

Subpart C—Organization

§ 5.100 Officials authorized to make certification under 5 U.S.C. 605(b) for any proposed and final rules.

The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to decisions made under the Regulatory Flexibility Act (5 U.S.C. 605(b)), to certify that a proposed or final rule, if issued, will not have a significant economic impact on a substantial number of small entities:

- (a) The Associate Commissioner for Regulatory Affairs (ACRA).
- (b) The Director, Center for Biologics Evaluation and Research (CBER).
- (c) The Director, Center for Drug Evaluation and Research (CDER).
- (d) The Director, Center for Devices and Radiological Health (CDRH).
- (e) The Director, Center for Food Safety and Applied Nutrition (CFSAN).
- (f) The Director, Center for Veterinary Medicine (CVM).
- (g) Other FDA Officials authorized to issue FEDERAL REGISTER documents.

[62 FR 48757, Sept. 17, 1997]

§ 5.101 Authority relating to waivers or reductions of prescription drug user fees.

The Director, Center for Drug Evaluation and Research (CDER), and the Associate Director for Policy, CDER, are authorized to perform all functions of the Commissioner of Food and Drugs relating to waivers or reductions of prescription drug user fees under the Prescription Drug User Fee Act of 1992, as originally enacted and as reauthorized by the FDA Modernization Act of 1997, except for the functions under 21 U.S.C. 379h(d)(1)(C) that pertain to situations where “the fees will exceed the anticipated present and future costs,” on behalf of CDER, the Center for Biologics Evaluation and Research, and any other FDA center. This authority pertains to waivers requested under the public health waiver provision (21 U.S.C. 379h(d)(1)(A)); the barrier to innovation waiver provision (21 U.S.C. 379h(d)(1)(B)); the applications submitted under section 505(b)(1) and (b)(2) of the Federal Food, Drug, and Cosmetic Act waiver provision (21 U.S.C. 379h(d)(1)(D)); the small business waiv-

er provision (21 U.S.C. 379h(d)(1)(E)); and to requests for refunds of fees if an application or supplement is withdrawn after filing (21 U.S.C. 379h(a)(1)(G)); as well as waivers, reductions, or refunds requested on any other basis except fees exceeding the cost. These authorities may not be further redelegated. (See § 5.20(h)(1) for the authority to reconsider any user fee decisions made by the Chief Mediator and Ombudsman, the Deputy Chief Mediator and Ombudsman, and/or the former Deputy User Fee Waiver Officer prior to July 1, 1999.)

[64 FR 59618, Nov. 3, 1999]

§ 5.200 Headquarters.

The central organization of the Food and Drug Administration consists of the following:

- OFFICE OF THE COMMISSIONER.¹
- Office of the Chief Counsel.
- Office of Equal Opportunity.
- Office of the Administrative Law Judge.
- Office of the Senior Associate Commissioner.
- Office of Executive Secretariat.
- Office of Public Affairs.
- Office of the Ombudsman.
- Office of Orphan Products Development.
- Office of Internal Affairs.
- Office of Executive Operations.
- Office of International and Constituent Relations.*
- Office of International Programs.
- Office of Consumer Affairs.
- Office of Women’s Health.
- Office of Special Health Issues.
- Office of Policy, Planning, and Legislation.*
- Office of Policy.
- Office of Planning.
- Office of Legislation.
- Office of Management and Systems.*
- Office of Human Resources and Management Services.
- Office of Information Resources Management.
- Office of Financial Management.
- Office of Facilities, Acquisitions, and Central Services.²

¹Mailing address: 5600 Fishers Lane, Rockville, MD 20857.

²Mailing address: 5630 Fishers Lane, Rockville, MD 20852.

