

# Query Result Report

Records: 240

Action Office: ALL

Received Via: BOTH

Control #:

Rec/Create Date: 11/11/2013

To 11/15/2013

Track: ALL

Due Date:

To

Signature:

Status Date:

To

Requester:

Requester Type:

Subject:

Status: ALL

Privacy:

Category: ALL

Special Interest: ALL

Entered By:

# Query Result Report

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Control #	Recd Date / Due Date	Requester	Action Offices	Subject	Status / Status Date
2013-8947	11/12/2013 12/11/2013	FOI Services, Inc.	FDA/OMPT/CDRH/OCER/DFOI/	K132297	Pending Action 11/12/2013
2013-8948	11/12/2013 12/11/2013	FOI Services, Inc.	FDA/OMPT/CDER/ORP/DIDP/	KYPROLIS - FAER	Closed 11/15/2013
2013-8949	11/12/2013 12/11/2013	The Karmel Law Firm	FDA/OC/OES/DFOI/	HILL-ROM, BATESVILLE, IN - ALL RECS 03/01/2011 - 11/08/2013	Closed 11/12/2013
2013-8950	11/12/2013 12/11/2013	John Movassaghi	FDA/OMPT/CDER/ORP/DIDP/	CHANTIX - AERS	Closed 11/18/2013
2013-8951	11/12/2013 12/11/2013	Biegler GmbH	FDA/OMPT/CDRH/OCER/DFOI/	K050123	Pending Action 11/12/2013
2013-8952	11/12/2013 12/11/2013	AccelaPHARM, LLC	FDA/OMPT/CDER/ORP/DIDP/	ICLUSIG - AERS	Closed 11/19/2013
2013-8953	11/12/2013 12/11/2013	Symbio, LLC	FDA/OGROP/ORPA-FO/SAN-DO/SAN-CB/	DOW PHARMACEUTICAL SCIENCES, PETALUMA, CA - EIR LAST THREE YEARS	Pending Action 11/12/2013
2013-8954	11/12/2013 12/11/2013	AccelaPHARM, LLC	FDA/OMPT/CDER/ORP/DIDP/	OMONTYS - AERS	Closed 11/18/2013
2013-8955	11/12/2013 12/17/2013	REED SMITH LLP	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	BENEFIX - TEST METHODS, SPECIFICATIONS, TEST RESULTS ETC	Pending Action 11/20/2013
2013-8956	11/12/2013 12/11/2013	Loland, Hans P	FDA/OMPT/CDER/ORP/DIDP/	ICLUSIG - AERS	Closed 11/18/2013
2013-8957	11/12/2013 12/11/2013	August, Nathaniel	FDA/OMPT/CDER/ORP/DIDP/	OMONTYS - CASE REPORTS	Closed 11/18/2013
2013-8958	11/12/2013 12/11/2013	Elliot Grysen	FDA/OMPT/CDER/ORP/DIDP/	METHADONE - AERS	Closed 11/18/2013
2013-8959	11/12/2013 12/11/2013	INTERNATIONAL CONSORTIUM OF INVESTIGATIVE JOURNALISTS	FDA/OMPT/CDER/ORP/DIDP/	SCHERING, BERLEX, BAYER - DDMAC LETTERS	Partial Response 11/21/2013
2013-8960	11/12/2013 12/11/2013	iRhythm Technologies, Inc.	FDA/OMPT/CDRH/OCER/DFOI/	K122184	Pending Action 11/12/2013
2013-8961	11/12/2013 12/11/2013	LRGHealthcare	FDA/OMPT/CDRH/OCER/DFOI/	BAXTER HEALTHCARE CORPORATION - WARNING LETTER UPDATES, STATUS RECS 04/01/2013 - 11/08/2013	Pending Action 11/12/2013
2013-8962	11/12/2013 12/11/2013	D D Bregar	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	BREMNER FOODS, PRINCETON, KY - INSPECTION RECS, LAB RESULTS 08/01/2013 - 10/31/2013	Pending Action 11/12/2013
2013-8963	11/13/2013 12/12/2013	BRIDGER BIOMED INC	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	ORTHOHELIX, MEDINA, OH - 483, RESPONSES, WARNING LETTERS 01/03/2012 - 11/11/2013	Closed 11/18/2013

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Control #	Recd Date / Due Date	Requester	Action Offices	Subject	Status / Status Date
2013-8964	11/13/2013 12/12/2013	BURGESS, BERNIE	FDA/OMPT/CDER/ORP/DIDP/	DSI RESPONSE TO OIG/HHS RE: I3938	Duplicate Request 11/13/2013

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2013-8965	11/13/2013 12/12/2013	Tracy Johnson-Hall	FDA/OGROP/ORR/NE-FO/NWE-DO/NWE-	PRODUCT RECALLS FOR FIRMS IN MAINE 01/01/2008 - 12/31/2011	Pending Action 11/13/2013

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			CB/		
2013-8966	11/13/2013 12/12/2013	Tracy Johnson-Hall	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	PRODUCT RECALLS FOR FIRMS IN MARYLAND 01/01/2008 - 12/31/2011	Pending Action 11/13/2013
2013-8967	11/13/2013 12/12/2013	Tracy Johnson-Hall	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	PRODUCT RECALLS FOR FIRMS IN MICHIGAN 01/01/2008 - 12/31/2011	Pending Action 11/13/2013
2013-8968	11/13/2013 12/12/2013	Goodell DeVries Leech & Dann LLP	FDA/OC/OES/DDM/	JOINT MTG OF THE ARTHRITIS ADVISORY COMMITTEE AND DRUG SAFETY AND RISK ASSESSMENT COMMITTEE - TRANSCRIPT 10/09/1996 - 10/09/1996	Pending Action 11/13/2013
2013-8969	11/13/2013 12/12/2013	INTERNATIONAL CONSORTIUM OF INVESTIGATIVE JOURNALISTS	FDA/OMPT/CDER/ORP/DIDP/	BAYER WHITE PAPER SUBMITTED TO FDA RE YASMIN 01/07/2004 - 12/31/2004	Withdrawn Closed w/o Charges 11/14/2013
2013-8970	11/13/2013 12/12/2013	FOI Services, Inc.	FDA/OMPT/CTP/OD/	CTP GUIDANCE TO TRAIN STAFF RE SE DETERMINATIONS - CORR, RESEARCH, BACKGROUND, ETC	Pending Action 11/13/2013
2013-8971	11/13/2013 12/12/2013	GOJO Industries, Inc.	FDA/OMPT/CDER/ORP/DIDP/	FDA MTG RE CITIZEN PETITION AND/OR TIME AND EXTENT APPLICATION TO SUPPORT HYDROGEN PEROXIDE INCLUSION IN THE TENTATIVE FINAL MONOGRAPH FOR HEALTHCARE ANTISEPTIC PRODUCTS	Withdrawn Closed w/o Charges 11/15/2013
2013-8972	11/13/2013 12/12/2013	Harvard Extension School	FDA/OMPT/CDER/ORP/DIDP/	NDA 020468 S035 SUPPLEMENT APPROVAL LETTER	Pending Action 11/13/2013

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Control #	Recd Date / Due Date	Requester	Action Offices	Subject	Status / Status Date
2013-8973	11/13/2013 12/12/2013	Shire Human Genetic Therapies, Inc	FDA/OGROP/ORR/NE-FO/NWE-DO/NWE-	SHIRE HUMAN GENETIC THERAPY, BELMONT, MA - EIR 06/02/2011 - 06/02/2011	Pending Action 11/13/2013

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Control #	Recd Date / Due Date	Requester	Action Offices	Subject	Status / Status Date
			CB/		

