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January–December 2013

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Availability of Masked and De-Identified Non-Summary Safety and Efficacy Data – *60290 (Oct 1)*
Consolidation of Wound Care Products Containing Live Cells – *49528 (Aug 14)*
Cooperative Agreements:

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North Carolina State University Prestage Department of Poultry Science and the Piedmont Research Station – *37549 (Jun 21)*
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Debarment Orders:
Adrian Vela – *14304 (Mar 5)*
Anneri Izurieta; Conviction Reversal – *42787 (Jul 17)*
Ashley Brandon Foyle – *25456 (May 1)*
Bruce I. Diamond; Denial of Hearing – *68455 (Nov 14)*
Cheng Yi Liang – *14556 (Mar 6)*
David Freeman – *26784 (May 8)*
Richard Stowell – *13068 (Feb 26)*
Shu Bei Yuan – *16680 (Mar 18)*
Yuri Izurieta; Conviction Reversal – *42787 (Jul 17)*
Determinations:
Adderall (Amphetamine Aspartate; Amphetamine Sulfate; Dextroamphetamine Saccharate; Dextroamphetamine Sulfate) Tablet and 13 Other Drug Products – *67365 (Nov 12)*
BANZEL (Rufinamide) Tablet, 100 Milligrams – *69856 (Nov 21)*
Benadryl Injection and Two Other Drug Products – *17933 (Mar 25)*
CORDRAN (Flurandrenolide) Ointment USP, 0.025% and 0.05% – *35038 (Jun 11)*
CYTOXAN (Cyclophosphamide) for Injection – *47321 (Aug 5)*
Differin – *6823 (Jan 31)*
GEREF (Sermorelin Acetate) Injection, 0.5 Milligrams Base/Vial and 1.0 Milligrams Base/Vial, and GEREF (Sermorelin Acetate) Injection, 0.05 Milligrams Base/Amp – *14095 (Mar 4)*
INTAL (cromolyn sodium) Inhalation Capsule, 20 Milligrams – *63227 (Oct 23)*
INVEGA (Paliperidone) Extended-Release Tablet, 12 Milligrams – *66009 (Nov 4)*
Laviv – *13685 (Feb 28)*
LIDEX (fluocinonide) Cream and LIDEX-E (fluocinonide) Cream and Nine Other Drug Products – *50420 (Aug 19)*
METADATE ER (Methylphenidate Hydrochloride) Extended-Release Tablet, 10 Milligrams – *40484 (Jul 5)*
MOBAN (Molindone Hydrochloride); Tablets (5, 10, 25, 50, and 100 mg) and Capsules (5, 10, and 25 mg) – *66742 (Nov 6)*
OPANA ER (Oxymorphone Hydrochloride) – *38053 (Jun 25)*
Oxycontin (Oxycodone Hydrochloride) – *23273 (Apr 18)*
PARAFLEX (Chlorzoxazone) Tablets, 250 Milligrams – *63228 (Oct 23)*
Potassium Citrate, 10 Milliequivalents/Packet and 20 Milliequivalents/ Packet – *63228 (Oct 23)*
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REV-EYES (Dapiprazole Hydrochloride Ophthalmic Solution), 0.5 Percent – *27971 (May 13)*
SUBOXONE (Buprenorphine Hydrochloride and Naloxone Hydrochloride) Sublingual Tablets, 2 Milligrams/0.5 Milligrams and 8 Milligrams/2 Milligrams – *34108 (Jun 6)*
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Draft Guidance for Industry and Staff:
Abbreviated New Drug Application Submissions; Refuse-to-Receive Standards – *60292 (Oct 1)*
Abbreviated New Drug Applications: Stability Testing of Drug Substances and Products – *37231 (Jun 20)*
Abbreviated New Drug Applications; Stability Testing of Drug Substances and Products, Questions and Answers – *52931 (Aug 27)*
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Acceptable Full-Length and Abbreviated Donor History Questionnaires, etc., for Use in Screening Donors of Source Plasma – *13071 (Feb 26)*
