

# Query Result Report

Records: 207

Action Office: ALL

Received Via: BOTH

Control #:

Rec/Create Date: 02/25/2013

To 03/01/2013

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                           |
|-----------|--------------------------|----------------------------|-----------------------------------|--|--|
| 2013-1394 | 02/25/2013<br>03/25/2013 | FOI SERVICES INC           | OM/OSS/OPILS/DFI/                 | 2012-7067  | Closed<br>03/12/2013                           |
| 2013-1395 | 02/25/2013<br>03/25/2013 | Malhotra, Shibani          | FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/ | HOSPIRA, INC, LAKE FOREST, IL - 483,<br>UNTITLED LETTER (06/01/2012 -<br>02/22/2013) | Pending Action<br>02/25/2013                   |
| 2013-1396 | 02/25/2013<br>03/25/2013 | Framingham Heart Study     | FDA/OMPT/CDRH/OCER/DFOI/          | K941546, K980176, K890100  | Closed<br>03/12/2013                           |
| 2013-1397 | 02/25/2013<br>03/25/2013 | Hyman, Phelps and McNamara | FDA/OF/CFSAN/OCD/EOS/             | US AGENT FOR REGISTERED FOREIGN<br>FOOD FACILITIES                                   | Delogged (not a FOIA<br>Request)<br>02/26/2013 |
| 2013-1398 | 02/25/2013<br>03/25/2013 | Framingham Heart Study     | FDA/OMPT/CDRH/OCER/DFOI/          | K932673, K910859, K882378 ETC  | Closed<br>03/12/2013                           |

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| 2013-1399 | 02/25/2013<br>03/25/2013 | BERMAN DEVALERIO ET AL | FDA/OGROP/ORR/NE-FO/NWE-DO/NWE- | ABIOMED, INC - COMMUNICATIONS WITH FDA RE IMPELLA RECOVER LP 2.5 PERCUTANEOUS CARDIAC SUPPORT SYSTEM | Pending Action<br>02/25/2013 |

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| Control # | Recd Date / Due Date     | Requester                           | Action Offices                    | Subject  | Status / Status Date                        |
|-----------|--------------------------|-------------------------------------|-----------------------------------|--|---|
|           |                          |                                     | CB/<br>FDA/OMPT/CDRH/OCER/DFOI/   |  |   |
| 2013-1400 | 02/25/2013<br>03/25/2013 | AccessClosure, Inc.                 | FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ | ACCESSCLOSURE, MOUNTAIN VIEW, CA - EIR (08/01/2011 - 08/30/2011)           | Delogged (not a FOIA Request)<br>02/26/2013 |
| 2013-1401 | 02/25/2013<br>03/25/2013 | Alfa Laval Tank Equipment           | FDA/OF/CFSAN/OCD/EOS/             | FCN 302, FCN 297   | Pending Action<br>02/25/2013                |
| 2013-1402 | 02/25/2013<br>03/25/2013 | FOI SERVICES INC                    | OM/OSS/OPILS/DFI/                 | 2013-227   | Closed<br>03/21/2013                        |
| 2013-1403 | 02/25/2013<br>03/25/2013 | Saretsky Katz Dranoff & Glass, LLP  | FDA/OF/CFSAN/OCD/EOS/             | DMAA CONTAINING PRODUCTS - AERS (06/01/2012 - 02/22/2013)                  | Pending Action<br>02/25/2013                |
| 2013-1404 | 02/25/2013<br>03/25/2013 | FOI SERVICES INC                    | OM/OSS/OPILS/DFI/                 | 2012-7254  | Closed<br>03/12/2013                        |
| 2013-1405 | 02/25/2013<br>03/25/2013 | C & H International Co.             | FDA/OMPT/CDRH/OCER/DFOI/          | K020851  | Pending Action<br>02/25/2013                |
| 2013-1406 | 02/25/2013<br>03/25/2013 | Framingham Heart Study              | FDA/OMPT/CDRH/OCER/DFOI/          | K903315, K830654, K912573 ETC  | Closed<br>03/21/2013                        |
| 2013-1407 | 02/25/2013<br>03/25/2013 | Erica Winter, Noven Pharmaceuticals | FDA/OMPT/CDER/ORP/DIDP/           | ANSAID - PHARMACOLOGY REVIEW, MEDICAL/SAFETY REVIEW, CLINICAL PHARMACOLOGY | Closed<br>02/27/2013                        |
| 2013-1408 | 02/25/2013<br>03/25/2013 | Framingham Heart Study              | FDA/OMPT/CDRH/OCER/DFOI/          | K921777, K934722, K934311 ETC  | Closed<br>03/21/2013                        |
| 2013-1409 | 02/25/2013<br>03/25/2013 | B. Braun Medical Inc.               | FDA/OMPT/CDER/ORP/DIDP/           | NDA 17643 - SBA, MEDICAL REVIEW, CLINICAL/PHARMACOLOGY REVIEW              | Closed<br>02/27/2013                        |
| 2013-1410 | 02/25/2013<br>03/25/2013 | Framingham Heart Study              | FDA/OMPT/CDRH/OCER/DFOI/          | K896095, K862158, K900773 ETC  | Closed<br>03/21/2013                        |
| 2013-1411 | 02/25/2013<br>03/25/2013 | FOI SERVICES INC                    | FDA/OMPT/CDER/ORP/DIDP/           | ANDA 203263  | Pending Action<br>02/25/2013                |
| 2013-1412 | 02/25/2013<br>03/25/2013 | FOI SERVICES INC                    | FDA/OMPT/CDER/ORP/DIDP/           | HAMELN PHARMACEUTICALS, HAMELN, GERMANY - EIR, 483 (06/04/12-06/14/12)     | Pending Action<br>02/25/2013                |
| 2013-1413 | 02/25/2013<br>03/25/2013 | B. Braun Medical Inc.               | FDA/OMPT/CDER/ORP/DIDP/           | NDA 18786  | Closed<br>02/26/2013                        |
| 2013-1414 | 02/25/2013<br>03/25/2013 | Malhotra, Shibani                   | ORA/<br>ORA/ORO/DIOP/             | HOSPIRA, INC - IMPORT BAN (11/02/2012 - 02/22/2013)                        | Pending Action<br>02/25/2013                |

