2000 - 03/01/2016
2016-2290	03/21/2016 04/18/2016	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORA/ OC/ORA/	Remona Gopaul Shiseido Americas Corporation	LAURA MERCIER TOPICALLY APPLIED COSMETICS - COMPALINTS 01/03/2014 - 01/01/2016
2016-2291	03/21/2016 04/18/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rahul Jeewani IIFL Capital	LUPIN LIMITED, INDIA - 483 03/23/2015 - 04/08/2015
2016-2292	03/21/2016 04/18/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rahul Jeewani IIFL Capital	LUPIN LIMITED, INDIA - 483 01/01/2016 - 01/31/2016
2016-2293	03/21/2016 04/18/2016	FDA/OMPT/CDRH/OCE/DID/	Christopher Thomas Donner SI-TECHNOLOGY, LLC	K120792
2016-2294	03/21/2016 04/18/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Poorna Venkatesan Jefferies India Pvt Ltd	LUPIN,CADILA, INDIA - 483 12/01/2015 - 03/17/2016
2016-2295	03/21/2016 04/18/2016	FDA/OMPT/CDRH/OCE/DID/	Nahbee Jong TheraNova LLC	K993592
2016-2296	03/21/2016	FDA/OMPT/CDER/GRP/DIDP/	Yolonda Colson, MD, PhD	FERUMOXYTOL - AERS

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	04/18/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRIGHAM AND WOMEN'S HOSPITAL	
2016-2297	03/21/2016 04/18/2016	FDA/OMPT/CDRH/OCE/DID/	Kathryn Becker Kathryn Becker	K062187
2016-2298	03/21/2016 04/18/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 21812/S9
2016-2299	03/21/2016 04/18/2016	FDA/OMPT/CDRH/OCE/DID/	Susan Alpert Susan Alpert	K133932
2016-2300	03/21/2016 04/18/2016	FDA/OMPT/CDRH/OCE/DID/	Denise Wrestler Ideal Implant Inc.	Breast Implant Exemption E1996002
2016-2301	03/21/2016 04/18/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jaya Lakshmi Ayyagari Dr. Reddy's Laboratories Inc.	NDA 016093
2016-2302	03/21/2016 04/20/2016	FDA/OC/OES/DFOI/	Eric Young Kessler Topaz Meltzer Check LLP	COMM BETWEEN FDA AND ST JUDE MEDICAL, INC - RECS RE FOIA EXEMPTION 4 12/31/2008 - 01/01/2013
2016-2303	03/21/2016 04/18/2016	FDA/OGROP/ORAP/FO/SAN- DO/SAN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	ANAZOHEALTH CORPORATION, LAS VEGAS, NV - EIR, 483, RESPONSE 12/01/2014 - 12/29/2014\
2016-2304	03/21/2016 04/18/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sok Kang Trevena, Inc.	NDA 020630
2016-2305	03/21/2016 04/18/2016	FDA/OMPT/CDRH/OCE/DID/ FDA/OGROP/ORAP/CE-FO/MIN- DO/MIN-CB/	Maulik Shah Citadel Investment Group	MEDTRONIC - CONSENT DECREE, WARNING LETTER, RESPONSE 01/01/2010 - 03/17/2016
2016-2306	03/21/2016 04/18/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Zeba Siddiqui THOMSON REUTERS	LUPIN LTD, GOA, INDIA - 483 01/01/2016 - 03/17/2016
2016-2307	03/21/2016	FDA/OMPT/CDER/GRP/DIDP/	Leanne Usa	ANDA 208167

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	04/18/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Wockhardt USA LLC	
2016-2308	03/21/2016 04/18/2016	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	Rachel Johnson FOI Services, Inc.	METAGENICS - WARNING LETTER RECS
2016-2309	03/21/2016 04/18/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ronald F. Miszewski Ronald F. Miszewski	MERCK - RECS RE MONTELUKAST SODIUM AND TUMOR NECROSIS FACTOR ALPHA 01/01/1999 - 03/17/2016
2016-2310	03/21/2016 04/18/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DDM/ FDA/OFVM/CFSAN/OCD/EOS/	Anthony Connors Anthony Connors	2015-5950 ADMIN FILE
2016-2311	03/21/2016 04/18/2016	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	LESLIE RAMSEY FDA NEWS	BELLEGROVE MEDICAL SUPPLY INC, REDMOND, WA; ERICKSON LABS NORTHWEST LLC, KIRKLAND, WA; INTL REHABILITATIVE SCIENCES INC, VANCOUVER, WA - 483 1/1-2/29/16
2016-2312	03/21/2016 04/18/2016	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	LESLIE RAMSEY FDA NEWS	AGROPHARMA LABS INC, SALINAS, PR; JANSSEN ORTHO LLC, GURABO, PR - 483 1/1-2/29/16
2016-2313	03/21/2016 04/18/2016	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	LESLIE RAMSEY FDA NEWS	ABBOTTS COMPOUNDING PHARMACY INC, BERKELEY, CA; RECHARGEABLE POWER ENERGY NORTH AMERICA INC, LAS VEGAS, NV; BIOZONE LABS INC, PITTSBURG, CA - 483 1/1-2/29/16
2016-2314	03/21/2016 04/18/2016	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	LESLIE RAMSEY FDA NEWS	DORNEYVILLE PHARMACY, ALLENTOWN, PA; CAPINTEC INC, PITTSBURGH, PA; JEFFREYS DRUG STORE, CANONSBURG, PA - 483 1/1-2/29/16
2016-2315	03/21/2016 04/18/2016	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	LESLIE RAMSEY FDA NEWS	STAUBACH BARROR WATER SYSTEMS INC, SCHENECTADY, NY; TOPIDERM INC, AMITYVILLE, NY; KNIGHT DENTAL GROUP INC, RONKONKOMA, NY - 483 1/1-2/29/16
2016-2316	03/21/2016 04/18/2016	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	LESLIE RAMSEY FDA NEWS	KEYSTONE LABS INC, MEMPHIS, TN - 483 1/1-2/29/16
2016-2317	03/21/2016 04/18/2016	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	LESLIE RAMSEY FDA NEWS	DAVLIN INDUSTRIES INC, MONROE TOWNSHIP, NJ; ELITE LABORATORIES INC, NORTHVALE, NJ; STOKES PHARMACY, MOUNT LAUREL, NJ - 483 1/1-2/29/16

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2016-2318	03/21/2016 04/18/2016	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	LESLIE RAMSEY FDA NEWS	AMERICAN MEDICAL SYSTEMS LLC, MINNETONKA, MN; OTOTRONIX LLC, WHITE BEAR LAKE, MN - 483 1/1-2/29/16
2016-2319	03/21/2016 04/18/2016	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	LESLIE RAMSEY FDA NEWS	RIVERSIDE WATER TECHNOLOGY INC, PERRYVILLE, MO - 483 1/1-2/29/16
2016-2320	03/21/2016 04/18/2016	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	LESLIE RAMSEY FDA NEWS	ACTUALIZE DESIGN & MANUFACTURING LLC, BUDA, TX; WHITEHILL MANUFACTURING INC, STAFFORD, TX; IDEAL IMPLANT INC, DALLAS, TX - 483 1/1-2/29/16
2016-2321	03/21/2016 04/18/2016	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	LESLIE RAMSEY FDA NEWS	SOMA ACCESS SYSTEMS LLC, ENGLEWOOD, CO; SPECTRANETICS CORP, COLORADO SPRINGS, CO; HOGGAN SCIENTIFIC LLC, SALT LAKE CITY, UT - 483 1/1-2/29/16
2016-2322	03/21/2016 04/18/2016	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	LESLIE RAMSEY FDA NEWS	SHERTECH LABORATORIES LLC, DUNCAN, SC; CARLTONS DUNWOODY PHARMACY CORP, DUNWOODY, GA - 483 1/1-2/29/16
2016-2323	03/21/2016 04/18/2016	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	LESLIE RAMSEY FDA NEWS	STRESSA INC, BUENA VISTA, VA; QIAGEN SCIENCES LLC, GERMANTOWN, MD; BTE TECHNOLOGIES INC, HANOVER, MD - 483 1/1-2/26/16
2016-2324	03/21/2016 04/18/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	LESLIE RAMSEY FDA NEWS	SANOCHEMIA PHARMAZEUTIKA AG, NUEFELD AN DER LEITHA, AUSTRIA; NOVO NORDISK AS, HILEROD, DENMARK; SANOFI PASTEUR SA, MARCY IETOILE, FRANCE - 483 1/1-2/29/16
2016-2325	03/21/2016 04/18/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LESLIE RAMSEY FDA NEWS	WOCKHARDT LTD, SHENDRA AURANGABAD, INDIA; BAXTER ONCOLOGY GMBH, BIELEFELD, GERMANY; F HOFFMAN LAROCHE LTD, BASEL, SWITZERLAND - 483 1/1-2/29/16
2016-2326	03/21/2016 04/18/2016	FDA/OMPT/CDRH/OCE/DID/	LESLIE RAMSEY FDA NEWS	GUENTER BISSINGER MEDIZINTECHNIK GMBH, TENINGEN, GERMANY; ARTHOCARE DE COSTA RICA SRL, AURORA DE HEREDIA, COSTA RICA; CITAGENIX INC, LAVAL, CANADA - 483 1/1-2/29/16
2016-2327	03/21/2016 04/18/2016	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	LESLIE RAMSEY FDA NEWS	BUDERER DRUG COMPANY INC, PERRYSBURG, OH; CENTRAL ADMIXTURE PHARMACY SERVICES INC, VALLEY VIEW, OH; OHIO WILLOWOOD CO, MOUNT STERLING, OH - 483 1/1-2/29/16
2016-2328	03/21/2016 04/18/2016	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	LESLIE RAMSEY FDA NEWS	COMMON SENSE DENTAL PRODUCTS INC II, SPRING LAKE, MI; UNIQUE INSTRUMENTS, INC, BRIDGEPORT, MI; MORRIS INNOVATIVE INC, BLOOMINGTON, IN - 483 1/1-2/29/16
2016-2329	03/21/2016 04/18/2016	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	LESLIE RAMSEY FDA NEWS	CARDIOCOMMAND INC, TAMPA, FL; ACTAVIS LABORATORIES FL INC, SUNRISE, FL; LEX INC, MEDLEY, FL - 483 1/1-2/29/16
2016-2330	03/21/2016	FDA/OGROP/ORANE-FO/NWE-	LESLIE RAMSEY	ARZOL CHEMICAL CO, KEENE, NH; NEW ENGLAND HOME

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	04/18/2016	DO/NWE-CB/ OC/ORO/ OC/ORO/ FDA/OGROP/ORO/NE-FO/NWE-DO/NWE-CB/	FDA NEWS	THERAPIES INC, SOUTHBOROUGH, MA; BIOGEN INC, CAMBRIDGE, MA - 483 1/1-2/29/16
2016-2331	03/21/2016 04/18/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LESLIE RAMSEY FDA NEWS	INSTITUTT FOR ENERGITEKNIKK, KJELLER, NORWAY; HAUPT PHARMA BERLIN GMBH, BERLIN, GERMANY; AVENTIS PHARMA LTD, CREWE, UK - 483 1/1-2/29/16
2016-2332	03/21/2016 04/18/2016	FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	LESLIE RAMSEY FDA NEWS	SPECIALTY SILICONE FABRICATORS INC, TUSTIN, CA; HOLOGIC INC, SAN DIEGO, CA; AMERICAN IMEX, IRVINE, CA - 483 1/1-2/29/16
2016-2333	03/21/2016 04/18/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PHILLIP RAKHUNOV POLLACK SOLOMON ET AL	FERRING PHARMACEUTICALS INC - PREPOPIK AER
2016-2334	03/21/2016 04/18/2016	FDA/OMPT/CDRH/OCE/DID/	ASHLEY FICKETT ULTHERA INC	K100874, K112626
2016-2335	03/21/2016 04/18/2016	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORO/CE-FO/NWJ-DO/NWJ-CB/	BETHANY KENNEDY EMORD & ASSOCIATES, P.C.	NATURAL SOLUTIONS FOUNDATION - WARNING LTR RESP 9/23/15, EMAILS, LTRS, ETC
2016-2336	03/21/2016 04/18/2016	FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/ OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/	BETHANY KENNEDY EMORD & ASSOCIATES, P.C.	YOUNGEVITY INTERNAITONAL LLC - CORR, CCMLPLNTS 1/14 TO PRESENT
2016-2337	03/22/2016 04/19/2016	FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	MOHAMMED ALHATOU, ORANGEBURG, SC - EIR, 483, RESPONSE 05/27/2014 - 06/26/2014
2016-2338	03/22/2016 04/19/2016	FDA/OGROP/ORO/CE-FO/PHI-DO/PHI-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	ALEJANDRO HOBERMAN, MD, PITTSBURGH, PA - EIR, 483, RESPONSE 01/01/2015 - 02/04/2015
2016-2339	03/22/2016 04/19/2016	FDA/OGROP/ORO/CE-FO/PHI-DO/PHI-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	AMEDRA PHARMACEUTICALS, LLC, HORSHAM, PA - EIR, 483, RESPONSE 03/01/2015 - 03/11/2015

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2016-2340	03/22/2016 04/19/2016	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	ST PETER'S UNIVERSITY HOSPITAL CPHSR, NEW BRUNSWICK, N J - EIR, 483, RESPONSE 12/19/2013 - 01/13/2014
2016-2341	03/22/2016 04/19/2016	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	MEDPREP CONSULTING, TINTON FALLS, NJ - EIR, 483, RESPONSE 03/15/2013 - 04/04/2013
2016-2342	03/22/2016 04/19/2016	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	KARAMO AN CHILOMBO, MD, HUNTINGTON PARK, CA - EIR, 483, RESPONSE 10/30/2012 - 01/10/2013
2016-2343	03/22/2016 04/19/2016	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	MASSBIOLOGICS, BOSTON, MA - EIR, 483, RESPONSE 05/13/2014 - 05/20/2014
2016-2344	03/22/2016 04/19/2016	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	NORTHAMPTON HOSPITAL CORPORATION, DBA EASTON HOSPITAL CORPORATION, EASTON, PA - EIR, 483, RESPONSE 06/16/2014 - 06/30/2014
2016-2345	03/22/2016 04/22/2016	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	MPI RESEARCH, MATTAWAN, MI - EIR, 483, RESPONSE 10/10/2014 - 10/10/2014
2016-2346	03/22/2016 04/19/2016	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	CHARLES RIBER LABORATORIES PRECLINICAL SERVICES, RENO, NV - EIR, 483, RESPONSE 09/21/2015 - 09/29/2015
2016-2347	03/22/2016 04/19/2016	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Chalkley Walter THOMSON REUTERS (SCIENTIFIC) SAS	COVANCE LABORATORIES, INC, MADISON, WI - EIR, 483, RESPONSE 10/21/2014 - 11/03/2014
2016-2348	03/22/2016 04/19/2016	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	NEWBORN BLOOD BANKING, LAND O LAKES, FL - EIR, 483, RESPONSE 06/01/2013 - 06/11/2013
2016-2349	03/22/2016 04/19/2016	OC/ORAO/CI/ OC/ORAO/CI/	Anthony Connors Anthony Connors	MARTIN MCDERMOTT - INVESTIGATION RECS 01/01/2000 - 01/02/2004

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		FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/		
2016-2350	03/22/2016 04/19/2016	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ OC/ORA/OCI/ OC/ORA/OCI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anthony Connors Anthony Connors	HADI M GHANDOUR, DEREK ETTINGER, JOEL DESMARAIS ETC P INVESTIGATION RECS 01/01/1997 - 01/06/2006
2016-2351	03/22/2016 04/19/2016	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	QPS, LLC, NEWARK, DE - EIR, 483, RESPONSE 10/20/2014 - 10/24/2014
2016-2352	03/22/2016 04/19/2016	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/ORO/DIOP/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Zetetic, Inc. Zetetic, Inc.	FDA ENTRY DOCUMENTATION REQUEST (REFUSAL) 0025545-4
2016-2353	03/22/2016 04/19/2016	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/ORO/DIOP/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	Zetetic, Inc. Zetetic, Inc.	FDA ENTRY DOCUMENTATION REQUEST (REFUSAL) 0025211-3
2016-2354	03/22/2016 04/19/2016	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/ORO/DIOP/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	Zetetic, Inc. Zetetic, Inc.	FDA ENTRY DOCUMENTATION REQUEST (REFUSAL) 0025301-2
2016-2355	03/22/2016 04/19/2016	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/ORO/DIOP/	Zetetic, Inc. Zetetic, Inc.	FDA ENTRY DOCUMENTATION REQUEST (REFUSAL) 0025354-1

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		FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/		
2016-2356	03/22/2016 04/19/2016	OC/ORR/ OC/ORR/	Christopher McDaniel Buzzfeed News	SODIUM THIOPIENTAL - SHIPMENTS DETAINED BY FDA IN ARIZONA AND TEXAS D97-0846078-4/1/1, D97-0846119-6/1/1
2016-2357	03/22/2016 04/19/2016	FDA/OGROP/ORR/PA-FO/SAN-DO/SAN-CB/	Kurt Martin Wm. E. Martin & Sons Co., Inc.	KATHLEEN LEWIS - EMAILS RE PEANUT, PEANUT ALLERGEN, PEANUT PROBLEM ETC 12/14/2015 - 03/18/2016
2016-2358	03/22/2016 04/19/2016	FDA/OMPT/CDRH/OCE/DID/	Margaret Batchelder NeoMetrics, Inc.	K151981 K132947
2016-2359	03/22/2016 04/19/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 20931 REMS MODIFICATION LETTER
2016-2360	03/22/2016 04/19/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jaya Ayyagari Dr. Reddy's Laboratories Inc.	NDA 020622 SBA Supplement 93 Supplement 95 Supplement 96
2016-2361	03/22/2016 04/19/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Poornaa Venkatesan Jefferies India Pvt Ltd	NATCO PHARMA'S MAHBOOB NAGAR, AUROBINDO PHARMA UNIT IV - 483 01/01/2016 - 03/18/2016
2016-2362	03/22/2016 04/19/2016	FDA/OMPT/CDRH/OCE/DID/	Shikha Sherchan Shikha Sherchan	K150453
2016-2363	03/22/2016 04/19/2016	FDA/OMPT/CDRH/OCE/DID/	Yiling He ShineMed LLC	K111825 K062850
2016-2364	03/22/2016 04/19/2016	FDA/OFVM/CFSAN/OCD/EOS/	Dr. Ray Matulka BURDOCK GROUP	RECS RE GRAS FOR ELEMENTAL IRON
2016-2365	03/22/2016 04/19/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kelly Sayter, FRP GROWER KETCHAM ET AL	VALPROATE/DEPAKOTE - RECS RE BLACK BOX WARNING 01/01/2006 - 12/31/2009
2016-2366	03/22/2016 04/19/2016	FDA/OMPT/CDRH/OCE/DID/	Corinne Colaianni RMS Medical Products	RMS MEDICAL PRODUCTS - TRADE COMPLAINT
2016-2367	03/22/2016	FDA/OC/OES/DFOI/	Gina Ecolino	CFSAN FOIA REQUESTS 02/25/2016 - 03/21/2016

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	04/19/2016		BEVERIDGE & DIAMOND	
2016-2368	03/22/2016 04/19/2016	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	Valerie Ahmuty TherapeuticsMD, Inc	SANCILIO AND COMPANY, RIVIERA BEACH, FL - EIR 09/21/2015 - 03/01/2016
2016-2369	03/22/2016 04/19/2016	OC/CVM/OCD/	Sandy O'Kelley Merial Inc	BRAVECTO AERS
2016-2370	03/22/2016 04/19/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rahul Jeewani IIFL Capital	LUPIN, INDIA - 483 01/02/2015 - 03/18/2016
2016-2371	03/22/2016 04/19/2016	FDA/OGROP/ORR/ORO/DIOP/	Christopher McDaniel Buzzfeed News	DIOP SPREADSHEET OF IMPORTED DRUGS FOR SODIUM THIOPIENTAL, PANCURONIUM BROMIDE, POTASSIUM CHLORIDE
2016-2372	03/22/2016 04/19/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ronald F. Miszewski Ronald F. Miszewski	CORR BETWEEN FDA AND MERCK RE CLINICAL TRIAL NCT00557284
2016-2373	03/22/2016 04/19/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jaya Lakshmi Ayyagari Dr. Reddy's Laboratories Inc.	ANDA 205473 SBA
2016-2374	03/22/2016 04/19/2016	OC/ORR/ORM/ OC/ORR/ORM/	Tate Borcoman Tate Borcoman / Integrated Solutions	LIST OF CDRH INSPECTIONS 01/01/2016 - 03/18/2016
2016-2375	03/22/2016 04/19/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	LURASIDONE HCI ANDA
2016-2376	03/22/2016 04/19/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	RANDAL MATHIS MATHIS & DONHEISER	INDIVIDUAL RECS - VAERS RPT
2016-2377	03/22/2016 04/19/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DANIEL G JARCHO ALSTON & BIRD LLP	TEVA PHARMACEUTICAL INDUSTRIES LTD, GODOLLO, HUNGARY - 483 1/21-29/16
2016-2378	03/22/2016	FDA/OMPT/CDER/GRP/DIDP/	DON J MIZERK	MYLAN PHARMS INC -SEROQUEL XR (QUETIAPINE

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	04/19/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	HUSCH BLACKWELL LLP	FUMARATE EXTENDED RELEASE TABS) ANDA 202-228 TENTATIVE APRVL LTR 7/8/14
2016-2379	03/22/2016 04/19/2016	FDA/OC/OES/DFOI/	JOSEPH DRAKE DRAKE 00886-093, JOSEPH	SUBOXONE - INGREDIENTS, DOSE, PURPOSE
2016-2380	03/22/2016 04/19/2016	FDA/OC/OCC/	ALLAN BLUTSTEIN AR2	MERRICK GARLAND - CHIEF COUNSEL EMALS 3/16/16
2016-2381	03/22/2016 04/19/2016	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/	NORAH SHERAY POPSALOT LLC	POPSALOT LLC - CMLPNT 2/16
2016-2382	03/22/2016 04/19/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PHILLIP RAKHUNOV POLLACK SOLOMON DUFFY LLP	FERRING PHARMACEUTICALS INC - PREPOPIK AERS
2016-2383	03/22/2016 04/19/2016	FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LAUREN DILLON DILLON, LAUREN	TRUMP NETWORK, CUSTOM ESSENTIALS, PRIVA TEST, ETC - LTRS, MEMOS, PHONE RECS, ETC
2016-2384	03/22/2016 04/19/2016	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/NE-FO/NWE- DO/NWE-CB/	DENISE PENDERGAST HIGH LINER FOODS	ENTRY #300-5577301-3 - TEST RESULTS
2016-2385	03/22/2016 04/19/2016	FDA/OGROP/ORO/SW-FO/DAL- DO/DAL-CB/	CHELSEA B RENDELMAN ESQ WADE CLARK MULCAHY	AMERICOLD LOGISTICS LLC, DALLAS, TX - AMMONIA LEAK INVESTIGATION 7/9/15, RPTS, MEMOS, ETC
2016-2386	03/22/2016 04/19/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PETER S REICHERTZ SHEPPARD MULLIN RICHTER & HAMPTON, LLP	LUITPOLD PHARMACEUTICALS INC - VENOFER (IRON SUCROSE INJ) NDA 21-135 AERS 4/1/14 TO PRESENT
2016-2387	03/22/2016 04/19/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PETER S REICHERTZ SHEPPARD MULLIN RICHTER & HAMPTON, LLP	LUITPOLD PHARMACEUTICALS INC - INJECTAFER (FERRIC CARBOXYLMALTOSE INJ) NDA 203-565 AERS 4/1/15 TO PRESENT

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-2388	03/22/2016 04/19/2016	FDA/OMPT/CDRH/OCE/DID/	CARAGH FAY ESQ FAY LAW GROUP PA	KARL STORZ - MORCELLATOR DVC WARNING LTRS, 483S, CORR, ETC
2016-2389	03/22/2016 04/19/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Charles Snow Hyman, Phelps & McNamara P.C.	NATIONAL DRUG CODE DIRECTORY 2002-2003
2016-2390	03/22/2016 04/19/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Aline Tschanz European Center of Pharmaceutical Medicine/Institute of Pharmaceutical Medicine, University of Basel	New Molecular Entity (NME) Drug and New Biologic Approval Reports, dating from December 1980 to December 1999
2016-2391	03/22/2016 04/19/2016	FDA/OC/OES/DFOI/	Dr. John Clark RiskBenefits, LLC	MEDWATCH REPORTS
2016-2392	03/22/2016 04/19/2016	FDA/OGROP/ORR/PA-FO/LOS- DO/LOS-CB/	Gabriel di Chiara Gabriel di Chiara	INDIO PRODUCTS, INC - REGISTRATION RECS 09/01/2010 - 03/18/2016
2016-2393	03/22/2016 04/19/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bharat Celly Research Delta Advisors	ZYDUS CADILA - 483 01/01/2016 - 03/31/2016
2016-2394	03/22/2016 04/19/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ronald F. Miszewski Ronald F. Miszewski	MONTELUKAST SODIUM - RECS WITH MERCK 01/01/1999 - 03/17/2016
2016-2395	03/22/2016 04/19/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shyam Srinivasan Goldman Sachs (India) Securities Private Ltd.	AUROBINDO PHARMA, INDIA - 483 01/29/2016 - 02/03/2016
2016-2396	03/22/2016 04/19/2016	FDA/OGROP/ORR/NE-FO/NWE- DO/NWE-CB/	Pam Zich Pamela Zich	JUDGE ROTENBERG CENTER - RESPONSE TO WARNING LETTER 10/03/2012 - 10/17/2012
2016-2397	03/23/2016 04/20/2016	FDA/OGROP/ORR/NE-FO/NYK- DO/NYK-DCB/ FDA/OGROP/ORR/PA-FO/LOS-	Esther Castillejo Columbia Journalism School	RESPONSES TO WARNING LETTERS

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		DO/LOS-CB/ FDA/OMPT/CDRH/OCE/DID/		
2016-2398	03/23/2016 04/20/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	Lim Meng How Crystal Aesthetics	CRYSTAL TOMATO BACTOLAC PHARMACEUTICAL CERTIFICATES OF FREE SALE
2016-2399	03/23/2016 04/20/2016	FDA/OMPT/CDRH/OCE/DID/	Kate Smith Laborie Medical Technologies Canada ULC	MEDICAL MEASUREMENT BV - EIR 11/16/2015 - 12/31/2015
2016-2400	03/23/2016 04/20/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lupin Limited FDA form 483 issued in Feb 2016 HDFC Securities	LUPIN, GOA, INDIA - 483 02/01/2016 - 02/29/2016
2016-2401	03/23/2016 04/20/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tom Dreisbach National Public Radio (NPR)	NDA 201655
2016-2402	03/23/2016 04/20/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K141410
2016-2403	03/23/2016 04/20/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nicholas Willoughby Nicholas Willoughby	ABILIFY - AERS
2016-2404	03/23/2016 04/20/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michelle Elizabeth Legiec Eagle Pharmaceuticals, Inc.	NDA 207793
2016-2405	03/23/2016 04/20/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gaurav Tinani Emkay Global Financial Services Limited	CIPLA, GOA, INDIA - 483 04/08/2015 - 04/17/2015
2016-2406	03/23/2016	FDA/OFVM/CFSAN/OCD/EOS/	Jack Faught	GRAS for Ethyl Formate Toxicity studies.

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	04/20/2016		Linde Gas North America, LLC	
2016-2407	03/23/2016 04/20/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tushar Manudhane Indianivesh securities	NATCO PHARMA, CHENNAI, INDIA - 483 02/01/2016 - 03/22/2016
2016-2408	03/23/2016 04/20/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bryan Czyzewski Bryan Czyzewski	TGR-120 (RP5264) AERS
2016-2409	03/23/2016 04/20/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bryan Czyzewski Bryan Czyzewski	DUVELISIB - AERS
2016-2410	03/23/2016 04/20/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bryan Czyzewski BARCLAYS	ZYDELIG - AERS
2016-2411	03/23/2016 04/20/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dheeresh Pathak Dheeresh Pathak	NATCO PHARMA LIMITED, INDIA - 483 02/01/2016 - 03/11/2016
2016-2412	03/23/2016 04/20/2016	FDA/OMPT/CDRH/OCE/DID/ OC/ORO/ORM/ OC/ORO/ORM/	Meagan Randall Meagan Randall	LIST OF DEVICE INSPECTIONS 01/01/2016 - 03/22/2016
2016-2413	03/23/2016 04/20/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Vivek Agrawal HDFC Securities	LUPIN LIMITED, GOA, INDIA - 483 02/01/2016 - 03/22/2016
2016-2414	03/23/2016 04/20/2016	FDA/OC/OES/DFOI/	Ryan Berghoff CENTER FOR FOOD SAFETY	ATTACHED LETTER
2016-2415	03/23/2016 04/20/2016	FDA/OGROP/ORO/CE-FO/PHI-DO/PHI-CB/	THOMPSON, RAY	AEI TECHNOLOGIES INC, PITTSBURGH, PA 8/26-9/18/15; ALMAC PHARMA SERVICES LLC, AUDUBON, PA 6/18-25/15; JOHNSON & JOHNSON CONSUMER INC, LITITZ, PA 9/16-21/15- 483

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2016-2416	03/23/2016 04/20/2016	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	THOMPSON, RAY	CROWN HEALTH CARE LAUNDRY SERVICES INC, SELMA, AL 4/40-5/27/15; MEDTRONIC SOFAMAR DANEK USA INC, MEMPHIS, TN 10/20-23/15; UPM PHARMACEUTICALS, BRISTOL, TN 8/3-14/15 - 483
2016-2417	03/23/2016 04/20/2016	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	THOMPSON, RAY	ALLOSOURCE INC, CENTENNIAL, CO 5/11-6/11/15; CARDINAL HEALTH 200 INC, DENVER, CO 5/20-22/15; WALKMED INFUSION LLC, ENGLEWOOD, CO 5/18-6/11/15 - 483
2016-2418	03/23/2016 04/20/2016	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	THOMPSON, RAY	3M COMPANY, SAINT PAUL, MN 8/25-9/1/15; MEDIVATORS INC, PLYMOUTH, MN 4/9-5/12/15; PACE ANALYTICAL LIFE SCIENCES LLC, OAKDALE, MN 4/23-5/4/15 - 483
2016-2419	03/23/2016 04/20/2016	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	THOMPSON, RAY	BF ASCHER & CO INC, LENEXA, KS 7/6-15/15; BAYER HELATH CARE LLC, SHAWNEE, KS 7/21-30/15; CRAMER PRODUCTS INC, GARDNER, KS 10/14-26/15 - 483
2016-2420	03/23/2016 04/20/2016	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	THOMPSON, RAY	CARDINAL HEALTH 414 LLC, FORT LAUDERDALE, FL 6/9-17/15; INNOVATIVE THERAPIES INC, POMPANO BEACH, FL 8/24-27/15; VISTA PHARM INC, LARGO, FL 5/11-28/15 - 483
2016-2421	03/23/2016 04/20/2016	FDA/OC/OES/DFOI/	GILBERT M26730, JOHN	PSYCHOPHARMACEUTICAL DRUGS - AER
2016-2422	03/23/2016 04/20/2016	OC/ORASW-FO/SEA-DO/SEA-CB/	ROCHELLE MONTES TERMINAL TRANSFER INC	ENTRY NO AD7-1404023-6 NOTICE OF ACTION #3
2016-2423	03/23/2016 04/20/2016	FDA/OC/OES/DDM/	SHARON H. GREEN COLUMBIA UNIV MAILMAN SCHOOL OF PUBLIC HEALTH HISTORY & ETHICS OF PUB HEALTH	DKT 2014-N-0189
2016-2424	03/23/2016 04/20/2016	FDA/OGROP/ORAPAF-FO/LOS-DO/LOS-CB/	LAW OFFICE OF SHAFIEL A KARIM	COSMO PHARM INC, HOLLYWOOD, CA; ROBINSON PHARMA INC, COSTA MESA, CA; ULTIMATE FORMULATIONS INC, INDUSTRY, CA - 483, WARNING LTRS 2014-2015
2016-2425	03/23/2016 04/20/2016	FDA/OMPT/CDER/ORP/DIDP/	DON J. MIZERK HUSCH BLACKWELL LLP	MYLAN PHARMS INC - SEROQUEL XR NDA 02-228
2016-2426	03/23/2016 04/20/2016	FDA/OMPT/CDER/ORP/DIDP/	Jonathan Jones CENTER FOR INVESTIGATIVE REPORTING	GONAL-F, PERGONAL, GONAL F RFF PEN ETC AERS

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-2427	03/23/2016 04/20/2016	OC/ORP/ OC/ORP/ FDA/OGROP/ORP/CE-FO/MIN-DO/MIN-CB/ FDA/OMPT/CDRH/OCE/DID/	Doe J	COMPLAINT RECS
2016-2428	03/23/2016 04/20/2016	OC/ORP/ OC/ORP/	Doe J	COMPLAINT RECS
2016-2429	03/23/2016 04/20/2016	FDA/OFVM/CFSAN/OCD/EOS/	DAVID W. PLUNKETT CENTER FOR SCIENCE IN PUBLIC INTEREST	ILLNESSES & DEATHS FROM SHELLFISH FROM VIBRIO VULNIFICUS 2014
2016-2430	03/23/2016 04/20/2016	FDA/OMPT/CDRH/OCE/DID/	ALYSSA WILLIAMS CASEY GERRY SCHENK ET AL	INDIVIDUAL RECS
2016-2431	03/23/2016 04/20/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCE/DID/	ELLEN A. PRESBY NEMEROFF LAW FIRM	JOHNSON & JOHNSON, DELTAGLIDE, NEXT MOBILITY - POWER ASSIST WHEELCHAIRS RPTS
2016-2432	03/23/2016 04/20/2016	FDA/OGROP/ORP/PA-FO/SAN-DO/SAN-CB/ OC/CVM/OCD/	STACEY BENJAMIN PRIZKER OLSEN ATTORNEYS	SALMONELLA HEIDELBERG INFECTIONS FOSTER POULTRY FARMS CHICKEN 2004-2014
2016-2433	03/23/2016 04/20/2016	FDA/OGROP/ORP/CE-FO/PHI-DO/PHI-CB/	PAUL B. CALLAHAN CHARLES RIVER	RESEARCH PATHOLOGY SERVICES INC, NEW BRITIAN, PA - EIR
2016-2434	03/23/2016 04/20/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/ORP/ OC/ORP/	DALE A. BAICH FEDERAL PUBLIC DEFENDER FOR THE DISTRICT OF ARIZONA	SODIUM THIOPIENTAL - CORR, IMPORTATION RECS, RPTS, ETC 1/1/14 TO PRESENT
2016-2435	03/23/2016 04/20/2016	FDA/OC/OES/DFOI/	Mohit Bhat Kline & Company	EIRS, EXHIBITS FOR AF ABLATION CATHETERS, ETC 01/01/2006 - 03/18/2016
2016-2436	03/23/2016 04/20/2016	FDA/OGROP/ORP/CE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORP/PA-FO/SAN-DO/SAN-CB/	RAQUEL RUTLEDGE MILWAUKEE JOURNAL	BECTON DICKINSON MEDICAL SYS; BECTON DICKINSON SA, BECTON DICKINSON & CO - EIR

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		FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OMPT/CDRH/OCE/DID/		
2016-2437	03/24/2016 04/21/2016	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Ryan D. Woods PRA Health Sciences	PRA HEALTH SCIENCES - EARLY DEVELOPMENT, NETHERLANDS - INSPECTION RECS 11/03/2014 - 09/11/2015
2016-2438	03/24/2016 04/21/2016	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	David Amor Medgineering Inc.	EPIPEN, AUVI-Q - SUBMISSION RECS
2016-2439	03/24/2016 04/21/2016	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Michael F Rettig Avantor Performance Materials, Inc.	AVANTOR PERFORMANCE MATERIALS, INC, PHILLIPSBURG, NJ, PARIS, KY - EIR 01/01/2013 - 03/21/2016
2016-2440	03/24/2016 04/21/2016	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Karen St. Onge NXSTAGE MEDICAL INC	ROQUETTE AMERICA, INCC, KEOKUK, IA ; MORTON SALT, INC, RITTMAN, OH; MORTON SALT, INC, GRAND SALINE, TX - EIR MOST RECENT
2016-2441	03/24/2016 04/21/2016	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	John Walsh James Alexander Corporation	BOC SCIENCES, SHIRLEY, NY - EIR, 483, RECALL RECS 03/01/2013 - 03/22/2016
2016-2442	03/24/2016 04/21/2016	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Ronald Hsu RBC CAPITAL MARKETS	CMC BIOLOGICS, XOMA CORPORATION, ICOS CORPORATION - 483 03/01/2005 - 03/01/2016
2016-2443	03/24/2016 04/21/2016	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	Eric Young Kessler Topaz Meltzer Check LLP	ST JUDE MEDICAL, INC, SYLMAR, CA, ARECIBO, PR - MEMO, FACTS ASSIGNMENT
2016-2444	03/24/2016 04/21/2016	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Duff Wilson Reuters News	GSK BIOSCIENCES - WHISTLEBLOWER EMAILS

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/ORA/OCI/ OC/ORA/OCI/		
2016-2445	03/24/2016 04/21/2016	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	Alex Tomasevic Tomasevic, Alex	METAGENICS, INC - WARNING LETTER RECS 07/01/2015 - 04/30/2016
2016-2446	03/24/2016 04/21/2016	FDA/OMPT/CDRH/OCE/DID/	Kathryn Shasha Kathryn Shasha	IUDS DATA, ADVERSE EVENTS 01/01/2009 - 01/22/2016
2016-2447	03/24/2016 04/28/2016	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	Abby Almonte OASIS MEDICAL INC	DOW CHEMICAL COMPANY METHOCEL CELLULOSE ETHERS PRODUCTION FACILITY, MIDLAND, MI; PLAQUEMINE, LA - EIR 01/01/2014 - 03/22/2016
2016-2448	03/24/2016 04/21/2016	FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/	Jaime Vassallo CourtLink Document Retrieval	2016-1707 CFSAN RESPONSE CERTIFIED
2016-2449	03/24/2016 04/21/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Brian D'Estrada Brian D'Estrada	PROPECIA NDA STUDY 094
2016-2450	03/24/2016 04/21/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rahul Singh Solanki Edelweiss	NATCO PHARMA, INDIA - 483 01/01/2016 - 03/21/2016
2016-2451	03/24/2016 04/21/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ayesha Adil The Weinberg Group	NDA 203952 SBA
2016-2452	03/24/2016 04/21/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FP/BL: S. Duckworth Olson & Cepuritis, Ltd.	PREPOPIK - APPROVAL PACKAGE CERTIFIED
2016-2453	03/24/2016 04/21/2016	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	John Walsh James Alexander Corporation	MONUMENT CHEMICAL HOUSTON LTD, HOUSTON, TX - EIR, 483, RECALL RECS 03/01/2013 - 03/22/2016
2016-2454	03/24/2016 04/21/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	John Walsh James Alexander Corporation	NOVO NORDISK, DENMARK - EIR, 483, RECALL RECS 03/01/2013 - 03/22/2016

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2016-2455	03/24/2016 05/20/2016	OC/ORP/ OC/ORP/ FDA/OFVM/CFSAN/OCD/EOS/	John Bogatko TOON OSMOND, P.L.L.C.	MULTI STATE SALMONELLA OUTBREAK TIED TO CUCUMBERS 08/15/2015 - 04/01/2016
2016-2456	03/24/2016 04/21/2016	FDA/OFVM/CFSAN/OCD/EOS/	Laura MacCleery Center for Science in the Public Interest	PURE CAFFEINE - AERS
2016-2457	03/24/2016 04/21/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Duff Wilson Reuters News	GVK CLINICAL RESEARCH ORGANIZATION INDIA - 483 MARCH 2015
2016-2458	03/24/2016 05/12/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Paul Knoepfler UC DAVIS	IND DR RICHARD BURT NORTHWESTERN UNIVERSITY - INSPECTIONAL CORR, REQUESTS FOR CHARGING PATIENTS 01/01/2010 - 03/23/2016
2016-2459	03/24/2016 04/21/2016	FDA/OFVM/CFSAN/OCD/EOS/	Michael J. O'Flaherty OLSSON FRANK WEEDA TERMAN MATZ PC	NEW INFANT FORMULA NOTIFICATION AND VERIFICATION SUBMISSION FOR ENFAMIL ENSPIRE INFANT FORMULA 01/01/2014 - 03/23/2016; New infant formula notification and verification
2016-2460	03/24/2016 04/21/2016	FDA/OMPT/CDRH/OCE/DID/	AVA M PAQUETTE CITIZENS COMMISSION ON HUMAN RIGHTS INTERNATIONAL	ECT DVC - RECLASSIFICATION FROM CLASS III TO CLASS II MEMOS, RPTS, ADVISORIES, ETC
2016-2461	03/24/2016 04/21/2016	FDA/OMPT/CDRH/OCE/DID/	BARRY E NEWMAN SPOHRER & DODD	STRYKER ORTHOPEDICS - TORX 6.5MM CANCELLOUS BONE SCREW, TRIDENT X3 POLYETHYLENE INSERT, TRIDENT HEMISPHERICAL ACETABULAR SHELL, ETC MDRS, RECALL NOTICES, SAFETY ALERTS, ETC
2016-2462	03/24/2016 04/21/2016	FDA/OFVM/CFSAN/OCD/EOS/	Anthony Connors Anthony Connors	THERMOLIFE INTERNATIONAL, LLC - INTERNAL COMMUNICATIONS RE CREATINE NITRATE, COMPLAINTS, ADVERSE EVENTS 01/01/2007 - 03/22/2016
2016-2463	03/24/2016 04/21/2016	FDA/OGROP/ORP/SE-FO/NOL-DO/NOL-CB/	John Walsh James Alexander Corporation	EXXON MOBIL CHEMICAL COMPANY, BATON ROUGE, LA - EIR, 483, RECALL RECS 10/01/2013 - 03/23/2016

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2016-2464	03/24/2016 04/21/2016	OC/CVM/OCD/	RYAN BERGHOFF Center For Food Safety	OXITEC LTD - GENETICALLY ENGINEERED AEDES AEGYPTI MOSQUITOES IN FL - COMM, CONSULTATION, RECS, ETC 9/10/15 TO PRESENT
2016-2465	03/24/2016 04/21/2016	FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/	John Walsh James Alexander Corporation	SHELL CHEMICAL LP, HOUSTON, TX - EIR, 483, RECALL RECS 02/01/2012 - 03/23/2016
2016-2466	03/24/2016 04/21/2016	FDA/OFVM/CFSAN/OCD/EOS/	DIANNE L CHAMBERS Hogan Lovells, LLP	FCN 1582, FCN 1492, FCN 1471
2016-2467	03/24/2016 04/21/2016	FDA/OGROP/ORR/CE-FO/NWJ-DO/NWJ-CB/	John Walsh James Alexander Corporation	FISHER SCIENTIFIC, FAIR LAWN, NJ - EIR, 483, RECALL RECS 03/01/2013 - 03/23/2016
2016-2468	03/24/2016 04/21/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Belmora LLC BELMORA LLC	ANDA 040218, ANDA 078250
2016-2469	03/24/2016 04/21/2016	FDA/OMPT/CDRH/OCE/DID/	Christopher Thomas Donner SI-TECHNOLOGY, LLC	K130185
2016-2470	03/24/2016 04/21/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K052289
2016-2471	03/24/2016 04/21/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K072123
2016-2472	03/24/2016 04/21/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K152437
2016-2473	03/24/2016 04/21/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARK J NASCA JR Ghost Tree Capital, LLC	HORIZON PHARMS - PATIENT ASSISTANCE PROGRAMS CORR
2016-2474	03/24/2016 04/21/2016	FDA/OMPT/CDRH/OCE/DID/	Marcella Garcia Marcella Garcia	K122413
2016-2475	03/24/2016 04/21/2016	FDA/OMPT/CDRH/OCE/DID/	Christopher Thomas Donner SI-TECHNOLOGY, LLC	K121741
2016-2476	03/24/2016 04/21/2016	FDA/OMPT/CDRH/OCE/DID/	Christopher Thomas Donner SI-TECHNOLOGY, LLC	K112316
2016-2477	03/24/2016 04/21/2016	FDA/OMPT/CDRH/OCE/DID/	Christopher Thomas Donner SI-TECHNOLOGY, LLC	K083894
2016-2478	03/24/2016	OC/ORR/ORM/	JULIE PATEL	LIST OF FIRMS IN ILLINOIS WITH FDA VIOLATIONS 1/1/13 TO

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	04/21/2016	OC/ORO/ORM/	BETTER GOVERNMENT ASSOCIATION	12/31/15
2016-2479	03/24/2016 04/21/2016	FDA/OMPT/CDRH/OCE/DID/	Zena Butris Thought Technology Ltd.	K972723
2016-2480	03/24/2016 04/21/2016	FDA/OFVM/CFSAN/OCD/EOS/	Phil Abreo True Fresh HPP	LIST OF CERTIFIED FOOD FACILITIES IN CA 01/01/2015 - 03/23/2016
2016-2481	03/24/2016 04/21/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rahul Singh Solanki Edelweiss	LUPIN, GOA, INDIA - 483 03/01/2016 - 03/22/2016
2016-2482	03/24/2016 04/21/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jennifer Miller Eli Lilly and Company - Global Patient Safety	NDA 207103 S2
2016-2483	03/25/2016 04/22/2016	FDA/OC/OES/DFOI/	Michal Leah Kanovsky Michal Leah Kanovsky	VINCE TOLINO, WALTER HARRIS, ETC - EMAILS RE GDUFA ETC; SF-50S 07/01/2012 - 03/22/2016
2016-2484	03/25/2016 04/22/2016	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	John Walsh James Alexander Corporation	QUAKER CITY OF PHILADELPHIA, PA - EIR, 483, RECALL RECS 06/01/2012 - 03/23/2016
2016-2485	03/25/2016 04/22/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Reena Harjai APCER Life Sciences, Inc.	TREANA - AERS DETAILED REPORT
2016-2486	03/25/2016 04/22/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jennifer Miller Eli Lilly and Company, Inc.	FASLODEX NDA 021344 S26
2016-2487	03/25/2016 04/22/2016	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	Rachel Johnson FOI Services, Inc.	ABBVIE, NORTH CHICAGO, IL - EIR
2016-2488	03/25/2016 04/22/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Anna Edney BLOOMBERG NEWS	DUXORUBICIN, DAUNORUBICIN - AERS
2016-2489	03/25/2016	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Abby Almonte	BECTON DICKINSON AND COMPANY, CANAAN, CT - EIR, COVER LETTER 01/01/2015 - 03/23/2016

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	04/22/2016		OASIS MEDICAL INC	
2016-2490	03/25/2016 04/22/2016	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	John Walsh James Alexander Corporation	EMD MILLIPORE CORPORATION, GIBBSTOWN, NJ - EIR, 483, RECALL RECS 09/01/2013 - 03/23/2016
2016-2491	03/25/2016 04/22/2016	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	John Walsh James Alexander Corporation	PENTA MANUFACTURING COMPANY, LIVINGSTON, NJ - EIR, 483, RECALL RECS 09/01/2013 - 03/23/2016
2016-2492	03/25/2016 04/22/2016	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	Rachel Johnson FOI Services, Inc.	ABBVIE MEDICAL DEVICE CENTER, WAUKEGAN, IL - EIR
2016-2493	03/25/2016 04/22/2016	FDA/OGROP/ORACE-FO/CINDO/CIN-CB/	John Walsh James Alexander Corporation	AMRESKO LLC, SOLON, OH - EIR, 483, RECALL RECS 03/01/2013 - 03/23/2016
2016-2494	03/25/2016 04/22/2016	FDA/OGROP/ORASE-FO/ATLDO/ATL-CB/	Ryan Trail WILLIAMS MULLEN CHRISTIAN & DOBBI	VIBRIO SPP BACTERIA IN SHELLFISH GROWN IN SOUTH CAROLINA WATERS
2016-2495	03/25/2016 04/22/2016	FDA/OMPT/CTP/OD/	Will Woodlee Kleinfeld, Kaplan & Becker, LLP	CTP POLICIES RE SECTION 905(J) SE REPORT APPLICATIONS WHO DO NOT RESPOND TO PRELIMINARY FINDING OF ADVICE/INFORMATION REQUEST LETTERS 06/22/2009 - 03/23/2016
2016-2496	03/25/2016 04/22/2016	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	John Walsh James Alexander Corporation	BIO-CLINICAL LABS, PHILIPSBURG, NJ - EIR, 483, RECALL RECS 03/01/2012 - 03/23/2016
2016-2497	03/25/2016 04/22/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Zachary Mietus The Weinberg Group	ANDA 091161
2016-2498	03/25/2016 04/22/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Zachary Mietus The Weinberg Group	ANDA 091161 BIOEQUIVALENCE SECTION
2016-2499	03/25/2016 04/22/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Reena Harjai APCER Life Sciences, Inc.	BUSULFEX NDA 020954 AERS
2016-2500	03/25/2016 04/22/2016	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Rachel Johnson FOI Services, Inc.	ABBVIE, WORCESTER, MA - EIR
2016-2501	03/25/2016 04/22/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ryan D. Woods PRA Health Sciences	PRA HEALTH SCIENCES, NETHERLANDS - INSPECTION RECS 08/01/2002 - 07/30/2010

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2016-2502	03/25/2016 04/22/2016	FDA/OGROP/ORR/SW-FO/DEN-DO/DEN-CB/	Ryan D. Woods PRA Health Sciences	PRA HEALTH SCIENCES, SALT LAKE CITY, UT - INSPECTION RECS 06/22/2015 - 07/21/2015
2016-2503	03/25/2016 04/22/2016	FDA/OFVM/CFSAN/OCD/EOS/	Michael J. O'Flaherty OLSSON FRANK WEEDA TERMAN MATZ PC	GRAS NOTIFICATION FOR USE OF LACTOFERRIN IN INFANT FORMULA
2016-2504	03/25/2016 04/22/2016	FDA/OMPT/CDRH/OCE/DID/	Essure PSRs, PSURs, ASRs and VA MDRs submitted to MedSun Device Events	ESSURE - ADVERSE EVENTS 01/01/2002 - 03/23/2016
2016-2505	03/25/2016 04/22/2016	FDA/OGROP/ORR/NE-FO/NWE-DO/NWE-CB/	John Walsh James Alexander Corporation	PHARMCO-AAPER, BROOKFIELD, CT - EIR, 483, RECALL RECS 11/01/2014 - 03/23/2016
2016-2506	03/25/2016 04/22/2016	OC/CVM/OCD/	Pankajkumar U Patel Piramal Enterprises Limited	ESTRUMATE ANADA 263
2016-2507	03/25/2016 04/22/2016	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDRH/OCE/DID/	Kris Christian FDAZILLA	QS CONTROL CORP, TAIWANT - 483 01/25/2016 - 01/28/2016
2016-2508	03/25/2016 05/26/2016	FDA/OC/OES/DFOI/	Michal Leah Kanovsky Michal Leah Kanovsky	VINCE TOLINO, TANIA TSE, ETC - SF50, POSITION DESCRIPTIONS, ETC
2016-2509	03/25/2016 04/22/2016	FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECS
2016-2510	03/25/2016 04/22/2016	FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECS
2016-2511	03/25/2016 04/22/2016	OC/ORR/ OC/ORR/	LORREN E.S. WALKER SCHRAMM WILLIAMS & ASSOCIATES INC	PRODUCT INFORMATION FOR RECALLED PISTACHIOS SOLD AT TEXAS STAR NUT; LIPAR FOODS; KANAN ENTERPRISES
2016-2512	03/25/2016 04/22/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Olena Izhak (University of Helsinki) Boston University, Department of Economics	ANDA APPROVAL LETTERS
2016-2513	03/25/2016 04/22/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jonathan Jones CENTER FOR INVESTIGATIVE REPORTING	BRAVELLE - AERS

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2016-2514	03/25/2016 04/22/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID HOFFMEISTER WILSON SONSINI ET AL	AMNEAL - DICLOFENAC ANDA 08-077 APRVL
2016-2515	03/25/2016 04/22/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GRESHAM pc Gresham, Dean	QUESTCOR PHARMACEUTICALS, INC - CORR, ATTACHMENTS WITH FDA RE ACTHAR GEL 03/01/2014 - 03/23/2016
2016-2516	03/25/2016 04/22/2016	FDA/OMPT/CDRH/OCE/DID/	James Boiani Epstein Becker Green	PCG MOLECULAR - WARNING LETTERS, UNTITLED LETTERS, ETC 10/01/2014 - 03/24/2016
2016-2517	03/25/2016 04/22/2016	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CDRH/OCE/DID/	KERRY SCHONWALD LOEWINSOHN FLEGLE ET AL	EMINENT SPINE LLC - INTERVERTEBRAL BODY FUSION DVCS AER
2016-2518	03/25/2016 04/22/2016	OC/ORA/OCI/ OC/ORA/OCI/	Sarah N. Lynch, Reuters Sarah Lynch, Reuters	OCI DETAIL TRAVEL VOUCHERS, COSTS ETC 01/01/2015 - 03/24/2016
2016-2519	03/28/2016 04/25/2016	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	Matthew A. Sanctis Springfield News-Sun	DOLE, SP RINGFIELD, OH - INSPECTION RECS, CORR RE LISTERIA OUTBREAK 01/01/2015 - 03/01/2016
2016-2520	03/28/2016 04/25/2016	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	John Walsh James Alexander Corporation	CORCO CHEMICAL CORPORATION, FAIRLESS HILLS, PA - EIR, RECALL RECS, 483 10/01/2013 - 03/24/2016
2016-2521	03/28/2016 04/25/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shlomit Strulov Shachar Lineberger cancer center	TRASTUZUMAB, PERTUZUMAB ETC - PATIENT DATA
2016-2522	03/28/2016 04/25/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jaymeth Maddox Scilucent, LLC	IDT BIOLOGIKA, GERMANY - 483, EIR 01/01/2010 - 03/24/2016
2016-2523	03/28/2016 04/25/2016	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Richard LeVasseur Kiel Laboratories, Inc.	KIEL LABORATORIES, FLOWERY BRANCH, GA - EIR 07/29/2015 - 01/20/2016
2016-2524	03/28/2016 04/25/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bharat Celly Research Delta Advisors	CADILA HEALTHCARE LIMITED, INDIA - 483 12/01/2015 - 03/25/2016

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2016-2525	03/28/2016 04/25/2016	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Coral Beach FOOD SAFETY NEWS	DOLA, SPRINGFIELD, OH - 483 01/01/2011 - 03/25/2016
2016-2526	03/28/2016 04/25/2016	FDA/OMPT/CDRH/OCE/DID/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Garth Conrad BARD PERIPHERAL VASCULAR INC	RECALL Z-1068-2016 - HEALTH HAZARD EVALUATION RECS
2016-2527	03/28/2016 04/25/2016	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Alcon Laboratories, Inc. Bentley, Jane	ALCON LABS, HUNTINGTON, WV - EIR 09/24/2015 - 09/25/2015
2016-2528	03/28/2016 04/25/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Richard Elias Elias Gutzler Spicer	TASIGNA - APPROVAL, LABELING ETC 01/01/2005 - 03/25/2016
2016-2529	03/28/2016 04/25/2016	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORA/ OC/ORA/	Tyler Smith CONSUMER REPORTS	DATA OF DOMESTIC, IMPORTED SEAFOOD FOR DRUG AND CHEMICAL RESIDUES 1999 TO PRESENT
2016-2530	03/28/2016 04/25/2016	FDA/OC/OES/DDM/	Kyle Dolinsky PEPPER HAMILTON LLP	PETITIONS FILED PURSUANT TO 21 CFR 60.30 , REVIEW RECS 03/07/1988 - 03/25/2016
2016-2531	03/28/2016 04/25/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jennifer Miller Eli Lilly and Company - Global Patient Safety	IBRANCE, FASLODEX EFFICACY SUPPLEMENTS - SBA
2016-2532	03/28/2016 04/25/2016	FDA/OMPT/CDRH/OCE/DID/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Garth Conrad BARD PERIPHERAL VASCULAR INC	RECALL Z-0737-2016 - HEALTH HAZARD EVALUATION RECS 12/28/2015 - 02/01/2016
2016-2533	03/28/2016 04/25/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/CVM/OCD/	Kristi O Smedley Center for Regulatory Services Inc.	NADA 12-350
2016-2534	03/28/2016 04/25/2016	FDA/OMPT/CDRH/OCE/DID/	Shibir Desai TERARECON INC	K143196 K091529
2016-2535	03/28/2016 04/25/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	K120087

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		FDA/OMPT/CDRH/OCE/DID/		
2016-2536	03/28/2016 04/25/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Snehal Shrivastava, MD, MS Mercy St. Vincent Medical Center, Toledo OH	AMOXICILLIN - CASE REPORTS PROLONGED QT INTERVAL ON EKG ETC 01/25/1979 - 03/25/2016
2016-2537	03/28/2016 04/25/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Snehal Shrivastava, MD, MS Mercy St. Vincent Medical Center, Toledo OH	AMOXICILLIN - TESTING FOR SIDSE EFFECT OF PROLONGATION OF QT INTERVAL ON EKG PRIOR TO APPROVAL 01/01/1979 - 03/25/2016
2016-2538	03/28/2016 04/25/2016	FDA/OMPT/CDRH/OCE/DID/	Robert Bailen WASHINGTON UNIVERSITY IN ST. LOUIS	K971809, K052457, K980814, ETC
2016-2539	03/28/2016 04/25/2016	FDA/OMPT/CDRH/OCE/DID/	Noah Wollowick Noah Wollowick	K142718
2016-2540	03/28/2016 04/25/2016	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/	VANASA WEERASINGHE PITA PAL FOODS	PITA PAL FOODS - EIR 6/3/3, 4/30/14
2016-2541	03/28/2016 07/25/2016	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/	HILL, JULIANNE	PENTOBARBITAL SODIUM - IMPORTS 6/25/15 TO PRESENT
2016-2542	03/28/2016 04/25/2016	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/ FDA/OFVM/CFSAN/OCD/EOS/	LORREN E.S. WALKER SCHRAMM WILLIAMS & ASSOCIATES INC	TEXAS STAR NUT FOOD CO, LIPARI FOODS, KANAN ENTERPRISES; AMERICAN GOURMET - SALMONELLA OUTBREAK
2016-2543	03/29/2016 04/26/2016	FDA/OMPT/CDRH/OCE/DID/	Judy Kline Judy Kline	K142969
2016-2544	03/29/2016 04/26/2016	FDA/OMPT/CDRH/OCE/DID/	Vicki Gail Urologix, LLC	K150786 K106417
2016-2545	03/29/2016 04/26/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jeff Ishizuka MASSACHUSETTS GENERAL HOSPITAL	CASE REPORTS 11010175, 10749318, 11078179

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2016-2546	03/29/2016 04/26/2016	OC/CVM/OCD/	Elizabeth Carney York Veterinary Housecalls	AFOXOLANER, FLURALANER - AERS
2016-2547	03/29/2016 04/26/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dr Girish Bakhru HSBC Securities and Capital Markets	NATCO PHARMA - 483 MARCH 2016
2016-2548	03/29/2016 04/26/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Matthew Jackson Matthew Jackson	ENUMERAL BIOMEDICAL HOLDINGS INC, MERCK SHARP & DOHME - RESEARCH AND DEVELOPMENT AGREEMENT RE DRUGS 12/01/2014 - 02/01/2016
2016-2549	03/29/2016 04/26/2016	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	Ayan Deb Nomura Financial Advisory Securities India Ltd	HOSPIRA, BOULDER, CO - EIR 06/01/2011 - 03/28/2016
2016-2550	03/29/2016 04/26/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bharat Celly Research Delta Advisors	NATCO, CHENNAI, INDIA - 483 01/01/2016 - 03/27/2016
2016-2551	03/29/2016 04/26/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ernesto Alamo Patterson Belknap Web & Tyler	NDA 020589, NDA 020944
2016-2552	03/29/2016 04/26/2016	FDA/OMPT/CDRH/OCE/DID/	Laurie Sang Sang, Eu Yan	K152989
2016-2553	03/29/2016 04/26/2016	OC/ORASORM/ OC/ORASORM/	Kris Christian FDAZILLA	LIST OF INSPECTIONS 02/24/2016 - 03/28/2016
2016-2554	03/29/2016 04/26/2016	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Ashvin Panchal KVK-Tech, Inc.	TEVA PHARMACEUTICALS, HORSHAM, PA; MUTUAL PHARMACEUTICALS, PHILADELPHIA, PA - 483 12/01/2012 - 01/31/2016
2016-2555	03/29/2016 04/26/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ernesto Alamo Patterson Belknap Webb & Tyler LLP	NDA 19784
2016-2556	03/29/2016 04/26/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kiran Kumar Gande LEADING PHARMA LLC	ANDA 084658

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2016-2557	03/29/2016 04/26/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bharat Celly Research Delta Advisors	ALEMBIC, INDIA - 483 02/15/2016 - 03/27/2016
2016-2558	03/29/2016 04/26/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anthony P Minerva WILLIAMS & CONNOLLY LLP	ACCUTANE EXPOSED PREGNANCIES 01/01/2002 - 12/31/2015
2016-2559	03/29/2016 04/26/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Chris Letter Odom & Des Roches, LLP	ANDA 076388
2016-2560	03/29/2016 04/26/2016	FDA/OMPT/CTP/OD/	Desmond Jenson Tobacco Control Legal Consortium	Tobacco Violation Report ID 15D00013
2016-2561	03/29/2016 04/26/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bharat Celly Research Delta Advisors	NATCO, INDIA - 483 01/01/2016 - 03/27/2016
2016-2562	03/29/2016 04/26/2016	OC/CVM/OCD/	Jennifer Kelley Virbac AH, Inc.	CLAVAMOX DROPS NADA 55-101
2016-2563	03/29/2016 04/26/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mo Dimbil ADVERSEEVENTS INC	ACTIQ, ABSTRAL, DURAGESIC ETC- AERS
2016-2564	03/29/2016 04/26/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ann Truscott Barton Health	CALDOLOR - AERS
2016-2565	03/29/2016 04/26/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Shauna Compton Shauna Compton	HARVONI - AERS, MEDWATCH

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		FDA/OMPT/CDER/ORP/DIDP/		
2016-2566	03/29/2016 04/26/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Margaret Dillon bioinspire technologies	NDA 019389
2016-2567	03/29/2016 04/26/2016	OC/ORO/ OC/ORO/	MICHELLE LINN FOX23 NEWS	MOLD OR MOLDY SUBSTANCES FOUND IN JUICE BOXES OR JUICE PUCHES - CMLPNTS 1/1/13 TO 3/15/16
2016-2568	03/29/2016 04/26/2016	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 2/22-26/16
2016-2569	03/29/2016 04/26/2016	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD Center for Regulator Services, Inc	FOI DAILY LOG 2/22-26/16
2016-2570	03/29/2016 04/26/2016	FDA/OC/OES/DFOI/	LESLIE RAMSEY FDA NEWS	FOI DAILY LOG 2/22-16/16
2016-2571	03/29/2016 04/26/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 2/22-26/16
2016-2572	03/29/2016 04/26/2016	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 2/22-26/16
2016-2573	03/29/2016 04/26/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 2/22-26/16
2016-2574	03/29/2016 04/26/2016	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 2/22-16/16
2016-2575	03/29/2016 04/26/2016	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 2/29/16-3/4/16
2016-2576	03/29/2016 04/26/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 2/29/16-3/4/16
2016-2577	03/29/2016 04/26/2016	FDA/OC/OES/DFOI/	LESLIE RAMSEY FDA NEWS	FOI DAILY LOG 2/29/16-3/4/16
2016-2578	03/29/2016 04/26/2016	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD Center for Regulator Services, Inc	FOI DAILY LOG 2/29/16-3/4/16
2016-2579	03/29/2016 04/26/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 2/29/16-3/4/16

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2016-2580	03/29/2016 04/26/2016	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 2/29/16-3/4/16
2016-2581	03/29/2016 04/26/2016	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 2/29/16-3/4/16
2016-2582	03/29/2016 04/26/2016	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 3/7-11/16
2016-2583	03/30/2016 04/27/2016	FDA/OMPT/CDRH/OCE/DID/	SEMRAU 07-B-2961, RICHARD	IMMUNALYSIS CORP - MARIJUANA TESTING KIT
2016-2584	03/30/2016 04/27/2016	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 3/7-11/16
2016-2585	03/30/2016 04/27/2016	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 3/7-11/16
2016-2586	03/30/2016 04/27/2016	FDA/OC/OES/DFOI/	WILLIAM A. OLSON, Ph.D. Center for Regulator Services, Inc	DAILY LOG 3/7-11/16
2016-2587	03/30/2016 04/27/2016	FDA/OC/OES/DFOI/	LESLIE RAMSEY FDA NEWS	DAILY LOG 3/7-11/16
2016-2588	03/30/2016 04/27/2016	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	CLOSED DAILY LOG 2/22-26/16
2016-2589	03/30/2016 04/27/2016	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY CLOSED LOG 2/29-3/4/16
2016-2590	03/30/2016 04/27/2016	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY CLOSED LOG 3/7-11/16
2016-2591	03/30/2016 04/27/2016	FDA/OC/OES/DFOI/	DAVID McFARLAND FDA REVIEW/FDA WEBVIEW	DAILY CLOSED LOG 2/22-26/16
2016-2592	03/30/2016 04/27/2016	FDA/OC/OES/DFOI/	DAVID McFARLAND FDA REVIEW/FDA WEBVIEW	DAILY CLOSED LOG 2/29-3/4/16
2016-2593	03/30/2016 04/27/2016	FDA/OC/OES/DFOI/	DAVID McFARLAND FDA REVIEW/FDA WEBVIEW	DAILY CLOSED LOG 3/7-11/16
2016-2594	03/31/2016 04/28/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY CLOSED LOG 2/22-26/16
2016-2595	03/31/2016	FDA/OC/OES/DFOI/	DEBI COHEN	DAILY CLOSED LOG 2/29-3/4/16

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	04/28/2016		WOLTERS KLUWER LAW & BUSINESS	
2016-2596	03/31/2016 04/28/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 3/7-11/16
2016-2597	03/31/2016 04/28/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY CLOSED LOG 3/7-11/16
2016-2598	03/31/2016 04/28/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 2/22-26/16
2016-2599	03/31/2016 04/28/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 2/29/16-3/4/16
2016-2600	03/31/2016 04/28/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 3/7-11/16
2016-2601	03/31/2016 04/28/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 3/7-11/16
2016-2602	04/01/2016 04/29/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	INVESTIGATION RECS
2016-2603	04/01/2016 04/29/2016	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/	Kelly Carver Texas Star Nut & Food Company, Inc	TEXAS STAR MACADAMIA NUTS SAMPLE RECS 03/13/2015 - 04/13/2015
2016-2604	04/01/2016 04/29/2016	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/	Kelly Carver Texas Star Nut & Food Company, Inc	TEXAS STAR MACADAMIA NUTS - RANDOM SAMPLING RECS 09/18/2015 - 10/23/2015
2016-2605	04/01/2016 04/29/2016	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/	Kelly Carver Texas Star Nut & Food Company, Inc	TEXAS STAR PISTACHIO NUTS - RANDOM SAMPLING RECS 03/04/2016 - 03/28/2016
2016-2606	04/01/2016 04/29/2016	OC/ORO/ORM/ OC/ORO/ORM/ FDA/OMPT/CDER/ORP/DIDP/	Kelly Klotz SSM St Clare Health Center	LIST OF FDA APPROVED, PREFERRED LABORATORY TESTING FACILITIES 11/27/2013 - 03/28/2016

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2016-2607	04/01/2016 04/29/2016	FDA/OGROP/ORAN/NE-FO/NWE-DO/NWE-CB/	Kris Christian FDAZILLA	SAFECOR HEALTH, LLC, WOBURN, MA - 483 10/05/2015 - 10/27/2015
2016-2608	04/01/2016 04/29/2016	FDA/OMPT/CDRH/OCE/DID/	Brady Palmquist Anybattery, Inc.	K936141
2016-2609	04/01/2016 04/29/2016	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink	2016-2444
2016-2610	04/01/2016 04/29/2016	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink	2016-960
2016-2611	04/01/2016 04/29/2016	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink	2016-1052
2016-2612	04/01/2016 04/29/2016	FDA/OMPT/CDRH/OCE/DID/	Sun Choi ADVANCED STERILIZATION PRODUCTS	K152060
2016-2613	04/01/2016 04/29/2016	FDA/OMPT/CDRH/OCE/DID/	Brady Palmquist Anybattery, Inc.	K935111
2016-2614	04/01/2016 04/29/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tushar Manudhane Indianivesh securities	LUPIN, INDIA - 483 02/01/2016 - 03/29/2016
2016-2615	04/01/2016 04/29/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kris Christian FDAZILLA	NATCO PHARMA, INDIA - 483 02/29/2016 - 03/07/2016
2016-2616	04/01/2016 04/29/2016	FDA/OMPT/CDRH/OCE/DID/	Brady Palmquist Anybattery, Inc.	K940842
2016-2617	04/01/2016 04/29/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	John S. Lopez Actavis Laboratories UT, Inc.	NDA 207589
2016-2618	04/01/2016	FDA/OMPT/CDRH/OCE/DID/	Sun Choi	K152060

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	04/29/2016		ADVANCED STERILIZATION PRODUCTS	
2016-2619	04/01/2016 04/29/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mo Dimbil ADVERSEEVENTS INC	ORKAMBI - AERS
2016-2620	04/01/2016 04/29/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Andrea Demakas ADVERSEEVENTS INC	LIZESS, VICODIN, AMPYRA ETC CASE REPORTS
2016-2621	04/01/2016 04/29/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Alexander Feo Alexander Feo	RAYALDEE - COMPLETE RESPONSE LETTER 03/14/2016 - 03/30/2016
2016-2622	04/01/2016 04/29/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Paresh Dave AMBIT CAPITAL	LUPIN, INDIA - 483 01/01/2016 - 03/29/2016
2016-2623	04/01/2016 04/29/2016	FDA/OMPT/CDRH/OCE/DID/	Brady Palmquist Anybattery, Inc.	K945869
2016-2624	04/01/2016 04/29/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Saroja Gorantla AurobindoUSA	ANDA 071294
2016-2625	04/01/2016 04/29/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Saroja Gorantla AurobindoUSA	ANDA 071938
2016-2626	04/01/2016 04/29/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Saroja Gorantla AurobindoUSA	ANDA 084774
2016-2627	04/01/2016	FDA/OMPT/CDER/GRP/DIDP/	Saroja Gorantla	ANDA 084773

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	04/29/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	AurobindoUSA	
2016-2628	04/01/2016 04/29/2016	FDA/OGROP/ORAP/FO/LOS-DO/LOS-CB/	Steven Burgueno Baked in the Sun	BAKED IN THE SUN, VISTA, CA - EIR 11/01/2015 - 03/30/2016
2016-2629	04/01/2016 04/29/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Margaret Dillon bioinspire technologies	NDA 018584
2016-2630	04/01/2016 04/29/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michelle Elizabeth Legiec Eagle Pharmaceuticals, Inc.	NDA 208194 SBA
2016-2631	04/01/2016 04/29/2016	FDA/OMPT/CDRH/OCE/DID/	Robert Lee Robert Lee	K981095
2016-2632	04/01/2016 04/29/2016	FDA/OMPT/CDRH/OCE/DID/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Zachary Mietus The Weinberg Group	ANDA 208077
2016-2633	04/01/2016 04/29/2016	FDA/OMPT/CDRH/OCE/DID/	Lynne McCormack DePuy Mitek, Inc.	K112423
2016-2634	04/01/2016 04/29/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Anjali Cordeiro BLOOMBERG NEWS	LUPIN, INDIA - 483 03/29/2015 - 03/29/2016
2016-2635	04/01/2016 04/29/2016	FDA/OGROP/ORAP/SE-FO/FLA-DO/FLA-CB/	Blake Goodner Bridger Healthcare	CATALENT INC, ST PETERSBURG, FL - 483, WARNING LETTER, RESPONSE 01/02/2015 - 03/30/2016
2016-2636	04/01/2016 04/29/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Blake Goodner Bridger Healthcare	RAYALDEE - COMPLETE RESPONSE LETTER 03/01/2016 - 03/30/2016
2016-2637	04/01/2016	FDA/OMPT/CDER/GRP/DIDP/	Aakash Agarwal	LUPIN, INDIA - 483 03/03/2015 - 03/29/2016

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	04/29/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Capital Mind	
2016-2638	04/01/2016 04/29/2016	FDA/OMPT/CDRH/OCE/DID/	Deborah Sheffield Deborah Sheffield	K790213
2016-2639	04/01/2016 04/29/2016	FDA/OMPT/CDRH/OCE/DID/	Robert Lee Robert Lee	K981095
2016-2640	04/01/2016 04/29/2016	FDA/OMPT/CDRH/OCE/DID/	Brian Godwin Ethicon	K141785
2016-2641	04/01/2016 04/29/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kevin Kong HEC Pharm USA Inc	NDA 205692
2016-2642	04/01/2016 04/29/2016	FDA/OO/OHR/	Thomas C Murphy Thomas Murphy	FDA-CDER-16-MP-1583884MH
2016-2643	04/01/2016 04/29/2016	FDA/OMPT/CDRH/OCE/DID/	Derek Nielsen Stasis Labs	K112478
2016-2644	04/01/2016 04/29/2016	FDA/OMPT/CDRH/OCE/DID/	Paul Arrendell KCI USA, Inc.	K133137
2016-2645	04/01/2016 04/29/2016	FDA/OMPT/CDRH/OCE/DID/	Paul Arrendell KCI USA, Inc.	K080011
2016-2646	04/01/2016 04/29/2016	FDA/OMPT/CDRH/OCE/DID/	Paul Arrendell KCI USA, Inc.	K111393
2016-2647	04/01/2016 04/29/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Deepak Malik Edelweiss	LUPIN, INDIA - 483 01/01/2016 - 03/28/2016
2016-2648	04/01/2016 04/29/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dr Girish Bakhru HSBC Securities and Capital Markets	LUPIN, INDIA - 483 02/01/2016 - 03/01/2016
2016-2649	04/01/2016 04/29/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Gaurav Tinani Emkay Global Financial Services	LUPIN, INDIA - 483 02/08/2016 - 02/19/2016

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Limited	
2016-2650	04/01/2016 04/29/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Vaibhav Dusad Morgan Stanley	LUPIN, INDIA; NATCO, INDIA - 483 01/01/2016 - 03/29/2016
2016-2651	04/01/2016 04/29/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JEFFREY R LARNARD GROLMAN LLP	SEROQUEL NDA 20-639/S026 - LBLG EXHIBIT A (CERTIFIED)
2016-2652	04/01/2016 04/29/2016	FDA/OMPT/CTP/OD/	NANCYELLEN KEANE ESQ TROUTMAN SANDERS LLP	GREAT SWAMP ENTERPRISES INC - CAYUGA KINGS BOX RED, GOLD, BLUE, ETC SUBSTANTIAL EQUIVALENCE APPLICATIONS (SE RPTS)
2016-2653	04/01/2016 04/29/2016	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAP/SW-FO/DAL-DO/DAL-CB/ OC/ORAP/ OC/ORAP/	BETHANY KENNEDY EMORD & ASSOCIATES, P.C.	YOUNGEVITY INTERNATIONAL INC - CMLPNTS, LTRS, EMAILS 1/14 TO PRESENT
2016-2654	04/01/2016 04/29/2016	FDA/OC/OES/DDM/	KYLE A DOLINSKY PEPPER HAMILTON LLP	DRUG, BIOLOGIC, MEDICAL DVC PATENT TERM EXTENSION PETITIONS 1998 TO 2014
2016-2655	04/01/2016 04/29/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	AUDREY ALIBRANTI EGAN ETHYPHARM USA CORP	NARCAN NDA 208-411 - CLNCL PHARMACOLOGY, BIOPHARMACEUTICS RVWS
2016-2656	04/01/2016 04/29/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DORI E ROCHARDS ESQ WESTERN AGRICULTURE RESOURCE AND BUSINESS ASSOCIATES LLP	ATTIX PHARMACEUTICALS - VIOLATION NOTICES, HOLDS, ETC; GINSENG, CINNAMON, HERBAL MIXES IMPORT CMLPNTS, INVESTIGATION 2011 TO PRESENT, ETC
2016-2657	04/01/2016 04/29/2016	FDA/OMPT/CDRH/OCE/DID/	MICHELLE RENO DANAHER LAGNESE PC	SIEMENS MEDICAL SOLUTIONS USA INC - AXIOM SIRESKOP SD IMAGE-INTENSIFIED FLUOROSCOPIC X-RAY MDR, CORR, RPTS, ETC
2016-2658	04/01/2016 04/29/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID LOHMAN MILLENNIUM MANAGEMENT LLC	ACTHAR GEL-SYNTHETIC (SERACTIDE ACETATE) - CURRENT LBLG

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-2659	04/01/2016 04/29/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDRH/OCE/DID/	JOHN RICHES GOLDWATER INSTITUTE	TRIOPLEX REAL-TIME RT-PCR ASSAY - APRVL, RVWS, ANALYSES, ETC
2016-2660	04/01/2016 04/29/2016	FDA/OGROP/ORACE-FO/CIN- DO/CIN-CB/	ALISON M GAFFEY MCCARTER & ENGLISH LLP	CAUDILL SEED & WAREHOUSE CO INC - ALFALFA SPROUTS, BROCCOLI SEEDS, BROCCOLI SEED EXTRACT SALMONELLA OUTBREAK, RECALL RECS
2016-2661	04/01/2016 04/29/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DANIEL B TREON TREON & SHOOK PLLC	SK LIFE SCIENCES INC - YKP3089 RPTS, CORR, FORMS, ETC; INDIVIDUAL RECS
2016-2662	04/01/2016 04/29/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAWN M CHITTY TORRENT PHARMA INC	KLONOPIN (CLONAZEPAM TABS) NDA 17-533 SBA
2016-2663	04/01/2016 04/29/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAWN M CHITTY TORRENT PHARMA INC	CATAPRESS TTS 1,2,3 (CLONIDINE FILM, EXTENDED RELEASE, TRANSDERMAL) NDA 18-891 - SBA
2016-2664	04/01/2016 04/29/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAWN M CHITTY TORRENT PHARMA INC	SANTYL (COLLAGENASE OINTMENT) BLA 101995 - SBA
2016-2665	04/01/2016 04/29/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KATE REYNOLDS MPH ROCKY MOUNTAIN POISON & DRUG CENTER	ACETAMINOPHEN PREPARATIONS - ISRS 7063306, 8356443, 8711037, ETC
2016-2666	04/01/2016 04/29/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KATE REYNOLDS MPH ROCKY MOUNTAIN POISON & DRUG CENTER	ACETAMINOPHEN PREPARATIONS - ISRS 9900289, 9916493, 10073830, ETC
2016-2667	04/01/2016 04/29/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PHILLIP RAKHUNOV POLLACK SOLOMON DUFFY LLP	FERRING PHARMACEUTICALS INC - PREPOPIK, SUPREP COMM 1/13 TO PRESENT

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-2668	04/01/2016 04/29/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARIA E DARNELL HILL DERMACEUTICALS INC	TOLAK (FLUOOURACIL 4% CREAM) NDA 22-259 - SBA
2016-2669	04/01/2016 04/29/2016	FDA/OMPT/CDRH/OCE/DID/	GARY PEKOE Arkios BioDevelopment International	INVITROGEN CORP - AIM-V MEDIUM K022086; VERIDEX LLC - CELL TRACKS ANALYZER II SYS K130794, CELLSEARCH CIRCULATING TUMOR CELL KIT K050245, ETC
2016-2670	04/01/2016 04/29/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KEVIN COBBS 40744-019 COBBS 40744-019, KEVIN D	GENITAL HERPES - NAMES OF MEDICATIONS, TREATMENT SCHEDULE
2016-2671	04/01/2016 04/29/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOSE HERNANDEZ 5WS CONSULTING LLC	DALIAN GOODWOOD MEDICAL CARE LTD, DALIANSHI, CHINA 4/17/15; QILU PHARMACEUTICAL CO LTD, JINAN, CHINA 5/19/15; HYBO PHARMACEUTICAL CO LTD, SHENZHEN, CHINA 6/26/15, ETC - -483S
2016-2672	04/01/2016 04/29/2016	FDA/OGROP/ORACE-FO/BLT- DO/BLT-CB/	MICHAEL D LEVIN HEALTH BUSINESS STRATEGIES	BIO-CAT INC, TROY, VA - EIRS, 483S, CO RESP, ETC 1/1/09 TO 3/21/16
2016-2673	04/01/2016 04/29/2016	FDA/OGROP/ORACE-FO/KAN- DO/KAN-CB/	MICHAEL D LEVIN HEALTH BUSINESS STRATEGIES	NATIONAL ENZYME CO, FROSYTH, MO - EIRS, 483S, WARNING LTRS, ETC 1/1/09 TO 3/21/16
2016-2674	04/01/2016 04/29/2016	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	2015-10205
2016-2675	04/04/2016 05/02/2016	FDA/OMPT/CDRH/OCE/DID/	Stephanie Heffner AMERICAN ACADEMY OF PERIODONTOLOGY	K151763
2016-2676	04/04/2016 05/02/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	A list of all FOIA requests closed for 3/1-31/2016
2016-2677	04/04/2016 05/02/2016	FDA/OMPT/CDRH/OCE/DID/	Paul Arrendell KCI USA, Inc.	K132080
2016-2678	04/04/2016 05/02/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 3/1-31/2016
2016-2679	04/04/2016	FDA/OMPT/CDRH/OCE/DID/	Cynthia J Pillar	K041680

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	05/02/2016		CJP Consulting, Inc.	
2016-2680	04/04/2016 05/02/2016	FDA/OMPT/CDRH/OCE/DID/	Jason J. Velligan Meyers & Flowers, LLC	K961939
2016-2681	04/04/2016 05/02/2016	FDA/OMPT/CDRH/OCE/DID/	jacci burgin collagen solutions	K122325
2016-2682	04/04/2016 05/02/2016	FDA/OMPT/CDRH/OCE/DID/	Derek Nielsen Stasis Labs	K110516
2016-2683	04/04/2016 05/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Raymond Kim Vera Therapeutics	IND RT001
2016-2684	04/04/2016 05/02/2016	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Heather McIntyre Mondelez Global LLC	MONDELEZ GLOBAL LLC, RICHMOND, VA- EIR 11/13/2013 - 11/19/2013
2016-2685	04/04/2016 05/02/2016	FDA/OMPT/CDRH/OCE/DID/	Jason J. Velligan Meyers & Flowers, LLC	K851422
2016-2686	04/04/2016 05/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	C.Srihari P.C.S Securities	LUPIN, INDIA - 483 03/01/2016 - 03/29/2016
2016-2687	04/04/2016 05/02/2016	FDA/OMPT/CDRH/OCE/DID/	James Peach Precision Biologic Inc.	K142132
2016-2688	04/04/2016 05/02/2016	FDA/OC/OES/DDM/	Jeff McBride Red Lion Medical Safety, Inc	FDA docket 2016-N-0436
2016-2689	04/04/2016 05/02/2016	FDA/OMPT/CDRH/OCE/DID/	Stephanie McFeeters The Daily Hampshire Gazette	MW5030529
2016-2690	04/04/2016 05/02/2016	FDA/OMPT/CDRH/OCE/DID/	Paul Arrendell KCI USA, Inc.	K113032
2016-2691	04/04/2016 05/02/2016	OC/ORACE/ORM/ OC/ORACE/ORM/	Quintiles Quintiles	LIST OF 482S 03/01/2016 - 03/25/2016
2016-2692	04/04/2016 05/02/2016	FDA/OMPT/CDRH/OCE/DID/	Paul Arrendell KCI USA, Inc.	K112341
2016-2693	04/04/2016 05/02/2016	FDA/OMPT/CDRH/OCE/DID/	Lynne McCormack DePuy Mitek, Inc.	K082079

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2016-2694	04/04/2016 05/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 91671
2016-2695	04/04/2016 05/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dr Girish Bakhru HSBC Securities and Capital Markets	ALEMBIC, PANELAV - 483 03/01/2016 - 03/29/2016
2016-2696	04/04/2016 05/02/2016	FDA/OFVM/CFSAN/OCD/EOS/ Lonza Inc.	MIT-CMIT and BIT Related FCNs Lonza Inc.	FCN 1515 FCN 1396 FCN 1453
2016-2697	04/04/2016 05/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Deepak Malik Edelweiss	ALEMBIC PHARMA, INDIA - 483 03/01/2016 - 03/28/2016
2016-2698	04/04/2016 05/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tushar Manudhane Indianivesh securities	ALEMBIC PHARMACEUTICALS, INDIA - 483 03/01/2016 - 03/29/2016
2016-2699	04/04/2016 05/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Deborah Hogerman UCB, Inc.	BLA 125504, S 001, 002
2016-2700	04/04/2016 05/02/2016	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OMPT/CDRH/OCE/DID/	William B. Harvey, III Harvey & Battey, PA	DICKS SPORTING GOODS - COMMUNICATIONS WITH FDA RE RECALL OF STE00118FG INVERSION TABLE 01/01/2014 - 03/28/2016
2016-2701	04/04/2016 05/02/2016	FDA/OMPT/CDRH/OCE/DID/	Hannah Grinage New Practices Inc	MUSES LABS, INC, RALEIGH, NC - 513(G) LETTER 03/01/2013 - 03/01/2016
2016-2702	04/04/2016 05/02/2016	FDA/OMPT/CDRH/OCE/DID/	Lacey Chessor PERMOBIL AB	PERMOBIL AB, SWEDEN - EIR 01/01/2016 - 03/28/2016
2016-2703	04/04/2016 05/02/2016	FDA/OMPT/CDRH/OCE/DID/	Phebe Varghese Terumo Medical Corporation	TERUMO MEDICAL CORPORATION - RECS RE ALLEGATIONS OF REGULATORY MISCONDUCT 10/02/2015 - 03/28/2016
2016-2704	04/04/2016 05/02/2016	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Charlene Palmquist Anybattery, Inc.	ANYBATTERY, INC - EIR 12/01/2015 - 12/31/2015

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2016-2705	04/04/2016 05/02/2016	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Ayan Deb Nomura Financial Advisory Securities India Ltd	TEVA, SELLERSVILLE, PA - EIR JULY 2011
2016-2706	04/04/2016 05/02/2016	FDA/OMPT/CDRH/OCE/DID/	Liane LaRochelle DEKA R&D	V-TECH COMMUNICATIONS LTD, CHINA - 483 03/14/2016 - 03/28/2016
2016-2707	04/04/2016 05/02/2016	FDA/OFVM/CFSAN/OCD/EOS/	Ryan Kath WBZ-TV	NABISCO, MONDELEZ INTERNATIONAL, MONTERREY, MEXICO - INSPECTION, INVESTIGATION REPORTS 01/01/2014 - 03/28/2016
2016-2708	04/04/2016 05/02/2016	FDA/OMPT/CDRH/OCE/DID/	Rui Li PURDUE UNIVERSITY	HOLOGIC TRIDENT SPECIMENT RADIOGRAPHY SYSTEM 510K
2016-2709	04/04/2016 05/02/2016	FDA/OO/OFBA/OAGS/	Richard Swietek Richard Swietek	PATIENTSLIKEME, EPIDEMCO.COM, BOOZALLEN - AGREEMENT WITH FDA, CONTRACTS, CRADA ETC 01/01/2012 - 03/29/2016
2016-2710	04/04/2016 05/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Deepak Malik Edelweiss	NATCO PHARMA, INDIA - 483 02/01/2016 - 03/28/2016
2016-2711	04/04/2016 05/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jaya Subramaniam Econdisc Contracting Solutions LLC	NATCO PHARMA, MSN LABORATORIES - 483 02/01/2016 - 03/29/
2016-2712	04/04/2016 05/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Krishna Kiran Konduri Spark Capital Advisors (I) Private Limited	NATCO PHARAM, NATCO ORGANICS LIMITED, INDIA - 483 01/01/2016 - 04/01/2016
2016-2713	04/04/2016 05/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Krishna Kiran Konduri Spark Capital Advisors (I) Private Limited	NATCO PHARMA LIMITED, INDIA - 483 01/01/2016 - 04/01/2016
2016-2714	04/04/2016 05/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rahul Jeewani IIFL Capital	CADILA HEALTHCARE LIMITED, INDIA - 483 01/01/2016 - 03/29/2016
2016-2715	04/04/2016 05/02/2016	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	Elizabeth A Engebretson Engebretson, Elizabeth	PHARMEDIUM SERVICES, LLC, LAKE FOREST, IL - 483 11/17/2015 - 01/29/2016

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		FDA/OC/OES/DFOI/ OC/ORO/ OC/ORO/		
2016-2716	04/04/2016 05/02/2016	FDA/OMPT/CDRH/OCE/DID/	Andy Sealfon RMS Medical Products	RMS MEDICAL PRODUCTS, REPRO-MEDI SYSTEMS, INC, CHESTER, NY - TRADE COMPLAINT 03/03/2015 - 03/03/2016
2016-2717	04/04/2016 05/02/2016	FDA/OO/OFBA/OAGS/	Steven Greenberg BRIGHAM AND WOMEN'S HOSPITAL	UNIVERSITY OF KANSAS MEDICAL CENTER - GRANT RECS 01/01/2013 - 12/31/2015
2016-2718	04/04/2016 05/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rahul Jeewani IIFL Capital	CADILA HEALTHCARE LIMITED, INDIA - 483 01/01/2016 - 03/29/2016
2016-2719	04/04/2016 05/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bharat Celly Research Delta Advisors	CADILA HEALTHCARE LIMITED, INDIA - 483 12/01/2015 - 03/28/2016
2016-2720	04/04/2016 05/02/2016	FDA/OMPT/CDRH/OCE/DID/	Mark Vreeke Edwards Lifesciences	ESSURE P020014
2016-2721	04/04/2016 05/02/2016	OC/ORO/ORM/ OC/ORO/ORM/	Darshan Mehta ET Now	LIST OF INSPECTIONS IN INDIA 02/01/2016 - 03/29/2016
2016-2722	04/04/2016 05/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ayan Deb Nomura Financial Advisory Securities India Ltd	ZYDUS CADILA, LUPIN - 483 10/01/2015 - 03/29/2016
2016-2723	04/04/2016 05/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dheeresh Pathak Dheeresh Pathak	ALEMBIC LIMITED, INDIA - 483 02/01/2016 - 03/29/2016
2016-2724	04/04/2016 05/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kris Christian FDAZILLA	PULIN, LTD, INDIA - 483 01/11/2016 - 01/15/2016
2016-2725	04/04/2016	FDA/OMPT/CDRH/OCE/DID/	Paul Arrendell	K111006

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	05/02/2016		KCI USA, Inc.	
2016-2726	04/04/2016 05/02/2016	FDA/OMPT/CDRH/OCE/DID/	Zach Malchano Zach Malchano	K092164 K060112 K002533
2016-2727	04/04/2016 05/02/2016	FDA/OMPT/CDRH/OCE/DID/	Paul Arrendell Paul Arrendell	K142272
2016-2728	04/04/2016 05/02/2016	FDA/OMPT/CDRH/OCE/DID/	Patricia Campbell Masimo Corporation	K083093 K113657 K122121 etc
2016-2729	04/04/2016 05/02/2016	FDA/OMPT/CDRH/OCE/DID/	Deborah Sheffield Deborah Sheffield	K102329
2016-2730	04/04/2016 05/02/2016	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Kris Christian FDAZILLA	TERUMO MEDICAL CORPORATION, ELKTON, MD - 483 10/19/2015 - 10/23/2015
2016-2731	04/04/2016 05/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jennifer Elrod, PharmD Self Regional Healthcare	ELIQUIS, APIXABAN - AERS 01/01/2012 - 03/29/2016
2016-2732	04/04/2016 05/02/2016	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Thomas Wilverding Central Admixture Pharmacy Services, Inc	CAPS, WALLINGFORD, CT - SAMPLE COLLECTION REPORTS, RESULTS 01/08/2016 - 03/29/2016
2016-2733	04/04/2016 05/02/2016	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Mary Paulson GlaxoSmithKline LLC	GLAXOSMITHKLINE LLC, AIKEN, SC - EIR 07/06/2015 - 07/10/2015;
2016-2734	04/04/2016 05/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Robb Lawrence Chesapeake Therapeutics	ANDA 080983 ANDA 083040
2016-2735	04/04/2016 05/02/2016	FDA/OC/OES/DFOI/	Andy Sealfon RMS Medical Products	REPRO-MED SYSTEMS, INC, CHESTER, NY - FOIA REQUESTS FOR 483 01/01/2016 - 03/29/2016
2016-2736	04/04/2016 06/15/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	John Lezdey JOHN LEZDEY	ALPHAONE PHARMACEUTICALS - IND 01/03/1999 - 12/30/2005
2016-2737	04/04/2016 05/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lauren Welling Sanders Phillips Grossman, LLC	RISPERDAL RECS 01/01/1990 - 03/31/2016

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/		
2016-2738	04/04/2016 05/02/2016	FDA/OMPT/CDRH/OCE/DID/	Patricia Campbell Masimo Corporation	K061585
2016-2739	04/04/2016 05/02/2016	FDA/OMPT/CDRH/OCE/DID/	Deborah Sheffield Deborah Sheffield	K150089
2016-2740	04/04/2016 05/02/2016	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink	2016-1982
2016-2741	04/04/2016 05/02/2016	FDA/OPPLA/OL/	Helen Smith Helen Smith	REP ALAN GRAYSON - CORR ETC 01/01/2007 - 03/30/2016
2016-2742	04/04/2016 05/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dustin Block IPD Analytics, LLC	ANDA 091190
2016-2743	04/04/2016 05/02/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K150055
2016-2744	04/04/2016 05/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sarah Zhang Wired Magazine	MIFEPRISTONE - IND 12/01/2014 - 03/31/2016
2016-2745	04/04/2016 05/02/2016	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Joe Warnhoff PERFORMANCE PRODUCTS, INC.	PERFORMANCE PRODUCTS, INC - EIR 02/09/2016 - 02/11/2016
2016-2746	04/04/2016 05/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Raymond Kim Vera Therapeutics	DSC127 IND
2016-2747	04/04/2016 05/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Stephen Friedlander Friedlander, Stephen A	RAYALDEE - COMPLETE RESPONSE LETTER 03/14/2016 - 03/25/2016
2016-2748	04/04/2016	FDA/OMPT/CDRH/OCE/DID/	Sean Whalen	MW5008249

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	05/02/2016		Sean Whalen	
2016-2749	04/04/2016 05/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Irene Hreno Irene Hreno	PROLIA - AERS
2016-2750	04/04/2016 05/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Shalini Patel UCB Inc. (Shalini Patel)	F94748311,F94825941,F94864241 ETC
2016-2751	04/04/2016 05/02/2016	OC/ORA/ORM/ OC/ORA/ORM/	Tushar Manudhane Indianivesh securities	LIST OF INSPECTIONS IN INDIA 03/01/2016 - 03/30/2016
2016-2752	04/04/2016 05/02/2016	OC/ORA/ORM/ OC/ORA/ORM/	M. Randall M. Randall	LIST OF DEVICE INSPECTIONS 03/01/2016 - 03/31/2016
2016-2753	04/04/2016 05/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Maureen Kielian Kielian, Maureen M	OXYCONTIN, OXYCODONE, HYDROCODONE ETC - AERS
2016-2754	04/04/2016 05/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 20687 S20
2016-2755	04/04/2016 05/02/2016	FDA/OMPT/CDRH/OCE/DID/	Renee Thornborough Omron Healthcare, Inc.	K042506
2016-2756	04/04/2016 05/02/2016	FDA/OC/OES/DFOI/	PATTI WALLER MARLER CLARK ATTYS	MULTISTATE OUTBREAK OF LISTERIA MONOCYTOGENES LINKED TO DOLE LEAFY GREENS 7/15 TO 1/16
2016-2757	04/04/2016 05/02/2016	FDA/OC/OES/DFOI/	PATTI WALLER MARLER CLARK ATTYS	RECALL OF AMERICAN BLEND BAGGED BY DOLE FRESH VEGETABLES 1/17/12
2016-2758	04/04/2016 05/02/2016	FDA/OC/OES/DFOI/	PATTI WALLER MARLER CLARK ATTYS	RECALL OF BAGGED SALAD BY DOLE FRESH VEGETABLES 6/22/12
2016-2759	04/04/2016 05/02/2016	FDA/OC/OES/DFOI/	PATTI WALLER MARLER CLARK ATTYS	RECALL OF DOLE ITALIAN BLEND SALAD BY DOLE FRESH VEGETABLES 8/22/12
2016-2760	04/04/2016 05/02/2016	FDA/OC/OES/DFOI/	PATTI WALLER MARLER CLARK ATTYS	RECALL OF SEVEN LETTUCES SALAD BY DOLE FRESH VEGETABLES 4/14/12

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2016-2761	04/04/2016 05/02/2016	FDA/OC/OES/DFOI/	PATTI WALLER MARLER CLARK ATTYS	RECALL OF DOLE HEARTS OF ROMAINE BY DOLE FRESH VEGETABLES 6/29/12
2016-2762	04/04/2016 05/02/2016	FDA/OC/OES/DFOI/	PATTI WALLER MARLER CLARK ATTYS	RECALL OF BAGGED ITALIAN STYLE SALAD BLENDS BY DOLE FRESH VEGETABLES 3/13/14
2016-2763	04/04/2016 05/02/2016	FDA/OC/OES/DFOI/	PATTI WALLER MARLER CLARK ATTYS	RECALL OF BAGGED SPINICH SALAD BY DOLE FRESH VEGETABLES 10/13/15
2016-2764	04/04/2016 05/02/2016		PHILLIP RAKHUNOV POLLACK SOLOMON DUFFY LLP	MOVIPREP - AER 9/1/06 TO PRESENT
2016-2765	04/04/2016 05/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELENA HOWELL Hogan Lovells, ILP	BASAGLAR NDA 05-692 SBA
2016-2766	04/04/2016 05/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	STEPHEN CORKERY NORTHSTAR HEALTHCARE	PLATEX LTD, NETANYA, ISRAEL - EIR
2016-2767	04/04/2016 05/02/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	THOMPSON, RAY	ACTAVIS UK LTD, BARNSTAPLE, UK 11/30/15 TO 12/4/15; AVENTIS PHARMA LTD, CREWE, UK 1/11/16 TO 1/15/16 - 483
2016-2768	04/04/2016 05/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID HOFFMEISTER WILSON SONSINI ET AL	AMNEAL - DICLOFENAC SODIUM ANDA 08-077 - APRVL
2016-2769	04/04/2016 05/02/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	MARTIN RUBENSTEIN HOWARD M FILE ATTY	INDIVIDUAL RECS

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2016-2770	04/04/2016 05/02/2016	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/ FDA/OMPT/CDRH/OCE/DID/	WILLIAM B. ATCHISON DENHAM LAW FIRM PLLC	INDIVIDUAL RECS
2016-2771	04/04/2016 05/02/2016	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	DANIELA S. SOLL ADVANCED BRAIN MONITORING	ADVANCED BRAIN MONITORING INC, CARLSBAD, CA - EIR
2016-2772	04/04/2016 05/02/2016	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/CVM/OCD/	PAUL B. CALLAHAN CHARLES RIVER	CHARLES RIVER LABORATORIES INC, GLENAMOY, COUNT MAYO, IRELAND - EIR 1/26-29/15
2016-2773	04/04/2016 05/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Aman Asha Aman Asha	LUPIN LIMITED, GOA, INDIA - CURRENT CLASSIFICATION 02/01/2016 - 04/03/2016
2016-2774	04/04/2016 05/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Raymond Kim Vera Therapeutics	DESFERAL - IND, NDA
2016-2775	04/04/2016 05/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Herman Woessner Herman Woessner	CONTALENT PHARMA SOLUTION, ST PETERSBURG, FL - 483 03/14/2016 - 03/31/2016
2016-2776	04/04/2016 05/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	TASIGNA - RECS RE LABELING REVISION 01/01/2010 - 03/30/2016
2016-2777	04/04/2016 06/29/2016	OC/ORAE/ OC/ORAE/	Marco Aurilio Marco Aurilio	EXTRACCIONES NATURALES SA DE CV, TEVAC SA DE CV ETC - PRIOR NOTICE RECS 01/01/2011 - 02/29/2016
2016-2778	04/04/2016 05/02/2016	FDA/OMPT/CDRH/OCE/DID/	Christopher Oxx Parker Waichman, LLP	MEDTRONIC INC APPLICATION FOR AN EXEMPTION PURSUANT TO 21 CFR Part 803.19 06/01/2013 - 01/01/2016

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2016-2779	04/04/2016 05/02/2016	OC/ORO/ OC/ORO/ FDA/OFVM/CFSAN/OCD/EOS/	David Greenstein David Greenstein	KRAFT FOODS GROUP, INC - INVESTIGATION RE PARMESAN CHEESE 03/31/2016 - 03/30/2016
2016-2780	04/04/2016 05/02/2016	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/ OC/ORO/	Tina Sigurdson ENVIRONMENTAL WORKING GROUP	EOS - AERS, CORR, INSPECTIONS
2016-2781	04/04/2016 05/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Alex Slack MAVERICK CAPITAL	CALCIFEDIOL - REVIEW OF NDA 03/01/2016 - 03/30/2016
2016-2782	04/04/2016 05/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Asim Abdul Glenmark Pharmaceuticals, Inc., USA	NDA 207923 SBA
2016-2783	04/04/2016 05/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gregory Renza JEFFERIES & CO	KALYDECO, ORKAMBI, JAKAFI ETC - AERS
2016-2784	04/04/2016 05/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Stephen A. Friedlander Friedlander, Stephen A	CATALENT, ST PETERSBURG, FL - 483 03/14/2015 - 03/25/2016
2016-2785	04/04/2016 05/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Scott Goldman Hyman, Phelps & McNamara P.C.	NDA 207920 SBA
2016-2786	04/04/2016 05/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 20687 REMS MODIFICATION LETTER
2016-2787	04/04/2016 05/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Shannpn Werner Froedtert Hospital	VENOFER - AERS

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-2788	04/04/2016 05/02/2016	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	Doe J	COMPLAINT RECS
2016-2789	04/04/2016 05/02/2016	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	Terry Herr TLH Consulting	CATALENT PHARMA SOLUTIONS, LLC, ST PETERSBURG, FL - 483 03/01/2016 - 03/31/2016
2016-2790	04/04/2016 05/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELENA HOWELL Hogan Lovells, ILP	ELI LILLY & CO - BASAGLAR APRVL
2016-2791	04/04/2016 05/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tushar Manudhane Indianivesh securities	CTX LIFESCIENCES PVT LIMITED - 483 02/01/2016 - 04/04/2016
2016-2792	04/04/2016 05/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Reena Harjai APCER Life Sciences, Inc.	NDA 021602 S027 SBA
2016-2793	04/04/2016 05/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	S ALBERT EDWARDS PHARM D	SEPTODONT - SETOCAINE(ARTICAINE) NDA 20-971
2016-2794	04/04/2016 05/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Giovanna Scapin Giovanna Scapin	AUGMENTIN, AMOXICILLIN/CLAVULANATE, CLAVULANIC ACID - AERS 04/06/1990 - 04/02/2016
2016-2795	04/04/2016 05/02/2016	FDA/OMPT/CDRH/OCE/DID/	Angie Fimalino Angie Fimalino	BAYER PLAN PROTOCOL PS16001/PSS001 ESSURE
2016-2796	04/04/2016 05/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Asim Abdul Glenmark Pharmaceuticals, Inc., USA	NDA 207930 SBA

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2016-2797	04/04/2016 05/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/CVM/OCD/	Kristi Smedley Center for Regulator Services, Inc	SHIJIAZHUNG RAINBOWLABS TECHNOLOGY CO, LTD, CHINA - EIR SINCE JULY 2013
2016-2798	04/04/2016 05/02/2016	FDA/OMPT/CDRH/OCE/DID/	KERRY SCHONWALD LOEWINSOHN FLEGLER ET AL	PLANO ORTHOPEDIC & SPORTS MEDICINE, DR STEPHEN P COURTNEY - RECS
2016-2799	04/05/2016 05/03/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Paige Stradley MERCHANT & GOULD	NDA 201280 FORM 3542, 3542A, COMMUNICATIONS, ETC
2016-2800	04/05/2016 05/03/2016	FDA/OMPT/CDRH/OCE/DID/	Samuel Blaustein Dunnington Bartholow & Miller LLP	ABBOTT LABORATORIES, ABBOTT DIABETES CARE INC - SUBMISSIONS RE FREESTYLE, FREESTYLE LITE GLUCOSE TEST STRIPS, CORR, RESEARCH 01/01/2013 - 07/30/2015
2016-2801	04/05/2016 05/03/2016	FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/ FDA/OMPT/CDRH/OCE/DID/ FDA/OGROP/ORANE-FO/NYK- DO/NYK-DCB/	Susan Schmidt susan schmidt	CCA INDUSTRIES PLUS WHITE TEETH WHITENING PRODUCTS - INSPECTION RECS, COMPLAINTS, ADVERSE EVENTS 03/08/2009 - 03/31/2016
2016-2802	04/05/2016 05/03/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Erin da Costa MSF UK	DR REDDY LABORATORIES - RESPONSE TO WARNING LETTER 11/05/2015 - 03/31/2016
2016-2803	04/05/2016 05/03/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	sandy suh Exeltis	ROXITHROMYCIN - NDA, ANDA, DMF 01/01/1900 - 01/01/2016
2016-2804	04/05/2016 05/03/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rahul Jeewani IIFL Capital	LUPIN LIMITED, INDIA - 483 10/01/2015 - 04/01/2016
2016-2805	04/05/2016 05/03/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Steven Woloshin The Dartmouth Institute for Health Policy and Clinical Practice	NDA, ANDA SUPPLEMENTS

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-2806	04/05/2016 05/03/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mark Ding Macquarie	ANIMAL RULE APPROVAL RATES
2016-2807	04/05/2016 05/03/2016	FDA/OFVM/CFSAN/OCD/EOS/	Thomas Cornelius Thomas Cornelius	HYDROXYCUT - AERS
2016-2808	04/05/2016 05/03/2016	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/ OC/ORO/	Rend Al-Mondhiry COUNCIL FOR RESPONSIBLE NUTRITION	GMP TRAINING, DIETARY SUPPLEMENT TRAINING, PROVIDED BY NATURAL PRODUCTS ASSOCIATION MARCH 2014 TO PRESENT TO ORA, CFSAN, REGIONAL/DISTRICT OFFICES AT FDA
2016-2809	04/05/2016 05/03/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joshua Klitzke SPECTRANETICS CORP	INDENA YUNG SHIN PHARMACEUTICAL CO LTD, SCINOPHARM TAIWAN LTD, ETC - 483 01/01/2010 - 04/01/2016
2016-2810	04/05/2016 05/03/2016	OC/CVM/OCD/	Kristi Smedley Center for Regulatory Services, Inc.	AAFCO 57.160 SUBMISSION RECS
2016-2811	04/05/2016 05/03/2016	OC/ORO/ OC/ORO/	Neil Intrater Neil Intrater	L'OREAL, REDKEN HAIR DYES, BLEACHES, HYDROGEN PEROXIDE DEVELOPER - COMPLAINTS 04/04/2006 - 04/04/2016
2016-2812	04/05/2016 05/03/2016	FDA/OO/OFBA/OAGS/	Rose Santos FOIA GROUP INC	HHSF223201000031 - CONTRACT, SOW, MODIFICATIONS ETC
2016-2813	04/05/2016 05/03/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ayan Nomura Financial Advisory Securities Pvt Ltd	DR REDDY - EIR 01/01/2014 - 04/01/2016
2016-2814	04/05/2016 06/02/2016	FDA/OFVM/CFSAN/OCD/EOS/	James Rathvon Paley Rothman	FCN 1445
2016-2815	04/05/2016 05/03/2016	FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/	Ian Sheffield Bridger Healthcare	ST JUDE MEDICAL, PLANO, TX - EIR 01/01/2014 - 04/04/2016
2016-2816	04/05/2016 05/03/2016	OC/ORO/ORM/ OC/ORO/ORM/	Genevieve Stevens Nivagen Pharmaceuticals, Inc.	LIST OF DOMESTIC AND FOREIGN PHARMACEUTICAL MANUFACTURING FACILITIES INSPECTIONS 03/01/2013 - 03/31/2016
2016-2817	04/05/2016 05/03/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Krishna Kiran Konduri Krishna Kiran, Spark Capital Advisors (I) Private Limited	LUPIN LIMITED, INDIA - 483 01/01/2016 - 04/01/2016

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2016-2818	04/05/2016 05/03/2016	FDA/OFVM/CFSAN/OCD/EOS/	Abhishek K. Gurnani Amin Talati & Upadhye, LLC	MEETING MINUTES FDA's GRAS NOTICE REVIEW TEAM 10/01/2015 - 12/31/2015
2016-2819	04/05/2016 05/03/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tushar Manudhane Indianivesh securities	LUPIN, INDIA - 483 01/01/2016 - 04/04/2016
2016-2820	04/05/2016 05/03/2016	FDA/OMPT/CDRH/OCE/DID/	Jonathan Elist Jonathan Elist	K983015
2016-2821	04/05/2016 05/03/2016	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 3/21-25/16
2016-2822	04/05/2016 05/03/2016	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 3/14-18/16
2016-2823	04/05/2016 05/03/2016	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 3/21-25/16
2016-2824	04/05/2016 05/03/2016	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 3/14-18/16
2016-2825	04/05/2016 05/03/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 3/21-25/16
2016-2826	04/05/2016 05/03/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 3/14-18/16
2016-2827	04/05/2016 05/03/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 3/21-25/16
2016-2828	04/05/2016 05/03/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 3/14-18/16
2016-2829	04/05/2016 05/03/2016	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 3/21-25/16
2016-2830	04/05/2016 05/03/2016	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 3/14-18/16

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2016-2831	04/05/2016 05/03/2016	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 3/21-25/16
2016-2832	04/05/2016 05/03/2016	FDA/OC/OES/DFOI/	KEN RIED WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 3/14-18/16
2016-2833	04/05/2016 05/03/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 3/21-25/16
2016-2834	04/05/2016 05/03/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 3/14-18/16
2016-2835	04/05/2016 05/03/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 3/21-25/16
2016-2836	04/05/2016 05/03/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 3/14-18/16
2016-2837	04/05/2016 05/03/2016	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 3/21-25/16
2016-2838	04/05/2016 05/03/2016	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 3/14-18/16
2016-2839	04/05/2016 05/03/2016	FDA/OC/OES/DFOI/	LESLIE RAMSEY FDA NEWS	FOI DAILY LOG 3/21-25/16
2016-2840	04/05/2016 05/03/2016	FDA/OC/OES/DFOI/	LESLIE RAMSEY FDA NEWS	FOI DAILY LOG 3/14-18/16
2016-2841	04/05/2016 05/03/2016	FDA/OC/OES/DFOI/	WILLIAM A OLSON Center for Regulator Services, Inc	FOI DAILY LOG 3/21-25/16
2016-2842	04/05/2016 05/03/2016	FDA/OC/OES/DFOI/	WILLIAM A OLSON Center for Regulator Services, Inc	FOI DAILY LOG 3/14-18/16
2016-2843	04/05/2016 05/03/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCE/DID/	RAY THOMPSON THOMPSON, RAY	MEDTRONIC INTERNATIONAL TRADING SARL, TOLOCHENAZ, SWITZERLAND 1/25-29/16; CELGENE CHEMICALS GMBH, ZOFINGEN, SWITZERLAND - 483S 1/25- 29/16
2016-2844	04/05/2016 05/03/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID HOFFMEISTER Wilson Sonsini Goodrich & Rosati	AMNEAL - ANDA 208-077 SBA

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-2845	04/05/2016 05/03/2016	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ALAN WITTENBERG LOPATIN & WITTENBERG	SANDOZ - INTROVALE RECALL RPTS, MEMOS 2011, 2012.2013
2016-2846	04/05/2016 06/17/2016	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORA/ OC/ORA/ FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	ANGELA M SPIVEY MCGUIREWOODS LLP	GOGO SQUEEZ - RECALL F-0012-2016 TO F-0024-2016 COMM WITH STATE OR LOCAL HEALTH ORGANIZATIONS, INTERVIEWS, RECORDINGS,ETC
2016-2847	04/05/2016 05/03/2016	OC/ORA/OCI/ OC/ORA/OCI/	CHRISTOPHER SOLIS GIDDENS GATTON JACOBUS PC	MOHAMED BASEL ASWARD MD, MISBRANDED DRUGS INVESTIGATION RECS
2016-2848	04/05/2016 05/03/2016	OC/ORA/ OC/ORA/	LESLIE T KRASNY Keller and Heckman LLP	KROGER, PALPHS, FRED MEYER, ETC - ICE CREAM AND ICE CREAM LIKE PRODS SPL, LAB RPTS, MICROBIOLOGICAL TESTING 3/1/15 TO 3/31/16
2016-2849	04/05/2016 05/03/2016	FDA/OMPT/CDRH/OCE/DID/	Joni Whitmore Baylor Scott & White Medical Center Carrollton	ROCHE DIAGNOSTICS ACCUCHECK INFORM II ETC - INTERFERING SUBSTANCES TESTED AND SUBMITTED TO FDA 01/01/2007 - 03/31/2016
2016-2850	04/05/2016 05/03/2016	FDA/OC/OCC/ OC/ORA/OCI/ OC/ORA/OCI/ OC/ORA/ OC/ORA/	Sarah N. Lynch, Reuters Sarah Lynch, Reuters	GEORGE KARAVETSOS, MARLENE FERNANDEZ-KARAVETSOS - RECS RE PAID PERMANENT CHANGE OF STATION MOVES 06/01/2014 - 03/31/2016
2016-2851	04/05/2016 05/03/2016	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Kelli Kennedy ASSOCIATED PRESS	JUICE BEAUTY, GEMDO COSMETICS - CORR WITH FDA, NOTES, SITE VISITS 01/01/2015 - 04/01/2016
2016-2852	04/05/2016 05/03/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bruce Hart SEATTLE GENETICS INC	ONIVYDE NDA 207793

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2016-2853	04/05/2016 05/03/2016	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Rohit Vanjani Rohit Vanjani	CATALENT, INC, ST PETERSBURG, FL - 483 03/14/2016 - 03/25/2016
2016-2854	04/05/2016 05/03/2016	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Kris Christian FDAZILLA	BRYAN CORPORATION, WOBURN, MA - 483 12/14/2011 - 12/15/2011
2016-2855	04/05/2016 05/03/2016	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Kris Christian FDAZILLA	PINE HOLLOW SPRINGS BOTTLING COMPANY INC, LOWELLVILLE, OH - 483 05/31/2011 - 05/31/2011
2016-2856	04/05/2016 05/03/2016	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Kris Christian FDAZILLA	PINE HOLLOW SPRINGS BOTTLING COMPANY INC, LOWELLVILLE, OH - 483 06/10/2015 - 06/10/2015
2016-2857	04/05/2016 05/03/2016	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Krishna Kiran Konduri Spark Capital Advisors (I) Private Limited	ALEMBIC PHARMACEUTICAL, INDIA - 483 01/01/2016 - 04/01/2016
2016-2858	04/05/2016 05/03/2016	OC/ORAOI/ OC/ORAOI/	Sarah N. Lynch, Reuters Sarah Lynch, Reuters	ANNUAL STATISTICS FOR PROSECUTIONS, ARRESTS, AND OPENED CASES 01/01/2008 - 03/31/2016
2016-2859	04/05/2016 05/03/2016	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Dr Kirill Milchakov I.M.Sechenov First Moscow Medical University	3% HYDROGEN PEROXIDE - NONCLINICAL OVERVIEW, NONCLINICAL SUMMARY 04/01/1950 - 04/01/2016
2016-2860	04/05/2016 05/03/2016	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Justin B. Brown JONES WARD PLC	FLUROQUINOLONE CASE REPORTS
2016-2861	04/05/2016 05/03/2016	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Donna Domingo Donna Domingo	AUREX LABORATORIES, EAST WINDSOR, NJ - COMPLAINT 140596, EIR, 483 ETC
2016-2862	04/05/2016 05/03/2016	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Brandon Feldcher Insight Instruments, Inc.	OCULUS SURGICAL, INC, PORT ST LUCIE, FL - EIR, WARNING LETTERS 01/01/2015 - 03/31/2016
2016-2863	04/05/2016 05/03/2016	FDA/OMPT/CDRH/OCE/DID/	Robyn Bonnett Robyn Bonnett	K152009 FILING REJECTIONS, ACCEPTANCES
2016-2864	04/06/2016 05/04/2016	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Pascal Besman Pascal Besman	VELTASSA - AERS
2016-2865	04/06/2016	FDA/OMPT/CDER/ERP/DIDP/	Pascal Besman	IBRANCE - AERS