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Acrylamide in Foods – *68852 (Nov 15)*
Active Controls in Studies to Demonstrate Effectiveness of a New Animal Drug for Use in Companion Animals – *63477 (Oct 24)*
Acute Bacterial Skin and Skin Structure Infections; Developing Drugs for Treatment – *63220 (Oct 23)*
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Animal Drugs and New Animal Drug Combination Products Administered; Medicated Feed or Drinking Water of Food-Producing Animals – *75570 (Dec 12)*
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Arsenic in Apple Juice; Action Level; Supporting Document for Action Level for Arsenic in Apple Juice; etc. – *56719 (Sep 13)*
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Bioequivalence Recommendations for Fluticasone Propionate; Salmeterol Xinafoate; Availability – *55263 (Sep 10)*
Bioequivalence Recommendations for Iron Sucrose – *66743 (Nov 6)*
Bioequivalence Recommendations for Mesalamine Rectal Suppositories – *46965 (Aug 2)*
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Patient-Focused Drug Development for Narcolepsy – *43209 (Jul 19)*
Pediatric Advisory Committee – *12763 (Feb 25); 49272 (Aug 13)*
Pediatric Ethics Subcommittee of the Pediatric Advisory Committee – *48438 (Aug 8)*
Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee – *63222, 63224 (Oct 23)*
Peripheral and Central Nervous System Drugs Advisory Committee – *20328 (Apr 4); 63478, 63481 (Oct 24)*
Prescription Drug User Fee Act Patient-Focused Drug Development – *21613 (Apr 11)*
Psychopharmacologic Drugs Advisory Committee – *13349 (Feb 27)*
Pulmonary-Allergy Drugs Advisory Committee – *17413 (Mar 21); 46976 (Aug 2)*
Reagan-Udall Foundation – *23960 (Apr 23)*
Rechanneling the Current Cardiac Risk Paradigm: Arrhythmia Risk Assessment During Drug Development without the Thorough QT Study – *36787 (Jun 19)*
Reproductive Health Drugs and the Drug Safety and Risk Management Advisory Committees – *2677 (Jan 14)*

Review and Regulation of Drugs for the Treatment of Amyotrophic Lateral Sclerosis – *6824 (Jan 31)*
Risk Communication Advisory Committee and Tobacco Products Scientific Advisory Committee – *37821 (Jun 24)*
Risk Communications Advisory Committee – *17414 (Mar 21); 42087 (Jul 15); 70954 (Nov 27)*
Rodent Carcinogenicity Testing of Pharmaceuticals – *16681 (Mar 18)*
Science Advisory Board to the National Center for Toxicological Research – *77687 (Dec 24)*
Science Board – *6332 (Jan 30)*
Science Board to Food and Drug Administration Advisory Committee – *13348 (Feb 27)*
Science Board to the Food and Drug Administration – *30317 (May 22)*
Seventh Annual Drug Information Association/Food and Drug Administration Statistics Forum – *13072 (Feb 26)*
Sickle Cell Disease; Patient-Focused Drug Development – *66747 (Nov 6)*
Sixth Annual Sentinel Initiative; Public Workshop – *67168 (Nov 8)*
Society of Clinical Research Associates/Food and Drug Administration – *55728 (Sep 11)*
Standardizing and Evaluating Risk Evaluation and Mitigation Strategies – *30313 (May 22)*
Strategies to Address Hemolytic Complications of Immune Globulin Infusions; Public Workshop – *79469 (Dec 30)*
