

through the Electronic Data Gathering, Analysis, and Retrieval ("EDGAR") system.¹ Compliance with the provisions of the Filer Manual is required in order to assure the timely acceptance and processing of filings made in electronic format. Filers should consult the Filer Manual in conjunction with the Commission's rules governing mandated electronic filing when preparing documents for electronic submission.²

In this update, several submission types have been added to accommodate electronic submission of certain investment company filings. Specifically, new EDGAR submission types "40-17F1" and "40-17F2" have been added to accommodate the filing of Forms N-17F-1³ and N-17F-2;⁴ submission type "N-23C-2," to accommodate filings under Rule 23c-2(b);⁵ and submission types "N-23C3A," "N-23C3B," and "N-23C3C," to accommodate the filing of Form N-23C-3,⁶ pursuant to Rule 23c-3.⁷

With respect to documents subject to review by the Division of Corporation Finance, two additional submission types have been added to accommodate more completely the electronic submission of filings made pursuant to

¹ The Filer Manual originally was adopted on April 1, 1993, and became effective on April 26, 1993. Release No. 33-6986 (April 1, 1993) [58 FR 18638]. The most recent update to the Filer Manual was adopted in Release No. 33-7394 (February 21, 1997) [61 FR 8877], and became effective on March 10, 1997.

² See Release Nos. 33-6977 (February 23, 1993) [58 FR 14628], IC-19284 (February 23, 1993) [58 FR 14848], 35-25746 (February 23, 1993) [58 FR 14999], and 33-6980 (February 23, 1993) [58 FR 15009] for a comprehensive treatment of the rules adopted by the Commission governing mandated electronic filing. See also Release No. 33-7122 (December 19, 1994) [59 FR 67752], in which the Commission made the EDGAR rules final and applicable to all domestic registrants and adopted minor amendments to the EDGAR rules; Release No. 33-7394, in which the Commission adopted the most recent update to the Filer Manual; and Release No. 33-7369 (December 5, 1996) [61 FR 65440], in which the Commission proposed additional minor technical amendments to the EDGAR rules.

³ 17 CFR 274.21 (certificate of accounting of securities and similar investments in the custody of management investment companies filed pursuant to Rule 17f-1).

⁴ 17 CFR 274.220 (certificate of accounting of securities and similar investments in the custody of management investment companies filed pursuant to Rule 7f-2).

⁵ 17 CFR 240.23c-2(b) (notice by closed-end investment companies of intention to call or redeem their own securities).

⁶ 17 CFR 274.221 (notification of periodic repurchase offer).

⁷ 17 CFR 240.23c-3. Submission type "N-23C3A" is to be used for filings made pursuant to Rule 23c-3(a) only; "N-23C3B," Rule 23c-3(b) only; and "N-23C3C," Rule 23c-3(a) and (b).

Rule 462(b)⁸ under the Securities Act of 1933.⁹

Rule 301 of Regulation S-T was amended to provide for the incorporation by reference of the Filer Manual into the Code of Federal Regulations, which incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. The effective date of the amendment to Rule 301 will remain March 10, 1997. A minor correction is being made to conform to the Office of Federal Register's requirements for incorporation by reference.

Technical issues surfaced on the afternoon of March 7, 1997 that prevented system implementation on March 10, 1997. The Commission, therefore, is postponing the implementation of the Manual from March 10, 1997 to March 24, 1997.

Need for Correction

As published, the final regulations contain an error which may prove to be misleading and is in need of clarification.

Correction of Publication

Accordingly, the publication on February 27, 1997 of the final regulations, which were the subject of FR Doc. 97-4797, is corrected as follows:

§ 232.301 [Corrected]

On page 8876, second column, in § 232.301, last line, add a sentence to the end of the section to read as follows:

* * * Copies may be inspected at the Office of the Federal Register, Suite 700, 800 North Capitol Street, N.W., Washington, D.C.

Dated: March 19, 1997.

By the Commission.

Jonathan G. Katz,

Secretary.

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⁸ 17 CFR 230.462(b).

