

Food and Drug Administration, HHS

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(1) A copy of the information you provided,

(2) The date the information was received by you,

(3) The date the information was provided to the other constituent part applicant(s), and

(4) The name and address of the other constituent part applicant(s) to whom you provided the information.

§ 4.104 How and where must you submit postmarketing safety reports for your combination product or constituent part?

(a) If you are a constituent part applicant, you must submit postmarketing safety reports in accordance with the regulations identified in § 4.102(b) that are applicable to your product based on its application type.

(b) If you are a combination product applicant, you must submit postmarketing safety reports required under § 4.102 in the manner specified in the regulation applicable to the type of report, with the following exceptions:

(1) You must submit the postmarketing safety reports identified in § 4.102(c)(1)(i) and (ii) in accordance with § 314.80(g) of this chapter if your combination product received marketing authorization under an NDA or ANDA or in accordance with § 600.80(h) of this chapter if your combination product received marketing authorization under a BLA.

(2) You must submit the postmarketing safety reports identified in § 4.102(c)(2)(ii) and (c)(3)(ii) in accordance with § 803.12(a) of this chapter if your combination product received marketing authorization under a device application.

§ 4.105 What are the postmarketing safety reporting recordkeeping requirements for your combination product or constituent part?

(a) If you are a constituent part applicant:

(1) You must maintain records in accordance with the recordkeeping requirements in the applicable regulation(s) described in § 4.102(b).

(2) You must maintain records required under § 4.103(b) for the longest time period required for records under the postmarketing safety reporting

regulations applicable to your product under § 4.102(b).

(b) If you are a combination product applicant, you must maintain records in accordance with the longest time period required for records under the regulations applicable to your product under § 4.102.

PART 5—ORGANIZATION

Subparts A–L [Reserved]

Subpart M—Organization

Sec.

5.1100 Headquarters.

5.1105 Chief Counsel, Food and Drug Administration.

5.1110 FDA Public Information Offices.

AUTHORITY: 5 U.S.C. 552; 21 U.S.C. 301–397.

SOURCE: 77 FR 15962, Mar. 19, 2012, unless otherwise noted.

Subparts A–L [Reserved]

Subpart M—Organization

§ 5.1100 Headquarters.

*Office of the Commissioner.*¹

Office of the Chief Counsel.

Office of the Executive Secretariat.

Freedom of Information Staff.

Dockets Management Staff.

*Office of the Chief Scientist.*¹

Office of Counter-Terrorism and Emerging Threats.

Office of Scientific Integrity.

Office of Regulatory Science and Innovation.

Division of Science Innovation and Critical Path.

Division of Scientific Computing and Medical Information.

Office of Scientific Professional Development.

Office of Health Informatics.

Office of Women's Health.

Office of External Affairs.

Office of Media Affairs.

Office of Communications.

Office of Health and Constituent Affairs.

Office of Minority Health.

*National Center for Toxicological Research.*²

Office of the Center Director.

Office of Management.

Office of Research.

Division of Biochemical Toxicology.

Division of Genetic and Molecular Toxicology.

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²Mailing address: Food and Drug Administration, 3900 NCTR Rd., Jefferson, AR 72079.

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Division of Microbiology.
Division of Systems Biology.
Division of Neurotoxicology.
Division of Bioinformatics and Biostatistics.
Office of Scientific Coordination.
*Office of Foods and Veterinary Medicine.*³
Communications and Public Engagement Staff.
Executive Secretariat Staff.
Office of Resource Planning and Strategic Management.
Strategic Planning and Budget Formulation Staff.
Risk Analytics Staff.
*Office of Coordinated Outbreak Response and Evaluation Network.*⁴
Prevention Staff.
Response Staff.
*Center for Food Safety and Applied Nutrition.*⁵
Office of the Center Director.
International Affairs Staff.
Executive Operations Staff.
Office of Management.
Safety Staff.
Division of Budget & Planning.
Division of Program Services.
Office of Analytics and Outreach.
Food Defense and Emergency Coordination Staff.
Biostatistics and Bioinformatics Staff.
Division of Education, Outreach and Information.
Education and Outreach Branch.
Information Center Branch.
Web Branch.
Division of Public Health Informatics and Analytics.
Epidemiology and Surveillance Branch.
Signals Management Branch.
Consumers Studies Branch.
Division of Risk and Decision Analysis.
Risk Analysis Branch.
Contaminant Assessment Branch.
Exposure Assessment Branch.
Office of Food Safety.
Retail Food Production Staff.
Multi-Commodity Foods Staff.
Division of Seafood Science and Technology.
Chemical Hazard Science Branch.
Microbiological Hazards Science Branch.
Division of Food Processing Science & Technology.
Process Engineering Branch.
Food Technology Branch.

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⁴Mailing address: 4300 River Rd., University Station (HFS-015), College Park, MD 20740.

⁵Mailing address: Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740.

Division of Plant and Dairy Food Safety.
Plant Products Branch.
Dairy and Egg Branch.
Division of Seafood Safety.
Shellfish and Aquaculture Policy Branch.
Seafood Processing and Technology Policy Branch.
Division of Produce Safety.
Fresh Produce Branch.
Processed Produce Branch.
Division of Dairy, Egg, and Meat Products.
Milk and Milk Products Branch.
Egg and Meat Products Branch.
Division of Plant Products and Beverages.
Plant Products Branch.
Beverages Branch.
Office of Cosmetics and Colors.
Division of Color Certification and Technology.
Division of Cosmetics.
Office of Regulatory Science.
Division of Analytical Chemistry.
Methods Development Branch.
Spectroscopy and Mass Spectrometry Branch.
Division of Microbiology.
Microbial Methods and Development Branch.
Molecular Methods and Subtyping Branch.
Division of Bioanalytical Chemistry.
Chemical Contaminants Branch.
Bioanalytical Methods Branch.
Office of Food Additive Safety.
Division of Food Contract Notifications.
Division of Biotechnology and GRAS Notice Review.
Division of Petition Review.
Office of Compliance.
Division of Enforcement.
Division of Field Programs and Guidance.
Office of Applied Research and Safety Assessment.
Division of Molecular Biology.
Division of Virulence Assessment.
Virulence Mechanisms Branch.
Immunobiology Branch.
Division of Toxicology.
Office of Regulations, Policy and Social Sciences.
Regulations and Special Government Employee Management Staff.
Division of Social Sciences.
Office of Nutrition and Food Labeling.
Food Labeling and Standards Staff.
Nutrition Programs Staff.
Office of Dietary Supplement Program.
Evaluation and Research Staff.
Regulatory Implementation Staff.
*Center for Veterinary Medicine.*⁶
Office of the Center Director.
Office of Management.
Program and Resources Management Staff.

