

(CBER) are authorized to issue the following notices under section 306 of the Federal Food, Drug, and Cosmetic Act (the act) which relate to the assigned functions of their organizations:

(a) Notices of opportunity for hearing on proposals for mandatory or permissive debarment.

(b) Notices ordering debarment when opportunity for a hearing has been waived.

(c) Notices ordering debarment where the person notifies the agency that the person acquiesces to debarment under section 306(c)(2)(B) of the act.

(d) Notices of opportunity for hearing on proposals denying an application to terminate debarment under section 306(d)(3) of the act.

(e) Orders denying an application to terminate debarment under section 306(d)(3) of the act when opportunity for a hearing has been waived.

[61 FR 8215, Mar. 4, 1996; 61 FR 11545, Mar. 21, 1996; 61 FR 14375, Apr. 1, 1996]

### 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]

#### § 5.200 Headquarters.

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

OFFICE OF THE COMMISSIONER.<sup>1</sup>

OFFICE OF THE ADMINISTRATIVE LAW JUDGE.

OFFICE OF EXECUTIVE SECRETARIAT.

OFFICE OF EQUAL EMPLOYMENT AND CIVIL RIGHTS.

OFFICE OF THE CHIEF COUNSEL.

OFFICE OF INTERNAL AFFAIRS.

OFFICE OF EXTERNAL AFFAIRS.

Industry and Small Business Liaison Staff.

Office of Special Health Issues.

Office of Consumer Affairs.

Office of Health Affairs.

Office of Legislative Affairs.

Office of Public Affairs.

Office of Women's Health.

Office of International Affairs.

OFFICE OF MANAGEMENT AND SYSTEMS.

Office of Planning and Evaluation.

Office of Human Resources and Management Services.

Office of Facilities, Acquisitions, and Central Services.

Office of Information Resources Management.

Office of Financial Management.

OFFICE OF POLICY.

Regulations Policy and Management Staff.

Policy Development and Coordination Staff.

Policy Research Staff.

International Policy Staff.

OFFICE OF OPERATIONS.

OFFICE OF SCIENCE.

OFFICE OF ORPHAN PRODUCTS DEVELOPMENT.

NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH.<sup>2</sup>

*Office of the Center Director*

Environmental Health and Program Assurance Staff.

Equal Employment Opportunity Staff.

Scientific Coordination Staff.

Technology Advancement Staff.

*Office of Planning and Resource Management*

Planning Staff.

<sup>1</sup>Mailing address: 5600 Fishers Lane, Rockville, MD 20857.

<sup>2</sup>Mailing address: Jefferson, AR 72079-9502.

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Financial Management Staff.  
Evaluation Staff.

*Office of Research*

Research Coordination Staff.  
Biomarkers Laboratory Staff.  
Division of Reproductive and Developmental Toxicology.  
Division of Genetic Toxicology.  
Division of Biochemical Toxicology.  
Division of Nutritional Toxicology.  
Division of Biometry and Risk Assessment.  
Division of Chemistry.  
Division of Microbiology.  
Division of Neurotoxicology.

*Office of Research Support*

Veterinary Services Staff.  
Information Technology Staff.  
Division of Administrative Services.  
Division of Facilities Engineering and Maintenance.

OFFICE OF REGULATORY AFFAIRS.<sup>3</sup>

*Office of the Associate Commissioner*

Contaminants Policy Coordination Staff.  
Equal Employment Opportunity Staff.  
Strategic Initiatives Staff.

*Office of Resource Management*

Division of Planning, Evaluation, and Management.  
Division of Information Systems.  
Division of Human Resource Development.  
Division of Management 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<sup>4</sup>*

Northeast Regional Office.<sup>5</sup>  
Mid-Atlantic Regional Office.<sup>6</sup>

<sup>3</sup>Mailing address: 5600 Fishers Lane, Rockville, MD 20857.