⁹ 15 U.S.C. 77a *et seq.* The new submission types are: S-4MEF (for use in connection with registration statements filed on Form S-4 [17 CFR 239.25]) and F-4MEF (for use in connection with registration statements on Form F-4 [17 CFR 239.34]). All other submission types used for Rule 462(b) filings were added to the EDGAR system in November 1995. See Release No. 33-7241 (November 13, 1995) [60 FR 57682].

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 5

Delegations of Authority and Organization

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations for delegations of authority to set forth the current organizational structure of the agency as well as the current addresses for headquarters and field offices. The agency is also redesignating certain sections of the regulations to allow for expansion in the delegation of authority section. This action is necessary to ensure the continued accuracy of the regulations.

EFFECTIVE DATE: March 24, 1997.

FOR FURTHER INFORMATION CONTACT:

L'Tonya J. Barnes, Division of Management Systems and Policy (HFA-340), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4807.

SUPPLEMENTARY INFORMATION:

The regulations are being amended in subpart C of part 5 (21 CFR part 5) to reflect the central organization of the agency and to provide current addresses for headquarters and field offices. The regulations are also being amended by redesignating §§ 5.100, 5.105, 5.110, and 5.115 as §§ 5.200, 5.205, 5.210, and 5.215, respectively, to permit the expansion of subpart B to allow for added delegations.

Notice and comment on these amendments are not necessary under the Administrative Procedure Act because this is a rule of agency organization (5 U.S.C. 553(b)).

List of Subjects in 21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 5 is amended as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. The authority citation for 21 CFR part 5 continues to read as follows:

Authority: 5 U.S.C. 504, 552, App. 2; 7 U.S.C. 138a, 2271; 15 U.S.C. 638, 1261-1282, 3701-3711a; secs. 2-12 of the Fair Packaging

and Labeling Act (15 U.S.C. 1451–1461); 21 U.S.C. 41–50, 61–63, 141–149, 467f, 679(b), 801–886, 1031–1309; secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–394); 35 U.S.C. 156; secs. 301, 302, 303, 307, 310, 311, 351, 352, 361, 362, 1701–1706, 2101 of the Public Health Service Act (42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 264, 265, 300u–300u–5, 300aa–1); 42 U.S.C. 1395y, 3246b, 4332, 4831(a), 10007–10008; E.O. 11490, 11921, and 12591.

§ 5.100 [Redesignated as § 5.200]

2. Section 5.100 is redesignated as § 5.200 and revised to read as follows:

§ 5.200 Headquarters.

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

Office of the Commissioner.¹

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.²

Office of the Center Director

Environmental Health and Program

Assurance Staff.

Equal Employment Opportunity Staff.

Scientific Coordination Staff.

Technology Advancement Staff.

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

² Mailing address: Jefferson, AR 72079–9502.

Office of Planning and Resource Management

Planning Staff.

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.³

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*⁴

Northeast Regional Office.⁵

Mid-Atlantic Regional Office.⁶

Southeast Regional Office.⁷

Midwest Regional Office.⁸

Southwest Regional Office.⁹

³ Mailing address: 5600 Fishers Lane, Rockville, MD 20857.

⁴ Mailing address: 7500 Standish Pl., rm. 250N, Rockville, MD 20855.

⁵ Mailing address: 850 Third Ave., Brooklyn, NY 11232.

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

⁷ Mailing address: 60 Eighth St. NE., Atlanta, GA 30309.

⁸ Mailing address: 20 North Michigan Ave., Chicago, IL 60606.

⁹ Mailing address: 7920 Elmbrook Dr., Dallas, TX 75247.

Pacific Area Office.¹⁰

Center for Biologics Evaluation and Research.¹¹

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.

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.¹²

Office of the Center Director

Advisors and Consultants Staff.

Pilot Drug Evaluation Staff.

Executive Operations Staff.

¹⁰ Mailing address: 13301 Clay St., Oakland, CA

94512.

¹¹ Mailing address: 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448.

¹² Mailing address: 1451 Rockville Pike, rm. 6027, Rockville, MD 20850.

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*¹³
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.
Center for Devices and Radiological Health.¹⁴
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*¹⁵
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*¹⁶
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*¹⁷
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.¹⁸
Division of Ophthalmic Devices.
Division of Dental, Infection Control, and General Hospital Devices.
*Office of Science and Technology*¹⁹
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 Surveillance and Biometrics*²⁰
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.²¹
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.

