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INFORMATION
GPO

in §3.4(b) and an assessment of the assignment of other combination products the sponsor wishes FDA to consider during the assignment of its combination product.

(d) Where to file: all communications pursuant to this subpart shall be addressed to the attention of the product jurisdiction officer. Such a request, in its mailing cover should be plainly marked ''Request for Designation.'' Concurrent submissions of electronic copies of Requests for Designation may be addressed to *combination@fda.gov*.

[56 FR 58756, Nov. 21, 1991, as amended at 68 FR 37077, June 23, 2003; 70 FR 49861, Aug. 25, 2005]

§ 3.8 Letter of designation.

(a) Each request for designation will be reviewed for completeness within 5 working days of receipt. Any request for designation determined to be incomplete will be returned to the applicant with a request for the missing information. The sponsor of an accepted request for designation will be notified of the filing date.

(b) Within 60 days of the filing date of a request for designation, the product jurisdiction officer will issue a letter of designation to the sponsor, with copies to the centers, specifying the agency component designated to have primary jurisdiction for the premarket review and regulation of the product at issue, and any consulting agency components. The product jurisdiction officer may request a meeting with the sponsor during the review period to discuss the request for designation. If the product jurisdiction officer has not issued a letter of designation within 60 days of the filing date of a request for designation, the sponsor's recommendation of the center with primary jurisdiction, in accordance with §3.7(c)(3), shall become the designated agency component.

(c) Request for reconsideration by sponsor: If the sponsor disagrees with the designation, it may request the product jurisdiction officer to reconsider the decision by filing, within 15 days of receipt of the letter of designation, a written request for reconsideration not exceeding 5 pages. No new information may be included in a request for reconsideration. The product jurisdiction officer shall review and act on the request in writing within 15 days of its receipt.

§ 3.9 Effect of letter of designation.

(a) The letter of designation constitutes an agency determination that is subject to change only as provided in paragraph (b) of this section.

(b) The product jurisdiction officer may change the designated agency component with the written consent of the sponsor, or without its consent to protect the public health or for other compelling reasons. A sponsor shall be given 30 days written notice of any proposed nonconsensual change in designated agency component. The sponsor may request an additional 30 days to submit written objections, not to exceed 15 pages, to the proposed change, and shall be granted, upon request, a timely meeting with the product jurisdiction officer and appropriate center officials. Within 30 days of receipt of the sponsor's written objections, the product jurisdiction officer shall issue to the sponsor, with copies to appropriate center officials, a written determination setting forth a statement of reasons for the proposed change in designated agency component. A nonconsensual change in the designated agency component requires the concurrence of the Principal Associate Commissioner.

[56 FR 58756, Nov. 21, 1991, as amended at 68 FR 37077, June 23, 2003]

§ 3.10 Stay of review time.

Any filing with or review by the product jurisdiction officer stays the review clock or other established time periods for agency action for an application for marketing approval or required investigational notice during the pendency of the review by the product jurisdiction officer.

Subpart B [Reserved]

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.

The Food and Drug Administration consists of the following:

Office of the Commissioner.
Office of Executive Secretariat.
Office of the Chief Counsel.
Office of the Counselor to the Commissioner.
  Office of Crisis Management.
  Office of Emergency Operations.
Office of Policy and Planning.
  Office of Policy.
  Policy Development and Coordination Staff.
  Regulations Policy and Management Staff.
  Regulations Editorial Section.
  Office of Planning.
  Planning Staff.
  Program Evaluation and Process Improvement Staff.
  Economics Staff.
  Risk Communications Staff.
Office of Legislation.
Office of External Affairs.
  Web Communications Staff.
  Office of External Relations.
  Communications Staff.
  Office of Public Affairs.
  Office of Special Health Issues.
Office of Minority Health.
Office of Women's Health.
Office of the Chief Scientist.
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.
National Center for Toxicological Research.
  Office of the Center Director.
  Office of Management.
  Office of Scientific Coordination.
  Office of Research.
  Division of Biochemical Toxicology.
  Division of Genetic and Molecular Toxicology.
  Division of Personalized Nutrition and Medicine.
  Biometry Branch.
  Pharmacogenomics Branch.
  Division of Microbiology.
  Division of Neurotoxicology.
  Division of Systems Biology.
Office of Operations.
Office of Equal Employment Opportunity.
  Conflict Prevention and Resolution Staff.
  Compliance Staff.
  Diversity Staff.
Office of Finance, Budget, and Acquisitions.
  Office of Budget.
  Office of Acquisitions and Grants Services.
  Division of Acquisition Operations.
  Division of Acquisition Support and Grants.
  Division of Acquisition Programs.
  Division of Information Technology.
  Office of Financial Operations.
  Office of Financial Management.
  User Fees Staff.
  Division of Accounting.
  Division of Budget Execution and Control.
  Office of Financial Services.
  Payroll Staff.
  Division of Payment Services.
  Division of Travel Services.
Office of Information Management.
  Division of Business Partnership and Support.
  Division of Chief Information Officer Support.
  Division of Systems Management.
  Division of Infrastructure Operations.
  Division of Technology.
Office of Management.
  Ethics and Integrity Staff.
  Office of Management Programs.
  Office of Security Operations.
  Office of Facilities, Engineering and Mission Support Services.
  Jefferson Lab Complex Staff.
  Business Operations and Initiatives Staff.
  Division of Operations Management and Community Relations.
  Auxiliary Program Management Branch.
  Logistics and Transportation Management Branch.
  Facilities Maintenance and Operations Branch.
  Division of Planning, Engineering, and Space Management.
  Planning and Space Management Branch.
  Employee Safety and Environmental Management Branch.
  Engineering Management Branch.
  Office of Library and Employee Services.
  Employee Resource and Information Center.
  FDA Biosciences Library.
  Public Services Branch.
  Technical Services Branch.
  FDA History Office.
  Division of Freedom of Information.
  Division of Dockets Management.
Office of Foods.
Center for Food Safety and Applied Nutrition.
Office of the Center Director.
  Executive Operations Staff.
  International Staff.

Office of Management.
Safety Staff.
Division of Planning and Budget and Planning.
Division of Program Services.
Office of Food Defense, Communication and Emergency Response.
Division of Education and Communication.
Division of Public Health and Biostatistics.
Office of Food Safety.
Retail Food and Cooperative Program Support Staff.
Division of Seafood Science and Technology.
Chemical Hazard Branch.
Microbiological Hazard Branch.
Division of Food Processing Science and Technology.
Process Engineering Branch.
Food Technology Branch.
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.
Office of Cosmetics and Colors.
Cosmetic Staff.
Division of Color Certification and Technology.
Office of Regulatory Science.
Division of Analytical Chemistry.
Methods Branch.
Spectroscopy and Mass Spectrometry Branch.
Division of Microbiology.
Microbial Methods and Development Branch.
Molecular Methods and Subtyping Branch.
Division of Bioanalytical Chemistry.
Bioanalytical Methods Branch.
Chemical Contaminants Branch.
Office of Food Additive Safety.
Division of Food Contact 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.
Division of Toxicology.
Office of Regulations, Policy, and Social Sciences.
Regulations and Special Government Employees Management Staff.
Division of Social Sciences.
Office of Nutrition, Labeling, and Dietary Supplements.
Nutrition Programs Staff.
Division of Dietary Supplement Programs.
Center for Veterinary Medicine.
Office of the Center Director.
Office of Management.
Management Logistics Staff.
Human Capital Management Staff.
Program and Resource Management Staff.
Talent Development Staff.
Budget Planning and Evaluation Staff.
Office of New Animal Drug Evaluation.
Division of Therapeutic Drugs for Non-Food Animals.
Division of Biometrics and Production Drugs.
Division of Therapeutic Drugs for Food Animals.
Division of Human Food Safety.
Division of Manufacturing Technologies.
Division of Scientific Support.
Division of Generic Animal Drugs.
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 Animal 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 Special Medical Programs.
Advisory Committee Oversight and Management Staff.
Good Clinical Practice Staff.
Office of Combination Products.
Office of Orphan Products Development.
Office of Pediatric Therapeutics.
Center for Biologics Evaluation and Research.
Office of the Center Director.
Regulations Policy Staff.
Quality Assurance Staff.
Office of Management.
Regulatory Information Management Staff.
Division of Planning, Evaluation, and Budget.
Division of Veterinary Services.
Division of Program Services.
Division of Scientific Advisors and Consultants.
Building Operations Staff.
Office of Compliance and Biologics Quality.
Division of Case Management.
Division of Inspections and Surveillance.
Division of Manufacturing and Product Quality.
Office of Biostatistics and Epidemiology.
Division of Biostatistics.
Division of Epidemiology.
Office of Information Management.
Division of Information Operations.
Division of Information Development.
Office of Blood Research and Review.
Policy and Publications Staff.
Division of Emerging and Transfusion Transmitted Diseases.
Division of Hematology.