<sup>4</sup>Mailing address: 7500 Standish Pl., rm. 250N, Rockville, MD 20855.

<sup>5</sup>Mailing address: 850 Third Ave., Brooklyn, NY 11232.

<sup>6</sup>Mailing address: 900 U. S. Customhouse, Second and Chestnut Sts., rm. 900, Philadelphia, PA 19106.

Southeast Regional Office.<sup>7</sup>  
Midwest Regional Office.<sup>8</sup>  
Southwest Regional Office.<sup>9</sup>  
Pacific Area Office.<sup>10</sup>

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH.<sup>11</sup>

*Office of the Center Director*

Equal Employment Opportunity Staff.  
Scientific Advisors and Consultants Staff.  
Quality Assurance Staff.  
Congressional and Public Affairs Staff.

*Office of Communication, Training and Manufacturers Assistance*

Division of Congressional and Public Affairs.  
Division of Manufacturers Assistance and Training.

*Office of Management*

Division of Management Services.  
Division of Applied Information Technology.  
Division of Planning, Evaluation, and Budget.

*Office of Compliance*

Division of Case Management.  
Division of Regulations and Policy.  
Division of Inspections and Surveillance.

*Office of Therapeutics Research and Review*

Division of Cytokine Biology.  
Division of Cellular and Gene Therapies.  
Division of Hematologic Products.  
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 Allergenic Products and Parasitology.  
Division of Bacterial Products.  
Division of Viral Products.  
Division of Vaccines and Related Products Applications.

*Office of Establishment Licensing and Product Surveillance*

Division of Product Quality Control.  
Division of Veterinary Services.  
Division of Biostatistics and Epidemiology.  
Division of Establishment Licensing.

<sup>7</sup>Mailing address: 60 Eighth St. NE., Atlanta, GA 30309.

<sup>8</sup>Mailing address: 20 North Michigan Ave., Chicago, IL 60606.

<sup>9</sup>Mailing address: 7920 Elmbrook Dr., Dallas, TX 75247.

<sup>10</sup>Mailing address: 13301 Clay St., Oakland, CA 94512.

<sup>11</sup>Mailing address: 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448.

**Food and Drug Administration, HHS**

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Division of Congressional Public Affairs.

*Office of Blood Research and Review*

Division of Blood Applications.

Division of Transfusion Transmitted Diseases.

Division of Hematology.

Division of Blood Establishment & Products.

CENTER FOR DRUG EVALUATION AND RESEARCH.<sup>12</sup>

*Office of the Center Director*

Advisors and Consultants Staff.

Pilot Drug Evaluation Staff.

Executive Operations Staff.

Equal Employment Opportunity Staff.

Regulatory Policy Staff.

*Office of Management*

Administrative Staff.

Division of Planning, Evaluation, and Resource Management.

Division of Management Services.

Division of Information Systems Design.

Division of Database Management.

*Office of Training and Communications*

Freedom of Information Staff.

Division of Training and Development.

Division of Communications Management.

Division of the Medical Library.

*Office of Compliance*

Division of Labeling and Nonprescription Drug Compliance.

Division of Prescription Drug Compliance and Surveillance.

Division of Manufacturing and Product Quality.

Division of Scientific Investigations.

*Office of Pharmaceutical Science*

*Office of the Director*

Product Quality Support Staff.

Operations Staff.

*Office of New Drug Chemistry*

Division of New Drug Chemistry I.

Division of New Drug Chemistry II.

Division of New Drug Chemistry III.

*Office of Generic Drugs<sup>13</sup>*

Division of Chemistry I.

Division of Chemistry II.

Division of Bioequivalence.

Division of Labeling and Program Support.

*Office of Clinical Pharmacology and Biopharmaceutics*

Division of Pharmaceutical Evaluation I.

Division of Pharmaceutical Evaluation II.

Division of Pharmaceutical Evaluation III.

*Office of Testing and Research*

Laboratory of Clinical Pharmacology.

