

(2) The Deputy Commissioner for Management and Systems and the Director, Office of Financial Management are authorized to perform the functions of the Commissioner under 21 U.S.C. 379h(d)(1)(C), as amended, to waive or reduce prescription drug user fees in situations where he/she finds that "the fees will exceed the anticipated present and future costs." This authority may not be further redelegated.

(3) The Deputy Commissioner or, in the event of a vacancy in that position, the Senior Associate Commissioner, Office of the Commissioner, is designated as the User Fee Appeals Officer. The User Fee Appeals Officer is authorized to hear and decide user fee waiver appeals. The decision of the User Fee Appeals Officer will constitute final agency action on such matters. This authority may not be further redelegated.

(i) Authority delegated in the following sections of this subpart may not be redelegated.

[43 FR 20487, May 12, 1978, as amended at 48 FR 43300, Sept. 23, 1983; 56 FR 36001, July 30, 1991; 57 FR 12875, Apr. 14, 1992; 58 FR 17095, Apr. 1, 1993; 59 FR 14549, Mar. 29, 1994; 61 FR 2414, Jan. 26, 1996; 62 FR 923, Jan. 7, 1997; 62 FR 48757, Sept. 17, 1997; 63 FR 41960, Aug. 6, 1998; 64 FR 59618, Nov. 3, 1999]

#### § 5.21 Emergency functions.

Each Regional Food and Drug Director is authorized, during any period when normal channels of direction are disrupted between the Food and Drug Administration headquarters and his region, to fully represent the Food and Drug Administration within his region in consonance with the Department of Health and Human Services regional emergency plans and to exercise the authority of the Commissioner for supervision of and direction to all Food and Drug Administration activities and use of resources within his region for continuity and for Federal Emergency Health Service operations. These same officials are authorized to provide in Regional Emergency Plans for the delegation of Food and Drug Administration regional authorities to heads of field activities when such activities are cut off from national and regional headquarters.

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

(a) The following officials are authorized to certify true copies of or extracts from any books, records, papers, or other documents on file within the Food and Drug Administration, to certify that copies are true copies of the entire file, to certify the complete original record, or to certify the non-existence of records on file within the Food and Drug Administration, and to cause the seal of the Department to be affixed to such certifications:

- (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.

**§5.22**

(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 Pre-market Approval, CFSAN.

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

(xiii) The Director, Office of Food Labeling, CFSAN.

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

(ii) The Associate Director and Deputy Associate Director for Management and Systems, CDRH.

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

(iv) For medical devices assigned to their respective divisions, the Division Directors, Office of Compliance, CDRH.

(v) The Director and Deputy Director, Office of Surveillance and Biometrics (OSB), CDRH, and the Director and Deputy Director, Division of Surveillance Systems (DSS), OSB, CDRH.

(vi) Freedom of Information Officers, 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.

**21 CFR Ch. I (4-1-00 Edition)**

(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, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

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

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

(iv) The Directors of the Offices of Drug Evaluation I, II, III, IV, and V, and the Director and Deputy Director of the Office of Epidemiology and Biostatistics, Office of Review Management, CDER.

(v) The Directors and Deputy Directors of the Offices of Testing and Research, Generic Drugs, New Drug Chemistry, and Clinical Pharmacology and Biopharmaceutics, Office of Pharmaceutical Science, CDER.

(vi) The Chief, Freedom of Information Staff, Office of Training and Communications, CDER.

(vii) The Directors of the Divisions of Labeling and Nonprescription Drug Compliance, Prescription Drug Compliance and Surveillance, and Manufacturing and Product Quality, 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) The following officials are authorized to cause the seal of the Department to be affixed to agreements, awards, citations, diplomas, and similar documents:

(1) Deputy Commissioners.

(2) The Associate and Deputy Associate Commissioners.

## Food and Drug Administration, HHS

## § 5.23

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

(c) The Chief, Regulations Editorial Section and his/her alternates, Regulations Policy and Management Staff, Office of Policy, Office of the Commissioner are authorized to certify true copies of FEDERAL REGISTER documents.

[50 FR 4858, Feb. 4, 1985, as amended at 58 FR 17095, Apr. 1, 1993; 60 FR 26826, May 19, 1995; 61 FR 9639, Mar. 11, 1996; 62 FR 2554, Jan. 17, 1997; 62 FR 67270, Dec. 24, 1997; 64 FR 4965, Feb. 2, 1999; 64 FR 49383, Sept. 13, 1999]

### § 5.23 Disclosure of official records.

(a) The following officials are authorized to make determinations to disclose official records and information under part 20 of this chapter, except that only the officials listed in paragraph (a)(1) of this section may disclose official records and information under §§ 20.82 and 20.85 of this chapter, and only officials listed in paragraph (a)(10) of this section may disclose information under § 20.89(c) of this chapter.

(1) Associate and Deputy Associate Commissioners.

(2)(i) The Director, Office of the Executive Assistant.

(ii) The Director, Executive Secretariat.

(iii) The Director, Program Management Staff.

(3) Executive Officer, Office of the Commissioner.

(4) The Chief, Dockets Management Branch, Division of Management Systems and Policy, Office of Management and Operations.

(5) Program officials at all organizational levels down to and including branch level for all Headquarters organizations.

(6) Regional Food and Drug Directors and District Directors.

(7) Director, Winchester Engineering and Analytical Center.

(8) Chiefs of branches Field/District Offices and Centers.

(9) Freedom of Information Officers and other employees engaged in Freedom of Information activities.

(10)(i) The Associate Commissioner for Regulatory Affairs, Deputy Associate Commissioner for Regulatory Af-

fairs, and Director, Office of Enforcement, FDA.

(ii) The Director, Deputy Director, and Associate Director for Policy Coordination and Public Affairs, Center for Biologics Evaluation and Research (CBER), and Director, Division of Congressional and Public Affairs, CBER.

(iii) The Director, Deputy Directors, and Associate Director for Science and Medical Affairs, Center for Drug Evaluation and Research (CDER).

(iv) The Director and Deputy Director for Regulations and Policy, Center for Devices and Radiological Health (CDRH).

(v) The Director, Center for Food Safety and Applied Nutrition (CFSAN), and Deputy Director for Systems and Support, CFSAN.

(vi) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(vii) The Director, Deputy Director, and Associate Director for Scientific Coordination, National Center for Toxicological Research (NCTR).

(b) The Chief, Product Information Management Branch, Division of Database Management, Office of Management, Center for Drug Evaluation and Research (CDER), is authorized to sign affidavits regarding the presence or absence of records of Registration of Drug Establishments.

(c) The following officials are authorized to sign affidavits regarding the presence or absence of medical device establishment registration records:

(1) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH).

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

(3) The Director and Deputy, Division of Program Operations, Office of Compliance, CDRH.

(4) The Chief, Information Processing and Automation Branch, Division of Program Operations, Office of Compliance, CDRH.

(5) The Director and Deputy Director, Office of Surveillance and Biometrics (OSB), CDRH, the Director and Deputy Director, Division of Surveillance Systems (DSS), OSB, CDRH, and the Chief Reporting Systems Monitoring Branch, DSS, OSB, CDRH.