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Control #	Recd Date / Due Date	Requester	Action Offices	Subject	Status / Status Date
2013-8974	11/13/2013 12/12/2013	Shire Human Genetic Therapies, Inc	FDA/OGROP/ORR/NE-FO/NWE-DO/NWE-	SHIRE HUMAN GENETIC THERAPIES, INC, BELMONT, MA - EIR 06/02/2011 - 06/02/2011	Pending Action 11/13/2013



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Control #	Recd Date / Due Date	Requester	Action Offices	Subject	Status / Status Date
			CB/		
2013-8975	11/13/2013 12/12/2013	Tracy Johnson-Hall	FDA/OGROP/ORА/SE-FO/NOL-DO/NOL-CB/	PRODUCT RECALLS IN LOUISIANA	Pending Action 11/13/2013
2013-8976	11/13/2013 12/12/2013	Tracy Johnson-Hall	FDA/OGROP/ORА/CE-FO/CHI-DO/CHI-CB/	PRODUCT RECALLS IN ILLINOIS 01/01/2008 - 12/31/2011	Pending Action 11/13/2013
2013-8977	11/13/2013 12/12/2013	GEORGETOWN UNIVERSITY SCHOOL OF MEDICINE	FDA/OMPT/CDER/ОРP/DIDP/	LEXAPRO - CASE REPORTS	Pending Action 11/13/2013
2013-8978	11/13/2013 12/12/2013	FOI Services, Inc.	FDA/OMPT/CDER/ОРP/DIDP/	ANDA 202881	Pending Action 11/13/2013
2013-8979	11/13/2013 12/12/2013	Ballenger, Barth, Hoefler & Lewis, LLP	OC/ORА/ OC/ORА/OE/	ON THE BORDER SAUCE - RECALL RECS 01/01/2009 - 11/11/2013	Closed 11/14/2013
2013-8980	11/13/2013 12/12/2013	Mouton, Benjamin	FDA/OC/OES/DFOI/	LIGACLIP MCA - MAUDE REPORTS, WARNING LETTERS, RECALLS 11/01/2013 - 11/11/2013	Closed 11/13/2013
2013-8981	11/13/2013 12/12/2013	GEORGETOWN UNIVERSITY SCHOOL OF MEDICINE	FDA/OMPT/CDER/ОРP/DIDP/	CITALOPRAM - CASE REPORTS	Pending Action 11/13/2013
2013-8982	11/13/2013 12/12/2013	ULMER & BERNE LLP	FDA/OMPT/CDER/ОРP/DIDP/	PAXIL - SBA	Pending Action 11/13/2013
2013-8983	11/13/2013 12/18/2013	REED SMITH LLP	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	RIXUBIS - TEST METHODS, SPECIFICATIONS, RESULTS ETC	Pending Action 11/20/2013
2013-8984	11/13/2013 12/12/2013	FOI Services, Inc.	FDA/OMPT/CDER/ОРP/DIDP/	ANDA 65068	Pending Action 11/13/2013
2013-8985	11/13/2013 12/12/2013	FOI Services, Inc.	FDA/OMPT/CDER/ОРP/DIDP/	ANDA 63014	Pending Action 11/13/2013
2013-8986	11/13/2013 12/12/2013	FOI Services, Inc.	FDA/OMPT/CDER/ОРP/DIDP/	20 MMU PENICILLIN G SODIUM - NDA/ANDA	Pending Action 11/13/2013
2013-8987	11/13/2013 12/12/2013	Harvard Kennedy School	FDA/OMPT/CDER/ОРP/DIDP/	FOREIGN DRUG PRODUCTS APPROVED 01/01/1990 - 10/31/2013	Withdrawn Closed w/o Charges 11/19/2013
2013-8988	11/13/2013 12/12/2013	Catalyst Pharmaceutical Partners	FDA/OGROP/ORА/CE-FO/NWJ-DO/NWJ-CB/	JACOBUS PHARMACEUTICAL CO, PLAINSBORO, NJ - EIR 01/01/2013 - 11/11/2103	Pending Action 11/13/2013
2013-8989	11/13/2013 12/12/2013	May, Sam J	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ОРP/DIDP/ OC/ORА/	BIOLOGICAL PRODUCT DEVIATIONS, ANNUAL, AND DISTRIBUTION REPORTS 11/08/2002 - 11/10/2008	Pending Action 11/13/2013

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Control #	Recd Date / Due Date	Requester	Action Offices	Subject	Status / Status Date
2013-8990	11/13/2013 12/12/2013	FDANEWS	FDA/OC/OES/DFOI/	FOIA REQUEST LOG 11/04/2013 - 11/08/2013	Closed 11/13/2013
2013-8991	11/13/2013 12/12/2013	iRhythm Technologies Inc.	FDA/OMPT/CDRH/OCER/DFOI/	K130294	Pending Action 11/13/2013
2013-8992	11/13/2013 12/12/2013	Marathon Pharmaceuticals, LLC	FDA/OMPT/CDER/ORP/DIDP/	WOCKHARDT LTD - 483 07/01/2013 - 11/01/2013	Closed 11/13/2013
2013-8993	11/13/2013 12/12/2013	Appco Pharmaceuticals Corporation	FDA/OMPT/CDER/ORP/DIDP/	NDA 012649 - INSERT	Closed 11/13/2013
2013-8994	11/13/2013 12/12/2013	Nielsen BioSciences, Inc.	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	CANDIN - APPROVAL LETTERS, SUMMARY BASIS FOR REGULATORY ACTION, APPROVAL HISTORY ETC 01/01/1994 - 12/31/1996	Pending Action 11/13/2013
2013-8995	11/13/2013 12/12/2013	Riconpharma, LLC	FDA/OMPT/CDER/ORP/DIDP/	ANDA 087203	Closed 11/18/2013
2013-8996	11/13/2013 12/12/2013	Tracy Johnson-Hall	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	PRODUCTS RECALLS FOR INDIANA FIRMS 01/01/2009 - 12/31/2011	Pending Action 11/13/2013
2013-8997	11/13/2013 12/12/2013	Tracy Johnson-Hall	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	PRODUCTS RECALLS FOR IOWA FIRMS 01/01/2009 - 12/31/2011	Pending Action 11/13/2013
2013-8998	11/13/2013 12/12/2013	Tracy Johnson-Hall	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	PRODUCTS RECALLS FOR IDAHO FIRMS 01/01/2009 - 12/31/2011	Pending Action 11/13/2013
2013-8999	11/13/2013 12/12/2013	COLLEGE OF WILLIAM AND MARY	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	PRODUCTS RECALLS FOR GEORGIA FIRMS 01/01/2009 - 12/31/2011	Pending Action 11/13/2013
2013-9000	11/13/2013 12/12/2013	Tracy Johnson-Hall	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/ FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	PRODUCTS RECALLS FOR KANSAS FIRMS 01/01/2009 - 12/31/2010	Pending Action 11/13/2013
2013-9001	11/13/2013 12/12/2013	Tracy Johnson-Hall	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	PRODUCTS RECALLS FOR HAWAII FIRMS 01/01/2008 - 12/31/2009	Pending Action 11/13/2013
2013-9002	11/13/2013 12/12/2013	Tracy Johnson-Hall	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	PRODUCTS RECALLS FOR INDIANA FIRMS 01/01/2009 - 12/31/2010	Duplicate Request 11/14/2013

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Control #	Recd Date / Due Date	Requester	Action Offices	Subject	Status / Status Date
2013-9003	11/13/2013 12/12/2013	Tracy Johnson-Hall	FDA/OGROP/ORR/NE-FO/NWE-DO/NWE-	PRODUCTS RECALLS FOR MASSACHUSETTS FIRMS 01/01/2008 - 12/31/2011	Pending Action 11/13/2013