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	05/04/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Pascal Besman	
2016-2866	04/06/2016 05/04/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dennis Everton Celgene Corporation	NDA 208246 SBA
2016-2867	04/06/2016 05/04/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Stephen Matics, PharmD Medical University of South Carolina: MUSC Drug Information Center	VISTOGARD - APPROVAL RECS
2016-2868	04/06/2016 05/04/2016	FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/ FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	Ian Sheffield Bridger Healthcare	SJ JUDE MEDICAL, INC, SUNNYVALE, CA; MINNETONKA, MN - EIR, 483, CORR 01/01/2014 - 04/04/2016
2016-2869	04/06/2016 05/04/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Amanda Nissen Amanda Nissen	ZMAPP - APPROVAL, CLINICAL TRIALS 01/01/2013 - 02/29/2016
2016-2870	04/06/2016 05/04/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	sandy suh Exeltis	ANDA 202085 BIOEQUIVALENCE REVIEW
2016-2871	04/06/2016 05/04/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	sandy suh Exeltis	ANDA 076675 BIOEQUIVALENCE REVIEW
2016-2872	04/06/2016 05/04/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Pascal Besman Pascal Besman	TAGRISSO - AERS
2016-2873	04/06/2016 05/04/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	sandy suh Exeltis	ANDA 076915 BIOEQUIVALENCE REVIEW

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-2874	04/06/2016 05/04/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Felice Sommerfield Fresenius Kabi USA LLC (Felice Sommerfield)	BENDEKA SBA
2016-2875	04/06/2016 05/04/2016	FDA/OMPT/CTP/OD/	Desmond Jenson Tobacco Control Legal Consortium	Potential Tobacco Violation Report ID14L00001
2016-2876	04/06/2016 05/04/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	sandy suh Exeltis	ANDA 091234 BIOEQUIVALENCE REVIEW
2016-2877	04/06/2016 05/04/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	sandy suh Exeltis	ANDA 201887 BIOEQUIVALENCE REVIEW
2016-2878	04/06/2016 05/04/2016	FDA/OMPT/CDRH/OCE/DID/	Alison Sathe Alison Sathe	K152915
2016-2879	04/06/2016 05/04/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	sandy suh Exeltis	ANDA 202789 BIOEQUIVALENCE REVIEW
2016-2880	04/06/2016 05/04/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCE/DID/	THOMPSON, RAY	PURAC BIOCHEM BV, GORINCHEM, NETHERLANDS 12/7/15-12/11/15; PHILIPS MEDICAL SYSTEMS, NETHERLANDS 2/1-5/16 - 483
2016-2881	04/06/2016 05/04/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WASHINGTON 301901, JAMES	RISPERDIOL - AER
2016-2882	04/06/2016 05/04/2016	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDER/GRP/DIDP/	MICHAEL D. LEVIN HEALTH BUSINESS STRATEGIES	SPECIALITY ENZYMES & BIOTECHNOLOGY, CHINO, CA; AST ENZYMES, CHINO, CA; ADVANCED ENZYME TECHNOLOGIES LTD, MALEGAON MIDC - EIR, 483, WARNING LTRS, CO RESP 1/09 TO 3/28/16

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2016-2883	04/06/2016 05/04/2016	FDA/OMPT/CDRH/OCE/DID/	ANDREAS PIGNI REGENLAB	IBSA INSTITUT BIOCHIMIQUE SA - SINOVIOL PMA P110005
2016-2884	04/06/2016 05/04/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ERIKA LIETZAN UNIVERSITY OF MISSOURI	NEW DRUG APPLICATIONS APPROVED 2007 - 2011
2016-2885	04/06/2016 05/04/2016	FDA/OC/OES/DFOI/	JAMES, ROBERT M	EMPLOYEE CONTACT LIST
2016-2886	04/06/2016 05/04/2016	FDA/OFVM/CFSAN/OCD/EOS/	DENNIS 1225369, JAMES	LIQUID CAUSTIC ACID - DANGERS WHEN MISHANDLED DURING THE CANNING PROCESS
2016-2887	04/06/2016 05/04/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KRISHNAN IYER SITEC LABS PVT LTD	DR ARINDAM DASGUPTA, MR JANG IK LEE , HECTOR COLON TORRES 11/15-18/11; DR GOPA BISWAS 6/17-21/13; SANDRA SANIGA 2/16-20/15 - EIR
2016-2888	04/06/2016 05/04/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/ORO/ OC/ORO/ FDA/OGROP/ORO/RO/DIOP/ FDA/OGROP/ORO/PA-FO/SEA-DO/SEA-CB/	JOHN F. JOHNSON III, Esq. BENJAMIN L ENGLAND & ASSOCIATES LLC	VIVA PHARMACEUTICAL - POTASSIUM CHLORIDE IMPORT & EXPORT 10/1/11 TO PRESENT
2016-2889	04/06/2016 05/04/2016	FDA/OMPT/CDRH/OCE/DID/	CHRISTOPHER J. PREDKO WARNER NORCROSS & JUDD LLP	SECURUS INC - IRTS THERMAL IMAGING PROBE K152402
2016-2890	04/06/2016 05/04/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KATE REYNOLDS ROCKY MOUNTAIN POISON & DRUG CENTER	4Q2015 - FAERS
2016-2891	04/06/2016	FDA/OMPT/CDER/GRP/DIDP/	KATE REYNOLDS	7175048, 11595030, 11622348, ETC - ACETAMINOPHEN

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	05/04/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ROCKY MOUNTAIN POISON & DRUG CENTER	PREPARATIONS - ISRS 7175048, 8664609, 8747119, ETC
2016-2892	04/06/2016 05/04/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ERIC J. ROTHSCHILD PEPPER HAMILTON LLP	AVANDIA NDA 21-071/S038 MTGS, CORR, RVWS
2016-2893	04/06/2016 05/04/2016	FDA/OGROP/ORACE-FO/CHI- DO/CHI-CB/ FDA/OGROP/ORACE-FO/MIN- DO/MIN-CB/ FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/ FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORAPA-FO/SAN- DO/SAN-CB/ FDA/OMPT/CDRH/OCE/DID/	MOHIT BHAT KLINE GROUP	STELLARTECH RESEARCH CORP, MILPITAS, CA; BOSTON SCIENTIFIC CORP, SAN JOSE, CA; ST JUDE MEDICAL, PLYMOUTH, MN - EIR
2016-2894	04/06/2016 05/04/2016	FDA/OMPT/CDRH/OCE/DID/	DANIEL I.A. SMULIAN GREENBERG TRAUIG	QUADROX I MICROPOROUS MEMBRANE OXYGENATORS, QUADROX ID DIFFUSION MEMBRANE OXYGENATORS, QUADROX IR HLS MODULES, ETC - CORR
2016-2895	04/06/2016 05/04/2016	FDA/OMPT/CDRH/OCE/DID/	DANIEL I.A. SMULIAN GREENBERG TRAUIG	QUADROX I ADULT, SMALL ADULT, PEDIATRIC, NEONATAL MICROPOROUS MEMBRANE OXYGENATORS K132829; QUADROX I ADULT, SMALL ADULT OXYGENATORS WITH & WITHOUT FILTER K150267
2016-2896	04/06/2016 05/04/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-860 - REQUEST LETTER ONLY
2016-2897	04/06/2016 05/04/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-859 - REQUEST LETTER ONLY
2016-2898	04/06/2016 05/04/2016	FDA/OMPT/CDRH/OCE/DID/	DANIEL I.A. SMULIAN GREENBERG TRAUIG	JOSTRA QUADROX D DIFFUSION MEMBRANE OXYGENATOR W/BIOLINE COATING K071774
2016-2899	04/06/2016 05/04/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-743 - REQUEST LETTER ONLY
2016-2900	04/06/2016 05/04/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-922 - REQUEST LETTER ONLY
2016-2901	04/06/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2016-925 - REQUEST LETTER ONLY

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	05/04/2016		MERCK & CO., INC.	
2016-2902	04/06/2016 05/04/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-1062 - REQUEST LETTER ONLY
2016-2903	04/06/2016 05/04/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-1361 - REQUEST LETTER ONLY
2016-2904	04/06/2016 05/04/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-1198 - REQUEST LETTER ONLY
2016-2905	04/06/2016 05/04/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-1005 - REQUEST LETTER ONLY
2016-2906	04/06/2016 05/04/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-1067 - REQUEST LETTER ONLY
2016-2907	04/06/2016 05/04/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-1084 - REQUEST LETTER ONLY
2016-2908	04/06/2016 05/04/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-1087 - REQUEST LETTER ONLY
2016-2909	04/06/2016 05/04/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-1121 - REQUEST LETTER ONLY
2016-2910	04/06/2016 05/04/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-1132 - REQUEST LETTER ONLY
2016-2911	04/06/2016 05/04/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-1216 - REQUEST LETTER ONLY
2016-2912	04/06/2016 05/04/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-1336 - REQUEST LETTER ONLY
2016-2913	04/06/2016 05/04/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-1391 - REQUEST LETTER ONLY
2016-2914	04/06/2016 05/04/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-1541 - REQUEST LETTER ONLY
2016-2915	04/06/2016 05/04/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-1549 - REQUEST LETTER ONLY
2016-2916	04/06/2016 05/04/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-1207 - REQUEST LETTER ONLY
2016-2917	04/06/2016 05/04/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-1555 - REQUEST LETTER ONLY

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2016-2918	04/06/2016 05/04/2016	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OMPT/CDRH/OCE/DID/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	TANYA GUARISCO BRUCE G CLARK & ASSOCIATES PC	BROKEN OR MISUSED DIALYSIS MACHINE TUBING, LUER ADAPTER, ETC
2016-2919	04/06/2016 05/04/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-1197 - REQUEST LETTER ONLY
2016-2920	04/06/2016 05/04/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-1199 - REQUEST LETTER ONLY
2016-2921	04/06/2016 05/04/2016	OC/ORAE/ OC/ORAE/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Ingrid Chrisco Ingrid Chrisco, True North Granola, LLC	911936, 948373, 948374 SAMPLE RECS
2016-2922	04/06/2016 05/04/2016	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	Gregory Goei Par Pharmaceuticals	CATALENT PHARMA SOLUTIONS, LLC, ST PETERSBURG, FL - EIR, 483 01/01/2009 - 12/31/2013
2016-2923	04/06/2016 05/04/2016	OC/ORAE/ORM/ OC/ORAE/ORM/	Nadja Popovich THE GUARDIAN	RECORD LAYOUTS FOR DATABASES CONTAINING INFORMATION ABOUT AIRLINE FOOD INSPECTION, SANITATION 01/01/2011 - 04/04/2016
2016-2924	04/06/2016 05/04/2016	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Gregory Goei Par Pharmaceuticals	CATALENT PHARMA SOLUTIONS, LLC, SOMERSET, NJ - EIR, 483 10/01/2012 - 04/01/2013
2016-2925	04/06/2016 05/04/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOSEPH WALKER Walker, Joseph	ZGN-440 AERS
2016-2926	04/06/2016 05/04/2016	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Aaron Smith-Levin OTG Research Group	CATALENT PHARMA, ST PETERSBURG, FL - 483 03/01/2016 - 04/05/2016
2016-2927	04/06/2016 05/04/2016	FDA/OC/OES/DDM/	Kristi Smedley Center for Regulator Services, Inc	Environmental Assessment and FONSI found in Docket 1995F0221 Natamycin Food by DuCott
2016-2928	04/06/2016 05/04/2016	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Sharon Gardner Gardner, Sharon	CATALENT INC, ST PETERSBURG, FL - 483 03/14/2016 - 03/25/2016
2016-2929	04/07/2016 05/05/2016	FDA/OC/OES/DFOI/	Oscar Ulises Preciado Olvera Universidad Nacional de Tucumán	Barker FM and Brainard GC (1991) The Direct Spectral Transmittance of the Excised Human Lens as a Function of Age (FDA 785345 0090 RA), U.S. Food and Drug Administration,

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				Washington, DC
2016-2930	04/07/2016 05/05/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Leanne Usa Wockhardt USA LLC	ANDA 205675 APPROVAL LETTER
2016-2931	04/07/2016 05/05/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Meg Morgen Baird	ZEPATIER - AERS
2016-2932	04/07/2016 05/05/2016	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	Trevor Campbell Trevor Campbell	CATALENT, ST PETERSBURG, FL - 483, CORR 03/13/2016 - 04/04/2016
2016-2933	04/07/2016 05/05/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Maria E. Doukas Morgan, Lewis & Bockius LLP	NDA 020845 - Form 3542
2016-2934	04/07/2016 05/05/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dustin Block IPD Analytics, LLC	NDA 017861 S009 LABELING REVISION
2016-2935	04/07/2016 05/05/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/OSMP/OOPD/	Giuseppa Gennaro Klox Technologies Inc.	SCIODERM INC, ALWYN COMPANY, INC, - APPROVALS, LETTERS, REVIEWS ETC RE ALLANTOIN
2016-2936	04/07/2016 05/05/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SIDDHARTH KARNAWAT SIDDHARTH KARNAWAT	LUPIN, GOA, INDIA - 483 01/01/2016 - 04/04/2016
2016-2937	04/07/2016 05/05/2016	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	LeAnn Seidl-Kollmer Nature's Way Product	SWISS CAPS, MIAMI, FL - EIR, 483, WARNING LETTER 04/01/2011 - 04/05/2016
2016-2938	04/07/2016 05/05/2016	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	Brian Kimmons Brian Kimmons	CATALENT, ST PETERSBURG, FL - 483 03/01/2016 - 04/05/2016
2016-2939	04/07/2016	FDA/OMPT/CDER/GRP/DIDP/	Jay Singhania	GLATOPA - AERS

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	05/05/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Singhania, Jay K	
2016-2940	04/07/2016 05/05/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Genevieve Stevens Nivagen Pharmaceuticals, Inc.	NDC 0187-5190-25, 0187-5190-35, 0187-5190-50, and NDA 050756 SBA
2016-2941	04/07/2016 05/05/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Genevieve Stevens Nivagen Pharmaceuticals, Inc.	NDC 0187-5198-04, NDA 019931 SBA
2016-2942	04/07/2016 05/05/2016	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Fran Silverman truthinadvertising.org	LIPOZENE, OBESITY RESEARCH INSTITUTE, CARLSBAD, CA, RENO, NV - AERS, 483
2016-2943	04/07/2016 05/05/2016	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	Lauren Blomberg Parexel International	CHETA NAND, MD, RICHLAND, WA - 483, EIR 10/06/2015 - 10/30/2015
2016-2944	04/07/2016 05/05/2016	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	Scott McCoy Scott McCoy	CATALENT, ST PETERSBURG, FL - 484 03/14/2016 - 03/29/2016
2016-2945	04/07/2016 05/05/2016	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	Jared Meggison JEFFERIES & CO	CATALENT PHARMA SOLUTIONS, ST PETERSBURG, FL - 483 03/10/2016 - 03/31/2016
2016-2946	04/07/2016 05/05/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joshua James Brinks Gilson & Lione	NDA 020947
2016-2947	04/07/2016 05/05/2016	FDA/OMPT/CDRH/OCE/DID/	Jane McCarthy Jane McCarthy	K152954
2016-2948	04/07/2016 05/05/2016	FDA/OMPT/CDRH/OCE/DID/	Holly Hallock TELEFLEX MEDICAL	K152082
2016-2949	04/07/2016	FDA/OMPT/CDER/GRP/DIDP/	Hajra Mazhar	CASE REPORTS 6867898; 6882788; 6902426; ETC

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	05/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Hajra Mazhar (University of Ottawa)	
2016-2950	04/07/2016 05/05/2016	FDA/OMPT/CDRH/OCE/DID/	Easton Riley-Massie RILEY LAW FIRM	CASE REPORT 4115651 RECS
2016-2951	04/07/2016 05/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Susan D. Macafee MACAFEE, S	HENRY SCHEIN PRIVATE LABEL BRANCH MEPIVACANE HYDROCHLORIDE 3%, HENRY SCHEIN PRIVATE LABEL BRAND MEPIVACANE HYDROCHLORIDE WITH LEVONORDEFIN 2% - REGISTRATION, REMOVAL ETC 01/01/2009 - 04/05/2016
2016-2952	04/07/2016 05/05/2016	FDA/OMPT/CDRH/OCE/DID/	Sun Choi ADVANCED STERILIZATION PRODUCTS	K140392
2016-2953	04/07/2016 05/05/2016	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	James McNeal National Enzyme Company, LLC	NUTRITION FORMULATORS, INC - 483, RESPONSE, EIR ETC 06/01/2014 - 04/06/2016
2016-2954	04/07/2016 05/05/2016	FDA/OMPT/CDRH/OCE/DID/	Steven Gunderson Steven Gunderson	THINPREP 2000 S011 APPROVAL REQUIRED FOR ADDITIONAL MANUFACTURING SITE FOR FILTER MANUFACTURER
2016-2955	04/07/2016 05/05/2016	FDA/OGROP/ORAPPA-FO/SEA-DO/SEA-CB/	John Walsh James Alexander Corporation	ROCKY MOUNTAIN BIOLOGICALS, INC, MISSOULA, MONTANA - EIR, 483, RECALL RECS 04/01/2012 - 04/06/2016
2016-2956	04/07/2016 05/05/2016	FDA/OMPT/CDRH/OCE/DID/	Marc C. Sanchez Contract In-House Counsel & Consl. LLC	ECLIPSE AESTHETICS, LLC - 510K RECS FOR MICRONEEDLING DEVICE
2016-2957	04/07/2016 05/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Neil D. Overholtz Aylstock, Witkin, Kreis & Overholtz, PLLC	LIST OR APPROVED PROTON PUMP INHIBITOR DRUGS 01/01/1992 - 04/06/2016
2016-2958	04/07/2016 05/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ross Weistroffer Ross Weistroffer	RECS SENT BY FDA TO DEA RE RECOMMENDATION FOR SCHEDULING OF MARIJUANA UNDER CONTROLLED SUBSTANCES ACT 08/17/2015 - 09/30/2015
2016-2959	04/07/2016 05/05/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Kris Christian FDAZILLA	CRUCCELL SWITZERLAND AG - EIR 09/08/2015 - 09/10/2015
2016-2960	04/07/2016 05/05/2016	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Roberto Ledesma Lewis & Lin, LLC	MOSCOT WHOLESALE CORP - COMPLAINT RECS, NOTICES OF INSPECTION 11/03/2015 - 04/06/2016

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2016-2961	04/07/2016 05/05/2016	FDA/OMPT/CDRH/OCE/DID/	David Clapper Minerva Surgical Inc.	CPT1400954
2016-2962	04/07/2016 05/05/2016	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Betsy Green Betsy Green Hankins	SABRA DIPPING COMPANY, COLONIAL HEIGHTS, VA-INSPECTION RECS ETC 09/01/2016 - 04/05/2016
2016-2963	04/07/2016 05/05/2016	OC/ORAOI/ OC/ORAOI/	Sarah N. Lynch, Reuters Sarah Lynch, Reuters	ANNUAL BREAKDOWN OF INTERNAL AFFAIRS STATISTICS 01/01/2012 - 04/06/2016
2016-2964	04/07/2016 05/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN BIRRENBACH INSTITUTE FOR CANNABIS	CORR FROM DEA REGARDING MARIJUANA SINCE 2012
2016-2965	04/07/2016 05/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JENNIFER NICHOLSON PILLAR5 PHARMA INC	ASPEN SVP PTY LTD, SOUTH AFRICA - EIR 5/1/12 TO 4/6/16
2016-2966	04/07/2016 05/05/2016	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	JONES, DAVID	THERANOS INC, PALO ALTO - 483 12/1/15 TO 3/31/16
2016-2967	04/07/2016 05/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MANDINA, VINCENT	OPKO HEALTH INC - RAYALDEE NDA 3/14-25/15
2016-2968	04/07/2016 05/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	THOMPSON, RAY	ALKEM LABORATORIES LTD, ANKLESHWAR, INDIA 9/14-18/15 & SOLAN, HIMACHAL PRADESH, INDIA 7/27-31/15; AUROBINDO PHARMA LTD, HYDERABAD, INDIA 6/18-26/15 - 483
2016-2969	04/07/2016 05/05/2016	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	THOMPSON, RAY	ST JUDE MEDICAL, ATLANTA, GA 6/6-26/15; HOSPIRA, ROCKY MOUNT, NC 9/14-24/15; UNIT DOSE SOLUTIONS INC 7/20-23/15 - 483
2016-2970	04/07/2016 05/05/2016	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	THOMPSON, RAY	GE HEALTHCARE, LAUREL MD 6/1-19/15; AG ESSENCE INC, RICHMOND, VA 3/30/15-5/14/15; TRYCO INC, MCLEAN, VA 6/28/15-7/23/15 - 483
2016-2971	04/07/2016 05/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	THOMPSON, RAY	AFFINITY BIOLOGICALS INC, ANCASTER, CANADA 6/8-11/15; AMVEX CORP, RICHMOND HILL, CANADA 6/15-18/15; BATRIK MEDICAL MFG INC, DORVAL, CANADA 7/13-16/15 - 483

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		FDA/OMPT/CDRH/OCE/DID/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/		
2016-2972	04/07/2016 05/05/2016	FDA/OGROP/ORACE-FO/CIN- DO/CIN-CB/	THOMPSON, RAY	DIAPHARMA GROUP INC, WEST CHESTER, OH 8/20-31/15; TRANSDERMAL CAP INC, CLEVELAND, OH 6/11-30/15 - 483
2016-2973	04/07/2016 05/05/2016	FDA/OFVM/CFSAN/OCD/EOS/	COLLEEN M. EVALE Keller and Heckman LLP	FCN 883
2016-2974	04/07/2016 05/05/2016	OC/ORACE/ OC/ORACE/	LESLIE T. KRASNY Keller and Heckman LLP	KROGER. RALPHS, FRED MEYER, ETC - ICE CREAM PRODUCTS TESTED FOR LISTERIA 3/1-31/16
2016-2975	04/07/2016 05/05/2016	FDA/OFVM/CFSAN/OCD/EOS/	JEREMY JOHNSON TADITIONAL MEDICINALS	ORGANIC INDIA - CORR ON DIETARY SUPPLEMENTS
2016-2976	04/07/2016 05/05/2016	FDA/OC/OES/DFOI/	AMIE N. VANELLA FAEGRE BAKER DANIELS	SIMPLY THICK LLC - FOI 12/9/15 TO PRESENT
2016-2977	04/08/2016 05/06/2016	OC/ORACE/ OC/ORACE/ FDA/OGROP/ORACE/ORO/DIOP/	Zetetic, Inc. Zetetic, Inc.	FDA ENTRY DOCUMENTATION REQUEST ALL DOCUMENTATION 03/16/2016 - 03/31/2016
2016-2978	04/08/2016 05/06/2016	FDA/OMPT/CDRH/OCE/DID/	Doe J	CPT1500805 RECS
2016-2979	04/08/2016 05/06/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	GLATOPA, GLATIRAMER ACETATE, COPAXONE - FAERS
2016-2980	04/08/2016 05/06/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gaurav Tlnani Emkay Global Financial Services Limited	LUPIN LTD, INDIA - 483 01/11/2016 - 01/15/2016
2016-2981	04/08/2016 05/06/2016	FDA/OGROP/ORACE-FO/FLA- DO/FLA-CB/	Yashieka Blount Kedrion Biopharma Inc.	BIOTEST PHARMACEUTICALS CORPORATION, BOCA RATON, FL - 483, EIR 01/01/2016 - 03/31/2016
2016-2982	04/08/2016 05/06/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	David Knauss AMAG Pharmaceuticals	DELALUTIN (NDA 010347), DELALUTIN (NDA 016911) SBA
2016-2983	04/08/2016	OC/CVM/OCD/	Kelly Beers (US Agent for Huvepharma EOOD)	VMF 5-284

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	05/06/2016		Huvepharma, Inc.	
2016-2984	04/08/2016 05/06/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Erica L Nicoll Novum Pharmaceutical Research Services	ANDA 208077
2016-2985	04/08/2016 05/06/2016	OC/ORO/OCI/ OC/ORO/OCI/	Sarah N. Lynch, Reuters Sarah Lynch, Reuters	A breakdown by FDA OCI field office of the number of man hours spent per year working on investigations pertaining to foreign unapproved medical products 01/01/2012 - 12/31/2015
2016-2986	04/08/2016 05/06/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Brian Zeiler Brian Zeiler	SCHEDULING MARIJUANA - RECOMMENDATIONS TO FDA 01/01/2014 - 03/31/2016
2016-2987	04/08/2016 05/06/2016	FDA/OMPT/CTP/OD/	Desmond Jenson Tobacco Control Legal Consortium	WARNING PLANS RE ADVERTISING - ALTADIS USA, INC, AMERICAN SNUFF CO, ETC 01/01/2010 - 12/31/2014
2016-2988	04/08/2016 05/06/2016	OC/ORO/OCI/ OC/ORO/OCI/	Sarah N. Lynch, Reuters Sarah Lynch, Reuters	Copies of any and all lab analysis reports from the investigative case files related to certain counterfeit drug investigations 01/01/2011 - 04/06/2016
2016-2989	04/08/2016 05/06/2016	FDA/OMPT/CDRH/OCE/DID/	Dave Hernon SonaCare Medical, LLC	EDAP TMS FRANCE S.A., EDAP TECHNOMED, INC - EIR, 483, RESPONSE ETC 01/01/2010 - 04/06/2016
2016-2990	04/08/2016 05/06/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dustin Block IPD Analytics, LLC	ANDA 202999
2016-2991	04/08/2016 05/06/2016	FDA/OFVM/CFSAN/OCD/EOS/	Sam Harper-Russell University of Queensland	BENZENE IN BEVERAGES GUIDANCE RECOMMENDATIONS
2016-2992	04/08/2016 05/06/2016	FDA/OMPT/CDRH/OCE/DID/	Barry S. Kelley Kelley, Barry	K151622
2016-2993	04/08/2016 05/06/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Maja Vencl-Joncic Glenmark Pharmaceuticals Inc	NDA 013790
2016-2994	04/08/2016 05/06/2016	FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	TEBBI CAMERON, TAMPA, FL - EIR, 483, RESPONSE 06/29/2015 - 07/02/2015
2016-2995	04/08/2016	FDA/OMPT/CDRH/OCE/DID/	John Zhuang	K072687

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	05/06/2016		JOHNSON & JOHNSON	
2016-2996	04/08/2016 05/06/2016	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	NAVILYST MEDICAL, MARLBOROUGH, MA - EIR, 483, RESPONSE 04/09/2014 - 05/28/2014
2016-2997	04/08/2016 05/06/2016	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	BAXTER HEALTHCARE SA, DBA BAXTER HEALTHCARE OF PUERTO RICO, AIBONITO, PR - EIR, 483, RESPONSE 03/10/2014 - 05/12/2014
2016-2998	04/08/2016 05/06/2016	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	TRI-TECH MANUFACTURING, RAPID CITY, SD - EIR, 483, RESPONSE 03/01/2015 - 04/03/2015
2016-2999	04/08/2016 05/06/2016	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Walter Chalkley THOMSON REUTERS	AIRGAS USA, LLC, LANSING, MI - EIR, 483, RESPONSE 03/18/2014 - 03/19/2014
2016-3000	04/08/2016 05/06/2016	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Walter Chalkley THOMSON REUTERS	GENTELL, BRISTOL, PA - EIR, 483, RESPONSE 07/29/2015 - 08/25/2015
2016-3001	04/08/2016 05/06/2016	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	ALEXANDER NEUMEISTER, NY, NY - EIR, 483, RESPONSE 07/16/2015 - 08/05/2015
2016-3002	04/08/2016 05/06/2016	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	Walter Chalkley THOMSON REUTERS	CHETA NAND, MD, RICHLAND, WA - EIR, 483, RESPONSE 10/06/2015 - 10/30/2015
2016-3003	04/08/2016 05/06/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Walter Chalkley THOMSON REUTERS	TAISHO PHARMACEUTICAL, CO, SAITAMA, JAPAN - 483 11/24/2015 - 11/27/2015
2016-3004	04/08/2016 05/06/2016	FDA/OMPT/CDRH/OCE/DID/	Francisco Valero Francisco Valero	K052309 K942694
2016-3005	04/08/2016 05/06/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ken Faenza Ascendant Mfg	NDA 008975 NDA 009854
2016-3006	04/08/2016 05/06/2016	FDA/OPPLA/OL/ FDA/OC/OES/ FDA/OFVM/CFSAN/OCD/EOS/	Bruce Friedrich The Good Food Institute	RECS RE 5/25/12 LETTER TO COMMISSIONER HAMBURG FROM SENATORS DAN COATS, RICHARD LUGAR, KIRSTEN GILLIBRAND RE STANDARDS OF IDENTITY AND DAIRY PRODUCTS 04/28/2010 - 04/07/2016
2016-3007	04/08/2016 06/09/2016	OC/CVM/OCD/ FDA/OFVM/CFSAN/OCD/EOS/	Kim E. Richman The Richman Law Group	GLYPHOSATE RESIDUE LEVELS RECS

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2016-3008	04/08/2016 05/06/2016	FDA/OFVM/CFSAN/OCD/EOS/	CAP of iron oxides (CAS Reg. No. 1332-37-2) Seinoh Optical Co., Ltd	CAP of iron oxides (CAS Reg. No. 1332-37-2), Color Index No. 77491
2016-3009	04/08/2016 05/06/2016	FDA/OC/OES/DDM/ FDA/OFVM/CFSAN/OCD/EOS/	Bruce Friedrich The Good Food Institute	RECS RE 2/28/97 CITIZEN PETITION FILED BY SOYFOODS ASSOCIATION OF AMERICA 97P-0078
2016-3010	04/08/2016 05/06/2016	FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORR/PA-FO/SAN-DO/SAN-CB/ FDA/OFVM/CFSAN/OCD/EOS/	Bruce Friedrich The Good Food Institute	RECS FROM SAN FRANCISCO DISTRICT, LOS ANGELES DISTRICT 2011-2012 RE SOY MILK, SOYMILK, SOY BEVERAGE, ETC
2016-3011	04/08/2016 05/06/2016	FDA/OMPT/CDRH/OCE/DID/	Marc C. Sanchez, Esq. Contract In-House Counsel & Consl. LLC	Additional Information requests or Not-Substantially Equivalent (NSE) notices sent to Refine USA LLC or its Agent in regards to a 510(k) submission for its Rejuvopen device
2016-3012	04/08/2016 05/06/2016	FDA/OMPT/CDRH/OCE/DID/ FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/	Elizabeth Ryan Bailey & Glasser LLP	ALERE INRATIO, INRATIO2 - AERS, COMPLAINTS, COMMUNICATIONS RE RECALL 04/01/2008 - 12/04/2014
2016-3013	04/08/2016 05/06/2016	FDA/OMPT/CDRH/OCE/DID/	St. Jude Bijan Khajebag	LETTERS FROM ST JUDE MEDICAL INFORMATION HOSPITALS AND DOCTORS ABOUT ATLAS DEFIBRILLATOR/PACEMAKERS 01/01/2005 - 01/01/2007
2016-3014	04/08/2016 05/06/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gaurav Tinani Emkay Global Financial Services Limited	CADILA HEALTHCARE LIMITED, INDIA - 483 08/28/2014 - 09/05/2014
2016-3015	04/08/2016 06/20/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Anju Kurian Fresenius Kabi USA	BK080010 BK080043
2016-3016	04/08/2016 05/06/2016	FDA/OC/OES/DFOI/	Jorge Millan hialeah technology center	K071638
2016-3017	04/11/2016 05/09/2016	OC/CVM/OCD/	CLARK SULLIVAN TROUTMAN SANDERS LLP	ULCEGARD (OMEPRAZOLE) NADA 141-227, GASTROGARD (OMEPRAZOLE) NADA 141-123 - SAFETY AND EFFECTIVENESS DATA
2016-3018	04/11/2016 05/09/2016	OC/ORR/ OC/ORR/ FDA/OGROP/ORR/NE-FO/NYK-DO/NYK-DCB/	PATRICK BROWN JUICES INTERNATIONAL INC	CARRORTJUICE DRINK, BEET AND CARROT DRINK, GINGER DRINK, ETC - CLOSTRIDIUM BOTULINUM TEST RESULTS
2016-3019	04/11/2016 05/09/2016	FDA/OC/OES/ FDA/OMPT/CDRH/OCE/DID/	AVA M PAQUETTE CITIZENS COMMISSION ON	ELECTROCONVULSIVE THERAPY (ECT) - RECLASSIFICATION FROM CLASS III TO CLASS II 1976 TO 2008

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			HUMAN RIGHTS INTERNATIONAL	
2016-3020	04/11/2016 05/09/2016	FDA/OFVM/CFSAN/OCD/EOS/	COLLEN M EVALE Keller and Heckman LLP	EMS-CHEMIE AG - FCN 883
2016-3021	04/11/2016 05/09/2016	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/	KELLY WARREN MARJON SPECIALTY FOODS INC	LISTERIA MONOCYTOGENES SPLS 1101236-038, 1101236-033- PULSED-FIELD GEL ELECTROPHORESIS (PFGE) ANALYSIS
2016-3022	04/11/2016 05/09/2016	FDA/OO/OFBA/OAGS/	S ALBERT EDWARDS PHARM D S ALBERT EDWARDS PHARM D	SOLICITATION FDA-1161141
2016-3023	04/11/2016 05/09/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ALLI KATZEN Hyman, Phelps & McNamara P.C.	PROCYSBI (CYSTEAMINE BITRARTRATE) DELAYED-RELEASE CAPS NDA 203-389 BIOEQV REQUIREMENTS OR RECOMMENDATIONS
2016-3024	04/11/2016 05/09/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	MICHEL PLUESS FHNW OCHSCHULE FUER TECHNIK	ISRS 9101924, 9558229, 9715979, ETC
2016-3025	04/11/2016 05/09/2016	FDA/OMPT/CTP/OD/	BRYAN M HAYNES TROUTMAN SANDERS LLP	EXACT ELITE BLUE 100 SIZE SOFT PACK, MARKET MENTHOL GOLD KING SIZE SOFT PACK, NEW YORK NEW YORK NONFILTER KING SIZE SOFT PACK, ETC - SUBSTANTIAL EQUIVALENCE APPLICATIONS (SE RPTS)
2016-3026	04/11/2016 05/09/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DANIEL J CUSHING CUSHING, DANIEL J	NEXTERONE NDA 22-352,S001,S002,S003, ETC
2016-3027	04/11/2016 05/09/2016	FDA/OC/OES/DFOI/	ELENA HOWELL CLARK Hogan Lovells, ILP	2016-2281
2016-3028	04/11/2016 05/09/2016	FDA/OMPT/CDRH/OCE/DID/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ROBERT SCHIFF SCHIFF & COMPANY	ELI LILLY, NOVO NORDISK, SANOFI, ETC - PRE-FILLED INSULIN PENS 510K
2016-3029	04/11/2016	FDA/OMPT/CDER/ORP/DIDP/	JOHN BIRRENBACH	DEA RECS REGARDING SCHEDULING OF CANNABINIOL (CBD) 2004 TO 2008

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	05/09/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	INSTITUTE FOR CANNABIS	
2016-3030	04/11/2016 05/09/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LANON P SMITH SMITH #AK-1953, LANON P	ABILIFY - AERS
2016-3031	04/11/2016 05/09/2016	FDA/OMPT/CDRH/OCE/DID/	ulrika almhojd RLS Global AB	K141012
2016-3032	04/11/2016 05/09/2016	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	FCN 1604
2016-3033	04/11/2016 05/09/2016	FDA/OMPT/CDRH/OCE/DID/	Ashlee Edwards Winkler Parham Smith and Archenhold LLC	K052601
2016-3034	04/11/2016 05/09/2016	FDA/OC/OES/DFOI/	Desmond Jenson Tobacco Control Legal Consortium	CTP FOIA LOG 06/22/2009 - 04/08/2016
2016-3035	04/11/2016 05/11/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Gina Mastrosimone Gina Mastrosimone	US Package Inserts for the vaccine PREVNAR 13 from the following dates: 1) Dec-2011 2) Jan-2013 3) Jan-2014 4) May-2015
2016-3036	04/11/2016 05/09/2016	FDA/OMPT/CDRH/OCE/DID/	Ed Speegle ANYBATTERY INC	K963305
2016-3037	04/11/2016 05/09/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K873422
2016-3038	04/11/2016 05/09/2016	FDA/OMPT/CDRH/OCE/DID/	Jing Gu W.H.P.M., Inc.	K143325
2016-3039	04/11/2016 05/09/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K864959
2016-3040	04/11/2016 05/09/2016	FDA/OMPT/CDRH/OCE/DID/	Margaret Dillon bioinspire technologies	K052099
2016-3041	04/11/2016 05/09/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Becky Hartman Teva Pharmaceuticals	PROAIR RESPICLICK - AERS
2016-3042	04/11/2016 05/27/2016	FDA/OMPT/CDRH/OCE/DID/	Satohiko Takanashi Kowa Company, Ltd.	K122481

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2016-3043	04/11/2016 05/23/2016	FDA/OMPT/CDRH/OCE/DID/	Chris Hunter BIOMET	Biomet Polaris 5.5 system 510K
2016-3044	04/11/2016 05/09/2016	OC/ORR/ORM/ OC/ORR/ORM/	Yixin Iris Wang UNIVERSITY OF MICHIGAN	CDER INSPECTIONS 01/01/1998 - 12/31/2015
2016-3045	04/11/2016 05/09/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	Documents reflecting the FDA's practices regarding the timing or priority of the review or approval of ANDAs and PAs
2016-3046	04/11/2016 05/09/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Yixin Iris Wang UNIVERSITY OF MICHIGAN	DRUG SHORTAGE RECS 01/01/2001 - 12/31/2015
2016-3047	04/11/2016 05/09/2016	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	Amerx Health Care Corp. Amerx Health Care Corp.	AMERX HEALTH CARE CORP, CLEARWATER, FL - EIR 02/01/2014 - 06/01/2014
2016-3048	04/11/2016 05/09/2016	FDA/OGROP/ORR/CE-FO/PHI-DO/PHI-CB/	Kris Christian FDAZILLA	MEDIMMUNE LLC, PHILADELPHIA, PA - 483 05/12/2015 - 05/20/2015
2016-3049	04/11/2016 05/09/2016	FDA/OGROP/ORR/NE-FO/NYK-DO/NYK-DCB/	Kris Christian FDAZILLA	PFIZER, PEARL RIVER, NY - 483 10/14/2014 - 10/31/2014
2016-3050	04/11/2016 05/09/2016	FDA/OMPT/CDRH/OCE/DID/	Corinne Colaianni RMS Medical Products	Attachment 1. CDRH/OC/DOE A Assignment, dated 02 July 2010
2016-3051	04/11/2016 05/09/2016	FDA/OMPT/CDRH/OCE/DID/	Hui Ouyang Cook Medical	K113565
2016-3052	04/11/2016 05/09/2016	FDA/OMPT/CDRH/OCE/DID/	Hui Ouyang Cook Medical	K093847
2016-3053	04/11/2016 05/09/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	C. Leah Wood, MS RAC Anika Therapeutics, Incorporated	NDA 016466, S 013 S 015 S 045
2016-3054	04/11/2016 05/09/2016	OC/ORR/ORM/ OC/ORR/ORM/	Kris Christian FDAZILLA	LIST OF INSPECTIONS 03/09/2016 - 04/11/2016
2016-3055	04/11/2016 05/09/2016	FDA/OMPT/CDRH/OCE/DID/	ulrika almhojd RLS Global AB	K061467; K090791; K073547
2016-3056	04/11/2016	FDA/OMPT/CDER/ORP/DIDP/	Becky Hartman	ADASUVE - AERS

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	05/09/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Teva Pharmaceuticals	
2016-3057	04/11/2016 05/09/2016	OC/ORA/ORM/ OC/ORA/ORM/	Kris Christian FDAZILLA	LIST OF INSPECTION CITATIONS 04/12/2015 - 04/11/2016
2016-3058	04/11/2016 05/09/2016	FDA/OMPT/CDRH/OCE/DID/	Illumireg Inc. illumireg inc.	K142648
2016-3059	04/11/2016 05/09/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lorrie klemons Lorrie klemons	IVERMECTIN AERS
2016-3060	04/11/2016 05/09/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SIDDHARTH KARNAWAT SIDDHARTH KARNAWAT	GLENMARK PHRAMA, INDIA - 483 04/03/2015 - 04/11/2016
2016-3061	04/11/2016 05/09/2016	FDA/OMPT/CDRH/OCE/DID/	Jiefeng Xi Celerite Technology	K112770
2016-3062	04/11/2016 05/09/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Becky Hartman Teva Pharmacovigilance	QUARTETTE - AERS
2016-3063	04/11/2016 05/09/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	John Clark MD RISKBENEFITS LLC	MEDWATCH 6034773 6934827 8221295
2016-3064	04/11/2016 05/09/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Becky Hartman Teva Pharmaceuticals	ZECUITY - AERS
2016-3065	04/11/2016 05/09/2016	FDA/OMPT/CDRH/OCE/DID/	Dane Popovski illumireg inc.	K141474
2016-3066	04/11/2016 05/09/2016	FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	James Rogers Valinor Management	INSYS THERAPEUTICS, ROUND ROCK, TX - 483, WARNING LETTERS

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2016-3067	04/11/2016 05/09/2016	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Tom Pritchett BioQuality Newsletter	AJINOMOTO ALTHEA, INC, SAN DIEGO, CA - 483 : 08/06/15
2016-3068	04/12/2016 05/10/2016	OC/ORAOCI/ OC/ORAOCI/	Anthony Connors Anthony Connors	COMMUNICATIONS BETWEEN FDA OCI AND MICHAEL KEPLINGER AND KEVIN SMITH OF NUTRITION DISTRIBUTION AKA ATHLETIC XTREME 04/05/2016 - 04/08/2016
2016-3069	04/12/2016 05/10/2016	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/ OC/ORAO/ OC/ORAO/	Callan Stein Donoghue Barrett & Singal PC	PROTOCOLS, PROCEDURES, MANUALS ETC BY WHICH FDA EMPLOYEES SHOULD TAKE BIOLOGICAL SAMPLES FROM INSPECTED FACILITIES 01/01/2012 - 01/01/2013
2016-3070	04/12/2016 05/10/2016	FDA/OFVM/CFSAN/OCD/EOS/	Anthony Connors Anthony Connors	COMMUNICATIONS BETWEEN DR PETER A COHEN AND FDA RE METHYLSYNEPHRINE 04/08/2015 - 04/08/2016
2016-3071	04/12/2016 05/10/2016	FDA/OMPT/CDRH/OCE/DID/	scott lovell Scott Lovell	INFUSE RECS SUBMITTED FEB 2014
2016-3072	04/12/2016 05/10/2016	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kendrick Luse EverPoint Asset Management	COPAXONE, GLATOPA - AERS, FOIA REQUESTS 01/01/2014 - 04/10/2016
2016-3073	04/12/2016 05/10/2016	OC/ORAO/ OC/ORAO/ OC/ORAO/ORM/ OC/ORAO/ORM/	Yixin Iris Wang Ross School of Business, University of Michigan	RECALL DATA RE DRUG QUALIFY PROBLEMS 01/01/1998 - 12/31/2015
2016-3074	04/12/2016 05/10/2016	FDA/OC/OES/DFOI/	Yixin Iris Wang Ross School of Business, University of Michigan	WARNING LETTERS SENT TO PHARMACEUTICAL COMPANIES 01/01/1998 - 12/31/2015
2016-3075	04/12/2016 05/10/2016	FDA/OMPT/CDRH/OCE/DID/ OC/ORAOCI/ OC/ORAOCI/	Doe J	CPT1400957 TICK:23733 RECS
2016-3076	04/12/2016 05/10/2016	FDA/OMPT/CDRH/OCE/DID/	John Tozzi BLOOMBERG NEWS	510K MODIFICATIONS GUIDANCE DOCUMENT DISCUSSED AT MEETING BETWEEN CDRH AND ADVAMED ON 7/29/15
2016-3077	04/12/2016 05/10/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gay Parsons Janssen Inc	9778362 9764641 9758097 ETC

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-3078	04/12/2016 05/10/2016	FDA/OMPT/CDRH/OCE/DID/	Mark H. Smith THERMO FISHER SCIENTIFIC	K041194
2016-3079	04/12/2016 05/10/2016	FDA/OMPT/CDRH/OCE/DID/	Mark H. SMith THERMO FISHER SCIENTIFIC	K110616
2016-3080	04/12/2016 05/10/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K123265
2016-3081	04/12/2016 05/10/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SIDDHARTH KARNAWAT SIDDHARTH KARNAWAT	GLENMARK PHARMA, INDIA - 483 04/03/2015 - 04/11/2016
2016-3082	04/12/2016 05/10/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Chirag Talati Kotak Securities	CADILA PHARMACEUTICALS, INDIA - 483 01/01/2014 - 04/12/2016
2016-3083	04/12/2016 05/10/2016	OC/ORA/ORM/ OC/ORA/ORM/	Frank Sanya Frank Sanya	List of FDA Approved Food Suppliers and Food Processing Companies in the United States
2016-3084	04/12/2016 05/10/2016	FDA/OFVM/CFSAN/OCD/EOS/	Amrit Bindra Amrit Bindra	FCN 607
2016-3085	04/12/2016 05/10/2016	OC/ORA/ORM/ OC/ORA/ORM/	Bharat Celly Research Delta Advisors	LIST OF INSPECTIONS 03/01/2016 - 03/31/2016
2016-3086	04/12/2016 05/10/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Gaurav Tinani Emkay Global Financial Services Limited	SUN PHARMACEUTICALS INDUSTRIES LTD, INDIA - 483 09/08/2014 - 09/19/2014
2016-3087	04/12/2016 05/10/2016	FDA/OMPT/CTP/OD/	Mark E. Greenwold CAMPAIGN FOR TOBACCO-FREE KIDS	TOBACCO PRODUCTS SUBJECT TO THE SUBSTANTIAL EQUIVALENCE REPORTS FILED WITH FDA PURSUANT TO SECTION 905(j) ON OR BEFORE 3/22/11 THAT REMAIN PENDING
2016-3088	04/12/2016 05/10/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Gaurav Tinani Emkay Global Financial Services Limited	ZYDUS CADILA, INDIA - 483 01/18/2016 - 01/22/2016
2016-3089	04/12/2016	FDA/OMPT/CBER/OCOD/DDOM/	Allison Caruana	COMMUNICATIONS RE BORRELLIA, MOUSE VACCINE,

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	05/10/2016	ALFB/ FDA/OO/OFBA/OAGS/	The Mayday Project	HUMAN VACCINE, ETC 01/01/1995 - 04/20/2016
2016-3090	04/13/2016 05/11/2016	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/ OC/ORO/ OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/CIN- DO/CIN-CB/	PATTI WALLER MARLER CLARK ATTYS	LISTERIA OUTBREAK FROM DOLE LEAFY GREENS 7/15 TO 1/16 MULTISTATE
2016-3091	04/13/2016 05/11/2016	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/SAN- DO/SAN-CB/	PATTI WALLER MARLER CLARK ATTYS	RECALL OF AMERICAN BLEND BAGGED BY DOLE FRESH VEGETABLES 10/17/12
2016-3092	04/13/2016 05/11/2016	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	LIST OF MANUFACTURERS AND IMPORTERS OF TOBACCO PRODUCTS FOR WHICH A USER FEE WAS RECEIVED DURING FIRST QUARTER OF FY2016, MANUFACTURERS AND IMPORTERS OF TOBACCO PRODUCTS FOR WHICH A USER FEE WAS ASSESSED DURING FIRST QUARTER OF FISCAL YEAR 2016
2016-3093	04/13/2016 05/11/2016	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/SAN- DO/SAN-CB/	PATTI WALLER MARLER CLARK ATTYS	RECALL OF BAGGED SALAD BY DOLE FRESH VEGETABLES 6/22/12
2016-3094	04/13/2016 05/11/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gaurav Tinani Emkay Global Financial Services Limited	DR REDDY'S LABORATORIES LTD, INDIA - 483 11/17/2014 - 11/21/2014
2016-3095	04/13/2016 05/11/2016	FDA/OGROP/ORO/SE-FO/FLA- DO/FLA-CB/	Teri DeaNauro American Industrial Plastics LLC	AMERICAN INDUSTRIAL PLASTICS LLC - INVESTIGATION RECS 08/01/2014 - 08/31/2014
2016-3096	04/13/2016 06/09/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Holli Vaughan BIOLOGICS CONSULTING GROUP	SBAL 101144 SBA
2016-3097	04/13/2016 05/23/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Holli Vaughan Biologics Consutling	BLA 103932 SBA

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2016-3098	04/13/2016 05/11/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	Dr. Sharon Jacob M.D. LOMA LINDA UNIVERSITY	ISOTHIAZOLINONE - AERS
2016-3099	04/13/2016 05/11/2016	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/CIN-DO/CIN-CB/	Megan Galey HUSCH BLACKWELL LLP	BLU PHARMACEUTICALS, LLC, FRANKLIN, KY - EIR, 483, WARNING LETTERS ETC
2016-3100	04/13/2016 05/11/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sheh-Li Chen University of North Carolina Medical Center	APIXABAN - APPROVAL LETTER, REVIEW DATA
2016-3101	04/13/2016 05/11/2016	FDA/OGROP/ORO/SW-FO/KAN-DO/KAN-CB/	Jason Devall Select Brands, LLC	SELECT BRANDS, SPRINGFIELD, MO - EIR 06/18/2015 - 07/10/2015
2016-3102	04/13/2016 05/11/2016	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/	PATTI WALLER MARLER CLARK ATTYS	RECALL OF DOLE ITALIAN BLEND SALAD BY DOLE FRESH VEGABLES 8/22/12
2016-3103	04/13/2016 05/11/2016	FDA/OGROP/ORO/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kevin Patel COWEN & GRINCH ATTYS	PATHEON PHARMACEUTICALS, CINCINNATI, OH, TRIANGLE PARK, NC, EVIONNAZ, SWITZERLAND - 483 02/01/2016 - 03/31/2016
2016-3104	04/13/2016 05/11/2016	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/	PATTI WALLER MARLER CLARK ATTYS	RECALL OF SEVEN LETTUCES SALAD BY DOLE FRESH VEGETABLES 4/14/12
2016-3105	04/13/2016 05/11/2016	FDA/OC/OES/DFOI/	Teri DeNauro American Industrial Plastics LLC	AMERICAN INDUSTRIAL PLASTICS LLC, DAYTONA, FL - FOIA REQUEASTS 02/01/2014 - 04/11/2016

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2016-3106	04/13/2016 05/23/2016	FDA/OMPT/CDRH/OCE/DID/	Globus Medical Chris Hunter	510K GLOBUS MEDICAL PEDICLE SCREW SYSTEM
2016-3107	04/13/2016 05/11/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michelle Ross - PointState Capital POINTSTATE CAPITAL LP	GLATOPA - AERS
2016-3108	04/13/2016 05/11/2016	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/SAN- DO/SAN-CB/	PATTI WALLER MARLER CLARK ATTYS	RECALL OF DOLE HEARTS OF ROMAINE BY DOLE FRESHVEGEGABLES 6/29/12
2016-3109	04/13/2016 05/11/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mark Smith SMITH, MARK D	GLATOPA, COPAXONE - AERS
2016-3110	04/13/2016 05/11/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dr Tom Brya GeneriCo Pharma LLC	SUCRALFATE FOREST LABS INC. APPROVAL RECS
2016-3111	04/13/2016 05/11/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Matt Ferner The Huffington Post	MOST RECENT EVALUATION OF SCIENCE AROUND MARIJUANA, SUBSEQUENT RECOMMENDATION FROM FDA RE CLASSIFICATION
2016-3112	04/13/2016 05/11/2016	FDA/OGROP/ORO/SE-FO/ATL- DO/ATL-CB/ FDA/OGROP/ORO/SW-FO/DAL- DO/DAL-CB/	Tom Harmon The PrivateBank	DIAMON PET FOOD PROCESSORS, GASTON, SC; PET SOLUTIONS LLC, DANVILLE, AR - EIR 04/12/2014 - 04/12/2016
2016-3113	04/13/2016 05/11/2016	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/SAN- DO/SAN-CB/	PATTI WALLER MARLER CLARK ATTYS	RECALL OF BAGGED ITALIAN STYLE BLENDS BY DOLE FRESH VEGETABLES 3/13/14
2016-3114	04/13/2016 05/11/2016	FDA/OMPT/CDRH/OCE/DID/	Mark H Smith THERMO FISHER SCIENTIFIC	K023928

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2016-3115	04/13/2016 05/11/2016	FDA/OMPT/CDRH/OCE/DID/	Mark H Smith Thermo Fisehr Scientific	K984361
2016-3116	04/13/2016 05/11/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-5916
2016-3117	04/13/2016 05/11/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-234
2016-3118	04/13/2016 05/11/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-6247
2016-3119	04/13/2016 05/11/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-806
2016-3120	04/13/2016 05/11/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-9649
2016-3121	04/13/2016 05/11/2016	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/SAN- DO/SAN-CB/	PATTI WALLER MARLER CLARK ATTYS	RECALL OF BAGGED SPINICH SALAD PRODUCED BY DOLE FRESH VEGETABLES 10/13/15
2016-3122	04/13/2016 05/11/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-2600
2016-3123	04/13/2016 05/11/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2014-8362
2016-3124	04/13/2016 05/11/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-9117
2016-3125	04/13/2016 05/11/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-1353
2016-3126	04/13/2016 05/11/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-9507
2016-3127	04/13/2016 05/11/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-9945
2016-3128	04/13/2016 05/11/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-118
2016-3129	04/13/2016 05/11/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-156

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2016-3130	04/13/2016 05/11/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-236
2016-3131	04/13/2016 05/11/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-427
2016-3132	04/13/2016 05/11/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-431
2016-3133	04/13/2016 05/11/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-483
2016-3134	04/13/2016 05/11/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-589
2016-3135	04/13/2016 05/11/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PEKICH, CHARLOTTE	9169360, 9311849, 9360506 - FAERS
2016-3136	04/13/2016 05/11/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-799
2016-3137	04/13/2016 05/11/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-800
2016-3138	04/13/2016 05/11/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-803
2016-3139	04/13/2016 05/11/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-898
2016-3140	04/13/2016 05/11/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-1030
2016-3141	04/13/2016 05/11/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOAN, HELTON	10108865, 3313504, 3571310 - FAERS
2016-3142	04/13/2016 05/11/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Wilson, Tina	7613057, 7862274, 7958441 - FAERS
2016-3143	04/13/2016	FDA/OMPT/CDER/ORP/DIDP/		3868984, 3951808, 3975794 - FAERS

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	05/11/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	VANAS, JULIE	
2016-3144	04/13/2016 05/11/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	VANAS, ANTON	9455996, 9478737, 9482096 - FAERS
2016-3145	04/13/2016 05/11/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K100574
2016-3146	04/13/2016 05/11/2016	FDA/OMPT/CDRH/OCE/DID/	Ronda Elliott INOVA DIAGNOSTICS INC	K141827
2016-3147	04/13/2016 05/11/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Danielle Abramson NOVEN PHARMACEUTICALS INC	XULANE - AERS
2016-3148	04/13/2016 05/11/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORO/CE-FO/CIN-DO/CIN-CB/	STREET, HILARY	RELIABLE DRUG PHARMACY, SAN FRANCISCO, CA - INVESTIGATON 2016
2016-3149	04/13/2016 05/11/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CUSHING, DANIEL J	NEXTERONE NDA 22-325/S009 - APRVL
2016-3150	04/13/2016 05/11/2016	FDA/OC/OES/DFOI/	NORTHRUP V13733, DAVID	LEUPROLIDE ACETATE; HISTRELIN - CAERS, LBLG
2016-3151	04/13/2016 05/11/2016	OC/ORO/ORM/ OC/ORO/ORM/	LESLIE RAMSEY FDA NEWS	PHARMACEUTICAL, BIOLOGIC, MEDICAL DVC, CLNCL TRIAL FACILITY LIST - 483 3/1-31/16
2016-3152	04/13/2016	FDA/OMPT/CDER/ORP/DIDP/		IND 060404

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	05/11/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TAUBENFELD, SIDNEY	
2016-3153	04/13/2016 05/11/2016	FDA/OMPT/CDRH/OCE/DID/	TREVOR L. BRADLEY CETRULO LLP	KAZ INC - VICKS VAPORIZER MODEL V150, V15OSG, V15OSGN APRVL
2016-3154	04/13/2016 05/11/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	ANI BYRNE Jamieson Laboratories	JAMIESON - FORM 3500, 3500A, 3500B 1/16 TO 3/31/16
2016-3155	04/13/2016 05/11/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	PERMETHRIN CREAM - AER
2016-3156	04/13/2016 05/11/2016	FDA/OC/OES/DFOI/	AMIE N. VANELLA FAEGRE BAKER DANIELS	SIMPLY THICK - REQUESTS 2/2/16 TO PRESENT
2016-3157	04/13/2016 05/11/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MATT FERNER HUFFINGTON POST	MARIJUANA - EVALUATION
2016-3158	04/13/2016 05/11/2016	FDA/OMPT/CDRH/OCE/DID/	LE, LOAN	FDA IDE APPVD PROJECTS REGARDING BRAIN & MEMORY 2010 TO PRESENT
2016-3159	04/13/2016 05/11/2016	FDA/OMPT/CTP/OD/	MARK E. GREENWOLD CAMPAIGN FOR TOBACCO-FREE KIDS	ALL TOBACCO PRODUCTS - SUBSTANTIAL EQUIVALENCE RPTS
2016-3160	04/13/2016 05/11/2016	FDA/OC/OES/DFOI/	Casey Barr Casey Barr	CATALENT, ST PETERSBURG, FL - 483
2016-3161	04/14/2016 05/12/2016	FDA/OC/OES/DFOI/	william teleisha william teleisha	CATALENT, INC - RAYALDEE COMPLETE RESPONSE LETTER, 483 02/01/2016 - 04/12/2016
2016-3162	04/14/2016 05/12/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kiran Kumar Gande LEADING PHARMA LLC	ANDA083177 RLD LABELING

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2016-3163	04/14/2016 05/12/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mary Beth Kepler Global Medical Device Consultants	ARC-183 IND 68200 STUDY RECS
2016-3164	04/14/2016 05/12/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Marisa Cummings PFIZER	XINXIANG TUOXIN BIOCHEMICAL CO, LTD, CHINA - 483 01/01/2015 - 12/31/2015
2016-3165	04/14/2016 05/12/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	S Sundaram BPEP India	ZYDUS, CADILA - 483 01/01/2016 - 04/13/2016
2016-3166	04/14/2016 05/12/2016	FDA/OMPT/CDRH/OCE/DID/	Shoval Dekel GLOBAL RESOURCES INTERNATIONAL	K130132 K883969
2016-3167	04/14/2016 05/12/2016	FDA/OMPT/CDRH/OCE/DID/	Jody Oyama Jody Oyama	K033485 K111226
2016-3168	04/14/2016 05/12/2016	FDA/OMPT/CDRH/OCE/DID/	Jill Delsman Salt Creek Medical	K041331
2016-3169	04/14/2016 05/12/2016	FDA/OMPT/CDRH/OCE/DID/	Michelle Parker Sysmex America, Inc.	K012372
2016-3170	04/14/2016 05/12/2016	FDA/OMPT/CDRH/OCE/DID/	Michelle Parker Sysmex America, Inc.	K070910
2016-3171	04/14/2016 05/12/2016	FDA/OMPT/CDRH/OCE/DID/	Michelle Parker Sysmex America, Inc.	K961054
2016-3172	04/14/2016 05/12/2016	FDA/OMPT/CDRH/OCE/DID/	Michelle Parker Sysmex America, Inc.	K053135
2016-3173	04/14/2016 05/12/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Qansy Salako AMAG Pharmaceuticals	PPD DEVELOPMENT, MIDDLETON, WI; SAFC, INC, MADISON, WI - QUALITY ASSURANCE PROFILE
2016-3174	04/14/2016	FDA/OMPT/CBER/OCOD/DDOM/	Kris Christian	SANOBI PASTEUR LIMITED, NORTH YORK, CANADA - EIR

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	05/12/2016	ALFB/	FDAZILLA	07/21/2015 - 08/10/2015
2016-3175	04/14/2016 05/12/2016	FDA/OFVM/CFSAN/OCD/EOS/	Priscilla Herpai DSM Biomedical	FAP 5B4464
2016-3176	04/14/2016 05/12/2016	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDRH/OCE/DID/	Joseph Scovel Joseph Scovel	K103233, RECALL Z-0192-2012
2016-3177	04/14/2016 05/12/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Gregory Rrenza JEFFERIES & CO	ADUCANUMAB - AERS
2016-3178	04/14/2016 05/12/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dr. Elliot Favus FAVUS INSTITUTIONAL RESEARCH LLC	ACTHAR GEL-SYNTHETIC (SERACTIDE ACETATE) LABELING
2016-3179	04/14/2016 05/12/2016	FDA/OC/OES/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDRH/OCE/DID/ FDA/OPPLA/OL/	Allison Caruana The Mayday Project	Any and all communications with IDSA or CDC regarding Lyme disease, Lyme vaccine, Lyme bills or the Antibiotic bill - 01/01/2006 - 04/16/2016
2016-3180	04/14/2016 05/12/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	EnBiotix, Inc. c/o Benjamin Perrone, Mgr Bus Dev EnBiotix, Inc.	BETHKIS - IND, PRE-IND MEETING FILINGS, NDA 01/01/2002 - 01/01/2012
2016-3181	04/14/2016 05/12/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kris Christian FDAZILLA	MEDIMMUNE PHARMA BV, NETHERLANDS - EIR 05/28/2015 - 06/05/2015
2016-3182	04/14/2016 05/12/2016	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Philipa Atta Atta, Philipa	MEDISCA, PLATTSBURGH, NY - EIR 10/10/2012 - 10/24/2012
2016-3183	04/14/2016 05/12/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K152356
2016-3184	04/14/2016 05/12/2016	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCE/DID/	W PATRICK NOONAN W PATRICK NOONAN	WESTRIDGE LABS, SANTA ANA, CA - EIRS, 483S, CO RESP, ETC

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2016-3185	04/14/2016 05/12/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SHERI O COVINGTON K&L Gates LLP	SEEBRI NEOHALER (GLYCOPYRROLATE) INHALATION POWDER - SUMMARY RVW, MEDICAL RVW, CLNCL PHARMACOLOGY RVW
2016-3186	04/14/2016 05/12/2016	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	SAM KENNEDY MORNING CALL	SANOFI PASTEUR, SWIFTWATER, PA - RESOLUTION OF THE DELAMINATION PROBLEMS 1/13 TO PRESENT
2016-3187	04/14/2016 05/12/2016	FDA/OMPT/CTP/OD/	LUIS FIGUEREDO FIGUEREDO LAW LLC	BRONCO CIGARETTES - LTRS 1/13 AND 2/4/14
2016-3188	04/14/2016 05/12/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LESLIE RAMSEY FDA NEWS	HETERO DRUGS LTD, MEDAK DISTRICT, INDIA 5/2/14; VISAKHAPATNAM, INDIA 9/29/14, 8/28/14 - 483S
2016-3189	04/14/2016 05/12/2016	OC/ORACE/ORM/ OC/ORACE/ORM/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JAMES CLAPPISON BIOQUELL UK LTD	UK CONTAINMENT LEVEL (CL)1 LABS IN THE USA
2016-3190	04/14/2016 05/12/2016	OC/ORACE/ORM/ OC/ORACE/ORM/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JAMES CLAPPISON BIOQUELL UK LTD	UK CONTAINMENT LEVEL (CL) 3 LABS IN THE USA
2016-3191	04/14/2016 05/12/2016	OC/ORACE/ORM/ OC/ORACE/ORM/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JAMES CLAPPISON BIOQUELL UK LTD	UK CONTAINMENT LEVEL (CL) 2 LABS IN THE USA

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2016-3192	04/15/2016 05/13/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Erica L Nicoll Novum Pharmaceutical Research Services	ANDA 208077
2016-3193	04/15/2016 05/27/2016	FDA/OFVM/CFSAN/OCD/EOS/ BURDOCK GROUP	Wendan Wang BURDOCK GROUP	MANNITOL - FOOD ADDITIVES, GRAS, ETC
2016-3194	04/15/2016 05/13/2016	FDA/OFVM/CFSAN/OCD/EOS/ BURDOCK GROUP	Wendan Wang BURDOCK GROUP	BEESWAX - FOOD ADDITIVES, GRAS, ETC
2016-3195	04/15/2016 05/13/2016	OC/ORO/OCI/ OC/ORO/OCI/	Sarah N Lynch Sarah Lynch, Reuters	FOREIGN UNAPPROVED MEDICAL PRODUCT CASES 01/01/2008 - 04/12/2016
2016-3196	04/15/2016 05/13/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Maria E. Doukas Morgan, Lewis & Bockius LLP	NDA 020845 - FORM 3542
2016-3197	04/15/2016 05/13/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Saroja Gorantla AUROLIFE PHARMA LLC	ANDA 071938
2016-3198	04/15/2016 05/13/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kris Christian FDAZILLA	MEDIMMUNE PHARMA BV, NETHERLANDS - 483 05/28/2015 - 06/05/2015
2016-3199	04/15/2016 05/13/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Danielle Abramson NOVEN PHARMACEUTICALS INC	ORTHO EVRA FAERS SUMMARY REPORT
2016-3200	04/15/2016 05/13/2016	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/CIN- DO/CIN-CB/	Vanesa Gonzales05 Vanesa Gonzales	ZEAL, VIVACIOUS, X2ZERO ETC LAB RESULTS
2016-3201	04/15/2016	FDA/OMPT/CDER/ORP/DIDP/	Genevieve Stevens	INDOCO REMEDIES LIMITED PLANT II, III, INDIA - 483 04/01/2015 - 04/12/2016

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	05/13/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Nivagen Pharmaceuticals, Inc.	
2016-3202	04/15/2016 05/13/2016	FDA/OGROP/ORANE-FO/NYK- DO/NYK-DCB/	Kristen Kim NYU SCHOOL OF MEDICINE	DR ALEXANDER NEUMEISTER - 06/17/2015 - 04/12/2016 483, EIR
2016-3203	04/15/2016 05/13/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mike Koehler Mike Koehler	POLYETHYLENE GLYCOL 3350, PEG 3350, MIRALAX ETC - AERS
2016-3204	04/15/2016 05/13/2016	FDA/OMPT/CDRH/OCE/DID/	Nancy Phan Globizz Corporation	K101128
2016-3205	04/15/2016 05/13/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Krishna Kiran Konduri Spark Capital Advisors (I) Private Limited	CADILA HEALTHCARE, INDIA - 483 02/01/2016 - 04/13/2016
2016-3206	04/15/2016 05/13/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Reena Harjai APCER Life Sciences, Inc.	NDA 208194 SBA
2016-3207	04/15/2016 05/13/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Amit Jolly BIOPHARM INSIGHT	COSENTYX - AERS
2016-3208	04/15/2016 05/13/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-427
2016-3209	04/15/2016 05/13/2016	FDA/OMPT/CDRH/OCE/DID/	Gavin Wang SigmaGraft, Inc.	K970321 K113246
2016-3210	04/15/2016 05/13/2016	FDA/OMPT/CDRH/OCE/DID/	Jason B. Campbell Greenleaf Health LLC	K153090
2016-3211	04/15/2016 05/13/2016	FDA/OMPT/CDRH/OCE/DID/	Jason B. Campbell Greenleaf Health LLC	K153153
2016-3212	04/15/2016 05/13/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Elliot Favus, MD FAVUS INSTITUTIONAL	NDA 008975 NDA 009854

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RESEARCH LLC	
2016-3213	04/15/2016 05/13/2016	FDA/OMPT/CDRH/OCE/DID/	John Zhuang JOHNSON & JOHNSON	K042216
2016-3214	04/15/2016 05/13/2016	OC/ORO/OCI/ OC/ORO/OCI/	Sarah N Lynch Sarah Lynch, Reuters	EMAILS BETWEEN TOM SOUTH AND SAICS, ASAICS RE FUMP, GRAND JURY MATERIALS 01/01/2016 - 04/13/2016
2016-3215	04/15/2016 05/13/2016	FDA/OMPT/CDRH/OCE/DID/	Mairad Cleary AventaMed	K810701 K812460 K830228
2016-3216	04/15/2016 05/13/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	BLA 125544
2016-3217	04/15/2016 05/13/2016	FDA/OMPT/CDRH/OCE/DID/	Alicia Napoli BacterioScan, Inc.	K070910 K022774
2016-3218	04/15/2016 05/13/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	joseph walker Walker, Joseph	SUBSYS - AERS
2016-3219	04/15/2016 05/13/2016	FDA/OMPT/CDRH/OCE/DID/	Nancy Phan Globizz Corporation	K090414
2016-3220	04/15/2016 05/13/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tanmoy Sadhukha AMRI	ANDA 40-557
2016-3221	04/15/2016 05/13/2016	FDA/OGROP/ORO/SW-FO/KAN-DO/KAN-CB/	FDA Inspection Records The Boeing Company	UNLIMITED WATER PROCESSING INC, ST LOUIS, MO - CLOSE OUT LETTER 03/02/2015 - 04/08/2016
2016-3222	04/15/2016 05/13/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John Kenny Aspen Pharma Trading Limited	DMF 26998
2016-3223	04/15/2016 05/13/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Melissa Malapit Celgene Corporation	TETYANA NEHRYCH CHAIR OF NEUROL OF LVIV NATL MED UNIV DEPT OF LVIV REG CTL HOSP 6 NEKRASOVA STR LVIV UKRAINE - 483 09/01/2010 - 04/13/2016

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-3224	04/15/2016 05/13/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jo Stephanie Culotta Fountain Park Pharmacy	SALLUS LABORATORIES - LETTER RE CAPTRACIN 05/01/2015 - 05/01/2016
2016-3225	04/15/2016 05/13/2016	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	XENOMETRICS, STILWELL, KS - 483, EIR 9/1/2015
2016-3226	04/15/2016 05/13/2016	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	AGRICULTURAL RESEARCH SERVICES, STUTTGART, AR - 483, EIR, 8/6/2013
2016-3227	04/15/2016 05/13/2016	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	BAS EVANSVILLE, MOUNT VERNON, IN - 483, EIR 6/22/2015
2016-3228	04/15/2016 05/13/2016	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	AVANZA DEVELOPMENT SERVICES, LLC, GAITHERSBURG, MD - 483, EIR 8/9/2013
2016-3229	04/15/2016 05/13/2016	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ENVIGO CRS INC, SOMERSET, NJ - EIR, 483 9/12/2014
2016-3230	04/15/2016 05/13/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K023245
2016-3231	04/15/2016 05/13/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K970887
2016-3232	04/15/2016 05/13/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K010998
2016-3233	04/15/2016 05/13/2016	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ICON LABORATORY SERVICES, WHITESBORO, NY - 483, EIR 6/26/2015
2016-3234	04/15/2016 05/13/2016	FDA/OMPT/CDRH/OCE/DID/	David Lehr COOK INCORPORATED	K964034
2016-3235	04/18/2016 05/16/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MILLER, JEFF	7049339, 7067753, 7098586 - FAERS
2016-3236	04/18/2016 05/16/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ABEL, SHARON	7372383, 7380757, 7385596 - FAERS

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2016-3237	04/18/2016 05/16/2016	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	JANET POPOVA RITTER CHUSID LLP	ANTONIO EMILIO BLANCO MD, ALEJANDRO PEREZ RN, US STEM CELL CLINIC LLC, US STEM CELL INC - RECS 4/15 TO 4/16
2016-3238	04/18/2016 05/16/2016	FDA/OC/OES/DFOI/	ALEXANDER J. VAROND Hyman, Phelps & McNamara P.C.	HIGH CHEMICAL CO - SARAPIN LBLG, EIR 2/19/40, 10/2/41, 1/1935 TO 12/21/1942
2016-3239	04/18/2016 05/16/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ALEXANDER J. VAROND Hyman, Phelps & McNamara P.C.	SARAPIN LBLG 1/1935 TO 12/31/1962
2016-3240	04/18/2016 05/16/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Allison Caruana Allison Caruana	COMMUNICATIONS WITH DAVID ROTH, BLACKSTONE INVESTMENT GROUP, GLOBAL LYME ALLIANCE ETC RE LYME DISEASE VACCINE, HUMAN SPECIMEN RESEARCH, ETC 01/01/1995 - 04/20/2016
2016-3241	04/18/2016 05/16/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MOLLY CONLIN BLUE RIDGE CAPITAL	GLATOPA (GLATIRAMER ACETATE INJECTION) EFFICACY
2016-3242	04/18/2016 05/16/2016	OC/ORR/ORM/ OC/ORR/ORM/	Jeff Kronenberg University of Idaho	LIST OF FOOD FIRMS WITH AN ACTIVE STATUS IN THE FDA OFFICIAL ESTABLISHMENT INVENTORY, CONTACT INFORMATION ISRAEL, CANADA 4/13/2015 - 04/13/2016
2016-3243	04/18/2016 05/16/2016	FDA/OMPT/CDRH/OCE/DID/	michael stango jupiter capital management, inc	DEPUY SYNTHES 510K TROCH NAIL KIT, CANNULATED HIP SCREW KIT, ETC 01/01/2010 - 04/13/2016
2016-3244	04/18/2016 05/16/2016	FDA/OC/OES/	Kathryn Watson Daily Caller News Foundation	DR MARGARET HAMBURG - EMAIL RE ZOHYDRO, LEVAQUIN, ETC 03/01/2009 - 03/01/2015
2016-3245	04/18/2016 05/16/2016	FDA/OC/OES/ OC/ORR/ OC/ORR/	Tim Requarth Tim Requarth (on assignment, NYT magazine)	FDA Budget report for FY1993
2016-3246	04/18/2016 05/16/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Steven Woloshin The Dartmouth Institute Ctr for Med and Media	APPROVAL RECS NDA, NDA SUPPLEMENTS
2016-3247	04/18/2016 05/16/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Laura Ruth FULD & COMPANY INC	ELIGARD - NDA 021343/S-033 NDA 021379/S-033 NDA 021488/S-030 NDA 021731/S-029

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2016-3248	04/18/2016 05/16/2016	OC/CVM/OCD/	Kelly Beers (US Agent for Huvepharma EOOD) Hivepharma, Inc.	NADA 040-181
2016-3249	04/18/2016 05/16/2016	OC/CVM/OCD/	Kelly Beers (US Agent for Huvepharma EOOD) Huvepharma, Inc.	NADA 007-087
2016-3250	04/18/2016 05/19/2016	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/OCI/ OC/ORO/OCI/	Sarah N Lynch Sarah Lynch, Reuters	GNC, VITAMIN WORLD, VITAMIN SHOPPE - LAB ANALYSIS REPORTS, INVESTIGATION FILES, COST INFORMATION 01/01/2014 - 04/14/2016
2016-3251	04/18/2016 05/16/2016	FDA/OC/OES/DFOI/	 Doe J	INDIVIDUAL RECS
2016-3252	04/18/2016 05/16/2016	FDA/OGROP/ORO/CE-FO/NWJ-DO/NWJ-CB/	Jennifer Hansgate EuroPharma, Inc	DIMENSIONAL MERCHANDISING INC, WHARTON, NJ - EIR, 483, RESPONSE 02/01/2013 - 05/31/2013
2016-3253	04/18/2016 05/16/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ted Keller EverPoint Asset Management	IONS-TTRrx AERS
2016-3254	04/18/2016 05/16/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Christina Jewett The Center for Investigative Reporting	All pages of "Study 21884" and "Study 22240 " that are referenced in the documentation related to the medication Gonal-F
2016-3255	04/18/2016 05/16/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Walter Chalkley THOMSON REUTERS	F HOFFMAN LAROCHE, SWITZERLAND - 483 03/31/2014 - 04/08/2014
2016-3256	04/18/2016 05/20/2016	FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	BAXTER HEALTHCARE COMPANY, LOS ANGELES, CA - 483, EIR, RESPONSE 03/03/2015 - 03/13/2015
2016-3257	04/18/2016 05/16/2016	FDA/OGROP/ORO/SE-FO/NOL-DO/NOL-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	DR REDDY'S LABORATORIES, SHREVEPORT, LA - 483, EIR, RESPONSE 09/10/2012 - 09/21/2012
2016-3258	04/18/2016 05/16/2016	FDA/OGROP/ORO/SW-FO/DEN-DO/DEN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	AMGEN, BOULDER, CO - 483, EIR, RESPONSE 02/03/2015 - 02/11/2015
2016-3259	04/18/2016	FDA/OGROP/ORO/PA-FO/SAN-	Walter Chalkley	220 LABORATORIES, RIVERSIDE, CA - 483, EIR, RESPONSE

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	05/16/2016	DO/SAN-CB/ FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	THOMSON REUTERS (SCIENTIFIC) SAS	02/25/2015 - 03/12/2015
2016-3260	04/18/2016 05/16/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	NEILSON, SUSIE	SKIN BLEACHING PRODUCTS CONTAINING HYDROQUINONE, ARBUTIN, GLUTATHIONE, MERCURY CORTICOSTERIODS - RECS
2016-3261	04/18/2016 05/16/2016	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	WALTER E MAY IRB, PIKESVILLE, MD - 483, EIR, RESPONSE 08/17/2015 - 08/21/2015
2016-3262	04/18/2016 05/16/2016	FDA/OGROP/ORAP/PA-FO/SAN-DO/SAN-CB/	Walter chalkley THOMSON REUTERS (SCIENTIFIC) SAS	GRIFOLS-CHIRON DIAGNOSTIC CORPORATION, EMERYVILLE, CA - 483, EIR, RESPONSE 05/01/2013 - 05/10/2013
2016-3263	04/18/2016 05/16/2016	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	DEIBEL LABORATORIES OF ILLINOIS, LINCOLNWOOD, IL - 483, EIR, RESPONSE 06/01/2012 - 06/13/2012
2016-3264	04/18/2016 05/16/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	LORCH ULRIKE, SURREY, UK - 483 06/10/2013 - 06/21/2013
2016-3265	04/18/2016 05/16/2016	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Walter Chalkley THOMSON REUTERS	TALECRIS PLASMA RESOURCES, ST PAUL, MN - 483, EIR, RESPONSE 06/10/2013 - 06/21/2013
2016-3266	04/18/2016 05/16/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kristi Smedley Center for Regulatory Services Inc.	COSMA, ITALY - 483 02/01/2013 - 06/01/2013
2016-3267	04/18/2016 05/16/2016	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Walter Chalkley THOMSON REUTERS	MATHESON TRI CASE, IRVING, TX - 483, EIR, RESPONSE 04/01/2014 - 04/17/2014
2016-3268	04/18/2016 05/16/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kristi Smedley Center for Regulatory Services Inc.	COSMA, ITALY - EIR, RESPONSE 02/01/2013 - 06/01/2013
2016-3269	04/18/2016 05/16/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mark Karvosky Partner Fund Managment	ALPROLIX - AERS

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/		
2016-3270	04/18/2016 05/16/2016	FDA/OC/OES/DFOI/	AMIDON 08B1873, JONATHAN	MILLER COORS - SPARKS WARNING LTR
2016-3271	04/18/2016 05/16/2016	FDA/OGROP/ORACE-FO/CIN- DO/CIN-CB/ FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/	PAUL CALLAHAN CHARLES RIVER	CHARLES RIVER, WILMINGTON, MA - EIR 9/14-25/15
2016-3272	04/18/2016 05/16/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	RACHEL FELONG BERNSTEIN LITOWITZ ET AL	CTI BIOPHARMA CORP - CLNCL HOLD INVESTIGATION RECS
2016-3273	04/18/2016 05/16/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OPPLA/OL/	HAMILTON, KEEGAN	RECORDS SCHEDULING MARIJUANA UNDER THE CONTROLLED SUBSTANCES ACT SINCE 10/2014
2016-3274	04/18/2016 05/16/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SIDNEY WOLFE MD PUBLIC CITIZEN	REQUESTS FROM FDA TO JANSSEN PHARMACEUTICALS - BAYER 1/12/16
2016-3275	04/19/2016 05/17/2016	FDA/OMPT/CDRH/OCE/DID/	Andre Pauptit Philips Electronics Nederland B.V. Philips Light & Health	K030883, K072331, K013623, ETC
2016-3276	04/19/2016 05/17/2016	FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/	Amanda Cruz Cal India - Specialty Enzymes & Biotechnologies	CAL INDIA, CHINO, CA - EIR 04/01/2014 - 04/14/2016
2016-3277	04/19/2016 05/17/2016	FDA/OGROP/ORACE-FO/BLT- DO/BLT-CB/	Daniel Bernier Hospira, a Pfizer Company	HUMAN GENOME SCIENCE, INC, ROCKVILLE, MD - 483 02/01/2016 - 04/14/2016
2016-3278	04/19/2016 05/17/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Brian Schlag Actelion Pharmaceuticals US, Inc.	NDA 20-699 S054, S057 - SBA

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2016-3279	04/19/2016 05/17/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	David Tukey EverPoint Asset Management	DARZALEX - AERS
2016-3280	04/19/2016 05/17/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Narratives of MTC cases related with liraglutide in FEARS NOVO NORDISK A/S	LIRAGLUTIDE - AERS
2016-3281	04/19/2016 05/17/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Mark Karvosky Partner Fund Managment	ELOCTATE - AERS
2016-3282	04/19/2016 05/17/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ted Keller EverPoint Asset Management	KYNAMRO - AERS
2016-3283	04/19/2016 05/17/2016	OC/ORO/OCI/ OC/ORO/OCI/	SPENCER KNAPP UNIV OF VERMONT MEDICAL CENTER	DR GAMAL ELTABBAKH - INVESTIGATION RECS
2016-3284	04/19/2016 05/17/2016	FDA/OC/OES/DFOI/	ANGELES DAVIES DAVIES, ANGELES	BAYER - ESSURE RECS
2016-3285	04/19/2016 05/17/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WILLIAM B FEDERMAN FEDERMAN & SHERWOOD	ESPERION THERAPEUTICS INC - ETC-1002 CORR 1/1/15 TO PRESENT
2016-3286	04/19/2016 05/17/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CAROLINE STOUT ECOR1 CAPITAL LLC	LINZESS, CONTRAVE, THIOLA, ETC - AERS
2016-3287	04/19/2016 05/17/2016	FDA/OFVM/CFSAN/OCD/EOS/	ERICA F SIBLEY EPSTEIN BECKER & GREEN PC	ACACIA RIGIDULA - RECS, CORR. CLAIMS, ETC
2016-3288	04/19/2016	FDA/OC/OES/DDM/	MICHAEL M GALLAGHER	JANSSEN PHARMACEUTICALS, JANSSEN RESEARCH &

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	05/17/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	CLARK LOVE HUTSON	DEVELOPMENT LLC - INVOKANA 15-DY ALERTS, RPTS, AERS, ETC
2016-3289	04/19/2016 05/17/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	STAR BLUE BLUE, STAR	LACTULOSE - RECS
2016-3290	04/19/2016 05/17/2016	FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECS
2016-3291	04/20/2016 05/18/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	John Walsh James Alexander Corporation	BIOSYNTH AG, SWITZERLAND - EIR, 483, RECALL 04/01/2012 - 04/15/2016
2016-3292	04/20/2016 05/18/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Aman Asha Aman Asha	LUPIN LIMITED, GOA, INDIA - EIR, RESPONSE TO 483 01/01/2016 - 04/15/2016
2016-3293	04/20/2016 05/18/2016	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCE/DID/	Brad E. Kelsky, Esq. Kelsky Law, P.A.	TERRY J WARD - WARNING LETTERS 01/01/2014 - 03/31/2016
2016-3294	04/20/2016 05/18/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Christopher Holcomb Gold Coast Medical Supply	API IN FDA NDC
2016-3295	04/20/2016 05/18/2016	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	Joe Kihm Joe Kihm	DEWMAR INTERNATIONAL BRAND MANAGEMENT COMPANY, INC - RECS RE WARNING LETTER 06/01/2015 - 04/15/2016
2016-3296	04/20/2016 05/18/2016	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	Sarah Seifert BUZZ MONKEYS INC	ROCKLINE INDUSTRIES, SHEBOYGAN, WI - EIR 10/01/2015 - 04/15/2016
2016-3297	04/20/2016 05/18/2016	FDA/OMPT/CTP/OD/	Desmond Jenson Tobacco Control Legal Consortium	SE0002138 THROUGH SE0002148
2016-3298	04/20/2016 05/18/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K150850

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2016-3299	04/20/2016 05/18/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K092150
2016-3300	04/20/2016 05/18/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K091608
2016-3301	04/20/2016 05/18/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K051496
2016-3302	04/20/2016 05/18/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K070015
2016-3303	04/20/2016 05/18/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K151532
2016-3304	04/20/2016 05/18/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDRH/OCE/DID/	Kelly Servick SCIENCE MAGAZINE	HARVARD APPARATUS REGENERATIVE TECHNOLOGY INC, DAVID GREEN, ETC - APPROVALS, CORR, ETC 01/01/2008 - 04/15/2016
2016-3305	04/20/2016 05/18/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Yunchou Tan Proteus Digital Health	ANDA 203769
2016-3306	04/20/2016 05/18/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K091703
2016-3307	04/20/2016 05/18/2016	FDA/OMPT/CDRH/OCE/DID/	Doe J	CPT13000718
2016-3308	04/20/2016 05/18/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Elliot Favus, MD FAVUS INSTITUTIONAL RESEARCH LLC	ACTHAR GEL-SYNTHETIC (SERACTIDE ACETATE, NDA 017861) AERS
2016-3309	04/20/2016 05/18/2016	FDA/OMPT/CDRH/OCE/DID/	Suzanne Jensen Kleinfeld, Kaplan & Becker, LLP	K143155
2016-3310	04/20/2016 05/18/2016	FDA/OGROP/ORO/PA-FO/SEA- DO/SEA-CB/	Charles Snow Hyman, Phelps & McNamara, P.C.	KIRKMAN LABORATORIES - WARNING LETTER RESPONSE TO JAN 2016 WARNING LETTER

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2016-3311	04/20/2016 05/18/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	James P. Tinsley, Esq. Tinsley Law & Consulting, PLLC	NDA 20-919
2016-3312	04/20/2016 05/18/2016	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Amber Hacker Alkermes, Inc.	ALKERMES, INC, WILMINGTON, OH - EIR 04/01/2015 - 04/30/2015
2016-3313	04/20/2016 05/18/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Brent Ekins Adventist Health Medical Center	REQUIP, ROPINIROLE - AERS
2016-3314	04/20/2016 05/18/2016	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDRH/OCE/DID/	Catherine Geyman Epic Risk Solutions Ltd	PATHEON FRANCE SAS, PATHEON API MANUFACTURING INC, GREENVILLE, SC, PATHEON PHARMACEUTICALS INC, CINCINNATI, OH ETC - EIR
2016-3315	04/20/2016 05/18/2016	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Stephen Miller STEPHEN MILLER ASSOCIATES	WALTERBORO CARDIOLOGY, WALTERBORO, SC - COMPLAINT, MEDICAL RECORDS 05/01/2015 - 04/17/2016
2016-3316	04/20/2016 05/18/2016	OC/ORACE/OCI/ OC/ORACE/OCI/	Sarah N Lynch Sarah Lynch, Reuters	Copies of any and all declination letters sent to AUSAs from FDA OCI which involve a prosecutor declining to charge a doctor in a FUMP case 01/01/2011 - 04/17/2016
2016-3317	04/20/2016 05/18/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	COLLINGWOOD, NMANO	6436387, 6459019, 6475707 - CAERS
2016-3318	04/20/2016 05/18/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID HOFFMEISTER WISLON SONSINI ET AL	GLAXO SMITH KLINE NDA 21-0787/S-52 CO RESP

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2016-3319	04/20/2016 05/18/2016	FDA/OC/OES/DFOI/	CARLOINE STOUT ECOR1 CAPITAL LLC	LOG SINCE 1/2015
2016-3320	04/20/2016 05/18/2016	FDA/OMPT/CDRH/OCE/DID/	EDWARD A. STEELE EAS CONSULTING GROUP LLC	HYALO GNY K094039
2016-3321	04/20/2016 05/18/2016	FDA/OMPT/CDRH/OCE/DID/	EDWARD A. STEELE EAS CONSULTING GROUP LLC	GLYCERIN & PARABEN FREE ASTROGLIDE K072647
2016-3322	04/20/2016 05/18/2016	FDA/OMPT/CDRH/OCE/DID/	EDWARD STEELE EAS CONSULTING GROUP LLC	HYALOGYN VAGINAL HYDRATING GEL K150883
2016-3323	04/20/2016 05/18/2016	FDA/OMPT/CDRH/OCE/DID/	EDWARD STEELE EAS CONSULTING GROUP LLC	REPLENS LONG LASTING VAGINAL MOISTURIZER K101098
2016-3324	04/20/2016 05/18/2016	FDA/OMPT/CDRH/OCE/DID/	EDWARD STEELE EAS CONSULTING GROUP LLC	ELEGANCE WOMANS LUBRIANT K070587
2016-3325	04/20/2016 05/18/2016	FDA/OC/OES/DDM/ FDA/OMPT/CDRH/OCE/DID/	JAMES H. HARTTEN ARENT FOX LLP	DCK FDA-2016-N-0436
2016-3326	04/20/2016 05/18/2016	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OMPT/CDRH/OCE/DID/	JODY MARKLING ST JUDE MEDICAL	ST JUDE MEDICAL, COSTA RICA 6/1-4/16; ST JUDE MEDICAL, ST PAUL, MN 5/5-6/14 - EIR
2016-3327	04/20/2016 05/18/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PAMELA SHEPPARD TARO PHARMACEUTICALS USA INC	AMNEAL PHARMS - DICLOFENAC SODIUM MEDICAL RVW, CHEMICAL RVW, LBLG
2016-3328	04/20/2016 05/18/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DON J. MIZERK HUSCH BLACKWELL LLP	COREPHARMA - NDA 60-6304 APRVL
2016-3329	04/20/2016 05/18/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PAMELA SHEPPARD TARO PHARMACEUTICALS USA INC	FOUGERA PHARMS INC - TACROLIMUS SBA, CHEMISTRY RVW, MEDICAL RVW
2016-3330	04/20/2016 05/18/2016	FDA/OPPLA/OL/	SAM FALCONER Arizona Democratic Party	CORR BETWEEN SENATOR JOHN McCAIN & FDA LIASON

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2016-3331	04/20/2016 05/18/2016	FDA/OFVM/CFSAN/OCD/EOS/	HILLARY ALDASSY INSTITUTE FOR ENVIRONMENTAL HEALTH INC	SALMONELLA ENTERITIDIS OUTBREAK 10/11
2016-3332	04/21/2016 05/19/2016	FDA/OMPT/CDRH/OCE/DID/	Alicia Bajada Medtronic Vascular, Inc.	K090661
2016-3333	04/21/2016 05/19/2016	FDA/OMPT/CDRH/OCE/DID/	Pivi Mesiranta Regulatory Affairs Manager Brainshake	K133849 K113830 K111516 ETC
2016-3334	04/21/2016 05/19/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dustin Block IPD Analytics, LLC	ANDA 206005
2016-3335	04/21/2016 05/19/2016	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sowmya Isola Solaris Pharma Corporation	NDA 021142M ANDA 074220, NDA 019323 ETC SBA
2016-3336	04/21/2016 05/19/2016	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/	Juli Wilson Sun Orchard Fruit Co	FRESH FROM TEXAS, SAN ANTONIO, TX - INSPECTION RECS, RFR SUBMISSIONS 04/05/2016 - 04/29/2016
2016-3337	04/21/2016 05/19/2016	FDA/OMPT/CDRH/OCE/DID/	Suzanne Jensen Kleinfeld, Kaplan & Becker, LLP	K860737
2016-3338	04/21/2016 05/19/2016	FDA/OMPT/CDRH/OCE/DID/	Judi Wallach Abbott Laboratories, Inc	DEN150009
2016-3339	04/21/2016 05/19/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	John M. Nardo MD John Nardo	PROZAC NDA
2016-3340	04/21/2016 05/19/2016	FDA/OMPT/CDRH/OCE/DID/	Louis-Paul Marin LOK North America Inc.	K132447
2016-3341	04/21/2016 05/19/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Anna Edney BLOOMBERG NEWS	CONTRAVE - AERS

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2016-3342	04/21/2016 05/19/2016	FDA/OC/OES/DFOI/	Walter Chalkley THOMSON REUTERS	FOIA DAILY LOG 01/01/2016 - 03/31/2016
2016-3343	04/21/2016 05/19/2016	OC/ORO/OCI/ OC/ORO/OCI/	Sarah N Lynch Sarah Lynch, Reuters	Copies of any and all declination letters sent to AUSA from the FDA's OCI - 01/01/2011 - 04/18/2016
2016-3344	04/21/2016 05/19/2016	FDA/OGROP/ORO/CE-FO/PHI-DO/PHI-CB/	Rachel Johnson FOI Services, Inc.	ALLIQUA BIOMEDICAL, LANGHORNE, PA - EIR, 483, ETC
2016-3345	04/21/2016 05/19/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Vaibhav Dusad Morgan Stanley	ALEMBIC PHARMA, INDIA - 483 03/08/2016 - 03/31/2016
2016-3346	04/21/2016 05/19/2016	FDA/OMPT/CDRH/OCE/DID/	Ruby Chiang Aeon Astron Europe B.V.	K100695
2016-3347	04/21/2016 05/19/2016	FDA/OC/OES/DDM/	Kristi Smedley Center for Regulator Services, Inc	FAP 2197 Environmental Assessment (EA) and FONSI - Docket No. 84F-0345
2016-3348	04/21/2016 05/19/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Carmen Ladner Five Prime Therapeutics, Inc.; Attn. Carmen Ladner	HERCEPTIN - SBA
2016-3349	04/21/2016 05/19/2016	FDA/OMPT/CDRH/OCE/DID/	Jocelyn Raposo Codman Neuro	K152700
2016-3350	04/21/2016 05/19/2016	FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	Adam Johnson Johnson, Adam	21ST CENTURY HEALTHCARE, TEMPE, AZ - EIR 04/01/2013 - 04/30/2013
2016-3351	04/21/2016 05/19/2016	FDA/OGROP/ORO/SW-FO/KAN-DO/KAN-CB/	Lindsey Sablan WINK News	DYNAMIC PET PRODUCTS, FRICK'S MEAT PRODUCTS, INC - INVESTIGATION, COMPLAINTS
2016-3352	04/21/2016 05/19/2016	FDA/OC/OES/DFOI/	Josh Fischman SCIENTIFIC AMERICAN	WARNING LETTERS CITING DATA INTEGRITY OR QUALITY PROBLEMS AND PHARMACEUTICAL MANUFACTURING FACILITIES 01/01/2014 - 01/01/2016
2016-3353	04/21/2016 05/19/2016	FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/ FDA/OMPT/CDRH/OCE/DID/	Corinne Colaianni RMS Medical Products	RMS MEDICAL PRODUCTS, CHESTER, NY - EIR JUNE 2015
2016-3354	04/21/2016 05/19/2016	FDA/OMPT/CDRH/OCE/DID/	Shelley White Simmons College	K851086
2016-3355	04/21/2016 05/19/2016	FDA/OGROP/ORO/CE-FO/MIN-DO/MIN-CB/	Eric Evans Orchard View Capital Advisors LP	BAUDETTE, MN - 483, EIR 01/01/2011 - 04/15/2016

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2016-3356	04/21/2016 05/19/2016	FDA/OFVM/CFSAN/OCD/EOS/	Brianna Schehr DSM Biomedical	CAP 7C0208
2016-3357	04/21/2016 05/19/2016	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/ORA/ OC/ORA/ OC/ORA/ORM/ OC/ORA/ORM/	L. D. Carpenter Kizzia Johnson PLLC	DRUG RECALL INFORMATION
2016-3358	04/21/2016 05/19/2016	FDA/OC/OES/DFOI/ OC/ORA/ORM/ OC/ORA/ORM/	Josh Long Natural Products INSIDER	DIETARY SUPPLEMENT REINSPECTION DATA
2016-3359	04/21/2016 05/19/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	G. Srinivas Zydus Pharmaceuticals USA Inc.	NDA 208246
2016-3360	04/21/2016 05/19/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Rachel Johnson FOI Services, Inc.	2014-9742 EMAILS
2016-3361	04/21/2016 05/19/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Rachel Johnson FOI Services, Inc.	2015-3556 EMAILS
2016-3362	04/21/2016 05/19/2016	FDA/OMPT/CDRH/OCE/DID/	Laura Granite JOHNS HOPKINS UNIVERSITY	K032115
2016-3363	04/21/2016 05/19/2016	FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/	Karen Marshall TARSA THERAPEUTICS INC	QS PHARMA, LLC, BOOTHWYN, PA - EIR 01/01/2014 - 04/19/2016
2016-3364	04/21/2016 05/19/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	pascal besman Pascal Besman	LCZ696 AERS

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-3365	04/21/2016 05/19/2016	OC/ORP/ OC/ORP/ FDA/OGROP/ORA/ORO/DIOP/	Zetetic, Inc. Zetetic, Inc.	FDA ENTRY DOCUMENTATION REQUEST ALL DOCUMENTATION 04/01/2016 - 04/15/2016
2016-3366	04/21/2016 05/19/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BrianT Laboratories, LLC Custopharm, Inc.	ANDA 203967 - Sequence 0002 and 0003
2016-3367	04/21/2016 05/19/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCE/DID/	Jenn Selvey Regulatory Services, Inc	K060804
2016-3368	04/21/2016 07/28/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	Robert J Sloan Lonza Inc.	FCN No. 1633 ;
2016-3369	04/21/2016 05/19/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Matt Renna Westfield Capital	GLATOPA - AERS
2016-3370	04/21/2016 05/19/2016	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	LESLIE RAMSEY FDA NEWS	FRONTIER MEDICAL DEVICES 7/24/15, MED-MIZER 7/6/15, MOREL COMPANY 8/27/15 - RESP TO 483S
2016-3371	04/21/2016 05/19/2016	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	LESLIE RAMSEY FDA NEWS	SECHRIST 9/12/15, BIO SB INC 4/3/15, BIT GROUP USA 8/17/15, ETC - RESP TO 483S
2016-3372	04/21/2016 05/19/2016	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	LESLIE RAMSEY FDA NEWS	SYNOVIS LIFE TECHNOLOGIES 6/17/15, GALIL MEDICAL 6/16/15, ALPHA SOURCE 5/11/15, ETC - RESP TO 483S
2016-3373	04/21/2016	FDA/OGROP/ORA/CE-FO/NWJ-	LESLIE RAMSEY	ZIMMER TRABECULAR METAL TECHNOLOGY 5/11/15, ALTO

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	05/19/2016	DO/NWJ-CB/	FDA NEWS	DEVELOPMENT 5/29/15, 86 HARRIET AVE CORP 6/11/15, ETC - RESP TO 483S
2016-3374	04/21/2016 05/19/2016	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	LESLIE RAMSEY FDA NEWS	MS SURGICAL 6/15/16, MEDTRONIC SOFAMOR DANEK 10/23/15 - RESP TO 483S
2016-3375	04/21/2016 05/19/2016	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	LESLIE RAMSEY FDA NEWS	FONAR CORP 5/22/15, BUXTON 5/20/15 - RESP TO 483S
2016-3376	04/21/2016 05/19/2016	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	LESLIE RAMSEY FDA NEWS	SYNERGETICS 6/9/15, MCNEIL CONSUMER PHARMACEUTICALS PRODUCTS 4/8/15 - RESP TO 483S
2016-3377	04/21/2016 05/19/2016	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	LESLIE RAMSEY FDA NEWS	VERATHON 8/3/15, ENDOGASTRIC SOLUTIONS 10/14/15, REVMEDX 11/23/15, ETC - RESP TO 483S
2016-3378	04/21/2016 05/19/2016	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	LESLIE RAMSEY FDA NEWS	HITACHI 4/21/15, OCUMETRICS 4/23/15, PENUMBRA 8/4/15, ETC - RESP TO 483S
2016-3379	04/21/2016 05/19/2016	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	LESLIE RAMSEY FDA NEWS	BAXTER HEALTHCARE 5/26/15 - RESP TO 483
2016-3380	04/21/2016 05/19/2016	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	LESLIE RAMSEY FDA NEWS	CARDINAL HEALTH 200 - RESP TO 483
2016-3381	04/21/2016 05/19/2016	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	LESLIE RAMSEY FDA NEWS	AUSTCO MARKETING & SERVICE 6/26/15, GRESCO 4/7/15, INTEGRITY SPINE 5/22/15, ETC - RESP TO 483S
2016-3382	04/21/2016 05/19/2016	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	LESLIE RAMSEY FDA NEWS	NDI MEDICAL 6/2/15, VESTIBULAR RESEARCH AND DEVELOPMENT 8/21/15 - RESP TO 483S
2016-3383	04/21/2016 05/19/2016	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	LESLIE RAMSEY FDA NEWS	ORGAN RECOVERY SYSTEMS 4/7/15, CAREFUSION 2200 5/7/15, ENDOPLUS 5/19/16, ETC - RESP TO 483S
2016-3384	04/21/2016 05/19/2016	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	LESLIE RAMSEY FDA NEWS	NORTH AMERICAN MEDICAL CORP 6/12/15 - RESP TO 483
2016-3385	04/21/2016 05/19/2016	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	LESLIE RAMSEY FDA NEWS	GE HEALTHCARE 6/19/15 - RESP TO 483
2016-3386	04/21/2016 05/19/2016	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	LESLIE RAMSEY FDA NEWS	ULTROID TECHNOLOGIES 4/15/15, DECIMAL 5/5/15, AVALON BIOMED 7/21/15, ETC - RESP TO 483S
2016-3387	04/22/2016 05/20/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MAHARIS, MERCEDES	AMAGRELIDE - AER
2016-3388	04/22/2016	FDA/OC/OES/DFOI/	Kris Christian	REDACTED 483, RESPONSES, EIR RELEASED SINCE 3/1/016

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	05/20/2016		FDAZILLA	
2016-3389	04/22/2016 05/20/2016	FDA/OMPT/OSMP/OOPD/	Santosh Ramamurthy Cote Orphan Consulting	Auxilium Pharmaceuticals Orphan Drug Designation Application for the treatment of advanced (involutional or residual stage) Dupuytren's disease ETC
2016-3390	04/22/2016 05/20/2016	FDA/OFVM/CFSAN/OCD/EOS/	Mike Morgan MORGAN & MORGAN	ENERGY DRINKS - RECORDS PREVIOUSLY RELEASED UNDER FOIA 01/04/2002 - 04/18/2016
2016-3391	04/22/2016 05/20/2016	FDA/OC/OES/DFOI/	William Chaudoin William Chaudoin	LIST OF UNAPPROVED DRUGS 01/01/2015 - 12/31/2015
2016-3392	04/22/2016 05/20/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jennifer Miller Eli Lilly and Company - Global Patient Safety	NDA 018780 S-1522
2016-3393	04/22/2016 05/20/2016	FDA/OMPT/CDRH/OCE/DID/	Doe J	CPT1500585
2016-3394	04/22/2016 05/20/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anjali Cordeiro BLOOMBERG NEWS	SECAN PHARMACEUTICALS - BIOEQUIVALENCE, BIOAVAILABILITY DATA RE LEVETIRACETAM
2016-3395	04/22/2016 05/20/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Banu Ramachandran Citron Pharma, LLC	NDA 019569
2016-3396	04/22/2016 05/20/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Frederic W. Bruhn, M.D. Frederic W. Bruhn, M.D.	CRESTOR - AERS
2016-3397	04/22/2016 05/20/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	Custom Device Annual Reports filed in 2015 (for 2014) and filed in 2016 (for 2015) for Biomet.
2016-3398	04/22/2016 05/20/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	Custom Device Annual Reports filed in 2015 (for 2014) and filed in 2016 (for 2015) for DePuy Orthopedics
2016-3399	04/22/2016 05/20/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sudipta Ganguly Cipla Ltd.	NDA 020148

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2016-3400	04/22/2016 05/20/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	Custom Device Annual Reports filed in 2015 (for 2014) and filed in 2016 (for 2015) for Zimmer
2016-3401	04/22/2016 05/20/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kimberly ezdebski Chartwell Life Science LLC	CHANGZHOU PHARMACEUTICAL, CHINA - EIR, 483 04/06/2015 - 04/04/2016
2016-3402	04/22/2016 05/20/2016	OC/ORR/ORM/ OC/ORR/ORM/	Eyal Maor FDAAWARE	LIST OF INSPECTIONS, WARNING LETTERS
2016-3403	04/22/2016 05/20/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kris Christian FDAZILLA	SRI KRISHNA PHARMACEUTICALS LTD - 483 12/01/2014 - 12/04/2014
2016-3404	04/22/2016 05/20/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ana Tiago FFUL	DEAR HEALTH CARE PROVIDER LETTERS RE HUMAN DRUGS 01/01/2010 - 12/31/2015
2016-3405	04/22/2016 05/20/2016	FDA/OMPT/CDRH/OCE/DID/	Doe J	COR15000081
2016-3406	04/22/2016 05/20/2016	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	Michael Filoromo Katz, Marshall & Banks, LLP	MEAN JOHNSON NUTRITION, EVANSVILLE, IN - EIR EXHIBITS 02/01/2016 - 02/05/2016
2016-3407	04/22/2016 05/20/2016	FDA/OC/OES/DFOI/	Matthew Allen Matthew Allen	CATALENT - 483 03/01/2016 - 03/30/2016
2016-3408	04/22/2016 05/20/2016	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Kris Christian FDAZILLA	SPECTRUM LABORATORY PRODUCTS, GARDENA, CA - 483 05/13/2015 - 05/13/2015
2016-3409	04/22/2016 05/20/2016	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Johanna Macnee Johanna Macnee	CHEMTRADE, MIDLOTHIAN, TX - EIR 12/17/2012 - 12/20/2012
2016-3410	04/22/2016 05/20/2016	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	MICHAEL D LEVIN HEALTH BUSINESS STRATEGIES	CREATIVE ENZYMES INC, SHIRLEY, NY - 483, EIR 1/09 TO 4/9/16
2016-3411	04/22/2016 05/20/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Abhay Shanbhag Abhay Shanbhag	ANJAN DRUGS PRIVATE LIMITED, INDIA - 483 01/01/2016 - 02/29/2016
2016-3412	04/22/2016	OC/CVM/OCD/	CHRISTINE FORGUES	INSECTS AS A PROTEIN SOURCE FOR FISH FEED - RECS

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	05/20/2016		SCLENKER MORGAN LEWIS & BOCKIUS LLP	
2016-3413	04/22/2016 05/20/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Amaury Sanchez Noven Pharmaceuticals, Inc.	ANDA 204403
2016-3414	04/22/2016 05/20/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Aaron McCarty THERMO FISHER SCIENTIFIC	Final Chemistry, Manufacturing, and Control Review of Baxter Internationals original Biologics License Application for their recombinant Coagulation Factor IX (Rixubis)
2016-3415	04/22/2016 05/20/2016	FDA/OMPT/CDRH/OCE/DID/	Rebecca Sporer Dentsply Sirona	K151763
2016-3416	04/22/2016 05/20/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Christina Jewett Reveal + The Center for Investigative Reporting	GONAL-F 8404659, 8137867, 8418402, ETC
2016-3417	04/22/2016 05/20/2016	FDA/OMPT/CDRH/OCE/DID/	Becky Li Micro-Tech (Nanjing) Co., Ltd.	K974018
2016-3418	04/22/2016 05/20/2016	FDA/OGROP/ORAP/PA-FO/SAN-DO/SAN-CB/	Kris Christian FDAZILLA	CHARLES RIVER LABORATORIES PRECLINICAL SERVICES, RENO, NV - 483 09/25/2015
2016-3419	04/22/2016 05/20/2016	FDA/OMPT/CDRH/OCE/DID/	NYROBIA FREEMAN CONMED LINVATEC CORP	SIMEX MEDIZINTECHNIK GMBH, DEISSLINGEN, DE - K113291
2016-3420	04/22/2016 05/20/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	PATRICK KELLY CONWAY HOMER & CHIN-CAPLAN PC	INDIVIDUAL RECS
2016-3421	04/22/2016 05/20/2016	FDA/OGROP/ORAP/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDRH/OCE/DID/ OC/ORAP/OCI/ OC/ORAP/OCI/	CHRISTOPHER WEAVER WALL STREET JOURNAL	THERANOS INC - RECS
2016-3422	04/22/2016 05/20/2016	FDA/OO/OHR/	CYNTHIA M. DEVERS WOLK LAW FIRM	INDIVIDUAL RECS

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2016-3423	04/22/2016 06/24/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	MAXWELL, KERI	HEP B VACCINE - CLNCL TRIAL
2016-3424	04/22/2016 05/20/2016	FDA/OC/OES/DFOI/	EAS CONSULTING GROUP LLC	81N 0033 VOL 34, 38
2016-3425	04/22/2016 05/20/2016	FDA/OC/OES/DFOI/	MICHAEL CIPRIANO FDA NEWS	DCK FDA 2015N5106
2016-3426	04/22/2016 05/20/2016	FDA/OC/OES/DFOI/	DEVIN GUSTAFSON SIDLEY AUSTIN LLP	ADVISORY COMMITTEE MTG 2004-2006
2016-3427	04/22/2016 05/20/2016	FDA/OC/OES/DFOI/	ELENA CLARK HOGAN LOVELLS LLP	DOXYCYCLINE OIP-0516, 99P4958, 01P0515
2016-3428	04/22/2016 05/20/2016	FDA/OC/OES/DFOI/	TAYLOR LEWIS NATIONAL CORPORATE RESEARCH	93D-0BG
2016-3429	04/22/2016 05/20/2016	FDA/OC/OES/DFOI/	ROSS RENDELMAN HOGAN LOVELLS LLP	FDA 1997-N-0059
2016-3430	04/22/2016 05/20/2016	FDA/OC/OES/DFOI/	ROSS RENDELMAN HOGAN LOVELLS LLP	2015-P-2854
2016-3431	04/22/2016 05/20/2016	FDA/OC/OES/DFOI/	TINA HU-RODGERS BUCHANAN INGERSOL PC	FDA 1980-H-0012
2016-3432	04/22/2016 05/20/2016	FDA/OC/OES/DFOI/	JOE C. FDA NEWS	CMC APRVD DRUGS
2016-3433	04/25/2016 05/23/2016	FDA/OGROP/ORACE-FO/DET- DO/DET-CB/	Zulfiqar Choudary, Zulfiqar	JABIL MI/USA - EIR 08/01/2014 - 08/01/2015
2016-3434	04/25/2016 05/23/2016	OC/ORACE/OCI/ OC/ORACE/OCI/	Sarah N Lynch REUTERS	LEGIT SCRIPTS - OFFICE OF INTERNAL AFFAIRS INVESTIGATION REPORT 01/01/2010 - 04/20/2016
2016-3435	04/25/2016 05/23/2016	FDA/OMPT/CDRH/OCE/DID/	510k Documentary IntroMedic Co., Ltd.	K153466
2016-3436	04/25/2016 05/23/2016	FDA/OFVM/CFSAN/OCD/EOS/	Josh Long Natural Products INSIDER	11/6/13 LETTER TO USPLABS FROM FDA RE MANDATORY RECALL
2016-3437	04/25/2016 05/23/2016	FDA/OC/OES/DDM/	Gordon Li Forward Observer	RECS RE HOME HIV TEST ADVISORY COMMITTEE 01/01/1994 - 12/31/1994
2016-3438	04/25/2016 05/23/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rahul Jeewani IIFL Capital	ALEMBIC PHARMACEUTICAL LIMITED, INDIA - 483 03/01/2016 - 03/31/2016

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2016-3439	04/25/2016 05/23/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Nora Limbourg Nora Limbourg	VENLAFAXINE - AERS
2016-3440	04/25/2016 05/23/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/CVM/OCD/	Mary Anne Kowalski Mary Anne Kowalski	NEXGARD - AERS
2016-3441	04/25/2016 05/23/2016	FDA/OMPT/CDRH/OCE/DID/	Glen Emelock The CRO Group, Inc.	K143752
2016-3442	04/25/2016 05/23/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Leanne Wockhardt USA LLC	Olmesartan Medoxomil ANDA # 204798; Pemetrexed Sodium Injection ANDA # 090352 TENTATIVE APPROVAL LETTERS
2016-3443	04/25/2016 05/23/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rahul Jeewani IIFL Capital	BIOCON LIMITED, INDIA - 483
2016-3444	04/25/2016 05/23/2016	FDA/OGROP/ORR/SW-FO/DEN-DO/DEN-CB/	Thad Knutson Thad Knutson	MILLERCOORS BREWERY, GOLDEN, CO - 483 01/01/2016 - 04/20/2016
2016-3445	04/25/2016 05/23/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Anjali Cordeiro BLOOMBERG NEWS	ZHEJIANG HUAHAI PHARMACEUTICAL CO - BIOEQUIVALENCE DATA
2016-3446	04/25/2016 05/23/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Poornaa Venkatesan Jefferies India Pvt Ltd	STRIDES, INDIA - 483 02/01/2015 - 04/20/2016
2016-3447	04/25/2016 05/23/2016	FDA/OMPT/CDRH/OCE/DID/	Lisa Anderson ConMed Corporation	K121194 K001450

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2016-3448	04/25/2016 05/23/2016	FDA/OC/OES/DFOI/	Rebecca Silcox Rebecca Silcox	SUCRALOSE - HEALTH EFFECTS
2016-3449	04/25/2016 05/23/2016	OC/ORO/ OC/ORO/ OC/ORO/ORM/ OC/ORO/ORM/	M. Randall M. Randall	List of Device Inspections 3/1/2016 to 4/20/2016
2016-3450	04/25/2016 05/23/2016	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	Information regarding the Tobacco Heating System 2.2 (THS 2.2)
2016-3451	04/25/2016 05/23/2016	FDA/OMPT/CDRH/OCE/DID/	Becky Li Micro-Tech (Nanjing) Co., Ltd.	K132535
2016-3452	04/25/2016 05/23/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Aakash Agarwal Wize Market Analytics	GLENMARK PHARMACEUTICALS, INDIA - 483 01/01/2016 - 04/21/2016
2016-3453	04/25/2016 05/23/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Genevieve DellaFera FERA PHARMACEUTICALS	NDA 204630, PROVAYBLUE SBA
2016-3454	04/25/2016 05/23/2016	FDA/OMPT/CDRH/OCE/DID/	Hui Ouyang Cook Medical	K150603
2016-3455	04/25/2016 05/23/2016	FDA/OC/OES/DFOI/	Gina Ecolino BEVERIDGE & DIAMOND	CFSAN FOIA REQUESTS 03/22/2016 - 04/21/2016
2016-3456	04/25/2016 05/23/2016	FDA/OMPT/CDRH/OCE/DID/	CASEY H HARGRODER KEBODEAUX HARGRODER ALEXANDER LLP	MENTOR WORLDWIDE LLC - SILICONE MEMORY GEL BREAST IMPLANTS NEW DESIGN APRVL RECS 2006
2016-3457	04/25/2016 05/23/2016	FDA/OC/OES/DFOI/	CHRIS WEAVER WALL STREET JOURNAL	2015-8760, 2015-10190, 2015-10236, 2016-1230
2016-3458	04/25/2016 05/23/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PAMELA SHEPPARD TARO PHARMACEUTICALS USA INC	FOUGERA PHARMS INC - TACROLIMUS OINTMENT ANDA 200-744; AMNEAL PHARMS - DICLOFENAC SODIUM GEL ANDA 208-077 SBA, MOR, LBLG, ETC
2016-3459	04/25/2016 05/23/2016	FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/	JEFFREY W PLAZA EHRlich PETRIELLO GUDIN & PLAZA	STRATUS PHARMACEUTICALS INC, MIAMI, FL - 483S, WARNING LTRS, SEIZURE OF PRODCTS, ETC 2011 TO PRESENT

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2016-3460	04/25/2016 05/23/2016	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	JEFFREY W PLAZA EHRlich PETRIELLO GUDIN & PLAZA	SONAR PRODUCTS INC, CARLSTADT, NJ - 483S, WARNING LTRS, CORR, ETC 2000 TO PRESENT
2016-3461	04/25/2016 05/23/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHRISTOPHER JOHNSTON W70642 JOHNSTON W70642, CHRISTOPHER	TRILAFON (PERPHENAZINE) - AERS
2016-3462	04/25/2016 05/23/2016	FDA/OC/OES/DFOI/	CHRIS WEAVER WALL STREET JOURNAL	THERANOS INC - FOIA REQUESTS 1/15 TO PRESENT
2016-3463	04/26/2016 05/24/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ayan Deb Nomura Financial Advisory Securities India Ltd	GLENMARK, INDIA - 483 02/01/2016 - 04/21/2016
2016-3464	04/26/2016 05/24/2016	FDA/OMPT/CDRH/OCE/DID/	Erkodent Erich Kopp GmbH Erkodent Erich Kopp GmbH	K072522
2016-3465	04/26/2016 05/24/2016	OC/ORACE/ OC/ORACE/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Doe J	CC145383
2016-3466	04/26/2016 05/24/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/OSMP/OOPD/	Steven Brooks Steven Brooks	SOTALOL - APPLICATION FOR ORPHAN DRUG DESIGNATION, REVIEW
2016-3467	04/26/2016 05/24/2016	FDA/OMPT/CDRH/OCE/DID/	Doron Harlev Affera, Inc.	PMA files for cardiac ablation systems and devices
2016-3468	04/26/2016 05/24/2016	FDA/OGROP/ORACE-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORACE-FO/LOS-DO/LOS-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	OEYAMA-MOTO CANCER RESEARCH FOUNDATION IRB, WEST COVINA, CA - EIR 08/11/2015 - 09/29/2015
2016-3469	04/26/2016 05/24/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tom Glaser Think Investments LP	STRIDES SHASUN - 483 01/01/2015 - 04/21/2016