Food and Drug Administration, HHS

§ 5.200

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH.³

Office of the Center Director.
Scientific Advisors and Consultants Staff.
Equal Employment Opportunity and Workforce Diversity Staff.
Quality Assurance Staff.
Regulations and Policy Staff.
Veterinary Services Staff.
Office of Management.
Regulatory Information Management Staff.
Division of Planning, Evaluation, and Budget.
Division of Management Services.
Office of Information Technology Management.
Division of Information Technology Operations.
Division of Information Technology Development.
Division of Information Technology Infrastructure.
Office of Compliance and Biologics Quality.
Team Biologics Liaison Staff.
Advertising and Promotional Labeling Staff.
Division of Case Management.
Division of Manufacturing and Product Quality.
Division of Inspections and Surveillance.
Office of Blood Research and Review.
Human Tissue Staff.
Policy and Publications Staff.
Division of Emerging and Transfusion Transmitted Diseases.
Division of Hematology.
Division of Blood Applications.
Office of Therapeutics Research and Review.
Division of Cellular and Gene Therapies.
Division of Therapeutic Proteins.
Division of Monoclonal Antibodies.
Division of Clinical Trial Design and Analysis.
Division of Application Review and Policy.
Office of Vaccines Research and Review.
Division of Bacterial, Parasitic, and Allergenic Products.
Division of Viral Products.

³Mailing address: 1401 Rockville Pike, Rockville, MD 20852-1448.

Division of Vaccines and Related Products Applications.
Office of Communication, Training, and Manufacturers Assistance.
Division of Disclosure and Oversight Management.
Division of Manufacturers Assistance and Training.
Division of Communication and Consumer Affairs.
Office of Biostatistics and Epidemiology.
Division of Biostatistics.
Division of Epidemiology.
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION.⁴
Office of the Center Director.
Food Safety Initiatives Staff.
Senior Science Advisor's Staff.
Office of Regulations and Policy.
Regulations Coordination Staff.
Office of Constituent Operations.
Consumer Education Staff.
International Activities Staff.
Industry Activities Staff.
Office of Management Systems.
Safety Management Staff.
Division of Information Resources Management.
Division of Planning and Financial Resources Management.
Division of Management Operations.
Division of Administrative Services Management.
Office of Operations.
Equal Employment Opportunity Staff.
Executive Operations Staff.
Office of Cosmetics and Colors.
Division of Programs and Enforcement Policy.
Division of Science and Applied Technology.
Office of Nutritional Products, Labeling, and Dietary Supplements.
Clinical Research and Review Staff.
Division of Compliance and Enforcement.
Division of Standards and Labeling Regulations.
Division of Nutrition Science Policy.
Division of Research and Applied Technology.
Office of Premarket Approval.
Division of Product Policy.
Division of Petition Control.

⁴Mailing address: 200 C St. SW., Washington DC 20204.

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Division of Health Effects Evaluation.
Division of Molecular Biological Research and Evaluation.
Division of Product Manufacture and Use.
Office of Plant and Dairy Foods and Beverages.
Division of Virulence Assessment.
Division of Pesticides and Industrial Chemicals.
Division of Natural Products.
Division of Food Processing and Packaging.
Division of Plant Product Safety.
Division of Dairy and Egg Safety.
Division of Risk Assessment.
Office of Seafood.
Division of Special Programs.
Division of Programs and Enforcement Policy.
Division of Science and Applied Technology.
Office of Special Research Skills.
Division of Toxicology Research.
Division of Microbiological Studies.
Office of Field Programs.
Division of Enforcement and Programs.
Division of HACCP Programs.
Division of Cooperative Programs.
Office of Scientific Analysis and Support.
Division of General Scientific Support.
Division of Mathematics.
Division of Market Studies.
CENTER FOR DRUG EVALUATION AND RESEARCH.¹
Office of the Center Director.
Equal Employment Opportunity Staff.
Executive Operations Staff.
Regulatory Policy Staff.
*Office of Management.*¹
Strategic Planning Staff.⁵
Division of Management and Budget.⁵
Division of Management Services.⁵
*Office of Training and Communication.*¹
Division of Communications Management.
Division of the Medical Library.
Division of Training and Development.
Division of Freedom of Information.