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			CB/		
2013-9004	11/13/2013 12/12/2013	Harvard Extension School	FDA/OMPT/CDER/ORP/DIDP/	NDA 020468/S-035 SUPPLEMENTAL APPROVAL LETTER	Duplicate Request 11/11/2013
2013-9005	11/12/2013 12/11/2013	William Stewart	FDA/OGROP/ORR/PA-FO/SAN-DO/SAN-CB/	JUST LIKE SUGAR - RECS 2004-2005	No Record(s) 11/19/2013
2013-9006	11/12/2013 12/11/2013	NorthStar Biomedical Associates	FDA/OMPT/CDRH/OCER/DFOI/	K911577	Pending Action 11/12/2013
2013-9007	11/12/2013 12/11/2013	BUCHANAN INGERSOLL & ROONEY PC	FDA/OC/OES/DFOI/	DKT 1976N-0377, SKT 1998P-1041, DKT 2013D-0880, ETC	Closed 11/12/2013
2013-9008	11/12/2013 12/11/2013	EAS CONSULTING GROUP LLC	FDA/OC/OES/DFOI/	OTC VOL 100022, 100035, 100036	Closed 11/12/2013
2013-9009	11/12/2013 12/11/2013	NATURAL RESOURCES DEFENSE COUNCIL	FDA/OC/OES/DFOI/	DKT 2011N-0146-0024	Closed 11/12/2013
2013-9010	11/12/2013 12/11/2013	KING & SPALDING	FDA/OC/OES/DFOI/	DKT 1978N-0272	Closed 11/12/2013
2013-9011	11/12/2013 12/11/2013	CITIZENS FOR HEALTH	FDA/OC/OES/DFOI/	DKT 2013P-0291	Closed 11/12/2013
2013-9012	11/12/2013 12/11/2013	COVINGTON & BURLING LLP	FDA/OC/OES/DFOI/	DKT 1992P-0487	Closed 11/12/2013
2013-9013	11/12/2013 12/11/2013	KLEINFELD, KAPLAN & BECKER	FDA/OC/OES/DFOI/	DKT 2008P-0407, DKT 2008P-0460	Closed 11/12/2013
2013-9014	11/12/2013 12/11/2013	VENABLE LLP	FDA/OC/OES/DFOI/	FERTILITY & MATERNAL HEALTH DRUGS A/C; JOINT A/C MTG BTWN FERTILITY & MATERNAL HEALTH DRUGS A/C	Closed 11/12/2013
2013-9015	11/12/2013 12/11/2013	COVINGTON & BURLING LLP	FDA/OC/OES/DFOI/	DKT 1975P-0006	Closed 11/12/2013
2013-9016	11/12/2013 12/11/2013	COVINGTON & BURLING LLP	FDA/OC/OES/DFOI/	DKT 2012D-1145-0006	Closed 11/12/2013
2013-9017	11/12/2013 12/11/2013	KING & SPALDING	FDA/OC/OES/DFOI/	DKT 2007D-0369	Closed 11/12/2013
2013-9018	11/12/2013 12/11/2013	COVINGTON & BURLING LLP	FDA/OC/OES/DFOI/	DKT 2004N-0279	Closed 11/12/2013
2013-9019	11/12/2013 12/11/2013	Rheonix. Inc.	FDA/OMPT/CDRH/OCER/DFOI/	K032194	Pending Action 11/12/2013
2013-9020	11/12/2013 12/11/2013	COVINGTON & BURLING LLP	FDA/OC/OES/DFOI/	DKT 1977N-0094	Closed 11/12/2013

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2013-9021	11/12/2013 12/11/2013	Rheonix, Inc.	FDA/OMPT/CDRH/OCER/DFOI/	K102911	Pending Action 11/12/2013
2013-9022	11/12/2013 12/11/2013	Non	FDA/OMPT/CDER/ORP/DIDP/	LOMITAPIDE - CORR RE AERS, DROP OUT RATES, PATIENT REGISTRIES ETC 12/01/2012 - 11/11/2013	Closed 11/18/2013
2013-9023	11/12/2013 12/11/2013	OLSSON FRANK & WEEDA	FDA/OC/OES/DFOI/	DKT 20013P-1293	Closed 11/12/2013
2013-9024	11/12/2013 12/11/2013	BRIDGER BIOMED INC	FDA/OMPT/CDRH/OCER/DFOI/	TORNIER, MONTBONNOT, FRANCE - 483, RESPONSE 01/03/2012 - 11/11/2013	Pending Action 11/12/2013
2013-9025	11/12/2013 12/11/2013	Jason DeYoung	FDA/OC/OES/DFOI/	FOOD FACILITY REGISTRATION DATA - OHIO, INDIANA, MICHIGAN	Closed Denial 11/14/2013
2013-9026	11/13/2013 12/12/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-7596 REQUEST LETTER	Closed 11/15/2013
2013-9027	11/13/2013 12/12/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-7447 - REQUEST LETTER	Closed 11/15/2013
2013-9028	11/13/2013 12/12/2013	BRIGHAM AND WOMEN'S HOSPITAL	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	TRANSFUSION RELATED FATALITIES DUE TO ANAPHYLAXIS	Pending Action 11/13/2013
2013-9029	11/13/2013 12/12/2013	Nanophthalmos	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	K101861	Closed 11/18/2013
2013-9030	11/13/2013 12/12/2013	Nanophthalmos	FDA/OMPT/CDRH/OCER/DFOI/	K123464	Pending Action 11/13/2013
2013-9031	11/13/2013 12/12/2013	FOI Services, Inc.	FDA/OMPT/CDRH/OCER/DFOI/	K021837	Pending Action 11/13/2013
2013-9032	11/13/2013 12/12/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-7228 - REQUEST LETTER	Closed 11/15/2013
2013-9033	11/13/2013 12/12/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-7397 - REQUEST LETTER	Closed 11/15/2013
2013-9034	11/13/2013 12/12/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-7445 - REQUEST LETTER	Closed 11/15/2013
2013-9035	11/13/2013 12/12/2013	Rheonix, Inc.	FDA/OMPT/CDRH/OCER/DFOI/	K111409	Pending Action 11/13/2013
2013-9036	11/13/2013 12/12/2013	INTERNATIONAL CONSORTIUM OF INVESTIGATIVE JOURNALISTS	FDA/OMPT/CDER/ORP/DIDP/	YASMIN - IMS, SERS DATABASE REVIEWS TO CALCULATE THROMBOEMBOLIC EVENT RATE	Withdrawn Closed w/o Charges 11/14/2013
2013-9037	11/13/2013 12/12/2013	Rheonix, Inc.	FDA/OMPT/CDRH/OCER/DFOI/	K121710	Pending Action 11/13/2013

