

Query Result Report

Records: 232

Action Office: ALL

Received Via: BOTH

Control #:

Rec/Create Date: 09/02/2013

To 09/06/2013

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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Control #	Recd Date / Due Date	Requester	Action Offices	Subject	Status / Status Date
2013-6856	09/03/2013 10/01/2013	McCombs, Mona	FDA/OF/CFSAN/OCD/EOS/ OC/OCC/ ORA/OCI/	PROTOCOL FOR TRANSPORTING ADULTERATED FOOD	Pending Action 09/02/2013
2013-6857	09/03/2013 10/01/2013	BLOOMBERG NEWS	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ORP/DIDP/	LIST OF DRUGS VOLUNTARILY WITHDRAWN BY SPONSOR, LIST OF DRUGS WITHDRAWN FOR SAFETY REASONS	Pending Action 09/02/2013
2013-6858	09/03/2013 10/01/2013	Christie Frayser	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	ORTHO DIAGNOSTIC SYSTEMS, INC, RARITAN, NJ - LOT NUMBER RHL 265B, RHL 265K, RHL232A - MEDWATCH ALERTS, PROCESSING, POWDER SUBSTANCE ETC	Pending Action 09/02/2013
2013-6859	09/03/2013 10/01/2013	UNIVERSITY OF NEW MEXICO	FDA/OMPT/CDER/ORP/DIDP/	RITUXIMAB - AERS	Pending Action 09/02/2013
2013-6860	09/03/2013 10/01/2013	Gina Pera	FDA/OMPT/CDER/ORP/DIDP/	ANDA 202608 - BIOEQUIVALENCE STUDIES	Pending Action 09/02/2013
2013-6861	09/03/2013 10/01/2013	Cempra Pharmaceuticals (Anita Fauchier)	FDA/OMPT/CDER/ORP/DIDP/	WOCKHARDT, INDIA - RESPONSE TO 483	Pending Action 09/02/2013
2013-6862	09/03/2013 10/01/2013	TUCKER ELLIS LLP	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	JOHNSON & JOHNSON, HORSHAM, PA - EIR, 483 4/14/11, 10/2/09, ETC	Pending Action 09/02/2013
2013-6863	09/03/2013 10/01/2013	Joyce Daubert	FDA/OMPT/CDER/ORP/DIDP/	DICLEGIS - EFFICACY STUDIES	Withdrawn Closed w/o Charges 09/03/2013
2013-6864	09/03/2013 10/01/2013	Ampro Industries, Inc.	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	KEYSTONE LABORATORIES, INC - WARNING LETTERS 01/01/2009 - 12/31/2011	Pending Action 09/02/2013
2013-6865	09/03/2013 10/01/2013	Tris Pharma, Inc.	FDA/OMPT/CDER/ORP/DIDP/	NDA 011552	Pending Action 09/02/2013
2013-6866	09/03/2013 10/01/2013	Tris Pharma, Inc.	FDA/OMPT/CDER/ORP/DIDP/	NDA 019478	Closed 09/05/2013
2013-6867	09/03/2013 10/01/2013	Tris Pharma, Inc.	FDA/OMPT/CDER/ORP/DIDP/	NDA 020198	Closed 09/05/2013
2013-6868	09/03/2013 10/01/2013	Tris Pharma, Inc.	FDA/OMPT/CDER/ORP/DIDP/	NDA 018482	Closed 09/05/2013
2013-6869	09/03/2013 10/01/2013	Tris Pharma, Inc.	FDA/OMPT/CDER/ORP/DIDP/	NDA 019684	Closed 09/05/2013
2013-6870	09/03/2013 10/01/2013	Tris Pharma, Inc.	FDA/OMPT/CDER/ORP/DIDP/	NDA 018333	Closed 09/06/2013