⁶Mailing address: Food and Drug Administration, 7519 Standish Pl., Rockville MD 20855.

Food and Drug Administration, HHS**§ 5.1100**

Human Capital Management Staff.
Talent Development Staff.
Management Logistics Staff.
Budget Planning and Evaluation Staff.
Office of New Animal Drug Evaluation.
Division of Therapeutic Drugs for Food Animals.
Division of Production Drugs.
Division of Therapeutic Drugs for Non-Food Animals.
Division of Human Food Safety.
Division of Manufacturing Technologies.
Division of Scientific Support.
Division of Generic Animal Drugs.
Division of Business Information Science and Management.
Office of Surveillance and Compliance.
Division of Surveillance.
Division of Animal Feeds.
Division of Compliance.
Division of Veterinary Product Safety.
Office of Research.
Division of Residue Chemistry.
Division of Applied Veterinary Research.
Division of Animal and Food Microbiology.
Office of Minor Use and Minor Species Animal Drug Development.
OFFICE OF MEDICAL PRODUCTS AND TOBACCO
*Office of Medical Products and Tobacco—Immediate Office.*⁷
*Office of Special Medical Programs—Immediate Office.*⁸
Advisory Committee Oversight and Management Staff.
Good Clinical Practice Staff.
Office of Pediatric Therapeutics.
Office of Orphan Products Development.
Office of Combination Products.
*Center for Biologics Evaluation and Research.*⁹
Office of the Center Director.
Executive Operations Staff.
Regulatory Information Management Staff.
Regulations and Policy Staff.
Records Management Staff.
Bioinformatics Support Staff.
Business Operations Staff.
Office of Management.
Planning and Performance Management Staff.
Division of Program Services.
Program Operations Branch.
Program Services Branch.
Division of Budget and Resource Management.
Budget Analysis and Formulation Branch.
Resource Management Branch.
Division of Program Services.
Building Operations Staff.
Program Management Services Branch.
Program Operations Branch.
Division of Scientific Advisors and Consultants.
Division of Veterinary Services.
Office of Compliance and Biologics Quality.
Division of Case Management.
Blood and Tissue Compliance Branch.
Advertising and Promotional Labeling Branch.
Biological Drug and Device Compliance Branch.
Division of Manufacturing and Product Quality.
Product Release Branch.
Manufacturing Review Branch I.
Manufacturing Review Branch II.
Applications Review Branch.
Division of Inspections and Surveillance.
Program Surveillance Branch.
Bioresearch Monitoring Branch.
Division of Biological Standards and Quality Control.
Laboratory of Analytical Chemistry and Blood Related Products.
Quality Assurance Branch.
Laboratory of Microbiology, In-vivo Testing and Standards.
Office of Blood Research and Review.
Administrative Staff.
Policy and Publication Staff.
Regulatory Project Management Staff.
Division of Emerging and Transfusion Transmitted Diseases.
Laboratory of Molecular Virology.
Laboratory of Emerging Pathogens.
Laboratory of Bacterial and Transmissible Spongiform Encephalopathy Agents.
Product Review Branch.
Division of Hematology Clinical Review.
Hematology Product Review Branch.
Clinical Review Branch.
Division of Blood Components and Devices.
Blood and Plasma Branch.
Devices and Review Branch.
Division of Hematology Research and Review.
Laboratory of Cellular Hematology.
Laboratory of Hemostasis.
Laboratory of Plasma Derivatives.
Laboratory of Biochemistry and Vascular Biology.
Office of Vaccine Research and Review.
Program Operations Staff.
Division of Bacterial, Parasitic, and Allergenic Products.
Laboratory of Immunobiochemistry.
Laboratory of Respiratory and Special Pathogens.
Laboratory of Bacterial Polysaccharides.
Laboratory of Mucosal Pathogens and Cellular Immunology.
Division of Viral Products.
Laboratory of Pediatric and Respiratory Viral Diseases.
Laboratory of Hepatitis Viruses.

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Laboratory of Retroviruses.
 Laboratory of DNA Viruses.
 Laboratory of Vector-Borne Diseases.
 Laboratory of Method Development.
 Laboratory of Immunoregulation.
 Division of Vaccines and Related Products Applications.
 Clinical Review Branch 1.
 Clinical Review Branch 2.
 CMC Review Branch 1.
 CMC Review Branch 2.
 CMC Review Branch 3.
 Review Management Support Branch.
Office of Communication, Outreach, and Development.
 Division of Disclosure and Oversight Management.
 Congressional and Oversight Branch.
 Access Litigation and Freedom of Information Branch.
 Division of Manufacturers Assistance and Training.
 Career Development and Directed Training Branch.
 Manufacturers Assistance and Technical Training Branch.
 Division of Communication and Consumer Affairs.
 Communication Technology Branch.
 Consumer Affairs Branch.
Office of Biostatistics and Epidemiology.
 Division of Biostatistics.
 Vaccine Evaluation Branch.
 Therapeutics Evaluation Branch.
 Division of Epidemiology.
 Pharmacovigilance Branch.
 Analytic Epidemiology Branch.
Office of Cellular, Tissue and Gene Therapies.
 Regulatory Management Staff.
 Division of Cellular and Gene Therapies.
 Cell Therapies Branch.
 Gene Therapies Branch.
 Gene Transfer and Immunogenicity Branch.
 Tumor Vaccine and Biotechnology Branch.
 Cellular and Tissue Therapy Branch.
 Division of Clinical Evaluation and Pharmacological Toxicology Review.
 General Medicine Branch.
 Pharmacology/Toxicology Branch.
 Oncology Branch.
 Division of Human Tissues.
 Human Tissue and Reproduction Branch.
*Center for Tobacco Products.*¹⁰
Office of the Center Director.
Office of Management.
 Acquisitions and Assistance Staff.
 Information and Technology Staff.
 Management and Logistics Staff.
 Division of Financial Management.
 Division of Human Capital.
Office of Regulations.
Office of Science.
 Regulatory Science and Management Staff.