*Office of Compliance.*⁶
Division of Manufacturing and Product Quality.
Division of Prescription Drug Compliance and Surveillance.
Division of Labeling and Non- Prescription Drug Compliance.
*Office of Information Technology.*¹
Quality Assurance Staff.
Technology Support Services Staff.
Division of Data Management and Services.
Division of Applications Development and Services.
Division of Infrastructure Management and Services.
*Office of Medical Policy.*¹
Division of Drug Marketing, Advertising, and Communication¹
Division of Scientific Investigations.⁶
*Office of Review Management.*¹
Advisors and Consultants Staff.²
*Office of Drug Evaluation I.*¹
Division of Cardio-Renal Drug Products.
Division of Neuropharmacological Drug Products.
Division of Oncology Drug Products.
*Office of Drug Evaluation II.*¹
Division of Metabolic and Endocrine Drug Products.
Division of Pulmonary and Allergy Drug Products.
Division of Anesthetic, Critical Care, and Addiction Drug Products.
*Office of Drug Evaluation III.*¹
Division of Gastrointestinal and Coagulation Drug Products.
Division of Medical Imaging and Radiopharmaceutical Drug Products.
Division of Reproductive and Urologic Drug Products.
Office of Drug Evaluation IV.
Division of Anti-Infective Drug Products.
Division of Anti-Viral Drug Products.
Division of Special Pathogen and Immunologic Drug Products. *Office of Drug Evaluation V.*
Division of Anti-Inflammatory, Analgesic, and Ophthalmologic Drug Products.
Division of Dermatologic and Dental Drug Products.
Division of Over-the-Counter Drug Products.

⁵Mailing address: 7500 Standish Pl., Rockville, MD 20855.

⁶Mailing address 7520 Standish Pl., Rockville, MD 20855.

Food and Drug Administration, HHS

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*Office of Biostatistics.*¹
Quantitative Methods Research Staff.

Division of Biometrics I.
Division of Biometrics II.
Division of Biometrics III.

Office of Post-Marketing Drug Risk Assessment.

Extramural Programs Staff.

Information Technology Staff.

Division of Drug Risk Evaluation I.
Division of Drug Risk Evaluation II.

*Office of Pharmaceutical Science.*¹

Quality Implementation Staff.¹
Operations Staff.¹

Office of Clinical Pharmacology and Biopharmaceutics.

Pharmacometrics Staff.

Division of Pharmaceutical Evaluation I.¹

Division of Pharmaceutical Evaluation II.¹

Division of Pharmaceutical Evaluation III.¹

*Office of Generic Drugs.*⁵

Division of Bioequivalence.

Division of Chemistry I.

Division of Chemistry II.

Division of Labeling and Program Support.

*Office of New Drug Chemistry.*¹

Division of New Drug Chemistry I.¹

Division of New Drug Chemistry II.¹

Division of New Drug Chemistry III.¹

*Office of Testing and Research.*¹

Regulatory Research and Analysis Staff.

Laboratory of Clinical Pharmacology.⁷

Division of Applied Pharmacology Research.⁸

Division of Testing and Applied Analytical Development.⁹

Division of Product Quality Research.¹

*Office of Regulatory Affairs.*¹

Contaminants Policy Coordination Staff.

Equal Employment Opportunity Staff.

Strategic Initiatives Staff.

Office of Resource Management.

⁷ Mailing address: Four Research Ct., Rockville, MD 20850.

⁸ Mailing address: 8308 Muirkirk Rd., Laurel, MD 20708.

⁹ Mailing address: 1114 Market St., St. Louis, MO 63101.

Division of Planning, Evaluation, and Management.

Division of Information Systems.

Division of Human Resource Development.

Division of Management Operations.

Division of Personnel Operations.

Office of Enforcement.

Medical Products Quality Assurance Staff.

Division of Compliance Management and Operations.

Division of Compliance Policy.

Office of Regional Operations.

Division of Federal-State Relations.

Division of Field Science.

Division of Emergency and Investigational Operations.

Division of Import Operations and Policy.

Office of Criminal Investigations.

Mid-Atlantic Area Office.¹⁰

Midwest Area Office.¹¹

Northeast Area Office.¹²

Pacific Area Office.¹³

Southeast Area Office.¹⁴

Southwest Area Office.¹⁵

CENTER FOR VETERINARY MEDICINE.¹⁶

Office of the Center Director.