Division of Blood Applications.
Office of Vaccines Research and Review.
Program Operation Staff.
Division of Product Quality.
Division of Bacterial, Parasitic, and Allergenic Products.
Division of Viral Products.
Division of Vaccines and Related Product Applications.
Office of Cellular, Tissue, and Gene Therapies.
Regulatory Management Staff.
Division of Cellular and Gene Therapies.
Division of Clinical Evaluation and Pharmacology/Toxicology.
Division of Human Tissues.
Office of Communication, Outreach and Development.
Division of Disclosure and Oversight Management.
Division of Manufacturers Assistance and Training.
Division of Communication and Consumer Affairs.
Center for Devices and Radiological Health.
Office of the Center Director.
Regulations Staff.
Office of Management Operations.
Division of Ethics and Management Operations.
Human Resource and Administrative Management Branch.
Integrity, Conference and Committee Management Branch.
Division of Planning, Analysis and Finance.
Planning Branch.
Financial Management Branch.
Office of Compliance.
Promotion and Advertising Policy Staff.
Program Management Staff.
Quality Management Program Staff.
Division of Bioresearch Monitoring.
Program Enforcement Branch A.
Program Enforcement Branch B.
Special Investigations Branch.
Division of Risk Management Operations.
Field Programs Branch.
Recall Branch.
Regulatory Policy Branch.
Division of Enforcement.
General Surgery Devices Branch.
Dental Ear, Nose, Throat and Ophthalmic Devices Branch.
Gastroenterology and Urology Branch.
General Hospital Devices Branch.
Division of Enforcement B.
Radiology, Anesthesiology, and Neurology Devices Branch.
Cardiac Rhythm and Electrophysiology Devices Branch.
Vascular and Circulatory Support Devices Branch.
Orthopedic and Physical Medicine Devices Branch.
Office of Device Evaluation.
Program Management Staff.
Program Operations Staff.
Pre-Market Approval Staff.
Investigational Device Exemption Staff.
Pre-Market Notification Section.
Division of Cardiovascular Devices.
Circulatory Support and Prosthetic Branch.
Interventional Cardiology Devices Branch.
Pacing, Defibrillators, and Leads Branch.
Cardiac Electrophysiology and Monitoring Devices Branch.
Peripheral Scads Vascular Devices Branch.
Division of Reproductive, Gastro-Renal, and Urological Devices.
Gynecology Devices Branch.
Urology and Lithotripsy Devices Branch.
Gastroenterology and Renal Devices Branch.
Division of Surgical, Orthopedic, and Restorative Devices.
General Surgery Devices Branch.
Restorative Devices Branch.
Plastic and Reconstructive Surgery Devices Branch.
Orthopedic Joint Devices Branch.
Orthopedic Spine Devices Branch.
Division of Ophthalmic, Neurological, and Ear, Nose, and Throat Devices.
Intraocular, Corneal, and Neuromaterial Devices Branch.
Ophthalmic Laser, Neuromuscular Stimulators, and Diagnostic Devices Branch.
Neurodiagnostic and Neurotherapeutic Devices Branch.
Ear, Nose, and Throat Devices Branch.
Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices.
General Hospital Devices Branch.
Infection Control Devices Branch.
Dental Devices Branch.
Anesthesiology and Respiratory Devices Branch.
Office of Science and Engineering Laboratories.
Management Support Staff.
Division of Biology.
Division of Chemistry and Materials Science.
Division of Solid and Fluid Mechanics.
Division of Physics.
Division of Imaging and Applied Mathematics.
Division of Solid and Fluid Mechanics.
Division of Electrical and Software Engineering.
Office of Communication, Education and Radiation Programs.
Program Operations Staff.
Staff College.
Division of Health Communication.
Web Communication Branch.
Risk Communication Branch.
Division of Small Manufacturers International and Consumer Assistance.
Technical Assistance Branch.

