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(d) The Chief, Regulations Editorial Section; Regulations Policy and Management Staff; Office of Policy, Planning, and Legislation; Office of the Commissioner, and his/her alternates are authorized to certify true copies of FEDERAL REGISTER documents. The Chief, Regulations Editorial Section; Regulations Policy and Management Staff; Office of Policy, Planning, and Legislation; and the Office of the Commissioner may designate alternates as required.

[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; 65 FR 34961, June 1, 2000]

§ 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) The Deputy Commissioner, the Deputy Commissioner for International and Constituent Relations, the Deputy Commissioner for Management and Systems, Senior Associate Commissioners, Associate and Deputy Associate Commissioners.

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

(ii) The Director, Office of the Executive Secretariat, Office of the Senior Associate Commissioner, Office of the Commissioner.

(3) Executive Officer, Office of the Commissioner.

(4)(i) The Director, Office of Human Resources and Management Services, Office of Management and Systems, Office of the Commissioner.

(ii) The Director, Division of Management Programs, Office of Human Resources and Management Services, Office of Management and Systems, Office of the Commissioner.

(iii) The Chief, Dockets Management Branch, Division of Management Pro-

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grams; Office of Human Resources and Management Services, Office of Management Services, Office of the Commissioner.

(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 Affairs, 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:

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(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.

(d) The Director, Office of Resource Management, Office of Regulatory Affairs is authorized to sign affidavits regarding the presence or absence of records in the files of that office.

(e) The Director and Deputy Director, Division of Product Certification, Office of Biological Product Review, Center for Biologics Evaluation and Research, are authorized to sign affidavits regarding the presence or absence of records of registration of blood product establishments.

[43 FR 29286, July 7, 1978, as amended at 48 FR 56946, Dec. 27, 1983; 49 FR 14932, Apr. 16, 1984; 50 FR 4859, Feb. 4, 1985; 51 FR 11428, Apr. 3, 1986; 54 FR 8315, Feb. 28, 1989; 55 FR 47053, Nov. 9, 1990; 57 FR 40318, Sept. 3, 1992; 59 FR 37419, July 22, 1994; 62 FR 2554, Jan. 17, 1997; 62 FR 67270, Dec. 24, 1997; 64 FR 4965, Feb. 2, 1999; 65 FR 34961, June 1, 2000]

§ 5.24 Authority relating to technology transfer.

(a) The Associate Commissioner for Regulatory Affairs is authorized to perform the functions of the Commissioner of Food and Drugs as requested by the Commissioner regarding the authority to disapprove or require modification of cooperative research and development agreements and licensing agreements and transmit written explanation of such approval or disapproval to the head of the laboratory concerned under sections 11(c)(5) (A) and (B) of the Stevenson-Wydler Technology Innovation Act of 1980 (the Act) (15 U.S.C. 3710a(c)(5) (A) and (B)), as amended.

(b) The following officials are authorized to perform the functions of the Commissioner of Food and Drugs as requested by the Commissioner under the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3701 *et seq.*), as amended, and Executive Order 12591 of April 10, 1987, except to the extent that redelegation of those functions is specifically limited in § 5.10(a)(29) of this part, as they pertain to the functions of their respective organizations, including the authority to perform the functions of laboratory directors under the Act as the heads of their respective Federal laboratories, subject to the discretion of the Commissioner of Food and Drugs to require that agreements entered into under section 11(a) of the Act (15 U.S.C. 3710a(a)) include provisions in accordance with section 11(c)(5)(A) of the Act (15 U.S.C. 3710a(c)(5)(A)):

(1) The Director, Center for Biologics Evaluation and Research.

(2) The Director, Center for Devices and Radiological Health.

(3) The Director, Center for Drug Evaluation and Research.

(4) The Director, Center for Food Safety and Applied Nutrition.

(5) The Director, Center for Veterinary Medicine.

(6) The Director, National Center for Toxicological Research.

(7) The Associate Commissioner for Regulatory Affairs.

[53 FR 26049, July 11, 1988]

§ 5.25 Research, investigation, and testing programs and health information and health promotion programs.

(a) The following officials are authorized under sections 301, 307, 311, 1701, 1702, 1703, and 1704 of the Public Health Service Act (the act) to establish research, investigation, and testing programs and health information and health promotion programs, which relate to their assigned functions, and to approve grants for conducting such programs:

(1) The Director and Deputy Director, National Center for Toxicological Research.

(2) The Director and Deputy Directors, Centers for Devices and Radiological Health (CDRH).