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| Control # | Recd Date / Due Date     | Requester                             | Action Offices                     | Subject  | Status / Status Date                       |
|-----------|--------------------------|---------------------------------------|------------------------------------|--|--|
| 2013-1415 | 02/25/2013<br>03/25/2013 | INC RESEARCH CONSULTING & SUBMISSIONS | FDA/OMPT/CDER/ORP/DIDP/            | JANUVIA - PEDIATRIC WRITTEN REQUEST FOR STUDIES AND AMENDMENTS   | Closed Denial<br>03/15/2013                |
| 2013-1416 | 02/25/2013<br>03/25/2013 | Boehringer Ingelheim Vetmedica, Inc.  | FDA/OMPT/CDER/ORP/DIDP/            | AUROBINDO PHARMA LTD, HYDERABAD, INDIA - EIR (09/17/2012 - 02/22/2013)   | Closed<br>03/11/2013                       |
| 2013-1417 | 02/25/2013<br>03/25/2013 | Step toe Therapeutics Inc.            | FDA/OMPT/CDER/ORP/DIDP/            | TBO -FILGRASTIM - SBA  | Withdrawn Closed w/o Charges<br>02/25/2013 |
| 2013-1418 | 02/25/2013<br>03/25/2013 | eFoodAlert                            | ORA/<br>CVM/OCD/                   | KASEL ASSOCIATED INDUSTRIES, DENVER, CO - 483, 423(A) LETTER   | Partial Response<br>02/26/2013             |
| 2013-1419 | 02/25/2013<br>03/25/2013 | Michael Muely                         | FDA/OMPT/CDRH/OCER/DFOI/           | K081304  | Pending Action<br>02/25/2013               |
| 2013-1420 | 02/25/2013<br>03/25/2013 | McGlynn, Glisson & Mouton             | FDA/OMPT/CDRH/OCER/DFOI/           | AMNISURE INTERNATIONAL, LLC - MEDICAL DEVICE CORRECTION LETTER 10/01/07  | Closed<br>03/14/2013                       |
| 2013-1421 | 02/25/2013<br>03/25/2013 | VENABLE LLP                           | FDA/OMPT/CDER/ORP/DIDP/            | AZO GESIC, AZO SEPTIC, AZO STANDARD, ETC - AERS  | Closed<br>02/27/2013                       |
| 2013-1422 | 02/25/2013<br>03/25/2013 | FLAVOR DEVELOPMENT CORP               | FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ | FLAVOR DEVELOPMENT CORP, NORWOOD, NJ - EIR 11/11   | Closed<br>03/15/2013                       |
| 2013-1423 | 02/25/2013<br>03/25/2013 | FDANEWS                               | FDA/OMPT/CDER/ORP/DIDP/            | GLOCHEM INDUSTRIES LTD, ANDRHA PRADESH, INDIA; SEVEN STAR PHARMACEUTICAL CO LTD, TAIPEI HSIENG, TAIWAN; BEIJING TAIYANG PHARMACEUTICAL INDUSTRY CO LTD, BEIJING, CHINA, ETC - 483S 1/1-31/13 | Acknowledgement Letter<br>02/25/2013       |
| 2013-1424 | 02/25/2013<br>03/25/2013 | FDANEWS                               | FDA/OMPT/CDRH/OCER/DFOI/           | BIOMET CO LTD, SEOUL, KOREAN; RUBIMED AG, HERGISWIL, SWITZERLAND - 483S 1/1-31/13  | Acknowledgement Letter<br>02/25/2013       |
| 2013-1425 | 02/25/2013<br>03/25/2013 | FDANEWS                               | FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ | PRIME ENTERPRISES INC, HIALEAH, FL; BELCHER PHARMACEUTICALS LLC, LARGO, FL; GADAL LABORATORIES INC, MIAMI, FL, ETC - 483S 1/1-31/13  | Acknowledgement Letter<br>02/25/2013       |
| 2013-1426 | 02/25/2013<br>03/25/2013 | FDANEWS                               | FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/ | LINCARE INC, OTTAWA, KS; MOBIUS THERAPEUTICS LLC, ST LOUIS, MO; RELIABLE BIOPHARMACEUTICAL CORP, OVERLAND, MO, ETC - 483S 1/1-31/13  | Closed<br>03/21/2013                       |
| 2013-1427 | 02/25/2013<br>03/25/2013 | FDANEWS                               | FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ | ALPHA MEDICAL INSTRUMENTS LLC, MISSION VIEJO, CA; HELIX MEDICAL LLC, CARPINTERIA, CA; ACUFOCUS INC, IRVINE, CA - 483S 1/1-31/13  | Closed<br>03/05/2013                       |

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|-----------|--------------------------|-----------|------------------------------------|---|----------------------|
| 2013-1428 | 02/25/2013<br>03/25/2013 | FDANEWS   | FDA/OGROP/ORR/CE-FO/MIN-DO/MIN-CB/ | BIRCHWOOD LABORATORIES INC, EDEN PRAIRIE, MN; FRONTIER MEDICAL PRODUCTS INC, PORT WASHINGTON, WI; ELECTRO KINETIC TECHNOLOGIES LLC, GERMANTOWN, WI - 483S 1/1-31/13 | Closed<br>03/06/2013 |

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|-----------|--------------------------|-----------|---------------------------------|--|--------------------------------------|
| 2013-1429 | 02/25/2013<br>03/25/2013 | FDANEWS   | FDA/OGROP/ORR/NE-FO/NWE-DO/NWE- | BIO-CONCEPT LABORATORIES INC,<br>SALEM, NH; BFS PHARMA INC,<br>RANDOLPH, MA; CENTRAL ADMIXTURE<br>PHARMACY SERVICES INC, WOBURN,<br>MA, ETC - 483S 1/1-31/13 | Acknowledgement Letter<br>02/25/2013 |

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| 2013-1430 | 02/25/2013<br>03/25/2013 | FDANEWS   | FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ | CONTRACT COATING INC,<br>HACKENSACK, NJ; MEDI PHYSICS INC,<br>SOUTHFIELD PLAINFIELD, NJ; OMEGA<br>PACKAGING CORP, TOTOWA, NJ, ETC -<br>483S 1/1-31/13   | Closed<br>03/22/2013                 |
| 2013-1431 | 02/25/2013<br>03/25/2013 | FDANEWS   | FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/ | LIFESOUTH COMMUNITY BLOOD<br>CENTERS INC, MADISON, AL; PETNET<br>SOLUTIONS INC, COVINGTON, LA; GAC<br>TECHNO CENTER, BIRMINGHAM, AL -<br>483S 1/1-31/13 | Acknowledgement Letter<br>02/25/2013 |



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| 2013-1432 | 02/25/2013<br>03/25/2013 | FDANEWS   | FDA/OGROP/ORR/NE-FO/NYK-DO/NYK- | AMES GOLDSMITH CORP, GLENS FALLS, NY; ADVANCE PHARMACEUTICAL INC, HOLTSVILLE, NY; FRESENIUS KABI USA LLC, GRAND ISLAND, NY, ETC - 483S<br>1/1-31/13 | Closed<br>03/13/2013 |

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|           |                          |           | DCB/                              |  |                                      |
| 2013-1433 | 02/25/2013<br>03/25/2013 | FDANEWS   | FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ | DRECHER ENTERPRISES INC, UPPER DARBY, PA; PIRAMAL CRITICAL CARE INC, BETHLEHEM, PA - 483S 1/1-31/13                      | Closed<br>03/14/2013                 |
| 2013-1434 | 02/25/2013<br>03/25/2013 | FDANEWS   | FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ | XLUMENA INC, MOUNTAIN VIEW, CA; AMEDICA BIOTECH INC, HAYWARD, CA; INVUITY INC, SAN FRANCISCO, CA - 483S 1/1-31/13        | Closed<br>03/15/2013                 |
| 2013-1435 | 02/25/2013<br>03/25/2013 | FDANEWS   | FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/ | MSD INTERNATIONAL GMBH PUERTO RICO BRANCH LLC, ARECIBO, PR; CARDINAL HEALTH PR 218 INC, ANASCO, PR - 483S 1/1-31/13      | Acknowledgement Letter<br>02/25/2013 |
| 2013-1436 | 02/25/2013<br>03/25/2013 | FDANEWS   | FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/ | BEZWECKEN INC, WILSONVILLE, OR; COMFORT ACRYLICS INC, CAMAS, WA; VANGUARD EMS INC, BEAVERTON, OR, ETC - 483S 1/1-31/13   | Acknowledgement Letter<br>02/25/2013 |
| 2013-1437 | 02/25/2013<br>03/25/2013 | FDANEWS   | FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ | WAYNE CONCEPT MANUFACTURING CO INC, FORT WAYNE, IN; CARACO PHARMACEUTICAL LABORATORIES INC, DETROIT, MI - 483S 1/1-31/13 | Closed<br>03/21/2013                 |

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| 2013-1438 | 02/25/2013<br>03/25/2013 | FDA NEWS  | FDA/OGROP/ORR/SW-FO/DEN-DO/DEN- | SHIPPERT ENTERPRISES LTD,<br>CENTENNIAL, CO - 483S 1/1-31/13 | Closed<br>02/28/2013 |

