

FEDERAL REGISTER INDEX

January–August 2020

Food and Drug Administration

RULES

Banned Devices:

Electrical Stimulation Devices for Self-Injurious or Aggressive Behavior – 13312 (Mar 6)

Definition of the Term Biological Product – 10057 (Feb 21)

Food Additive Regulation:

Synthetic Flavoring Agents and Adjuvants; Confirmation of Effective Date – 5555 (Jan 31)

Food Additives Permitted in Feed and Drinking Water of Animals:

Chromium Propionate – 48650 (Aug 12)

Food Additives Permitted:

Chromium Propionate; Feed and Drinking Water of Animals – 14565 (Mar 13)

Silicon Dioxide; Feed and Drinking Water of Animals – 33538 (Jun 2)

Vitamin D2 Mushroom Powder; Direct Addition to Food for Human Consumption – 41916 (Jul 13)

Food Labeling:

Gluten-Free Labeling of Fermented or Hydrolyzed Foods – 49240 (Aug 13)

Revision of the Nutrition and Supplement Facts Labels; Small Entity Compliance Guide – 6045 (Feb 4)

Guidance:

Classification of Posterior Cervical Screw Systems: Small Entity Compliance Guide – 26350 (May 4)

Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use – 43989 (Jul 21)

Required Warnings for Cigarette Packages and Advertisements: Small Entity Compliance Guide – 15710 (Mar 18)

Temporary Policy During the COVID-19 Public Health Emergency Regarding the Qualified Exemption from the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption – 34508 (Jun 5)

Temporary Policy Regarding Accredited Third-Party Certification Program Onsite Observation and Certificate Duration Requirements During the COVID-19 Public Health Emergency – 23919 (Apr 30)

Temporary Policy Regarding Preventive Controls and Foreign Supplier Verification Programs Food Supplier Verification Onsite Audit Requirements During the COVID-19 Public Health Emergency – 17008 (Mar 26)

Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices and Certain Devices Requiring Direct Marking – 39477 (Jul 1)

Medical Devices – 18439, 18444 (Apr 2)

Medical Devices:

Exemption From Premarket Notification; Class II Devices; Powered Wheeled Stretcher – 2018 (Jan 14)

Exemptions From Premarket Notification: Class II Devices – 44186 (Jul 22)

Immunology and Microbiology Devices; Classification of Human Immunodeficiency Virus Drug Resistance Genotyping Assay Using Next Generation Sequencing Technology – 7215 (Feb 7)

Petition for an Administrative Stay of Action; Electrical Stimulation Devices for Self-Injurious or Aggressive Behavior – 50950 (Aug 19)

Medical Devices; Radiology Devices:

Classification of the Radiological Computer Aided Triage and Notification Software – 3543 (Jan 22)

Classification of the Radiological Computer-Assisted Diagnostic Software for Lesions Suspicious for Cancer – 3540 (Jan 22)

New Animal Drug:

Approval of New Animal Drug Applications; Withdrawal of Approval of New Animal Drug Applications; Change of Sponsor – 45306 (Jul 28)

New Animal Drugs; Approval of New Animal Drug Applications; Withdrawal of Approval of New Animal Drug Applications; Change of Sponsor; Change of Sponsors' Name and Addresses – 18114 (Apr 1)

New Animal Drugs; Approval of New Animal Drug Applications;

Withdrawal of Approval of New Animal Drug Applications; Changes of Sponsor; Change of Sponsor's Address – 4204 (Jan 24)

New Animal Drugs; Withdrawal of Approval of a New Animal Drug Application; Withdrawal of Approval of Abbreviated New Animal Drug Applications – 4210 (Jan 24)

New Animal Drugs; Withdrawal of Approval of New Animal Drug Applications – 18125 (Apr 1)

Withdrawal of Approval of Abbreviated New Animal Drug Application – 45311 (Jul 28)

Office of Regulatory Affairs Division Director; Technical Amendments – 16549 (Mar 24); 50780 (Aug 18)

Postmarketing Safety Reports for Approved New Animal Drugs – 45505 (Jul 29)

Radiology Devices:

Reclassification of Medical Image Analyzers – 3545 (Jan 22)

Revocation of the Test for Mycoplasma – 51635 (Aug 21)

Tobacco Products; Required Warnings for Cigarette Packages and Advertisements – 15638 (Mar 18); 32293 (May 29)

Veterinary Feed Directive Drugs:

Contact Information – 50783 (Aug 18)

PROPOSED RULES

Annual Summary Reporting Requirements under the Right to Try Act – 44803 (Jul 24)

Cheeses and Related Cheese Products; Proposal to Permit the Use of Ultrafiltered Milk – 20891 (Apr 15)

Color Additive Petition:

CooperVision, Inc.; Withdrawal – 52081 (Aug 24)

Filing of Color Additive Petition:

GNT USA, Inc. – 27340 (May 8)

Filing of Food Additive Petition:

Adisseo France S.A.S. – 27692 (May 11)

Biomim GmbH – 26902 (May 6)

LANXESS Corp. – 7682 (Feb 11)

Unilever – 10632 (Feb 25)

Food Additives Permitted in Feed and Drinking Water of Animals:

Spent Bleaching Clay – 28898 (May 14)

Food Standards:

General Principles and Food Standards Modernization – 10107 (Feb 21); 21795 (Apr 20)

Import Data in the Automated Commercial Environment for Veterinary Devices – 46566 (Aug 3)

Laboratory Accreditation for Analyses of Foods – 11893 (Feb 28); 19114 (Apr 6)

Microbiology Devices:

Reclassification of Certain Hepatitis C Virus Antibody Assays Devices, To Be Renamed Hepatitis C Virus Antibody Tests – 18490 (Apr 2)

Reclassification of Human Immunodeficiency Virus Serological Diagnostic and Supplemental Tests and Human Immunodeficiency Virus Nucleic Acid Diagnostic and Supplemental Tests – 10110 (Feb 21)

Reclassification of Nucleic Acid-Based Hepatitis C Virus Ribonucleic Acid Assay Devices, To Be Renamed Nucleic Acid-Based Hepatitis C Virus Ribonucleic Acid Tests – 18483 (Apr 2)

Physical Medicine Devices:

Reclassification of Non-Invasive Bone Growth Stimulators – 49986 (Aug 17)

Premarket Tobacco Product Applications and Recordkeeping Requirements – 13840 (Mar 10)

Request for Information:

Consumption of Certain Uncommon Produce Commodities in the United States; Establishment of a Public Docket – 48124 (Aug 10)

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals – 5446 (Jan 30); 15187 (Mar 17); 29459 (May 15); 30965 (May 21); 31190 (May 22); 41591 (Jul 10); 53822 (Aug 31)

Food and Drug Administration

Agency Information Collection Activities; Proposals, Submissions, and Approvals:

- Accreditation Scheme for Conformity Assessment Pilot Program – 23521 (Apr 28)
- Additional Criteria and Procedures for Classifying Over-the-Counter Drugs as Generally Recognized as Safe and Effective and Not Misbranded - Time and Extent Applications for Nonprescription Drug Products – 45892 (Jul 30)
- Adverse Event Program for Medical Devices (Medical Product Safety Network) – 28954 (May 14)
- Advisory Committee Nomination Applications – 718 (Jan 7); 21249 (Apr 16)
- Animal Feed Regulatory Program Standards – 907 (Jan 8)
- Annual Reporting for Custom Device Exemption – 10175 (Feb 21); 41593 (Jul 10)
- Application for Participation in Food and Drug Administration Fellowship and Traineeship Programs – 5966 (Feb 3)
- Biologics License Application, Changes to an Approved Application, Labeling, Revocation and Suspension, Postmarketing Studies Status Reports, and Form FDA 356h – 3053 (Jan 17)
- Center for Tobacco Products, Food and Drug Administration Funded Trainee/Scholar Survey – 713 (Jan 7)
- Certificates of Confidentiality – 36602 (Jun 17)
- Certification of Identity for Freedom of Information Act and Privacy Act Requests – 18984 (Apr 3)
- Certification to Accompany Drug, Biological Product, and Device Applications or Submissions – 28955 (May 14)
- Channels of Trade Policy for Commodities With Residues of Pesticide Chemicals, for Which Tolerances Have Been Revoked, Suspended, or Modified by the Environmental Protection Agency Pursuant to Dietary Risk Considerations – 28639 (May 13)
- Channels of Trade Policy for Commodities with Residues of Pesticide Chemicals, for which Tolerances have been Revoked, Suspended, or Modified by the Environmental Protection Agency Pursuant to Dietary Risk Considerations – 47801 (Aug 6)
- Color Additive Certification Requests and Recordkeeping – 21250 (Apr 16); 45890 (Jul 30)
- Combination Products: How to Prepare a Pre-Request for Designation – 16369 (Mar 23)
- Communication Readership Survey; Withdrawal. – 21246 (Apr 16)
- Cosmetic Labeling Regulations and Voluntary Cosmetic Registration Program – 18993 (Apr 3); 44539 (Jul 23)
- Current Good Manufacturing Practice Regulations for Medicated Feeds – 12790 (Mar 4); 41594 (Jul 10)
- Current Good Manufacturing Practice Regulations for Type A Medicated Articles – 10170 (Feb 21); 41596 (Jul 10)
- Customer/Partner Service Surveys – 3389 (Jan 21); 51449 (Aug 20)
- Data To Support Drug Product Communications as Used by the Food and Drug Administration – 36591 (Jun 17)
- Dispute Resolution Procedures for Science-Based Decisions on Products by the Center for Veterinary Medicine – 50827 (Aug 18)
- Donor Risk Assessment Questionnaire for the Food and Drug Administration/National Heart, Lung, and Blood Institute-Sponsored Transfusion-Transmissible Infections Monitoring System--Risk Factor Elicitation – 922 (Jan 8)
- Donor Risk Assessment Questionnaire for the Food and Drug Administration/National Heart, Lung, and Blood Institute-Sponsored Transfusion-Transmissible Infections Monitoring System; Risk Factor Elicitation – 42001 (Jul 13)
- Drug Supply Chain Security Act Implementation – 23050 (Apr 24)
- Electronic Products – 3925 (Jan 23); 28958 (May 14)
- Electronic Records; Electronic Signatures – 49381 (Aug 13)
- Electronic Submission Process for Voluntary Allegations to the Center for Devices and Radiological Health – 7562 (Feb 10)
- Empirical Study of Promotional Implications of Proprietary Prescription Drug Names – 3392 (Jan 21)
- Endorser Status and Explicitness of Payment in Direct-to-Consumer Promotion – 4994 (Jan 28)
- Establishing and Maintaining a List of Manufacturers/Processors of Feed Additives, Premixes, Compound Feed, Distillers' Dried Grains, and Distillers' Dried Grains with Solubles for Use with Animals with Interest in Exporting to The People's Republic of China – 47796 (Aug 6)
- Establishing and Maintaining a List of U.S. Manufacturers/Processors of Feed Additives, Premixes, Compound Feed, Distillers' Dried Grains, and Distillers' Dried Grains with Solubles for Use with Animals with Interest in Exporting to The People's Republic of China – 21242 (Apr 16)
- Examination of Secondary Claim Disclosures and Biosimilar Disclosures in Prescription Drug Promotional Materials – 40659 (Jul 7)
- Exceptions or Alternatives to Labeling Requirements for Products Held by the Strategic National Stockpile – 39914 (Jul 2)
- Extralabel Drug Use in Animals – 47794 (Aug 6)
- Focus Groups as Used by the Food and Drug Administration (All Food and Drug Administration-Regulated Products) – 916 (Jan 8); 51450 (Aug 20)
- Food Additive, Color Additive (Including Labeling), Submission of Information to a Master File in Support of Petitions; and Electronic Submission Using Food and Drug Administration Form 3503 – 15188 (Mar 17)
- Food and Drug Administration Safety Communication Readership Survey – 13171 (Mar 6)
- Food Canning Establishment Registration, Process Filing, and Recordkeeping for Acidified Foods and Thermally Processed Low-Acid Foods in Hermetically Sealed Containers – 18995 (Apr 3); 44905 (Jul 24)
- Food Labeling Regulations – 6551 (Feb 5); 30711 (May 20)
- General Administrative Practice and Procedures – 1169 (Jan 9)
- Generic Clearance for Data to Support Cross-Center Collaboration for Social Behavioral Sciences Associated with Disease Prevention, Treatment, and the Safety, Efficacy, and Usage of Food and Drug Administration Regulated Products – 40655 (Jul 7)
- Generic Clearance for Qualitative Data to Support Social and Behavioral Research for Food, Dietary Supplements, Cosmetics, and Animal Food and Feed – 7564 (Feb 10); 40299 (Jul 6)
- Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery – 18989 (Apr 3)
- Good Laboratory Practice for Non-Clinical Laboratory Studies – 44900 (Jul 24)
- Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements – 18998 (Apr 3)
- Guidance for Industry on E6(R2) Good Clinical Practice; International Council for Harmonisation; Integrated Addendum to International Council for Harmonisation E6(R1) – 44902 (Jul 24)
- Hazard Analysis and Critical Control Point Procedures for the Safe and Sanitary Processing and Importing of Juice – 6555 (Feb 5)
- Health Care Providers' Understanding of Opioid Analgesic Abuse Deterrent Formulations – 6562 (Feb 5); 40663 (Jul 7)
- Healthcare Provider Perception of Boxed Warning Information Survey – 40292 (Jul 6)
- Human Cells, Tissues, and Cellular and Tissue-Based Products: Establishment Registration and Listing; Eligibility Determination for Donors; and Current Good Tissue Practice – 18985 (Apr 3)
- Human Drug Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act – 28961 (May 14)
- Human Tissue Intended for Transplantation – 1167 (Jan 9)
- Imports and Electronic Import Entries – 318 (Jan 3); 23048 (Apr 24)
- Index of Legally Marketed Unapproved New Animal Drugs for Minor Species – 714 (Jan 7); 23969 (Apr 30)
- Infant Formula Recall Regulations – 23367 (Apr 27); 48705 (Aug 12)
- Medical Device User Fee Cover Sheet and Device Facility User Fee Cover Sheet – 35939 (Jun 12)
- Medical Devices; Humanitarian Use Devices – 49379 (Aug 13)
- Medical Devices; Reports of Corrections and Removals – 10168 (Feb 21); 51451 (Aug 20)
- Nonbinding Feedback After Certain Food and Drug Administration Inspections of Device Establishments – 14684 (Mar 13)
- Obtaining Information to Understand Challenges and Opportunities Encountered by Compounding Outsourcing Facilities – 36857 (Jun 18)
- Patent Term Restoration; Due Diligence Petitions; Filing, Format, and Content of Petitions – 3934 (Jan 23)
- Pediatric Uses of Medical Devices – 21241 (Apr 16)
- Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products – 5965 (Feb 3)
- Postmarketing Safety Information Sharing by Constituent Part Applicants for Combination Products – 23971 (Apr 30); 47389 (Aug 5)
- Potential Tobacco Product Violations Reporting Form – 36597 (Jun 17)
- Premarket Approval of Medical Devices – 7311 (Feb 7)
- Premarket Notification Procedures – 21244 (Apr 16)
- Prior Notice of Imported Food – 30713 (May 20)