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2013-9038	11/13/2013 12/12/2013	Rheonix, Inc.	FDA/OMPT/CDRH/OCER/DFOI/	K122062	Pending Action 11/13/2013
2013-9039	11/13/2013 12/12/2013	Rheonix, Inc.	FDA/OMPT/CDRH/OCER/DFOI/	K130268	Pending Action 11/13/2013
2013-9040	11/13/2013 12/12/2013	Boca Pharmacal, LLC	FDA/OC/OES/DDM/	00P-1641/CP1	Pending Action 11/13/2013
2013-9041	11/13/2013 12/12/2013	Cardenas, Laura N	FDA/OFVM/CFSAN/OCD/EOS/	YOLI.COM -SAFETY, APPROVAL 10/01/2012 - 11/12/2013	Delogged (not a FOIA Request) 11/14/2013
2013-9042	11/13/2013 12/12/2013	KENYON & KENYON LLP	FDA/OMPT/CDER/ORP/DIDP/	NDA 21487 - SAFETY REVIEW	Withdrawn Closed w/o Charges 11/14/2013
2013-9043	11/13/2013 12/12/2013	INTERNATIONAL CONSORTIUM OF INVESTIGATIVE JOURNALISTS	FDA/OMPT/CDER/ORP/DIDP/	MINUTES OF TELECONFERENCE WITH SCHERING/BERLEX/BAYER RE SAFETY OF YASMIN 01/01/2000 - 12/21/2006	Withdrawn Closed w/o Charges 11/14/2013
2013-9044	11/13/2013 12/12/2013	KENYON & KENYON LLP	FDA/OMPT/CDER/ORP/DIDP/	NDA 21627 - CLINICAL PHARMACOLOGY BIOPHARMACEUTICS REVIEW	Withdrawn Closed w/o Charges 11/14/2013
2013-9045	11/13/2013 12/12/2013	Ritter, Chris	FDA/OGROP/ORAP-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	ORTHOSCAN HD WITH FLAT DETECTOR-OR - APPROVAL, COMPLIANCE RECS 01/01/2000 - 11/12/2013	Partial Response 11/18/2013
2013-9046	11/13/2013 12/12/2013	ADVERSEEVENTS INC	FDA/OMPT/CDER/ORP/DIDP/	ZIRGAN - AERS	Closed 11/18/2013
2013-9047	11/13/2013 12/12/2013	ADVERSEEVENTS INC	FDA/OMPT/CDER/ORP/DIDP/	VPRIV - AERS	Closed 11/18/2013
2013-9048	11/13/2013 12/12/2013	Patrick Knowles	FDA/OMPT/CDER/ORP/DIDP/	SAREPTA THERAPEUTICS - CORR, ARTICLES, NOTES RE ETEPLIRSEN 05/01/2013 - 11/12/2013	Pending Action 11/13/2013
2013-9049	11/13/2013 12/12/2013	CAUDLE, BRANDON	FDA/OMPT/CDER/ORP/DIDP/	VIREAOL - PI	Acknowledgement Letter 11/13/2013
2013-9050	11/13/2013 12/12/2013	CAUDLE, BRANDON	FDA/OMPT/CDER/ORP/DIDP/	COMPLERA - PI	Acknowledgement Letter 11/13/2013
2013-9051	11/13/2013 12/12/2013	CAUDLE, BRANDON	FDA/OMPT/CDER/ORP/DIDP/	TRIZIVIR - PI	Acknowledgement Letter 11/13/2013
2013-9052	11/13/2013 12/12/2013	CAUDLE, BRANDON	FDA/OMPT/CDER/ORP/DIDP/	EMTRIVA - PI	Acknowledgement Letter 11/13/2013

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2013-9053	11/13/2013 12/12/2013	MILLENNIUM MANAGEMENT LLC	FDA/OGROP/ORR/NE-FO/NWE-DO/NWE-	JUXTAPID ( LOMITAPIDE) FAERS; AEGERION PHARMACEUTICALS INC - 483, EIR, UNTITLED LTRS 8/1/13 TO PRESENT	Partial Response 11/18/2013

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Control #	Recd Date / Due Date	Requester	Action Offices	Subject	Status / Status Date
			CB/ FDA/OMPT/CDER/ORP/DIDP/		
2013-9054	11/13/2013 12/12/2013	MILLENNIUM MANAGEMENT LLC	FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	ONYX PHAMACEUTICALS INC; AMGEN INC - 483, EIR, UNTITLED LTRS 5/1/13 TO PRESENT; KYPROLIS (CARFILZOMIB) FAERS	Partial Response 11/19/2013
2013-9055	11/13/2013 12/12/2013	Center for Regulatory Services, Inc.	OC/CVM/OCD/	FAP 2226	Acknowledgement Letter 11/13/2013
2013-9056	11/13/2013 12/12/2013	IOVATE HEALTH SCIENCES INTERNATIONAL INC	FDA/OFVM/CFSAN/OCD/EOS/	CAERS 169605, 167755, 165504, 165500	Acknowledgement Letter 11/13/2013
2013-9057	11/13/2013 12/12/2013	MILLENNIUM MANAGEMENT LLC	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/ FDA/OMPT/CDER/ORP/DIDP/	SEATTLE GENETICS INC - 483, EIR , UNTITLED LTRS, 2/1/13 TO PRESENT; ADCETRIS (BRETUXIMAB VEDOTIN) FAERS	Partial Response 11/19/2013
2013-9058	11/13/2013 12/12/2013	S ALBERT EDWARDS, PHARM D	FDA/OMPT/CDER/ORP/DIDP/	LEVAQUIN - LBLG VERSION 3 & 8	Closed 11/18/2013
2013-9059	11/13/2013 12/12/2013	SHEPPARD MULLIN ET AL	FDA/OMPT/CDER/ORP/DIDP/	GENERAMEDIX - NULECIT ANDA 78-215 BIOEQUIV, CHEMISTRY RVW 10/1/09 TO PRESENT	Acknowledgement Letter 11/13/2013
2013-9060	11/13/2013 12/12/2013	MUCKROCK NEWS	FDA/OC/OES/DFOI/	SHUTDOWN DOCUMENTS	Acknowledgement Letter 11/13/2013
2013-9061	11/13/2013 12/12/2013	NIPRO Diagnostics	FDA/OMPT/CDRH/OCER/DFOI/	MW 5032320	Closed 11/19/2013
2013-9062	11/13/2013 12/12/2013	NIPRO Diagnostics	FDA/OMPT/CDRH/OCER/DFOI/	MW 5032049	Closed 11/19/2013
2013-9063	11/13/2013 12/12/2013	NIPRO Diagnostics	FDA/OMPT/CDRH/OCER/DFOI/	MW 5032347	Closed 11/19/2013
2013-9064	11/13/2013 12/12/2013	3M ESPE Dental Products	FDA/OMPT/CDRH/OCER/DFOI/	PULPDENT CORP - FLOURIDE VARNISH K093620	Acknowledgement Letter 11/13/2013
2013-9065	11/13/2013 12/12/2013	3M ESPE Dental Products	FDA/OMPT/CDRH/OCER/DFOI/	PULPDENT CORP - ACTIV VARNISH K112946	Acknowledgement Letter 11/13/2013
2013-9066	11/13/2013 12/12/2013	3M ESPE Dental Products	FDA/OMPT/CDRH/OCER/DFOI/	DENTAL TECHNOLOGIES INC - ALPHA PRO WHITE VARNISH K124025	Acknowledgement Letter 11/13/2013
2013-9067	11/13/2013 12/12/2013	3M ESPE Dental Products	FDA/OMPT/CDRH/OCER/DFOI/	ELEVATE ORAL CARE - SMARTCOAT NAF VARNISH K131376	Acknowledgement Letter 11/13/2013