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2016-3470	04/26/2016 05/24/2016	FDA/OMPT/CDRH/OCE/DID/	Clare Rosa Halo Medical Technologies	CPT1400805
2016-3471	04/26/2016 05/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jatin Kotian Emkay Global Financial Services Limited	SRI KRISHNA PHARMACEUTICALS, INDIA - 483 01/18/2016 - 01/22/2016
2016-3472	04/26/2016 05/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Chirag Talati Kotak Securities	CIPLA - 483 01/01/2015 - 04/21/2016
2016-3473	04/26/2016 05/24/2016	FDA/OMPT/CDRH/OCE/DID/	Elizabeth Torre Reckitt Benckiser LLC	K150841
2016-3474	04/26/2016 05/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	David Petrocine Aceto Corporation	NANJING KING-FRIEND BIOCHEMICAL PHARMACEUTICAL CO, LTD, CHINA - 483 05/01/2015 - 01/01/2016
2016-3475	04/26/2016 05/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	David Petrocine Aceto Corporation	YANTAI DONGCHENG BIOCHEMICALS CO LTD, CHINA - 483 05/01/2015 - 01/01/2016
2016-3476	04/26/2016 05/24/2016	FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	Bart van den Brand BIOMERIEUX INC	BIOMERIEUX INC, DURHAM, NC - EIR 01/24/2012 - 03/06/2012
2016-3477	04/26/2016 06/06/2016	FDA/OC/OES/DDM/	Thomas J. Peistrup Leech Tishman Fuscaldo & Lampl	FDA'S RULE MAKING DECISION PROCESS 21 CFR 348 10/02/1985 - 06/19/1992
2016-3478	04/26/2016 05/24/2016	OC/CVM/OCD/	Edie Lau VETERINARY INFORMATION NETWORK NEWS SERVICES	ZEUTERIN - AERS
2016-3479	04/26/2016 05/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Yao Li Ho Lyfe Capital	NDA 20586
2016-3480	04/26/2016 05/24/2016	FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/	Walter Chalkley THOMSON REUTERS	ALLERGY LABORATORIES, INC, OKLAHOMA CITY, OK - 483 09/16/2014 - 10/17/2014

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2016-3481	04/26/2016 05/24/2016	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Bart van den Brand BIOMERIEUX INC	BIOMERIEUX INC, DURHAM, NC - EIR 06/01/2013 - 06/11/2013
2016-3482	04/26/2016 05/24/2016	FDA/OMPT/CDRH/OCE/DID/	Marilynn Whitney COVINGTON & BURLING LLP	RECS RE MARCH 2016 WITH CDRH
2016-3483	04/26/2016 05/24/2016	FDA/OMPT/CDRH/OCE/DID/	Turna Ray Franz GenomeWeb	Submissions via the MedWatch Online Voluntary Reporting Form citing errors in the identification and/or classification of genetic variants in relation to genetic and genomic tests that are performed as FDA approved or cleared kits or performed at a single lab 6/13/2013 - 04/21/2016
2016-3484	04/26/2016 05/24/2016	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Grifols Biologicals Inc. Grifols Biologicals Inc.	GRIFOLS BIOLOGICALS INC, CITY OF INDUSTRY, CA - EIR 10/14/2015 - 10/20/2015
2016-3485	04/26/2016 05/24/2016	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Gregory Bergt Bergt Consulting Inc.	SRI KRISHNA PHARMACEUTICALS LTD, INDIA - 483 12/01/2014 - 12/04/2014
2016-3486	04/26/2016 05/24/2016	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Rachel Johnson FOI Services, Inc.	USTEKINUMAB - AERS FAERS
2016-3487	04/26/2016 05/24/2016	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Krishna Kiran Konduri Spark Capital Advisors (I) Private Limited	GLENMARK PHARMACEUTICALS, INDIA - 483 01/01/2016 - 04/08/2016
2016-3488	04/26/2016 05/24/2016	FDA/OMPT/CDRH/OCE/DID/	Leslie Fitch Wright Medical Technology	K101552
2016-3489	04/26/2016 05/24/2016	FDA/OMPT/CDRH/OCE/DID/	Ruby Chiang Aeon Astron Europe B.V.	K050446
2016-3490	04/26/2016 05/24/2016	FDA/OMPT/CDRH/OCE/DID/	Ruby Chiang Aeon Astron Europe B.V.	K133507
2016-3491	04/26/2016 05/24/2016	FDA/OMPT/CDRH/OCE/DID/	Ruby Chiang Aeon Astron Europe B.V.	K042197
2016-3492	04/26/2016 05/24/2016	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Abigail Pontz Abigail Pontz	MERCK & CO, KENILWORTH, NJ - 483 01/01/2015 - 12/31/2015
2016-3493	04/26/2016	FDA/OMPT/CDER/ERP/DIDP/	Rahul Jeewani	LAMBDA THERAPEUTIC RESEARCH, INDIA - 483 01/01/2015 - 04/22/2016

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	05/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	IIFL Capital	
2016-3494	04/26/2016 05/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jeannine Parton B. Braun Medical Inc.	NDA 19024
2016-3495	04/26/2016 05/24/2016	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Carl Elliott Carl Elliott University of Minnesota	UNIVERSITY OF MINNESOTA - EIR 10/04/2011 - 10/18/2011
2016-3496	04/26/2016 05/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michael Metschl ORBIMED ADVISORS LLC	TECFIDERA - AERS
2016-3497	04/26/2016 05/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rahul Jeewani IIFL Capital	ACCUTEST RESEARCH LABORATORIES, INDIA - 483 01/01/2015 - 04/22/2016
2016-3498	04/26/2016 05/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rahul Jeewani IIFL Capital	LUPIN BIORESEARCH CENTER, INDIA - 483 01/01/2015 - 04/22/2016
2016-3499	04/26/2016 05/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Genevieve Stevens Nivagen Pharmaceuticals, Inc.	ANDA 089414
2016-3500	04/26/2016 05/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Genevieve Stevens Nivagen Pharmaceuticals, Inc.	NDA 016199
2016-3501	04/26/2016 05/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Pete Arreola Novartis Pharmaceutical Corp.	MYLAN, INDIA - 483 04/04/2016 - 04/13/2016

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2016-3502	04/26/2016 05/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mo Dimbil ADVERSEEVENTS INC	FAERS REPORT 11720875
2016-3503	04/26/2016 05/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angela A. Stanton none	SOVALDI, DAKLINZA - AERS
2016-3504	04/26/2016 05/24/2016	FDA/OMPT/CDRH/OCE/DID/	helen Peng GE Healthcare	K133589
2016-3505	04/26/2016 05/24/2016	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDRH/OCE/DID/	ELLEN RELKIN ESQ WEITZ & LUXEMBERG PC	APEX SURGICAL, OMNILIDE SCIENCE INC - 483S, WARNING LTRS, INSPS; APEX K2 HIP STEM, APEX ARC HIP STEM IMPLANTS - MDRS, CLNCL STUDIES, ETC
2016-3506	04/26/2016 05/24/2016	FDA/OMPT/CDRH/OCE/DID/	LORI J BARR KIMBERLY CLARK CORP	KIMBERLY-SLARK CORP - HEAVY DUTY TAMPON & STICK K780058
2016-3507	04/26/2016 05/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JAKE MCDOWELL WEINBERG GROUP INC	UNIMED PHARMACEUTICALS INC - RECS
2016-3508	04/26/2016 05/24/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	MARTIN RUBENSTEIN HOWARD M FILE ATTY	INDIVIDUAL RECS - VAERS
2016-3509	04/26/2016 05/24/2016	FDA/OC/OES/DFOI/	DAVID SCHMIDT SCHMIDT, DAVID	Bard 3DMax Mesh MDRs and CDRH criminal charges against Davol Inc.
2016-3510	04/26/2016 05/24/2016	OC/ORAO/OCI/ OC/ORAO/OCI/	Sarah N Lynch REUTERS	MARY'S GONE CRACKERS - INVESTIGATION RECS 01/01/2014 - 04/21/2016
2016-3511	04/26/2016 05/24/2016	FDA/OMPT/OSMP/OOPD/	Steven Brooks Steven Brooks	SOTALOL HYDROCHLORIDE - ORPHAN DRUG DESIGNATION RECS
2016-3512	04/26/2016 05/24/2016	FDA/OMPT/OSMP/OOPD/	Steven Brooks Steven Brooks	SOTALOL HCI - ORPHAN DESIGNATION RECS

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2016-3513	04/26/2016 05/24/2016	FDA/OC/OES/DFOI/	SIDDHARTH KARNAWAT SIDDHARTH KARNAWAT	AUROBINDO PHARMA - WARNING LETTER
2016-3514	04/26/2016 05/24/2016	FDA/OC/OES/DFOI/	SIDDHARTH KARNAWAT SIDDHARTH KARNAWAT	LUPIN - WARNING LETTER
2016-3515	04/26/2016 05/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SIDDHARTH KARNAWAT SIDDHARTH KARNAWAT	CIPLA, INDIA - 483, WARNING LETTER 01/02/2015 - 04/22/2016
2016-3516	04/26/2016 05/24/2016	FDA/OMPT/OSMP/OOPD/	Steven Brooks Steven Brooks	AMIODARONE HCI - ORPHAN DRUG RECS
2016-3517	04/26/2016 05/24/2016	OC/CVM/OCD/	Bill Ryan Ryan, William G	All RA1932 forms for Osumia
2016-3518	04/26/2016 05/24/2016	FDA/OMPT/CDRH/OCE/DID/	Andrew Jackson Crawford Healthcare Ltd	K071354
2016-3519	04/26/2016 05/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Wendy Tian Tian, Wendy	NDA 006823 SBA
2016-3520	04/26/2016 05/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ayan Deb Nomura Financial Advisory Securities India Ltd	LUPIN - EIR 01/01/2016 - 04/26/2016
2016-3521	04/26/2016 05/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jann Kochel Velicept Therapeutics, Inc.	IND 71412
2016-3522	04/26/2016 05/24/2016	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink	2015-8918
2016-3523	04/26/2016 05/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	pascal besman Pascal Besman	PONATINIB - AERS
2016-3524	04/26/2016	FDA/OMPT/CDER/ORP/DIDP/	Daniel Zwerdling	FULL REPORT OF FDA SUPPLEMENTAL REVIEW OF

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	05/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	NPR	MEFLOQUINE ETC
2016-3525	04/26/2016 05/24/2016	FDA/OC/OES/DFOI/	Maureen Melvin Maureen Melvin	2014-3291
2016-3526	04/26/2016 05/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LESLIE RAMSEY FDA NEWS	2016-3081- GLENAMRK PHARMACEUTICALS 483S
2016-3527	04/26/2016 05/24/2016	FDA/OC/OES/DFOI/	Douglas Main Newsweek Magazine	DESI REVIEW ENZIFLUR
2016-3528	04/26/2016 05/24/2016	FDA/OMPT/CDRH/OCE/DID/	THERESE AVANT HOLLIS WRIGHT CLAY & VAIL PC	ABBOTT - BALANCE MIDDLEWEIGHT GUIDEWIRE STENT DELIVERY SYS RECALLS, MDRS, MODIFICATIONS, ETC LAST 3 YRS
2016-3529	04/26/2016 05/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rahul Jeewani IIFL Capital	LIST OF ANDAs USING SEMLER RESEARCH CLINICAL AND BIOANALYTICAL STUDIES ARE PART OF REGULATORY FILING
2016-3530	04/26/2016 05/24/2016	FDA/OMPT/CDRH/OCE/DID/	THERESE AVANT HOLLIS WRIGHT CLAY & VAIL PC	BOSTON SCIENTIFIC - EPIC SHORT SHAFT SELF-EXPANDING STENT RECALLS, MDRS, MODIFICATIONS, ETC LAST 3 YRS
2016-3531	04/26/2016 05/24/2016	FDA/OMPT/CDRH/OCE/DID/	THERESE AVANT HOLLIS WRIGHT CLAY & VAIL PC	COOK INC - FLEXOR ANSEL GUIDING SHEATH DYB INTRODUCER CATHETER RECALLS, MDRS, MODIFICATIONS, ETC LAST 3 YRS
2016-3532	04/26/2016 05/24/2016	OC/ORO/OCI/ OC/ORO/OCI/	SARAH N LYNCH THOMSON REUTERS	INTERNAL AFFAIRS INVESTIGATION
2016-3533	04/27/2016 05/25/2016	FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/	Kurt Martin Wm. E. Martin & Sons Co., Inc.	EMAILS FROM FDA SAN-DO RE PEANUT, PEANUT ALLERGAN, PEANUT PROTEINS 10/17/2015 - 04/21/2016
2016-3534	04/27/2016 05/25/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/CVM/OCD/	Mary Shapiro Evoke Law PC	CANNA COMPANION LLC - LABORATORY SOURCE
2016-3535	04/27/2016 05/25/2016	OC/CVM/OCD/	Mary Shapiro Evoke Law PC	CANNA-PET LLC - COMMUNICATIONS RE WARNING LETTER

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2016-3536	04/27/2016 05/25/2016	FDA/OMPT/CDRH/OCE/DID/	Juliana Remuszka Lieff Cabraser Heimann & Bernstein, LLP	BAUSH & LOMB - RECS PROVIDED TO FDA RE CRYSTELENS, TRULIGN INTRAOCULAR LENSES; AERS, INVESTIGATIONS, ETC 01/01/2000 - 04/22/2016
2016-3537	04/27/2016 05/25/2016	FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/	Gregory Goei Par Pharmaceuticals	IRVINE PHARMACEUTICAL SERVICES - 483 01/05/2015 - 03/31/2015
2016-3538	04/27/2016 05/25/2016	FDA/OMPT/CDRH/OCE/DID/	Frank Ferguson Ferguson Medical International	K931265
2016-3539	04/27/2016 05/25/2016	FDA/OC/OES/DFOI/	Jodi Brown Jodi Brown	PET FOOD RECALL RECS 01/01/2015 - 04/01/2016
2016-3540	04/27/2016 05/25/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Giridhar Prasad Jangly Dr. Reddy's Laboratories Inc.	DMF 14309 COVER LETTER
2016-3541	04/27/2016 05/25/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Melissa V. Malapit Celgene Corporation	ANTONIO M ALMEIDA, INSTITUTO PORTUGUES DE LISBOA DE FRANCISCO, PORTUGAL - EIR 11/01/2015 - 04/26/2016
2016-3542	04/27/2016 05/31/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Phillip Hwang UNIVERSITY OF WASHINGTON	Clinical and statistical review(s) for Boostrix (STN: BL 125106)
2016-3543	04/27/2016 05/25/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joshua Klitzke SPECTRANETICS CORP	INDENA, ITALY; YUNG SHIN PHARMACEUTICAL INDUSTRIAL CO, TAIWAN ETC - 483 01/01/2010 - 04/26/2016
2016-3544	04/27/2016 05/25/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Amisha Patel Dr. Reddy's Laboratories Inc.	In Vitro Methods Development and Validation for Generic Drugs listed under Drug Compliance Programs
2016-3545	04/27/2016 05/25/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Matthew Allen Matthew Allen	QSYMVIA, CONTRAVE, BELVIQ - AERS

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-3546	04/27/2016 05/25/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ryan Parr Magnetic Research Inc	PRE IND RECS MAGNETIC RESEARCH INC AND DIVISION OF IMAGING AND RADIOPHARMACEUTICAL DRUG PRODUCTS 07/01/1996 - 08/31/1996
2016-3547	04/27/2016 05/25/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shreyas Gowdar Shreyas Gowdar	STATIN USE - AERS
2016-3548	04/27/2016 05/25/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michael Sperling The Baupost Group	AURYXIA - AERS
2016-3549	04/27/2016 05/25/2016	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink	2016-3072
2016-3550	04/27/2016 05/25/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jennifer Miller Eli Lilly and Company - Global Patient Safety	First approval date for the approval of doxorubicin hydrochloride to treat soft tissue sarcoma
2016-3551	04/27/2016 05/25/2016	FDA/OC/OES/DFOI/	Michael Sperling The Baupost Group	KERYX BIOPHARMACEUTICALS, AURYXIA - FOIA REQUESTS 01/01/2010 - 04/26/2016
2016-3552	04/27/2016 05/25/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jodi Segal JOHNS HOPKINS UNIVERSITY SCHOOL OF MEDICINE & THE JOINT COMMITTEE ON CLINICAL INVESTIGATION	LEVOTHYROXINE, AMPHETAMINE, TAMSULOSIN - CASE NARRATIVES
2016-3553	04/27/2016 05/25/2016	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	KATHRYN D.SIMON, Ph.D. MERCK & CO., INC.	MERCK, DURHAM, NC - EIR 1/11-1/17/14
2016-3554	04/27/2016 05/25/2016	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	KATHRYN D. SIMON, Ph.D. MERCK & CO., INC.	MERCK, DURHAM, NC - EIR 11/17-24/14
2016-3555	04/27/2016 05/25/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ONEIL, RITA	7533382, 7535072, 7540627 - FAERS

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-3556	04/27/2016 05/25/2016	FDA/OMPT/CDRH/OCE/DID/	WIKE, CHARLES	K143014, K140706, K111993
2016-3557	04/27/2016 05/25/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAWN CHITTY TORRENT PHARMA INC	SYNALAR NDA 15-296 SBA
2016-3558	04/27/2016 05/25/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAWN CHITTY TORRENT PHARMA INC	BETAMETHASONE DIPROPIONATE NDA 19-141 SBA
2016-3559	04/27/2016 05/25/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAWN CHITTY TORRENT PHARMA INC	CLEOCIN T NDA 50-537 SBA
2016-3560	04/27/2016 05/25/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAWN CHITTY TORRENT PHARMA INC	LIDOCAINE ANDA 80-198 SBA
2016-3561	04/27/2016 05/25/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAWN CHITTY TORRENT PHARMA INC	CLOBETASOL PROPIONATE ANDA 74-220 SBA
2016-3562	04/27/2016 05/25/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAWN CHITTY TORRENT PHARMA INC	CLOBETASOL PROPIONATE ANDA 74-407 SBA
2016-3563	04/27/2016 05/25/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAWN CHITTY TORRENT PHARMA INC	TOPICORT ANDA 73-193 SBA
2016-3564	04/27/2016 05/25/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAWN CHITTY TORRENT PHARMA INC	DESONIDE NDA 17-426 SBA

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2016-3565	04/27/2016 05/25/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAWN CHITTY TORRENT PHARMA INC	DESONIDE NDA 17-426 SBA
2016-3566	04/27/2016 05/25/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAWN CHITTY TORRENT PHARMA INC	DESONIDE NDA 17-010 SBA
2016-3567	04/27/2016 05/25/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAWN CHITTY TORRENT PHARMA INC	FLUCINONIDE OINTMENT NDA 75-008 SBA
2016-3568	04/27/2016 05/25/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAWN CHITTY TORRENT PHARMA INC	DESOWEN ANDA 72-354 SBA
2016-3569	04/27/2016 05/25/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAWN CHITTY TORRENT PHARMA INC	FLUCINONIDE CREAM ANDA 72-494 SBA
2016-3570	04/27/2016 05/25/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAWN CHITTY TORRENT PHARMA INC	BETAMETHASONE DIPROPIONATE NDA 19-141 SBA
2016-3571	04/27/2016 05/25/2016	FDA/OC/OES/DFOI/	DOUGLASS A. KREIS AYLSTOCK WITKIN KREIS ET AL	ATRIUM; MAQUET - C-QUR OMEGA 3 BARRIER 510K
2016-3572	04/27/2016 05/31/2016	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	DANIEL B. SNELLINGS MORRIS BART LLC	HOSPIRA, LAKE FOREST, IL - RESP TO INVESTIGATION 1/19/14-2/7/14, RESP TO WARNING LTR 5/9/13
2016-3573	04/27/2016 05/25/2016	FDA/OMPT/CDRH/OCE/DID/	JOHN CARREYROU WALL STREET JOURNAL	EMAILS BETWEEN US ARMY EMPLOYEE & FDA OFFICIALS REGARDING THERANOS INC
2016-3574	04/27/2016	FDA/OC/OES/DFOI/	DIANNE L. CHAMBERS	2016-2779

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	05/25/2016		HOGAN LOVELLS LLP	
2016-3575	04/28/2016 05/26/2016	FDA/OC/OES/DFOI/	Rachel Heckert Rachel Heckert	PLEXUS WORLDWIDE PRODUCTS 04/03/2015 - 04/03/2016
2016-3576	04/28/2016 05/26/2016	FDA/OMPT/CDRH/OCE/DID/	Emily Leongini ARENT FOX LLP	CPT1300644 CPT1300642 CPT1400035 ETC
2016-3577	04/28/2016 05/26/2016	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Angela Henslee Henslee, Angela	CHALMERS P. WYLIE VA AMBULATORY CARE CENTER, COLUMBUS, OH - 483 01/01/2012 - 04/25/2016
2016-3578	04/28/2016 05/26/2016	OC/ORACE/ORM/ OC/ORACE/ORM/	Kris Christian FDAZILLA	LIST OF INSPECTIONS 03/23/2016 - 04/25/2016
2016-3579	04/28/2016 05/26/2016	FDA/OMPT/CDRH/OCE/DID/	Nicholas Antaki Evergaze Technology Inc.	K910124
2016-3580	04/28/2016 05/26/2016	FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/	Rachel A Potter UNIVERSITY OF VIRGINIA	MEETINGS RE MENU LABELING, VENDING MACHINE RULEMAKING 03/23/2010 - 12/01/2014
2016-3581	04/28/2016 05/26/2016	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Dirk J. Horne Coating Place Inc.	COATING PLACE, VERONA, WI - EIR (CERTIFIED) 03/15/2016 - 04/30/2016
2016-3582	04/28/2016 05/26/2016	FDA/OC/OES/DFOI/	Doe J	OLYMPUS ENDOSCOPES - MDR, WARNING LETTER 01/01/2015 - 04/26/2016
2016-3583	04/29/2016 05/27/2016	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K103106
2016-3584	04/29/2016 05/27/2016	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	List of all FOIA requests regarding Xyrem
2016-3585	05/02/2016 05/31/2016	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	THOMPSON, RAY	REMEDY REPACK IC, INDIANA, PA - 483 10/28/15 - 11/23/15
2016-3586	05/02/2016 05/31/2016	FDA/OGROP/ORACE-FO/SEA-DO/SEA-CB/	THOMPSON, RAY	TZ MEDICAL INC, PORTLAND, OR 10/5/15 - 11/3/15; MAKING COSMETICS INC, SNOQUALMIE, WA 12/8/15 - 1/15/16 - 483
2016-3587	05/02/2016 05/31/2016	FDA/OGROP/ORACE-FO/SJN-DO/SJN-CB/	THOMPSON, RAY	ZIMMER MAUNFACTURING BV, MERCEDIA, PR 10/28/15 - 11/17/15; AGROPHARMA LABS INC, SALINAS, PR 1/11/16 - 2/12/16 - 483
2016-3588	05/02/2016 05/31/2016	FDA/OGROP/ORACE-FO/NOL-DO/NOL-CB/	THOMPSON, RAY	DR REDDYS LABS LOUISIANA, SHREVEPORT, LA 10/20/15 - 11/10/15 - 483
2016-3589	05/02/2016 05/31/2016	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	THOMPSON, RAY	ELITE LABS INC, NORTHVALE, NJ 1/5/16 - 2/2/16 - 483
2016-3590	05/02/2016 05/31/2016	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Tyler Grigery Tyler Grigery	OCI EMPLOYEES RECEIVING PERFORMANCE AWARD WITHOUT COMPLETING PERFORMANCE PERIOD

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2016-3591	05/02/2016 05/31/2016	OC/OROA/ OC/OROA/	Tyler Grigery Tyler Grigery	PHILIP WALSKY, SAMANTHA WILDE - EMAILS, TEXTS, ETC 01/01/2006 - 03/01/2016
2016-3592	05/02/2016 05/31/2016	OC/OROA/ OC/OROA/	Jennifer Moreno Berkeley Law Death Penalty Clinic	TEXAS DEPARTMENT OF CRIMINAL JUSTICE - CORR WITH FDA RE DENIAL OF APPEAL TO DETAIL SHIPMENT OF SODIUM THIOPIENTAL 01/01/2015 - 04/25/2016
2016-3593	05/02/2016 05/31/2016	FDA/OGROP/OROA/NE-FO/NWE- DO/NWE-CB/	THOMPSON, RAY	SMITH & NEPHEW INC, MANSFIELD, MA 11/17/15 - 12/8/15; AVEDRO INC, WALTHAM, MA 1/19/16 - 2/10/16 - 483
2016-3594	05/02/2016 05/31/2016	FDA/OGROP/OROA/SE-FO/ATL- DO/ATL-CB/	THOMPSON, RAY	WAVEFORM INC, MARIETTA, GA 1/27/16 - 2/19/16; EISAI INC, RESEACH TRIANGLE PARK, NC 12/2/15 - 12/10/15 - 483
2016-3595	05/02/2016 05/31/2016	OC/OROA/ OC/OROA/	Jennifer Moreno Berkeley Law Death Penalty Clinic	RECS RE FDA AND STATE/FEDERAL AGENCIES RE SODIUM THIOPIENTAL, CORR WITH ARIZONA, NEBRASKA, OHIO; ETC - 01/01/2015 - 04/25/2016
2016-3596	05/02/2016 05/31/2016	FDA/OC/OES/DDM/	Marion Gugan Premières Lignes	Paul Newberne's Final Report on Nitrites : Newberne, P. M. 1978. Final Report on Contract No. FDA 74-2181
2016-3597	05/02/2016 05/31/2016	FDA/OGROP/OROA/CE-FO/MIN- DO/MIN-CB/	THOMPSON, RAY	BELL PHARMACEUTICALS INC, BELLE PLAINE, MN 11/17- 20/15; CRITICARE SYSTEMS INC, WAUKESHA, WI 11/2-20/15 - 483
2016-3598	05/02/2016 06/01/2016	FDA/OC/OES/DFOI/ FDA/OGROP/OROA/CE-FO/DET- DO/DET-CB/ FDA/OGROP/OROA/CE-FO/MIN- DO/MIN-CB/ FDA/OGROP/OROA/CE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/OROA/CE-FO/PHI- DO/PHI-CB/ FDA/OGROP/OROA/NE-FO/NWE- DO/NWE-CB/ FDA/OGROP/OROA/NE-FO/NYK- DO/NYK-DCB/ FDA/OGROP/OROA/PA-FO/SAN- DO/SAN-CB/ FDA/OGROP/OROA/PA-FO/SEA- DO/SEA-CB/ FDA/OGROP/OROA/SE-FO/ATL- DO/ATL-CB/ FDA/OGROP/OROA/SE-FO/SJN- DO/SJN-CB/	Jonathan Kaufman WILLIAM BLAIR & CO	CATALENT, INC; ALBANY MOLECULAR INC; PATHEON INC - 483 01/01/2006 - 04/26/2016

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		FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/		
2016-3599	05/02/2016 05/31/2016	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Giridhar Prasad Jangly Dr. Reddy's Laboratories Inc.	GERITEX CORP, MOUNT VERNON, NY - EIR LAST THREE INSPECTIONS
2016-3600	05/02/2016 05/31/2016	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	THOMPSON, RAY	ZIMMER BIOMET, WARSAW, IN 10/19/15 - 11/20/15; INDIANA UNIVERSITY HOSPITAL, INDIANAPOLIS, IN 12/15/15 - 2/3/16; ANALYTICAL CONTROL SYS INC 2/16-29/16 - 483
2016-3601	05/02/2016 05/31/2016	FDA/OMPT/CTP/OD/	Toni Clarke THOMSON REUTERS	CORR WITH OMB AND FDA RE FLAVORINGS IN E-CIGARETTES IN CONNECTION WITH THE FDA'S TOBACCO DEEMING REGULATIONS 12/01/2015 - 04/26/2016
2016-3602	05/02/2016 05/31/2016	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	John Birrenbach The Institute for Cannabis	COMMUNICATIONS, MEMOS, REQUESTS ETC FROM HHS TO FDA RE SCHEDULING OF CANNABINOL, CBD, OR OTHER COMPONENT OF MARIJUANA 01/01/2004 - 01/01/2008
2016-3603	05/02/2016 05/31/2016	FDA/OMPT/CDRH/OCE/DID/	Nichole Early Medical Action Industries an Owens and Minor Company	K812992
2016-3604	05/02/2016 05/31/2016	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	THOMPSON, RAY	WHITEHILL MANUFACTURING INC, STAFFORD, TX 12/9/15 - 1/20/16; API RESOURCES LLC, SAN ANTONIO, TX 1/26-28/16 - 483
2016-3605	05/02/2016 06/13/2016	FDA/OMPT/CTP/OD/	Marisa Glassman MORGAN & MORGAN	RECS RE WARNING LETTER TO SANTA FE TOBACCO CO 01/02/2015 - 04/26/2016
2016-3606	05/02/2016 05/31/2016	FDA/OMPT/CDRH/OCE/DID/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDRH/OCE/DID/	Karen St. Onge NXSTAGE MEDICAL INC	B BRAUN MELSUNGEN AG, MELSUNGEN GERMANY - EIR ETC 02/02/2015 - 07/01/2015
2016-3607	05/02/2016 05/31/2016	OC/ORA/ OC/ORA/	Kim Schmelzer PMT Corporation	RECS RE Complaint Number 139525

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		FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/		
2016-3608	05/02/2016 05/31/2016	FDA/OMPT/CDRH/OCE/DID/	Imran Karim Imran Karim	K123999
2016-3609	05/02/2016 05/31/2016	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	THOMPSON, RAY	ADAPTA MEDICAL INC, COLORADO SPRINGS, CO 11/9/15 - 12/2/15; EDWARDS LIFESCIENCES LLC, DRAPER, UT 11/2-20/15 ; SPECTRANETICS CORP, COLORADO SPRINGS, CO 11/30/15-1/21/16 - 483
2016-3610	05/02/2016 05/31/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca Dandeker Morgan, Lewis & Bockius LLP	ERCROS, SA, SPAIN - EIR 01/01/2014 - 01/01/2015
2016-3611	05/02/2016 05/31/2016	FDA/OFVM/CFSAN/OCD/EOS/	Donald Schmitt ToxStrategies, Inc.	GRAS 478
2016-3612	05/02/2016 05/31/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Melissa V. Malapit Celgene Corporation	VALERIA SANTINI AZIENDA, ITALY - EIR 10/01/2015 - 04/26/2016
2016-3613	05/02/2016 05/31/2016	FDA/OMPT/CDRH/OCE/DID/	Scott Goldman Hyman, Phelps & McNamara P.C.	K964853
2016-3614	05/02/2016 05/31/2016	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	THOMPSON, RAY	OHIO MEDICAL CORP, GURNEE, IL 3/16/15 - 12/29/15; STERIS ISOMEDIX SERVICES, LIBERTYVILLE, IL 9/25/15 - 12/3/15; ADVOCATE LUTHERAN GENERAL HOSPITAL, PARK RIDGE, IL 12/3/15 - 1/11/16 - 483
2016-3615	05/02/2016 05/31/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John Birrenbach The Institute for Cannabis	I request a copy of any and all communications, memos, requests for information made by HHS to the FDA regarding the re-scheduling of Marijuana.
2016-3616	05/02/2016 05/31/2016	FDA/OFVM/CFSAN/OCD/EOS/	Rajiv Datar Rajiv Datar	FAP 3B2925
2016-3617	05/02/2016 05/31/2016	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	THOMPSON, RAY	INVACARE CORP, ELYRIA, OH 7/16/15 - 12/9/15; 3M COMPANY, MILFORD, OH 11/4-6/15; INNOVATIVE STERILIZATION TECHNOLOGIES LLC, DAYTON, OH 10/6/15 - 11/4/15 - 483
2016-3618	05/02/2016 05/31/2016	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORASW-FO/DEN-	Fran Silverman truthinadvertising.org	4LIFE RESEARCH USA LLC, WEST SANDY, UT - 483, AERS 01/01/2004 - 04/26/2016

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		DO/DEN-CB/		
2016-3619	05/02/2016 05/31/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Elaine Ogunbiyi CorePharma, LLC (Subsidiary of Impax Laboratories)	ANDA 077996; AERS DATED 04/02/2007, 07/02/2007, 10/01/2007, ETC
2016-3620	05/02/2016 05/31/2016	OC/ORO/ OC/ORO/ FDA/OC/OES/	Sheila Kaplan STAT (Boston Globe Media)	FDA LABORATORIES - INSPECTION RECS, EMAILS ETC 03/01/2011 - 04/15/2016
2016-3621	05/02/2016 05/31/2016	FDA/OC/OES/DFOI/	Michael Kolb Mainetti Mainetti & O'Connor, PC	MIRAGEL - AERS SCLERAL BUCKLE
2016-3622	05/02/2016 05/31/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	APCER Life Sciences APCER Life Sciences, Inc.	ANDA 207096 SBA
2016-3623	05/02/2016 05/31/2016	FDA/OGROP/ORO/SE-FO/FLA- DO/FLA-CB/	THOMPSON, RAY	AIG TECHNOLOGIES INC, POMPANO BEACH, FL 9/27/15 - 11/17/15; DERMAZONE SOLUTIONS INC, ST PETERSBURG, FL 10/28/15 - 11/24/15; PHARMCO LABORATORIES INC, TITUSVILLE, FL 11/9-30/15 - 483
2016-3624	05/02/2016 06/06/2016	FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORO/PA-FO/SAN- DO/SAN-CB/	Flanigan v. Western Milling Grossman Roth Yaffa Cohen, P.A.	WESTERN MILLING, LLC - EIR EXHIBITS, RESPONSES, ETC 01/01/2015 - 04/27/2016
2016-3625	05/02/2016 05/31/2016	OC/ORO/ORM/ OC/ORO/ORM/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Raksha Thadani Edelweiss Financial Services	NUMBER OF INSPECTIONS OF INDIAN DRUG COMPANIES, NUMBER OF 483 ISSUED, NUMBER OF FACILITIES 01/01/2000 - 04/27/2016
2016-3626	05/02/2016 05/31/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Irma Almazan Kinerk, Schmidt & Sethi, PLLC	ZEPHIRAN - COMPLAINTS, AERS, USAGE ETC
2016-3627	05/02/2016 05/31/2016	FDA/OMPT/CDRH/OCE/DID/	Michael Auld, PE ETHICON ENDO-SURGERY, A JOHNSON & JOHNSON	K151163

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			COMPANY	
2016-3628	05/02/2016 05/31/2016	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	THOMPSON, RAY	DISCUS DENTAL LLC, ONTARIO, CA 11/3-23/15; RESPIRONICS CALIFORNIA INC, CARLSBAD, CA 11/9/15 - 1/5/16; GENLABS CORP, CHINO, CA 12/7-11/15 - 483
2016-3629	05/02/2016 05/31/2016	FDA/OMPT/CDRH/OCE/DID/	Freddie Lee Epic International (Thailand) Co., Ltd.	K140133
2016-3630	05/02/2016 05/31/2016	FDA/OMPT/CDRH/OCE/DID/	Freddie Lee Epic International (Thailand) Co., Ltd.	K142319
2016-3631	05/02/2016 05/31/2016	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	THOMPSON, RAY	ADVANCE PHARMACEUTICAL INC, HOLTSVILLE, NY 11/12/15 - 12/2/15; ALTAIRE PHARMACEUTICALS INC, AQUEBOGUE, NY 11/30/15 - 12/15/15; MALLINCKRODT INC, HOBART, NY 1/26-29/16 - 483
2016-3632	05/02/2016 05/31/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Julie Burnett Julie Burnett	ONDANSETRON - AERS
2016-3633	05/02/2016 05/31/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Amaury Sanchez Noven Pharmaceuticals, Inc.	ANDA 200675 ACTAVIS LABS UT INC ANDA Approval 8/23/2012
2016-3634	05/02/2016 05/31/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 208411
2016-3635	05/02/2016 05/31/2016	FDA/OFVM/CFSAN/OCD/EOS/	Madhu Soni, Ph.D. SONI & ASSOCIATES INC	GRAS 537
2016-3636	05/02/2016 05/31/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Holli Vaughan Biologics Consulting	BLA 103334 SBA
2016-3637	05/02/2016 05/31/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	A list of all FOIA requests closed for 4/1-30/2016

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2016-3638	05/02/2016 05/31/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 4/1-30/2016
2016-3639	05/02/2016 05/31/2016	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	THOMPSON, RAY	Cs BIO COMPANY, MENLO PARK, CA 11/16/15 - 12/7/15; ACORN NMR INC, LIVERMORE, CA 12/8-11/15; BIOZONE LABORATORIES INC PITTSBURG, CA 11/3/16-1/26/16 - 483
2016-3640	05/02/2016 05/31/2016	FDA/OFVM/CFSAN/OCD/EOS/	CHRIS HENDEL CONSUMER REPORTS	DIETARY SUPPLEMENTS - AER 2012-2016
2016-3641	05/02/2016 05/31/2016	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDRH/OCE/DID/	RICK ROSATI ACTEON NORTH AMERICA INC	PRODUITS DENTAIRE PIERRE ROLLAND K923876
2016-3642	05/02/2016 05/31/2016	FDA/OMPT/CDRH/OCE/DID/	ANNE M. HULL HUTTON & HUTTON	ICE MAN COLD THERAPY, ST VISTA, CA - AER SINCE 2011
2016-3643	05/02/2016 05/31/2016	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	PIERCE, TRICIA	CMPLNT 143578
2016-3644	05/02/2016 05/31/2016	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	HARRISON, ANTOINETTE	CMPLNT 142873
2016-3645	05/02/2016 05/31/2016	OC/CVM/OCD/	JANICE KARIBIAN VIRBAC INC	N-141257-F-0082-CA - SUBMISSION
2016-3646	05/02/2016 05/31/2016	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	CASSANDRA LINDER SYNERGY HEALTH	SYNERGY HEALTH, DENVER, CO - EIR
2016-3647	05/03/2016 06/01/2016	FDA/OC/OES/DFOI/	ALEXANDER HAAS KING & SPALDING	PREVIOUSLY RELEASED RECS 1/1/12 TO PRESENT
2016-3648	05/03/2016 06/01/2016	FDA/OMPT/CDRH/OCE/DID/	LESLIE RAMSEY FDA NEWS	APEX HEALTH CARE MFG INC, MIN HSIUNG SHIANG, TAIWAN; MERIT MEDICAL IRELAND LTD, GALWAY, IRELAND; BIOTRONIK SE & CO KG, BERLIN, GERMANY, ETC - 483S 3/1-31/16
2016-3649	05/03/2016 06/01/2016	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	LESLIE RAMSEY FDA NEWS	XCELIENCE LLC, TAMPA, FL; MEDTRONIC XOMED INC, JACKSONVILLE, FL; OSCOR INC, PALM HARBOR, FL, ETC - 483S 3/1-31/16
2016-3650	05/03/2016 06/01/2016	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	LESLIE RAMSEY FDA NEWS	BIOMIMETIC THERAPEUTICS LLC, FRANKLIN, TN; SOMNOWELL INC, BELLEVUE, TN; MEDAUS INC, BIRMINGHAM, AL, ETC - 483S 3/1-31/16
2016-3651	05/03/2016 06/01/2016	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	LESLIE RAMSEY FDA NEWS	WT FARLEY INC, CAMARILLO, CA; STASON PHARMACEUTICALS INC, IRVINE, CA; NEODONTICS INC, SUN VALLEY, CA, ETC - 483S 3/1-31/16
2016-3652	05/03/2016 06/01/2016	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	LESLIE RAMSEY FDA NEWS	PETNET SOLUTIONS INC, WOBURN, MA; ADDENT INC, DANBURY, CT; LOON MEDICAL INC, TOLLAND, CT, ETC -

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2016-3653	05/03/2016 06/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LESLIE RAMSEY FDA NEWS	OLON SPA, SETTIMO TORINESE, ITALY; EDMOND PHARMA SRL, PADERNO DUGNANO, ITALY; GMT FINE CHEMICLS, COUVET, SWITZERLAND, ETC - 483S 3/1-31/16
2016-3654	05/03/2016 06/01/2016	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	LESLIE RAMSEY FDA NEWS	CR BARD INC, QUEENSBURY, NY; TIME-CAP LABORATORIES INC, FARMINGDALE, NY; MSKCC RMIPC, NEW YORK, NY - 483S 3/1-31/16
2016-3655	05/03/2016 06/01/2016	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	LESLIE RAMSEY FDA NEWS	ACCUPAC INC, LANSDALE, PA - 483S 3/1-31/16
2016-3656	05/03/2016 06/01/2016	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	LESLIE RAMSEY FDA NEWS	PROTEUS DIGITAL HEALTH INC, HAYWARD, CA; MEDITECH LABORATORIES INC, LAS VEGAS, NV; FAENCAL TARTARIC PRODUCT INC, FRESNO, CA - 483S 3/1-31/16
2016-3657	05/03/2016 06/01/2016	FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	LESLIE RAMSEY FDA NEWS	BLU CARIBE INC, DORADO, PR - 483S 3/1-31/16
2016-3658	05/03/2016 06/01/2016	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	LESLIE RAMSEY FDA NEWS	CENTER FOR LIFE INC, SAINT HELENS, OR; US VASCULAR LLC, BEAVERTON, OR - 483S 3/1-31/16
2016-3659	05/03/2016 06/01/2016	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	LESLIE RAMSEY FDA NEWS	LEADING PHARMA LLC, FAIRFIELD, NJ; US ORGANIC GROUP CORP, PASSAIC, NJ - 483S 3/1-31/16
2016-3660	05/03/2016 06/01/2016	FDA/OFVM/CFSAN/OCD/EOS/	Deborah Attwood Steptoe & Johnson LLP	PEROXYCHEM LLC - LETTER REQUEST TO FDA TO REVISE LISTINGS FOR FCN 993, 1379 01/01/2016 - 04/27/2016
2016-3661	05/03/2016 06/01/2016	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	BENEDICT S LIAO, MD, WEST COVINA, CA - EIR, 483, RESPONSE 08/11/2015 - 09/29/2015
2016-3662	05/03/2016 06/16/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Holli Vaughan Biologics Consutling	BLA 103931
2016-3663	05/03/2016 06/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LUIS DIESTRE IE BUSINESS SCHOOL	ORANGE BOOK ASCII FORMAT 01/01/1995 - 04/01/2016
2016-3664	05/03/2016 06/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	pascal besman Pascal Besman	MOVANTIK FAERS, CASE RPTS
2016-3665	05/03/2016	OC/ORA/	Astrid Galvan	SODIUM THIOPENTAL SHIPMENT TO ARIZONA

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	06/01/2016	OC/ORAI/	THE ASSOCIATED PRESS	DEPARTMENT OF CORRECTIONS 07/13/2015 - 04/27/2016
2016-3666	05/03/2016 06/01/2016	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORAI/ OC/ORAI/ FDA/OGROP/ORAI/ORO/DIOP/ FDA/OC/OES/DFOI/	Marc C. Sanchez, Esq. Contract In-House Counsel & Consl. LLC	KRATOM RECS RE ENFORCEMENT, IMPORT, ETC 12/20/2015 - 04/27/2016
2016-3667	05/03/2016 06/01/2016	FDA/OO/OFBA/OAGS/	Paul Marta Hawk Institute for Space Sciences	GOVERNMENT PURCHASE CASE HOLDERS 01/01/2014 - 04/27/2016
2016-3668	05/03/2016 06/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	joseph walker Walker, Joseph	SUBSYS - NARRATIVE CASE REPORTS
2016-3669	05/03/2016 06/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Amaury Sanchez Noven Pharmaceuticals, Inc.	ANDA 202346 SBA
2016-3670	05/03/2016 06/01/2016	FDA/OGROP/ORAI/CE-FO/MIN- DO/MIN-CB/	Luis Mulet, Jr. Antares Pharma, Inc.	ANTARES PHARMA - CONSUMER COMPLAINTS 141918, 143955
2016-3671	05/03/2016 06/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Genevieve Stevens Nivagen Pharmaceuticals, Inc.	SM BIOMED, MALAYSIA - 483 03/01/2016 - 04/30/2016
2016-3672	05/03/2016 06/01/2016	FDA/OGROP/ORAI/CE-FO/MIN- DO/MIN-CB/	Martin Lueders Lueders, Martin J	EXPRESS DIAGNOSTICS INT'L, INC, BLUE EARTH, MN - INSPECTION RECS 09/01/2015 - 04/27/2016
2016-3673	05/03/2016 06/01/2016	FDA/OFVM/CFSAN/OCD/EOS/	Marc C. Sanchez, Esq. Contract In-House Counsel & Consl. LLC	KRATOM - RECS RE CONSUMPTION AS FOOD, DIETARY SUPPLEMENT, BEVERAGES
2016-3674	05/03/2016 06/01/2016	FDA/OGROP/ORAI/CE-FO/CHI- DO/CHI-CB/	LESLIE RAMSEY FDA NEWS	MALLINCKRODT INC, GREENVILLE, IL; PINNACLE BIOLOGICS INC, CHICAGO, IL; AVA INC, WILLOWBROOK, IL - 483S 3/1-31/16
2016-3675	05/03/2016 06/01/2016	FDA/OGROP/ORAI/CE-FO/CIN- DO/CIN-CB/	LESLIE RAMSEY FDA NEWS	AVERY DENNISON CORP/AVERY DENNISON MEDICAL, MENTOR, OH; VEXOS, LAGRANGE, OH; CIRCLE PRIME MANUFACTURING INC, CUYAHOGA FALLS, OH - 483S 3/1- 31/16
2016-3676	05/03/2016	FDA/OC/OES/DFOI/	Sheila Kaplan	BACKLOG OF MAINTENANCE AND REPAIR FOR BUILDINGS

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	06/01/2016		Boston Globe Media	OUTSIDE WHITE OAK 01/01/2012 - 04/15/2016
2016-3677	05/03/2016 06/01/2016	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	LESLIE RAMSEY FDA NEWS	STONEGATE PHARMACY LP, AUSTIN, TX; ZS PHARMA INC, COPPELL, TX - 483S 3/1-31/16
2016-3678	05/03/2016 06/01/2016	FDA/OMPT/CDRH/OCE/DID/	Karen Bannick McQuoid Karen Bannick McQuoid	K053137, K006110, K071713, ETC 510K SUMMARIES
2016-3679	05/03/2016 06/01/2016	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	LESLIE RAMSEY FDA NEWS	IPAX INC, ENGLEWOOD, CO - 483S 3/1-31/16
2016-3680	05/03/2016 06/01/2016	FDA/OMPT/CDRH/OCE/DID/	Freddie Lee Epic International (Thailand) Co., Ltd.	K140131
2016-3681	05/03/2016 06/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bennett Edelman Bennett Edelman	ANDA 077206 ANDA 077670 ANDA 077397
2016-3682	05/03/2016 06/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Aydin Harston ROTHWELL FIGG ET AL	IND 74841
2016-3683	05/03/2016 06/01/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K152923
2016-3684	05/03/2016 06/01/2016	FDA/OMPT/CDRH/OCE/DID/	Lior Berkner Cardicell	K150564 K113514 K142476
2016-3685	05/03/2016 06/01/2016	FDA/OMPT/CDRH/OCE/DID/	Teffany Hutto Encore Medical, L.P.	D980003/S007
2016-3686	05/03/2016 06/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SIDDHARTH KARNAWAT SIDDHARTH KARNAWAT	AUROBINDO PHARMA, INDIA - 483 04/03/2015 - 04/28/2016
2016-3687	05/03/2016 06/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SIDDHARTH KARNAWAT SIDDHARTH KARNAWAT	AUROBINDO, INDIA - 483 04/03/2015 - 04/28/2016
2016-3688	05/03/2016	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	LESLIE RAMSEY	VENTLAB LLC, GRAND RAPIDS, MI; ORCHID ORTHOPEDIC SOLUTIONS LLC, FARMINGTON HILLS, MI; CENTURY

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	06/01/2016		FDA NEWS	PHARMACEUTICALS, INDIANAPOLIS, IN, ETC - 483S 3/1-31/16
2016-3689	05/03/2016 06/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LESLIE RAMSEY FDA NEWS	MYLAN LABORATORIES LTD, PITHAMPUR DISTRICT DHAR, INDIA; SANOFI CHIMIE, ARAMON, FRANCE; MARUHA NICHIRO CORP, UTSUNOMIYA, JAPAN - 483S FEBRUARY 1-29, 2016.
2016-3690	05/03/2016 06/01/2016	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	LESLIE RAMSEY FDA NEWS	SAFEOP SURGICAL INC, HUNT VALLEY, MD; MICROAIRE SURGICAL INSTRUMENTS LLC, CHARLOTTESVILLE, VA; PROFESSIONAL ARTS PHARMACY, BALTIMORE, MD - 483S 3/1-31/16
2016-3691	05/03/2016 06/01/2016	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	LESLIE RAMSEY FDA NEWS	VESOCCLUDE MEDICAL LLC, RALEIGH, NC - 483S 3/1-31/16
2016-3692	05/03/2016 06/01/2016	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 3/28/16-4/1/16
2016-3693	05/03/2016 06/01/2016	FDA/OC/OES/DFOI/	LESLIE RAMSEY FDA NEWS	FOI DAILY LOG 3/28/16-4/1/16
2016-3694	05/03/2016 06/01/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 3/28/16-4/1/16
2016-3695	05/03/2016 06/01/2016	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD Center for Regulator Services, Inc	FOI DAILY LOG 3/28/16-4/1/16
2016-3696	05/03/2016 06/01/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 3/28/16-4/1/16
2016-3697	05/03/2016 06/01/2016	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 3/28/16-4/1/16
2016-3698	05/03/2016 06/01/2016	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 3/28/16-4/1/16
2016-3699	05/03/2016 06/01/2016	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 4/4-8/16
2016-3700	05/03/2016 06/01/2016	FDA/OC/OES/DFOI/	LESLIE RAMSEY FDA NEWS	FOI DAILY LOG 4/4-8/16
2016-3701	05/03/2016 06/01/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 4/4-8/16
2016-3702	05/04/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson	K133764

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	06/02/2016		FOI Services, Inc.	
2016-3703	05/04/2016 06/02/2016	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Giridhar Prasad Jangly Dr. Reddy's Laboratories Inc.	LNK INTERNATIONAL INC, NY - 483, EIR
2016-3704	05/04/2016 06/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SIDDHARTH KARNAWAT SIDDHARTH KARNAWAT	AUROBINDO, INDIA - 483 04/03/2015 - 04/28/2016;
2016-3705	05/04/2016 06/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Phillip Hwang UNIVERSITY OF WASHINGTON	Clinical and statistical reviews for FluMist
2016-3706	05/04/2016 06/02/2016	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Jennifer Gehrke Gordon Labs Inc	GORDON LABORATORIES, INC, CARSON, CA - EIR 06/29/2015 - 07/10/2015
2016-3707	05/04/2016 06/02/2016	FDA/OC/OES/DFOI/	Debra A. Matthews Debra A. Matthews Attorney at Law, LLC	MENTOR WORLDWIDE, LLC - EIR PREVIOUSLY RELEASED 05/01/2010 - 04/28/2016
2016-3708	05/04/2016 06/02/2016	FDA/OC/OES/DFOI/	Joseph Piscitelli Matson Driscoll & Damico	ROSE ACRE FARMS, INC WHITE COUNTY EGG FARM - DATE OF WARNING LETTER POSTING 07/01/2011 - 07/31/2011
2016-3709	05/04/2016 06/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 21196/S19
2016-3710	05/04/2016 06/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Christina Jewett Reveal + The Center for Investigative Reporting	LUPRON ETC - AERS
2016-3711	05/04/2016 06/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michael Romanovsky Michael Romanovsky	CHIASMA, INC - MEETING MINUTES ETC RE TRIALS ETC
2016-3712	05/04/2016	FDA/OMPT/CDER/GRP/DIDP/	SIDDHARTH KARNAWAT	AUROBINDO, INDIA - 483 04/03/2015 - 04/28/2016

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	06/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SIDDHARTH KARNAWAT	
2016-3713	05/04/2016 06/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	James Rogers Valinor Management	DONNATAL - CORR, REGULATORY RECS 01/01/2013 - 04/29/2016
2016-3714	05/04/2016 06/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	11118063; 11122298; 11211979; 11227671
2016-3715	05/04/2016 06/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	BLA 125261 S 103
2016-3716	05/04/2016 06/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	10998130; 11025846; 11038557; ETC
2016-3717	05/04/2016 06/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	11074094 KEYTRUDA
2016-3718	05/04/2016 06/02/2016	FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	Kris Christian FDAZILLA	ZS PHARMA, INC, COPPELL, TX - 483 03/17/2016 - 03/29/2016
2016-3719	05/04/2016 06/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shara Ambrosecchia Wilshire Pharmaceutical Inc	ANDA 076467 SBA
2016-3720	05/04/2016 06/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shara Ambrosecchia Wilshire Pharmaceutical Inc	ANDA 202298 SBA

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-3721	05/04/2016 06/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PETER S. REICHERTZ SHEPPARD MULLIN ET AL	AMERICAN REGENT INC - MULTI TRACE 5 AER
2016-3722	05/04/2016 06/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PETER S. REICHERTZ SHEPPARD MULLIN ET AL	AMERICAN REGENT - MULTI TRACE 4 AER
2016-3723	05/04/2016 06/02/2016	FDA/OMPT/CDRH/OCE/DID/	Bruce Jackson Lake Street Capital Markets	MEETING WITH JEFFERY SHUREN RE TRANSENERIX - MINUTES, AGENDA 01/19/2016 - 01/19/2016
2016-3724	05/04/2016 06/02/2016	FDA/OMPT/CDRH/OCE/DID/	Lisa Anderson ConMed Corporation	K153513
2016-3725	05/04/2016 06/02/2016	FDA/OMPT/CDRH/OCE/DID/	Kelly Carty ALLERGAN INC.	P990074/S002
2016-3726	05/04/2016 06/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PETER S. REICHERTZ SHEPPARD MULLIN ET AL	ZINC SULFATE - AER
2016-3727	05/04/2016 06/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PETER S. REICHERTZ SHEPPARD MULLIN ET AL	MANGANESE SULFATE - AER
2016-3728	05/04/2016 06/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jennifer Miller Eli Lilly and Company - Global Patient Safety	NDA 050467 050629
2016-3729	05/04/2016 06/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Guillaume Buell Labaton Sucharow LLP	TECFIDERA SAFETY REVIEWS
2016-3730	05/04/2016 06/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PETER S. REICHERTZ SHEPPARD MULLIN ET AL	CHROMIUM CHLORIDE - AER

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2016-3731	05/04/2016 06/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	11050831 ZERBAXA
2016-3732	05/04/2016 06/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PETER S. REICHERTZ SHEPPARD MULLIN ET AL	COPPER SULFATE - AER
2016-3733	05/04/2016 06/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	11163690 VICTRELIS
2016-3734	05/04/2016 06/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	11031004; 11031727; 11058184; ETC BELSOMRA
2016-3735	05/04/2016 06/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	11106611 LIPTRUZET
2016-3736	05/04/2016 06/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PETER S. REICHERTZ SHEPPARD MULLIN ET AL	SELENIUM (SELENIOS ACID) AER
2016-3737	05/04/2016 06/02/2016	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	Heather Dudek BAXTER HEALTHCARE CORPORATION	GLOBAL PHARMACOVIGILANCE, DEERFIELD, IL - EIR 04/06/2015 - 04/10/2015
2016-3738	05/04/2016 06/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEVIN PYUN CONSONANCE CAPITAL	LINZESS PMA APRVL 2012

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2016-3739	05/04/2016 06/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHRISTINE KRONMILLE BTG INTERNATIONAL INC	FAERS - 10172727, 10216459, 10232321, ETC
2016-3740	05/04/2016 06/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Elliot Favus, MD FAVUS INSTITUTIONAL RESEARCH LLC	PATROMER - AERS
2016-3741	05/04/2016 06/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Abhay Shanbhag Abhay Shanbhag	UNIMARK REMEDIES, LTD, INDIA - 483 01/01/2014 - 04/29/2016
2016-3742	05/04/2016 06/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joe McCann Slingshot Insights	LINZESS - AERS
2016-3743	05/04/2016 06/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Najib Babul California Institute of Advanced Management	NDA 017690 NDA 017694
2016-3744	05/04/2016 06/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Christian Schneider Christian Schneider	BOEHRINGER INGELHEIM GMBH & CO - 483 02/01/2016 - 03/31/2016
2016-3745	05/04/2016 06/02/2016	FDA/OMPT/CDRH/OCE/DID/	Karen E. Warden, PhD BackRoads Consulting Inc.	K141953
2016-3746	05/04/2016 06/02/2016	FDA/OC/OES/DFOI/	ELLIOT FAVUS, MD. FAVUS INSTITUTIONAL RESEARCH LLC	2016 LOG
2016-3747	05/04/2016 06/02/2016	FDA/OMPT/CDRH/OCE/DID/	MATT NOVAK GAWKER MEDIA	TERANOS - 2012 INVESTIGATION
2016-3748	05/04/2016 06/02/2016	FDA/OGROP/ORP/SE-FO/FLA- DO/FLA-CB/	CURTIS HAMILTON ECI Pharmaceuticals, LLC	PURE SOURCE, DORAL, FL 9/22/11 - 2/24/14; ANSHI PHARMACEUTICAL INC, ZHONGSHAN, CHINA - 5/14/10 - 10/31/12 - EIR

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2016-3749	05/04/2016 06/02/2016	FDA/OC/OES/DFOI/	WILLIAM A. OLSON Center for Regulator Services, Inc	DAILY LOG 4/18-22/16
2016-3750	05/04/2016 06/02/2016	FDA/OC/OES/DFOI/	WILLIAM A. OLSON Center for Regulator Services, Inc	DAILY LOG 4/11-15/16
2016-3751	05/04/2016 06/02/2016	FDA/OC/OES/DFOI/	WILLIAM A. OLSON Center for Regulator Services, Inc	DAILY LOG 4/4-8/16
2016-3752	05/04/2016 06/02/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED DAILY LOGS 4/18-22/16
2016-3753	05/04/2016 06/02/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED LOG 4/11-15/16
2016-3754	05/04/2016 06/02/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED DAILY LOG 4/4-8/16
2016-3755	05/04/2016 06/02/2016	FDA/OC/OES/DFOI/	LESLIE RAMSEY FDA NEWS	DAILY LOG 4/18-22/16
2016-3756	05/04/2016 06/02/2016	FDA/OC/OES/DFOI/	LESLIE RAMSEY FDA NEWS	DAILY LOG 4/11-15/16
2016-3757	05/04/2016 06/02/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 4/11-15/16
2016-3758	05/04/2016 06/02/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 4/18-22/16
2016-3759	05/04/2016 06/02/2016	FDA/OC/OES/DFOI/	Kristi Smedley Center for Regulatory Services Inc.	PHARMAX REGISTRATION RECS
2016-3760	05/04/2016 06/02/2016	FDA/OC/OES/DFOI/	LARUEN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 4/11-15/16
2016-3761	05/04/2016 06/02/2016	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 4/18-22/16
2016-3762	05/04/2016 06/02/2016	FDA/OC/OES/DFOI/	BABARA JONES DOMINION GROUP INC	DAILY LOG 4/18-22/16
2016-3763	05/04/2016 06/02/2016	FDA/OC/OES/DFOI/	DOMINION GROUP INC	DAILY LOG 4/11-15/16
2016-3764	05/04/2016	FDA/OC/OES/DFOI/	BARBARA JONES	DAILY LOG 4/4-8/16

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	06/02/2016		DOMINION GROUP INC	
2016-3765	05/04/2016 06/02/2016	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 4/18-22/16
2016-3766	05/04/2016 06/02/2016	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 4/11-15/16
2016-3767	05/04/2016 06/02/2016	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 4/4-8/16
2016-3768	05/05/2016 06/03/2016	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID FUSTER 347389 FUSTER 347389, DAVID	TOLUIDINE BLUE (1% TOLONIUM CHLORIDE) - APRVD USES, STUDIES, RESTRICTIONS, ETC
2016-3769	05/05/2016 06/03/2016	FDA/OFVM/CFSAN/OCD/EOS/	SUFYAN ZAFAR MD IOVATE HEALTH SCIENCES INTERNATIONAL INC	IOVATE, HYDROXYCUT, SMARTBURN, ETC - CAERS
2016-3770	05/05/2016 06/03/2016	FDA/OFVM/CFSAN/OCD/EOS/	DIANNE L CHAMBERS Hogan Lovells, LLP	KIND LLC - WARNING LTR RESP, CORR, MTG SUMMARIES, ETC
2016-3771	05/05/2016 06/03/2016	FDA/OFVM/CFSAN/OCD/EOS/	GEORGE W LEMEL Keller and Heckman LLP	FCN 1597
2016-3772	05/05/2016 06/03/2016	FDA/OC/OES/DFOI/	COLIN BYRD BYRD, COLIN	DOLE FOOD CO, SPRINGFIELD, OH - LISTERIA RECS
2016-3773	05/05/2016 06/03/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	COLIN BYRD BYRD, COLIN	QUEST DIAGNOSTICS - ZIKA TEST APRVL RECS

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2016-3774	05/05/2016 06/03/2016	FDA/OC/OES/DFOI/	HENRY S STOLAR STOLAR, HENRY S	QUINCY BIOSCIENCE MANUFACTURING INC, MADISON, WI - CURRENT STATUS OF FDA ACTIONS, CIVIL OR CRIMINAL ACTIONS, CORR, ETC
2016-3775	05/05/2016 06/03/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAGNEY HOLLANDER SSI INVESTMENT MANAGEMENT INC	LINZESS - AERS
2016-3776	05/05/2016 06/03/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Katy Andrews warwick uni.	LINZESS - AERS 11877015 11779572 11472596 ETC
2016-3777	05/05/2016 06/03/2016	OC/ORO/ORM/ OC/ORO/ORM/	Quintiles Quintiles	LIST O FDA FORM 482 04/01/2016 - 04/30/2016
2016-3778	05/05/2016 06/03/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jigisha Vyas Jigisha Vyas	WOCKHARDT LTD, INDIA - EIR
2016-3779	05/05/2016 06/03/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Meng Chen MALLINCKRODT PHARMACEUTICALS	RECOTHROM - AERS
2016-3780	05/05/2016 06/03/2016	FDA/OGROP/ORO/CE-FO/NWJ- DO/NWJ-CB/	Jennifer Squillante Disposable Hygiene LLC	BENTLEY LABORATORIES LLC, EDISON, NJ - 483 01/06/2012 - 04/30/2016
2016-3781	05/05/2016 06/03/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Montse Caralt Almirall, S.A.	NDA 019966, NDA 019322, NDA 020340, ETC
2016-3782	05/05/2016 06/03/2016	FDA/OC/OES/DDM/	CHRISTOPHER HENDEL CONSUMER REPORTS	ENDOCRINOLOGIC AND METABOLIC DRUGS A/C - MINS, TRANS 12/7/10
2016-3783	05/05/2016 06/03/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Phil Kobierowski Phil Kobierowski	NUCYNTA - AERS
2016-3784	05/05/2016	FDA/OMPT/CDER/ORP/DIDP/	COLIN BYRD	TRAINING FOR PAINKILLER PRESCRIBERS - FDA

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	06/03/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BYRD, COLIN	REJECTED RECOMMENDATION 2012
2016-3785	05/05/2016 06/03/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANNA NOWOGRODZKI MUCKROCK	FILBANSERIN - CONFLICT OF INTEREST STATEMENTS
2016-3786	05/05/2016 06/03/2016	FDA/OPPLA/OL/	ANTHONY ROBERTS MUCKROCK	SEN CLAIRE MCCASKILL - RESP TO REQUEST 4/7/16
2016-3787	05/05/2016 06/03/2016	FDA/OMPT/CDRH/OCE/DID/	BENJAMIN M ZEGARELLI ESQ MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C.	OLEA MEDICAL - NERUROSCAPE K083491
2016-3788	05/05/2016 06/03/2016	FDA/OMPT/CDRH/OCE/DID/	BENJAMIN ZEGARELLI ESQ MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C.	ACTA MEDICAL LLC - INTRAVASCULAR ADMINISTRATION SET K121803, EMPTY EVA SOLUTION CONTAINMER K121161
2016-3789	05/05/2016 06/03/2016	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 3/28/16-4/1/16
2016-3790	05/05/2016 06/03/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 3/28/16-4/1/16
2016-3791	05/05/2016 06/03/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Douglas Main Newsweek Magazine	NDA FOR PRODUCTS CONTAINING FLUORIDE; NDA FOR ENZIFLUOR
2016-3792	05/05/2016 06/03/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Phillip Hwang UNIVERSITY OF WASHINGTON	ACAM2000 BLA 125158
2016-3793	05/05/2016 06/03/2016	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOI REQUESTS 3/28/16-4/1/16
2016-3794	05/05/2016 06/03/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bharat Celly Research Delta Advisors	AUROBINDO - INSPECTION CLASSIFICATION 08/01/2015 - 05/02/2016
2016-3795	05/05/2016 06/03/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 3/28/16-4/1/16

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2016-3796	05/05/2016 06/03/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sudipta Ganguly CIPLA LTD	CLARIS LIFESCIENCES, INDIA - 483 04/01/2015 - 05/02/2016
2016-3797	05/05/2016 06/03/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Margot Cleveland Cleveland, Margot J	KALYDECO, ORKAMBI - AERS
2016-3798	05/05/2016 06/03/2016	OC/CVM/OCD/	Rob Grubb COOK ANIMAL HEALTH	NADA 128-620 FOIA SUMMARY
2016-3799	05/05/2016 06/03/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-1713 - REQUEST LETTER ONLY
2016-3800	05/05/2016 06/03/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-1723 - REQUEST LETTER ONLY
2016-3801	05/05/2016 06/03/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-1772 - REQUEST LETTER ONLY
2016-3802	05/05/2016 06/03/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-1778 & 2016-1781 - REQUEST LETTERS ONLY
2016-3803	05/05/2016 06/03/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-1780 - REQUEST LETTER ONLY
2016-3804	05/05/2016 06/03/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-1797 - REQUEST LETTER ONLY
2016-3805	05/05/2016 06/03/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-1821 - REQUEST LETTER ONLY
2016-3806	05/05/2016 06/03/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-1924 - REQUEST LETTER ONLY
2016-3807	05/05/2016 06/03/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-1944 - REQUEST LETTER ONLY
2016-3808	05/05/2016 06/03/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-1847 - REQUEST LETTER ONLY
2016-3809	05/05/2016 06/03/2016	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 4/4-8/16
2016-3810	05/05/2016	FDA/OC/OES/DFOI/	DEBI COHEN	CLOSED FOI REQUESTS 4/4-8/16

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	06/03/2016		WOLTERS KLUWER LAW & BUSINESS	
2016-3811	05/05/2016 06/03/2016	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOI REQUESTS 4/4-8/16
2016-3812	05/05/2016 06/03/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 4/4-8/16
2016-3813	05/05/2016 06/03/2016	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 4/11-15/16
2016-3814	05/05/2016 06/03/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 4/11-15/16
2016-3815	05/05/2016 06/03/2016	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOI REQUESTS 4/11-15/16
2016-3816	05/05/2016 06/03/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 4/11-15/16
2016-3817	05/05/2016 06/03/2016	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 4/18-22/16
2016-3818	05/05/2016 06/03/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 4/18-22/16
2016-3819	05/05/2016 06/03/2016	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOI REQUESTS 4/18-22/16
2016-3820	05/05/2016 06/03/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 4/18-22/16
2016-3821	05/06/2016 06/06/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	John Walsh James Alexander Corporation	HOSPIRA HEALTHCARE INDIA PVT LTD - EIR, 482, RECALLS, 483 04/01/2012 - 05/03/2016
2016-3822	05/06/2016 06/06/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Genevieve Stevens Nivagen Pharmaceuticals, Inc.	NDA 204078 SBA
2016-3823	05/06/2016 06/06/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kristi Smedley Center for Regulator Services, Inc	NADA 141-327

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2016-3824	05/06/2016 06/06/2016	FDA/OMPT/CDRH/OCE/DID/	Matthew Trachtenberg BECTON, DICKINSON AND COMPANY	K122142 K130886 K132272
2016-3825	05/06/2016 06/06/2016	FDA/OMPT/CDRH/OCE/DID/	Matthew Trachtenberg BECTON, DICKINSON AND COMPANY	K053563 K133951 K123766 ETC
2016-3826	05/06/2016 06/06/2016	FDA/OMPT/CDRH/OCE/DID/	Matthew Trachtenberg BECTON, DICKINSON AND COMPANY	K060298 K080587 K093789 ETC
2016-3827	05/06/2016 06/06/2016	FDA/OGROP/ORR/CE-FO/NWJ- DO/NWJ-CB/	John Walsh James Alexander Corporation	JAMES ALEXANDER CORPORATION, BLAIRSTOWN, NJ - EIR, 483, RECALLS ETC 04/01/2013 - 05/03/2016
2016-3828	05/06/2016 06/06/2016	FDA/OGROP/ORR/PA-FO/LOS- DO/LOS-CB/	Darren Walsh Edwards Lifesciences	EDWARDS LIFE SCIENCES, IRVINE, CA - EIR 01/01/2015 - 05/03/2016
2016-3829	05/06/2016 06/06/2016	FDA/OGROP/ORR/SE-FO/FLA- DO/FLA-CB/	Mick Downs Invacare Corporation	INVACARE, SANFORD, FL - EIR, EXHIBITS 10/17/2014 - 05/03/2016;
2016-3830	05/06/2016 06/06/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Martina Steiper PharmaLex GmbH	IND 68,200 FINAL REPORT OF STUDIES
2016-3831	05/06/2016 06/06/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Phillip Hwang UNIVERSITY OF WASHINGTON	Clinical and/or Statistical Reviews for Zostavax
2016-3832	05/06/2016 06/06/2016	FDA/OGROP/ORR/PA-FO/SEA- DO/SEA-CB/	Ronald Hsu RBC CAPITAL MARKETS	CAPSUGEL, BEND, OR - 483 06/01/2015 - 05/03/2016
2016-3833	05/06/2016 06/06/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Borja Ruiz Laboratorios Litaphar S.A.	PRECLINICAL STUDIES SUBMITTED RE ALAGEBRIUM

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2016-3834	05/06/2016 06/06/2016	FDA/OFVM/CFSAN/OCD/EOS/	Joshua Mattern Bodybuilding.com	JYM PRODUCTS - AERS
2016-3835	05/06/2016 06/06/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Genevieve Stevens Nivagen Pharmaceuticals, Inc.	ANDA 078868, ANDA 091502, NDA 021447 SBA
2016-3836	05/06/2016 06/06/2016	FDA/OMPT/CDRH/OCE/DID/	Meriam Youssef BECTON, DICKINSON AND COMPANY	K140516; K151398
2016-3837	05/06/2016 06/06/2016	FDA/OMPT/CDRH/OCE/DID/	MAUDE THIBAUT UMANO MEDICAL	UMANO MEDICAL, QC, CANADA - EIR 5/27-30/13
2016-3838	05/06/2016 06/06/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	BENNETT RAWICKI GIBSON DUNN & CRUTCHER LLP	APOTEX, RICHMOND HILL, CANADA; BANGALORE, INDIA; ONTARIO, CANADA, ETC - 483S 1/09 TO PRESENT
2016-3839	05/06/2016 06/06/2016	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCE/DID/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	BRAD FORSTHOFF FORSTHOFF, BRAD	KENT PRECISION FOODS GROUP - THICK-IT INSTANT FOOD AND BEVERAGE THICKENER ORIGINAL FORMULA RECS
2016-3840	05/06/2016 06/06/2016	OC/ORA/ OC/ORA/	Doe J	DASANI BOTTLED WATER CMLPNT
2016-3841	05/06/2016 06/06/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CINDY SHEARER UNIV OF MISSOURI SCHOOL OF LAW LIBRARY	EVER APPROVED DRUGS LIST
2016-3842	05/06/2016 06/06/2016	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	LAURA SIXKILLER DLA PIPER LLP US	FRESH FROZEN FOODS, JEFFERSON, GA; THOMASVILLE, GA - INSP, INVESTIGATION, AUDIT, ETC LAST 10 YRS, ETC

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2016-3843	05/06/2016 06/06/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DEBASHIS MOHANTY LUPIN PHARMACEUTICALS INC	CTX LIFE SCIENCES PVT LTD, GUJARAT, INDIA - 483 2/19/16
2016-3844	05/06/2016 06/06/2016	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SE-FO/FLA- DO/FLA-CB/	PATRICIA BOOZER BOOZER, PATRICIA	CMPLNT 145241
2016-3845	05/06/2016 09/09/2016	FDA/OFVM/CFSAN/OCD/EOS/	MELISSA MCWILLIAMS BULK CHMEICAL SERVICES	COATEX SAS, COATEX NETHERLANDS BV - FCN 1046; BASF SE - FCN 1150
2016-3846	05/06/2016 06/06/2016	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SE-FO/ATL- DO/ATL-CB/	ANTOINETTE HARRISON HARRISON, ANTOINETTE	CMPLNT 142873
2016-3847	05/06/2016 06/06/2016	FDA/OMPT/CDRH/OCE/DID/	LAUREN C FANTINI DUFFY & PARTNERS	CARBOFIX ORTHOPEDICS LTD - MDRS
2016-3848	05/06/2016 06/06/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	LEVAQUIN, CIPRO, AVELOX - AERS FROM DATE OF APRVL TO PRESENT
2016-3849	05/06/2016 06/06/2016	FDA/OMPT/CDRH/OCE/DID/	MARVIN L SUSSMAN PHD SUSSMAN, MARVIN L	MEDTRONIC NEUROSURGERY - SHUNT, CENTRAL NERVOUS SYSTEM AND COMPONENTS K152700
2016-3850	05/06/2016 06/06/2016	FDA/OMPT/CDRH/OCE/DID/	DARREN WALSH Edwards Lifesciences	EDWARDS LIFESCIENCES SINGAPORE - EIR 2015
2016-3851	05/06/2016 06/06/2016	FDA/OMPT/CDRH/OCE/DID/	ANTONELLA ROSSI IMS INTERNAZIONALE MEDICO SCIENTIFICA SRL	HOLOGIC INC - AFFIRM PRONE BIOPSY SYS K153486
2016-3852	05/06/2016 06/06/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Genevieve Stevens Nivagen Pharmaceuticals, Inc.	ANDA 083329 ANDA 084114 ANDA 083386 ETC
2016-3853	05/06/2016 06/06/2016	OC/ORO/ OC/ORO/	TROY HAYDEN FOX 10 NEWS	SODIUM THIPENTAL - SEIZURE INVESTIGATION
2016-3854	05/06/2016	FDA/OMPT/CDER/ORP/DIDP/	Gay Parsons	METHYLPHENIDATE - CASE REPORTS

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	06/06/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Janssen Inc. Canada	
2016-3855	05/06/2016 06/06/2016	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Mick Downs Invacare Corporation	INVACARE, ELYRIA, OH - EIR, EXHIBITS ETC 06/15/2015 - 12/09/2015
2016-3856	05/06/2016 06/06/2016	FDA/OPPLA/OL/	ANTHONY ROBERTS MUCKROCK	SEN MARKEY - CORR, RECS, LTR 4/26/16 TO COMMISSIONER CALIFF
2016-3857	05/06/2016 06/06/2016	FDA/OC/OES/DFOI/	Eric Michael Schultz CRUSER & MITCHELL LLP	DICKS SPORTING GOODS FITNESS GEAR INVERSION TABLES RECALL RECS 07/01/2014 - 10/01/2015
2016-3858	05/06/2016 06/06/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	MICHEL PLUESS FHNW HOCHSCHULE FUER TECHNIK	AERS QUARTERLY DATA 10/12 TO 12/15
2016-3859	05/06/2016 06/06/2016	FDA/OC/OCC/	Chuck Soder Crain's Cleveland Business	MODIFIED CONSENT DECREE XELLIA PHARMACEUTICALS RE BEN VENUE LABORATORIES
2016-3860	05/06/2016 06/06/2016	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Elisa Burger SPI Pharma, Inc.	PARTICLE DYNAMICS HOLDING, SEYMOUR, IN, ST LOUIS, MO - EIR 01/01/2014 - 05/03/2016
2016-3861	05/06/2016 06/06/2016	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	CLOSED FOI REQUESTS - EIRS, 483S 1/16 TO PRESENT
2016-3862	05/06/2016 06/06/2016	OC/CVM/OCD/	Chauncey Baldwin Zoetis Inc.	Complete copy of the official assay method for nicarbazin in feeds
2016-3863	05/06/2016 06/06/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Barry Pressman PureTek Corporation	SRI KRISHNA PHARMACEUTICALS LTD, INDIA - EIR OCT 2015
2016-3864	05/06/2016 06/06/2016	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Doe J	CMPLNT
2016-3865	05/06/2016 06/06/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Amaury Sanchez Noven Pharmaceuticals, Inc.	NDA 019813 S33 SBA

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-3866	05/06/2016 06/06/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dustin Block IPD Analytics, LLC	ANDA 206285 TENTATIVE APPROVAL LETTER
2016-3867	05/06/2016 06/06/2016	OC/ORP/ OC/ORP/ FDA/OGROP/ORP/PA-FO/SEA-DO/SEA-CB/	JoNel Aleccia Seattle Times	CRF FROZEN FOODS, PASCO, WA - 483 01/13/2013 - 05/02/2016
2016-3868	05/06/2016 06/06/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Genevieve Stevens Nivagen Pharmaceuticals, Inc.	NDA 022362 NDA 021176 SBA
2016-3869	05/06/2016 06/06/2016	FDA/OMPT/CTP/OD/	Eunice Neeley UCSF	TOTAL EXPOSURE STUDY DATASET
2016-3870	05/06/2016 06/06/2016	FDA/OMPT/CDRH/OCE/DID/	Matthew Trachtenberg BECTON, DICKINSON AND COMPANY	K032164 K043529 K061328 ETC
2016-3871	05/06/2016 06/06/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doug Bolesch PROSKAUER ROSE ET AL	ETANERCEPT DATE OF REPORT
2016-3872	05/06/2016 06/06/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Genevieve Stevens Nivagen Pharmaceuticals, Inc.	ANDA 078868 ANDA 091502 NDA 021447 SBA
2016-3873	05/06/2016 06/06/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Earl Goehring THE DEGGE GROUP, LTD.	MEDDRA MEDWATCH FORMS
2016-3874	05/06/2016 06/06/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Amaury Sanchez Noven Pharmaceuticals, Inc.	NDA 019813 S44 SBA

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2016-3875	05/06/2016 06/06/2016	FDA/OMPT/CDRH/OCE/DID/	Darren Walsh Edwards Lifesciences	EDWARDS LIFESCIENCES SINGAPORE - EIR 01/01/2014 - 05/03/2016
2016-3876	05/06/2016 06/06/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Amaury Sanchez Noven Pharmaceuticals, Inc.	NDA 021829 S1, S2, SBA
2016-3877	05/06/2016 06/06/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Genevieve Stevens Nivagen Pharmaceuticals, Inc.	NDA 022362 NDA 021176 SBA
2016-3878	05/06/2016 06/06/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Martina Steiper PharmaLex GmbH	ARC183 IND 68,200 PHASE I STUDY RECS
2016-3879	05/06/2016 06/06/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Brian Malkin MCGUIREWOODS LLP	DULOXETINE BIOEQUIVALENCE REVIEWS
2016-3880	05/06/2016 06/06/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-2548 - REQUEST LETTER ONLY
2016-3881	05/06/2016 06/06/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-2931 - REQUEST LETTER ONLY
2016-3882	05/06/2016 06/06/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-2449 - REQUEST LETTER ONLY
2016-3883	05/06/2016 06/06/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-3005 - REQUEST LETTER ONLY
2016-3884	05/06/2016 06/06/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-2372 - REQUEST LETTER ONLY
2016-3885	05/06/2016 06/06/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-3024 - REQUEST LETTER ONLY
2016-3886	05/06/2016 06/06/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-2545 - REQUEST LETTER ONLY
2016-3887	05/06/2016	FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16)	2016-2949 - REQUEST LETTER ONLY

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	06/06/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	MERCK & CO., INC.	
2016-3888	05/06/2016 06/06/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-3059 - REQUEST LETTER ONLY
2016-3889	05/06/2016 06/06/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-3063 - REQUEST LETTER ONLY
2016-3890	05/06/2016 06/06/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-3077 - REQUEST LETTER ONLY
2016-3891	05/06/2016 06/06/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-3135 - REQUEST LETTER ONLY
2016-3892	05/06/2016 06/06/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-3141 - REQUEST LETTER ONLY
2016-3893	05/06/2016 06/06/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-3144 - REQUEST LETTER ONLY
2016-3894	05/06/2016 06/06/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-3142 - REQUEST LETTER ONLY
2016-3895	05/06/2016 06/06/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-3143 - REQUEST LETTER ONLY
2016-3896	05/06/2016 06/06/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-3212 - REQUEST LETTER ONLY
2016-3897	05/06/2016 06/06/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-3235 - REQUEST LETTER ONLY
2016-3898	05/06/2016 06/06/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-3236 - REQUEST LETTER ONLY
2016-3899	05/06/2016 06/06/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-3423 - REQUEST LETTER ONLY
2016-3900	05/06/2016 06/06/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-3547 - REQUEST LETTER ONLY

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2016-3901	05/06/2016 06/06/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-3492 - REQUEST LETTER ONLY
2016-3902	05/06/2016 06/06/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-3502 - REQUEST LETTER ONLY
2016-3903	05/06/2016 06/06/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-1972 - REQUEST LETTER ONLY
2016-3904	05/06/2016 06/06/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-2028 - REQUEST LETTER ONLY
2016-3905	05/06/2016 06/06/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-2052 - REQUEST LETTER ONLY
2016-3906	05/06/2016 06/06/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-2078 - REQUEST LETTER ONLY
2016-3907	05/06/2016 06/06/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-2078 - REQUEST LETTER ONLY
2016-3908	05/06/2016 06/06/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-2192 - REQUEST LETTER ONLY
2016-3909	05/06/2016 06/06/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-2272 - REQUEST LETTER ONLY
2016-3910	05/06/2016 06/06/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-1970 - REQUEST LETTER ONLY
2016-3911	05/06/2016 06/06/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-2278 - REQUEST LETTER ONLY
2016-3912	05/06/2016 06/06/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-2283 - REQUEST LETTER ONLY
2016-3913	05/06/2016 06/06/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-2286 - REQUEST LETTER ONLY
2016-3914	05/06/2016 06/06/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-2309 - REQUEST LETTER ONLY
2016-3915	05/06/2016 06/06/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-2369 - REQUEST LETTER ONLY
2016-3916	05/06/2016 06/06/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-2376 - REQUEST LETTER ONLY
2016-3917	05/06/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2016-2394 - REQUEST LETTER ONLY

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	06/06/2016		MERCK & CO., INC.	
2016-3918	05/06/2016 06/06/2016	FDA/OMPT/CDRH/OCE/DID/	Daniel Hoefer EndoChoice, Inc.	K160044
2016-3919	05/06/2016 06/06/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K121190
2016-3920	05/06/2016 06/06/2016	FDA/OMPT/CDRH/OCE/DID/	Daniel Hoefer EndoChoice, Inc.	K140149
2016-3921	05/06/2016 06/06/2016	FDA/OC/OES/DFOI/	Daniel Hoefer EndoChoice, Inc.	K122470
2016-3922	05/09/2016 06/07/2016	FDA/OC/OES/ FDA/OC/OEXA/OC/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOSEPH W CORMIER Hyman, Phelps & McNamara P.C.	LINZESS (LINACLOTIDE) - RPTS, CORR SUBMITTED TO THE OFFICE OF THE COMMISSIONER, CDER
2016-3923	05/09/2016 06/07/2016	FDA/OMPT/CDRH/OCE/DID/	JUSTIN CHOU Walkup, Melodia, Kelly and Schoenberger	TFS MANUFACTURING PTY LTD - TFS MINI-SLING K050418
2016-3924	05/09/2016 06/07/2016	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	MEDHAT GORGY PYRAMID LABORATORIES, INC.	PYRAMID LABORATORIES INC, COSTA MESA, CA - EIRS 1/5-15-15, 5/27/15-6/5/15
2016-3925	05/09/2016 06/07/2016	OC/ORAP/ORM/ OC/ORAP/ORM/	GAIL LESSICK LACHMAN CONSULTANT SERVICES INC	DRUG COMPANIES, MEDICAL DVC MFRS, BLOOD ESTABLISHMENTS, ETC - FOREIGN AND DOMESTIC INSPS, 483S 3/1/16-4/30/16
2016-3926	05/09/2016 06/07/2016	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LYNNE MILLICAN MILLICAN, LYNNE	LUPRON DEPOT-PED (LEUPROLIDE) - AERS 4/85 TO PRESENT
2016-3927	05/09/2016 06/07/2016	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/	LYNNE MILLICAN MILLICAN, LYNNE	LUPRON DEPOT, LUPRON DEPOT-PED 2.8 MULTI-DOSE VIAL - AERS 4/85 TO PRESENT

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2016-3928	05/09/2016 06/07/2016	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LYNNE MILLICAN MILLICAN, LYNNE	LUPRON (LEUPROLIDE) 2.8 MG MULTI-DOSE VIAL - AERS 4/85 TO PRESENT
2016-3929	05/09/2016 06/07/2016	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LYNNE MILLICAN MILLICAN, LYNNE	;UPRON DEPT (LEUPROLIDE) 3.7 MG, 7.5 MG, 11.25 MG, ETC - AERS 4/85 TO PRESENT
2016-3930	05/09/2016 06/07/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Phillip Hwang UNIVERSITY OF WASHINGTON	PREVNAR - CLINICAL REVIEWS STN 125324
2016-3931	05/09/2016 06/07/2016	FDA/OGROP/ORAP/PA-FO/LOS- DO/LOS-CB/	John Walsh James Alexander Corporation	SPECTRUM CHEMICAL & LABORATORY PRODUCTS, GARDENA, CA - 483, EIR, RECALL RECS 05/01/2012 - 05/04/2016
2016-3932	05/09/2016 06/07/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dustin Block IPD Analytics, LLC	ANDA 201962 ANDA 202019 ANDA 201920 TENTATIVE APPROVAL LETTERS
2016-3933	05/09/2016 06/07/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K130265
2016-3934	05/09/2016 06/07/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tushar Manudhane Indianivesh securities	STRIDES ARCOLAB, INDIA - 483 MOST RECENT 02/01/2016 - 05/31/2016

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2016-3935	05/09/2016 06/07/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K081389
2016-3936	05/09/2016 06/07/2016	OC/ORR/ORM/ OC/ORR/ORM/	Mark Prinz Registrar Corp	WARNING LETTER SPREADSHEET
2016-3937	05/09/2016 06/07/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Paige Stradley MERCHANT & GOULD	Form 3542 or Form 3542a submitted to the FDA by any NDA holder for NDA 201280 (Tradjenta), NDA 201281 (Jentaduet) in connection with US Patent No. 8,178,541 (CERTIFIED)
2016-3938	05/09/2016 06/07/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K150942
2016-3939	05/09/2016 06/07/2016	FDA/OMPT/CDRH/OCE/DID/	Valerie DeSousa DYKEMA GOSSETT PLLC	PMA P930038 INSTRUCTIONS FOR USE ALL SUPPLEMENTS
2016-3940	05/09/2016 06/08/2016	OC/ORR/ OC/ORR/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Cherie Eason Cauthorn Nohr & Owen	TALON COMPOUNDING PHARMACY, SAN ANTONIO, TX - INSPECTION RECS ETC 01/01/2008 - 05/04/2016
2016-3941	05/09/2016 06/07/2016	FDA/OMPT/CDRH/OCE/DID/	Valerie DeSousa DYKEMA GOSSETT PLLC	PMA P930038 INSTRUCTIONS FOR USE WITH APPLICATION
2016-3942	05/09/2016 06/07/2016	OC/ORR/ OC/ORR/ FDA/OGROP/ORR/ORO/DIOP/	Zetetic, Inc. Zetetic, Inc.	FDA ENTRY DOCUMENTATION REQUEST ALL DOCUMENTATION 04/16/2016 - 04/30/2016
2016-3943	05/09/2016 06/07/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	M. Carme Anglada MEDICHEM	ANDA 074434 LABELING
2016-3944	05/09/2016 06/07/2016	FDA/OC/OES/DFOI/	Aakash Agarwal Wize Market Analytics	Date Range: 01/01/2016 - 04/30/2016; Hi. We are refiling this request based on the confirmation # FDA1625566. The Fee limitation mentioned for this is \$46. Attached here is the list of companies along with their 158 FEI number. With this FOIA filing, we request you to let us know from the attached list, the FEI's that have been issued a form 483 from 1-Jan-2016 to 30-Apr-

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				16;
2016-3945	05/09/2016 06/07/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Martina Steiper PharmaLex GmbH	ARCHEMIX - FINAL REPORTS OF PHASE 1 STUDIES IN THE US UNDER IND 68,200
2016-3946	05/09/2016 06/07/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Katiemarie Wing K&L Gates, LLP	ADVERTISEMENTS ANDA 203106 NDA 019123 ANDA 074726
2016-3947	05/09/2016 06/07/2016	FDA/OMPT/CDRH/OCE/DID/	William J Gorman GORMAN CONSULTING INC	K121795
2016-3948	05/09/2016 06/07/2016	FDA/OMPT/CDRH/OCE/DID/	Nickie Power Elekta Limited	K111862
2016-3949	05/09/2016 06/07/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Janet Grochowski Positive Health Program Division of HIV, ID and Global Medicine	DOLUTEGRAVIR - AERS
2016-3950	05/09/2016 06/07/2016	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	Betsy Green Betsy Green Hankins	SABRA DIPPING COMPANY, COLONIAL HEIGHTS, VA - 483, CONSUMER COMPLAINTS 01/05/2015 - 05/03/2016
2016-3951	05/09/2016 06/07/2016	FDA/OMPT/CDRH/OCE/DID/	Liane LaRoche DEKA R&D	K153449
2016-3952	05/09/2016 06/07/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Trish O'Donnell Ironwood Pharmaceuticals	FAERS 1115186 1110698 1110586 ETC
2016-3953	05/09/2016 06/07/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jenna Durney EIRGEN PHARMA LTD	ANDA 203174
2016-3954	05/09/2016 06/07/2016	FDA/OMPT/CDRH/OCE/DID/	Guy Gardner Monica Healthcare Inc.	K142583
2016-3955	05/09/2016 06/07/2016	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	Rachel Johnson FOI Services, Inc.	CATALENT PHARMA SOLUTIONS, ST PETERSBURG, FL - RESPONSE 483 03/25/2016

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2016-3956	05/09/2016 06/07/2016	FDA/OMPT/CDRH/OCE/DID/	CAROLYN CHISHOLM Carolyn Chisholm	K050418
2016-3957	05/09/2016 06/07/2016	FDA/OMPT/CDRH/OCE/DID/	Joseph G. Keary, MS, MBA Irwin Army Community Hospital	K931374
2016-3958	05/09/2016 06/07/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	pascal besman Pascal Besman	IBRUTINB - AERS
2016-3959	05/09/2016 06/07/2016	FDA/OMPT/CDRH/OCE/DID/	Joseph M. Ascenzi JMA Consulting	K101769
2016-3960	05/09/2016 06/07/2016	FDA/OMPT/CDRH/OCE/DID/	Marc C. Sanchez, Esq. Contract In-House Counsel and Consultants, LLC	K092780
2016-3961	05/09/2016 06/07/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K150504
2016-3962	05/09/2016 06/07/2016	FDA/OMPT/CDRH/OCE/DID/	Matt Otten SecQure Surgical	K110824. K130596
2016-3963	05/09/2016 06/07/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michele Sinoway LACHMAN CONSULTANT SERVICES, INC.	The list of Drugs products that FDA has ever approved whether for just safety or for safety and efficacy
2016-3964	05/10/2016 06/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SIDDHARTH KARNAWAT SIDDHARTH KARNAWAT	AUROBINDO PHARMA, INDIA - 483
2016-3965	05/10/2016 06/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SIDDHARTH KARNAWAT SIDDHARTH KARNAWAT	SUNPHARMA , OHM LAB, INDIA - 483 05/01/2015 - 05/05/2016
2016-3966	05/10/2016 06/08/2016	FDA/OMPT/CDRH/OCE/DID/	Eric Yamada Eric Yamada	CPT1600022
2016-3967	05/10/2016 06/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SIDDHARTH KARNAWAT SIDDHARTH KARNAWAT	TORRENT PHARMA, INDIA - 483 01/01/2015 - 05/05/2016;

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2016-3968	05/10/2016 06/08/2016	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Ben Lenhart Robson, PC	INVACARE CORPORATION - INDEPENDENT EXPERT AUDIT RECS 08/01/2015 - 04/30/2016
2016-3969	05/10/2016 06/08/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shashi Karnawat SIDDHARTH KARNAWAT	SUNPHARMA, INDIA - 483 01/01/2015 - 05/05/2016
2016-3970	05/10/2016 06/08/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SIDDHARTH KARNAWAT SIDDHARTH KARNAWAT	TORRENT PHARMA INDIA - 483 01/01/2015 - 05/05/2016
2016-3971	05/10/2016 06/08/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SIDDHARTH KARNAWAT SIDDHARTH KARNAWAT	AUROBINDO PHARMA UNIT 1 UNIT 5 UNIT 8 AND UNIT 9 MEDAK INDIA - 483 01/01/2015 - 05/05/2016
2016-3972	05/10/2016 06/08/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SIDDHARTH KARNAWAT SIDDHARTH KARNAWAT	AUROBINDO PHARMA UNIT 11 SRIKAKULAM,INDIA - 483 01/02/2015 - 05/05/2016
2016-3973	05/10/2016 06/08/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shikhar Shrestha UNIVERSITY OF NEW MEXICO	MEDWATCH REPORTS 7348527 5829650 6723026 ETC
2016-3974	05/10/2016 06/08/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shikhar Shrestha UNIVERSITY OF NEW MEXICO	MEDWATCH REPORTS 31696573043299 6727630 ETC
2016-3975	05/10/2016 06/29/2016	FDA/OC/OES/DFOI/	Eyal Maor FDAAWARE	EIR RELEASE UNDER FOIA 09/17/2015 - 05/01/2016
2016-3976	05/10/2016 06/08/2016	FDA/OC/OES/DFOI/	Eyal Maor FDAAWARE	483, EIR VARIOUS FIRMS 01/01/2015 - 05/01/2016
2016-3977	05/10/2016	FDA/OMPT/CDRH/OCE/DID/	Joseph Ascenzi	K013056

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	06/08/2016		JMA Consulting	
2016-3978	05/10/2016 06/08/2016	FDA/OMPT/CTP/OD/	Cody hicks Cody Hicks	STUDIES RE PREMIUM CIGARS 01/01/2011 - 05/05/2016
2016-3979	05/10/2016 06/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Heather Luna Cutanea Life Sciences, Inc.	NDA 050769
2016-3980	05/10/2016 06/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lubiprostone Sucampo Pharma Americas, LLC	AMITIZA - AERS
2016-3981	05/10/2016 06/08/2016	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Glen Kelley kaleo, Inc.	MERIDIAN MEDICAL TECHNOLOGIES - 483 10/09/2013 - 05/05/2016
2016-3982	05/10/2016 06/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	Marc Young Nationwide pharmaceutical	NUMBER OF REPORTED LOTS WITH COUNTRY OF ORIGIN IN INDIA, CHINA FOR NDC 05/01/2011 - 05/05/2016
2016-3983	05/10/2016 06/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Andreas Wesley Canadian Broadcasting Corporation	PATHEON INC, ONTARIO, CANADA - 483 01/01/2013 - 07/01/2013
2016-3984	05/10/2016 06/08/2016	FDA/OMPT/CDRH/OCE/DID/	COLLEEN M DURRAN Fresenius Medical Care North America	GAMBRO RENAL PRODUCTS INC - PRISMAFLEX M150 SET K080519
2016-3985	05/10/2016 06/08/2016	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	KIMBERLY LIGHT BioPro, Inc	2016-618 - CERTIFIED RECS
2016-3986	05/10/2016 06/08/2016	FDA/OC/OES/ FDA/OFVM/CFSAN/OCD/EOS/	JAWANA COLEMAN LANIER LAW FIRM	COSMETIC TALC AND ASBESTOS/ASBESTIFORM TALC - CORR, MEMOS, PROPOSED RULE MAKING, ETC
2016-3987	05/10/2016 06/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANDY KERR NORTH AMERICAN INDUSTRIAL HEMP COUNCIL, INC.	NATIONAL DRUG CONTROL POLCY, DRUG ENFORCEMENT AGENCY LTR 4/4/15 REGARDING INDUSTRIAL HEMP

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2016-3988	05/10/2016 06/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JAMES H HARTTEN ARENT FOX LLP	CHROMIC CHLORIDE INJ - AERS
2016-3989	05/10/2016 06/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JAMES H HARTTEN ARENT FOX LLP	CUPRIC SULFATE INJ - AERS
2016-3990	05/10/2016 06/08/2016	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/SEA- DO/SEA-CB/	Jesse Newman THE WALL STREET JOURNAL	CRF FROZEN FOODS LLC, PASCO, WA - INSPECTION RECS 01/01/2013 - 05/09/2016
2016-3991	05/10/2016 06/08/2016	FDA/OC/OES/DFOI/	Guillaume Buell Labaton Sucharow LLP	BIOGEN, TECFIDERA - FOIA REQUESTS, RESPONSES 01/01/2015 - 05/06/2016
2016-3992	05/10/2016 06/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JAMES H HARTTEN ARENT FOX LLP	SLENIIOUS ACID INJ - AERS
2016-3993	05/10/2016 06/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JAMES H HARTTEN ARENT FOX LLP	ZINC SULFATE INJ - AERS
2016-3994	05/10/2016 06/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JAMES H HARTTEN ARENT FOX LLP	MANGANESE SULFATE INJ - AERS
2016-3995	05/10/2016 06/08/2016	FDA/OGROP/ORO/CE-FO/NWJ- DO/NWJ-CB/	RAVI DESHPANDE ACINO PRODUCTS LLC	UNIPACK INC (US PHARMICEUTICALS), BELLEVILLE, NJ - EIR, 483 MOST RECENT
2016-3996	05/10/2016 06/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN LIVESAY 1108120 Livesay 1108120, John	EFFEXOR IR, EFFEXOR XR - AERS
2016-3997	05/10/2016	FDA/OGROP/ORO/CE-FO/MIN- DO/MIN-CB/	SUSAN NEWMAN	KAYTEE EXACT HANDFEEDING FORMULA - CMLPLNTS

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	06/08/2016		NEWMAN, SUSAN	
2016-3998	05/10/2016 06/08/2016	FDA/OC/OES/DFOI/	Heidi Busz Zimmer Biomet	K031673 K030902
2016-3999	05/11/2016 06/09/2016	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	User Fee information for tobacco companies
2016-4000	05/11/2016 06/09/2016	FDA/OMPT/CTP/OD/	Andrew Thompson Andrew Thompson	Any study results and findings supporting the statement premium cigars have a negative impact on public health
2016-4001	05/11/2016 06/09/2016	FDA/OMPT/CTP/OD/	LOUIS WILLIAMS LOUIS WILLIAMS	All studies done for or by the FDA on premium cigars, specifically those that are suggested to show cigars are a public health risk
2016-4002	05/11/2016 06/09/2016	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/ FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Curt Devine Cable News Network (CNN)	CENTER FOR REPRODUCTIVE MEDICINE, LUTZ, FL; REPROMED FERTILITY CENTER, DALLAS, TX; FLORIDA FERTILITY INSTITUTE ETC - INSPECTION RECS ETC
2016-4003	05/11/2016 06/09/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dustin Block IPD Analytics, LLC	NDA 04485/S-003 APPROVAL LETTER
2016-4004	05/11/2016	FDA/OMPT/CDER/ORP/DIDP/	Sandra Lemon	TRI-SPRINTEC - AERS

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	06/09/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mick Levin, P.L.C.	
2016-4005	05/11/2016 06/09/2016	FDA/OMPT/CTP/OD/	Kyle Baxter Cigar Rights of America	CIGARS - RESEARCH AND FINDINGS
2016-4006	05/11/2016 06/09/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rahul Solanki Edelweiss	ZYG PHARMA, INDORE, INDIA - 483 04/01/2016 - 05/05/2016
2016-4007	05/11/2016 06/09/2016	FDA/OC/OES/DFOI/	Joseph M Ascenzi JMA Consulting	K062795
2016-4008	05/11/2016 06/09/2016	FDA/OMPT/CDRH/OCE/DID/	Randy Merry Randy Merry	K100071
2016-4009	05/11/2016 06/09/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	David O Clayton, MD CFCG	ARIPIPRAZOLE - CASE REPORT SUMMARIES
2016-4010	05/11/2016 06/09/2016	FDA/OMPT/CTP/OD/	Michael Crook Michael Crook	All studies done for or by the FDA on premium cigars, specifically those that are suggested to show cigars are a public health risk
2016-4011	05/11/2016 06/09/2016	FDA/OC/OES/DFOI/	RUBY GILL VAVE HEALTHCARE	GE VSCAN DIAGNOSTIC ULTRASOUND SYS K092756
2016-4012	05/11/2016 06/09/2016	OC/ORR/ OC/ORR/ FDA/OGROP/ORR/NE-FO/NYK- DO/NYK-DCB/	FIGUEROA, GENARA	CMPLNT 144118
2016-4013	05/11/2016 06/09/2016	FDA/OC/OES/DFOI/	MENARD CDCR AH-8804, BRANDON	MEDICATION DEFERRAL LIST
2016-4014	05/11/2016 06/09/2016	FDA/OGROP/ORR/CE-FO/MIN- DO/MIN-CB/ FDA/OGROP/ORR/SW-FO/DEN- DO/DEN-CB/	PAUL MOBLEY BIORAY	VITALITY WORKS INC, ALBUQUERQUE, NM - 483 MOST RECENT
2016-4015	05/11/2016 06/09/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	EMILY MARDEN SIDLEY AUSTIN LLP	APRVD DRUGS SINCE 1938

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2016-4016	05/11/2016 06/09/2016	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	KATHRYN CADORETTE STERIS CORP	INTERGRATED MEDICAL SYS INTL INC, BIRMINGHAM, AL - EIR 1/16
2016-4017	05/11/2016 06/09/2016	FDA/OFVM/CFSAN/OCD/EOS/	Devon Powell Devon Powell	BEIJING GINKGO GROUP, ALGAE LIFE SCIENCES - NDI, GRAS, ETC 01/01/2010 - 05/06/2016
2016-4018	05/11/2016 06/13/2016	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	KATHRYN CADORETTE STERIS CORP	INTEGRATED MEDICAL SYS INTL INC, KELLER, TX - EIR 2/16
2016-4019	05/11/2016 06/09/2016	FDA/OFVM/CFSAN/OCD/EOS/	Merle Zimmermann AMERICAN HERBAL PRODUCTS ASSOCIATION	RESPONSES TO NDI NUMBERED 844 OR HIGHER 06/01/2014 - 02/06/2016
2016-4020	05/11/2016 06/09/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bhushan Chandratre Indoco Remedies Ltd	NDA 202155 S13
2016-4021	05/11/2016 06/09/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MAYUR TIPNIS MAYUR TIPNIS	CLARIS LIFESCIENCES, INDIA - 483 05/01/2015 - 05/06/2016
2016-4022	05/11/2016 06/09/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Unapproved Potassium Chloride Amin Talati & Upadhye, LLC	PHARMACEUTICAL ASSOCIATES INC RECS RE UNAPPROVED PRODUCT
2016-4023	05/11/2016 06/09/2016	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	KATHRYN CADORETTE STERIS CORP	INTEGRATED MEDICAL SYS INTL INC, HILLSBOROUGH, NJ - EIR 2/16
2016-4024	05/11/2016 06/09/2016	FDA/OC/OES/DFOI/	Joseph Ascenzi JMA Consulting	K024180
2016-4025	05/11/2016 06/09/2016	OC/CVM/OCD/	Rob Grubb COOK ANIMAL HEALTH	NADA 137-600 Safe-Guard (fenbendazole) Type A Medicated Article NADA 132-872 Safe-Guard/Panacur (fenbendazole) Paste 10% NADA 139-189 Safe-Guard (fenbendazole) Feedblock
2016-4026	05/11/2016 06/09/2016	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	KATHRYN CADORETTE STERIS CORP	INTEGRATED MEDICAL SYS INTL INC, CHESTERFIELD, MO - EIR 12/15

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2016-4027	05/11/2016 06/09/2016	OC/ORO/ OC/ORO/	Elsie Nolan WBZ-TV	NABISCO GRAHAM CRACKERS, BAKED GOODS - CONSUMER COMPLAINTS RE STRONG CHEMICAL ODOR 01/24/2016 - 05/05/2016
2016-4028	05/11/2016 06/09/2016	FDA/OMPT/CDRH/OCE/DID/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Andrew Hoyal Luvera Law Firm	CASES OF CATHETER BREAKAGE REFERENCED IN FDA SAFETY COMMUNICATION 01/01/2005 - 06/28/2012
2016-4029	05/11/2016 06/09/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	David O Clayton, MD CFCG	Studies on Child and Adolescent use of Cymbalta, done by the company in exchange for patent extension
2016-4030	05/11/2016 06/09/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	David Corbin David Corbin	JEAN FRANCOIS HENRI GESCHWIND, MD - FORM 1572, CV 05/01/1996 - 05/06/2016
2016-4031	05/11/2016 06/09/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	NastLaw LLC NastLaw LLC	TAKEDA PHARMACEUTICALS USA INC - RECS RE APPROVAL OF PREVACID 05/10/1995 - 05/06/2016
2016-4032	05/11/2016 06/09/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	NastLaw LLC NastLaw LLC	ASTRAZENECA - RECS RE APPROVAL OF PRILOSEC 09/14/1989 - 05/06/2016
2016-4033	05/11/2016 06/09/2016	FDA/OMPT/CDRH/OCE/DID/	JOSEPH LAWLOR HAYES & BOONE LLP	OCULUS INNOVATIVE SCIENCES - CERAMAX SKIN BARRIER CREAM K152055
2016-4034	05/11/2016 06/09/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ OC/ORO/ OC/ORO/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ OC/ORO/ OC/ORO/	Orit Pinchuk Kamada Ltd. c/o Biologics Consulting	LIST OF INSPECTIONS FROM DIVISION OF MANUFACTURING AND PRODUCT QUALITY, OFFICE OF COMPLIANCE AND BIOLOGICS QUALITY RE KAMADA ESTABLISHMENT FOR BLA 125325 GLASSIA
2016-4035	05/11/2016 06/09/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	NastLaw LLC NastLaw LLC	ASTRAZENECA - RECS RE APPROVAL OF NEXIUM 02/20/2001 - 05/06/2016

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-4036	05/11/2016 06/09/2016	FDA/OMPT/CDRH/OCE/DID/	Michael Shultis Michael Shultis	BACtrack consumer breathalyzer BACtrack Breathalyzers 510K
2016-4037	05/11/2016 06/09/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Thomas J Moore INSTITUTE FOR SAFE MEDICATION PRACTICES	CDER CLOSED REQUIREMENT AND 506B REPORTABLE COMMITMENT RECORDS 01/01/2009 - 05/01/2016
2016-4038	05/11/2016 06/09/2016	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORR/SE-FO/ATL- DO/ATL-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/ORR/OCI/ OC/ORR/OCI/	Anthony Connors Anthony Connors	COMMUNICATIONS BETWEEN FDA AND NUTRITION DISTRIBUTION RE SARMS 01/02/2015 - 05/08/2016
2016-4039	05/11/2016 06/09/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JAMES H. HARTTEN ARENT FOX LLP	INJECTABLE RX DRUGS - AER
2016-4040	05/11/2016 06/09/2016	FDA/OFVM/CFSAN/OCD/EOS/	Anthony Connors Anthony Connors	ATHLETIC XTREME AND NUTRITION DISTRIBUTION - AERS
2016-4041	05/11/2016 06/09/2016	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORR/PA-FO/SAN- DO/SAN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Anthony Connors Anthony Connors	IRONMAG LABS, ROBERT DIMAGGIO - COMPLAINTS, INSPECTIONS, ETC 01/02/2015 - 05/01/2016
2016-4042	05/11/2016 06/09/2016	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORR/SE-FO/ATL- DO/ATL-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Anthony Connors Anthony Connors	COMMUNICATIONS BETWEEN FDA AND GTX, INC RE SARMS 01/04/2008 - 05/08/2016

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/ORO/OCI/ OC/ORO/OCI/		
2016-4043	05/11/2016 06/09/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JAMES H. HARTTEN ARENT FOX LLP	INJECTABLE RX DRUGS - AER
2016-4044	05/11/2016 06/09/2016	FDA/OMPT/CDRH/OCE/DID/	STEPHEN T. FOWLER GREENBERG & TRAUIG ATTORNEYS AT LAW	GORE - ACUSEAL VASCULAR GRAFT K130215; HERO - GRAFT K124039; HERO - VASCULAR ACCESS DVC K071778
2016-4045	05/11/2016 06/09/2016	FDA/OC/OES/DFOI/	DAVID BEERY PHARM3R	REQUESTED 483'S
2016-4046	05/11/2016 06/09/2016	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/ORO/DIOP/ FDA/OGROP/OIP/	TONY CORBO Food and Water Watch	INTERNATIONAL COMPARABILITY ASSESSMENT TOOLS (ITHAT LED TO THE SYSTEMS RECOGNITION AGREEMENTS BTWNN FDA & NEW ZEALAND MINISTRY FOR PRIMARY INDUSTRIES, CANADIAN FOOD INSPECTION AGENCY AND CANADA DEPT OF HEALTH
2016-4047	05/11/2016 06/09/2016	FDA/OPPLA/OL/	JULIA A. WAGNER KERCSMAR & FELTUS PLLC	DESIGNER ANABOLIC STEROID CONTROL ACT OF 2014 - TIFFANY GUARASCIO COMM 5/29/14-6/18/14; REP FRANK PALLONE COMM, TECHNIAL ASSISTANCE ON HR 4771, ETC
2016-4048	05/11/2016 06/09/2016	FDA/OC/OES/DFOI/	Allison Caruana The Mayday Project	COMMUNICATIONS WITH MONSANTO RE LYME DISEASE, TICKS BORNE DISEASE, ETC 01/01/2009 - 04/30/2016
2016-4049	05/12/2016 06/10/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PAMELA SHEPPARD TARO PHARMACEUTICALS USA INC	ALLERGAN INC - ACZONE (DAPSONE) GEL NDA 207-154 SBA, MOR, LBLG, ETC
2016-4050	05/12/2016 06/10/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PAMELA SHEPPARD TARO PHARMACEUTICALS USA INC	RENAISSANCE PHARMA - ELIMITE (PERMETHRIN) CREAM NDA 19-855 SBA, MOR, LBLG, ETC
2016-4051	05/12/2016 06/10/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID CORBIN Corbin, David	HAINAN HAILING CHEMIPARMA CORPORATION LTD, HAIKOU, CHINA - 483S, GDUFA ARREARS LIST

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2016-4052	05/12/2016 06/10/2016	FDA/OFVM/CFSAN/OCD/EOS/	SUSAN MATTHEES GENERAL MILLS	KIND LLC - CORR REGARDING THE USE OF THE WORD HEALTHY
2016-4053	05/12/2016 06/10/2016	OC/ORO/ORM/ OC/ORO/ORM/	LESLIE RAMSEY FDA NEWS	PHARMACEUTICAL, BIOLOGICS, MEDICAL DVC MFG FACILITIES IN AND OUTSIDE THE US - 483S 4/1-30/16
2016-4054	05/12/2016 06/10/2016	OC/ORO/ORM/ OC/ORO/ORM/	LESLIE RAMSEY FDA NEWS	CLNCL TRIAL FACILITIES AND INVESTIGATORS IN AND OUTSIDE OF THE US - 483S 4/1-30/16
2016-4055	05/12/2016 06/10/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	CASE REPORTS 6604298 4123460 5997035 ETC
2016-4056	05/12/2016 06/10/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Karen Hyde Hyde, Karen	PHENERGAN DEMEREOL METHADONE - APPROVAL HISTORY, LABELING ETC
2016-4057	05/12/2016 06/10/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Genevieve Stevens Nivagen Pharmaceuticals, Inc.	TIZANIDINE HYDROCHLORIDE ANDA 091502, CHLORPROMAZINE HYDROCHLORIDE ANDA 083329, ANDA 084114, ETC - SBA
2016-4058	05/12/2016 06/10/2016	FDA/OGROP/ORO/NE-FO/NWE-DO/NWE-CB/	Kris Christian FDAZILLA	N-MOLECULAR INC DBA IBA MOLECULAR NORTH AMERICA, HAVERHILL, MA - 483 08/03/2015 - 08/07/2015
2016-4059	05/12/2016 06/10/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCE/DID/	Kris Christian FDAZILLA	PENN PHARMACEUTICAL SERVICES LTD, WALES - 483 02/04/2013 - 02/07/2013
2016-4060	05/12/2016 06/10/2016	FDA/OC/OES/DFOI/	Amie N. Vanella Faegre Baker Daniels LLP	DOLE SPRINGFIELD, OH - OUTBREAK RECS 09/01/2015 - 05/09/2016
2016-4061	05/12/2016 06/10/2016	FDA/OGROP/ORO/NE-FO/NWE-DO/NWE-CB/	Eric Evans Orchard View Capital Advisors LP	OCULAR THERAPEUTIX, BEDFORD, MA - EIR, 483 03/07/2015 - 05/09/2016
2016-4062	05/12/2016 06/10/2016	OC/ORO/ORM/ OC/ORO/ORM/	Aakash Agarwal Wize Market Analytics	LIST OF 483 TO INDIAN FIRMS 01/01/2016 - 05/10/2016
2016-4063	05/12/2016 06/10/2016	FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/	Walter Chalkley THOMSON REUTERS	APOTHECA SUPPLY INC DBA APOTHECARES, DECATUR, AL - EIR, 483, RESPONSE 02/10/2015 - 02/12/2015

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		FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	(SCIENTIFIC) SAS	
2016-4064	05/13/2016 06/13/2016	FDA/OC/OES/DFOI/	Sara Ebrahimi Sara Ebrahimi	MENTOR MEMORYGEL GEL-FILLED BREAST IMPLANTS - MANUFACTURING STANDARDS, PMA
2016-4065	05/13/2016 06/13/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Margaret Berg Core-Rx Communications	ZOON KC LETTER RE RH-SENSITIZATION DURING PREGNANCY 01/01/1996 - 12/31/1996
2016-4066	05/13/2016 06/13/2016	OC/ORARM/ OC/ORARM/	Kris Christian FDAZILLA	LIST OF RELEASABLE INSPECTION CITATIONS FROM FACTS 5/10/2015 - 05/09/2016
2016-4067	05/13/2016 06/13/2016	FDA/OMPT/CDRH/OCE/DID/	Kendrick Moxon CITIZENS COMMISSION ON HUMAN RIGHTS	MECTA CORPORATION SUBMISSION RE MEDICAL DEVICE ADVERSE EVENT CAUSED BY ELECTROCONVULSIVE THERAPY DEVICE ETC
2016-4068	05/13/2016 06/13/2016	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDRH/OCE/DID/	Doe J	FOLLOW UP RECS
2016-4069	05/13/2016 06/13/2016	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Lukas Vrbka The Schuster Institute For Investigative Journalism	JUDGE ROTENBERG CENTER, CANTON, MA - INSPECTION RECS, THIRD PARTY REVIEWS 09/01/1986 - 06/01/2016
2016-4070	05/13/2016 06/13/2016	OC/ORAOI/ OC/ORAOI/	Kyle Pederson Tyson & Mendes	OCI CERTIFIED INVENTORY OF EVIDENCE FILE NUMBER 172398; DOCUMENTS REFERENCED; REPORTS RE PHYSICAL EVIDENCE ETC
2016-4071	05/13/2016 06/13/2016	OC/ORAO/ OC/ORAO/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Zetetic, Inc. Zetetic, Inc.	FDA ENTRY DOCUMENTATION REQUEST EAM-0025354-1
2016-4072	05/13/2016 06/13/2016	OC/ORAO/ OC/ORAO/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Zetetic, Inc. Zetetic, Inc.	FDA ENTRY DOCUMENTATION REQUEST (REFUSAL) EAM-0025301-2
2016-4073	05/13/2016 06/13/2016	OC/ORAO/ OC/ORAO/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Zetetic, Inc. Zetetic, Inc.	FDA ENTRY DOCUMENTATION REQUEST (REFUSAL) EAM-0025211-3
2016-4074	05/13/2016 06/13/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	APCER Life Sciences APCER Life Sciences, Inc.	ANDA 091193