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|           |                          |                                    | CB/                                    |  |                                      |
| 2013-1439 | 02/25/2013<br>03/25/2013 | UBS GLOBAL ASSET MANAGEMENT        | FDA/OGROP/ORR/SE-FO/SJN-DO/SJN-CB/     | INTEGRA, ANASCO, PR - 483 10/12 TO 11/12   | Acknowledgement Letter<br>02/25/2013 |
| 2013-1440 | 02/25/2013<br>03/25/2013 | EAS Consulting Group, LLC          | FDA/OF/CFSAN/OCD/EOS/                  | SUNTORY LTD - ACUTE TOXICITY TEST HGT-94-23; HGT-94-26   | Acknowledgement Letter<br>02/25/2013 |
| 2013-1441 | 02/25/2013<br>03/25/2013 | FAUST 01B2507, BRIAN               | FDA/OF/CFSAN/OCD/EOS/                  | POTASSIUM - AER  | Acknowledgement Letter<br>02/25/2013 |
| 2013-1442 | 02/25/2013<br>03/25/2013 | FDANEWS                            | FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/     | MID-CONTINENT PACKAGING INC,ENID, OH; FRESENIUS MEDICAL CARE NORTH AMERICA TEXAS, IRVING, TX; RAPID TRAUMA LLC, SAN ANTONIO, TX, ETC - 43S 1/1-31/13 | Closed<br>03/18/2013                 |
| 2013-1443 | 02/25/2013<br>03/25/2013 | DEGGE GROUP LTD                    | FDA/OMPT/CDER/ORP/DIDP/                | ISRS 7362873, 7388962, 7389714, ETC  | Acknowledgement Letter<br>02/25/2013 |
| 2013-1444 | 02/25/2013<br>03/25/2013 | DEGGE GROUP LTD                    | FDA/OMPT/CDER/ORP/DIDP/                | ISRS 8438483, 8438487, 8438491 ETC   | Acknowledgement Letter<br>02/25/2013 |
| 2013-1445 | 02/25/2013<br>03/25/2013 | DEGGE GROUP LTD                    | FDA/OMPT/CDER/ORP/DIDP/                | ISRS 8122655, 8130611, 8130617 ETC   | Acknowledgement Letter<br>02/25/2013 |
| 2013-1446 | 02/25/2013<br>03/25/2013 | DEGGE GROUP LTD                    | FDA/OMPT/CDER/ORP/DIDP/                | ISRS 7616861, 7621864, 7630337, ETC  | Closed<br>03/12/2013                 |
| 2013-1447 | 02/25/2013<br>03/25/2013 | Atkins Intellectual Property, PLLC | FDA/OF/CFSAN/OCD/EOS/<br>ORR/ORO/DIOP/ | B&B INTERNATIONAL, NY, NY - VIOLATIONS 200 TO 10/04  | Acknowledgement Letter<br>02/25/2013 |
| 2013-1448 | 02/25/2013<br>03/25/2013 | Atkins Intellectual Property, PLLC | FDA/OF/CFSAN/OCD/EOS/<br>ORR/ORO/DIOP/ | OST AQUA ZAO, CHERNOGOLOVKA, RUSSIA - VIOLATIONS 2000 TO PRESENT   | Acknowledgement Letter<br>02/25/2013 |
| 2013-1449 | 02/25/2013<br>03/25/2013 | Atkins Intellectual Property, PLLC | FDA/OF/CFSAN/OCD/EOS/<br>ORR/ORO/DIOP/ | AQUA LIFE , CHEMOGOLOVKA, RUSSIA - VIOLATIONS 2000 TO PRESENT  | Closed<br>03/18/2013                 |
| 2013-1450 | 02/25/2013<br>03/25/2013 | FDANEWS                            | FDA/OGROP/ORR/CE-FO/CIN-DO/CIN-CB/     | WRENCARE, MIDDLETOWN, OH; DIAGNOSTIC HYBRIDS INC, ATHENS, OH; SCM TRUE AIR TECHNOLOGIES LLC, LOUISVILLE, KY, ETC - 483S                              | Closed<br>03/20/2013                 |
| 2013-1451 | 02/25/2013<br>03/25/2013 | FDANEWS                            | FDA/OGROP/ORR/CE-FO/CHI-DO/CHI-CB/     | CORPAK MEDSYSTEMS INC, BUFFALO GROVE, IL; ALMA LASERS INC, BUFFALO GROVE, IL - 483S 1/1-31/13  | Acknowledgement Letter<br>02/25/2013 |
| 2013-1452 | 02/25/2013<br>03/25/2013 | TRAUB LIEBERMAN STRAUS ET AL       | FDA/OMPT/CDER/ORP/DIDP/<br>ORR/        | FRANCKS LAB INC - BRILLIANT BLUE G; TRIAMCINOLONE INJECTION  | Partial Response<br>03/04/2013       |

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| 2013-1453 | 02/25/2013<br>03/25/2013 | FDANEWS   | FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ | JOHNS HOPKINS UNIV PET CENTER, BALTIMORE, MD; HUMAN BIOSCIENCES INC, GAITHERSBURG, MD; VISIONARY OPTICS LLC, FRONT ROYAL, VA - 483S 1/1-31/13 | Acknowledgement Letter<br>02/25/2013 |
| 2013-1454 | 02/25/2013<br>03/25/2013 | FDANEWS   | FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ | MEDI-FARE DRUG AND HOME HEALTH CENTER, BLACKSBURG, SC; NCONTRACT SURGICAL INC, MORRISVILLE, NC - 483S 1/1-31/13                               | Acknowledgement Letter<br>02/25/2013 |

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| 2013-1455 | 02/25/2013<br>03/25/2013 | WAGNER LYNN ET AL | FDA/OGROP/ORR/SW-FO/DEN-DO/DEN- | DA VITA HEALTHCARE PARTNERS INC - INVESTIGATION RECS | Pending Action<br>03/12/2013 |

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|           |                          |                                      | CB/<br>FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/                   |  |                                      |
| 2013-1456 | 02/25/2013<br>03/25/2013 | GALLAGHER & KENNEDY PA               | FDA/OF/CFSAN/OCD/EOS/<br>FDA/OGROP/ORO/PA-FO/LOS-DO/LOS-CB/ | THERMOLIFE INTERNATIONAL LLC - PUMP BOL, E BOL, T, BOL - CORR, INVESTIGATIONS, AER 1/05 TO 12/11 | Acknowledgement Letter<br>02/25/2013 |
| 2013-1457 | 02/25/2013<br>03/25/2013 | JH BARR & ASSOCIATES LLC             | OM/OSS/OPILS/DFI/   | CLOSED FOI REQUESTS 2/4-8/13   | Closed<br>02/25/2013                 |
| 2013-1458 | 02/25/2013<br>03/25/2013 | JH BARR & ASSOCIATES LLC             | OM/OSS/OPILS/DFI/   | DAILY LOG 2/4-8/13   | Closed<br>02/25/2013                 |
| 2013-1459 | 02/25/2013<br>03/25/2013 | FOI SERVICES INC                     | OM/OSS/OPILS/DFI/   | CLOSED FOI REQUESTS 2/4-8/13   | Closed<br>02/25/2013                 |
| 2013-1460 | 02/25/2013<br>03/25/2013 | FOI SERVICES INC                     | OM/OSS/OPILS/DFI/   | DAILY LOG 2/4-8/13   | Closed<br>02/25/2013                 |
| 2013-1461 | 02/25/2013<br>03/25/2013 | WOLTERS KLUWER LAW & BUSINESS        | OM/OSS/OPILS/DFI/   | DAILY LOG 2/4-8/13   | Closed<br>02/25/2013                 |
| 2013-1462 | 02/25/2013<br>03/25/2013 | WOLTERS KLUWER LAW & BUSINESS        | OM/OSS/OPILS/DFI/   | CLOSED FOI REQUESTS 2/4-8/13   | Closed<br>02/25/2013                 |
| 2013-1463 | 02/25/2013<br>03/25/2013 | CanReg, Inc.                         | OM/OSS/OPILS/DFI/   | CLOSED FOI REQUESTS 2/4-8/13   | Closed<br>02/25/2013                 |
| 2013-1464 | 02/25/2013<br>03/25/2013 | CanReg, Inc.                         | OM/OSS/OPILS/DFI/   | DAILY LOG 2/4-8/13   | Closed<br>02/25/2013                 |
| 2013-1465 | 02/25/2013<br>03/25/2013 | Center for Regulatory Services, Inc. | OM/OSS/OPILS/DFI/   | DAILY LOG 2/4-8/13   | Closed<br>02/25/2013                 |
| 2013-1466 | 02/25/2013<br>03/25/2013 | FDA REVIEW/FDA WEBVIEW               | OM/OSS/OPILS/DFI/   | CLOSED FOI REQUESTS 2/4-8/13   | Closed<br>02/25/2013                 |
| 2013-1467 | 02/25/2013<br>03/25/2013 | WASHINGTON INFORMATION SOURCE        | OM/OSS/OPILS/DFI/   | DAILY LOG 2/4-8/13   | Closed<br>02/25/2013                 |
| 2013-1468 | 02/25/2013<br>03/25/2013 | WASHINGTON INFORMATION SOURCE        | OM/OSS/OPILS/DFI/   | DAILY LOG 2/4-8/13   | Closed<br>02/25/2013                 |
| 2013-1469 | 02/25/2013<br>03/25/2013 | BEVERIDGE & DIAMOND                  | FDA/OF/CFSAN/OCD/EOS/<br>OM/OSS/OPILS/DFI/                  | CFSAN FOIA REQUESTS (02/01/2013 - 02/25/2013)  | Closed<br>02/25/2013                 |
| 2013-1470 | 02/26/2013<br>03/26/2013 | Stocking, John                       | FDA/OMPT/CDRH/OCER/DFOI/                                    | K081697  | Pending Action<br>02/26/2013         |
| 2013-1471 | 02/26/2013<br>03/26/2013 | Brent Arbogast                       | OM/OSS/OPILS/DFI/   | FREQUENTLY REQUESTED RECORDS   | Closed<br>02/26/2013                 |

