

Food and Drug Administration, HHS

§ 5.28

program and to approve grants for conducting the program under section 356 of the Act.

(c) The Associate and Deputy Associate Commissioner for Management and Operations, the Director and Deputy Director of the Division of Contracts and Grants Management of the Office of Management and Operations, the Chief of the State Contracts and Assistance Agreements Branch, and the Chief of the Grants and Assistance Agreements Section of that Division and Office 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 of the National Center for Toxicological Research is authorized under section 301, as amended by Pub. L. 95-622, of the Public Health Service Act to make available to educational institutions, for biomedical and behavioral research, laboratory animals bred for research purposes of the Center which are not required to support Center research programs.

[45 FR 7783, Feb. 5, 1980, as amended at 45 FR 27924, Apr. 25, 1980; 46 FR 17758, Mar. 20, 1981; 48 FR 56946, Dec. 27, 1983; 49 FR 14932, 14936, Apr. 16, 1984; 50 FR 4859, Feb. 4, 1985; 54 FR 8316, Feb. 28, 1989; 57 FR 45295, Oct. 1, 1992; 59 FR 42491, Aug. 18, 1994; 62 FR 2554, Jan. 17, 1997; 62 FR 67270, Dec. 24, 1997]

§ 5.26 Service fellowships.

Under authority of sections 207(g) and 208(f) of the Public Health Service 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:

(a) Deputy Commissioners.

(b) The Director and Deputy Director, National Center for Toxicological Research (NCTR), and the Director, Office of Management, NCTR.

(c) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), and the Direc-

tor, Office of Systems and Management, CDRH.

(d) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), the Associate Director for Research, CBER, and Office Directors.

(e) The Director and Deputy Directors, Center for Food Safety and Applied Nutrition (CFSAN), and Director, Office of Management Systems, CFSAN.

(f) The Director and Deputy Director, Center for Veterinary Medicine (CVM), and the Director, Office of Management, CVM.

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

(h) The Director, Office of Resource Management, Office of Regulatory Affairs.

(i) The Director, Office of Human Resources Management, Office of Management and Systems.

[48 FR 56946, Dec. 27, 1983, as amended at 49 FR 14932, 14936, Apr. 16, 1984; 50 FR 4859, Feb. 4, 1985; 54 FR 8316, Feb. 28, 1989; 59 FR 5317, Feb. 4, 1994; 59 FR 42491, Aug. 18, 1994; 62 FR 2554, Jan. 17, 1997; 62 FR 67270, Dec. 24, 1997]

§ 5.27 Patent term extensions for human drug products, medical devices, and food and color additives.

The Associate Commissioner for Health Affairs is authorized to perform the functions delegated to the Commissioner under section 156 of title 35 U.S. Code (35 U.S.C. 156), except for the holding of informal hearings pursuant to 35 U.S.C. 156(d)(2)(B)(ii).

[50 FR 9424, Mar. 8, 1985]

§ 5.28 Cardiac pacemaker devices and pacemaker leads.

The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to a registry of all cardiac pacemaker devices and pacemaker leads for which payment was made under the Social

§ 5.29

Security Act (42 U.S.C. 1395y(h)(1), (2)(A), and (3)), as amended.

[62 FR 67270, Dec. 24, 1997]

§ 5.29 Functions pertaining to safer vaccines.

The Director, Center for Biologics Evaluation and Research (CBER), and the Associate Director for Policy Coordination and Public Affairs, CBER, are authorized to perform the functions of the Commissioner of Food and Drugs under part C, subtitle 2 of title XXI of the Public Health Service Act (42 U.S.C. 300aa-25 *et seq.*), as amended, and the National Childhood Vaccine Injury Act of 1986 (42 U.S.C. 300aa-1 note), as amended hereafter, as follows:

(a) Section 2125 of the Public Health Service Act (42 U.S.C. 300aa-25)—Recording and reporting of information.

(b) Section 2127 of the Public Health Service Act (42 U.S.C. 300aa-27)—Mandate for safer childhood vaccines.

(c) Section 2128 of the Public Health Service Act (42 U.S.C. 300aa-28)—Manufacturer recordkeeping and reporting.

(d) Section 312 of the National Childhood Vaccine Injury Act of 1986—Related studies, except that the authority to provide for notice and opportunity for public hearing on the review of vaccines and related illnesses and conditions under sections 312(a) and 312(d) of the National Childhood Vaccine Injury Act of 1986 is not redelegated by the Commissioner.

(e) Section 313 of the National Childhood Vaccine Injury Act of 1986—Study of other vaccine risks, except that the authority to provide for notice and opportunity for public hearing on the establishment of guidelines regarding the risks to children of certain vaccines under section 313(a)(1)(B) and (b) of the National Childhood Vaccine Injury Act of 1986 is not redelegated by the Commissioner.

(f) Section 314 of the National Childhood Vaccine Injury Act of 1986—Review of warnings, use instructions, and precautionary information.

[58 FR 17106, Apr. 1, 1993]

§ 5.30 Hearings.

(a) The following officials are authorized to designate officials to hold informal hearings that relate to their as-

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

signed functions under sections 305, 404(b), and 801(a) of the Federal Food, Drug, and Cosmetic Act; section 6 of the Fair Packaging and Labeling Act; section 9(b) of the Federal Caustic Poison Act; and section 5 of the Federal Import Milk Act. Officials so designated are delegated authority vested in the Secretary of Agriculture by 7 U.S.C. 2217 (43 Stat. 803) to administer to take from any person an oath, affirmation, affidavit, or deposition for use in any prosecution or proceeding under, or in enforcement of, any law as cited in this part:

(1) The Director and Deputy Directors, Center for Food Safety and Applied Nutrition (CFSAN), and the Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(2) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER); the Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER; and the Director and Deputy Director, Office of Compliance, CDER.

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

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

(5) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), and the Directors and Deputy Directors of the Offices of Biological Product Review, Biologics Research, and Compliance, CBER.

(6) Regional Food and Drug Directors.

(7) District Directors.

(8) The Director, St. Louis Branch.

(b) The Director and Deputy Directors, CDRH, are authorized to hold hearings, and to designate other officials to hold informal hearings, under section 360(a) of the Public Health Service Act.

(c) The following officials are authorized to serve as the presiding officer, and to designate other Food and Drug Administration employees to serve as the presiding officer, at a regulatory hearing and to conduct such a hearing pursuant to the provisions of part 16 of this chapter. An official can serve as