- Prior Notice of Imported Food under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 – 6955 (Feb 6)
- Radioactive Drug Research Committees – 3390 (Jan 21); 39913 (Jul 2)
- Rapid Response Surveys – 6559 (Feb 5); 50030 (Aug 17)
- Recommendations to Reduce the Risk of Transfusion-Transmitted of Infection in Whole Blood and Blood Components; Agency Guidance – 716 (Jan 7); 18983 (Apr 3)
- Recordkeeping and Records Access Requirements for Food Facilities – 19489 (Apr 7); 45888 (Jul 30)
- Recordkeeping and Reporting Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing Material From Cattle – 49657 (Aug 14)
- Registration of Human Drug Compounding Outsourcing Facilities and Associated Fees under the Federal Food, Drug, and Cosmetic Act – 51442 (Aug 20)
- Reporting Associated with Animal Drug and Animal Generic Drug User Fees – 3929 (Jan 23); 39917 (Jul 2)
- Special Protocol Assessment – 320 (Jan 3)
- Special Protocol Assessment; Guidance for Industry – 18991 (Apr 3)
- Study of Disclosures to Health Care Providers – 40300 (Jul 6)
- Study of Multiple Indications in Direct-to-Consumer Television Advertisements – 40296 (Jul 6)
- Study of Oncology Indications in Direct-to-Consumer Television Advertising – 5213 (Jan 29)
- Submission of Petitions–Food Additive, Color Additive (Including Labeling), Submission of Information to a Master File in Support of Petitions; and Electronic Submission Using Food and Drug Administration Form 3503 – 52353 (Aug 25)
- Temporary Marketing Permit Applications – 21247 (Apr 16); 47793 (Aug 6)
- Testing Communications on Medical Devices and Radiation-Emitting Products – 7566 (Feb 10)
- Third Party Disclosure and Recordkeeping Requirements for Reportable Food – 28951 (May 14); 48542 (Aug 11)
- Tracking Network for PETNet, LivestockNet, and SampleNet – 17583 (Mar 30)
- Voluntary National Retail Food Regulatory Program Standard – 10172 (Feb 21)
- Voluntary National Retail Food Regulatory Program Standards – 41588 (Jul 10)
- Voluntary Qualified Importer Program – 6556 (Feb 5); 35937 (Jun 12)
- Amendment of Temporary Marketing Permit:
Canned Pacific Salmon Deviating From Identity Standard – 23047 (Apr 24)
- Animal Drug User Fee Rates and Payment Procedures for Fiscal Year 2021 – 46635 (Aug 3)
- Animal Generic Drug User Fee Rates and Payment Procedures for Fiscal Year 2021 – 46647 (Aug 3)
- Approval of Product under Voucher:
Rare Pediatric Disease Priority Review Voucher – 33163 (Jun 1)
- Assessing the Resource Needs of the Generic Drug User Fee Amendments – 46658 (Aug 3)
- Assessing the Resource Needs of the Prescription Drug User Fee Act and Biosimilar User Fee Act – 19149 (Apr 6)
- Authorization of Emergency Use of Certain Medical Devices during COVID-19 – 34638 (Jun 5); 42407 (Jul 14)
- Best Practices in Drug and Biological Product Postmarket Safety Surveillance for Food and Drug Administration Staff; Draft Document – 13170 (Mar 6)
- Biosimilar User Fee Rates for Fiscal Year 2021 – 47220 (Aug 4)
- Charter Renewal:
Advisory Committee; Arthritis Advisory Committee – 30966 (May 21)
Advisory Committee; Vaccines and Related Biological Products Advisory Committee – 5964 (Feb 3)
Gastrointestinal Drugs Advisory Committee – 13905 (Mar 10)
Pharmaceutical Science and Clinical Pharmacology Advisory Committee – 509 (Jan 6)
- Decision Not to Designate an Addition to the Current List of Tropical Diseases in the Federal Food, Drug, and Cosmetic Act:
Clonorchiasis – 42868 (Jul 15)
Coccidioidomycosis – 42871 (Jul 15)
- Designating Additions to the Current List of Tropical Diseases in the Federal Food, Drug, and Cosmetic Act – 42860, 42883 (Jul 15)
- Determination of Regulatory Review Period for Purposes of Patent Extension:
CARTIVA – 41999 (Jul 13)
- ELZONRIS – 53824 (Aug 31)
- FASENRA – 12793 (Mar 4)
- ILUMYA – 12565 (Mar 3)
- INGREZZA – 12928 (Mar 5)
- INTRAROSA – 8879 (Feb 18)
- ISTENT INJECT TRABECULAR MICRO-BYPASS SYSTEM – 42863 (Jul 15)
- MAVYRET – 3694 (Jan 22)
- OXERVATE – 51446 (Aug 20)
- POTELIGEO – 53823 (Aug 31)
- VYLEESI – 51448 (Aug 20)
- XEPI – 41996 (Jul 13)
- Determination that Products Were Not Withdrawn from Sale for Reasons of Safety or Effectiveness:
CARDENE (Nicardipine Hydrochloride) Injection, 25 Milligrams/10 Milliliters – 3933 (Jan 23)
NEO TECT KIT (Kit for the Preparation of Technetium TC-99m Depreotide Injection) – 12565 (Mar 3)
Potassium Chloride in 5 percent Dextrose and 0.225 percent Sodium Chloride Injection, 5 Milliequivalents, 10 Milliequivalents, 15 Milliequivalents, 20 Milliequivalents, 30 Milliequivalents, and 40 Milliequivalents, in Plastic Containers – 15194 (Mar 17)
- Drug Products Not Withdrawn from Sale for Reasons of Safety or Effectiveness:
ZOVIRAX (Acyclovir) Oral Capsules, 200 Milligrams – 39918 (Jul 2)
- Drug Products Not Withdrawn from Sale for Reasons Other Than Safety or Effectiveness:
DEXTROSE in Plastic Container (Dextrose) Injectable, 30 Grams/100 Milliliters, 40 Grams/100 Milliliters, 60 Grams/100 Milliliters, and 70 Grams/100 Milliliters – 37954 (Jun 24)
TENEX (Guanfacine Hydrochloride) Tablets, 1 Milligram, 2 Milligrams, and 3 Milligrams – 37953 (Jun 24)
- Electronic Study Data Submission:
Data Standards; Support and Requirement Begin for Study Data Tabulation Model Version 1.7 Implementation Guide 3.3 and for Define-Extensible Markup Language Version 2.1; Requirement Ends for Study Data Tabulation Model Version 1.3 Implementation Guide 3.1.3 – 40658 (Jul 7)
- Electronic Study Data Submission; Data Standards:
Support and Requirement Begin for Study Data Tabulation Model Version 1.7 Implementation Guide 3.3 and for Define-Extensible Markup Language Version 2.1; Requirement Ends for Study Data Tabulation Model Version 1.3 Implementation Guide 3.1.3; Correction – 51450 (Aug 20)
Support and Requirement Begin for Study Data Tabulation Model Version 1.8 with Standard for Exchange of Nonclinical Data Implementation Guide--Animal Rule Version 1.0 – 14205 (Mar 11)
- Electronic Submissions; Data Standards:
Support for Standard for the Exchange of Nonclinical Data – 42411 (Jul 14)
Support for the International Institute of Electrical and Electronics Engineers Bioinformatics Computations and Analyses Standard for Bioinformatic Workflows – 44304 (Jul 22)
- Establishment of a Public Docket:
Approved Drug Products With Therapeutic Equivalence Evaluations (the "Orange Book") – 33165 (Jun 1)
Listing of Patent Information in the Orange Book – 33169 (Jun 1)
Use of Codeine-Containing Analgesics in Children Under 12 Years of Age Subsequent to Genetic Testing – 38901 (Jun 29)
- Final Debarment Order:
Brenda Elise Edwards – 15791 (Mar 19)
Charles Jeffrey Edwards – 15481 (Mar 18)
Euton M. Laing – 44898 (Jul 24)
Gerald Tighe – 15790 (Mar 19)
Jagen D. Lewicki – 15190 (Mar 17)
Jin Su Park – 44904 (Jul 24)
John Seil Lee – 44907 (Jul 24)
Matthew Dailey – 15193 (Mar 17)
Michael P. Casey – 15480 (Mar 18)
Paul J. Elmer – 44899 (Jul 24)
Robert Richard Jodoin – 15195 (Mar 17)
Stephen Kalinoski – 15792 (Mar 19)
Zhang Xiao Dong – 15191 (Mar 17)
- Food and Drug Administration Modernization Act of 1997:
Modifications to the List of Recognized Standards, Recognition List Number: 053 – 17584 (Mar 30)

