

**List of Subjects in 16 CFR Part 1000**

Organization and functions (government agencies).

Accordingly, 16 CFR part 1000 is amended as follows:

**PART 1000—[AMENDED]**

1. The authority citation for part 1000 continues to read as follows:

**Authority:** 5 U.S.C. 552(a).

2. Section 1000.12 is revised to read as follows:

**§ 1000.12 Organizational structure.**

The Consumer Product Safety Commission is composed of the principal units listed in this section.

(a) The following units report directly to the Chairman of the Commission:

- (1) Office of the General Counsel;
- (2) Office of Congressional Relations;
- (3) Office of the Secretary;
- (4) Office of the Inspector General;
- (5) Office of Equal Employment

Opportunity and Minority Enterprise;

- (6) Office of the Executive Director.

(b) The following units report directly to the Executive Director of the Commission:

- (1) Office of the Budget;
- (2) Office of Hazard Identification and Reduction;

(3) Office of Information and Public Affairs;

- (4) Office of Compliance;
- (5) Office of Planning and Evaluation;
- (6) Office of Human Resources

Management;

- (7) Office of Information Services;
- (8) Directorate for Administration;
- (9) Directorate for Field Operations.

(c) The following units report directly to the Assistant Executive Director for Hazard Identification and Reduction:

- (1) Directorate for Epidemiology;
- (2) Directorate for Economic Analysis;
- (3) Directorate for Health Sciences;
- (4) Directorate for Engineering

Sciences;

- (5) Directorate for Laboratory

Sciences.

3. The heading of section 1000.24 is revised to read as follows:

**§ 1000.24 Office of Compliance.**

\* \* \* \* \*

4. Section 1000.26 is revised to read as follows:

**§ 1000.26 Office of Information Services.**

The Office of Information Services, which is managed by the Assistant Executive Director for Information Services, is responsible for general policy, controlling and conducting managerial activities and operations relating to the collection, use, and dissemination of information by the

agency. The Office manages the Commission's information system that supports all its program activities. The Office provides automated data processing and operational support for data collection, information retrieval, report generation, electronic mail, and statistical and mathematical operations of the agency. The Office maintains the agency's local area networks and develops and supports other network applications. The Office develops plans for improving agency operations through the use of information technology. The Office's functional responsibilities include planning, organizing, and directing information resources management (including records management and related requirements), and the managing of the agency's management directives system. The Office manages the Commission's telecommunications services including the agency's toll-free Hotline by which the public reports hazardous consumer products and receives information about product recalls and product hazards. It also oversees operation of the Commission's Internet and fax-on-demand services.

5. Section 1000.32 is revised to read as follows:

**§ 1000.32 Directorate for Administration.**

The Directorate for Administration, which is managed by the Associate Executive Director for Administration, is responsible for formulating general administrative policies supporting the Commission in the areas of financial management, procurement, and general administrative support services including property and space management, physical security, printing, and warehousing. The Directorate is responsible for the payment, accounting, and reporting of all expenditures within the Commission and for operating and maintaining the Commission's accounting system and subsidiary Management Information System which allocates staff work time and costs to programs and projects.

**§§ 1000.7, 1000.19 and 1000.24 [Amended]**

6. Part 1000 is further amended by removing the term "Compliance and Enforcement" each time it appears and inserting the term "Compliance" in its place, in the following locations:

- a. Section 1000.7(b) (two times).
- b. Section 1000.19.
- c. Section 1000.24 (two times).

Dated: May 15, 1995.

**Sadye E. Dunn,**

*Secretary, Consumer Product Safety Commission.*

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**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 covering the certification of true documents and use of the Department seal in order to update this authority to reflect recent changes to organizational structures within FDA.

**EFFECTIVE DATE:** May 19, 1995.

**FOR FURTHER INFORMATION CONTACT:**

L'Tonya Barnes, Division of Management Systems and Policy (HFA-340), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4976.

**SUPPLEMENTARY INFORMATION:** FDA is amending the regulations in § 5.22 *Certification of true copies and use of Department seal* (21 CFR 5.22) in order to update this authority to reflect recent changes to organizational structures within FDA. Revisions and deletions have been made to reflect current titles. Also, the following additions have been made to bring the list of officials up-to-date: the Deputy Commissioners; the Director, Division of Management Operations, and Chief, Administrative Management Branch, Office of Resource Management, Office of Regulatory Affairs (ORA); the Director, FDA History Staff, ORA; the Director, Office of Policy, Planning, and Strategic Initiatives, Center for Food Safety and Applied Nutrition (CFSAN); the Director, Office of Management Systems, CFSAN; the Director, Office of Cosmetics and Colors, CFSAN; the Director, Office of Plant and Dairy Foods and Beverages, CFSAN; the Director, Office of Seafood, CFSAN; the Director, Office of Special Nutritionals, CFSAN; the Director, Office of Special Research Skills, CFSAN; the Director, Office of Constituent Operations, CFSAN; the Director, Office of Field Programs, CFSAN; the Director, Office of Premarket Approval, CFSAN; the Director, Office of Scientific Analysis and Support, CFSAN; and the Director, National Forensic Chemistry Center.

Further redelegation of the authority delegated is not authorized at this time. Authority delegated to a position by title may be exercised by a person officially

designated to serve in such position in an acting capacity or on a temporary basis.