Office of Management and Communications.

Administrative Staff.

Communications Staff.

Program Planning and Evaluation Staff.

Information Resources Management Staff.

Office of New Animal Drug Evaluation.

Division of Therapeutic Drugs for Food Animals.

Division of Biometrics and Production Drugs.

Division of Therapeutic Drugs for Non-Food Animals.

Division of Human Food Safety.

¹⁰ Mailing address: 900 U.S. Courthouse, Second Chestnut St., Philadelphia, PA 19106.

¹¹ Mailing address: 901 Warrenville Rd., suite 360, Lisle, IL 60532.

¹² Mailing address: 850 Third Ave., Brooklyn, NY 11232.

¹³ Mailing address: 13301 Clay St., Oakland, CA 94512.

¹⁴ Mailing address: 60 Eighth St. NE., Atlanta, GA 30309.

¹⁵ Mailing address: 7920 Elmbrook Rd., Dallas, TX, 75247.

¹⁶ Mailing address: 7500 Standish Pl., MPN-2, Rockville, MD 20855.

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Division of Manufacturing Technologies.
Office of Surveillance and Compliance.
Division of Surveillance.
Division of Animal Feeds.
Division of Compliance.
Division of Epidemiology.
Office of Research.
Administrative Staff.
Division of Residue Chemistry.
Division of Animal Research.
Division of Animal and Food Microbiology.
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH.¹⁷
Office of the Center Director.
Equal Employment Opportunity Staff.
Office of Systems and Management.
Integrity Committee and Conference Management Staff.
Division of Management Operations.
Division of Information Dissemination.
Division of Information Technology Management.
Division of Planning, Analysis, and Finance.
Office of Compliance.
Promotion and Advertising Policy Staff.
Division of Bioresearch Monitoring.
Division of Program Operations.
Division of Enforcement I.
Division of Enforcement II.
Division of Enforcement III.
Office of Device Evaluation.
Program Management Staff.
Program Operations Staff.
Division of Cardiovascular, Respiratory, and Neurological Devices.
Division of Reproductive, Abdominal, Ear, Nose, Throat, and Radiological Devices.
Division of General and Restorative Devices.
Division of Clinical Laboratory Devices.
Division of Ophthalmic Devices.
Division of Dental, Infection Control, and General Hospital Devices.
Office of Science and Technology.
Division of Mechanics and Materials Science.
Division of Life Sciences.
Division of Physical Sciences.

Division of Electronics and Computer Sciences.
Division of Management Information and Support Services.
Office of Health and Industry Programs.
Program Operations Staff.
Regulations Staff.
Staff College.
Division of Device User Programs and Systems Analysis.
Division of Small Manufacturers Assistance.
Division of Mammography Quality and Radiation Programs.
Division of Communication Media.
Office of Surveillance and Biometrics.
Issues Management Staff.
Division of Biostatistics.
Division of Postmarket Surveillance.
Division of Surveillance Systems.
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH.¹⁸
Office of the Center Director.
Environmental Health and Program Assurance Staff.
Office of Research.
Technology Advancement Staff.
Division of Biochemical Toxicology.
Division of Genetic and Reproductive Toxicology.
Division of Biometry and Risk Assessment.
Division of Microbiology.
Division of Chemistry.
Division of Neurotoxicology.
Division of Veterinary Services.
Division of Molecular Epidemiology.
Office of Management.
Office of Management Services.
Contracts and Procurement Staff.
Division of Facilities, Engineering, and Maintenance.
Division of Administrative Services.
Office of Planning, Finance and Information Technology.
Division of Planning.
Division of Financial Management.
Division of Information Technology.

[65 FR 19830, Apr. 13, 2000]

§ 5.205 Chief Counsel, Food and Drug Administration.

The Chief Counsel to the Commissioner of Food and Drugs is the Associate General Counsel, Food and Drug

¹⁷Mailing address: 9200 Corporate Blvd., Rockville, MD 20850.

¹⁸Mailing address: 3900 NCTR Dr., Jefferson, AR 72079.