Food and Drug Administration

- Food Safety Modernization Act Domestic and Foreign Facility Reinspection, Recall, and Importer Reinspection Fee Rates for Fiscal Year 2021 – 46669 (Aug 3)
- Food Safety Modernization Act Third-Party Certification Program User Fee Rate for Fiscal Year 2021 – 46659 (Aug 3)
- Food Safety Modernization Act Voluntary Qualified Importer Program User Fee Rate for Fiscal Year 2021 – 46666 (Aug 3)
- Generic Drug User Fee Rates for Fiscal Year 2021 – 46662 (Aug 3)
- Guidance Documents Related to Coronavirus Disease 2019 – 28010 (May 12)
- Guidance:
- Acute Myeloid Leukemia: Developing Drugs and Biological Products for Treatment – 49383 (Aug 13)
 - Adaptive and Other Innovative Designs for Effectiveness Studies of New Animal Drugs – 42887 (Jul 15)
 - Appeal Options Available to Mammography Facilities Concerning Adverse Accreditation Decisions, Suspension/Revocation of Certificates, or Patient and Physician Notification Orders – 44097 (Jul 21)
 - Arthroscopy Pump Tubing Sets Intended for Multiple Patient Use--Premarket Notification (510(k)) Submissions – 4997 (Jan 28)
 - Biological Product Deviation Reporting for Blood and Plasma Establishments – 14682 (Mar 13)
 - Biomarkers and Surrogate Endpoints in Clinical Studies to Support Effectiveness of New Animal Drugs – 42879 (Jul 15)
 - Biosimilars and Interchangeable Biosimilars: Licensure for Fewer than All Conditions of Use for Which the Reference Product Has Been Licensed – 7313 (Feb 7)
 - Bone Anchors--Premarket Notification (510(k)) Submissions – 12563 (Mar 3)
 - Bridging for Drug-Device and Biologic-Device Combination Products – 8597 (Feb 14)
 - Cancer Clinical Trial Eligibility Criteria: Brain Metastases – 41992 (Jul 13)
 - Cancer Clinical Trial Eligibility Criteria: Minimum Age Considerations for Inclusion of Pediatric Patients – 41989 (Jul 13)
 - Cancer Clinical Trial Eligibility Criteria: Patients with Human Immunodeficiency Virus, Hepatitis B Virus, or Hepatitis C Virus Infections – 41990 (Jul 13)
 - Cancer Clinical Trial Eligibility Criteria: Patients with Organ Dysfunction or Prior or Concurrent Malignancies – 41993 (Jul 13)
 - Cannabis and Cannabis-Derived Compounds: Quality Considerations for Clinical Research – 44305 (Jul 22)
 - Certificates of Confidentiality; Extension of Comment Period – 921 (Jan 8)
 - Chemistry, Manufacturing, and Control Information for Human Gene Therapy Investigational New Drug Applications – 5447 (Jan 30)
 - Civil Money Penalties Relating to the ClinicalTrials.gov Data Bank – 50028 (Aug 17)
 - Clinical Drug Interaction Studies and In Vitro Drug Interaction Studies; Cytochrome P450 Enzyme- and Transporter-Mediated Drug Interactions – 3932 (Jan 23)
 - Clinical Investigations for Prostate Tissue Ablation Devices – 42858 (Jul 15)
 - Community-Acquired Bacterial Pneumonia – 38143 (Jun 25)
 - Competitive Generic Therapies – 14948 (Mar 16)
 - Compliance Policy for the Quantity of Bioavailability and Bioequivalence Samples – 51036 (Aug 19)
 - Compounding Animal Drugs From Bulk Drug Substances – 9783 (Feb 20)
 - Compounding Animal Drugs from Bulk Drug Substances – 35936 (Jun 12)
 - Contact Dermatitis from Topical Drug Products for Cutaneous Application: Human Safety Assessment – 13657 (Mar 9)
 - COVID-19: Developing Drugs and Biological Products for Treatment or Prevention – 29949 (May 19)
 - Cytomegalovirus in Transplantation; Developing Drugs to Treat or Prevent Disease – 27418 (May 8)
 - Demonstrating Substantial Evidence of Effectiveness for Human Drug and Biological Products – 4670 (Jan 27)
 - Developing and Labeling In vitro Companion Diagnostic Devices for a Specific Group of Oncology Therapeutic Products – 20696 (Apr 14)
 - Development of a Shared System Risk Evaluation and Mitigation Strategy; Reopening of Comment Period – 15788 (Mar 19)
 - Development of Anti-Infective Drug Products for the Pediatric Population – 39193 (Jun 30)
 - Documents Related to Coronavirus Disease 2019 – 31513 (May 26)
 - Documents Related to Coronavirus Disease 2019 (COVID-19) – 38372 (Jun 26)
 - Documents Related to Coronavirus Disease 2019; Availability – 46641 (Aug 3)
 - Drug Products Labeled as Homeopathic – 918 (Jan 8); 14947 (Mar 16)
 - Drug-Drug Interaction Assessment for Therapeutic Proteins – 48259 (Aug 10)
 - Enforcement Priorities for Electronic Nicotine Delivery Systems and Other Deemed Products on the Market without Premarket Authorization – 720 (Jan 7)
 - Enforcement Priorities for Electronic Nicotine Delivery Systems and Other Deemed Products on the Market without Premarket Authorization (Revised) – 23973 (Apr 30)
 - Evaluating Cancer Drugs in Patients with Central Nervous System Metastases – 53007 (Aug 27)
 - Exocrine Pancreatic Insufficiency Drug Products--Submitting New Drug Applications; Withdrawal of Guidance – 12932 (Mar 5)
 - Expiration Dating of Unit-Dose Repackaged Solid Oral Dosage Form Drug Products – 45889 (Jul 30)
 - Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule; Withdrawal – 23968 (Apr 30)
 - Hematologic Malignancies: Regulatory Considerations for Use of Minimal Residual Disease in Development of Drug and Biological Products for Treatment – 4668 (Jan 27)
 - Hospital-Acquired Bacterial Pneumonia and Ventilator-Associated Bacterial Pneumonia – 38142 (Jun 25)
 - Human Gene Therapy for Hemophilia – 5444 (Jan 30)
 - Human Gene Therapy for Rare Diseases – 5451 (Jan 30)
 - Human Gene Therapy for Retinal Disorders – 5454 (Jan 30)
 - Inclusion of Older Adults in Cancer Clinical Trials – 13167 (Mar 6)
 - Inorganic Arsenic in Rice Cereals for Infants – 47797 (Aug 6)
 - Institutional Review Board Review of Individual Patient Expanded Access Requests for Investigational Drugs and Biological Products During the COVID-19 Public Health Emergency – 35311 (Jun 9)
 - International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; Stability Testing of New Veterinary Drug Substances and Medicinal Products in Climatic Zones III and IV – 20693 (Apr 14)
 - Interpreting Sameness of Gene Therapy Products Under the Orphan Drug Regulations – 5445 (Jan 30)
 - Interpreting Sameness of Gene Therapy Products Under the Orphan Drug Regulations; Extension of Comment Period – 22740 (Apr 23)
 - Levonorgestrel; Intrauterine Device – 3924 (Jan 23)
 - Limited Population Pathway for Antibacterial and Antifungal Drugs – 47799 (Aug 6)
 - Long Term Follow-Up After Administration of Human Gene Therapy Products – 5452 (Jan 30)
 - Male Breast Cancer: Developing Drugs for Treatment – 48706 (Aug 12)
 - Marketing Status Notifications under Section 506I of the Federal Food, Drug, and Cosmetic Act; Content and Format – 48541 (Aug 11)
 - Mitigation Strategies to Protect Food Against Intentional Adulteration – 8599 (Feb 14)
 - Mitigation Strategies to Protect Food against Intentional Adulteration – 32040 (May 28)
 - Mucopolysaccharidosis Type III (Sanfilippo Syndrome): Developing Drugs for Treatment – 6561 (Feb 5)
 - Multiple Function Device Products: Policy and Considerations – 45640 (Jul 29)
 - Non-Clinical and Clinical Investigation of Devices Used for the Treatment of Benign Prostatic Hyperplasia – 42406 (Jul 14)
 - Nonbinding Feedback After Certain Food and Drug Administration Inspections of Device Establishments – 22429 (Apr 22)
 - Nonclinical Safety Evaluation of the Immunotoxic Potential of Drugs and Biologics – 9784 (Feb 20)
 - Notifying the Food and Drug Administration of a Permanent Discontinuance or Interruption in Manufacturing under Section 506C of the Federal Food, Drug, and Cosmetic Act – 18247 (Apr 1)
 - Orange Book - Questions and Answers – 33167 (Jun 1)
 - Patient-Focused Drug Development: Collecting Comprehensive and Representative Input – 36600 (Jun 17)
 - Pediatric Study Plans for Oncology Drugs: Questions and Answers – 2746 (Jan 16)
 - Peripheral Percutaneous Transluminal Angioplasty and Specialty Catheters--Premarket Notification (510(k)) Submissions – 1812 (Jan 13)
 - Peripheral Vascular Atherectomy Devices--Premarket Notification Submissions – 8296 (Feb 13)