Research Staff.
 Division of Regulatory Project Management.
 Regulatory Project Management Branch I.
 Regulatory Project Management Branch II.
 Regulatory Project Management Branch III.
 Regulatory Project Management Branch IV.
 Division of Regulatory Science Informatics.
 Division of Product Science.
 Division of Individual Health Science.
 Division of Population Health Science.
 Division of Non-Clinical Science.
Office of Health Communication and Education.
 Division of Public Health Education.
 Division of Health, Scientific, and Regulatory Communication.
Office of Compliance and Enforcement.
 Division of Enforcement and Manufacturing.
 Division of Promotion, Advertising and Labeling.
 Division of State Programs.
 Division of Business Operations.
*Center for Drug Evaluation and Research.*¹¹
Office of the Center Director.
 Controlled Substance Staff.
 Professional Affairs and Stakeholder Engagement Staff.
 Counter-Terrorism and Emergency Coordination Staff.
 Drug Shortages Staff.
Office of Regulatory Policy.
 Division of Regulatory Policy I.
 Division of Regulatory Policy II.
 Division of Regulatory Policy III.
 Division of Regulatory Policy IV.
 Division of Information Disclosure Policy.
 Proactive Disclosure Branch.
 Freedom of Information Branch.
Office of Management.
 Strategic Programs and Initiatives Staff.
 Ethics Liaison Staff.
 Division of Budget Execution and Resource Management.
 Budget Execution Branch.
 Acquisitions Support Branch.
 Financial Accountability Branch.
 Division of Management Services.
 Human Capital Management Branch.
 Human Capital Programs Branch.
 Facilities Operations Branch.
 Property and Travel Services Branch.
 Leave and Performance Management Branch.
 Division of User Fee Management and Budget Formulation.
 Generics Branch.
 Policy and Operations Branch.

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¹¹Mailing address: 10903 New Hampshire Ave., Bldg. 51, Silver Spring, MD 20993.

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Brands Branch.
Office of Communications.
Division of Online Communications.
Division of Health Communications.
Division of Drug Information.
Office of Compliance.
Program Management and Analysis Staff.
Office of Manufacturing Quality.
Manufacturing Guidance and Policy Staff.
Division of Drug Quality I.
Global Compliance Branch I.
Global Compliance Branch II.
Division of Drug Quality II.
Global Compliance Branch III.
Global Compliance Branch IV.
Office of Unapproved Drugs and Labeling Compliance.
Division of Prescription Drugs.
Prescription Drugs Branch.
Compounding and Pharmacy Practices Branch.
Division of Non-Prescription Drugs and Health Fraud.
Over-the-Counter Drugs Branch.
Health Fraud Branch.
Office of Scientific Investigations.
Policy Staff.
Division of Enforcement and Postmarket Safety.
Compliance Enforcement Branch.
Postmarketing Safety Branch.
Division of Clinical Compliance Evaluation.
Good Clinical Practice Compliance Oversight Branch.
Good Clinical Practice Assessment Branch.
Office of Drug Security, Integrity and Response.
Division of Import Exports and Recalls.
Recalls and Shortages Branch.
Import Export Compliance Branch.
Division of Supply Chain Integrity.
Supply Chain Strategy and Policy Branch.
Supply Chain Response and Enforcement Branch.
Office of Program and Regulatory Operations.
Project Management and Coordination Staff I.
Project Management and Coordination Staff II.
Drug Registration and Listing Staff.
Office of Medical Policy.
Office of Prescription Drug Promotion.
Division of Consumer Drug Promotion.
Division of Professional Drug Promotion.
Office of Medical Policy Initiatives.
Division of Medical Policy Development.
Division of Medical Policy Programs.
Division of Clinical Trial Quality.
Office of Translational Science.
Program Management and Analysis Staff.
Office of Biostatistics.
Division of Biometrics I.
Division of Biometrics II.
Division of Biometrics III.
Division of Biometrics IV.
Division of Biometrics V.
Division of Biometrics VI.
Division of Biometrics VII.
Division of Biometrics VIII.
Office of Clinical Pharmacology.
Division of Clinical Pharmacology I.
Division of Clinical Pharmacology II.
Division of Clinical Pharmacology III.
Division of Clinical Pharmacology IV.
Division of Clinical Pharmacology V.
Division of Pharmacometrics.
Division of Applied Regulatory Science.
Office of Computational Science.
Office of Study Integrity and Surveillance.
Division of New Drug Bioequivalence Evaluation.
Division of Generic Drug Bioequivalence Evaluation.
Office of Executive Programs.
Division of Learning and Organizational Development.
Scientific and Regulatory Education Branch.
Training Design and Delivery Branch.
Leadership and Organizational Development Branch.
Division of Executive Operations.
Division of Advisory Committee and Consultant Management.
Office of Surveillance and Epidemiology.
Regulatory Science Staff.
Regulatory Affairs Staff.
Program Management and Analysis Staff.
Project Management Staff.
Office of Medication Error Prevention and Risk Management.
Division of Medication Error Prevention and Analysis.
Division of Risk Management.
Office of Pharmacovigilance and Epidemiology.
Division of Epidemiology I.
Division of Epidemiology II.
Division of Pharmacovigilance I.
Division of Pharmacovigilance II.
Office of New Drugs.
Program Management and Analysis Staff.
Pharmacology/Toxicology Staff.
Regulatory Affairs Staff.
Office of Drug Evaluation I.
Division of Cardiovascular and Renal Products.
Division of Neurology Products.
Division of Psychiatry Products.
Office of Drug Evaluation II.
Division of Metabolism and Endocrinology Products.
Division of Pulmonary, Allergy, and Rheumatology Products.
Division of Anesthesia, Analgesia, and Addiction Products.
Office of Drug Evaluation III.
Division of Gastroenterology and Inborn Effects Products.
Division of Bone, Reproductive and Urologic Products.
Division of Dermatology and Dental Products.
Office of Antimicrobial Products.
Division of Anti-Infective Products.