International Relations and External Affairs Staff.
Regulatory Assistance Branch.
Division of Mammography Quality and Radiation Programs.
Inspection and Compliance Branch.
Information Management Branch.
Diagnostic Devices Branch.
Electronic Devices Branch.
Division of Communication Media.
Television Design and Development Branch.
Division of Freedom of Information.
Freedom of Information Branch A.
Freedom of Information Branch B.
Office of Surveillance and Biometrics.
Program Management Staff.
Division of Biostatistics.
Cardiovascular and Ophthalmic Devices Branch.
Diagnostic Devices Branch.
General and Surgical Devices Branch.
Division of Postmarket Surveillance.
Product Evaluation Branch 1.
Product Evaluation Branch 2.
Information Analysis Branch.
MDR Policy Branch.
Division of Patient Safety Partnership.
Patient Safety Branch 1.
Patient Safety Branch 2.
Division of Epidemiology.
Epidemiology Evaluation and Research Branch 1.
Epidemiology Evaluation and Research Branch 2.
Office of In Vitro Diagnostic Device Evaluation and Safety.
Division of Chemistry and Toxicology Devices.
Division of Immunology and Hematology Devices.
Division of Microbiology Devices.
Division of Radiological Devices.
Center for Drug Evaluation and Research.
Office of the Center Director.
Controlled Substances Staff.
Safe Use Staff.
Office of Regulatory Policy.
Division of Regulatory Policy I.
Division of Regulatory Policy II.
Division of Regulatory Policy III.
Division of Information Disclosure Policy.
Office of Management.
Division of Management and Budget.
Planning and Resource Management Branch.
Management Analysis Branch.
Division of Management Services.
Program Management Services Branch.
Interface Management Branch.
Office of Communications.
Division of Online Communications.
Division of Health Communications.
Division of Drug Information.
Office of Surveillance and Epidemiology.
Regulatory Science Staff.
Regulatory Affairs Staff.
Executive Operations and Strategic Planning Staff.
Technical Information Staff.
Program Management and Analysis Staff.
Project Management Staff.
Office of Medication Error Prevention.
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 Compliance.
Office of Drug Security, Integrity, and Recalls.
Division of Import Operations and Recalls.
Recall Coordination Branch.
Import Operations Branch.
Division of Supply Chain Integrity.
Office of Unapproved Drugs and Labeling Compliance.
Division of Prescription Drugs.
Prescription Drugs Branch.
Compounding and Pharmacy Practice Branch.
Division of Non-Prescription Drugs and Health Fraud.
Over-the-Counter Drugs Branch.
Health Fraud and Consumer Outreach Branch.
Office of Manufacturing and Product Quality.
Division of International Drug Quality.
International Compliance Branch I.
International Compliance Branch II.
Division of Domestic Drug Quality.
Domestic Compliance Branch 1.
Domestic Compliance Branch 2.
Division of Policy, Collaboration, and Data Operations.
Regulatory Policy and Communications Branch.
Drug Surveillance and Data Reporting Branch.
Division of GMP Assessment.
Biotech Manufacturing Assessment Branch.
New Drug Manufacturing Assessment Branch.
Generic Drug Manufacturing Assessment Branch.
Office of Scientific Investigations.
Division of Bioequivalence and Good Laboratory Practice Compliance.
Good Laboratory Practice Branch.
Bioequivalence Branch.
Division of Good Clinical Practice Compliance.
Good Clinical Practice Enforcement Branch
Good Clinical Practice Assessment Branch
Division of Safety Compliance.
Post Market Safety Branch.
Human Subject Protection Branch.