Policy for Diagnostics Testing in Laboratories Certified to Perform High Complexity Testing under the Clinical Laboratory Improvement Amendments Prior to Emergency Use Authorization for Coronavirus Disease-2019 During the Public Health Emergency – 13169 (Mar 6)

Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency – 16370 (Mar 23)

Pre-Submission Consultation Process for Animal Food Additive Petitions or Generally Recognized as Safe Notices – 8297 (Feb 13)

Pregnancy, Lactation, and Reproductive Potential: Labeling for Human Prescription Drug and Biological Products--Content and Format – 45894 (Jul 30)

Principles for Selecting, Developing, Modifying, and Adapting Patient-Reported Outcome Instruments for Use in Medical Device Evaluation – 53820 (Aug 31)

Product Labeling for Laparoscopic Power Morcellators – 11093 (Feb 26)

Product-Specific Guidance – 12567 (Mar 3); 20694 (Apr 14); 34453 (Jun 4)

Product-Specific Guidances – 53826 (Aug 31)

Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products--Questions and Answers – 6201 (Feb 4)

Proprietary Names for New Animal Drugs – 33162 (Jun 1)

Providing Regulatory Submissions for Medical Devices in Electronic Format – 42864 (Jul 15)

Providing Regulatory Submissions in Alternate Electronic Format – 14202 (Mar 11)

Providing Regulatory Submissions in Electronic Format--Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (Revision 7) – 10448 (Feb 24)

Q3C(R8) Recommendations for the Permitted Daily Exposures for Three Solvents--2-Methyltetrahydrofuran, Cyclopentyl Methyl Ether, and Tert-Butyl Alcohol--According to the Maintenance Procedures for the Guidance Q3C Impurities: Residual Solvents; International Council for Harmonisation – 31785 (May 27); 34638 (Jun 5)

Q3D(R1) Elemental Impurities; International Council for Harmonisation – 14203 (Mar 11)

Recommendations for Clinical Laboratory Improvement Amendments of 1988 Waiver Applications for Manufacturers of In Vitro Diagnostic Devices – 11091 (Feb 26)

Recommendations for Dual 510(k) and Clinical Laboratory Improvement Amendments Waiver by Application Studies – 11089 (Feb 26)

Recommendations to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt Jakob Disease by Blood and Blood Components – 5668 (Jan 31)

Recommendations to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt Jakob Disease by Blood and Blood Components; – 36593 (Jun 17)

Restricted Delivery Systems: Flow Restrictors for Oral Liquid Drug Products – 15478 (Mar 18)

Review and Update of Device Establishment Inspection Processes and Standards – 38900 (Jun 29)

Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products – 36595 (Jun 17)

Revised Recommendations to Reduce the Risk of Transfusion-Transmitted Malaria – 36598 (Jun 17)

Safety and Performance Based Pathway Device-Specific Guidances – 49655 (Aug 14)

Select Updates for Peripheral Vascular Atherectomy Devices - Premarket Notification Submissions – 41987 (Jul 13)

Setting Endotoxin Limits During Development of Investigational Oncology Drugs and Biological Products – 45643 (Jul 29)

Slowly Progressive, Low-Prevalence Rare Diseases with Substrate Deposition that Results from Single Enzyme Defects: Providing Evidence of Effectiveness for Replacement or Corrective Therapies – 14949 (Mar 16)

Soft (Hydrophilic) Daily Wear Contact Lenses--Performance Criteria for Safety and Performance Based Pathway – 12788 (Mar 4)

Special Considerations, Incentives, and Programs to Support the Approval of New Animal Drugs for Minor Uses and for Minor Species – 42876 (Jul 15)

Standardized Medicated Feed Assay Limits – 11369 (Feb 27); 23369 (Apr 27)

Submission of Plans for Cigarette Packages and Cigarette Advertisements – 16103 (Mar 20)

Submission of Plans for Cigarette Packages and Cigarette Advertisements (Revised) – 32401 (May 29)

Submitting Initial Pediatric Study Plans and Amended Initial Pediatric Study Plans – 46672 (Aug 3)

Technical Considerations for Demonstrating Reliability of Emergency-Use Injectors Submitted under a Biologics License Application, New Drug Application, or Abbreviated New Drug Application – 22427 (Apr 22)

Testing of Retroviral Vector-Based Human Gene Therapy Products for Replication Competent Retrovirus During Product Manufacture and Patient Follow-up – 5448 (Jan 30)

The 510(k) Third Party Review Program – 14489 (Mar 12)

The Deemed To Be a License Provision of the Biologics Price Competition and Innovation Act: Questions and Answers – 12930 (Mar 5)

Type 2 Diabetes Mellitus: Evaluating the Safety of New Drugs for Improving Glycemic Control – 13903 (Mar 10)

Use of Data from Foreign Investigational Studies to Support Effectiveness of New Animal Drugs – 42867 (Jul 15)

Use of Real-World Data and Real-World Evidence to Support Effectiveness of New Animal Drugs – 42880 (Jul 15)

