

Query Result Report

Records: 253

Action Office: ALL

Received Via: BOTH

Control #:

Rec/Create Date: 09/23/2013

To 09/27/2013

Track: ALL

Due Date:

To

Signature:

Status Date:

To

Requester:

Requester Type:

Subject:

Status: ALL

Privacy:

Category: ALL

Special Interest: ALL

Entered By:

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Records: 253

Control #	Recd Date / Due Date	Requester	Action Offices	Subject	Status / Status Date
2013-7542	09/23/2013 10/22/2013	Somnarus Inc	FDA/OMPT/CDRH/OCER/DFOI/	K121319, K113862	Pending Action 09/23/2013
2013-7543	09/23/2013 10/22/2013	Grifols Plasmacare	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	GRIFOLS PLASMACARE, TERRE HAUTE, IN - 482, EIR (01/01/2011 - 12/31/2011)	Closed 09/26/2013
2013-7544	09/23/2013 10/22/2013	Thema s.r.l.	FDA/OMPT/CDRH/OCER/DFOI/	K121418	Pending Action 09/23/2013
2013-7545	09/23/2013 10/22/2013	MORGAN, LEWIS & BOCKIUS	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	PFIZER, ROCHESTER, MI - EIR 11/13/2012 - 12/13/2012	Pending Action 09/23/2013
2013-7546	09/23/2013 10/22/2013	MORGAN, LEWIS & BOCKIUS	FDA/OMPT/CDER/ERP/DIDP/	FORMOSA LABORATORIES, TAOYUAN, TAIWAN - 483 05/07/2012 - 05/10/2012	No Record(s) 09/26/2013
2013-7547	09/23/2013 10/22/2013	MORGAN, LEWIS & BOCKIUS	FDA/OMPT/CDER/ERP/DIDP/	FORMOSA LABORATORIES, TAOYUAN, TAIWAN - EIR (05/07/2012 - 05/10/2012)	Closed 09/30/2013
2013-7548	09/23/2013 10/22/2013	BIRCHWOOD LABORATORIES INC	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	OH SO CLEAN, INC, SAN FRANCISCO, CA - RESPONSES, CORRECTIVE ACTION, ETC 09/01/2010 - 07/19/2012	Pending Action 09/23/2013
2013-7549	09/23/2013 10/22/2013	THE NEW YORK TIMES	FDA/OMPT/CDER/ERP/DIDP/	BUPRENORPHINE ADDICTION PRODUCTS - AERS 03/11/2013 - 09/20/2013	Closed 09/26/2013
2013-7550	09/23/2013 10/22/2013	TECHLAB, Inc.	FDA/OMPT/CDRH/OCER/DFOI/	K032222	Pending Action 09/23/2013
2013-7551	09/23/2013 10/22/2013	Greenberg Traurig, P.A.	FDA/OMPT/CDER/ERP/DIDP/	ANDA 077656, ANDA 077658	Closed 09/30/2013
2013-7552	09/23/2013 10/22/2013	Morgan, Lewis & Bockius LLP	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	PFIZER, INC, ROCHESTER, MN - EIR 06/11/2012 - 06/15/2012	Pending Action 09/23/2013
2013-7553	09/23/2013 10/22/2013	Asta Fluidic Technologies, Inc.	FDA/OMPT/CDRH/OCER/DFOI/	K990641, K892241, K071652	Pending Action 09/23/2013
2013-7554	09/23/2013 10/22/2013	Rice Voelker	FDA/OMPT/CDRH/OCER/DFOI/	FDA, MEDSUUN, INTUTIVE SURGICAL - CORR RE SMALL SAMPLE SURVEY OF DA VINCI SURGICAL SYSTEM 05/01/2013 - 09/20/2013	Pending Action 09/23/2013
2013-7555	09/23/2013 10/22/2013	HARVARD UNIVERSITY	FDA/OMPT/CDRH/OCER/DFOI/	PMA WTIH APPROVED PEDIATRIC SUBPOPULATIONS FOR 2012 01/01/2012 - 12/31/2012	Pending Action 09/23/2013

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Control #	Recd Date / Due Date	Requester	Action Offices	Subject	Status / Status Date
2013-7556	09/23/2013 10/22/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORR/NE-FO/NYK-DO/NYK-	GLUTATHIONE CORP, ELMSFORD, NY - 483, CO RESP WARNING LTR, ETC 9/12 TO 10/12	Acknowledgement Letter 09/23/2013

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			DCB/		
2013-7557	09/23/2013 10/22/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORPA-FO/SAN-DO/SAN-CB/	ACCLARENT, MENLO PARK, CA - 483, CO RESP, WARNING LTR, ETC 1/13 TO 2/13	Acknowledgement Letter 09/23/2013
2013-7558	09/23/2013 10/22/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	MEGA SUN INC, ST LOUIS, MO - 483, CO RESP, WARNING LTR, ETC 2/13 TO 3/13	Acknowledgement Letter 09/23/2013
2013-7559	09/23/2013 10/22/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OMPT/CDER/ORP/DIDP/	AGNESIAN HEALTHCARE, FOND DU LAC, WI - 483, CO RESP, WARNING LTR, ETC 11/12	Acknowledgement Letter 09/23/2013

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Control #	Recd Date / Due Date	Requester	Action Offices	Subject	Status / Status Date
2013-7560	09/23/2013 10/22/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORR/NE-FO/NWE-DO/NWE-	BIOCOMPATIBLES INC, OXFORD, CT - 483, CO RESP, WARNING LTR, ETC 2/13 TO 4/13	Acknowledgement Letter 09/23/2013

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Control #	Recd Date / Due Date	Requester	Action Offices	Subject	Status / Status Date
			CB/		
2013-7561	09/23/2013 10/22/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORO/PA-FO/SEA-DO/SEA-CB/	OLYMPIA WOMEN'S HEALTH, OLYMPIA, WA - 483, CO RESP, WARNING LTR, ETC 2/13 TO 3/13	Acknowledgement Letter 09/23/2013
2013-7562	09/23/2013 10/22/2013	WASHINGTON INFORMATION SOURCE	FDA/OMPT/CDER/ORP/DIDP/	HOSPIRA HEALTHCARE INDIA, ARIPERUMBURDUR, INDIA - 483, CO RESP, WARNING LTR, ETC 10/12	Acknowledgement Letter 09/23/2013
2013-7563	09/23/2013 10/22/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORO/PA-FO/SEA-DO/SEA-CB/	PUGET SOUND BLOOD CENTER, SEATTLE, WA - 1/13 TO 2/13	Acknowledgement Letter 09/23/2013
2013-7564	09/23/2013 10/22/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/	FINEMOST CORP, CERRITOS, CA - 483, CO RESP, WARNING LTR 9/12	Acknowledgement Letter 09/23/2013

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Control #	Recd Date / Due Date	Requester	Action Offices	Subject	Status / Status Date
2013-7565	09/23/2013 10/22/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORR/NE-FO/NWE-DO/NWE-	ALEXION PHARMACEUTICALS, CHESHIRE, CT - 483, CO RESP, WARNING LTR, ETC 7/12 TO 8/12	Acknowledgement Letter 09/23/2013

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			CB/		
2013-7566	09/23/2013 10/22/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORPA-FO/SEA-DO/SEA-CB/	MICHAEL RING MD, SPOKANE, WA - 483, CO RESP. WARNING LTR, ETC 7/12 TO 8/12	Acknowledgement Letter 09/23/2013
2013-7567	09/23/2013 10/22/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	AMRESKO, SOLON, OH - 483, CO RESP WARNING LTR, ETC 10/12 TO 12/12	Acknowledgement Letter 09/23/2013
2013-7568	09/23/2013 10/22/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	AIONEX, GOODLETTSVILLE, TN - 483, CO RESP WARNING LTR, ETC 11/12	Acknowledgement Letter 09/23/2013
2013-7569	09/23/2013 10/22/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	ACELL INC, COLUMBIA, MD - 483, CO RESP, WARNING LTR, ETC 11/12 TO 12/12	Closed 09/24/2013
2013-7570	09/23/2013 10/22/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	AUTOMATED OPHTHALMICS, COLUMBIA, MD - 483, CO RESP, WARNING LTR, ETC 2/13 TO 3/13	Acknowledgement Letter 09/23/2013