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2016-4075	05/13/2016 06/13/2016	FDA/OC/OES/DFOI/	Eyal Maor FDAAWARE	483 RELEASED UNDER FOIA 12/15/2015 - 05/01/2016
2016-4076	05/13/2016 06/13/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joanne Izyk Correvio LLC (A Cardiome company)	CADILA HEALTHCARE LIMITED, INDIA - EIR 01/02/2015 - 05/09/2016
2016-4077	05/13/2016 06/13/2016	FDA/OPPLA/OL/	Lauren Nardella The Rose Sheet/Informa	RESPONSE TO REP FRANK PALLONE RE WEN CLEANSING CONDITIONER
2016-4078	05/13/2016 06/13/2016	OC/ORR/ORM/ OC/ORR/ORM/	Kris Christian FDAZILLA	LIST OF INSPECTIONS 04/06/2016 - 05/09/2016
2016-4079	05/13/2016 06/13/2016	FDA/OGROP/ORR/NE-FO/NWE-DO/NWE-CB/	Lukas Vrbka The Schuster Institute For Investigative Journalism	CORR BETWEEN FDA AND MASSACHUSETTS AGENCIES RE JUDGE ROTENBERG EDUCATIONAL CENTER, BEHAVIOR RESEARCH INSTITUTE, ETC 09/01/1986 - 06/01/2016
2016-4080	05/13/2016 06/13/2016	FDA/OC/OES/DDM/ FDA/OMPT/CTP/OD/	Jeff Stier National Center for Public Policy Research	CORR BEWTEEN FDA AND OMB RE PROPOSED AND FINAL REGULATION FOR DEEMING 04/01/2014 - 05/09/2016
2016-4081	05/13/2016 06/13/2016	FDA/OGROP/ORR/CE-FO/MIN-DO/MIN-CB/	Joyce Minard BOSTON SCIENTIFIC	DBOSTON SCIENTIFIC, COON RAPIDS, MN - EIR 02/17/2016 - 02/24/2016
2016-4082	05/13/2016 06/13/2016	FDA/OMPT/CDRH/OCE/DID/	Kevin Minnich B. Braun Medical Inc.	K151650
2016-4083	05/13/2016 06/13/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Susan M. Sabol Janssen Pharmaceutical Companies	FAERS F117344941, F112743221, F108722901, ETC
2016-4084	05/13/2016 06/13/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-2345
2016-4085	05/13/2016 06/13/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-2346
2016-4086	05/13/2016 06/13/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-2347
2016-4087	05/13/2016 06/13/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-2377
2016-4088	05/13/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2016-2554

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	06/13/2016		MERCK & CO., INC.	
2016-4089	05/13/2016 06/13/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-2861
2016-4090	05/13/2016 06/13/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-3480
2016-4091	05/13/2016 06/13/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-9521
2016-4092	05/13/2016 06/13/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Andy Washkowitz Andy Washkowitz	Sacituzumab Govitecan AERS
2016-4093	05/13/2016 06/13/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-234
2016-4094	05/13/2016 06/13/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-785
2016-4095	05/13/2016 06/13/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-799
2016-4096	05/13/2016 06/13/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-800
2016-4097	05/13/2016 06/13/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-804
2016-4098	05/13/2016 06/13/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-806
2016-4099	05/13/2016 06/13/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-1058
2016-4100	05/13/2016 06/13/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-2339
2016-4101	05/13/2016 06/13/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-2134
2016-4102	05/13/2016 06/13/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-2008
2016-4103	05/13/2016 06/13/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-980

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2016-4104	05/13/2016 06/13/2016	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	CEUTICAL LABS	CEUTICAL LABS INC, DALLAS, TX - EIR, 483 REDACTED
2016-4105	05/13/2016 06/13/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MICHAEL M. GALLAGHER CLARK LOVE HUTSON	INVOKANA (CANAGLIFLOZIN) APRVL
2016-4106	05/13/2016 06/13/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-1113
2016-4107	05/13/2016 06/13/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-1202
2016-4108	05/13/2016 06/13/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-1650
2016-4109	05/13/2016 06/13/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MICHAEL M. GALLAGHER CLARK LOVE HUTSON	INVOKANA (CANAGLIFLOZIN) EFFICACY RVW
2016-4110	05/13/2016 06/13/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-1854
2016-4111	05/13/2016 06/13/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-2006
2016-4112	05/13/2016 06/13/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-1353
2016-4113	05/13/2016 06/13/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-1855
2016-4114	05/13/2016 06/13/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-1894
2016-4115	05/13/2016 06/13/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-1936
2016-4116	05/13/2016 06/13/2016	FDA/OMPT/CDRH/OCE/DID/	KATHERINE A. DEBSKI BAIN MAZZA ET AL	IHEAR MEDICAL INC - IHEAR TEST K151025
2016-4117	05/13/2016 06/13/2016	OC/ORASOCI/ OC/ORASOCI/ FDA/OGROP/ORASW-FO/LOS-	Doe J	CMPLNT 138570

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		DO/LOS-CB/		
2016-4118	05/16/2016 06/14/2016	FDA/OC/OES/DFOI/	KENNETH MYERS 97A9468 MYERS #97 A 7468, KENNETH	NY DEPT OF CORRECTIONS AND COMMUNITY SUPERVISION'S FOOD PROGRAM - SOY PRODUCTS RECS
2016-4119	05/16/2016 06/14/2016	OC/ORAI/ OC/ORAI/	JENNIFER M MORENO Berkeley Law Death Penalty Clinic	SODIUM THIOPIENTAL - IMPORT RECS, CORR
2016-4120	05/16/2016 06/14/2016	FDA/OMPT/CDRH/OCE/DID/	TREY THORSEN HARTMANN USA INC	HARTMANN K091338
2016-4121	05/16/2016 06/14/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Chris Letter Odom & Des Roches, LLC	ANDA 076420
2016-4122	05/16/2016 06/14/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kiran Kumar Gande LEADING PHARMA LLC	ANDA 070791 SBA
2016-4123	05/16/2016 06/14/2016	FDA/OMPT/CDRH/OCE/DID/	510K Submission Records with Detailed Info St Jude Medical/Zhi Chai	K070242
2016-4124	05/16/2016 06/14/2016	FDA/OMPT/CDRH/OCE/DID/	Plamena Entcheva-Dimitrov Preferred Clinical Research LLC	K141119
2016-4125	05/16/2016 06/14/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	POLYDRUG LABORATORIES PVT LTD, INDIA - 483 03/16/2015 - 03/23/2015
2016-4126	05/16/2016 06/14/2016	FDA/OGROP/ORAI/CE-FO/NWJ-DO/NWJ-CB/	Walter Chalkley THOMSON REUTERS	TERUMO MEDICAL CORPORATION, SOMERSET, NJ - EIR, 483, RESPONSE 10/19/2015 - 10/23/2015
2016-4127	05/16/2016 06/14/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Christina Jewett Reveal + The Center for Investigative Reporting	7359330, 7359368, 7428162, ETC
2016-4128	05/16/2016 06/14/2016	FDA/OMPT/CDRH/OCE/DID/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	SORIN GROUP, GERMANY - 483 08/24/2015 - 08/27/2015
2016-4129	05/16/2016	FDA/OMPT/CDRH/OCE/DID/	Judi Wallach	K153361

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	06/14/2016		Abbott Laboratories, Inc	
2016-4130	05/16/2016 06/14/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	INDIVIDUAL RECS
2016-4131	05/16/2016 06/14/2016	FDA/OGROP/ORR/SW-FO/DAL- DO/DAL-CB/	Sara Ebrahimi Sara Ebrahimi	MENTOR TEXAS LP, COPPELL, TX - 483 05/10/2000 - 07/10/2013
2016-4132	05/16/2016 06/14/2016	FDA/OC/OES/DFOI/	Theresa Alexander PROCTER & GAMBLE COMPANY	Pyrimamine RECS
2016-4133	05/16/2016 06/14/2016	FDA/OMPT/CDRH/OCE/DID/	Ross Eglow The Rosen Law Firm, P.A.	TRANSENERIX INC SURGIBOT SYSTEM - 510K 04/01/2016 - 05/01/2016
2016-4134	05/16/2016 06/14/2016	FDA/OMPT/CDRH/OCE/DID/	Kevin Minnich B. Braun Medical Inc.	K153293
2016-4135	05/16/2016 06/14/2016	FDA/OMPT/CDRH/OCE/DID/	Kevin Minnich B. Braun Medical Inc.	K143482
2016-4136	05/16/2016 06/14/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Martin A. Lessem, J.D. ZIOPHARM Oncology	AVASTIN - SBA FOR GLIOBLASTOMA INDICATION
2016-4137	05/16/2016 06/14/2016	FDA/OMPT/CDRH/OCE/DID/	Robert Mahler - Ansell Ansell Healthcare Products LLC	K150110 K142805
2016-4138	05/16/2016 06/14/2016	FDA/OMPT/CDRH/OCE/DID/	Suzanne Lucas Air Techniques, Inc.	K111736
2016-4139	05/16/2016 06/14/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jeremiah Mitzelfelt University of Maryland- College Park	NDA 020622
2016-4140	05/16/2016 06/14/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K081635
2016-4141	05/16/2016 06/14/2016	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCE/DID/	Molly Redden THE GUARDIAN	K011996, K960341, K95333 ETC
2016-4142	05/16/2016 06/14/2016	FDA/OGROP/ORR/CE-FO/PHI- DO/PHI-CB/	John Tozzi BLOOMBERG NEWS	CUSTOM ULTRASONICS - CORR WITH FDA 11/12/2015 TO PRESENT

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		FDA/OMPT/CDRH/OCE/DID/		
2016-4143	05/16/2016 06/14/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Pascal Besman Pascal Besman	PRALUENT AERS
2016-4144	05/16/2016 06/14/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Pascal Besman Pascal Besman	REPATHA - AERS
2016-4145	05/16/2016 06/14/2016	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORACE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORACE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORACE-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORACE-FO/DEN-DO/DEN-CB/ FDA/OMPT/CTP/OD/ FDA/OGROP/ORACE-FO/DAL-DO/DAL-CB/	Rachel Johnson FOI Services, Inc.	TOBACCO MANUFACTURER INSPECTIONS - 483, WARNING LETTER, RESPONSE ETC 10/1/15 TO 4/30/16
2016-4146	05/17/2016 06/15/2016	FDA/OMPT/CTP/OD/ FDA/OO/OHR/	William McGrath Potomac Law Group, PLLC	RECS RE INCREASE IN FTE, TRAINING GOALS, ETC FOR CTP STAFF FOR DEEMING TOBACCO PRODUCTS
2016-4147	05/17/2016 06/15/2016	FDA/OC/OES/ FDA/OPPLA/OP/	William McGrath Potomac Law Group, PLLC	DRAFT OR FINAL REGULATORY IMPACT ANALYSIS REPORT BY OMB, FDA ECONOMICS STAFF, ETC RE FINAL RULE DEEMING TOBACCO PRODUCTS; COST/BENEFIT ANALYSYS 04/28/2014 - 05/10/2016
2016-4148	05/17/2016 06/15/2016	FDA/OC/OES/DFOI/	Salena Zellers Safety Research and Strategies	RECS A PROSPECTIVE RANDOMIZED MULTICENTER TRIAL OR AMNIOREDUCTION V SELECTIVE FETOSCOPE LASER FOR THE TREATMENT OF SEVERE TTTS 07/01/2002 - 12/01/2009

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2016-4149	05/17/2016 06/15/2016	FDA/OMPT/CTP/OD/	Stacy Ehrlich Kleinfeld Kaplan and Becker LLP	CTP SUBSTANTIAL EQUIVALENCE REPORT REVIEWERS' GUIDE, GUIDANCE, CHECKLIST MOST RECENT RE INTERNAL CTP REVIEW OF SE REPORTS 05/11/2016 - 05/31/2016
2016-4150	05/17/2016 06/15/2016	FDA/OMPT/CTP/OD/	Desmond Jenson Tobacco Control Legal Consortium	All records and communications associated with Potential Tobacco Violation Report ID 15D00013
2016-4151	05/17/2016 06/15/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K140389
2016-4152	05/17/2016 06/15/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Christina Jewett Reveal + The Center for Investigative Reporting	NDA 20-263/S-028
2016-4153	05/17/2016 06/15/2016	FDA/OMPT/CTP/OD/	Jeff Stier National Center for Public Policy Research	CORR, MEETING MINUTES, TRANSCRIPTS ETC FROM FDA TO OMB RE PROPOSED AND FINAL REGULATION DEEMING TOBACCO PRODUCTS 04/01/2007 - 04/15/2014
2016-4154	05/17/2016 06/15/2016	FDA/OFVM/CFSAN/OCD/EOS/	Celeste Wheeler KLEINFELD, KAPLAN & BECKER	CORR WITH KIND LLC RE USE OF "HEALTHY" ON LABELS
2016-4155	05/17/2016 06/15/2016	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	John Walsh WALSH, JOHN J	PARCHEM FINE & SPECIALTY CHEMICALS, NEW ROCHELLE, NY - EIR, 483, RECALL RECS 05/01/2012 - 05/11/2016
2016-4156	05/17/2016 06/15/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mark A. McAndrew TAFT STETTINIUS & HOLLISTER	NDA 205678
2016-4157	05/17/2016 06/15/2016	OC/CVM/OCD/	Jaime Vassallo LexisNexis CourtLink	RECS RE CVM ENFORCEMENT DISCRETION RE DISTRIBUTION OF IV FLUID PRODUCTS; ADDITIONAL SHIPMENTS OF IV FLUID PRODUCTS ARRIVING INTO THE US; ETC
2016-4158	05/17/2016 06/15/2016	FDA/OMPT/CDRH/OCE/DID/	Lacey Chessor PERMOBIL AB	: MOTION CONCEPTS, CANADA - EIR LAST SIX YEARS
2016-4159	05/17/2016 06/15/2016	FDA/OMPT/CDRH/OCE/DID/	Lacey Chessor PERMOBIL AB	PERMOBIL AB, SWEDEN - EIR 01/01/2016 - 05/11/2016
2016-4160	05/17/2016 06/15/2016	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Doug G. Myers Synergy Health AST, LLC	SYNERGY HEALTH AST LLC, OLDSMAR, FL - EIR 07/30/2015 - 07/30/2015
2016-4161	05/17/2016 06/15/2016	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	The Schuster Institute For Investigative Journalism	CORR RE JUDGE ROTENBERG EDUCATIONAL CENTER, BEHAVIOR RESEARCH INSTITUTE, ELECTRONIC

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		FDA/OMPT/CDRH/OCE/DID/	The Schuster Institute For Investigative Journalism	STIMULATION DEVICE ETC 09/01/1986 - 05/11/2016
2016-4162	05/17/2016 06/15/2016	FDA/OC/OES/DFOI/	Tong Zhou University of Hong Kong	NEW DRUG REGULATION
2016-4163	05/17/2016 06/15/2016	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Jason Goldsmith AngioDynamics, Inc.	ANGIODYNAMICS, QUEENSBURY, NY - EIR 01/01/2014 - 05/11/2016
2016-4164	05/17/2016 06/15/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Laura Ruth FULD & COMPANY INC	NDA 21-343: S26, S28, S29, S31, S32; APPROVAL LETTERS
2016-4165	05/17/2016 06/15/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jaime Vassallo LexisNexis CourtLink	GLATOPA, GLATIRAMER ACETATE, COPAXONE - AERS
2016-4166	05/17/2016 06/15/2016	FDA/OMPT/CDRH/OCE/DID/	Kimberly Waller Ximedica	SURGIBOT SYSTEM 510K
2016-4167	05/17/2016 06/15/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Emily Krulewitz The Weinberg Group	MIRAPREX ER NDA 2242
2016-4168	05/17/2016 06/15/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Katiemarie Wing K&L Gates, LLP	NDA 205122 NDA 19123 FORM 2253
2016-4169	05/17/2016 06/15/2016	FDA/OFVM/CFSAN/OCD/EOS/	Sanjay Karnik Amin Talati & Upadhye, LLC	KIND, LLC - COMMUNICATIONS WITH FDA FOLLOWING WARNING LETTER; RECS RE "HEALTHY AND TASTY", "HEALTHY" 03/16/2015 - 05/10/2016
2016-4170	05/17/2016 06/15/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dustin Block IPD Analytics, LLC	TENTATIVE APPROVAL LETTER ANDA 202023 ANDA 202255 ANDA 202597 ETC
2016-4171	05/17/2016 06/15/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Anjali Cordeiro BLOOMBERG NEWS	ANDA 205102 MOST RECENT BIOEQUIVALENCE REVIEW

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-4172	05/17/2016 06/15/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	DIRECT REPORTS, MEDWATCH REPORTS and ANY SOURCE DOCUMENTS 11272657 ; 11287517 ; fDULERA aka FORMOTEROL MOMETASONE,
2016-4173	05/17/2016 06/15/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	DIRECT REPORTS, MEDWATCH REPORTS ANY SOURCE DOCUMENTS 11392306; 11392361; 11395075; ETC VICTRELIS aka BOCEPREVIR
2016-4174	05/17/2016 06/15/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	DIRECT REPORTS, MEDWATCH REPORTS ANY SOURCE DOCUMENTS THE FOLLOWING 11295681 ZERBAXA
2016-4175	05/17/2016 06/15/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	DIRECT REPORTS, MEDWATCH REPORTS ANY SOURCE DOCUMENTS 11239710; 11247353; 11292256; ETC BELSOMRA
2016-4176	05/17/2016 06/15/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	DIRECT REPORTS, MEDWATCH REPORTS ANY SOURCE DOCUMENTS CASE NUMBERS: 11247046; 11247860; 11253722 ; ETC
2016-4177	05/17/2016 06/15/2016	FDA/OC/OCC/ FDA/OMPT/CDRH/OCE/DID/	MITCHELL L STOLTZ ELECTRONIC FRONTIER FOUNDATION	USE OF SECTION 1201 OF THE DIGITAL MILLENNIUM COPYRIGHT ACT IN FDA ENFORCEMENT ACTIVITIES
2016-4178	05/17/2016 06/15/2016	FDA/OC/OES/DDM/ FDA/OMPT/CDRH/OCE/DID/	JAMES H SMITH McKool Smith	DKT 2016N-0436
2016-4179	05/17/2016 06/15/2016	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAP/SE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORAP/SW-FO/DEN-DO/DEN-CB/	KATHRYN B GRAY Ogletree Deakins Nash Smoak & Stewart, PLLC	OCTAPHARMA PLASMA INC, SAN DIEGO, CA, CHARLOTTE, NC; LIFE SERA INC, SAN DIEGO, CA, CLARKSTON, GA; ALPHA THERAPEUTIC CORP, LOS ANGELES, CA, NEW YORK, NY, ETC - EIRS, 483S, WARNING LTRS, ETC 1/00 TO PRESENT
2016-4180	05/17/2016 06/15/2016	OC/ORAP/OCI/ OC/ORAP/OCI/	JODI L NOFSINGER BERMAN & SIMMONS PA	INDIVIDUAL RECS

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2016-4181	05/17/2016 06/15/2016	FDA/OC/OES/DFOI/	BERYL LIPTON MUCKROCK	FDA GUIDELINES AND REGULATIONS REGARDING SUBMISSION AND PROCESSING OF FOIA REQUESTS AND APPEALS
2016-4182	05/17/2016 06/15/2016	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	RAVI DESHPANDE ACINO PRODUCTS LLC	UNIPACK INC (US PHARMACEUTICALS), BELLEVILLE, NJ - EIR, 483, CO RESP
2016-4183	05/17/2016 06/15/2016	FDA/OC/OES/DDM/	DR SARAH HARTLEY UNIV OF NOTTINGHAM SCHOOL OF SOCIOLOGY AND SOCIAL POLICY	DKT 2014N-2235
2016-4184	05/18/2016 06/16/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Hina Waheed Professional Compounding Centers of America (PCCA)	LISTING OF ALL DRUG ESTABLISHMENTS REGISTERED IN 2014, 2015
2016-4185	05/18/2016 06/16/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tyler Van Buren COWEN AND COMPANY	COPAXONE 20 MG, COPAXONE 40 MG, GLATOPA - AERS
2016-4186	05/18/2016 06/16/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dustin Block IPD Analytics, LLC	ANDA 077342 APPROVAL LETTER
2016-4187	05/18/2016 06/16/2016	FDA/OMPT/CDRH/OCE/DID/	Marc C. Sanchez, Esq. Contract In-House Counsel and Consultants, LLC	K160259 K100874
2016-4188	05/18/2016 06/16/2016	OC/ORAE/ OC/ORAE/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	SERVICE FIRST PHARMACIES DBA MADISON DRUGS, HUNTSVILLE, AL - EIR, 483, RESPONSE 08/03/2015 - 08/13/2015
2016-4189	05/18/2016 06/16/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	Conditional approval letters for 5 Nitro-Dur ANDAs
2016-4190	05/18/2016 06/16/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John Walsh James Alexander Corporation	MANUS AKTTEVA BIOPHARMA LLP, INDIA - 483, EIR, RECALL RECS

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2016-4191	05/18/2016 06/16/2016	FDA/OMPT/CDRH/OCE/DID/	Diane Rutherford Ken Block Consulting	K941327
2016-4192	05/18/2016 06/16/2016	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	JOE WARNHOFF PERFORMANCE PRODUCTS, INC.	NICH MARKETERS, INC, COLUMBUS, OH - 483 01/23/2007
2016-4193	05/18/2016 06/16/2016	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Deborah Scott Scott, Deborah	TRANSDERMAL CAP INC - 483, RESPONSES 01/01/2015 - 05/12/2016
2016-4194	05/18/2016 06/16/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	Pablo Perhacs Searcy Denney Scarola Barnhart & Shipley, P.A.	HEALTH HAZARD EVALUATIONS, WORKSHEETS, ACTION MEMOS RE TEVA PROPOFOL INJECTABLE EMULSION 07/01/2009 - 12/31/2009
2016-4195	05/18/2016 06/16/2016	FDA/OC/OES/	Joe Williams CQ Roll Call	FDA COMMISSIONER CALIFF MEETINGW TIH AMERICAN'S HEALTH INSURANCE PLANS - BACKGROUND MATERIALS 03/08/2016 - 03/08/2016
2016-4196	05/18/2016 06/16/2016	FDA/OMPT/CDRH/OCE/DID/	Shalini Satta AncestryDNA	K141410 K110701
2016-4197	05/18/2016 06/16/2016	FDA/OMPT/CDRH/OCE/DID/	jeanne lee Hollister Incorporated	K864218
2016-4198	05/18/2016 06/16/2016	FDA/OMPT/CDRH/OCE/DID/	Brandon Mikulski Inter-Med/vista dental products	K123215
2016-4199	05/18/2016 06/16/2016	FDA/OMPT/CDRH/OCE/DID/	Crosstex International Medivators Inc.	K031681
2016-4200	05/18/2016 06/16/2016	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Jessica Newman Jessica Newman	LABORATORY SERVICES INC, CARTERET, NJ - EIR, 483 02/27/2014 - 03/05/2014
2016-4201	05/18/2016 06/16/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	DIRECT REPORTS, MEDWATCH REPORTS ANY SOURCE DOCUMENTS 11445349 DIFICID
2016-4202	05/18/2016 06/16/2016	FDA/OFVM/CFSAN/OCD/EOS/	Alessandra Potenza The Verge	KAVA KAVA, KAVA PEPPER, AWA, ETC - AERS
2016-4203	05/18/2016 06/16/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Erika Kirsch UBC: An Express Scripts Company	Supplementary suggestions for preparing an integrated summary of safety information in an original NDA submission and for organizing information in periodic safety updates (Leber guidelines)

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-4204	05/18/2016 06/16/2016	FDA/OC/OES/DFOI/	Catherine Geyman Epic Risk Solutions Ltd	STICHTING SANQUIN BLOEDVOORZIENING , NETHERLANDS, CAF-DCF, BELGIUM, PATHEON, GREENVILLE, SC, COSMO SPA, ITALY - EIR, 483 05/01/2014 - 05/01/2016
2016-4205	05/18/2016 06/16/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	DIRECT REPORTS, MEDWATCH REPORTS ANY SOURCE DOCUMENTS 11329532; 11358829; 11386022; ETC KEYTRUDA
2016-4206	05/18/2016 06/22/2016	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/ FDA/OGROP/ORA/CE-FO/CHI- DO/CHI-CB/	John Walsh JAMES ALEXANDER CORP	HOSPIRA, LAKE FOREST, NY - EIR, 483, RECALL 05/01/2012 - 05/12/2016
2016-4207	05/18/2016 06/16/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Susan Lee Cadian Capital	GLATOPA - AERS
2016-4208	05/18/2016 06/16/2016	FDA/OC/OES/DFOI/	Angela Tonello Angela Tonello	PARAGARD INTRA UTERINE DEVICE - ADVERSE EVENTS
2016-4209	05/18/2016 06/16/2016	FDA/OFVM/CFSAN/OCD/EOS/	Gina Ecolino Beveridge & diamond, P.C.	CFSAN FOIA REQUESTS 04/22/2016 - 05/17/2016
2016-4210	05/18/2016 06/16/2016	FDA/OC/OES/DFOI/	Brianna Newman Sage Research and Design LLC	MAUDE REPORTS RE INFUSION PUMPS 01/01/2007 - 05/13/2016
2016-4211	05/18/2016 06/16/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Steven Tish DSM CAPITAL	LINZESS - AERS
2016-4212	05/18/2016 06/16/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Marc Young Nationwide pharmaceutical	LIST OF API BY NDC NUMBER
2016-4213	05/18/2016 06/16/2016	FDA/OMPT/CDRH/OCE/DID/	Vivian Kelly Fidia Pharma USA Inc.	CPT1500777
2016-4214	05/18/2016 06/16/2016	FDA/OMPT/CDRH/OCE/DID/	James Bonds Facet Technologies, LLC	K922441

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2016-4215	05/18/2016 06/16/2016	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Abhishek K. Gurnani Amin Talati & Upadhye, LLC	GANEDEN BIOTECH - CORR RE WARNING LETTER 01/01/2005 - 05/13/2016
2016-4216	05/18/2016 06/16/2016	FDA/OMPT/CDRH/OCE/DID/	James Bonds Facet Technologies, LLC	K931828
2016-4217	05/18/2016 06/16/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dinesh Reddy Anugu Insys Therapeutics, Inc.	NDA 010571 SBA
2016-4218	05/18/2016 06/16/2016	FDA/OC/OES/DFOI/	John Morris John Morris	ESSURE APPROVAL RECS 01/01/1999 - 12/31/2004
2016-4219	05/18/2016 06/16/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 83273
2016-4220	05/18/2016 06/16/2016	FDA/OMPT/CDRH/OCE/DID/	Pivi Mesiranta Regulatory Affairs Manager Brainshake	K143236
2016-4221	05/18/2016 06/16/2016	OC/ORACE/ORM/ OC/ORACE/ORM/	Vrijesh Kasera Edelweiss Financial Services	LIST OF DRUG INSPECTIONS 01/01/2000 - 05/13/2016
2016-4222	05/18/2016 06/16/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TRACY ACKER SUPERNUS PHARMACEUTICALS INC	JANSSEN PHARMACEUTICALS - TOPAMAX NDA 20-505 MEDICAL RVW
2016-4223	05/18/2016 06/16/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JIM MORRIS NSF HEALTH SCIENCES	RECIPHARM KARLSKOAGA AB, SWEDEN - EIR
2016-4224	05/18/2016 06/16/2016	FDA/OGROP/ORACE-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCE/DID/	MICHAEL P. O LAW OFFICES OF MICHAEL ODAY	BIOPLATE INC, LOS ANGELES, CA - RIGID FIXATION PLATING SYS APRVL, K0628219, 483
2016-4225	05/18/2016 06/16/2016	FDA/OFVM/CFSAN/OCD/EOS/	Blane Wilson Blane Wilson	DARK CHOCOLATE PRODUCERS LISTED IN SURVEY OF MILK IN DARK CHOCOLATE PRODUCTS 01/01/2016 - 05/13/2016
2016-4226	05/18/2016	OC/CVM/OCD/	Susan Thixton	CPG 675.400 DATA

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	06/16/2016		Susan Thixton/Association for Truth in Pet Food	
2016-4227	05/18/2016 06/16/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jill Feldman Medac Pharma, Inc.	IDT Biologika GmbH, Am Pharmapark, Dessau-Rosslau, Saxony-Anhalt, Germany EIR 8/31/15
2016-4228	05/18/2016 06/16/2016	FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/	BERNALES, MAURIZIO	ADVANCED GENERIC CORP, MIAMI, FL - EIR, 483,
2016-4229	05/18/2016 06/16/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nancy Klett Cerium Pharmaceuticals	CITRON RESEARCH RECS 12/01/2013 - 03/31/2014; Related to Citron Research's publications dated 2/27/2014 and 3/14/
2016-4230	05/18/2016 06/16/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Pascal Besman Pascal Besman	KYNAMRO - FAERS
2016-4231	05/18/2016 06/16/2016	FDA/OGROP/ORO/SE-FO/NOL-DO/NOL-CB/	Zaneta Lowe WREG-TV	KELLOGG, MEMPHIS, TN - RECS RE EMPLOYEE INCIDENT 01/04/2013 - 12/31/2016
2016-4232	05/18/2016 06/16/2016	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2016-3632
2016-4233	05/18/2016 06/16/2016	FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/	BERNABE, POLA	LLORENS PHARMACEUTICAL INTERNATIONAL DIVISION, MIAMI, FL - EIR, 483
2016-4234	05/18/2016 06/16/2016	FDA/OC/OES/DFOI/	Maria merchant Somnarus Inc	K071230
2016-4235	05/18/2016 06/16/2016	FDA/OC/OES/DFOI/	510k Documentary IntroMedic Co., Ltd.	K101250
2016-4236	05/18/2016 06/16/2016	FDA/OGROP/ORO/SE-FO/SJN-DO/SJN-CB/	POLA BERNABE BERNABE, POLA	LLORENS PHARMACEUTICALS CORP, CAGUAS, PR - EIR, 483
2016-4237	05/18/2016 06/16/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHRISTINE N. SANG, MD, MPH BRIGHAM & WOMEN'S HOSPITAL	MORPHINE, SUCCINYLCHOLINE; CURARE - OPERATING ROOM USES
2016-4238	05/18/2016	FDA/OMPT/CDER/ORP/DIDP/	CHRISTINE KRONMILLER	5950308, 5996187, 6062053 - FAERS

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	06/16/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BTG INTERNATIONAL INC	
2016-4239	05/18/2016 06/16/2016	FDA/OC/OES/DFOI/	LEWIS, TOM	OLYMPUS - DUODENOSCOPES RECALL
2016-4240	05/18/2016 06/16/2016	FDA/OMPT/CDRH/OCE/DID/	CHRISTINE LIVOTI DEERFIELD INSTITUTE	BAXTER - VIVIA HIGH DOSE HEMODIALYSIS SYS MTG MINS, TRANS, CORR, ETC 4/22/16
2016-4241	05/18/2016 06/16/2016	FDA/OMPT/CTP/OD/	MATT NOVAK Gizmodo/Gawker Media	ELECTRONIC CIGARETTES CORR SENT TO OR FROM MITCH ZELLER 5/10 TO PRESENT
2016-4242	05/18/2016 06/16/2016	FDA/OC/OES/DFOI/	WALKER 188417, DAVID	KOSHER - GUIDELINES
2016-4243	05/18/2016 06/16/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	NOVOLOG - AER
2016-4244	05/18/2016 06/16/2016	FDA/OMPT/CDRH/OCE/DID/	CATHERINE E. ADAMS RDR SOLUTIONS CONSULTING LLC	KUBTEC - MOZART W/TOMOSPEC APRVL
2016-4245	05/18/2016 06/16/2016	FDA/OMPT/CDRH/OCE/DID/	ROBERT J. SEWELL LIGHTFOOT FRANKLIN & WHITE LLC	LIMACORPORATE - LIMA SMR MODULAR SHOULDER REPLACEMENT SYS
2016-4246	05/18/2016 06/16/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JESSICA WARREN INTERCEPT PHARMACEUTICALS INC	NEW ZEALAND PHARMACEUTICAL LTD, MANAWATU, WANGANUI NEW ZEALAND - EIR, 483
2016-4247	05/19/2016 06/17/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GAURAV KARNAWAT GAURAV KARNAWAT	AUROBINDO PHARMA UNIT 11 SRIKAKULAM,INDIA AND AURONEXT, BHIWANDI,INDIA 483 04/03/2015 - 05/14/2016
2016-4248	05/19/2016 06/17/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GAURAV KARNAWAT GAURAV KARNAWAT	AUROBINDO PHARMA UNIT - 1, UNIT 5 , UNIT 8 ,UNIT 9 MEDAK,INDIA 483 04/03/2015 - 05/14/2016
2016-4249	05/19/2016	FDA/OMPT/CBER/OCOD/DDOM/	Phillip Hwang	Requesting original clinical and statistical review for Gardasil-9

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	06/17/2016	ALFB/	UNIVERSITY OF WASHINGTON	
2016-4250	05/19/2016 06/17/2016	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Terry Herr TLH Consulting	PHARMACIA AND UPJOHN, KALAMAZOO, MI - 483, EIR 01/03/2014 - 05/14/2016
2016-4251	05/19/2016 06/17/2016	FDA/OC/OES/DFOI/	S Lori Brown S Lori Brown	ALLERGAN, CALIFORNIA - EIR RE SALINE BREAST IMPLANTS 01/01/2011 - 05/15/2016
2016-4252	05/19/2016 06/17/2016	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Terry Herr TLH Consulting	BANNER, PHARMACAPS, GREENSBORO, NC - EIR 10/01/2015 - 11/01/2016
2016-4253	05/19/2016 06/17/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Spencer Hayes Spencer Hayes	IMAGING CONTRAST AERS IN ALABAMA
2016-4254	05/19/2016 06/17/2016	FDA/OMPT/CDRH/OCE/DID/	Ryan Massey MEDTRONIC	K141830
2016-4255	05/19/2016 06/17/2016	FDA/OMPT/CDRH/OCE/DID/	JOHN MORRIS MORRIS, JOHN	ESSURE - ANIMAL TRIAL DESIGN PRIOR TO IDE APRVL
2016-4256	05/19/2016 06/17/2016	FDA/OC/OES/DFOI/	CATHERINE GEYMAN Epic Risk Solutions Ltd	STICHTING, COSMO - EIRS, 483S
2016-4257	05/19/2016 06/17/2016	OC/ORACE/ORM/ OC/ORACE/ORM/	JONATHAN KAUFMAN WILLIAM BLAIR & CO	CATALENT, PATHEON, AMRI- 483S LAST 10 YRS
2016-4258	05/19/2016 06/17/2016	OC/ORACE/ORM/ OC/ORACE/ORM/ FDA/OFVM/CFSAN/OCD/EOS/	CHRISTOPHER HENDEL CONSUMER REPORTS	DIETARY SUPPLEMENT MFRS - INSPS, NUMBER OF FACILITIES FY2010 TO FY2016
2016-4259	05/19/2016 07/26/2016	FDA/OC/OES/DFOI/ FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/ FDA/OGROP/ORACE-FO/CINDO/CIN-CB/ FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OGROP/ORACE-FO/MINDO/MIN-CB/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	MERLE ZIMMERMANN AMERICAN HERBAL PRODUCTS ASSOCIATION	US PHARMACEUTICAL CORP, DECATUR, GA 3/24-31/15; VALENTINE ENTERPRISES INC, LAWRENCEVILLE, GA 4/6-10/15; SPRINGTIME INC, 8/17-18/15, ETC - EIR ENDORSEMENT, 483S

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		FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/		
2016-4260	05/19/2016 06/17/2016	FDA/OMPT/CDRH/OCE/DID/	PATRIK WESTERKULL MSC ENG PH OTORIX AB	ENTIFIC MEDICAL SYSTEMS INC - BAHA HEADBAND K002913
2016-4261	05/19/2016 06/17/2016	FDA/OMPT/OSMP/OCF/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	NATAN PHEIL Norfolk Medical Products, Inc.	SAFETY TOLERABILITY AND EFFICACY STUDY OF VX-01 COMBINATION PRODUCT IN SUBJECTS WITH TYPE 1 DIABETES MELLITUS; VIACYTE FILINGS TO DATE
2016-4262	05/19/2016 06/17/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Connie Law The Children of Philadelphia	MERCAPTOPURINE - AERS
2016-4263	05/19/2016 06/17/2016	OC/ORA/ORM/ OC/ORA/ORM/	M. Randall M. Randall	List of Device Inspections - 1/1/2016 to 5/16/2016

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2016-4264	05/19/2016 06/17/2016	OC/ORR/ORM/ OC/ORR/ORM/	Jessica Wade THOMSON REUTERS	LIST OF FOREIGN AND DOMESTIC DRUG INSPECTIONS 09/01/2015 - 05/16/2016
2016-4265	05/19/2016 06/17/2016	OC/ORR/ORM/ OC/ORR/ORM/	quintiles Quintiles	LIST OF 482 NOTICE OF INSPECTIONS FOR DRUGS, BIOLOGICS, AND DEVICES 05/01/2016 - 05/31/2016
2016-4266	05/19/2016 06/17/2016	OC/ORR/ OC/ORR/ FDA/OGROP/ORR/ORO/DIOP/	Zetetic, Inc. Zetetic, Inc.	FDA ENTRY DOCUMENTATION REQUEST ALL DOCUMENTATION 05/01/2016 - 05/15/2016
2016-4267	05/19/2016 06/17/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gary Schneider Evidera	FAERS REPORTS 5890637 6139921 7622825 ETC
2016-4268	05/19/2016 06/17/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Marc Elia BRIDGER CAPITAL LLC	PRALUENT, REPATHA - AERS
2016-4269	05/19/2016 06/17/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gay Parsons Janssen Inc. Canada	GENERIC METHYLPHENIDATE HYDROCHLORIDE ER - AERS, MEDWATCH
2016-4270	05/19/2016 06/17/2016	FDA/OMPT/CDRH/OCE/DID/	Doe J	RIVERSTONE RESOURCES SDN BHN - K150689; INDIVIDUAL RECS
2016-4271	05/20/2016 07/01/2016	FDA/OC/OES/DFOI/	Kris Christian FDAZILLA	483s, RESPONSES, EIR PREVIOUSLY RELEASED 04/07/2016 - 05/09/2016
2016-4272	05/20/2016 06/20/2016	FDA/OFVM/CFSAN/OCD/EOS/	Elizabeth Sweis INTERTEK	FRAUNHOFER INSTITUT VERAHRENSTENCHNIK UNDER VERPACKUNG NO OBJECTION LETTER 05/16/2016 - 06/14/2016
2016-4273	05/20/2016 06/20/2016	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORR/ OC/ORR/	Michael Landa Michael Landa	SUMMARY OF ANALYTICAL RESUULTS FROM LEAD AND CADMIUM IN FOOD SAMPLING SINCE JANUARY 2011 01/03/2011 - 05/16/2016
2016-4274	05/20/2016 06/20/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Irma Almazan Kinerk, Schmidt & Sethi PLLC	ZEPHIRAN - PRODUCT INFORMATION, PACKAGING INSERTS, LABELING 01/01/2010 - 05/16/2016
2016-4275	05/20/2016	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson	Correspondence between FDA & Mars regarding peanut in

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	06/20/2016		FOI Services, Inc.	chocolate
2016-4276	05/20/2016 06/20/2016	FDA/OFVM/CFSAN/OCD/EOS/	Dr. Grant B. Kenion Henkel Corporation	FCN1505, 1583, 1584, 1596, 1597 REVIEWER FINAL COMMENTS
2016-4277	05/20/2016 06/20/2016	FDA/OPPLA/OL/	Richard Newman RND Services, LLC	RESPONSE RE LETTER TO STEPHEN OSTROFF FROM COMMITTEE ON ENERGY AND COMMERCE 9/2/15 09/02/2015 - 12/31/2015
2016-4278	05/20/2016 06/20/2016	FDA/OMPT/CDRH/OCE/DID/	Joachim Lindqvist Joachim Lindqvist	K983406 INDICATIONS FOR USE
2016-4279	05/20/2016 06/20/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bob van Osdel Nexgen Pharma, Inc.	ANDA 040502 BIOEQUIVALENCY REVIEW RECS
2016-4280	05/20/2016 06/20/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michael Bonck ST. JOSEPH MEDICAL CENTER	REMICADE - AERS
2016-4281	05/20/2016 06/20/2016	FDA/OMPT/CDRH/OCE/DID/ FDA/OFVM/CFSAN/OCD/EOS/	Elizabeth Sweis INTERTEK	GNEUSS KUNSTSOFFTECHNIK GHBM - NO OBJECTION LETTER NO 151 05/16/2016 - 06/14/2016
2016-4282	05/20/2016 06/20/2016	FDA/OMPT/CDRH/OCE/DID/ FDA/OPPLA/OL/	Jeanne Lenzer The BMJ and publisher Little, Brown	FDA RESPONSE TO INQUIRY BY SENATOR SOLOMON P ORTIZ RE VNS INVESETIGATION; POST SURVEILLANCE STUDIES 01/01/1997 - 05/16/2016
2016-4283	05/20/2016 06/20/2016	FDA/OFVM/CFSAN/OCD/EOS/	Elizabeth Seis INTERTEK	NO OBJECTION LETTER 146 FRAUNHOFER INSTITUT VERAHRENSTECHNIK
2016-4284	05/20/2016 06/20/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Liz DeAngelo THE INSTITUTE FOR TRANSFUSION MEDICINE	STN BL 102379/5057 APPROVAL LETTER VIRGINIA BLOOD SERVICES
2016-4285	05/20/2016 06/20/2016	FDA/OFVM/CFSAN/OCD/EOS/	Michael Landa Michael Landa	RECS RE SUSAN MAYNE ANSWERS 01/02/2006 - 01/01/2015
2016-4286	05/20/2016 06/20/2016	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Rachel Johnson FOI Services, Inc.	ROCK RIVER MANUFACTURING, WINNEBAGO, NE - INSPECTION RECS 07/28/2015
2016-4287	05/20/2016 06/20/2016	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Eileen Castillo A.I.G. Technologies, Inc.	AIG TECHNOLOGIES, INC, DEERFIELD BEACH, FL - EIR 11/17/2015 - 05/17/2016
2016-4288	05/20/2016 06/20/2016	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	Rachel Johnson FOI Services, Inc.	SKOOKUM CREEK TOBACCO, SHELTON, WA - INSPECTION RECS 09/02/2015

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2016-4289	05/20/2016 06/20/2016	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Rachel Johnson FOI Services, Inc.	Hérons Landing Smoke Shop, Irving, NY (09/25/2015); J Conrad Seneca dba Six Nations Manufacturing, Irving, NY (08/26/2015); Lake Erie Tobacco Company, Kill Buck, NY (09/22/2015); ETC - EIR, 483, WARNING LETTER ETC
2016-4290	05/20/2016 06/20/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Valerie Gallagher perrigo	PROPYLTHIOURACIL - ANDA A084543
2016-4291	05/20/2016 06/20/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kristi Smedley Center for Regulatory Services Inc.	HAUPT PHARMA WOLFRATSHAUSEN GGMH, GERMANY - EIR 05/17/2016 - 05/17/2016
2016-4292	05/20/2016 06/20/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kristi Smedley Center for Regulator Services, Inc	HAUPT PHARMA WOLFRATSHAUSEN, GERMANY - 483 05/17/2016 - 05/17/2016
2016-4293	05/20/2016 06/20/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Marc Elia BRIDGER CAPITAL LLC	LINZESS - AERS
2016-4294	05/20/2016 06/20/2016	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	2016-3186 COMPLETE RESPONSE
2016-4295	05/20/2016 06/20/2016	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	RILEY, ZACHARY	UNIVERSITY OF MISSOURI HEALTHCARE SYSTEM - INVESTIGATION, RPTS, CORR, ETC 5/21/08 TO 7/25/08
2016-4296	05/20/2016 06/20/2016	FDA/OFVM/CFSAN/OCD/EOS/	GEORGE W. LEMEL Keller and Heckman LLP	FCN 475
2016-4297	05/20/2016 06/20/2016	OC/ORASORM/ OC/ORASORM/	WALTER E. CHALKLEY THOMSON REUTERS (SCIENTIFIC) SAS	DRUG AND BIOLOGIC MFRS, REPACKERS.PACKERS, CONTROL LABS, ETC - FOREIGN AND DOMESTIC INSPS 1/16 TO 3/16
2016-4298	05/20/2016 06/20/2016	FDA/OC/OES/DFOI/	Fucetola, Ralph	ACCEPTABLE VOLTAGE TO HUMAN SKIN - INVESTIGATION
2016-4299	05/23/2016 06/21/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LESLIE RAMSEY FDA NEWS	JUZEN CHEMICAL CORP, TOYAMA, JAPAN; LUPIN LTD, GOA, INDIA; TTY BIOPHARM CO LTD, CHUNG-LI CITY, TAIWAN, ETC - 483S 3/1-31/16

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-4300	05/23/2016 06/21/2016	FDA/OFVM/CFSAN/OCD/EOS/	JAH I HASANATI #D15084 HASANATI #D15084, JAH I	SODIUM ASCORBATE, FERROUS FUMARATE, PALMITATE, ETC - CAERS, USEFULNESS
2016-4301	05/23/2016 06/21/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PATRICIA ANDERSON MAPI USA INC	CYCLE PHARMACEUTICALS LTD - INDOMETHACIN CAPS ANDA 70-353, ANDA 70-354
2016-4302	05/23/2016 06/21/2016	FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECS
2016-4303	05/23/2016 06/21/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-8113
2016-4304	05/23/2016 06/21/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-8296
2016-4305	05/23/2016 06/21/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-8450
2016-4306	05/23/2016 06/21/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-8501
2016-4307	05/23/2016 06/21/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2013-1826
2016-4308	05/23/2016 06/21/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-8531
2016-4309	05/23/2016 06/21/2016	FDA/OGROP/OR A/CE-FO/MIN-DO/MIN-CB/	Kathleen Schutz AWH Capital, L.P.	ALGOSTIM LLC, ALGOVITA IMPLANTED PULSE GENERATOR STIMULATOR RECALL 0Z-1192-2016 3/01/2016 - RECALL LETTER 03/31/2016
2016-4310	05/23/2016 06/21/2016	FDA/OGROP/OR A/NE-FO/NYK-DO/NYK-DCB/	Alexander Kerzhner Threeline Imports, Inc.	COMPLAINT RE COD LIVER PRODUCTS IMPORTED OR SOLD BY THREELINE IMPORTS 03/01/2016 - 05/17/2016
2016-4311	05/23/2016 06/21/2016	FDA/OGROP/OR A/PA-FO/SEA-DO/SEA-CB/	Traci Jensen AO Operations LLC dba River Point Farms	AO OPERATIONS LLC DBA RIVER POINT FARMS, HERMISTON, OR - EIR 12/01/2015 - 12/15/2015
2016-4312	05/23/2016 06/21/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	Post-Market Surveillance Survey PS15001 for K142282
2016-4313	05/23/2016 06/21/2016	FDA/OGROP/OR A/PA-FO/SEA-DO/SEA-CB/	Traci Jensen AO Operations LLC dba River Point Farms	RIVER POINT FARMS, HERMISTON, OR - EIR 12/01/2015 - 12/15/2015

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2016-4314	05/23/2016 06/21/2016	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	Shauna Ross Nutra Manufacturing, Inc	NUTRA MANUFACTURING, ANDERSON, SC - EIR 02/22/2016 - 02/24/2016
2016-4315	05/23/2016 06/21/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-8530
2016-4316	05/23/2016 06/21/2016	OC/CVM/OCD/	Chauncey Baldwin Zoetis Inc.	Any and all laboratory procedures or assay methods entitled "Determination of Nicarbazine in Feeds Using High Performance Liquid Chromatography" or similar title
2016-4317	05/23/2016 06/21/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-6558
2016-4318	05/23/2016 06/21/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Vrijesh Kasera Edelweiss Financial Services Ltd	GLAND PHARMA LTD, INDIA - 483, EIR 09/01/2015 - 05/17/2016
2016-4319	05/23/2016 06/21/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2013-8688
2016-4320	05/23/2016 06/21/2016	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	Jerilyn Spencer Horizon Pharmaceuticals, Inc	HORIZON PHARMACEUTICALS, INC, RIVIERA BEACH, FL - EIR 10/27/2015 - 11/05/2015
2016-4321	05/23/2016 06/21/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2014-7984
2016-4322	05/23/2016 06/21/2016	FDA/OMPT/CTP/OD/	Desmond Jenson Tobacco Control Legal Consortium	LIST OF TOBACCO PRODUCTS FILED WITH FDA UNDER 905(J) AS OF 5/1/16
2016-4323	05/23/2016 06/21/2016	FDA/OGROP/ORR/CE-FO/MIN-DO/MIN-CB/	Kathleen Schutz AWH Capital, L.P.	ALGOSTIM LLC, ALGOVITA IMPLANTED PULSE GENERATOR STIMULATOR, RECALL Z-1192-2016 URGETN FIELD SAFETY NOTICE 1/21/16
2016-4324	05/23/2016 06/21/2016	FDA/OO/OFBA/OAGS/	Chris Glorioso NBC New York	CONTRACTS RECS RE MAUDE MAINTENANCE, UPGRADES 01/01/2005 - 05/17/2016
2016-4325	05/23/2016 06/21/2016	FDA/OPPLA/OL/	Maria Hegstad Inside EPA	FDA RESPONSES TO US SENATE RE 12/17/15 LETTER RE STATUS OF PENDING UPDATE TO JOIN FDA-EPA ADVICE TO WOMEN OF CHILDBEARING AGE ON SEAFOOD CONSUMPTION 12/17/2015 - 05/17/2016 ; FDA RESPONSE TO SENATOR MIKE ENZI RE 1/28/16 LETTER
2016-4326	05/23/2016 06/21/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tanmoy Sadhukha Albany Molecular Research Inc.	NDA 22374 (OMAPRO)
2016-4327	05/23/2016	FDA/OGROP/ORR/SW-FO/DAL-	Rachel Johnson	SENECA-CAYUGA TOBACCO COMPANY, GROVE, OK -

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	06/21/2016	DO/DAL-CB/	FOI Services, Inc.	INSPECTION RECS 07/21/2015
2016-4328	05/23/2016 06/21/2016	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Melissa Malapit Celgene Corporation	DAVID SIEGEL HACKENSACK UNIVERSITY MEDICAL CENTER CANCER CENTER, HACKENSACK, NJ - 483 07/01/2012 - 05/17/2016
2016-4329	05/23/2016 06/21/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Daven Mody Impax Laboratories, Inc.	DUOPA NDA 203952 APPROVAL RECS
2016-4330	05/23/2016 06/21/2016	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Shauna Ross Nutra Manufacturing, Inc	NUTRA MANUFACTURING, GREENVILLE, SC - EIR 02/29/2016 - 03/03/2016
2016-4331	05/23/2016 06/21/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Paul Danese FDABLE LLC	FAERS CASE Numbers / CASE IDs 4037489 4086054 5738053 ETC
2016-4332	05/23/2016 06/21/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Paul Danese FDABLE LLC	FAERS case IDs Case Numbers 3768674 5927029 5927939 ETC
2016-4333	05/23/2016 06/21/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Robert Stief Robert Stief	XANAX AERS
2016-4334	05/23/2016 06/21/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Olena Izhak Boston University, Department of Economics	ANDA APPROVAL LETTERS
2016-4335	05/24/2016 06/22/2016	FDA/OC/OES/DFOI/	LORI A CARR LORI A CARR INC	HOWMEDICA OSTEONICS CORP - RESTORATION ADM SYS K072020
2016-4336	05/24/2016 06/22/2016	FDA/OC/OES/DFOI/	LORI A CARR LORI A CARR INC	BIOMET INC - METAL ON METAL ACETABULAR SYS K993438
2016-4337	05/24/2016 06/22/2016	FDA/OC/OES/DFOI/	LORI A CARR LORI A CARR INC	CENTRIPULSE ORTHOPEDICS INC - EPISILON METASUL ACETABULAR INSSERTS K033634
2016-4338	05/24/2016 06/22/2016	FDA/OC/OES/DFOI/	LORI A CARR LORI A CARR INC	ENCORE ORTHOPEDICS INC - FMP METAL/METAL ACETABULAR INSERT K003250

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2016-4339	05/24/2016 06/22/2016	FDA/OC/OES/DFOI/	LORI A CARR LORI A CARR INC	BIOMET INC - M2A 28MM RINGLOC LINER K002379
2016-4340	05/24/2016 06/22/2016	FDA/OC/OES/DFOI/	LORI A CARR LORI A CARR INC	BIOMET INC - M2A MAGNUM SYS K042037
2016-4341	05/24/2016 06/22/2016	FDA/OC/OES/DFOI/	LORI A CARR LORI A CARR INC	SULZER ORTHOPEDICS INC - INTER-OP METASUL ACETABULAR SYS K974728
2016-4342	05/24/2016 06/22/2016	FDA/OMPT/CDRH/OCE/DID/	LESLIE RAMSEY FDA NEWS	CAVEX HOLLAND BV, HEARLEM, NETHERLANDS; JOSSI ORTHOPEDICS AG, ISLIKON, SWITZERLAND; SANKEI CO LTD, ICHIHARA CITY, JAPAN, ETC - 483S 4/1-30/16
2016-4343	05/24/2016 06/22/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	LESLIE RAMSEY FDA NEWS	ADIMMUNE CORP, TAICHUNG CITY, TAIWAN; SYNCO BIO PARTNERS BV, AMSTERDAM, NETHERLANDS - 483S 4/1-31/16
2016-4344	05/24/2016 06/22/2016	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	LESLIE RAMSEY FDA NEWS	PISGAH LABS INC, PISGAH FOREST, NC; CR BARD INC, COVINGTON, GA; J DAVID LENTZ III MD, GEORGIA CLINICAL RESEARCH, SNELLVILLE, GA - 483S 4/1-31/16
2016-4345	05/24/2016 06/22/2016	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	LESLIE RAMSEY FDA NEWS	PHARMACEUTICS INTERNATIONAL INC, COCKEYSVILLE, MD; REFLEXONIC LLC, FREDERICK, MD - 483S 4/1-31/16
2016-4346	05/24/2016 06/22/2016	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	LESLIE RAMSEY FDA NEWS	FORCE DIAGNOSTICS INC, BANNOCKBURN, IL; PQ CORP, UTICA, IL - 483S 4/1-31/16
2016-4347	05/24/2016 06/22/2016	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	LESLIE RAMSEY FDA NEWS	HOMWOOD HEALTHCARE PRODUCTS INC, DUBLIN, OH - 483S 4/1-31/16
2016-4348	05/24/2016 06/22/2016	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	LESLIE RAMSEY FDA NEWS	AGGREDYNE INC, HOUSTON, TX; BAPTIST HEALTH MEDICAL OWERS PHARMACY AND INFUSION SERVICES, LITTLE ROCK, AR; HENRY RUIZ MD, DOCTORS HOSPITAL AT RENAISSANCE, EDINBURG, TX - 483S 4/1-30/16
2016-4349	05/24/2016 06/22/2016	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	LESLIE RAMSEY FDA NEWS	CHEMATICS INC, NORTH WEBSTER, IN; EMERGENT BIODEFENSE OPERATIONS LANDING LLC, LANSING, MI; JAY H SANDBERG DO, OAKLAND MEDICAL CENTER, TROY, MI - 483S 4/1-30/16
2016-4350	05/24/2016 06/22/2016	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	LESLIE RAMSEY FDA NEWS	AMERX HEALTH CARE CORP, CLEARWATER, FL; ABSOLUTE PHARMACY LLC, LUTZ, FL; 2K INNOVATIONS INC, ST AUGUSTINE, FL, ETC - 483S 4/1-30/16
2016-4351	05/24/2016 06/22/2016	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	LESLIE RAMSEY FDA NEWS	WASHINGTON UNIVERSITY SCHOOL MEDICINE, ST LOUIS, MO; ALAN ZAJARIAS MD, ST LOUIS, MO - 483S 4/1-30/16
2016-4352	05/24/2016 06/22/2016	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	LESLIE RAMSEY FDA NEWS	PURE TEK CORP, SAN FERNANDO, CA; REGENE, LANCASTER, CA; RHINO PEDIATRIC ORTHOPEDIC DESIGNS INC, TEMECULA, CA, ETC - 483S 4/1-30/16
2016-4353	05/24/2016	FDA/OGROP/ORASW-FO/KAN-	Walter Chalkley	ANTIGEN LABORATORIES, LIBERTY, MO - EIR, 483,

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	06/22/2016	DO/KAN-CB/	THOMSON REUTERS (SCIENTIFIC) SAS	RESPONSE 02/11/2013 - 02/15/2013
2016-4354	05/24/2016 06/22/2016	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	3M COMPANY, ST PAUL, MN - EIR, 483, RESPONSE 08/25/2015 - 09/01/2015
2016-4355	05/24/2016 06/22/2016	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	B BRAUN MEDICAL, IRVINE, CA - EIR, 483, RESPONSE 11/01/2013 - 11/13/2013
2016-4356	05/24/2016 06/22/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Walter Chalkley THOMSON REUTERS	SRI KRISHNA PHARMACEUTICALS LTD, INDIA - 483 12/01/2014 - 12/04/2014
2016-4357	05/24/2016 06/22/2016	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	JAMES N MOY, MD, RUSH UNIVERSITY MEDICAL, CHICAGO, IL - EIR, 483, RESPONSE 09/07/2015 - 09/30/2015
2016-4358	05/24/2016 06/22/2016	FDA/OGROP/ORASE-FO/FLADO/FLA-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	JOSHUA M HARE, MD, UNIVERSITY OF MIAMI, MIAMI, FL - EIR, 483, RESPONSE 07/06/2015 - 08/04/2015
2016-4359	05/24/2016 06/22/2016	FDA/OGROP/ORACE-FO/PHIDO/PHI-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	CSL BEHRING, KING OF PRUSSIA, PA - EIR, 483, RESPONSE 09/01/2012 - 01/14/2012
2016-4360	05/24/2016 07/11/2016	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	JERRY S POWELL, MD, UNIVERSITY OF CALIFORNIA, SACRAMENTO, CA - EIR, 483, RESPONSE 08/17/2015 - 08/21/2015
2016-4361	05/24/2016 06/22/2016	FDA/OGROP/ORAPA-FO/SEADO/SEA-CB/	Chalkley Walter THOMSON REUTERS	HANS D OCHS, MD, SEATTLE CHILDREN'S RESEARCH INSTITUTE, SEATTLE, WA - EIR, 483, RESPONSE 07/23/2015 - 08/05/2015
2016-4362	05/24/2016 06/22/2016	FDA/OGROP/ORASE-FO/FLADO/FLA-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	LINCARE HOLDINGS, INC, CLEARWATER, FL - EIR, 483, RESPONSE 06/01/2015 - 06/12/2015
2016-4363	05/24/2016 06/22/2016	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	LESLIE RAMSEY FDA NEWS	BRIAN E DRIVER MD, MINNEAPOLIS, MN - 483S 4/1-30/16
2016-4364	05/24/2016 06/22/2016	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	ST JUDE MEDICAL, CARDIOMEMS, ATLANTA, GA - EIR, 483, RESPONSE 06/08/2015 - 06/26/2015
2016-4365	05/24/2016	FDA/OGROP/ORACE-FO/PHI-	Walter Chalkley	MEDICAL COMPONENTS, INC DBA MEDCOMP,

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	06/22/2016	DO/PHI-CB/	THOMSON REUTERS (SCIENTIFIC) SAS	HARLEYSVILLE, PA - EIR, 483, RESPONSE 01/13/2015 - 02/12/2015;
2016-4366	05/24/2016 07/20/2016	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	MIRAMER LABS, INC, SANTA CLARA, CA - EIR, 483, RESPONSE 07/22/2015 - 08/17/2015
2016-4367	05/24/2016 06/22/2016	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	LESLIE RAMSEY FDA NEWS	BRUKER DALTONICS INC, BILLERICA, MA; PRECISION OPTICS CORPORATION INC, GARDNER, MA; KAT IMPLANTS LLC, PORTSMOUTH, NH, ETC - 483S 4/1-30/16
2016-4368	05/24/2016 06/22/2016	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	OCTAPharma PLASMA, LYNCHBURG, VA - EIR, 483, RESPONSE 09/17/2014 - 09/24/2014
2016-4369	05/24/2016 06/22/2016	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	SUSAN L STRAMER, CHARLOTTE, NC - EIR, 483, RESPONSE 08/06/2013 - 08/08/2013
2016-4370	05/24/2016 06/22/2016	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	LESLIE RAMSEY FDA NEWS	MYCONE DENTAL SUPPLY CO INC (KEYSTONE INDUSTRIES), GIBBSTOWN, NJ - 483S 4/1-30/16
2016-4371	05/24/2016 06/22/2016	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	WYETH BIOPHARMA DIVISION OF WYETHER PHARMACEUTICALS, ANDOVER, MA - EIR, 483, RESPONSE 01/12/2015 - 02/20/2015
2016-4372	05/24/2016 06/22/2016	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	CAREFUSION 213, EL PASO, TX - EIR, 483, RESPONSE 06/17/2015 - 06/25/2015
2016-4373	05/24/2016 06/22/2016	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	LESLIE RAMSEY FDA NEWS	MATRIX MACHINING TECHNOLOGIES INC, MEMPHIS, TN; MRP LLC, NASHVILLE, TN - 483S 4/1-30/16
2016-4374	05/24/2016 06/22/2016	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	LYNN K BOSHKOVA, MD, PORTLAND, OR - EIR, 483, RESPONSE 10/30/2012 - 11/14/2012
2016-4375	05/24/2016 06/22/2016	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	BRISTOL MYERS SQUIBB, EAST SYRACUSE, NY - EIR, 483, RESPONSE 09/23/2014 - 09/25/2014
2016-4376	05/24/2016 06/22/2016	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	DIXIE HEALTH, MARIETTA, GA - EIR, 483, RESPONSE 12/06/2012 - 12/12/2012
2016-4377	05/24/2016 06/22/2016	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	LESLIE RAMSEY FDA NEWS	ANGIODYNAMICS INC (NAVILYST MEDICAL INC), GLENS FALLS, NY; SONOMED INC, NEW HYDE PARK, NY; PINE PHARMACY AND HOME CARE PRODUCTS CENTER INC, WILLIAMSVILLE, NY - 483S 4/1-30/16

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2016-4378	05/24/2016 06/22/2016	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Walter Chakley THOMSON REUTERS (SCIENTIFIC) SAS	MERCK AND CO, DURHAM, NC - EIR, 483, RESPONSE 11/17/2014 - 11/24/2014
2016-4379	05/24/2016 06/22/2016	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Walter Chakley THOMSON REUTERS (SCIENTIFIC) SAS	JOHN W MCGETTIGAN, MD, TUSCON, AZ - EIR, 483, RESPONSE 03/06/2014 - 03/12/2014
2016-4380	05/24/2016 06/22/2016	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Walter Chakley THOMSON REUTERS	LYDIE L HAZAN, MD, LOS ANGELES, CA - EIR, 483, RESPONSE 01/22/2015 - 02/25/2015
2016-4381	05/24/2016 06/22/2016	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	LESLIE RAMSEY FDA NEWS	ASPIRE BARIATRICS INC, KING OF PRUSSIA, PA; DELAVAU LLC, PHILADELPHIA, PA; SPRAY-TEK INC, BETHLEHEM, PA - 483S 4/1-30/16
2016-4382	05/24/2016 06/22/2016	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Walter Chakley THOMSON REUTERS (SCIENTIFIC) SAS	THOMAS B LEEMHUIS, CINCINNATI, OH - EIR, 483, RESPONSE 04/29/2013 - 05/06/2013
2016-4383	05/24/2016 06/22/2016	OC/CVM/OCD/	Barbara Rhoads-Weaver Sustainable Law, PLLC	BUSERELIN - APPROVAL RECS 01/01/1996 - 05/18/2016;
2016-4384	05/24/2016 06/22/2016	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	LESLIE RAMSEY FDA NEWS	DESIREE MEDEIROS MD, KAPIOLANI MEDICAL CENTER FOR WOMEN & CHILDREN, HONOLULU, HI; JOHN G COSTOUROS MD, REDWOOD CITY, CA - 483S 4/1-30/16
2016-4385	05/24/2016 06/22/2016	FDA/OMPT/CDRH/OCE/DID/	Matt Otten EndoPrime	K133338 K141153 K130744
2016-4386	05/24/2016 06/22/2016	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Ramona Dougherty Dougherty, Ramona	FIBROCELL TECHNOLOGIES, INC, EXTON, PA - EIR, 483 10/12/12
2016-4387	05/24/2016 06/22/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John Walsh James Alexander Corporation	SHELL CHEMICALS CORUNNA, ONTARIO, CANDANA - EIR, 483, 482 ETC 05/01/2012 - 05/18/2016;
2016-4388	05/24/2016 06/22/2016	FDA/OMPT/CDRH/OCE/DID/	Helena Lovick Bacterin International, Inc.	K132071
2016-4389	05/24/2016 06/22/2016	FDA/OMPT/CDRH/OCE/DID/	Tim Shea US Laser Worx, Inc	K102781
2016-4390	05/24/2016 06/22/2016	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OFVM/CFSAN/OCD/EOS/	Kelly Carver Texas Star Nut & Food Company, Inc	Recall Event #73507- Recall of Texas Star Pistachios stereotype or species for the positive test from the random sampling program
2016-4391	05/24/2016 06/22/2016	FDA/OMPT/CDRH/OCE/DID/	Doe J	COMPLAINT RECS

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2016-4392	05/24/2016 06/22/2016	FDA/OC/OES/DDM/	Cynthia Cheung UC San Diego	FDA-2014-N-2235
2016-4393	05/24/2016 06/22/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nathan Beaver FOLEY & LARDNER LLP	QUEDEXY ER NDA 205122
2016-4394	05/24/2016 06/22/2016	FDA/OMPT/CTP/OD/	Dan Mullen Steptoe & Johnson LLP	VISITOR LOGS AT CTP 05/18/2015 - 05/18/2016
2016-4395	05/24/2016 06/22/2016	FDA/OMPT/CDRH/OCE/DID/	Rob Toth, Ph.D. Virbio, Inc.	K151593, K150831, K141358, ETC
2016-4396	05/24/2016 06/22/2016	FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/ FDA/OFVM/CFSAN/OCD/EOS/	Kelly Carver Texas Star Nut & Food Company, Inc	Recall Event #72340 Texas Star Macadamia Nuts stereotype or species for the positive test from the random sampling program
2016-4397	05/24/2016 06/22/2016	FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/ FDA/OFVM/CFSAN/OCD/EOS/	Kelly Carver Texas Star Nut & Food Company, Inc	Recall Event #70794 Texas Star Macadamia Nuts stereotype or species for the positive test from the random sampling program
2016-4398	05/24/2016 06/22/2016	FDA/OGROP/ORR/SE-FO/SJN-DO/SJN-CB/	LESLIE RAMSEY FDA NEWS	MEDTRONIC PUERTO RICO OPERATIONS CO, JUNCOS, PR - 483S 4/1-30/16
2016-4399	05/24/2016 06/22/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Amisha Patel Dr. Reddy's Laboratories Inc.	MOEHS IBERICA S.L., BARCELONA, SPAIN - 483 05/01/2016 - 05/19/2016
2016-4400	05/24/2016 06/22/2016	FDA/OGROP/ORR/PA-FO/SEA-DO/SEA-CB/	LESLIE RAMSEY FDA NEWS	VIPER TECHNOLOGIES LLC (THOREX), PORTLAND, OR; EVANGELICAL CHRISTIAN MINISTRY (HEALTH & HERBS), ALBANY, OR; MARTHA I BUITRAGO MC, IDAHO FALLS, ID - 483S 4/1-30/16
2016-4401	05/24/2016 06/22/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kluge: FOIA Request Cook Law Group, LLC: Matthew E. Cook	BATRIUM, VANCOYCIN - REPORTS
2016-4402	05/24/2016 06/22/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ayan Deb Nomura Financial Advisory Securities India Ltd	MOEHS CATALANA SL, SPAIN - 483 02/21/2016 - 02/29/2016
2016-4403	05/24/2016	FDA/OMPT/CDER/ORP/DIDP/	dheeresh pathak	TORRENT PHARMACEUTICALS LIMITED, INDIA - 483

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	06/22/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dheeresh Pathak	05/01/2016 - 05/24/2016
2016-4404	05/24/2016 06/22/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gaurav Tinani Emkay Global	TORRENT PHARMACEUTICAL LTD, INDIA - 483 04/06/2015 - 04/10/2015
2016-4405	05/24/2016 06/22/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gaurav Tinani Emkay Global	TORRENT PHARMACEUTICALS LTD, INDIA - 483 05/01/2016 - 05/23/2016
2016-4406	05/24/2016 06/22/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anubhav Aggarwal CREDIT SUISSE	STRIDES, INDIA - 483 02/15/2016 - 05/25/2016
2016-4407	05/24/2016 06/22/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Paul Danese FDABLE LLC	4037489 4086054 5738053 ETC
2016-4408	05/24/2016 06/22/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rahul Jeewani IIFL Capital	TORRENT PHARMACEUTICALS, INDIA - 483 04/01/2016 - 05/24/2016
2016-4409	05/24/2016 06/22/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lupin Ltd. Aden G	LUPIN, GOA, INDIA - 483 RESPONSE, EIR 01/01/2016 - 05/20/2016
2016-4410	05/24/2016 06/22/2016	FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECS
2016-4411	05/24/2016 06/22/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RANDALL E SMITH SHAHEEN & GORDON PA	IMBRUVIA, IBRITINIB - AERS

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2016-4412	05/24/2016 06/22/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LESLIE RAMSEY FDA NEWS	BOEHRINGER INGELHEIM PHARMA GMBH & CO KG, INGELHEIM AM RHEIN, GERMANY; PATHEON FRANCE SAS, BOURGOIN JAILLIEU, FRANCE; MYLAN LABORATORIES LTD, BANGALORE, INDIA - 483S 4/1-31/16
2016-4413	05/24/2016 06/22/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-7878
2016-4414	05/24/2016 06/22/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-8112
2016-4415	05/24/2016 06/22/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-7413
2016-4416	05/24/2016 06/22/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-7720
2016-4417	05/24/2016 06/22/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-6870
2016-4418	05/24/2016 06/22/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-6572
2016-4419	05/24/2016 06/22/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-6454
2016-4420	05/24/2016 06/22/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-4948
2016-4421	05/24/2016 06/22/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-4650
2016-4422	05/24/2016 06/22/2016	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-7905
2016-4423	05/25/2016 06/23/2016	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	Rachel Johnson FOI Services, Inc.	TISSUETECH, MIAMI, FL; UMTB BIOMEDICAL, MIAMI, FL; REGENERATIVE PROCESSING PLANT, PALM HARBOR, FL - EIR, 483
2016-4424	05/25/2016 06/23/2016	FDA/OGROP/ORR/SE-FO/NOL-DO/NOL-CB/	Rachel Johnson FOI Services, Inc.	BIODLOGICS, CORDOVA, TN, NUTECH MEDICAL, BIRMINGHAM, AL - EIR, 483
2016-4425	05/25/2016 06/23/2016	FDA/OGROP/ORR/CE-FO/NWJ-DO/NWJ-CB/	Rachel Johnson FOI Services, Inc.	HLI CELLULAR THERAPEUTICS, CEDAR KNOLLS, NJ - EIR, 483
2016-4426	05/25/2016 06/23/2016	FDA/OMPT/CDRH/OCE/DID/	Armin Schon ClearCut Medical Ltd.	K160240
2016-4427	05/25/2016	FDA/OC/OES/DFOI/	Matt Sanctis	RECS RE DOLE OUTBREAK INVESTIGATIONS 09/01/2015 -

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	06/23/2016	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Springfield News-Sun	05/19/2016
2016-4428	05/25/2016 06/23/2016	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Rachel Johnson FOI Services, Inc.	WIXI APPTTEC, PHILADELPHIA, PA - EIR, 483
2016-4429	05/25/2016 06/23/2016	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Melissa Malapit Celgene Corporation	BRAD KAHL, UNIVERSITY OF WISCONSIN HOSPITAL AND CLINICS, MADISON, WI - 483 05/01/2015 - 05/19/2016
2016-4430	05/25/2016 06/23/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K151649
2016-4431	05/25/2016 07/28/2016	OC/ORACE/ OC/ORACE/ OC/ORACE/ORM/ OC/ORACE/ORM/ OC/ORACE/ OC/ORACE/	Jessica Bender Patheon Biologics LLC	ENVIRONMENTAL MONITORING SYSTEM OBSERVATIONS 0/01/2014 - 09/30/2015
2016-4432	05/25/2016 06/23/2016	FDA/OGROP/ORACE-SW-FO/KAN-DO/KAN-CB/	Bart van den Brand BIOMERIEUX INC	BIOMERIEUX, ST LOUIS, MO - EIR JULY 2015
2016-4433	05/25/2016 07/11/2016	OC/ORACE/ OC/ORACE/ FDA/OGROP/ORACE/ORO/DIOP/	Juthathip Jongwanich Thammasat University	IMPORT ALERTS 01/01/2002 - 12/12/2010
2016-4434	05/25/2016 06/23/2016	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	RECS RE E-CIGARETTE STATEMENT
2016-4435	05/25/2016 06/23/2016	FDA/OMPT/CDRH/OCE/DID/	Toshio Murata NIDEK INC	K153239
2016-4436	05/25/2016 06/23/2016	FDA/OMPT/CDRH/OCE/DID/	Toshio Murata NIDEK INC	K123542
2016-4437	05/25/2016 06/23/2016	FDA/OGROP/ORACE-SW-FO/KAN-DO/KAN-CB/	Bart van den Brand BIOMERIEUX INC	BIOMERIEUX, ST LOUIS, MO - EIR 06/01/2014 - 06/30/2014
2016-4438	05/25/2016 06/23/2016	FDA/OFVM/CFSAN/OCD/EOS/	Susan Feeser Innovative Chemical Technologies Inc.	FCN 884
2016-4439	05/25/2016 06/23/2016	OC/CVM/OCD/	Doe J	INDIVIDUAL RECS
2016-4440	05/25/2016 06/23/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Irina Koffler Mizuho USA	NDA 007504, 017861, 008317, ETC - LABELING, DEFICIENCIES, ETC

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2016-4441	05/25/2016 06/23/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Amisha Patel Dr. Reddy's Laboratories Inc.	ANDA 204841 SBA
2016-4442	05/25/2016 06/23/2016	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ABBVIE INC, NORTH CHICAGO, IL - 483, EIR 9/12/2014
2016-4443	05/25/2016 06/23/2016	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	EDWARDS LIFESCIENCES, LLC, IRVINE, CA - 483, EIR
2016-4444	05/25/2016 06/23/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rikki Lauren Horner JONES WARD PLC	MIRENA FINAL REVIEW OF POSTMARKETING REPORTS BY MIRIAM CHEBAB
2016-4445	05/25/2016 06/23/2016	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	RECS RE ENSPIRE INFANT FORMULA INREDIENTS
2016-4446	05/25/2016 06/23/2016	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	RECS RE MILK FAT IN INFANT FORMULA
2016-4447	05/25/2016 06/23/2016	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	TRS LABS INC, ATHENS, GA - 483, EIR 1/23/2013
2016-4448	05/25/2016 06/23/2016	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	MICHAEL GALLAGHER CLARK LOVE HUTSON	2016-3288
2016-4449	05/25/2016 06/23/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mehul Govani PLD Acquisition LLC	NDA 020193 SBA
2016-4450	05/25/2016 06/23/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rahul Solanki Edelweiss	CIPLA - 483 01/01/2016 - 05/24/2016
2016-4451	05/25/2016 06/23/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Gaurav Tinani Emkay Global	CIPLA LTD, INDIA - 483 07/27/2015 - 08/07/2015;

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-4452	05/25/2016 06/23/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/ORP/ OC/ORP/ OC/ORP/ORM/ OC/ORP/ORM/	Poornaa Venkatesan Jefferies India Pvt Ltd	SUN PHARMA, LUPIN, CIPLA, DR REDDY'S, CADILA - 483 12/01/2016 - 05/25/2016
2016-4453	05/25/2016 06/23/2016	OC/ORP/ OC/ORP/	STELLON, RONALD	UNIQUE PHARMACEUTICALS LTD, TEMPLE TX - EIR
2016-4454	05/25/2016 06/23/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Aman Asha Aman Asha	SUN PHARMA, HALOL, INDIA - EIR 01/01/2016 - 05/24/2016
2016-4455	05/25/2016 06/23/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Gaurav Tinani Emkay Global	TORRENT PHARMACEUTICALS LTD, INDIA - 483 03/23/2015 - 03/31/2015
2016-4456	05/25/2016 06/23/2016	FDA/OGROP/ORP/SE-FO/ATL-DO/ATL-CB/	BRENNAN WHALEN ROBBINS ARROYO LLP	FRESH FROZEN FOODS LLC, JEFFERSON, GA - CMLNT, 483
2016-4457	05/25/2016 06/23/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	zachary Mietus The Weinberg Group	EVER APPROVED LIST OF DRUGS
2016-4458	05/25/2016 06/23/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shiyin Yee Shiyin yee	NDA 01271
2016-4459	05/25/2016 06/23/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jackson DSouza Jackson DSouza	CIPLA, GOA, INDIA - EIR 04/08/2015 - 05/20/2016

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2016-4460	05/25/2016 07/08/2016	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/ OC/ORO/	JENNIFER F. PERSINGER JOHNSON AYERS ET AL	CURL UP AND DYE INC - CPMLNTS SINCE 2006
2016-4461	05/25/2016 06/23/2016	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink	2016-3986
2016-4462	05/25/2016 06/23/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RAVI DESHPANDE ACINO PRODUCTS LLC	MYLAN PHARM INC - MESALAMINE RECTAL SUPPOSITORIES SBA
2016-4463	05/25/2016 06/23/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORO/ OC/ORO/ OC/ORO/ORM/ OC/ORO/ORM/	JUIL LEE YONSEI UNIVERSITY	ARCHIVED RECALLS, MARKET WITHDRAWALS & SAFETY ALERTS
2016-4464	05/25/2016 06/23/2016	FDA/OGROP/ORO/CE-FO/PHI-DO/PHI-CB/	ANNE E. JOHNSON LYSTN, LLC	SAMPLE RESULTS
2016-4465	05/25/2016 06/23/2016	FDA/OMPT/CDRH/OCE/DID/	RUBY GILL VAVE HEALTHCARE	PHILIPS LUMIFY K152899
2016-4466	05/25/2016 06/23/2016	FDA/OGROP/ORO/PA-FO/SEA-DO/SEA-CB/ FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/	RYAN BURKE VITAL PLAN	SUMMIT LAKE LABS, KETTLE FALLS, WA; SOLARA INC, MIAMI, FL - 483
2016-4467	05/25/2016 06/23/2016	FDA/OMPT/CDRH/OCE/DID/	COLLEEN M. DURRAN FRESENIUS MEDICAL CARE	GAMBRO RENAL PRODUCTS INC - PRISMAFLEX HF1000 & HF1400 K042938
2016-4468	05/25/2016 07/21/2016	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/	SHUI LI ROBBINS KAPLAN LLP	SUNWIN INTERNATIONAL - GLUCOSYLATED STEVIOL GLYCOSIDES GRAS
2016-4469	05/25/2016 06/23/2016	FDA/OMPT/CTP/OD/	RALPH S. TYLER VENABLE LLP	TOBACCO PRODUCT DEEMING REGULATION 5/10/16
2016-4470	05/25/2016	OC/ORO/		INDIVIDUAL RECS

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	06/23/2016	OC/ORO/ FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	Doe J	
2016-4471	05/25/2016 06/23/2016	FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/ OC/CVM/OCD/	RICHARDSON, MICHAEL	CENTINELA FOOD & PET SUPPLIERS - WELCOME HOME DRY DUCK JERKY TREATS 2015 TO PRESENT
2016-4472	05/25/2016 06/23/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BECKY SAVANT REAUD MORGAN & QUINN LLP	105135803, 105876032, 106222452 ETC - AER
2016-4473	05/25/2016 06/23/2016	FDA/OC/OES/DFOI/	Alex Zimmerman Brainspec	K121434
2016-4474	05/25/2016 06/23/2016	FDA/OO/OFBA/OAGS/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAINNE L. CHAMBERS HOGAN LOVELLS US LLP	FDA-SS-1116099, FDA-SOL-1120929, FRA-FD-14-019
2016-4475	05/25/2016 06/23/2016	OC/ORO/ OC/ORO/	BRITTNY HOPWOOD PETA	CENSUS OF ALL DOGS HELD FOR RESEARCH
2016-4476	05/25/2016 06/23/2016	FDA/OFVM/CFSAN/OCD/EOS/	GEORGE W. LEMEL Keller and Heckman LLP	FCN 475
2016-4477	05/25/2016 06/23/2016	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCE/DID/	RANDAL A KAUFFMAN HOUSIERE DURANT HOUSIERE LLP	MEDTRONIC LUMBAR DRAIN - 510K, AER
2016-4478	05/26/2016 08/09/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	TRUDY MESSER MULLER BRAZIL LLP	INDIVIDUAL RECS - VAERS
2016-4479	05/26/2016 06/24/2016	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	Doe J	DASANI WATER CMLNT
2016-4480	05/26/2016 06/24/2016	FDA/OMPT/CDRH/OCE/DID/	VICTORIA FOSS LAKE REGION MEDICAL	ST JUDE MEDICAL - RELFEXION SPIRAL VARIABLE CATHETER K062251
2016-4481	05/26/2016 09/22/2016	FDA/OFVM/CFSAN/OCD/EOS/	Christen Mowad GEISINGER MEDICAL CENTER	PRESERVATICE USAGE DATA IN VCRP 01/01/2013 - 05/20/2016

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2016-4482	05/26/2016 06/24/2016	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Jeanine Gouveia Aerie Pharmaceuticals Inc.	BAUSCH & LOMB, TAMPA, FL - EIR, 483 02/08/2016 - 02/18/2016;
2016-4483	05/26/2016 06/24/2016	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Urgent Field Safety Notice dated January 21 2016 AWH Capital, L.P.	ALGOSTIM LLC, ALGOVITA IMPLANTED PULSE GENERATOR STIMULATOR RECALL Z-1193-2016 73150 - URGENT FIELD SAFETY NOTICE 1/21/16
2016-4484	05/26/2016 06/24/2016	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Algostim LLC - Algovita External Pulse Generator, Trial Stim AWH Capital, L.P.	ALGOSTIM LLC ALGOVITA EXTERNAL PULSE GENERATOR RECALL Z-1194-2016 URGENT FIELD SAFETY NOTICE 1/21/16
2016-4485	05/26/2016 06/24/2016	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Mike Hughlett MINNEAPOLIS STAR TRIBUNE	SUNOPTA, CROOKSTON, MN - 483, 482, EIR 01/20/2011 - 05/20/2016
2016-4486	05/26/2016 06/24/2016	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Rachel Johnson FOI Services, Inc.	OSIRIS THERAPEUTICS, COLUMBIA, MD - INSPECTION RECS
2016-4487	05/26/2016 06/24/2016	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Rachel Johnson FOI Services, Inc.	AMNIOX, ATLANTA, GA - EIR, 483
2016-4488	05/26/2016 06/24/2016	OC/ORAE/ OC/ORAE/ FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/ FDA/OFVM/CFSAN/OCD/EOS/	Molly Gulbrandson Faegre Baker Daniels LLP	CRF FROZEN FOODS MULTISTATE LISTERIOSIS OUTBREAK GENETIC TESTING DATA
2016-4489	05/26/2016 06/24/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Karen Britt RTI Surgical, Inc.	MEDWATCH REPORT
2016-4490	05/26/2016 06/24/2016	FDA/OC/OES/DFOI/ OC/ORAE/ORM/ OC/ORAE/ORM/	George Ball INDIANA UNIVERSITY	FOOD RECALL DATA 01/01/1998 - 01/01/2016
2016-4491	05/26/2016 06/24/2016	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Rachel Johnson FOI Services, Inc.	PINNACLE TRANSPLANT TECHNOLOGIES, PHOENIX, AX; HUMAN REGENERATIVE TECHNOLOGIES, REDONDO BEACH, CA - 483, EIR
2016-4492	05/26/2016 06/24/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K991818
2016-4493	05/26/2016 06/24/2016	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	Rachel Johnson FOI Services, Inc.	ALLOSOURCE, CENTENNIAL, CO - EIR, 483
2016-4494	05/26/2016 06/24/2016	FDA/OMPT/CDRH/OCE/DID/	Hans Mellberg Energous Corp	LIST OF COMPANIES, PRODUCT USING NON-IONIZING RF MICROWAVES OR MILLIMETER WAVES FOR SCANNING OR TREATMENT 01/03/2000 - 05/20/2016
2016-4495	05/26/2016	OC/ORAE/	Michael Mignano	RECALL AND SAFETY ALERTS ARCHIVE IN EXCEL FORMAT

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	06/24/2016	OC/ORO/ OC/ORO/ORM/ OC/ORO/ORM/ OC/ORO/ OC/ORO/	Teamsters Local Union 830	
2016-4496	05/26/2016 06/24/2016	FDA/OGROP/ORO/CE-FO/MIN-DO/MIN-CB/	Algostim LLC - Nuvectra - Algovita Spinal Cord Stimulation S AWH Capital, L.P.	ALGOSTIM LLC, NUVECTRA ALGOVITA SPINAL CORRD STIMULATION SYSTEM RECALL Z-1600-2016 RECALL EVENT ID 73884 RECALL NOTICE
2016-4497	05/26/2016 06/24/2016	FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/	Rachel Johnson FOI Services, Inc.	AMNIOTIC THERAPIES, FARMERS BRANCH, TX; SEED BIOTECH, DALLAS, TX - INSPECTION RECS
2016-4498	05/26/2016 06/24/2016	FDA/OMPT/CDRH/OCE/DID/	Steve Ellman Steve Ellman	RECS RE MEETNIG BETWEEN JEFFREY SHUREN AND TRANSENTERIX 01/01/2016 - 05/20/2016
2016-4499	05/26/2016 06/24/2016	FDA/OMPT/CDRH/OCE/DID/	Ed Chin FOI MEDTRONIC	K153203
2016-4500	05/26/2016 06/24/2016	FDA/OMPT/CDRH/OCE/DID/	Lena Pak Lena Pak	K103346
2016-4501	05/26/2016 06/24/2016	OC/ORO/ORM/ OC/ORO/ORM/	Frank Sanya Frank Sanya	LIST OF FIRMS THAT MANUFACTURE CASSAVA OR YAM FLOUR
2016-4502	05/26/2016 06/24/2016	FDA/OGROP/ORO/PA-FO/SEA-DO/SEA-CB/	Steve Hesler S Hesler Compliance Engineering	CADWELL INDUSTRIES, KENNEWICK, WA - EIR MOST RECENT
2016-4503	05/26/2016 06/24/2016	FDA/OMPT/CDRH/OCE/DID/	Gayle Cooper Ecolab, Inc.	K011265, K013721, K131528
2016-4504	05/26/2016 06/24/2016	FDA/OC/OES/DFOI/	Abhay Shanbhag Abhay Shanbhag	CLARIS INJECTIBLES LTD, INDIA - 483 MAY 2015
2016-4505	05/26/2016 06/24/2016	FDA/OC/OES/DFOI/	John Walsh James Alexander Corporation	BENZOCAINE USP API MANUFACTURERS - 483 ETC 05/01/2013 - 05/18/2016
2016-4506	05/27/2016 06/27/2016	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORO/CE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORO/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	Rachel Johnson FOI Services, Inc.	INFANT FORMULA INSPECTION RECS

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		FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/		
2016-4507	05/27/2016 08/02/2016	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Rachel Johnson FOI Services, Inc.	ABBOT, MEAD JOHNSON, GERBER ETC - EIR
2016-4508	05/27/2016 06/27/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Phillip Hwang UNIVERSITY OF WASHINGTON	VIVOTIF, TYPHIM VI - CLINICAL REVIEW
2016-4509	05/27/2016 06/27/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Phillip Hwang UNIVERSITY OF WASHINGTON	PNEMOVAX 23, TICE BCG, VAQTA ETC CLINICAL REVIEWS
2016-4510	05/27/2016 06/27/2016	OC/ORASORM/ OC/ORASORM/	Kris Christian FDAZILLA	LIST OF INSPECTIONS 04/20/2016 - 05/23/2016
2016-4511	05/27/2016 06/27/2016	FDA/OFVM/CFSAN/OCD/EOS/ OC/CVM/OCD/	Adnan Al-Beitawi Adnan Al-Beitawi	LIST OF FDA APPROVED ARTIFICIAL INGREDIENTS AND COLORS THAT QUALIFY AS GRAS 05/01/2015 - 05/23/2016
2016-4512	05/27/2016 06/27/2016	FDA/OMPT/CDRH/OCE/DID/	Jerzy Wojcik EdgeOne Medical Inc	K123691
2016-4513	05/27/2016 06/27/2016	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Steve Rogers Zoetis Inc.	HMS VETERINARY DEVELOPMENT, TULARE, CA - EIR, 483, WARNING LETTERS ETC 07/01/2013 - 05/23/2016
2016-4514	05/27/2016 06/27/2016	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Steve Rogers Zoetis Inc.	CHERI-HILL KENNEL AND SUPPLY, STANWOOD, MI - EIR, 483, WARNING LETTER ETC 07/01/2013 - 05/23/2016
2016-4515	05/27/2016 06/27/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Steven W. Ramsdell and/or Christopher Lacerne Sunstein Kann Murphy & Timbers LLP	REFACTO (PLA 98-0137)
2016-4516	05/27/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Phillip Hwang	IMOVAX, IPOL, MENOMUNE, ETC - CLINICAL REVIEW

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	06/27/2016		UNIVERSITY OF WASHINGTON	
2016-4517	05/27/2016 06/27/2016	FDA/OFVM/CFSAN/OCD/EOS/	Mark Preston Mark Preston	RECS RE APPROVED NAME FOR ERYNGIUM FOETIDUM L
2016-4518	05/27/2016 06/27/2016	FDA/OMPT/CDRH/OCE/DID/	Jerzy Wojcik EdgeOne Medical Inc	K122513
2016-4519	05/27/2016 06/27/2016	FDA/OMPT/CDRH/OCE/DID/	Jery Wojcik EdgeOne Medical Inc	K051188
2016-4520	05/27/2016 06/27/2016	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Steve Rogers Zoetis Inc.	VETERINARY PATHOLOGY SERVICES, MASON, OH - EIR, 483, WARNING LETTER ETC 07/01/2013 - 05/23/2016
2016-4521	05/27/2016 06/27/2016	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Steve Rogers Zoetis Inc.	COVANCE LABORATORIES, MADISON, WI - EIR, 483, WARNING LETTER ETC 07/01/2013 - 05/23/2016
2016-4522	05/27/2016 06/27/2016	FDA/OC/OES/DFOI/	Bobby Schochet OLSSON FRANK WEEDA TERMAN MATZ PC	FOIA 04-012910; 04012911; 04011350
2016-4523	05/27/2016 06/27/2016	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Steve Rogers Zoetis Inc.	BERTEK, INC, GREENBRIAR, AR- EIR, 483, WARNING LETTER ETC 07/01/2013 - 05/23/2016
2016-4524	05/27/2016 06/27/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Robyn Ross Robyn Ross	SOY PEPTONE IN VACCINES
2016-4525	05/27/2016 06/27/2016	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Steve Rogers Zoetis Inc.	YOUNG VETERINARY SERVICES, TURLOCK, CA - EIR, 483, WARNING LETTER ETC 07/01/2013 - 05/23/2016
2016-4526	05/31/2016 06/28/2016	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 4/25-29/16
2016-4527	05/31/2016 06/28/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 4/25-29/16
2016-4528	05/31/2016 06/28/2016	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOI REQUESTS 4/25-29/16
2016-4529	05/31/2016 06/28/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 4/25-29/16
2016-4530	05/31/2016 06/28/2016	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 5/2-6/16
2016-4531	05/31/2016	FDA/OC/OES/DFOI/	DEBI COHEN	CLOSED FOI REQUESTS 5/2-6/16

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	06/28/2016		WOLTERS KLUWER LAW & BUSINESS	
2016-4532	05/31/2016 06/28/2016	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOI REQUESTS 5/2-6/16
2016-4533	05/31/2016 06/28/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 5/2-6/16
2016-4534	05/31/2016 06/28/2016	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 5/9-13/16
2016-4535	05/31/2016 06/28/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 5/9-13/16
2016-4536	05/31/2016 06/28/2016	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOI REQUESTS 5/9-13/16
2016-4537	05/31/2016 06/28/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 5/9-13/16
2016-4538	05/31/2016 06/28/2016	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 4/25-29/16
2016-4539	05/31/2016 06/28/2016	FDA/OC/OES/DFOI/	LELSIE RAMSEY FDA NEWS	FOI DAILY LOG 4/25-29/16
2016-4540	05/31/2016 06/28/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 4/25-29/16
2016-4541	05/31/2016 06/28/2016	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD Center for Regulator Services, Inc	FOI DAILY LOG 4/25-29/16
2016-4542	05/31/2016 06/28/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 4/25-29/16
2016-4543	05/31/2016 06/28/2016	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 4/25-29/16
2016-4544	05/31/2016 06/28/2016	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 4/25-29/16
2016-4545	05/31/2016 06/28/2016	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 5/2-6/16
2016-4546	05/31/2016	FDA/OC/OES/DFOI/	LESLIE RAMSEY	FOI DAILY LOG 5/2-6/16

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	06/28/2016		FDA NEWS	
2016-4547	05/31/2016 06/28/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 5/2-6/16
2016-4548	05/31/2016 06/28/2016	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD Center for Regulator Services, Inc	FOI DAILY LOG 5/2-6/16
2016-4549	05/31/2016 06/28/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 5/2-6/16
2016-4550	05/31/2016 06/28/2016	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 5/2-6/16
2016-4551	05/31/2016 06/28/2016	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 5/2-6/16
2016-4552	05/31/2016 06/28/2016	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 5/2-6/16
2016-4553	05/31/2016 06/28/2016	FDA/OC/OES/DFOI/	LELSIE RAMSEY FDA NEWS	FOI DAILY LOG 5/9-13/16
2016-4554	05/31/2016 06/28/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 5/9-13/16
2016-4555	05/31/2016 06/28/2016	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD Center for Regulator Services, Inc	FOI DAILY LOG 5/9-13/16
2016-4556	05/31/2016 06/28/2016	FDA/OC/OES/DFOI/	Joseph M Ascenzi JMA Consulting	K081724
2016-4557	05/31/2016 06/28/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 5/9-13/16
2016-4558	05/31/2016 06/28/2016	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 5/9-13/16
2016-4559	05/31/2016 06/28/2016	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 5/9-13/16
2016-4560	06/01/2016 06/29/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAWN M. CHITTY TORRENT PHARMA INC	CLOBETASOL; DESOXIMETASONE; DESONIDE, ETC

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-4561	06/01/2016 06/29/2016	FDA/OMPT/CDRH/OCE/DID/	KIRSTEN VALLEY ROUTE 92 MEDICAL	K150802
2016-4562	06/01/2016 06/29/2016	OC/ORO/ OC/ORO/	JENNIFER F. PERSINGER JOHNSON AYERS ET AL	CURL UP & DYE INC - CMLPTS
2016-4563	06/01/2016 06/29/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	HAYES, SPENCER	GADOLINIUM - AER SINCE 2011
2016-4564	06/01/2016 06/29/2016	OC/ORO/ORM/ OC/ORO/ORM/	KIM C. CAPONE PORZIO LIFE SCIENCES	ALL PDMA INSPECTIONS 2012 TO PRESENT
2016-4565	06/01/2016 06/29/2016	FDA/OMPT/CDRH/OCE/DID/	DANIEL DAVY STERIS CORP	ALBERT BROWNE LTD, LEICESTER, UK - EIR
2016-4566	06/01/2016 06/29/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LIOA ZILBERSON N2B LTD	AVINIR PHARMS - ONZETRA XSAIL (SUMATRIPTAN SUCCINATE) NDA 206-099 RVW
2016-4567	06/01/2016 06/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-4310
2016-4568	06/01/2016 06/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-4633
2016-4569	06/01/2016 06/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-4188
2016-4570	06/01/2016 06/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-2885
2016-4571	06/01/2016 06/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2014-8913
2016-4572	06/01/2016 06/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-2881
2016-4573	06/01/2016 06/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2014-8322
2016-4574	06/01/2016 06/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-4980

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2016-4575	06/01/2016 06/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-4987
2016-4576	06/01/2016 06/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-4634
2016-4577	06/01/2016 06/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-4147
2016-4578	06/01/2016 06/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-4631
2016-4579	06/01/2016 06/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-4121
2016-4580	06/01/2016 06/29/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	2015-4800
2016-4581	06/01/2016 06/29/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LESLIE RAMSEY FDA NEWS	RESP TO ALL GENERIC DRUG COMPANIES FROM 1/1 TO 4/30/16
2016-4582	06/01/2016 06/29/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PAMELA SHEPPARD TARO PHARMACEUTICALS USA INC	ALLERGAN INC - ACZONE N207154 SBA, MEDICAL RVW, LBLG
2016-4583	06/01/2016 06/29/2016	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FILL FROMS
2016-4584	06/01/2016 06/29/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PAMELA SHEPPARD TARO PHARMACEUTICALS USA INC	EUROHLTH; LUITPOLD; SANDOZ - FENOLDOPAM MESYLATE SBA, MEDICAL RVW, LBLG
2016-4585	06/01/2016 06/29/2016	FDA/OMPT/CDRH/OCE/DID/	LAWRENCE F. TRACEY TRACEY & FOX	KARL STORZ ENDOSCOPY AMERICA INC - K946147/A; K010346; K011841 ETC
2016-4586	06/01/2016 06/29/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BECKY SAVANT REAUD MORGAN & QUINN LLP	8956016, 10286313, 10289946 ETC - AER

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2016-4587	06/02/2016 06/30/2016	FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Anthony Farmer Anthony Farmer	EMAILS TO AND FROM EMPLOYEES OF DR STANISLAW BURZYNSKI CLINICAL TRIALS 01/01/2016 - 05/19/2016
2016-4588	06/02/2016 06/30/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Melissa V. Malapit Celgene Corporation	MELETIOS DIMOPOULOS, DEPARTMENT OF CLINICAL THERAPEUTICS/UNIVERSITY OF ATHENS 483 10/13/2014 - 05/20/2016
2016-4589	06/02/2016 06/30/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Amy Ledbetter Davis, Snyder, Williford & Lehn, P.A.	PROMETHAZINE - AERS
2016-4590	06/02/2016 06/30/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	J. Karl Gross Leydig, Voit & Mayer, Ltd.	NDA 20-733 SBA
2016-4591	06/02/2016 06/30/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Matthew Allen Matthew Allen	CONCORDIA HEALTHCARE, METHOD PHARMACEUTICALS, WINDER LABS ETC - COMMUNICATIONS WITH FDA RE DONNATAL ETC 01/01/2010 - 05/18/2016
2016-4592	06/02/2016 06/30/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Russ Kick Russ Kick	FDA STUDIES FOR DEA RE MARIJUANA
2016-4593	06/02/2016 06/30/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MEDICAKOREA Co.,Ltd MEDICAKOREA Co.,Ltd.	CALDEROL CAPSULE USAGE, INDICATIONS
2016-4594	06/02/2016 06/30/2016	FDA/OMPT/CDRH/OCE/DID/	Monica King, Assoc. Director, Regulatory Affairs Halyard Health	MAXTER CATHETERS, FRANCE - EIR, MEETING MINUTES
2016-4595	06/02/2016	FDA/OGROP/ORR/PA-FO/LOS-	Lauren Welling	PATHWAY GENOMICS, INC CANCERINTERCEPT DETECT -

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	06/30/2016	DO/LOS-CB/ FDA/OMPT/CDRH/OCE/DID/	Sanders Phillips Grossman, LLC	AERS, APPLICATIONS, CORR ETC
2016-4596	06/02/2016 06/30/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Zachary Mietus The Weinberg Group	EPHEDRINE, EPHEDRINE SULFATE - NDA NUMBER, APPROVAL DATE 06/30/1906 - 05/23/2016
2016-4597	06/02/2016 06/30/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anubhav agarwal CREDIT SUISSE	TORRENT PHARMA, INDIA - 483 05/09/2016 - 05/23/2016
2016-4598	06/02/2016 06/30/2016	FDA/OMPT/CDRH/OCE/DID/	Alexandria S. Cash Bird Law Group, P.C.	INDIVIDUAL RECS
2016-4599	06/02/2016 07/01/2016	FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OPPLA/OL/	Sheila Kaplan Boston Globe Media	STANISLAW BURZYNSKI - CORR BETWEEN FDA AND NATIONAL CANCER INSTITUT, TEXAS MEDICAL BOARD; CORR BETWEEN US LAWMAKER AND FDA RE BURZYNSKI, CLINIC 01/01/2011 - 05/22/2016
2016-4600	06/02/2016 06/30/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John Walsh James Alexander Corporation	DISHMAN PHARMACEUTICALS AND CHEMICALS LIMITED, INDIA - EIR, 483, ETC 05/01/2012 - 05/23/2016
2016-4601	06/02/2016 06/30/2016	OC/ORR/OCI/ OC/ORR/OCI/	Doe J	INDIVIDUAL RECS
2016-4602	06/02/2016 06/30/2016	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	LeAnn Seidl-Kollmer Nature's Way Product	XYMOGEN DIETARY SUPPLEMENT, ORLANDO, FL - EIR, 483 05/09/2006 - 05/24/2016
2016-4603	06/02/2016 06/30/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John Walsh James Alexander Corporation	NORBROOK SRO, CZECH REPUBLIC - EIR, 483, 482 05/01/2012 - 05/24/2016
2016-4604	06/02/2016 06/30/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John Walsh James Alexander Corporation	YICHENG CHEMICAL CORPORATION, CHINA - EIR, 483, 482 ETC 05/01/2012 - 05/24/2016

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2016-4605	06/02/2016 06/30/2016	FDA/OMPT/CDRH/OCE/DID/	Alex Zimmerman Brainspec	K113145
2016-4606	06/02/2016 06/30/2016	FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/	Sue Peixotto UNIVERSITY OF TEXAS AT AUSTIN	SETON IRB, AUSTIN, TX - 483 01/01/2007 - 05/24/2016
2016-4607	06/02/2016 06/30/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Martina Steiper PharmaLex GmbH	ARC183 IND AERS
2016-4608	06/02/2016 06/30/2016	FDA/OMPT/CDRH/OCE/DID/	Robert Hill Robert Hill	K121881
2016-4609	06/02/2016 06/30/2016	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	John Walsh James Alexander Corporation	HOSPIRA, ROCKY MOUNT, NC - EIR, 483, 482 05/01/2012 - 05/24/2016
2016-4610	06/02/2016 06/30/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	danzia xie The University of Chicago	SUMMARY OF AERS DATA
2016-4611	06/02/2016 06/30/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Charles Naggar Alston and Bird LLP	NDA 201280 NDA 201281 NDA 021462 SBA
2016-4612	06/02/2016 06/30/2016	FDA/OMPT/CDRH/OCE/DID/	Daniel Hoefer EndoChoice, Inc.	K150618
2016-4613	06/02/2016 06/30/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Charles Snow Hyman, Phelps & McNamara P.C.	NDA 20076 SBA
2016-4614	06/02/2016 06/30/2016	OC/ORR/ OC/ORR/ FDA/OGROP/ORR/CE-FO/PHI-DO/PHI-CB/	Fred DeMaio Fred DeMaio	COMPLAINT CLOSE OUT
2016-4615	06/02/2016	FDA/OMPT/CDRH/OCE/DID/	Alex Zimmerman	K991568

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	06/30/2016		Brainspec	
2016-4616	06/02/2016 06/30/2016	FDA/OMPT/CDRH/OCE/DID/	Maria Merchant Somnarus Inc	ADVANCED BRAIN MONITORING INC - LABELING RECS FOR ARES UNICORDER
2016-4617	06/02/2016 06/30/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tam Nguyen NATIONAL INSTITUTES OF HEALTH	NDA 50685 NDA 50686
2016-4618	06/02/2016 06/30/2016	FDA/OMPT/CDRH/OCE/DID/	Lori Burns GLOBUS MEDICAL	K974186
2016-4619	06/02/2016 06/30/2016	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORA/ OC/ORA/ FDA/OGROP/ORR/SW- FO/SWID/SWID-CB/	Christine M. Humphrey, Esq. C.Humphrey & Associates, P.A.	ENTRY KM6-0145567-8 RECS, IMPORT SAMPLE 955114
2016-4620	06/02/2016 06/30/2016	FDA/OMPT/CDRH/OCE/DID/	Lori Burns GLOBUS MEDICAL	K113770
2016-4621	06/02/2016 06/30/2016	FDA/OGROP/ORR/SW-FO/DAL- DO/DAL-CB/	Jane Bentley, Alcon Laboratories, Inc. BENTLEY, A	ALCON RESEARCH LTD, HOUSTON, TX - EIR 01/12/2016 - 01/21/2016
2016-4622	06/02/2016 06/30/2016	FDA/OMPT/OSMP/OOPD/	CYNTHIA BERRINGER Kadmon Pharmaceuticals, LLC	AFATINIB, GEFITINIB, OSIMERTINIB ORPHAN DESIGNATION RECS
2016-4623	06/02/2016 06/30/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CARLOS RIVERA-ADROVET Cempra Pharmaceuticals, Inc.	WOCKHARDT LIMITED, INDIA - 483 11/01/2015 - 12/31/2016
2016-4624	06/02/2016 06/30/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Hajra Mazhar Hajra Mazhar (University of Ottawa)	4040801; 5696721; 6104787; ETC
2016-4625	06/02/2016 06/30/2016	FDA/OMPT/CDRH/OCE/DID/	Brian Schmidt Ecolab	K023283 K023282 K021288 ETC
2016-4626	06/02/2016 06/30/2016	FDA/OC/OES/DDM/	John Birrenbach The Institute for Cannabis	FDA-2011-P-0671
2016-4627	06/02/2016	OC/ORR/	Vital Choice Seafoods	916083 916084 LAB RESULTS

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	06/30/2016	OC/ORO/ FDA/OGROP/ORO/PA-FO/SEA-DO/SEA-CB/	vital Choice Seafoods	
2016-4628	06/02/2016 06/30/2016	FDA/OMPT/CDRH/OCE/DID/	Lori Burns GLOBUS MEDICAL	K012634
2016-4629	06/02/2016 06/30/2016	FDA/OMPT/CDRH/OCE/DID/	Lori Burns GLOBUS MEDICAL	K012648
2016-4630	06/02/2016 06/30/2016	FDA/OMPT/CDRH/OCE/DID/	Lori Burns GLOBUS MEDICAL	K984498
2016-4631	06/02/2016 06/30/2016	FDA/OMPT/CDRH/OCE/DID/	Lori Burns GLOBUS MEDICAL	K011034
2016-4632	06/02/2016 06/30/2016	FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/	Jane Bentley / Alcon Laboratories, Inc. Bentley, Jane	ALCON RESEARCH, FORT WORTH, TX - EIR 01/25/2016 - 01/28/2016
2016-4633	06/02/2016 06/30/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Daniel Wolle PIPER JAFFRAY & CO	KYNAMRO - AERS, LABELING REVISION
2016-4634	06/02/2016 06/30/2016	OC/ORO/ OC/ORO/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORO/CE-FO/MIN-DO/MIN-CB/	Robert Scott Robert Scott	FINAL REPORT OF INVESTIGATION CONCERNING FDA INVESTIGATION OF MULTISTATE ECOLI 0157 INFECTIONS LINKED TO ALFALFA SPROUTS FROM ACK AND THE GREEN SPROUTS
2016-4635	06/02/2016 06/30/2016	FDA/OMPT/CDRH/OCE/DID/	LORI A CARR LORI A CARR INC	HOWMEDICA OSTEONICS CORP - TRIATHLON PRESS-FIT TOTAL KNEE SYS K051380
2016-4636	06/02/2016 06/30/2016	FDA/OMPT/CDRH/OCE/DID/	LORI A CARR LORI A CARR INC	HOWMEDICA OSTEONICS CORP - DURACON TOTAL KNEE SYS WITH PERI-APATIE COATING K032418
2016-4637	06/02/2016 06/30/2016	FDA/OMPT/CDRH/OCE/DID/	LORI A CARR LORI A CARR INC	HOWMEDICA OSTEONICS CORP - TRIATHLON POSTERIORLY STABLIZED FEMORAL COMPONENT K042993
2016-4638	06/02/2016 06/30/2016	FDA/OMPT/CDRH/OCE/DID/	LORI A CARR LORI A CARR INC	HOWMEDICA OSTEONICS CORP - TRIATHLON CRUCIATE RETAINING TOTAL KNEE K040267
2016-4639	06/02/2016 06/30/2016	FDA/OMPT/CDRH/OCE/DID/	LORI A CARR LORI A CARR INC	HOWMEDICA OSTEONICS CORP - DURACON TOTAL KNEE SYS WITH PERI-APATITE COATING K032418
2016-4640	06/02/2016	FDA/OMPT/CDRH/OCE/DID/	LORI A CARR	HOWMEDICA OSTEONICS CORP - DURACON TOTAL KNEW

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	06/30/2016		LORI A CARR INC	SYS K032163
2016-4641	06/02/2016 06/30/2016	FDA/OMPT/CDRH/OCE/DID/	LORI A CARR LORI A CARR INC	BIOARCHITECTS USA LLC - PATIENT SPECIFIC CRANIAL/CRANIOFACIAL PLATE K151692
2016-4642	06/02/2016 06/30/2016	FDA/OMPT/CDRH/OCE/DID/	LORI A CARR LORI A CARR INC	SULZER ORTHOPEDICS INC - INTER-OP METASUL HOODED AND PROTRUSIO ACETABULAR INSERTS K001536
2016-4643	06/02/2016 06/30/2016	FDA/OMPT/CDRH/OCE/DID/	LORI A CARR LORI A CARR INC	SULZER MEDICA - APR METASUL ACETABULAR INSERT K993569
2016-4644	06/02/2016 06/30/2016	FDA/OMPT/CDRH/OCE/DID/	LORI A CARR LORI A CARR INC	WRIGHT MEDICAL TECHNOLOGY INC - PROFEMUR Z REVISION HIP STEM K121221
2016-4645	06/02/2016 06/30/2016	FDA/OMPT/CDRH/OCE/DID/	LORI A CARR LORI A CARR INC	ENCORE MEDICAL LP - METAL/METAL HIP SYS K040354
2016-4646	06/02/2016 06/30/2016	FDA/OMPT/CDRH/OCE/DID/	LORI A CARR LORI A CARR INC	STRYKER ORTHOPAEDICS - TRIATHLON TOTAL KNEE SYS K053514
2016-4647	06/02/2016 06/30/2016	FDA/OMPT/CDRH/OCE/DID/	LORI A CARR LORI A CARR INC	HOWMEDICA OSTEONICS CORP - TRIATHLON TS KNEE SYS K070095
2016-4648	06/02/2016 06/30/2016	FDA/OMPT/CDRH/OCE/DID/	LORI A CARR LORI A CARR INC	OXFORD PERFORMANCE MATERIALS - OSTEOFAB PATIENT SPECIFIC FACIAL DVC K133809
2016-4649	06/02/2016 06/30/2016	FDA/OC/OES/DFOI/	Lauren Greer McGuireWoods Consulting	RECS RE CDC NOTIFICATION ON SURGICAL SITE INFECTIONS
2016-4650	06/02/2016 06/30/2016	FDA/OMPT/CDRH/OCE/DID/	LORI A CARR LORI A CARR INC	WRIGHT MEDICAL TECHNOLOGY INC - PROFEMUR TL HIP STEM K060358
2016-4651	06/02/2016 06/30/2016	FDA/OO/OHR/	Fernando McMillan Fernando McMillan	RECS RE SELECTION OF POSITION IN WAKEFILED, MA RESIDENT AGENT IN CHARGE 03/01/2016 - 04/01/2016
2016-4652	06/02/2016 06/30/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sam Mort Sam Mort	SIMEC AG, SWITZERLAND - 483 01/01/2005 - 05/25/2016
2016-4653	06/02/2016 06/30/2016	FDA/OMPT/CDRH/OCE/DID/	LORI A CARR LORI A CARR INC	ZIMMER INC - NEXEL TOTAL ELBOW K123862
2016-4654	06/02/2016 06/30/2016	FDA/OMPT/CDRH/OCE/DID/	Louis-Paul Marin LOK North America Inc.	K130040
2016-4655	06/02/2016 06/30/2016	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Gary Stoller CONNECTICUT HEALTH	TUN ASIAN FOODS AND EDO SUSHI EXPRESS - INSPECTION REPORTS, CORR 01/03/1997 - 05/26/2016

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			INVESTIGATIVE TEAM	
2016-4656	06/02/2016 06/30/2016	FDA/OMPT/CDRH/OCE/DID/	LORI A CARR LORI A CARR INC	ZIMMER INC - COONRAD/MORREY TOTAL ELBOW MODEL 8105 K053189
2016-4657	06/02/2016 06/30/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kristen Kristen Carrier	SGLT2 INHIBITORS - AERS
2016-4658	06/02/2016 06/30/2016	FDA/OMPT/CDRH/OCE/DID/	LORI A CARR LORI A CARR INC	ZIMMER INC - COONRAD/MORREY ELBOW CEMENT RESTRICTOR K040389
2016-4659	06/02/2016 06/30/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ted Keller EverPoint Asset Management	KYNAMRO CASE 10072363
2016-4660	06/02/2016 06/30/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John Walsh James Alexander Corporation	JINZHOU JIUTAI PHARAMCEUTICAL CO LTD, CHINA - EIR, 483, 482 ETC 05/01/2012 - 05/26/2016
2016-4661	06/02/2016 06/30/2016	FDA/OMPT/CDRH/OCE/DID/	LORI A CARR LORI A CARR INC	ZIMMER INC - COONRAD/MORREY TOTAL ELBOW MODEL 32-8105 K001989
2016-4662	06/02/2016 06/30/2016	FDA/OMPT/CDRH/OCE/DID/	LORI A CARR LORI A CARR INC	ZIMMER INC - COONRAD/MORREY TOTAL ELBOW NEW HINGE PIN K973357
2016-4663	06/02/2016 06/30/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John Walsh James Alexander Corporation	RAMDEV CHEMICALS PVT LTD, INDIA - EIR, 483, 482 ETC 05/01/2012 - 05/26/2016
2016-4664	06/02/2016 06/30/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kiran Kumar Gande Leading Pharma, LLC	NDA 019906 SBA
2016-4665	06/02/2016 06/30/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Barry Pressman PureTek Corporation	KENALOG - MANUFACTURER INFORMATION

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2016-4666	06/02/2016 06/30/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Phillip Hwang UNIVERSITY OF WASHINGTON	COMBAX, BIOTHRAX - CLINICAL REVIEW
2016-4667	06/02/2016 06/30/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	pascal besman Pascal Besman	OLAPARIB
2016-4668	06/02/2016 06/30/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	pascal besman Pascal Besman	DARATUMUMAB AERS
2016-4669	06/02/2016 06/30/2016	FDA/OMPT/CDRH/OCE/DID/	Elliott Brown, MD YALE SCHOOL OF MEDICINE	K150563
2016-4670	06/02/2016 06/30/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Christina Jewett Reveal + The Center for Investigative Reporting	LUPRON REPORTS 6972268, 6990305, 8521819, ETC
2016-4671	06/02/2016 06/30/2016	FDA/OMPT/CDRH/OCE/DID/	Patrick Ryan Patrick Ryan	K910007
2016-4672	06/02/2016 06/30/2016	FDA/OMPT/CDRH/OCE/DID/	LORI A CARR LORI A CARR INC	ZIMMER INC - COONRAD III TOTAL ELBOW K883665
2016-4673	06/02/2016 06/30/2016	FDA/OGROP/ORA/CE-FO/CIN- DO/CIN-CB/ FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/	Jordan Aubey KOAM-TV	JT NATURALS, JOPLIN, MO - 483 02/09/2016 - 02/26/2016
2016-4674	06/02/2016 06/30/2016	FDA/OMPT/CDRH/OCE/DID/	Patricia Campbell Masimo Corporation	K000126
2016-4675	06/02/2016 06/30/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Phillip Hwang UNIVERSITY OF WASHINGTON	AGRIFLU, BCG VACCINE, DECAVAC, ETC - CLINICAL REVIEW
2016-4676	06/02/2016 06/30/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Phillip Hwang UNIVERSITY OF WASHINGTON	CERVARIX - CLINICAL REVIEW
2016-4677	06/02/2016 06/30/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Anita Lammers SCL St. Mary's Hospital	MEDWATCH REPORT