Use of Serological Tests to Reduce the Risk of Transfusion-Transmitted Human T-Lymphotropic Virus Types I and II – 6957 (Feb 6)

Use of The Seafood List to Determine Acceptable Seafood Names – 42412 (Jul 14)

Hearing:
 Devices Proposed for a New Use With an Approved, Marketed Drug; Followup – 27419 (May 8)

International Drug Scheduling:
 Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; Isotonitazene; MDMB-4en-PINACA; CUMYL-PEGACLONE; Flubromazolam; Clonazepam; Diclazepam; 3-MeO-PCP; DIPHENIDINE; 2-MEO-DIPHENIDINE; 5-MEO-DALT; and 3-FLUOROPHENMETRAZINE (3-FPM); – 47217 (Aug 4)

List of Bulk Drug Substances for which there is a Clinical Need under Section 503B of the Federal Food, Drug, and Cosmetic Act – 46126 (Jul 31)

Medical Device User Fee Rates for Fiscal Year 2021 – 46673 (Aug 3)

Meetings:
 Advancing Animal Models for Antibacterial Drug Development; Public Workshop – 6549 (Feb 5)

Allergenic Products Advisory Committee – 10451 (Feb 24)

Allergenic Products Advisory Committee; Cancellation – 17583 (Mar 30)

Blood Products Advisory Committee – 8299 (Feb 13)

Blood Products Advisory Committee; Postponed – 16368 (Mar 23)

Cardiovascular and Renal Drugs Advisory Committee – 41053 (Jul 8)

Cellular, Tissue, and Gene Therapies Advisory Committee – 14951 (Mar 16)

Center for Drug Evaluation and Research Standard Core Sets; Clinical Outcome Assessments and Endpoints Grant Program – 51445 (Aug 20)

Circulatory System Devices Panel of the Medical Devices Advisory Committee – 14681 (Mar 13); 51453 (Aug 20)

Cosmetic Products Containing Talc – 51035 (Aug 19)

Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee – 52609 (Aug 26)

Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments – 31783 (May 27)

Fiscal Year 2020 Generic Drug Regulatory Science Initiatives; Public Workshop – 13905 (Mar 10)

Fiscal Year 2020 Generic Drug Regulatory Science Initiatives; Public Workshop; Remote Only – 23968 (Apr 30)

Food and Drug Administration Hiring and Retention Interim Assessment – 41995 (Jul 13)

Food and Drug Administration Rare Disease Day 2020: Supporting the Future of Rare Disease Product Development – 3384 (Jan 21)

Food and Drug Administration/Federal Trade Commission Workshop on a Competitive Marketplace for Biosimilars – 6203 (Feb 4)

Generic Drug User Fee Amendments – 38378 (Jun 26)

Independent Third-Party Assessment of Investigational New Drug Food and Drug Administration-Sponsor Communication Practices in Prescription Drug User Fee Act VI – 44098 (Jul 21)