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2013-6871	09/03/2013 10/01/2013	FOI Services, Inc.	FDA/OMPT/CTP/OD/	RECS RE FOUR TOBACCO PRODUCTS DETERMINED NSE	Pending Action 09/02/2013
2013-6872	09/03/2013 10/01/2013	Joyce Daubert	FDA/OC/OES/DDM/	BENDECTIN - ADVISORY COMMITTEE	Pending Action 09/02/2013
2013-6873	09/03/2013 10/01/2013	EXPONENT, INC.	FDA/OMPT/CDER/ORP/DIDP/	CARBINOXAMINE CONTAINING DRUGS - DEATH REPORTS	Pending Action 09/02/2013
2013-6874	09/03/2013 10/01/2013	UPMC St. Margaret Hospital	FDA/OMPT/CDER/ORP/DIDP/	FLUOROQUINOLONES - AERS	Pending Action 09/02/2013
2013-6875	09/03/2013 10/01/2013	FOI Services, Inc.	FDA/OF/CFSAN/OCD/EOS/	FCN 939	Pending Action 09/03/2013
2013-6876	09/03/2013 10/01/2013	James Alexander Corporation	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WELCH, HOLME, AND CLARK COMPANY, NEWARK, NJ - EIR, 483, RECALL 08/29/2011 - 08/29/2013	Pending Action 09/03/2013
2013-6877	09/03/2013 10/01/2013	Law Offices of Brian D. Witzer, Inc.	FDA/OMPT/CDER/ORP/DIDP/	ANDA 065156	Pending Action 09/03/2013
2013-6878	09/03/2013 10/01/2013	James Alexander Corporation	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	TOKYO CHEMICAL INDUSTRY COMPANY, LTD, PORTLAND, OR - EIR, 483 RECALLS 08/29/2010 - 08/29/2013	Pending Action 09/03/2013
2013-6879	09/03/2013 10/01/2013	Lachman Consultants	FDA/OMPT/CDER/ORP/DIDP/	ANDA 91052	Pending Action 09/03/2013
2013-6880	09/03/2013 10/01/2013	Stryker IMT	FDA/OMPT/CDRH/OCER/DFOI/	K111970	Pending Action 09/03/2013
2013-6881	09/03/2013 10/01/2013	Materialise NV	FDA/OMPT/CDRH/OCER/DFOI/	K130126, K131129	Pending Action 09/03/2013
2013-6882	09/03/2013 10/01/2013	GASSNER, VIRGINIA	FDA/OMPT/CDER/ORP/DIDP/	MYSOLINE/PRIMIDONE - AERS 01/01/2011 - 09/01/2013	Closed 09/09/2013
2013-6883	09/03/2013 10/01/2013	Smiles and Laughs Co.	FDA/OMPT/CDRH/OCER/DFOI/	STATISTICS COLLECTED BY FDA RE MQSA	Pending Action 09/03/2013
2013-6884	09/03/2013 10/01/2013	Tris Pharma, Inc.	FDA/OMPT/CDER/ORP/DIDP/	NDA 019183	Closed 09/05/2013
2013-6885	09/03/2013 10/01/2013	Walker, Joseph	FDA/OMPT/CDER/ORP/DIDP/	TECFIDERA - ISR	Closed 09/09/2013
2013-6886	09/03/2013 10/01/2013	LEXINGTON CLINIC	FDA/OMPT/CDRH/OCER/DFOI/	K121920	Pending Action 09/03/2013
2013-6887	09/03/2013 10/01/2013	Lexington Intl LLC	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	K113097	Closed 09/04/2013

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2013-6888	09/03/2013 10/01/2013	Lexington Intl LLC	FDA/OMPT/CDRH/OCER/DFOI/	K122950	Pending Action 09/03/2013
2013-6889	09/03/2013 10/01/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	FOI DAILY LOG 8/1/13-31/2013	Closed 09/06/2013
2013-6890	09/03/2013 10/01/2013	Delp, William H	FDA/OMPT/CDRH/OCER/DFOI/	MEDICAL DEVICES CLEARED TO BE MARKETED UNDER 868.5470	Pending Action 09/03/2013
2013-6891	09/03/2013 10/01/2013	Mathys & Squire LLP	FDA/OMPT/CDER/ORP/DIDP/	SUGEN, INC - IND SU6668	Pending Action 09/03/2013
2013-6892	09/03/2013 10/01/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	CLOSED FOIA REQUESTS ON CD 8/1-31/2013	Closed 09/06/2013
2013-6893	09/03/2013 10/01/2013	Hyman, Phelps & McNamara, P.C.	FDA/OMPT/CDER/ORP/DIDP/	OFFICE OF GENERIC DRUGS STATISTICAL REPORT FOR JULY AND AUGUST 2013	Pending Action 09/03/2013
2013-6894	09/03/2013 10/01/2013	Tris Pharma, Inc.	FDA/OMPT/CDER/ORP/DIDP/	NDA 020142	Closed 09/04/2013
2013-6895	09/03/2013 10/01/2013	Traywick Law Offices	FDA/OC/OES/DDM/	JOINT MEETING OF THE ENDOCRINOLOGIC AND METABOLIC DRUGS ADVISORY COMMITTEE - TRANSCRIPT	Pending Action 09/03/2013
2013-6896	09/03/2013 10/01/2013	FOI Services, Inc.	FDA/OMPT/CTP/OD/	TOBACCO SUBSTANTIAL EQUIVALENCE ORDERS	Closed 09/03/2013
2013-6897	09/03/2013 10/01/2013	FOI Services, Inc.	FDA/OMPT/CDRH/OCER/DFOI/	K130793	Pending Action 09/03/2013
2013-6898	09/03/2013 10/01/2013	FOI Services, Inc.	FDA/OMPT/CTP/OD/ OC/OEXA/OPA/	RECS RE CTP PRESS RELEASE	Pending Action 09/03/2013
2013-6899	09/03/2013 10/01/2013	FOI Services, Inc.	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	F&F FOODS, CHICAGO, IL - EIR	Pending Action 09/03/2013
2013-6900	09/03/2013 10/01/2013	Longseth, David M	ORA/ FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	SAMPLE RESULTS	Closed 09/09/2013
2013-6901	09/03/2013 10/01/2013	FOI Services, Inc.	FDA/OMPT/CDER/ORP/DIDP/	NANJING KING-FRIEND BIOCHEMICAL, CHINA - EIR, 483, ETC	Pending Action 09/03/2013
2013-6902	09/03/2013 10/01/2013	Tris Pharma, Inc.	FDA/OMPT/CDER/ORP/DIDP/	NDA 204242	Withdrawn Closed w/o Charges 09/03/2013