Summit on Color in Medical Imaging; Public Workshops – *18611 (Mar 27)*
Synergizing Efforts in Standards Development for Cellular Therapies and Regenerative Medicine Products – *43889 (Jul 22)*
Tobacco Product Analysis Scientific Workshop – *33424 (Jun 4)*
Tobacco Products Scientific Advisory Committee – *20927 (Apr 8); 38059 (Jun 25)*
Transmissible Spongiform Encephalopathies Advisory Committee – *11207 (Feb 15)*
Trial Designs and Endpoints for Liver Disease Secondary to Nonalcoholic Steatohepatitis; Public Workshop – *46351 (Jul 31)*
Vaccines and Related Biological Products Advisory Committee – *5465 (Jan 25); 20663 (Apr 5); 60884 (Oct 2)*
Veterinary Oversight of Antimicrobial Use in Livestock, Impact on Stakeholders – *14801 (Mar 7)*
New Animal Drugs:
Ag-Mark, Inc., et al.; Withdrawal – *14803 (Mar 7)*
Animal Drug User Fee Rates and Payment Procedures – *46955 (Aug 2)*
Arsanilic Acid; Withdrawal of Approval – *70566 (Nov 26)*
Carbarsone; Roxarsone; Withdrawal – *70062 (Nov 22)*
Diethylcarbamazine; Nicarbazin; Penicillin; Roxarsone; Withdrawal – *52536 (Aug 23)*
Quali-Tech Products, Inc.; Bambermycins; Pyrantel; Tylosin; Virginiamycin; Withdrawal – *52535 (Aug 23)*
New Drug Applications:
Bracco Diagnostics et al.; Withdrawals – *43210 (Jul 19)*
Generic Drug User Fee, Drug Master File, Final Dosage Form Facility, and Active Pharmaceutical Ingredient Facility Fee – *46977 (Aug 2)*
GlaxoSmithKline LLC; BEXXAR; Withdrawal – *63226 (Oct 23)*
ORAFLEX; Eli Lilly and Co.; Withdrawals – *33426 (Jun 4)*
Pfizer, Inc.; BEXTRA; Withdrawal – *46984 (Aug 2)*
Purdue Pharma, LP; OXYCONTIN; Withdrawal – *48177 (Aug 7)*
Smith Miller and Patch Inc., et al.; Opportunity for a Hearing; Withdrawal – *66748 (Nov 6)*
Nominations:
Food Advisory Committee – *79700 (Dec 31)*
Steering Committee for Innovation in Medical Evidence Development and Surveillance Program – *23961 (Apr 23)*
Tobacco Products Scientific Advisory Committee – *64505 (Oct 29)*
Voting and/or Nonvoting Consumer Representatives on Public Advisory Committees or Panels, etc. – *12331 (Feb 22); 37551 (Jun 21)*
Voting Members on Public Advisory Panels or Committees – *9060 (Feb 7); 29757 (May 21)*
Pilot Projects:
Pilot Program for Parallel Review of Medical Products; Extension – *76628 (Dec 18)*
Transport Format for the Submission of Regulatory Study Data – *70954 (Nov 27)*
Premarket Approvals:
Acceptance and Filing Reviews – *101 (Jan 2)*
Canned Tuna Deviating from Identity Standard – *2273 (Jan 10)*
Clinical Pharmacogenomics; Clinical Studies, Labeling, Evaluation – *5816 (Jan 28)*
Medical Devices; Safety and Effectiveness Summaries – *950 (Jan 7)*
Total Product Life Cycle – *16676 (Mar 18)*
Prescription Drug Labeling:
Nicotine Replacement Therapy Products for Over-the-Counter Human Use – *19718 (Apr 2)*
Regulatory Review Periods for Patent Extensions:
Beyaz – *6826 (Jan 31)*
Xalkori – *6826 (Jan 31)*
User Fees:
Prescription Drug User Fee Act; Benefit-Risk Plan – *15019 (Mar 8)*
Prescription Drug User Fee Act; Workload Adjuster Evaluation – *26374 (May 6)*
Prescription Drug User Fee Rates – *46980 (Aug 2)*
Prescription Drug User Fee Rates; Correction – *53152 (Aug 28)*