Food and Drug Administration

- March 10 through April 30, 2020, Public Meetings; Postponement, Cancellation, or Remote Only – 15789 (Mar 19)
- Medical Device User Fee Amendments for Fiscal Years 2023 Through 2027 – 13165 (Mar 6)
- Medical Device User Fee Amendments for Fiscal Years 2023 through 2027 – 18992 (Apr 3)
- Medical Device User Fee Amendments for Fiscal Years 2023 Through 2027; Postponement – 21445 (Apr 17)
- Medical Imaging Drugs Advisory Committee – 9782 (Feb 20)
- Modernizing the Food and Drug Administration's Data Strategy – 924 (Jan 8); 23832 (Apr 29)
- New Drugs Regulatory Program Modernization: Implementation of the Integrated Assessment of Marketing Applications and Integrated Review Documentation; Public Workshop – 49377 (Aug 13)
- Nonprescription Drugs Advisory Committee – 6565 (Feb 5)
- Oncologic Drugs Advisory Committee – 4326 (Jan 24); 33686 (Jun 2); 44100 (Jul 21)
- Oncologic Drugs Advisory Committee; Establishment of a Public Docket – 37458 (Jun 22)
- Ophthalmic Devices Panel of the Medical Devices Advisory Committee – 18249 (Apr 1)
- Ophthalmic Devices Panel of the Medical Devices Advisory Committee; Postponement – 23970 (Apr 30)
- Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee – 10447 (Feb 24); 45642 (Jul 29)
- Patient Engagement Advisory Committee – 508 (Jan 6); 53382 (Aug 28)
- Patient-Focused Drug Development for Stimulant Use Disorder – 8877 (Feb 18)
- Patient-Focused Drug Development for Vitiligo – 8004 (Feb 12)
- Pediatric Advisory Committee – 44541 (Jul 23); 49657 (Aug 14)
- Phibro Animal Health Corp.; Carbadox in Medicated Swine Feed: Opportunity for Hearing; Withdrawal – 43852 (Jul 20)
- Preparation for International Cooperation on Cosmetics Regulation 14th Annual Meeting; Cancellation – 17088 (Mar 26)
- Preparation for International Cooperation on Cosmetics Regulation Fourteenth Annual Meeting – 12569 (Mar 3)
- Prescription Drug User Fee Act of 2017; Electronic Submissions and Data Standards – 6547 (Feb 5)
- Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee – 53383 (Aug 28)
- Pulmonary-Allergy Drugs Advisory Committee – 9780 (Feb 20); 48539 (Aug 11)
- Pulmonary-Allergy Drugs Advisory Committee; Postponed – 19491 (Apr 7)
- Reauthorization of the Prescription Drug User Fee Act – 35096 (Jun 8)
- Science Advisory Board to the National Center for Toxicological Research Advisory Committee – 43587 (Jul 17)
- Scientific and Ethical Considerations for the Inclusion of Pregnant Women in Clinical Trials – 14207 (Mar 11)
- Stakeholder Engagement on ICH E6: Guideline for Good Clinical Practice; Public Web Conference – 30965 (May 21)
- Testing Methods for Asbestos in Talc and Cosmetic Products Containing Talc – 1317 (Jan 10)
- United States Food and Drug Administration and Health Canada Joint Regional Consultation on the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use – 13659 (Mar 9)
- Vaccines and Related Biological Products Advisory Committee – 507 (Jan 6); 48544 (Aug 11); 53385 (Aug 28)
- New Animal Drug Application:
Alaco, Inc., et al.; Proposal to Withdraw Approval of Seven; Opportunity for a Hearing – 919 (Jan 8)
- New Drug Application:
Elite Laboratories, Inc., et al.; Withdrawal of Approval of 23 Abbreviated – 909 (Jan 8)
- Fresenius USA, Inc., et al.; Proposal To Withdraw Approval of 249 Abbreviated; Opportunity for a Hearing – 1160 (Jan 9)
- Pharmacia and Upjohn Co., et al.; Withdrawal of Approval of 19 – 915 (Jan 8)
- New Drug Applications:
InvaGen Pharmaceuticals, Inc.; Withdrawal of Approval; Trandolapril Tablets – 41998 (Jul 13)
- Pan American Laboratories, LLC, et al.; Withdrawal of Approval of Three – 15192 (Mar 17)
- Roerig Division of Pfizer Inc., et al.; Withdrawal of Approval of 10 – 44096 (Jul 21)
- New Drug Applications; Withdrawal:
Pentaerythritol Tetranitrate – 42002 (Jul 13)
- Office of Minority Health and Health Equity Strategic Priorities – 23366 (Apr 27)
- Office of Minority Health and Health Equity Strategic Priorities;
Establishment of a Public Docket – 316 (Jan 3)
- Outsourcing Facility Fee Rates for Fiscal Year 2021 – 47225 (Aug 4)
- Pilot Program for Request for Designation and Pre-Request for Designation Electronic Submissions – 47389 (Aug 5)
- Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency:
Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff – 29461 (May 15)