Office of New Drugs.
Pediatric and Maternal Health Staff.
Program Management Analysis 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 Reproductive and Urologic Products.
Division of Dermatology and Dental Products.
Office of Antimicrobial Products.
Division of Anti-Infective Products.
Division of Anti-Viral Products.
Division of Transplant and Ophthalmology Products.
Office of Drug Evaluation IV.
Division of Nonprescription Clinical Evaluation.
Division of Nonprescription Regulation Development.
Division of Medical Imaging Products.
Office of Hematology and Oncology Drug Products.
Division of Oncology Products 1.
Division of Oncology Products 2.
Division of Hematology Products.
Division of Hematology Oncology Toxicology.
Office of Pharmaceutical Science.
Program Activities Review Staff.
Operations Staff.
Science and Research Staff.
New Drug Microbiology Staff.
Office of Generic Drugs.
Division of Bioequivalence 1.
Division of Bioequivalence 2.
Division of Labeling and Program Support.
Labeling Review Branch.
Regulatory Branch.
Review Support Branch.
Division of Chemistry I.
Division of Chemistry II.
Division of Chemistry III.
Division of Chemistry IV.
Division of Clinical Review.
Division of Microbiology.
Office of New Drug Quality Assessment.
Division of New Drug Quality Assessment I.
Branch I.
Branch II.
Branch III.
Division of New Drug Quality Assessment II.
Branch IV.
Branch V.
Branch VI.
Division of New Drug Quality Assessment III.
Branch VII.
Branch VIII.
Branch IX.
Office of Testing and Research.
Division of Drug Safety Research.
Division of Pharmaceutical Analysis.
Division of Product Quality Research.
Office of Biotechnology Products.
Division of Monoclonal Antibodies.
Division of Therapeutic Protein.
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.
Office of Executive Programs.
Division of Training and Development.
Training and Development Branch I.
Training and Development Branch II.
Division of Executive Operations.
Division of Advisory Committee and Consultant Management.
Office of Translational Science.
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.
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.
Office of Counter-Terrorism and Emergency Coordination.
Office of Planning and Informatics.
Office of Planning and Analysis.
Office of Business Informatics.
Division of Records Management.
Division of Regulatory Review Support.
Division of Business Analysis and Reporting.
Division of Project Development.
Center for Tobacco Products.
Office of the Center Director.
Office of Management.
Office of Policy.
Office of Regulations.
Office of Science.
Office of Health Communication and Education.
Office of Compliance and Enforcement.
Office of Global Regulatory Operations and Policy.
Office of International Programs.
Office of Regulatory Affairs.