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- Division of Anti-Viral Products.
- Division of Transplant and Ophthalmology Products.
- Office of Drug Evaluation IV.*
- Division of Nonprescription Drug Products.
- Division of Medical Imaging Products.
- Division of Pediatrics and Maternal Health.
- Office of Hematology and Oncology Drug Products.*
- Division of Oncology Products I.
- Division of Oncology Products II.
- Division of Hematology Products.
- Division of Hematology Oncology Toxicology.
- Office of Strategic Programs.*
- Office of Program and Strategic Analysis.*
- Program Evaluation and Implementation Staff.
- Economics Staff.
- Performance Analysis and Data Services Staff.
- Lean Management Staff.
- Office of Business Informatics.*
- Division of Regulatory Review and Drug Safety Services and Solutions.
- Division of Business Management Services and Solutions.
- Division of Data Management Services and Solutions.
- Division of Drug Quality and Compliance Services and Solutions.
- Office of Generic Drugs.*
- Clinical Safety Surveillance Staff.
- Program Management and Analysis Staff.
- Communications Staff.
- Office of Research and Standards.*
- Division of Therapeutic Performance.
- Division of Quantitative Methods and Modeling.
- Office of Bioequivalence.*
- Division of Bioequivalence I.
- Division of Bioequivalence II.
- Division of Bioequivalence III.
- Division of Clinical Review.
- Office of Generic Drug Policy.*
- Division of Legal and Regulatory Support.
- Division of Policy Development.
- Office of Regulatory Operations.*
- Division of Labeling Review.
- Division of Filing Review.
- Division of Project Management.
- Division of Quality Management Systems.
- Office of Pharmaceutical Quality.*
- Scientific Staff.
- Program Management and Analysis Staff.
- Office of Biotechnology Products.*
- Division of Biotechnology Review and Research I.
- Division of Biotechnology Review and Research II.
- Division of Biotechnology Review and Research III.
- Division of Biotechnology Review and Research IV.
- Office of New Drug Products.*
- Division of Life Cycle API.
- Life Cycle Branch I.
- Life Cycle Branch II.
- Life Cycle Branch III.
- Division of New Drug API.
- New Drug Branch I.
- New Drug Branch II.
- Division of New Drug Products I.
- New Drug Products Branch I.
- New Drug Products Branch II.
- New Drug Products Branch III.
- Division of New Drug Products II.
- New Drug Products Branch IV.
- New Drug Products Branch V.
- New Drug Products Branch VI.
- Division of Biopharmaceutics.
- Biopharmaceutics Branch I.
- Biopharmaceutics Branch II.
- Biopharmaceutics Branch III.
- Office of Policy for Pharmaceutical Quality.*
- Division of Regulations, Guidance and Standards.
- Policy Development and Evaluation Branch I.
- Policy Development and Evaluation Branch II.
- Compendial Operations and Standards Branch.
- Division of Internal Policies and Programs.
- Policy Development and Evaluation Branch I.
- Policy Development and Evaluation Branch II.
- Office of Process and Facilities.*
- Division of Process Assessment I.
- Process Assessment Branch I.
- Process Assessment Branch II.
- Process Assessment Branch III.
- Division of Process Assessment II.
- Process Assessment Branch IV.
- Process Assessment Branch V.
- Process Assessment Branch VI.
- Division of Process Assessment III.
- Process Assessment Branch VII.
- Process Assessment Branch VIII.
- Process Assessment Branch IX.
- Division of Microbiology Assessment.*
- Microbiology Assessment Branch I.
- Microbiology Assessment Branch II.
- Microbiology Assessment Branch III.
- Microbiology Assessment Branch IV.
- Division of Inspectional Assessment.*
- Inspectional Assessment Branch I.
- Inspectional Assessment Branch II.
- Inspectional Assessment Branch III.
- Office of Surveillance.*
- Division of Quality Intelligence, Risk Analysis, and Modeling.
- Data Integrity Branch.
- Quality Intelligence Branch.
- Analysis and Modeling Branch.
- Division of Quality Surveillance Assessment.
- Quality Deviation and Assessment Branch.
- Inspection Assessment Branch.
- Office of Testing and Research.*
- Division of Product Quality Research.
- Product Quality Branch I.

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Product Quality Branch II.
Division of Pharmaceutical Analysis.
Pharmaceutical Analysis Branch I.
Pharmaceutical Analysis Branch II.
Office of Program and Regulatory Operations.
Division of Regulatory and Business Process Management I.
Regulatory and Business Process Management Branch I.
Regulatory and Business Process Management Branch II.
Division of Regulatory and Business Process Management II.
Regulatory and Business Process Management Branch III.
Regulatory and Business Process Management Branch IV.
Division of Operational Excellence, Learning, and Professional Development.
Learning and Professional Development Branch.
Organizational Excellence Branch.
Office of Lifecycle Drug Products.
Division of Immediate Release Products I.
Immediate Release Branch I.
Immediate Release Branch II.
Immediate Release Branch III.
Division of Immediate Release Products II.
Immediate Release Branch IV.
Immediate Release Branch V.
Immediate Release Branch VI.
Division of Modified Release Products.
Modified Release Branch I.
Modified Release Branch II.
Modified Release Branch III.
Division of Liquid-Based Products.
Liquid-Based Branch I.
Liquid-Based Branch II.
Liquid-Based Branch III.
Division of Post-Marketing Activities I.
Post-Marketing Branch I.
Post-Marketing Branch II.
Division of Post-Marketing Activities II.
Post-Marketing Branch III.
Post-Marketing Branch IV.
Post-Marketing Branch V.
Center for Devices and Radiological Health.¹²
Office of the Center Director.
Quality Management Staff.
Office of Communication and Education.
Digital Communication Media Staff.
Program Management Operations Staff.
Division of Communication.
External Communications Branch.
Web and Graphics Branch.
Internal Communication Branch.
Division of Employee Training and Development.
Employee Development Branch.
Technology and Learning Management Branch.
Division of Industry and Consumer Education.

Premarket Programs Branch.
Postmarket and Consumer Branch.
Division of Information Disclosure.
Freedom of Information Branch A.
Freedom of Information Branch B.
Office of Management.
Planning and Program Analysis Staff.
Division of Acquisition Services.
Advanced Acquisitions.
Simplified Acquisitions.
Acquisition Planning Assistance.
Division of Workforce Management.
Recruitment.
Human Capital Management.
Special Programs.
Division of Management Services.
Travel and Conference Management.
Committee Management and Planning.
Space and Facilities Management.
Division of Financial Management.
Budget Formulation.
Budget Execution.
Financial Accountability.
Office of Policy.
Guidance, Legislation and Special Projects.
Regulatory Documents and Special Projects.
Office of Product Evaluation and Quality.
Quality and Analytics Staff.
Clinical and Scientific Policy Staff.
Strategic Initiatives Staff.
Regulation, Policy and Guidance Staff.
Compliance and Quality Staff.
Operations Staff.
Office of Regulatory Programs.
Division of Regulatory Programs 1 (Division of Submission Support).
Division of Regulatory Programs 2 (Division of Establishment Support).
Division of Regulatory Programs 3 (Division of Market Intelligence).
Office of Clinical Evidence and Analysis.
Division of Clinical Evidence and Analysis 1 (Division of Clinical Science and Quality).
Division of Clinical Evidence and Analysis 2 (Division of Biostatistics).
Office of Health Technology 1 (OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices).
Division of Health Technology 1A (Division of Ophthalmic Devices).
Division of Health Technology 1B (Division of Dental Devices).
Division of Health Technology 1C (Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices).
Office of Health Technology 2 (OHT2: Office of Cardiovascular Devices).
Division of Health Technology 2A (Division of Cardiac Electrophysiology, Diagnostics, and Monitoring Devices).
Division of Health Technology 2B (Division of Circulatory Support, Structural and Vascular Devices).