Regulatory Research and Analysis Staff.

Division of Product Quality Research.

Division of Applied Pharmacology Research.

Division of Testing and Applied Analytical Development.

*Office of Review Management*

*Office of the Director*

Advisors and Consultants Staff.

*Office of Drug Evaluation I*

Division of Neuropharmacological Drug Products.

Division of Oncology Drug Products.

Division of Cardio-Renal Drug Products.

Division of Drug Marketing, Advertising and Communication.

*Office of Drug Evaluation II*

Division of Metabolic and Endocrine Drug Products.

Division of Pulmonary Drug Products.

*Office of Drug Evaluation III*

Division of Gastrointestinal and Coagulation Drug Products.

Division of Anesthetic, Critical Care, and Addiction Drug Products.

Division of Medical Imaging and Radiopharmaceutical Drug Products.

*Office of Drug Evaluation IV*

Division of Anti-Infective Drug Products.

Division of Anti-Viral 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.

*Office of Epidemiology and Biostatistics*

Quantitative Methods and Research Staff.

Division of Pharmacovigilance and Epidemiology.

Division of Biometrics I.

Division of Biometrics II.

Division of Biometrics III.

Division of Biometrics IV.

<sup>12</sup> Mailing address: 1451 Rockville Pike, rm. 6027, Rockville, MD 20850.

<sup>13</sup> Mailing address: 7500 Standish Pl., rm. 286, Rockville, MD 20855.

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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH.<sup>14</sup>

*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 Health and Industry Programs<sup>15</sup>*

Division of Device User Programs and Systems Analysis.

Division of Small Manufacturers Assistance.

Division of Mammography Quality and Radiation Programs.

Division of Communication Media.

Program Operations Staff.

*Office of Compliance<sup>16</sup>*

Promotion and Advertising Policy Staff.

Division of Program Operations.

Division of Bioresearch Monitoring.

Division of Enforcement I.

Division of Enforcement II.

Division of Enforcement III.

*Office of Device Evaluation<sup>17</sup>*

Program Operations Staff.

Program Management Staff.

Division of Cardiovascular, Respiratory, and Neurological Devices.

Division of Reproductive, Abdominal, Ear, Nose, and Throat, and Radiological Devices.

Division of General and Restorative Devices.

Division of Clinical Laboratory Devices.<sup>18</sup>

Division of Ophthalmic Devices.

Division of Dental, Infection Control, and General Hospital Devices.

*Office of Science and Technology<sup>19</sup>*

Division of Mechanics and Materials Science.

Division of Life Sciences.

Division of Physical Sciences.

Division of Electronics and Computer Sciences.

<sup>14</sup>Mailing address: 9200 Corporate Blvd., Rockville, MD 20850.

<sup>15</sup>Mailing address: 1350 Piccard Dr., Rockville, MD 20850.

<sup>16</sup>Mailing address: 2098 Gaither Rd., Oak Grove Corporate Park, Rockville, MD 20850.

<sup>17</sup>Mailing address: 9200 Corporate Blvd., Rockville, MD 20850.

<sup>18</sup>Mailing address: 2098 Gaither Rd., Rockville, MD 20850.

<sup>19</sup>Mailing address: 12720 Twinbrook Pkwy., Bldg. 1, Rockville, MD 20857.

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Division of Management, Information, and Support Services.

*Office of Surveillance and Biometrics<sup>20</sup>*

Division of Biostatistics.

Division of Postmarket Surveillance.

Division of Surveillance Systems.

*Office of Health and Industry Programs*

Division of Device User Programs and Systems Analysis.

Division of Small Manufacturers Assistance.

Division of Mammography Quality and Radiation Programs.

Division of Communication Media.

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION.<sup>21</sup>

*Office of the Center Director*

Equal Employment Opportunity Staff.

*Office of Beltsville Technical Operations*

*Office of Policy, Planning and Strategic Initiatives*

Executive Operations Staff.