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2013-9068	11/13/2013 12/12/2013	HOGAN LOVELLS LLP	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	DEPUY ORTHOPEDICS INC - K011533, K031495, K031803 ETC	Partial Response 11/18/2013
2013-9069	11/13/2013 12/12/2013	HOGAN LOVELLS US LLP	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	DEPUY ORTHOPEDICS INC - K983014, K033273, K043058	Acknowledgement Letter 11/13/2013
2013-9070	11/13/2013 12/12/2013	OFW LAW	FDA/OMPT/CDER/ORP/DIDP/	REMODULIN (TREPASTINIL) NDA 21- 272/S020 APRVL	Acknowledgement Letter 11/13/2013
2013-9071	11/13/2013 12/12/2013	SEIDMAN, ROBERT	FDA/OMPT/CDER/ORP/DIDP/	HP ACTHAR NDA N008372 SBA	Closed 11/18/2013
2013-9072	11/13/2013 12/12/2013	ANDRUS HOOD & WAGSTAFF PC	FDA/OMPT/CDRH/OCER/DFOI/	BOSTON SCIENTIFIC CORP - BLUE SUI SLING K121754	Acknowledgement Letter 11/13/2013

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2013-9073	11/13/2013 12/12/2013	LINCARE INC	FDA/OGROP/ORR/NE-FO/NYK-DO/NYK-	HOME HEALTH PAVILLION, NEWBURGH, NY - 483, EIR, WARNING LTR 1/98 TO PRESENT	Acknowledgement Letter 11/13/2013

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			DCB/		
2013-9074	11/13/2013 12/12/2013	BAKER & HOSTETLER, LLP	FDA/OC/OES/DFOI/	MINOR DELETIONS	Partial Denial 11/15/2013
2013-9075	11/13/2013 12/12/2013	ESPTAIN BECKER ET AL	FDA/OC/OES/DFOI/	MINOR DELETIONS	Partial Denial 11/15/2013
2013-9076	11/13/2013 12/12/2013	WINSTON & STRAWN LLP	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OGROP/OIP/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	LIBERT VEGETABLE OIL - INVESTIGATIONS 2008 TO 2010	Acknowledgement Letter 11/13/2013
2013-9077	11/13/2013 12/12/2013	PUBLIC CITIZEN	FDA/OMPT/CDER/GRP/DIDP/	KETOCONAZOLE - SAFETY & EFFICACY	Acknowledgement Letter 11/13/2013
2013-9078	11/14/2013 12/13/2013	FOI Services, Inc.	FDA/OMPT/CDRH/OCER/DFOI/	K031328	Pending Action 11/14/2013
2013-9079	11/14/2013 12/13/2013	FOI Services, Inc.	FDA/OMPT/CDRH/OCER/DFOI/	K080668	Pending Action 11/14/2013
2013-9080	11/14/2013 12/13/2013	FOI Services, Inc.	FDA/OMPT/CDRH/OCER/DFOI/	K130366	Pending Action 11/14/2013
2013-9081	11/14/2013 12/13/2013	FOI Services, Inc.	FDA/OMPT/CDRH/OCER/DFOI/	K101431	Pending Action 11/14/2013
2013-9082	11/14/2013 12/13/2013	FOI Services, Inc.	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	K022236	Closed 11/18/2013
2013-9083	11/14/2013 12/13/2013	FOI Services, Inc.	FDA/OMPT/CDRH/OCER/DFOI/	K102511	Pending Action 11/14/2013
2013-9084	11/14/2013 12/13/2013	ADVERSEEVENTS INC	FDA/OMPT/CDER/GRP/DIDP/	LATUDA - AERS	Closed 11/19/2013
2013-9085	11/14/2013 12/13/2013	ADVERSEEVENTS INC	FDA/OMPT/CDER/GRP/DIDP/	ONFI - AERS	Closed 11/19/2013
2013-9086	11/14/2013 12/13/2013	ADVERSEEVENTS INC	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	ZEMAIRA - AERS	Pending Action 11/14/2013
2013-9087	11/14/2013 12/13/2013	ADVERSEEVENTS INC	FDA/OMPT/CDER/GRP/DIDP/	ISOPTO CARPINE - AERS	Closed 11/19/2013
2013-9088	11/14/2013 12/13/2013	ADVERSEEVENTS INC	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	EDARBYCLOR, INTERMEZZO, EYLEA - AERS	Pending Action 11/14/2013

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2013-9089	11/14/2013 12/13/2013	ADVERSEEVENTS INC	FDA/OMPT/CDER/ORP/DIDP/	XIAFLEX - AERS	Closed 11/21/2013
2013-9090	11/14/2013 12/13/2013	ADVERSEEVENTS INC	FDA/OMPT/CDER/ORP/DIDP/	LASTACRAFT - AERS	Closed 11/19/2013
2013-9091	11/14/2013 12/13/2013	ADVERSEEVENTS INC	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	GLASSIA - AERS	Pending Action 11/14/2013
2013-9092	11/14/2013 12/13/2013	ADVERSEEVENTS INC	FDA/OMPT/CDER/ORP/DIDP/	STAXYN - AERS	Pending Action 11/14/2013
2013-9093	11/14/2013 12/13/2013	ADVERSEEVENTS INC	FDA/OMPT/CDER/ORP/DIDP/	JAKAFI - AERS	Closed 11/21/2013
2013-9094	11/14/2013 12/13/2013	ADVERSEEVENTS INC	FDA/OMPT/CDER/ORP/DIDP/	ERIVEDGE - AERS	Pending Action 11/14/2013
2013-9095	11/14/2013 12/13/2013	ADVERSEEVENTS INC	FDA/OMPT/CDER/ORP/DIDP/	XTANDI - AERS	Pending Action 11/14/2013
2013-9096	11/14/2013 12/13/2013	ADVERSEEVENTS INC	FDA/OMPT/CDER/ORP/DIDP/	SIRTURO, ELIQUIS, SIGNIFOR - AERS	Pending Action 11/14/2013
2013-9097	11/14/2013 12/13/2013	ADVERSEEVENTS INC	FDA/OMPT/CDER/ORP/DIDP/	ADCIRCA - AERS	Pending Action 11/14/2013
2013-9098	11/14/2013 12/13/2013	ADVERSEEVENTS INC	FDA/OMPT/CDER/ORP/DIDP/	ARCALYST - AERS	Closed 11/21/2013
2013-9099	11/14/2013 12/13/2013	ADVERSEEVENTS INC	FDA/OMPT/CDER/ORP/DIDP/	BIDIL - AERS	Closed 11/21/2013
2013-9100	11/14/2013 12/13/2013	ADVERSEEVENTS INC	FDA/OMPT/CDER/ORP/DIDP/	EGRIFTA - AERS	Closed 11/19/2013
2013-9101	11/14/2013 12/13/2013	Waycross Partners	FDA/OMPT/CDER/ORP/DIDP/	SAREPTA THERAPEUTICS - MTG MINUTES 11/8/13	Closed Denial 11/19/2013
2013-9102	11/14/2013 12/13/2013	ADVERSEEVENTS INC	FDA/OMPT/CDER/ORP/DIDP/	PERJETA - AERS	Closed 11/21/2013
2013-9103	11/14/2013 12/13/2013	ADVERSEEVENTS INC	FDA/OMPT/CDER/ORP/DIDP/	KYPROLIS - AERS	Closed 11/21/2013
2013-9104	11/14/2013 12/13/2013	ADVERSEEVENTS INC	FDA/OMPT/CDER/ORP/DIDP/	LOESTRIN FE - AERS	Closed 11/21/2013
2013-9105	11/14/2013 12/13/2013	ADVERSEEVENTS INC	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	APTIOM, GAZYVA, ADEMPAS ETC	Pending Action 11/14/2013