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		FDA/OMPT/CDRH/OCE/DID/		
2016-4678	06/02/2016 06/30/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	Pooja Jain Elsevier - Attn to: Pooja Jain	SECTION 915 POST MARKETING REVIEWS 01/01/2007 - 05/26/2016
2016-4679	06/02/2016 06/30/2016	FDA/OMPT/CDRH/OCE/DID/	LORI A CARR LORI A CARR INC	PLUS ORTHOPEDICS AG - POLARCUP DUAL MOBILITY SYS K070278
2016-4680	06/02/2016 06/30/2016	FDA/OMPT/CDRH/OCE/DID/	Crystal Easterby Ultralite Enterprises Inc	K761179
2016-4681	06/02/2016 06/30/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tayjes Shah The Miller Firm LLC	ACETAMINOPHEN - RECS RE REVISED DRUG LABELING 07/01/2013 - 10/01/2014
2016-4682	06/02/2016 06/30/2016	FDA/OMPT/CDRH/OCE/DID/	LORI A CARR LORI A CARR INC	HOWMEDICA OSTEONICS CORP - ADM AND ADM/MDM DURATION INSERTS, ADM AND ADM/MDM X3 INSERTS K112556
2016-4683	06/02/2016 06/30/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Benjamin Adam Dennis MERCER UNIVERSITY	Glargine U-300 Lispro U-200 Degludec U-200 Humulin R U-500 AERS
2016-4684	06/03/2016 07/01/2016	FDA/OGROP/ORAC/CE-FO/MIN-DO/MIN-CB/	Brett A. Thompson Coats and Bennett	GINSENG - WARNING LETTERS, NOTICES, COMMUNICATIONS RE WISCONSIN ENTITIES, INDIVIDUALS RE FALSE ADVERTISING ETC 01/01/2005 - 05/27/2016
2016-4685	06/03/2016 07/01/2016	FDA/OFVM/CFSAN/OCD/EOS/	Michael Liskow Wolf Haldenstein Adler Freeman & Herz LLP	RECS RE NESTLE SPRING WATER
2016-4686	06/03/2016 07/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rahul Jeewani IIFL Capital	LUPIN LIMITED, INDIA - INSPECTION CLASSIFICATION STATUS 01/01/2016 - 05/27/2016
2016-4687	06/03/2016 07/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAWN M. CHITTY TORRENT PHARMA INC	FLUOCINONIDE NDA 191-17 - SBA

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2016-4688	06/03/2016 07/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAWN M. CHITTY TORRENT PHARMA INC	PERIGO - NYSTATIN ANDA 62-472 SBA
2016-4689	06/03/2016 07/01/2016	FDA/OMPT/CDRH/OCE/DID/	aaron kalfa NFW Marketing	K040396
2016-4690	06/03/2016 07/01/2016	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Abby Almonte OASIS MEDICAL INC	DOW CORNING CORPORATION, HEMLOCK, MI - EIR, COVER LETTER MORE RECENT
2016-4691	06/03/2016 07/01/2016	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	VICTORIA K. HUGHES MILLSTONE MEDICAL OUTSOURCING	MILLSTONE OUTSOURCING INC LLC, OLIVE BRANCH, MS - EIR 6/17/14, 9/21/15
2016-4692	06/03/2016 07/01/2016	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	Thomas Smith Morgan Stanley	ZS PHARMA, TX, CA - 483 01/01/2014 - 05/27/2016
2016-4693	06/03/2016 07/01/2016	FDA/OMPT/CTP/OD/	William McGrath Potomac Law Group, PLLC	Finding of No Significant Impact EX0000026
2016-4694	06/03/2016 07/01/2016	FDA/OFVM/CFSAN/OCD/EOS/	ELYSE KINGERY DEGGE GROUP LTD	169717, 169766, 169767 - MEDWATCH
2016-4695	06/03/2016 07/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Martina Steiper PharmaLex GmbH	ARC183 STUDY RECS
2016-4696	06/03/2016 07/01/2016	FDA/OMPT/CDRH/OCE/DID/	WEN, CHARLIE	CORR BETWEEN FDA & ECLEAR INT'L LTD - ECLIGNER K143499
2016-4697	06/03/2016 07/01/2016	FDA/OMPT/CDRH/OCE/DID/	WEN, CHARLIE	CORR BETWEEN FDA & MARTZ INC - DENTTI SYS K151965
2016-4698	06/03/2016 07/01/2016	FDA/OMPT/CDRH/OCE/DID/	WEN, CHARLIE	CORR BETWEEN FDA & QSERVE AMERICA INC - CLEARPATH ALIGNER K123514
2016-4699	06/03/2016 07/01/2016	FDA/OC/OES/DFOI/	KELEHER, MADELINE	DIETARY SUPPLEMENT PROGRAM - BUDGET, STAFF
2016-4700	06/03/2016	FDA/OMPT/CDRH/OCE/DID/	LORI COHEN	KOTEX SECURITY TAMPONS - U K141294

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	07/01/2016		GREENBERG TRAUIG LLP	
2016-4701	06/03/2016 07/01/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Aakash Agarwal Wize Market Analytics	PIRAMAL ENTERPRISES LIMITED, INDIA - 483 03/04/2016 - 05/12/2016
2016-4702	06/03/2016 07/01/2016	FDA/OMPT/CDRH/OCE/DID/	LOIR COHEN GREENBERG TRAUIG LLP	KOTEX STICK TAMPONS K872018
2016-4703	06/03/2016 07/01/2016	FDA/OMPT/CDRH/OCE/DID/	LORI COHEN GREENBERG TRAUIG LLP	KOTEX - SECURITY TUBE TAMPON K885194
2016-4704	06/03/2016 07/01/2016	FDA/OMPT/CDRH/OCE/DID/	LORI COHEN GREENBERG TRAUIG LLP	KOTEX NATURAL CURVED TAMPON K 896512
2016-4705	06/03/2016 07/01/2016	FDA/OMPT/CDRH/OCE/DID/	LORI COHEN GREENBERG TRAUIG LLP	KOTEX CLICK TAMPONS K091749
2016-4706	06/03/2016 07/01/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	Garry M Wiltshire The Dow Chemical Company	FCN 1597
2016-4707	06/03/2016 07/01/2016	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	Joe McCann Slingshot Insights	ZS PHARMA - WARNING LETTERS, 483 01/01/2014 - 05/27/2016
2016-4708	06/03/2016 07/01/2016	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	Molly Gulbrandson Faegre Baker Daniels LLP	CRF FROZEN FOODS MULTISTATE LISTERIOSIS OUTBREAK PASCO, WA INSPECTION RECS 01/01/2010 - 05/27/2016
2016-4709	06/03/2016 07/01/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Peter R. Breggin, MD Center for the Study of Psychiatry	SERTRALINE - AERS
2016-4710	06/03/2016 07/01/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	11789470 VICTRELIS

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2016-4711	06/03/2016 07/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	11789395 RAGWITEK
2016-4712	06/03/2016 07/01/2016	FDA/OMPT/CDRH/OCE/DID/	Kevin Drizen GlycoBioSciences Inc.	CPT1500792
2016-4713	06/03/2016 07/01/2016	FDA/OMPT/CDRH/OCE/DID/	aaron kalfa NFW Marketing	3M ESPE DENTAL PRODUCTS DEVICE LISTING NUMBERS
2016-4714	06/03/2016 07/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	11615773 ; 11664259 ; 11672696 ETC JANUVIA, JANUMET
2016-4715	06/03/2016 07/01/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K133022
2016-4716	06/03/2016 07/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	11596326; 11596863; 11632193; BELSOMRA
2016-4717	06/03/2016 07/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	11588625 ; 11663953 ; 11793766 DULERA
2016-4718	06/03/2016 07/01/2016	FDA/OMPT/CDRH/OCE/DID/	LORI COHEN GREENBERG TRAUIG LLP	KOTEX CLICK TAMPONS - U K103311
2016-4719	06/03/2016 07/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	11595688 ; 11635937 ; 11695965 KEYTRUDA
2016-4720	06/03/2016 07/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	11736323 DIFICID

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-4721	06/03/2016 07/01/2016	FDA/OFVM/CFSAN/OCD/EOS/	Garry M Wiltshire The Dow Chemical Company	FCN 1584
2016-4722	06/03/2016 07/01/2016	FDA/OMPT/CDRH/OCE/DID/	LORI COHEN GREENBERG TRAUIG LLP	KOTEX SLEEK TAMPONS - U K112635
2016-4723	06/03/2016 07/01/2016	FDA/OMPT/CDRH/OCE/DID/	Erin K Spiegel Evergreen Research, Inc	K983119
2016-4724	06/03/2016 07/01/2016	FDA/OFVM/CFSAN/OCD/EOS/	Garry M Wiltshire The Dow Chemical Company	FCN 1583
2016-4725	06/03/2016 07/01/2016	FDA/OMPT/CDRH/OCE/DID/	LOIR COHEN GREENBERG TRAUIG LLP	KOTEX CLICK TAMPONS - U K113036
2016-4726	06/03/2016 07/01/2016	FDA/OMPT/CDRH/OCE/DID/	LOIR COHEN GREENBERG TRAUIG LLP	KOTEX SECURITY TUBE TAMPON K853192
2016-4727	06/03/2016 07/01/2016	FDA/OC/OES/DFOI/ FDA/OGROP/OIP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SCOTT PARKER REPUBLICAN NATIONAL COMMITTEE	RECS REFERRING TO ANY CLINTON FOUNDATION DOMAIN 1/21/09 TO 2/1/13
2016-4728	06/03/2016 07/01/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rose Goldberg-Gale Rose Goldberg-Gale	LEVAQUIN BLACK BOX WARNING
2016-4729	06/03/2016 07/01/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Grady Yount Saint Francis Medical Center	NEULASTA ON-BODY INJECTOR - AERS
2016-4730	06/03/2016 07/01/2016	FDA/OGROP/ORACE-FO/CHI- DO/CHI-CB/ FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORACE-FO/NYK- DO/NYK-DCB/	Dewey Steadman Dewey Steadman	AKORN, DECATUR, IL; SOMERSET, NJ; AMITYVILLE, NY - 483 01/01/2009 - 04/30/2016
2016-4731	06/03/2016	FDA/OMPT/CDRH/OCE/DID/	Aras Aslan	IOLMaster 700 Ac-Powered Slitlamp Biomicroscope 510K

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	07/01/2016		ALCON	
2016-4732	06/03/2016 07/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Peter R. Breggin, MD Center for the Study of Psychiatry	LORAZEPAM - AERS
2016-4733	06/03/2016 07/01/2016	FDA/OMPT/CTP/OD/	Doe J	CMPLNT 15K00042 11/30/15
2016-4734	06/03/2016 07/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Peter R. Breggin, MD Center for the Study of Psychiatry	BUTALBITAL - AERS
2016-4735	06/03/2016 07/01/2016	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	Doe J	COMPLAINT RECS
2016-4736	06/03/2016 07/01/2016	FDA/OFVM/CFSAN/OCD/EOS/	Garry M Wiltshire The Dow Chemical Company	FCN 1596
2016-4737	06/03/2016 07/01/2016	FDA/OMPT/CDRH/OCE/DID/	BRICE E. BRYAN, Esq. Law offices of Brice E Bryan and Associates	CORR BETWEEN FDA & SMITH & NEPHEW RE BIRMINGHAM HIP RESURFACING SYSTEM
2016-4738	06/03/2016 07/01/2016	FDA/OMPT/CDRH/OCE/DID/	Doe J	CPT 1500035
2016-4739	06/03/2016 07/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Katherine Nami Yoon UNIVERSITY OF PITTSBURGH	Downloadable Database File of Postmarketing Requirements and Commitments that were updated October 2015
2016-4740	06/03/2016 07/01/2016	FDA/OMPT/CDRH/OCE/DID/	WEN, CHARLIE	CORR BETWEEN FDA & CLEAR CORRECT INC K082556
2016-4741	06/03/2016 07/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sandra Lopez Universidad de Ciencias Aplicadas y Ambientales UDCA	METOCLOPRAMIDE - AERS RE ANXIETY
2016-4742	06/03/2016 07/01/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Katherine Nami Yoon UNIVERSITY OF PITTSBURGH	CBER PMRs/PMCs 7/1/2008 to 5/31/2016
2016-4743	06/03/2016	FDA/OMPT/CDER/ORP/DIDP/	Katherine Nami Yoon	CDER PMRs/PMCs 8/1/2015 to 5/31/2016

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2016-4744	06/03/2016 07/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Katherine Nami Yoon UNIVERSITY OF PITTSBURGH	2015-7282 FOLLOW UP
2016-4745	06/03/2016 07/01/2016	FDA/OC/OES/DFOI/	SARAH FITZPATRICK 60 MINUTES	KIMBERLY CLARK CORP, ROSWELL, GA - 483, CORR 3/20-28/12
2016-4746	06/03/2016 07/01/2016	FDA/OMPT/CDRH/OCE/DID/	Tao Fan for a copy of K052846 (Statement) Tao Fan	K052846
2016-4747	06/03/2016 07/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID BEERY PHARM3R	FAERS - 2015 QUARTER 4 RELEASE
2016-4748	06/03/2016 07/01/2016	FDA/OC/OES/DFOI/	JESSICA KNOPP CUNNING VORYS SATER SEYMOUR & PEASE LLP	DOLE FRESH VEGETABLES INC, SPRINGFIELD, OH - LISTERIA MONOCYTOGENES 1/15 TO 2/16
2016-4749	06/03/2016 07/15/2016	FDA/OC/OES/DDM/	DENNIS C. GUCCIARDO HOGAN LOVELLS LLP	DCK 784-3028, 78N-3072, 78N-3073 ETC
2016-4750	06/03/2016 07/01/2016	FDA/OMPT/CDRH/OCE/DID/	DENNIS C. GUCCIARDO HOGAN LOVELLS LLP	DEPUY ORTHOPAEDICS INC - ONE PICCO CUP MOM THR, ASR RESURFACING, CERAMIC ON METAL THR APRVL
2016-4751	06/03/2016 07/01/2016	FDA/OC/OES/DDM/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Barry Sugarman Diverstech Co.	UNIMED PETITION; FDA LETTER
2016-4752	06/03/2016 07/01/2016	FDA/OMPT/CDRH/OCE/DID/	Dr. Yossi Muncher Eximo Medical Ltd	K123632, K071227, K060012, ETC
2016-4753	06/03/2016 07/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Christian Schneider Christian Schneier	BOEHRINGER INGELHEIM PHARMA GMBH & CO, KG - RESPONSE TO WL 03/01/2016 - 03/31/2016

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2016-4754	06/03/2016 07/01/2016	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	FOIA requests by Wall Street Journal regarding E coli.
2016-4755	06/03/2016 07/01/2016	FDA/OC/OES/DFOI/	Nathaniel Ewing OZ Management	REUTERS FOIA REQUESTS RE CHIPOTLE
2016-4756	06/03/2016 07/01/2016	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	FOIA requests by Reuters regarding E. coli.
2016-4757	06/03/2016 07/01/2016	FDA/OC/OES/DFOI/	Jatin Kotian Emkay Global	CORDEN PHARMA, ITALY 05/21/2015 - 05/29/2015
2016-4758	06/03/2016 07/01/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Gaurav Tinani Emkay Global	MICRO LABS LTD, VERNA, INDIA - 483 05/05/2014 - 05/13/2014
2016-4759	06/03/2016 07/01/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	Jatin Kotian Emkay Global	MEGAFINE PHARMA LIMITED, INDIA - 483 05/11/2015 - 05/15/2015
2016-4760	06/03/2016 07/01/2016	FDA/OC/OES/DFOI/	Jatin Kotian Emkay Global	CIPLA, INDIA - 483 07/27/2015 - 07/08/2015
2016-4761	06/03/2016 07/01/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	CORDEN PHARMA LATINA SPA, ITALY- 483 05/21/2015 - 05/29/2015
2016-4762	06/03/2016 07/01/2016	FDA/OC/OES/DFOI/	Walter Chalkley THOMSON REUTERS	MEGAFINE PHARMA LIMITED, INDIA - 483 05/11/2015 - 05/15/2015
2016-4763	06/03/2016 07/01/2016	FDA/OC/OES/DFOI/	Andrew Berens Morgan Stanley	ZS PHARMACEUTICALS, TX- 483 01/01/2016 - 06/02/2016
2016-4764	06/03/2016 07/01/2016	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCE/DID/	CureApp, Inc. CureApp, Inc.	K100066
2016-4765	06/03/2016 07/01/2016	FDA/OC/OES/DFOI/	Rhett Brown Rhett Brown, Lazard Asset Management	RECS RE ACHTAR GEL
2016-4766	06/03/2016	FDA/OC/OES/DFOI/	Adrian C. Azer	POSTING DATE ROSE ACRE FARMS, INC WARNING LETTER 07/14/2011 - 06/02/2016

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	07/01/2016		Gilbert LLP	
2016-4767	06/06/2016 07/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BERNARD J ERNST ERNST, BERNARD J	RU-486 ABORTION PILL, PLAN B MORINIG AFTER PILL, EMVERGENCY CONTRACEPTION - ANNUAL PRODUCTION, SALES, AERS, ETC
2016-4768	06/06/2016 07/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ROBERT O GROVES WAGSTAFF & CARTMELL LLP	ZOFRAN (ONDANSETRON) - ISRS 6297187, 6434653, 6376998, ETC
2016-4769	06/06/2016 07/05/2016	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	All 483s issued to Chipotle 01/01/2013 to present
2016-4770	06/06/2016 07/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MICHAEL S HAIRSTON #1064200 Hairston, Michael	PREDNISONE - AERS
2016-4771	06/06/2016 07/05/2016	FDA/OO/OFBA/OAGS/	JAMES DAWKINS STAPLES BUSINESS ADVANTAGE	CONTRACT SPECIALISTS AND CREDIT CARD HOLDERS FROM THE FDA
2016-4772	06/06/2016 07/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAWN M CHITTY TORRENT PHARMA INC	CLOBETASOL CREAM NDA 74-220, DESONIDE OINTMENT NDA 17426, LIDOCAINE OINTMENT NDA 80-198, ETC
2016-4773	06/06/2016 07/05/2016	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Doe J	PINNACLE HOSPITAL, CROWN POINT, IN - INSPECTION RECS 02/29/2016 - 05/31/201
2016-4774	06/06/2016 07/05/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 5/1-31/2016
2016-4775	06/06/2016 07/05/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	A list of all FOIA requests closed for 5/1-31/2016
2016-4776	06/06/2016 07/05/2016	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/ OC/ORO/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORAPA-FO/SEA-	Rachel Johnson FOI Services, Inc.	Correspondence between FDA & Chipotle. Please see attached

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		DO/SEA-CB/		
2016-4777	06/06/2016 07/05/2016	FDA/OC/OES/DFOI/	Abbott Stark Ogee	DERMACEUTICAL LABORATORIES LLC - EIR, 483 04/01/2015 - 04/30/2015
2016-4778	06/06/2016 07/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Evelina Lin LOYOLA UNIVERSITY MEDICAL CENTER	NORFLOXACIN ORANGE BOOK DATA
2016-4779	06/06/2016 07/05/2016	FDA/OMPT/CDRH/OCE/DID/	Kate Kuffner Global Cardiac Monitors, Inc.	K000609
2016-4780	06/06/2016 07/05/2016	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/SEA- DO/SEA-CB/	Rachel Johnson FOI Services, Inc.	CHIPOTLE MEXICAN GRILL - LAB REPORTS
2016-4781	06/06/2016 07/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ted Keller EverPoint Asset Management	VELTASSA - AERS
2016-4782	06/06/2016 07/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	David Wilfret Symmune Therapeutics	IND 4190
2016-4783	06/06/2016 07/05/2016	FDA/OC/OES/DFOI/	Nathaniel Ewing OZ Management	CHIPOTLE MEXICAN GRILL - 483 01/01/2013 - 05/25/2016
2016-4784	06/06/2016 07/05/2016	OC/ORO/ORM/ OC/ORO/ORM/	Tate Borcoman Tate Borcoman / Integrated Solutions	LIST OF CDRH INSPECTION 02/01/2016 - 05/31/201
2016-4785	06/06/2016 07/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Paola Teegarden Athenex Inc.	NDA 020305
2016-4786	06/06/2016 07/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Aakash Agarwal Wize Market Analytics	CADILA HEALTHCARE, PIRAMAL ENTERPRISES, STRIDES ARCOLAB ETC - 483 01/01/2016 - 04/20/2016

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2016-4787	06/06/2016 07/05/2016	FDA/OGROP/OIP/	Tim Schwab Food & Water Watch	COMMUNICATIONS BETWEEN FDA AND HEALTH CANADA RE AQUABOUNTY SALMON 02/01/2011 - 05/31/2016
2016-4788	06/06/2016 07/05/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Anokhi Kapasi THE DEGGE GROUP, LTD.	SEVEN MEDWATCH FORMS
2016-4789	06/06/2016 07/05/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Salil Mangi Salil mangi	VELTASSA AERS
2016-4790	06/06/2016 07/05/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/ORO/ OC/ORO/ OC/ORO/ORM/ OC/ORO/ORM/	Eyal Maor FDAAWARE	INSPECTION DATA
2016-4791	06/06/2016 07/05/2016	FDA/OGROP/ORO/CE-FO/MIN-DO/MIN-CB/	Luke Grocholl SIGMA ALDRICH COMPANY LTD	SIGMA ALDRICH CORPORATION, MILWAUKEE, WI - 483 12/01/2011 - 12/31/2011
2016-4792	06/06/2016 07/05/2016	FDA/OC/OCC/ FDA/OFVM/CFSAN/OCD/EOS/	John Thies John Thies	RECS BETWEEN FDA AND PROSECUTORS RE DIETARY SUPPLEMENTS 01/01/2013 - 05/31/2016
2016-4793	06/06/2016 07/05/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joe McCann Slingshot Insights	VELTASSA
2016-4794	06/06/2016 07/05/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sara Koblitz Fish and Richardson P.C.	Correspondence between ANDA sponsors and OGD Division of Labeling Review relating to section viii carve-out of carvedilol congenital heart failure indication
2016-4795	06/06/2016	FDA/OMPT/CBER/OCOD/DDOM/	Charmaine Sutton	BK120067

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	07/05/2016	ALFB/	The Tamarack Group	
2016-4796	06/06/2016 07/05/2016	FDA/OMPT/CDRH/OCE/DID/	Toshio Murata NIDEK INC	K954167
2016-4797	06/06/2016 07/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jaime Vassallo LexisNexis CourtLink	GA/Cop/Glat FAERS
2016-4798	06/06/2016 07/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tanmoy Sadhukha Albany Molecular Research Inc.	NDA 11757
2016-4799	06/06/2016 07/05/2016	FDA/OMPT/CDRH/OCE/DID/	Alexandra Alsberg Evi Health, LLC	K953442 K003128 K133981
2016-4800	06/06/2016 07/05/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Kristiina Gilkey Alliance Partners, LLC	BK150221
2016-4801	06/06/2016 07/05/2016	FDA/OMPT/CDRH/OCE/DID/	Gary Syring Quality and Regulatory Associates, LLC	K970418
2016-4802	06/06/2016 07/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gail Lessick Lachman Consultants	Number of ANDA approvals, tentative approvals and original ANDAs for the month of May 2016
2016-4803	06/06/2016 07/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Daniel Kolitz Daniel Kolitz	NDA 204326
2016-4804	06/06/2016 07/05/2016	FDA/OMPT/CDRH/OCE/DID/	Laure-Cecile Martin DTF medical	K141742 K020518 K150499, etc
2016-4805	06/06/2016 07/05/2016	FDA/OMPT/CDRH/OCE/DID/	ROBERT BOOTH ROBERT BOOTH	CPT1500714
2016-4806	06/06/2016 07/05/2016	FDA/OGROP/ORAP/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORAP/PA-FO/SAN- DO/SAN-CB/	Pat Hillenmeyer (Ms.) AbbVie Inc.	GILEAD SCIENCES, FOSTER CITY, CA- EIR, 483 01/01/2014 - 06/01/2016

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2016-4807	06/06/2016 07/05/2016	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Pat Hillenmeyer (Ms.) AbbVie Inc.	GILEAD, FOSTER CITY, CA - 483, EIR 04/01/2016 - 06/03/2016
2016-4808	06/06/2016 07/05/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sandy Lee B&H Consulting Services, Inc.	NDA 020629 SBA
2016-4809	06/06/2016 07/05/2016	FDA/OMPT/CDRH/OCE/DID/	ROBERT BOOTH ROBERT BOOTH	CPT1500797
2016-4810	06/06/2016 07/05/2016	OC/ORPA/ OC/ORPA/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Lisa Lampros Lisa Lampros	Consumer Complaint #144444 Field Report
2016-4811	06/06/2016 07/05/2016	FDA/OMPT/CDRH/OCE/DID/	Jay Mansour InoLife Technologies Inc	K945873, K003864, K003741, ETC
2016-4812	06/06/2016 07/05/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Hemal Somaiya Hemal Somaiya	LYNPARZA FAERS
2016-4813	06/06/2016 07/05/2016	FDA/OMPT/CDRH/OCE/DID/	Lewis Ward Ward, Lewis	K100874
2016-4814	06/06/2016 07/05/2016	OC/ORPA/ OC/ORPA/ FDA/OGROP/ORARO/DIOP/	Zetetic, Inc. Zetetic, Inc.	FDA ENTRY DOCUMENTATION REQUEST ALL DOCUMENTATION MAY 16, 2016 MAY 31, 2016
2016-4815	06/06/2016 07/05/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Emily Krulewitz The Weinberg Group	NDA 208253 SBA
2016-4816	06/06/2016 07/05/2016	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lesley White Solve Consulting International Pty Ltd	ANDA204605/000 ANDA202459/00 ANDA078830/000, ETC.

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2016-4817	06/06/2016 07/05/2016	FDA/OGROP/ORPA/FO/SEA-DO/SEA-CB/	Evan Bush The Seattle Times	HORIZON AIR INDUSTRIES - 483, CORR 01/08/2016 - 06/01/2016
2016-4818	06/06/2016 07/05/2016	FDA/OC/OES/DFOI/	Bridget Schrader Schrader, Bridget M	LUPRON RECS 01/01/1995 - 06/04/2016
2016-4819	06/06/2016 07/05/2016	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Silvia Lee Relypsa, Inc.	VELTASSA - AERS
2016-4820	06/07/2016 07/06/2016	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/OSMP/OOPD/ FDA/OGROP/ORPA/FO/SAN-DO/SAN-CB/	SHERI O COVINGTON K&L Gates LLP	ALEXION PHARMS - KANUMA (SEBELIPASE ALFA) BLA 125561 SUBMISSION, RVW, CORR, ETC
2016-4821	06/07/2016 07/06/2016	FDA/OMPT/OSMP/OCP/	SHARI MYSZKA 3M ESPE Dental Products	SINCLAIR PHARMACEUTICALS LTD - DECAPINOL ORAL RINSE REQUEST FOR DESIGNATION (RFD) APPLICATION 2004.013
2016-4822	06/07/2016 07/06/2016	FDA/OO/OFBA/OAGS/	DANIEL JONAS HEITECH SERVICES INC	CONTRACT NUMBER HHSF223201000031I
2016-4823	06/07/2016 07/06/2016	FDA/OO/OFBA/OAGS/ FDA/OC/OES/DFOI/	DANIEL JONAS HEITECH SERVICES INC	CONTRACT NUMBER HHSF223201000031I PROPOSAL RECS
2016-4824	06/07/2016 07/06/2016	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	JOHN FRATTI FRATTI, JOHN	LEVAQUIN, LEVOFLOXACIN - AERS 5/09 TO 3/15
2016-4825	06/07/2016 07/06/2016	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Gaurav Tinani Emkay Global	SANDOZ PRIVATE LTD, INDIA - 483 08/12/2014 - 08/29/2014
2016-4826	06/07/2016 07/06/2016	FDA/OGROP/ORASE/FO/NOL-DO/NOL-CB/	Blake Goodner Bridger Healthcare	WRIGHT MEDICAL, ARLINGTON, TN - 483, WARNING LETTER, RESPONSE LETTER 01/02/2015 - 06/01/2016
2016-4827	06/07/2016 07/06/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Steve Ramsdell / Elizabeth Spar Sunstein Kann Murphy & Timbers	REFACTO - DATE OF PACKAGE INSERT, SEQUENCE 02/02/1998 - 03/07/2000

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			LLP	
2016-4828	06/07/2016 07/06/2016	FDA/OMPT/CDRH/OCE/DID/	Rachelle Fitzgerald ConMed Corporation	K143404
2016-4829	06/07/2016 07/06/2016	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORAPA-FO/LOSDO/LOS-CB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Matthew Morris Matthew MORris	LSG Sky Chefs, Dallas DFW Airport facility(s); Washington IAD Airport facility(s); LSG Sky Chefs, Los Angeles LAX Airport facility(s) ETC - EIR05/01/2016 - 06/02/2016
2016-4830	06/07/2016 07/06/2016	FDA/OFVM/CFSAN/OCD/EOS/	Sara Jonasson BIM Kemi Sweden AB	FCN 1445
2016-4831	06/07/2016 07/06/2016	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lesley White Solve Consulting International Pty Ltd	ANDA 78830 COMPLETE RESPONSE LETTER
2016-4832	06/07/2016 07/06/2016	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Blake Goodner Bridger Healthcare	MALLINCHKRODT, ST LOUIS, MO - 483, WARNING LETTERS, RESPONSE LETTERS 01/02/2015 - 06/01/2016
2016-4833	06/07/2016 07/06/2016	OC/ORAI/ OC/ORAI/ OC/ORAI/OCI/ OC/ORAI/OCI/	Sarah N Lynch REUTERS	TIME OFF AWARD FORMS FOR AGENTS IN MIAMI FIELD OFFICE IN CONNECTION WITH PROTECTIVE DETAIL PROVIDE TO THE ACRA, EMAILS 01/01/2015 - 06/01/2016
2016-4834	06/07/2016 07/06/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Gaurav Tinani Emkay Global	MYLAN LABORATORIES, INDIA - 483 08/01/2014 - 02/15/2015
2016-4835	06/07/2016 07/06/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Anjali Cordeiro BLOOMBERG NEWS	ANDA 204821 BIOEQUIVALENCE REVIEW

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-4836	06/07/2016 07/06/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joy Mashaal Senvest Management LLC	SUBSYS - AERS
2016-4837	06/07/2016 07/06/2016	FDA/OFVM/CFSAN/OCD/EOS/	Maegan Faisch TRUTH IN ADVERTISING	4LIFE TRANSFER FACTOR GLUCOACH - WARNING LETTER RECS ETC 01/01/2000 - 05/01/2016
2016-4838	06/07/2016 07/06/2016	FDA/OC/OES/DFOI/ FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Dan Mitchell CLARAGH MOUNTAIN INVESTMENT	SANCILIO AND COMPANY - 483, RESPONSE 12/12/2015 - 06/01/2016
2016-4839	06/07/2016 07/06/2016	FDA/OMPT/CDRH/OCE/DID/	Armin Schon ClearCut Medical Ltd.	K160240
2016-4840	06/07/2016 07/06/2016	FDA/OMPT/CDRH/OCE/DID/	Suhitha Uppal Intuitive Surgical, Inc.	K120361 K142521 K130542 etc
2016-4841	06/07/2016 07/06/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ZEPATIER AERS
2016-4842	06/07/2016 07/06/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ATORVASTATIN - AERS
2016-4843	06/07/2016 07/06/2016	FDA/OMPT/CDRH/OCE/DID/	CAROLINE NEWSOME NEWSOME MELTON	EZ LOCK DOCKING BASE MODEL BL-7317, MODEL BL-6290 - CMLPNTS
2016-4844	06/07/2016 07/06/2016	FDA/OMPT/CDRH/OCE/DID/	CAROLINE NEWSOME NEWSOME MELTON	KANGERTECH - KANGER NEBOX STARTER KIT CMLPNTS
2016-4845	06/07/2016 07/06/2016	FDA/OMPT/CDRH/OCE/DID/	THERESE AVANT HOLLIS WRIGHT CLAY & VAIL PC	AFFINITY CAGE SYS P000028
2016-4846	06/07/2016 07/06/2016	FDA/OMPT/CDRH/OCE/DID/	Beth Luoma DuVal & Associates, P.A.	K152569
2016-4847	06/07/2016	FDA/OMPT/CDRH/OCE/DID/	Sam Shaban	K032030, K032481, K040839

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	07/06/2016		Bio American Worldwide	
2016-4848	06/07/2016 07/06/2016	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Giridhar Prasad Jangly Dr. Reddy's Laboratories Inc.	GERITEX CORP, MOUNT VERNON, NY - 483 01/01/2014 - 06/02/2016
2016-4849	06/07/2016 07/07/2016	FDA/OMPT/CDRH/OCE/DID/	THERESE AVANT HOLLIS WRIGHT CLAY & VAIL PC	GLOBUS MEDICAL COALITION - INTEGRATED PLATE & SPACER SYS 510K
2016-4850	06/07/2016 07/06/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dustin Block IPD ANALYTICS LLC	ANDA No. 202023 ANDA No. 202255 ANDA No. 202597 ETC TENTATIVE APPROVAL LETTERS
2016-4851	06/07/2016 07/06/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Owen Kao Owen Kao	ZHEJIANG APELOA JIAYUAN CO LTD, CHINA - 483 11/30/2015 - 12/05/2015
2016-4852	06/07/2016 07/06/2016	FDA/OMPT/CDRH/OCE/DID/	THERESE AVANT HOLLIS WRIGHT CLAY & VAIL PC	BAK/CERVICAL INTERBODY FUSION SYS P980048
2016-4853	06/07/2016 07/06/2016	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Andrew Berens, MD Morgan Stanley	ZS PHARMACEUTICALS, TX - EIR 01/01/2016 - 06/02/2016
2016-4854	06/07/2016 07/06/2016	FDA/OFVM/CFSAN/OCD/EOS/	Vadim Krifuks Denolva Omega Products, Inc	NDI notification and other documents filed by Qualitas Health Inc in the period from March 1st, 2014 to June 2nd, 2016
2016-4855	06/07/2016 07/06/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Charles Naggar Alston and Bird LLP	TRADEJENTA - IND; JENTADUETO - IND; ETC
2016-4856	06/07/2016 07/06/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Linh Chu Intarcia Therapeutic Inc	Clinical package and any information concerning specifically anti-exenatide antibody (ADA) response for e Byetta-NDA: 21-919, Bydureon-NDA: 22-200
2016-4857	06/07/2016 07/06/2016	OC/ORASORM/ OC/ORASORM/	Michele Sinoway LACHMAN CONSULTANT SERVICES, INC.	PRE-APPROVAL INSPECTIONS OF DRUG MANUFACTURERS 01/01/2015 - 12/31/2015
2016-4858	06/07/2016 07/06/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Nikhilesh Singh OrphoMed Inc	VIBERZI - AERS

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-4859	06/07/2016 07/06/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Nivedita Valentine B&S Healthcare	ORAL GLYCOPYRRONIUM - ADVERSE EVENT DATA
2016-4860	06/07/2016 07/06/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Penn State post-market study PENNSYLVANIA STATE UNIVERSITY	History of the quarterly updates on the post-market requirements and commitments database for drugs
2016-4861	06/07/2016 07/06/2016	OC/CVM/OCD/	Frances Cheng PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS	Institutional Animal Care and Use Committee-approved experimental protocols from laboratories operated by the Center for Veterinary Medicine that were categorized under Animal Welfare Act pain and distress Category E; Adverse Events 01/01/2015 - 06/02/2016
2016-4862	06/08/2016 07/07/2016	FDA/OMPT/CDRH/OCE/DID/	Daniel Hue United Pacific Company	K993123
2016-4863	06/08/2016 07/07/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Bryan Silvey BAXALTA US INC	BAXALTA ORTH, AUSTRIA - EIR 05/13/2015 - 12/08/2015
2016-4864	06/08/2016 07/07/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel King The Rosen Law Firm	AFREZZA PULMONARY FUNCTION GATEWAY ISSUE RECS
2016-4865	06/08/2016 07/07/2016	FDA/OGROP/ORR/SW-FO/DEN- DO/DEN-CB/	Walter Chalkley THOMSON REUTERS	SORIN GROUP USA, INC, ARVADA, CO - EIR, 483, RESPONSE 08/24/2015 - 09/01/2015
2016-4866	06/08/2016 07/07/2016	FDA/OMPT/CDRH/OCE/DID/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Walter Chalkley THOMSON REUTERS	BBT BIOTECH GMBH, GERMANY - 483 05/04/2015 - 05/07/2015
2016-4867	06/08/2016 07/07/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Walter Chalkley THOMSON REUTERS	TAI HENG INDUSTRY CO, LTD, CHINA- 483 05/04/2015 - 05/11/2015
2016-4868	06/08/2016	FDA/OMPT/CDRH/OCE/DID/	RICARDO M. SCHOENING	HBS HEADLESS BONE SCREW K030302

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	07/07/2016		SCHOENING & ASSOCIATES	
2016-4869	06/08/2016 07/07/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Frances Cheng PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS	Institutional Animal Care and Use Committee-approved experimental protocols from laboratories operated by the Center for Biologics Evaluation and Research that were categorized under Animal Welfare Act pain and distress Category E; adverse events 01/01/2015 - 06/03/2016
2016-4870	06/08/2016 07/07/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mirit Hemy Mirit Hemy	CIPRODEX OTIC - AERS
2016-4871	06/08/2016 07/07/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 20872 S23 SUPPLEMENTAL APPROVAL RECS
2016-4872	06/08/2016 07/07/2016	FDA/OFVM/CFSAN/OCD/EOS/ OC/CVM/OCD/	Frances Cheng PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS	Institutional Animal Care and Use Committee-approved experimental protocols from laboratories operated by the Center for Food Safety and Applied Nutrition that were categorized under Animal Welfare Act pain and distress Category E; adverse events 01/01/2015 - 06/03/2016
2016-4873	06/08/2016 07/07/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lynn E. Bayless Voyager Therapeutics, Inc.	NDA 203952 SBA
2016-4874	06/08/2016 07/07/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHAMP Y29434, SEAN PHILLIP	TRILEPTAL; VISTARIL; ZOLOFT - LBLG
2016-4875	06/08/2016 07/07/2016	FDA/OO/OFBA/OAGS/	Gopal Krishnan, Gopal	HHSF22301009T HHSF223200950015I
2016-4876	06/08/2016 07/07/2016	FDA/OC/OES/DFOI/	Goldberg, Nathan	CHOBANI YOGART BARCODE 947-01033
2016-4877	06/08/2016 07/07/2016	FDA/OMPT/CDRH/OCE/DID/	Ryan Knutson THE WALL STREET JOURNAL	RADIOFREQUENCY INTERAGENCY WORKGROUP - MEETING MINUTES, REPORTS, MATERIALS ETC 01/01/2011 - 06/03/2016
2016-4878	06/08/2016 07/07/2016	FDA/OGROP/ORO/PA-FO/SEA- DO/SEA-CB/	Molly Gulbrandson Faegre Baker Daniels LLP	CRF FROZEN FOODS - COMMUNICATIONS 09/01/2010 - 06/03/2016

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2016-4879	06/08/2016 07/07/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Alfred Sarkissian GEORGE MASON UNIVERSITY	ORANGE BOOK PATENTS 01/01/1984 - 06/03/2016
2016-4880	06/08/2016 07/07/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jatin Kotian Emkay Global	CIPLA LTD, INDIA - 483 02/25/2013 - 03/01/2013
2016-4881	06/08/2016 07/07/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KATHLEEN PORUPSKI MYLAN NV	ZHEJIANG JIUZHOU PHARMACEUTICAL CO LTD, JIAOJIANG TAIZHOU, ZHEJIANG PROVINCE - 483 1/16
2016-4882	06/08/2016 07/14/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OC/OES/DFOI/	Myrisha Lewis IIT Chicago-Kent College of Law	OVASCIENCE - CORR WITH FDA 01/01/2011 - 12/31/2014;
2016-4883	06/08/2016 09/01/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Myrisha Lewis IIT Chicago-Kent College of Law	LETTER TO SPONSORS/RESEARCHERS - NAMES OF RECIPIENTS, RESPONSES 01/01/2001 - 12/31/2001
2016-4884	06/08/2016 07/07/2016	FDA/OPPLA/OL/	Myrisha Lewis IIT Chicago-Kent College of Law	CHALLENGES OF THE NEXT CENTER - CONGRESSIONAL TESTIMONY 03/07/2001 - 03/30/2001
2016-4885	06/08/2016 07/07/2016	FDA/OC/OES/DFOI/	Eyal Maor FDAAWARE	483 RELEASED UNDER FOIA 05/01/2016 - 05/31/2016
2016-4886	06/08/2016 07/07/2016	FDA/OC/OES/DFOI/	RYAN WILDER POINT 72 ASSET MANAGEMENT LP	LOKELMA (ZIRCONIUM SILICATE) 483
2016-4887	06/08/2016 07/07/2016	FDA/OC/OES/DFOI/	Mary Patton Armstrong ARMSTRONG, MARY	HEMOSENSE, INC, ALERE SAN DIEGO - 483 07/13/2006 - 06/27/2012
2016-4888	06/08/2016 07/07/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K093905
2016-4889	06/08/2016 07/07/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	NALIN C PARIKH HIGH CHEMICAL CO	SARAPIN NDA - UNREDACTED
2016-4890	06/08/2016 07/07/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K093416

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2016-4891	06/08/2016 07/07/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K123637
2016-4892	06/08/2016 07/07/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K121597
2016-4893	06/08/2016 07/07/2016	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2016-3867 2016-3990
2016-4894	06/08/2016 07/07/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Hemal Somaiya Hemal Somaiya	LYNPARZA - AERS
2016-4895	06/08/2016 07/07/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	MICHAEL MANCINELLI CONWAY HOMER & CHIN- CAPLAN PC	INDIVIDUAL RECS
2016-4896	06/08/2016 07/07/2016	FDA/OC/OES/DFOI/	Kimberly Waller Ximedica	K112208
2016-4897	06/08/2016 07/07/2016	FDA/OC/OES/DFOI/	DAVID BEERY PHARM3R	LOG 2015 & 2016
2016-4898	06/08/2016 07/07/2016	FDA/OC/OES/DFOI/	Kwesi Frimpong-Boateng, PhD Prescient Healthcare Group	ZS-9 PLANT, COPPELL, TX - 483
2016-4899	06/09/2016 07/08/2016	FDA/OGROP/ORR/SE-FO/FLA- DO/FLA-CB/ FDA/OMPT/CTP/OD/	ATSEDEMARIAM ROBINSON DE'ASIA THE ANGEL FOOD STORE	DE'ASIA THE ANGEL FOOD STORE, JACKSONVILLE, FL - CTP WARNING LTRS 11/15 TO 5/16, PHONE RECS
2016-4900	06/09/2016 07/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	OLIVER PRICHARD NORTH RUN CAPITAL LP	TEVA PHARMACEUTICAL INDUSTRIES, GODOLLO, HUNGARY - 483 MOST RECENT
2016-4901	06/09/2016 07/08/2016	FDA/OC/OES/DFOI/	DAVID KASKEL KASKEL, DAVID	MEMORIAL SLOAN KETTERING BOARD OF DIRECTOR'S MTG - MINS 7/2/74
2016-4902	06/09/2016 07/08/2016	FDA/OMPT/CDRH/OCE/DID/	WILLIAM P MURRAY III Wilkes & McHugh, P.A.	HYGENIC INTANGIBLE PROPERTY HOLDING CO, PERFORMANCE HEALTH LLC, PHW HOLDINGS INC, ETC - THERA-BRANDS SUBMISSIONS
2016-4903	06/09/2016 07/08/2016	FDA/OGROP/ORR/CE-FO/CHI- DO/CHI-CB/	LINDSEY MCGOWAN STERIS CORP	ISOMEDIX OPERATIONS INC, LIBERTYVILLE, IL - EIRS 1/8/14 TO 2/5/15
2016-4904	06/09/2016	FDA/OGROP/ORR/NE-FO/NWE- DO/NWE-CB/	Lukas Vrbka	JUDGE ROTENBERG CENTER - COMPLAINT, 482, EMAIL ETC 06/04/1990 - 06/01/2005

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	07/08/2016		The Schuster Institute For Investigative Journalism	
2016-4905	06/09/2016 07/08/2016	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Garth Conrad BARD PERIPHERAL VASCULAR INC	BARD PERIPHERAL VASCULAR INC, TEMPE, AZ - EIR 01/01/2015 - 12/31/2015
2016-4906	06/09/2016 07/08/2016	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Garth Conrad BARD PERIPHERAL VASCULAR INC	BARD PERIPHERAL VASCULAR INC, TEMPE, AZ - EIR 03/01/2006 - 12/31/2006
2016-4907	06/09/2016 07/08/2016	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Garth Conrad BARD PERIPHERAL VASCULAR INC	BARD PERIPHERAL VASCULAR INC, TEMPE, AZ - EIR 04/01/2003 - 12/31/2003
2016-4908	06/09/2016 07/08/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K111610
2016-4909	06/09/2016 07/08/2016	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jeanine Gouveia Aerie Pharmaceuticals Inc.	ASTA ZENECA, COPPELL, TX - EIR, RESPONSE, COMPLETE RESPONSE LETTER 01/01/2016 - 05/27/2016
2016-4910	06/09/2016 07/08/2016	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Garth Conrad Bard Peripheral Vascular, Inc.	BARD PERIPHERAL VASCULAR INC, TEMPE, AZ - 483 03/01/2006 - 03/31/2006
2016-4911	06/09/2016 07/08/2016	FDA/OGROP/ORAPA-FO/SEADO/SEA-CB/	Pat Hillenmeyer (Ms.) AbbVie, Inc.	GILDEAD SCIENCES, SEATTLE, VA - 483, EIR 01/01/2014 - 06/01/2016
2016-4912	06/09/2016 07/08/2016	FDA/OMPT/CTP/OD/	Will Woodlee Kleinfeld, Kaplan & Becker, LLP	CTP SE NUMBBER OF FINAL ACTIONS 06/22/2009 - 06/06/2016
2016-4913	06/09/2016 07/08/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Phillip Hwang UNIVERSITY OF WASHINGTON	HAVRIX, INFANRIX - CLINICAL REVIEWSI
2016-4914	06/09/2016 07/08/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	B103795/5286
2016-4915	06/09/2016 07/08/2016	FDA/OMPT/CDRH/OCE/DID/	Diraviam Thirugnanam Perfint Healthcare Pvt Ltd	K152473
2016-4916	06/09/2016 07/08/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michelle Taylor ARIAD Pharmaceuticals, Inc	ICLUSIG AERS

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2016-4917	06/09/2016 07/08/2016	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Garth Conrad BARD PERIPHERAL VASCULAR INC	BARD PERIPHERAL VASCULAR INC, TEMPE, AZ - EIR 02/01/2016 - 09/01/2016
2016-4918	06/09/2016 07/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Paul Lavigne Washington University/Barnes-Jewish Hospital	NDA 019885 NDA 020184 BLA 103172 ETC - CLINICAL TRIAL RECS
2016-4919	06/09/2016 07/08/2016	FDA/OFVM/CFSAN/OCD/EOS/	Beatrice Maingi SAFE FOODS CORPORATION	FCN 1490
2016-4920	06/09/2016 07/08/2016	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Garth Conrad BARD PERIPHERAL VASCULAR INC	BARD PERIPHERAL VASCULAR INC, TEMPE, AZ - EIR 02/01/2015 - 12/31/2015
2016-4921	06/09/2016 07/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Janet Whitley BIOMARIN PHARM	NDA 19815
2016-4922	06/09/2016 07/08/2016	FDA/OC/OES/DFOI/ FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	Josh Long Informa Exhibitions/Natural Products INSIDER	ABBA PHARMA, INC Tampa, FL; Summit Beverage Group LLC, Marian, VA; Formulife INC Dallas, TX etc - 483
2016-4923	06/09/2016 07/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jatin Kotian Emkay Global	TEVA PHARMACEUTICALS, GODOLLO, HUNGARY - 483 01/21/2016 - 06/29/2016
2016-4924	06/09/2016 07/08/2016	FDA/OMPT/CDRH/OCE/DID/	Brian Godwin Ethicon	K111202

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2016-4925	06/09/2016 08/25/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Rachel Johnson FOI Services, Inc.	BK080043
2016-4926	06/09/2016 07/08/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Rachel Johnson FOI Services, Inc.	BK080010
2016-4927	06/09/2016 07/08/2016	OC/ORO/ORM/ OC/ORO/ORM/	Sarah Sorscher PUBLIC CITIZEN	LIST OF INSPECTIONS WITH PAC CODES 56002A 56002I 56D017 56D015 01/01/2010 - 04/01/2016
2016-4928	06/10/2016 07/11/2016	FDA/OMPT/CTP/OD/	Darlene A. Soto Darlene A. Soto	LIST OF COMPANIES REPORTING MANUFACTURED TOBACCO REMOVALS AND TOBACCO IMPORTED PRODUCTS TO CTP FOR USER FEE ASSESSMENTS 10/01/2015 - 06/01/2016
2016-4929	06/10/2016 07/11/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kathleen Porupski MYLAN NV	ZHEJIANG JIUZHOU PHARMACEUTICAL CO, LTD - 483 01/01/2016 - 06/07/2016
2016-4930	06/10/2016 07/11/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Poornaa Venkatesan Jefferies India Pvt Ltd	DR REDDY'S, INDIA - 483 01/01/2016 - 06/30/2016
2016-4931	06/10/2016 07/11/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Leanne Usa Wockhardt USA LLC	PAR PHARMACEUTICALS TENTATIVE APPROVAL LETTER DESVENLAFAXINE
2016-4932	06/10/2016 07/11/2016	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	Giridhar Prasad Jangly Dr. Reddy's Laboratories Inc.	ADVANCED ANALYTICAL TESTING LABORATORIES INC, NORTH BRUNSWICK, NJ - 483, EIR
2016-4933	06/10/2016 07/11/2016	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	Giridhar Prasad Jangly Dr. Reddy's Laboratories Inc.	EPIC PHARMA, LAURELTON, NY - EIR, 483
2016-4934	06/10/2016 07/11/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sara Wexler Koblitz Fish and Richardson P.C.	TEVA, GLENMARK CARVEDILOL - AERS
2016-4935	06/10/2016 07/11/2016	FDA/OMPT/CDRH/OCE/DID/	Peter Kollings EMED Technologies Corporation	K151650
2016-4936	06/10/2016 07/11/2016	FDA/OMPT/CDRH/OCE/DID/	Kimberly Waller Ximedita	K131962

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2016-4937	06/10/2016 07/11/2016	OC/ORa/OCI/ OC/ORa/OCI/	Sarah N Lynch Sarah Lynch, Reuters	MEMOS, INTERVIEWS WITH DOCTORS WHO PURCHASED FOREIGN, UNAPPROVED DRUGS FROM MEDICAL DEVICE KING AKA MDK, PHARMALOGICAL ETC 01/01/2013 - 12/31/2015
2016-4938	06/10/2016 07/11/2016	FDA/OGROP/ORa/SE-FO/ATL-DO/ATL-CB/	Giridhar Prasad Jangly Dr. Reddy's Laboratories Inc.	CUSTOM ANALYTICS LLC, DALZELL, SC - 483, EIR
2016-4939	06/10/2016 07/11/2016	FDA/OFVM/CFSAN/OCD/EOS/	Martin Hoagland Nalco, An Ecolab Company	Executive summary and systemic toxicity critical review memos used by FDA to set the ADI for HEDP (1-hydroxyethane 1,1-diphosphonic acid) and ATMP (aminotris(methylenephosphonic acid)); CEDI for HEDP and ATMP; final Toxicology and Chemistry memos from the most recent FCN where FDA considered the safety of exposure to HEDP and ATMP.
2016-4940	06/10/2016 07/20/2016	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	RECS RE DEVELOPMENT AND TESTING OF REFERENCE CIGARETTE 1R6F
2016-4941	06/10/2016 07/11/2016	FDA/OMPT/CDRH/OCE/DID/	Richard Noctis Richard Noctis	K08055 K123209 K052355
2016-4942	06/10/2016 07/11/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Andrew Jensen University of California, Los Angeles Department of Orthopaedics	NDC IDENTIFIERS FOR THE MEDICATION TRANEXAMIC ACID 01/01/1972 - 06/06/2016
2016-4943	06/10/2016 07/11/2016	FDA/OFVM/CFSAN/OCD/EOS/	Eleanor DaCosta United States Pharmacopeial Convention (USP)	CINNAMOMUM CASSIA TWIG - AERS
2016-4944	06/10/2016 07/11/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	G.Srinivas Zydus Pharmaceuticals USA Inc.	NDA 007409 SBA
2016-4945	06/10/2016 07/11/2016	FDA/OFVM/CFSAN/OCD/EOS/	Eleanor DaCosta United States Pharmacopeial Convention (USP)	LACROBACILLUS ACIDOPHILUS - AERS
2016-4946	06/13/2016 07/12/2016	OC/ORa/ORM/ OC/ORa/ORM/	LESLIE RAMSEY FDA NEWS	PHARMACEUTICAL, BIOLOGICAL, MEDICAL DVC FACILITIES IN THE US & OUTSIDE US - 483 5/1-31/16
2016-4947	06/13/2016 07/12/2016	OC/ORa/ORM/ OC/ORa/ORM/	LESLIE RAMSEY FDA NEWS	CINICAL TRIAL FACILITIES & INVESTIGATORS - 483 5/1-31/16
2016-4948	06/13/2016 07/12/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HAYES, SPENCER	6627254, 9879854, 6246717 GADOLINIUM - AER

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2016-4949	06/13/2016 07/12/2016	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	JEANINE GOUVEIA AARIE PHARMACEUTICALS	ZS PHARMA, COPELL, TX - EIR, 483 1/16 TO 5/27/16
2016-4950	06/13/2016 07/12/2016	FDA/OFVM/CFSAN/OCD/EOS/	ALESSANDRA POTENZA The Verge	KAVA - AER
2016-4951	06/13/2016 07/12/2016	OC/ORAS/ OC/ORAS/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Doe J	CMPLNT 145616
2016-4952	06/13/2016 07/12/2016	FDA/OMPT/CDRH/OCE/DID/	CHRISTINE LIVOTI DEERFIELD INSTITUTE	FDA MTG MINUTES REGARDING BAXTERS VIVIA HIGH DOSE HEMODIALYSIS SYSTEM 4/22/16
2016-4953	06/13/2016 07/12/2016	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	CHRISTINE LIVOTI DEERFIELD INSTITUTE	ZS PHARMA. COPPELL, TX - EIR 3/16
2016-4954	06/13/2016 07/12/2016	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	Courtney Roman Fresenius Kabi USA, LLC	FRESENIUS KABI USA - EIR AUG/SEPT 2015
2016-4955	06/13/2016 07/12/2016	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	COATES-LAYNE, SHANNON	SCANTIBODIES LABORATORY INC, SANTEE, CA - EIR, 483
2016-4956	06/13/2016 07/12/2016	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Eloisa Valencia Kite Pharma	PROMETHEUS LABORATORIES, SAN DIEGO, CA - EIR 06/01/2013 - 09/30/2015
2016-4957	06/13/2016 07/12/2016	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Farideh Marzi Vege-Kurl	VEGE-KURL INC, GLENDALE, CA - EIR 08/12/2014 - 08/12/2015
2016-4958	06/13/2016 07/12/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARC RENDELL, MD ASSOCIATION OF DIABETES INVESTIGATORS	INSULIN DEGLUDEC, INSULIN DEGLUDEC ASPART, INSULIN DEGLUDEC LIRAGLUTIDE - RECS
2016-4959	06/13/2016 07/12/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ROBERT GROVES, Esq. WAGSTAFF & CARTMELL LLP	ZOFAN (ONDANSETRON) AER 7220530, 7224575, 7522841 ETC
2016-4960	06/13/2016 07/12/2016	FDA/OC/OES/DDM/	CINNAMON S. BLOSS, Ph.D. UNIVERSITY OF CALIFORNIA SAN DIEGO	DOCKET FDA-2014-N-2235
2016-4961	06/13/2016	FDA/OC/OES/DFOI/	Michael P. Vitek	ORINDYL - LIST OF REQUESTS 06/06/1970 - 06/06/2016

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	07/12/2016		Cognosci, Inc.	
2016-4962	06/13/2016 07/12/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kristen Kristen Carrier	Canagliflozin, Empagliflozin, Dapagliflozin RECS RE 20 CASES
2016-4963	06/13/2016 07/12/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Katherine Nami Yoon UNIVERSITY OF PITTSBURGH	PMRs/PMCs (reportable under Section 506B) that were established between 7/1/2015 to 5/31/2016 by CDER
2016-4964	06/13/2016 07/12/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dustin Block IPD ANALYTICS LLC	ANDA 206032 TENTATIVE APPROVAL LETTER
2016-4965	06/13/2016 07/12/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DIANNE L. CHAMBERS HOGAN LOVELLS LLP	DEXCEL PHARMA - LANSOPRAZOLE NDA 20-825 APRVL, RVW, INSERT
2016-4966	06/13/2016 07/12/2016	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Kirsten Jackson Kasowitz, Benson, Torres & Friedman LLP	AGRO AMERICA LLC, DUNWOODY, GA - INSPECTION RECS, RECALLS, COMPLAINTS, CORR 06/08/2006 - 06/08/2016
2016-4967	06/13/2016 07/22/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Doe J	INDIVIDUAL RECS
2016-4968	06/13/2016 07/12/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GAURAV KARNAWAT GAURAV KARNAWAT	WOCKHARDT LIMITED, INDIA - EIR 01/01/2016 - 06/08/2016
2016-4969	06/13/2016 07/12/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Blake Goodner Bridger Healthcare	TEVA PHARMACEUTICALS, GODOLLO, HUNGARY - 483, WARNING LETTERS, RESPONSES 01/02/2015 - 06/06/2016
2016-4970	06/13/2016 07/12/2016	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	Rob Eberhardt Robert Eberhardt	MATTEHORN GROUP DBA DELUXE ICE CREAM - RECS RE ILLNESS, DEATH 01/01/2005 - 06/10/2010
2016-4971	06/13/2016	FDA/OMPT/CDER/GRP/DIDP/	SIDDHARTH KARNAWAT	WOCKHARDT LIMITED, INDIA - EIR 01/01/2016 - 06/08/2016

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	07/12/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SIDDHARTH KARNAWAT	
2016-4972	06/13/2016 07/12/2016	FDA/OMPT/CDRH/OCE/DID/	Robert Sokolowski MEDELA, INC.	K150476
2016-4973	06/13/2016 07/12/2016	FDA/OMPT/CDRH/OCE/DID/	Markus Buetler Medela AG	K133276
2016-4974	06/13/2016 07/12/2016	FDA/OMPT/CDRH/OCE/DID/	Hilary Baldwin Stryker AG	K120425 K123837
2016-4975	06/13/2016 07/12/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Katie Hafner THE NEW YORK TIMES	SANOFI TAXOTERE - PROPOSED LABEL UPDATE RE ALOPECIA 01/01/2004 - 12/31/2015
2016-4976	06/13/2016 07/12/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joseph Reo BAYER HEALTHCARE	NDA 202236
2016-4977	06/13/2016 07/12/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Peter R. Breggin, MD Center for the Study of Psychiatry	TRAZODONE - AERS
2016-4978	06/13/2016 07/12/2016	FDA/OGROP/ORR/CE-FO/MIN- DO/MIN-CB/ FDA/OGROP/ORR/SW-FO/KAN- DO/KAN-CB/	Mike Hughlett MINNEAPOLIS STAR TRIBUNE	GENERAL MILLS, KANSAS CITY, MO - 483, 482, EIR 01/09/2011 - 06/09/2016
2016-4979	06/13/2016 07/12/2016	FDA/OMPT/CDRH/OCE/DID/	Jaclyn Docs Acuitive Technologies	K010911
2016-4980	06/13/2016 07/12/2016	FDA/OMPT/CDRH/OCE/DID/	Jaclyn Docs Acuitive Technologies	K041105
2016-4981	06/13/2016 07/12/2016	FDA/OMPT/CDRH/OCE/DID/	Suhitha Uppal Intuitive Surgical, Inc.	K152319
2016-4982	06/13/2016 07/12/2016	FDA/OGROP/ORR/SW-FO/DEN- DO/DEN-CB/	Ian Sheffield Bridger Healthcare	SPECTRANETICS CORPORATION, COLORADO SPRINGS, CO - EIR, 483, CORR 01/01/2015 - 06/09/2016
2016-4983	06/13/2016	FDA/OFVM/CFSAN/OCD/EOS/	Eleanor DaCosta	RHODIOLA CREMULATA AKA SEDUM CREMULATUM AERS

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	07/12/2016		United States Pharmacopeial Convention (USP)	
2016-4984	06/14/2016 07/13/2016	FDA/OFVM/CFSAN/OCD/EOS/	Eleanor DaCosta United States Pharmacopeial Convention (USP)	SEDUM CRENULATUM - AERS
2016-4985	06/14/2016 07/13/2016	FDA/OMPT/CDRH/OCE/DID/	Stephanie Elvin Fisher & Paykel Healthcare	K152029
2016-4986	06/14/2016 07/13/2016	FDA/OGROP/ORR/SW-FO/DEN-DO/DEN-CB/	Thad Knutson Thad Knutson	MILLERCOORS BREWERY, GOLDEN, CO - 483 01/01/2016 - 05/01/2016
2016-4987	06/14/2016 07/13/2016	FDA/OFVM/CFSAN/OCD/EOS/	Wendan Wang BURDOCK GROUP	OXALATE DECARBOXYLASE - RECS RE GRAS, FAP, NDIN
2016-4988	06/14/2016 07/13/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCE/DID/	YH Tham Innolates Sdn. Bhd.	INNOLATEX, MALAYSIA - EIR 01/17/2011 - 01/20/2011
2016-4989	06/14/2016 07/13/2016	FDA/OFVM/CFSAN/OCD/EOS/	Eleanor DaCosta United States Pharmacopeial Convention (USP)	COFFEE FRUIT EXTRACT - AERS
2016-4990	06/14/2016 07/13/2016	FDA/OMPT/CDRH/OCE/DID/	Bruce Anneaux Zeus Industrial Products, Inc.	PMA P820083 SUMMARY OF SAFETY AND EFFECTIVENESS
2016-4991	06/14/2016 07/13/2016	FDA/OMPT/CDRH/OCE/DID/	Jack O. Burwell, Jr. Jack O. Burwell, Jr	CPT1500789
2016-4992	06/14/2016 07/13/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	Eleanor DaCosta United States Pharmacopeial Convention (USP)	LACTOBACILLUS RHAMNOSUS - AERS
2016-4993	06/14/2016 07/13/2016	FDA/OC/OESA/OMA/	Matt Novak Gawker Media / Gizmodo	CHIPOTLE TALKING POINTS SENT OR RECEIVED BY OFFICE OF MEDIA AFFAIRS 04/03/2015 - 06/09/2016
2016-4994	06/14/2016 07/13/2016	FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/	Ian Sheffield Bridger Healthcare	DEXCOM, SAN DIEGO, CA - EIR, 483, CORR 11/29/2015 - 06/10/2016
2016-4995	06/14/2016 07/13/2016	FDA/OC/OES/DFOI/ FDA/OC/OES/DDM/	Hui Wang Target Health Inc.	ATTACHED LETTER

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2016-4996	06/14/2016 07/13/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Giridhar Prasad Jangly Dr. Reddy's Laboratories Inc.	LUNDBECK PHARMACEUTICALS ITALY - 483, EIR LAST THREE INSPECTIONS
2016-4997	06/14/2016 07/13/2016	FDA/OMPT/CDRH/OCE/DID/	Anna Hwang Acclarent, Inc.	K152121 K153555
2016-4998	06/14/2016 07/13/2016	FDA/OC/OES/DFOI/	TAMMY ARDISTER THORNTON WEINBERG WHEELER ET AL	ROTISSERIE CHICKEN SALAD E COLI OUTBREAK IN MO, CO, CA, UT, VA, MT - LAB NOTEBOOKS, ANALYSIS, W/S, ETC
2016-4999	06/14/2016 07/13/2016	FDA/OC/OES/DFOI/	JESSE FROEHLING FROEHLING, JESSE	STRYKER - REJUVENATE MODULAR HIP SYS RECALL RECS
2016-5000	06/14/2016 07/13/2016	OC/ORO/OCI/ OC/ORO/OCI/	R JAMES MADIGAN III Patterson Belknap Webb & Tyler LLP	ABBOTT, LIFESCAN, ROCHE - BLOOD GLUCOSE TESTING STRIPS THEFT, DIVERSION OR COUNTERFEITING, ETC MEMOS, NOTES, CORR, ETC LAST 3 YRS
2016-5001	06/14/2016 07/13/2016	OC/CVM/OCD/	REBECCA L DANDEKER MORGAN LEWIS & BOCKIUS LLP	DSM INNOVATION INC - INACTIVE MODIFIED YEAST AS A COMPONENT OF ANIMAL FEED CORR, SUBMISSIONS, RECS, ETC
2016-5002	06/14/2016 07/13/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sara Koblitz Fish and Richardson P.C.	AERS 8179182 9115772 9186606 ETC
2016-5003	06/14/2016 07/13/2016	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SE-FO/NOL-DO/NOL-CB/	Doe J	COMPLAINT 140126
2016-5004	06/14/2016 07/13/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GAURAV KARNAWAT GAURAV KARNAWAT	AUROBINDO PHARMA, INDIA - 483 03/01/2016 - 06/10/2016
2016-5005	06/14/2016 07/13/2016	FDA/OFVM/CFSAN/OCD/EOS/	Seth A. Mailhot Michael Best and Friedrich LLP	CAP 3C0298 CAP 4C0299 CAP 5C0301 ETC
2016-5006	06/14/2016 07/13/2016	FDA/OMPT/CDRH/OCE/DID/	Crystal Buffert Crystal Buffert	CDRH CUSTOMER SATISFACTION SURVEY RESULTS 01/01/2016 - 06/10/2016
2016-5007	06/14/2016 07/13/2016	FDA/OGROP/ORO/CE-FO/DET-DO/DET-CB/	Elisa Burger SPI Pharma, Inc.	PD PHARMATECH, SEYMOUR, IN - EIR 01/01/2010 - 06/10/2016

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2016-5008	06/14/2016 07/13/2016	FDA/OO/OHR/	Eyal Maor FDA/AWARE	SATHEESH THOMAS - CV
2016-5009	06/14/2016 07/13/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Alexander M M Shepherd MD PhD FRCPE UTHSCSA	ALPRAZOLAM, CLONAZEPAM, ZOLPIDEM - AERS
2016-5010	06/14/2016 07/13/2016	FDA/OFVM/CFSAN/OCD/EOS/	K O Smedley Center for Regulatory Services Inc.	FCN No. 618 Form 3480, Page 23-End of Part VI (List of Attachments) and ATTACHMENT 30
2016-5011	06/14/2016 07/13/2016	FDA/OMPT/CDRH/OCE/DID/	David Weissman The York Dispatch	LivaNova/Sorin Stockert 3T, Cincinnati Sub-Zero 33W and Hemotherm, and Terumo HX2 - MDR
2016-5012	06/14/2016 07/13/2016	FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/	Elisa Burger SPI Pharma, Inc.	PARTICLE DYNAMICS INTERNATIONAL, LLC, BRENTWOOD, MO - EIR 05/01/2011 - 05/31/2011
2016-5013	06/14/2016 07/13/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K052596
2016-5014	06/15/2016 07/14/2016	FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/	Carla Smith Clear Lake Bakery- Michaels Cookies	CLEAR LAKE BAKERY, SOUTH CLEAR LAKE, IA - EIR 11/01/2015 - 06/04/2016
2016-5015	06/15/2016 07/14/2016	FDA/OFVM/CFSAN/OCD/EOS/	Jennifer Hastings General Mills- QRO	BURZACO MANUFACTURING, BUENOS AIRES, ARGENTINA - EIR, 483 12/01/2015 - 04/30/2016
2016-5016	06/15/2016 07/14/2016	FDA/OC/OES/DFOI/	Catherine Geyman Epic Risk Solutions Ltd	TEVA PHARMACEUTICAL WORKS PRIVATE LIMITED, HUNGARY - EIR, 483 PREVIOUSLY RELEASED 01/01/2014 - 06/11/2016
2016-5017	06/15/2016 07/15/2016	FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/	Jing Liang Jing Liang	ZS PHARMA, ASTRAZENACA COPPELL, TX - RESPONSE TO 483 03/04/2016 - 06/11/2016
2016-5018	06/15/2016 07/14/2016	FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORR/SW-FO/DEN-DO/DEN-CB/ FDA/OC/OES/DFOI/	Jing Liang Jing Liang	ZS PHARMA, ASTRAZENACA, BOULDER, CO; COPPELL, TX - 483, WARNING LETTERS, CONSENT DECREE ETC 03/01/2016 - 06/11/2016
2016-5019	06/15/2016 07/14/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Gina Nellesen Fish & Richardson P.C.	AVASTIN, LUCENTIS, EYLEA - US PATENTS
2016-5020	06/15/2016 07/14/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	pascal besman Pascal Besman	SAVAYSA - AERS

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2016-5021	06/15/2016 07/14/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	pascal besman Pascal Besman	ELIQUIS - AERS
2016-5022	06/15/2016 07/14/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	pascal beman Pascal Besman	XARELTO - AERS
2016-5023	06/15/2016 07/14/2016	FDA/OC/OES/DFOI/	Bonnie Fletcher Price FINNEGAN HENDERSON ET AL	Certified copies of Medical Review and Pharmacology Review for New Drug Application 20-791
2016-5024	06/16/2016 07/15/2016	FDA/OC/OES/DFOI/	Kristina Niehoff VA	SOURCE OF STATISTIC
2016-5025	06/16/2016 07/15/2016	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	Alexandra Ajmo LIFE EXTENSION	GOOD SUPER FOODS LLC, GARDEN CITY, ID - EIR 01/01/2011 - 06/02/2016
2016-5026	06/16/2016 07/15/2016	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Alexandra Ajmo LIFE EXTENSION	MASTIX MEDICA, HUNT VALLEY, MD - EIR 01/01/2012 - 06/02/2016
2016-5027	06/16/2016 07/15/2016	FDA/OFVM/CFSAN/OCD/EOS/	John Stevenson Levy Konigsberg	TESTING ON TALC POWDER BY CTFA, MEMOS, ETC
2016-5028	06/16/2016 07/15/2016	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ OC/ORA/ OC/ORA/	Anthony Roberts Anthony Roberts	COMMUNICATIONS, RECS BETWEEN NJ-DO CCC AND J. TRANKLE, NCCC RE SALE OF CREATINE NITRATE 01/02/2015 - 06/13/2016
2016-5029	06/16/2016 07/15/2016	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Alexandra Ajmo LIFE EXTENSION	CLIENTELE, INC, SURISE, FL - EIR 01/01/2012 - 06/02/2016
2016-5030	06/16/2016 07/15/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K111068
2016-5031	06/16/2016 07/15/2016	FDA/OC/OES/DFOI/	Christian Blank Singer Legal Group	NOVASURE MAUDE REPORT 06/07/2013 - 12/31/2013
2016-5032	06/16/2016 07/15/2016	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Alexandra Ajmo LIFE EXTENSION	UNIQUE ENCAPSULATION TECHNOLOGY, LANDING, NJ - EIR 01/01/2013 - 06/02/2016
2016-5033	06/16/2016	FDA/OC/OES/DFOI/	Gary Stoller	UNIVERSITY OF CONNECTICUT INSPECTION RECS 01/01/2014 - 06/10/2016

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	07/15/2016		CONNECTICUT HEALTH INVESTIGATIVE TEAM	
2016-5034	06/16/2016 07/15/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jay Shah Maine Medical Center	SULFASALAZINE AERS
2016-5035	06/16/2016 07/15/2016	FDA/OMPT/CDRH/OCE/DID/	Ron Jeffrey CAS Medical Systems, Inc.	K160526
2016-5036	06/16/2016 07/15/2016	FDA/OGROP/ORAP/FO/LOS-DO/LOS-CB/ OC/ORAP/OCI/ OC/ORAP/OCI/	Erin M. Carrillo, Attorney The Carrillo Law Firm, PLLC	NUTEC INTERNATIONAL LLC, NUMED LLC, GUSTAVO FELIX NUNEZ - INSPECTIONS ETC 01/01/2007 - 06/01/2016
2016-5037	06/16/2016 07/15/2016	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORAP/SE-FO/ATL-DO/ATL-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/ORAP/OCI/ OC/ORAP/OCI/	Anthony Roberts Anthony Roberts	PIRACETAM - EMAILS RE WARNING LETTER, ETC 01/01/2004 - 06/13/2016
2016-5038	06/16/2016 07/15/2016	FDA/OMPT/CDRH/OCE/DID/	FDA1521185 L.W. Ward and Associates, Inc.	RADIOCHROMIC - INVESTIGATION RESULTS
2016-5039	06/16/2016 07/15/2016	FDA/OMPT/CDRH/OCE/DID/	THOMPSON, RAY	MEKO, SARSTEDT, GERMANY; PFM MEDICAL TITANIUM GMBH, NUREMBERG, GERMANY; TROKAMED GMBH, GEISINGEN, GERMANY -483
2016-5040	06/16/2016 07/15/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jaya Ayyagari Dr. Reddy's Laboratories Inc.	DMF 14428 DEFICIENCY LETTER ETC
2016-5041	06/16/2016 07/15/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ari Altstedter BLOOMBERG NEWS	LUPIN LTD, INDIA - 483 06/12/2015 - 06/13/2016
2016-5042	06/16/2016	FDA/OMPT/CDER/GRP/DIDP/		KING BRAND HEALTHCARE PRODUCTS LTD,

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	07/15/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCE/DID/	THOMPSON, RAY	COLLINGWOOD, CANADA; AB SCIEX, CONCORD, CANADA; EAU ZONE HUILES ET FRAGRANCES LTEE, MONTREAL, CANADA - 483
2016-5043	06/16/2016 07/15/2016	FDA/OGROP/ORR/PA-FO/LOS- DO/LOS-CB/	Alexandra Ajmo LIFE EXTENSION	ASEPTIC SOLUTIONS USA, LLC DBA FLAVOR ARTISTRY, CORONA, CA - EIR 01/01/2011 - 06/02/2016
2016-5044	06/16/2016 07/15/2016	FDA/OMPT/CDRH/OCE/DID/	THOMPSON, RAY	DORO INC, OTTAWA, CANADA; AVMOR, LAVAL, CANADA; LAC MAC, LONDON, CANADA - 483
2016-5045	06/16/2016 07/15/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Melissa V. Malapit Celgene Corporation	THIERRY FACON HOSPITAL C, FRANCE - EIR 09/04/2014 - 06/13/2016
2016-5046	06/16/2016 07/15/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jing Zou AiPing Pharmaceutical Inc.	Impurity Analytical Procedures for the Benzonatate RLD
2016-5047	06/16/2016 07/27/2016	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDRH/OCE/DID/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	THOMPSON, RAY	CRYSTAL CLAIRE COSMETICS INC, EAST YORK, CANADA; CUSTOM FOAM SYSTEMS LTD, KITCHENER, CANADA; JUBILANT HOLLISTER STIER GENERAL, KIRKLAND, CANADA - 483
2016-5048	06/16/2016 07/15/2016	FDA/OGROP/ORR/SW-FO/KAN- DO/KAN-CB/	Diane W Mueller EAG INC d.b.a. Chemir	EAG INC DBA CHEMIR, MARYLAND HEIGHTS, MO - RESPONSE TO OBSERVATIONS 08/22/2014
2016-5049	06/16/2016 08/19/2016	FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OO/OHR/	Michael Pearlman Michael Pearlman	Email Records.
2016-5050	06/16/2016 07/15/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	THOMPSON, RAY	MYLAN LABORATORIES LTD, PITHAMPUR, INDIA; SGS INDIA PRIVATE LTD, NAVI MUMBAI, INDIA; AMOLI ORGANICS PVT LTD, VAPI, INDIA - 483

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2016-5051	06/16/2016 07/15/2016	OC/ORА/ORM/ OC/ORА/ORM/	Kris Christian FDAZILLA	LIST OF INSPECTION CITATIONS
2016-5052	06/16/2016 07/15/2016	FDA/OMPT/CDRH/OCE/DID/	THOMPSON, RAY	IONISOS SAS, DAGNEUX, FRANCE; LABORATORIES MERCK SHARP & DOHME CHIBRET MIRABEL, RIOM, FRANCE; INEX SILICONE, PUISUEX LE HAUBERGER, FRANCE - 483
2016-5053	06/16/2016 07/15/2016	FDA/OFVM/CFSAN/OCD/EOS/	Silvia Ulm BURDOCK GROUP	ULTRAVIOLET COW/BOVINE MILK - REGULATORY STATUS, CONSUMPTION, SAFETY INFORMATION
2016-5054	06/16/2016 07/15/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K151321
2016-5055	06/16/2016 07/15/2016	FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/	Debashis Mohanty Lupin Pharmaceuticals, Inc.	LUPIN PHARMACEUTICALS, INDIA - EIR APRIL 2015
2016-5056	06/16/2016 07/15/2016	OC/ORА/ORM/ OC/ORА/ORM/	THOMPSON, RAY	GMP, GLP, GCP INSPECTIONS 3/1/16 TO 6/1/16
2016-5057	06/16/2016 07/15/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K022845
2016-5058	06/16/2016 07/15/2016	FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/	IRA WEISBERG Amherst Pharmaceuticals	ZOLPIMIST ORAL SPRAY NDA 022196 ANNUAL REPORTS
2016-5059	06/16/2016 07/15/2016	FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/	Scott Goldman Hyman, Phelps & McNamara P.C.	Fluocinonide Cream, 0.05%, submitted by Taro NDA
2016-5060	06/16/2016 07/15/2016	FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/ FDA/OMPT/CDER/ОРP/DIDP/	Scott Goldman Hyman, Phelps & McNamara P.C.	NDA 019117
2016-5061	06/16/2016 07/15/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Laura Groth Northwestern Medicine Lake Forest Hospital	Allosource Human Cell and Tissue Establishment Registration letter for 2009, 2010, 2011 01/01/2009 - 12/31/2011
2016-5062	06/16/2016 07/15/2016	OC/ORА/OCI/ OC/ORА/OCI/	ANTHONY ROBERTS MUCKROCK	XINLI LI, SHANHAI, CHINA - RECS

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2016-5063	06/16/2016 07/15/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	CASE NUMBERS 3039224 ; 3312293 ; 3537412 ; ETC
2016-5064	06/16/2016 07/15/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-3831 - REQUEST LETTER ONLY
2016-5065	06/16/2016 07/15/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEN REID WASHINGTON INFORMATION SOURCE	LERNAPHARM, SAINT LAURENT, QC - 483, EIR
2016-5066	06/16/2016 07/15/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-3848 - REQUEST LETTER ONLY
2016-5067	06/16/2016 07/15/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-3739 - REQUEST LETTER ONLY
2016-5068	06/16/2016 07/15/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-4249 - REQUEST LETTERS ONLY
2016-5069	06/16/2016 07/15/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-4238 - REQUEST LETTERS ONLY
2016-5070	06/16/2016 07/15/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-4130 - REQUEST LETTERS ONLY
2016-5071	06/16/2016 07/15/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-4127 - REQUEST LETTERS ONLY
2016-5072	06/16/2016 07/15/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-4083 - REQUEST LETTERS ONLY
2016-5073	06/16/2016 07/15/2016	FDA/OGROP/ORO/SE-FO/SJN- DO/SJN-CB/ FDA/OGROP/ORO/SW-FO/DAL- DO/DAL-CB/	WAYNE SADOWSKI NOVARTIS PHARMACEUTICAL CORPORATION	MOHAMED FAISAL KHAN, MD, OKLAHOMA CITY, OK 3/10- 16/15; DR CARLOS PANTOJAS, SAN JUAN, PR 2/10-23/15 - 482, 483, EIR
2016-5074	06/16/2016 07/15/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-4055 - REQUEST LETTERS ONLY
2016-5075	06/16/2016 07/15/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-3973, 2016-3974 - REQUEST LETTERS ONLY
2016-5076	06/16/2016 07/15/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-4509 - REQUEST LETTER ONLY

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2016-5077	06/16/2016 07/15/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-4489 - REQUEST LETTER ONLY
2016-5078	06/16/2016 07/15/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-4478 - REQUEST LETTER ONLY
2016-5079	06/16/2016 07/15/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-3952 - REQUEST LETTER ONLY
2016-5080	06/16/2016 07/15/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-4267 - REQUEST LETTERS ONLY
2016-5081	06/16/2016 07/15/2016	FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/	WAYNE SADOWSKI NOVARTIS PHARMACEUTICAL CORPORATION	DR KEITH ROBINSON, OAKLAND PARK, FL - 482, 483, EIR 6/23 TO 7/3/14
2016-5082	06/16/2016 07/15/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-4407 - REQUEST LETTER ONLY
2016-5083	06/16/2016 07/15/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-4280 - REQUEST LETTERS ONLY
2016-5084	06/16/2016 07/15/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-4331 & 2016-4332 - REQUEST LETTERS ONLY
2016-5085	06/16/2016 07/15/2016	FDA/OFVM/CFSAN/OCD/EOS/	RANI M. THOMAS NOVARTIS PHARMACEUTICAL CORPORATION	USE OF CARBON IN FOOD & FEEDS
2016-5086	06/16/2016 07/15/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FATHY, RAMIE	DRUGS WITHDRAWN FROM MARKET 2000-2016
2016-5087	06/16/2016 07/15/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DON J. MIZERK HUSCH BLACKWELL LLP	PAR PHARM INC (DEXTROAMPHETAMINE SACCHARATE) ANDA 06-159 APRVL
2016-5088	06/16/2016 08/09/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	MICHAEL MANCINELLI CONWAY HOMER & CHIN-CAPLAN PC	INDIVIDUAL RECS
2016-5089	06/16/2016 07/15/2016	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SE-FO/FLA-	Doe J	CMPLNT 145241

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		DO/FLA-CB/ FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/		
2016-5090	06/17/2016 07/18/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K071132
2016-5091	06/17/2016 07/18/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jann Kochel Velicept Therapeutics, Inc.	IND 71,412
2016-5092	06/17/2016 07/18/2016	FDA/OMPT/CDRH/OCE/DID/	Luke Huang Televere Systems LLC	K113449 K142718
2016-5093	06/17/2016 07/18/2016	FDA/OMPT/CDRH/OCE/DID/	robert hill Robert Hill	K121811
2016-5094	06/17/2016 07/18/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lisa Magill Foran Lisa Magill Foran	XARELTO - CLINICAL STUDIES
2016-5095	06/17/2016 07/18/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kiran Kumar Gande Leading Pharma, LLC	NDA 017871
2016-5096	06/17/2016 07/18/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kris Christian Acorda Therapeutics, Inc.	NDA 018651 SBA
2016-5097	06/17/2016 07/18/2016	FDA/OGROP/ORR/NE-FO/NWE-DO/NWE-CB/	Justin Hakala Morgan & Meyers, PLC	SMITH & NEPHEW, INC, ANDOVER, MA - RECS RE 2015 INSPECTION 03/01/2015 - 06/13/2016
2016-5098	06/17/2016 07/18/2016	FDA/OFVM/CFSAN/OCD/EOS/	Kate Wersinger Steptoe & Johnson LLP	FOOD CONTACT MODIFICATIONS 1569, 1600
2016-5099	06/17/2016 07/18/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mike Koehler Mike Koehler	POLYETHYLENE 3350, MIRALAX, GOLYTELY - SUMMARY REPORTS

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2016-5100	06/17/2016 07/18/2016	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2016-4231
2016-5101	06/17/2016 07/18/2016	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2016-4488
2016-5102	06/17/2016 07/18/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anubhav Aggarwal CREDIT SUISSE	AUROBINDO API FACILITY, INDIA - 483 06/01/2016 - 06/14/2016
2016-5103	06/17/2016 07/18/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ali Scrimenti Ali Scrimenti	SGLT2 INHIBITORS 19 CASES AERS
2016-5104	06/17/2016 07/18/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anubhav Aggarwal Credit Suisse First Boston	GLENMARK, GOA, INDIA - 483 06/01/2016 - 06/14/2016
2016-5105	06/17/2016 07/18/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Matthew Katten Citadel Investment Group	CABOMETYX LENVIMA ORKAMBI ETC RAW DATA
2016-5106	06/17/2016 07/18/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Debashis Mohanty Lupin Pharmaceuticals, Inc.	ZAROXOLYN CHANGES IN APPROVED SUPPLEMENT 039
2016-5107	06/17/2016 07/18/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Vinay Bhatt Leading Pharma, LLC	NDA 018714 SBA
2016-5108	06/17/2016 07/18/2016	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	DANNY VOGEL Wilson Elser Moskowitz Edelman & Dicker, LLP	COSMETIC DERMATOLOGY WARNING LTR 12/3/15 - RECS
2016-5109	06/17/2016 07/18/2016	OC/ORR/ OC/ORR/	JOSHUA B SHANCER GOLDBERG WEISMAN ET AL	ZECUITY - CMLNPTS 9/1/15 TO PRESENT

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2016-5110	06/17/2016 07/18/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kyle Jaeger ATTN: FRANK BEAN, STORE MANAGER	FDA LETTER TO DEA RE AGENCY RECOMMENDATION ON THE RESCHEDULING OF MARIJUANA UNDER THE CONTROLLED SUBSTANCES ACT 06/15/2015 - 06/14/2016
2016-5111	06/17/2016 07/18/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bryan Goldsmith Bryan Goldsmith	APADAZ - COMPLETE RESPONSE LETTER
2016-5112	06/17/2016 07/18/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	John Walsh James Alexander Corporation	JINZHOU JIUTAI PHARMACEUTICAL CO LTD, RAMDEV CHEMICALS PVT LTD, DISHMAN PHARMACEUTICALS AND CHEMICALS LIMITED ETC - EIR, 483, 482 ETC 06/01/2012 - 06/14/2016
2016-5113	06/17/2016 07/18/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	ZS-9 COMPLETE RESPONSE LETTER
2016-5114	06/17/2016 07/18/2016	FDA/OMPT/CDRH/OCE/DID/	HEATHER M BONNET-HEBERT Mandell, Schwartz & Boisclair	BOSTON SCIENTIFIC - GENESYS HTA SYS CONTROL UNIT, GENESYS HTA PROCERVA PROCEDURE SHEATH - MDR
2016-5115	06/17/2016 07/18/2016	FDA/OGROP/ORR/SE-FO/ATL- DO/ATL-CB/	Jeremy A. Gottlieb CORPORATE RESOLUTIONS INC	DANIEL SHAPIRO REPRODUCTIVE BIOLOGY ASSOCIATES, ATLANTA, GA - 48306/01/2012 - 01/01/2014
2016-5116	06/17/2016 07/18/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Charles Snow Hyman, Phelps & McNamara, P.C.	FDA DETERMINATIONS, MEMOS RE DECISION TO AWARD PERIODS OF 180 DAY EXCLUSIVITY FOR DOXYCYCLINE HYCLATE DELAYED RELEASE TABLETS ANDA 090431 AND SUPPLEMENTS
2016-5117	06/17/2016 07/18/2016	FDA/OMPT/CDRH/OCE/DID/	LISA K HOWARD Segal McCambridge Singer & Mahoney	REX MEDICAL LP, ARGON MEDICAL DEVICES INC - OPTION RETRIEVABLE VENA CAVA FILTER, OPTION ELITE RETRIEVABLE INFERIOR VENA FILTER RPTS, CLNCL STUDIES, CMLPNTS, ETC
2016-5118	06/17/2016 07/18/2016	FDA/OFVM/CFSAN/OCD/EOS/	KEVIN S FRIES COSMETIC INGREDIENT REVIEW	AMMONIUM PERSULFATE, POTASSIUM PERSULFATE, SODIUM PERSULFATE - VOLUNTARY COSMETIC REGISTRATION PROGRAM RECS
2016-5119	06/17/2016 07/18/2016	FDA/OC/OES/DFOI/ OC/ORR/ OC/ORR/	BRIAN PATRICK BYRNE Vocativ.com	FOODS, DRUGS, BIOLOGICS, MEDICAL DVCS, ELECTRONIC PRODUCTS THAT GIVE OFF RADIATION; COSMETICS, VETERINARY PRODUCTS, TOBACCO PRODUCTS ADVERTISEMENTS ON INSTAGRAM, TWITTER, FACEBOOK AND SNAPCHAT - CMLPNTS 1/14 TO 5/16

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2016-5120	06/17/2016 07/18/2016	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	K MICHELLE VASSALLO Lincare Holdings	ATLANTIC MEDICAL LLC, MS - EIRS, 483S, WARNING LTRS 1/98 TO PRESENT
2016-5121	06/17/2016 07/18/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DDM/	Qi Cheng Aleon Pharm International	Cefixime chewable tablet Suitability petition package (application No.: 04P-0263)
2016-5122	06/17/2016 07/18/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rose Santos FOIA GROUP INC	RECS RE ADDITION OF WARNING TO LABEL OF PRESCRIPTION AND OTCC IBUPROFREN PRODUCTS ABOUT SEVERE ALLERGIC REACTION, ETC
2016-5123	06/17/2016 07/18/2016	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	K MICHELLE VASSALLO Lincare Holdings	MAVERICK HEALTHCARE HOLDINGS II INC, MAVERICK HEALTHCARE GROUP LLC, FOUNDERS HEALTHCARE LLC, LIFECARE SOLUTIONS INC, ETC - EIRS, 483S, WARNING LTRS 1/98 TO PRESNET
2016-5124	06/17/2016 07/18/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELENA HOWELL CLARK HOGAN LOVELLS US LLP	ABBOTT - VICODIN (ACETAMINOPHEN, HYDROCODONE BITARTRATE) NDA 85-667 APRVL RECS
2016-5125	06/17/2016 07/18/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DDM/	ELENA HOWELL CLARK HOGAN LOVELLS US LLP	MIKART - HYDROCODONE BITARTRATE, ACETAMINOPHEN TABS SUITABILITY PETITION, FDA RESP
2016-5126	06/17/2016 07/18/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELENA HOWELL CLARK HOGAN LOVELLS US LLP	ABBVIE - VICODIN (ACETAMINOPHEN, HYDROCODONE BITARTRATE) NDA 88-058 APRVL RECS
2016-5127	06/17/2016 07/18/2016	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	DIANE MUELLER CHEMIR-EAG INC	CHEMIR-EAG INC - CO RESP 8/20/14
2016-5128	06/17/2016 07/18/2016	FDA/OC/OES/DFOI/	JOHN C RICHTER KING & SPALDING	ABIOMED INC - RECS
2016-5129	06/20/2016 07/19/2016	FDA/OC/OES/DFOI/	david jjean david jjean	LINK TO MAUDE REPORTS

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2016-5130	06/20/2016 07/19/2016	FDA/OC/OES/DFOI/	Tonya Cole PharmIntell	ZIMMER BIOMET, ORTHOSOFT, ZIMMER CAS - WARNING LETTER 01/01/2016 - 06/15/2016
2016-5131	06/20/2016 07/19/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Walter G. Jump, Pharm.D. CORNERSTONE REGULATORY	DRUG APPROVAL DATABASE MISSING DATA
2016-5132	06/20/2016 07/19/2016	OC/ORA/OCI/ OC/ORA/OCI/	Anthony Roberts Anthony Roberts	EMAILS RE RON KRAMER, THERMOLIFE 01/01/2008 - 01/04/2013
2016-5133	06/20/2016 07/19/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K083103
2016-5134	06/20/2016 07/19/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K061232
2016-5135	06/20/2016 07/19/2016	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/ORO/DIOP/	Zetetic, Inc. Zetetic, Inc.	FDA ENTRY DOCUMENTATION REQUEST ALL DOCUMENTATION JUNE 01, 2016 JUNE 15, 2016
2016-5136	06/20/2016 07/19/2016	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ OC/ORA/OCI/ OC/ORA/OCI/	Anthony Roberts Anthony Roberts	RON KRAMER - INVESTIGATION RECS 01/05/2007 - 01/04/2013
2016-5137	06/20/2016 07/19/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lily Huang Evergreen	KO DA PHARMACEUTICAL CO, TAIWAN - EIR 05/25/2015 - 05/31/2016
2016-5138	06/20/2016 07/19/2016	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Craig Giammona BLOOMBERG NEWS	COMMUNICATIONS BETWEEN FDA AND WHOLE FOOD MARKET IN RE INSPECTIONS IN MASSACHUSETTS IN FEB 2016 01/01/2016 - 06/15/2016
2016-5139	06/20/2016 07/19/2016	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	Tom Harmon The Privatebank	PARTICLE DYNAMICS INTERNATIONAL, ST LOUIS, MO - EIR MOST RECENT 01/01/2015 - 06/15/2016
2016-5140	06/20/2016 07/19/2016	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Erik H. Beck Erik Beck	LETTER WITH ATTACHMENTS FROM WHOLE FOODS MARKET INC TO NEW ENGLAND DISTRICT 03/01/2016 - 03/31/2016
2016-5141	06/20/2016 07/19/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gary Schneider Evidera	FAERS 11271251

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2016-5142	06/20/2016 07/19/2016	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Rebecca Morel Rebecca Morel	FISH OIL ARSENIC INVESTIGATION 12/03/2015 - 12/03/2015
2016-5143	06/20/2016 08/11/2016	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Jesse Newman THE WALL STREET JOURNAL	WHOLE FOODS MARKET INC - INSPECTION RECS FROM COMMISSARY KITCHENS, NORTH ATLANTIC KITCHEN 06/01/2014 - 06/15/2016
2016-5144	06/20/2016 07/19/2016	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDRH/OCE/DID/	Diane Arpino Shenzhen Mindray Biomedical Electronics Co. Ltd	SHENZHEN MINDRAY BIOMEDICAL ELECTRONICS CO LTD, MAHWAH, NJ - EIR 05/01/2015 - 06/15/2016
2016-5145	06/20/2016 07/19/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Amisha Patel Dr. Reddy's Laboratories Inc.	ANDA 205342
2016-5146	06/20/2016 07/19/2016	FDA/OMPT/CDRH/OCE/DID/	Barbara Deay Televere Systems LLC	K141440
2016-5147	06/20/2016 07/19/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K002599
2016-5148	06/20/2016 07/19/2016	FDA/OMPT/CDRH/OCE/DID/	Marilynn Whitney COVINGTON & BURLING LLP	K012530
2016-5149	06/20/2016 07/19/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID KIM Partner Fund Management	LANNETT COINC - COCAINE HCI CORR
2016-5150	06/20/2016 08/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	CHARLES GOLDMAN ESQ	UNICHEM - HYDROCHLOROTHIAZIDE RECALL 5/21/15 TO PRESENT
2016-5151	06/20/2016	FDA/OMPT/CDER/ORP/DIDP/	DAVID HOFFMEISTER	APOTEX ANDA 91-161 RVW

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	07/19/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WILSON SONSINI ET AL	
2016-5152	06/20/2016 07/27/2016	FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	Doe J	ST JUDE MEDICAL - MODEL SN-14679640; LEAD MODEL 3219 SN 3989773 RECALL 8/19/06 TO 6/16/16
2016-5153	06/20/2016 07/19/2016	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FILL FROMS
2016-5154	06/20/2016 07/19/2016	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	Doe J	CMPLNT 144282
2016-5155	06/20/2016 07/19/2016	FDA/OMPT/CDRH/OCE/DID/	DEVON C. BRUCE POWER ROGERS & SMITH PC	CYNOSURE - PICOSURE PICO TATTO REMOVAL CMPLNTS, EFFICACY 1/1/13 TO PRESENT
2016-5156	06/20/2016 07/19/2016	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/ FDA/OGROP/ORA/SE-FO/SJN- DO/SJN-CB/	RICHARD P. CASSETTA BRYAN CAVE LLP	COMBE INC - JUST FOR MEN PRODUCTS AER LAST 10 YEARS
2016-5157	06/20/2016 07/19/2016	FDA/OC/OES/DFOI/	ERIC M. HOLLNAGEL Evergreen Research, Inc	K113351
2016-5158	06/20/2016 07/19/2016	FDA/OMPT/CDRH/OCE/DID/	TRACIE HILL BIOMIMETIC THERAPEUTICS	BIOMETRIC THERAPEUTICS - G010340, P040013 GEM 21S (B-TCP/rhPDGH-BB) FDA CORR
2016-5159	06/20/2016 07/19/2016	FDA/OMPT/CDRH/OCE/DID/	TRACIE HILL BIOMIMETIC THERAPEUTICS	BIOMETRIC THERAPEUTICS - G050118, P100006 AUGMENT BONE GRAFT FDA CORR
2016-5160	06/20/2016 07/19/2016	FDA/OMPT/CDRH/OCE/DID/	TRACIE HILL BIOMIMETIC THERAPEUTICS	BIOMETRIC THERAPEUTICS - G070007, G090133 AUGMENT INJECTIBLE BONE GRAFT
2016-5161	06/20/2016 07/19/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	HICKS, THOMAS	CLNCL TRAIL NCT02235844
2016-5162	06/20/2016 07/19/2016	FDA/OO/OFBA/OAGS/	MICHAEL MAGUIRE HAWAT GROUP ANALYTICS	HISTORICAL FEDERAL PROCUREMENT & CONTRACTING SOLICITATION AND PROTEST ACTIONS
2016-5163	06/20/2016 07/19/2016	FDA/OC/OES/DFOI/	Doe J	UNSPECIFIC
2016-5164	06/20/2016	FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/	CHRISTOPHER J. WATSON	UPMC PRESBYTERIAN HOSPITAL & UPMC MONTEFIORE HOSPITAL - MOLD OUTBREAK 2013 TO PRESENT

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	07/19/2016		DICKIE MCCAMEY & CHILCOTE	
2016-5165	06/20/2016 07/19/2016	FDA/OMPT/CDRH/OCE/DID/	BARBARA LOUISELL PAYNE MITCHELL LAW GROUP	SERI SURGICAL SCAFFOLD APRVL
2016-5166	06/20/2016 07/19/2016	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	AMY ERICKSON HAGEN REPRO TECH LIMITED	FLORIDA INSTITUTE OF REPRODUCTIVE SCIENCES & TECHNOLOGY, WESTON, FL - EIR, 483, WARNING LTR, CO RESP
2016-5167	06/20/2016 07/19/2016	FDA/OFVM/CFSAN/OCD/EOS/	JOAN SYLVAIN BAUGHAN Keller and Heckman LLP	2-METHYL-2-PROPENENITRILE - NO OBJECTION LTR
2016-5168	06/20/2016 07/19/2016	FDA/OO/OHR/ FDA/OC/OES/DFOI/ OC/ORR/ OC/ORR/	GILLIS PATRICK, FLANAGAN	SF 61 & 61B
2016-5169	06/21/2016 07/20/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Terry Enfield Kleinfeld, Kaplan & Becker, LLP	EVER APPROVED DRUG PRODUCTS
2016-5170	06/21/2016 07/20/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mary Olson Mary Olson (Tulane University)	REQUEST LETTERS ISSUED BY FDA FOR DRUGS RECEIVING PEDIATRIC EXCLUSIVITY DETERMINATIONS 06/16/1997 - 06/16/2016
2016-5171	06/21/2016 07/20/2016	FDA/OMPT/OSMP/OOPD/	Elena Howell Clark Hogan Lovells	AMPYRA ORPHAN PRODUCT DESIGNATION RECS
2016-5172	06/21/2016 07/20/2016	FDA/OMPT/CDRH/OCE/DID/	Sherrie Coval-Goldsmith CSA Medical	CPT1600212
2016-5173	06/21/2016 07/20/2016	OC/CVM/OCD/	Jennifer Kelley Virbac AH, Inc.	INAD 010104
2016-5174	06/21/2016 07/20/2016	FDA/OMPT/CDRH/OCE/DID/	Taneli Vrnemi Mega Electronics Ltd	K152701 K160064 K142743
2016-5175	06/21/2016 07/20/2016	FDA/OO/OHR/	Eyal Maor FDAAWARE	CARLA J LUNDI - CV
2016-5176	06/21/2016 07/20/2016	FDA/OO/OHR/	Anna Edney BLOOMBERG NEWS	LIST OF EMPLOYEES IN OFFICE OF GENERIC DRUGS
2016-5177	06/21/2016 07/20/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Katherine Kaempchen Forward Pharma Gmbh- Katherine	1134395; 11433938; 11685946; ETC

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kaempchen	
2016-5178	06/21/2016 07/20/2016	FDA/OFVM/CFSAN/OCD/EOS/	Cathryn Sacra EAS Consulting Group, LLC	GRN 464
2016-5179	06/21/2016 07/20/2016	FDA/OFVM/CFSAN/OCD/EOS/	Cathryn Sacra EAS Consulting Group, LLC	GRN 465
2016-5180	06/21/2016 07/20/2016	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORACE-FO/MIN- DO/MIN-CB/ FDA/OGROP/ORASE-FO/FLA- DO/FLA-CB/ FDA/OGROP/ORASW-FO/DEN- DO/DEN-CB/ FDA/OGROP/ORASE-FO/NOL- DO/NOL-CB/ FDA/OGROP/ORASW-FO/DEN- DO/DEN-CB/ FDA/OGROP/ORAPA-FO/SAN- DO/SAN-CB/ OC/OR/ OC/OR/	Michael J. Barton Plunkett Cooney	UNITED NATURALS, LIGHTHOUSE ENTERPRISES, VIVA BOTANICALS ETC - CONSENT DECREES, ACTION LETTERS ETC 01/07/2012 - 06/16/2016
2016-5181	06/21/2016 07/20/2016	FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/	Michael Cappetta NBC NEWS	WHOLE FOODS WARNING LETTER - PHOTOS, VIDEOS
2016-5182	06/21/2016 07/20/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	INDIVIDUAL RECS
2016-5183	06/21/2016 07/20/2016	FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/	Shiyao Ling RBC CAPITAL MARKETS	WHOLE FOODS MARKET, EVERETT, MA - 483, RESPONSE
2016-5184	06/21/2016 07/20/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Eric Evans Orchard View Capital Advisors LP	NDA 001504
2016-5185	06/21/2016 07/20/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	PATRICK KELLY CONWAY HOMER & CHIN-	INDIVIDUAL RECS

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2016-5186	06/21/2016 07/20/2016	FDA/OMPT/CDRH/OCE/DID/	DEBRA R TOMLINSON BACON THORNTON & PALMER LLP	BIOMET INC - VANGUARD SSK INTERIOK FEMORAL JWH (POSTERIOR STABILIZED KNEE SYS); VANGUARD COMPLETE KNEE SYS K113550
2016-5187	06/22/2016 07/21/2016	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	TOLMAR, FORT COLLINS, CO - EIR, 483, RESPONSE 06/01/2015 - 06/18/2015
2016-5188	06/22/2016 07/21/2016	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Chalkley Walter THOMSON REUTERS (SCIENTIFIC) SAS	TEVA PHARMACEUTICALS USA, SELLERSVILLE, PA - EIR, 483, RESPONSE 06/01/2013 - 06/05/2013
2016-5189	06/22/2016 07/21/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K092090
2016-5190	06/22/2016 07/21/2016	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	WATSON LABORATORIES, CORONA, CA - 483, EIR, RESPONSE 11/01/2014 - 12/08/2014
2016-5191	06/22/2016 07/21/2016	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	CELSUS LABORATORIES, CINCINNATI, OH - 483, EIR, RESPONSE 11/01/2014 - 11/14/2014
2016-5192	06/22/2016 07/21/2016	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	BAXTER HEALTHCARE CORPORATION, IRVINE, CA - 483, EIR, RESPONSE 06/01/2013 - 06/05/2013
2016-5193	06/22/2016 07/21/2016	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	MEDTECH PRODUCTS, TARRYTOWN, NY - 483, EIR, RESPONSE 08/01/2015 - 08/24/2015
2016-5194	06/22/2016 07/21/2016	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	BAXTER HEALTHCARE OF PUERTO RICO, GUAYAMA, PR - 483, EIR, RESPONSE 02/01/2015 - 02/06/2015
2016-5195	06/22/2016 07/21/2016	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	LYON CAROLINE, MD, UNIVERSITY OF VERMONT COLLEGE OF MEDICINE - 483, EIR, RESPONSE 12/21/2015 - 01/06/2016
2016-5196	06/22/2016 07/21/2016	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Walter Chalkley THOMSON REUTERS	NEXGEN PHARMA, ROSENBERG, TX - 483, EIR, RESPONSE 05/01/2015 - 05/29/2015
2016-5197	06/22/2016 07/21/2016	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	AKORN, INC, DECATUR, IL - 483, EIR, RESPONSE 06/01/2014 - 06/06/2014
2016-5198	06/22/2016	FDA/OGROP/ORAPA-FO/SEA-	Walter Chalkley	MICHAEL RECHT, MD, PORTLAND, OR - 483, EIR,

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	07/21/2016	DO/SEA-CB/	THOMSON REUTERS (SCIENTIFIC) SAS	RESPONSE 03/01/2013 - 03/25/2013
2016-5199	06/22/2016 07/21/2016	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	KOBAYASHI, ROGER, MS , PAPILLION, NE - 483, EIR, RESPONSE JAN 2016
2016-5200	06/22/2016 07/21/2016	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	JAMES L BORDERS, MD, LEXINGTON, KY - 483, EIR, RESPONSE 04/01/2014 - 04/04/2014
2016-5201	06/22/2016 07/21/2016	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Walter Chalkley THOMSON REUTERS	ACTAVIS PLC, JERSEY CITY, NJ - 483, EIR, RESPONSE 02/01/2012 - 02/14/2012
2016-5202	06/22/2016 07/21/2016	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	CITRA LABS, BRAINTREE, MA - 483, EIR, RESPONSE 11/01/2014 - 11/21/2014
2016-5203	06/22/2016 07/21/2016	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	BRISTOL MEYERS SQUIBB, PRINCETON, NJ - 483, EIR, RESPONSE 04/01/2012 - 04/05/2012
2016-5204	06/22/2016 07/21/2016	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Walter Chalkley THOMSON REUTERS	BASF CORPORATION, BISHOP, TX - 483, EIR, RESPONSE 10/01/2013 - 10/25/2013
2016-5205	06/22/2016 07/21/2016	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	PHYSIO-CONTROL, REDMOND, WA - 483, EIR, RESPONSE 06/01/2015 - 06/26/2015
2016-5206	06/22/2016 07/21/2016	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	NUVASIVE, GUAYNABO, PR - 483, EIR, RESPONSE 02/01/2014 - 02/11/2014
2016-5207	06/22/2016 07/21/2016	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Chalkley Walter THOMSON REUTERS (SCIENTIFIC) SAS	PERRIGO COMPANY, ALLEGAN, MI - 483, EIR, RESPONSE 11/01/2013 - 11/07/2013
2016-5208	06/22/2016 07/21/2016	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	MYLAN, CAGUAS, PR - 483, EIR, RESPONSE 05/01/2015 - 05/22/2015
2016-5209	06/22/2016 07/21/2016	FDA/OMPT/CDRH/OCE/DID/	Dr. Yossi Muncher Eximo Medical Ltd.	K040067 K043465
2016-5210	06/22/2016 07/21/2016	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	ENCOMPAS UNLIMITED, SARASOTA, FL - 483, EIR, RESPONSE 11/01/2014 - 11/18/2014
2016-5211	06/22/2016	FDA/OMPT/CDER/ORP/DIDP/	Gaurav Tinani	AUROBINDO, INDIA - EIR 01/04/2016 - 06/30/2016

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	07/21/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Emkay Global	
2016-5212	06/22/2016 07/21/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michael Monahan ACADIA Pharmaceuticals Inc.	Complaint #5450 referenced in the last paragraph of Section II in the NUPLAZID Clinical Inspection Summary dated 09 March 2016 from Cara Alfaro, PharmD to Brendan Muoio, PharmD for NDA 207318
2016-5213	06/22/2016 07/21/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ted Keller EverPoint Asset Management	NUPLAZID - AERS
2016-5214	06/22/2016 07/21/2016	FDA/OO/OHR/	Thomas Murphy Thomas Murphy	FDA-CDER-16-MP-1583884MH
2016-5215	06/22/2016 07/21/2016	FDA/OMPT/CDRH/OCE/DID/	Steve Dowell DePuy Synthes Spine	ZIMMER BIOMET CAS/ORTHOISOFT, MONTREAL, QUEBEC, CANADA - WARNING LETTER, RESPONSE 05/15/2016 - 06/15/2016
2016-5216	06/22/2016 07/21/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John Birrenbach The Institute for Cannabis	FDA-2011-P-0671 CDER COMMUNICATIONS
2016-5217	06/22/2016 07/21/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MAYUR TIPNIS MAYUR TIPNIS	TEVA PHARMACEUTICALS GENERIC EPI-PEN COMPLETE RESPONSE LETTER
2016-5218	06/22/2016 07/21/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	BENZAEPRIIL - AERS
2016-5219	06/22/2016 07/21/2016	FDA/OGROP/ORP/SW-FO/KAN-DO/KAN-CB/	Joy Prislinger BioLife Plasma Services L.P.	BIOLIFE PLASMA, DUBUQUE, IA - EIR 05/11/2015 - 05/12/2015
2016-5220	06/22/2016 07/21/2016	FDA/OGROP/ORP/SE-FO/ATL-DO/ATL-CB/	Julia Fisher PFIZER	PFIZER, ROCKY MOUNT, NC - EIR 06/03/2014 - 06/17/2016
2016-5221	06/22/2016 07/21/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	LUPRON, LUPRON DEPOT, ETC - AERS

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2016-5222	06/22/2016 07/21/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mildred Menos The Life Raft Group	SUN PHARMACEUTICALS WARNING LETTER - RESPONSE, FOLLOW UP 12/17/2015 - 06/17/2016
2016-5223	06/22/2016 07/21/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Paul Lipkin Paul Lipkin	AFRIN - AERS
2016-5224	06/22/2016 07/21/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Vincent J. Ricci Folger Hill Asset Management	INSYS THERAPEUTICS SPEAKER PROGRAM FOR SUBSYS RECS
2016-5225	06/22/2016 07/21/2016	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/ FDA/OGROP/ORO/ORO/DIOP/	Baikal Herbs, Ltd. Abady Law Firm, P.C.	BAIKAL HERBS - RECS RE PETITION TO REMOVE FROM DETENTIONS
2016-5226	06/22/2016 07/21/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SHERIEF MORSY, Esq. FARUQI & FARUQI LLP	LES LABORATORIES SERVIER; XOMA CORP - RECS
2016-5227	06/22/2016 07/21/2016	FDA/OC/OES/DFOI/	SHERIEF MORSY, Esq. FARUQI & FARUQI LLP	LES LABORATORIES SERVIER; XOMA CORP - CLNCL TRIALS, PROTOCOLS, ETC
2016-5228	06/22/2016 07/21/2016	FDA/OGROP/ORO/CE-FO/NWJ-DO/NWJ-CB/	RYAN KATH WBZ TV 4/CBS BOSTON	NABISCO, NJ - EIR 2/9/15
2016-5229	06/22/2016 09/15/2016	FDA/OFVM/CFSAN/OCD/EOS/	JENNIFER HASTINGS GENERAL MILLS	BURZACO MANUFACTURING, BUENOS AIRES, ARGENTINA - EIR, 483 1/25/16
2016-5230	06/23/2016 07/22/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Lee Padgett Lee Padgett	STEPHEN GOLDFINCH, YAIR ADERETH, CALEDONIA CONSULTING CO - LICENSE TO MANUFACTURE AND SELL UMBILICAL STEM CELLS 02/01/2006 - 11/30/2008
2016-5231	06/23/2016 07/22/2016	FDA/OMPT/CDRH/OCE/DID/	Noelle Law Noelle Law	BIOTRONIK SE & CO KG, GERMANY - 483 03/07/2016 - 03/10/2016
2016-5232	06/23/2016	FDA/OGROP/ORO/NE-FO/NWE-	Ria Misra	WHOLE FOODS NORTH ATLANTIC KITCHEN -

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	07/22/2016	DO/NWE-CB/	Gizmodo / Gawker Media	INVESTIGATION, CORR 07/01/2015 - 06/20/2016
2016-5233	06/23/2016 07/22/2016	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	Manish Bhatt Colgate Palmolive	COLGATE PALMOLIVE, MORRISTOWN, TN - EIR 04/18/2016 - 06/20/2016
2016-5234	06/23/2016 07/22/2016	FDA/OMPT/CDRH/OCE/DID/	Sam Shaban Bio American Worldwide	K143527
2016-5235	06/23/2016 07/22/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	ANDA 200936
2016-5236	06/23/2016 07/22/2016	FDA/OMPT/CDRH/OCE/DID/	Mercedes McClintic MICROAIRE SURGICAL INSTRUMENTS	K072684 K102219
2016-5237	06/23/2016 07/22/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sandy Lee, B&H Consulting Services, Inc. B&H Consulting Services, Inc.	LABORATORIO REIG JOFRE SA, BARCELONA, SPAIN - 483 05/01/2015 - 06/20/2016
2016-5238	06/23/2016 07/22/2016	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Rachel Johnson FOI Services, Inc.	AKORN, IL, NY, NJ - 483
2016-5239	06/23/2016 07/22/2016	FDA/OMPT/CDRH/OCE/DID/	Lee Grant MEDTRONIC SOFAMOR DANEK	K152304
2016-5240	06/23/2016 07/22/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K141620
2016-5241	06/23/2016 07/22/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/CVM/OCD/	Sonya Mann Critical Path Services LLC	PHIBRO SAUDE ANIMAL INTERNACIONAL LTDA AV, BRAZIL - 483 02/29/2016 - 03/04/2016
2016-5242	06/23/2016 07/22/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Christina Jewett The Center for Investigative Reporting	LUPRON, LUPRON DEPOT, ETC - AERS

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-5243	06/23/2016 07/22/2016	FDA/OMPT/CDRH/OCE/DID/	Shaylee Masilunas Philips Respironics, Inc.	K153673
2016-5244	06/23/2016 07/22/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Edward Toke Bjolgerud University of Glasgow	TNF-ALPHA INHIBITORS (ETANERCEPT, INFLIXIMAB, ETC) - AERS
2016-5245	06/23/2016 07/22/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	G. Srinivas Zydus Pharmaceuticals USA Inc.	ANDA 202459
2016-5246	06/24/2016 09/30/2016	FDA/OC/OES/DFOI/	Kris Christian FDAZILLA	PREVIOUSLY RELEASED 483, RESPONSE, EIR 05/12/2016 - 06/13/2016
2016-5247	06/24/2016 07/25/2016	FDA/OC/OES/DFOI/	Samantha Kaplan Doherty & Progar LLC	INVACARE - PREVIOUSLY RELEASED RECS 03/01/2010 - 06/14/2016
2016-5248	06/24/2016 08/09/2016	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/	Joshua Eggnatz Eggnatz, Lopatin, & Pascucci	COTTONELLE, KIMBERLY CLARK, METHYLISOTHIAZOLINONE - LABELING, CORR, COMPLAINTS ETC 01/01/2006 - 06/16/2016;
2016-5249	06/24/2016 07/25/2016	FDA/OGROP/ORO/SW-FO/DEN-DO/DEN-CB/	Dave Hill CEO of BSO, LLC BSO LLC	BSO, LAKEWOOD, CO - INSPECTION RECS, NOTES Date Range: 12/15/2015 - 05/31/2016
2016-5250	06/24/2016 07/25/2016	FDA/OMPT/OSMP/OOPD/	Mayank Dixit Mayank Dixit	SUN PHARMACEUTICALS IND LTD - REQUEST LETTER FOR DESIGNING GEMCITABINE READY TO USE AS ORPHAN DRUG FOR PANCREATIC AND OVARIAN CANCER
2016-5251	06/24/2016 07/25/2016	FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/	Anthony Roberts Anthony Roberts	IRONMAG LABS - TRADE COMPLAINT RECS
2016-5252	06/24/2016 07/25/2016	FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	Austreberto Alvarez jr. Monterey Mushrooms, Inc.	MONTEREY MUSHROOMS INC, WATSONVILLE, CA - 483 01/01/2016 - 04/01/2016
2016-5253	06/24/2016 07/25/2016	FDA/OMPT/CDRH/OCE/DID/	Samantha Baron Boston Consulting Group	Establishment Registration and Medical Device Listing files from 2000-2014
2016-5254	06/24/2016 07/25/2016	FDA/OGROP/ORO/PA-FO/SEA-DO/SEA-CB/ FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/	Stephanie Lee Buzzfeed News	NSPIRED NATURAL FOODS, ASHLAND, OR; OASIS BRANDS, MIAMI, FFL - 483, EIR