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2013-6903	09/03/2013 10/01/2013	BOTKINCHEMIE	FDA/OF/CFSAN/OCD/EOS/	FAP Octadecanoic acid 2-2-hydroxyethyl) octadecylaminoethyl ester (CAS Reg. No. 52497-24-2), (octadecylimino) diethylene distearate (CAS Reg. No. 94945-28-5), and octadecyl bis(hydroxyethyl)amine (CAS Reg. No. 10213-78-2)	Pending Action 09/03/2013
2013-6904	09/03/2013 10/01/2013	MASSACHUSETTS COLLEGE OF PHARMACY	FDA/OC/OES/DDM/	1997 report by CDER titled "Retrospective review of ecotoxicity data submitted in environmental assessments for public display." (Docket No. 96N-0057)	Pending Action 09/03/2013
2013-6905	09/03/2013 10/01/2013	EAS CONSULTING GROUP LLC	FDA/OMPT/CDER/ORP/DIDP/	DOXYCYCLINE INJ ANDA 50-442 - APRVL LTR, LBLG, MEDICAL RVW, ETC	Closed 09/04/2013
2013-6906	09/03/2013 10/01/2013	EAS CONSULTING GROUP LLC	FDA/OMPT/CDER/ORP/DIDP/	DOXORUBINCIN LIPOSOME ANDA 50-718 - APRVL LTR, LBLG, MEDICAL RVW, ETC	Closed 09/04/2013
2013-6907	09/03/2013 10/01/2013	EAS CONSULTING GROUP LLC	FDA/OMPT/CDER/ORP/DIDP/	VISTARIL (HYDROXYUZINE PALMOATE) NDA 11-459 - APRVL LTR, LBLG, MEDICAL RVW, ETC	Closed 09/04/2013
2013-6908	09/03/2013 10/01/2013	EAS CONSULTING GROUP LLC	FDA/OMPT/CDER/ORP/DIDP/	DOXYCYCLINE INJ ANDA 62-475 - APRVL LTR, LBLG, MEDICAL RVWS, ETC	Acknowledgement Letter 09/03/2013
2013-6909	09/03/2013 10/01/2013	DR REDDY'S LABORATORIES INC	FDA/OMPT/CDER/ORP/DIDP/	DR REDDY'S LABS LTD - ATORVASTATIN CALCIUM ORAL ANDA 091-650 - SBA	Withdrawn Closed w/o Charges 09/05/2013
2013-6910	09/03/2013 10/01/2013	DR REDDY'S LABORATORIES INC	FDA/OMPT/CDER/ORP/DIDP/	DR REDDY'S LABS LTD - ATORVASTATIN CALCIUM ANDA 203-257 SBA	Withdrawn Closed w/o Charges 09/05/2013
2013-6911	09/03/2013 10/01/2013	COUNTRY PURE FOODS	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	GREGORY PACKAGING, NEWARK, NJ - EIR MOST RECENT	Acknowledgement Letter 09/03/2013
2013-6912	09/03/2013 10/01/2013	COUNTRY PURE FOODS	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	CITRUS SYSTEMS INC, HOPKINS, MN - EIR MOST RECENT	Acknowledgement Letter 09/03/2013
2013-6913	09/03/2013 10/01/2013	COUNTRY PURE FOODS	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	M&B JUICE, TAMPA, FL - EIR MOST RECENT	Acknowledgement Letter 09/03/2013
2013-6914	09/03/2013 10/01/2013	COUNTRY PURE FOODS	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	KING JUICE CO, MILWAUKEE, WI - EIR MOST RECENT	Acknowledgement Letter 09/03/2013
2013-6915	09/03/2013 10/01/2013	OUTWATER & PINCKES LLP	FDA/OC/OES/DFOI/	ALCOA CIRCLE, CORONA, CA - POLYETHYLENE, PET BOTTLES & CONTAINERS SALES, LAB RPTS, WARNING LTRS, ETC 1/1/06 TO P RESENT	Closed (Fee-related) 09/04/2013
2013-6916	09/03/2013 10/01/2013	TARO PHARMACEUTICALS USA INC	FDA/OMPT/CDER/ORP/DIDP/	AQUA PHARMS - CORDRAN LOTION TOPICAL NDA 13-790 SBA	Acknowledgement Letter 09/03/2013
2013-6917	09/03/2013 10/01/2013	FOI Services, Inc.	FDA/OMPT/CDER/ORP/DIDP/	OLMESARTAN - ISRS 6585297, 7454426, 7457740, ETC	Closed 09/09/2013

