

## §5.24

and Research (CBER); and the Director and Deputy Director, Office of Communication, Training, and Manufacturer's Assistance (OCTMA), CBER.

(iii) The Director and Deputy Director, CDER; the Directors, Office of Review Management and Office of Pharmaceutical Science, CDER; the Associate Director for Medical Policy, CDER; the Associate Director for Regulatory Policy, CDER, and the Director, Division of Information Disclosure Policy, Office of Regulatory Policy, CDER.

(iv) The Director, CDRH, the Deputy Director for Regulations and Policy and the Deputy Director for Science, CDRH.

(v) The Director and Deputy Director, CFSAN.

(vi) The Director and Deputy Director, CVM.

(vii) The Director, the Deputy Center Directors, Offices of Research and Management, respectively, and the Deputy Director for Washington Operations, NCTR.

(b) The Chief, Information Management Team, Division of Data Management and Services, Office of Information Technology, CDER, is authorized to sign affidavits regarding the presence or absence of records of Registration of Drug Establishments. This official may not further redelegate this authority.

(c) The following officials are authorized to sign affidavits regarding the presence or absence of medical device establishment registration records and these officials may not further redelegate this authority:

(1) The Director, the Deputy Director for Regulations and Policy, and the Deputy Director for Science, CDRH.

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

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

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

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this official may not further redelegate this authority.

(e) The Director and Deputy Directors, CBER, the Director and Deputy Director, Office of Blood Research and Review (OBRR), and the Director and Deputy Director, Division of Blood Applications, OBRR, CBER, are authorized to sign affidavits regarding the presence or absence of records of registration of blood product establishments. These officials may not further redelegate this authority.

### §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 section 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 (Commissioner) requested by the Commissioner under the Act (15 U.S.C. 3701 *et seq.*), as amended, and Executive Order 12591 of April 10, 1987 (except to the extent that re delegation of those functions is specifically limited in §5.10(a)(26)), 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 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.

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(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.

(c) These officials may not further redelegate these authorities.

### **§ 5.25 Research, investigation, and testing programs and health information and 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 PHS Act) (42 U.S.C. 241, 242l, 243, 300u, 300u-1, 300u-2, 300u-3) 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, the Deputy Director for Washington Operations, and the Deputy Center Directors, Offices of Research and Management, respectively, National Center for Toxicological Research (NCTR).

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

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

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

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

(6) The Director and Deputy Director, the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(7) The Director, Office of Orphan Products Development (OPD), Office of the Senior Associate Commissioner (OSAC), Office of the Commissioner (OC).

(b) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH, are authorized to establish an electronic product radiation control program and to approve grants for conducting the program

under section 532 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ii).

(c) The Senior Associate Commissioner for Management and Systems, Office of Management and Systems (OMS), OC; the Director and Deputy Director, Office of Facilities, Acquisitions, and Central Services (OFACS), OMS, OC; the Director, Division of Contracts and Procurement Management (DCPM), OFACS, OMS, OC; and the Chief Grants Management Officer and the Grants Management Officer, DCPM, OFACS, OMS, OC are authorized to sign and issue all notices of grant awards and amendments thereto and sign and issue notices of suspension and termination thereof for grants approved under the authority delegated in paragraphs (a) and (b) of this section.

(d) The Director, NCTR, is authorized under section 301 of the PHS Act (42 U.S.C. 241), as amended by Public Law 95-622, to make available to educational institutions, for biomedical and behavioral research, laboratory animals bred for research purposes of the Center that are not required to support Center research programs.

(e) The Senior Associate Commissioner for Management and Systems may further redelegate the authorities in paragraph (c) of this section. With the exception for paragraph (c) of this section, these officials may not further redelegate these authorities.

### **§ 5.26 Service fellowships.**

(a) Under authority of sections 207(g) and 208(f) of the PHS Act (42 U.S.C. 209(g) and 210(f)), and within the limits of an approved service fellowship plan, the following officials are authorized to designate persons to receive service fellowships, appoint service fellows, and determine specific stipend rates for individual actions within the ranges established under an approved service fellowship plan:

(1) The Deputy Commissioner; the Senior Associate Commissioner; the Deputy Commissioner for International and Constituent Relations; the Senior