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2016-5255	06/24/2016 07/25/2016	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/ FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/ FDA/OMPT/CDRH/OCE/DID/ FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	Arlene Tessitore Arlene Tessitore	LIST OF ELECTROCONVULSIVE THERAPY MACHINES REGULATED; INSPECTION RECS MECTA CORPORATION; SOMATIC, LAKE BLUFF, IL 01/01/1976 - 06/20/2016
2016-5256	06/24/2016 07/25/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Leon Guo Master Herbs USA Inc	CHINA RESOURCES SANJIU MEDICAL AND PHARMACEUTICAL CO LTD - EIR 01/01/2014 - 01/01/2016
2016-5257	06/24/2016 07/25/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anubhav Aggarwal CREDIT SUISSE	LUPIN, GOA, INDIA - INSPECTION CLASSIFICATION 05/01/2016 - 06/21/2016;
2016-5258	06/24/2016 07/25/2016	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Digestive Care, Inc DIGESTIVE CARE, INC.	SCIENTIFIC PROTEIN LABORATORIES, WAUNAKEE, WI - 483 , EIR 09/21/2015 - 06/21/2016;
2016-5259	06/24/2016 07/25/2016	FDA/OMPT/CDRH/OCE/DID/	Jiefeng Xi Celerite Technology	K153479
2016-5260	06/24/2016 07/25/2016	FDA/OMPT/CDRH/OCE/DID/	Jiefeng Xi Celerite Technology	K122217, K133821, K143203
2016-5261	06/24/2016 07/25/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dustin Block IPD ANALYTICS LLC	ANDA 206005 APPROVAL LETTER
2016-5262	06/24/2016 07/25/2016	FDA/OMPT/CDRH/OCE/DID/	Jason Brooke Brooke Consulting, LLC	K153239
2016-5263	06/24/2016 07/25/2016	FDA/OMPT/CDRH/OCE/DID/	Marysa E. Loustalot Hansen Medical	K082385
2016-5264	06/24/2016 07/25/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Christina Chow Brookline Advisors	NDA 022250 CLINICAL PHARMACOLOGY REVIEW
2016-5265	06/24/2016	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson	FCN 1604

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	08/08/2016		FOI Services, Inc.	
2016-5266	06/24/2016 07/25/2016	FDA/OFVM/CFSAN/OCD/EOS/	Tribute Energy, Inc Tribute Energy, Inc	FCN 1056
2016-5267	06/24/2016 07/25/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kenneth B Mackay Dart NeuroScience LLC	CARBIDOPA LEVODOPA SINEMET APPROVAL RECS
2016-5268	06/24/2016 07/25/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Thomas Krol Novadiol	CALDEROL - AERS
2016-5269	06/24/2016 07/25/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dinesh Anugu Insys Therapeutics, Inc.	DURLAZA NDA 200671 SBA
2016-5270	06/24/2016 07/25/2016	FDA/OFVM/CFSAN/OCD/EOS/	KEVIN FRIES COSMETIC INGREDIENT REVIEW	AMMONIUM PERSULFATE, POTASSIUM PERSULFATE, SODIUM PERSULFATE - REPORTING OF USE
2016-5271	06/24/2016 07/25/2016	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	DIANE MUELLER CHEMIR-EAG INC	CHEMIR-EAG INC, CAPITAL HEIGHT, MO - CO RESP 8/20/14
2016-5272	06/24/2016 07/25/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	AARON R RICE BUTLER SNOW LLP	MERCK & CO INC, MERCK RESEARCH LABS - PROPECIA, PROSCAR, FINASTERIDE PERIODIC SAFETY UPDATE RPT
2016-5273	06/24/2016 07/25/2016	FDA/OC/OES/DFOI/	LUKE F CALLAHAN WAGSTAFF & CARTMELL LLP	ATRIUM MEDICAL CORP, MAQUET HOLDING BV & CO KG, MAQUET CARDIOVASCULAR LLC, ETC - EIRS, 483S, CORR, ETC
2016-5274	06/24/2016 07/25/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	NOAH GILLESPIE SCHULTE, ROTH & ZABEL LLP	MALLINCKRODT PAHRS - HP ACTHAR GEL (REPOSITORY CORTICOTROPIN INJ) MARKETING MATERIALS, ADVERTISING, CORR, ETC
2016-5275	06/24/2016 07/25/2016	FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECS; WARTIME MEDICAL DVCS COMPLIANCE, K112924 SUBMISSION RECS, ETC
2016-5276	06/24/2016 07/25/2016	FDA/OC/OES/DDM/	R CLAY MILLING ESQ HENRY SPIEGEL MILLING LLP	DKT 1977N-0094

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2016-5277	06/24/2016 07/25/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	THOMAS M HICKS HICKS, THOMAS	AIDAN FOUNDATION - ALLOGENIC HUMAN UMBILICAL CORD MESENCHYMAL STEM CELLS NCT02235844
2016-5278	06/24/2016 07/25/2016	FDA/OMPT/CDRH/OCE/DID/	BRIGID DECOURSEY BONDOC SIDLEY AUSTIN LLP	ENDOSCOPIC DVCS MFRS - CORR 11/14/11
2016-5279	06/24/2016 07/25/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID L SILBERSTEIN Valeant Pharmaceuticals North America LLC	SOLA BARNES HIND - BENOXINATE HCL OPHTHALMIC SOL ANDA 84-149 RVWS
2016-5280	06/24/2016 07/25/2016	FDA/OMPT/CDRH/OCE/DID/	LISA YEE YEE, LISA	CPT1600379
2016-5281	06/24/2016 07/25/2016	FDA/OC/OES/DFOI/	NATHAN R DUFRENE DUFRENE, NATHAN R	MEDTRONIC - SYNCHROMED II PROGRAMMABLE INFUSION PUMP Cmplnts, MDRs, EIRs, ETC
2016-5282	06/24/2016 07/25/2016	FDA/OFVM/CFSAN/OCD/EOS/	JOHN MARCHANT BUSINESS360 INC	LIST OF INFANT FORMULA MFG PLANTS IN THE US
2016-5283	06/24/2016 07/25/2016	FDA/OMPT/CDRH/OCE/DID/	R O DEAN GUIDELINE MEDICAL	KCI USA - NEGATIVE PRESSURE WOUND THERAPY K132741
2016-5284	06/24/2016 07/25/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	PAREXEL, BERLIN, GERMANY - EIR, 483
2016-5285	06/24/2016 07/25/2016	FDA/OC/OES/DDM/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DDM/	RACHEL WU BUDD LARNER PC	LIST OF ORPHAN DRUG AND BIOLOGICAL DESIGNATIONS 9/01 TO 11/01
2016-5286	06/24/2016 07/25/2016	FDA/OMPT/CDRH/OCE/DID/	Liza Meak NBC Bay Area News (KNTV)	CERVICAL CORPECTOMY CAGE PRODUCTS - AERS
2016-5287	06/24/2016 07/25/2016	FDA/OGROP/ORO/PA-FO/SEA- DO/SEA-CB/ FDA/OMPT/CDRH/OCE/DID/	Kendrick Moxon CITIZENS COMMISSION ON HUMAN RIGHTS	MECTA CORPORATION - CORR 01/01/2000 - 06/21/2016
2016-5288	06/24/2016 07/25/2016	FDA/OMPT/CDRH/OCE/DID/	RICHARD E HUGHES PHD UNIV OF MICHIGAN	DEPUY - MODIFIED ACETABULAR CUP SYS K900832; APR AND APR II PRESS-FIT UNIVERSAL HIP SYS K905781; REFLECTION ACETABULAR COMPONENT K932755, ETC

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2016-5289	06/24/2016 07/25/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Katherine Kaempchen Forward Pharma Gmbh- Katherine Kaempchen	TECFIDERA - AERS
2016-5290	06/24/2016 07/25/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DDM/	JULIANNE HILL HILL, JULIANNE	MIDAZOLAM HCL, HYDROMORPONE HCL, ROCURONIUM BROMIDE - 503N BULKS LIST
2016-5291	06/24/2016 07/25/2016	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DINESH PATEL Unipack, Inc.	ACINO PRODUCTS LLC - EIRS, 483S, CO RESP, ETC 1/10 TO PRESENT
2016-5292	06/24/2016 07/25/2016	FDA/OFVM/CFSAN/OCD/EOS/	Michael F. Jacobson Center for Science in the Public Interest	FACTS UP FRONT - RECS PROVIDED BY GROCERY MANUFACTURER'S ASSOCIATION 01/01/2010 - 06/21/2016
2016-5293	06/24/2016 07/25/2016	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2016-4730
2016-5294	06/24/2016 07/25/2016	OC/ORA/OCI/ OC/ORA/OCI/	ANTHONY ROBERTS MUCKROCK	OPERATION GRASSHOPPER - RECS
2016-5295	06/24/2016 07/25/2016	FDA/OMPT/OSMP/OCP/ FDA/OC/OES/	James A Boiani Epstein Becker Green	PROCEDURES, POLICIES, CHARTERS ETC RE FDA COMBINATION PRODUCTS COUNCIL 03/01/2016 - 06/21/2016
2016-5296	06/24/2016 07/25/2016	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/ OC/ORA/OCI/ OC/ORA/OCI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANTHONY ROBERTS MUCKROCK	DONALD WOOD, COMPETITIVE EDGE LABS, MKZ EXPORTS - RECS
2016-5297	06/24/2016	FDA/OMPT/CDRH/OCE/DID/	MIKE PEARSON	COMPEX WIRELESS USA - K143551

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	07/25/2016		REHABTRONICS INC	
2016-5298	06/24/2016 07/25/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Phillip Hwang UNIVERSITY OF WASHINGTON	CLINICAL REVIEW FOR VACCINES - STN 103944 ETC
2016-5299	06/24/2016 07/25/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	PAREXEL, MIDDLESEX, UK - EIR, 483
2016-5300	06/24/2016 07/25/2016	FDA/OMPT/CDRH/OCE/DID/	MIKE PEARSON REHABTRONICS INC	POWERDOT PD-01 MUSCLE STIMULATOR K150078
2016-5301	06/24/2016 07/25/2016	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	Rachel Johnson FOI Services, Inc.	PAREXEL, BILLERICA, MA - EIR, 483
2016-5302	06/24/2016 07/25/2016	FDA/OC/OES/DFOI/	Joan Stitt UG2CD-16 MERCK & CO., INC.	2016-3832
2016-5303	06/24/2016 07/25/2016	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	SEBASTIAN DE ANDRACA ALFA INTERNATIONAL SEAFOOD INC	ENTRY #RD8-0021558-7 - ANALYTICAL RECS
2016-5304	06/24/2016 07/25/2016	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	SEBASTAIN DE ANDRACA ALFA INTERNATIONAL SEAFOOD INC	ENTRY #RD8-0021590-0 - ANALYTICAL RECS
2016-5305	06/24/2016 07/25/2016	FDA/OC/OES/DFOI/	Gina Ecolino Beveridge & diamond, P.C.	CFSAN FOIA REQUESTS 05/18/2016 - 06/23/2016
2016-5306	06/24/2016 07/25/2016	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	SEBASTIAN DE ANDRACA ALFA INTERNATIONAL SEAFOOD INC	ENTRY #RD8-0021594-2 - ANALYTICAL RECS
2016-5307	06/27/2016 07/26/2016	OC/ORA/ OC/ORA/ OC/ORA/ORM/ OC/ORA/ORM/	Poornaa Venkatesan Jefferies India Pvt Ltd	NUMBER OF INSPECTIONS OF INDIAN DRUG FACILITIES, NUMBER OF 483S 01/01/2013 - 06/28/2016
2016-5308	06/27/2016 07/26/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Phillip Hwang UNIVERSITY OF WASHINGTON	ACAM2000 CLINICAL REVIEW
2016-5309	06/27/2016	FDA/OMPT/CDER/ORP/DIDP/	Gunther Birznieks	NDA 22192/S-015 MEMO FROM EXCLUSIVITY BOARD

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	07/26/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Vanda Pharmaceuticals, Inc	
2016-5310	06/27/2016 07/26/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Phillip Hwang UNIVERSITY OF WASHINGTON	ENGERIX-B (STN: 103239) FluLaval (STN: BL 125163) CLINICAL REVIEW
2016-5311	06/27/2016 07/26/2016	FDA/OMPT/CDRH/OCE/DID/	Manish Ahuja BioTex Inc.	K983045
2016-5312	06/27/2016 07/26/2016	FDA/OMPT/CDRH/OCE/DID/	Manish Ahuja BioTex Inc.	K974479
2016-5313	06/27/2016 07/26/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Courtney O'Connell Courtney O'Connell	NDA 18553 SBA
2016-5314	06/27/2016 07/26/2016	FDA/OMPT/CDRH/OCE/DID/	Manish Ahuja BioTex Inc.	K920633
2016-5315	06/27/2016 07/26/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Thomas Krol Novadiol	CALDEROL - AERS
2016-5316	06/27/2016 07/26/2016	FDA/OGROP/ORASW-FO/KAN- DO/KAN-CB/	Tyler South Legacy Pharmaceutical Packaging, LLC	LEGACY PHARMACEUTICAL PACKAGING, LLC, EARTH CITY, MO - EIR 06/01/2015 - 06/22/2016
2016-5317	06/27/2016 07/26/2016	FDA/OMPT/CDRH/OCE/DID/	Ruby Chiang Aeon Astron Europe B.V.	K132343
2016-5318	06/27/2016 07/26/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Uendra Topiwala Dr. Reddy's Laboratories Inc.	LATUDA ANDA 208002
2016-5319	06/27/2016 07/26/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Thomas Krol Novadiol	CALDEROL - AERS
2016-5320	06/27/2016	FDA/OMPT/CDER/GRP/DIDP/	Eyal Maor	PAR ACTIVE TECHNOLOGIES, ALATHUR, INDIA - 483 5/52016

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	07/26/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FDA/AWARE	
2016-5321	06/27/2016 07/26/2016	OC/ORA/ OC/ORA/	Stephen Snow Bendin Sumrall & Ladner, LLC	INNOVATION COMPOUNDING, KENNESAW, GA - EIR
2016-5322	06/27/2016 07/26/2016	FDA/OFV/M/CFSAN/OCD/EOS/ DEPARTMENT OF CHEMISTRY WEST VIRGINIA/UNIVERSITY	Gene S. Hall	75 DAY PREMARKET NOTIFICATION FOR PROVINAL NEW DIETARY INGREDIENT NOTIFICATION 819
2016-5323	06/27/2016 07/26/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rhondolyn Smith Georgia Cancer Specialists	FERRIECIT - AERS
2016-5324	06/27/2016 07/26/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Heather Dudek BAXTER HEALTHCARE CORPORATION	CLARIS INJECTABLES LIMITED, INDIA - EIR 05/01/2015 - 05/31/2015
2016-5325	06/27/2016 07/26/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sue Sutter Pink Sheet	BLA 25544
2016-5326	06/27/2016 07/26/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Lisa Robertson Rawls McNelis + Mitchell	INDIVIDUAL RECS
2016-5327	06/27/2016 07/26/2016	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	Michelle Kelley Covidien LLC (owned by Medtronic)	COVIDIEN, AUGUSTA, GA - EIR 08/31/2015 - 09/03/2015
2016-5328	06/27/2016 07/26/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kimberly Trickett NDA Partners LLC	NDA 19797
2016-5329	06/27/2016 07/26/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bharat Celly Research Delta Advisors	SUN PHARMACEUTICALS GLEEVEC APPROVAL RECS
2016-5330	06/27/2016	FDA/OC/OES/DFOI/	Desmond Jenson	2015-8071

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	07/26/2016		Tobacco Control Legal Consortium	
2016-5331	06/27/2016 07/26/2016	FDA/OMPT/OSMP/OOPD/	Marilynn Whitney COVINGTON & BURLING LLP	OFFICE OF ORPHAN PRODUCTS SOPP 420, VERSION #3
2016-5332	06/27/2016 08/24/2016	FDA/OC/OCC/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/OSMP/OOPD/	051330-0018 LATHAM & WATKINS	BENDEKA - MEMOS, LETTERS, EMAILS ETC
2016-5333	06/27/2016 07/26/2016	FDA/OGROP/ORAP/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDRH/OCE/DID/ FDA/OGROP/ORAP/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORAP/SW-FO/DAL-DO/DAL-CB/	Daniel F. Olejko Bragalone Conroy PC	PROPEL ORTHODONCTIC DEVICES - COMPLAINT, INSPECTIONS, APPROVALS ETC 01/01/2007 - 06/22/2016
2016-5334	06/27/2016 07/26/2016	FDA/OC/OES/DDM/	Bahareh Davidson USC School of Pharmacy	ONCOLOGIC DRUGS ADVISORY COMMITTEE 55TH MEETING - SLIDES 12/18/97
2016-5335	06/27/2016 07/26/2016	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	CTP AERS JAN TO JUNE 2016
2016-5336	06/27/2016 07/26/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lisa Organisak Sunovion Pharmaceuticals Canada Inc.	Fingolimod Pediatric Written Request
2016-5337	06/27/2016 07/26/2016	FDA/OMPT/CDRH/OCE/DID/	Sara Ebrahimi Sara Ebrahimi	LETTER FROM MENTOR TO FDA RE HIGH BLEED PATCH USED IN SILICONE BREAST IMPLANTS NOVEMBER 2005
2016-5338	06/27/2016 07/26/2016	FDA/OC/OES/DDM/	Christina Jewett Reveal + The Center for Investigative Reporting	FDA-2013-P-1510 PETITION AND RESPONSE
2016-5339	06/27/2016 07/26/2016	FDA/OMPT/CDRH/OCE/DID/	Sarah Simani MAS Lawgroup	ETHICON PHYSIOMESH FLEXIBLE COMPOSITE MESH PHY 2025V - AERS, CORR WITH ETHICON
2016-5340	06/27/2016 07/26/2016	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	Melissa Feather Feather, Melissa	PLEXUS - WARNING LETTER FOLLOW UP RECS 01/01/2016 - 06/22/2016
2016-5341	06/27/2016	FDA/OMPT/CDER/ORP/DIDP/	Anthony Soscia	ANDA 040905

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	07/26/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Atlantic Pharmaceuticals, Inc	
2016-5342	06/27/2016 07/26/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anthony Soscia Atlantic Pharmaceuticals, Inc	ANDA 089049
2016-5343	06/27/2016 07/26/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anthony Soscia Atlantic Pharmaceuticals, Inc	ANDA 090313
2016-5344	06/27/2016 07/26/2016	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	REVIMID, REVLIMID - ORPHAN DESIGNATION RECS 09/20/2001
2016-5345	06/27/2016 07/26/2016	FDA/OGROP/ORANE-FO/NYK- DO/NYK-DCB/	Giridhar Prasad Dr. Reddy's Laboratories Inc.	CEROVENE, VALLEY COTTAGE, NY - THREE MOST RECENT 483
2016-5346	06/27/2016 07/26/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Yaakov Sidikman Afton Capital Partners	ISOMERIC PHARMACY SOLUTIONS, LLC; PHARMEDIUM SERVICES, LLC; QUVA PHARMA INC ETC - AERS
2016-5347	06/27/2016 07/26/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tim Henkel VenatoRx Pharmaceuticals, Inc.	NDA 050679
2016-5348	06/27/2016 07/26/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gunther Birznieks Vanda Pharmaceuticals, Inc	FANAPT - MEMO PREPARED BY FDA RE ELIGIBILITY FOR THREE YEAR EXCLUSIVITY 05/01/2016 - 06/17/2016
2016-5349	06/27/2016 07/26/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	REMS Modification Notification Letter 10/06/2015 for Sabril
2016-5350	06/27/2016 07/26/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gunther Birznieks Vanda Pharmaceuticals, Inc	FANAPT - MEETING MINUTES RE THREE YEAR EXCLUSIVITY

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2016-5351	06/27/2016 07/26/2016		CINDY SHEARRER UNIVERSITY OF MISSOURI	EVER APPROVED DRUGS LIST 5/12/16
2016-5352	06/27/2016 07/26/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	MICHEL PLUESS FHNW HOCHSCHULE FUER TECHNIK	1000 FAERS RTPS 10/12 TO 12/15
2016-5353	06/27/2016 07/26/2016	FDA/OC/OES/DFOI/	Joy Lazaroff Joy Lazaroff	OUTLOOK DISTRIBUTION FOR RETIREMENT CLUB
2016-5354	06/27/2016 07/26/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CAROLINE STOUT ECOR1 CAPITAL LLC	PEMBROLIZUMAB, NIVOLUMAB, ATEZOLIZUMAB - AER SINCE 1/13
2016-5355	06/27/2016 07/26/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DDM/	DIANNE L. CHAMBERS HOGAN LOVELLS LLP	HYDROXYPROGERTERONE CAPROATE - SUBMISSIONS
2016-5356	06/27/2016 08/26/2016	FDA/OMPT/OSMP/OOPD/	MORGAN A. RETTIG Latham & Wakins LLP	ALL ORPHAN ANALYSIS BY OPD SINCE 2006
2016-5357	06/27/2016 08/05/2016	FDA/OMPT/OSMP/OOPD/	ANDREW D. PRINS Latham & Wakins LLP	AMBISOME, AVONEX, BENEFIX ETC - ALL ANALYSIS
2016-5358	06/27/2016 07/26/2016	FDA/OC/OES/DFOI/	SHEHEE 7068914151338, GREGORY	INDIVIDUAL RECS
2016-5359	06/27/2016 07/26/2016	FDA/OMPT/CDRH/OCE/DID/	BROWN 27110/3572073, SANDERS	RFID IMPLANT CHIPS - CMLPLNTS
2016-5360	06/27/2016 07/26/2016	FDA/OGROP/ORACE-FO/CIN- DO/CIN-CB/	CARPENTER LIPPS & LELAND LLP	COOPER FARM, PAULDING MILL - COLLECTION RPTS 884177-884180, 883771-883774
2016-5361	06/27/2016	FDA/OGROP/ORACE-FO/ATL-	SCOTT DAMON	IPN USA COPR, PEACHTREE CITY, GA - CMLPLNTS, INSP,

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	07/26/2016	DO/ATL-CB/	BUTLER WEIHMULLER ET AL	RECALL 2013 TO PRESENT
2016-5362	06/27/2016 07/26/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	AMY PERDOMO WEINBERG WHEELER ET AL	SURGICAL TISSUE OR ORGAN TRANSPLANT - Cmplnts 2010 TO PRESENT
2016-5363	06/27/2016 07/26/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SMITH B64568, PAUL	PRILOSEC - AER
2016-5364	06/27/2016 07/26/2016	FDA/OC/OES/DFOI/	TUDUJ M05570, TOM	AMBIEN - AER
2016-5365	06/27/2016 07/26/2016	FDA/OC/OES/DFOI/	TUDUJ M05570, TOM	AMBIEN CR - AER
2016-5366	06/27/2016 07/26/2016	FDA/OC/OES/DFOI/	TUDUJ M05570, TOM	ZOLPIDEM MR
2016-5367	06/27/2016 07/26/2016	FDA/OC/OES/DFOI/	TUDUJ M05570, TOM	BUPRIOPION - AER
2016-5368	06/27/2016 07/26/2016	FDA/OC/OES/DFOI/	TUDUJ M05570, TOM	WELLBUTRIN - AER
2016-5369	06/27/2016 07/26/2016	FDA/OC/OES/DFOI/	TUDUJ M05570, TOM	ZOLPIDEM - AER
2016-5370	06/28/2016 07/27/2016	FDA/OC/OES/DFOI/	Bharat Celly Research Delta Advisors	LIST OF INSPECTIONS FOR NEXT MONTH
2016-5371	06/28/2016 07/27/2016	FDA/OFVM/CFSAN/OCD/EOS/	Coleen Waldenmayer Waldenmayer, Coleen	Section VIII of i2006 Guidance for Industry on the Use of Recycled Plastics In Food Packaging
2016-5372	06/28/2016 07/27/2016	FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/	Stephen H. Bryant, Jr. Fruit of the Earth, Inc.	FRUIT OF THE EARTH, GRAND PRAIRIE, TX - EIR 03/01/2015 - 06/21/2016
2016-5373	06/28/2016 07/27/2016	FDA/OMPT/CDRH/OCE/DID/	Garth Conrad BARD PERIPHERAL VASCULAR INC	OSB ALGORITHM AND TRENDING PROCESSES USED ON MAUDE DATABASE FOR DETERMINING SIGNALS 01/01/2016 - 06/24/2016
2016-5374	06/28/2016 07/27/2016	FDA/OMPT/CDRH/OCE/DID/	Garth Conrad BARD PERIPHERAL VASCULAR INC	FDA SAFETY COMMUNICATION LUBRICIOUS COATING SEPARATION FROM INTRAVASCULAR MEDICAL DEVICES 01/01/2015 - 11/23/2015
2016-5375	06/28/2016 07/27/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K153371
2016-5376	06/28/2016	FDA/OGROP/ORASW-FO/CHI-	Guyneth Outsen	HEARTHSIDE FOODS, KENTWOOD, MI; HEARTHSIDE

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	07/27/2016	DO/CHI-CB/ FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORACE-FO/NOL-DO/NOL-CB/	Hearthside Foods	FOODS, GRAND RAPIDS, MI; ETC 01/01/2012 - 06/22/2016
2016-5377	06/28/2016 07/27/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Christina Jewett The Center for Investigative Reporting	LUPRON DEPOT-PED - APPROVAL RECS
2016-5378	06/28/2016 07/27/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lesley D'Albini D'Albini, Lesley	VYVANCE - AERS
2016-5379	06/28/2016 07/27/2016	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Troy Wilkins BASF Corporation	DIVIS LABORATORIES, DIVIS NUTRACEUTICALS, INDIA, NJ - 483 01/01/2000 - 06/27/2016
2016-5380	06/28/2016 07/27/2016	FDA/OMPT/OSMP/OOPD/	SZYMON JAROSLAWSKI PHD AIX-MARSEILLE UNIV	PURIXAN (MERCAPTOPURINE ORALSOL), GAZYVA (OBINUTUZUMAB), ZYDELIG (IDELALISIB), ETC - ORPHAN DRUG DESIGNATION
2016-5381	06/28/2016 07/27/2016	FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECS
2016-5382	06/28/2016 07/27/2016	FDA/OMPT/CDRH/OCE/DID/	Daniel Hue UPC MEDICAL SUPPLIES	K052731
2016-5383	06/28/2016 07/27/2016	FDA/OC/OES/DFOI/	LOUIS M FLORA LAVIN & ASSOCIATES PC	ZIMMER - PERSONA KNEE IMPLANT RECALL RECS 1/13 TO PRESENT; PRODUCT FAILURE RPTS
2016-5384	06/28/2016 07/27/2016	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION	FOI DAILY LOG 6/6-10/16

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			SOURCE	
2016-5385	06/28/2016 07/27/2016	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 6/6-10/16
2016-5386	06/28/2016 07/27/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 6/6-10/16
2016-5387	06/28/2016 07/27/2016	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD Center for Regulator Services, Inc	FOI DAILY LOG 6/6-10/16
2016-5388	06/28/2016 07/27/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 6/6-10/16
2016-5389	06/28/2016 07/27/2016	FDA/OC/OES/DFOI/	LESLIE RAMSEY FDA NEWS	FOI DAILY LOG 6/6-10/16
2016-5390	06/28/2016 07/27/2016	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 6/13-17/16
2016-5391	06/28/2016 07/27/2016	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 6/13-17/16
2016-5392	06/28/2016 07/27/2016	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 6/13-17/16
2016-5393	06/28/2016 07/27/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 6/13-17/16
2016-5394	06/28/2016 07/27/2016	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD Center for Regulatory Services Inc.	FOI DAILY LOG 6/13-17/16
2016-5395	06/28/2016 07/27/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 6/13-17/16
2016-5396	06/28/2016 07/27/2016	FDA/OC/OES/DFOI/	LESLIE RAMSEY FDA NEWS	FOI DAILY LOG 6/13-17/16
2016-5397	06/28/2016 07/27/2016	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 6/6-10/16
2016-5398	06/28/2016 07/27/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 5/30/16-6/3/16
2016-5399	06/28/2016 07/27/2016	FDA/OC/OES/DFOI/	LESLIE RAMSEY FDA NEWS	FOI DAILY LOG 5/30/16-6/3/16

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2016-5400	06/28/2016 07/27/2016	FDA/OC/OES/DFOI/	Paul J. Sampson Wilkinson Walsh + Eskovitz	KETEK - RECS PREVIOUSLY RELEASED UNDER FOIA 01/01/2001 - 06/24/2016
2016-5401	06/28/2016 07/27/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rafid Azad Rafid Azad	KEYTRUDA - AERS
2016-5402	06/28/2016 07/27/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rafid Azad Rafid Azad	OPDIVO - AERS
2016-5403	06/28/2016 07/27/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-4428
2016-5404	06/28/2016 07/27/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-4075
2016-5405	06/28/2016 07/27/2016	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink	2016-4975
2016-5406	06/28/2016 07/27/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-4045
2016-5407	06/28/2016 07/27/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-3631
2016-5408	06/28/2016 07/27/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-3418
2016-5409	06/28/2016 07/27/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-3049
2016-5410	06/28/2016 07/27/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-2010
2016-5411	06/29/2016 07/28/2016	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	DAILY LOG 5/16-20/16
2016-5412	06/29/2016 07/28/2016	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	DAILY LOG 5/23-27/16
2016-5413	06/29/2016 07/28/2016	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION	DAILY LOG 5/30-6/3/16

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2016-5414	06/29/2016 07/28/2016	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 5/16-20/16
2016-5415	06/29/2016 07/28/2016	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 5/23-27/16
2016-5416	06/29/2016 07/28/2016	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 5/30-6/3/16
2016-5417	06/29/2016 07/28/2016	FDA/OC/OES/DFOI/	LESLIE RAMSEY FDA NEWS	DAILY LOG 5/16-20/16
2016-5418	06/29/2016 07/28/2016	FDA/OC/OES/DFOI/	LESLIE RAMSEY FDA NEWS	DAILY LOG 5/23-27/16
2016-5419	06/29/2016 07/28/2016	FDA/OC/OES/DFOI/	WILLIAM A. OLSON, Ph.D. Center for Regulator Services, Inc	DAILY LOG 5/16-20/16
2016-5420	06/29/2016 07/28/2016	FDA/OC/OES/DFOI/	WILLIAM A. OLSON, Ph.D. Center for Regulator Services, Inc	DAILY LOG 5/23-27/16
2016-5421	06/29/2016 07/28/2016	FDA/OC/OES/DFOI/	WILLIAM A. OLSON, Ph.D. Center for Regulator Services, Inc	DAILY LOG 5/30-6/3/16
2016-5422	06/29/2016 07/28/2016	FDA/OC/OES/DFOI/	DAVID MacFARLAND FDA REVIEW/FDA WEBVIEW	DAILY CLOSED LOG 5/16-20/16
2016-5423	06/29/2016 07/28/2016	FDA/OC/OES/DFOI/	DAVID MacFARLAND FDA REVIEW/FDA WEBVIEW	DAILY CLOSED LOG 5/23-27/16
2016-5424	06/29/2016 07/28/2016	FDA/OC/OES/DFOI/	DAVID MacFARLAND FDA REVIEW/FDA WEBVIEW	DAILY CLOSED LOG 5/30-6/3/16
2016-5425	06/29/2016 07/28/2016	FDA/OC/OES/DFOI/	DAVID MacFARLAND FDA REVIEW/FDA WEBVIEW	DAILY CLOSED LOG 6/6-10/16
2016-5426	06/29/2016 07/28/2016	FDA/OC/OES/DFOI/	DAVID MacFARLAND FDA REVIEW/FDA WEBVIEW	DAILY CLOSED LOG 6/13-17/16
2016-5427	06/29/2016 07/28/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 5/16-20/16
2016-5428	06/29/2016 07/28/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 5/16-20/16
2016-5429	06/29/2016 07/28/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 5/23-27/16

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2016-5430	06/29/2016 07/28/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 5/23-27/16
2016-5431	06/29/2016 07/28/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED LOG 5/30-6/3/16
2016-5432	06/29/2016 07/28/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 6/6-10/16
2016-5433	06/29/2016 07/28/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 6/13-17/16
2016-5434	06/29/2016 07/28/2016	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 5/9-13/16
2016-5435	06/29/2016 07/28/2016	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 5/16-20/16
2016-5436	06/29/2016 07/28/2016	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 5/23-27/16
2016-5437	06/29/2016 07/28/2016	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 5/30-6/3/16
2016-5438	06/29/2016 07/28/2016	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY CLOSED LOG
2016-5439	06/29/2016 07/28/2016	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY CLOSED LOG 5/23-27/16
2016-5440	06/29/2016 07/28/2016	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY CLOSED LOG 5/30-6/3/16
2016-5441	06/29/2016 07/28/2016	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY CLOSED LOG 6/6-10/16
2016-5442	06/29/2016 07/28/2016	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY CLOSED LOG 6/13-17/16
2016-5443	06/29/2016 07/28/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 5/16-20/16
2016-5444	06/29/2016 07/28/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 5/23-27/16
2016-5445	06/29/2016 07/28/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW &	DAILY LOG 5/30-6/3/16

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			BUSINESS	
2016-5446	06/29/2016 07/28/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED LOG 5/16-20/16
2016-5447	06/29/2016 07/28/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED LOG 5/23-27/16
2016-5448	06/29/2016 07/28/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED LOG 5/30-6/3/16
2016-5449	06/29/2016 07/28/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED LOG 6/6-10/16
2016-5450	06/29/2016 07/28/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED LOG 6/13-17/16
2016-5451	06/30/2016 07/29/2016	FDA/OC/OES/DFOI/	Jaclyn Docs Acuitive Technologies	K071177
2016-5452	06/30/2016 07/29/2016	FDA/OC/OES/DFOI/	Jaclyn Docs Acuitive Technologies	K061863
2016-5453	06/30/2016 07/29/2016	FDA/OC/OES/DFOI/	Gaurav Tinani Emkay Global	LUPIN, GOA, INDIA - 483 03/07/2016 - 03/11/2016
2016-5454	06/30/2016 07/29/2016	FDA/OC/OES/DFOI/	Bo Erickson CBS NEWS	FOIA LOG 05/01/2016 - 06/30/2016
2016-5455	07/01/2016 08/23/2016	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/ FDA/OMPT/CDRH/OCE/DID/	MICHAEL SULLIVAN SUKMAN YAGODA	INDIVIDUAL RECS
2016-5456	07/01/2016 08/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DDM/	RICHARD A OETHEIMER GOODWIN PROCTER LLP	MAKENA, HYDROXYPROGESTERONE CAPROATE, 17-ALPHA HYDROXYPROGESTERONE, ETC - SUBMISSIONS FOR INCLUSION ON ANY LIST OF BULK DRUG SUBSTANCES
2016-5457	07/01/2016 08/01/2016	FDA/OMPT/CDRH/OCE/DID/	SHINWOO LEE YOUNG WON MEDICAL CO LTD	YOUNOG WON MEDICAL CO LTD, GYEONGGI-DO, SOUTH KOREA - EIR
2016-5458	07/01/2016	FDA/OMPT/CDER/ORP/DIDP/	DAVID M HOFFMEISTER	CDER FTE CEILING, FTE ONBOARD PLUS EOD CHART; OPQ

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	08/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WILSON SOSINI GOODRICH & ROSATI	TABLE OF ORGANIZATION 5/16, ETC
2016-5459	07/01/2016 08/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DDM/	KIM C CAPONE PORZIO BROMBERG & NEWMAN PC	MAKENA, HYDROXYPROGESTERONE CAPROATE, HYDROXYPROGESTERONE, 17-ALPHA HYDROXYPROGESTERONE, ETC SUBMISSIONS FOR INCLUSION ON ANY LIST OF BULK SUBSTANCES
2016-5460	07/01/2016 08/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/CVM/OCD/	Doe J	SANDOZ - DEPO-MEDROL TESTING ON ANIMALS
2016-5461	07/01/2016 08/01/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	PATRICK KELLY CONWAY HOMER & CHIN- CAPLAN PC	INDIVIDUAL RECS
2016-5462	07/01/2016 09/16/2016	FDA/OMPT/CTP/OD/	ERIC H KARP WITMER KARP WARNER & RYAN LLP	TOBACCO COMPLIANCE CHECKS AND INVESTIGATIONS IN FLORIDA
2016-5463	07/01/2016 08/09/2016	FDA/OGROP/ORACE-FO/DET- DO/DET-CB/ FDA/OMPT/CDRH/OCE/DID/	LOUIS M FLORA LAVIN & ASSOCIATES PC	PERSONA KNEE IMPLANTS - RECALL RECS 1/13 TO PRESENT
2016-5464	07/01/2016 08/01/2016	FDA/OC/OES/DDM/	DIANNE L CHAMBERS HOGAN LOVELLS US LLP	DKT 1994P-0429
2016-5465	07/01/2016 08/01/2016	FDA/OC/OES/DFOI/	SCOTT B LAUFENBERG LAUFENBERG, SCOTT	INDIVIDUAL RECS
2016-5466	07/01/2016 08/11/2016	FDA/OC/OES/DFOI/	Eyal Maor FDAAWARE	PREVIOUSLY RELEASED 483 06/01/2016 - 06/30/2016
2016-5467	07/01/2016 08/15/2016	FDA/OC/OES/DFOI/	Eyal Maor FDAAWARE	PREVIOUSLY RELEASED EIR 05/01/2016 - 06/30/2016
2016-5468	07/01/2016 08/01/2016	FDA/OFVM/CFSAN/OCD/EOS/	Raymond LUO Shanghai SUNGO Management Consulting CO., Ltd.	SUZHOU FULL FORTUNE FOOD CO - 483 05/16/2016 - 05/17/2016
2016-5469	07/01/2016	OC/ORACE/OCI/	Sarah N Lynch	INVESTIGATIVE REFERRALS FOR CLOSED CASES 01/01/2009 - 06/27/2016

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	08/01/2016	OC/ORAO/OCI/	REUTERS	
2016-5470	07/01/2016 08/01/2016	FDA/OFVM/CFSAN/OCD/EOS/	ALICE WU REACH24H CONSULTING GROUP	FCN 112, 268, 385, ETC
2016-5471	07/01/2016 08/01/2016	FDA/OGROP/ORAO/SE-FO/NOL-DO/NOL-CB/	Alok Dalal CLSA India Pvt Ltd	DR REDDY'S LABORATORIES LOUISIAN LLC, SHREVEPORT, LA - 483 10/01/2015 - 12/31/2015
2016-5472	07/01/2016 08/01/2016	FDA/OGROP/ORAO/CE-FO/CHIDO/CHI-CB/	Sara Wood Illinois Retina Associates, SC	PAULINE MERRILL, MD, RUSH UNIVERSITY HOSPITAL, CHICAGO, IL - 483, EIR, RESPONSE 01/02/1998 - 12/31/2003
2016-5473	07/01/2016 08/01/2016	FDA/OC/OES/DFOI/	KATHERINE GRAVES KAZAN MCCLAIN ET AL	ASBESTOS CONTAMINATION OF COSMETIC TALC - RECS
2016-5474	07/01/2016 08/01/2016	FDA/OGROP/ORAO/PA-FO/SEADO/SEA-CB/ FDA/OFVM/CFSAN/OCD/EOS/	Jacqueline Kuler Amin Talati & Upadhye, LLC	CORR BETWEEN FDA AND HEATHER & COMPANY FOR IBS, LLC, HEATHER'S TUMMY CARE ETC 08/01/2000 - 06/27/2016
2016-5475	07/01/2016 08/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LESLIE RAMSEY FDA NEWS	ALCHEM INTERNATIONAL LTD, FARIDABAD, INDIA; FARMEA, ANDERS CEDEX, FRANCE; SYMRISE AG, HOLZMINDEN, GERMANY, ETC - 483S 4/1-30-16
2016-5476	07/01/2016 08/01/2016	FDA/OGROP/ORAO/SE-FO/ATLDO/ATL-CB/	Michael Trant McKesson Packaging Services, a business unit of McKesson Corporation	MCKESSON PACKAGING FACILITY, CONCORD, NC - EIR 05/19/2014 - 05/29/2014
2016-5477	07/01/2016 08/01/2016	FDA/OMPT/CDRH/OCE/DID/	Judi Wallach Abbott Laboratories, Inc	K160729
2016-5478	07/01/2016 08/01/2016	FDA/OMPT/CDRH/OCE/DID/	LESLIE RAMSEY FDA NEWS	SHINA CORP, GONGJU-SI, KOREA; INPECO SPA, BORGONE SUSA, ITALY; NEO VISION CO LTD, WONJU, KOREA, ETC - 483S 5/1-31/16
2016-5479	07/01/2016 08/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dustin Block IPD Analytics, LLC	ANDA 205814 APPROVAL LETTER
2016-5480	07/01/2016 08/01/2016	FDA/OFVM/CFSAN/OCD/EOS/	Leslie Edwards Waters, Kraus & Paul	LETTER FROM SEYMOUR LEWIN 8/2/72 CERTIFIED
2016-5481	07/01/2016 08/01/2016	FDA/OGROP/ORAO/SE-FO/ATLDO/ATL-CB/	LESLIE RAMSEY FDA NEWS	FACET TECHNOLOGIES LLC, ATLANTA, GA; CORNING INC, DURHAM, NC; PANDAH CO, KERNESVILLE, NC, ETC - 483S 5/1-31/16
2016-5482	07/01/2016	FDA/OFVM/CFSAN/OCD/EOS/	Stephanie Otts	TWO RECOMMENDATIONS ISSUED BY THE HCFSAN HHE

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	08/01/2016		University of Mississippi School of Law	BOARD 12/01/1991 - 10/31/1993
2016-5483	07/01/2016 08/01/2016	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	LESLIE RAMSEY FDA NEWS	SANOBI PASTEUR BIOLOGICS LLC, ROCKVILLE, MD - 483S 5/1-31/16
2016-5484	07/01/2016 08/01/2016	FDA/OMPT/CDRH/OCE/DID/	Laura Drinkwater, Secretary Vision Chips, Inc.	VISION CHIPS 510K
2016-5485	07/01/2016 08/01/2016	FDA/OMPT/CDRH/OCE/DID/	Ellen Yarnall Nexmed, Inc.	K991882
2016-5486	07/01/2016 08/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John Melvin Seran Bioscience, Inc.	GVK BIOSCIENCES PRIVATE LIMITED INOAGENT LABORATORIES PRIVATE LIMITED; JUBILANT CHEMSYS LIMITED, INDIA 01/01/2013 - 06/15/2016 - 483, 482
2016-5487	07/01/2016 08/01/2016	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	LESLIE RAMSEY FDA NEWS	PHARMAFORCE INC, NEW ALBANY, OH - 483S 5/1-31/16
2016-5488	07/01/2016 08/01/2016	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	LESLIE RAMSEY FDA NEWS	ZEVACOR PHARMA INC, DALLAS, TX - 483S 5/1-31/16
2016-5489	07/01/2016 08/01/2016	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	LESLIE RAMSEY FDA NEWS	YUSEF MANUFACTURING LABORATORIES LLC, CLEARFIELD, UT - 48ES 5/1-31/16
2016-5490	07/01/2016 08/01/2016	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	LESLIE RAMSEY FDA NEWS	PHARMAKON LONG TERM CARE PHARMACY INC, NOBLESVILLE, IN; BAXTER PHARMACEUTICAL SOLUTIONS LLC, BLOOMINGTON, IN - 483S 5/1-31/16
2016-5491	07/01/2016 08/01/2016	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	LESLIE RAMSEY FDA NEWS	HEARTWAVE INC, MIAMI LAKES, FL; CAPILLUS LLC, DORAL, FL; BELCHER PHARMACEUTICALS LLC, LARGO, FL - 483S 5/1-31/16
2016-5492	07/01/2016 08/01/2016	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	LESLIE RAMSEY FDA NEWS	METRIX CO, DUBUQUE, IA - 483S 5/1-31/16
2016-5493	07/01/2016 08/01/2016	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	LESLIE RAMSEY FDA NEWS	AMEDITECH INC, SAN DIEGO, CA - 483S 5/1-31/16
2016-5494	07/01/2016 08/01/2016	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	LESLIE RAMSEY FDA NEWS	CARDIA INC, EAGAN, MN - 483S 5/1-31/16
2016-5495	07/01/2016 08/01/2016	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	LESLIE RAMSEY FDA NEWS	MEDICAL LASER SYSTEMS INC, BRANFORD, CT; MILBAR LABORATORIES INC, EAST HAVEN, CT; TENDER CORP, LITTLETON, NH - 483S 5/1-31/16
2016-5496	07/01/2016 08/01/2016	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	LESLIE RAMSEY FDA NEWS	RESTORE MEDICAL SOLUTIONS INC, MEMPHIS, TN - 483S 5/1-31/16

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2016-5497	07/01/2016 08/01/2016	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	LESLIE RAMSEY FDA NEWS	HERSCO-ORTHOTIC LABS CORP, LONG ISLAND CITY, NY; HEALTHWAY HOME PRODUCTS INC, PULASKI, NY; EQUIBAL INC, UNIONVILLE, NY - 483S 5/1-31/16
2016-5498	07/01/2016 08/01/2016	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	LESLIE RAMSEY FDA NEWS	SAFE-TEC CLINICAL PRODUCTS INC, IVYLAND, PA - 483S 5/1-31/16
2016-5499	07/01/2016 08/01/2016	FDA/OMPT/CDRH/OCE/DID/	Chung Yeh Shape Memory Medical	K112567 K043371 K093123
2016-5500	07/01/2016 08/01/2016	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	LESLIE RAMSEY FDA NEWS	SUNRISE MEDICAL (US) LLC, FRESNO, CA; VOLCANO ATHEROMED INC, MENLO PARK, CA; WELL CARE COMPOUNDING PHARMACY, LAS VEGAS, NV - 483S 5/1-31/16
2016-5501	07/01/2016 08/01/2016	FDA/OMPT/CDRH/OCE/DID/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Olena Izhak Boston University, Department of Economics	ANDA APPROVAL LETTERS
2016-5502	07/01/2016 08/01/2016	FDA/OC/OEXA/OMA/	Kathryn Foxhall Kathryn Foxhall	SANDY WALSH, JEFF VENTURA, DEBRA KOTZ ETC - SENT EMAILS 06/06/2016 - 06/08/2016
2016-5503	07/01/2016 08/01/2016	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Rachel Johnson FOI Services, Inc.	WHOLE FOODS MARKETS - 483, CORR
2016-5504	07/01/2016 08/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bharat Celly Research Delta Advisors	LUPIN INDORE, INDIA - STATUS OF INSPECTION 01/24/2015 - 06/27/2016
2016-5505	07/01/2016 08/01/2016	FDA/OMPT/CDRH/OCE/DID/	Paul Cascone The Argen Corporation	K160498
2016-5506	07/01/2016 08/01/2016	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	LESLIE RAMSEY FDA NEWS	GRAFOR INC, JUANA DIAZ, PR; JANSSEN ORTHO LLC, GURABO, PR - 483S 5/1-31/16
2016-5507	07/01/2016 08/01/2016	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	LESLIE RAMSEY FDA NEWS	BALLARD PLAZA PHARMACY 1 INC, SEATTLE, WA - 483S 5/1-31/16
2016-5508	07/01/2016 08/01/2016	FDA/OMPT/CDRH/OCE/DID/	Taeko Kikuchi CureApp, Inc.	K082315
2016-5509	07/01/2016 08/01/2016	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Jim Reiter Unitron Hearing	UNITRON HEARING, PLYMOUTH, MN - EIR 01/05/2016 - 01/31/2016
2016-5510	07/01/2016	FDA/OMPT/CDER/ORP/DIDP/	LESLIE RAMSEY	MYLAN LABORATORIES LTD, JIGANI, INDIA; ASPEN SVP

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	08/01/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FDA NEWS	PTY LTD, PORT ELIZABETH, SOUTH AFRICA; BAYER BITTERFELD GMBH, BITTERFELD-WOLFEN, GERMANY - 483S 5/1-31/16
2016-5511	07/01/2016 08/01/2016	FDA/OMPT/CDRH/OCE/DID/	Gary Syring Quality and Regulatory Associates, LLC	K991903
2016-5512	07/05/2016 08/02/2016	FDA/OC/OES/DFOI/	Teal Kenny Teal Kenny	GLYPHOSATE - FOIA RQUESTS, RELEASED RECS 07/02/2012 - 07/02/2016
2016-5513	07/05/2016 08/02/2016	FDA/OMPT/CDRH/OCE/DID/	Assaf Azulay Top Li-Med Technologies LTD	K033913
2016-5514	07/05/2016 08/02/2016	FDA/OC/OES/DDM/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Myrisha Lewis IIT Chicago-Kent College of Law	FDA-1997-N-0011 RULEMAKING PACKAGE, RECS RE SORTING OF PUBLIC COMMENTS
2016-5515	07/05/2016 08/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Laurence Glick Harefield Pharma Associates Limited	NDA 22572
2016-5516	07/05/2016 08/02/2016	FDA/OMPT/CDRH/OCE/DID/	Vanee Suri INTERSURGICAL INC	K984254
2016-5517	07/05/2016 08/02/2016	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Thomas Dominy SterRX, LLC.	STERRX, PLATTSBURGH, NY - EIR 01/01/2016 - 06/28/2016
2016-5518	07/05/2016 08/02/2016	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Ingrid Gibson PFIZER, INC	PFIZER INC, PEARL RIVER, NY - EIR 10/31/2014 - 06/30/2016
2016-5519	07/05/2016 08/02/2016	FDA/OC/OES/DFOI/	Russ Kick Russ Kick	Date Range: 01/01/2006 - 12/31/2015; I am requesting all previously released FOIA logs, covering any time period. This refers to FOIA logs released for any reason - FOIA request, appeal, or lawsuit; court order; Congressional request; proactive release; etc. If some of these logs are on your website, sending me the link will suffice. However, if there are other previously released FOIA logs that are not on your website, I ask that those be sent to me. Further, I request that these files be sent in any and all digital formats in which they exist (PDF, Excel, database, Word, etc.). Under the terms of the E-FOIA Amendments of 1996, Section 5, if a document exists in electronic format, it must be released in that format upon request. ;
2016-5520	07/05/2016 08/02/2016	OC/ORAN/ OC/ORAN/	9JU-0000499-9 Ferreiro Company Corp	ENTRY 9JU-0000499-9 LAB REPORTS

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		FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORA/ORO/DIOP/		
2016-5521	07/05/2016 08/02/2016	OC/CVM/OCD/	Kristi Smedley276 Center for Regulatory Services Inc.	FAP 2282
2016-5522	07/05/2016 08/02/2016	FDA/OMPT/CDRH/OCE/DID/	James R. Radmore The Radmore Firm LLC	ZIMMER INC TRINICA PLATE RECS #2184052-2012-00026 #2184052-2012-00027 #2184052-2012-00028 #2184052-2012-00029
2016-5523	07/05/2016 08/02/2016	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Andrew B. Yaffa Grossman Roth Yaffa Cohen, P.A.	US STEM CELL INC FKA BIOHEART, INC, DR SHAREEN GREENBAUM -WARNING LETTERS, RESPONSES, INSPECTIONS ETC 01/01/2015 - 06/28/2016
2016-5524	07/05/2016 08/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Carolyn Manning Manning, Carolyn	LYRICA - AERS
2016-5525	07/05/2016 08/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 203952
2016-5526	07/05/2016 08/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anthony Soscia Atlantic Pharmaceuticals, Inc	ANDA 040028
2016-5527	07/05/2016 08/02/2016	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Ana Panyko Halo Pharmaceutical, Inc.	DELAVAU LLC, PHILADELPHIA, PA - EIR 09/01/2013 - 05/31/2016
2016-5528	07/05/2016 08/02/2016	OC/ORAE/ OC/ORAE/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/ORO/DIOP/	Coca-Cola001 Genesis Imports & Exports LLC	EMBOTELLADORA DE FUERTE S DE R DE CV - FACILITY NUMBER
2016-5529	07/05/2016 08/02/2016	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORASW-FO/KAN-	Ben Elgin BLOOMBERG NEWS	SCHWAN'S GLOBAL SUPPLY CHAIN, INC - 483, RESPONSE 01/01/2010 - 06/28/2016

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		DO/KAN-CB/		
2016-5530	07/05/2016 08/02/2016	OC/ORO/ OC/ORO/	Chris McDaniel Buzzfeed News	RESPONSES SENT TO ARIZONA AND TEXAS IN APRIL 2016 RE DETAINED SODIUM THIOPENTAL ENTRY D97-0846078-4/1/1, D97-0846119-6/1/1
2016-5531	07/05/2016 08/02/2016	FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	Scott Brown Laboratory Corporation of America Holdings	ILS GENOMICS LLC, MORRISVILLE, NC - EIR MARCH 2015
2016-5532	07/05/2016 08/02/2016	FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	JOSE GIRON, MD, ORLANDO, FL - EIR, 483, RESPONSE 09/01/2015 - 10/08/2015
2016-5533	07/05/2016 08/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Zeba Siddiqui THOMSON REUTERS	QUEST LIFE SCIENCES, SEMLER RESEARCH, INDIA - 483, NOTICES 12/01/2014 - 06/29/2016
2016-5534	07/05/2016 08/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 208025
2016-5535	07/05/2016 08/02/2016	FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	NEURALIGHT HD, PHOENIX, AZ - EIR, 483, RESPONSE
2016-5536	07/05/2016 08/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sy-Shi Wang Verseon Corporation	PRADAXA - SBA
2016-5537	07/05/2016 09/06/2016	OC/ORO/ OC/ORO/	Elsie Nolan WBZ-TV	AMAZON - COMPLAINTS RE ANIMAL DROPPINGS 01/29/2012 - 06/29/2016
2016-5538	07/05/2016 08/02/2016	FDA/OGROP/ORO/CE-FO/BLT-DO/BLT-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Utkarsh Gandhi Utkarsh Gandhi	ALEMBIC LIMITED, INDIA - 483 06/19/2016 - 06/25/2016

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-5539	07/05/2016 08/02/2016	FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	SR BURZYNSKI MANUFACTURING FACILITY, STAFFORD, TX - EIR, 483, RESPONSE 05/09/2015 - 05/19/2015
2016-5540	07/05/2016 08/02/2016	FDA/OMPT/CDRH/OCE/DID/	Sara Ebrahimi Sara Ebrahimi	P030053 APPROVAL LARGE STUDY, 27 REPORTS FROM THE OSB LEAD LARGE PAS SCHEDULE
2016-5541	07/05/2016 08/02/2016	FDA/OMPT/CDRH/OCE/DID/	Dhwani Thakkar Thakkar, Dhwani	K123265
2016-5542	07/05/2016 08/02/2016	FDA/OMPT/CDRH/OCE/DID/	Dhwani Thakkar Thakkar, Dhwani	K130223
2016-5543	07/05/2016 08/02/2016	FDA/OC/OES/DFOI/	James Gianoutsos Circadiance, LLC	K100011
2016-5544	07/05/2016 08/02/2016	FDA/OMPT/CDRH/OCE/DID/	Susan Tivedo ABBOTT POINT OF CARE INC	INTERNAL REVIEW CORR RE K053110 11/01/2005 - 03/31/2013
2016-5545	07/05/2016 08/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GAURAV KARNAWAT GAURAV KARNAWAT	LUPIN, INDIA - 483 01/01/2016 - 06/30/2016
2016-5546	07/05/2016 08/02/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K153698
2016-5547	07/05/2016 08/02/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GAURAV KARNAWAT GAURAV KARNAWAT	WOCKHARDT, INDIA - 483 04/01/2016 - 06/30/2016
2016-5548	07/05/2016 08/02/2016	FDA/OMPT/CDRH/OCE/DID/	Sara Ebrahimi Sara Ebrahimi	P910037 P910038 REPORTS - 01/01/1992 - 01/01/2007
2016-5549	07/05/2016 08/02/2016	FDA/OGROP/ORR/PA-FO/SAN-DO/SAN-CB/	Alexander Marcantonio Lombard Odier Asset Management	DYNAVAX - 483 01/01/2015 - 06/30/2016
2016-5550	07/06/2016 08/03/2016	FDA/OC/OES/DFOI/	Mark Kraft Rock West Medical, LLC	K042960
2016-5551	07/06/2016 08/03/2016	FDA/OC/OES/DFOI/	Mark Kraft Rock West Medical, LLC	K103025
2016-5552	07/06/2016	FDA/OC/OES/DFOI/	Mark Kraft	K091405

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	08/03/2016		Rock West Medical, LLC	
2016-5553	07/06/2016 08/03/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John R. Fouts John R. Fouts	RECOMMENDATION TO DEA RE RECLASSIFICATION OF CANNABIS IN THE US
2016-5554	07/06/2016 08/03/2016	FDA/OC/OES/DFOI/ FDA/OMPT/OSMP/OOPD/	Meriem Gaval Cote Orphan, LLC	ORPHAN DRUG DESIGNATION APPLICCATIONS FOR KRYSTEXXA
2016-5555	07/06/2016 08/03/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Alec White HEALTHCOR MANAGEMENT LP	EXPAREL - AERS
2016-5556	07/06/2016 08/03/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gay Parsons Janssen Inc. Canada	METHYLPHENIDATE 10052958, 10052961, 10052962, ETC
2016-5557	07/06/2016 08/03/2016	FDA/OMPT/CDRH/OCE/DID/	Diana Taylor, Sr. Regulatory Specialist RTI Surgical (Pioneer Surgical is a wholly owned subsidiary of RTI)	K961267
2016-5558	07/06/2016 08/03/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K160526
2016-5559	07/06/2016 08/03/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ashley Swanson & Amanda Starc The Wharton School, University of Pennsylvania	DRUG APPLICATION DATES
2016-5560	07/06/2016 08/03/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Stuart Goldberg Litespeed Partners	EXPAREL - AERS
2016-5561	07/06/2016 08/03/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jaya Lakshmi Ayyagari Dr. Reddy's Laboratories Inc.	ANDA 208167
2016-5562	07/06/2016	FDA/OMPT/CDRH/OCE/DID/	Wayne Billings	CORIN CORMET ADVANCED HIP RESURFACING SYSTEM

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	08/03/2016		Fellers, Snider, Blankenship, Bailey & Tippens, P.C.	SAMPLE INFORMED CONSENT FORM
2016-5563	07/06/2016 08/03/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ted Keller EverPoint Asset Management	EXPAREL - AERS
2016-5564	07/06/2016 08/03/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gregory Renza JEFFERIES & CO	KALYDECO, ORKAMBI, JAKAFIT ETC - AERS
2016-5565	07/06/2016 08/03/2016	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/SEA-DO/SEA-CB/	Molly Gulbrandson Faegre Baker Daniels LLP	OREGON POTATO COMPANY DBA FREEZE PACK - TESTING DATA 01/01/2012 - 06/30/2016
2016-5566	07/06/2016 08/03/2016	FDA/OMPT/CDRH/OCE/DID/	Diana Taylor, Sr. Regulatory Specialist RTI Surgical (Pioneer Surgical is a wholly owned subsidiary of RTI)	K000734
2016-5567	07/06/2016 08/03/2016	FDA/OMPT/CDRH/OCE/DID/	Mark Kraft Rock West Medical Devices LLC	K092342
2016-5568	07/06/2016 08/03/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Blake Goodner Bridger Healthcare	ORGANON CORTOPHIN ZINC ACTH PRESCRIBING INFORMATION, LABELING 01/04/1985 - 06/30/2016
2016-5569	07/06/2016 08/03/2016	FDA/OMPT/CDRH/OCE/DID/	Mark Kraft Rock West Medical, Inc	K881609
2016-5570	07/06/2016 08/03/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Morgan Williams BARCLAYS	EXPEREL - AERS
2016-5571	07/06/2016 08/03/2016	FDA/OMPT/CDRH/OCE/DID/	Diana Taylor, Sr. Regulatory Specialist RTI Surgical (Pioneer Surgical is a wholly owned subsidiary of RTI)	K974016
2016-5572	07/06/2016	FDA/OMPT/CDRH/OCE/DID/	Mark Kraft	K053547

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	08/03/2016		Rock West Medical Devices, LLC	
2016-5573	07/06/2016 08/03/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gaurav Tinani Emkay Global	LUPIN LTD, INDORE, INDIA - EIR 01/23/2015 - 01/23/2015
2016-5574	07/06/2016 08/03/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jaya Lakshmi Ayyagari Dr. Reddy's Laboratories Inc.	ANDA 206877 TENTATIVE APPROVAL LETTER
2016-5575	07/06/2016 08/03/2016	FDA/OMPT/CDRH/OCE/DID/	Diana Taylor, Sr. Regulatory Specialist RTI Surgical (Pioneer Surgical is a wholly owned subsidiary of RTI)	K992617
2016-5576	07/06/2016 08/03/2016	FDA/OC/OES/DDM/	Blake Goodner Bridger Healthcare	FDA-2014-P-0377
2016-5577	07/06/2016 08/03/2016	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Amanda Dykeman Amanda Dykeman/ ASHES Nonprofit	CONCEPTUS INC - 483 3/28/97
2016-5578	07/06/2016 08/03/2016	FDA/OFVM/CFSAN/OCD/EOS/	SUSAN MATTHEES GENERAL MILLS	ULTRA-FILTERED MILK IN YOGURT - COMM
2016-5579	07/06/2016 08/03/2016	FDA/OC/OES/DFOI/	ELENA HOWELL CLARK HOGAN LOVELLS US LLP	2016-3963
2016-5580	07/06/2016 09/09/2016	OC/ORA/OCI/ OC/ORA/OCI/ FDA/OGROP/ORA/ORO/DIOP/	COLIN C CORTBUS DAILY POST	DRUGS TESTED INTERCEPTED AS PART OF THE OPERATION THAT ORIGINATE/WERE SENT FROM THE REPUBLIC OF VANUATU - FDA OPERATION BAIT OR SWITCH RECS 2005, NUMBER OF ITEMS INTERCEPTED OR SEIZED BY FDA OR ITS PARTNERS SINCE 2010
2016-5581	07/06/2016 08/03/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GARY L WILSON ROBINS KAPLAN LLC	ABILIFY - DRUG SAFETY COMM, LABEL OR MEDICATION GUIDE 5/3/16
2016-5582	07/06/2016 08/03/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOANN DAWSON ELI LILLY & CO	ZINBRYTA - APRVL RECS

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2016-5583	07/06/2016 08/03/2016	FDA/OC/OES/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OPPLA/OL/	LARRY KLAYMAN FREEDOM WATCH INC	DR MARGARET HAMBURG, JOHNSON & JOHNSON, JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH & DEVELOPMENT LLC, ETC - LEVAQUIN CORR/COMM 5/09 TO PRESENT
2016-5584	07/06/2016 08/03/2016	FDA/OC/OES/DFOI/	ELENA HOWELL CLARK HOGAN LOVELLS US LLP	2016-3841
2016-5585	07/06/2016 08/03/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	EVELYN CARPENTER CARPENTER, EVELYN	GABAPENTIN (NEURONTIN) - AERS
2016-5586	07/06/2016 08/11/2016	FDA/OMPT/CTP/OD/	JOSEPH G FALCONE HERBERT SMITH FREEHILLS	CLNCL TRIALS NCT02247908 FUNDED BY FDA GRANT P30CA016086-38S2 - EFFECT OF PICTORIAL CIGARETTE PACK WARNINGS ON CHANGES IN SMOKING BEHAVIOR 6/6/16
2016-5587	07/06/2016 08/03/2016	FDA/OC/OES/DFOI/	ANA MARIA ABREU VELEZ MD GEORGIA DERMATOPATHOLOGY ASSOCIATES	GILEAD SCIENCES , FOSTER CITY, CA - WHY MOST MEDICATIONS HAVE UNDERGONE FAST TRACK AND PRIORITY RVW, NAMES OF COMMITTEE MEMBERS WHO APPRVED MEDICATIONS, ETC
2016-5588	07/06/2016 08/03/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	PATRICK KELLY CONWAY HOMER & CHIN-CAPLAN PC	INDIVIDUAL RECS (CERTIFIED)
2016-5589	07/06/2016 08/03/2016	FDA/OGROP/ORANE-FO/NYK- DO/NYK-DCB/	John W. Reinhardt, Esq. John W. Reinhardt, Esq.	NUTRIGET, INC - INSPECTION REPORTS, WARNINGS 01/01/2007 - 06/30/2016
2016-5590	07/06/2016 08/10/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OO/OFBA/OAGS/ FDA/OC/OES/DFOI/ FDA/OO/OFBA/OAGS/	Mary Blasy Robbins Geller Rudman & Dowd LLP	EMERGENT BIOSOLUTIONS INC - COMMUNICATIONS WITH FDA RE CDC PROCUREMENT, 2016 SOLICITATION NOTICE ; COMMUNICATIONS WITH FDA, HHS, CDC BARDA 01/01/2015 - 06/30/2016
2016-5591	07/06/2016 08/03/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jamie Lee Collins ROBBINS ARROYO LLP	ESPERION THERAPEUTICS INC - MEETING MINUTES ETC RE MEETING AUGUST 2015 WITH FDA 08/01/2015 - 08/31/2016
2016-5592	07/07/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	FOI DAILY LOG 6/1-30/2016

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	08/04/2016		MERCK & CO., INC.	
2016-5593	07/07/2016 08/04/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	CLOSED REQUESTS 6/1-30/2016
2016-5594	07/07/2016 08/04/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mary Hancock Registrar Corp	SPREADSHEET OF DRUG MASTER FILE SUBMISSIONS 01/01/2016 - 06/30/2016
2016-5595	07/07/2016 08/04/2016	FDA/OMPT/CDRH/OCE/DID/	Avner Avrahami Medical Quant Ltd	K080102 K071445 K061614
2016-5596	07/07/2016 08/04/2016	FDA/OFVM/CFSAN/OCD/EOS/	Susan Cho NUTRASOURCE INC	GRN 000279 GRN 000311 CORR
2016-5597	07/07/2016 08/04/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gaurav Tinani Emkay Global	LUPIN LTD, INDORE, INDIA - EIR 01/23/2015 - 01/23/2015
2016-5598	07/07/2016 08/04/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Erin Jensen Erin Jensen	METRONIDAZOLE - AERS
2016-5599	07/07/2016 08/04/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gaurav Tinani Emkay Global	LUPIN LTD, MANDIDEEP, INDIA - EIR 02/08/2016 - 02/19/2016
2016-5600	07/07/2016 08/04/2016	FDA/OMPT/CDRH/OCE/DID/	Jim Papac Levo USA	LEVO LAE 510K
2016-5601	07/07/2016 08/04/2016	FDA/OFVM/CFSAN/OCD/EOS/	Jennifer Jobrack, on behalf of FARE Food Allergy Research & Education (FARE)	HEALTH HAZARD EVALUATIONS FOR CLASS 1 AND CLASS 2 RECALLS FOR PEANUT BUTTER FLOUR 04/01/2016 - 07/31/2016
2016-5602	07/07/2016 08/04/2016	FDA/OFVM/CFSAN/OCD/EOS/	Susan Cho NUTRASOURCE INC	GRN 571 CORR
2016-5603	07/07/2016 08/04/2016	FDA/OC/OES/DFOI/	Yaakov Sidikman Afton Capital Partners	2015-7076
2016-5604	07/07/2016	FDA/OMPT/CDRH/OCE/DID/	E Barozzi	OSB Lead-Device Failure Study P030053

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	08/04/2016		E Barozzi	
2016-5605	07/07/2016 08/04/2016	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/ORO/DIOP/ FDA/OGROP/ORO/SE-FO/NOL- DO/NOL-CB/	Mark Prinz Registrar Corp	RECS RE REFUSAL OF ENTRY 799-0348158-3
2016-5606	07/07/2016 08/04/2016	FDA/OFVM/CFSAN/OCD/EOS/	Susan Cho Nutrasource Diagnostics Inc.	GRN 000545 CORR
2016-5607	07/07/2016 08/04/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kay Pearson Kay Pearson	XERALTO - AERS
2016-5608	07/07/2016 08/04/2016	FDA/OFVM/CFSAN/OCD/EOS/	Susan Cho Nutrasource Diagnostics Inc.	GRN 000279 GRN 000311 CORR
2016-5609	07/07/2016 08/04/2016	FDA/OFVM/CFSAN/OCD/EOS/	Susan S Cho Nutrasource Diagnostics Inc.	GRN 000186 GRN 000197 CORR
2016-5610	07/07/2016 08/04/2016	FDA/OMPT/CDRH/OCE/DID/	Charlotta Smlander Mediteq Svenkebo AB	K131660, K033514 K030714
2016-5611	07/07/2016 08/04/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jon Baum Jon Baum	AMLODIPINE, LISINOPRIL - AERS
2016-5612	07/07/2016 08/04/2016	FDA/OMPT/CDRH/OCE/DID/	Riyaz Bashir TEMPLE UNIVERSITY	EKOSONIC CONTINUOUS FLUSH CATHETER - APPROVAL RECS
2016-5613	07/07/2016 08/04/2016	FDA/OMPT/CDRH/OCE/DID/	Bryan Nowroozi Mimeo Labs, Inc.	K160511
2016-5614	07/07/2016 08/04/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bhagwan S Chaudhary National Institute of Securities Markets, Navi Mumbai	LUPIN LTD, INDORE, INDIA - EIR 01/01/2015 - 07/01/2016
2016-5615	07/07/2016 08/04/2016	FDA/OGROP/ORO/NE-FO/NWE- DO/NWE-CB/	Jesse Newman THE WALL STREET JOURNAL	WHOLE FOODS MARKET RESPONSE TO FDA RE CORRECTIONS 06/27/2016 - 07/04/2016
2016-5616	07/07/2016	FDA/OMPT/CDER/GRP/DIDP/	Dr Malcolm Wilson	DASATINIB - FIFTEEN AERS REPORTS

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	08/04/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Department of Respiratory Medicine, Cairns Hospital, Queensland, Australia	
2016-5617	07/08/2016 08/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	James J. Nicklaus HAGENS BERMAN SOBOL SHAPIRO LLP	TENTATIVE AND FINAL APPROVAL ROUTING SHEETS FOR ANDA 076898; CHEMISTRY REVIEW SECTION OF SBA
2016-5618	07/08/2016 08/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	James J. Nicklaus HAGENS BERMAN SOBOL SHAPIRO LLP	TENTATIVE AND FINAL APPROVAL ROUTING SHEETS FOR ANDA 078857; CHEMISTRY REVIEW SECTION OF SBA
2016-5619	07/08/2016 08/05/2016	FDA/OGROP/ORACE-FO/BLT- DO/BLT-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Vikram Deswal East Bridge Capital Management, L.P.	JUBILANT LIFE SCIENCE, ROORKEE, INDIA; SALISBURY,MD - 483 01/01/2015 - 07/05/2016
2016-5620	07/08/2016 08/05/2016	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DDM/	Josh Long Informa Exhibitions/Natural Products INSIDER	RECS RE CBD MARKETED AS DIETARY SUPPLEMENT OR CONVENTIONAL FOOD ETC
2016-5621	07/08/2016 08/05/2016	FDA/OMPT/CDRH/OCE/DID/	James Lewis LEWIS, JAMES H	REQUEST TO BE REPACKAGER/RELABELER OF PREFORMED CROWN 07/01/2010 - 07/01/2016
2016-5622	07/08/2016 08/05/2016	FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/	Aaron Leibowitz Gatehouse Media New England	WHOLE FOODS RESPONSE TO WARNING LETTER; RESPONSE TO 483
2016-5623	07/08/2016 08/05/2016	OC/ORA/ OC/ORA/	Sarah N Lynch REUTERS	ASSOCIATE COMMISSIONER FO REGULATORY AFFAIRS MELINDA PLASIER - CALENDARS, LOGS, ETC 10/01/2012 - 07/05/2016
2016-5624	07/08/2016 08/05/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Alexey Eliseev MirImmune Inc	Preclinical safety and efficacy file of the CAR-T experimental treatment currently in clinical trials
2016-5625	07/08/2016 08/05/2016	FDA/OMPT/CDRH/OCE/DID/	James Lewis LEWIS, JAMES H	REQUEST BY CORNERSTONE BIOCOMP TO BECOME A REPACKAGER/RELABELER

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2016-5626	07/08/2016 08/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Juliana Neves Licks Attorneys	KETOROLAC TROMETHAMINE DRUGS - TECHNICAL INFORMATION RE MARKETING APPROVAL APPLICATIONS FOR GENERIC OR SIMILAR VERSIONS 01/01/1993 - 12/31/2003
2016-5627	07/08/2016 08/05/2016	FDA/OPPLA/OL/	Josh Long Informa Exhibitions/Natural Products INSIDER	RESPONSE TO LETTER TO REP JASON CHAFFETZ 03/01/2016 - 03/15/2016
2016-5628	07/08/2016 08/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ike Swetlitz STAT	TEVA PHARMACEUTICAL INDUSTRIES - LETTER RE ANDA TO MANUFACTURE EPINEPHRINE AUTO-INJECTOR 02/01/2016 - 02/29/2016
2016-5629	07/08/2016 08/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ted Keller EverPoint Asset Management	NUPLAZID - AERS
2016-5630	07/08/2016 08/05/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	James T Wong Wong, James T	Title: Potency Determination of Inactivated Influenza Virus Vaccines by the Single Radial Immunodiffusion (SRID) Method Document ID:000333 Title: SRID Image Analysis Document ID: 000467
2016-5631	07/08/2016 08/05/2016	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/NWJ- DO/NWJ-CB/ FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/OCI/ OC/ORO/OCI/	Doe J	COMPLAINT FOLLOW UP RECS
2016-5632	07/08/2016 08/05/2016	FDA/OFVM/CFSAN/OCD/EOS/	Anthony Roberts Anthony Roberts	DIETARY SUPPLEMENT TRADE COMPLAINTS 01/02/2015 - 07/05/2016
2016-5633	07/08/2016 08/05/2016	FDA/OFVM/CFSAN/OCD/EOS/	Wendy Lane Wendy Lane	MONSTER ENERGY CORP, ROCKSTART ENERGY, RED BULL ETC - AERS 10/01/2012 - 07/05/2016;
2016-5634	07/08/2016 08/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Morgan Rettig LATHAM & WATKINS	COMPLETE RESPONSE LETTERS ISSUESD IN 2016 TO MERCK RE ZETIA, VYTORIN
2016-5635	07/08/2016	FDA/OGROP/ORO/SE-FO/FLA-	Colleen Johns	SANCILIO & COMPANY, INC - EIR, CORR 09/21/2015 -

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	08/05/2016	DO/FLA-CB/	Sancilio & Company	07/05/2016
2016-5636	07/08/2016 08/05/2016	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	FCN 878
2016-5637	07/08/2016 08/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	James Cheung CITADEL LLC	EXPAREL - AERS
2016-5638	07/08/2016 08/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anthony Mournian Anthony F. Mournian, Attorney at Law	FALSE POSITIVE TEST RESULTS INDICATING USE OF THC WHILE USING PANTOPRAZOLE FOR TREATMENT OF GERD 01/01/2005 - 07/01/2016
2016-5639	07/08/2016 08/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Irina Koffler MIZUHO SECURITIES USA INC	EXPAREL - AERS
2016-5640	07/08/2016 08/05/2016	OC/CVM/OCD/	Abhishek Pareek Alivira Animal Health	CATOSAL - FOIA SUMMARY
2016-5641	07/08/2016 08/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jaime Vassallo LexisNexis CourtLink	GA/Cop/Glat FAERS
2016-5642	07/08/2016 08/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Christina Jewett Reveal + The Center for Investigative Reporting	LUPRON 10016614, 10483868, 11009541, ETC
2016-5643	07/08/2016 08/05/2016	FDA/OC/OES/DFOI/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	FOIA DAILY LOG 04/01/2016 - 06/30/2016
2016-5644	07/08/2016 08/05/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	ADVANCED MEDICAL OPTICS, CHINA - EIR
2016-5645	07/08/2016 08/05/2016	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	Colleen Grace Donofrio Babst Calland Clements & Zomnir, P.C.	PQ GROVE CORPORATION, UTICA, IL - EIR 04/12/2016 - 07/06/2016
2016-5646	07/08/2016	OC/CVM/OCD/	Sandra O'Kelley	NADA 141-426 VETERINARY SAFETY REPORTS

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	08/05/2016		Merial, Inc.	
2016-5647	07/08/2016 08/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	joseph walker Walker, Joseph	ORKAMBI - AERS
2016-5648	07/08/2016 08/05/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	JENNIFER GRAMLING SAMSTER KONKEL ET AL	INDIVIDUAL RECS (CERTIFIED)
2016-5649	07/08/2016 08/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LISA MCNEELY MCNEELY, LISA	INDIVIDUAL RECS
2016-5650	07/08/2016 08/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DOMINIQUE KENDRICK RPH SAGENT PHARMACEUTICALS INC	OAK PHARMS - NEMBUTAL SODIUM (PENTOBARBITAL SODIUM) ANDA 83-246; MYLAN INSTITUTIONAL - PENTOBARBITAQL SODIUM ANDA 206-404 THERAPEUTIC EQUIVALENTS, APRVL LTRS, RVWS, ETC
2016-5651	07/08/2016 08/05/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Doe J	INDIVIDUAL RECS, Cmplnts
2016-5652	07/08/2016 08/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID J NORTHRUP V13733 NORTHRUP V13733, DAVID J	DEPO-PROVERA, MEDROXYPROGESTERONE ACETATE - PI
2016-5653	07/08/2016 08/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ROBERT GROVES ESQ WAGSTAFF & CARTMELL LLP	ZOFTRAN (ONDANSETRON) - ISRS 9129045, 9526523, 9170541, ETC
2016-5654	07/08/2016 08/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	FENTANYL PATCHES - AERS
2016-5655	07/08/2016 08/05/2016	FDA/OGROP/ORO/SE-FO/FLA- DO/FLA-CB/	JAMIE COLGIN COLGIN CONSULTING INC	DR JOSE GIRON MD, ORLANDO, FL - EIR, 483 9/1/15-10/8/15
2016-5656	07/08/2016 08/19/2016	FDA/OGROP/ORO/CE-FO/CHI- DO/CHI-CB/	Laurie Benjamin Benjamin, Laurie	DR GEORG SPRINGER, CHICAGO MEDICAL SCHOOL - RECS; DR LECIA APANTAKU - 483S 1998, 2004 WARNING LTRS, APRVLS, ETC

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		FDA/OMPT/CBER/OCOD/DDOM/ ALFB/		
2016-5657	07/08/2016 08/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MICHAEL MESA MESA SCIENCE ASSOCIATES INC	EPIPENS, AUVI-Q - CMLPLNTS
2016-5658	07/08/2016 08/05/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HARRIET DOWNING UNIV OF BRISTOL SCHOOL OF SOCIAL AND COMMUNITY MEDICINE	CHILDREN'S DROPS FOR EAR PAIN - CEDAR REAMDOMISED CONTROLLED TRIAL AND OBSERVATIONAL COHORT STUDY
2016-5659	07/08/2016 08/05/2016	FDA/OC/OES/DFOI/	AMIE N VANELLA Faegre Baker Daniels LLP	SIMPLY THICK LLC, SIMPLY THICK - FOIA REQUESTS 4/6/16 TO PRESENT
2016-5660	07/08/2016 08/05/2016	FDA/OC/OES/DFOI/	casey pustelnik Porex Corporation	K811036
2016-5661	07/08/2016 08/05/2016	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2016-4685
2016-5662	07/08/2016 08/05/2016	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2016-5292
2016-5663	07/08/2016 08/05/2016	FDA/OC/OES/DFOI/	Ken Faenza Ascendant Mfg	2013-8702
2016-5664	07/08/2016 08/05/2016	FDA/OC/OES/DFOI/	Azimun Jamal CapsoVision, Inc.	K123864
2016-5665	07/08/2016 08/05/2016	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink	2016-4444
2016-5666	07/08/2016 08/05/2016	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink	2016-4768
2016-5667	07/11/2016 08/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Matt Jackson Matt Jackson	HEPLISAV-B - AERS
2016-5668	07/11/2016 08/08/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K082385

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2016-5669	07/11/2016 08/08/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K131482
2016-5670	07/11/2016 08/08/2016	FDA/OMPT/CDRH/OCE/DID/	D Michelle Williams Action Products, Inc.	K811528
2016-5671	07/11/2016 08/08/2016	FDA/OMPT/CDRH/OCE/DID/	Maria Wagner Prismatik Dentalcraft, Inc.	K953235
2016-5672	07/11/2016 08/08/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K094044
2016-5673	07/11/2016 08/08/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K083169
2016-5674	07/11/2016 08/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Matt Jackson Matt Jackson	HEPLISAV-B - REVIEWER'S NOTES
2016-5675	07/11/2016 08/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dominique Kendrick Sagent Pharmaceuticals, Inc.	ANDA 083246 - APPROVAL LETTER, SBA; ANDA 083246 - APPROVAL LETTER, SBA; ANDA 206404 - APPROVAL LETTER, SBA
2016-5676	07/11/2016 08/08/2016	FDA/OMPT/CDRH/OCE/DID/	Victoria Rothwell Immunexpress	K160911
2016-5677	07/11/2016 08/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tatiana Forman G&W LABORATORIES INC	NDA 065067 SBA
2016-5678	07/11/2016 08/08/2016	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/ORO/DIOP/	Zetetic, Inc. Zetetic, Inc.	FDA ENTRY DOCUMENTATION REQUEST ALL DOCUMENTATION JUNE 16, 2016 JUNE 30, 2016
2016-5679	07/11/2016 08/08/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K153563
2016-5680	07/11/2016 08/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John Kendzior Duane Morris, LLP	US COMPOUNDING PHARMACY, CONWAY, AR - MEDWATCH REPORTS 01/01/2016 - 07/06/2016

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2016-5681	07/11/2016 08/08/2016	FDA/OMPT/CDRH/OCE/DID/	L Capote PA L Capote PA	K022584
2016-5682	07/11/2016 08/08/2016	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink	2016-4959
2016-5683	07/11/2016 08/08/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	Nancy Klett Cerium Pharmaceuticals	NDA 017861 PACKAGE INSERT
2016-5684	07/11/2016 08/08/2016	FDA/OC/OES/DFOI/	John Stevenson Levy Konigsberg	2015-3223
2016-5685	07/11/2016 08/08/2016	FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/	JAMES S ROGERS JAMES S ROGERS LAW OFCS	CHIPOTLE E COLI OUTBREAK 2015 - INVESTIGATION RECS; INDIVIDUAL RECS
2016-5686	07/11/2016 08/08/2016	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	MITCHELL J YELSKY YELSKY & LONARDO LAW OFCS	KALMBACH FEEDS INC - 483S, CO RESP 1/15 TO PRESENT
2016-5687	07/11/2016 08/08/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BEJAMIN L ENGLAND ESQ BENJAMIN L ENGLAND & ASSOCIATES LLC	BULK INGREDIENT DRUG PRODUCT LISTINGS SUBMITTED BY DOMESTIC AND FOREIGN ESTABLISHMENTS 1/11 TO PRESENT
2016-5688	07/11/2016 08/08/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KARLA GLUEK Gustafson Gluek	ASACOL, ASACOL HD, DELZICOL - CORR, CLNCL STUDIES, REGULATORY SUBMISSIONS, ETC

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2016-5689	07/11/2016 08/08/2016	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	HENRY S STOLAR STOLAR, HENRY S	QUINCY MANUFACTURING INC - PREVAGEN COMM, FDA ACTIONS 5/15 TO PRESENT
2016-5690	07/11/2016 08/08/2016	FDA/OC/OES/ FDA/OMPT/CDRH/OCE/DID/ FDA/OPPLA/OP/ OC/ORA/ OC/ORA/	BRIAN MERCHANT MERCHANT, BRIAN	APPLE - HEALTHKIT, RESEARCH KIT, CAREKIT, ETC APPLICATIONS; MOBILE MEDICAL APPLICATIONS GUIDELINES 2/9/15, ETC
2016-5691	07/11/2016 08/08/2016	FDA/OC/OES/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OPPLA/OP/ FDA/OPPLA/OL/	KATHLEEN M CASEY AMERICAN BRIDGE 21ST CENTURY	JOHN THUNE, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, OFFICE OF THE COMMISSIONER, OFFICE OF POLICY - CORR 2003 TO 2005
2016-5692	07/11/2016 08/08/2016	FDA/OMPT/CDRH/OCE/DID/	LAUREN DAVIS ESQ Andrews & Thornton	BAIR HUGGER TOTAL TEMPERATURE MANAGEMENT SYS MODEL 505 WARMING UNIT K960167
2016-5693	07/11/2016 08/08/2016	FDA/OC/OES/DFOI/	LAUREN DAVIS ESQ Andrews & Thornton	BAIR HUGGER TEMPERATURE MANAGEMENT SYS K021473
2016-5694	07/11/2016 08/08/2016	FDA/OC/OES/DFOI/	LAUREN DAVIS ESQ Andrews & Thornton	MODIFICATION TO BAIR HUGGER TEMPERATURE MANAGEMENT SYS K053645
2016-5695	07/11/2016 08/08/2016	FDA/OMPT/CDRH/OCE/DID/	LAUREN DAVIS ESQ Andrews & Thornton	BAIR HUGGER TEMPERATURE MANAGEMENT SYS K041686
2016-5696	07/11/2016 08/08/2016	FDA/OMPT/CDRH/OCE/DID/	LAUREN DAVIS ESQ Andrews & Thornton	AUGUSTINE MEDICAL - BAIR HUGGER MODEL 750 TOTAL TEMPERATURE MANAGEMENT SYS K001149
2016-5697	07/11/2016 08/08/2016	FDA/OMPT/CDRH/OCE/DID/	LAUREN DAVIS ESQ Andrews & Thornton	BAIR PAWS TEMPERATURE MANAGEMENT SYS MODEL 850 K060865
2016-5698	07/11/2016 10/06/2016	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Marie Boyd University of South Carolina School of Law	RECS RE INSECTS, BUGS AS FOOD
2016-5699	07/11/2016 08/08/2016	FDA/OC/OES/DFOI/	JON POLZINE POLZINE, JON	INDIVIDUAL RECS
2016-5700	07/11/2016 08/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Katiemarie Wing K&L Gates LLP	UNAPPROVED POTASSIUM CHLORIDE FOR ORAL SOLUTION - CORR BETWEEN FDA AND SANDOZ, INC, UPSHER-SMITH, UPSHER-SMITH LABORATORIES, INC ETC 06/01/2016 - 07/05/2016
2016-5701	07/11/2016	FDA/OMPT/CDRH/OCE/DID/	Paul Chung	NEVRO CORP - CORR WITH FDA RE SENZA SPINAL CORD STIMULATOR, LABEL 07/09/2014 - 07/06/2016

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	08/08/2016		Chung, Paul	
2016-5702	07/11/2016 08/08/2016	FDA/OMPT/CDRH/OCE/DID/	Sally He Micro-Tech (Nanjing) Co., Ltd.	GUIDANCE OR TEST STANDARDS FOR NON CLINICAL TESTS OF NON-VASCULAR STENTS
2016-5703	07/11/2016 08/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tomohiro Nishimura KEIO UNIVERSITY SCHOOL OF MEDICINE	CASE REPORTS 4116443, 5767480, 5835886, ETC
2016-5704	07/11/2016 08/08/2016	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ OC/ORA/ OC/ORA/	Chelsey McIntyre Chelsey McIntyre	NEMOURS, AL DUPONT HOSPITAL, WILMINGTON, DE - INSPECTION REPORT 06/01/2016 - 07/01/2016
2016-5705	07/11/2016 08/08/2016	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Melissa Malapit Celgene Corporation	TIFFANI HAMILTON ATLANTA DERMATOLOGY, VEIN & RESEARCH CENTER, ALPHARETTA, GA - EIR 04/01/2014 - 07/11/2016
2016-5706	07/11/2016 08/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Katherine Kaempchen Forward Pharma Gmbh- Katherine Kaempchen	CASE REPORTS 12395888, 11866956, 11078171, ETC
2016-5707	07/11/2016 08/08/2016	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	Jon Brumbaugh BIOTRONIK, INC.	BIOTRONIK, INC, LAKE OSWEGO, OR - EIR 01/01/2014 - 07/07/2016
2016-5708	07/11/2016 08/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Zachary Mietus The Weinberg Group	ANDA 78699
2016-5709	07/11/2016 08/08/2016	FDA/OC/OES/DFOI/	Patrick T. Cusack Patrick Cusack	INDIVIDUAL RECS
2016-5710	07/11/2016 08/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 208923
2016-5711	07/11/2016 08/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tushar Manudhane Anand Rathi Securities	CADILA HEALTHCARE, MORAIYA - EIR 05/01/2016 - 07/08/2016

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2016-5712	07/11/2016 08/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SIDDHARTH KARNAWAT SIDDHARTH KARNAWAT	CADILA HEALTHCARE, INDIA - EIR 01/01/2016 - 07/07/2016
2016-5713	07/11/2016 08/08/2016	OC/CVM/OCD/	Doe J	VETERINARY ADVERSE EVENT REPORT
2016-5714	07/11/2016 08/08/2016	FDA/OGROP/ORAP/PA-FO/SAN-DO/SAN-CB/	Pat Hillenmeyer (Ms.) AbbVie, Inc.	GILEAD SCIENCES, FOSTER CITY, CA - EIR, 483, RESPONSE 01/01/2016 - 06/30/2016
2016-5715	07/11/2016 08/08/2016	FDA/OC/OES/DFOI/	Sarah Persinger DINSMORE & SHOHL	EIR FOR PHARMACIES, OUTSOURCING FACILITIES 01/01/2014 - 07/01/2016
2016-5716	07/11/2016 08/08/2016	FDA/OC/OES/DFOI/	Matt Jackson Matt Jackson	FOIA LOG 07/01/2015 - 07/01/2016
2016-5717	07/12/2016 08/09/2016	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCE/DID/	Paul Chung MILLENNIUM MANAGEMENT LLC	DEXCOM - RECS RE CONTINUOUS GLUCOSE MONITOR APPLICATION PROCESS TO GAIN DOSING CLAIM; DECISION TO HOLD FDA PANEL IN JULY 21 TO DISCUSS APPLICATION; ADVERSE EVENTS 07/11/2014 - 07/06/2016
2016-5718	07/12/2016 08/09/2016	OC/ORAP/ OC/ORAP/ OC/ORAP/OCI/ OC/ORAP/OCI/	Sarah N Lynch REUTERS	ASSET FORFEITURE, TOBACCO CASES - ANNUAL DATA 10/01/2008 - 07/06/2016
2016-5719	07/12/2016 08/09/2016	FDA/OGROP/ORAP/NE-FO/NWE-DO/NWE-CB/	Thomas Smith Morgan Stanley	OCULAR THERAPEUTIX, MA - 483 01/01/2014 - 07/06/2016
2016-5720	07/12/2016 08/09/2016	OC/ORAP/ OC/ORAP/ FDA/OGROP/ORAP/NE-FO/NYK-DO/NYK-DCB/	Mary Hancock Registrar Corp	CRYSTAL PHARMA S AU - RECS RE REFUSAL OF ENTRY 315-0088666-4
2016-5721	07/12/2016 08/09/2016	FDA/OO/OFBA/OAGS/ OC/ORAP/OCI/ OC/ORAP/OCI/	Sarah N Lynch REUTERS	COPY OF CONTRACT BETWEEN FDA OCI AND PUERTO RICO POLICE DEPARTMENT, INVOICES, TIMESHEETS 01/01/2013 - 07/06/2016
2016-5722	07/12/2016 08/09/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ZHENG ZHAO Center for Pharmaceutical Information and Engineering Research	CSPC ZHONGNUO PHARM CO, CHINA; HISUN PFIZER PHARMACEUTICALS CO, CHINA; SHANGHAI DESANO CHEMICAL PHARMACEUTICAL CO LTD, CHINA - 483 01/01/2015 - 07/01/2016;

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2016-5723	07/12/2016 08/09/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID HOFFMEISTER Wilson Sonsini Goodrich & Rosati, P.C.	TEVA - ANDA 77-342 APRVL LTR
2016-5724	07/12/2016 08/16/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	MARY BLASY Robbins Geller Rudman & Dowd LLP	EMERGENT BIOSOLUTIONS INC, BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY (BARDA) - BIOTHRAX VACCINE COMM 1/1/15 TO 6/30/16
2016-5725	07/12/2016 08/09/2016	FDA/OMPT/CDRH/OCE/DID/	MARC HANN HERAEUS KULZER INC	K812805
2016-5726	07/12/2016 08/09/2016	FDA/OGROP/ORAP/PA-FO/LOS- DO/LOS-CB/	BLAIRE LAM-GREENE Q & R CANADA INC	MICRO QUALITY LABORATORIES INC, BURBANK, CA - EIR 10/29/14-11/6/14
2016-5727	07/12/2016 08/09/2016	FDA/OGROP/ORAP/PA-FO/LOS- DO/LOS-CB/	MARK RUBIN LUMINA HEALTH PRODUCTS INC	POSITIVE POWER NUTRITION, MURRIETA, CA - EIRS, 483S 3/16 TO PRESENT
2016-5728	07/12/2016 08/09/2016	FDA/OC/OES/DFOI/	SUSAN WOLF ABRAMOWITZ AXELSON WILLIAMOWSKY BENDER & FISHMAN PC	ELEVATOR MAINTENANCE CONTACT INFO, MAINTENANCE LOGS
2016-5729	07/12/2016 08/09/2016	FDA/OGROP/ORACE-FO/BLT- DO/BLT-CB/ FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/ FDA/OGROP/ORAP/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORAP/PA-FO/SAN- DO/SAN-CB/ FDA/OGROP/ORASE-FO/FLA- DO/FLA-CB/ FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/	Connie Jones Tissue Banks International	TBI BALTIMORE/DC MEDICAL EYE BANK OF MARYLAND, BALTIMORE, MD; TBI BOSTON, BOSTON, MA; TBI ORLANDO/MEDICAL EYE BANK OF FLORIDA ETC - EIR 01/07/2012 - 07/07/2016
2016-5730	07/12/2016 08/09/2016	FDA/OGROP/ORAP/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORAP/PA-FO/SAN- DO/SAN-CB/	Paul Knoepfler UC DAVIS	MARK BERMAN, ELLIOT LANDER, CELL SURGICAL NETWORK - 483, WARNING LETTERS, UNTITLED LETTERS ETC 07/03/2015 - 07/07/2016
2016-5731	07/12/2016 08/09/2016	FDA/OMPT/CTP/OD/ OC/ORAO/CI/ OC/ORAO/CI/	Sarah N Lynch THOMSON REUTERS	BUDGE DOCUMENTS TO SHOW ANNUAL BREAKDOWN OF TOBACCO USER FEES THAT CTP HAS EARMARKED OR ALLOCATED FOR USE, OCI PLANS TO CTP 01/01/2009 - 07/07/2016

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2016-5732	07/12/2016 08/09/2016	FDA/OMPT/CDRH/OCE/DID/	Jiefeng Xi Celerite Technology	K120800
2016-5733	07/12/2016 08/09/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bobbie Brown Nostrum Laboratories, Inc.	ZHEJIANG HAISEN PHARMACEUTICAL CO LTD, CHINA - EIR 03/01/2015 - 04/30/2015
2016-5734	07/12/2016 08/09/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K153673
2016-5735	07/12/2016 08/09/2016	FDA/OFVM/CFSAN/OCD/EOS/	Nicolas Meneses Buhler AG	FAP 1M4727
2016-5736	07/12/2016 08/09/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gaurav Tinani Emkay Global	LUPIN LTD, INDIA - 483 06/29/2016 - 07/07/2016
2016-5737	07/12/2016 08/09/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Stephen Minkin Stephen Minkin	CORR, NOTES RE COLLECTION OF BLOOD PLASMA FROM PRISON INMATES IN ARKANSAS PENAL INSTITUTIONS 01/01/1984 - 12/31/1994
2016-5738	07/12/2016 08/09/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	RECS RE EXCLUSIVITY OF GLYCOPYRROLATE
2016-5739	07/12/2016 08/09/2016	FDA/OFVM/CFSAN/OCD/EOS/	William Thanhauser Center for Science in the Public Interest	DR PAULA R TRUMBO , CRYSTAL RIVERS - CORR WITH COCA COLA, AMERICAN BEVERAGE ASSOCIATION, ETC 01/01/2010 - 07/06/2016
2016-5740	07/12/2016 08/09/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Glen Kelley kaleo, Inc.	NDA 208411 SBA
2016-5741	07/13/2016 08/10/2016	FDA/OC/OES/DFOI/	Olga Vysotskaya Orb Intelligence	LIST OF REGISTERED FOOD FACILITIES 01/01/2016 - 07/07/2016
2016-5742	07/13/2016	FDA/OMPT/CDRH/OCE/DID/	Naomi Amano	K020234 K020235 K051321 CLIA WAIVER RECS

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	08/10/2016		Naomi Amano	
2016-5743	07/13/2016 08/10/2016	FDA/OMPT/CDRH/OCE/DID/	Naomi Amano Naomi Amano	K020234 K020235 K051321 CLIA WAIVER RECS
2016-5744	07/13/2016 08/10/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nancy Klett Cerium Pharmaceuticals	ANDA 091019 SBA
2016-5745	07/13/2016 08/10/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Matt Jackson Newtyn Management	DYNAVAX TECHNOLOGIES - COMPLETE RESPONSE LETTER 01/01/2013 - 02/28/2013
2016-5746	07/13/2016 08/10/2016	FDA/OGROP/ORAC/CE-FO/NWJ-DO/NWJ-CB/	Lydia Mulvany BLOOMBERG NEWS	COLONNA BROTHERS, NORTH BERGEN, NJ - 483, EIR, COMPLAINTS ETC01/01/2010 - 07/08/2016
2016-5747	07/13/2016 08/10/2016	FDA/OFVM/CFSAN/OCD/EOS/	Mojtaba Heydari Shiraz University of Medical Sciences	CINNAMON, CINNAMOMUM - AERS
2016-5748	07/13/2016 08/10/2016	FDA/OMPT/CDRH/OCE/DID/	Katrina Josefa Mulvihill Dr. Katrina Mulvihill	Pre market approval studies and post market studies for Mentor Saline smooth round morbid breast implants before 1999 01/01/1990 - 12/01/1998
2016-5749	07/13/2016 08/10/2016	FDA/OMPT/CDRH/OCE/DID/	Brandon Mikulski vista dental products	K150020
2016-5750	07/13/2016 08/10/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dr. Robert P. Baker Husson University School of Pharmacy	BENADRYL, PERIACTIN - LABEL REVISION HISTORY
2016-5751	07/13/2016 08/10/2016	FDA/OGROP/ORAC/CE-FO/MIN-DO/MIN-CB/	Robert L. Epstein, MD Epstein, Robert L	MERCY HEALTH SYSTEM OF JANESVILLE, WI IRB - REPORT, CORR 02/01/2016 - 07/11/2016
2016-5752	07/13/2016 08/10/2016	FDA/OMPT/CDRH/OCE/DID/	Kinnari Shah Medivators Inc.	K090636, K051595, K020875
2016-5753	07/13/2016 08/22/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Michael Griffith Chimera BioTechnology, Inc	NOVOSEVEN - AERS
2016-5754	07/13/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Douglas B. Farquhar	Copies of all adverse reaction reports received by FDA in 2015 or 2016, involving amniotic tissue products manufactured by

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	08/10/2016		Hyman, Phelps & McNamara P.C.	Amniotic Therapies LLC
2016-5755	07/13/2016 08/10/2016	FDA/OGROP/ORPA-FO/LOS-DO/LOS-CB/	RONALD DOUROS JAMES ALEXANDER CORP	B BRAUN MEDICAL, IRVINE, CA - 482, 483, RECALL
2016-5756	07/13/2016 08/10/2016	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	RONALD DOUROS JAMES ALEXANDER CORP	UNION CARBIDE CORP, TEXAS CITY, TX - 482, 482, RECALL
2016-5757	07/13/2016 08/10/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WARD 1026408, ADAM	RISPERDAL - AER
2016-5758	07/13/2016 08/10/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MURRAY P YANKS PA	DECADRON - AER 7/17/15
2016-5759	07/13/2016 08/10/2016	FDA/OMPT/CDRH/OCE/DID/	LAUREN DAVIS, Esq. Andrews & Thornton	HEATER COLLER DVC CONTAMINATION 1/10 TO 2/29/16
2016-5760	07/13/2016 08/10/2016	FDA/OFVM/CFSAN/OCD/EOS/	Doe J	RESULTS OF THE EXPERIMENTAL STUDY ON CONSUMER RESPONES TO WHOLE GRAIN LBLG STATEMENTS ON FOOD PACKAGES
2016-5761	07/13/2016 08/10/2016	FDA/OFVM/CFSAN/OCD/EOS/	JOANNA R. DRAKE IACM	ANALYTICAL RESULTS FOR EACH FD&C COLOR ADDITIVE FOR THE FOOD CATEGORIES CONSIDERED IN EXPOSURE ESTIMATE PAGES 35-39
2016-5762	07/13/2016 08/10/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	BENICAR - LOCATION OF MANUFACTURE 01/01/2010 - 07/07/2016
2016-5763	07/13/2016 08/10/2016	OC/ORASORM/ OC/ORASORM/	Kris Christian FDAZILLA	LIST OF INSPECTIONS 06/08/2016 - 07/11/2016
2016-5764	07/13/2016 08/10/2016	FDA/OC/OES/DFOI/	Zachary Mietus The Weinberg Group	FOIA LOGS 1/1/1990 to 12/30/2010 and 6/1/2015 - 7/12/2016
2016-5765	07/13/2016 08/10/2016	FDA/OC/OES/DFOI/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	John Melvin Seran Bioscience, Inc.	BIO-CONCEPT LABORATORIES INC, SALEM, NH - 482, 483 01/01/2011 - 12/31/2014
2016-5766	07/14/2016 08/11/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Linda McCauley Allergan, Inc	NDA 208073

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-5767	07/14/2016 08/11/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Paresh Dave AMBIT CAPITAL	ZYDUS CADILA, MORAIYA, INDIA - EIR; LUPIN DABHASA, INDIA - 483 01/01/2016 - 07/14/2016
2016-5768	07/14/2016 08/11/2016	FDA/OMPT/CDRH/OCE/DID/	Sean Phipps BARNES & THORNBURG LLP	K993407
2016-5769	07/14/2016 08/11/2016	FDA/OMPT/CDRH/OCE/DID/	Sean Phipps BARNES & THORNBURG LLP	K970074
2016-5770	07/14/2016 09/02/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Stephen Minkin Stephen Minkin	CORR, NOTIFICATION FROM FDA RE SAFETY RISKS OF BLOOD PLASMA COLLECTION FROM PRISON INMATES 01/01/1984 - 12/31/1994
2016-5771	07/14/2016 09/02/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Stephen Minkin Stephen Minkin	RECS RE 1983 FDA-INITIATED INTERNATIONAL RECALL OF BLOOD PLASMA LIKELY TAINTED WITH HEP B
2016-5772	07/14/2016 08/11/2016	FDA/OMPT/OSMP/OOPD/	Rachel Johnson FOI Services, Inc.	ORPHAN DRUG DESIGNATION REVIMID - INTERNAL CORR, CORR WITH APPLICANT, ETC
2016-5773	07/14/2016 08/11/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Susan Weinbach CONVENTUS BIOMEDICAL SOLUTIONS INC	NDA 21361
2016-5774	07/14/2016 08/11/2016	FDA/OMPT/CDRH/OCE/DID/	Charles Snow Hyman, Phelps & McNamara, P.C.	CORR BETWEEN FDA AND PHENOMENEX RE ADVERTISING, PROMOTION OF IN VITRO DIAGNOSTIC DEVICES 01/01/2016 - 07/12/2016
2016-5775	07/14/2016 08/11/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Doe J	MEDWATCH FOLLOW UP RECS 11/12/2015 - 07/12/2016
2016-5776	07/14/2016 08/11/2016	FDA/OMPT/CDRH/OCE/DID/	Jiefeng Xi Celerite Technology	K121195
2016-5777	07/14/2016 08/11/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	ANDA 78830
2016-5778	07/14/2016 08/11/2016	FDA/OGROP/ORAP/PA-FO/LOS- DO/LOS-CB/	Jackie Boktor Trace-Ability Inc.	PETNET, CULVER CITY, CA.; CARDINAL HEALTH NUCLEAR PHARMACY, VAN NUYS, CA; UCLA AHMANSON BIOMEDICAL CYCLOTRON FACILITY - INSPECTOR NOTES 01/01/2014 - 12/31/2015

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2016-5779	07/14/2016 08/11/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Zachary Mietus The Weinberg Group	ANDA 074507 ANDA 074707 ANDA 076569 ETC BIOEQUIVALENCE RECS
2016-5780	07/14/2016 08/11/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Guillaume Buell Guillaume Buell/Labaton Sucharow	VALEANT PHARMACEUTICALS INTERNATIONAL INC, - RECS, COMM RE PHARMACIES IN NETWORK, DRUG PRICING, ETC 01/01/2013 - 07/11/2016
2016-5781	07/14/2016 08/11/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 14901 SUPP APPROVAL RECS
2016-5782	07/14/2016 08/11/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Paul Danese FDABLE LLC	FAERS 8871601, 9163153, 9256819, ETC
2016-5783	07/14/2016 08/11/2016	FDA/OC/OES/DFOI/ FDA/OC/OES/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OPPLA/OP/	Tim Schwab Food & Water Watch	RECS RE FUTURE BIOTECHNOLOGY PRODUCTS AND OPPORTUNITIES TO ENHANCED CAPABILITIES OF THE BIOTECHNOLOGY REGULATORY SYSTEM
2016-5784	07/14/2016 08/11/2016	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/CIN- DO/CIN-CB/ FDA/OGROP/ORO/SE-FO/FLA- DO/FLA-CB/	Mary Hancock Registrar Corp	AEK-1765778-1 EQW-0015870-1 REFUSAL RECS
2016-5785	07/14/2016 08/11/2016	FDA/OMPT/CDRH/OCE/DID/	John Von Thaden United Dental Resources Corporation	K151295
2016-5786	07/14/2016 08/11/2016	FDA/OMPT/CDRH/OCE/DID/	Estela Celi STRYKER CORPORATION MEDICAL DIVIS	K931588 K102180
2016-5787	07/15/2016 08/12/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Elizabeth N. Dupras B&H Consulting Services, Inc.	IND 055195

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2016-5788	07/15/2016 08/12/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Carla Scarmazzi KING & SPALDING	ANDA 200675 ANDA 202346 TOOLS USED IN ADDITION TO PATCH TO HOLD IN PLACE ON SKIN DURING BIOEQUIVALENCE EVALUATION
2016-5789	07/15/2016 08/12/2016	FDA/OMPT/CDRH/OCE/DID/	Hyphen EIR 2016 Aniara Diagnostica	HYPHEN BIOMED, FRANCE - EIR 06/27/2016 - 06/30/2016
2016-5790	07/15/2016 08/12/2016	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	Joe Arevalo Joe Arevalo & Associates, Ltd	ENTRY 93Q-2005800-1 ENTRY SUMMARY, INWARD MANIFEST, COMMERCIAL INVOICE ETC
2016-5791	07/15/2016 08/12/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K152556
2016-5792	07/15/2016 08/12/2016	FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	Eloisa Valencia Kite Pharma	HOSPIRA, ROCKY MOUNT, NC - MOST RECENT EIR
2016-5793	07/15/2016 08/12/2016	FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/	Mary-Ellen Kelly PharmaTech, LLC	PHARMATECH, LLC, DAVIE, FL - EIR 03/02/2016 - 03/31/2016
2016-5794	07/15/2016 08/12/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rahul Jeewani IIFL Capital	LUPIN, LIMITED, GOA, INDIA - EIR JULY 2015
2016-5795	07/15/2016 08/12/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Suchira Ghosh Axinn, Veltrop & Harkrider LLP	RAPTIM RESEARCH PVT LTD, INDIA - EIR MOST RECENT
2016-5796	07/15/2016 08/12/2016	FDA/OC/OES/DFOI/	darrin s jones darrin s jones	DR MANUEL PEREZ MD, ORLANDO, FL - CORPORATE INTEGRITY AGREEMENT, MDR, COMPLAINTS WINTER PARK MEMORIAL HOSPITAL ETC
2016-5797	07/15/2016 08/12/2016	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	Joe Arevalo Joe Arevalo & Associates, Ltd	ENTRY 93Q-2005800-1 ENTRY SUMMARY, INWARD MANIFEST, COMMERCIAL INVOICE ETC
2016-5798	07/15/2016	FDA/OC/OES/DFOI/	Rachel Johnson	2016-4730

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	08/12/2016		FOI Services, Inc.	
2016-5799	07/15/2016 08/12/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rahul Jeewani IIFL Capital	CADILA HEALTHCARE LIMITED, INDIA - EIR 01/01/2016 - 07/12/2016
2016-5800	07/15/2016 08/12/2016	FDA/OMPT/CDRH/OCE/DID/	Jennifer Jackson Straumann USA, LLC	INSTITUT STRAUMANN AG, SWITZERLAND - EIR 09/01/2008 - 12/31/2009
2016-5801	07/15/2016 08/12/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rayna E. Kessler Robins Kaplan LLP	OLMESARTAN MEDOXOMIL - ANALYSES, REVIEWS, REPORTS ETC RE GASTROINTESTINAL TRACT 01/01/2012 - 07/11/2016
2016-5802	07/15/2016 08/12/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joe Gallagher eVenus Pharmaceutical Laboratories Inc.	ANDA 090943 SBA
2016-5803	07/15/2016 08/12/2016	FDA/OMPT/CDRH/OCE/DID/	Kinnari Shah Medivators Inc.	K153689, K153392, K141163
2016-5804	07/15/2016 08/12/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Gary Fanger Rise Therapeutics	IND AG013
2016-5805	07/15/2016 08/12/2016	FDA/OGROP/ORAN/NE-FO/NWE-DO/NWE-CB/	Eloisa Valencia Kite Pharma	BECTON DICKINSON, CANAAN, CT - EIR MOST RECENT
2016-5806	07/15/2016 08/12/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nadia Shikarpuria Nadia Shikarpuria	PROPECIA - AERS

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2016-5807	07/15/2016 08/12/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joe Gallagher eVenus Pharmaceutical Laboratories Inc.	ANDA 091649 SBA
2016-5808	07/15/2016 08/12/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joe Gallagher eVenus Pharmaceutical Laboratories Inc.	ANDA 202593 SBA
2016-5809	07/15/2016 08/12/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ike Swetlitz STAT	ANDA 090725
2016-5810	07/15/2016 08/12/2016	OC/ORO/ OC/ORO/	Doe J	CONSUMER COMPLAINT 146027
2016-5811	07/15/2016 08/12/2016	OC/ORO/ OC/ORO/	Jeffrey Wagner TEXAS CHILDREN'S HOSPITAL	SAMPLE RESULTS 966730, 966731, 966727, ETC
2016-5812	07/15/2016 08/12/2016	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2015-3506
2016-5813	07/15/2016 08/12/2016	FDA/OMPT/CDRH/OCE/DID/	Luke Klein UNIVERSITY OF WATERLOO	K152384
2016-5814	07/15/2016 08/12/2016	OC/ORO/ OC/ORO/	Doe J	CONSUMER COMPLAINT 146027
2016-5815	07/15/2016 08/12/2016	FDA/OMPT/CDRH/OCE/DID/	DANIELA HERMANN HERMANN MEDIZINTECHNIK GMBH	HERMANN MEDIZINTECHNIK GMBH - EIR 6/15-17/16
2016-5816	07/15/2016 08/12/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	NINA VAUGHAN RITEDOSE CORP	MYLAN LABS LTD, NAVI MUMBAI, INDIA - 483 7/15
2016-5817	07/15/2016 08/12/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MUHAMMAD 706732	MEDROXYPROGESTERONE ACETATE - LBLG

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2016-5818	07/15/2016 08/12/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	SALVACYL; MEDROXYPROGESTERONE - LBLG, CLNCL STUDY
2016-5819	07/15/2016 08/12/2016	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/	SAMANTHA MYERS ROANOKE CLAIMS SERVICES	JKUB LLC - ENTRY NO AGTOO118555
2016-5820	07/15/2016 08/12/2016	FDA/OC/OES/DFOI/	Tin Brian Nguyen Andrews & Thornton	RECS RE WEN HAIR PRODUCTS PREVIOUSLY RELEASED UNDER FOIA
2016-5821	07/15/2016 08/12/2016	FDA/OFVM/CFSAN/OCD/EOS/	DAVID J. ETTINGER Keller and Heckman LLP	FNC 650
2016-5822	07/15/2016 08/29/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	JOHN A MACORETTA SPECTOR ROSEMAN & KODROFF	GLAXO SMITH KLINE LLC - MUMPS VACCINE NDA & SUPPLEMENTS
2016-5823	07/15/2016 08/12/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KATE REYNOLDS ROCKY MOUNTAIN POISON & DRUG CENTER	FAERS - 8297778, 9186095, 10441643
2016-5824	07/15/2016 08/12/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KATE REYNOLDS ROCKY MOUNTAIN POISON & DRUG CENTER	FAERS - 7546906, 7546908, 7951550 ETC
2016-5825	07/15/2016 08/12/2016	FDA/OFVM/CFSAN/OCD/EOS/ OC/CVM/OCD/	GEORGE W. LEMEL Keller and Heckman LLP	FAP 2293
2016-5826	07/15/2016 08/12/2016	FDA/OFVM/CFSAN/OCD/EOS/	GEORGE W LEMEL Keller and Heckman LLP	FCN 963
2016-5827	07/15/2016 08/12/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RICHARD H WOODS LEVIN PAPANTONIO ET AL	TESTOSTERONE REPLACEMENT THERAPY PRODUCTS - Cmplnts
2016-5828	07/15/2016 08/12/2016	FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/	JEANNE MARIE MALUSH PRITZKER OLSEN	SALMONELLA VIRCHOW OUTBREAK - RECS

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		OC/ORAI/ FDA/OGROP/ORAI/SE-FO/FLA- DO/FLA-CB/		
2016-5829	07/15/2016 08/12/2016	FDA/OC/OES/DFOI/ FDA/OC/OES/	ALLAN BLUTSTEIN AMERICA RISING ADVANCED RESEARCH	EMAILS BTWN JEREMY SHARP & EVAN BAYH 7/15 TO PRESENT
2016-5830	07/15/2016 08/12/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16 MERCK & CO., INC.	2016-5182 - REQUEST LETTER ONLY
2016-5831	07/15/2016 08/12/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-5357 - REQUEST LETTER ONLY
2016-5832	07/15/2016 08/12/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-5099 - REQUEST LETTER ONLY
2016-5833	07/15/2016 08/12/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-5002 - REQUEST LETTER ONLY
2016-5834	07/15/2016 08/12/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-5290 - REQUEST LETTER ONLY
2016-5835	07/15/2016 08/12/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-5401 - REQUEST LETTER ONLY
2016-5836	07/15/2016 08/12/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-4586 - REQUEST LETTER ONLY
2016-5837	07/15/2016 08/12/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-5052 - REQUEST LETTER ONLY
2016-5838	07/15/2016 08/12/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-4677 - REQUEST LETTER ONLY
2016-5839	07/15/2016 08/12/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-5354 - REQUEST LETTER ONLY
2016-5840	07/15/2016 08/12/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-4593 - REQUEST LETTER ONLY
2016-5841	07/15/2016 08/12/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-5103 - REQUEST LETTER ONLY
2016-5842	07/15/2016 08/12/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-5177 - REQUEST LETTER ONLY
2016-5843	07/15/2016 08/12/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-4967 - REQUEST LETTER ONLY

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2016-5844	07/15/2016 08/12/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-4610 - REQUEST LETTER ONLY
2016-5845	07/15/2016 08/12/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-4657 - REQUEST LETTER ONLY
2016-5846	07/15/2016 08/12/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-5272 - REQUEST LETTER ONLY
2016-5847	07/15/2016 08/12/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-4675 - REQUEST LETTER ONLY
2016-5848	07/15/2016 08/12/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-5244 - REQUEST LETTER ONLY
2016-5849	07/18/2016 08/15/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	TEVA PHARMACEUTICALS WORDS CO LTD, HUNARY - 483 01/21/2016 - 01/29/2016
2016-5850	07/18/2016 08/15/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	AUSTIN BIOTECHNOLOGY INC, TAIWAN - 483 05/28/2015 - 05/29/2015
2016-5851	07/18/2016 08/15/2016	FDA/OGROP/ORR/SE-FO/FLA- DO/FLA-CB/ FDA/OMPT/CDRH/OCE/DID/	Scott Garrod Scott Garrod	DENTAL BRANDS FOR LESS, DAVIE, FL - APPROVALS, INSPECTION RECS, REGISTRATIONS 01/01/2010 - 07/12/2016
2016-5852	07/18/2016 08/15/2016	FDA/OGROP/ORR/SE-FO/FLA- DO/FLA-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	JEFFRY JACQMEIN, MD, JACKSONVILLE, FL - EIR, 483, RESPONSE 3/18/14
2016-5853	07/18/2016 08/18/2016	FDA/OGROP/ORR/CE-FO/DET- DO/DET-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	HURLEY MEDICAL CENTER IRB, FLINT, MI - EIR, 483, RESPONSE 08/01/2015 - 08/21/2015
2016-5854	07/18/2016 09/12/2016	FDA/OGROP/ORR/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORR/PA-FO/SAN- DO/SAN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	NIDEK, INC, FREMONT, CA - EIR, 483, RESPONSE 04/01/2014 - 04/14/2014
2016-5855	07/18/2016 08/15/2016	FDA/OGROP/ORR/SE-FO/ATL- DO/ATL-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	NORTHEAST GEORGIA MEDICAL CENTER IRB - EIR, 483, RESPONSE 9/11/14
2016-5856	07/18/2016	FDA/OGROP/ORR/CE-FO/DET-	Walter Chalkley	FRANCISCAN ST ELIZABETH HEALTH IRB, LAFAYETTE, IN -