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| Control # | Recd Date / Due Date     | Requester              | Action Offices                                | Subject  | Status / Status Date                       |
|-----------|--------------------------|------------------------|---|--|--|
| 2013-1472 | 02/26/2013<br>03/26/2013 | Framingham Heart Study | FDA/OMPT/CDRH/OCER/DFOI/                      | K120834, K060967, K924125 ETC  | Closed<br>03/21/2013                       |
| 2013-1473 | 02/26/2013<br>03/26/2013 | Framingham Heart Study | FDA/OMPT/CDRH/OCER/DFOI/                      | K063696, K041191, K010566 ETC  | Pending Action<br>02/26/2013               |
| 2013-1474 | 02/26/2013<br>03/26/2013 | TauTona Group          | FDA/OMPT/CDRH/OCER/DFOI/<br>OM/OSS/OPILS/DFI/ | K980431  | Closed<br>02/26/2013                       |
| 2013-1475 | 02/26/2013<br>03/26/2013 | TauTona Group          | FDA/OMPT/CDRH/OCER/DFOI/                      | K992991  | Pending Action<br>02/26/2013               |
| 2013-1476 | 02/26/2013<br>03/26/2013 | TauTona Group          | FDA/OMPT/CDRH/OCER/DFOI/<br>OM/OSS/OPILS/DFI/ | K013625  | Closed<br>02/26/2013                       |
| 2013-1477 | 02/26/2013<br>03/26/2013 | TauTona Group          | FDA/OMPT/CDRH/OCER/DFOI/<br>OM/OSS/OPILS/DFI/ | K050246  | Closed<br>02/27/2013                       |
| 2013-1478 | 02/26/2013<br>03/26/2013 | SOMMER LAW GROUP, PC   | FDA/OMPT/CDRH/OCER/DFOI/                      | RODAN & FIELDS AMP MR MICRO-NEEDLE ROLLER - CLASSIFICATION RECS        | Pending Action<br>02/26/2013               |
| 2013-1479 | 02/26/2013<br>03/26/2013 | TissueNet              | FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/            | ALLOGRAFT INNOVATIONS, GAINESVILLE, FL - 483 (11/01/2012 - 02/25/2013) | Pending Action<br>02/26/2013               |
| 2013-1480 | 02/26/2013<br>03/26/2013 | FDANEWS                | OM/OSS/OPILS/DFI/                             | FOIA LOG (02/18/2013 - 02/22/2013)                                     | Closed<br>03/15/2013                       |
| 2013-1481 | 02/26/2013<br>03/26/2013 | CELERION               | FDA/OMPT/CTP/OD/                              | TAR AND NICOTINE CONTENT OF CIGARETTES                                 | Withdrawn Closed w/o Charges<br>03/04/2013 |
| 2013-1482 | 02/26/2013<br>03/26/2013 | FOI SERVICES INC       | CVM/OCD/                                      | TYPE C FEED ASSAY FOR NICARB 25%                                       | Pending Action<br>02/26/2013               |
| 2013-1483 | 02/26/2013<br>03/26/2013 | Simpson, Scott B       | FDA/OGROP/ORR/SW-FO/DAL-DO/DAL-CB/            | INVESTIGATION RECS   | Closed<br>03/18/2013                       |
| 2013-1484 | 02/26/2013<br>03/26/2013 | NIPRO Diagnostics      | FDA/OMPT/CDRH/OCER/DFOI/                      | MW5009109  | Closed<br>03/05/2013                       |
| 2013-1485 | 02/26/2013<br>03/26/2013 | NIPRO Diagnostics      | FDA/OMPT/CDRH/OCER/DFOI/                      | MW5027038  | Closed<br>03/04/2013                       |
| 2013-1486 | 02/26/2013<br>03/26/2013 | NIPRO Diagnostics      | FDA/OMPT/CDRH/OCER/DFOI/                      | MW5016600  | Acknowledgement Letter<br>02/26/2013       |
| 2013-1487 | 02/26/2013<br>03/26/2013 | NIPRO Diagnostics      | FDA/OMPT/CDRH/OCER/DFOI/                      | MW5009261  | Closed<br>03/05/2013                       |



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| Control # | Recd Date / Due Date     | Requester                         | Action Offices   | Subject   | Status / Status Date                 |
|-----------|--------------------------|-----------------------------------|--|---|--------------------------------------|
| 2013-1488 | 02/26/2013<br>03/26/2013 | NIPRO Diagnostics                 | FDA/OMPT/CDRH/OCER/DFOI/   | MW5017757   | Closed<br>03/05/2013                 |
| 2013-1489 | 02/26/2013<br>03/26/2013 | NIPRO Diagnostics                 | FDA/OMPT/CDRH/OCER/DFOI/   | MW5012580   | Closed<br>03/05/2013                 |
| 2013-1490 | 02/26/2013<br>03/26/2013 | NIPRO Diagnostics                 | FDA/OMPT/CDRH/OCER/DFOI/   | MW5019215   | Closed<br>03/05/2013                 |
| 2013-1491 | 02/26/2013<br>03/26/2013 | NIPRO Diagnostics                 | FDA/OMPT/CDRH/OCER/DFOI/   | MW5019473   | Closed<br>03/05/2013                 |
| 2013-1492 | 02/26/2013<br>03/26/2013 | NIPRO Diagnostics                 | FDA/OMPT/CDRH/OCER/DFOI/   | MW5005390   | Closed<br>03/05/2013                 |
| 2013-1493 | 02/26/2013<br>03/26/2013 | NIPRO Diagnostics                 | FDA/OMPT/CDRH/OCER/DFOI/   | MW5009108   | Closed<br>03/05/2013                 |
| 2013-1494 | 02/26/2013<br>03/26/2013 | NIPRO Diagnostics                 | FDA/OMPT/CDRH/OCER/DFOI/   | MW5002772   | Closed<br>03/05/2013                 |
| 2013-1495 | 02/26/2013<br>03/26/2013 | OFW LAW                           | OM/OSS/OPILS/DFI/<br>FDA/OMPT/CDRH/OCER/DFOI/                        | CDRH UNTITLED LTRS 12/1/11 TO PRESENT   | Pending Action<br>02/26/2013         |
| 2013-1496 | 02/26/2013<br>03/26/2013 | OLSSON FRANK WEEDA TERMAN MATZ PC | OM/OSS/OPILS/DFI/  | CDRH UNTITLED LTRS  | Closed<br>03/01/2013                 |
| 2013-1497 | 02/26/2013<br>03/26/2013 | SCOTT #JY1512/L-27, SEAN          | FDA/OMPT/CDER/ORP/DIDP/<br>OC/OCC/<br>OM/OSS/OPILS/DFI/              | ASTRAZENECA PHARMS - SEROQUEL OFF-LABEL MARKETING, SETTLEMENT AGREEMENT, CMLPNTS, ETC | Acknowledgement Letter<br>02/26/2013 |
| 2013-1498 | 02/26/2013<br>03/26/2013 | MCKENNA LONG & ALDRIDGE LLP       | FDA/OGROP/ORPA-FO/LOS-DO/LOS-CB/<br>FDA/OGROP/ORPA-FO/SAN-DO/SAN-CB/ | NATURAL SELECTION FOODS, EARTHBOUND FARMS, TAYLOR FARMS - EIRS, 483S 1/06 TO PRESENT  | Hold<br>03/20/2013                   |