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2013-6918	09/03/2013 10/01/2013	Siegfried USA, LLC	FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	PROPARACAINE HCL DMF 26989 - LIST OF CURRENT CUSTOMERS	Partial Response 09/06/2013
2013-6919	09/03/2013 10/01/2013	WASHINGTON, PAMELA	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	GENERAL MILLS CEREAL LLC, GOLDEN VALLEY, MN - RAISIN NUT BRAN CEREAL CMLPNTS	No Record(s) 09/09/2013
2013-6920	09/03/2013 10/01/2013	Keller and Heckman LLP	FDA/OF/CFSAN/OCD/EOS/	FCN 772	Acknowledgement Letter 09/03/2013
2013-6921	09/03/2013 10/01/2013	COVINGTON & BURLING LLP	FDA/OMPT/CTP/OD/	TOBACCO PRODS - EIGHT NOT SUBSTANTIALY EQUIVALENT (NSE) ORDERS, APPL, RVW, ETC	Acknowledgement Letter 09/03/2013
2013-6922	09/03/2013 10/01/2013	OLSSON FRANK WEEDA TERMAN BODE MATZ	FDA/OF/CFSAN/OCD/EOS/	REGULATROY & OR ENFORCEM3ENT IN MEASURES PERTAINING TO USSE OF THE WORD FRESH IN FOOD LBLG - CORR RECS 9/08 TO PRESENT	Acknowledgement Letter 09/03/2013
2013-6923	09/03/2013 10/01/2013	CENTER FOR FOOD SAFETY	FDA/OC/OES/DDM/ FDA/OF/CFSAN/OCD/EOS/	DKT 2006P-0101/CP1	Acknowledgement Letter 09/03/2013
2013-6924	09/03/2013 10/01/2013	MERZ PHARMACEUTICALS GMBH	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	AMERICAN BEEKEEPER FEDERATION INC, AMERICAN HONEY PRODUCERS ASSOCIATION INC, NATIONAL HONEY PACKERS & DEALERS ASSN, ETC - STANDARD OF IDENITY FOR HONY CORR	Partial Response 09/06/2013
2013-6925	09/03/2013 10/01/2013	PHOENIX REGULATORY ASSOCIATES LTD	CVM/OCD/	DIAMOND V - TRANSITION COW STUDIES CORR	Acknowledgement Letter 09/03/2013
2013-6926	09/03/2013 10/01/2013	AbbVie, Inc.	ORA/ ORA/ORO/DIOP/	ABBVIE INC - IMPORTS, PREDICT SCORES 1/1/13-7/15/13	Acknowledgement Letter 09/03/2013
2013-6927	09/03/2013 10/01/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-258	Acknowledgement Letter 09/03/2013
2013-6928	09/03/2013 10/01/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-262	Acknowledgement Letter 09/03/2013
2013-6929	09/03/2013 10/01/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2012-8579	Acknowledgement Letter 09/03/2013
2013-6930	09/03/2013 10/01/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2012-8580	Acknowledgement Letter 09/03/2013
2013-6931	09/03/2013 10/01/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2012-8643	Acknowledgement Letter 09/03/2013

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2013-6932	09/03/2013 10/01/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2012-8721	Acknowledgement Letter 09/03/2013
2013-6933	09/03/2013 10/01/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2012-8730	Acknowledgement Letter 09/03/2013
2013-6934	09/03/2013 10/01/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2012-8782	Acknowledgement Letter 09/03/2013
2013-6935	09/03/2013 10/01/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2012-8567	Acknowledgement Letter 09/03/2013
2013-6936	09/03/2013 10/01/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2012-8988	Acknowledgement Letter 09/03/2013
2013-6937	09/03/2013 10/01/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2012-8992	Acknowledgement Letter 09/03/2013
2013-6938	09/03/2013 10/01/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2012-8993	Acknowledgement Letter 09/03/2013
2013-6939	09/03/2013 10/01/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2012-8996	Acknowledgement Letter 09/03/2013
2013-6940	09/03/2013 10/01/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2012-9094	Acknowledgement Letter 09/03/2013
2013-6941	09/03/2013 10/01/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-2420	Acknowledgement Letter 09/03/2013
2013-6942	09/03/2013 10/01/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-2421	Acknowledgement Letter 09/03/2013
2013-6943	09/03/2013 10/01/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-1523	Acknowledgement Letter 09/03/2013
2013-6944	09/03/2013 10/01/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-1542	Acknowledgement Letter 09/03/2013
2013-6945	09/03/2013 10/01/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-1596	Acknowledgement Letter 09/03/2013
2013-6946	09/03/2013 10/01/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-1951	Acknowledgement Letter 09/03/2013
2013-6947	09/03/2013 10/01/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-1887	Acknowledgement Letter 09/03/2013
2013-6948	09/03/2013 10/01/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-1915	Acknowledgement Letter 09/03/2013
2013-6949	09/03/2013 10/01/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-2423	Acknowledgement Letter 09/03/2013