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	08/18/2016	DO/DET-CB/	THOMSON REUTERS (SCIENTIFIC) SAS	EIR, 483, RESPONSE 12/3/14
2016-5857	07/18/2016 08/15/2016	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Walter Chakley THOMSON REUTERS (SCIENTIFIC) SAS	PIKESVILLE MEDICAL CENTER INC, IRB, PIKESVILLE, KY - EIR, 483, RESPONSE 8/28/15
2016-5858	07/18/2016 08/15/2016	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Walter Chakley THOMSON REUTERS (SCIENTIFIC) SAS	AMERICAN CATHETER CORP, STUART, FL - EIR, 483, RESPONSE 01/01/2016 - 01/28/2016
2016-5859	07/18/2016 08/18/2016	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Walter Chakley THOMSON REUTERS (SCIENTIFIC) SAS	JAMES HARRIS, MD, SOUTH BEND, IN - EIR, 483, RESPONSE 02/01/2016 - 02/05/2016
2016-5860	07/18/2016 08/15/2016	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	Walter Chakley THOMSON REUTERS (SCIENTIFIC) SAS	NEIL JOSEPHSON, MD, SEATTLE, WA - EIR, 483, RESPONSE 4/30/13
2016-5861	07/18/2016 08/15/2016	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ OC/OR/ OC/OR/	Walter Chakley THOMSON REUTERS (SCIENTIFIC) SAS	VANN HEALTHCARE SERVICES, GLASGOW, KY - EIR, 483, RESPONSE 9/24/14
2016-5862	07/18/2016 08/15/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Walter Chakley THOMSON REUTERS (SCIENTIFIC) SAS	KO DA PHARMACEUTICAL CO, TAIWAN - 483 05/25/2015 - 05/27/2015
2016-5863	07/18/2016 08/15/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Walter Chakley THOMSON REUTERS	SHANGHAI DESANO CHEMICAL PHARMACEUTICAL CO, LTD, CHINA - 483 05/04/2015 - 05/07/2015
2016-5864	07/18/2016 08/15/2016	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Walter Chakley THOMSON REUTERS	CHARLES JOST MD, MESA, AZ - EIR, 483, RESPONSE 04/01/2015 - 04/29/2015
2016-5865	07/18/2016 08/15/2016	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Walter Chakley THOMSON REUTERS (SCIENTIFIC) SAS	TRANSDERMAL CAP, CLEVELAND, OH - EIR, 483, RESPONSE 06/01/2015 - 06/30/2015
2016-5866	07/18/2016 08/15/2016	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Walter Chakley THOMSON REUTERS	SPECTRUM PHARMACEUTICALS, IRVINE, CA- EIR, 483, RESPONSE 3/31/15
2016-5867	07/18/2016 08/15/2016	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Walter Chakley THOMSON REUTERS (SCIENTIFIC) SAS	BOSTON SCIENTIFIC CORPORATION, SAINT PAUL, MN - EIR, 483, RESPONSE 09/01/2014 - 09/19/2014

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2016-5868	07/18/2016 08/15/2016	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	IMPLADENT, HOLLIS, NY - EIR, 483, RESPONSE 09/01/2013 - 09/26/2013
2016-5869	07/18/2016 08/15/2016	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	Walter chalkley THOMSON REUTERS (SCIENTIFIC) SAS	SAGE PHARMACEUTICALS, SHREVEPORT, LA - EIR, 483, RESPONSE 2/17/12
2016-5870	07/18/2016 08/18/2016	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	VENTLAB, LLC, GRAND RAPIDS, MI - EIR, 483, RESPONSE 3/2/15
2016-5871	07/18/2016 08/15/2016	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Walter Chakley THOMSON REUTERS (SCIENTIFIC) SAS	MEDTRONIC BIOMEDICUS, GRAND RAPIDS, MI - EIR, 483, RESPONSE 09/01/2014 - 09/11/2014
2016-5872	07/18/2016 08/15/2016	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	Walter Chakley THOMSON REUTERS (SCIENTIFIC) SAS	STERIS ISOMEDIX SERVICES, LIBERTYVILLE, IL - EIR, 483, RESPONSE 1/8/14
2016-5873	07/18/2016 08/15/2016	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	HOWARD M GROSS, MD, DAYTON, OH - EIR, 483, RESPONSE 1/14/15
2016-5874	07/18/2016 08/15/2016	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Walter Chalkley THOMSON REUTERS	GENENTECH, OCEANSIDE, CA - EIR, 483, RESPONSE 5/21/15
2016-5875	07/18/2016 08/15/2016	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	CUTISPHARMA, WILMINGTON, MA - EIR, 483, RESPONSE 1/29/14
2016-5876	07/18/2016 08/15/2016	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	CARDINAL HEALTH, FORT LAUDERDALE, FL - EIR, 483, RESPONSE 6/17/15
2016-5877	07/18/2016 08/15/2016	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	BARR LABORATORIES, FOREST, VA - EIR, 483, RESPONSE 12/18/15
2016-5878	07/18/2016 08/15/2016	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	ACTAVIS LABORATORIES, SUNRISE, FL - EIR, 483, RESPONSE 1/14/15
2016-5879	07/18/2016 08/15/2016	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Walter Chalkley THOMSON REUTERS	MEDIMMUNE, PHILADELPHIA, PA - EIR, 483, RESPONSE 5/20/15
2016-5880	07/18/2016	FDA/OGROP/ORASE-FO/FLA-	Walter Chakley	AGNES E UBANI, MD, TAMPA, FL - EIR, 483, RESPONSE

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	08/15/2016	DO/FLA-CB/	THOMSON REUTERS (SCIENTIFIC) SAS	6/6/13
2016-5881	07/18/2016 08/15/2016	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	KEYSTONE LABORATORIES, MEMPHIS, TN - EIR, 483, RESPONSE 8/29/12
2016-5882	07/18/2016 08/15/2016	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	LUPIN PHARMACEUTICALS, BALTIMORE, MD - EIR, 483, RESPONSE 5/23/14
2016-5883	07/18/2016 08/15/2016	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	OPMX, SAN DIEGO, CA - EIR, 483, RESPONSE 2/20/13
2016-5884	07/18/2016 08/15/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OPPLA/OL/	Adam Susser LATHAM & WATKINS	FDA RESPONSE TO FRANK PALLONE
2016-5885	07/18/2016 08/15/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Aline Fairweather PEPPER HAMILTON & SCHEETZ	NDA 18082, NDA 18723, NDA 19680
2016-5886	07/18/2016 08/15/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joann Delenick Delenick, Joann C	SUPREP AERS
2016-5887	07/18/2016 08/15/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ike Swetlitz STAT	CORR BETWEEN FDA AND SANDOZ RE ANDA 090725
2016-5888	07/18/2016 08/29/2016	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Chloe Sorvino FORBES MAGAZINE	COMMUNICATIONS BETWEEN FDA AND JAMES LEPRINO OF LEPRINO FOODS, WARNING LETTERS, RECALLS, ETC 01/01/2006 - 07/01/2016

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		FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/		
2016-5889	07/18/2016 08/15/2016	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Luke Rosseel KJC Law Firm, LLC	CAMBRIDGE BIOMEDICAL, BOSTON, MA - INSPECTION RECS 03/01/2014 - 10/31/2014
2016-5890	07/18/2016 08/15/2016	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	Therapeutic Proteins International, LLC Therapeutic Proteins International, LLC	THERAPEUTIC PROTEINS INTERNATIONAL LLC, CHICAGO, IL- EIR 01/01/2015 - 07/13/2016
2016-5891	07/18/2016 08/15/2016	FDA/OFVM/CFSAN/OCD/EOS/	Carrie Kahn Cardno ChemRisk	Wenninger, J.A. 1984. "Denial of petition for 'Labeling of Warning on the Hazardous Effects Produced by Asbestos in Cosmetic Talc' from Philippe Douillet." 7/11/84; Taylor, L. 1984. "Request for CAC Evaluation of the Hazard of Asbestos Contamination of Cosmetic Talc." FDA Memo dated Nov. 15, 1984.
2016-5892	07/18/2016 08/15/2016	OC/ORA/ORM/ OC/ORA/ORM/	Eyal Maor FDAAWARE	INSPECTION DATA
2016-5893	07/18/2016 08/15/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MELANIE HASEK PRA Health Sciences	TORAY INDUSTRIES - NALFURAFINE HCL IND 101,322 PRE-IND SUBMISSIONS, CORR 12/1/07 TO 12/18/08
2016-5894	07/18/2016 10/06/2016	FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	MICHAEL S THOMAS MATECUN THOMAS OLSON	NATURE MADE, PHARMAVITE VITAMINS - SALMONELLA RECALL RECS
2016-5895	07/18/2016 08/15/2016	OC/CVM/OCD/ OC/ORA/ OC/ORA/ FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	KRISTINE M YOUNG Mayer Brown LLP	BLUE BUFFALO COMPANY LTD - MISLABELED INGREDIENTS, CORR, RECALL RECS, ETC
2016-5896	07/18/2016 08/15/2016	FDA/OFVM/CFSAN/OCD/EOS/	DAVID J ETTINGER Keller and Heckman LLP	FCN 650 - RVW MEMO
2016-5897	07/18/2016	FDA/OMPT/CDER/GRP/DIDP/	A LUKE SMITH	SANDOZ - MINOCYCLINE HCL EXTENDED-RELEASE TABS

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	08/15/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RADICE LAW FIRM	ANDA 90-422 APRVL ROUTING SUMMARY
2016-5898	07/18/2016 08/15/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID HOFFMEISTER Wilson Sonsini Goodrich & Rosati, P.C.	SANDOZ - TIGECYCLINE ANDA 91-620 APRVL LTR
2016-5899	07/18/2016 08/15/2016	FDA/OC/OES/DFOI/	JONATHAN BONILLA Texas Attorney General	SEROQUEL, SEROQUEL XR - RVWS 10/06, 10/08
2016-5900	07/18/2016 08/15/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PATRICK O'LEARY SIDLEY AUSTIN LLP	PRIORITY LIST FOR PRODUCT-SPECIFIC BIOEQV GUIDANCE DEVELOPMENT
2016-5901	07/18/2016 08/15/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PATRICK O'LEARY SIDLEY AUSTIN LLP	TRANSDERMAL FENTANYL SYS - CORR 1/1/16 TO PRESENT
2016-5902	07/18/2016 08/15/2016	OC/ORO/ OC/ORO/	Doe J	INDIVIDUAL RECS
2016-5903	07/18/2016 08/15/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	A LUKE SMITH ESQ RADICE LAW FIRM	RANBAXY - MINOCYCLINE HCL EXTENDED-RELEASE TABS ANDA 91-118 APRVL ROUTING SUMMARY
2016-5904	07/18/2016 08/15/2016	FDA/OMPT/CDRH/OCE/DID/	YONEI MIZUNO NIDEK CO LTD	SOFTWARE CO LTD - LSFQ-NAVI K153239
2016-5905	07/18/2016 08/15/2016	FDA/OC/OES/DFOI/	JAMES STRUVER KNOWLEDGE ECOLOGY INTERNATIONAL	FOI DAILY LOG 1/1/15 TO PRESENT
2016-5906	07/18/2016 08/15/2016	FDA/OC/OES/DFOI/	Jonathan Jones Center for Investigative Reporting/REVEAL	IVF, ASSISTED REPRODUCTION CLINICS HANDLING HUMAN REPRODUCTIVE TISSUES - WARNING LETTERS, INSPECTION RECS, ETC 01/01/2010 - 07/06/2016
2016-5907	07/18/2016 08/15/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 7/4-8/16
2016-5908	07/18/2016	FDA/OC/OES/DFOI/	DAVID MCFARLAND	CLOSED FOI REQUESTS 7/4-8/16

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	08/15/2016		FDA REVIEW/FDA WEBVIEW	
2016-5909	07/18/2016 08/15/2016	FDA/OC/OES/DFOI/	DEBI COHEN FDA REVIEW/FDA WEBVIEW	CLOSED FOI REQUESTS 7/4-8/16
2016-5910	07/18/2016 08/15/2016	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 7/4-8/16
2016-5911	07/18/2016 08/15/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 6/27/16-7/1/16
2016-5912	07/18/2016 08/15/2016	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOI REQUESTS 6/27/16-7/1/16
2016-5913	07/18/2016 08/15/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 6/27/16-7/1/16
2016-5914	07/18/2016 08/15/2016	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 6/27/16-7/1/16
2016-5915	07/18/2016 08/15/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 6/20-24/16
2016-5916	07/18/2016 08/15/2016	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOI REQUESTS 6/20-24/16
2016-5917	07/18/2016 08/15/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 6/20-24/16
2016-5918	07/18/2016 08/15/2016	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 6/20-24/16
2016-5919	07/19/2016 08/16/2016	FDA/OC/OES/DFOI/ FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORACE-FO/PHI- DO/PHI-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCE/DID/ OC/CVM/OCD/	Katherine Williams Certified Quality Associates, Inc.	INSPECTIONS RECS

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2016-5920	07/19/2016 08/16/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K160511
2016-5921	07/19/2016 08/16/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michael Cipriano Informa / Natural Products Insider	IND CLINICAL HOLD LETTERS 2016, RECS RE HOLDS LIFTED 01/01/2016 - 07/14/2016
2016-5922	07/19/2016 08/16/2016	FDA/OC/OES/DDM/ FDA/OMPT/CDRH/OCE/DID/	Clifford Rieders, Esq. Rieders, Clifford A	ADVISORY COMMITTEE RECOMMENDATIONS, DECISIONS RE CLASS III PMA APPROVAL FOR LINUX SD
2016-5923	07/19/2016 08/16/2016	FDA/OMPT/CDRH/OCE/DID/	Shoval Dekel GLOBAL RESOURCES INTERNATIONAL	K883968 K911997
2016-5924	07/19/2016 08/16/2016	FDA/OMPT/CDRH/OCE/DID/	Maritza Ward HealthTronics	S&E SUMMARY P970019
2016-5925	07/19/2016 08/16/2016	FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/	Daniel Pearce ACP Inc.	ACP INC, CEDAR RAPIDS, IA - EIR 01/01/2010 - 12/31/2012
2016-5926	07/19/2016 08/16/2016	FDA/OMPT/CDRH/OCE/DID/	John D'Angelo Align Technology	K123402
2016-5927	07/19/2016 08/16/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kelly Reich Biologics Consulting Group, Inc.	NDA 020378
2016-5928	07/19/2016 08/16/2016	FDA/OMPT/CDRH/OCE/DID/	Doe J	K100441
2016-5929	07/19/2016 08/16/2016	FDA/OMPT/OSMP/OOPD/	Elisha D.O. Roberson WASHINGTON UNIVERSITY IN ST. LOUIS	ABBVIE HUMIRA ORPHAN DESIGNATION RECS
2016-5930	07/19/2016 08/16/2016	FDA/OGROP/ORR/PA-FO/SAN-DO/SAN-CB/	Rami Musleh Vitafarm Labs Inc.	GIMBALS BROTHERS, SOUTH SAN FRANCISCO, CA - 483 01/02/2015 - 07/14/2016
2016-5931	07/19/2016 08/16/2016	FDA/OMPT/CDRH/OCE/DID/	Rebecca Walters Ethicon Endo-Surgery, Inc.	K093217 K131861 K133845 K143132 K151794
2016-5932	07/19/2016 08/16/2016	FDA/OMPT/CDRH/OCE/DID/	Jia Huang Boston Scientific Inc.	K101298 K120084 K152802

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2016-5933	07/19/2016 08/16/2016	FDA/OMPT/OSMP/OOPD/	Robb Lawrence Chesapeake Therapeutics	DEPOMED ORPHAN DESIGNATION REQUEST GABAPENTIN
2016-5934	07/19/2016 08/16/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Evan Stover Evan Stover	PATHEON ITALIA - 483 05/01/2015 - 07/14/2016
2016-5935	07/19/2016 08/16/2016	FDA/OMPT/OSMP/OOPD/	Robb Lawrence Chesapeake Therapeutics	HORIZANT ORPHAN DESIGNATION RECS
2016-5936	07/19/2016 08/16/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORA/ OC/ORA/ FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	Conor Heaton Pfaff, Gill & Ports, Ltd.	RECS RE RECALL D-1329-2015
2016-5937	07/19/2016 08/16/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Paul Danese FDABLE LLC	FAERS REPORTS 8871601, 9163153, 9256819, ETC
2016-5938	07/19/2016 08/16/2016	FDA/OGROP/ORACE-FO/ATL-DO/ATL-CB/	Carla Nolden Nolden , Carla D	AMERICAN RED CROSS SOUTHERN REGION FACILITIES, GEORGIA - EIR 12/08/2015 - 01/14/2016
2016-5939	07/19/2016 08/16/2016	FDA/OMPT/CDRH/OCE/DID/	Elizabeth Skale Weir and Partners, LLP	P950022 S001 - S076
2016-5940	07/19/2016 08/16/2016	FDA/OMPT/CDRH/OCE/DID/	Nancy Phan Globizz Corporation	K151764
2016-5941	07/19/2016 08/16/2016	FDA/OMPT/CDRH/OCE/DID/	Crystal Buffert Buffert, Crystal	RESPONSES TO CDRH CUSTOMER SATISFACTION SURVEY FOR ODE 01/01/2016 - 07/01/2016
2016-5942	07/19/2016 08/16/2016	FDA/OMPT/CDRH/OCE/DID/	Nancy Phan Globizz Corporation	K153753
2016-5943	07/19/2016 08/16/2016	FDA/OMPT/CDRH/OCE/DID/	Nancy Phan Globizz Corporation	K141421
2016-5944	07/19/2016	FDA/OMPT/CDER/ORP/DIDP/	Paige Stradley	DATE OF FIRST COMMERCIAL MARKETING WHICH HAS DISCLOSED TO FDA PURSUANT TO 21 CFR 314.107(c)(4)

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	08/16/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MERCHANT & GOULD	ANDA 200043
2016-5945	07/19/2016 08/16/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michael Stern COVINGTON & BURLING LLP	ANDA 075961
2016-5946	07/19/2016 08/16/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michael Stern COVINGTON & BURLING LLP	ANDA 075976
2016-5947	07/19/2016 08/16/2016	FDA/OFVM/CFSAN/OCD/EOS/	Kristi O Smedley Center for Regulatory Services Inc.	FAP 2286
2016-5948	07/19/2016 08/16/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joe Gallagher eVenus Pharmaceutical Laboratories Inc.	ANDA 091649 ROUTING APPROVAL SUMMARY
2016-5949	07/19/2016 08/16/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michael Stern COVINGTON & BURLING LLP	ANDA 075965 ORIGINAL LABELING
2016-5950	07/19/2016 08/16/2016	FDA/OGROP/ORACE-FO/MIN- DO/MIN-CB/	Steve Tellier KSTP-TV LLC	KWONG TUNG FOODS, INC, MINNEAPOLIS, MN - INSPECTION RECS 01/01/2006 - 07/15/2016
2016-5951	07/19/2016 08/16/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michael Stern COVINGTON & BURLING LLP	ANDA 075961 S 3 ORIGINAL LABEL
2016-5952	07/19/2016 08/16/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Maja Vencl-Joncic Glenmark Pharmaceuticals Inc	ANDA 208077
2016-5953	07/19/2016 08/16/2016	FDA/OFVM/CFSAN/OCD/EOS/	ANI BYRNE Jamieson Laboratories	JAMIESON - FORM FDA 3500, 3500A, 3500B

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2016-5954	07/19/2016 08/16/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	FOSOMAX (ALENDRONATE SODIUM) - AERS
2016-5955	07/19/2016 08/16/2016	FDA/OMPT/CDRH/OCE/DID/	THOMAS J ZINNANTI THOMASVILLE MEDICAL INC	GOMCO CIRCUMCISION CLAMP K926535
2016-5956	07/19/2016 08/16/2016	FDA/OMPT/CDRH/OCE/DID/	JOSEPH SANT'ANGELO MEDPAK LLC	LIQUID BANDAGE K032948
2016-5957	07/19/2016 08/16/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	THERESA K SERFASS SERFASS, THERESA K	OPDIVO - RECS, AERS
2016-5958	07/19/2016 08/16/2016	OC/CVM/OCD/	GREG BERGT Bergt Consulting Inc.	NADA 055-085 - DRUG SUMMARY
2016-5959	07/19/2016 08/16/2016	FDA/OMPT/CDRH/OCE/DID/	SHELLEY K WHITE PHD MPH Simmons College	VAGINAL MESH PRODUCTS - K851086, K120897, K011025, ETC
2016-5960	07/20/2016 08/17/2016	FDA/OMPT/CDRH/OCE/DID/	Assaf Azulay Top Li-Med Technologies LTD	K030688
2016-5961	07/20/2016 08/17/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCE/DID/	Sriraam Rathi ICICI Securities Ltd	K030688
2016-5962	07/20/2016 08/17/2016	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	DAILY LOG 6/20-24/16
2016-5963	07/20/2016 08/17/2016	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	DAILY LOG 6/27/16 -7/1/16
2016-5964	07/20/2016 08/17/2016	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	DAILY LOG 7/4-8/16
2016-5965	07/20/2016 08/17/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 6/20-24/16

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2016-5966	07/20/2016 08/17/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 6/27/16 - 7/1/16
2016-5967	07/20/2016 08/17/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 7/4-8/16
2016-5968	07/20/2016 08/17/2016	FDA/OC/OES/DFOI/	LAUREN BARR JH BARR & ASSOCIATES LLC	DAILY LOG 6/20-24/16
2016-5969	07/20/2016 08/17/2016	FDA/OC/OES/DFOI/	JH BARR & ASSOCIATES LLC	DAILY LOG 6/27/16 - 7/1/16
2016-5970	07/20/2016 08/17/2016	FDA/OC/OES/DFOI/	LAUREN BARR JH BARR & ASSOCIATES LLC	DAILY LOG 7/4-8/16
2016-5971	07/20/2016 08/17/2016	FDA/OC/OES/DFOI/	DOMINION GROUP INC	DAILY LOG 6/20-24/16
2016-5972	07/20/2016 08/17/2016	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 6/27/16 - 7/1/16
2016-5973	07/20/2016 08/17/2016	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 7/4-8/16
2016-5974	07/20/2016 08/17/2016	FDA/OC/OES/DFOI/	WILLIAM OLSON Center for Regulator Services, Inc	DAILY LOG 6/20-24/16
2016-5975	07/20/2016 08/17/2016	FDA/OC/OES/DFOI/	WILLIAM OLSON Center for Regulator Services, Inc	DAILY LOG 6/27/16 - 7/1/16
2016-5976	07/20/2016 08/17/2016	FDA/OC/OES/DFOI/	WILLIAM OLSON Center for Regulator Services, Inc	DAILY LOG 7/4-8/16
2016-5977	07/20/2016 08/17/2016	FDA/OC/OES/DFOI/	LESLIE RAMSEY FDA NEWS	DAILY LOG 6/20-24/16
2016-5978	07/20/2016 08/17/2016	FDA/OC/OES/DFOI/	LESLIE RAMSEY FDA NEWS	DAILY LOG 6/27/16 - 7/1/16
2016-5979	07/20/2016 08/17/2016	FDA/OC/OES/DFOI/	LESLIE RAMSEY FDA NEWS	DAILY LOG 7/4-8/16
2016-5980	07/20/2016 08/17/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 6/20-24/16
2016-5981	07/20/2016 08/17/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 6/27/16 - 7/1/16

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2016-5982	07/20/2016 08/17/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 7/4-8/16
2016-5983	07/20/2016 08/17/2016	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Chloe Bird PCCA	Date Range: 01/01/2015 - 07/18/2016; This is a request under the Freedom of Information Act, 5 U.S.C. Sec. 552. I request that a copy of documents containing the following information be provided to me: (1) A complete listing of all foreign Imported Drug Products, listed alphabetically by product name. The list should include the labeler code of the manufacturer, the product code for the product, the package code, the name of the product, strength of the product, Quantity per package code, Drug Type, Date listed, Manufacturer name, Manufacturer DUNS, Manufacturer FEI, Resident Agent, Importer of Record (all listed on registration), full address, country of origin and Business Operations Type. (2) A complete listing of all NDC numbers issued to US manufacturers of drug products. Request detailed in attached document. (3) A complete listing of all NDC numbers issued to both US and foreign drug firms listed in the Legacy DRLs (paper) database Request detailed in attached document...
2016-5984	07/21/2016 08/18/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Robert Blaskiewicz Robert Blaskiewicz	SR BURZYNSKI - RESPONSE TO WARNING LETTER 03/01/2016 - 07/16/2016
2016-5985	07/21/2016 08/18/2016	FDA/OC/OES/DFOI/	Lew Romje Lew Romje	RECS PROVIDED OT STAR TRIBUNE RE MEDTRONIC RETROSPECTIVE CHART REVIEW 01/01/2002 - 07/30/2016
2016-5986	07/21/2016 08/18/2016	FDA/OC/OES/DFOI/	Daniel S. Weinberg Daniel Weinberg	RECORDS OF REQUESTS FROM PHIZER ETC
2016-5987	07/21/2016 08/18/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	INDIVIDUAL RECS
2016-5988	07/21/2016 08/18/2016	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	Darren Walsh Edwards Lifesciences	EDWARDS LIFESCIENCES, IRVINE, CA - EIR 02/01/2016 - 02/15/2016
2016-5989	07/21/2016 08/18/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mo Dimbil ADVERSEEVENTS INC	HP ACTHAR GEL - AERS
2016-5990	07/21/2016	FDA/OMPT/CDER/ORP/DIDP/	Daniel Lin	LEMTRADA - SBA

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	08/18/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	AbbVie Inc.	
2016-5991	07/21/2016 08/18/2016	FDA/OMPT/CDRH/OCE/DID/	Jaclyn Docs Acuitive Technologies	K120486
2016-5992	07/21/2016 08/18/2016	FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/	Sue S Peixotto University of Texas at Austin Dell Medical School	UNIVERSITY OF TEXAS AT AUSTIN - 483 01/01/2010 - 07/18/2016
2016-5993	07/21/2016 08/18/2016	FDA/OMPT/CDRH/OCE/DID/	510(k) documents for K161421 Zhou, Ximei	K161421
2016-5994	07/21/2016 08/18/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Susan Todd Teligent Pharma, Inc.	NDA 050558
2016-5995	07/21/2016 08/18/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mo Dimbil ADVERSEEVENTS INC	ABSTRAL, ACTIQ, DURAGESIC ETC - AERS
2016-5996	07/21/2016 08/18/2016	FDA/OGROP/ORASW-FO/DEN- DO/DEN-CB/	Darren Walsh Edwards Lifesciences	EDWARDS LIFESCIENCES, DRAPER, UT - EIR 4/18/16- 5/20/16
2016-5997	07/21/2016 08/18/2016	FDA/OGROP/ORASW-FO/KAN- DO/KAN-CB/	Michael Mlodzik Boehringer Ingelheim Vetmedica, Inc.	BOEHRINGER INGELHEIM VETMEDICA, JOSEPH, MO - EIR 08/10/2015 - 08/14/2015
2016-5998	07/21/2016 08/18/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	casey pustelnik Porex Corporation	DRUG MASTER FILE 18121
2016-5999	07/21/2016 08/18/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rita Riess CONCERT PHARMACEUTICALS INC	NDA 10721
2016-6000	07/21/2016 08/18/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Suchira Ghosh Axinn, Veltrop & Harkrider LLP	RAPTIM RESEARCH PVT LTD, MUMBAI, INDIA - EIR SUMMARY FEB 2015

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-6001	07/21/2016 08/18/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sriraam Rathi ICICI Securities Ltd	SHILPA MEDICARE LIMITED FORMULATION UNIT, INDIA - 483 8/26/15
2016-6002	07/21/2016 08/18/2016	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OC/OES/DFOI/	Gina Ecolino Beveridge & diamond, P.C.	LIST OF CFSAN FOIA REQUESTS 06/25/2016 - 07/19/2016
2016-6003	07/21/2016 08/18/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Stuart Goldberg Litespeed Partners	NOTES, LETTERS, TRANSCRIPTS RE INDIVIOR RBP-7000
2016-6004	07/21/2016 08/18/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joe Gallagher eVenus Pharmaceutical Laboratories Inc.	ANDA 203793 APPROVAL LETTER
2016-6005	07/21/2016 08/18/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K151491
2016-6006	07/21/2016 08/18/2016	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Kristin Donahoo Sunovion Pharmaceuticals Inc.	3M NORTHRIDGE - 483, EIR 09/09/2014 - 09/17/2014
2016-6007	07/21/2016 08/18/2016	FDA/OC/OES/DFOI/	Mark Nasca Ghost Tree Capital	AKORN PHARMACEUTICALS - 483 01/01/2013 - 07/18/2016
2016-6008	07/21/2016 08/18/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Terry A. Jacobson MD Emory University Terry Jacobson MD	NDA 21654 NDA 21853 NDA 204977 RECS RE POOLING ANALYSIS
2016-6009	07/21/2016 08/18/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Robert Silverman SILVERMAN, ROBERT	NDA 19698 NDA 19645 SBA
2016-6010	07/21/2016 08/18/2016	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	FCN 1030
2016-6011	07/21/2016 08/18/2016	FDA/OMPT/CDRH/OCE/DID/	Charles Snow Hyman, Phelps & McNamara, P.C.	K161039

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2016-6012	07/21/2016 08/18/2016	FDA/OFVM/CFSAN/OCD/EOS/	Bronzson Woods Ambrosia Labs	July 2016 CFSAN Memo pertaining to import entry EVJ-0172772-9
2016-6013	07/21/2016 08/18/2016	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink	2016-5473
2016-6014	07/21/2016 08/18/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rafid Azad Rafid Azad	PRAXBIND - AERS
2016-6015	07/21/2016 08/18/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Natasha Hoque SANDOZ CANADA INC.	AKOVAZ - SBA
2016-6016	07/21/2016 08/18/2016	FDA/OC/OES/DFOI/	Catherine Geyman Epic Risk Solutions Ltd	CORDEN PHARMA - EIR, 483 PREVIOUSLY RELEASE 05/01/2014 - 09/17/2016
2016-6017	07/21/2016 08/18/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K160403
2016-6018	07/22/2016 08/19/2016	FDA/OC/OES/DDM/	Thea Graybill As You Sow	DKT 94P0036/CPI
2016-6019	07/22/2016 08/19/2016	FDA/OC/OES/DFOI/	Bianca Nunes COVINGTON & BURLING LLP	RECS RELEASED UNDER FOIA RE WHOLE FOODS 01/01/2016 - 07/19/2016
2016-6020	07/22/2016 08/19/2016	FDA/OMPT/CDRH/OCE/DID/	William Mandel Eigen	K153073
2016-6021	07/22/2016 08/19/2016	FDA/OMPT/CDRH/OCE/DID/	Izumi Maruo MIC INTERNATIONAL CORP	NIKKISO CO LTD SHIZUOKA PLANT, JAPAN, THAILAND - EIR 02/15/2016 - 02/22/2016
2016-6022	07/22/2016 08/19/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K092863
2016-6023	07/22/2016 08/19/2016	FDA/OMPT/CDRH/OCE/DID/	Joseph M Ascenzi JMA Consulting	K141693
2016-6024	07/22/2016 08/19/2016	FDA/OFVM/CFSAN/OCD/EOS/	Eleanor DaCosta United States Pharmacopeial Convention (USP)	CINNAMOMUM CASSIA TWIG - MEDWATCH REPORTS
2016-6025	07/22/2016 08/19/2016	FDA/OMPT/CDRH/OCE/DID/	Dhwani Thakkar Thakkar, Dhwani	K153249

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2016-6026	07/22/2016 08/19/2016	OC/CVM/OCD/	Elizabeth Carney Elizabeth Carney, DVM	AFOXOLANER, FLURALANER, SAROLANER - AERS
2016-6027	07/22/2016 08/19/2016	FDA/OC/OES/DFOI/	Francesca Reindel Stanford University (Biodesign Student Project)	K060526
2016-6028	07/22/2016 08/19/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John Benner Quinlan Partners	LABELING LOWER DOSE ESTROGEN-ALONE PRODUCTS FOR SYMPTOMS OF VVA - TRANSCRIPT, VIDEO, ATTENDEE LIST ETC 11/01/2015 - 07/20/2016
2016-6029	07/22/2016 08/19/2016	OC/ORA/ORM/ OC/ORA/ORM/	Ryan Smith Janus Capital Group: ATTN RYAN SMITH	INTAS, APOTEX, ACCORD, ETC - LIST OF INSPECTIONS 01/01/2015 - 07/19/2016
2016-6030	07/22/2016 08/19/2016	FDA/OC/OES/DDM/	Tarae L. Howell NIXON PEABODY LLP	DKT FDA-2007-P-0234 CERTIFIED
2016-6031	07/22/2016 08/19/2016	FDA/OMPT/CDRH/OCE/DID/	Lew Romje Lew Romje	COMM BETWEEN FDA AND MEDTRONIC RE FINDING, CONCERNS OF SUBSTANTIAL EQUIVALENCE OF 510K SUBMISSIONS FOR VERTE-STACK 01/01/2003 - 12/31/2003
2016-6032	07/22/2016 08/19/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dustin Block IPD Analytics, LLC	ANDA 206098 TENTATIVE APPROVAL LETTER
2016-6033	07/22/2016 08/19/2016	OC/ORA/ORM/ OC/ORA/ORM/	Jatin Kotian Jatin Kotian	LIST OF INSPECTIONS 04/01/2016 - 06/30/2016
2016-6034	07/22/2016 08/19/2016	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/ORO/DIOP/	Zetetic, Inc. Zetetic, Inc.	FDA ENTRY DOCUMENTATION JULY 01, 2016 JULY 15, 2016
2016-6035	07/22/2016 08/30/2016	FDA/OC/OES/DFOI/	Kris Christian FDAZILLA	PREVIOUSLY RELEASED 483, EIR, RESPONSE 06/09/2016 - 07/11/2016
2016-6036	07/22/2016 08/19/2016	OC/ORA/ORM/ OC/ORA/ORM/	Kris Christian FDAZILLA	LIST OF INSPECTION CITATIONS 07/12/2015 - 07/11/2016
2016-6037	07/22/2016 08/19/2016	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	Kristen Painter MINNEAPOLIS STAR TRIBUNE	GENERAL MILLS, KANSAS CITY, KA - 482, EIR, 483 ETC 05/01/2016 - 07/20/2016
2016-6038	07/22/2016 08/19/2016	FDA/OC/OES/DFOI/	Nazmin Amir-Khan Amir-Khan, Nazmin	54 FR 28872, 28881

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2016-6039	07/22/2016 08/19/2016	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	LeAnn Seidl-Kollmer Nature's Way Product	DREAMPAK, NEW BERLIN, WI - 483, EIR 07/06/2005 - 07/19/2016
2016-6040	07/22/2016 08/19/2016	FDA/OMPT/CDRH/OCE/DID/	Howard Liu ACON LABORATORIES INC	K801270 K003987
2016-6041	07/22/2016 08/19/2016	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	LESLIE RAMSEY FDA NEWS	KCAS, SHAWNEE, KS; BAYER HEALTH, SHAWNEE, KS; ANALYTICAL CHEMISTRY LABS, COLUMBIA, MO - 483
2016-6042	07/22/2016 08/19/2016	OC/ORORM/ OC/ORORM/	LESLIE RAMSEY FDA NEWS	LIST OF PHARMACEUTICAL, DVC, BIOLOGIC MANUFACTURING FACILITIES - 483 6/1-30/16
2016-6043	07/22/2016 08/19/2016	OC/OR/ OC/OR/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	SAMANTHA MYERS ROANOKE CLAIMS SERVICES	ERNIMICH INC - ENTRY NO AGT00101965
2016-6044	07/22/2016 08/19/2016	FDA/OC/OES/DFOI/	JEREMY M. DWORK MEYERS FOZI LLP	SUNRISE MEDICAL LLC - QUICKIE WHEELCHAIR CMLPTS 1/09 TO PRESENT
2016-6045	07/22/2016 08/19/2016	FDA/OMPT/CDRH/OCE/DID/	Jaclyn Docs Acuitive Technologies	K091088
2016-6046	07/22/2016 08/19/2016	FDA/OMPT/CDRH/OCE/DID/	Jaclyn Docs Acuitive Technologies	K052931
2016-6047	07/22/2016 08/19/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	BRANDON KELLER, Esq. KELLER LAW LLC	DISEASES OR MEDICAL CONDITIONS CAUSED BY GROWTH HORMONES
2016-6048	07/22/2016 08/19/2016	FDA/OMPT/CDRH/OCE/DID/	Jaclyn Docs Acuitive Technologies	K060917
2016-6049	07/22/2016 08/19/2016	FDA/OMPT/CDRH/OCE/DID/	Jaclyn Docs Acuitive Technologies	K081917
2016-6050	07/22/2016 08/19/2016	FDA/OMPT/CDRH/OCE/DID/	Jaclyn Docs Acuitive Technologies	K062466
2016-6051	07/22/2016 08/19/2016	FDA/OPPLA/OL/	SAM FALCONER Arizona Democratic Party	ALL LOGS OF EMAILS REGARDING SENATOR JOHN MCCAIN & FDA 2/12 TO PRESENT
2016-6052	07/22/2016 08/19/2016	FDA/OMPT/CDRH/OCE/DID/	Jaclyn Docs Acuitive Technologies	K053344
2016-6053	07/22/2016 08/19/2016	FDA/OMPT/CDRH/OCE/DID/	Jaclyn Docs Acuitive Technologies	K971723
2016-6054	07/22/2016	FDA/OMPT/CDRH/OCE/DID/		BRAINSCOPE LLC, BETHESDA, MD K143643

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	08/19/2016		THORNTON, KIRTLEY	
2016-6055	07/22/2016 08/19/2016	FDA/OC/OES/DFOI/	GLORIA A. WORCH BAXTER BAKER ET AL	NEW ENGLAND COMPOUND PHARMACY INC - ESI REFLECTING NECC, METHYLPREDNISOLONE ACETATE DATA
2016-6056	07/22/2016 08/19/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SPURLOCK, KATIE	CLINDAMYCIN, PROCTOFOAM - AER
2016-6057	07/22/2016 08/19/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MELISSA V. MALAPIT Celgene Corporation	ALL RECORDS REGARDING HUMAN DRUGS
2016-6058	07/25/2016 08/22/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Susan Todd Teligent Pharma, Inc.	NDA 050578
2016-6059	07/25/2016 08/22/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Susan Todd Teligent Pharma, Inc.	NDA 019090
2016-6060	07/25/2016 08/22/2016	FDA/OFVM/CFSAN/OCD/EOS/	Tim Manning Commonwealth Laboratories, LLC	RECS RE SHELF LIFE OF GRANULATED SUGAR 06/15/2010 - 07/19/2016
2016-6061	07/25/2016 08/22/2016	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	Min Than NEW YORK CITY HEALTH AND HOSPITAL	INFUSION OPTIONS INC - RESPONSE TO WARNING LETTER 03/21/2016 - 07/19/2016
2016-6062	07/25/2016 08/22/2016	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	Andrew Finkelstein Susquehanna Financial Group	AKORN, DECATUR, IL - SUMMARY OF 483 JUNE 2016
2016-6063	07/25/2016 08/22/2016	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	Paula Morrison Paula morrison	CC 145938 RESPONSE TO COMPLAINT
2016-6064	07/25/2016 08/22/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ron Marchesani Samsung Biologics	SAMSUNG BIOLOGICS, KOREA - EIR 05/01/2015 - 07/20/2016

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2016-6065	07/25/2016 08/22/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dave Facklam CTI Clinical Trial & Consulting Services	HYROXYUREA - APPROVAL PACKAGE FOR SICKLE SELL APPROVAL INDICATION
2016-6066	07/25/2016 08/22/2016	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Pat Hillenmeyer (Ms.) AbbVie	PHARMACEUTICS INTERNATIONAL INC, HUNT VALLEY, MD - EIR 05/25/2011 - 07/20/2016; 483 2016
2016-6067	07/25/2016 08/22/2016	FDA/OMPT/CDRH/OCE/DID/	Gary Syring Quality and Regulatory Assoc. LLC	K0113977
2016-6068	07/25/2016 08/22/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ian Chia Pacira Pharmaceuticals, Inc.	NULOJIX - AERS
2016-6069	07/25/2016 08/22/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Colleen Johns Sancilio & Company, Inc.	CHEMPORT, INC, KOREA - EIR
2016-6070	07/25/2016 08/22/2016	FDA/OMPT/OSMP/OOPD/	Rachel Johnson FOI Services, Inc.	IMIQUIMOD ORPHAN DESIGNATION RECS
2016-6071	07/25/2016 08/22/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SKS SINGH SKS Singh	WOCKHARDT, INDIA - EIR 05/01/2016 - 07/21/2016
2016-6072	07/25/2016 08/22/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anubhav Aggarwal CREDIT SUISSE	WOCKHARDT, INDIA - EIR 06/15/2016 - 07/21/2016
2016-6073	07/25/2016 08/22/2016	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	Jeff Ho Folger Hill Asset Management	AKORN PHARMACEUTICALS, HI-TECH PHARMA, DECCATUR, IL - 483 01/01/2016 - 07/21/2016
2016-6074	07/25/2016 08/22/2016	FDA/OMPT/CDRH/OCE/DID/	Glenn Persello Multi Radiance Medical	K151816
2016-6075	07/25/2016	FDA/OC/OES/DFOI/	Ken Faenza	BIOSIM, NDA 017861 - FOIA REQUESTS

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	08/22/2016		Ascendant Mfg	
2016-6076	07/25/2016 08/22/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K992832
2016-6077	07/25/2016 08/22/2016	FDA/OMPT/CTP/OD/	Stephanie Resnik COVINGTON & BURLING LLP	RECS RE TOXICOLOGICAL MODELS, TESTS, ETC FOR REVIEWING SUBSTANTIAL EQUIVALENCE REPORTS TO DETERMINE WHETHER A NEW TOBACCO PRODUCT RAISES QUESTIONS OF PUBLIC HEALTH AS COMPARED TO THE PREDICATE PRODUCT 01/01/2012 - 07/20/2016
2016-6078	07/25/2016 08/22/2016	FDA/OMPT/CDRH/OCE/DID/	Jeffrey M Williams on behalf of SNC Holdings Jeffrey M Williams	K040687 K052118 K061051
2016-6079	07/25/2016 08/22/2016	FDA/OC/OES/DFOI/	LOUIS SLESIN MICROWAVE NEWS	NTP/NIEHS ANIMAL EXPOSURE STUDIES ON CELL PHONE RADIATION
2016-6080	07/25/2016 08/22/2016	FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/	JONATHAN JONES Center for Investigative Reporting/REVEAL	HUNTINGTON REPRODUCTIVE CENTER, PASADENA, CA; HRC FERTILITY, LAGUNA HILLS, CA; SOUTHERN CALIFORNIA REPRODEUCTIVE CENTER, BEVERLY HILLS, CA, ETC - INSP LTRS, WARNING LTRS, PENALTIES, ETC 1/10 TO PRESENT
2016-6081	07/25/2016 08/22/2016	FDA/OC/OES/DDM/	REBECCA ANDERSON PHD ANDERSON, REBECCA J	ARTHRITIS ADVISORY COMMITTEE MTG - ENBREL (ETANERCEPT) TRANS 9/16/98
2016-6082	07/25/2016 08/22/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	DIANE HARPER MD MPH MS UNIV OF LOUISVILLE SCHOOL OF MEDICINE	GARDISIL9 EXTENSION BLA/STN 125508/15
2016-6083	07/25/2016 08/22/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HELMAR C OLSON OLSON, HELMAR C	PFIZER - ZOLOFT AERS
2016-6084	07/25/2016 08/22/2016	FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORR/PA-FO/SAN-DO/SAN-CB/	JANET SIPRASERT INTERNATIONAL DELICACIES INC	INTERNATIONAL DELICACIES INC, RICHMOND, CA - EIR 3/24/16
2016-6085	07/25/2016 08/22/2016	FDA/OMPT/CDRH/OCE/DID/	KIMBAL R KIDWELL KIDWELL, KIMBAL R	ETHICON INC - INTERRUPTED #1 PROLENE SUTURES BANNED BY THE FDA 2/12-16/10
2016-6086	07/25/2016 08/22/2016	FDA/OC/OES/DFOI/ OC/ORR/ORM/ OC/ORR/ORM/	JONATHAN KAUFMAN WILLIAM BLAIR & CO	PATHEON - 483S 2011 TO 1994; CATALENT - 483S 2011 TO PRESENT
2016-6087	07/25/2016	FDA/OGROP/ORR/CE-FO/CIN-	JENNIFER CARRAGHER	MORTON SALT INC, RITTMAN, OH - EIRS 8/14

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	08/22/2016	DO/CIN-CB/	ALMAC GROUP	
2016-6088	07/25/2016 08/22/2016	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	JENNIFER CARRAGHER ALMAC GROUP	CHURCH AND DWIGHT CO INC, OLD FORT, OH - EIR 6/15
2016-6089	07/25/2016 08/22/2016	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	JENNIFER CARRAGHER ALMAC GROUP	CHURCH AND DWIGHT CO INC, GREEN RIVER, WY - EIR 4/15
2016-6090	07/25/2016 08/22/2016	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	AMY WENSLEY AMERICA FIRST LEGAL SERVICES, INC.	7301 TRINITY BLVD, FORT WORTH, TX - INSPS, CORR, RPTS, ETC 1/10 TO PRESENT
2016-6091	07/26/2016 08/23/2016	FDA/OC/OES/DFOI/	Livia Thevenard Cook THE UNIVERSITY OF ARIZONA	STUDY DRUGS CORRESPONDING TO INSPECTIONS
2016-6092	07/26/2016 08/23/2016	FDA/OMPT/CTP/OD/	Stephanie Resnik COVINGTON & BURLING LLP	RECS RE TOXICOLOGICAL MODELS, TESTS, ETC FDA APPLIES IN REVIEWING APPLICATIONS FOR MODIFIED RISK TOBACCO PRODUCTS TO DETERMINE WHETHER MRTP WILL SIGNIFICANTLY REDUCE HARM ETC 01/01/2012 - 07/20/2016
2016-6093	07/26/2016 08/23/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tatiana Forman G&W LABORATORIES INC	EFUDEX SBA
2016-6094	07/26/2016 08/23/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tatiana Forman G&W LABORATORIES INC	ADRUCIL SBA
2016-6095	07/26/2016 08/23/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tatiana Forman G&W LABORATORIES INC	TOLAK SBA
2016-6096	07/26/2016 08/23/2016	FDA/OMPT/CDRH/OCE/DID/	Jim Kusters Moria, Inc.	K113479
2016-6097	07/26/2016 08/23/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Scott Goldman Hyman, Phelps & McNamara P.C.	NDA 208056

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2016-6098	07/26/2016 08/23/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Edward Eichmann Xellia Pharmaceuticals USA	NDC 67919-011-01 LABELING
2016-6099	07/26/2016 08/23/2016	FDA/OFVM/CFSAN/OCD/EOS/	Scott Burya akzonobel	FCN 1460
2016-6100	07/26/2016 08/23/2016	FDA/OMPT/CDRH/OCE/DID/	Jim Kusters Moria, Inc.	K082947
2016-6101	07/26/2016 08/23/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Aeri Kim CHA Biotech	NDA BECAPLERMIN
2016-6102	07/26/2016 08/23/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Kristy Smith Rawls McNelis & Mitchell	INDIVIDUAL RECS
2016-6103	07/26/2016 08/23/2016	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	SE determination information March 2016 to present
2016-6104	07/26/2016 08/23/2016	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	Information regarding SE determinations for Altria, Philip Morris, US Smokeless Tobacco
2016-6105	07/26/2016 08/23/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anubhav Aggarwal CREDIT SUISSE	LUPIN, GOA, INDIA - EIR 06/20/2016 - 07/15/2016
2016-6106	07/26/2016 08/23/2016	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K101104
2016-6107	07/26/2016 08/23/2016	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	Information regarding NSE order for Maverick Menthol Silver Box 100
2016-6108	07/26/2016 08/23/2016	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/SW-FO/DAL- DO/DAL-CB/ FDA/OC/OES/DFOI/	Carlos B Evergreen Evergreen, Carlos	SAMPLE RESULTS 765093
2016-6109	07/26/2016 08/23/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anubhav Aggarwal CREDIT SUISSE	CADILA HEALTHCARE MORAIYA, INDIA - EIR 06/15/2016 - 07/15/2016

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2016-6110	07/26/2016 08/23/2016	FDA/OMPT/CTP/OD/	Stephanie Resnik COVINGTON & BURLING LLP	RECS RE TOXICOLOGICAL MODELS, TESTS, ETC FDA APPLIES WHEN REVIEWING A PREMARKET TOBACCO APPLICATION TO DETERMINE WHETHER THE NEW TOBACCO PRODUCT IS APPROPRIATE FOR THE PUBLIC HEALTH 01/01/2012 - 07/20/2016
2016-6111	07/26/2016 08/23/2016	FDA/OFVM/CFSAN/OCD/EOS/	Stacy Ehrlich Kleinfeld Kaplan and Becker LLP	CORR RE 3/5/12 WARNING LETTER BREATHABLE FOODS RE AEROSHOT 02/01/2012 - 07/20/2016
2016-6112	07/26/2016 08/23/2016	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Joshua M. Lurie, Esq. Furst & Lurie, LLP	NOURHAN TRADING GROUP, LLC, AVENEL, NJ - TESTING, INSPECTION, ETC 01/01/2010 - 07/21/2016
2016-6113	07/26/2016 08/23/2016	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Gael Tisack Terumo Cardiovascular Systems Corp.	TERUMO CARDIOVASCULAR SYSTSEMS CORPORATION, ANN ARBOR, MI - EIR 05/01/2016 - 05/31/2016
2016-6114	07/26/2016 08/23/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ADITYA KHEMKA DSP BLACKROCK MUTUAL FUND	IPCA, INDORE, INDIA - EIR 04/01/2016 - 07/21/2016;
2016-6115	07/26/2016 08/23/2016	FDA/OMPT/CDRH/OCE/DID/	Susan Joseph MEHTA LAW, L.C.	INDIVIDUAL RECS
2016-6116	07/26/2016 08/23/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Audrey Zhang NYU SCHOOL OF MEDICINE	MOST RECENT DRAFT OF COMPREHENSIVE INVENTORY OF ALL SURROGATE ENDPOINTS USED TO APPROVE NEW DRUGS
2016-6117	07/26/2016 08/24/2016	FDA/OC/OES/DFOI/ FDA/OPPLA/OL/	Audrey Zhang NYU SCHOOL OF MEDICINE	LOG OF CONGRESSIONAL CORR 01/01/2016 - 06/30/2016
2016-6118	07/26/2016 08/23/2016	FDA/OMPT/CDRH/OCE/DID/	Ian Sheffield Bridger Healthcare	ZIMMER BIOMET HOLDINGS, CANADA - EIR, 483, CORR ETC 07/21/2014 - 07/21/2016
2016-6119	07/26/2016 08/23/2016	FDA/OC/OES/DFOI/ OC/ORACE/ OC/ORACE/ FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORACE-SW-FO/KAN-DO/KAN-CB/	JEANNEMARIE MALUSH PRITZKER OLSEN	PIZZA RANCH INC - E COLI OUTBREAK CORR, INSP RECS, ENFORCEMENT ACTIONS, ETC 2015-2016
2016-6120	07/26/2016	FDA/OO/OHR/	EVELYN LOMBARDO CUSSON	INDIVIDUAL RECS

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	08/25/2016		GORDON FEINBLATT LLC	
2016-6121	07/26/2016 08/23/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PENLAND L WOODS Woods, Penland L	PLIVA KRAKOW SA - FLAGYL (METRONIDAZOLE) AERS
2016-6122	07/26/2016 08/23/2016	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	K MICHELLE VASSALLO Lincare Holdings	ADVANCED CARDIO SERVICES INC, CA - EIRS, 483S, WARNING LTRS 1/98 TO PRESENT
2016-6123	07/26/2016 08/23/2016	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	CHRISTINE LIVOTI DEER FIELD INSTITUTE	AKORN INC, DECATUR, IL - 483S 2015 TO PRESENT
2016-6124	07/26/2016 08/23/2016	FDA/OC/OES/DFOI/ OC/ORA/OCI/ OC/ORA/OCI/	VICTOR BURGOS UNITED STATES ANTI-DOPING AGENCY	DR THOMAS W LUTON INVESTIGATION 2011 TO 2013
2016-6125	07/26/2016 08/23/2016	FDA/OC/OES/DFOI/	IDALIA STARK 3M ESPE Dental Products	BISCO INC - THERACAL LC K063237
2016-6126	07/26/2016 08/23/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	KRISTEN KOHR KOHR, KRISTEN	INDIVIDUAL RECS
2016-6127	07/27/2016 08/24/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Charles Snow Hyman, Phelps & McNamara, P.C.	NDA 207793 ACTION PACKAGE/SBA
2016-6128	07/27/2016 08/24/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Laurel Benyo PHARMAFORCE INC	ANDA 201211 LABELING, INSERT ETC
2016-6129	07/27/2016 08/24/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	LUPRON RECS, AERS

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2016-6130	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Avanir Pharmaceuticals, Inc. Avanir Pharmaceuticals, Inc.	NUEDEXTA, ONZETRA XSAIL AERS
2016-6131	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mahidhar Chinta Dr. Reddy's Laboratories Inc.	ANDA 203976, ANDA 20446 TENTATIVE APPROVAL LETTERS
2016-6132	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michelle J. Looby Gustafson Gluek PLLC	ANDA 200562 TENTATIVE AND FINAL APPROVAL ROUTING SHEETS
2016-6133	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mahidhar Chinta Dr. Reddy's Laboratories Inc.	ANDA 200630 ANDA 206285 ANDA 206286 TENTATIVE APPROVAL LETTERS
2016-6134	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jeff Glassman CETYLITE INDUSTRIES INC	NDA 208032
2016-6135	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/CVM/OCD/	Carrie Morgan OFW LAW	RECS TO OR FROM CDER TO OR FROM CVM RE SYNERCID, DALFOPRISTIN, QUINUPRISTIN ETC
2016-6136	07/27/2016 08/24/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-4375
2016-6137	07/27/2016 08/24/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-4371
2016-6138	07/27/2016 08/24/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-5203
2016-6139	07/27/2016 08/24/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-1685

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2016-6140	07/27/2016 08/24/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-5196
2016-6141	07/27/2016 08/24/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-4359
2016-6142	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ryan Meyers KLJ Associates	INVOKANA, INVOKAMET, JARDIANCE ETC AERS
2016-6143	07/27/2016 08/24/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-2922
2016-6144	07/27/2016 08/24/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-4996
2016-6145	07/27/2016 08/24/2016	FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	Ted Keller EverPoint Asset Management	BAUSCH & LOMB, TAMPA, FL - 483, WARNING LETTER 05/01/2013 - 07/22/2016
2016-6146	07/27/2016 08/24/2016	FDA/OMPT/CDRH/OCE/DID/	Jeff Goehring YOUNG & THOMPSON	K130419
2016-6147	07/27/2016 08/24/2016	FDA/OMPT/CTP/OD/	Celeste Wheeler KLEINFELD, KAPLAN & BECKER	CORR RE VOLUNTARY GRANDFATHERED STATUS DETERMINATION REQUESTS FOR TUCSON CIGARETTE PRODUCTS ETC
2016-6148	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sanket Shah THE DEGGE GROUP LTD	NDA 21978 STUDY RECS
2016-6149	07/27/2016 08/24/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-4692
2016-6150	07/27/2016 08/24/2016	FDA/OMPT/CDRH/OCE/DID/	Jacob BenArie Gynamics Women Health Ltd	K060526 K131198
2016-6151	07/27/2016 08/24/2016	OC/ORO/OCI/ OC/ORO/OCI/	Patrick T. Cusack Private Citizen - Patrick T. Cusack	RECS RE INVESTIGATIONS OF FEMALE SPECIAL AGENTS IN ATLANTA DISTRICT OFFICE 02/01/2013 - 05/01/2014
2016-6152	07/27/2016 08/24/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-2266
2016-6153	07/27/2016 08/24/2016	FDA/OMPT/CDRH/OCE/DID/	Darren Walsh Edwards Lifesciences	EDWARDS LIFESCIENCES, DOMINICAN REPUBLIC - EIR 12/01/2015 - 12/31/2016

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2016-6154	07/27/2016 08/24/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-2981
2016-6155	07/27/2016 08/24/2016	OC/ORO/ OC/ORO/	JS Loyd Loyd, Jon	RECS RE SUGAR MANUFACTURER IN CONAGRA RECALL OF PF CHANG HOME MENU BRAND 07/06/2016 - 07/23/2016
2016-6156	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Carla Scarmazzi, FDA Specialist KING & SPALDING	NDA 22483 PROMOTIONAL MATERIALS ETC
2016-6157	07/27/2016 08/24/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2015-5600
2016-6158	07/27/2016 08/24/2016	FDA/OGROP/ORO/CE-FO/CIN-DO/CIN-CB/	Tami Ujii Teikoku Pharma USA, Inc.	CAMCO CHEMICAL CO, FLORENCE, KY; PHARMAFORCE, INC, HILLIARD, OH; KUTOL PRODUCTS CO, SHARONVILLE, OH ETC - 483 01/01/2011 - 07/22/2016
2016-6159	07/27/2016 08/24/2016	FDA/OC/OES/DFOI/	Brendon Integlia Wells Fargo Securities, LLC	VALEANT FACILITY RECS
2016-6160	07/27/2016 09/07/2016	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/DET-DO/DET-CB/	Kathy Barnes Kathy Barnes	COMPLAINT RECS
2016-6161	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Craig Vargo THE OHIO STATE UNIVERSITY	DOXORUBICIN HYDROCHLORIDE - RECS RE PACKAGE INSERT CHANGE 01/01/2012 - 07/22/2016
2016-6162	07/27/2016 08/24/2016	FDA/OC/OES/DFOI/	Bowman Cox Informa / Natural Products Insider	BAUSCH & LOMB, INC, TAMPA, FLA - 483 03/06/2015 - 03/06/2015
2016-6163	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Carla Scarmazzi, FDA Specialist KING & SPALDING	NDA 21005 PROMOTION RECS ETC
2016-6164	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Vincent Andolina AuroMedics Pharma LLC	CTX LIFESCIENCES PRIVATE LTD, INDIA - 483 01/01/2016 - 07/22/2016
2016-6165	07/27/2016	FDA/OMPT/CDRH/OCE/DID/	Kris Christian	BIOTRONIK AG, SWITZERLAND - 483 09/21/2015 - 09/24/2015

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	08/24/2016		FDAZILLA	
2016-6166	07/27/2016 08/24/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-4932
2016-6167	07/27/2016 08/24/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-4521
2016-6168	07/27/2016 08/24/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-4442
2016-6169	07/27/2016 08/24/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-4352
2016-6170	07/27/2016 08/24/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2016-3067
2016-6171	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	AGGRENOX RECS
2016-6172	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	EXFORGE RECS
2016-6173	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	HUMULIN R RECS
2016-6174	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	CARAFATE RECS
2016-6175	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	HUMIRA RECS
2016-6176	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	LEVEMIR FLEXTOUCH RECS

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2016-6177	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	LEVEMIR RECS
2016-6178	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	VICTOZA 3-PAK
2016-6179	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	COMBIGAN RECS
2016-6180	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	EXELON RECS
2016-6181	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	EPIDUO RECS
2016-6182	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	TRADJENTA RECS
2016-6183	07/27/2016 08/24/2016	FDA/OMPT/CDRH/OCE/DID/	WILLIAM BRODBECK STERIS CORP	K153689
2016-6184	07/27/2016 08/24/2016	FDA/OMPT/CDRH/OCE/DID/	JOHN M. FITZPATRICK, Esq. TOWE FITZPATRICK PLLC	CONCENSUS ORTHOPEDICS - ARTIFICIAL KNEE JOINTS CMLNPTS
2016-6185	07/27/2016 08/24/2016	FDA/OC/OES/DFOI/ FDA/OFVM/CFSAN/OCD/EOS/	FORSTHOFF, BRAD	KENT PRECISION - THICK IT RECS
2016-6186	07/27/2016	FDA/OPPLA/OL/	STEVE REILLY	RESPONSE TO 4/21/16 LETTER FROM SENATOR EDWARD

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	08/24/2016		USA TODAY	MARKEY TO COMMISSIONER ROBERT CALIFF REGARDING OPIOID PAINKILLERS
2016-6187	07/27/2016 08/24/2016	FDA/OMPT/CDRH/OCE/DID/	LEONARD NASS COMPRESSION THERAPY CONCEPTS	VASOPRESS SUPREME MINI (MW 5062564) 5/26/16 - RPT
2016-6188	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	PREMARIN VAGINAL RECS
2016-6189	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	ENBREL RECS
2016-6190	07/27/2016 08/24/2016	FDA/OMPT/CDRH/OCE/DID/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	NAMENDA XR RECS
2016-6191	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	FHUMALOG KWIKPEN RECS
2016-6192	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	JANUMET RECS
2016-6193	07/27/2016 08/24/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	PATRICK KELLY CONWAY HOMER & CHIN-CAPLAN PC	INDIVIDUAL RECS
2016-6194	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	PATADAY RECS
2016-6195	07/27/2016	FDA/OMPT/CBER/OCOD/DDOM/	PARTICK KELLY	INDIVIDUAL RECS

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	08/24/2016	ALFB/	CONWAY HOMER & CHIN-CAPLAN PC	
2016-6196	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	ORTHO-TRI-CY LO 28 RECS
2016-6197	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	JANUVIA RECS
2016-6198	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	LANTUS RECS
2016-6199	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	ABILIFY RECS
2016-6200	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	SYMBICORT RECS
2016-6201	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	TAMIFLU RECS
2016-6202	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	CIALIS RECS
2016-6203	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	VIAGRA RECS

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-6204	07/27/2016 08/24/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Berns Weiss LLP Berns Weiss LLP	SUBOXONE RECS
2016-6205	07/27/2016 08/24/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Berns Weiss LLP Berns Weiss LLP	SUBOXONE RECS
2016-6206	07/27/2016 08/24/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Berns Weiss LLP Berns Weiss LLP	ZETIA RECS
2016-6207	07/27/2016 08/24/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Berns Weiss LLP Berns Weiss LLP	XARELTO RECS
2016-6208	07/27/2016 08/24/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Berns Weiss LLP Berns Weiss LLP	NOVOLOG FLXPEN MIX 70/30 RECS
2016-6209	07/27/2016 08/24/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Berns Weiss LLP Berns Weiss LLP	BYSTOLIC RECS
2016-6210	07/27/2016 08/24/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Berns Weiss Berns Weiss LLP	SYNTHROID RECS
2016-6211	07/27/2016 08/24/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Berns Weiss Berns Weiss LLP	CRESTOR RECS

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2016-6212	07/27/2016	FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss	VENTOLIN HFA RECS
	08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP	
2016-6213	07/27/2016	FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss	NEXIUM RECS
	08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP	
2016-6214	07/27/2016	FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss	NEXIUM RECS
	08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP	
2016-6215	07/27/2016	FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP	TRAVATAN Z RECS
	08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP	
2016-6216	07/27/2016	FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP	RESPIMAT RECS
	08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP	
2016-6217	07/27/2016	FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP	ATRIPLA RECS
	08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP	
2016-6218	07/27/2016	FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP	SPIRIVA RECS
	08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP	
2016-6219	07/27/2016	FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP	PATANOL
	08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP	
2016-6220	07/27/2016	FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP	DUREZOL RECS

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	08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP	
2016-6221	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	XOPENEX HFA RECS
2016-6222	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	ASMANEX TWISTHALER RECS
2016-6223	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	MYRBETRIQ RECS
2016-6224	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	LOTEMAX RECS
2016-6225	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	ULORIC RECS
2016-6226	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	ADVAIR HFA RECS
2016-6227	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	ELIQUIS RECS
2016-6228	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	CHANTIX RECS

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2016-6229	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	PRADAXA RECS
2016-6230	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	AVODART RECS
2016-6231	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Berns Weiss LLP Berns Weiss LLP	ZOSTAVAX RECS
2016-6232	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	LEVEMIR FLEXPEN RECS
2016-6233	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	AZOR RECS
2016-6234	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	AMITIZA RECS
2016-6235	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	NORVIR RECS
2016-6236	07/27/2016	FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP	RELPAX RECS

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	08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP	
2016-6237	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	EFFIENT RECS
2016-6238	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	DULERA RECS
2016-6239	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	FOCALIN XR RECS
2016-6240	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	VYTORIN RECS
2016-6241	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	SEROQUEL XR RECS
2016-6242	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss Berns Weiss LLP	LYRICA RECS
2016-6243	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss Berns Weiss LLP	VYVANSE RECS
2016-6244	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	INVOKANA RECS

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2016-6245	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss Berns Weiss LLP	LANTUS SOLOSTAR RECS
2016-6246	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss Berns Weiss LLP	ADVAIR DISKUS RECS
2016-6247	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	NOVOLOG RECS
2016-6248	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	VESICARE RECS
2016-6249	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	PREMARIN RECS
2016-6250	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	BENICAR HCT RECS
2016-6251	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	LO LOESTRIN FE RECS
2016-6252	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	LUMIGAN RECS

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-6253	07/27/2016 08/24/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Berns Weiss LLP Berns Weiss LLP	ONGLYZA RECS
2016-6254	07/27/2016 08/24/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Berns Weiss LLP Berns Weiss LLP	RANEXA RECS
2016-6255	07/27/2016 08/24/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Berns Weiss LLP Berns Weiss LLP	TRUVADA RECS
2016-6256	07/27/2016 08/24/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Berns Weiss LLP Berns Weiss LLP	WELCHOL RECS
2016-6257	07/27/2016 08/24/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Berns Weiss LLP Berns Weiss LLP	NOVOLOG FLEXPEN RECS
2016-6258	07/27/2016 08/24/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Berns Weiss LLP Berns Weiss LLP	LINZESS RECS
2016-6259	07/27/2016 08/24/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Berns Weiss LLP Berns Weiss LLP	LATUDA RECS
2016-6260	07/27/2016 08/24/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Berns Weiss LLP Berns Weiss LLP	CELEBREX RECS

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2016-6261	07/27/2016	FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP	NASONEX RECS
	08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP	
2016-6262	07/27/2016	FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP	ALPHAGAN P RECS
	08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP	
2016-6263	07/27/2016	FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP	VIIBRYD RECS
	08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP	
2016-6264	07/27/2016	FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP	PROVENTIL HFA RECS
	08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP	
2016-6265	07/27/2016	FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP	BENICAR RECS
	08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP	
2016-6266	07/27/2016	FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP	VOLTAREN G RECS
	08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP	
2016-6267	07/27/2016	FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP	THYROID RECS
	08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP	
2016-6268	07/27/2016	FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP	DIOVAN RECS
	08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP	
2016-6269	07/27/2016	FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP	HUMALOG RECS

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	08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP	
2016-6270	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	STRATTERA RECS
2016-6271	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	NUVARING RECS
2016-6272	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	MINASTRIN 24 FE RECS
2016-6273	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Berns Weiss LLP Berns Weiss LLP	AFLURIA RECS
2016-6274	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	DEXILENT RECS=
2016-6275	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	FLOVENT HF RECS
2016-6276	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	NAMENDA RECS

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2016-6277	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	PRISTIQ RECS
2016-6278	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	TOPROL-XL RECS
2016-6279	07/27/2016 08/24/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Berns Weiss LLP Berns Weiss LLP	OXYCONTIN RECS
2016-6280	07/27/2016 08/24/2016	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jeff Ho Folger Hill Asset Management	AKORN PHARMACEUTICALS, HI-TECH PHARMA - 483 01/01/2016 - 07/21/2016
2016-6281	07/28/2016 08/25/2016	FDA/OMPT/CDRH/OCE/DID/	Doe J	INDIVIDUAL RECS
2016-6282	07/28/2016 08/25/2016	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/ORO/DIOP/	Rachel Johnson FOI Services, Inc.	FDA PRODUCT CODES FOR USE WITHIN THE ACE/ITDS SYSTEM
2016-6283	07/28/2016 08/25/2016	FDA/OMPT/CDRH/OCE/DID/	Jim Kusters Moria, Inc.	K090633
2016-6284	07/28/2016 08/25/2016	FDA/OMPT/CDRH/OCE/DID/	Jim Kusters Moria, Inc.	K150323
2016-6285	07/28/2016 08/25/2016	OC/ORA/ORM/ OC/ORA/ORM/	Shyam Srinivasan Goldman Sachs India Securities Private Limited	LIST OF INSPECTIONS IN INDIA 10/01/2014 - 07/23/2016
2016-6286	07/28/2016 08/25/2016	FDA/OMPT/CDRH/OCE/DID/	Jim Kusters Moria, Inc.	K112098

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2016-6287	07/28/2016 08/25/2016	OC/OROA/ OC/OROA/	Robert Martin Robert Martin	CC 144483 FIELD REPORT
2016-6288	07/28/2016 08/25/2016	OC/OROA/ORM/ OC/OROA/ORM/	Eyal Maor FDAAWARE	LIST OF INSPECTIONS 07/01/2016 - 07/31/2016
2016-6289	07/28/2016 08/25/2016	OC/OROA/ OC/OROA/ FDA/OGROP/OROA/PA-FO/LOS-DO/LOS-CB/	Jason McComb Jason McComb	CONSUMER COMPLAINT 146242 RECS
2016-6290	07/28/2016 08/25/2016	FDA/OMPT/CTP/OD/	Eric F. Facer Law Offices of Eric F. Facer, PLLC	CAYUGA LAKE TRADING STORE, SENECA FALLS, NY - INVESTIGATION RECS 01/01/2015 - 07/25/2016
2016-6291	07/28/2016 08/25/2016	OC/OROA/ OC/OROA/ FDA/OGROP/OROA/SW-FO/DAL-DO/DAL-CB/	Cheryl Enlow Renaissance Food Group	GH FOODS SOUTHWEST, LLC, HOUSTON, TX - LAB RESULTS 07/11/2016 - 07/20/2016
2016-6292	07/28/2016 08/25/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Cherie Grishin Golden Genesis	DATA COLLECTED THROUGH BPDR PROCESS RE VIRAL MARKER RATES IN PAID VERSUS NONPAID BLOOD AND PLASMA DONORS
2016-6293	07/29/2016 08/26/2016	OC/OROA/ OC/OROA/ FDA/OGROP/OROA/NE-FO/NYK-DO/NYK-DCB/	Doe J	INDIVIDUAL RECS
2016-6294	07/29/2016 08/26/2016	FDA/OMPT/CDRH/OCE/DID/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCE/DID/	SCARATO, THEODORA	NATIONAL TOXICOLOGY PROGRAM RODENT STUDY ON CARCINOGENICITY - RECS 5/25/26 - 7/1/16
2016-6295	07/29/2016 08/26/2016	FDA/OC/OES/DFOI/	SARAH A.WESTBY SHIPMAN & GOODWIN LLP	ADH HEALTH PRODUCTS - ABC DOPHILUS POWDER 11/14
2016-6296	07/29/2016 08/26/2016	FDA/OC/OES/DFOI/	SARAH A. WESTBY SHIPMAN & GOODWIN LLP	SOLGAR INC, LEONIA, NJ; HAZELTON, PA - ABC DOPHILUS POWDER EIR 11/14
2016-6297	07/29/2016 08/26/2016	FDA/OGROP/OROA/NE-FO/NWE-DO/NWE-CB/	KIM C. CAPONE PORZIO LIFE SCIENCES	GENOA HEALTHCARE CO, NORWICH, CT; GENOA HEALTHCARE OF CT, NEW LONDON, CT, MANCHESTER, CT - EIR , 483
2016-6298	07/29/2016	FDA/OC/OES/DFOI/	MURIEL L. CARRINGTON	MERIDIAN DIAGNOSTICS INC, MCHENRY, IL - PARA PAK K792712

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	08/26/2016		MERIDIAN BIOSCIENCE INC	
2016-6299	08/01/2016 08/29/2016	FDA/OC/OES/DFOI/	ELENA HOWELL CLARK HOGAN LOVELLS US LLP	2016-4525
2016-6300	08/01/2016 08/29/2016	FDA/OC/OES/DFOI/	ELENA HOWELL CLARK HOGAN LOVELLS US LLP	2011-4227
2016-6301	08/01/2016 08/29/2016	FDA/OC/OES/DFOI/	ELENA HOWELL CLARK HOGAN LOVELLS US LLP	2015-4017
2016-6302	08/01/2016 08/29/2016	FDA/OC/OES/DFOI/	ELENA HOWELL CLARK HOGAN LOVELLS US LLP	2014-6115
2016-6303	08/01/2016 08/29/2016	FDA/OC/OES/DFOI/	ELENA HOWELL CLARK HOGAN LOVELLS US LLP	2013-6692
2016-6304	08/01/2016 08/29/2016	FDA/OC/OES/DFOI/	ENENA HOWELL CLARK HOGAN LOVELLS US LLP	2014-2874
2016-6305	08/01/2016 08/29/2016	FDA/OMPT/CDRH/OCE/DID/	CAROLYN POIRIER PAXMED INTL	BIOLUX RESEARCH LTD - ORTHOPULSE K143120
2016-6306	08/01/2016 08/29/2016	FDA/OMPT/CDRH/OCE/DID/	john taube John Taube - Teleflex Medical	K820878 APPROVAL LETTER
2016-6307	08/01/2016 08/29/2016	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Jeanine Gouveia Aerie Pharmaceuticals Inc.	OCULAR THERAPEUTIX, BEDORD, MA - EIR 01/01/2016 - 06/30/2016
2016-6308	08/01/2016 08/29/2016	FDA/OFVM/CFSAN/OCD/EOS/	Judith Hill Intertek Scientific & Regulatory Consultancy	MEMOS CITED IN DOCKET
2016-6309	08/01/2016 08/29/2016	FDA/OMPT/CDRH/OCE/DID/	CAROLYN POIRIER PAXMED INTL	ORTHOACCEL TECHNOLOGIES INC - ACCELEDENT AURA K153048
2016-6310	08/01/2016 08/29/2016	FDA/OMPT/CDRH/OCE/DID/	CAROLYN POIRIER PAXMED INTL	ORTHOACCEL TECHNOLOGIES INC - ACCELEDENT AURA K130643
2016-6311	08/01/2016 08/29/2016	FDA/OMPT/CDRH/OCE/DID/	CAROLYN POIRIER PAXMED INTL	ORTHOACCEL TECHNOLOGIES INC - ACCELEDENT K110661
2016-6312	08/01/2016 08/29/2016	FDA/OC/OES/DFOI/	ELENA HOWELL CLARK HOGAN LOVELLS US LLP	2013-853
2016-6313	08/01/2016 08/29/2016	FDA/OC/OES/DFOI/	STEPHEN SUAREZ POINT72 ASSET MANAGEMENT LP	BAUSCH & LOMB, TAMPA, FL - EIRS, 483S, GENERAL INSP
2016-6314	08/01/2016	FDA/OMPT/CDER/ORP/DIDP/	LISA MUELLER	DEXCEL PHARMA TECHNOLOGIES LTD - LANSOPRAZOLE

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	08/29/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michael Best and Friedrich LLP	DELAYED RELEASE ORALLY DISINTEGRATING TABS NDA 208-025 RVW RECS, PI
2016-6315	08/01/2016 08/29/2016	FDA/OC/OES/DFOI/	Eyal Maor FDAAWARE	483s RELEASED 07/01/2016 - 07/31/2016
2016-6316	08/01/2016 08/29/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tatiana Forman G&W LABORATORIES INC	FLUOROURACIL - SBA
2016-6317	08/01/2016 08/29/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	William Turney DSM Nutritional Products LLC	SINOBEST COSMECEUTICAL CO LTD - EIR 09/14/2015 - 01/14/2016
2016-6318	08/01/2016 08/29/2016	FDA/OC/OES/DFOI/	Eyal Maor FDAAWARE	PREVIOUSLY RELEASED EIR 07/01/2016 - 07/31/2016
2016-6319	08/01/2016 08/29/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ronnie Moore TOURO COLLEGE OF PHARMACY	ANDA HYDROCORTISONE ACETATE 25 MG SUPPOSITORY, CHLORHEXIDINE GLUCONATE 0.12% ORAL SOLUTION, ACETAMINOPHEN 80 MG SUPPOSITORY
2016-6320	08/01/2016 08/29/2016	FDA/OC/OES/DFOI/	Natalie Goodin Biorep Technologies, Inc.	K964853
2016-6321	08/01/2016 08/29/2016	FDA/OFVM/CFSAN/OCD/EOS/	Gary Ruskin U.S. Right to Know	PAULA R TRUMBO, CRYSTAL RIVERS - EMAILS WITH INTERNATIONAL LIFE SCIENCES INSTITUTE, AMERICAN BEVERAGE ASSOCIATION, COCAL COLA ETC 01/01/2013 - 07/26/2016
2016-6322	08/01/2016 08/29/2016	FDA/OMPT/CDRH/OCE/DID/	Chenxi Li PuraCap Pharmaceutical, LLC	K110732
2016-6323	08/01/2016 08/29/2016	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	Patricia Schnoor CAPILLUS LLC	CAPILLUS LLC, MIAMI, FL - EIR 05/10/2016 - 07/26/2016
2016-6324	08/01/2016 08/29/2016	FDA/OMPT/CDRH/OCE/DID/	Chenxi Li PuraCap Pharmaceutical, LLC	K110727
2016-6325	08/01/2016 08/29/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 50819 S 12

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-6326	08/01/2016 08/29/2016	FDA/OMPT/CDRH/OCE/DID/	Chenxi Li PuraCap Pharmaceutical, LLC	K091719
2016-6327	08/01/2016 08/29/2016	FDA/OMPT/CDRH/OCE/DID/	LT Gregory H. Ciaccio Ciaccio, LT Gregory H	FLEX BELT STUDY RECS 07/24/2000 - 07/26/2016
2016-6328	08/01/2016 08/29/2016	FDA/OMPT/CDRH/OCE/DID/	Chenxi Li PuraCap Pharmaceutical, LLC	K090585
2016-6329	08/01/2016 08/29/2016	FDA/OMPT/CDRH/OCE/DID/	Youqin Tian Alcon Novartis Division	P980040/S065
2016-6330	08/01/2016 08/29/2016	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/PHI- DO/PHI-CB/	Mary Hancock Registrar Corp	WILLIE'S CACAO LTD - RECS RE REFUSAL OF UPS- 6307564-4
2016-6331	08/01/2016 08/29/2016	FDA/OMPT/CDRH/OCE/DID/	Chenxi Li PuraCap Pharmaceutical, LLC	K121559
2016-6332	08/01/2016 08/29/2016	FDA/OMPT/CDRH/OCE/DID/	Chenxi Li PuraCap Pharmaceutical, LLC	K152055
2016-6333	08/01/2016 08/29/2016	FDA/OFVM/CFSAN/OCD/EOS/	Audrey K. patterson King Williams LLP	QUANTITY OF CONTENTS COMPENDIUM
2016-6334	08/01/2016 08/29/2016	FDA/OC/OES/DFOI/	Anna Edney BLOOMBERG NEWS	BAUSCH & LOMB, TAMPA, FL - 483 MOST RECENT
2016-6335	08/01/2016 08/29/2016	FDA/OFVM/CFSAN/OCD/EOS/ OC/ORO/ OC/ORO/ OC/ORO/ORM/ OC/ORO/ORM/ OC/ORO/ORO/DFS/ OC/ORO/ORO/DFS/	John F. Whiteside, Jr. American Scallop Association, Inc.	METHOD, PROTOCOL USED BY QUALIFIED FDA SEAFOOD SENSORY ANALYSTS TO DETERMINE WHETHER THERE ARE DEFINITE AND PERSISTENT ATTRIBUTES INDICATIVE OF DECOMPOSITION IN SCALLOPS ETC
2016-6336	08/01/2016 08/29/2016	FDA/OC/OES/DFOI/	Catherine Geyman Epic Risk Solutions Ltd	HIMKA FARMACEUTICAL, PORTUGAL; WEST-WARD PHARMACEUTICALS, EATONTOWN, NJ; ETC - EIR, 483 PREVIOUSLY RELEASED 01/01/2014 - 07/26/2016
2016-6337	08/01/2016 08/29/2016	FDA/OMPT/OSMP/OOPD/	Rachel Johnson FOI Services, Inc.	AMPYRA - ORPHAN DRUG INFORMATION
2016-6338	08/01/2016	FDA/OMPT/CDER/GRP/DIDP/	Zachary Mietus	NDA 006470 ANDA 080001 ANDA 089373

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	08/29/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	The Weinberg Group	
2016-6339	08/01/2016 08/29/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K100534
2016-6340	08/01/2016 08/29/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Matthew C. Weiner Hilliard & Shadowen LLP	ANDA 77830
2016-6341	08/01/2016 08/29/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Matthew C. Weiner Hilliard & Shadowen LLP	ANDA 077451
2016-6342	08/01/2016 08/29/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Matthew C. Weiner Hilliard & Shadowen LLP	ANDA 077451
2016-6343	08/01/2016 08/29/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K112277
2016-6344	08/01/2016 08/29/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Zachary Mietus The Weinberg Group	ANDA 83159 SBA
2016-6345	08/01/2016 08/29/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Matthew C. Weiner Hilliard & Shadowen LLP	ANDA 077451
2016-6346	08/01/2016 08/29/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	NAOMI JL HALPERN ARENT FOX LLP	LIST OF DRUG EFFICACY STUDY IMPLEMENTATION (DESI)
2016-6347	08/01/2016 08/29/2016	OC/ORP/ OC/ORP/	Doe J	SAMPLE RESULTS 925358, CONSULT 146104

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		FDA/OGROP/ORACE-FO/DET-DO/DET-CB/		
2016-6348	08/01/2016 08/29/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JONATHAN W EMORD EMORD & ASSOCIATES, P.C.	HYDROCORTISONE ACETATE DRUG PROD - APRVD LBLG, LABEL, PI, APRVL LTR, ETC
2016-6349	08/01/2016 08/29/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PENLAND L WOODS Woods, Penland L	PILVA KRAKOW SA - METRONIDAZOLE CLASS II RECALL AERS
2016-6350	08/02/2016 08/30/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joseph H. Mattingly III Joseph H. Mattingly III, Attorney	DR REDDYS LABS LTD - LABEL RECS RE ONDANSETRON HYDROCHLORIDE TABLETS 12/01/2006 - 12/31/2014
2016-6351	08/02/2016 08/30/2016	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Doe J	ORAWELL USA, PHILADELPHIA, PA - EIR 06/29/2011 - 08/05/2011
2016-6352	08/02/2016 08/30/2016	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Arlene Tessitore Arlene Tessitore	MECTA CORPORATION, TUALATIN, OR; SOMATICS, LLC, VENICE, FL - INSPECTION RECS 01/06/2012 - 07/27/2016
2016-6353	08/02/2016 08/30/2016	FDA/OMPT/CDRH/OCE/DID/	KOTERA BHIMAYA KOTERA BHIMAYA	LETTER FROM BRYAN BENESCH TO KAISER PERMANENTE RE INTRAOCULAR LENSES 06/17/2016 - 06/17/2016
2016-6354	08/02/2016 08/30/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michael Swartzon Michael Swartzon	KRS GLOBAL BIOTECHNOLOGY, INC, BOCA RATON, FL - ADVERSE EVENTS
2016-6355	08/02/2016 08/30/2016	FDA/OMPT/CDRH/OCE/DID/	Mathe Young Mosny Kavi Asset Management	CYBERDYNE INC - APPLICATION TO MARKET HAL DEVICE FOR MEDICAL USE, REVISED APPLICATION 01/01/2014 - 07/27/2016
2016-6356	08/02/2016 08/30/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lindsey Jennings Medical University of South Carolina Division of Emergency Medicine	PEGLOTICASE - AERS
2016-6357	08/02/2016 08/30/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRANDON KELLER ESQ KELLER LAW LLC	HUMAN GROWTH HORMONE - ALLOWABLE USE RECS

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2016-6358	08/02/2016 08/30/2016	FDA/OPPLA/OL/	STEVE REILLY USA TODAY	SEN JEANNE SHAHEEN, SEN RICHARD DURBAN 9/18/15 LTR TO COMMISSIONER ROBERT M CALIFF REGARDING THE APRVL OF OPIOD PAINKILLERS FOR CHILDREN
2016-6359	08/02/2016 08/30/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Daniel Kolitz Daniel Kolitz	NDA 11522 ADDITIONAL RECS
2016-6360	08/02/2016 08/30/2016	OC/CVM/OCD/	ROSALYN DOBKIN DOBKIN, ROSALYN	HOFFMAN LA ROCHE - MADRIBON RECS
2016-6361	08/02/2016 08/30/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Katherine Eban FORTUNE MAGAZINE	RECORDS OF MEETINGS HELD BY ACTING DIRECTOR OF CDER OFFICE OF COMPLIANCE THOMAS COSGROVE 02/01/2016 - 03/31/2016
2016-6362	08/02/2016 08/30/2016	FDA/OC/OES/DFOI/ FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jonathan Kaufman WILLIAM BLAIR & CO	PATHEON 483S Date Range: 1/01/2014 - 07/28/2016
2016-6363	08/02/2016 08/30/2016	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	Joy Prislinger BioLife Plasma Services L P	BIOLIFE PLASMA CENTER, WALKER, MI - EIR 05/29/2015 - 05/29/2015
2016-6364	08/02/2016 08/30/2016	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	Joy Prislinger BioLife Plasma Services L P	BIOLIFE PLASMA CENTER, HARRISONBURG, VA - EIR 08/31/2015 - 09/02/2015
2016-6365	08/02/2016 08/30/2016	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	Joy Prislinger BioLife Plasma Services L P	BIOLIFE PLASMA CENTER. CHEYENNE, WY - EIR 09/14/2015-09/16/2015
2016-6366	08/02/2016 08/30/2016	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	Joy Prislinger BioLife Plasma Services L P	BIOLIFE PLASMA CENTER, LAKELAND, FL - EIR 09/21/2015 - 09/25/2015
2016-6367	08/02/2016 08/30/2016	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	Joy Prislinger BioLife Plasma Services L P	BIOLIFE PLASMA CENTER, WAITE PARK, MN - EIR 06/03/2015 - 06/09/2015
2016-6368	08/02/2016 08/30/2016	FDA/OC/OES/DFOI/	Jamee Cook Jamee Cook	POLY IMPLANT PROTHESES RECS 01/01/1995 - 07/22/2016

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2016-6369	08/02/2016 08/30/2016	FDA/OC/OES/DFOI/	Priya Jambhekar PBS Regulatory Consulting for Accellient/Lecigon	APPROVAL LETTER FOR DUODOPA APPLICATION FOR ORPHAN DESIGNATION
2016-6370	08/02/2016 08/30/2016	FDA/OC/OES/DFOI/	Kayla McBride Verified Credentials Inc.	CONFIRMATION OF CANDIDATE
2016-6371	08/02/2016 08/30/2016	FDA/OMPT/CDRH/OCE/DID/	Matthew Trachtenberg BECTON, DICKINSON AND COMPANY	COMPANION MEDICAL INPEN SYSTEM 510K 01/01/2014 - 07/31/2016
2016-6372	08/02/2016 08/30/2016	FDA/OGROP/ORASW-FO/KAN- DO/KAN-CB/	Joy Prisliger BioLife Plasma Services L P	BIOLIFE PLASMA CENTER, DUBUQUE, IA - EIR 05/11/2015 - 05/11/2015
2016-6373	08/02/2016 08/30/2016	FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/	Ayu Takahashi-Tu SOC America Inc.	MYRA'S BAKERY, INC, BLOOMFIELD, NJ; INTEGRATED ANALYTICAL LABORATORY, LLC, RANDOLPH, NJ; ETC - 483 01/01/2015 - 06/30/2016
2016-6374	08/02/2016 08/30/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ronald torlini MEDA PHARMACEUTICALS INC	CHEMI SPA PATRICIA ITALY - 483, EIR 03/24/2014 - 07/01/2016
2016-6375	08/02/2016 08/30/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Audrey Zhang NYU SCHOOL OF MEDICINE	LIST OF PRODUCTS GRANTED BREAKTHROUGH DESIGNATION 2013 TO PRESENT
2016-6376	08/02/2016 08/30/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Richard Fairgrieve Richard Fairgrieve	DCVax-L RECS RE SCREEN HALT ETC 06/30/2015 - 07/15/2016
2016-6377	08/02/2016 08/30/2016	FDA/OGROP/ORACE-FO/MIN- DO/MIN-CB/	Paul Fenster Paul Fenster	NANCY SWEITZER, MADISON, WI - 483 09/01/2015 - 09/30/2015
2016-6378	08/02/2016 08/30/2016	FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/	Joy Prisliger BioLife Plasma Services L P	BIOLIFE PLASMA SERVICES, BROKEN ARROW, OK - EIR 09/10/2014 - 09/12/2014
2016-6379	08/02/2016 08/30/2016	OC/ORASORM/ OC/ORASORM/	M. Randall Meagan Randall	LIST OF DEVICE INSPECTIONS 01/01/2016 - 07/28/2016
2016-6380	08/02/2016 08/30/2016	OC/CVM/OCD/	Rama Krishna Prasad B V Cronus Research Labs Private Limited	NADA 012-437 FOIA SUMMARY
2016-6381	08/02/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	A list of all FOIA requests closed for 7/1-31/2016

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	08/30/2016		MERCK & CO., INC.	
2016-6382	08/02/2016 08/30/2016	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 7/1-31/2016
2016-6383	08/02/2016 08/30/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	RAMIPRIL - AERS
2016-6384	08/02/2016 08/30/2016	FDA/OMPT/CDRH/OCE/DID/	Trang Adams AMERICAN ORTHODONTICS	K890749
2016-6385	08/02/2016 08/30/2016	FDA/OMPT/CDRH/OCE/DID/	Trang Adams AMERICAN ORTHODONTICS	K891372
2016-6386	08/02/2016 08/30/2016	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2016-540
2016-6387	08/02/2016 08/30/2016	FDA/OC/OES/DFOI/	Doe J	NEW USDA DIETARY GUIDLELINES
2016-6388	08/02/2016 08/30/2016	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	BRENDON INTEGLIA Wells Fargo Securities, LLC	VALEANT, TAMPA, FL - INSP RECS 1/16 TO 7/16
2016-6389	08/02/2016 08/30/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	INDIVIDUAL RECS
2016-6390	08/03/2016 08/31/2016	FDA/OGROP/ORR/PA-FO/SEA-DO/SEA-CB/	Joy Prislinger BioLife Plasma Services L P	BIOLIFE PLASMA CENTER, HAYDEN, ID - EIR 11/19/2014 - 11/21/2014
2016-6391	08/03/2016 08/31/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rajender Singh Mankind Pharma Ltd.	NDA N020193
2016-6392	08/03/2016 08/31/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jatin Kotian Jatin Kotian	ALEMBIC, INDIA - EIR 04/01/2015 - 04/30/2015
2016-6393	08/03/2016 08/31/2016	FDA/OMPT/CDRH/OCE/DID/	Christina Miracle CSZ	K040911

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2016-6394	08/03/2016 08/31/2016	FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/ FDA/OGROP/ORR/PA-FO/SEA-DO/SEA-CB/	Joy Prislinger BioLife Plasma Services L P	BIOLIFE PLASMA SERVICES LP, HAYDEN, IA - EIR 11/19/2014 - 11/21/2014
2016-6395	08/03/2016 08/31/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jatin Kotian Emkay Global	ALEMBIC PHARMACEUTICALS - EIR 03/01/2016 - 03/31/2016
2016-6396	08/03/2016 08/31/2016	FDA/OC/OES/DFOI/	Kayla McBride Verified Credentials Inc.	BACKGROUND SCREENING
2016-6397	08/03/2016 08/31/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Audrey Zhang NYU SCHOOL OF MEDICINE	LIST OF FAST TRACK APPROVALS
2016-6398	08/03/2016 08/31/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michele Crawley Cipla USA, Inc.	CIPLA LTD DMF
2016-6399	08/03/2016 08/31/2016	FDA/OMPT/CDRH/OCE/DID/	Mona Pournorouz Pathway Communications	K152139
2016-6400	08/03/2016 08/31/2016	FDA/OMPT/CDRH/OCE/DID/	Mona Pournorouz Pathway Communications	K141167
2016-6401	08/03/2016 08/31/2016	FDA/OGROP/ORR/PA-FO/SEA-DO/SEA-CB/	Rachel Johnson FOI Services, Inc.	BYBEE, PASCO, WA - EIR, 483
2016-6402	08/03/2016 08/31/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anna Edney BLOOMBERG NEWS	DULOXETINE - AERS
2016-6403	08/03/2016 08/31/2016	FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/	Ashley Nickle THE PACKER A VANCE PUBLICATION	WARREN PRODUCE, EDINBURG, TX - 483 07/18/2016 - 07/31/2016
2016-6404	08/03/2016 08/31/2016	OC/ORR/ OC/ORR/	Thomas J. Dominy, Supervising Pharmacist SterRX, LLC.	STERX, LLC - EIR 01/01/2016 - 07/29/2016

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2016-6405	08/03/2016 08/31/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John Bjork Vanek Vickers & Masini PC	ATAXANAVIR - TENTATIVE, FINAL APPROVAL ROUTING SUMMARY
2016-6406	08/03/2016 08/31/2016	FDA/OFVM/CFSAN/OCD/EOS/	Emily Krulewitz The Weinberg Group	PETITION TO AFFIRM GRAS Status of Isomalt (GRASP 6G0321, referenced in 55 FR 42484) and Petition to Affirm the GRAS Status of Maltitol (GRASP 6G0319, referenced in 51 FR 45955)
2016-6407	08/03/2016 08/31/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ted Keller EverPoint Asset Management	NUPLAZID - AERS
2016-6408	08/03/2016 08/31/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John Bjork Vanek Vickers & Masini PC	GALANTAMINE HYDROBROMIDE - TENTATIVE, FINAL APPROVAL ROUTING SUMMARY
2016-6409	08/03/2016 08/31/2016	FDA/OMPT/CDRH/OCE/DID/	Mona Pournorouz Pathway Communications	K132447
2016-6410	08/03/2016 08/31/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ted Keller EverPoint Asset Management	PIMAVEANSERIN REPORTS 12507321 12520599
2016-6411	08/03/2016 08/31/2016	FDA/OMPT/CDRH/OCE/DID/	Mona Pournorouz Pathway Communications	K121197
2016-6412	08/03/2016 08/31/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tushar Manudhane Anand Rathi Securities	SUN PHARMACEUTICALS AND INDUSTRIES LIMITED, INDIA - 483 06/01/2016 - 07/30/2016
2016-6413	08/03/2016 08/31/2016	FDA/OMPT/CDRH/OCE/DID/	Joseph Ascenzi JMA Consulting	K984413
2016-6414	08/03/2016 08/31/2016	FDA/OMPT/CDRH/OCE/DID/	Ashley Les Seventh Sense Biosystems, Inc,	K983517
2016-6415	08/03/2016 08/31/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	James J. Nicklaus HAGENS BERMAN SOBOL	The tentative and final FDA approval routing sheets for ANDA 078857

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SHAPIRO LLP	
2016-6416	08/03/2016 08/31/2016	FDA/OC/OES/DFOI/	Michael Lazar MarketSphere Consulting	UNPAID CHECKS, ETC
2016-6417	08/03/2016 08/31/2016	FDA/OMPT/CDRH/OCE/DID/	Evan Luxon Esculon	K993592
2016-6418	08/03/2016 08/31/2016	FDA/OC/OES/DFOI/	Matt Jackson Matt Jackson	FOIA REQUESTS RE PROMETIC LIFE SCIENCES 08/02/2006 - 08/02/2016
2016-6419	08/03/2016 08/31/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	YIING-FANG JETTERS SANOFI PASTEUR	VAERS FOR DTP VACCINE - INDIVIDUAL RECS
2016-6420	08/03/2016 08/31/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	YING-FANG JEFFERS SANOFI PASTEUR	VAERS RPT FOR TDAP VACCINE - INDIVIDUAL RECS
2016-6421	08/03/2016 08/31/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	YING-FANG JEFFERS SANOFI PASTEUR	VAERS RPT FOR TDAP VACCINE - INDIVIDUAL RECS
2016-6422	08/03/2016 08/31/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	YING-FANG JEFFERS SANOFI PASTEUR	VAERS RPT FOR TDAP VACCINE - INDIVIDUAL RECS
2016-6423	08/03/2016 08/31/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	YING-FANG JEFFERS SANOFI PASTEUR	VAERS RPT FOR TDAP VACCINE - INDIVIDUAL RECS
2016-6424	08/03/2016 08/31/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	YING-FANG JEFFERS SANOFI PASTEUR	VAERS RPT FOR DTAP VACCINE - INDIVIDUAL RECS
2016-6425	08/03/2016 08/31/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	YING-FANG JEFFERS SANOFI PASTEUR	VAERS RPT FOR DTAP VACCINE - INDIVIDUAL RECS
2016-6426	08/03/2016 08/31/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	YING-FANG JEFFERS SANOFI PASTEUR	VAERS RPT FOR TDAP VACCINE - INDIVIDUAL RECS
2016-6427	08/03/2016 08/31/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	YING-FANG JEFFERS SANOFI PASTEUR	VAERS RPT FOR TDAP VACCINE - INDIVIDUAL RECS
2016-6428	08/03/2016 08/31/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	YING-FANG JEFFERS SANOFI PASTEUR	VAERS RPT FOR TDAP VACCINE - INDIVIDUAL RECS
2016-6429	08/03/2016 08/31/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	YING-FANG JEFFERS SANOFI PASTEUR	VAERS RPT FOR TRIVALENT INFLUENZA VACCINE - INDIVIDUAL RECS
2016-6430	08/03/2016 08/31/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	YING FANG JEFFERS SANOFI PASTEUR	VAERS RPT FOR TRIVALENT INFLUENZA VACCINE - INDIVIDUAL RECS
2016-6431	08/03/2016	FDA/OMPT/CBER/OCOD/DDOM/	YING-FANG JEFFERS	VAERS RPT FOR TRIVALENT INFLUENZA VACCINE -

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	08/31/2016	ALFB/	SANOI PASTEUR	INDIVIDUAL RECS
2016-6432	08/03/2016 08/31/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	YING-FANG JEFFERS SANOI PASTEUR	VAERS RPT FOR TDAP VACCINE - INDIVIDUAL RECS
2016-6433	08/03/2016 08/31/2016	FDA/OC/OES/DFOI/	CATHLEEN HUANG BOWLES & VERNA LLP	S MARTINELLI & CO - RECALL
2016-6434	08/03/2016 08/31/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FRED BARRERA, Esq. LAW OFFICE OF ALFREDO A BARRERA III	MTG MINUTES FOR CARBAVANCE TO BARDA BY THE MEDICINES CO; FDA MTG MINUTES FOR AZTREONAM, AVIBACTAM TO BARDA BY ASTRA ZENECA
2016-6435	08/03/2016 08/31/2016	FDA/OC/OES/DFOI/	MANISCALCO, ALEXANDER	ISOLEX 300i MAGNETIC CELL SELECTION SYS 1999 TO PRESENT
2016-6436	08/03/2016 08/31/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED DAILY LOG 7/11-15/16
2016-6437	08/03/2016 08/31/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 7/11-15/16
2016-6438	08/03/2016 08/31/2016	FDA/OC/OES/DFOI/	LAUREN BARR JH BARR & ASSOCIATES LLC	CLOSED DAILY LOG 7/11-15/16
2016-6439	08/03/2016 08/31/2016	FDA/OC/OES/DFOI/	LAUREN BARR JH BARR & ASSOCIATES LLC	DAILY LOG 7/11-15/16
2016-6440	08/03/2016 08/31/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY CLOSED LOG 7/11-15/16
2016-6441	08/03/2016 08/31/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 7/11-15/16
2016-6442	08/03/2016 08/31/2016	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	DAILY LOG 7/11-15/16
2016-6443	08/03/2016 08/31/2016	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 7/11-15/16
2016-6444	08/03/2016 08/31/2016	FDA/OC/OES/DFOI/	WILLIAM OLSON Center for Regulator Services, Inc	DAILY LOG 7/11-15/16
2016-6445	08/03/2016 08/31/2016	FDA/OC/OES/DFOI/	LESLIE RAMSEY FDA NEWS	DAILY LOG 7/11-15/16

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2016-6446	08/03/2016 08/31/2016	FDA/OC/OES/DFOI/	DAVID McFARLAND FDA REVIEW/FDA WEBVIEW	DAILY CLOSED LOG 7/11-15/16
2016-6447	08/04/2016 09/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jaime Vassallo LexisNexis CourtLink	GA/Cop/Glat FAERS
2016-6448	08/04/2016 09/01/2016	FDA/OMPT/CDRH/OCE/DID/	Trang Adams AMERICAN ORTHODONTICS	K893396
2016-6449	08/04/2016 09/01/2016	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	Jill Freedman Jill Freedman	BELCHER PHARMACEUTICALS, LARGO, FL; PHARMACARE, DAVIE, FL - 483 01/01/2014 - 08/01/2016
2016-6450	08/04/2016 09/01/2016	FDA/OGROP/ORR/PA-FO/SAN-DO/SAN-CB/	Gregory Young THORATEC LABORATORIES	THORATEC, PLEASANTON, CA - EIR 02/18/2014 - 08/01/2016
2016-6451	08/04/2016 09/01/2016	FDA/OC/OES/DFOI/	Madi Alexander BLOOMBERG BNA	FOOD RECALL DATA 01/01/2005 - 12/31/2015
2016-6452	08/04/2016 09/01/2016	FDA/OC/OES/DFOI/	Seema Rao Indian Council for Research on International Economic Relations (ICRIER)	INDIAN INSPECTION DATA 01/01/2010 - 08/01/2016
2016-6453	08/04/2016 09/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Brendon Integlia Wells Fargo Securities, LLC	MYLAN - CORR FOLLOWING WARNING LETTER RE INDIA FACILITIES 08/01/2015 - 08/01/2016
2016-6454	08/04/2016 09/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Hugh Sandler Nussbaum Law Group, P.C.	ANDA 202240
2016-6455	08/04/2016 09/01/2016	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Catherine Geyman Epic Risk Solutions Ltd	PATHEON ITALIA SPA, ITALY - EIR, 483 PREVIOUSLY RELEASED; WARNING LETTER, CLOSEOUT LETTER 08/01/2014 - 08/01/2016
2016-6456	08/04/2016 09/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	George Yu SCHIFF HARDIN LLP	NDA 018310 SBA

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		FDA/OMPT/CDER/ORP/DIDP/		
2016-6457	08/04/2016 09/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Paul Danese FDABLE LLC	FAERS REPORTS 10370780, 10435833, 10450819, ETC
2016-6458	08/04/2016 09/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Vince Widdison Widdison, Vince	ALINIA - AERS
2016-6459	08/04/2016 09/01/2016	FDA/OMPT/CDRH/OCE/DID/	Gary Syring Quality and Regulatory Associates, LLC	K962283
2016-6460	08/04/2016 09/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Todd Rodzen Todd Rodzen	SAREPTA ADVISORY COMM PANEL - TESTIMONY 12/01/2015 - 08/01/2016
2016-6461	08/04/2016 09/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sarah Sorscher PUBLIC CITIZEN	EDRLS RECS 10/01/2013 - 03/31/2016
2016-6462	08/04/2016 09/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sarah Sorscher PUBLIC CITIZEN	RECS FROM DATABASE OF REGISTERED OUTSOURCING FACILITIES 10/01/2013 - 03/31/2016
2016-6463	08/04/2016 09/01/2016	FDA/OMPT/CDRH/OCE/DID/	Flora Huang Flora Huang	CARDIOVERTER DEFIBRILLATORS, CARDIO RESYNCHRONIZATION - EXECUTIVE SUMMARIES, CLINICAL REVIEWS
2016-6464	08/04/2016 09/01/2016	FDA/OMPT/CDRH/OCE/DID/	Kyrylo Shvetsov Buffalo Filter	K111441
2016-6465	08/04/2016 09/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michael L Koehler Michael Koehler	POLYETHYLENE GLYCOL - AERS
2016-6466	08/04/2016	FDA/OC/OES/DFOI/	Douglas Oliver	ADVERSE EVENTS RE CELLULAR THERAPIES

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	09/01/2016	OC/OR/ OC/OR/	Douglas Oliver	
2016-6467	08/04/2016 09/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Laura Keuling Time-Cap Labs, Inc.	NOVACYL SAINT FONS USINE DE SAINT CHIMIE, FRANCE - EIR, 483 : 06/08/2015 - 12/23/2015
2016-6468	08/04/2016 09/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Donald Ellis Donald Ellis	OCULAR THERAPEUTIX - COMPLETE RESPONSE LETTER FOR DEXTENZA 08/22/2016 - 08/29/2016
2016-6469	08/04/2016 09/01/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mark Deming Bittersweet Holding Company	ORANGE BOOK DATA
2016-6470	08/04/2016 09/01/2016	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Gregory Young THORATEC LABORATORIES	THORATEC, BURLINGTON, MA - EIR 05/29/2014 - 08/01/2016;
2016-6471	08/04/2016 09/01/2016	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Gregory Young THORATEC LABORATORIES	THORATEC LABORATORIES, PLEASANTON, CA - EIR 11/10/2015 - 08/01/2016
2016-6472	08/04/2016 09/01/2016	FDA/OC/OES/DFOI/ OC/OR/ OC/OR/ OC/OR/ORM/ OC/OR/ORM/	Kevin Nious NBC Bay Area News (KNTV)	FOOD RELATED REGISTRATION, COMPLAINTS, EIRS IN CALIFORNIA 01/01/2011 - PRESENT
2016-6473	08/05/2016 09/02/2016	FDA/OMPT/CDRH/OCE/DID/	Janis Demetrulias Technikos Research Associates LLC	K131084
2016-6474	08/05/2016 09/02/2016	FDA/OMPT/CDRH/OCE/DID/	Nancy Phan Globizz Corporation	K103646
2016-6475	08/05/2016 09/02/2016	FDA/OMPT/CDRH/OCE/DID/	Ron Armstrong The Armstrong Firm, PLLC	K091508
2016-6476	08/05/2016 09/02/2016	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Guido Mase Vermont Center for Integrative Herbalism	SHIRE CITY HERBALS, PITTSFIELD, MA - 483 04/01/2016 - 05/01/2016
2016-6477	08/05/2016	FDA/OFVM/CFSAN/OCD/EOS/	Melissa Lahullier	RECS RE HIBISCUS JUICE PERMITTED UNDER US FRUIT

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	09/02/2016		Teawolf LLC	JUICE REGULATIONS 01/01/1995 - 12/31/1995
2016-6478	08/05/2016 09/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Omar Yasso Omar Yasso	SOLODYN - AERS
2016-6479	08/05/2016 09/14/2016	FDA/OMPT/CDRH/OCE/DID/	Elina Linetsky UNIVERSITY OF MIAMI	DIETHYLDIYHIOCARBAMATE COPPER TEST SYSTEM, OXALYDIHYDRAZIDE COPPER TEST SYSTEM - 510K
2016-6480	08/05/2016 09/02/2016	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Heather MacNaughton PBM Nutritionals LLC, dba Perrigo Nutritionals	PBM NUTRITIONALS LLC, COVINGTON, OH - EIR 09/28/2015 - 12/31/2015
2016-6481	08/05/2016 09/02/2016	FDA/OFVM/CFSAN/OCD/EOS/	Courtland Imel Ceutical Laboratories, Inc.	THERMOLIFE INTERNATIONAL LLC CREATINE NITRATE REPORT 696
2016-6482	08/05/2016 09/02/2016	FDA/OMPT/CDRH/OCE/DID/	Elina Linetsky UNIVERSITY OF MIAMI	POLYMER TECHNOLOGY SYSTEMS, INC 510K FOR BIOSCANNER PLUS GLUCOSE TEST SYSTEM
2016-6483	08/05/2016 09/02/2016	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	GRN 000582
2016-6484	08/05/2016 09/02/2016	OC/CVM/OCD/	Bergt Consulting Inc. Bergt Consulting Inc.	NADA 055-080 FOIA SUMMARY
2016-6485	08/05/2016 09/02/2016	FDA/OMPT/CDRH/OCE/DID/	Dhwani Thakkar Thakkar, Dhwani	K091106
2016-6486	08/05/2016 09/02/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	YING-FANG JEFFERS SANOFI PASTEUR	VAERS RPT FOR TRIVALENT VACCINE - INDIVIDUAL RECS
2016-6487	08/05/2016 09/02/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	YING-FANG JEFFERS SANOFI PASTEUR	VAERS RPT FOR TRIVALENT INFLUENZA - INDIVIDUAL RECS
2016-6488	08/05/2016 09/02/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	YING-FANG JEFFERS SANOFI PASTEUR	VAERS RPT FOR TRIVALENT INFLUENZA - INDIVIDUAL RECS
2016-6489	08/05/2016 09/02/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	YING-FANG JEFFERS SANOFI PASTEUR	VAERS RPT FOR TRIVALENT INFLUENZA - INDIVIDUAL RECS
2016-6490	08/05/2016 09/02/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	YING-FANG JEFFERS SANOFI PASTEUR	VAERS RPT FOR TRIVALENT INFLUENZA - INDIVIDUAL RECS
2016-6491	08/05/2016 09/02/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	YING-FANG JEFFERS SANOFI PASTEUR	VAERS RPT FOR TRIVALENT INFLUENZA - INDIVIDUAL RECS
2016-6492	08/05/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	YING-FANG JEFFERS	VAERS RPT FOR TRIVALENT INFLUENZA - INDIVIDUAL RECS

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	09/02/2016		SANOI PASTEUR	
2016-6493	08/05/2016 09/02/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	YING-FANG JEFFERS SANOI PASTEUR	VAERS RPT FOR TRIVALENT INFLUENZA - INDIVIDUAL RECS
2016-6494	08/05/2016 09/02/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	YING-FANG JEFFERS SANOI PASTEUR	VAERS RPT FOR TRIVALENT INFLUENZA - INDIVIDUAL RECS
2016-6495	08/05/2016 09/02/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	YING-FANG JEFFERS SANOI PASTEUR	VAERS RPT FOR TRIVALENT INFLUENZA - INDIVIDUAL RECS
2016-6496	08/05/2016 09/02/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	YING-FANG JEFFERS SANOI PASTEUR	VAERS RPT FOR TRIVALENT INFLUENZA - INDIVIDUAL RECS
2016-6497	08/05/2016 09/02/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	YING-FANG JEFFERS SANOI PASTEUR	VAERS RPT FOR TRIVALENT INFLUENZA - INDIVIDUAL RECS
2016-6498	08/05/2016 09/02/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	YING-FANG JEFFERS SANOI PASTEUR	VAERS RPT FOR TRIVALENT INFLUENZA - INDIVIDUAL RECS
2016-6499	08/05/2016 09/02/2016	FDA/OGROP/ORACE-FO/BLT- DO/BLT-CB/	LESLIE RAMSEY FDA NEWS	TUBULAR FABRICATIONS INDUSTRY INC, PETERSBURG, VA; TRIAID INC, CUMBERLAND, MD; NUO THERAPEUTICS, GAITHERSBURG, MD -483 6/1-30/16
2016-6500	08/05/2016 09/02/2016	FDA/OGROP/ORACE-FO/CIN- DO/CIN-CB/	LESLIE RAMSEY FDA NEWS	CINTAS CORP, MASON, OH; TOSOH BIOSCIENCE INC, GROVE CITY, OH - 483 6/1-30/16
2016-6501	08/05/2016 09/02/2016	FDA/OGROP/ORACE-FO/DET- DO/DET-CB/	LESLIE RAMSEY FDA NEWS	PD PHARMATECH LLC, SEYMOUR, IN; RTI SURGICAL INC, MARQUETTE, MI, ETHOX MEDICAL LLC, GRAND RAPIDS, MI - 483 6/1-30/16
2016-6502	08/05/2016 09/02/2016	FDA/OGROP/ORASW-FO/DEN- DO/DEN-CB/ OC/ORAC/ OC/ORAC/	LESLIE RAMSEY FDA NEWS	ISOMERIC PHARMACY SOLUTION LLC, SALT LAKE CITY, UT -483 6/1-30/16
2016-6503	08/05/2016 09/02/2016	FDA/OGROP/ORASW-FO/KAN- DO/KAN-CB/	LESLIE RAMSEY FDA NEWS	HOSPIRA INC, McPHERSON, KS; PENNER MFG INC, AURORA, NE - 483 6/1-30/16
2016-6504	08/05/2016 09/02/2016	FDA/OGROP/ORACE-FO/MIN- DO/MIN-CB/	LESLIE RAMSEY FDA NEWS	AMERICAN ORTHODONTICS CORP, SHEBOYGAN, WI; W & C dba THE APOTHECARY, SARTELL, MN - 483 6/1-30/16
2016-6505	08/05/2016 09/02/2016	FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/	LESLIE RAMSEY FDA NEWS	VILLAGE PHARMACY, ALLENTOWN, PA; SEWAREN INNOVATIVE PHARMACEUTICAL PCKG, AVENEL, NJ - 483 6/1-30/16
2016-6506	08/05/2016 09/02/2016	FDA/OGROP/ORASE-FO/NOL- DO/NOL-CB/	LESLIE RAMSEY FDA NEWS	ARCIPLEX LLC, NASHVILLE, TN - 483 6/1-30/16
2016-6507	08/05/2016	FDA/OMPT/CDER/ORP/DIDP/	LESLIE RAMSEY	CHONGQING PHARMA RESEARCH INSTITUTE CO LTD, ZHONGQING, CHINA; MSD INTL GMBH, SINGAPORE,

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	09/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FDA NEWS	SINGAPORE; APOTEX RESEARCH PRIVATE LTD, BANGALORE, INDIA - 483 6/1-30/16
2016-6508	08/05/2016 09/02/2016	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	LESLIE RAMSEY FDA NEWS	SANOBI PASTEUR BIOLOGICS LLC, ROCKVILLE, MD - 483 6/1-30/16
2016-6509	08/05/2016 09/02/2016	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	LESLIE RAMSEY FDA NEWS	BEND RESEARCH INC, BEND, OR; PARKS MEDICAL ELECTRONICS, INC, ALOHA, OR; LIGHTSCALPEL, LLC, WOODINVILLE, WA - 483 6/1-30/16
2016-6510	08/05/2016 09/02/2016	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	LESLIE RAMSEY FDA NEWS	PATHEON PUERTO RICO, MANATI, PR - 483 6/1-30/16
2016-6511	08/05/2016 09/02/2016	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	LESLIE RAMSEY FDA NEWS	JAJCO INC, SOUTH SAN FRANCISCO, CA; AARON BLACKLEDGE MD, SAN FRANCISCO, CA - 483 6/1-30/16
2016-6512	08/05/2016 09/02/2016	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	LESLIE RAMSEY FDA NEWS	TROY MANUFACTURING INC, HAZLE TOWNSHIP, PA; G&W PA LABORATORIES LLC, SELLERSVILLE, PA; ENCLARA PHARMACIA INC, SHARON HILL, PA - 483 6/1-3/16
2016-6513	08/05/2016 09/02/2016	FDA/OMPT/CDRH/OCE/DID/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	LESLIE RAMSEY FDA NEWS	ENVITEC WISMAR GMBH, WISMAR, GERMANY; KRELL PRECISION CO LTD, YANGZHOU, CHINA; ANTHOGRYR, SALLANCHES, FRANCE - 483 6/1-30/16
2016-6514	08/05/2016 09/02/2016	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	LESLIE RAMSEY FDA NEWS	REGION CARE INC, GREAT NECK, NY; AMES GOLDSMITH CORP, GLEN FALLS, NY; NATRIUM PRODUCTS INC, CORTLAND, NY - 483 6/1-30/16
2016-6515	08/05/2016 09/02/2016	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	LESLIE RAMSEY FDA NEWS	CARWILD CORP, NEW LONDON, CT; HOLOGIC INC, BEDFORD, MA; HOLOGIC INC, MALBOROUGH, MA - 483 6/1-30/16
2016-6516	08/05/2016 09/02/2016	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	LESLIE RAMSEY FDA NEWS	CUSTOM RESEARCH LABS INC, GARDENA, CA; UNIVERSITY OF CA, LOS ANGELES, LOS ANGELES, CA; AR HINKEL CO INC, CHATSWORTH THOUSAND OAKS, CA - 483 6/1-30/16
2016-6517	08/05/2016 09/02/2016	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	LESLIE RAMSEY FDA NEWS	ADVANCED RADIATION MEASUREMENT INC, PORT ST LUCIE; FL VALJEAN CORP, INDIAN HARBOUR BEACH, FL; SYNERGY PHARMACY SERVICES INC, PALM HARBOR, FL - 483 6/1-30/16
2016-6518	08/05/2016 09/02/2016	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	LESLIE RAMSEY FDA NEWS	INTERX TECHNOLOGIES, RICHARDSON, TX; STRUCKMYER MEDICAL, MESQUITE, TX; DHALIWAL LABORATORIES LLC, DALLAS, TX - 483 6/1-30/16
2016-6519	08/05/2016 09/02/2016	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	LESLIE RAMSEY FDA NEWS	EK INDUSTRIES, JOLIET, IL; HYDROX LABORATORIES, ELGIN, IL; AKORN INC, DECATUR, IL - 483 6/1-30/16
2016-6520	08/05/2016 09/02/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LESLIE RAMSEY FDA NEWS	INTERQUIM SA, SAINT CUGAT DEL VALLES, SPAIN; OPOCRIN LABORATORIO, CORLO DI FORMIGINE, ITALY, LABORATOIRE ATLAS INC, ANJOU, CANADA - 483 6/1-30/16