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Control #	Recd Date / Due Date	Requester	Action Offices	Subject	Status / Status Date
2013-7571	09/23/2013 10/22/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORR/SW-FO/DEN-DO/DEN-	EDWARDS LIFESCIENCES, DRAPER, UT - 483, CO RESP, WARNING LTR, ETC 1/13 TO 2/13	Acknowledgement Letter 09/23/2013

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Control #	Recd Date / Due Date	Requester	Action Offices	Subject	Status / Status Date
			CB/		
2013-7572	09/23/2013 10/22/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORAW-SW-FO/DAL-DO/DAL-CB/	ELECTROMEDICAL PRODUCTS INTERNATIONAL INC, MINERAL WELLS, TX - 483, CO RESP, WARNING LTR, ETC 1/13 TO 2/13	Closed 09/26/2013
2013-7573	09/23/2013 10/22/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORAW-PA-FO/LOS-DO/LOS-CB/	K S CHOI CORP, LOS ANGELES, CA - 483, CO RESP, WARNING LTR, ETC 12/12 TO 2/13	Acknowledgement Letter 09/23/2013
2013-7574	09/23/2013 10/22/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORAW-PA-FO/SEA-DO/SEA-CB/	RIVERPOINT MEDICAL, PORTLAND, OR - 483, CO RESP, WARNING LTR, ETC 1/13 TO 2/13	Acknowledgement Letter 09/23/2013
2013-7575	09/23/2013 10/22/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORAW-CE-FO/BLT-DO/BLT-CB/	VALLEY HEALTH WINCHESTER MEDICAL CENTR IRB, WINCHESTER, VA - 483, CO RESP WARNING LTR, ETC 1/13 TO 2/13	Closed 09/24/2013
2013-7576	09/23/2013 10/22/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORAW-CE-FO/NWJ-DO/NWJ-CB/	CISPHARMA, CRANBURY, NJ - 483, CO RESP, WARNING LTR, ETC 3/12 TO 4/12	Acknowledgement Letter 09/23/2013
2013-7577	09/23/2013 10/22/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORAW-CE-FO/CHI-DO/CHI-CB/	ALMA LASERS INC, BUFFALO GROVE, IL - 483, CO RESP, WARNING LTR, ETC 1/13	Closed 09/27/2013
2013-7578	09/23/2013 10/22/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORAW-PA-FO/LOS-DO/LOS-CB/	ALPHA MEDICAL INSTRUMENTS, MISSION VIEJO, CA - 483, CO RESP, WARNING LTR, ETC 12/12 TO 1/13	Acknowledgement Letter 09/23/2013

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Control #	Recd Date / Due Date	Requester	Action Offices	Subject	Status / Status Date
2013-7579	09/23/2013 10/22/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORR/NE-FO/NYK-DO/NYK-	TRANSONIC SYSTEMS INC, ITHACA, NY - 483, CO RESP, WARNING LTR, ETC 2/13 TO 3/13	Acknowledgement Letter 09/23/2013

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			DCB/		
2013-7580	09/23/2013 10/22/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	BIOMEDIX INC, BLOOMINGTON, IN - 483, CO RESP, WARNING LTR 2/13 TO 3/13	Closed 09/27/2013
2013-7581	09/23/2013 10/22/2013	WELLS FARGO	FDA/OMPT/CDER/ORP/DIDP/	KALYDECO, JAKAFI, TECFIDERA, ETC - AERS 07/01/2013 - 09/30/2013	Closed 09/30/2013
2013-7582	09/23/2013 10/22/2013	Malhotra, Neil	FDA/OMPT/CDER/ORP/DIDP/	CM-AT - EFFICACY, ADVERSE EVENTS 09/01/2010 - 09/23/2013	Closed Denial 09/30/2013
2013-7583	09/23/2013 10/22/2013	HUES, TOLEDO .	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	COAPT SYSTEMS - NOVIELLE GEL CLNCL TRIALS, AER	Acknowledgement Letter 09/23/2013
2013-7584	09/23/2013 10/22/2013	MILLENNIUM MANAGEMENT LLC	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDER/ORP/DIDP/	NPS PHARMACEUTICALS - GATTEX FAERS, EIR, 483, UNTITLED LTRS	Partial Response 09/26/2013

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Control #	Recd Date / Due Date	Requester	Action Offices	Subject	Status / Status Date
2013-7585	09/23/2013 10/22/2013	MILLENNIUM MANAGEMENT LLC	FDA/OGROP/ORR/NE-FO/NWE-DO/NWE-	AEGERION PHARMACEUTICALS INC - JUXTAPID (LOMITAPIDE) AER, EIR, 483, UNTITLED LTRS	Partial Response 09/26/2013

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			CB/ FDA/OMPT/CDER/ORP/DIDP/		
2013-7586	09/23/2013 10/22/2013	MILLENNIUM MANAGEMENT LLC	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	ISIS PHARMACEUTICALS INC - 483, EIR, UNTITLED LTRS 1/13 TO PRESENT	No Record(s) 09/24/2013
2013-7587	09/23/2013 10/22/2013	MILLENNIUM MANAGEMENT LLC	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	SEATTLE GENETICS INC - EIR, 483, UNTITLED LTRS 4/13 TO PRESENT	Acknowledgement Letter 09/23/2013
2013-7588	09/23/2013 10/22/2013	MILLENNIUM MANAGEMENT LLC	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	THERAPEUTICS INC - EIR, 483, UNTITLED LTRS 1/10 TO PRESENT	No Record(s) 09/24/2013
2013-7589	09/23/2013 10/22/2013	FDANEWS	FDA/OC/OES/DFOI/	FOIA REQUEST LOG 09/16/2013 - 09/20/2013	Closed 09/27/2013
2013-7590	09/23/2013 10/22/2013	MILLENNIUM MANAGEMENT LLC	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDER/ORP/DIDP/	DEPOMED - GRALISE (GABAPENTIN) FAERS, UNTITLED LTRS 1/11 TO PRESENT	Partial Response 09/25/2013
2013-7591	09/23/2013 10/22/2013	DEERFIELD INSTITUTE	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	BIOGEN IDEC INC - 483	Acknowledgement Letter 09/23/2013

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Control #	Recd Date / Due Date	Requester	Action Offices	Subject	Status / Status Date
2013-7592	09/23/2013 10/22/2013	ELI LILLY & CO	FDA/OGROP/ORR/NE-FO/NWE-DO/NWE-	DYAX CORP, CAMBRIDGE, MA - 483 7/11	Acknowledgement Letter 09/23/2013

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Control #	Recd Date / Due Date	Requester	Action Offices	Subject	Status / Status Date
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2013-7593	09/23/2013 10/22/2013	KYRIAKIDIS., JOANNA	ORA/	AMERIDOSE LLC, WESTBOROUGH, MA - EIR	Closed Denial 09/30/2013
2013-7594	09/23/2013 10/22/2013	LONDON, DAVID	ORA/OCI/	INDIVIDUAL RECS	Acknowledgement Letter 09/23/2013
2013-7595	09/23/2013 10/22/2013	WALLACE III EM3049, JOSEPH	FDA/OMPT/CDER/ORP/DIDP/	RITALIN - AER	Closed 09/30/2013
2013-7596	09/23/2013 10/22/2013	HAWKINS, DIANA	FDA/OMPT/CDER/ORP/DIDP/	MEDWATCH RPT	Closed 09/30/2013
2013-7597	09/23/2013 10/22/2013	HAGANS BERMAN ET AL	FDA/OO/OFBA/OAGS/	ASTELLAS PHARMA INC - PROGRAF (TACROLIMUS) DOCS	Acknowledgement Letter 09/23/2013
2013-7598	09/23/2013 10/22/2013	FRANCIS, ANA	FDA/OF/CFSAN/OCD/EOS/	LTR FROM UNITED TO FDA	Acknowledgement Letter 09/23/2013
2013-7599	09/23/2013 10/22/2013	HOGAN LOVELLS LLP	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	IVERA MEDICAL CORP - INVESTIGATIONS	Acknowledgement Letter 09/23/2013
2013-7600	09/23/2013 10/22/2013	THOMAS THOMAS & HAFER	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	GPR CO, ROYERSFORD, PA - INVESTIGATIONS, CORR	Acknowledgement Letter 09/23/2013
2013-7601	09/23/2013 10/22/2013	CONWAY, HOMER & CHIN-CAPLAN PC	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	INDIVIDUAL RECS	Acknowledgement Letter 09/23/2013
2013-7602	09/23/2013 10/22/2013	MORRISON MAHONEY LLP	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	ENDO WRIST HOT SHEARS - RECALL	Acknowledgement Letter 09/23/2013
2013-7603	09/23/2013 10/22/2013	FOREST RESEARCH INSTITUTE	FDA/OMPT/CDER/ORP/DIDP/	AMITIZA (LUBIPROSTONE) NDA 21-908/S-011 APRVL	Acknowledgement Letter 09/23/2013
2013-7604	09/23/2013 10/22/2013	ITC	FDA/OMPT/CDRH/OCER/DFOI/	PRO TIME - MICROCOAGULATION SYS K961835	Closed 09/26/2013
2013-7605	09/23/2013 10/22/2013	SKERTIC, MARK	FDA/OC/OES/DFOI/	2006-9732, 2008-7899, 2012-6322 ETC	Closed 09/26/2013
2013-7606	09/24/2013 10/23/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	HAIR LABS INC, NASHVILLE, TN - 483, CO RESP, WARNING LTR, ETC 4/13	Acknowledgement Letter 09/24/2013