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Division of Health Technology 2C (Division of Coronary and Peripheral Interventional Devices).

Office of Health Technology 3 (OHT3: Office of Gastrorenal, ObGyn, General Hospital and Urology Devices).

Division of Health Technology 3A (Division of Renal, Gastrointestinal, Obesity, and Transplant Devices).

Division of Health Technology 3B (Division of Reproductive, Gynecology and Urology Devices).

Division of Health Technology 3C (Division of Drug Delivery and General Hospital Devices, and Human Factors).

Office of Health Technology 4 (OHT4: Office of Surgical and Infection Control Devices).

Division of Health Technology 4A (Division of General Surgery Devices).

Division of Health Technology 4B (Division of Infection Control and Plastic Surgery Devices).

Office of Health Technology 5 (OHT5: Office of Neurological and Physical Medicine Devices).

Division of Health Technology 5A (Division of Neurological, Neurointerventional and Neurodiagnostic Devices).

Division of Health Technology 5B (Division of Neuromodulation and Physical Medicine Devices).

Office of Health Technology 6 (OHT6: Office of Orthopedic Devices).

Division of Health Technology 6A (Division of Joint Arthroplasty Devices).

Division of Health Technology 6B (Division of Spinal Devices).

Division of Health Technology 6C (Division of Stereotaxic, Trauma and Restorative, Devices).

Office of Health Technology 7 (OHT7: Office of In Vitro Diagnostics and Radiological Health).

Division of Program Operations and Management.

Division of Chemistry and Toxicology Devices.

Chemistry Branch.

Diabetes Branch.

Toxicology Branch.

Cardio-Renal Diagnostics Branch.

Division of Molecular Genetics and Pathology.

Molecular Pathology and Cytology Branch.

Molecular Genetics Branch.

Division of Immunology and Hematology Devices.

Hematology Branch.

Immunology and Flow-Cytometry Branch.

Division of Microbiology Devices.

Viral Respiratory and HPV Branch.

General Viral and Hepatitis Branch.

General Bacterial and Antimicrobial Susceptibility Branch.

Bacterial Respiratory and Medical Countermeasures Branch.

Division of Radiological Health.

Magnetic Resonance and Electronic Products Branch.

Diagnostic X-Ray Systems Branch.

Nuclear Medicine and Radiation Therapy Branch.

Mammography, Ultrasound and Imaging Software Branch.

Division of Mammography Quality Standards.

Office of Science and Engineering Laboratories.

Immediate Office of the Director

Division of Applied Mechanics.

Division of Biomedical Physics.

Division of Biology, Chemistry and Materials Science.

Division of Imaging, Diagnostics, and Software Reliability.

Division of Administrative and Laboratory Support.

Office of Strategic Partnerships and Technology Innovation.

Innovation.

Division of All Hazards Response Science and Strategic Partnerships.

Medical Device Development Tools.

Health of Women.

Pediatrics and Special Populations.

All Hazards Readiness Response and Cybersecurity.

Patient Science and Engagement.

Partnerships to Advance Innovation and Regulatory Science.

Science and Special Projects Incubator.

Standards and Conformity Assessment Program.

Division of Digital Health.

Operational Excellence.

Technical and Policy Leadership Strategic Partnerships and Initiatives 1.

Technical and Policy Leadership Strategic Partnerships and Initiatives 2.

Strategic Initiatives and Special Projects.

Division of Technology and Data Services.

Business and Transformation Services.

Data Services.

Technology Services.

*Office of Global Regulatory Operations and Policy.*¹³

*Office of International Programs.*¹⁴

*Office of Regulatory Affairs.*¹⁵

Office of the Associate Commissioner for Regulatory Affairs.

Executive Secretariat Staff.

Information Technology Staff.

*Office of Resource Management.*¹⁶

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Food and Drug Administration, HHS

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Division of Planning Evaluation and Management.
Program Planning and Workforce Management Branch.
Program Evaluation Branch.
Division of Budget Formulation and Execution.
Division of Human Resources Development.
Division of Management Operations.
*Office of Criminal Investigations.*¹⁷
Mid-Atlantic Area Office.
Philadelphia Resident Unit.
Midwest Area Office.
Northeast Area Office.
Boston, MA Resident Unit.
Pacific Area Office.
San Francisco, CA Resident Unit.
Southeast Area Office.
San Juan, PR Resident Unit.
Atlanta, GA Resident Unit.
New Orleans, LA Resident Unit.
Southwest Area Office.
Dallas, TX Resident Unit.
Office of Communications and Quality Program Management.
Quality Management Systems Staff.
Project Coordination Staff.
Division of Communications.
Public Affairs and Editorial Services Branch.
Web and Digital Media Strategies Branch.
*Office of Partnerships.*¹⁸
Standards Implementation Staff.
Contracts and Grants Staff.
*Office of Policy and Risk Management.*¹⁹
Food and Feed Policy Staff.
Medical Products and Tobacco Policy Staff.
Risk Management Staff.
Division of Planning Evaluation and Management.
Program Evaluation Branch.
Work Planning Branch.
*Office of Operations.*²⁰
Audit Staff.
*Office of Enforcement and Import Operations.*²¹
Division of Enforcement.
Division of Compliance Systems.
Enforcement Systems Branch.
Import Compliance Systems Branch.
Division of Import Operations.
Import Operations and Maintenance Branch.
Import Program Development and Implementation Branch.

¹⁷ Mailing address: 7500 Standish Pl., MPN2 Building, Rockville, MD 20855.

¹⁸ Mailing address: 12420 Parklawn Dr., Element Building, Rockville, MD 20857.

¹⁹ Mailing address: 12420 Parklawn Dr., Element Building, Rockville, MD 20857.

²⁰ Mailing address: 10903 New Hampshire Ave., Bldg. 31, Silver Spring, MD 20993.

²¹ Mailing address: 12420 Parklawn Dr., Element Building, Rockville, MD 20857.