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2013-6950	09/03/2013 10/01/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-1186	Acknowledgement Letter 09/03/2013
2013-6951	09/03/2013 10/01/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-1188	Acknowledgement Letter 09/03/2013
2013-6952	09/03/2013 10/01/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-1924	Acknowledgement Letter 09/03/2013
2013-6953	09/03/2013 10/01/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-1271	Acknowledgement Letter 09/03/2013
2013-6954	09/03/2013 10/01/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-2022	Acknowledgement Letter 09/03/2013
2013-6955	09/03/2013 10/01/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-2051	Acknowledgement Letter 09/03/2013
2013-6956	09/03/2013 10/01/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-1395	Acknowledgement Letter 09/03/2013
2013-6957	09/03/2013 10/01/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-2068	Acknowledgement Letter 09/03/2013
2013-6958	09/03/2013 10/01/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-1426	Acknowledgement Letter 09/03/2013
2013-6959	09/03/2013 10/01/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-2093	Closed 09/05/2013
2013-6960	09/03/2013 10/01/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-2397	Closed 09/05/2013
2013-6961	09/03/2013 10/01/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-1432	Closed 09/05/2013
2013-6962	09/03/2013 10/01/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-1451	Closed 09/05/2013
2013-6963	09/03/2013 10/01/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-2110	Closed 09/06/2013
2013-6964	09/03/2013 10/01/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-1479	Closed 09/05/2013
2013-6965	09/03/2013 10/01/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-1921	Closed 09/05/2013
2013-6966	09/03/2013 10/01/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-2305	Closed 09/06/2013
2013-6967	09/03/2013 10/01/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-2427	Closed 09/06/2013

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2013-6968	09/04/2013 10/02/2013	Allianz	FDA/OMPT/CDER/ORP/DIDP/	MTG MINUTES FROM 7/23/13 AND ANY PRE-MEETING AND POST-MEETING CORR BETWEEN FDA AND SAREPTA RE ETEPLIRSEN FOR TREATMENT OF DUCHENE'S MUSCULAR DYSTROPHY 01/01/2013 - 08/28/2013	Closed Denial 09/06/2013
2013-6969	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-2221	Closed 09/05/2013
2013-6970	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-1700	Closed 09/05/2013
2013-6971	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-1701	Closed 09/05/2013
2013-6972	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-1702	Closed 09/05/2013
2013-6973	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-1805	Closed 09/05/2013
2013-6974	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-1835	Closed 09/06/2013
2013-6975	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-1836	Closed 09/05/2013
2013-6976	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-1884	Closed 09/05/2013
2013-6977	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-1704	Closed 09/05/2013
2013-6978	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-1719	Closed 09/05/2013
2013-6979	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-1765	Closed 09/05/2013
2013-6980	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-1741	Closed 09/09/2013
2013-6981	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-1754	Closed 09/09/2013
2013-6982	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-1761	Closed 09/10/2013
2013-6983	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-1789	Closed 09/05/2013
2013-6984	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-1792	Closed 09/09/2013

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2013-6985	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-742	Closed 09/05/2013
2013-6986	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-756	Closed 09/05/2013
2013-6987	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-789	Closed 09/05/2013
2013-6988	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-794	Closed 09/05/2013
2013-6989	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-792	Closed 09/05/2013
2013-6990	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-802	Closed 09/05/2013
2013-6991	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-799	Closed 09/05/2013
2013-6992	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-800	Closed 09/05/2013
2013-6993	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-803	Closed 09/05/2013
2013-6994	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-811	Closed 09/06/2013
2013-6995	09/04/2013 10/02/2013	ZETETIC INC	FDA/OGROP/OR/SE-FO/FLA-DO/FLA-CB/	SMITHS MEDICAL CATHETERS ENTRY #109-0875029-1 - RECS	Acknowledgement Letter 09/04/2013
2013-6996	09/04/2013 10/02/2013	339 GROUP LLC	OC/OL/	SEN MITCH MCCONNELL - FEDERAL FUNDING LEGISLATION, REGULATIONS, RECOMMENDATIONS, ETC CORR, RESP	No Record(s) 09/05/2013
2013-6997	09/04/2013 10/02/2013	GORDON & REES LLP	FDA/OGROP/OR/PA-FO/SAN-DO/SAN-CB/	NEXT SEAFOOD INC, HAYWARD, CA - EIRS, TEST RESULTS, LTRS, ETC 2/22/08-12/31/08	Acknowledgement Letter 09/04/2013
2013-6998	09/04/2013 10/02/2013	MOTLEY RICE LLC	FDA/OGROP/OR/PA-FO/SAN-DO/SAN-CB/	HOSPIRA INC, MORGAN HILL, CA - INSP 4/21-22/09 RECS	Acknowledgement Letter 09/04/2013
2013-6999	09/04/2013 10/02/2013	HOGAN LOVELLS LLP	FDA/OC/OES/DFOI/	2013-6529	Acknowledgement Letter 09/04/2013
2013-7000	09/04/2013 10/02/2013	HOGAN LOVELLS LLP	FDA/OC/OES/DFOI/	2013-6250	Acknowledgement Letter 09/04/2013
2013-7001	09/04/2013 10/02/2013	DANYSH, KURT	FDA/OC/OES/DFOI/	MEDICAL DICTIONARY FOR REGULATORY ACTIVITIES (MEDDRA)	Closed (Fee-related) 09/04/2013
2013-7002	09/04/2013 10/02/2013	DANYSH, KURT	FDA/OC/OES/DFOI/	ISRS 4638251-3, 4655315-9, 5074682-8, ETC	Closed (Fee-related) 09/04/2013