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Control #	Recd Date / Due Date	Requester	Action Offices	Subject	Status / Status Date
2013-7607	09/24/2013 10/23/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORR/NE-FO/NWE-DO/NWE-	CONAIR CORP, STAMFORD, CT - 483, CO RESP, WARNING LTR, ETC 5/13	Acknowledgement Letter 09/24/2013

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Control #	Recd Date / Due Date	Requester	Action Offices	Subject	Status / Status Date
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2013-7608	09/24/2013 10/23/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	LIFESERVE BLOOD CENTER, DES MOINES, IA - 483, CO RESP, WARNING LTR, ETC 6/13	Acknowledgement Letter 09/24/2013
2013-7609	09/24/2013 10/23/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	LUMIQUICK DIAGNOSTICS INC, SANTA CLARA, CA - 483, CO RSP, WARNING LTR, ETC 11/12 TO 12/12	Acknowledgement Letter 09/24/2013
2013-7610	09/24/2013 10/23/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	ZEPPESSIS REPROCESSING LLC, GARDEN CITY, ID - 483, CO RESP, WARNING LTR, ETC 4/13	Acknowledgement Letter 09/24/2013
2013-7611	09/24/2013 10/23/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	PETER SCHIFF ENTERPRISES, COOKEVILLE, TN - 483, CO RESP, WARNING LTR, ETC 3/13 TO 4/13	Acknowledgement Letter 09/24/2013
2013-7612	09/24/2013 10/23/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	AMRESCO, SOLON, OH - EIR, RESP, CORR 10/12 TO 12/12	Acknowledgement Letter 09/24/2013
2013-7613	09/24/2013 10/23/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	AIONEX, GOODLETTSVILLE, TN - EIR, RESP, CORR 11/12	Acknowledgement Letter 09/24/2013
2013-7614	09/24/2013 10/23/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	RIVERPOINT MEDICAL, PORTLAND, OR - EIR, RESP, CORR 1/13 TO 2/13	Acknowledgement Letter 09/24/2013
2013-7615	09/24/2013 10/23/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	K S CHOI CORP, LOS ANGELES, CA - EIR, RESP, CORR 12/12 TO 2/13	Closed Denial 09/30/2013
2013-7616	09/24/2013 10/23/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	FINEMOST CORP, CERRITOS, CA - EIR, RESP, CORR 9/12	Acknowledgement Letter 09/24/2013

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2013-7617	09/24/2013 10/23/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORR/NE-FO/NWE-DO/NWE-	GYRUS ACMI, STAMFORD, CT - EIR, RESP, CORR 7/12 TO 8/12	Acknowledgement Letter 09/24/2013

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2013-7618	09/24/2013 10/23/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORR/NE-FO/NYK-DO/NYK-	GLUTATHIONE CORP, ELMSFORD, NY - EIR, RESP, CORR 9/12 TO 10/12	Acknowledgement Letter 09/24/2013

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2013-7619	09/24/2013 10/23/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORR/NE-FO/NWE-DO/NWE-	ALEXION PHARMS, CHESHIRE, CT - EIR, RESP, CORR 7/12 TO 8/12	Acknowledgement Letter 09/24/2013

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			CB/		
2013-7620	09/24/2013 10/23/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORPA/FO/SEA-DO/SEA-CB/	MICHAEL RING MD, SPOKANE, WA - EIR, RESP, CORR 7/12 TO 8/12	Acknowledgement Letter 09/24/2013
2013-7621	09/24/2013 10/23/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORPA/FO/SEA-DO/SEA-CB/	PARKS MEDICAL ELECTRONIC, ALOHA, OR - 483, CO RESP, WARNING LTR, ETC 7/12 TO 8/12	Acknowledgement Letter 09/24/2013
2013-7622	09/24/2013 10/23/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	LIFEWATCH SERVICES, ROSEMONT, IL - 483, CO RESP, WARNING LTR, ETC 8/12 TO 9/12	Acknowledgement Letter 09/24/2013
2013-7623	09/24/2013 10/23/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORPA/FO/SEA-DO/SEA-CB/	BACTERIN INTERNATIONAL, BELGRADE, MT - 483, CO RESP, WARNING LTR, ETC 7/12	Acknowledgement Letter 09/24/2013
2013-7624	09/24/2013 10/23/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	ABBEY COLOR, PHILADELPHIA, PA - 483, CO RESP, WARNING LTR, ETC 3/12	Acknowledgement Letter 09/24/2013
2013-7625	09/24/2013 10/23/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	SOVEREIGN PHARM, FORT WORTH, TX - 483, CO RESP, WARNING LTR, ETC 1/12 TO 2/12	Acknowledgement Letter 09/24/2013
2013-7626	09/24/2013 10/23/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	JANET K TILLISCH MD, FARGO, ND - 483, CO RESP, WARNING LTR, ETC 4/13	Partial Response 09/30/2013
2013-7627	09/24/2013 10/23/2013	WASHINGTON INFORMATION SOURCE	FDA/OMPT/CDER/ORP/DIDP/	WOCKHARDT LTD, AURANGABAD, INDIA - 483, CO RESP, WARNING LTR, ETC 3/13	Acknowledgement Letter 09/24/2013
2013-7628	09/24/2013 10/23/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORPA/FO/SAN-DO/SAN-CB/	INTUITIVE SURGICAL INC, SUNNYVALE, CA - 483, CO RESP, WARNING LTR, ETC 4/13 TO 5/13	Acknowledgement Letter 09/24/2013
2013-7629	09/24/2013 10/23/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	STEWART COMPUNDING PHARMACY, FAYETTEVILLE, NC - 483, CO RESP, WARNING LTR, ETC 3/13	Acknowledgement Letter 09/24/2013
2013-7630	09/24/2013 10/23/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	ANSAR GROUP, PHILADELPHIA, PA - 483, CO RESP, WARNING LTR, ETC 5/12 TO 6/12	Acknowledgement Letter 09/24/2013
2013-7631	09/24/2013 10/23/2013	OUTWATER & PINCKES LLP	FDA/OMPT/CDRH/OCER/DFOI/	APOGEE - POLYETHYLENE AND PET BOTTLES AND CONTAINERS INVESTIGATIONS, TESTING, LAB RPTS, ETC	Acknowledgement Letter 09/24/2013
2013-7632	09/24/2013 10/23/2013	X-GEN PHARMACEUTICALS INC	FDA/OMPT/CDER/ORP/DIDP/	INDOCO REMEDIES LTD, GOA, INDIA - DRUG PROD DOSAGE FORMS, INSPECTIONAL STATUS, INSPS LAST 3 YRS	Acknowledgement Letter 09/24/2013
2013-7633	09/24/2013 10/23/2013	Lytle, Robert	OC/OCC/	LAWS, RULES, REGULATIONS ETC WHICH FDA USES TO SUPPORT THE CLAIM THAT THE FDA DOES NOT RECOGNIZE PRIVATE MEMBERSHIP ASSOCIATIONS	Acknowledgement Letter 09/24/2013