*Office of Regulatory Science.*²²
Food and Feed Scientific Staff.
Medical Products and Tobacco Scientific Staff.
Laboratory Operations and Support Staff.
*Office of Food and Feed Operations.*²³
Division of Food Defense Targeting.
Division of Food and Feed Program Operations and Inspections.
Food and Feed Program Operations Branch.
Food and Feed Inspection Branch.
Food and Feed Trip Planning Branch.
*Office of Medical Products and Tobacco Operations.*²⁴
Division of Products and Tobacco Program Operations.
Medical Device and Tobacco Program Operations Branch.
Team Biological Branch.
Division of Medical Products and Tobacco Inspections.
Medical Products and Tobacco Inspection Branch.
Drug Inspection Branch.
Medical Products and Tobacco Trip Planning Branch.
*Regional Field Office, Northeast Region, Jamaica, NY.*²⁵
Operations Staff.
Intergovernmental Affairs Staff.
District Office New York.²⁶
Domestic Compliance Branch.
Domestic Investigations Branch.
Resident Post Long Island, NY.
Resident Post White Plains, NY.
Resident Post Albany, NY.
Resident Post Binghamton, NY.
Resident Post Rochester, NY.
Resident Post Newburgh, NY.
Resident Post Syracuse, NY.
Import Operations Branch (Downstate).
Resident Post Port Elizabeth, NJ.
Import Operations Branch (Upstate).
Resident Post Champlain, NY.
Resident Post Alexandra Bay, NY.
Resident Post Massena, NY.
Resident Post Ogdensburg, NY.
Northeast Regional Laboratory.²⁷
Microbiological Science Branch.
Chemistry Branch 1.
Chemistry Branch 2.

²² Mailing address: 12420 Parklawn Dr., Element Building, Rockville, MD 20857.

²³ Mailing address: 12420 Parklawn Dr., Element Building, Rockville, MD 20857.

²⁴ Mailing address: 12420 Parklawn Dr., Element Building, Rockville, MD 20857.

²⁵ Mailing address: 158-15 Liberty Ave., Jamaica, NY 11433.

²⁶ Mailing address: 158-15 Liberty Ave., Jamaica, NY 11433.

²⁷ Mailing address: 158-15 Liberty Ave., Jamaica, NY 11433.

New England District Office.²⁸
 Compliance Branch.
 Investigations Branch.
 Resident Post Augusta, ME.
 Resident Post Bridgeport, CT.
 Resident Post Concord, NH.
 Resident Post Hartford, CT.
 Resident Post Providence, RI.
 Resident Post Worcester, MA.
 Resident Post Calais, ME.
 Resident Post Houlton, ME.
 Resident Post Highgate, VT.
 Winchester Engineering and Analytical Center.²⁹
 Analytical Branch.
 Engineering Branch.
*Regional Field Office, Southwest Region, Dallas, TX.*³⁰
 State Cooperative Programs Staff.
 Resident Post Pharr.
 Dallas District Office.³¹
 Compliance Branch.
 Investigations Branch.
 Resident Post Austin, TX.
 Resident Post Fort Worth, TX.
 Resident Post Houston, TX.
 Resident Post San Antonio, TX.
 Resident Post Oklahoma City, OK.
 Resident Post Little Rock, AR.
 Kansas City District Office.³²
 Investigations Branch.
 Resident Post Wichita, KS.
 Resident Post Omaha, NE.
 Resident Post Des Moines, IA.
 Resident Post Springfield, MO.
 Resident Post St Louis, MO.
 Resident Post Davenport, IA.
 Compliance Branch.
 Denver District Office.³³
 Compliance Branch.
 Investigations Branch.
 Resident Post Salt Lake City, UT.
 Resident Post Albuquerque, NM.
 Arkansas Regional Laboratory.³⁴
 General Chemistry Branch.
 Pesticide Chemistry Branch.
 Microbiology Branch.
 Southwest Import District Office Dallas, TX.³⁵

²⁸Mailing address: 1 Montvale Ave., 4th Floor, Stoneham, MA 02180–3500.

²⁹Mailing address: 109 Holton St., Winchester, MA 01890.

³⁰Mailing address: 4040 North Central Expressway, Dallas, TX 75204–3128.

³¹Mailing address: 4040 North Central Expressway, Suite 300, Dallas, TX 75204–3128.

³²Mailing address: 8050 Marshal Dr., Suite 250, Lenexa, KS 66214.

³³Mailing address: Sixth Avenue and Kipling Street, Building 20, P.O. Box 25087, Denver, CO 80255–0087—Denver Federal Center.

³⁴Mailing address: 3900 NCTR Rd., Bldg. 26, Jefferson, AR 72079.

³⁵Mailing address: 4040 North Central Expressway, Suite 300, Dallas, TX 75204–3128.

Compliance Branch.
 Investigations Branch.
 Resident Post Calexico.
 Resident Post Eagle Pass.
 Resident Post El Paso Bota.
 Resident Post El Paso Bota Westmoreland.
 Resident Post El Paso Ysleta Bridge.
 Resident Post Houston (SWID).
 Resident Post Laredo #2 Bridge.
 Resident Post Laredo Columbia Bridge.
 Resident Post Laredo World Trade Bridge.
 Resident Post Los Tomates.
 Resident Post Nogales #1.
 Resident Post Nogales #2.
 Resident Post Otay Mesa #1.
 Resident Post Otay Mesa #2.
 Resident Post Pharr.
 Resident Post Rio Grande City.
 Resident Post San Luis.
 Kansas City Laboratory.³⁶
 Denver Laboratory.³⁷
*Central Regional Field Office Chicago IL.*³⁸
 State Cooperative Programs Staff I.
 State Cooperative Programs Staff II.
 Regional Operations Staff.
 Baltimore District Office Baltimore, MD.³⁹
 Compliance Branch.
 Investigations Branch.
 Resident Post Charleston, WV.
 Resident Post Falls Church, VA.
 Resident Post Seva.
 Resident Post Richmond, VA.
 Resident Post Roanoke, VA.
 Resident Post Dundalk Marine Terminal, MD.
 Resident Post Morgantown, WV.
 District Office Cincinnati, OH.⁴⁰
 Compliance Branch.
 Investigations Branch.
 Resident Post Brunswick, OH.
 Resident Post Columbus, OH.
 Resident Post Toledo, OH.
 Resident Post Louisville, KY.
 Forensic Chemistry Center.⁴¹
 Inorganic Chemistry Branch.
 Organic Chemistry Branch.
 District Office Parsippany, NJ.⁴²
 Compliance Branch.
 Investigations Branch.

³⁶Mailing address: 11510 West 80th St., Lenexa, KS 66214.

³⁷Mailing address: Sixth Avenue and Kipling Street, Building 20, Denver, CO 80255–0087—Denver Federal Center.