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2013-7003	09/04/2013 10/02/2013	BIOSCREEN TESTING SERVICES INC	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	BEAUTY-FILL, PISCATAWAY, NJ - EIRS, 483S, WARNING LTRS LAST 5 YRS	Acknowledgement Letter 09/04/2013
2013-7004	09/04/2013 10/02/2013	FDA NEWS	ORA/ORM/	PHARMACEUTICAL, BIOLOGICS, MEDICAL DVC MFG, CLNCL TRIAL FACILITIES IN AND OUTSIDE THE US - 483S 8/1-31/13	Closed 09/05/2013
2013-7005	09/04/2013 10/02/2013	Center for Regulatory Services, Inc.	FDA/OF/CFSAN/OCD/EOS/	LYONDELL BASELL INDUSTRIES - ETHYLENE/PROPYLENE COPOLYMERS FCN 1051	Acknowledgement Letter 09/04/2013
2013-7006	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-809	Closed 09/06/2013
2013-7007	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-812	Closed 09/06/2013
2013-7008	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-833	Closed 09/06/2013
2013-7009	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-876	Closed 09/06/2013
2013-7010	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-974	Closed 09/06/2013
2013-7011	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-1381	Closed 09/05/2013
2013-7012	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-1201	Closed 09/06/2013
2013-7013	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-1029	Acknowledgement Letter 09/04/2013
2013-7014	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-1061	Closed 09/06/2013
2013-7015	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-2212	Closed 09/06/2013
2013-7016	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-4627	Closed 09/06/2013
2013-7017	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-4636	Acknowledgement Letter 09/04/2013
2013-7018	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-4862	Closed 09/06/2013
2013-7019	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-4864	Acknowledgement Letter 09/04/2013

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2013-7020	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-5178	Closed 09/05/2013
2013-7021	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-2929	Closed 09/05/2013
2013-7022	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-2947	Acknowledgement Letter 09/04/2013
2013-7023	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-2963	Closed 09/06/2013
2013-7024	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-3050	Closed 09/05/2013
2013-7025	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-3296	Closed 09/05/2013
2013-7026	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-4349	Closed 09/06/2013
2013-7027	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-2568	Acknowledgement Letter 09/04/2013
2013-7028	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-2515	Acknowledgement Letter 09/04/2013
2013-7029	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-2498	Acknowledgement Letter 09/04/2013
2013-7030	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-2485	Closed 09/05/2013
2013-7031	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-2484	Acknowledgement Letter 09/04/2013
2013-7032	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-4342	Acknowledgement Letter 09/04/2013
2013-7033	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-2483	Acknowledgement Letter 09/04/2013
2013-7034	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-4068	Acknowledgement Letter 09/04/2013
2013-7035	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-4065	Acknowledgement Letter 09/04/2013
2013-7036	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-4202	Acknowledgement Letter 09/04/2013
2013-7037	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-3340	Acknowledgement Letter 09/04/2013

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2013-7038	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-2753	Acknowledgement Letter 09/04/2013
2013-7039	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-2602	Acknowledgement Letter 09/04/2013
2013-7040	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-3483	Acknowledgement Letter 09/04/2013
2013-7041	09/04/2013 10/02/2013	MERCK & CO., INC.	FDA/OC/OES/DFOI/	2013-4586	Acknowledgement Letter 09/04/2013
2013-7042	09/04/2013 10/02/2013	James Alexander Corporation	FDA/OC/OES/DFOI/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	NATUREX - EIR, 483, RECALL 07/01/2011 - 09/03/2013	Acknowledgement Letter 09/04/2013
2013-7043	09/04/2013 10/02/2013	the Wood Burditt group	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	ORGAN RECOVERY SYSTEMS, INC, ITASCA, IL - EIR, 483, 482 ETC 1/1/11 TO PRESENT	Pending Action 09/04/2013
2013-7044	09/05/2013 10/03/2013	COVINGTON & BURLING LLP	FDA/OC/OES/DDM/	DKT FDA-1996-N-0050	Closed 09/05/2013
2013-7045	09/05/2013 10/03/2013	Hyman, Phelps and McNamara	FDA/OC/OES/DDM/	DKT FDA-2013-P-0283	Closed 09/05/2013
2013-7046	09/05/2013 10/03/2013	MEDICAL WASTE SERVICES	ORA/	FDA MANDATED DESTRUCTION ACTIVITY LOS ANGELES, CA 1/12 TO 3/31/13	Acknowledgement Letter 09/05/2013
2013-7047	09/05/2013 10/03/2013	DELPHINUS MEDICAL TECHNOLOGIES INC	FDA/OMPT/CDRH/OCER/DFOI/	IVU IMAGING CORP - SOFIA ATUS IMAGING DVC K080555	Acknowledgement Letter 09/05/2013
2013-7048	09/05/2013 10/03/2013	MELODY CHRISTIAN ACADEMY	ORA/OCI/	INDIVIDUAL RECS	Acknowledgement Letter 09/05/2013
2013-7049	09/05/2013 10/03/2013	HEALY, HILARY	FDA/OMPT/CDER/ORP/DIDP/	XOLAIR - AER	Acknowledgement Letter 09/05/2013
2013-7050	09/05/2013 10/03/2013	ERIC F GREENBERG PC	FDA/OF/CFSAN/OCD/EOS/	FCN 815	Acknowledgement Letter 09/05/2013
2013-7051	09/05/2013 10/03/2013	BONNER KIERNAN TREBACH ET AL	FDA/OMPT/CDER/ORP/DIDP/ ORA/	NEW ENGLAND COMPOUNDING CTR, FRAMINGHAM, MA - METHYLPREDNISOLONE ACETATE INVESTIGATION, INSP, RECS	Acknowledgement Letter 09/05/2013
2013-7052	09/05/2013 10/03/2013	LAVIN O'NEIL RICCI CEDRONE & DISIPIO	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/ FDA/OMPT/CDER/ORP/DIDP/	AVANTIX LABORATORIES; TDM PHARMACEUTICAL RESEARCH LLC - 482, 483, EIR, BIOEQUIV	Acknowledgement Letter 09/05/2013
2013-7053	09/05/2013 10/03/2013	BENJAMIN L ENGLAND & ASSOCIATES LLC	ORA/ ORA/ORO/DIOP/	FDA REGULATED ARTICLES 1/08 TO PRESENT	Acknowledgement Letter 09/05/2013