¹⁴ Mailing address: 9200 Corporate Blvd., Rockville, MD 20850.

¹⁵ Mailing address: 1350 Piccard Dr., Rockville, MD 20850.

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

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

¹⁸ Mailing address: 2098 Gaither Rd., Rockville, MD 20850.

¹⁹ Mailing address: 12720 Twinbrook Pkwy., Bldg. 1, Rockville, MD 20857.

²⁰ Mailing address: 1350 Piccard Dr., Rockville, MD 20850.

²¹ Mailing address: 200 C St. SW., Washington, DC 20204.

¹³ Mailing address: 7500 Standish Pl., rm. 286, Rockville, MD 20855.

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.

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.²²

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.

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.

§ 5.105 [Redesignated as § 5.205]

3. Section 5.105 is redesignated as § 5.205.

4. Section 5.110 is redesignated as § 5.210 and revised to read as follows:

§ 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.

5. Section 5.115 is redesignated as § 5.215 and revised to read as follows:

§ 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.
New England District Office: One Montvale Ave., Stoneham, MA 02180.
Buffalo District Office: 599 Delaware Ave., Buffalo, NY 14202.

MID-ATLANTIC REGION

Regional Field Office: 900 U.S. Customhouse, Second and Chestnut Sts., rm. 900, Philadelphia, PA 19106.
Philadelphia District Office: 900 U.S. Customhouse, Second and Chestnut Sts., rm. 900, Philadelphia, PA 19106.
Baltimore District Office: 900 Madison Ave., Baltimore, MD 21201-2199.
Cincinnati District Office: 1141 Central Pkwy., Cincinnati, OH 45202-1097.

New Jersey District Office: Waterview Corporate Center, 10 Waterview Blvd., 3d Floor, Parsippany, NJ 07054.

SOUTHEAST REGION

Regional Field Office: 60 Eighth St. NE., Atlanta, GA 30309.

Southeast Regional Laboratory: 60 Eighth St. NE., Atlanta, GA 30309.

Atlanta District Office: 60 Eighth St. NE., Atlanta, GA 30309.

Nashville District Office: 297 Plus Park Blvd., Nashville, TN 37217.

New Orleans District Office: 4298 Elysian Fields Ave., New Orleans, LA 70122.

Florida District Office: 7200 Lake Ellenor Dr., suite 120, Orlando, FL 32809.

San Juan District Office: 466 Fernandez Juncos Ave., San Juan, PR 00901-3223.

MIDWEST REGION

Regional Field Office: 20 North Michigan Ave., rm. 510, Chicago, IL 60602.

Chicago District Office: 300 South Riverside Plaza, suite 550, South Chicago, IL 60606.

Detroit District Office: 1560 East Jefferson Ave., Detroit, MI 48207-3179.

Minneapolis District Office: 240 Hennepin Ave., Minneapolis, MN 55401-1912.

SOUTHWEST REGION

Regional Field Office: 7920 Elmbrook Dr., Dallas, TX 75247-4982.

Dallas District Office: 3310 Live Oak St., Dallas, TX 75204.

Denver District Office: Bldg. 20, Denver Federal Center, Sixth and Kipling Sts., P.O. Box 25087, Denver, CO 80225-0087.

Kansas City District Office: 11630 West 80th St., Lenexa, KS 66214.

St. Louis Branch: 12 Sunnen Dr., St. Louis, MO 63143.

PACIFIC REGION

Regional Field Office: 1301 Clay St., suite 1180-N, Oakland, CA 94612-5217.
San Francisco District Office: 1431 Harbor Bay Parkway, Alameda, CA 94502-7070.

Los Angeles District Office: 19900 MacArthur Blvd., suite 300, Irvine, CA 92715-2445.

Seattle District Office: 22201 23d Dr. SE., Bothell, WA 98021-4421.

Dated: March 17, 1997.

William K. Hubbard,
Associate Commissioner for Policy Coordination.

[FR Doc. 97-7278 Filed 3-21-97; 8:45 am]

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²² Mailing address: 7500 Standish Pl., MPN-2, Rockville MD 20855.