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2013-7634	09/24/2013 10/23/2013	STUTE, HANK	FDA/OMPT/CDRH/OCER/DFOI/	PARAGON VISION SCIENCES - CPT1200119	Acknowledgement Letter 09/24/2013
2013-7635	09/24/2013 10/23/2013	IOVATE HEALTH SCIENCES INTERNATIONAL INC	FDA/OC/OES/DFOI/	CAERS 167755, 165500, 165504	Closed (Fee-related) 09/25/2013
2013-7636	09/24/2013 10/23/2013	TARASUK, JOHN	FDA/OO/OFBA/OAGS/	ROBERT WOTKOWSKI, KEYSTONE PROPERTY RESOURCES INC; MAURICE ELECTRIC - CONTRACT RECS	Acknowledgement Letter 09/24/2013
2013-7637	09/24/2013 10/23/2013	GOODWIN PROCTER LLP	FDA/OMPT/CDRH/OCER/DFOI/	PARKER HANNIFIN CORP - INDEGO EXOSKELETON RECS	Acknowledgement Letter 09/24/2013
2013-7638	09/24/2013 10/23/2013	ASCEND CAPITAL LLC	FDA/OMPT/CDRH/OCER/DFOI/	INSULET CORP - OMNIPOD MDRS 1/13 TO PRESENT	Acknowledgement Letter 09/24/2013

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Control #	Recd Date / Due Date	Requester	Action Offices	Subject	Status / Status Date
2013-7639	09/24/2013 10/23/2013	ACTITECH	FDA/OGROP/ORR/SW-FO/DEN-DO/DEN-	INNOVATIVE FLEXPAK, SPRINGVILLE, UT - REGISTRATION TYPE, STATUS, AUDIT RPTS	Acknowledgement Letter 09/24/2013

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			CB/		
2013-7640	09/24/2013 10/23/2013	ABBOTT POINT OF CARE INC	FDA/OMPT/CDRH/OCER/DFOI/	TAS PT ONE TEST CARD K955843; COAG-1 PT TEST CARD K882456; COAG-1 PT-NC TEST CARD K904325, ETC	Acknowledgement Letter 09/24/2013
2013-7641	09/24/2013 10/23/2013	ALLTECH INC	CVM/OCD/ FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/	DIAMOND V, CEDAR RAPIDS, IA - CORR 7/13 TO 8/13	Acknowledgement Letter 09/24/2013
2013-7642	09/24/2013 10/23/2013	ALLTECH INC	CVM/OCD/ FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/	PURINA ANIMAL NUTRITION LLC, ST LOUIS, MO - 483S, CORR LAST TEN YRS	Acknowledgement Letter 09/24/2013
2013-7643	09/24/2013 10/23/2013	REXAM HEALTHCARE	FDA/OMPT/CDER/ORP/DIDP/	REXAM - ACKNOWLEDGEMENT LTRS FOR TYPE III DMFS	Acknowledgement Letter 09/24/2013
2013-7644	09/25/2013 10/24/2013	KIPA AB	FDA/OMPT/CDRH/OCER/DFOI/	PMA P000039	Pending Action 09/25/2013
2013-7645	09/25/2013 10/24/2013	Karl Gallegos	FDA/OMPT/CDER/ORP/DIDP/	MINOCYCLINE - FAERS	Closed 09/27/2013
2013-7646	09/25/2013 10/24/2013	DISCOVERY CAPITAL MANAGEMENT	FDA/OMPT/CDER/ORP/DIDP/	REGADENOSCAN - FAERS	Closed 09/27/2013
2013-7647	09/25/2013 10/24/2013	STRYKER SUSTAINABILITY SOLUTIONS	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	K101797	Closed 09/26/2013
2013-7648	09/25/2013 10/24/2013	ICRS, LLC	FDA/OF/CFSAN/OCD/EOS/	PAFA DATABASED DATA 09/01/1980 - 08/30/2013	Pending Action 09/25/2013
2013-7649	09/25/2013 10/24/2013	Chen, Coco	FDA/OMPT/CDER/ORP/DIDP/	BRILACIDIN - PHASE 1 AND PHASE 2 CLINICAL STUDY RESULTS	Pending Action 09/25/2013
2013-7650	09/25/2013 10/24/2013	Bionova Medical	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	K060046	Closed 09/26/2013
2013-7651	09/25/2013 10/24/2013	N/A	FDA/OMPT/CDER/ORP/DIDP/	INTERMUNE - AERS	Pending Action 09/25/2013
2013-7652	09/25/2013 10/24/2013	FITZPATRICK CELLA HARPER & SCINTO	FDA/OMPT/CDRH/OCER/DFOI/	K971819	Pending Action 09/25/2013
2013-7653	09/25/2013 10/24/2013	Insys Therapeutics, Inc.	FDA/OMPT/CDER/ORP/DIDP/	NDA 204242 - SBA	Withdrawn Closed w/o Charges 09/25/2013
2013-7654	09/25/2013 10/24/2013	CANTOR FITZGERALD	FDA/OMPT/CDER/ORP/DIDP/	LINZESS - FAERS	Closed 09/27/2013

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Control #	Recd Date / Due Date	Requester	Action Offices	Subject	Status / Status Date
2013-7655	09/25/2013 10/24/2013	Drug Regulations	FDA/OMPT/CDER/ORP/DIDP/	USV LIMITED, INDIA - 483 01/01/2013 - 09/24/2013	Closed 09/30/2013
2013-7656	09/25/2013 10/24/2013	FOI Services, Inc.	FDA/OMPT/CDRH/OCER/DFOI/	K100831	Pending Action 09/25/2013
2013-7657	09/25/2013 10/24/2013	FOI Services, Inc.	FDA/OMPT/CDRH/OCER/DFOI/	K112394	Pending Action 09/25/2013
2013-7658	09/25/2013 10/24/2013	TECHLAB, Inc.	FDA/OMPT/CDRH/OCER/DFOI/	K023599	Pending Action 09/25/2013
2013-7659	09/25/2013 10/24/2013	Hapten Pharmaceuticals, LLC	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/OSMP/OOPD/	CEPTARIS - APPROVAL RECS 01/01/2004 - 09/01/2013	Pending Action 09/25/2013
2013-7660	09/25/2013 10/24/2013	Orthospace Ltd	FDA/OMPT/CDRH/OCER/DFOI/	K121216	Pending Action 09/25/2013
2013-7661	09/25/2013 10/24/2013	Quad Capital	FDA/OMPT/CDRH/OCER/DFOI/ ORA/	ICU MEDICAL, INC - CONSUMER COMPLAINTS 01/01/2007 - 09/24/2013	Pending Action 09/25/2013
2013-7662	09/25/2013 10/24/2013	Soltec ventures	FDA/OF/CFSAN/OCD/EOS/ ORA/	ALDRICH CHEMICAL CO - IMPORT RECS FOR SEA SNAIL	Pending Action 09/25/2013
2013-7663	09/25/2013 10/24/2013	Blessing-Maire, Kelly A	FDA/OMPT/CDER/ORP/DIDP/	VICTOZA - AERS	Closed 09/27/2013
2013-7664	09/25/2013 10/24/2013	UNIVERSITY OF BRITISH COLUMBIA	FDA/OC/OES/DFOI/	FOIA REQUEST LOG 01/01/2004 - 08/31/2013	Closed 09/25/2013
2013-7665	09/25/2013 10/24/2013	Chen, Coco	FDA/OMPT/CDER/ORP/DIDP/	KEVETRIN - PHAES I CLINICAL TRIALS, ADVERSE EVENTS	Closed Denial 09/30/2013
2013-7666	09/25/2013 10/24/2013	Mangrove Partners	FDA/OMPT/CDER/ORP/DIDP/	TAKEDA - CORR WITH FDA RE OMONTYS, PEGINESATIDE	Closed 09/27/2013
2013-7667	09/25/2013 10/24/2013	BLOOMBERG NEWS	FDA/OMPT/CDER/ORP/DIDP/	SUN PHARMACEUTICAL INDUSTRIES LTD, CARACO PHARMACEUTICAL LABORATORIES (09/23/2011 - 09/24/2013)	Pending Action 09/25/2013