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| Control # | Recd Date / Due Date     | Requester                       | Action Offices   | Subject   | Status / Status Date           |
|-----------|--------------------------|---------------------------------|--|---|--------------------------------|
| 2013-1499 | 02/26/2013<br>03/26/2013 | PROJECT ON GOVERNMENT OVERSIGHT | FDA/OMPT/CDER/ORP/DIDP/<br>FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/<br>FDA/OGROP/ORANE-FO/NYK-DO/NYK- | PRADAXA - AERS; BOEHRINGER<br>INGELHEIM, DANBURY, CT; COLUMBUS,<br>OH, PETERSBURG, VA - EIRS; RE-LY<br>TRIALS - CLNCL SITES, NAMES OF<br>INVESTIGATORS, ETC | Partial Response<br>03/13/2013 |

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| Control # | Recd Date / Due Date     | Requester  | Action Offices   | Subject   | Status / Status Date                 |
|-----------|--------------------------|--|--|---|--------------------------------------|
|           |                          |  | DCB/<br>FDA/OGROP/ORPA/PA-FO/LOS-DO/LOS-CB/<br>FDA/OGROP/ORPA/SE-FO/ATL-DO/ATL-CB/<br>FDA/OGROP/ORPA/SE-FO/FLA-DO/FLA-CB/<br>FDA/OGROP/ORPA/SW-FO/KAN-DO/KAN-CB/ |   |                                      |
| 2013-1500 | 02/26/2013<br>03/26/2013 | MOTT, VIRGINIA L   | FDA/OMPT/CDER/ORP/DIDP/  | NAPROXEN - AERS   | Closed<br>02/27/2013                 |
| 2013-1501 | 02/26/2013<br>03/26/2013 | UNIV OF FLORIDA COLLEGE OF AGRICULTURE AND LIFE SCIENCES | FDA/OF/CFSAN/OCD/EOS/  | ASSESSMENT OF THE NET EFFECTS OF FISH CONSUMPTION DURING PREGNACY - FINAL DRAFT | Acknowledgement Letter<br>02/26/2013 |
| 2013-1502 | 02/26/2013<br>03/26/2013 | CLARK, CHRISTY   | FDA/OMPT/CDER/ORP/DIDP/  | PROPRANOLOL - AERS  | Closed<br>02/27/2013                 |
| 2013-1503 | 02/26/2013<br>03/26/2013 | WOOD LAW FIRM LLC  | FDA/OF/CFSAN/OCD/EOS/<br>ORA/OCI/  | IDS SPORTS - MASS TABS INVESTIGATION RECS                                       | Acknowledgement Letter<br>02/26/2013 |
| 2013-1504 | 02/26/2013<br>03/26/2013 | SMC DIRECT LLC   | FDA/OMPT/CDRH/OCER/DFOI/   | BINAX CLEARVIEW ADVANCED STRAP A K091489 - CLIA WAIVER APPL                     | Referral (Outside FDA)<br>02/26/2013 |
| 2013-1505 | 02/26/2013<br>03/26/2013 | SMC DIRECT LLC   | FDA/OMPT/CDRH/OCER/DFOI/   | WAMPOLE LABS - CLEARVIEW HCG COMBO K992187 CLIA WAIVER APPL                     | Referral (Outside FDA)<br>02/26/2013 |
| 2013-1506 | 02/26/2013<br>03/26/2013 | SMC DIRECT LLC   | FDA/OMPT/CDRH/OCER/DFOI/   | BINAX - NOW STREP A CARD K960712 CLIA WAIVER APPL                               | Referral (Outside FDA)<br>02/26/2013 |
| 2013-1507 | 02/26/2013<br>03/26/2013 | SMC DIRECT LLC   | FDA/OMPT/CDRH/OCER/DFOI/   | WAMPOLE LABS - CLEARVIEW HCG II K953988 CLIA WAIVER APPL                        | Referral (Outside FDA)<br>02/26/2013 |
| 2013-1508 | 02/27/2013<br>03/27/2013 | FOI SERVICES INC   | OM/OSS/OPILS/DFI/  | 2012-5936   | Closed<br>03/14/2013                 |
| 2013-1509 | 02/27/2013<br>03/27/2013 | FOI SERVICES INC   | OM/OSS/OPILS/DFI/  | 2012-6045   | Closed<br>03/14/2013                 |
| 2013-1510 | 02/27/2013<br>03/27/2013 | FOI SERVICES INC   | OM/OSS/OPILS/DFI/  | 2012-2938   | Closed<br>03/14/2013                 |
| 2013-1511 | 02/27/2013<br>03/27/2013 | FOI SERVICES INC   | OM/OSS/OPILS/DFI/  | 2012-6015   | Closed<br>03/14/2013                 |

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| Control # | Recd Date / Due Date     | Requester         | Action Offices                  | Subject   | Status / Status Date |
|-----------|--------------------------|-------------------|---------------------------------|---|----------------------|
| 2013-1512 | 02/27/2013<br>03/27/2013 | 4LIFE RESEARCH LC | FDA/OGROP/ORR/SW-FO/DEN-DO/DEN- | CSBNUTRITION, LINDON, UT - WARNING<br>LETTER, 483 (07/02/2012 - 12/28/2012) | Closed<br>03/04/2013 |

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| Control # | Recd Date / Due Date     | Requester              | Action Offices                     | Subject  | Status / Status Date         |
|-----------|--------------------------|------------------------|------------------------------------|--|------------------------------|
|           |                          |                        | CB/                                |  |                              |
| 2013-1513 | 02/27/2013<br>03/27/2013 | The SWAIM390 Companies | FDA/OGROP/ORR/PA-FO/LOS-DO/LOS-CB/ | WISDOM PROTEINS INC, SAN DIEGO, CA<br>- INSPECTION RECS (01/01/2009 -<br>12/31/2012) | Partial Denial<br>03/19/2013 |
| 2013-1514 | 02/27/2013<br>03/27/2013 | St. Jude Medical       | FDA/OMPT/CDRH/OCER/DFOI/           | P030017 S134   | Pending Action<br>02/27/2013 |
| 2013-1515 | 02/27/2013<br>03/27/2013 | Crowell & Moring LLP   | FDA/OF/CFSAN/OCD/EOS/              | FCN 246  | Pending Action<br>02/27/2013 |

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| Control # | Recd Date / Due Date     | Requester               | Action Offices                  | Subject   | Status / Status Date         |
|-----------|--------------------------|-------------------------|---------------------------------|---|------------------------------|
| 2013-1516 | 02/27/2013<br>03/27/2013 | HEALTHCOR MANAGEMENT LP | FDA/OGROP/ORR/NE-FO/NYK-DO/NYK- | APP PHARMACEUTICALS, LLC, GRAND ISLAND - CORR (01/01/2010 - 02/26/2013) | Pending Action<br>02/27/2013 |

