

Food and Drug Administration, HHS

§ 5.30

(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; and due diligence determinations.

(a) The Director, Center for Drug Evaluation and Research (CDER) and the Associate Director for Policy, CDER, are authorized to perform the functions delegated to the Commissioner of Food and Drugs under 35 U.S.C. 156, as amended, except for making due diligence determinations and holding of informal hearings under 35 U.S.C. 156(d)(2)(B).

(b) The Chief Mediator and Ombudsman, Office of the Ombudsman, Office of the Senior Associate Commissioner, Office of the Commissioner, is authorized to perform the functions delegated to the Commissioner to make due diligence determinations under 35 U.S.C. 156(d)(2)(B), as amended, except for holding of informal hearings under 35 U.S.C. 156(d)(2)(B)(ii).

[65 FR 34962, June 1, 2000]

§ 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 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 assigned 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:

§5.31

(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 the presiding officer in a particular hearing only if he or she satisfies the requirements of §16.42(b) of this chapter with respect to the action that is the subject of the hearing. Such officials are delegated authority vested in the Secretary of Agriculture by 7 U.S.C. 2217 (43 Stat. 803) to administer or to take from any person an oath, affirmation, or deposition for use in any prosecution or proceeding under, or in enforcement of, any law as cited in this part:

(1) The Chief Mediator and Ombudsman, Office of the Ombudsman, Office

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of the Senior Associate Commissioner, Office of the Commissioner.

(2) The Director and Deputy Directors, CFSAN.

(3) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, 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.

(4) The Director and Deputy Directors, CDRH.

(5) The Director and Deputy Director, CVM.

(6) The Director and Deputy Director, CBER, and the Directors and Deputy Directors of the Offices of Biological Product Review, Biologics Research, and Compliance, CBER.

(7) Regional Food and Drug Directors.

(8) District Directors.

(9) The Director, St. Louis Branch.

(10) Such other FDA official as is designated by the Commissioner by memorandum in the proceeding.

[48 FR 8440, Mar. 1, 1983, as amended at 48 FR 56946, Dec. 27, 1983; 49 FR 14932, 14936, Apr. 16, 1984; 51 FR 32452, Sept. 12, 1986; 54 FR 8316, Feb. 28, 1989; 54 FR 9034, Mar. 3, 1989; 59 FR 42491, Aug. 18, 1994; 62 FR 2554, Jan. 17, 1997; 62 FR 67270, Dec. 24, 1997; 65 FR 34962, June 1, 2000]

§5.31 Petitions under part 10.

(a) For drugs assigned to their organizations, the following officials are authorized to grant or deny citizen petitions submitted under §10.30 of this chapter for a stay of an effective date in §201.59 of this chapter for compliance with certain labeling requirements for human prescription drugs.

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

(ii) The Directors and Deputy Directors of the Offices of Biological Product Review and Biologics Research, CBER.

(iii) The Directors and Deputy Directors of the divisions in the Offices of Biological Product Review and Biologics Research, CBER.

(2)(i) The Director, Deputy Center Director for Review Management, and