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Control #	Recd Date / Due Date	Requester	Action Offices	Subject	Status / Status Date
2013-7668	09/25/2013 10/24/2013	DUKE UNIVERSITY	FDA/OGROP/ORR/NE-FO/NYK-DO/NYK-	OHSAWA FOUNDATION, NY, NY - INSPECTION RECS 01/01/1960 - 01/01/1970	Pending Action 09/25/2013

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			DCB/		
2013-7669	09/25/2013 10/24/2013	DUKE UNIVERSITY	FDA/OGROP/ORR/PA-FO/SAN-DO/SAN-CB/	NEW AGE NATURAL FOODS STORE, SAN FRANCISCO, CA - INSPECTION RECS 01/01/1964 - 12/31/1973	Pending Action 09/25/2013
2013-7670	09/25/2013 10/24/2013	MORNINGSTAR COSULTING INC	FDA/OF/CFSAN/OCD/EOS/	MONSTER ENERGY DRINKS - AERS	Pending Action 09/25/2013
2013-7671	09/25/2013 10/24/2013	FOI Services, Inc.	FDA/OGROP/ORR/CE-FO/BLT-DO/BLT-CB/	LORILLARD TOBACCO, DANVILLE, VA - INSPECTOR DIARIES	Pending Action 09/25/2013

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Control #	Recd Date / Due Date	Requester	Action Offices	Subject	Status / Status Date
2013-7672	09/25/2013 10/24/2013	Ascension Technology Corporation	FDA/OGROP/ORR/NE-FO/NWE-DO/NWE-	ASCENSION TECHNOLOGY CORPORATION, SHELBURNE, VT - INVESTIGATION STATUS	Pending Action 09/25/2013

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Control #	Recd Date / Due Date	Requester	Action Offices	Subject	Status / Status Date
			CB/		
2013-7673	09/25/2013 10/24/2013	Prirista	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ORP/DIDP/	SHIRE, LEXINGTON, MA - BIOLOGICS PRODUCT DEVIATION REPORTS 09/01/2012 - 09/23/2013	Pending Action 09/25/2013
2013-7674	09/25/2013 10/24/2013	Brian Lemasters	FDA/OMPT/CDRH/OCER/DFOI/	INSPIRE-MD - ADVERSE EVENTS, 483 1/01/2010 - 09/22/2013	Pending Action 09/25/2013
2013-7675	09/25/2013 10/24/2013	STRELECKI, SAMUEL J	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	IRONWOOD CANCER AND RESEARCH CENTER, DR MIKHAIL SHTIVELBAND 03/01/2012 - 12/31/2012	Pending Action 09/25/2013
2013-7676	09/25/2013 10/24/2013	Shapiro Capital Management	FDA/OMPT/CDER/ORP/DIDP/	MALLINKRODT PHARMACEUTICALS MNK-395 - NDA	Closed Denial 09/30/2013
2013-7677	09/25/2013 10/24/2013	Catapult. Ltd.	FDA/OMPT/CDER/ORP/DIDP/	JETREA - AERS	Closed 09/27/2013

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Control #	Recd Date / Due Date	Requester	Action Offices	Subject	Status / Status Date
2013-7678	09/25/2013 10/24/2013	DUKE UNIVERSITY	FDA/OGROP/ORR/NE-FO/NWE-DO/NWE-	EREWHON TRADING CO - INSPECTION RECS 01/01/1966 - 12/31/1973	No Record(s) 09/27/2013

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Control #	Recd Date / Due Date	Requester	Action Offices	Subject	Status / Status Date
			CB/		
2013-7679	09/25/2013 10/24/2013	Wilson Sonsini Goodrich & Rosati, P.C.	FDA/OMPT/CDER/ORP/DIDP/	MECHLORETHAMINE HYDROCHLORIDE - APPROVAL HISTORY	Closed 09/30/2013
2013-7680	09/25/2013 10/24/2013	UNIVERSITY OF FLORIDA	FDA/OC/OES/DFOI/	FOIA REQUEST LOG 01/01/2008 - 08/01/2013	Closed 09/25/2013
2013-7681	09/25/2013 10/24/2013	Pura Vida Investments	FDA/OMPT/CDRH/OCER/DFOI/	JUXTAPED, KYNAMRO - AERS	Pending Action 09/25/2013
2013-7682	09/25/2013 10/24/2013	FOI Services, Inc.	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	AMERICAN SNUFF - EXHIBITS 10/3/2011	Pending Action 09/25/2013
2013-7683	09/25/2013 10/24/2013	OLSSON FRANK WEEDA TERMAN MATZ PC	FDA/OF/CFSAN/OCD/EOS/ ORA/	CADMIUM IN CHOCOLATE - SAFETY ASSESSMENT MEMO & RPT 9/18/13	Closed 09/26/2013
2013-7684	09/25/2013 10/24/2013	CAROLLO, RUSSELL	FDA/OMPT/CTP/OD/ OC/OEXA/OPA/	SERVICES, COUNSEL, ADVICE PROVIDED BY GOOGLE - CORR, FOIA REQUESTS, TRAVEL RECS, ETC	Acknowledgement Letter 09/25/2013
2013-7685	09/25/2013 10/24/2013	PRICE, GRETA S	FDA/OC/OES/DFOI/	INDIVIDUAL RECS	No Record(s) 09/25/2013
2013-7686	09/25/2013 10/24/2013	Keller and Heckman LLP	FDA/OF/CFSAN/OCD/EOS/	NIPPON STEEL & SUMITOMO METAL CORP - FCN 1253	Acknowledgement Letter 09/25/2013
2013-7687	09/25/2013 10/24/2013	RENE MEDICAL	FDA/OMPT/CDRH/OCER/DFOI/	FLOWMEDICA INC - BENEPHIT BIFURCATED INFUSION CATHETER, BENEPHIT 5FR INTRODUCER SHEATH SYS K050205	Acknowledgement Letter 09/25/2013
2013-7688	09/25/2013 10/24/2013	RENE MEDICAL	FDA/OMPT/CDRH/OCER/DFOI/	FLOWMEDICA INC - BENEPHIT INFUSION SYS K082163	Acknowledgement Letter 09/25/2013
2013-7689	09/25/2013 10/24/2013	DAVID ROSEN & ASSOCIATES PC	FDA/OMPT/CDRH/OCER/DFOI/	MAQUET CADRIOPULMONARY AG - QUADROX ID DIFFUSION MEMBRANE OXYGENATOR K112360 RECS 1/11 TO 12/11	Acknowledgement Letter 09/25/2013
2013-7690	09/25/2013 10/24/2013	DAVID ROSEN & ASSOCIATES PC	FDA/OGROP/ORR/CE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDRH/OCER/DFOI/	MAQUET CARDIOPULMONARY AG, MAQUET CARDIOVASCULAR LLC - EIRS. 483S. WARNING LTRS, ETC	Acknowledgement Letter 09/25/2013
2013-7691	09/25/2013 10/24/2013	DAVID ROSEN & ASSOCIATES PC	FDA/OGROP/ORR/CE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDRH/OCER/DFOI/	MAQUET CARDIOPULMOMARY AG - QUADROX ID DIFFUSION MEMBRANE OXYGENATOR RECALL RECS,CORR, RVWS, ETC	Acknowledgement Letter 09/25/2013
2013-7692	09/25/2013 10/24/2013	DAVID ROSEN & ASSOCIATES PC	FDA/OMPT/CDRH/OCER/DFOI/	MAQUET CARDIOPULMONARY AG - QUADROX ID DIFFUSION MEMBRANE OXYGENATOR K101153	Acknowledgement Letter 09/25/2013

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2013-7693	09/25/2013 10/24/2013	BROOKS RAND LABS	FDA/OF/CFSAN/OCD/EOS/	RICE DATA EXCEL FORMAT	Acknowledgement Letter 09/25/2013
2013-7694	09/25/2013 10/24/2013	HILL, MELISSA D	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	INDIVIDUAL RECS	Hold 09/26/2013
2013-7695	09/25/2013 10/24/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORR/PA-FO/SEA-DO/SEA-CB/	OLYMPIA WOMENS HEALTH, OLYMPIA, WA - EIR, CO RESP 2/13 TO 3/13	Acknowledgement Letter 09/25/2013
2013-7696	09/25/2013 10/24/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	BIOMERIEUX, DURHAM, NC - EIRS, RESP, CORR 1/12 TO 3/12	Acknowledgement Letter 09/25/2013
2013-7697	09/25/2013 10/24/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/	CELLETEX THERAPEUTICS, SUGARLAND, TX - EIRS, RESP, CORR 4/12	Acknowledgement Letter 09/25/2013
2013-7698	09/25/2013 10/24/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORR/PA-FO/SEA-DO/SEA-CB/	PUGET SOUND BLOOD CENTER, SEATTLE, WA - 1/13 TO 2/13	Acknowledgement Letter 09/25/2013