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2013-9106	11/14/2013 12/13/2013	ADVERSEEVENTS INC	FDA/OMPT/CDER/ORP/DIDP/	INLYTA - AERS	Pending Action 11/14/2013
2013-9107	11/14/2013 12/13/2013	ADVERSEEVENTS INC	FDA/OMPT/CDER/ORP/DIDP/	EPIDUO - AERS	Closed 11/21/2013
2013-9108	11/14/2013 12/13/2013	ADVERSEEVENTS INC	FDA/OMPT/CDER/ORP/DIDP/	QNASI - AERS	Closed 11/19/2013
2013-9109	11/14/2013 12/13/2013	ADVERSEEVENTS INC	FDA/OMPT/CDER/ORP/DIDP/	ULFESIA - AERS	Pending Action 11/14/2013
2013-9110	11/14/2013 12/13/2013	ADVERSEEVENTS INC	FDA/OMPT/CDER/ORP/DIDP/	ZYMAXID - AERS	Pending Action 11/14/2013
2013-9111	11/14/2013 12/13/2013	ADVERSEEVENTS INC	FDA/OMPT/CDER/ORP/DIDP/	BOSULIF - AERS	Pending Action 11/14/2013
2013-9112	11/14/2013 12/13/2013	QIAGEN Inc.	FDA/OMPT/CDRH/OCER/DFOI/	QIAGEN - EIR 01/01/2013 - 11/12/2013	Pending Action 11/14/2013
2013-9113	11/14/2013 12/13/2013	ADVERSEEVENTS INC	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	XYNTHA - AERS	Pending Action 11/14/2013
2013-9114	11/14/2013 12/13/2013	THENELL & ASSOCIATES LLC	FDA/OFVM/CFSAN/OCD/EOS/	MON 87769 Biotechnology Notification File No. 117	Pending Action 11/14/2013
2013-9115	11/14/2013 12/13/2013	ADVERSEEVENTS INC	FDA/OMPT/CDER/ORP/DIDP/	7533182, 7533186, 7533200, ETC - CASE REPORTS	Closed 11/18/2013
2013-9116	11/14/2013 12/13/2013	FOI Services, Inc.	FDA/OMPT/CDRH/OCER/DFOI/	K093659	Pending Action 11/14/2013
2013-9117	11/14/2013 12/13/2013	INTELLIJECT LLC	FDA/OMPT/CDER/ORP/DIDP/	NDA 019430 - MANUFACTURING CHANGES	Pending Action 11/14/2013
2013-9118	11/14/2013 12/13/2013	Dartmouth Inst. Cent. For Med. Media.	FDA/OMPT/CDER/ORP/DIDP/	Annual Report on Postmarketing Requirements and Commitments from Eisai Inc for Belviq (lorcaserin, NDA 22529) submitted to FDA on August 20, 2013; Annual Report on Postmarketing Requirements and Commitments from Vivus Inc for Qsmia (phentermine/topiramate, NDA 22580) submitted to FDA on September 16, 2013	Pending Action 11/14/2013
2013-9119	11/14/2013 12/13/2013	THE ORANGE COUNTY REGISTER	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	UNIVERSITY OF CALIFORNIA IRVINE - 483 01/01/2009 - 11/30/2013	Pending Action 11/14/2013
2013-9120	11/14/2013 12/13/2013	Reckitt Benckiser Inc.	FDA/OMPT/CDER/ORP/DIDP/	TADAFIL, CIALIS - AERS SUMMARY	Closed 11/19/2013

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2013-9121	11/14/2013 12/13/2013	THENELL & ASSOCIATES LLC	FDA/OFVM/CFSAN/OCOD/EOS/	MON 87705 (MON-8775-6) Biotechnology Notification File No. 121	Pending Action 11/14/2013
2013-9122	11/14/2013 12/13/2013	Changzhou Holymed Products Co., ltd	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	K050207, K021692	Partial Response 11/18/2013
2013-9123	11/14/2013 12/13/2013	ROANOKE CLAIMS SERVICES	OC/ORO/ FDA/OGROP/ORO/SW-FO/DAL-DO/DAL-CB/	QUALITY PRODUCE - ENTRY #FS300471133 NOTICES FOR REQUEST OF INFORMATION (CF28), NOTICE OF ACTION, CBP REDELIVER NOTICES (CF4647), ETC	Acknowledgement Letter 11/14/2013
2013-9124	11/14/2013 12/13/2013	CONWAY, HOMER & CHIN-CAPLAN PC	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	INDIVIDUAL RECS	Acknowledgement Letter 11/14/2013
2013-9125	11/14/2013 12/13/2013	JOHNSON, MICHELLE R	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	VAERS DATA - FLU VACCINE IN MARYLAND 01/01/2009 - 10/01/2013	Pending Action 11/14/2013
2013-9126	11/14/2013 12/13/2013	Matt McKeever	FDA/OMPT/CDER/ORP/DIDP/	SAREPTA THERAPEUTICS - PREMEETING COMMENTS, MEETING MINUTES 04/01/2013 - 11/08/2013	Closed Denial 11/19/2013
2013-9127	11/14/2013 12/13/2013	JOHNSON, MICHELLE R	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	VAERS DATA - FLU VACCINE VIRGINIA, DC 01/01/2009 - 10/31/2013	Pending Action 11/14/2013
2013-9128	11/14/2013 12/13/2013	karmadata, Inc.	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ORP/DIDP/	Submitted Investigational New Drug Applications (Form 1571) and Statements of Investigator (Form 1572) to the FDA on File from January 1, 2007 to Present	Pending Action 11/14/2013

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2013-9129	11/14/2013 12/13/2013	LIGHTFOOT FRANKLIN & WHITE LLC	FDA/OGROP/ORR/SW-FO/DEN-DO/DEN-	WWW.THEHCDROPS.COM, THE HCG DROPS LLC - HOMEOPATHIC HCG RECS	Acknowledgement Letter 11/14/2013

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			CB/ FDA/OMPT/CDER/ORP/DIDP/		
2013-9130	11/14/2013 12/13/2013	LONDON SCHOOL OF ECONOMICS AND POLITICAL SCIENCE	FDA/OMPT/CDER/ORP/DIDP/	ABILIFY, PRADAXA, PRISTIQ, ETC - EFFICACY TRIALS 2000 TO 2010	Withdrawn Closed w/o Charges 11/20/2013
2013-9131	11/14/2013 12/13/2013	BUTLER SNOW LLP	FDA/OC/OES/DFOI/	DKT 1978N-2650	Acknowledgement Letter 11/14/2013
2013-9132	11/14/2013 12/13/2013	BIOCARE MEDICAL	FDA/OMPT/CDRH/OCER/DFOI/	K120663	Acknowledgement Letter 11/14/2013
2013-9133	11/14/2013 12/13/2013	RETROPHIN INC	FDA/OMPT/CDER/ORP/DIDP/	JOHNSON AND JOHNSON, ORTHO-MCNEIL-JANSSEN PHARMS DIVISION/SK BIOPHARMACEUTICALS - CARISBAMATE RECS	Acknowledgement Letter 11/14/2013
2013-9134	11/14/2013 12/13/2013	CAUDLE, BRANDON	FDA/OMPT/CDER/ORP/DIDP/	RETROVIR - PI	Closed 11/20/2013
2013-9135	11/14/2013 12/13/2013	MEDSKER, TIMOTHY JOSEPH	OC/ORAO/OCI/	INDIVIDUAL RECS	Closed 11/18/2013
2013-9136	11/14/2013 12/13/2013	INSTITUTE FOR SAFE MEDICATION PRACTICES	FDA/OMPT/CDER/ORP/DIDP/	MEDWATCH RPTS CODED AS MEDICATION ERRORS 10/1-31/13	Acknowledgement Letter 11/14/2013
2013-9137	11/14/2013 12/13/2013	GENERAL PHYSIOTHERAPY, INC.	FDA/OGROP/ORO/SW-FO/KAN-DO/KAN-CB/	GENERAL PHYSIOTHERAPY INC, ST LOUIS, MO - EIR MOST RECENT	Closed 11/15/2013
2013-9138	11/14/2013 12/13/2013	PATH	FDA/OMPT/CDRH/OCER/DFOI/	K080040	Pending Action 11/14/2013
2013-9139	11/14/2013 12/13/2013	Tracy Johnson-Hall	FDA/OGROP/ORO/CE-FO/CIN-DO/CIN-CB/	PRODUCT RECALL DATA FOR OHIO FIRMS 01/01/2008 - 12/31/2011	Pending Action 11/14/2013