#### 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, 354, 361, 362, 1701–1706; 2101, 2125, 2127, 2128 of the Public Health Service Act (42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 263b, 264, 265, 300u–300u–5, 300aa–1, 300aa–25, 300aa–27, 300aa–28); 42 U.S.C. 1395y, 3246b, 4332, 4831(a), 10007–10008; E.O. 11490, 11921, and 12591; secs. 312, 313, 314 of the National Childhood Vaccine Injury Act of 1986, Pub. L. 99–660 (42 U.S.C. 300aa–1 note).

2. Section 5.22 is amended by revising paragraphs (a)(1) through (a)(13) and by adding new paragraph (a)(14), by revising paragraphs (b)(1) and (b)(2), and by adding new paragraph (b)(3) to read as follows:

#### § 5.22 Certification of true copies and use of Department seal.

- (a) \* \* \*
- (1) The Deputy Commissioners.
  - (2) The Associate and Deputy Associate Commissioners.
  - (3)(i) The Director, Office of Executive Operations.
  - (ii) The Director, Executive Secretariat.
  - (iii) The Director, Program Management Staff.
  - (4) The Executive Assistant to the Commissioner, Office of the Commissioner.
  - (5)(i) The Director and Deputy Director, Office of Enforcement, Office of Regulatory Affairs (ORA).
  - (ii) The Director and Deputy Director, Office of Regional Operations, ORA.
  - (iii) The Director and Deputy Director, Office of Resource Management, ORA.
  - (iv) The Director, Division of Management Operations, and Chief, Administrative Management Branch, Office of Resource Management, ORA.

(v) The Director, FDA History Staff, ORA.

(6)(i) The Director, Division of Management Systems and Policy, Office of Management (OM).

(ii) The Chief, Dockets Management Branch, Division of Management Systems and Policy, OM.

(7) The Director, Freedom of Information Staff, Office of Public Affairs.

(8)(i) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER).

(ii) The Director, Office of Management, CBER.

(iii) The Directors and Deputy Directors of the Office of Compliance, CBER.

(iv) The Director of Congressional and Public Affairs Staff, Office of the Center Director, CBER.

(v) The Chief, Surveillance and Policy Branch and Consumer Safety Officers, Office of Compliance, CBER.

(9)(i) The Director and Deputy Directors, Center for Food Safety and Applied Nutrition (CFSAN).

(ii) The Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(iii) The Director, Office of Management Systems, CFSAN.

(iv) The Director, Office of Cosmetics and Colors, CFSAN.

(v) The Director, Office of Plant and Dairy Foods Beverages, CFSAN.

(vi) The Director, Office of Seafood, CFSAN.

(vii) The Director, Office of Special Nutritional, CFSAN.

(viii) The Director, Office of Special Research Skills, CFSAN.

(ix) The Director, Office of Constituent Operations, CFSAN.

(x) The Director, Office of Field Programs, CFSAN.

(xi) The Director, Office of Premarket Approval, CFSAN.

(xii) The Director, Office of Scientific Analysis and Support, CFSAN.

(10)(i) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH).

(ii) The Director, Office of Management Services, CDRH.

(iii) The Director and Deputy Director, Office of Compliance, CDRH.

(iv) The Director and Deputy Director, Division of Compliance Programs, CDRH.

(v) The Director and Deputy Director, Office of Standards and Regulations, CDRH.

(11)(i) The Director and Deputy Directors, Center for Veterinary Medicine (CVM).

(ii) The Director and Deputy Director, Office of Management, CVM.

(iii) The Director and Deputy Director, Office of Surveillance and Compliance, CVM.

(iv) The Director, Division of Compliance, Office of Surveillance and Compliance, CVM.

(v) The Chief, Case Guidance Branch, Division of Compliance, Office of Surveillance and Compliance, CVM.

(12)(i) The Director and Deputy Director, National Center for Toxicological Research (NCTR).

(ii) The Director, Office of Research Support, NCTR.

(13)(i) The Director and Deputy Director, Center for Drug Evaluation and Research (CDER).

(ii) The Directors and Deputy Directors of the Offices of Management, Epidemiology and Biostatistics, Compliance, Drug Evaluation I, Drug Evaluation II, Research Resources, Generic Drugs, and Over-the-Counter Drug Evaluation, CDER.

(iii) The Chief and Freedom of Information Officers, Freedom of Information Staff, Office of Management, CDER.

(iv) The Director, Division of Management and Budget, Office of Management, CDER.

(v) The Directors of the Divisions of Drug Labeling Compliance, Drug Quality Evaluation, Manufacturing and Product Quality, and Scientific Investigations, Office of Compliance, CDER.

(14)(i) Regional Food and Drug Directors.

(ii) District Directors.

(iii) The Director, St. Louis Branch.

(iv) The Director, New York Laboratory Division, Northeast Region.

(v) The Director, Southeast Regional Laboratory, Southeast Region.

(vi) The Director, National Forensic Chemistry Center.

(b) \* \* \*

(1) Deputy Commissioners.

(2) The Associate and Deputy Associate Commissioners.

(3) The Director, Office of Human Resources Management, Office of Management.

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Dated: May 9, 1995.

**William B. Schultz,**

*Deputy Commissioner for Policy.*

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#### 21 CFR Part 520

#### Oral Dosage Form New Animal Drugs; Chlortetracycline Soluble Powder Concentrate

**AGENCY:** Food and Drug Administration, HHS.