*Office of Programs*

Beltsville Technical Operations Staff.

*Office of Cosmetics and Colors*

Division of Programs and Enforcement Policy.

Division of Science and Applied Technology.

*Office of Food Labeling*

Division of Programs and Enforcement Policy.

Division of Technical Evaluation.

Division of Science and Applied Technology.

*Office of Premarket Approval*

Division of Product Policy.

Division of Petition Control.

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 Programs and Enforcement Policy.

Division of Virulence Assessment.

Division of Pesticides and Industrial Chemicals.

Division of Natural Products.

Division of Food Processing and Packaging.

<sup>20</sup>Mailing address: 1350 Piccard Dr., Rockville, MD 20850.

<sup>21</sup>Mailing address: 200 C St. SW., Washington, DC 20204.

## Food and Drug Administration, HHS

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### *Office of Seafood*

Division of Special Programs.  
Division of Programs and Enforcement Policy.  
Division of Science and Applied Technology.

### *Office of Special Nutritionals*

Clinical Research and Review Staff.  
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 Systems and Support*

Quality Assurance Staff.

### *Office of Constituent Operations*

Consumer Education Staff.  
Legislative Activities Staff.  
Industry Activities Staff.  
International Activities Staff.

### *Office of Field Programs*

Division of Enforcement.  
Division of HACCP Programs.  
Division of Cooperative Programs.  
Division of Field Program Planning and Evaluation.

### *Office of Management Systems*

Safety Management Staff.  
Division of Information Resources Management.  
Division of Planning and Resources Management.

### *Office of Scientific Analysis and Support*

Division of Mathematics.  
Division of General Scientific Support.  
Division of Market Studies.

CENTER FOR VETERINARY MEDICINE.<sup>22</sup>

### *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 Surveillance and Compliance*

Division of Compliance.  
Division of Animal Feeds.  
Division of Epidemiology and Surveillance.

<sup>22</sup>Mailing address: 7500 Standish Pl., MPN-2, Rockville MD 20855.

### *Office of New Animal Drug Evaluation*

Division of Biometrics and Production Drugs.  
Division of Manufacturing Technologies.  
Division of Therapeutic Drugs for Food Animals.  
Division of Therapeutic Drugs for Non-Food Animals.  
Division of Human Food Safety.

### *Office of Research*

Administrative Staff.  
Division of Residue Chemistry.  
Division of Animal Research.  
[62 FR 13822, Mar. 24, 1997]

## **§ 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 Division, Office of the General Counsel, Department of Health and Human Services, Room 6-57, 5600 Fishers Lane, Rockville, MD 20857.

[46 FR 8455, Jan. 27, 1981, as amended at 56 FR 8709, Mar. 1, 1991. Redesignated at 62 FR 13824, Mar. 24, 1997]

## **§ 5.210 FDA Public Information Offices.**

(a) *Dockets Management Branch (HFA-305)*. The Dockets Management Branch Public Room is located in rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857. Telephone: 301-443-1753.

(b) *Freedom of Information Staff (HFI-35)*. The Freedom of Information Public Room is located in rm. 12A-30, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD 20857. Telephone: 301-443-6310.

(c) *Press Relations Staff (HFI-40)*. The Press Offices are located in rm. 15-05, Parklawn Bldg., 5600 Fisher Lane, Rockville, MD 20857. Telephone: 301-443-3285; and in rm. 3807, FB-8, 200 C St. SW., Washington, DC 20204. Telephone 202-205-4144.

[62 FR 13824, Mar. 24, 1997]

## **§ 5.215 Field structure.**

### NORTHEAST REGION

*Regional Field Office*: 850 Third Ave., Brooklyn, NY 11232.

*Northeast Regional Laboratory*: 850 Third Ave., Brooklyn, NY 11232-1593.

*New York District Office*: 850 Third Ave., Brooklyn, NY 11232-1593.