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2013-9140	11/14/2013 12/13/2013	Tracy Johnson-Hall	FDA/OGROP/ORR/NE-FO/NYK-DO/NYK-	PRODUCT RECALL DATA FOR NEW YORK FIRMS 01/01/2008 - 12/31/2011	Pending Action 11/14/2013

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Control #	Recd Date / Due Date	Requester	Action Offices	Subject	Status / Status Date
			DCB/		
2013-9141	11/14/2013 12/13/2013	Tracy Johnson-Hall	FDA/OGROP/OR/SE-FO/ATL-DO/ATL-CB/	PRODUCT RECALL DATA FOR NORTH CAROLINA FIRMS 01/01/2009 - 12/31/2011	Pending Action 11/14/2013
2013-9142	11/14/2013 12/13/2013	Tracy Johnson-Hall	FDA/OGROP/OR/PA-FO/SEA-DO/SEA-CB/	PRODUCT RECALL DATA FOR OREGON FIRMS 01/01/2008 - 12/31/2011	Pending Action 11/14/2013
2013-9143	11/14/2013 12/13/2013	Tracy Johnson-Hall	FDA/OGROP/OR/CE-FO/PHI-DO/PHI-CB/	PRODUCT RECALL DATA FOR PENNSYLVANIA FIRMS 01/01/2008 - 12/31/2011	Pending Action 11/14/2013

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2013-9144	11/14/2013 12/13/2013	Tracy Johnson-Hall	FDA/OGROP/ORR/NE-FO/NWE-DO/NWE-	PRODUCT RECALL DATA FOR RHODE ISLAND FIRMS 01/01/2009 - 12/31/2011	Pending Action 11/14/2013

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			CB/		

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2013-9145	11/14/2013 12/13/2013	DAVA PHARMACEUTICALS INC	FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORAN/NE-FO/NYK-DO/NYK-	CHARTWELL PHARMS, CONGERS, NY - QUALITY ASSURANCE PROFILE (QAP), CO RESP, EIR 9/19/12	Acknowledgement Letter 11/14/2013

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			DCB/		
2013-9146	11/14/2013 12/13/2013	VANDERBILT UNIVERISTY MEDICAL CENTER	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	BLOOD PRODUCT TRANSFUSION FATALITES - RECS 2005 TO PRESENT	Acknowledgement Letter 11/14/2013
2013-9147	11/14/2013 12/13/2013	HEARTLAND LIONS EYE BANKS	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	INDIANA LIONS EYE AND TISSUE TRANSPLANT BANK, INDIANAPOLIS,IN - EIR, 483, RECALLS LAST 2 YRS	Acknowledgement Letter 11/14/2013

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2013-9148	11/14/2013 12/13/2013	HEARTLAND LIONS EYE BANKS	FDA/OGROP/ORR/SW-FO/DEN-DO/DEN-	VRL LABS, CENTENNIAL, CO - EIR, 483, RECALLS LAST 2 YRS	Acknowledgement Letter 11/14/2013

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2013-9149	11/14/2013 12/13/2013	HEARTLAND LIONS EYE BANKS	FDA/OGROP/ORR/SW-FO/DEN-DO/DEN-	LABS INC, CENTENNIAL, CO - EIR, 483, RECALLS LAST 2 YRS	Acknowledgement Letter 11/14/2013

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			CB/		
2013-9150	11/14/2013 12/13/2013	HEARTLAND LIONS EYE BANKS	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	LIFESOURCE, ROSEMONT, IL - EIR, 483, RECALLS LAST 2 YRS	Acknowledgement Letter 11/14/2013
2013-9151	11/14/2013 12/13/2013	HEARTLAND LIONS EYE BANKS	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	MIDWEST TRANSPLANT NETWORK, WESTWOOD, KS - EIR, 483, RECALLS LAST 2 YRS	Acknowledgement Letter 11/14/2013
2013-9152	11/14/2013 12/13/2013	HEARTLAND LIONS EYE BANKS	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	SIGHTLIFE, SEATTLE, WA - EIR, 483, RECALLS LAST 2 YRS	Acknowledgement Letter 11/14/2013
2013-9153	11/14/2013 12/13/2013	HEARTLAND LIONS EYE BANKS	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	MID-AMERICA TRANSPLANT SERVICES, ST LOUIS, MO - EIR, 483, RECALLS LAST 2 YRS	Acknowledgement Letter 11/14/2013
2013-9154	11/14/2013 12/13/2013	HEARTLAND LIONS EYE BANKS	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	IOWA LIONS EYE BANK, CORALVILLE, IA - EIR, 483, RECALLS LAST 2 YRS	Acknowledgement Letter 11/14/2013
2013-9155	11/14/2013 12/13/2013	HEARTLAND LIONS EYE BANKS	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	MIDWEST TRANSPLANT NETWORK, KANSAS CITY, KS - EIR, 483, RECALLS LAST 2 YRS	Acknowledgement Letter 11/14/2013
2013-9156	11/14/2013 12/13/2013	Traditional Medicinals, Inc.	FDA/OFVM/CFSAN/OCD/EOS/	GOLDEN TEMPLE OF OREGON LLC, EASY WEST TEA COMPANY LLC (YOGI TEA) - NOTIFICATION LTRS 1995 TO PRESENT	Acknowledgement Letter 11/14/2013
2013-9157	11/14/2013 12/13/2013	Traditional Medicinals, Inc.	FDA/OFVM/CFSAN/OCD/EOS/	TADIN INC, TADIN HERB AND TEA CO (TADIN AND/OR LIFESTYLE AWARENESS) - NOTIFICATION LTRS 208 TO PRESENT	Acknowledgement Letter 11/14/2013
2013-9158	11/15/2013 12/16/2013	Tracy Johnson-Hall	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	PRODUCT RECALLS FOR FIRMS IN MINNESOTA 01/01/2008 - 12/31/2011	Pending Action 11/15/2013
2013-9159	11/15/2013 12/16/2013	Tracy Johnson-Hall	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	PRODUCT RECALLS FOR FIRMS IN WASHINGTON 01/01/2008 - 12/31/2011	Pending Action 11/15/2013
2013-9160	11/15/2013 12/16/2013	Tracy Johnson-Hall	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	PRODUCT RECALLS FOR FIRMS IN VIRGINIA 01/01/2009 - 12/31/2010	Pending Action 11/15/2013

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Control #	Recd Date / Due Date	Requester	Action Offices	Subject	Status / Status Date
2013-9161	11/15/2013 12/16/2013	Tracy Johnson-Hall	FDA/OGROP/ORAN/NE-FO/NWE-DO/NWE-	PRODUCT RECALLS FOR FIRMS IN VERMONT 01/01/2009 - 12/31/2011	Pending Action 11/15/2013

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Records: 240

Control #	Recd Date / Due Date	Requester	Action Offices	Subject	Status / Status Date
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Records: 240

Control #	Recd Date / Due Date	Requester	Action Offices	Subject	Status / Status Date
2013-9162	11/15/2013 12/16/2013	Tracy Johnson-Hall	FDA/OGROP/ORR/SW-FO/DEN-DO/DEN-	PRODUCT RECALLS FOR FIRMS IN UTAH 01/01/2009 - 12/31/2011	Pending Action 11/15/2013