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2013-7699	09/25/2013 10/24/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORR/SW-FO/DEN-DO/DEN-	WESTONE LABORATORIES, COLORADO SPRINGS, CO - EIR, CO RESP 7/12	Acknowledgement Letter 09/25/2013

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			CB/		
2013-7700	09/25/2013 10/24/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/OR/SE-FO/FLA-DO/FLA-CB/	NEXERA MEDICAL, FORT LAUDERDALE, FL - EIR, CO RESP 7/12	Acknowledgement Letter 09/25/2013
2013-7701	09/25/2013 10/24/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/OR/CE-FO/MIN-DO/MIN-CB/	COCOKEFIR LLC, MEDINA, MN - EIR, CO RESP 5/12	Acknowledgement Letter 09/25/2013
2013-7702	09/25/2013 10/24/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/OR/SE-FO/NOL-DO/NOL-CB/	TISSUE BANK INT'L, MEMPHIS, TN - 483, CO RESP, WARNING LTR 6/12	Acknowledgement Letter 09/25/2013
2013-7703	09/25/2013 10/24/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/OR/CE-FO/NWJ-DO/NWJ-CB/	LAKEWOOD LLC, LAKEWOOD, NJ - EIRS, RESP, CORR 2/12 TO 3/12	Acknowledgement Letter 09/25/2013
2013-7704	09/25/2013 10/24/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/OR/CE-FO/PHI-DO/PHI-CB/	MIR-COM PRODUCTS, CENTRAL CITY, PA - EIR, RESP, CORR 6/12	Acknowledgement Letter 09/25/2013
2013-7705	09/25/2013 10/24/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/OR/CE-FO/CHI-DO/CHI-CB/	MARTIN S BALIN MD, CHICAGO, IL - EIR, RESP, CORR 6/12 TO 8/12	Acknowledgement Letter 09/25/2013
2013-7706	09/25/2013 10/24/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/OR/CE-FO/MIN-DO/MIN-CB/	COCOKEFIR LLC, MEDINA, MN - 483, CO RESP, WARNING LTR 5/12	Acknowledgement Letter 09/25/2013
2013-7707	09/25/2013 10/24/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/OR/SE-FO/FLA-DO/FLA-CB/	NEXERA MEDICAL, FORT LAUDERDALE, FL - 483, CO RESP, WARNING LTR 7/12	Acknowledgement Letter 09/25/2013

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2013-7708	09/25/2013 10/24/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORR/SW-FO/DEN-DO/DEN-	WESTONE LABORATORIES, COLORADO SPRINGS, CO - 483, CO RESP, WARNING LTR 7/12	Acknowledgement Letter 09/25/2013

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Control #	Recd Date / Due Date	Requester	Action Offices	Subject	Status / Status Date
			CB/		
2013-7709	09/25/2013 10/24/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/	PERFORMANCE PRODUCTS, ST LOUIS, MO - 483, CO RESP, WARNING LTR 7/12	Acknowledgement Letter 09/25/2013
2013-7710	09/25/2013 10/24/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORR/CE-FO/CHI-DO/CHI-CB/	MARTIN A BALIN MD, CHICAGO, IL - 483, CO RESP, WARNING LTR 6/12 TO 8/12	Acknowledgement Letter 09/25/2013

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Control #	Recd Date / Due Date	Requester	Action Offices	Subject	Status / Status Date
2013-7711	09/25/2013 10/24/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORR/NE-FO/NWE-DO/NWE-	GYRUS ACMI, STAMFORD, CT - 483, CO RESP, WARNING LTR 7/12 TO 8/12	Acknowledgement Letter 09/25/2013

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			CB/		
2013-7712	09/25/2013 10/24/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	STATRX USA, GAINESVILLE, GA - 483, CO RESP, WARNING LTR 2/12	Acknowledgement Letter 09/25/2013
2013-7713	09/25/2013 10/24/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	I SHAY COSMETICS, GARDEN, CA - 483, CO RESP, WARNING LTR 2/12	Acknowledgement Letter 09/25/2013

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2013-7714	09/25/2013 10/24/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORR/NE-FO/NWE-DO/NWE-	BIOCOMPATIBLES INC, OXFORD, CT - EIR, CO RESP 2/13 TO 4/13	Acknowledgement Letter 09/25/2013

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Control #	Recd Date / Due Date	Requester	Action Offices	Subject	Status / Status Date
			CB/		
2013-7715	09/25/2013 10/24/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	AGNESIAN HEALTHCARE, FOND DU LAC, WI - EIR, CO RESP 11/12	Acknowledgement Letter 09/25/2013
2013-7716	09/25/2013 10/24/2013	Japan Asia Clinical Research Product Creation Unit, Eisai Co., Ltd	FDA/OMPT/CDER/ORP/DIDP/	CLINICAL INVESTIGATORS - 483 (01/01/2008 - 09/25/2013)	Pending Action 09/25/2013
2013-7717	09/25/2013 10/24/2013	Brandi Kopp	ORA/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	JUICE PLUS COMPLETE - TEST RESULTS (06/24/2013 - 09/24/2013)	Pending Action 09/25/2013
2013-7718	09/25/2013 10/24/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	MEGA SUN INC, ST LOUIS, MO - EIR, CO RESP 2/12 TO 3/12	Acknowledgement Letter 09/25/2013
2013-7719	09/25/2013 10/24/2013	The Doyle Firm	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDRH/OCER/DFOI/	STRYKER TRIDENT HIP SYSTEM - RECALL RECS, WARNING LETTER (01/01/2006 - 09/24/2013)	Pending Action 09/25/2013
2013-7720	09/25/2013 10/24/2013	FOI Services, Inc.	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	AMERICAN SNUFF, WINSTON-SALEM, NC - INVESTIGATOR DIARIES	Pending Action 09/25/2013
2013-7721	09/25/2013 10/24/2013	FOI Services, Inc.	FDA/OC/OES/ FDA/OMPT/CTP/OD/	E CIGARETTE REGULATIONS - CORR	Pending Action 09/25/2013
2013-7722	09/25/2013 10/24/2013	FOI Services, Inc.	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	LORRILARD TOBACCO, DANVILLE, VA - EXHIBITS FOR 7/26/2012 INSPECTION	Pending Action 09/25/2013
2013-7723	09/25/2013 10/24/2013	University of Akron Research Foundation	FDA/OMPT/CDRH/OCER/DFOI/	P960052	Pending Action 09/25/2013
2013-7724	09/25/2013 10/24/2013	Merial Limited	CVM/OCD/	MERIAL LIMITED - RECS RE G-002819-G-0002-AD, G-002893-G-0002-AD, G-002819 G-002893	Pending Action 09/25/2013
2013-7725	09/25/2013 10/24/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	ACCLARENT, MENLO PARK, CA - EIR, CO RESP 1/13 TO 2/13	Acknowledgement Letter 09/25/2013
2013-7726	09/25/2013 10/24/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	PERFORMANCE PRODUCTS, ST LOUIS, MO - EIR, RESP,CORR 7/12	Acknowledgement Letter 09/25/2013
2013-7727	09/25/2013 10/24/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	VALLEY HEALTH WINCHESTER MEDICAL CTR IRB, WINCHESTER, VA - EIR, CO RESP 1/13 TO 2/13	Acknowledgement Letter 09/25/2013
2013-7728	09/25/2013 10/24/2013	Raza, Zeeshan	FDA/OMPT/CDRH/OCER/DFOI/	HEPAHOPE - CLINICAL HOLD RECS 01/01/2000 - 09/24/2013	Pending Action 09/25/2013
2013-7729	09/25/2013 10/24/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	STATRX USA, GAINESVILLE, GA - EIR, RESP, CORR 2/12	Acknowledgement Letter 09/25/2013
2013-7730	09/25/2013 10/24/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	INNOVACYN INC, RIALTO, CA - 483, CO RESP, WARNING LTR 11/11 TO 12/11	Acknowledgement Letter 09/25/2013