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| Control # | Recd Date / Due Date     | Requester         | Action Offices                     | Subject   | Status / Status Date         |
|-----------|--------------------------|-------------------|------------------------------------|---|------------------------------|
|           |                          |                   | DCB/                               |   |                              |
| 2013-1517 | 02/27/2013<br>03/27/2013 | RND Services, LLC | ORA/                               | CENTRAL ADMIXTURE PHARMACY SERVICES, INC, WOBURN, MA - 483 2013   | Pending Action<br>02/27/2013 |
| 2013-1518 | 02/27/2013<br>03/27/2013 | G&W Labs          | FDA/OMPT/CDER/ORP/DIDP/            | ANDA 064022, ANDA 062124 - SBA                                    | Closed<br>03/04/2013         |
| 2013-1519 | 02/27/2013<br>03/27/2013 | Eisai Inc.        | FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ | EISAI, RESEARCH TRIANGLE PARK, NC - EIR (07/01/2011 - 12/31/2011) | Pending Action<br>02/27/2013 |
| 2013-1520 | 02/27/2013<br>03/27/2013 | Justin O'Connor   | FDA/OF/CFSAN/OCD/EOS/              | ASPARTAME IN MILK, DAIRY PRODUCTS (01/01/2008 - 02/26/2013)       | Pending Action<br>02/27/2013 |
| 2013-1521 | 02/27/2013<br>03/27/2013 | Masep Infini      | FDA/OMPT/CDRH/OCER/DFOI/           | K111862   | Pending Action<br>02/27/2013 |
| 2013-1522 | 02/27/2013<br>03/27/2013 | FOI SERVICES INC  | FDA/OMPT/CDRH/OCER/DFOI/           | K110012   | Pending Action<br>02/27/2013 |

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| Control # | Recd Date / Due Date     | Requester                   | Action Offices                  | Subject   | Status / Status Date |
|-----------|--------------------------|-----------------------------|---------------------------------|---|----------------------|
| 2013-1523 | 02/27/2013<br>03/27/2013 | Compliance Specialists, LLC | FDA/OGROP/ORR/SW-FO/DEN-DO/DEN- | SIMILASAN CORPORATION, HIGHLANDS RANCH, CO; SIMILASAN AG, JONEN SWITZERLAND - 483 (04/08/2011 - 05/27/2011) | Closed<br>03/05/2013 |



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| Control # | Recd Date / Due Date     | Requester                 | Action Offices  | Subject   | Status / Status Date                       |
|-----------|--------------------------|---------------------------|---|---|--|
|           |                          |                           | CB/<br>FDA/OMPT/CDER/GRP/DIDP/                                |   |  |
| 2013-1524 | 02/27/2013<br>03/27/2013 | FOI SERVICES INC          | FDA/OMPT/CDRH/OCER/DFOI/<br>OM/OSS/OPILS/DFI/                 | K100818   | Pending Action<br>02/27/2013               |
| 2013-1525 | 02/27/2013<br>03/27/2013 | Masep Infini              | FDA/OMPT/CDRH/OCER/DFOI/                                      | K102915   | Pending Action<br>02/27/2013               |
| 2013-1526 | 02/27/2013<br>03/27/2013 | Ripple LLC                | FDA/OMPT/CDRH/OCER/DFOI/                                      | K090957   | Pending Action<br>02/27/2013               |
| 2013-1527 | 02/27/2013<br>03/27/2013 | Ripple LLC                | FDA/OMPT/CDRH/OCER/DFOI/                                      | K123255   | Pending Action<br>02/27/2013               |
| 2013-1528 | 02/27/2013<br>03/27/2013 | Jeff Varelman             | FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/<br>FDA/OMPT/CDER/GRP/DIDP/ | KING BIO INC, ASHEVILLE, NC -<br>INSPECTION RECORDS, ADVERSE<br>EVENT REPORTS, ETC (01/01/2009 -<br>01/01/2013) | Pending Action<br>02/27/2013               |
| 2013-1529 | 02/27/2013<br>03/27/2013 | Ripple LLC                | FDA/OMPT/CDRH/OCER/DFOI/                                      | K082629   | Pending Action<br>02/27/2013               |
| 2013-1530 | 02/27/2013<br>03/27/2013 | IPD ANALYTICS LLC         | FDA/OMPT/CDER/GRP/DIDP/                                       | LETTER DATED 04/28/1988 FROM C PECK<br>OF CDER RE 5 YEAR STATUTORY<br>EXCLUSIVITY                               | Closed<br>03/11/2013                       |
| 2013-1531 | 02/27/2013<br>03/27/2013 | N/A                       | CVM/OCD/<br>FDA/OMPT/CDER/GRP/DIDP/                           | CIS-TESTOSTERONE - APPROVAL<br>RECS, DATES FOR HUMAN AND ANIMAL<br>DRUGS; DESI RECS                             | Pending Action<br>02/27/2013               |
| 2013-1532 | 02/27/2013<br>03/27/2013 | DIAZ, BRENDA LIZ          | FDA/OGROP/ORR/SE-FO/SJN-DO/SJN-CB/                            | SAMPLE RESULTS  | Withdrawn Closed w/o Charges<br>03/21/2013 |
| 2013-1533 | 02/27/2013<br>03/27/2013 | KLEINFELD KAPLAN & BECKER | OC/OM/OMP/DDM/  | DKT 2001P-0586, 2002P-0469  | Closed<br>02/27/2013                       |

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| Control # | Recd Date / Due Date     | Requester          | Action Offices                  | Subject                         | Status / Status Date                 |
|-----------|--------------------------|--------------------|---------------------------------|---------------------------------|--------------------------------------|
| 2013-1534 | 02/27/2013<br>03/27/2013 | ASCEND CAPITAL LLC | FDA/OGROP/ORR/NE-FO/NWE-DO/NWE- | ABIOMED - CLOSE OUT LTR 6/10/11 | Acknowledgement Letter<br>02/27/2013 |

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| Control # | Recd Date / Due Date     | Requester                        | Action Offices   | Subject   | Status / Status Date                 |
|-----------|--------------------------|----------------------------------|--|---|--------------------------------------|
|           |                          |                                  | CB/  |   |                                      |
| 2013-1535 | 02/27/2013<br>03/27/2013 | DICIOLLA, DARLENE                | FDA/OMPT/CDER/ORP/DIDP/  | CMLNT 10846   | Acknowledgement Letter<br>02/27/2013 |
| 2013-1536 | 02/27/2013<br>03/27/2013 | FAUST 01B2507, BRIAN .           | OM/OSS/OPILS/DFI/  | SCHIYGOHRENIA - CAUSES  | No Record(s)<br>03/04/2013           |
| 2013-1537 | 02/27/2013<br>03/27/2013 | FAVUS INSTITUTIONAL RESEARCH LLC | OM/OSS/OPILS/DFI/  | 2013 DRUG REQUEST LOG   | Closed<br>02/27/2013                 |
| 2013-1538 | 02/27/2013<br>03/27/2013 | FAVUS INSTITUTIONAL RESEARCH LLC | FDA/OMPT/CDER/ORP/DIDP/  | PONATINIB (ICLUSIG) - AER 2012 TO PRESENT                         | No Record(s)<br>03/18/2013           |
| 2013-1539 | 02/27/2013<br>03/27/2013 | OAKES, TIMOTHY                   | FDA/OMPT/CDER/ORP/DIDP/<br>FDA/OMPT/CDRH/OCER/DFOI/                      | TANDEM DIABETES CARE INC - INSULIN DELIVERY SYS K111210           | Acknowledgement Letter<br>02/27/2013 |
| 2013-1540 | 02/27/2013<br>03/27/2013 | CORK INSTITUTE OF TECHNOLOGY     | FDA/OMPT/CDRH/OCER/DFOI/   | ACCLARENT INC, MENLO PK, CA - K082188                             | Acknowledgement Letter<br>02/27/2013 |
| 2013-1541 | 02/27/2013<br>03/27/2013 | CORK INSTITUTE OF TECHNOLOGY     | FDA/OMPT/CDRH/OCER/DFOI/   | ACCLARENT INC, MENLO PARK, CA - K103595                           | Acknowledgement Letter<br>02/27/2013 |
| 2013-1542 | 02/27/2013<br>03/27/2013 | DEKA RESEARCH & DEVELOPMENT CORP | FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/                                       | HOSPIRA INC, LAKE FOREST, IL - 483 1/13                           | Closed<br>03/08/2013                 |
| 2013-1543 | 02/27/2013<br>03/27/2013 | ZETETIC                          | FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/                                       | ENTRY NO EHP00765942  | Acknowledgement Letter<br>02/27/2013 |
| 2013-1544 | 02/27/2013<br>03/27/2013 | JUDD ULRICH ET AL                | FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/<br>FDA/OMPT/CDRH/OCER/DFOI/           | SILVER BAY LLC - RECALL, AER                                      | Partial Response<br>03/19/2013       |
| 2013-1545 | 02/27/2013<br>03/27/2013 | JUDD ULRICH ET AL                | FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/<br>FDA/OMPT/CDRH/OCER/DFOI/           | QUASAR BIO-TECH INC - RECALL, AER                                 | Partial Response<br>03/19/2013       |
| 2013-1546 | 02/27/2013<br>03/27/2013 | THERMOMEDICS                     | FDA/OMPT/CDRH/OCER/DFOI/   | THERMOMEDICS - K080759, K090361                                   | Acknowledgement Letter<br>02/27/2013 |
| 2013-1547 | 02/27/2013<br>03/27/2013 | HOGAN LOVELLS LLP                | OM/OSS/OPILS/DFI/<br>OM/OSS/OPILS/DFI/                                   | 2012-8987   | Closed<br>03/14/2013                 |
| 2013-1548 | 02/27/2013<br>03/27/2013 | LINCARE INC                      | FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/<br>FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/ | PURE OXYGEN LLC, OHIO; PA - 483, EIR, WARNING LTR 1/05 TO PRESENT | Closed<br>03/15/2013                 |
| 2013-1549 | 02/27/2013<br>03/27/2013 | BAKER & HOSTETLER, LLP           | ORA/OCI/   | DR ANTHONY GALEA - INVESTIGATION                                  | Acknowledgement Letter<br>02/27/2013 |