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2013-7054	09/05/2013 10/03/2013	STERLING MEDICAL TECHNOLOGIES INC	FDA/OMPT/CDRH/OCER/DFOI/	HYSTEROSALPINGOGRAPHY & SONOHSTYEROGRAPHY CATHETER SET K092969	Acknowledgement Letter 09/05/2013
2013-7055	09/06/2013 10/04/2013	NATIONAL CORPORATE RESEARCH	FDA/OC/OES/DDM/	DKT FDA-1996-N-0050	Closed 09/06/2013
2013-7056	09/06/2013 10/04/2013	FOI Services, Inc.	FDA/OMPT/CDRH/OCER/DFOI/	K051671	Pending Action 09/06/2013
2013-7057	09/06/2013 10/04/2013	Medos Medizintechnik AG	FDA/OMPT/CDRH/OCER/DFOI/	K090449	Pending Action 09/06/2013
2013-7058	09/06/2013 10/04/2013	the Wood Burditt group	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	UNIVERSITY OF FLORIDA, CERHB, FLORIDA BIOLOGIX, ALACHUA, FL - - 482, 483 EIR ETC	Pending Action 09/06/2013
2013-7059	09/06/2013 10/04/2013	MEDTRONIC	FDA/OMPT/CDRH/OCER/DFOI/	K123633	Pending Action 09/06/2013
2013-7060	09/06/2013 10/04/2013	Hulsey Oliver & Mahar, LLP	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	AMERICAN CUSTOM BLENDERS, LLC, JEFFERSON, GA - 01/01/2011 - 09/03/2013	Pending Action 09/06/2013
2013-7061	09/06/2013 10/04/2013	FDANEWS	FDA/OC/OES/DFOI/	FOIA DISCLOSURE LOG (08/26/2013 - 08/30/2013)	Pending Action 09/06/2013
2013-7062	09/06/2013 10/04/2013	Mark Skertic	FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	RANBAXY PHARMACEUTICALS - PREVIOUSLY RELEASED RECORDS 04/01/2004 - 06/01/2013	Pending Action 09/06/2013

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2013-7063	09/06/2013 10/04/2013	James Alexander Corporation	FDA/OGROP/ORR/NE-FO/NYK-DO/NYK-	SCHOTT GLASS, ELMSFORD, NY - EIR, 483, RECALL (08/01/2011 - 09/03/2013)	Pending Action 09/06/2013

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			DCB/		
2013-7064	09/06/2013 10/04/2013	James Alexander Corporation	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	POREX TECHNOLOGIES, FAIRBURN, GA - 483, EIR, RECALL 06/01/2011 - 09/03/2013;	Pending Action 09/06/2013
2013-7065	09/06/2013 10/04/2013	James Alexander Corporation	FDA/OGROP/ORR/CE-FO/MIN-DO/MIN-CB/	TEEL PLASTICS, INC, BARABOO, WI - 483, EIR, RECALL 08/01/2011 - 09/03/2013	Closed 09/09/2013
2013-7066	09/06/2013 10/04/2013	James Alexander Corporation	FDA/OGROP/ORR/CE-FO/BLT-DO/BLT-CB/	KLOCKNER PENTAPLAST OF AMERICA, INC, GORDONSVILLE, VA - 483, EIR, RECALL 08/01/2011 - 09/03/2013	Pending Action 09/06/2013
2013-7067	09/06/2013 10/04/2013	APTIV SOLUTIONS	FDA/OMPT/CDRH/OCER/DFOI/	K120218 K113655 K113222 ETC	Pending Action 09/06/2013
2013-7068	09/06/2013 10/04/2013	Clariant Corporation	FDA/OC/OES/DFOI/ FDA/OF/CFSAN/OCD/EOS/	FCN 809	Pending Action 09/06/2013
2013-7069	09/06/2013 10/04/2013	Tris Pharma, Inc.	FDA/OMPT/CDER/ORP/DIDP/	NDA 020450	Closed 09/09/2013
2013-7070	09/06/2013 10/04/2013	BRIGHAM AND WOMEN'S HOSPITAL	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ORP/DIDP/	RECS THAT SUMMARIZE NOVEL NEW DRUGS APPROVED IN EACH CALENDAR 01/01/1979 - 12/31/2010	Pending Action 09/06/2013
2013-7071	09/06/2013 10/04/2013	NATIONAL MILK PRODUCERS FEDERATION	FDA/OF/CFSAN/OCD/EOS/ FDA/OC/OES/DDM/	FDA-2013-N-0888 - PETITION	Pending Action 09/06/2013
2013-7072	09/06/2013 10/04/2013	Tom Rhodes Law Firm, P.C.	FDA/OMPT/CDER/ORP/DIDP/ ORR/	SPECIALTY COMPOUNDING RECALL OF CALCIUM GLUCONATE	Pending Action 09/06/2013
2013-7073	09/06/2013 10/04/2013	LCC Consulting, LLC	FDA/OMPT/OSMP/OOPD/	QUTENZA - ORPHAN PRODUCT DESIGNATION	Pending Action 09/06/2013