³⁸Mailing address: 20 N. Michigan Ave., Suite 510, Chicago, IL 60602.

³⁹Mailing address: 6000 Metro Dr., Suite 101, Baltimore, MD 21215.

⁴⁰Mailing address: 6751 Steger Dr., Cincinnati, OH 45237.

⁴¹Mailing address: 6751 Steger Dr., Cincinnati, OH 45237.

⁴²Mailing address: 10 Waterview Blvd., 3rd Floor, Parsippany, NJ 07054—Waterview Corporate Center.

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Resident Post Voorhees, NJ.
Resident Post North Brunswick, NJ.
District Office Philadelphia, PA.⁴³
Compliance Branch.
Investigations Branch.
Resident Post Harrisburg, PA.
Resident Post Pittsburgh, PA.
Resident Post Wilkes-Barre, PA.
Resident Post Wilmington, PA.
District Office Chicago, IL.⁴⁴
Compliance Branch.
Investigations Branch.
Resident Post Peoria, IL.
Resident Post Hinsdale, IL.
Resident Post Gurnee, IL.
Resident Post Springfield, IL.
Resident Post O'Hare Airport.
District Office Minneapolis, MN.⁴⁵
Compliance Branch.
Investigations Branch.
Resident Post La Crosse, WI.
Resident Post Green Bay, WI.
Resident Post Milwaukee, WI.
Resident Post Madison, WI.
Resident Post Fargo, ND.
Resident Post Stevens Point, WI.
Resident Post Sioux, SD.
District Office Detroit, MI.⁴⁶
Compliance Branch.
Investigations Branch.
Resident Post Kalamazoo, MI.
Resident Post South Bend, IN.
Resident Post Indianapolis, IN.
Resident Post Evansville, IN.
Resident Post
Philadelphia Laboratory.⁴⁷
Detroit Laboratory.⁴⁸
*Southeast Regional Field Office Atlanta, GA.*⁴⁹
State Cooperative Programs Staff
Atlanta District Office.⁵⁰
Compliance Branch.
Investigations Branch.
Resident Post Savannah, GA.
Resident Post Tifton, GA.
Resident Post Charlotte, NC.
Resident Post Greensboro, NC.
Resident Post Greenville, NC.

⁴³Mailing address: 200 Chestnut St., Room 900, Philadelphia, PA 19106—U.S. Customs House.

⁴⁴Mailing address: 550 West Jackson Blvd., Suite 1500, Chicago, IL 60661.

⁴⁵Mailing address: 250 Marquette Ave., Suite 600, Minneapolis, MN 55401.

⁴⁶Mailing address: 300 River Pl., Suite 5900, Detroit, MI 48207.

⁴⁷Mailing address: 200 Chestnut St., Room 900, Philadelphia, PA 19106—U.S. Customs House.

⁴⁸Mailing address: 300 River Pl., Suite 5900, Detroit, MI 48207.

⁴⁹Mailing address: 60 Eighth St. NE., Atlanta, GA 30309.

⁵⁰Mailing address: 60 Eighth St. NE., Atlanta, GA 30309.

Resident Post Raleigh, NC.
Resident Post Charleston, SC.
Resident Post Columbia, SC.
Resident Post Greenville, SC.
Resident Post Asheville, NC.
Florida District Office.⁵¹
Compliance Branch.
Investigations Branch.
Resident Post Jacksonville, FL.
Resident Post Miami, FL.
Resident Post Tallahassee, FL.
Resident Post Tampa, FL.
Resident Post Boca Raton, FL.
Resident Post Ft. Meyers, FL.
Resident Post Port Everglades, FL.
New Orleans, LA, District Office.⁵²
Compliance Branch.
Investigations Branch.
Resident Post Baton Rouge, LA.
Resident Post Lafayette, LA.
Resident Post Covington, LA.
Resident Post Jackson, MS.
Resident Post Mobile, AL.
Nashville Branch.
Resident Post Knoxville, TN.
Resident Post Memphis, TN.
Resident Post Birmingham, AL.
Resident Post Montgomery, AL.
San Juan District Office.⁵³
Compliance Branch.
Investigations Branch.
Resident Post Aquada, PR.
Resident Post Ponce, PR.
Southeast Regional Laboratory Atlanta, GA.⁵⁴
Chemistry Branch I.
Microbiology Branch.
Atlanta Center for Nutrient Analysis.
Chemistry Branch II.
San Juan Laboratory.⁵⁵
*Regional Field Office, Pacific Region, Oakland, CA.*⁵⁶
State Cooperative Programs Staff.
District Office San Francisco, CA.⁵⁷
Compliance Branch.
Investigations Branch.
Resident Post Las Vegas, NV.
Resident Post Fresno, CA.
Resident Post Sacramento, CA.
Resident Post Honolulu, HI.
Resident Post San Jose, CA.

⁵¹Mailing address: 555 Winderley Pl., Suite 200, Maitland, FL 32751.

⁵²Mailing address: 404 BNA Dr., Building 200, Suite 500, Nashville, TN 37217.

⁵³Mailing address: 466 Fernandez Juncos Ave., San Juan, PR 00901.

⁵⁴Mailing address: 60 Eighth St., Atlanta, GA 30309.

⁵⁵Mailing address: 466 Fernandez Juncos Ave., San Juan, PR 00901.

⁵⁶Mailing address: 1301 Clay St., Room 1180N, Oakland, CA 94612.

⁵⁷Mailing address: 1431 Harbor Bay Pkwy., Alameda, CA 94502.

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Resident Post Stockton, CA.
 Resident Post South San Francisco.
 District Office Los Angeles, CA.⁵⁸
 Compliance Branch.
 Import Operations Branch.
 Resident Post Los Angeles Airport.
 Resident Post Ontario, CA—Import.
 Domestic Investigations Branch.
 Resident Post Woodland Hills, CA.
 Resident Post San Diego, CA.
 Resident Post Tempe, AZ.
 Resident Post Ontario, CA—Domestic.
 District Office Seattle, WA.⁵⁹
 Compliance Branch.
 Investigations Branch.
 Resident Post Anchorage, AK.
 Resident Post Boise, ID.
 Resident Post Portland, ID.
 Resident Post Spokane, WA.
 Resident Post Oroville, WA.
 Resident Post Portland, OR—Airport.
 Resident Post Blaine, WA.
 Resident Post Helena, MT.
 Resident Post Sweetgrass, MT.
 Resident Post Tacoma, WA.
 Resident Post Puget Sound, WA.
 Pacific Regional Laboratory Southwest.⁶⁰
 Food Chemistry Branch.
 Drug Chemistry Branch.
 Microbiology Branch.
 Pacific Regional Laboratory Northwest.⁶¹
 Chemistry Branch.
 Microbiology Branch.
 Seafood Products Research Center.
Office of Operations.
Office of Business Services.
 Business Operations Staff.
 Employee Resource and Information Center.
 Division of Ethics and Integrity.
Office of Equal Employment Opportunity.
 Compliance Staff.
Office of Finance, Budget, and Acquisitions.
Office of Budget.
 Division of Budget Formulation.
 Division of Budget Execution and Control.
Office of Acquisition and Grant Services.
 Division of Acquisition Operations.
 Division of Acquisition Programs.
 Division of Acquisition Support and Grants.
 Division of Information Technology.
Office of Financial Operations.
Office of Financial Management.
Office of Financial Services.
Office of Human Resources.
 Commission Corps Affairs Staff.