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Records: 240

Control #	Recd Date / Due Date	Requester	Action Offices	Subject	Status / Status Date
			CB/		
2013-9163	11/15/2013 12/16/2013	Tracy Johnson-Hall	FDA/OGROP/ORPA-FO/SAN-DO/SAN-CB/	PRODUCT RECALLS FOR FIRMS IN NEVADA 01/01/2009 - 12/31/2011	Pending Action 11/15/2013
2013-9164	11/15/2013 12/16/2013	Tracy Johnson-Hall	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	PRODUCT RECALLS FOR FIRMS IN NEW JERSEY 01/01/2008 - 12/31/2011	Pending Action 11/15/2013
2013-9165	11/15/2013 12/16/2013	Tracy Johnson-Hall	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	PRODUCT RECALLS FOR FIRMS IN NEBRASKA 01/01/2008 - 12/31/2011	Pending Action 11/15/2013

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Control #	Recd Date / Due Date	Requester	Action Offices	Subject	Status / Status Date
2013-9166	11/15/2013 12/16/2013	Tracy Johnson-Hall	FDA/OGROP/ORR/NE-FO/NWE-DO/NWE-	PRODUCT RECALLS FOR FIRMS IN NEW HAMPSHIRE 01/01/2009 - 12/31/2010	Pending Action 11/15/2013

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Control #	Recd Date / Due Date	Requester	Action Offices	Subject	Status / Status Date
			CB/		
2013-9167	11/15/2013 12/16/2013	Tracy Johnson-Hall	FDA/OGROP/ORAs/SW-FO/DAL-DO/DAL-CB/	PRODUCT RECALLS FOR FIRMS IN TEXAS 01/01/2008 - 12/31/2011	Pending Action 11/15/2013
2013-9168	11/15/2013 12/16/2013	Tracy Johnson-Hall	FDA/OGROP/ORAs/PA-FO/SEA-DO/SEA-CB/	PRODUCT RECALLS FOR FIRMS IN MONTANA 01/01/2008 - 12/31/2010	Pending Action 11/15/2013
2013-9169	11/15/2013 12/16/2013	Tracy Johnson-Hall	FDA/OGROP/ORAs/CE-FO/MIN-DO/MIN-CB/	PRODUCT RECALLS FOR FIRMS IN WISCONSIN 01/01/2008 - 12/31/2011	Pending Action 11/15/2013
2013-9170	11/15/2013 12/16/2013	Tracy Johnson-Hall	FDA/OGROP/ORAs/SE-FO/NOL-DO/NOL-CB/	PRODUCT RECALLS FOR FIRMS IN TENNESSEE 01/01/2008 - 12/31/2011	Pending Action 11/15/2013
2013-9171	11/15/2013 12/16/2013	Tracy Johnson-Hall	FDA/OGROP/ORAs/SW-FO/KAN-DO/KAN-CB/	PRODUCT RECALLS FOR FIRMS IN MISSOURI 01/01/2008 - 12/31/2011	Pending Action 11/15/2013
2013-9172	11/15/2013 12/16/2013	Tracy Johnson-Hall	FDA/OGROP/ORAs/SE-FO/ATL-DO/ATL-CB/	PRODUCT RECALLS FOR FIRMS IN SOUTH CAROLINA 01/01/2009 - 12/31/2010	Pending Action 11/15/2013
2013-9173	11/15/2013 12/16/2013	Tracy Johnson-Hall	FDA/OGROP/ORAs/SE-FO/NOL-DO/NOL-CB/	PRODUCT RECALLS FOR FIRMS IN MISSISSIPPI 01/01/2009 - 12/31/2011	Pending Action 11/15/2013
2013-9174	11/15/2013 12/16/2013	Tracy Johnson-Hall	FDA/OGROP/ORAs/SW-FO/DAL-DO/DAL-CB/	PRODUCT RECALLS FOR FIRMS IN OKLAHOMA 01/01/2009 - 12/31/2010	Pending Action 11/15/2013
2013-9175	11/15/2013 12/16/2013	Rivkin Radler LLP	FDA/OMPT/CDER/ORP/DIDP/	NDA 019839 - CMC, STABILITY	Closed 11/18/2013
2013-9176	11/15/2013 12/16/2013	Innovative Science Solutions	FDA/OMPT/CDER/ORP/DIDP/	BLA 101995	Withdrawn Closed w/o Charges 11/15/2013
2013-9177	11/15/2013 12/16/2013	Patino & Associates, P.A.	FDA/OFVM/CFSAN/OCDEOS/ FDA/OGROP/ORAs/CE-FO/NWJ-DO/NWJ-CB/	LAMHAM KEMP & BARCLAY, WESTWOOD, NJ - INVESTIGATION RECS,FLORIDA WATER APRVL, RECS, CORR. ETC	Acknowledgement Letter 11/15/2013
2013-9178	11/15/2013 12/16/2013	NIXON PEABODY LLP	FDA/OMPT/CDRH/OCER/DFOI/	CONTACT SURGICAL INC - NUMERIS GUIDED COAGULATION SYS W/VISITRAX MODELS CSK 121, 122, 123, 125 K090202	Acknowledgement Letter 11/15/2013
2013-9179	11/15/2013 12/16/2013	RICHARDS KIBBE & ORBE LLP	FDA/OMPT/CDER/ORP/DIDP/	QUESTCOR PHARMACEUTICALS INC - ACTHAR GEL NDA 22-432	Acknowledgement Letter 11/15/2013
2013-9180	11/15/2013 12/16/2013	CONSUMER REPORTS	FDA/OMPT/CTP/OD/	E CIGARETTES - AER THRU 11/13	Acknowledgement Letter 11/15/2013
2013-9181	11/15/2013 12/16/2013	MORELLI RATNER PC	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	IVIG BLOD PRODUCT W/HEPATITIS - CASE 6288271, 6305352	Acknowledgement Letter 11/15/2013
2013-9182	11/15/2013 12/16/2013	McDONALD LAW FIRM	FDA/OGROP/ORAs/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	BARD PERIPHERAL VASCULAR INC - MDRS, ENFORCEMENT RPTS, MARKETING MATERIALS, ETC	Acknowledgement Letter 11/15/2013



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2013-9183	11/15/2013 12/16/2013	McDONALD LAW FIRM	FDA/OGROP/ORR/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	INTUITIVE SURGICAL INC - MDRS, ENFORCEMENT RTPS, MARKETING MATERIALS, ETC	Acknowledgement Letter 11/15/2013
2013-9184	11/15/2013 12/16/2013	SADAKA ASSOCIATES LLC	FDA/OC/OES/DDM/ FDA/OGROP/ORR/CE-FO/PHI-DO/PHI-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	MERCK - ZOSTAVAX 483, EIR, CO RESP, WARNING LTR 1/17, 2/15, 4/28/08	Acknowledgement Letter 11/15/2013
2013-9185	11/15/2013 12/16/2013	CEPEDA 12R0035, JUNIOR LORENZO	FDA/OFVM/CFSAN/OCD/EOS/ FDA/OMPT/CDER/ORP/DIDP/	EMBREL (ETANERCEPT) - CAERS, INGREDIENTS	Acknowledgement Letter 11/15/2013
2013-9186	11/15/2013 12/16/2013	WARD, JEANIE	FDA/OMPT/CDER/ORP/DIDP/	POLYETHYLENE GLYCOL 3350 - AER	Acknowledgement Letter 11/15/2013