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2013-7731	09/25/2013 10/24/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORR/PA-FO/SAN-DO/SAN-CB/	COMAPNY INTUITIVE SURGICAL INC, SUNNYVALE, CA - EIR, RESP, CORR 4/13 TO 5/13	Acknowledgement Letter 09/25/2013

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2013-7732	09/25/2013 10/24/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORR/NE-FO/NWE-DO/NWE-	SPINE FRONTER, BEVERLY, MA - 483, CO RESP, WARNING LTR 5/12 TO 7/12	Acknowledgement Letter 09/25/2013

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2013-7733	09/25/2013 10/24/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORPA/FO/LOS-DO/LOS-CB/	I SHAY COSMETICS, GARDENA, CA - EIR, RESP, CORR 2/12	Acknowledgement Letter 09/25/2013
2013-7734	09/25/2013 10/24/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORACE/FO/NWJ-DO/NWJ-CB/	LAKEWOOD LLC, LAKEWOOD, NJ - 483, CO RESP, WARNING LTR 2/12 TO 3/12	Acknowledgement Letter 09/25/2013
2013-7735	09/25/2013 10/24/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORACE/FO/CIN-DO/CIN-CB/	SCM TRUE AIR TECHNOLOGIES, LOUISVILLE, KY - EIR, RESP, CORR 5/13	Acknowledgement Letter 09/25/2013
2013-7736	09/25/2013 10/24/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORACE/FO/PHI-DO/PHI-CB/	MIR COM PRODUCTS, CENTRAL CITY, PA - 483, CO RESP, WARNING LTR 6/12	Acknowledgement Letter 09/25/2013
2013-7737	09/25/2013 10/24/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORASW/FO/DAL-DO/DAL-CB/	CELL TEX THERAPEUTICS, SUGARLAND, TX - 483, CO RESP, WARNING LTR 4/12	Acknowledgement Letter 09/25/2013
2013-7738	09/25/2013 10/24/2013	WASHINGTON INFORMATION SOURCE	FDA/OGROP/ORASE/FO/ATL-DO/ATL-CB/	BIOMERIEUX, DURHAM, NC - 483, CO RESP, WARNING LTR 1/12 TO 3/12	Acknowledgement Letter 09/25/2013
2013-7739	09/26/2013 10/25/2013	WKEF/WRGT TV	FDA/OMPT/CDER/ORP/DIDP/	MIRENA IUD - AERS	Closed 09/30/2013
2013-7740	09/26/2013 10/25/2013	NOVARTIS ANIMAL HEALTH US INC	CVM/OCD/	NADA 141-406 FOIA SUMMARY	Pending Action 09/26/2013
2013-7741	09/26/2013 10/25/2013	PROCTER & GAMBLE	FDA/OGROP/ORASE/FO/NOL-DO/NOL-CB/	GLAXOSMITHKLINE, MEMPHIS, TN - INSPECTION RECS 09/01/1990 - 09/25/2013	Pending Action 09/26/2013
2013-7742	09/26/2013 10/25/2013	The National Academies (Institute of Medicine)	FDA/OMPT/CDER/ORP/DIDP/	NDA 050786 - ACTION LETTER	Closed 09/27/2013
2013-7743	09/26/2013 10/25/2013	BEVERIDGE & DIAMOND PC	FDA/OC/OES/DFOI/	FOIA REQUESTS FILED WITH CFSAN 08/01/2012 - 09/25/2013	Closed 09/26/2013
2013-7744	09/26/2013 10/25/2013	KENYON & KENYON LLP	FDA/OMPT/CDER/ORP/DIDP/	IND 21487 - CLINICAL STUDY	Pending Action 09/26/2013
2013-7745	09/26/2013 10/25/2013	Intertox, Inc.	FDA/OMPT/CDRH/OCER/DFOI/	K914776	Pending Action 09/26/2013
2013-7746	09/26/2013 10/25/2013	BioTex Inc.	FDA/OMPT/CDRH/OCER/DFOI/	K944463	Pending Action 09/26/2013
2013-7747	09/26/2013 10/25/2013	BURGESS, BERNIE	FDA/OGROP/ORACE/FO/MIN-DO/MIN-CB/	EI ENDORSEMENT FOR FEI 3004927371	Pending Action 09/26/2013
2013-7748	09/26/2013 10/25/2013	Hyman, Phelps & McNamara P.C.	FDA/OF/CFSAN/OCD/EOS/	ZARBEE - COMMUNICATIONS WITH FDA RE LABEL CLAIMS	Pending Action 09/26/2013
2013-7749	09/26/2013 10/25/2013	FOI Services, Inc.	FDA/OF/CFSAN/OCD/EOS/	FAP 1041	Pending Action 09/26/2013

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2013-7750	09/26/2013 10/25/2013	FOI Services, Inc.	FDA/OF/CFSAN/OCDEOS/	FAP 1041	Pending Action 09/26/2013
2013-7751	09/26/2013 10/25/2013	FOI Services, Inc.	FDA/OMPT/CDER/ORP/DIDP/	NDA 18680 - FINAL LABELING AND PATIENT INSERT; NDA 18680 S 60-MATERIALS SENT OR RECEIVED BY FDA	Pending Action 09/26/2013
2013-7752	09/26/2013 10/25/2013	Garcia, Michelle	FDA/OMPT/CDRH/OCER/DFOI/	ESSURE - ADVERSE EVENTS	Pending Action 09/26/2013
2013-7753	09/26/2013 10/25/2013	HOGAN LOVELLS US LLP	ORA/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	C PACIFIC FOODS - CANNED MUSHROOM SLICED 6 CANS RECALL F-17590-2013 ANALYTICAL RECS, TEST RESULTS	Acknowledgement Letter 09/26/2013
2013-7754	09/26/2013 10/25/2013	HOGAN LOVELLS US LLP	ORA/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	CROWN PACIFIC INTERNATIONAL LLC - HAWAII FRESH SWEET BASIL F-1873-2013 ANALYTICAL RECS, TEST RESULTS	Acknowledgement Letter 09/26/2013
2013-7755	09/26/2013 10/25/2013	HOGAN LOVELLS US LLP	ORA/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	BAO GONG DA INC - AMERICAN GINSENG F-153-2013 ANALYTICAL RECS, TEST RESULTS	Acknowledgement Letter 09/26/2013
2013-7756	09/26/2013 10/25/2013	B BRAUN MEDICAL INC	FDA/OMPT/CDRH/OCER/DFOI/	B BRAUN MEDICAL INC - INFUSOMAT SPACE PUMP INFUSION SYS SOFTWARE J K103572; PERFUSOR SPACE SYRINGE PUMP SOFTWARE J K122452 REVIEWER'S NOTES	Acknowledgement Letter 09/26/2013
2013-7757	09/26/2013 10/25/2013	DAY PITNEY LLP	FDA/OMPT/CDRH/OCER/DFOI/	ADVVERSE EVENT KEYS 3053543, 3906483, 2531355	Acknowledgement Letter 09/26/2013
2013-7758	09/26/2013 10/25/2013	ABBOTT POINT OF CARE INC	FDA/OMPT/CDRH/OCER/DFOI/	OPTIC MEDICAL SYSTEMS - K131126	Acknowledgement Letter 09/26/2013
2013-7759	09/26/2013 10/25/2013	REILLY POZNER LLP	FDA/OMPT/CDER/ORP/DIDP/	EFFEXOR (VENLAFAXINE HCL) NDA 20-151 - CORR, APRVL LTRS, AERS, ETC	Acknowledgement Letter 09/26/2013
2013-7760	09/26/2013 10/25/2013	DENVER HEALTH ROCKY MOUNTAIN POISON & DRUG CENTER	FDA/OMPT/CDER/ORP/DIDP/	ISR 7382479, 7814351, 8067430, ETC - COUGH & COLD PREPARATIONS	Acknowledgement Letter 09/26/2013
2013-7761	09/26/2013 10/25/2013	S ALBERT EDWARDS, PHARM D	FDA/OMPT/CDER/ORP/DIDP/	PRESCRIPTION DRUG WRAP -UP (DESI-2) - RONDEX, CARBAXAFED LTR	Acknowledgement Letter 09/26/2013
2013-7762	09/26/2013 10/25/2013	PROJECT ON GOVERNMENT OVERSIGHT	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/ORP/DIDP/	PRADAXA - AERS 12/31/12 TO PRESENT	Closed 09/30/2013
2013-7763	09/26/2013 10/25/2013	FRIEDMAN, ROBERT	FDA/OMPT/CDER/ORP/DIDP/	BUCCASTEM 3MG TABS - AERS 1969 TO PRESENT	Withdrawn Closed w/o Charges 09/30/2013
2013-7764	09/26/2013 10/25/2013	PORZIO LIFE SCIENCES	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	CARACO PHARMACEUTICAL LABORATORIES LTD, CRANBURY, NJ - EIRS, 483S 6/28/11	Acknowledgement Letter 09/26/2013