Management Analysis Services Staff.
 Business Operations Staff.
 Division of Workforce Relations.
 Division of Policy, Programs, and Executive Resources.
 Division of Human Resource Services for Office of the Commissioner/Office of Operations.
 Division of Human Resource Services for Office of Foods and Veterinary Medicine/Office of Global Operations and Policy.
 Division of Human Resource Services for Office of Medical Products and Tobacco.
 FDA University.
Office of Facilities, Engineering and Mission Support Services.
 Jefferson Laboratories Complex Staff.
 Division of Operations Management and Community Relations.
 Division of Planning, Engineering and Safety Management.
Office of Information Management and Technology.
Office of Information Management.
Office of Technology and Delivery.
 Division of Infrastructure Operations.
 Division of Application Services.
 Division of Delivery Management and Support.
Office of Business and Customer Assurance.
 Division of Business Partnership and Support.
 Division of Management Services.
Office of Enterprise and Portfolio Management.
Office of Safety, Security, and Crisis Management.
Office of Security Operations.
Office of Crisis Management.
Office of Emergency Operations.
*Office of Policy, Planning, Legislation, and Analysis.*⁶²
 Management and Operations Staff.
 Intergovernment Affairs Staff.
Office of Policy.
 Regulations Policy and Management Staff.
 Policy Development and Coordination Staff.
Office of Planning.
 Planning Staff.
 Program Evaluation and Process Improvement Staff.
 Economics Staff.
 Risk Communication Staff.
Office of Legislation.
Office of Public Health Strategy and Analysis.
 [81 FR 78033, Nov. 7, 2016, as amended at 83 FR 13106, Mar. 27, 2018; 85 FR 18440, Apr. 2, 2020]
 EDITORIAL NOTE: At 85 FR 72906, Nov 16, 2020, §5.1100 was amended; however, the amendment could not be incorporated due to the inaccurate amendatory instruction.

⁵⁸Mailing address: 19701 Fairchild Rd., Irvine, CA 92612.

⁵⁹Mailing address: 22215 26th Ave. SE., Suite 210, Bothell, WA 98021.

⁶⁰Mailing address: 19701 Fairchild Rd., Irvine, CA 92612.

⁶¹Mailing address: 22201 23rd Dr. SE., Bothell, WA 98021-4421.

⁶²Mailing address: 10903 New Hampshire Ave., Silver Spring, MD 20993.

Food and Drug Administration, HHS

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§ 5.1105 Chief Counsel, Food and Drug Administration.

The Office of the Chief Counsel's mailing address is White Oak Bldg. 1, 10903 New Hampshire Ave., Silver Spring, MD 20993.¹

[85 FR 72906, Nov. 16, 2020]

§ 5.1110 FDA public information offices.

(a) *Dockets Management Staff.* The Dockets Management Staff public room is located in rm. 1061, 5630 Fishers Lane, Rockville, MD 20852, Telephone: 301-827-6860.

(b) *Freedom of Information Staff.* The Freedom of Information Staff's Public Reading Room is located at the address available on the agency's web site at <http://www.fda.gov>.

(c) *Press Relations Staff.* Press offices are located in White Oak Bldg. 1, 10903 New Hampshire Ave., Silver Spring, MD 20993, Telephone: 301-827-6242; and at 5001 Campus Dr., College Park, MD 20740, Telephone: 301-436-2335.

[77 FR 15962, Mar. 19, 2012, as amended at 79 FR 68114, Nov. 14, 2014; 81 FR 49895, July 29, 2016; 88 FR 45064, July 14, 2023]

PART 7—ENFORCEMENT POLICY

Subpart A—General Provisions

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- 7.1 Scope.
- 7.3 Definitions.
- 7.12 Guaranty.
- 7.13 Suggested forms of guaranty.

Subpart B [Reserved]

Subpart C—Recalls (Including Product Corrections)—Guidance on Policy, Procedures, and Industry Responsibilities

- 7.40 Recall policy.
- 7.41 Health hazard evaluation and recall classification.
- 7.42 Recall strategy.

¹The Office of the Chief Counsel (also known as the Food and Drug Division, Office of the General Counsel, Department of Health and Human Services), while administratively within the Office of the Commissioner, is part of the Office of the General Counsel of the Department of Health and Human Services.

- 7.45 Food and Drug Administration-requested recall.
- 7.46 Firm-initiated recall.
- 7.49 Recall communications.
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Subpart D [Reserved]

Subpart E—Criminal Violations

- 7.84 Opportunity for presentation of views before report of criminal violation.
- 7.85 Conduct of a presentation of views before report of criminal violation.
- 7.87 Records related to opportunities for presentation of views conducted before report of criminal violation.

AUTHORITY: 21 U.S.C. 321-393; 42 U.S.C. 241, 262, 263b-263n, 264.

SOURCE: 42 FR 15567, Mar. 22, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 7.1 Scope.

This part governs the practices and procedures applicable to regulatory enforcement actions initiated by the Food and Drug Administration pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*) and other laws that it administers. This part also provides guidance for manufacturers and distributors to follow with respect to their voluntary removal or correction of marketed violative products. This part is promulgated to clarify and explain the regulatory practices and procedures of the Food and Drug Administration, enhance public understanding, improve consumer protection, and assure uniform and consistent application of practices and procedures throughout the agency.

[43 FR 26218, June 16, 1978, as amended at 65 FR 56476, Sept. 19, 2000]

§ 7.3 Definitions.

(a) *Agency* means the Food and Drug Administration.

(b) *Citation* or *cite* means a document and any attachments thereto that provide notice to a person against whom criminal prosecution is contemplated of the opportunity to present views to the agency regarding an alleged violation.