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2016-6521	08/08/2016 09/06/2016	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	JOSEPH G STOWELL PURDUE GMP CENTER LLC	PURDUE GMP CENTER LLC, WEST LAFAYETTE, IN - EIR 7/17-19/12
2016-6522	08/08/2016 09/06/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	JALYN - AERS 2/16/16 TO PRESENT
2016-6523	08/08/2016 09/06/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MICHAEL SWARTZON MD Michael Swartzon	VITAMIN COCKTAIL 10 C - AERS
2016-6524	08/08/2016 09/06/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CAROL CLARK-EVANS BTG INTERNATIONAL INC	VARITHENA NDA 205-098 - CLNCL AND QUALITY ASSESSMENT RPTS
2016-6525	08/08/2016 09/06/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRIAN MICHEL MD MICHEL, BRIAN	JARDIANCE, INVOKANA - RPTS
2016-6526	08/08/2016 09/06/2016	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	Elliot Wilbur Elliot Wilbur	AKORN, DECATUR, IL; HI TECH PHARMACAL, AMITYVILLE, NY - 483 05/10/2016 - 07/31/2016
2016-6527	08/08/2016 09/06/2016	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	Jeffrey Kalicka Mangrove Partners	IRADIMED CORPORATION - 483, WARNING LETTERS 01/02/2015 - 08/02/2016
2016-6528	08/08/2016 09/06/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Parimal Upadhyay Mankind Pharma Ltd.	NDA 017011
2016-6529	08/08/2016 09/06/2016	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	Norbert Gottesman Triple Gate Capital	BAUSCH & LOMB, TAMPA, FL - EIR, 483 01/01/2016 - 08/01/2016
2016-6530	08/08/2016 09/06/2016	FDA/OFVM/CFSAN/OCD/EOS/	Michael Hambly Michael Hambly	Memorandum to the File: Scientific Review of the Beneficial Physiological Effects of Non-Digestible Carbohydrates for

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				Meeting the FDA Definition of Dietary Fiber
2016-6531	08/08/2016 09/06/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michelle J. Looby Gustafson Gluek PLLC	ANDA 200562 SBA
2016-6532	08/08/2016 09/06/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Peter Harwin Fairmount Funds	RUXOLITINIB - SUPPLEMENTAL NDA INDICATION REVIEW RECS
2016-6533	08/08/2016 09/06/2016	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	Doe J	INDIVIDUAL RECS
2016-6534	08/08/2016 09/06/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sofia Muravnik Silenseed Ltd	ZOLADEX SBA
2016-6535	08/08/2016 09/06/2016	FDA/OMPT/CDRH/OCE/DID/	510(k) for Roche Diagnostic Accu-Chek Advantage Meter UNIVERSITY OF MIAMI	K000365 K864224
2016-6536	08/08/2016 09/06/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Parimal Upadhyay Mankind Pharma Ltd.	NDA 017388
2016-6537	08/08/2016 09/06/2016	FDA/OMPT/CDRH/OCE/DID/	Nancy Phan Globizz Corporation	K040490
2016-6538	08/08/2016 09/06/2016	FDA/OGROP/ORAP/PA-FO/SEA-DO/SEA-CB/	Kevin Rudiger Kevin Rudiger	TSILLAN CELLARS, CHELAN, WA - INSPECTIONS, ENFORCEMENT RECS 01/01/2002 - 08/01/2016
2016-6539	08/08/2016 09/06/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Azza AbuDagga PUBLIC CITIZEN	BENZOCAINE MEDWATCH REPORTS 109 FAERS CASES
2016-6540	08/08/2016 09/06/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MICHAEL J MCGAHEY mcgahey, Michael	INDIVIDUAL RECS

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		FDA/OMPT/CDER/ORP/DIDP/		
2016-6541	08/08/2016 09/06/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RAVI DESHPANDE ACINO PRODUCTS LLC	FOREST LABS - CANASA (MESALAMINE) SUPPOSITORIES ANDA 21-252 SBA
2016-6542	08/08/2016 09/06/2016	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Amy L. Smith-Compos Taylor Anderson, LLP	COASTAL GREENS VEGETABLE COMPANY, LLC, OXNARD, CA- INSPECTION RECS 01/01/2015 - 08/03/2016
2016-6543	08/08/2016 09/06/2016	FDA/OMPT/CDRH/OCE/DID/	Liane LaRoche DEKA R&D	K160252
2016-6544	08/08/2016 09/06/2016	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	SEBASTIAN DE ANDRACA ALFA INTERNATIONAL SEAFOOD INC	ENTRY RD8-0021651-0 - ANALYTICAL PACKAGE
2016-6545	08/08/2016 09/06/2016	OC/CVM/OCD/	Carrie Morgan OFW LAW	SYNERCID, DALFORPISTIN, QUINUPRISTIN ETC - RECS FROM CVM 01/01/2016 - 08/03/2016
2016-6546	08/08/2016 09/06/2016	FDA/OMPT/CDRH/OCE/DID/	Jeffrey Ward Cash Jeffrey Cash	K110116
2016-6547	08/08/2016 09/06/2016	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	SEBASTAIN DE ANDRACA ALFA INTERNATIONAL SEAFOOD INC	ENTRY RD8-0021621-3 - ANALYTICAL PACKAGE
2016-6548	08/08/2016 09/06/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K152276
2016-6549	08/08/2016 09/06/2016	FDA/OMPT/CDRH/OCE/DID/	ARQUILLIERE Withings	ATTEN ELECTRONIC, DONGGUAN, CHINA - EIR 04/01/2014 - 08/01/2014
2016-6550	08/08/2016 09/06/2016	FDA/OMPT/CDRH/OCE/DID/	Liane LaRoche DEKA R&D	K160056
2016-6551	08/08/2016 09/06/2016	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	RANIL M FERNANDO BIOSCREEN TESTING SERVICES INC	ACCUGENIX INC, NEWARK, DE - EIRS, 483S, WARNING LTRS LAST FIVE YRS
2016-6552	08/08/2016 09/06/2016	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Doe J	RECS RE COMPLAINT 146341

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2016-6553	08/08/2016 09/06/2016	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	RANIL M FERNANDO BIOSCREEN TESTING SERVICES INC	AMA LABORATORIES, NEW YORK CITY, NY - EIRS, 483S, WARNING LTRS LAST 5 YRS
2016-6554	08/08/2016 09/06/2016	FDA/OC/OES/DFOI/	Zachary Mietus The Weinberg Group	FOIA LOG 2015
2016-6555	08/08/2016 09/06/2016	FDA/OMPT/CDRH/OCE/DID/	Toshio Murata NIDEK INC	K161509
2016-6556	08/08/2016 09/06/2016	FDA/OMPT/CDRH/OCE/DID/	Liane LaRochelle DEKA R&D	K160482
2016-6557	08/08/2016 09/06/2016	FDA/OMPT/CDRH/OCE/DID/	Glenn Borrett Medela AG	K160449
2016-6558	08/08/2016 09/06/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K152911
2016-6559	08/08/2016 09/06/2016	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	JAMIE COLGIN COLGIN CONSULTING INC	DR ALEXANDER NEUMEISTER, NEW YORK, NY - EIR 7/16/15-8/5/15
2016-6560	08/08/2016 09/06/2016	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	JAMIE COLGIN COLGIN CONSULTING INC	DR CHETA NAND, RICHLAND, WA - EIR 10/6-30/15
2016-6561	08/09/2016 09/07/2016	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Abby Almonte OASIS MEDICAL INC	UNITHER, ROCHESTER, NY - EIR, COVER LETTER 01/01/2012 - 08/03/2016
2016-6562	08/09/2016 09/07/2016	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Pat Hillenmeyer (Ms.) AbbVie	KEITH AQUA, MD, VISIONS CLINICAL RESEARCH, WELLINGTON, FL - RESPONSE TO 483 04/01/2015 - 08/03/2016
2016-6563	08/09/2016 09/07/2016	FDA/OC/OES/DDM/	Michael A. Kaminski PROCTER & GAMBLE	DKT 81N-033P
2016-6564	08/09/2016 09/07/2016	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Art Rankis Art Rankis	PROFESSIONAL CONTRACT STERILIZATION, TAUNTON, MA - EIR, ATTACHMENTS, ETC 03/01/2016 - 08/03/2016
2016-6565	08/09/2016 09/07/2016	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Abby Almonte OASIS MEDICAL INC	BECTON DICKINSON COMPANY, CANAAN, CT - EIR, COVER LETTER 01/01/2012 - 08/03/2016
2016-6566	08/09/2016 09/07/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Abby Almonte OASIS MEDICAL INC	LABORATORIES UNITHER, FRANCE - EIR, COVER LETTER 01/01/2012 - 08/03/2016
2016-6567	08/09/2016 09/07/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Abby Almonte OASIS MEDICAL INC	EXCELVISION, FRANCE - EIR, COVER LETTER 01/01/2012 - 08/03/2016

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2016-6568	08/09/2016 09/07/2016	OC/ORA/OCI/ OC/ORA/OCI/	Sarah N Lynch REUTERS	OFFICE OF INTERNAL AFFAIRS REPORT RE NORTHEAST REGIONAL LABORATORY, PACIFIC REGIONAL NORTHWEST LABORATORY 01/01/2014 - 07/03/2016
2016-6569	08/09/2016 09/07/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Itrat Harrold IMPAX LABORATORIES INC	IMPAX LABORATORIES RYTARY RECS UNREDACTED
2016-6570	08/09/2016 09/07/2016	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	Jonathan Ellis Argus Leader	SOUTH DAKOTA LIONS EYE AND TISSUE BANK, SIOUX FALLS, SD, RAPID, SD, BISMARCK, ND - INSPECTION REPORTS, COMPLAINTS, ETC 01/01/2010 - 08/04/2016
2016-6571	08/09/2016 09/07/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nancy Klett Nancy Klett	ANDA 207096
2016-6572	08/09/2016 09/07/2016	FDA/OMPT/CTP/OD/	William A McGrath Potomac Law Group, PLLC	EX0000026 ENVIRONMENT ASSESSMENT, FINDING OF NO SIGNIFICANT IMPACT
2016-6573	08/09/2016 09/07/2016	FDA/OC/OES/DFOI/	Zehra Madhany PFIZER	K081953
2016-6574	08/09/2016 09/07/2016	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/ORO/DIOP/	Zetetic, Inc. Zetetic, Inc.	FDA ENTRY DOCUMENTATION REQUEST ALL DOCUMENTATION JULY 16, 2016 JULY 31, 2016
2016-6575	08/09/2016 09/07/2016	FDA/OC/OES/DFOI/	Daniel Derfel derfel, daniel	BIOTEST PHARMACEUTICALS LAB, BOCA RATON, FL - 483 01/01/2016 - 08/01/2016
2016-6576	08/09/2016 09/07/2016	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	Kristen Painter STAR TRIBUNE	GENERAL MILLS, KANSAS CITY, MO - EIR, SAMPLES, COLLECTION REPORTS ETC 04/01/2016 - 08/04/2016
2016-6577	08/09/2016 09/07/2016	FDA/OMPT/CDRH/OCE/DID/	Charles Cannon Cannon, Charles	MDR 5473663 CORR WITH MANUFACTURER, HEALTHCARE PROVIDERS
2016-6578	08/09/2016 09/07/2016	FDA/OC/OES/DDM/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Lauren Krickl COOLEY LLP	Transcript of FDA Proceedings, Biological Response Modifiers Advisory Committee, Nineteenth Meeting, July 25, 1997 DATE POSTED ONLINE
2016-6579	08/09/2016 09/07/2016	FDA/OMPT/CDRH/OCE/DID/	Steve Scott Steve Scott	TRANSCRIPT OF MEETING WITH BIOELECTRONICS CORP RE K152432
2016-6580	08/09/2016	FDA/OMPT/CDER/ORP/DIDP/	Amanda Zirelli	IMLYGIC REPORT 1257379 MEDWATCH REPORT

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	09/07/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	AMGEN, INC.	
2016-6581	08/09/2016 09/07/2016	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-5187
2016-6582	08/09/2016 09/07/2016	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K111935
2016-6583	08/09/2016 09/07/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Maja Vencl-Joncic Glenmark Pharmaceuticals Inc	NDA 203050
2016-6584	08/09/2016 09/07/2016	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K111421
2016-6585	08/09/2016 09/07/2016	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2014-9801
2016-6586	08/09/2016 09/07/2016	FDA/OC/OES/DFOI/	IND Safety Reporting Conference MCGUIREWOODS LLP	Procedures for Reinstating Eligibility of Disqualified Clinical Investigators to Receive Investigational Articles
2016-6587	08/09/2016 09/07/2016	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Trenton Williams Nutra Manufacturing, Inc	NOVEL INGREDIENTS, EAST HANOVER, NJ - EIR 10/01/2015 - 08/05/2016
2016-6588	08/09/2016 09/07/2016	FDA/OMPT/CDRH/OCE/DID/	Pablo A. Sosa, Esq. William A. Gallina, PLLC	SMITH & NEPHEW COMP FEM JOURNEY UNI OXINIUM LT MED RL/LM SZ 4, LOT 13DM18720, MODEL 71422344; INSERT JOURNEY TIB LM/RL SZ3-4 LOG139427, LOT 13AM10953, MODEL 71422251; TIBIAL BASE JOURNEY UNI LM/RL SZ3 LOG139427, LOT 12GM04722, MODEL 71422423 RECALL RECS
2016-6589	08/09/2016 09/07/2016	FDA/OMPT/CDRH/OCE/DID/	John Padalino Kemp Smith LLP	K153309
2016-6590	08/09/2016 09/07/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tania John Nutrasource Diagnostics Inc.	VASCEPA - INVESTIGATOR BROCHURE
2016-6591	08/09/2016 09/07/2016	FDA/OC/OES/DFOI/	Ohad Menachem OMM Imports, Inc. D/B/A Zero Gravity	K101190
2016-6592	08/09/2016	FDA/OMPT/CDRH/OCE/DID/	Paul Cascone	K130991

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	09/07/2016		The Argen Corporation	
2016-6593	08/09/2016 09/07/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	BLA125057 Supplement 322 approved 4/24/13
2016-6594	08/09/2016 09/07/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K152061
2016-6595	08/09/2016 09/07/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anna Edney BLOOMBERG NEWS	WOCKHARDT, INDIA - 483 RE IMPORT ALERT
2016-6596	08/09/2016 09/07/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Alka Chandna People for the Ethical Treatment of Animals (PETA)	RECS RE TRANSFER OF NONHUMAN PRIMATES FROM PRIMATES PRODUCTS INC TO FDA CBER 02/01/2015 - 08/04/2015
2016-6597	08/09/2016 09/07/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Vivek Agrawal Citigroup Global Markets India Private Limited	WOCKHARDT LIMITED, INDIA - 483 11/01/2015 - 12/31/2015
2016-6598	08/10/2016 09/08/2016	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORO/PA-FO/SEA- DO/SEA-CB/ OC/CVM/OCD/	Anthony Sackett Anthony Sackett	KINGDOM PETS, LLC, GLOBAL LINKS LLC, HILLSIDE FARMS LLS - COMPLAINTS 01/01/2006 - 07/31/2016
2016-6599	08/10/2016 09/08/2016	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/PA-FO/SEA- DO/SEA-CB/	Donald W. Fulton Donald Fulton M.D,	CFR FROZEN FOODS CO - COMM WITH FDA, COMPLAINTS 01/01/2015 - 08/05/2016
2016-6600	08/10/2016 09/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Christina Jewett The Center for Investigative Reporting	LUPRON - REVIEW, MEMO RE MEDWATCH REPORTS 3/34/99 ETC
2016-6601	08/10/2016	FDA/OFVM/CFSAN/OCD/EOS/	Donald W. Fulton	CRF FROZEN FOODS - ADVERSE EVENT REPORTS 04/23/2016 - 08/31/2016

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	09/08/2016		Donald Fulton M.D.	
2016-6602	08/10/2016 09/08/2016	FDA/OFVM/CFSAN/OCD/EOS/	Yuriy Malenkiy Yuriy Malenkiy	PAFA DATA 01/01/2016 - 08/06/2016
2016-6603	08/10/2016 09/08/2016	FDA/OC/OES/DFOI/	Christina Tomczak Christina Tomczak	STN#: 125324 PREVNAR RECS
2016-6604	08/10/2016 09/08/2016	FDA/OC/OES/DFOI/	Josh Pereira Joshua Pereira	RECS RE KRATOM, MITRAGYNA SPECIOSA 01/01/2013 - 08/07/2016
2016-6605	08/10/2016 09/08/2016	FDA/OC/OES/DFOI/	Julianne Perry Julianne Perry	LIST OF DAIRY SUPPLIERS 01/01/2016 - 08/07/2016
2016-6606	08/10/2016 09/08/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Julianna Koczone Upsher-Smith Laboratories, Inc	CMC reviews of Entocort EC 3 mg Capsule (AstraZeneca)
2016-6607	08/10/2016 09/08/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	A. LUKE SMITH RADICE LAW FIRM	COMMUNICATION BETWEEN OC/DMPQ & OGD 6/19/07
2016-6608	08/10/2016 09/08/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	A. LUKE SMITH RADICE LAW FIRM	DIOVAN (VALSARTAN) - RANBAXY ROUTING SHEET
2016-6609	08/10/2016 09/08/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	A. LUKE SMITH RADICE LAW FIRM	RANBAXY - DIOVAN (VALSARTAN) APRVL
2016-6610	08/10/2016 09/08/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	A LUKE SMITH RADICE LAW FIRM	RANBAXY - NEXIUM ANDA APRVL
2016-6611	08/10/2016 09/08/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	A. LUKE SMITH RADICE LAW FIRM	RANBAXY - RAYATAZ ANDA APRVL

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2016-6612	08/10/2016 09/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	A. LUKE SMITH RADICE LAW FIRM	RANBAXY - RAZADYNE ANDA APRVL
2016-6613	08/10/2016 09/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	A LUKE SMITH RADICE LAW FIRM	RANBAXY - VALCYTE ANDA APRVL
2016-6614	08/10/2016 09/08/2016	FDA/OC/OES/DFOI/	A LUKE SMITH RADICE LAW FIRM	RANBAXY - EIR, 483, WARNING LTR, CO RESP
2016-6615	08/10/2016 09/08/2016	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	JAMIE COLGIN COLGIN CONSULTING INC	PIKEVILLE MEDICAL CENTER INC - 483, EIR 8/2015
2016-6616	08/10/2016 09/08/2016	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	JAMIE COLGIN COLGIN CONSULTING INC	OEYAMA MOTO CANCER RESEARCH FOUNDATION IRB - EIR, 483 8/15, 9/15
2016-6617	08/10/2016 09/08/2016	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	JAMIE COLGIN COLGIN CONSULTING INC	JAMAICA HOSPITAL INSTITUTIONAL RVW BOARD - 483, EIR 8/15
2016-6618	08/10/2016 09/08/2016	FDA/OMPT/CTP/OD/	MCFADDEN 95A6279, REGINALD	REYNOLDS AMIERCAN INC - CHEMICAL USED TO TREAT TOBACCO
2016-6619	08/10/2016 09/08/2016	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	KIRSTEN JACKSON Kasowitz, Benson, Torres & Friedman LLP	SANTA BARBARA STEAKHOUSE - TEST DATA 12/2014 - 5/2015
2016-6620	08/10/2016 09/08/2016	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	OMA SCANDURRA COUNTRY LIFE LLC	COUNRTY LIFE LLC, HAUPPAUGE, NY - 483, EIR 5/1/16 TO PRESENT
2016-6621	08/10/2016 09/08/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	MANISCALCO, ALEXANDER	ISOLEX 300i MAGNETIC CELL SELECTION SYS CORR, AERS, ETC
2016-6622	08/10/2016 09/08/2016	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	HUANG, CATHY	S MARTINELLI - RECALL BEFORE 2006
2016-6623	08/10/2016 09/08/2016	FDA/OFVM/CFSAN/OCD/EOS/	SUFYAN ZAFAR, MD IOVATE HEALTH SCIENCES INTERNATIONAL INC	IOVATE, HYDROXYCUT, BCAA ETC - CAERS 2/1/16 TO PRESENT
2016-6624	08/10/2016 09/08/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HAYES, SPENCER	GADOLINIUM - AERS

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2016-6625	08/10/2016 09/08/2016	FDA/OC/OES/DFOI/	CAMA, DOMENICK	PROYECTO CAPITAN TONDIQUE, HIALEAH, FL; DOMINICK CAMA, HIALEAH, FL - RECS
2016-6626	08/10/2016 09/08/2016	FDA/OGROP/ORR/SW-FO/KAN- DO/KAN-CB/	J. ROBERT YEOMAN B AND R COMPLIANCE ASSOCIATES LLC	ICL PERFORMANCE PRODUCTS LP, LAWRENCE, KS - EIR
2016-6627	08/10/2016 09/08/2016	FDA/OPPLA/OL/	AUDREY ZHANG NYU SCHOOL OF MEDICINE	LOG OF CONGRESSIONAL CORR 6/2012 TO 12/2015
2016-6628	08/10/2016 09/08/2016	FDA/OC/OES/DFOI/ FDA/OGROP/ORR/PA-FO/LOS- DO/LOS-CB/	SEAN THOMAS HIGGINS Andrews & Thornton	2016-5820 REDACTIONS TO EIR, EXHIBITS
2016-6629	08/10/2016 09/08/2016	FDA/OMPT/CDRH/OCE/DID/	MYSHA LUBKE BAKER & BOTTS, L.L.P.	USE OF STANDARDS IN FDA REGULATORY OVERSIGHT OF NEXT GENERATION SEQUENCING NSG BASED IN VITRO DIAGNOSTICS USED FOR DIAGNOSING GERMLINE DISEASES - 7/8/16 GUIDANCE
2016-6630	08/10/2016 09/08/2016	OC/CVM/OCD/	COMPTON, EDWARD	SANDOZ - ANIMAL TESTING PRIOR TO APRVL OF DEPO MEDROL FOR USE IN HUMANS IN 1999, SIDE EFFECTS KNOWN IF GIVEN TO ANIMALS
2016-6631	08/10/2016 09/08/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ROSETTA JEFFRIES MERCK & CO., INC.	FULL SOURCE MEDWATCH RPT
2016-6632	08/10/2016 09/08/2016	OC/ORR/ OC/ORR/ FDA/OGROP/ORR/NE-FO/NWE- DO/NWE-CB/	HARRISON, ANTOINETTE	CMPLNT 124873
2016-6633	08/11/2016 09/09/2016	FDA/OMPT/OSMP/OOPD/	Charles Snow Hyman, Phelps & McNamara, P.C.	MYALEPT - ORPHAN DRUG DESIGNATION RECS
2016-6634	08/11/2016 09/09/2016	FDA/OMPT/CTP/OD/	Daniel Hoover Daniel Hoover	RECS RE ELECTRONIC CIGARETTES
2016-6635	08/11/2016 09/09/2016	FDA/OMPT/OSMP/OOPD/	Charles Snow Hyman, Phelps & McNamara P.C.	METRELEPTIN - ORPHAN DRUG DESIGNATION RECS
2016-6636	08/11/2016 09/09/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Paige Stradley MERCHANT & GOULD	FORM 3542, FORM 3542a NDA 202714 PATENTS IN ORANGE BOOK

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-6637	08/11/2016 09/09/2016	FDA/OFVM/CFSAN/OCD/EOS/	Cathryn Sacra EAS Consulting Group, LLC	New Infant Formula Notification for Enfamil Enspire manufactured by Mead Johnson Nutrition
2016-6638	08/11/2016 09/09/2016	FDA/OMPT/CDRH/OCE/DID/	Richard Fulton Nfinium Vascular, LLC	K092623
2016-6639	08/11/2016 09/09/2016	FDA/OMPT/CDRH/OCE/DID/	Natalie Goodin Biorep Technologies	K010727
2016-6640	08/11/2016 09/09/2016	FDA/OMPT/CDRH/OCE/DID/	Natalie Goodin Biorep Technologies	K123571
2016-6641	08/11/2016 09/09/2016	FDA/OMPT/CDRH/OCE/DID/	Alex Johnson Inter - Med	P020008
2016-6642	08/11/2016 09/09/2016	FDA/OC/OES/DFOI/	Caitlin O'Bryan, Brown & Toner	ADVANCE 35 LP LOW PROFILE BALLOON CATHETER - ALL RECS 08/01/1990 - 08/08/2016
2016-6643	08/11/2016 09/09/2016	FDA/OGROP/ORAP/PA-FO/SEA-DO/SEA-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OCC/	Michael Connett Fluoride Action Network	KIRKMAN LABORATORIES - RECS RE WARNING LETTER 01/01/2016 - 08/08/2016
2016-6644	08/11/2016 09/09/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K150203
2016-6645	08/11/2016 09/09/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jessica Kocian Jessica Kocian	POMALYST - AERS
2016-6646	08/11/2016 09/09/2016	FDA/OC/OES/DDM/ FDA/OFVM/CFSAN/OCD/EOS/	Alok Disa Earthjustice	RECS RE REGULATION OF HAIR DYE THAT CONTAIN LEAD ACETATE AS A COLOR ADDITIVE
2016-6647	08/11/2016 09/09/2016	FDA/OGROP/ORAP/PA-FO/SAN-DO/SAN-CB/	Mary Armstrong Mary Armstrong	HEMOSENSE CORPORATE RESPONSE LETTERS OR CAPA TO WARNING LETTERS 10/4/05, 11/29/06
2016-6648	08/11/2016 09/09/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Katherine Kaempchen Forward Pharma Gmbh- Katherine Kaempchen	DIMETHYLFUMARATE - CASE REPORTS 12333053, 12364253, 12364782, ETC

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-6649	08/11/2016 09/09/2016	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	Monica Murphy Nitto Denko Avecia Inc.	NITTO DENKO AVECIA INC, CINCINNATI, OH - EIR 10/27/2015 - 10/30/2015
2016-6650	08/11/2016 09/09/2016	FDA/OC/OES/DFOI/	Ines V Rosario-Justicia DLA PIPER LLP US	FOIA LOG 01/01/2014 - 08/08/2016
2016-6651	08/11/2016 09/09/2016	FDA/OFVM/CFSAN/OCD/EOS/	Marilynn Whitney COVINGTON & BURLING LLP	RED BULL ENERGY DRINK PRODUCTS AERS 10/01/2013 - 07/15/2016
2016-6652	08/11/2016 09/09/2016	FDA/OFVM/CFSAN/OCD/EOS/	Marilynn Whitney COVINGTON & BURLING LLP	ROCKSTAR ENERGY DRINKS 10/01/2013 - 07/15/2016
2016-6653	08/11/2016 09/09/2016	FDA/OC/OES/DFOI/	Vanessa A. Lavelly Cravath, Swaine & Moore LLP	2015-8061 CERTIFIED RECS
2016-6654	08/11/2016 09/09/2016	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Maggie Cichocki PPD	DR ELLIOT ISRAEL, BRIGHAM & WOMANS HOSPITAL, BOSTON, MA - 483, EIR 11/01/2015 - 08/08/2016
2016-6655	08/11/2016 09/09/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Abhay Shanbhag Abhay Shanbhag	WOCKHARDT LIMITED, INDIA - 483 08/01/2015 - 08/09/2016
2016-6656	08/11/2016 09/09/2016	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	DANIEL FUSCO GLOBAL FOOD TRADING CORP.	ENTRY NO. 594-0268353-2 (OUR REF# 3707) COLLECTION REPORTS, ENTRY NO. H77-0155066-4 (OUR REF# 3727) COLLECTION REPORTS, WORKSHEETS
2016-6657	08/11/2016 09/09/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bingwu Yu Fresenius Kabi USA, LLC	MITOMYCIN (ANDA # 064144) LABELING RECS
2016-6658	08/11/2016 09/09/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Hugh Sandler Nussbaum Law Group, P.C.	ANDA 202240 CHEMISTRY REVIEW OF SBA
2016-6659	08/11/2016 09/09/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Zachary Mietus The Weinberg Group	BIOEQUIVALENCE SECTION OF ANDA 090711

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2016-6660	08/12/2016 09/12/2016	FDA/OC/OES/DFOI/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	David Lebowitz Morgan Stanley	ALEXION PHARMACEUTICALS, SMITHFIELD, RI - 483 07/01/2016 - 08/31/2016; 2013 WARNING LETTER
2016-6661	08/12/2016 09/12/2016	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Jim Austin Arizona Nutritional Supplements	ARIZONA NUTRITIONAL SUPPLEMENTS, CHANDLER, AZ - EIR 03/29/2016 - 04/07/2016
2016-6662	08/12/2016 09/12/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sue Cox Wukela Law Firm	VIMPAT - AERS
2016-6663	08/12/2016 09/12/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jake McDowell The Weinberg Group	ANDA 090821 PRODUCT NUMBER 001 BIOEQUIVALENCE RECS
2016-6664	08/12/2016 09/12/2016	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Ellen Huet BLOOMBERG NEWS	HAMPTON CREEK MIXES CONTAINING NATIVE FOREST COCONUT MILK POWDER - RECALL RECS, TEST RESULTS 08/15/2015 - 08/09/2016
2016-6665	08/12/2016 09/12/2016	FDA/OO/OFBA/OAGS/	JoAnne Melfi INTEGRITYOne Partners	HHSF223200950013C STATEMENT OF WORK, MODIFICATIONS
2016-6666	08/12/2016 09/12/2016	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Rachel Johnson FOI Services, Inc.	HODO SOY BEANERY, OAKLAND, CA - TAYLOR FARMS, SALINAS, CA; NIMAN RANCH, OAKLAND, CA ETC - 483, CORR
2016-6667	08/12/2016 09/12/2016	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	KARRO FOOD GROUP, TULIP LTD, UK - 483, CORR 08/01/2015 TO PRESENT
2016-6668	08/12/2016 09/12/2016	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/ OC/ORAOCI/ OC/ORAOCI/	Wayne Risher The Commercial Appeal	KELLOGG'S, MEMPHIS, TN - CRIMINAL INVESTIGATION RECS, INSPECTION RECS 03/01/2016 - 08/09/2016
2016-6669	08/12/2016 09/12/2016	FDA/OMPT/CDRH/OCE/DID/	Angelika Scherp BUSINESS SUPPORT INTERNATIONAL	K030857
2016-6670	08/12/2016 09/12/2016	FDA/OMPT/CDRH/OCE/DID/	Angelika Scherp BUSINESS SUPPORT INTERNATIONAL	K991426
2016-6671	08/12/2016 09/12/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Christopher Holcomb Gold Coast Medical Supply	API DATA

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2016-6672	08/12/2016 09/12/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ted Keller EverPoint Asset Management	CASE REPORTS 12520599 12568812 12507321 ETC
2016-6673	08/12/2016 09/12/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jacob Morelan Jacob Morelan	HEALIX INFUSION THERAPY, INC - REGISTRATION AS OUTSOURCING FACILITY , CANCELLATION 01/01/2014 - 08/09/2016
2016-6674	08/12/2016 09/12/2016	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	FCN 707 REVIEWS
2016-6675	08/12/2016 09/12/2016	FDA/OMPT/CDRH/OCE/DID/	Kathryn Becker Kathryn Becker	K101423 K990498 K014027
2016-6676	08/12/2016 09/12/2016	FDA/OFVM/CFSAN/OCD/EOS/	Eleanor DaCosta United States Pharmacopeial Convention (USP)	MENAQUINONE-7 AERS
2016-6677	08/12/2016 09/12/2016	OC/ORA/ OC/ORA/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	PLAINSBORO PHARMACY, PLAINSBORO, NJ - EIR, 483, RESPONSE 07/30/2014 - 07/30/2014
2016-6678	08/12/2016 09/12/2016	FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	NORTH HILLS MEDICAL RESEARCH, NORTH RICHLAND HILLS, TX - EIR, 483, RESPONSE 02/01/2016 - 02/18/2016
2016-6679	08/12/2016 09/12/2016	FDA/OGROP/ORR/CE-FO/CIN-DO/CIN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	GENPAK SOLUTIONS LLC, HILLIARD, OH - EIR, 483, RESPONSE 08/03/2015 - 08/12/2015
2016-6680	08/12/2016 09/12/2016	FDA/OGROP/ORR/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	ADAMSON ANALYTICAL LABORATORIES, INC, CORONA, CA - EIR, 483, RESPONSE 08/04/2015 - 08/14/2015
2016-6681	08/12/2016 09/12/2016	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	FCN 1276 REVIEWS
2016-6682	08/12/2016 09/12/2016	FDA/OMPT/CDRH/OCE/DID/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	GUANGZHOU HAISHI BIOLOGICAL TECHNOLOGY CO LTD, CHINA - 483 07/20/2015 - 07/24/2015

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2016-6683	08/12/2016 09/12/2016	FDA/OMPT/CDRH/OCE/DID/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	XIAMEN ORIGIN BIOTECH CO LTD, CHINA - 483 01/18/2016 - 01/20/2016
2016-6684	08/12/2016 09/12/2016	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	NADARAJAH, JANAKI, MD, AIYAN DIABETES CENTER, MARTINEZ, GA - EIR, 483, RESPONSE 01/25/2016 - 02/04/2016
2016-6685	08/12/2016 09/12/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Genevieve Stevens Nivagen Pharmaceuticals, Inc.	ANDA 062298 SBA
2016-6686	08/12/2016 09/12/2016	FDA/OMPT/CDRH/OCE/DID/	Alex Johnson Inter - Med	K062961
2016-6687	08/12/2016 09/12/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	SMITHKLINE BEECHAM LIMITED, UK - 483 07/02/2015 - 07/10/2015
2016-6688	08/12/2016 09/12/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Neena M Bitritto-Garg ROBERT W. BAIRD & CO INC	ETEPLIRSEN - RECS RE DIFFERING PROFESSIONAL OPINIONS PROCEEDING 01/01/2016 - 08/10/2016
2016-6689	08/12/2016 09/12/2016	FDA/OMPT/CDRH/OCE/DID/	Veeraraghavan Sundar SBK Professional Services	K122424 K151789 K140737
2016-6690	08/12/2016 09/12/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Darlene O'Banion Revance Therapeutics	BLA 103000, S 5260
2016-6691	08/12/2016 09/12/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Darlene O'Banion Revance Therapeutics	BLA 103000, S 5252, 103000, S 5282 REVIEW RECS
2016-6692	08/12/2016	FDA/OMPT/CDRH/OCE/DID/	BENJAMIN M ZEGARELLI	EPIC RESEARCH & DIAGNOSTICS INC - EPIC CLEARVIEW SYS; BRAINSCOPE COMPANY IC - BRAINSCOPE AHEAD

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	09/12/2016		Mintz Levin Cohn Ferris Glovsky & Popeo PC	100; AUXOGYN INC - EEVA SYS, ETC Q-SUBMISSION MTGS RELATING TO DE NOVO APPLICATIONS, ETC
2016-6693	08/12/2016 09/12/2016	FDA/OO/OHR/	SONYA GAIL SLATON REID LAW FIRM LLC	VACANCY ANNOUNCEMENT HHS-FDA-MP-15-1223716 SAMPLE PERFORMANCE PLAN, PMAP, EVALUATION FACTORS, ETC
2016-6694	08/12/2016 09/12/2016	OC/ORO/OCI/ OC/ORO/OCI/	BRITNI DONNELSON FELLER WENDT LLC	HEPATITIS C EXPOSURE LITIGATION INVESTIGATION RECS 6/1/06 TO PRESENT
2016-6695	08/12/2016 09/12/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHELSEA JERRY HOGAN LOVELLS US LLP	KENDALL MCGRAW LABS, AMERICAN HOSPITAL SUPPLY CORP - AMERISAL BALANCED SALT SOL RECS
2016-6696	08/12/2016 09/12/2016	FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/	WILLIAM J MCGOWAN SILVER MCGOWAN & SILVER PC	NATIVE TRADING ASSOCIATES, HOGANSBURG, NY - INSP EXHIBITS 8/7/14
2016-6697	08/12/2016 09/12/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MICHAEL D SHUMSKY KIRKLAND & ELLIS LLP	SUBOXONE (BUPROMORPHINE AND NALOXONE) SUBLINGUAL FILM - FORMS 3542 OR 3542A
2016-6698	08/12/2016 09/12/2016	FDA/OGROP/ORO/CE-FO/MIN-DO/MIN-CB/	PAUL B CALLAHAN CHARLES RIVER LABS	COVANCE, MADISON, WI - 483
2016-6699	08/12/2016 09/12/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BETHANY KENNEDY EMORD & ASSOCIATES, P.C.	PHARMACIA AND UPJOHN - NDA 8-917; MEDA PHARMS - NDA 17-351; PFIZER GLOBAL - NDA 9-176,E TC APRVL RECS
2016-6700	08/12/2016 09/12/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TRACY POWELL COLEHILL ENTERPRISES LTD	PRESCIENCE LLC - 3-BROMOPYRUVATE (3-BRPA OF PSL-001) IND FOR PHASE 1 CLNCL EVALUATION APPLICATION
2016-6701	08/12/2016 09/12/2016	FDA/OC/OES/DFOI/	DANIEL GREENE PHD CLEMSON UNIV DEPT OF FINANCE	EMAILS REGARDING THE APPOINTMENT OF JANE E HENNEY MD TO THE BOARDS OF DIRECTORS OF AMERISOURCEBERGEN CORP AND CIGNA CORP
2016-6702	08/12/2016 09/12/2016	FDA/OFVM/CFSAN/OCD/EOS/	JOANNA R DRAKE VERTO LEGAL SOLUTIONS LLC	SALMONELLA IN RETAIL SPICE PACKAGES - TWO YEAR NATIONWILDE STUDY FY2014, FY2015
2016-6703	08/12/2016 09/12/2016	FDA/OC/OES/DDM/	DAVID L SCHARBERG SCHARBERG, DAVID L	RESULTS OF THE NONCL TOXICOLOGY LABORATORY GOOD LABORATORY PRACTICES PILOT COMPLIANCE PROGRAM

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2016-6704	08/12/2016 09/12/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	DARYL MICHALIK MICHALIK, DARYL	GTI INC - THROMBO TYPE (HPA 1-6,16) AND THROMBO TYPE 1 (HPA 1) BK050040
2016-6705	08/12/2016 09/12/2016	FDA/OMPT/CDRH/OCE/DID/	EITEZAZ MAHMOOD Eitezaz Mahmood	ECHOPIXEL TRUE 3D VIEWR, OSIRIX MD BRIGHTMATTER PLANNING SOFTWARE, ORTHOVIS PREOPERATIVE SURGICAL NAVIGATION ADVANCED PLATFORM AND SURGERY REHEARSAL PLATFORM MIMIC SOFTWARE - PREPARKET APPROVAL SAFETY AND EFFECTIVENESS RECS 08/11/1998 - 08/10/2016
2016-6706	08/12/2016 09/12/2016	FDA/OC/OES/DDM/	CHRISTOPHER HENDEL CONSUMER REPORTS	JOINT MTG OF THE BONE, REPRODUCTIVE AND UROLOGIC DRUGS A/C AND DRUG SAFETY AND RISK MANAGEMENT A/C - MINS, TRANS 6/4/15
2016-6707	08/12/2016 09/12/2016	OC/CVM/OCD/	ANIKA LARSON UNIV OF WASHINGTON SCHOOL OF PUBLIC HEALTH	ANTIBIOTIC RESISTANCE OF BACTERIA ON SAMPLES COLLECTED FROM RETAIL MEAT IN THE US - RECS 1996 TO 2015
2016-6708	08/12/2016 09/12/2016	FDA/OMPT/CDRH/OCE/DID/	BOSMAT FRIEDMAN MJ REGULATORY AFFAIRS CONSULTANTS	HOSPITECH RESPIRATION LTD - ANAPNOGUARD ENDOTRACHEAL TUBE K093126
2016-6709	08/12/2016 09/12/2016	FDA/OMPT/CDRH/OCE/DID/	BOSMAT FRIEDMAN MJ REGULATORY AFFAIRS CONSULTANTS	COVIDIEN - KANGAROO FEEDING TUBES WITH IRIS TECHNOLOGY K123555
2016-6710	08/12/2016 09/12/2016	FDA/OMPT/CDRH/OCE/DID/	BOSMAT FRIEDMAN MJ REGULATORY AFFAIRS CONSULTANTS	POTRERO MEDICAL INC - ACCURYN MONITORING SYS K153655
2016-6711	08/12/2016 09/12/2016	FDA/OGROP/ORAP/PA-FO/LOS- DO/LOS-CB/	JAMIE COLGIN COLGIN CONSULTING INC	DR BENEDICT SCHUE-SCHIE LIAO, OEYAMA-MOTO CANCER RESEARCH FOUNDATION - EIR, 483 10/17-18/12
2016-6712	08/12/2016 09/12/2016	FDA/OGROP/ORAP/PA-FO/LOS- DO/LOS-CB/	JAMIE COLGIN COLGIN CONSULTING INC	DR BENEDICT S LIAO - EIR, 483 8/11/15-9/29/15
2016-6713	08/15/2016 09/13/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Travis Allen Travis Allen	ELECTRONIC DRUG REPROTS FOR HUMAN DRUG COMPOUNDING OUTSOURCING FACILITIES 06/01/2015 - 06/30/2016
2016-6714	08/15/2016 09/13/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Darlene O'Banion Revance Therapeutics	BLA 125274 S 105 BLA 125274 S 102
2016-6715	08/15/2016	FDA/OMPT/CDER/GRP/DIDP/	Darlene O'Banion	BLA 125360, S 067

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	09/13/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Revance Therapeutics	
2016-6716	08/15/2016 09/13/2016	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michael Connett Fluoride Action Network	RECS RE 1/13/16 WARNING LETTER TO KIRKMAN LABORATORIES AND ENFORCEMENT ACTION 01/01/2016 - 08/10/2016
2016-6717	08/15/2016 09/13/2016	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Hannah Lee CelVitali Medical	CH LABORATORIES INC, GARDENA, CA - 482 07/12/2016 - 08/10/2016
2016-6718	08/15/2016 09/13/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Brenda Sandburg THE PINK SHEET	ZECUITY PATCH - AERS
2016-6719	08/15/2016 09/13/2016	FDA/OC/OES/DFOI/	Valerie Benka Alliance for Contraception in Cats & Dogs (ACC&D)	NEUTERSOL INJECTABLE SOLUTION FOR DOGS RECS
2016-6720	08/15/2016 09/13/2016	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	Jeff Eden schwabe williamson and wyatt	NSPIRED NATURAL FOODS, ASHLAND, OR - 483 01/01/2006 - 07/31/2016
2016-6721	08/15/2016 09/13/2016	FDA/OC/OES/DFOI/	Christopher Bailey NATURAL PRODUCTS ASSOCIATION	FDA NUTRITION REVIEW PROJECT 12/01/2014 - 12/31/2014
2016-6722	08/15/2016 09/13/2016	OC/ORA/ OC/ORA/	Sarah N Lynch REUTERS	ORA LABORATORY AUDITS 01/01/2013 - 08/10/2016
2016-6723	08/15/2016 09/13/2016	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	RECS RE SAFFLOWER COLOR
2016-6724	08/15/2016 09/13/2016	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	Jeanine Gouveia Aerie Pharmaceuticals Inc.	BAUSCH & LOMB, TAMPA, FL - EIR 03/02/2015 - 07/31/2015
2016-6725	08/15/2016 09/13/2016	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	RECS RE PURPLE CORN COLOR
2016-6726	08/15/2016 09/13/2016	FDA/OFVM/CFSAN/OCD/EOS/	Brandon Schilling Brandon Schilling	RAW MILK CHEESE SUMMARY OF TEST RESULTS 01/01/2014 - 08/10/2016
2016-6727	08/15/2016	FDA/OGROP/ORA/PA-FO/SEA-	Rachel Johnson	OREGON POTATO COMPANY, PASCO, WA - INSPECTION

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	09/13/2016	DO/SEA-CB/	FOI Services, Inc.	RECS MARCH 2016
2016-6728	08/15/2016 09/13/2016	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	GARDENIA BLUE COLOR RECS
2016-6729	08/15/2016 09/13/2016	FDA/OGROP/ORAP/PA-FO/SEA-DO/SEA-CB/	Doug Main Newsweek Magazine	KIRKMAN LABORATORIES - FDA RESPONSE TO ANTHONY YOUNG AND PETER MATHERS JULY 2016
2016-6730	08/15/2016 09/13/2016	OC/ORAP/ OC/ORAP/	Sarah Lynch REUTERS	COMPLAINTS FILED AGAINST ORA LABORATORIES 01/01/2013 - 08/10/2016
2016-6731	08/15/2016 09/13/2016	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	Keith Curran Covance Inc.	GILEAD SCIENCES, INC, FOSTER CITY, CA - EIR 04/10/2013 - 07/25/2014
2016-6732	08/15/2016 09/13/2016	FDA/OO/OFBA/OAGS/	Scott A. Hodes Scott A. Hodes, Attorney at Law	HHS FDA IT HELPDESK CONTRACT WINNING PROPOSAL, CONTRACT, AMENDMENTS
2016-6733	08/15/2016 09/13/2016	FDA/OMPT/CDRH/OCE/DID/	Mr. Michael McSweeney McSweeney, Michael	PMA P010030
2016-6734	08/15/2016 09/13/2016	FDA/OMPT/CDRH/OCE/DID/	Sally He Micro-Tech (Nanjing) Co., Ltd.	K140561
2016-6735	08/15/2016 09/13/2016	FDA/OMPT/CDRH/OCE/DID/	Sally He Micro-Tech (Nanjing) Co., Ltd.	K150692
2016-6736	08/15/2016 09/13/2016	FDA/OMPT/CDRH/OCE/DID/	Sally He Micro-Tech (Nanjing) Co., Ltd.	K152572
2016-6737	08/15/2016 09/13/2016	FDA/OMPT/CDRH/OCE/DID/	Sally He Micro-Tech (Nanjing) Co., Ltd.	K153088
2016-6738	08/15/2016 09/13/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rahul Murkya JEFFERIES & CO	SUN PHARMACEUTICALS, LUPIN, CIPLA - 483 04/01/2016 - 08/11/2016
2016-6739	08/15/2016 09/13/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rahul Murkya JEFFERIES & CO	AUROBINDO, WOCKHARDT, CADILA HEALTHCARE - 483 04/01/2016 - 08/11/2016
2016-6740	08/15/2016 09/13/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rahul Murkya JEFFERIES & CO	STRIDES SHASUN, DR REDDY'S LABORATORIES, NATCO PHARMA -483 04/01/2016 - 08/11/2016

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2016-6741	08/15/2016 09/13/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCE/DID/	Dr. Stephen Bourque STEPHEN BOURQUE	ALERE ICUP MULTI DRUG SCREEN TESTING DEVICE - 510K WAIVER APPLICATION RECS, AWARD LETTER, COMPLAINTS ETC 01/01/1998 - 08/11/2016; VICKS VAPO INHALER NASAL DECONGESTANT - COMPLAINTS ETC
2016-6742	08/15/2016 09/13/2016	FDA/OGROP/ORACE-FO/DET- DO/DET-CB/	N. Brent Conatser ELANCO ANIMAL HEALTH	DOW AGROSCIENCES HARBOR BEACH, MI - EIR 05/02/2016 - 08/10/2016
2016-6743	08/15/2016 09/13/2016	FDA/OMPT/CDRH/OCE/DID/	Chris Smith Symmetry Surgical Inc.	K942597, K982428, K020698 FIRST PARTY
2016-6744	08/15/2016 09/13/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Anthony Soscia Atlantic Pharmaceuticals, Inc	BLA 101995
2016-6745	08/15/2016 09/13/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ronen Sarraf Sarraf Gentile LLP	TOKAI PHARMACEUTICALS INC - COMMUNICATIONS WITH FDA RE GALETERONE, ANALYSIS 01/01/2012 - 08/10/2016
2016-6746	08/15/2016 09/13/2016	FDA/OMPT/CDRH/OCE/DID/	Richard Fulton M.D. Nfinium Vascular, LLC	K040010 K092623 FIRST PARTY
2016-6747	08/15/2016 09/13/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Vivian Zhang OTSUKA PHARMACEUTICAL DEVELOPMENT & COMMERCIALIZATION, INC.	MEDWATCH 3849307 4122667 5764691ETC
2016-6748	08/15/2016 09/13/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Vanita Dimri Sr Manager Regulatory Affairs Indivior Inc	A Randomized, Double-blind, Placebo- and Positive-Controlled, Parallel Group, Dose Escalating Study to Evaluate the Effect of Buprenorphine Delivered by the Buprenorphine Transdermal System (BTDS) at 10- and 40-mg Dose Levels on QT Intervals in Healthy Adult Volunteers -NDA 21-306 Submission Date Nov 11, 2009, SDN 089 Protocol Number BUP1011
2016-6749	08/15/2016 09/13/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCE/DID/	Lewis Ward L.W. Ward and Associates, Inc.	K131895
2016-6750	08/15/2016	FDA/OMPT/CDRH/OCE/DID/	Lewis Ward	K143646

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	09/13/2016		L.W. Ward and Associates, Inc.	
2016-6751	08/15/2016 09/13/2016	FDA/OMPT/CDRH/OCE/DID/	Lewis Ward L.W. Ward and Associates, Inc.	K131912
2016-6752	08/15/2016 09/13/2016	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 7/18-22/16
2016-6753	08/15/2016 09/13/2016	FDA/OMPT/CDRH/OCE/DID/	Lewis Ward L.W. Ward and Associates, Inc.	K141943
2016-6754	08/15/2016 09/13/2016	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Pat Hillenmeyer (Ms.) AbbVie, Inc.	JOHN D GABRIEL, MD, NORTH RICHLAND HILLS, TX - EIR, 483, RESPONSE 01/01/2016 - 08/11/2016
2016-6755	08/15/2016 09/13/2016	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 7/18-22/16
2016-6756	08/15/2016 09/13/2016	FDA/OMPT/CDRH/OCE/DID/	Lewis Ward L.W. Ward and Associates, Inc.	K102525
2016-6757	08/15/2016 09/13/2016	FDA/OMPT/CDRH/OCE/DID/	Mathew Fairfax Surgical Technology Laboratories, Inc	K160744K121173 K072076
2016-6758	08/15/2016 09/13/2016	FDA/OC/OES/DFOI/	Kayla McBride Verified Credentials Inc.	VERIFICATION
2016-6759	08/15/2016 09/13/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 7/18-22/16
2016-6760	08/15/2016 09/13/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mari S. Golub UNIVERSITY OF CALIFORNIA, DAVIS	FULL REPORT OF PRECLINICAL STUDY DESCRIBED ON THE FDA LABEL FOR NDA 018936
2016-6761	08/15/2016 09/13/2016	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD Center for Regulator Services, Inc	FOI DAILY LOG 7/18-22/16
2016-6762	08/15/2016 09/13/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 7/18-22/16
2016-6763	08/15/2016 09/13/2016	FDA/OMPT/CDRH/OCE/DID/	Lewis Ward L.W. Ward and Associates, Inc.	K082982
2016-6764	08/15/2016 09/13/2016	OC/ORAS/ OC/ORAS/	Casey Strom, Personally Casey Strom	NETOVI INC - COMPLAINT FOLLOW UP RECS 07/28/2016 - 08/11/2016

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		FDA/OGROP/ORO/PA-FO/SEA-DO/SEA-CB/ FDA/OMPT/CDRH/OCE/DID/		
2016-6765	08/15/2016 09/13/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Genevieve Stevens Nivagen Pharmaceuticals, Inc.	NDA 050207 SBA
2016-6766	08/15/2016 09/13/2016	OC/ORO/ORM/ OC/ORO/ORM/	Hal Pepper University of Tennessee Extension Service	LIST OF RABBIT PROCESSORS IN TN 01/01/2010 - 08/11/2016
2016-6767	08/15/2016 09/13/2016	FDA/OMPT/CDRH/OCE/DID/	Andrew C. McMurray Henriks LLP	GOMCO CIRCUMCISION CLAMP 510K
2016-6768	08/15/2016 09/13/2016	FDA/OMPT/CDRH/OCE/DID/	Kendall Covington Sisu Global Health	K945775, K901138
2016-6769	08/15/2016 09/13/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kyle Jaeger ATTN: FRANK BEAN, STORE MANAGER	FDA RECOMMENDATION TO THE DEA RE PETITIONS TO RESCHEDULE MARIJUANA UNDER THE CONTROLLED SUBSTANCES ACT , INTERNAL COMMUNICATIONS WITH DEA RE SCHEDULING 01/02/2015 - 08/11/2016
2016-6770	08/15/2016 09/13/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCE/DID/	Philippe Sun NANG KUANG PHARMACEUTICAL CO., LTD	NDC 0641-0273-25
2016-6771	08/15/2016 09/13/2016	FDA/OMPT/CDRH/OCE/DID/	Jackie Buckley BIO-RAD LABORATORIES, INC.	K082227
2016-6772	08/15/2016 09/13/2016	FDA/OC/OES/DFOI/	LESLIE RAMSEY FDA NEWS	FOI DAILY LOG 7/18-22/16
2016-6773	08/15/2016 09/13/2016	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 7/18-22/16
2016-6774	08/15/2016 09/13/2016	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 7/25-29/15
2016-6775	08/15/2016 09/13/2016	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 7/25-29/15

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2016-6776	08/15/2016 09/13/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 7/25-29/15
2016-6777	08/15/2016 09/13/2016	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD Center for Regulator Services, Inc	FOI DAILY LOG 7/25-29/15
2016-6778	08/15/2016 09/13/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 7/25-29/15
2016-6779	08/15/2016 09/13/2016	FDA/OC/OES/DFOI/	LESLIE RAMSEY FDA NEWS	FOI DAILY LOG 7/25-29/15
2016-6780	08/15/2016 09/13/2016	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 7/25-29/15
2016-6781	08/15/2016 09/13/2016	OC/ORO/ORM/ OC/ORO/ORM/	Kris Christian FDAZILLA	LIST OF INSPECTION CITATIONS 08/09/2015 - 08/08/2016
2016-6782	08/15/2016 09/13/2016	FDA/OC/OES/DFOI/	Jeffrey Churchill HEALTH POLICY ASSOCIATES INC.	K140951
2016-6783	08/15/2016 09/13/2016	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2016-680
2016-6784	08/16/2016 09/14/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Becky Hartman Teva Pharmaceuticals	ADASUVE - AERS
2016-6785	08/16/2016 09/14/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Becky hartman Teva Pharmaceuticals	ZECUITY - AERS
2016-6786	08/16/2016 09/14/2016	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	NEUROLUMEN, OKLAHOMA CITY, OK - EIR, 483, RESPONSE 12/13/13
2016-6787	08/16/2016 09/14/2016	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	STRYKER ENDOSCOPY, SAN JOSE, CA - EIR, 483, RESPONSE 10/8/14
2016-6788	08/16/2016 09/14/2016	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	TERUMO MEDICAL CORPORATION, ELKTON, MD - EIR, 483, RESPONSE 10/23/15

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2016-6789	08/16/2016 09/14/2016	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	PINNACLE BIOLOGICS, CHICAGO, IL - EIR, 483, RESPONSE 3/15/16
2016-6790	08/16/2016 09/14/2016	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	VALEANT PHARMACEUTICALS INTERNATIONAL, BRIDGEWATER, NJ - EIR, 483, RESPONSE 6/26/14
2016-6791	08/16/2016 09/14/2016	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	GE HEALTHCARE, LAUREL, MD - EIR, 483, RESPONSE 6/19/15
2016-6792	08/16/2016 09/14/2016	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	COVIDIENT, NORFOLK, NE - EIR, 483, RESPONSE 4/17/15
2016-6793	08/16/2016 09/14/2016	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	BECTON DICKINSON AND COMPANY, BD BIOSCIENCES, SAN JOSE, CA - EIR, 483, RESPONSE 6/19/15
2016-6794	08/16/2016 09/14/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Robert Kemp Natrium Products Inc. Attn Bob Kemp	ANDA 203124 ANDA213151
2016-6795	08/16/2016 09/14/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Banu Ramachandran Citron Pharma, LLC	NDA 003402 SBA
2016-6796	08/16/2016 09/14/2016	FDA/OMPT/CDRH/OCE/DID/	Andrew DeNinno Smith & Brink, P.C.	K070612
2016-6797	08/16/2016 09/14/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Richard G Einig Einig, Richard G	INDOCO REMEDIES LIMITED, GOA, INDIA - EIR 10/24/2015 - 10/29/2015
2016-6798	08/16/2016 09/14/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/ORAI/	Ronald C Stellon Stellon Consulting, LLC	TRAINING MATERIALS FOR CDER, ORO TRAINING FOR FIELD RE INSPECTING 503A AND 503B 01/01/2016 - 08/12/2016

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		OC/ORO/		
2016-6799	08/16/2016 09/14/2016	FDA/OMPT/CDRH/OCE/DID/	MaryBeth Gaczias FOX CHASE CANCER CENTER	ANGIO CATH PROTECTIVSAFETY IV CATHETER MEDWATCH REPORT 01/28/2016 - 02/28/2016
2016-6800	08/16/2016 09/14/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Manal Ziadeh Manal Ziadeh, University of Maryland at Clinical Pharmacy Associates	PHENTERMINE - AERS
2016-6801	08/16/2016 09/14/2016	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	Rachel Johnson FOI Services, Inc.	BAUSCH & LOMB, TAMPA, FL - RECALL RECS 1/1/15 TO PRESENT
2016-6802	08/16/2016 09/14/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gail A. Sater Treon & Shook, PLLC	INDIVIDUAL RECS
2016-6803	08/16/2016 09/14/2016	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	Fran Silverman Truthinadvertising.org (TINA.org)	NERIUM INTERNATIONAL, ADDISON, TX- INSPECTION RECS, ADVERSE EVENTS 01/01/2011 - 08/12/2016
2016-6804	08/16/2016 09/14/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gerry Hickey Synergy Regulatory Services LLC	NME NDA/BLAs DATA 01/01/2013 - 08/12/2016
2016-6805	08/16/2016 09/14/2016	FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/	Cristina Gayle Angelic Bakehouse	ANGELIC BAKEHOUSE INC, CYBROS - INSPECTION RECS 11/01/2009 - 08/12/2016
2016-6806	08/16/2016 09/14/2016	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	Rachel Johnson FOI Services, Inc.	BAUSCH & LOMB, TAMPA, FL - INSPECTION RECS
2016-6807	08/16/2016 09/14/2016	FDA/OMPT/OSMP/OOPD/	Rachel Johnson FOI Services, Inc.	OOPD MEMOS RE ORPHAN EXCLUSIVITY FOR DUOPA
2016-6808	08/16/2016 09/14/2016	FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	FRESENIUS USA, CONCORD, CA - EIR, 483, RESPONSE 2/22/13
2016-6809	08/16/2016 09/14/2016	FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	BIOMET, WARSAW, IN - 483, EIR, RESPONSE 6/30/14

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2016-6810	08/16/2016 09/14/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Becky Hartman Teva Pharmaceuticals	PRO AIR RESPICLICK - AERS
2016-6811	08/16/2016 09/14/2016	FDA/OGROP/ORR/SE-FO/SJN-DO/SJN-CB/	Richard G Einig Einig, Richard G	BLU CARIBE, DORADO, PR - EIR 08/04/2015 - 08/14/2015
2016-6812	08/16/2016 09/14/2016	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kendrick Luse EverPoint Asset Management	ORKAMBI - AERS; FOIA REQUESTS
2016-6813	08/16/2016 09/14/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anna Edney BLOOMBERG NEWS	FDA MOST RECENT ANALYSIS OF WHETHER DEA SHOULD RESCHEDULE MARIJUANA
2016-6814	08/16/2016 09/14/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michael Chris Neglia Dabo LLC	RECS RE CANNABIS
2016-6815	08/16/2016 09/14/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Becky Hartman Teva Pharmaceuticals	CINQUAIR, RESLIZUMAB - AERS
2016-6816	08/16/2016 09/14/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Melanie Hicken CNN	ABILIFY, ARISTADA, ETC - AERS CASE REPORTS
2016-6817	08/16/2016 09/14/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KRISTI SMEDLEY Center for Regulatory Services Inc.	HAUPT PHARMA, GERMANY - EIR 08/12/2016 - 08/12/2016
2016-6818	08/16/2016 09/14/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Chris Barnett Chris Barnett	MICOCYCLINE - AERS

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2016-6819	08/16/2016 09/14/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sabrina atack Sabrina Atack	ELLAONE - AERS
2016-6820	08/16/2016 09/14/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Daniel Sem AviMed Pharmaceuticals, LLC	IND DMP-543
2016-6821	08/16/2016 09/14/2016	OC/ORA/ OC/ORA/	Innovation Compounding, Inc c/o Bendin Sumrall & Ladner, LLC Innovation Compounding c/o Bendin Sumrall & Ladner, LLC	INNOVATION COMPOUNDING, INC, KENNESAW, GA - EIR 02/01/2016 - 06/19/2016
2016-6822	08/16/2016 09/14/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Matthew Jackson Matthew Jackson	COMPLETE RESPONSE LETTERS FOR GRANISETRON CONTROLLED RELEASE IN CHEMOTHERAPY INDUCED NAUSEA AND VOMITING
2016-6823	08/16/2016 09/14/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Vivian Zhang OTSUKA PHARMACEUTICAL DEVELOPMENT & COMMERCIALIZATION, INC.	CILOSTAZOL 3849307 5764691 5854162 ETC
2016-6824	08/16/2016 09/14/2016	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Alexandra Ajmo LIFE EXTENSION	UNIQUE ENCAPSULATION TECHNOLOGY, LANDING, NJ - EIR 06/01/2016 - 08/15/2016
2016-6825	08/16/2016 09/14/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Daniel Kolitz Daniel Kolitz	PROPOSED NEW DRUGS REJECTED BY FDA WITH AMPHETAMINE 01/01/1980 - 08/15/2016
2016-6826	08/16/2016 09/14/2016	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	Darren Walsh Edwards Lifesciences	EDWARDS LIFE SCIENCES, DRAPER, UT - EIR 11/01/2015 - 11/20/2015
2016-6827	08/16/2016 09/14/2016	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Jim Austin Arizona Nutritional Supplements	ARIZONA NUTRITIONAL SUPPLEMENTS, CHANDLER, AZ - EIR 05/15/2016 - 07/15/2016
2016-6828	08/16/2016 09/14/2016	FDA/OMPT/CDRH/OCE/DID/	Ronda Elliott INOVA DIAGNOSTICS INC	K113610

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2016-6829	08/16/2016 09/14/2016	FDA/OGROP/ORPA-FO/LOS-DO/LOS-CB/	Jim Austin Arizona Nutritional Supplements	ARIZONA NUTRITIONAL SUPPLEMENTS, CHANDLER, AZ - EIR 05/15/2016 - 07/15/2016
2016-6830	08/16/2016 09/14/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rafid Azad Rafid Azad	VIBREZI - AERS
2016-6831	08/16/2016 09/14/2016	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Doreen Frank ENVISAGE CONSULTING LLC	KRAMER LABORATORIES RESPONSE TO WARNING LETTER 11/22/2005 - 11/21/2006
2016-6832	08/16/2016 09/14/2016	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	Darren Walsh Edwards Lifesciences	EDWARDS LIFESCIENCES, DRAPER, UT - EIR 04/18/2016 - 05/20/2016
2016-6833	08/16/2016 09/14/2016	OC/ORPA/ OC/ORPA/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	DREW BASKIN ESQ BUTLER LAW GROUP	REPTILE INDUSTRIES - ARTIC MICE SALMONELLA OUTBREAK INVESTIGATION RECS
2016-6834	08/16/2016 09/14/2016	FDA/OC/OES/DFOI/	CAREY GILLAM US RIGHT TO KNOW	USDA, FDA, EPA, MONSANTO - TESTING FOR RESIDUES OF GLYPHOSATE HERBICIDE ON FOOD, GRAINS, ETC EMAIL CORR 1/1/14-7/5/16
2016-6835	08/16/2016 09/14/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	AMY VITERI WPLG-TV	BLOOD TRANSMISSION, COLLECTION FROM DONORS REGARDING ZIKA; DEVELOPMENT OF VACCINE
2016-6836	08/16/2016 09/14/2016	FDA/OC/OES/DFOI/ FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	GREG MAGNUSON MAGNUSON, GREG	EAGLE CREEK MARATHON, IINDIANAPOLIS, IN - TOBACCO VIOLATIONS,WARNING LTRS, CIVIL MONEY PENALTIES,ETC
2016-6837	08/16/2016 09/14/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 7/18-22/16
2016-6838	08/16/2016 09/14/2016	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOI REQUESTS 7/18-22/16
2016-6839	08/16/2016 09/14/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 7/18-22/16
2016-6840	08/16/2016 09/14/2016	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 7/18-22/16
2016-6841	08/16/2016 09/14/2016	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 7/25-29/16
2016-6842	08/16/2016	FDA/OC/OES/DFOI/	DAVID MCFARLAND	CLOSED FOI REQUESTS 7/25-29/16

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	09/14/2016		FDA REVIEW/FDA WEBVIEW	
2016-6843	08/16/2016 09/14/2016	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 7/25-29/16
2016-6844	08/16/2016 09/14/2016	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 7/25-29/16
2016-6845	08/17/2016 09/15/2016	OC/ORO/ORM/ OC/ORO/ORM/	LESLIE RAMSEY FDA NEWS	PHARMACEUTICAL, BIOLOGIC, MEDICAL DVC FACILITIES, CLNCL FACILITIES - 483 7/1-31/16
2016-6846	08/17/2016 09/15/2016	FDA/OC/OES/DFOI/	HIROHATA, JAMES	AER REQUEST CONTACT INFO
2016-6847	08/17/2016 09/15/2016	FDA/OMPT/CTP/OD/	MARK E GREENWOLD CAMPAIGN FOR TOBACCO-FREE KIDS	SAME CHARACTERISTICS SUBSTANTIAL EQUIV RPT 3/4/2015
2016-6848	08/17/2016 09/15/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TED KELLER EverPoint Asset Management	DUOPA 1/16 TO PRESENT; RYTARY 1/15 TO PRESENT; PRALUENT & REPATHA 1/10 TO PRESENT - AER
2016-6849	08/17/2016 09/15/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	TUSHAR MANUDHANE Anand Rathi Securities	ANKALESHWAR FACILITY OF WOCKHARDT - 483
2016-6850	08/17/2016 09/15/2016	OC/ORO/ OC/ORO/ FDA/OGROP/ORO/CE-FO/NWJ-DO/NWJ-CB/	Doe J	CMPLNT 146341
2016-6851	08/17/2016 09/15/2016	FDA/OGROP/ORO/SW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/	ELIZABETH A GILLESPIE, Esq. TENGE LAW FIRM	INDIVIDUAL RECS
2016-6852	08/17/2016 09/15/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID HOFFMEISTER WILSON SONSINI ET AL	CUBICIN SUPPLEMENT NDA 02-1572/S-52 APRVL LTR
2016-6853	08/17/2016 09/15/2016	FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	GARETH L. FARRELL DAILY HERALD	RESERS FINE FOODS - READY TO EAT SALAD 483 AFTER 2013 - 2015, CO RESP, CORR

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2016-6854	08/17/2016 09/15/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BENNETT RAWICKI GIBSON DUNN & CRUTCHER LLP	WINTAC LTD, NELAMANGALA, BANGALORE, INDIA - 483, WARNING LTR, ETC; APOTEX PHARMACHEM INDIA PRIVATE LTD, BANGALORE, INDIA 483, EIR
2016-6855	08/17/2016 09/15/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HERSCHEL J GADDY, Ph.D. PHARMACOSMOS INC & PHARMACOSMOS AS	PHARMACOSMOS AS, HOLBAEK, DENMARK - EIR 12/16-20/13 NON REDACTED
2016-6856	08/17/2016 09/15/2016	FDA/OMPT/CDRH/OCE/DID/	JOHN E. JESSEE JESSEE READ ET AL	INDIVIDUAL RECS
2016-6857	08/17/2016 09/15/2016	FDA/OC/OES/DFOI/	Doe J	EPIPEN - GENERIC, COUPON
2016-6858	08/17/2016 09/15/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	H. DAVID BLAIR BLAIR & STROUD ATTYS	6563028, 6630888, 6898817, ETC
2016-6859	08/17/2016 09/15/2016	FDA/OGROP/ORR/NE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORR/CE-FO/NWJ-DO/NWJ-CB/	LUKE CALLAHAN WAGSTAFF & CARTMELL LLP	MAQUET, WAYNE, NJ - INSP AFTER CONSENT DECREE 2/15
2016-6860	08/18/2016 09/16/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	G. Srinivas Zydus Pharmaceuticals USA Inc.	PROTAMINE SULFATE INJECTION REVIEW RECS
2016-6861	08/18/2016 09/16/2016	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	Rachel Johnson FOI Services, Inc.	RJ REYNOLDS, TOBACCOVILLE, NC, WINSTON-SALEM, NC - INSPECTION RECS
2016-6862	08/18/2016 09/16/2016	FDA/OC/OES/DFOI/	AAMIR QAMAR MASTERCONTROL INC	LIST OF REGISTERED COMPANIES 08/15/2016 - 08/31/2016
2016-6863	08/18/2016 09/16/2016	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	TOBACCO PRODUCT ADVERSE EVENTS
2016-6864	08/18/2016 09/16/2016	FDA/OFVM/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	OLD SCHOOL LAB/CODISIA - AERS
2016-6865	08/18/2016 09/16/2016	FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/	Amy L. Smith-Compos Taylor Anderson, LLP	COASTAL GREENS VEGETABLE COMPANY, LLC, OXNARD, CA - INSPECTION RECS, RECALLS, SAMPLES ETC

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				01/01/2015 - 08/15/2016
2016-6866	08/18/2016 09/16/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Carrie Underhill Akorn, Inc.	NDA 007085 MOST RECENT LABELING
2016-6867	08/18/2016 09/16/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Genevieve Stevens Nivagen Pharmaceuticals, Inc.	ANDA 062298 SBA
2016-6868	08/18/2016 09/16/2016	FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/	Melissa V. Malapit Malapit, Melissa V	ANTHONY HOU, INLAND RHEUMATOLOGY CLINICAL TRIALS INC, UPLAND, CA - EIR 06/01/2013 - 08/15/2016
2016-6869	08/18/2016 09/16/2016	FDA/OGROP/ORR/CE-FO/CIN-DO/CIN-CB/	Melissa Malapit Malapit, Melissa V	SANFORD WOLFE, STAT RESEARCH INC, DAYTON, OH - EIR 06/01/2013 - 08/15/2016
2016-6870	08/18/2016 09/16/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Alex Johnson Inter - Med	ANDA 040811
2016-6871	08/18/2016 09/16/2016	FDA/OMPT/CDRH/OCE/DID/	Alex Johnson Inter - Med	K141077
2016-6872	08/18/2016 09/16/2016	FDA/OMPT/CDRH/OCE/DID/	Alex Johnson Inter - Med	K072222
2016-6873	08/18/2016 09/16/2016	FDA/OMPT/CDRH/OCE/DID/	Alex Johnson Inter - Med	K073088
2016-6874	08/18/2016 09/16/2016	FDA/OMPT/CDRH/OCE/DID/	Alex Johnson Inter - Med	K071037
2016-6875	08/18/2016 09/16/2016	FDA/OMPT/CDRH/OCE/DID/	Alex Johnson Inter - Med	K121993
2016-6876	08/18/2016 09/16/2016	FDA/OMPT/CDRH/OCE/DID/	Alex Johnson Inter - Med	K123329
2016-6877	08/18/2016 09/16/2016	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink	2016-5653
2016-6878	08/18/2016 09/16/2016	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink	2015-8079

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2016-6879	08/18/2016 09/16/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lori Combs Lori Combs	GADOLINIUM - APPROVAL FOR USE AS A CONTRAST AGENT FOR MRI
2016-6880	08/18/2016 09/16/2016	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Dominick DiPaolo Dominick DiPaolo	TYRX INC, MONMOUTH JUNCTION, NJ - 483 2/12/16
2016-6881	08/18/2016 09/16/2016	FDA/OMPT/CDRH/OCE/DID/	Nathan Hunt Immunarray, Inc	PRESUBMISSION MEETING RECS R BANYAN BIOMARKERS
2016-6882	08/19/2016 09/19/2016	FDA/OC/OES/DFOI/	JEFFREY S ABRAHAM ABRAHAM FRUCHTER & TWERSKY LLP	2016-3012
2016-6883	08/19/2016 09/19/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BETH CLAY HAWK INTERNATIONAL LLC	MARIJUANA, INDUSTRIAL HEMP, CBD OIL, ETC - SCHEDULING, REGISTERING TO GROW
2016-6884	08/19/2016 09/19/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SUSAN THORNTON STRONGBRIDGE BIOPHARMA	SOMATULINE DEPOT (LANREOTIDE ACETATE) NDA 22-074 - SBA
2016-6885	08/19/2016 09/19/2016	FDA/OFVM/CFSAN/OCD/EOS/	RICHMAN P CASSETTA BRYAN CAVE LLP	JUST FOR MEN HAIR PRODUCTS - CAERS 79839, 79988, 98022, ETC
2016-6886	08/19/2016 09/19/2016	FDA/OC/OES/DFOI/	DR RANDALL SINGER DVM MPVM PHD UNIV OF MINNESOTA COLLEGE OF VETERINARY MEDICINE	PFGE PATTERN JF6X01.0045, JF6X01.0258, JF6X01.0326, ETC
2016-6887	08/19/2016 09/19/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PETER KLAUSNER BARON & BUDD PC	BRISTOL-MYERS SQUIBB, SANOFI-AVENTIS US LLC, SANOFI-SYNTHELABO INC - PLAVIX (CLOPIDOGREL, CLOPIDOGREL BISULPHATE) LAB DATA, MEMOS, RPTS, ETC
2016-6888	08/19/2016 09/19/2016	OC/ORA/ OC/ORA/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	MICHAEL M ROSENSAFT KATTEN MUCHIN ROSENMAN LLP	FDA LAB, PHARMALOGICAL INC, MEDICAL DEVICE KING, ETC - Cmplnts, Rpts
2016-6889	08/19/2016	FDA/OC/OES/DFOI/	HIRAM C SLOAN	AMERICAN MEDICAL SYSTEMS INC - INFLATABLE PENILE PROSTHESIS CURRENT FDA COMPLIANCE

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	09/19/2016		SLOAN, HIRAM C	REQUIREMENTS
2016-6890	08/19/2016 09/19/2016	FDA/OC/OES/DFOI/ OC/ORO/ORM/ OC/ORO/ORM/	DAMARYS DEL CATILLO GOYA DE PUERTO RICO INC	OFFICIAL ESTABLISHMENT INVENTORY (OEI) OF FIRMS IN PUERTO RICO
2016-6891	08/19/2016 09/19/2016	FDA/OGROP/ORO/CE-FO/MIN-DO/MIN-CB/	HIRAM SLOAN SLOAN, HIRAM C	AMERICAN MEDICAL SYSTEMS INC, MINNETONKA, MN - WARNING LTR 4/10/14 FOLLOW-UP AND COMPLIANCE, 483S, CORR
2016-6892	08/19/2016 09/19/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Doe J	INDIVIDUAL RECS
2016-6893	08/19/2016 09/19/2016	FDA/OC/OES/DFOI/	Kris Christian FDAZILLA	483, RESPONSE, EIR PREVIOUSLY RELEASED 07/07/2016 - 08/08/2016
2016-6894	08/19/2016 09/19/2016	FDA/OGROP/ORO/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORO/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORO/PA-FO/SEA-DO/SEA-CB/	Julianne Perry Julianne Perry	BERKELEY YFARMS, HAYWARD, CA; CLOVER STORNETTA, PETALUMA, CA ETC - 483 01/01/2016 - 08/16/2016 OR MOST RECENT
2016-6895	08/19/2016 09/19/2016	OC/ORO/ OC/ORO/	Robert Murphy St. Mary's Medical Center	RESPONSE LETTER FROM LEITERS PHARMACY 03/01/2016 - 08/16/2016
2016-6896	08/19/2016 09/19/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Erin Austin FITZPATRICK, CELLA, HARPER & SCINTO	ZHEJIANG HISUN PHARMACEUTICAL CO, LTD, CHINA - 483 01/01/2014 - 08/16/2016
2016-6897	08/19/2016 09/19/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jimena B Alvarez Advocate Lutheran General Hospital	LUPRON - AERS
2016-6898	08/19/2016 09/19/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jonathan Nolan REED TECHNOLOGY AND INFORMATION SERVICES INC	LIST OF REGISTRANTS AND DUNS NUMBERS THAT HAVE SUBMITTED ACTIVE DRUG ESTABLISHMENT REGISTRATIONS 10/01/2015 - 08/16/2016
2016-6899	08/19/2016 09/19/2016	FDA/OMPT/CDRH/OCE/DID/	Joseph Califano Hydromer, inc	K 813209 K810023
2016-6900	08/19/2016 09/19/2016	FDA/OMPT/CDRH/OCE/DID/	Jennifer Jackson Straumann USA, LLC	K152385

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2016-6901	08/19/2016 09/19/2016	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/ OC/ORA/ OC/ORA/	Tracy Vedder KOMO TV NEWS	UNIVERSITY OF WASHINGTON MEDICAL CENTER - INSPECTIONS RECS 05/02/2016 - 08/18/2016
2016-6902	08/19/2016 09/19/2016	FDA/OMPT/CDRH/OCE/DID/	Christopher T. Donner SI-TECHNOLOGY, LLC	K161210
2016-6903	08/19/2016 09/19/2016	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	COMPARATIVE BIOSCIENCES, SUNNYVALE, CA - EIR, 483, RESPONSE 12/9/16
2016-6904	08/19/2016 09/19/2016	FDA/OMPT/CDRH/OCE/DID/	Jinjoo OH J&Partners Law Firm	MEDICAL DEVICE REGISTRATION 3006978611 CERTIFIED
2016-6905	08/19/2016 09/19/2016	FDA/OFVM/CFSAN/OCD/EOS/	Sylvester Mosley The Coca-Cola Company	FCN 000329 000904
2016-6906	08/19/2016 09/19/2016	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Kathy Trier CORIN USA	CORIN LTD, TAMPA, FL - EIR 03/05/2015 - 03/05/2015
2016-6907	08/19/2016 09/19/2016	OC/ORA/ OC/ORA/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORASW-FO/SWID/SWID-CB/	Pablo Valencia Camel Services USA Customs Broker	WJL-0049553-0 ENTRY LAB RESULTS
2016-6908	08/22/2016 09/20/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Melissa Malapit Celgene Corporation	EUGENE SHMELEV CITY HOSPITAL, MOSCOW, RUSSIA - 483 03/01/2008 - 08/16/2016
2016-6909	08/22/2016 09/20/2016	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Melissa Malapit Celgene Corporation	JEFFREY GOLDEN UNIVERSITY OF CALIFORNIA SAN FRANCISCO - 483 02/01/2011 - 08/16/2016
2016-6910	08/22/2016 09/20/2016	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	TANDEM LABS A LABCORP COMPANY, WEST TRENTON, NJ - EIR, 483, RESPONSE 2/10/15
2016-6911	08/22/2016 09/20/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lena Shalem Rutgers New Jersey Medical School	CHOLECALCIFEROL VITAMIN D3 50,000 FIRST AVAILABLE OTC
2016-6912	08/22/2016	FDA/OGROP/ORACE-FO/CHI-	Walter Chalkley	ABBVIE, ABBOTT PARK, IL - EIR, 483, RESPONSE 12/9/14

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	09/20/2016	DO/CHI-CB/	THOMSON REUTERS (SCIENTIFIC) SAS	
2016-6913	08/22/2016 09/20/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ken Tong Ken Tong	LYNPARZA - ISR
2016-6914	08/22/2016 09/20/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ayesha Adil The Weinberg Group	ANDA 091161
2016-6915	08/22/2016 09/20/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Celia White Athenex, Inc	NDA 018024
2016-6916	08/22/2016 09/20/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	Amy Taylor Copyright Clearance Center	LYCASIN - 24 MONTHS SAFETY STUDY ETC
2016-6917	08/22/2016 09/20/2016	OC/ORA/ OC/ORA/	Beth Greenfield YAHOO FINANCE	ORIBE CLEANSING CONDITIONER, PUREOLOGY CLEANSING CONDITIONER, L'OREAL CLEANSING CONDITIONER COMPLAINTS 01/01/2014 - 08/16/2016
2016-6918	08/22/2016 09/20/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Gina Mastro Simone Gina Mastro Simone	ROTATEQ, ROTARIX, MENCHIBRIX PACKAGE INSERTS
2016-6919	08/22/2016 09/20/2016	OC/ORA/ORM/ OC/ORA/ORM/	Mary Hancock Registrar Corp	FOREIGN FOOD FACILITIES THAT RECEIVED 483 10/1/2011 - 06/30/2016
2016-6920	08/22/2016 09/20/2016	FDA/OGROP/ORR/SE-FO/FLA- DO/FLA-CB/	Walter Chalkley THOMSON REUTERS (SCIENTIFIC) SAS	NOVEN PHARMACEUTICALS, INC, MIAMI, FL - EIR, 483, RESPONSE 06/22/2015 - 07/10/2015
2016-6921	08/22/2016 09/20/2016	FDA/OMPT/CDRH/OCE/DID/	Eric Fredrickson HARMAN LAW LLC	K134032; K132028; K122528
2016-6922	08/22/2016 09/20/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Monica Dhakar Yale New Haven Hospital	FELBAMATE, FELBATOL - AERS

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-6923	08/22/2016 09/20/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Felipe A. Priast Felipe A. Priast	DRUG SAMPLE DISTRIBUTION RECS GENENTECH INC 01/01/2014 - 12/31/2015
2016-6924	08/22/2016 09/20/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michael Johnson Michael Johnson, MD	CDER Application Number: 200534 Orig1s000 SUMMARY REVIEW
2016-6925	08/22/2016 09/20/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 200293 TENTATIVE APPROVAL LETTER
2016-6926	08/22/2016 09/20/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ali Afnan Step Change Pharma Inc	UNIMARK REMEDIES LTD, INDIA - 483 05/16/2015 - 05/23/2015
2016-6927	08/22/2016 09/20/2016	FDA/OO/OFBA/OAGS/	Alison Cooke Harris Corporation	HHSF22301001T FDA-SOL-1118371 TASK ORDER, MODIFICATIONS
2016-6928	08/22/2016 09/20/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ali Afnan Step Change Pharma Inc	WARNING LETTER UNIMARK REMEDIES, INDIA 10/01/2015 - 08/01/2016
2016-6929	08/22/2016 09/20/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KyungBok Son Seoul National University College of Medicine	PATENT DATA
2016-6930	08/22/2016 09/20/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Xinsheng Xie Frontage Laboratories, Inc.	CRESTOR (ROSUVASTATIN CALCIUM) SBA
2016-6931	08/22/2016 09/20/2016	FDA/OMPT/CDRH/OCE/DID/	Avital Levertov - Elcam Medical ELCAM MEDICAL	K122837

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2016-6932	08/22/2016 09/20/2016	FDA/OMPT/CDRH/OCE/DID/	Avital Levertov - Elcam Medical ELCAM MEDICAL	K013362
2016-6933	08/22/2016 09/20/2016	FDA/OMPT/CDRH/OCE/DID/	K993553, K082205 Precision Biologic Inc.	K993553 K082205
2016-6934	08/22/2016 09/20/2016	OC/ORO/ORM/ OC/ORO/ORM/	Merle Zimmermann AMERICAN HERBAL PRODUCTS ASSOCIATION	LISTING OF GMP INSPECTIONS UNDER 21 CFR PART 111 01/01/2016 - 07/31/2016
2016-6935	08/22/2016 09/20/2016	FDA/OMPT/CDRH/OCE/DID/	GRAEME MORRIS ULTRATONE SCIENTIFIC INSTRUMENTS LTD	ULTRATONE SCIENTIFIC INSTRUMENTS LTD UNITED KINGDOM - EIR 01/01/2016 - 08/19/2016
2016-6936	08/22/2016 09/20/2016	FDA/OMPT/CDRH/OCE/DID/	Garrett Mosley UCLA	K946276
2016-6937	08/22/2016 09/20/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	BLA 125522/S1
2016-6938	08/22/2016 09/20/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Andy Washkowitz venBio LLC	PIMAVANSERIN - AERS
2016-6939	08/22/2016 09/20/2016	FDA/OC/OES/DFOI/	Peter Manilla Manilla LLC	K021356
2016-6940	08/22/2016 09/20/2016	FDA/OMPT/CDRH/OCE/DID/	Peter Manilla Manilla LLC	K131198
2016-6941	08/22/2016 09/20/2016	FDA/OMPT/CTP/OD/	Ines Chapela Ines Chapela	AMERICAN SPIRIT CIGARETTES - SUBSTANTIAL EQUIVALENCE, COMPOSITION INFORMATION 06/30/1982 - 08/19/2016
2016-6942	08/22/2016 09/20/2016	FDA/OFVM/CFSAN/OCD/EOS/	Audrey McAvoy THE ASSOCIATED PRESS	HEPATITIS A TEST RECORDS FOR SCALLOPS IMPORTED FROM PHILIPPINES AND DISTRIBUTED BY SEA PORT PRODUCTS CORP 08/01/2016 - 08/20/2016
2016-6943	08/22/2016 09/20/2016	FDA/OMPT/CDRH/OCE/DID/	Lyle Middendorf LI-COR Biosciences	DEN100016 K093579
2016-6944	08/22/2016 09/20/2016	FDA/OC/OEXA/OMA/	John Manthei Manthei, John R	RECS RE FDA TWEETS ABOUT WEN PRODUCTS
2016-6945	08/22/2016	FDA/OMPT/CDER/ORP/DIDP/	Megan Towey	PMA COVER LETTERS, PAYMENT STUBS 08/01/2011 -

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	09/20/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCE/DID/	CBS NEWS	08/19/2016
2016-6946	08/22/2016 09/20/2016	FDA/OMPT/CDRH/OCE/DID/	Dhwani Thakkar Thakkar, Dhwani	K020481
2016-6947	08/22/2016 09/20/2016	FDA/OMPT/CDRH/OCE/DID/	Ken Tong Ken Tong	LYNPARZA AERS
2016-6948	08/22/2016 09/20/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Donna Bitzelberger VENABLE LLP	NDA 21-168/S-007 8/14/2003 CERTIFIED
2016-6949	08/22/2016 09/20/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Amanda Zirelli AMGEN, INC.	FAERS 12573797
2016-6950	08/22/2016 09/20/2016	FDA/OC/OES/DFOI/	Robert Ciolek Catalent Pharma Solutions, LLC	CMC BIOLOGICS - 483 08/01/2016 - 08/31/2016
2016-6951	08/22/2016 09/20/2016	FDA/OMPT/CDRH/OCE/DID/	David Antoon David Antoon (Speaker/Volunteer for Health Watch USA and Consumer Union Safe Patient Project)	RECS RES DATE OF SUBMISSION OF IDE BY INTUITIVE SURGICAL INC TO FDA RE DA VINCI ROBOT; DATES OF IDE SUBMISSTED BY GLICKMAN UROLOGICAL & KIDNEY INSTITUTE RE DA VINCI ROBOT
2016-6952	08/22/2016 09/20/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jaya Ayyagari Dr. Reddy's Laboratories Inc.	ANDA 207193 TENTATIVE APPROVAL LETTER
2016-6953	08/22/2016 09/20/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dona Diec University of Kansas School of Pharmacy	ANNUAL DRUG SHORTAGE REPORT SUBMITTED BY CDER 01/01/2015 - 12/31/2015
2016-6954	08/22/2016	FDA/OC/OES/DFOI/	Jaime Vassallo	2016-6350

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	09/20/2016		LexisNexis CourtLink	
2016-6955	08/22/2016 09/20/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K102511
2016-6956	08/22/2016 09/20/2016	FDA/OC/OES/DFOI/	Greg Elliott MALLINCKRODT PHARMACEUTICALS	HOSPIRA, ROCKY MOUNT, NC - 483, EIR 03/02/2013 - 08/18/2016
2016-6957	08/22/2016 09/20/2016	FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/	Steve Rogers Zoetis Inc.	STILLMEADOW INC, SUGAR LAND, TX - 482, 483, EIR ETC 01/01/2013 - 08/18/2016
2016-6958	08/22/2016 09/20/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Denise Hein Denise Hein	ROTASHIELD, ROTATEQ, ROTARIX VACCINES - CLINICAL SAFETY AND EFFICACY TRIALS 08/01/1980 - 08/20/2016
2016-6959	08/22/2016 09/20/2016	FDA/OFVM/CFSAN/OCD/EOS/	William W. Blair William W. Blair	IMERYS AMERIA INC, LUZENAC AMERICA INC, RIO TINTO ETC - CORR RE TALCUM POWDER, JOHNSON'S BABY POWDER ETC 01/01/1970 - 08/18/2016
2016-6960	08/22/2016 09/20/2016	OC/ORAS/ OC/ORAS/ OC/ORAS/ORM/ OC/ORAS/ORM/	Mary Hancock Registrar Corp	SPREADSHEET OF FIRMS THAT RECEIVED WARNING LETTERS 10/01/2011 - 06/30/2016
2016-6961	08/22/2016 09/20/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Melanie Burkhold Melanie Burkhold	SAVAYSA - AERS
2016-6962	08/22/2016 09/20/2016	FDA/OMPT/CDRH/OCE/DID/	Israel Deutsch Hospitech Respiration Ltd. Israel Deutsch	TRU CUFF INFLATION DEVICE - APPROVAL RECS
2016-6963	08/22/2016 09/20/2016	FDA/OMPT/CDRH/OCE/DID/ OC/ORAS/ OC/ORAS/ FDA/OGROP/ORASORO/DIOP/	Janice Harmon Kerr, Russell and Weber, PLC	ABBOTT LABORATORIES FREESTYLE DIABETIC TEST STRIPS - RECS RE IMPORTATION OF DIABETIC TEST STRIPS TO THE US AND/OR SALE OF INTERNATIONAL VERSION OF TEST STRIPS IN THE US 01/01/2011 - 08/18/2016
2016-6964	08/22/2016 09/20/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rev. Bryan A. Krumm, CNP Rev. Bryan A. Krumm, CNP	REVIEW CONDUCTED BY DOUGLAS THROCKMORTON AND CDER FOR THE DEA RE RESCHEDULING PETITION FOR CANNIBIS 01/01/2010 - 07/19/2016
2016-6965	08/22/2016 09/20/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Greg Gambill Greg Gambill	CLINIMMUNE LABS, UNIVERSITY OF COLORADO CORD BLOOD BANK BLA TO EXTEND DATING PERIOD OF HPC CORD BLOOD PRODUCT ETC

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2016-6966	08/22/2016 09/20/2016	FDA/OC/OES/DFOI/	KINNEY 835603, JAMES ALLEN	SECTION 348 FOOD ADDITIVES; SECTION 331 TO 362 DVC HANDLING; DRUG LBLG
2016-6967	08/22/2016 09/20/2016	FDA/OMPT/CDRH/OCE/DID/	SUTTERER, KAREN	CMPLNT 1600104
2016-6968	08/22/2016 09/20/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OFVM/CFSAN/OCD/EOS/	SANCHEZ C53210, JOSE	RISPERDAL - AER
2016-6969	08/22/2016 09/20/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	NORTHROP V13733, DAVID J	LEUPROLIDE ACETATE; HISTRELIN - CLNCL TRIAL STUDIES
2016-6970	08/22/2016 09/20/2016	FDA/OMPT/CDRH/OCE/DID/	DANIEL O'CONNELL PROMETHEUS MEDICAL CORPORATION	FIBERTECH GMBH/ LEONI FIBER OPTICS INC, - 510K
2016-6971	08/22/2016 09/20/2016	FDA/OMPT/CTP/OD/	KATHY CIAMBRONE ITG BRANDS	MAVERICK - MENTHOL SILVER BOX 100S RVWS
2016-6972	08/23/2016 09/21/2016	FDA/OMPT/CDRH/OCE/DID/	Laura Green Laura Green, LLC	K120546
2016-6973	08/23/2016 09/21/2016	FDA/OMPT/CDRH/OCE/DID/	Laura Green Laura Green, LLC	K153444
2016-6974	08/23/2016 09/21/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 207621
2016-6975	08/23/2016 09/21/2016	FDA/OMPT/CDRH/OCE/DID/	Marilynn Whitney COVINGTON & BURLING LLP	K161507
2016-6976	08/23/2016 09/21/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Suzanne Jensen Kleinfeld Kaplan & Becker LLP	NDA 207621 SBA
2016-6977	08/23/2016	FDA/OMPT/CDRH/OCE/DID/	Somi Ekwealor	K083707

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	09/21/2016		STRYKER ENDOSCOPY	
2016-6978	08/23/2016 09/21/2016	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2016-4685
2016-6979	08/23/2016 09/21/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Avni Balwani IMPAX LABORATORIES INC	GLYBURIDE, METFORMIN HYDROCHLORIDE ANNUAL REPORTS
2016-6980	08/23/2016 09/21/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Frank Weippert Frank Weippert	K062368 K041847
2016-6981	08/23/2016 09/21/2016	FDA/OMPT/CDRH/OCE/DID/	laura green Laura Green, LLC	K151372
2016-6982	08/23/2016 09/21/2016	FDA/OMPT/OSMP/OOPD/	Brad Sippy Tremeau Pharmaceuticals, Inc.	FEIBA ORPHAN DESIGNATION RECS, CORR BETWEEN BAXALTA AND OPD
2016-6983	08/23/2016 09/21/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Alessandro Protti Fondazione IRCCS Ca' Granda, Ospedale Maggiore Policlinico	LINEZOLID - DATA RE LACTIC ACIDOSIS
2016-6984	08/23/2016 09/21/2016	FDA/OGROP/ORAC/CE-FO/CHI-DO/CHI-CB/	Nikhil Marathe Nikhil Marathe	MORTON GROVE PHARMACEUTICALS, INC, MORTON GROVE, IL - 483 01/01/2016 - 08/21/2016
2016-6985	08/23/2016 09/21/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Andre von Muller von Muller, Andre	BK030036 BK090020
2016-6986	08/23/2016 09/21/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Cathy Dreifort Dreifort, Cathy	HARVONI - AERS
2016-6987	08/23/2016 09/21/2016	FDA/OC/OES/DFOI/	Sherie Ham Wilkes & McHugh, P.A.	PRIDE MOBILITY MODEL POWERED WHEELCHAIR MAUDE REPORTS 01/01/2004 - 08/22/2016
2016-6988	08/23/2016 09/21/2016	FDA/OC/OES/DFOI/	Gina Ecolino BEVERIDGE & DIAMOND	CFSAN FOIA REQUESTS 07/20/2016 - 08/22/2016
2016-6989	08/23/2016	FDA/OC/OES/DFOI/	Erick Turner, M.D.	FOIA LOGS 07/01/2012 - 06/30/2016

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	09/21/2016		Oregon Health & Science University	
2016-6990	08/23/2016 09/21/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Acuna Adaptive RC LLC	2006-12480
2016-6991	08/24/2016 09/22/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Scott Goldman Hyman, Phelps & McNamara P.C.	IBRANCE NDA 207103 RECS RE 3 YEAR EXCLUSIVITY
2016-6992	08/24/2016 09/22/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lauren Vaks ETHYPHARM USA CORP	ANDA 202103
2016-6993	08/24/2016 09/22/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K082750
2016-6994	08/24/2016 09/22/2016	FDA/OMPT/CDRH/OCE/DID/	Stephanie Wright Kinamed, Inc.	K092178 K120772 K091799
2016-6995	08/24/2016 09/22/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Matt Binder Matt Binder	INFLIXIMAB ZARXIO APPROVAL RECS
2016-6996	08/24/2016 09/22/2016	FDA/OMPT/CDRH/OCE/DID/	Andre von Muller Biowy - Andre von Muller	K040262 K080399
2016-6997	08/24/2016 09/22/2016	FDA/OMPT/CDRH/OCE/DID/	Dr. Najib Babul California Institute of Advanced Management	NDA N20357
2016-6998	08/24/2016 09/22/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ZHENG ZHAO Center for Pharmaceutical Information and Engineering Research	SUNSHINE LAKE PHARMA CO LTD, CHINA; QILA TIANHE PHARMACEUTICAL CO, CHINA; ETC - 483 01/01/2015 - 07/01/2016
2016-6999	08/24/2016 09/22/2016	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	Rachel Johnson FOI Services, Inc.	HOLLY SPRAKER-PERLMAN, PRIMARY CHILDRENS HOSPITAL SALT LAKE CITY, UT - INSPECTION RECS
2016-7000	08/24/2016 09/22/2016	FDA/OFVM/CFSAN/OCD/EOS/	Daryoush Toofanian Daryoush Toofanian	IDEAL PROTEIN - APPROVAL RECS 01/01/2005 - 01/01/2014
2016-7001	08/24/2016	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Melissa Mack	ERIC LOFQUIST, HARDY ANIMAL NUTRITION - RESPONSE, FOLLOW UP CORR - 02/01/2016 - 06/30/2016

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	09/22/2016		Melissa Mack	
2016-7002	08/24/2016 09/22/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Robert Skully OhioHealth	ENZALUTAMIDE - AERS
2016-7003	08/24/2016 09/22/2016	FDA/OMPT/CDRH/OCE/DID/	Andre von Muller Biowy - Andre von Muller	K083873 K110914
2016-7004	08/24/2016 09/22/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Zachary Mietus The Weinberg Group	NDA 019018 SBA
2016-7005	08/24/2016 09/22/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Scott Goldman Hyman, Phelps & McNamara P.C.	FASLODEX NDA 021344 THREE YEAR EXCLUSIVITY RECS
2016-7006	08/24/2016 09/22/2016	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Rebecca Smith Rebecca Smith	KALMBACH FEES INC, UPPER SANDUSKY, OH - 483 01/01/2006 - 01/01/2016
2016-7007	08/24/2016 09/22/2016	FDA/OC/OES/DFOI/	Leona Grage Leona Grage	AQUABOUNTY APPROVAL RECS
2016-7008	08/24/2016 09/22/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Becky Hartman Teva Pharmaceuticals	GLATOPA - AERS
2016-7009	08/25/2016 09/23/2016	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Rachel Johnson FOI Services, Inc.	ITG BRANDS, GREENSBORO, NC, DANVILLE, VA - INSPECTION RECS
2016-7010	08/25/2016 09/23/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Olena Izhak University of Helsinki (FINLAND)	8 ANDA APPROVAL LETTERS
2016-7011	08/25/2016 09/23/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Benjamin Newton United BioSource Corporation	NATPARA 11793088 11811063 11889651 11892691 11894827 12084622

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-7012	08/25/2016 09/23/2016	FDA/OMPT/CDRH/OCE/DID/	Sarah Forga Biomed Diagnostics	K896296
2016-7013	08/25/2016 09/23/2016	FDA/OFVM/CFSAN/OCD/EOS/	Christopher Bailey NATURAL PRODUCTS ASSOCIATION	Dietary supplement labels from Certificates of Free Sale (COFS) electronic submission applications 01/01/2012 - 08/24/2016
2016-7014	08/25/2016 09/23/2016	FDA/OMPT/CDRH/OCE/DID/	Trang Adams AMERICAN ORTHODONTICS	K123118
2016-7015	08/25/2016 09/23/2016	FDA/OMPT/CDRH/OCE/DID/	Trang Adams AMERICAN ORTHODONTICS	K152086
2016-7016	08/25/2016 09/23/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michele Sinoway LACHMAN CONSULTANT SERVICES, INC.	NDA 019329, SODIUM CHLORIDE 23.4% IN PLASTIC CONTAINER LABEL, INSERT
2016-7017	08/25/2016 09/23/2016	FDA/OMPT/CDRH/OCE/DID/	Hans Beinke Siemens Medical Solution USA, Inc.	153331
2016-7018	08/25/2016 09/23/2016	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Pat Hillenmeyer (Ms.) AbbVie, Inc.	RICHARD R FURMAN, MD, NEW YORK, NY - EIR 07/01/2016 - 08/24/2016
2016-7019	08/25/2016 09/23/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dustin Block IPD Analytics, LLC	ANDA 205814
2016-7020	08/25/2016 09/23/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Clark Sullivan Sullivan IP Solutions	HYDROXOCOBALAMIN - GUIDELINES
2016-7021	08/25/2016 09/23/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Darlene O'Banion Revance Therapeutics	Botox BLA 103000, Supplement 5260 Supplement 5252 Supplement 5282 ETC
2016-7022	08/25/2016 09/23/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shane Gassman BIMEDA INC	ZHEJIANG JIUZHOU PHARMACEUTICAL CO LTD - EIR MOST RECENT 01/01/2016 - 08/24/2016

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		FDA/OMPT/CDER/GRP/DIDP/		
2016-7023	08/25/2016 09/23/2016	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	Sharene Badiola Asymmetry Capital Management, LP	AKORN PHARMACEUTICALS, DECATUR, IL - 483, EIR, CORR 03/01/2016 - 08/24/2016
2016-7024	08/25/2016 09/23/2016	FDA/OC/OES/DFOI/	AAMIR QAMAR MASTERCONTROL INC	REGISTRATION INFORMATION 08/15/2016 - 08/31/2016
2016-7025	08/25/2016 09/23/2016	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Dorian DiBartolomeo WBNS - TV	CIN-16-492668-20 FOLLOW UP RECS
2016-7026	08/25/2016 09/23/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	L Bell CBI	S180 BLA 125031
2016-7027	08/25/2016 09/23/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	BLA 125160/S213
2016-7028	08/25/2016 09/23/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Darlene O'Banion Revance Therapeutics	Botox BLA 103000, Supplement 5252 Supplement 5260 Supplement 5282 etc
2016-7029	08/25/2016 09/23/2016	FDA/OMPT/CDRH/OCE/DID/	McKenzie Cato Hyman, Phelps & McNamara, P.C.	K160644
2016-7030	08/25/2016 09/23/2016	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Pat Hillenmeyer (Ms.) AbbVie, Inc.	LYDIE HAZAN, MD, AXIS CLINICAL TRIALS, LOS ANGELES, CA - EIR 08/15/2016 - 08/24/2016
2016-7031	08/25/2016 09/23/2016	FDA/OMPT/CDRH/OCE/DID/	Gary Johnston Gary Johnston	K142488
2016-7032	08/25/2016 09/23/2016	FDA/OC/OEXA/OMA/	Kathleen M. Roberts North American Metal Packaging Alliance, Inc.	FDA RESPONSE TO CNN FOR A STATEMENT IN RESPONSE TO ARTICLE "CANNED FOODS LINKED TO BPA RISK IN NEW STUDY"
2016-7033	08/25/2016 09/23/2016	FDA/OC/OES/DFOI/	xiao,he xiao,he	FDA FINES 01/27/1996 - 08/01/2006
2016-7034	08/25/2016 09/23/2016	FDA/OMPT/CDRH/OCE/DID/	Jason Stauffer PRIMUS PHARMACEUTICALS INC	K072306 K062653 K061331 ETC

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2016-7035	08/25/2016 09/23/2016	FDA/OMPT/OSMP/OOPD/	Brad Sippy Tremeau Pharmaceuticals, Inc.	DESMOPRESSIN ACETATE ORPHAN DESIGNATION RECS 01/22/1991 - 03/07/1994
2016-7036	08/25/2016 09/23/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Kristy Smith Rawls McNelis & Mitchell	INDIVIDUAL RECS
2016-7037	08/25/2016 09/23/2016	FDA/OMPT/CDRH/OCE/DID/	Edward J Kaplan MD Edward J Kaplan MD	K915156
2016-7038	08/25/2016 09/23/2016	FDA/OGROP/ORPA-FO/LOS- DO/LOS-CB/	Jackie Boktor Trace-Ability Inc.	PETNET, CULVER CITY, CA.; CARDINAL HEALTH NUCLEAR PHARMACY, VAN NUYS, CA; UCLA AHMANSON BIOMEDICAL CYCLOTRON FACILITY - EIR, INSPECTOR NOTES 01/01/2012 - 07/31/2016
2016-7039	08/25/2016 09/23/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Christopher Carter MYLAN INC	HOSPIRA, INDIA - 483 2016
2016-7040	08/25/2016 09/23/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mona Gogia Cadila Pharmaceuticals Limited	CADILA PHARMACEUTICALS, LTD, INDIA - EIR REPORT FOR BE STUDY CENTER 06/30/2014 - 07/14/2014
2016-7041	08/25/2016 09/23/2016	OC/ORP/ORM/ OC/ORP/ORM/	Eyal Maor FDA AWARE	LIST OF INSPECTIONS 08/01/2016 - 08/31/2016
2016-7042	08/25/2016 09/23/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Melissa Malapit Celgene Corporation	KAZIMIERZ KULICZKOWSKI, POLAND - 483 09/01/2015 - 08/23/2016
2016-7043	08/25/2016 09/23/2016	FDA/OC/OES/DFOI/	Christopher Bailey NATURAL PRODUCTS ASSOCIATION	DIETARY SUPPLEMENT GMP INSPECTIONS 01/01/2008 - 08/24/2016
2016-7044	08/26/2016 09/26/2016	FDA/OGROP/ORP/CE-FO/BLT- DO/BLT-CB/	Rachel Johnson FOI Services, Inc.	TOBACCO INSPECTION RECS 4/1/16 TO PRESENT

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2016-7045	08/26/2016 09/26/2016	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Anne Garstka TissueGene, Inc	LONZA BIOLOGICS, SINGAPORE - EIR, 483, RESPONSE 08/01/2002 - 08/25/2016
2016-7046	08/26/2016 09/26/2016	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Walter Chalkley THOMSON REUTERS	FRONTIDA BIOPHARM, PHILADELPHIA, PA - 483, EIR, RESPONSE 06/15/2015 - 07/17/2015
2016-7047	08/26/2016 09/26/2016	FDA/OFVM/CFSAN/OCD/EOS/	Marc C. Sanchez, Esq. Contract In-House Counsel and Conls. LLC (FDA Atty)	AHLSTROM TEABAG PAPER, NOTIFICATION FOR A FOOD CONTACT SUBSTANCE FORMULA NOTIFICATION NON HEAT TEA BAG PAPER; GLATFELTER TEA BAG PAPER NON HEAT SEALED TEA BAG PAPER, HEAT SEALED TEA BAG PAPER
2016-7048	08/26/2016 09/26/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kathryn Roach Duke Clinical Research Institute, Duke University	JNANA SANJEEVINI MEDICAL CENTER, INDIA - 483 04/08/2016 - 07/01/2016
2016-7049	08/26/2016 09/26/2016	FDA/OMPT/CDRH/OCE/DID/	Cindy Walters BECTON, DICKINSON AND COMPANY	SAFETY GLIDE SYRINGE CATALOG NUMBER 305932, LOT NUMBER 6110553 NEEDLE FAILURE REPORT
2016-7050	08/26/2016 09/26/2016	FDA/OFVM/CFSAN/OCD/EOS/	Michael Beuselinck Michael Beuselinck	NATURE'S ONE INC - COMMUNICATIONS RE WARNING LETTER 09/26/2012 - 02/03/2016
2016-7051	08/26/2016 09/26/2016	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	JOE WARNHOFF PERFORMANCE PRODUCTS, INC.	O'NEAL SCIENTIFIC, ST LOUIS, MO - 483 05/18/2016 - 05/19/2016
2016-7052	08/26/2016 09/26/2016	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	Yigal Nochomovitz Citi	PORTOLA PHARMACEUTICAL, BOTHELL, WA - 483 01/01/2016 - 08/25/2016
2016-7053	08/26/2016 09/26/2016	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	JOE WARNHOFF PERFORMANCE PRODUCTS, INC.	PERFORMANCE PRODUCTS, ST LOUIS, MO - EIR 02/09/2016 - 02/11/2016
2016-7054	08/26/2016 09/26/2016	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kathryn Roach Duke Clinical Research Institute, Duke University	DR A SHARDA ENDOCRINOLOGY DIABETES CENTER, BANGALORE, INDIA - 483 04/08/2016 - 07/01/2016

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2016-7055	08/26/2016 09/26/2016	FDA/OC/OES/DFOI/	Jared S. Hoipkins BLOOMBERG NEWS	ANIMAL DRUGS ADVERSE EVENTS
2016-7056	08/26/2016 09/26/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ted Keller EverPoint Asset Management	DUOPA DETAILED ADVERSE EVENT REPORT 01/01/2015 - 08/25/2016
2016-7057	08/26/2016 09/26/2016	FDA/OMPT/CDRH/OCE/DID/	Amina Abdal MicroAire Surgical Instruments, LLC	K080133
2016-7058	08/26/2016 09/26/2016	FDA/OGROP/ORR/NE-FO/NYK-DO/NYK-DCB/	Walter Chalkley THOMSON REUTERS	AMNEAL PHARMACEUTICALS, BROOKHAVEN, NY - EIR, 483, RESPONSE 5/16/14
2016-7059	08/26/2016 09/26/2016	FDA/OGROP/ORR/PA-FO/SAN-DO/SAN-CB/	Walter Chalkley THOMSON REUTERS	CARDINAL HEALTH 414 LLC, COLTON, CA - EIR, 483, RESPONSE 5/1/14
2016-7060	08/26/2016 09/26/2016	FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/	Walter Chalkley THOMSON REUTERS	CSL PLASMA, SPRINGFIELD, MO - EIR, 483, RESPONSE 1/31/14
2016-7061	08/26/2016 09/26/2016	FDA/OMPT/CDRH/OCE/DID/	Kurt McCauley Mesalabs	K151482 DATA, METHODS TO SUPPORT 30 MINUTE READOUT TIME CLAIM
2016-7062	08/26/2016 09/26/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Benjamin Newton United BioSource Corporation	GLATOPA - REPORTS 11325326 11434280 11445823 ETC
2016-7063	08/26/2016 09/26/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	David Tukey EverPoint Asset Management	DARZALEX AERS
2016-7064	08/26/2016 09/26/2016	OC/CVM/OCD/	Gina Ecolino BEVERIDGE & DIAMOND	OXITEC LTD - COMMUNICATIONS BETWEEN FDA AND EPA
2016-7065	08/26/2016 09/26/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jennifer Miller Eli Lilly and Company	NDA 021344 S 26 SBA
2016-7066	08/26/2016 09/26/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K111319
2016-7067	08/26/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson	K031889

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	09/26/2016		FOI Services, Inc.	
2016-7068	08/26/2016 09/26/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K120061
2016-7069	08/26/2016 09/26/2016	FDA/OMPT/CDRH/OCE/DID/	Rachel Johnson FOI Services, Inc.	K020435
2016-7070	08/26/2016 09/26/2016	FDA/OMPT/CDRH/OCE/DID/	Filter sampler premarket approval K771985 Porex Corporation	K771985
2016-7071	08/26/2016 09/26/2016	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCE/DID/	ANNE M HULL HUTTON & HUTTON LAW FIRM, L.L.C.	INDIVIDUAL RECS; TAMPAX TAMPONS - WARNINGS, LBLG, MDRS, ETC 2010 TO 2016
2016-7072	08/26/2016 09/26/2016	FDA/OC/OES/DFOI/	MICHAEL CHRISTOPHER NEGILA NEGILA, MICHAELCHRISTOPHER	FDA DECISION THAT CANNABIS IS OF NO MEDICAL VALUE - BIBLIOGRAPHY, RESEARCH SOURCES, RECS, ETC 1/69 TO PRESENT
2016-7073	08/26/2016 09/26/2016	FDA/OC/OES/DFOI/	ROSS TOWNSEND PHARM D TOWNSEND, ROSS	PALLADIA (TOCERANIB PHOSPHATE), METRONIDAZOLE - PANCREATITIS IN DOGS AND CATS
2016-7074	08/26/2016 09/26/2016	FDA/OO/OFBA/OAGS/	F BRENDEN COLLER COZEN & O'CONNOR	SCIENCE BASED AUTHENTICATION OF DIETARY SUPPLEMENTS PROJECT NUMBER U01FD004246 - GRANT APPLICATIONS, CORR, FINAL DRAFTS, ETC
2016-7075	08/26/2016 09/26/2016	OC/ORO/ OC/ORO/	Mark Turner Mark Turner	503B OUTSOURCING SEMI-ANNUAL REPORT RECS 06/01/2015 - 08/18/2016
2016-7076	08/26/2016 09/26/2016	FDA/OMPT/CTP/OD/	Ryan J. Potts RAI Services Company	FDA REVIEW OF LORILLARD NEWPORT SMOOTH GOLD MENTHOL BOX 100 SE REPORT 0004860 AND NEWPORT GOLD MENTHOL BOX SE 0004864
2016-7077	08/26/2016 09/26/2016	FDA/OFVM/CFSAN/OCD/EOS/	Mark Deming Polsinelli PC	CERAMIC TABLEWARE 44T384 NAME AND ADDRESS
2016-7078	08/26/2016 09/26/2016	FDA/OC/OCC/ FDA/OC/OES/DDM/ FDA/OMPT/CDRH/OCE/DID/	John Lomas DENTONS US LLP	PRODUCT CLASSIFICATION FOR INFUSION PUMP DEVICES - ADMINISTRATIVE RECS ETC
2016-7079	08/26/2016 09/26/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Vinay Patil Cote Orphan, LLC	DES NDA
2016-7080	08/26/2016 09/26/2016	FDA/OC/OES/DFOI/	REBECCA COBBS SLOANE AND WALSH	HI-TECH PHARMACEUTICALS INC - ACACIA RIGDULA, B- METHYLPHENETHYLAMINE (BMPEA) WARNING LTRS, CORR, CMLPNTS, ETC

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2016-7081	08/26/2016 09/26/2016	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	MICHAEL MANCINELLI CONWAY HOMER & CHIN- CAPLAN PC	INDIVIDUAL RECS
2016-7082	08/26/2016 09/26/2016	FDA/OC/OES/DFOI/	MATT NOVAK GAWKER MEDIA	LIST OF MOTION PICTURE FILMS AND VIDEOS HELD AT FDA
2016-7083	08/26/2016 09/26/2016	OC/ORO/ OC/ORO/	CANDESS L ZONA-MENDOLA ROBINS CLOUD LLP	INDIVIDUAL RECS - DOLE LISTERIA OUTBREAK 2015-2016
2016-7084	08/26/2016 09/26/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID HOFFMEISTER Wilson Sonsini Goodrich & Rosati, P.C.	APOTEX ANDA 201-536 - TENTATIVE APRVL LTR
2016-7085	08/26/2016 09/26/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DAVID HOFFMEISTER Wilson Sonsini Goodrich & Rosati, P.C.	CUBIST - NDA 21-572 FDA FORM 3452 FOR PATENT #9,138,456
2016-7086	08/26/2016 09/26/2016	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MICHAEL A CRONIN PHARM D SHIRE	ENTOCORT EC NDA 21-324.S012,S013 - CHEMISTRY RVW, NONCLNCL PHARMACOLOGY, TOXICOLOGY RVWS
2016-7087	08/26/2016 09/26/2016	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/ORO/PA-FO/LOS- DO/LOS-CB/	GINA MAGIERI KHON2 NEWS	KOHA ORIENTAL FOODS, HAWAII; TRUE WORKD FOOD, HAWAII; SEA PORT PRODUCTS CORP, ETC - EIRS, WARNINGS, EIRS, ETC 2014-2016; HAWAII HEPATITIS A OURBREAK 2016 INVESTIGATIONS