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2013-7074	09/06/2013 10/04/2013	THE ASSOCIATED PRESS	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORR/NE-FO/NWE-DO/NWE-	TAYLOR FARMS DE MEXICO - 483, INVESTIGATION RECS 09/01/2003 - 09/03/2013	Pending Action 09/06/2013

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			CB/ FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORR/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORR/SE-FO/NOL-DO/NOL-CB/		
2013-7075	09/06/2013 10/04/2013	CAS MEDICAL SYSTEMS INC	FDA/OMPT/CDRH/OCER/DFOI/	NONIN MEDICAL INC - K102715	Acknowledgement Letter 09/06/2013
2013-7076	09/06/2013 10/04/2013	III SOLUTION LABORARY	FDA/OMPT/CDRH/OCER/DFOI/	SYNAPSE 3D LUNG & ABDOMEN ANAYLIS - K130542; MIPLATFORM MEDICAL IMAGING SUITE - K131424	Acknowledgement Letter 09/06/2013
2013-7077	09/06/2013 10/04/2013	DR REDDY'S LABORATORIES INC	FDA/OMPT/CDER/ORP/DIDP/	ATORVASTATIN CALCIUM TABS - ANDA 91-650, 203-257 BIOEQV RVWS, MODULE 3.2P.1 COMPOSITION SECTION	Acknowledgement Letter 09/06/2013
2013-7078	09/06/2013 10/04/2013	ROCKY MOUNTAIN POISON AND DRUG CENTER	FDA/OF/CFSAN/OCD/EOS/	RED BULL, MONSTER, ROCK STAR, ETC - CAERS 2010 TO PRESENT	Acknowledgement Letter 09/06/2013
2013-7079	09/06/2013 10/04/2013	CAUDLE #20711-058, BRANDON LEE	FDA/OMPT/CDER/ORP/DIDP/	TRUVADA - PI	Closed 09/09/2013
2013-7080	09/06/2013 10/04/2013	KOWINSKY, BARBARA	FDA/OMPT/CDER/ORP/DIDP/	BASF Grenzach GmbH - EIR JULY 2011	Pending Action 09/06/2013
2013-7081	09/06/2013 10/04/2013	James Alexander Corporation	FDA/OGROP/ORR/CE-FO/NWJ-DO/NWJ-CB/	ATLANTIC SCALE COMPANY, NUTLEY, NJ - EIR, 483, RECALL (04/01/2011 - 09/03/2013) ;	Pending Action 09/06/2013
2013-7082	09/06/2013 10/04/2013	James Alexander Corporation	FDA/OGROP/ORR/CE-FO/NWJ-DO/NWJ-CB/	BRANDT BOX & PAPAER CO, COLUMBIA, NJ - EIR, 483, RECALL 08/01/2011 - 09/03/2013	Pending Action 09/06/2013
2013-7083	09/06/2013 10/04/2013	James Alexander Corporation	FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/	ACCU-GLASS LLC, ST LOUIS, MO - EIR, 483, RECALL 08/01/2011 - 09/03/2013	Pending Action 09/06/2013
2013-7084	09/06/2013 10/04/2013	James Alexander Corporation	FDA/OGROP/ORR/CE-FO/NWJ-DO/NWJ-CB/	FRUTAROM USA, INC, NORTH BERGEN, NJ - EIR, 483, RECALL 06/01/2011 - 09/03/2013	Pending Action 09/06/2013
2013-7085	09/06/2013 10/04/2013	James Alexander Corporation	FDA/OGROP/ORR/CE-FO/NWJ-DO/NWJ-CB/	GERRESHEIMER GLASS INC, VINELAND, NJ - EIR, 483, RECALL 07/01/2011 - 09/03/2013	Pending Action 09/06/2013

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2013-7086	09/06/2013 10/04/2013	James Alexander Corporation	FDA/OGROP/ORR/NE-FO/NYK-DO/NYK-	MID-YORK PRESS, INC, SHERBURNE, NY - EIR, 483, RECALL 07/01/2011 - 09/03/2013	Pending Action 09/06/2013

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			DCB/		
2013-7087	09/06/2013 10/04/2013	James Alexander Corporation	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	STERIPRO LABS, ITASCA, IL - EIR, 483, RECALL 08/01/2011 - 09/03/2013	Pending Action 09/06/2013