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| Control # | Recd Date / Due Date     | Requester                       | Action Offices  | Subject  | Status / Status Date                   |
|-----------|--------------------------|---------------------------------|---|--|--|
| 2013-1550 | 02/27/2013<br>03/27/2013 | EASLEY 103481, KENT A           | FDA/OF/CFSAN/OCD/EOS/   | SOY - AER  | Duplicate Request<br>02/28/2013        |
| 2013-1551 | 02/28/2013<br>03/28/2013 | SL Chapman LLC                  | FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/<br>FDA/OMPT/CDRH/OCER/DFOI/ | AMS 800 URINARY CONTROL PUMP WITH INHIBIZONE; RESERVOIR, PENILE PROSTHESIS 100 CC, IMPLANT, EXTENDER 100 CC ETC - ALERTS, RECALLS, SAGETY COMMUNICATIONS | Pending Action<br>02/28/2013           |
| 2013-1552 | 02/28/2013<br>03/28/2013 | Framingham Heart Study          | FDA/OMPT/CDRH/OCER/DFOI/                                      | K792281, K820193, K923657  | Closed<br>03/07/2013                   |
| 2013-1553 | 02/28/2013<br>03/28/2013 | Pribanic & Pribanic, L.L.C.     | ORA/<br>FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/                     | INDIVIDUAL RECS  | Closed<br>03/18/2013                   |
| 2013-1554 | 02/28/2013<br>03/28/2013 | NBC NEWS                        | FDA/OMPT/CDER/ORP/DIDP/<br>FDA/OF/CFSAN/OCD/EOS/              | DMAA - AERS (01/01/2006 - 02/27/2013)  | Closed<br>03/13/2013                   |
| 2013-1555 | 02/28/2013<br>03/28/2013 | UNIVERSITY OF TORONTO           | FDA/OMPT/CDER/ORP/DIDP/<br>FDA/OF/CFSAN/OCD/EOS/              | MSG - AERS (01/01/1985 - 12/31/2012)   | Pending Action<br>02/28/2013           |
| 2013-1556 | 02/28/2013<br>03/28/2013 | Georgia Tech Research Institute | FDA/OMPT/CDRH/OCER/DFOI/                                      | K944765  | Pending Action<br>02/28/2013           |
| 2013-1557 | 02/28/2013<br>03/28/2013 | NBC NEWS                        | FDA/OF/CFSAN/OCD/EOS/   | USPLABS, JACK3D - AERS (2006-2013)   | Duplicate Request<br>03/04/2013        |
| 2013-1558 | 02/28/2013<br>03/28/2013 | UH Hilo College of Pharmacy     | FDA/OMPT/CDER/ORP/DIDP/                                       | IMNM WITH HMG-COA REDUCTASE INHIBITOR THERAPY - AERS (01/01/1987 - 02/27/2013)   | Closed<br>03/18/2013                   |
| 2013-1559 | 02/28/2013<br>03/28/2013 | Remington Medical, Inc.         | FDA/OMPT/CDRH/OCER/DFOI/                                      | K990519  | Pending Action<br>02/28/2013           |
| 2013-1560 | 02/28/2013<br>03/28/2013 | WHITE, HORTENSE S               | OM/OSS/OPILS/DFI/   | SPICES, FOOD DYES - RECS   | Not Reasonably Described<br>03/13/2013 |
| 2013-1561 | 02/28/2013<br>03/28/2013 | MARY D LEWIS LLC                | FDA/OMPT/CBER/OCOD/DDOM/ALFB/                                 | INDIVIDUAL RECS  | Acknowledgement Letter<br>02/28/2013   |
| 2013-1562 | 02/28/2013<br>03/28/2013 | LATHAM & WATKINS LLP            | FDA/OMPT/CDRH/OCER/DFOI/                                      | KARMELSONIX (ISONEA) - PERSONAL WHEEZOMETER K090863; PULMOTRACK 5050 K101022   | Closed<br>03/05/2013                   |
| 2013-1563 | 02/28/2013<br>03/28/2013 | ODOM & DES ROCHES LLP           | FDA/OMPT/CDER/ORP/DIDP/<br>OM/OMP/DODM/                       | DKT 2012P-1028; ACTAVIS ELIZABETH LLC - ANDA 91-422, AMNEAL PHARMS - ANDA 203-136  | Partial Response<br>03/14/2013         |
| 2013-1564 | 02/28/2013<br>03/28/2013 | MEADE, DORIS .                  | FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/                             | BEEHIVE BOTANICALS INC, HAYWARD, WI - 483 7/23-25/12   | Closed<br>03/06/2013                   |