- Prescription Drug User Fee Rates for Fiscal Year 2021 – 46651 (Aug 3)
- Priority Review Voucher:
Rare Pediatric Disease Product – 3935 (Jan 23); 52354 (Aug 25)
- Process for Making Available Guidance Documents Related to Coronavirus Disease 2019 – 16949 (Mar 25)
- Process for Publishing Emergency Use Authorizations for Medical Devices During Coronavirus Disease 2019 – 33685 (Jun 2)
- Prospective Grant of an Exclusive Patent License:
Development, Production, and Commercialization of a Seasonal Influenza Vaccine – 23365 (Apr 27)
- Purple Book Enhancement; Establishment of a Public Docket – 12927 (Mar 5)
- Rare Disease Clinical Trial Networks – 33163 (Jun 1)
- Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments – 47799 (Aug 6)
- Request for Comments:
Electronic Common Technical Document v4.0 Technical Conformance Guide; Food and Drug Administration Electronic Common Technical Document v4.0 Module 1 Implementation Package – 10449 (Feb 24)
- Improving 510(k) Submission Preparation and Review: Voluntary Electronic Submission Template and Resource Pilot Program – 11371 (Feb 27)
- Office of Women's Health Strategic Priorities; Establishment of a Public Docket – 41591 (Jul 10)
- Request for Information:
Vaping Products Associated With Lung Injuries – 8875 (Feb 18); 20692 (Apr 14)
- Request for Nomination:
Individuals and Consumer Organizations for Advisory Committees – 3386 (Jan 21); 41050 (Jul 8)
- Individuals and Industry Organizations for the Patient Engagement Advisory Committee – 8298 (Feb 13)
- Nonvoting Industry Representatives and Request for Nominations for Nonvoting Industry Representatives on the Blood Products Advisory Committee – 3923 (Jan 23)
- Tobacco Products Scientific Advisory Committee – 31192 (May 22)
- Voting Members for the Patient Engagement Advisory Committee – 5450 (Jan 30)
- Voting Members on a Public Advisory Committee; Pharmacy Compounding Advisory Committee – 36594 (Jun 17)
- Voting Members on a Public Advisory Committee; Technical Electronic Product Radiation Safety Standards Committee – 3052 (Jan 17)
- Request for Notification of Stakeholder Intention to Participate:
Prescription Drug User Fee Act; Stakeholder Consultation Meetings on the Prescription Drug User Fee Act Reauthorization – 40662 (Jul 7)
- Revocation of Approved Method:
Phibro Animal Health Corp.; Carbadox in Medicated Swine Feed – 43853 (Jul 20)
- Phibro Animal Health Corp.; Carbadox in Medicated Swine Feed; Correction – 47798 (Aug 6)
- Revocation of Authorization of Emergency Use of an In Vitro Diagnostic Device for Detection and/or Diagnosis of Zika Virus – 44908 (Jul 24)
- Revocation of Authorization:
Emergency Use of an In Vitro Diagnostic Device for Detection of Antibodies Against SARS-CoV-2, the Virus that Causes Coronavirus Disease 2019 (COVID-19) – 42414 (Jul 14)
- Emergency Use of In Vitro Diagnostic Devices for Detection of and/or Diagnosis of Zika or Ebola Virus – 910 (Jan 8)

Revocation of Biologics License:

Eli Lilly and Co.; LARTRUVO – 43587 (Jul 17)

Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds; Reopening of the Comment Period – 14206 (Mar 11)

Training Program for Regulatory Project Managers; Information Available to Industry – 13164 (Mar 6)

Withdrawal of Approval of Abbreviated New Drug Applications:

Watson Laboratories, Inc.; Oxycodone Hydrochloride and Ibuprofen Tablets – 46657 (Aug 3)

Withdrawal of Approval of Abbreviated New Drug Applications; Correction: Mylan Institutional LLC et al. – 36598 (Jun 17)

Withdrawal of Approval of New Drug Application: Hospira Inc., et al.; – 28016 (May 12)

Hospira, Inc., et al. – 10177 (Feb 21)

Janssen Pharmaceuticals, Inc., et al. – 28950 (May 14)

Mylan Institutional, LLC et al. – 13661 (Mar 9)

Pfizer Inc., et al. – 38144 (Jun 25)

Vasodilan Injection and Tablets Containing Isoxsuprine Hydrochloride – 42882 (Jul 15)

Vioform-Hydrocortisone Cream, Ointment, and Lotion Containing Iodochlorhydroxyquin and Hydrocortisone – 42877 (Jul 15)

Wockhardt Limited, et al. – 8598 (Feb 14)

ZECUITY (sumatriptan iontophoretic transdermal system); Teva Branded Pharmaceutical Products R and D, Inc. – 39913 (Jul 2)

Withdrawal of Approval of New Drug Applications; Correction:

Elite Laboratories, Inc. – 19491 (Apr 7)

Hospira, Inc., et al. – 37459 (Jun 22)