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2013-7765	09/26/2013 10/25/2013	SAK, DAN	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	BACK CENTER, MELBOURNE, FL - MULTI-DOSE CONTAINER OF MPA PICTURE	Acknowledgement Letter 09/26/2013
2013-7766	09/26/2013 10/25/2013	COSMETIC INGREDIENT REVIEW	FDA/OF/CFSAN/OCD/EOS/	PENTAERYTHRYL TETRA-DL-T-BUTYL HYDROXYHYDROCINAMATE - CHEMICAL & PHYSICAL PROPERTIES, METABOLISM BIOAVL, DERMAL PENETRATION, ETC	Acknowledgement Letter 09/26/2013
2013-7767	09/26/2013 10/25/2013	FAIN ANDERSON VANDERHOEF PLLC	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	KINGPIN TATTOO INC - ONE TATTOO INK RECALL F-2112-2012 RPTS, FINAL CONCLUSIONS	Acknowledgement Letter 09/26/2013
2013-7768	09/26/2013 10/25/2013	K&L GATES	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORR/PA-FO/SEA-DO/SEA-CB/	METAGENIC INC, GIG HARBOR, WA - WARNING LTR SEA 13-27 CORR, NOTES, DOCUMENTATION, ETC 8/12/13	Acknowledgement Letter 09/26/2013
2013-7769	09/27/2013 10/28/2013	Garcia, Michelle	FDA/OMPT/CDRH/OCER/DFOI/	ESSURE - FIVE YEAR POST APPROVAL STUDY	Pending Action 09/27/2013
2013-7770	09/27/2013 10/28/2013	BURGESS, BERNIE	FDA/OMPT/CDER/ORP/DIDP/	COMPLAINTS FILED IN CDER DATABASE AFTER 1639	Pending Action 09/27/2013
2013-7771	09/27/2013 10/28/2013	Luis Rolfo	FDA/OMPT/CDRH/OCER/DFOI/	CUTOFF LEVELS FOR PSYCHEMEDICS MARIJUANA HAIR DRUG TEST	Withdrawn Closed w/o Charges 09/27/2013
2013-7772	09/27/2013 10/28/2013	Hotswaqp Stockholm AB	FDA/OMPT/CDRH/OCER/DFOI/	K881183	Pending Action 09/27/2013
2013-7773	09/27/2013 10/28/2013	Capstone Investment Advisors	FDA/OMPT/CDRH/OCER/DFOI/	NUMBER OF FACILITIES APPROVED FOR DIGITAL MAMMOGRAPHY SCREENING BY YEAR; NUMBER OF DIGITAL MAMMOGRAPHY MACHINES APPROVED FOR SERVICE BY YEAR; NUMBER OF FACILITIES APPROVED FOR TOMOSYNTHESIS 3D DIGITAL MAMMOGRAPHY BY YEAR ETC	Pending Action 09/27/2013
2013-7774	09/27/2013 10/28/2013	Cochrane Skin Group	FDA/OMPT/CDER/ORP/DIDP/	ADVERSE EVENT SUMMARIES - VARIOUS DRUGS	Pending Action 09/27/2013
2013-7775	09/27/2013 10/28/2013	N/A	FDA/OMPT/CDRH/OCER/DFOI/	ESSURE - FIVE YEAR POST STUDY	Pending Action 09/27/2013
2013-7776	09/27/2013 10/28/2013	Hyman, Phelps & McNamara P.C.	FDA/OMPT/OSMP/OOPD/	NYMALIZE - ORPHAN DRUG DESIGNATION	Pending Action 09/27/2013
2013-7777	09/27/2013 10/28/2013	Integrated Plasmonics	FDA/OMPT/CDRH/OCER/DFOI/	K914469, K913105, K990688 ETC	Pending Action 09/27/2013
2013-7778	09/27/2013 10/28/2013	FOI Services, Inc.	FDA/OMPT/CDRH/OCER/DFOI/	K101200	Pending Action 09/27/2013

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2013-7779	09/27/2013 10/28/2013	Thomson Reuters/Reuters News	CVM/OCD/	ZILPATEROL - AERS	Pending Action 09/27/2013
2013-7780	09/27/2013 10/28/2013	FOI Services, Inc.	FDA/OMPT/CDRH/OCER/DFOI/	K101250	Pending Action 09/27/2013
2013-7781	09/27/2013 10/28/2013	FOI Services, Inc.	FDA/OMPT/CDRH/OCER/DFOI/	K103025	Pending Action 09/27/2013
2013-7782	09/27/2013 10/28/2013	none	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	IND 15376	Closed Denial 09/30/2013
2013-7783	09/27/2013 10/28/2013	FOI Services, Inc.	FDA/OMPT/CDRH/OCER/DFOI/	K103088	Pending Action 09/27/2013
2013-7784	09/27/2013 10/28/2013	FOI Services, Inc.	FDA/OMPT/CDRH/OCER/DFOI/	K123864	Pending Action 09/27/2013
2013-7785	09/27/2013 10/28/2013	Elorac Inc.	FDA/OMPT/CDER/ORP/DIDP/	Oxylone Topical fluorometholone NDA	Closed 09/30/2013
2013-7786	09/27/2013 10/28/2013	Chilton Investment Company	FDA/OMPT/CDER/ORP/DIDP/	QSYMIA - AERS	Closed 09/30/2013
2013-7787	09/27/2013 10/28/2013	Jeffrey Gardner	FDA/OMPT/CDER/ORP/DIDP/	IPI-145 - AERS	Closed Denial 09/30/2013
2013-7788	09/27/2013 10/28/2013	COWEN AND COMPANY	FDA/OMPT/CDRH/OCER/DFOI/	P950022/S042	Pending Action 09/27/2013
2013-7789	09/27/2013 10/28/2013	Jeffrey Gardner	FDA/OMPT/CDER/ORP/DIDP/	PRO044, PRO045, PRO053 - AERS	Closed Denial 09/30/2013
2013-7790	09/27/2013 10/28/2013	ABC NEWS	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/ FDA/OMPT/CTP/OD/	VAPOR SHARK, VAPOR HOG; E-CIGARETTE - COMPLAINTS 09/01/2013 - 09/26/2013	Pending Action 09/27/2013
2013-7791	09/27/2013 10/28/2013	Eccleston and Wolf, PC	FDA/OMPT/CDER/ORP/DIDP/ ORA/	NECC - METHYLPREDNISOLONE ACETATE 80 Mg/ml Lot 05212012@68	Pending Action 09/27/2013
2013-7792	09/27/2013 10/28/2013	INC RESEARCH CONSULTING & SUBMISSIONS	FDA/OMPT/CDER/ORP/DIDP/	NYCOMED, SINGEN, GERMANY - EIR 6/2/09	Pending Action 09/27/2013
2013-7793	09/27/2013 10/28/2013	Rebekah Cafrelli	FDA/OGROP/ORR/CE-FO/PHI-DO/PHI-CB/	HERSHEY MEDICAL CENTER BLOOD BANK - REPORTS SUBMITTED TO FDA 07/11/2013 - 08/15/2013	Pending Action 09/27/2013
2013-7794	09/27/2013 10/28/2013	Angela Lynch	FDA/OMPT/CDRH/OCER/DFOI/	STOP/ESSURE - TRIAL RECS	Pending Action 09/27/2013