Office of Resource Management.
Division of Planning, Evaluation, and Management.
Program Planning and Workforce Management Branch.
Program Evaluation Branch.
Division of Human Resource Development.
Division of Management Operations.
Office of Enforcement.
Division of Compliance Management and Operations.
Division of Compliance Policy.
Division of Compliance Information and Quality Assurance.
Office of Regional Operations.
Division of Federal-State Relations.
State Contracts Staff.
State Information Staff.
Public Affairs and Health Fraud Staff.
Division of Field Science.
FERN National Program Branch.
Scientific Compliance and Regulatory Review Branch.
Laboratory Operations Branch.
Division of Import Operations and Policy.
Systems Branch.
Operations and Policy Branch.
Division of Foreign Field Investigations.
International Operations Branch.
Foreign Food Branch.
Foreign Drug Branch.
Foreign Devices Branch.
Division of Domestic Field Investigations.
Team Biologics Staff.
National Expert Staff.
Domestic Operations Branch.
Division of Food Defense Targeting.
Office of Criminal Investigations.
Mid-Atlantic Area Office.
Midwest Area Office.
Northeast Area Office.
Pacific Area Office.
Southeast Area Office.
Southwest Area Office.
Regional Food and Drug Directors.
Regional Field Office, Central Region, Chicago, IL.
State Cooperative Programs Staff I.
State Cooperative Programs Staff II.
Regional Operations Staff.
District Office, Baltimore, MD.
Compliance Branch.
Investigations Branch.
District Office, Cincinnati, OH.
Compliance Branch.
Investigations Branch.
Forensic Chemistry Center.
Inorganic Chemistry Branch.
Organic Chemistry Branch.
District Office, Parsippany, NJ
Compliance Branch.
Investigations Branch.
District Office, Philadelphia, PA.
Compliance Branch.
Investigations Branch.
Laboratory Branch.
District Office, Chicago, IL.
Compliance Branch.
Investigations Branch.
District Office, Minneapolis, MN.
Compliance Branch.
Investigations Branch.
District Office, Detroit, MI.
Compliance Branch.
Investigations Branch.
Laboratory Branch.
Regional Field Office, Northeast Region, Jamaica, NY.
Operations Staff.
Intergovernmental Affairs Staff.
District Office, New York.
Domestic Compliance Branch.
Domestic Investigations Branch.
Import Operations Branch (Downstate).
Import Operations Branch (Upstate).
Northeast Regional Laboratory.
Microbiological Science Branch.
Food Chemistry Branch.
Drug Chemistry Branch.
District Office New England.
Compliance Branch.
Investigations Branch.
Winchester Engineering and Analytical Center.
Analytical Branch.
Engineering Branch.
Regional Field Office, Pacific Region, Oakland, CA.
District Office, San Francisco, CA
Compliance Branch.
Investigations Branch.
Laboratory Branch.
District Office, Los Angeles, CA.
Compliance Branch.
Domestic Investigations Branch.
Import Operations Branch.
District Office, Seattle, WA.
Compliance Branch.
Investigations Branch.
Pacific Regional Laboratory Southwest Los Angeles, CA.
Food Chemistry Branch.
Drug Chemistry Branch.
Microbiology Branch.
Pacific Regional Laboratory Northwest Bothell, WA.
Chemistry Branch.
Microbiology Branch.
Seafood Products Research Center.
Regional Field Office, Southeast Region, Atlanta, GA.
District Office, Atlanta, GA.
Compliance Branch.
Investigations Branch.
District Office, FL.
Compliance Branch.
Investigations Branch.
District Office, New Orleans, LA.
Compliance Branch.
Investigations Branch.
Nashville Branch.
District Office, San Juan, PR.
Compliance Branch.
Investigations Branch.

Laboratory Branch.
Southeast Regional Laboratory, Atlanta, GA.
Chemistry Branch I.
Microbiology Branch.
Atlanta Center for Nutrient Analysis.
Chemistry Branch II.
Regional Field Office, Southwest Region.
District Office, Dallas, TX.
Compliance Branch.
Investigations Branch.
District Office, Kansas City, MO.
Compliance Branch.
Investigations Branch.
Science Operations Branch.
Total Diet and Pesticide Research Center.
District Office, Denver, CO.
Compliance Branch.
Investigations Branch.
Laboratory Branch.
Arkansas Regional Laboratory.
General Chemistry Branch.
Pesticide Chemistry Branch.
Microbiology Branch.
Southwest Import District Office, Dallas, TX.
Compliance Branch.
Investigations Branch.

§ 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.

§ 5.1110 FDA public information offices.

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

(b) *Division of Freedom of Information*. The Division of Freedom of Information public room is located in rm. 1050, Element Bldg., 12420 Parklawn Dr., Rockville, MD 20857, Telephone: 301–796–3900.

(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 5100 Paint Branch Pkwy., College Park, MD 20740, Telephone: 301–436–2335.

PART 7—ENFORCEMENT POLICY

Subpart A—General Provisions

Sec.
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.
7.45 Food and Drug Administration-requested recall.
7.46 Firm-initiated recall.
7.49 Recall communications.
7.50 Public notification of recall.
7.53 Recall status reports.
7.55 Termination of a recall.
7.59 General industry guidance.

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