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| 2013-1565 | 02/28/2013<br>03/28/2013 | REPRIEVE                          | ORA/<br>ORA/ORO/DIOP/  | PENTOBARBITAL SODIUM POWDER - IMPORT RECS 7/12 TO PRESENT  | Acknowledgement Letter<br>02/28/2013 |
| 2013-1566 | 02/28/2013<br>03/28/2013 | CLARKE LAW OFFICES                | FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/<br>FDA/OMPT/CDRH/OCER/DFOI/ | INDIVIDUAL RECS  | Partial Response<br>03/06/2013       |
| 2013-1567 | 02/28/2013<br>03/28/2013 | MUCKROCK NEWS                     | FDA/OF/CFSAN/OCD/EOS/  | OCEANA - SEAFOOD FRAUD IN AMERICA RECS 2/21/13   | Acknowledgement Letter<br>02/28/2013 |
| 2013-1568 | 02/28/2013<br>03/28/2013 | EAS Consulting Group, LLC         | FDA/OMPT/CDER/ORP/DIDP/  | ISOSORBIDE (DINITRATE AND/OR MONONITRATE) - API/BULK PROD LISTINGS 1/10 TO PRESENT   | Acknowledgement Letter<br>02/28/2013 |
| 2013-1569 | 02/28/2013<br>03/28/2013 | SUAREZ & MONTERO LAW OFCS         | FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/                             | MALTA HATUEY BEVERAGE - RECALL RECS, RPTS, PRESS RELEASES, ETC   | Acknowledgement Letter<br>02/28/2013 |
| 2013-1570 | 03/01/2013<br>03/29/2013 | Alan Buchwald, M.D., Inc.         | FDA/OMPT/CDER/ORP/DIDP/  | BODY BUILDING PRODUCTS AND HIDDEN STEROIDS: ENFORCEMENT BARRIERS - REFERENCES, ADVERSE EVENTS                                    | Pending Action<br>03/01/2013         |
| 2013-1571 | 03/01/2013<br>03/29/2013 | Pacira Pharmaceuticals, Inc.      | FDA/OMPT/CDER/ORP/DIDP/  | EXPAREL - SBA  | Pending Action<br>03/01/2013         |
| 2013-1572 | 03/01/2013<br>03/29/2013 | FOI SERVICES INC                  | FDA/OMPT/CDER/ORP/DIDP/  | LABOR L+S, GERMANY - INVESTIGATOR DIARIES (01/24/2013 - 02/01/2013)  | Closed Denial<br>03/05/2013          |
| 2013-1573 | 03/01/2013<br>03/29/2013 | FOI SERVICES INC                  | FDA/OMPT/CDER/ORP/DIDP/  | LABOR L+S, GERMANY - EIR, 483, RESPONSE, ETC (01/24/2013 - 02/01/2013)   | Partial Denial<br>03/18/2013         |
| 2013-1574 | 03/01/2013<br>03/29/2013 | Morphographics, LLC               | FDA/OMPT/CDRH/OCER/DFOI/                                       | K031493  | Pending Action<br>03/01/2013         |
| 2013-1575 | 03/01/2013<br>03/29/2013 | UNIVERSITY OF ILLINOIS AT CHICAGO | FDA/OMPT/CDER/ORP/DIDP/  | SAVELLA - AERS (01/01/2003 - 02/28/2013)   | Closed<br>03/08/2013                 |
| 2013-1576 | 03/01/2013<br>03/29/2013 | Paul Effler MD                    | FDA/OMPT/CBER/OCOD/DDOM/ALFB/                                  | SUMMARY BASIS FOR REGULATORY ACTION CSL LIMITED INFLUENZA VIRUS VACCINE  | Hold<br>03/12/2013                   |
| 2013-1577 | 03/01/2013<br>03/29/2013 | ORIGEN BIOMEDICAL                 | FDA/OMPT/CDRH/OCER/DFOI/                                       | K991864  | Pending Action<br>03/01/2013         |
| 2013-1578 | 03/01/2013<br>03/29/2013 | FOI SERVICES INC                  | FDA/OMPT/CDRH/OCER/DFOI/                                       | K121270  | Pending Action<br>03/01/2013         |
| 2013-1579 | 03/01/2013<br>03/29/2013 | FOI SERVICES INC                  | FDA/OMPT/CDRH/OCER/DFOI/                                       | K121270  | Duplicate Request<br>03/01/2013      |
| 2013-1580 | 03/01/2013<br>03/29/2013 | SMC DIRECT LLC                    | FDA/OMPT/CDRH/OCER/DFOI/                                       | BINAX, CLEARVIEW ADVANCED STREP A MODEL 737-430 K091489; BINAX, NOW STREP A TEST K960712; ACON, QUICK A RAPID TEST STRIP K010582 | Acknowledgement Letter<br>03/01/2013 |

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| 2013-1581 | 03/01/2013<br>03/29/2013 | BATTELLE                                 | FDA/OMPT/CBER/OCOD/DDOM/ALFB/       | INDIVIDUAL RECS   | Hold<br>03/11/2013                   |
| 2013-1582 | 03/01/2013<br>03/29/2013 | PROCTER & GAMBLE COMPANY                 | FDA/OMPT/CDRH/OCER/DFOI/            | UROMED IMPRESS SOFTPATCH - UNREDACTED   | Acknowledgement Letter<br>03/01/2013 |
| 2013-1583 | 03/01/2013<br>03/29/2013 | JH BARR & ASSOCIATES LLC                 | OM/OSS/OPILS/DFI/                   | CLOSED FOI LOG 2/11-15/13   | Closed<br>03/01/2013                 |
| 2013-1584 | 03/01/2013<br>03/29/2013 | JH BARR & ASSOCIATES LLC                 | OM/OSS/OPILS/DFI/                   | DAILY LOG 2/11-15/13  | Closed<br>03/01/2013                 |
| 2013-1585 | 03/01/2013<br>03/29/2013 | FOI SERVICES INC                         | OM/OSS/OPILS/DFI/                   | DAILY LOG 2/11-15/13  | Closed<br>03/01/2013                 |
| 2013-1586 | 03/01/2013<br>03/29/2013 | FOI SERVICES INC                         | OM/OSS/OPILS/DFI/                   | CLOSED FOI LOG 2/11-15/13   | Closed<br>03/01/2013                 |
| 2013-1587 | 03/01/2013<br>03/29/2013 | DOMINION GROUP INC                       | OM/OSS/OPILS/DFI/                   | DAILY LOG 2/11-15/13  | Closed<br>03/01/2013                 |
| 2013-1588 | 03/01/2013<br>03/29/2013 | WOLTERS KLUWER LAW & BUSINESS            | OM/OSS/OPILS/DFI/                   | CLOSED FOI REQUESTS 2/11-15/13  | Closed<br>03/01/2013                 |
| 2013-1589 | 03/01/2013<br>03/29/2013 | WOLTERS KLUWER LAW & BUSINESS            | OM/OSS/OPILS/DFI/                   | DAILY LOG 2/11-15/13  | Closed<br>03/01/2013                 |
| 2013-1590 | 03/01/2013<br>03/29/2013 | CanReg, Inc.                             | OM/OSS/OPILS/DFI/                   | CLOSED REQUESTS LOG 2/11-15/13  | Closed<br>03/01/2013                 |
| 2013-1591 | 03/01/2013<br>03/29/2013 | CanReg, Inc.                             | OM/OSS/OPILS/DFI/                   | DAILY LOG 2/11-15/13  | Closed<br>03/01/2013                 |
| 2013-1592 | 03/01/2013<br>03/29/2013 | Center for Regulatory Services, Inc.     | OM/OSS/OPILS/DFI/                   | DAILY LOG 2/11-15/13  | Closed<br>03/01/2013                 |
| 2013-1593 | 03/01/2013<br>03/29/2013 | WASHINGTON INFORMATION SOURCE            | OM/OSS/OPILS/DFI/                   | DAILY LOG 2/11-15/13  | Closed<br>03/01/2013                 |
| 2013-1594 | 03/01/2013<br>03/29/2013 | FDA REVIEW/FDA WEBVIEW                   | OM/OSS/OPILS/DFI/                   | CLOSED REQUESTS LOG 2/11-15/13  | Closed<br>03/01/2013                 |
| 2013-1595 | 03/01/2013<br>03/29/2013 | FOI SERVICES INC                         | FDA/OMPT/CDER/ORP/DIDP/             | NOTICES SENT BY FDA IN 1985 TO MANUFACTURERS OF NEUROLEPTIC DRUGS REGARDING LABEL WARNINGS FOR TARDIVE DYSKINESIA | Pending Action<br>03/01/2013         |
| 2013-1596 | 03/01/2013<br>03/29/2013 | Saint Joseph's Translational Research In | FDA/OGROP/ORAC/CE-FO/MIN-DO/MIN-CB/ | AMERICAN PRECLINICAL SERVICES, MINNEAPOLIS, MN - 483 (01/01/2011 - 03/01/2013)                                    | Closed<br>03/06/2013                 |
| 2013-1597 | 03/01/2013<br>03/29/2013 | QUINN EMANUEL ET AL                      | FDA/OMPT/CDER/ORP/DIDP/             | PRESCRIPTION DRUG WRAP-UP LIST  | Pending Action<br>03/01/2013         |

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| 2013-1598 | 03/01/2013<br>03/29/2013 | NOVEN PHARMACEUTICALS INC             | FDA/OMPT/CDER/ORP/DIDP/  | NDA 018766 - MEDICAL RVW | Withdrawn Closed w/o Charges<br>03/07/2013 |
| 2013-1599 | 03/01/2013<br>03/29/2013 | Ei Inc.                               | FDA/OMPT/CDRH/OCER/DFOI/ | K083087, K052643         | Pending Action<br>03/01/2013               |
| 2013-1600 | 03/01/2013<br>03/29/2013 | INC RESEARCH CONSULTING & SUBMISSIONS | FDA/OMPT/CDER/ORP/DIDP/  | SBA 202608               | Pending Action<br>03/01/2013               |